Webinar 'Harmonized Healthcare Standards'

Latest developments regarding the preparation of harmonized standards for Healthcare.

We start at 14:00 CET

Webinar moderator

Els SOMERS
Project Manager
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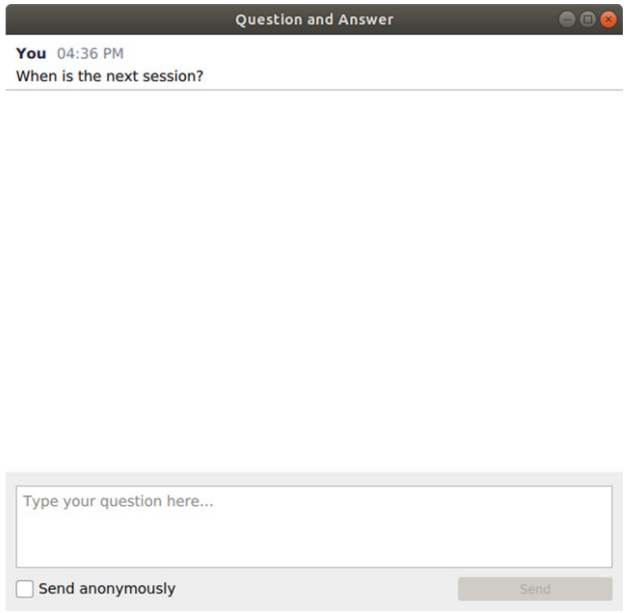
Get the most out of the webinar today

- You are muted
- Use the Q&A panel to submit your questions



- Talk about us on Twitter #training4standards @Standards4EU

Agenda

Webinar 'Harmonized healthcare standards'		
14:00-14:05	Introduction & practicalities	Els Somers (CEN-CENELEC)
14:05-14:15	Welcome remarks	Sarah c Sim (SIS – Chair of ABHS)
14:10-14:25	HAS system and role of HAS consultants	Federico Musso (European Commission, DG GROW/ H.3)
14:25-14:40	EC advice for a successful Annex ZA/ZZ	Mario Gabrielli Cossellu (European Commission, DG SANTE/ D.3)
14:40-14:50	Normative references in standards	Frédéric Mlanao – Harmonized Standards Compliance Account Manager (CEN-CENELEC)
15:00-15:10	The Harmonization procedure	Jennifer Ogbonna – Project Manager Healthcare (CEN-CENELEC)
15:10-15:45	Good Practices of Annex ZA	CEN-CENELEC JTC 03 and CEN/TC 204
15:45-15:55	Key points	Jennifer Ogbonna – Project Manager CEN-CENELEC
16:00	Conclusion & closing	Sarah c Sim (SIS – Chair of ABHS)

Welcome remarks

By Sarah c Sim
SIS – Chair of ABHS – Advisory Board for Healthcare Standards

HAS system and the role of the HAS consultants under the new contract

Federico Musso (European Commission, DG GROW/ H.3)

Main new elements of the future HAS Consultants system

- **Increase of budget**: from 2200 man-days per year for HAS Consultants services to 3400 (ca. 55% more) – pre-defined allocation among sectors.
- **More communication and meeting participation**: from 20% to 25% (maximum).
- Introduction of feedback mechanism (in case of negative assessments at FV).
- Introduction of a **new task for the contractor**: Communication and information to the Technical Bodies of the ESOs and to the Commission services, in order to train and explain the beneficiaries of the system on its functioning.
- Introduction of **"conditional compliance"** assessment result option.

The technical specifications for the new contract

- The Technical Specifications of the call for tenders describe the system and how it will work (https://etendering.ted.europa.eu/cft/cft-documents.html?cftId=9845).
- The specifications provide a full description of the scope of the system, of all related tasks and contain clarifications on the relevant aspects.
- The new elements of the system have been introduced to improve its working, based on the experience gained during the implementation of the previous contract and on the feedback received from the ESOs and from the desk officers of the Commission.
- The overall intention of the new contract is to ensure a high degree of continuity of the HAS Consultants system, improving it where possible but keeping its main principles.

Increase of resources

- From 2200 person-days per year to 3400 (Task 10 + Task 20), with a fixed pre-allocation per sector – this is a limit to the amount of work to be carried out each year for a specific sector. **For the Medical Devices Regulations the amount of resources allocated is 300 man-days per year**.
- Pre-allocation to be reviewed each year by Commission in cooperation with EY to decide distribution of person-days per sector for the successive 12 months period(s) on the basis of practical experience during the first 12 months and on the basis of the evolution of actual work programmes of the ESOs and related deadlines.
- From 20% to 25% maximum of each consultant's person-days for Task 20 (Communication) – hard limit, no flexibility.
- Consultants can attend (on an ad-hoc basis and upon justified invitation) meetings of ESOs/TCs and of Commission expert groups – but no AdCo groups nor coordination groups of notified bodies.

Work for Medical Devices has restarted

- The system became operational again short after the launch webinar on 13.09.2022.
- 7 HAS Consultants for Medical Devices have been (re)contracted.
- The absence for ca. 6 months of HAS Consultants generated a small backlog of draft harmonised standards to be assessed under the Medical Devices Regulations. In addition, new assessment requests were submitted after the relaunch of the HAS system.
- Status on 12.01.2023: out of 27 assessment requests submitted for the Medical Devices sector, 10 have been completed and sent back to the ESOs; 5 have been completed by the consultants and are undergoing the internal quality review check before sending them back to the ESOs; 6 assessment were ongoing; 1 assessment request was not clear and it was pending a clarification from CCMC; and 5 were still awaiting to be processed.

- CEN-CENELEC webinar on re-start of the HAS system: link

Introduction of “feedback mechanism”

- CD, ENQ and FV assessments remain as before.
- In addition, in case of a negative assessment at FV stage, possibility for the ESOs to revise the draft standard and then to request a second FV assessment – this is a right that ESOs now have.
- This way, the exceptional PUB limited-scope assessment no longer needed.
- Possibility for Commission services to request an assessment of a final standard, formally proposed for OJ-citation, for the purpose of deciding whether to cite it in the OJ or not.

New possible assessment outcome

- So far, only binary outcome possible: compliance vs. non-compliance.
- From now on, third possible outcome: conditional compliance.
- This option is meant exclusively for those standards, being part of a series developed in parallel, containing normative references to each other.
- In case the only reason for a non-compliance outcome would be the fact that the normative references are to draft standards (prENs) being developed in parallel, then conditional compliance outcome must be used now.

