Webinar
Assessment of European Standards for the General Product Safety Directive (GPSD - 2001/95/EC)
20 May 2020
Guidelines for online meeting

- By default, **mute** yourself
- Use efficiently the chat box, by writing “**floor**” or your name
- Possibility to ask **questions at the end of each slide**
- Speak clearly and slowly & introduce your name
# Programme overview

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<th>TIMING</th>
<th>SESSION</th>
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<tr>
<td>14:00-14:15</td>
<td>Welcome and opening remarks</td>
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<tr>
<td></td>
<td><em>Cinzia Missirol, Director Standardization &amp; Digital Solutions, CEN and CENELEC</em></td>
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<tr>
<td></td>
<td><em>Pinuccia Contino, Head of Unit DG JUST E4 &quot;Product safety”, European Commission</em></td>
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<tr>
<td>14:15-14:45</td>
<td>Working with the HAS Consultant framework</td>
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<td>This session will explain the practical implementation of the relations between CEN - CENELEC (CCMC, members, Technical Bodies, Technical Body secretariats and Officers) the European Commission, HAS Contractor and HAS Consultants during the preparation of European Standards intended to be cited in the European Union Official Journal. This will cover namely the process with the different stages of assessment and the timeframe.</td>
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<tr>
<td></td>
<td><em>Geert Maes, Customer Solution Manager Electrotechnology, CEN and CENELEC</em></td>
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<td><em>Goncalo Ascensao, Account Manager Production, CEN and CENELEC</em></td>
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<tr>
<td>14:45-15:00</td>
<td>Q&amp;A</td>
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<tr>
<td>15:00-15:30</td>
<td>General Product Safety Directive (2001/95/EC) &amp; Drafting an Annex ZZ</td>
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<td>This session will explain the specificities of the General Product Safety Directive (2001/95/EC) and its legal basis.</td>
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<td></td>
<td><em>Francisco Javier VERDERA MARÍ, HAS Consultant</em></td>
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<tr>
<td>15:30-15:45</td>
<td>Next steps</td>
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<td>This session will provide an overview of projects concerned and exceptions agreed for the transition period. More information will be given for the bilateral contacts between Technical Bodies and HAS Consultants. Information available (templates, CEN and CENELEC BOSS).</td>
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<td><em>Claire DALIER, Project Manager Energy &amp; Living, CEN and CENELEC</em></td>
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<tr>
<td>15:45-16:00</td>
<td>Q&amp;A</td>
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<tr>
<td>16:00</td>
<td>End of Training</td>
</tr>
</tbody>
</table>
Welcome and opening remarks

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Working with the HAS Consultant framework

- ASSESSMENTS
- HAS Contractor Consultants
- MEETINGS
- People & tasks
Relations for a joint assessment

- HAS Contractor
- Consultants
- Steering group involving sectors
- Technical Bodies
- ISO - IEC
- CEN CLC
- EC
- HAS Contractor
- Consultants
- Contractual arrangement
- Common understanding
- Organisational Operational
- Working relationship Assessments, meetings
HAS CONTRACTOR = Ernst & Young (EY)

The formal contact point towards EC and ESO’s, with 3 main tasks:

- Administrative & logistical tasks to coordinate the tasks and work of the consultants, including recruitment
- Horizontal verifications and checks of non-technical nature with regard to documents to be assessed by the consultants
- Evaluation of the assessment results and the effectiveness of the assessment concept in order to make recommendations to the Commission

The Contractor will be managing the pool of harmonized standards consultants 'HAS Consultants'
HAS CONSULTANT

The independent experts selected, hired and managed by the HAS Contractor to perform the following main tasks:

- ‘Compliance assessment' of the documents drafted by the ESO’s
- 'Communication' to the technical bodies of the ESO’s to give advice in order to contribute compliance of the drafted documents with the EC's standardization requests → MEETINGS
Assessments

the Work Item (WI) needs to be:

- linked to the relevant legislation and standardization request
  - In the Technical Body Work Programme
  - Reflected as such in the database