New task for contractor

- EY must provide systematic communication and information to the Technical Bodies of the ESOs and to the Commission services (i.e., to the main users and beneficiaries of the system) to increase knowledge and understanding of the HAS Consultants scope of work, how the system is designed and how it functions in practice.
- Events will be organised to this purpose, also jointly with the ESOs.
- This task includes the elaboration by EY of data, statistics and qualitative analyses to be used during the communication and training activities, and the obligation to maintain this set of information continuously updated.

Main principles unchanged but clarified where necessary

- HAS Consultants assess only and exclusively harmonised standards (and GPSD standards, which a legislative proposal in the pipeline will make equivalent to harmonised standards).
- HAS Consultants work for the Commission, supporting the legal obligations to carry out the assessment/evaluation tasks pursuant to Articles 10(5) and 10(6) of the Standardisation Reg.
- The HAS Consultants will not participate in the drafting and consensus building processes of the ESOs and will not have any drafting responsibilities for harmonised standards. They are not responsible for providing scientific, legal or technical advice which would go beyond normal assessment tasks defined in this Contract.
- The role of the HAS Consultants is not to compensate possible gaps in the technical, scientific or legal expertise of a technical body.

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Many thanks for your attention!

Questions?

Federico Musso

European Commission

DG GROW – Unit H.3 “Standards Policy”

Federico.MUSSO@ec.europa.eu

European Commission

Specificities of MDR – IVDR – EC advice for a successful Annex ZA/ZZ OJEU citation

Mario Gabrielli Cossellu (European Commission, DG SANTE/ D.3)

The EU Regulations on medical devices and their specificities

- **Regulation (EU) 2017/745 on medical devices** (MDR) – applicable as from **26 May 2021**
- **Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices** (IVDR) – applicable as from **26 May 2022**

- These new Regulations replace the previous Directives to align with the developments of the sector over the last 20 years, with the priority to ensure a **robust, transparent and sustainable regulatory framework** and maintain a **high level of safety**, while supporting **innovation**

- They have been developed according the "New Approach" and "New Legislative Framework" policies, with a number of **specificities** in particular on economic operators, common specifications, notified bodies, clinical evaluations and investigations, post-market surveillance, expert laboratories and panels, information, traceability and registration, etc.; plus specific **transitional provisions**

Standardisation in support of the EU Regulations on medical devices

- As for the other EU harmonisation legislation on health, safety and performance of industrial and consumer goods in the internal market, the general safety and performance requirements of the MDR and the IVDR are supported by **harmonised European standards**, defined and ruled at horizontal level by Regulation (EU) No 1025/2012

- Compliance with harmonised European standard is **not compulsory** (unless otherwise specified), and when their references are published in the *Official Journal of the European Union* (OJEU), the use of that harmonised European standards confers **presumption of conformity** with the requirements the standards aim to cover

- Current state of play:
  - **MDR/IVDR standardisation request** (M/575) in force since May 2021, with an upcoming first amendment, and a second one in preparation
  - publication of lists in the OJEU in 2021 and 2022, for the **MDR** (16 references) and for the **IVDR** (10 references); new lists under preparation

The structure of a harmonised European standard and its Annex(es) Z

- A **harmonised European standard** typically contains:
  - a **European foreword**, providing the key references to the applicable EU legislation
  - the **normative clauses**, including scope, terms and definitions, technical methods/solutions, normative references, etc.
  - one or more **informative Annexes Z** (ZA, ZB, … ZZ), describing the relationship(s) between the harmonised European standard and the requirements of the EU piece(s) of legislation the standard aims to cover
- In the EU Healthcare sector (medical devices and *in vitro* diagnostic medical devices ruled by the MDR and the IVDR respectively), most of the harmonised European standards drafted by CEN and CENELEC are based on or developed in parallel with **international standards** developed by ISO and IEC (through the Vienna and Frankfurt agreements) so the normative clauses of the harmonised European standard coincide with those of the corresponding international standard
- Therefore, the **role of Annex(es) Z** in these standards is even more important to ensure that the harmonised European standard is suitable to support the requirements of EU legislation and to be cited in the OJEU to confer presumption of conformity

A successful Annex Z for citation of the standard in the OJEU?

- The **key elements** for informative Annex(es) Z to harmonised European standards are described in the European Commission's "Vademecum on European standardisation" and in the relevant documents/templates agreed between the European Commission and the European standardisation organisations CEN and CENELEC, including:
  - an introductory/explanatory text
  - one or more tables with the relevant requirements of the EU legislation the standard aims to cover, the clauses/subclauses of the standard that cover the requirements, and remarks/notes when necessary to clarify the coverage
  - other useful information on the use of the standard to cover the requirements, where applicable
- An **adequate Annex Z** must be clear, unambiguous, well structured in describing the relationship between the legal requirements and the clauses of the standard – so, with all the necessary information for the user of the standard (user-oriented)
- Annexes Z and the harmonised European standard as a whole are assessed by the "HAS consultants" in different stages of its development, while the **final assessment and decision** about the citation in the OJEU for the provision of presumption of conformity remain for the Commission services in charge of the sector

Normative references in standards

Frédéric Mlanao – Harmonised Standards Compliance Account Manager (CEN-CENELEC)

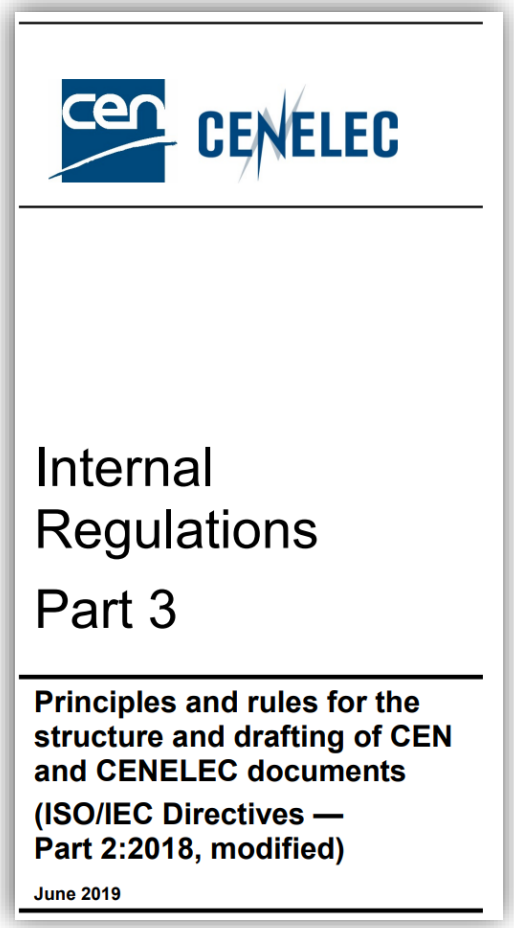
CEN-CENELEC IR-3: rules for normative references

Internal Regulations Part 3 (IR-3)

'Principles and rules for the structure and drafting of CEN and CENELEC documents (ISO/IEC Directives — Part 2:2018, modified)'

→ CEN BOSS

→ CENELEC BOSS



Clause 2 ‘Normative references’

IR-3 Clause 15: Normative references

15 Normative references

15.1 Purpose or rationale

The Normative references clause lists, for information, those documents which are cited in the text in such a way that some or all of their content constitutes requirements of the document.

Information on how these references apply is found in the place where they are cited in the document, and not in the Normative references clause.

- **Informative:** a source of reference for the convenience of the user
- **How references apply**: in the body of the text!

Normative references in hENs

Is the normative reference included in clauses of hEN giving presumption of conformity?

YES → EC requirements and IR-3 apply

NO → IR-3 apply

European Commission

Normative references & legislation

EC position on normative references

- Normative references form an integral part of hENs → **normative references should be dated**
- Undated normative reference creates dynamic reference → difficult for EC to control its continued suitability to give presumption of conformity

European Commission

Normative references in hENs

- Normative references can be hENs or non-hENs
- Normative references **should be:**
  - **dated**
  - **active**
  - **published when hEN is adopted**

- **Vademecum Part 3** (section 2.8.3): guidance on the use of normative references in hEN → **Reference document for EC**

- **Don't:** use normative references that are outdated/withdrawn; non-publicly available documents; draft standards; etc

Normative references in hENs

Homegrown standards

Normative references **should be dated** in Clause 2 and **in body of standard**

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 1011-4:2000[1], *Welding - Recommendations for welding of metallic materials - Part 4: Arc welding of aluminium and aluminium alloys*

EN 12644-1:2001+A1:2008, *Cranes - Information for us*

EN 60204-1:2018, *Safety of machinery - Electrical requirements (IEC 60204-1:2005, modified)*

EN ISO 4413:2010, *Hydraulic fluid power - General rules and safety requirements for systems and their components (ISO 4413:2010)*

EN ISO 10042:2018, *Welding - Arc-welded joints in imperfections (ISO 10042:2018)*

EN ISO 12100:2010, *Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO 12100:2010)*

5.9.3 Electrical equipment

The electrical design and equipment shall comply with the requirements of EN 60204-1.

5.9.2 Hydraulic equipment

The hydraulic design and equipment shall comply with the requirements of EN ISO 4413.

Normative references in hENs

▶ Homegrown standards

Normative references **should be dated** in Clause 2 and **in body of standard**

Good practice: specify

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 1011-4:2000, *Welding - Recommendations for welding of metallic materials - Part 4: Arc welding of aluminium and aluminium alloys*

EN 60204-1:2006, *Safety of machinery* *0204 1:2005, modified*

EN ISO 4413:2010, *Hydraulic fluid power* *13:2010)*

EN ISO 10042:2018, *Welding - Arc-welded* *imperfections (ISO 10042:2018)*

EN ISO 12100:2010, *Safety of machinery* *reduction (ISO 12100:2010)*

5.9.3 Electrical equipment

The electrical design and equipment shall comply with the requirements of EN 60204-1:2006, Clause X.

5.9.2 Hydraulic equipment

The hydraulic design and equipment shall comply with the requirements of EN ISO 4413:2010, Clause X.

Normative references in hENs

Special attention when drafting **amendment of published hENs**

- TCs to review if normative references are dated and active in published hEN → **if not, date normative references in amendment**

Normative references

Replace Clause 2 with the following:

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3767-5:2016, *Tractors, machinery for agriculture and forestry, powered lawn and garden equipment — Symbols for operator controls and other displays — Part 5: Symbols for manual portable forestry machines*

ISO 3864-1:2011, *Graphical symbols — Safety colours and safety signs — Part 1: Design principles for safety signs and safety markings*

ISO 5681:2020, *Equipment for crop protection — Vocabulary*

ISO 9357:1990, *Equipment for crop protection — Agricultural sprayers — Tank nominal volume and filling hole diameter*

ISO 11684:1995, *Tractors, machinery for agriculture and forestry, powered lawn and garden equipment — Safety signs and hazard pictorials — General principles*

ISO 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction*

ISO 13857:2019, *Safety of machinery — Safety distances to prevent hazard zones being reached by upper and lower limbs*

ISO 14982:1998, *Agricultural and forestry machinery — Electromagnetic compatibility — Test methods and acceptance criteria*

ISO 19732:2007, *Equipment for crop protection — Sprayer filters — Colour coding for identification*

ISO 19932-1:2013, *Equipment for crop protection — Knapsack sprayers — Part 1: Safety and environmental requirements*

ISO 19932-2:2013, *Equipment for crop protection — Knapsack sprayers — Part 2: Test methods*

ISO 22867:2011, *Forestry and gardening machinery — Vibration test code for portable hand-held machines with internal combustion engine — Vibration at the handles*

ISO 22868:2021, *Forestry and gardening machinery — Noise test code for portable hand-held machines with internal combustion engine — Engineering method (Grade 2 accuracy)*

IEC 61032:1997, *Protection of persons and equipment by enclosures — Probes for verification*

Normative references in hENs

Special attention when drafting **amendment of published hENs**

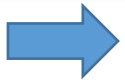
- **Modifying a normative reference in the body of the text**
  = modifying it also in Clause 2

Original standard:

> This test shall be carried out at the predicted mean contact force appropriate to the maximum design speed for the pantograph. The mean contact force shall fulfil the requirements of EN 50367:2012, 7.3, Table 6 for the designated speed.