AND

- registered in an EC approved Work Programme for the Standardization Request (where relevant)

→ Ensure Technical Body Work Programme is up-to-date!
Interaction with the standards development

Consultant(s) → HAS Contractor

Consultant(s) → Desk officer

Desk officer → HAS Contractor

Consultant(s) → Desk officer

Desk officer → Consultant(s)

DRAFTING
ENQUIRY
DRAFTING

TC
CCMC and NSB/NC secretariat
Preparation/editing/translation/finalisation

ENQUIRY/FORMAL VOTE

FV
PUB.
Assessments

When can an assessment be requested?

- at drafting stage --> at TC request!
- at Enquiry stage --> automatically done by CCMC
- at Formal vote stage --> automatically done by CCMC
- documents which have been voted upon --> exceptionally!

Duration:

- In principle, 5 weeks after notification to HAS contractor E&Y
## Interaction with the standards development

### Assessments

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>'Compliant'</td>
<td>The publication of the references in the OJ is normally possible without any specific notice</td>
</tr>
<tr>
<td>'Partial compliance'</td>
<td>The publication of the references in the OJ could be possible with a notice; such a notice shall be outlined in the report for already adopted standards and for documents assessed before formal vote.</td>
</tr>
<tr>
<td>'Lack of compliance'</td>
<td>The publication in the OJ is likely not possible before the document is revised</td>
</tr>
</tbody>
</table>
Assessments

WHERE TO FIND

LIVELINK ‘HAS PLATFORM’

SET YOUR NOTIFICATIONS!

For CLC: ask CCMC for help
Assessments

**REVIEW (challenge)**
- on justified disagreement of the Technical Body
- as specific as possible
- related to the work item
- can relate to (examples)
  - Interpretations of guidance that have not been agreed upon;
  - debatable interpretations Essential Requirements (ER) and their consequences for particular products covered in the respective standard
  - the consultants interfering in the drafting and consensus building processes of the ESO’s or providing scientific, legal or technical comments which would go beyond normal assessment tasks;
  - deviation from sector specific arrangements that have been validated with the EC.

**decision to request a review of an assessment must be supported by a consultation of CCMC, relevant sector fora, etc**

**Duration:**
- normally 3 weeks after notification to HAS CONTRACTOR (EY)

**Who and How**
- Technical Body Secretary to request a review to the CCMC Project Manager
Assessments: DRAFTING STAGE (indicative)

- ‘Working Draft – 20.60’
  (Parallel work: equivalent stages)
- TC Secretary to submit to CCMC the Working Draft
  - According to process CEN BOSS & CENELEC BOSS
  - Transmission notice to indicate request for assessment
  - Foresee the specific (European) elements
    - First draft Annex ZA/ZZ or indication of intended coverage of E.R.
    - For parallel work: CD-text
    - When available:
      - Justification of Normative refs, risk assessment, ...
      - **CLC specific**: consider common mods, Annex ZA, ..

- As per reception of Assessment report:
  - available to Technical Body on LIVELINK
Assessments: DRAFTING STAGE (indicative)

Dealing with the outcome

- consider the outcome of the assessment and comments
  - USE THE COMMENTING TABLES

- challenge of the assessment (review)
  - exceptional at this stage
  - does not stop development

→ Possibly call ‘meeting’
Assessments: ENQUIRY stage

**TRIGGERS**

- Homegrown work: transmission notice for Enquiry
- Parallel work under VA: DIS text to translation
- Parallel work under FA: assessment triggered by transmission notice for A11 or submission of Annex ZZ

Interaction with the standards development
Assessments: ENQUIRY stage

- TC Secretary to submit ENQUIRY TEXTS/ELEMENTS according to process in CEN BOSS & CENELEC BOSS
  
  *note: // procedure will run automatically but needs to be completed!*

- Events will automatically trigger assessment → correct identification in work programme!

- Ensure specific (European) elements are included

- Annex ZZ/ZA indicating coverage of E.R.