Amendment:

> **13 Modification to 6.3, Validation of pantograph models**
>
> *Replace in the fourth paragraph* "EN 50367:2012" *by* "EN 50367:2020".
>
> *Replace the 13th paragraph by* "For the calculation of Q, the frequencies with a measured apparent mass below 2 kg shall be excluded.".



> **2 Modification to Clause 2, Normative references**
>
> *Replace* "EN 50119:2009" *by* "EN 50119:2020".
>
> *Replace* "EN 50367:2012, *Railway applications — Current collection systems — Technical criteria for the interaction between pantograph and overhead line (to achieve free access)*" *by* "EN 50367:2020, *Railway applications - Fixed installations and rolling stock - Criteria to achieve technical compatibility between pantographs and overhead contact line*".

Parallel work with ISO

When developing EN ISO standard (Vienna Agreement (VA))

- Normative references are listed in Clause 2 (reflecting references in the body of the standard)
- Same EU requirements apply
- Dated normative references are default solution
- Additional solutions are available

[CEN webinar 'Drafting harmonized standards - IR3 rules, requirements and normative references']

Normative references in hENs

- **EN IEC standards**

  Normative references **shall be dated** through **Annex ZA**

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60112:2003, *Method for the determination of the proof and the comparative tracking indices of solid insulating materials*

IEC 60423:2007, *Conduit systems for cable management – Outside diameters of conduits for electrical installations and threads for conduits and fittings*

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*
IEC 60529:1989/AMD1:1999/AMD2:2013, *Degrees of protection provided by enclosures (IP Code)*

IEC 60695-2-11:2000[2], *Fire hazard testing – Part 2-11: Glowing/hot-wire based test methods – Glow-wire flammability test method for end-products*

IEC 60695-10-2:2003[3], *Fire hazard testing – Part 10-2: Abnormal heat – Ball pressure test*

IEC 60981:2004, *Extra-heavy duty rigid steel conduits*

IEC 61032:1997, *Protection of persons and equipment by enclosures – Probes for verification*

IEC 61140:2001, *Protection against electric shock – Common aspects for installation and equipment*

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60112	2003	Method for the determination of the proof and the comparative tracking indices of solid insulating materials	EN 60112	2003
IEC 60423	2007	Conduit systems for cable management - Outside diameters of conduits for electrical installations and threads for conduits and fittings	EN 60423	2007
IEC 60529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529	1991
			+ corrigendum May 1993	1993
+ A1	1999		+ A1	2000
+ A2	2013		+ A2	2013
IEC 60695-2-11	2000	Fire hazard testing - Part 2–11: Glowing/hot-wire based test methods - Glow-wire flammability test method for end products	EN 60695-2-11	2014
IEC 60695-10-2	2003	Fire hazard testing - Part 10–2: Abnormal heat - Ball pressure test	EN 60695-10-2	2014
IEC 60981	2004	Extra-heavy duty electrical rigid steel conduits	-	-
IEC 61032	1997	Protection of persons and equipment by enclosures - Probes for verification	EN 61032	1998

Normative references in hENs

- **EN IEC standards**

  Normative references **shall be dated** through **Annex ZA**

  - **IEC reference not dated, and European equivalent exists**
    => Date the European equivalent

Publication	Year	Title	EN/HD	Year
IEC 60112	-	Method for the determination of the proof and the comparative tracking indices of solid insulating materials	EN 60112	2003

  - **IEC reference not dated, but no European equivalent exists**
    => Date the IEC reference + footnote "Dated as no European equivalent exists"

IEC 62873-2	2016[3]	Residual current operated circuit-breakers for household and similar use – Part 2: Residual current devices (RDCs) – Vocabulary	-	-

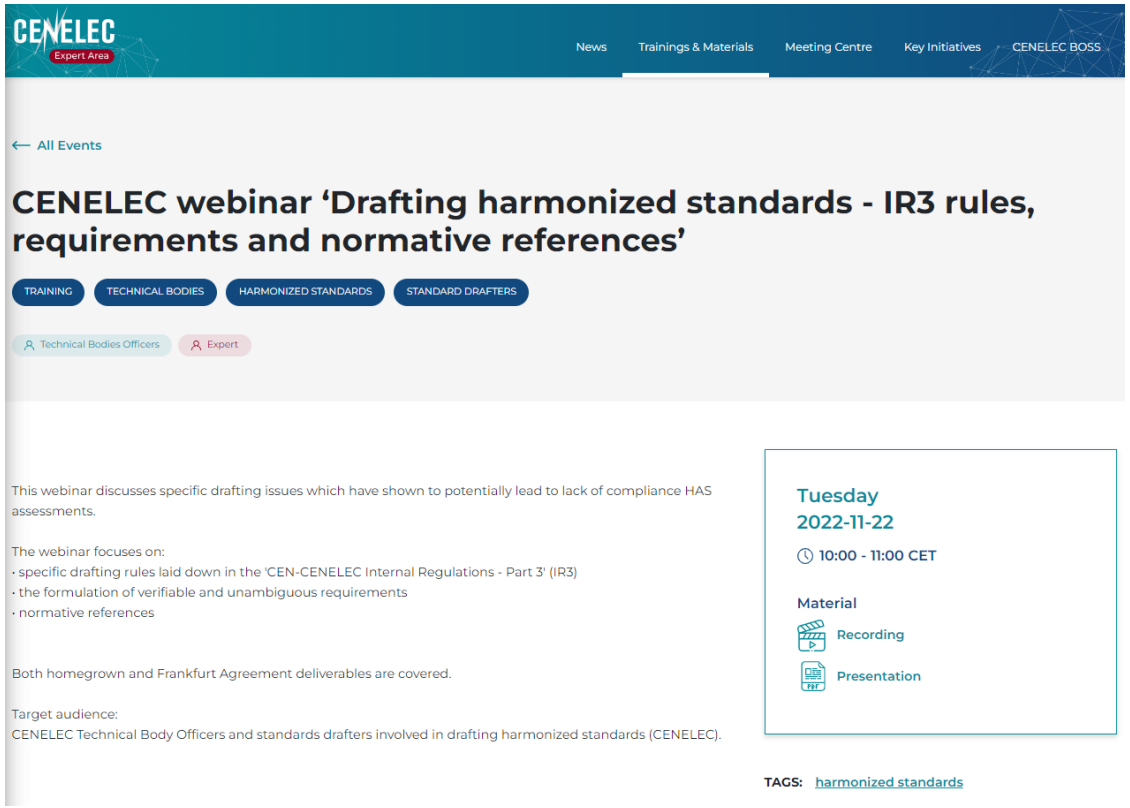
[3] Dated as no European equivalent exists.

Normative references

- Normative references should be EN/ISO/IEC published standards
- Normative reference shall not be Technical Reports
- Normative references should not be Technical Specifications
- Undated references are possible when informative or not providing any legal effect

Normative references

- 2022-11-22: CEN webinar and CENELEC Webinar ‘Drafting harmonized standards - IR3 rules, requirements and normative references’



Break (10 mins)

The Harmonization procedure

Jennifer Ogbonna – Project Manager Healthcare (CEN-CENELEC)

Standards development process

Harmonized standards (hEN) are developed in the same way as any other EN in CEN and CENELEC – but with additional considerations:

- **Mandatory for hEN:**

  All harmonized standards **shall** include an **informative Annex ZA** (CEN), **Annex ZZ** (CENELEC), demonstrating the relationship between the clauses of the standard and the regulatory requirements,

  For standards developed under the Vienna Agreement, the '**normative Annex ZA.2**' shall be included **(EN ISO)**

  For standards developed under the Frankfurt Agreement, **the 'normative Annex ZA'** shall be included **(EN IEC)**

- **Consultant assessments:**

  The HAS consultants assess the compliance of a standard with Regulation (and standardization request) requirements, via communicating with and delivering assessments to the TCs - they work on behalf of the EC.

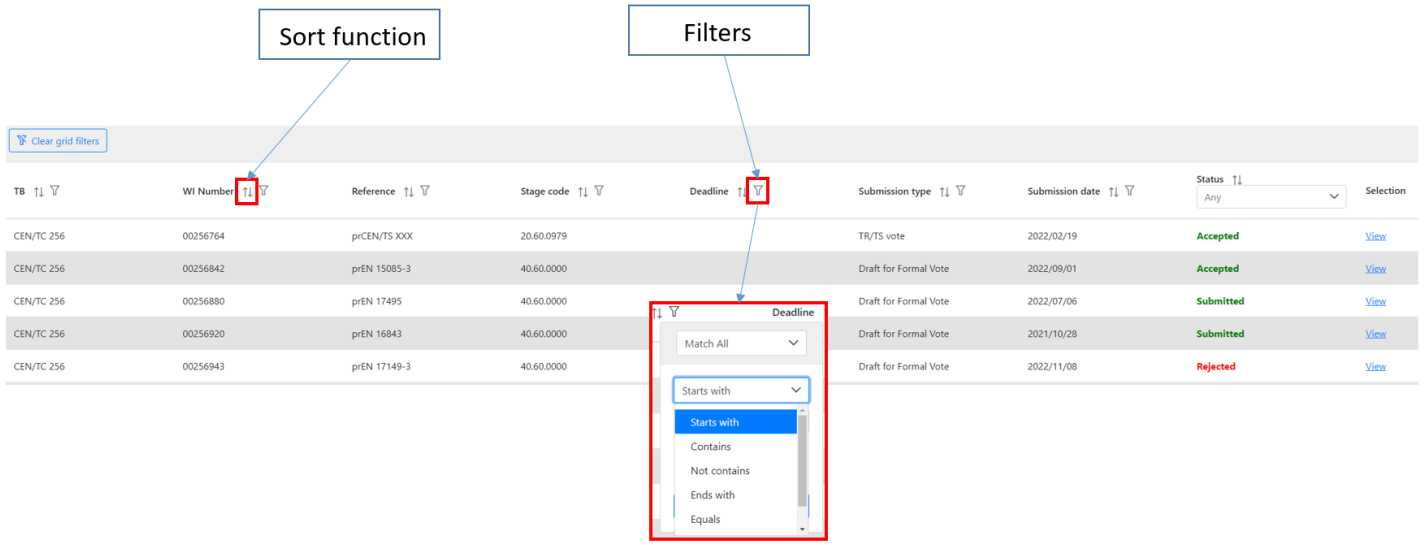
HAS assessment

- 1st Working draft (Optional) - Recommended
- Enquiry stage – DIS/CDV
- Formal Vote stage – FDIS
- Last Confirmatory Assessment (LCA)
  - before Formal Vote (or)
  - after Formal Vote
- EC has final decision on citation in OJEU

Only 1 assessment per stage

Submission Interface

- Submission of standardization documents by Technical Body Secretaries to CCMC
- Direct link: https://submissioninterface.cencenelec.eu/
- Training on Submission interface CEN on 24-11-2022 and 06-12-2022
- Training on Submission interface CENELEC on 24-11-2022 and 06-12-2022



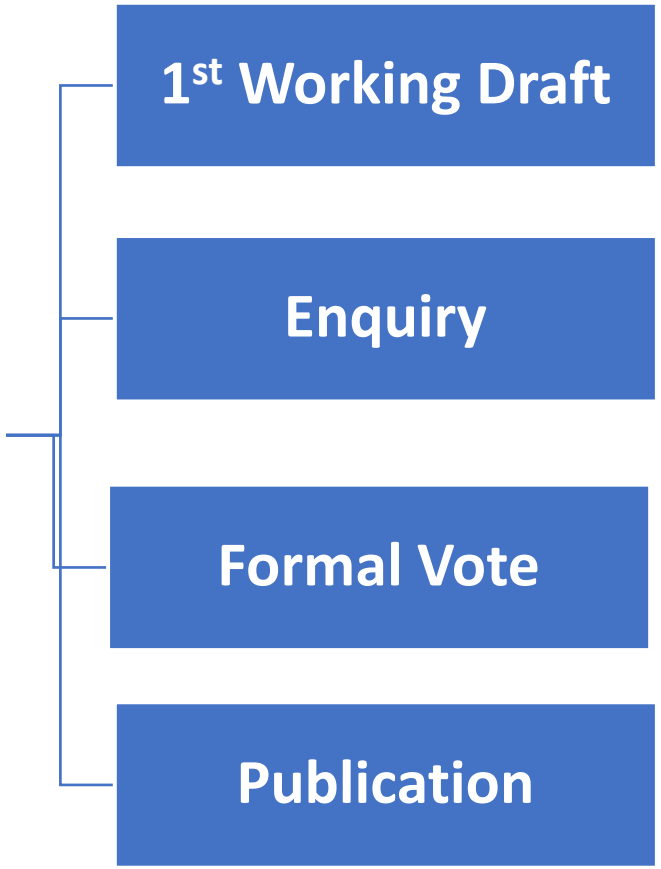
Remember!