- Transmission notice to mention relevant documentation
  
  *Note: Possibly complementing the // procedure*

- Commenting table on previous assessments

  - Supporting risk assessment, ...

  - Evaluation of Normative references relevant for intended ‘Presumption of conformity’ → dating, availability, older versions, ...

  - CLC specific: consider common mods, Annex ZA,..

As per reception of Assessment report:

- Available to Technical Body on LIVELINK
Assessments: ENQUIRY stage

Dealing with the outcome

Assessment result 'compliant'
if all other criteria are met: possibility to skip FV
Assessments: ENQUIRY stage
Dealing with the outcome

Assessment result ‘partial compliance’ – ‘lack of compliance’
- Launch of Enquiry is not delayed
- Organize CRM
  - Good practice
    - Systematically plan ahead
    - Try to involve the HAS Contractor/Consultant and EC Desk Officer*
- Aim = resolve issues & jointly take difficult decisions in a transparent way
  - without technical changes → possibility to skip FV (all other criteria met)
  - with technical changes → prepare final draft for FV with more assurance
- Issues not resolved?
  - Decide on the future of the project, e.g. proceeding as a non-harmonized standard.
  - BT shall be consulted to endorse the decision.

* For exceptional & very litigious cases
Assessments: FORMAL VOTE stage

TRIGGERS

Homegrown work: transmission notice for Formal Vote

Parallel work under VA: ISO text submitted to CCMC

Parallel work under FA: assessment triggered by transmission notice for A11 or Annex ZZ
Assessments: Formal Vote stage

- TC Secretary to submit FV TEXTS/ELEMENTS according to process in CEN BOSS & CENELEC BOSS
  - note: // procedure will run automatically but needs to be completed!
  - events will automatically trigger assessment
  - correct identification in work programme!
- Ensure specific (European) elements are included (also in ISO text)
  - Annex ZZ/ZA indicating coverage of E.R.
  - Transmission notice to mention relevant documentation
  - Note: Possibly complementing the // procedure
- Commenting table on previous assessments
  - Supporting risk assessment, ...
  - Evaluation of Normative References relevant for intended ‘Presumption of conformity’
    - dating, availability, older versions, ...
  - CLC specific: consider common mods, Annex ZA, ..

As per reception of Assessment report:
- available to Technical Body on LIVELINK
Assessments : Formal Vote stage

HOMEGROWN

Dealing with the outcome

Assessment result ‘partial compliance’ – ‘lack of compliance’

- Start of vote suspended for max 12 weeks in order to:
  - to resolve any issues and timely inform CCMC should any changes to the text be necessary
  - Workshop – webmeeting with relevant stakeholders
  - decide on challenge of assessment or not
  - Inform/consult BT

- If within 7 weeks after original assessment no news from the Technical Body relevant BT Member will be triggered for a proposal to BT within 1 week

- Immediately inform TC Secretariat and the BT Member/Permanent Delegate of the NSB/NC holding secretariat

See also the Guidance document for technical bodies on practical measures when dealing with a negative assessment at Formal Vote stage.
Assessments : Formal Vote stage

VA – parallel with ISO

Dealing with the outcome

Assessment result ‘partial compliance’ – ‘lack of compliance’

- No delay of Formal Vote on international text (not modified)
- organize ‘last call’ meeting with national participants and as far as possible: the HAS Contractor/consultants, the sectoral Desk Officer and DG Grow B3. BT to be consulted on the outcome

See also the Guidance document for technical bodies on practical measures when dealing with a negative assessment at Formal Vote stage.
Assessments: Formal Vote stage
FA – parallel with IEC

Dealing with the outcome

⚠ Assessment result ‘partial compliance’ – ‘lack of compliance’

⇒ Immediately inform TC Secretariat and the BT Permanent Delegate of the NC holding secretariat

⚠ No delay of Formal Vote on international text (not modified)