- Homegrown harmonized standards in support of EU legislation → TCs shall check compliance against a checklist
- Checklist contains aspect to be considered when drafting harmonized standards
- The use and submission of checklist for homegrown is mandatory
- TC Secretary to ensure that the checklist is filled out and submitted to CCMC via the submission interface
- CCMC will reject text without checklist
- Strong recommendation for the use of checklist for drafting hEN under VA and FA (with ISO/IEC lead)

Checklist – Items to be considered when drafting standards answering a Standardisation Request and to be offered for citation in the OJEU

/	***Check the following questions*** *– if you answer yes to all the questions, the draft is probably ready for submission to CCMC (and HAS Consultant assessment).*	*Check*
General	Is this draft standard listed in a Standardisation Request / covered by a Mandate? Is this reflected in Projex-online database? *NB: This information is normally already provided in the NWIP form.* *NB: If not, contact the TC secretariat. A possible way forward is to propose to the European Commission to add this work item in a (revised) Standardisation Request. This is not applicable if the standard is covered by an open Mandate (e.g. M/396 Machinery)*	☐ ☐
	If the HAS assessment was performed (i.e. optional assessment at First Working Draft (FWD) stage or assessment at Enquiry stage), has the WG answered all comments from the HAS Consultant(s)? *NB: The last column of the HAS Assessment Report ('Observations of the secretariat') at previous stage shall be filled in with the information on how the comments have been addressed.*	☐
	If the text deals with requirements that are not linked to essential requirements of EU legislation, are these requirements in separate clauses, so that in Annex Z only the clauses covering essential requirements are identified?	☐
European foreword	If the standard is a revision, are the significant changes with respect to the previous edition precisely defined? *NB: The list of the significant changes with respect to the previous edition is an important element of the useful information to the standard users. It should not be too vague.* *NB: When the list of significant technical changes is extensive, it may be included in an informative annex. A reference to that annex shall be included in the foreword, preferably after the generic sentence that refers to the superseded document.*	☐
	Does it include the following sentences "The standard has been prepared under a standardisation request given to CEN/CENELEC by the European Commission and the European Free Trade Association, and support essential	☐

Homegrown



- ✓ Draft standard (including the Annex ZA or ZZ)

- ✓ Draft standard (including the Annex ZA or ZZ)
- ✓ Recommendation to include responses to the Consultant's comments at 1st Working Draft
- ✓ Checklist

- ✓ Draft standard (including the Annex ZA or ZZ)
- ✓ Responses to the Consultants' comments received at Enquiry
- ✓ Table of comments from the enquiry + checklist

- ✓ If positive Formal Vote + HAS positive assessment
- ✓ CCMC takes positive voted text at FV for publication

All documents shall be submitted to CCMC via the submission interface

Parallel EN ISO

1st Working Draft

- ✓ Informative Annex ZA and normative Annex ZA.2 -> **submit to CCMC**

Enquiry

- ✓ Informative Annex ZA and normative Annex ZA.2 -> **submit to ISO**
- ✓ CCMC is notified of the date that ISO will launch the **DIS (Enquiry)** and on that date CCMC will align by launching // Enquiry

Formal Vote

- ✓ Informative Annex ZA and normative Annex ZA.2 -> **submit to ISO**
- ✓ CCMC is notified of the date that ISO will launch the **FDIS (//FV)** and on that date CCMC will align by launching // Formal Vote

Publication

- ✓ If positive Formal Vote + positive HAS Assessment -> publication
- ✓ If a revised Annex ZA is needed following a lack compliance, the revised Annex ZA (including Table ZA.2) -> **submit to CCMC ->** HAS assessment -> Technical Board approve -> publication

Parallel EN IEC

1st Working Draft

- ✓ Informative Annex ZZ
- ✓ Normative Annex ZA

Enquiry

- ✓ Informative Annex ZZ
- ✓ Normative Annex ZA
- ✓ Risk Assessment if any
- ✓ Recommendation to include responses to the Consultant's comments at 1st Working Draft

Formal Vote

- ✓ Informative Annex ZZ (send the Annex again to CCMC, even if unchanged!)
- ✓ Normative Annex ZA (send the Annex again to CCMC, even if unchanged!)
- ✓ Risk Assessment (send the Annex again to CCMC, even if unchanged!)
- ✓ Responses to the Consultants' comments received at Enquiry

Publication

- ✓ Informative Annex ZZ
- ✓ Normative Annex ZA
- ✓ Risk Assessment
- ✓ Responses to the Consultants' comments received at Formal Vote

All documents are to submitted to CCMC via the submission interface after 1 March 2023

Remember!

- Proactiveness to address the comments of the HAS consultants
- Homegrown
  - If positive HAS assessment at Enquiry stage, CCMC will launch the Formal Vote
  - If negative HAS assessment at Enquiry stage, the Formal Vote is suspended for 12 weeks and resubmission of a new draft for Formal Vote
- Parallel work CCMC shall align with the dates set by ISO and IEC at DIS/CDV and FDIS stage even in case of lack of compliance

Good Practices from Technical Bodies

Dr Jos van Vroonhoven (CEN-CENELEC JTC 03)
Convener of ISO/TC210 – IEC/SC62A JWG1
Project leader EN ISO 14971 in CEN-CENELEC JTC3

Practices for EN ISO 14971

EN ISO 14971, Medical devices – Application of risk management to medical devices

Development of the European Annex Z

Practices for EN ISO 14971

Revision project of ISO 14971 approved by ISO/TC210 in November 2016

- Better alignment with changing regulatory requirements (upcoming MDR, IVDR)
- More accurate requirements and explanations (reducing risk as far as possible)
- More emphasis on benefits to the patient and the benefit-risk balance
- Resolving the content deviations in EN ISO 14971:2012

Committee Draft (CD) for comments in December 2017

Draft International Standard (DIS) for ballot in July 2018

Parallel vote on prEN ISO 14971 in CEN-CENELEC JTC3 in July 2018

- Annexes ZA-ZC (MDD, IVDD, AIMDD) and ZD-ZE (MDR, IVDR)

Practices for EN ISO 14971

Updated Annexes ZA-ZE in November 2018 after elaborate HAS feedback

Discussion with HAS consultant in CEN-CLC JTC3 meeting in January 2019 on further improvements before consolidating the FDIS text

Only 2 minor comments:

- Refer to "risk management system" that ensures a RM process is in place
- More instructive requirement for manufacturers to disclose significant residual risks

Final Draft International Standard (FDIS, FprEN) for ballot in May 2019

Negative HAS assessment in July 2019 with new comments (*big surprise!*)

The assessment was challenged by CEN-CENELEC JTC3

Practices for EN ISO 14971

Peer review by independent HAS consultant in October 2019, resulting in “partial compliance” with a few minor issues to be resolved

Publication of ISO 14971 in December 2019, simultaneously with EN ISO 14971:2019 but without Annex ZA-ZE

Updated Annex ZA-ZE in September 2020 to resolve HAS comments

Full re-assessment by 3 HAS consultants in December 2020
Result was negative with further new comments (*surprise again!*)
The assessment was challenged again by CEN-CENELEC JTC3

Practices for EN ISO 14971

Discussions with Mario Gabrielli Cossellu (European Commission) in March-May 2021

- Pragmatic discussions focused on harmonization and resolving any issues
- No more actions for the annexes for MDD, IVDD, AIMDD
- Focus on Annex ZA (MDR) and Annex ZB (IVDR)

Approval by European Commission and CEN-CENELEC in Sept/Oct 2021

Publication of EN ISO 14971:2019/A11:2021 in December 2021

Citation in OJEU in support of MDR and IVDR in May 2022

Practices for EN ISO 14971

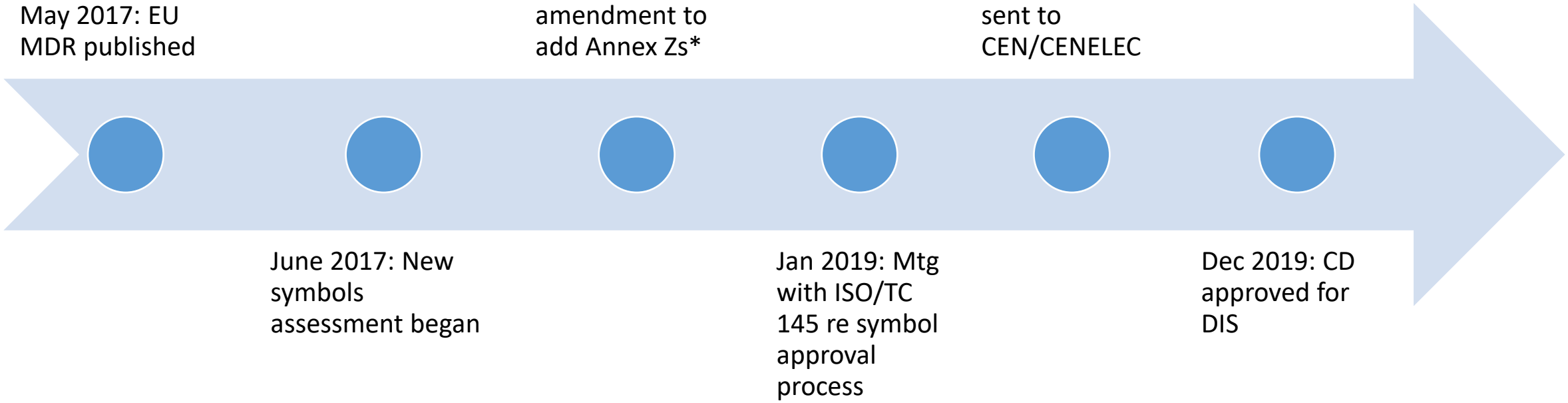
Learning points for “better practices” in standards assessment:

- Criteria should be clear, understandable (e.g. *neutrality principle?*)
- Criteria should be fixed and transparent (*no moving goal posts!*)
- Assessments should be pragmatic and focused on achieving positive results rather than on searching for any issues
- Assessments should focus on the Tables in Annex Z, explaining the coverage of the GSPR by the requirements in the EN

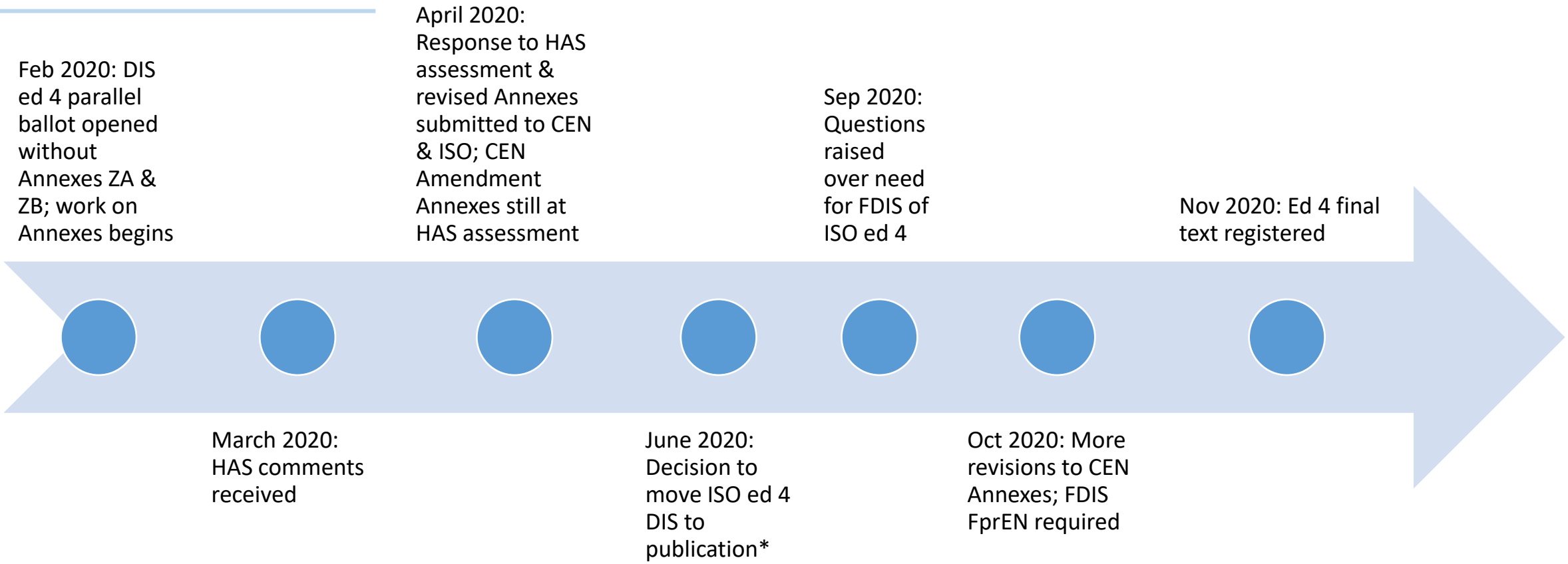
Good Practices from Technical Bodies

Lena Cordie-Bancroft (CEN-CENELEC JTC 03)
Convener of ISO/TC 210 WG 3
ISO/TC 210 Liaison to ISO/TC 145 SC3