⚠ Start of vote on common mods suspended for max 12 weeks in order to:
  - to resolve any issues and timely inform CCMC should any changes to the text be necessary
  - decide on challenge of assessment or not
  - Inform/consult BT

If within 7 weeks after original assessment no news from the Technical Body, relevant BT Member/Permanent Delegate will be triggered for a proposal to BT within 1 week

⚠ Attention point: implementation dates

⚠ See also the Guidance document for technical bodies on practical measures when dealing with a negative assessment at Formal Vote stage.
Assessments: after Formal Vote (exceptional process)

- Technical Body Secretary to send request to CCMC
- Challenge possible (review of assessment)

EN already made available
- Technical modifications necessary? → TB to consider appropriate actions, consult BT

EN not yet made available
- Immediately inform BT of need to suspend the process
- ‘ratification’ or ‘making available’ suspended for max. 17 weeks
Interaction with the standards development

MEETINGS

▲ Who & How to Request?
- European Technical body Secretary (TC level)
- Link for virtual and F2F meetings

▲ Which meetings?
- Technical body meetings (TC or WG)
- European, where relevant: ISO/IEC
- Related to ‘assessment’ and/or ‘Communication’ → advice to contribute to compliance on WI
- Preference for remote participation
- Request to plan meeting schedule accordingly!

Meeting requests are not needed for written exchanges (requiring clarifications by e-mail directly to the consultant) or for phone calls and short video calls (less than 4 hours).
### Areas covered

<table>
<thead>
<tr>
<th>Personal Protective Equipment</th>
<th>ATEX</th>
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<tr>
<td>Construction Products</td>
<td>Pressure Equipment &amp; Simple Pressure Vessels</td>
</tr>
<tr>
<td>Recreational Craft</td>
<td>Toys</td>
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<tr>
<td>LVD</td>
<td>Cableways</td>
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<tr>
<td>Railways</td>
<td>Gas Appliances</td>
</tr>
<tr>
<td>Radio Equipment</td>
<td>Medical Devices, Pyrotechnics &amp;</td>
</tr>
<tr>
<td>EMC</td>
<td></td>
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</tbody>
</table>

Explosives  
Metrology  
Machinery (incl. lifts & pesticide equipment)

⚠️ Now also GPSD
General Product Safety Directive (2001/95/EC) & Drafting the Annex ZZ

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See separate presentation
Next steps

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- Webinar info 20 May 2020
- Information at TC plenary meetings
- Bilateral exchanges with TC Chair/Secretariat
- Continuous dialogue with the EC Services