Harmonisation Journey for ISO 15223-1



Harmonisation Journey for ISO 15223-1



Harmonisation Journey for ISO 15223-1

May 2021:
EU MDR
went into
force

July 2021:
ISO 15223-1
ed 4
published

Dec 2021:
FDA
recognised

Jan 2022: EU
harmonised
to MDR &
IVDR

Dec 2022 –
Amendment
1 opened

Challenges

Need for symbols to comply with MDR required an early revision – but not guaranteed to be completed in time

CEN requested amendment to 15223-1 ed 3 requesting annexes for harmonisation

Decoupling from Vienna Agreement necessary in order to do amendment on ed 3 and revision to ed 4 in parallel

Are HAS comments considered technical changes?

Gap in publication of ISO vs EN ISO

What happens to ed 3 annexes?

Availability of non-ISO TC 145 approved symbols

Lessons Learned

Refer to GSPRs during CD & DIS processes

- Keep good notes of where GSPRs are met and of rational!

Stay organised

- Have a primary person responsible for the Annexes and communication to CEN

Revision control is your best friend!

- Keep previous revision history as reference

Communication with HAS consultant helped clear away red-tape

- Allows better understanding of reasoning on both sides

Results

Harmonisation of Edition 4 achieved six months after publication!

Amendment to Edition 3 cancelled.

Good Practices from Technical Bodies

Dr Eamonn Hoxey

Chair CEN/TC 204

Convenor CEN/TC 204 WG6

Background

- CEN/TC 204 'Sterilization of medical devices’
- Scope - Standardization in the field of validation and monitoring of sterilization processes as used in manufacturing of medical devices
- 21 published standards or parts of standards
  - 2 parts EN only
  - 19 standards or parts of standards adoptions of ISO deliverables
- M/575 Standardization request
  - 18 existing standards listed
  - 2 new standards listed
  - Most standards listed for both MDR and IVDR
  - 4 additional standards requested to be added – and more to follow

Strategy to address M/575

- Revisions of existing ENs
- On-going revisions of ISO standards
- European amendments of ISO adoptions to revise Annex Zs
  - CEN TC 204/WG12 created to manage European amendments and creation of Annex Zs
- 8 CEN TC 204 standards listed in OJ

EN ISO 14160:2021

Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives - Requirements for characterization, development, validation and routine control of a sterilization process for medical devices (ISO 14160:2020)

- Only MDR is applicable due to scope of standard
- Annex Zs created as part of the ISO revision process under Vienna Agreement
- Annex Zs covered in parallel ballots

Annex Z creation

- Limited number of General Safety and Performance Requirements (GSPRs) relevant
  - GSPR 11 – Infection and microbial contamination
    - 11.3 Devices with specific microbial state
    - 11.4/11.5 Sterile devices
- Each GSPR includes compound requirements
  - Not all elements of each GSPR in scope of the standard
  - Exclusions stated in Annex Z
- Template already developed for standards listed in OJ
- Template updated with each set of comments from HAS Consultant

Annex Z challenges

- Definition of medical device
  - ISO adoption with medical device definition taken from GHTF
  - Added text to Annex Z to indicate that MDR definition takes precedence for purposes of European regulation
- Scope
  - ISO TC 198 scope is health care products – CEN TC 204 scope is medical devices
  - ISO 14160 scope is limited to medical devices
  - Some other ISO adoptions have a more general scope of health care products
  - Broader scope also addressed in Annex Z of applicable documents
- Evolving requirements of Annex Zs
  - New comments at each HAS Consultant review
  - Changing format for European Forward and Annex Z

Annex Z preparation experience

- Establish good coordination and relationships with equivalent ISO TC and WGs for Vienna Agreement work
- Clearly identify GSPRs that are intended to be covered by the standard
- Identify all the components of the applicable GSPRs
- Check that each component of the applicable GSPR is explicitly covered
- Try and keep up to date with changes in format and expectations of the European Forewords and Annex Z
- Take advantage of each HAS Consultant review
  - Discuss HAS Consultant comments and potential solutions

Key Points

Jennifer Ogbonna (CEN-CENELEC)

Key Points

Normative Reference

- Normative references: common reason for lack of compliance assessment or non-citation
- Document on normative references: IR-3
- Normative references: dated, active and published
- Homegrown standards: normative references should be dated in Clause 2 and in body of standard
- Parallel ISO/CEN -> normative references should be dated in Annex ZA.2
- Parallel IEC/CENELEC -> normative reference should be dated in Annex ZA
- Refer to normative reference in clauses as Requirements (SHALL)

Apply Guidance & Document and Useful links

- Guidance on normative references in harmonized standards
- Guidance document on the use of Table ZA.2 to date undated Normative references
- Forms and templates
- CEN BOSS: Drafting European standards for citation in the OJEU
- CENELEC BOSS: Drafting EN IEC standards for citation in the OJEU
- **Checklist Generic**

Key Points

HAS assessment

- Start the process as early as possible!

  i.e. with the assessment request of the first working draft: the consultant would flag compliance issues early in the process

- Systematically provide feedback!

  TC shall provide feedback by responding, in writing, to the HAS consultant's comments
  (column: observations from the secretariat)

- HAS tool for communication with HAS consultant if comments are unclear

European Standardization Organizations

Closing remarks

By Sarah c Sim (SIS – Chair of ABHS)

Thank you for your participation!

Next events

2023-02-07 – 7th Cybersecurity Standardisation Conference