People

- CEN and CENELEC BOSS
- Annex ZA/ZZ template
- HAS Livelink Platform

Tools

- CCMC Production Team
- CCMC Sectoral PM

Process

- Process agreed by CEN and CENELEC Technical Boards as of 2018 and apply to all sectors
<table>
<thead>
<tr>
<th>Mandates</th>
<th>TC 1</th>
<th>TC 2</th>
<th>Title</th>
<th>1st Choice consultant</th>
<th>2nd Choice consultant</th>
<th>3rd Choice consultant</th>
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<tbody>
<tr>
<td>M/253</td>
<td>CEN/ TC 252</td>
<td></td>
<td>Baby walking frames</td>
<td>M. Krzystolik</td>
<td>S. Carruthers</td>
<td>A. Rankin</td>
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<tr>
<td>M/259</td>
<td>CEN/ SS H99</td>
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<td>Consumer Safety of oil lamps</td>
<td>M. Krzystolik</td>
<td>J. Roed</td>
<td>A. Rankin</td>
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<tr>
<td>M/264</td>
<td>CEN/ TC 252</td>
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<td>Child care articles</td>
<td>A. Rankin</td>
<td>S. Carruthers</td>
<td>J. Roed</td>
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<tr>
<td>M/266</td>
<td>CEN/ TC 355</td>
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<td>Safety of consumers and children- lighters</td>
<td>A. Rankin</td>
<td>M. Krzystolik</td>
<td>J. Roed</td>
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<tr>
<td>M/285</td>
<td>CEN/ TC 93</td>
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<td>Ladders</td>
<td>G. Bedotti</td>
<td>A. Rankin</td>
<td>J. Roed</td>
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<td>M/293</td>
<td></td>
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<td>withdrawn (tbc)</td>
<td>A. Rankin</td>
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<td>J. Roed</td>
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<tr>
<td>M/309</td>
<td>CEN/ TC 248</td>
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<td>Draw strings on children’s clothing</td>
<td>A. Hillersborg</td>
<td>A. Rankin</td>
<td>J. Roed</td>
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<tr>
<td>M/372</td>
<td>CEN/ TC 136</td>
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<td>Floating leisure products</td>
<td>S. Carruthers</td>
<td>A. Hillersborg</td>
<td>A. Rankin</td>
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<tr>
<td>M/425</td>
<td>CEN/ TC 401</td>
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<td>Fire Safety</td>
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<td>Cigarettes lighters</td>
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<td>A. Rankin</td>
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<td>CLC/ TC 108X</td>
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<td>Safety of music players</td>
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<td>Safety of child-care articles</td>
<td>A. Hillersborg</td>
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<tr>
<td>M/465</td>
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<td>M/497</td>
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<td>A. Hillersborg</td>
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<td>M/505</td>
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<td>G. Bedotti</td>
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<td>J. Roed</td>
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<td>Stationary training equipment</td>
<td>M. Krzystolik</td>
<td>S. Carruthers</td>
<td>A. Rankin</td>
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<td>M/507</td>
<td>CEN/ TC 136</td>
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<td>Gymnastic equipment</td>
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<td>S. Carruthers</td>
<td>A. Rankin</td>
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<td>M/508</td>
<td>CEN/ TC 333</td>
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<td>Bicycles</td>
<td>M. Krzystolik</td>
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<td>A. Rankin</td>
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<td>M/527</td>
<td>CEN/ TC 252</td>
<td>CEN/ TC 207</td>
<td>Children’s seats</td>
<td>A. Rankin</td>
<td>S. Carruthers</td>
<td>J. Roed</td>
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<td>Laser products</td>
<td>J. Roed</td>
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<td>S. Lundbech</td>
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<td>Alcohol-powered flueless fireplaces</td>
<td>X. Lefebvre</td>
<td>A. Rankin</td>
<td>J. Roed</td>
</tr>
</tbody>
</table>
Implementation phase

- For the Work Items -> publication expected in May/June 2020
  - HAS assessment at PUB.
  - No Annex ZA/ZZ required.

- For the Work Items -> Voting stage on-going or ENQ/FV draft already submitted to CCMC
  - HAS assessment automatically performed at ENQ and FV stage.
  - No Annex ZA/ZZ required.

- For all other Work Items in development as of June 2020
  - HAS assessment automatically performed at ENQ and FV stage.
  - Annex ZA/ZZ required.
Information exchange at EU level

CEN-CENELEC have a status of Observer

**Consumer Safety Network, DG JUST:** Establish cooperation between Member States, stakeholders and the Commission, in relation to product safety. Ensure consistent implementation of the legislation within the EU:

- 3 meetings / year
- Regular exchanges with EC Sectorial Policy Officers
Background information

- Annex ZA (CEN) / ZZ (CENELEC) template
- CEN BOSS / CENELEC BOSS dedicated section on European Standards for citation in the European Union Official Journal
- HAS support: has.support@be.ey.com
CEN-CENELEC TCs: Contact the HAS Consultant allocated for your work
- Request meeting form
- HAS support has.support@be.ey.com

CEN-CENELEC TCs: Request an initial assessment at FWD stage when needed (for instance for a new standard, etc.);

CEN-CENELEC WGs (as in most cases, the TC delegates the resolution of comments to the relevant WG): Comments from assessment report at Enquiry stage to be fully taken into account during the comment resolution meeting;

CCMC is there to help!
Thank you for your participation!