Webinar of 2023-01-24

'Webinar 'Harmonized Healthcare Standards'

Questions & Answers

1	Are the HAS consultants allowed to attend WG meetings?	The HAS consultants for Healthcare Engineering can participate as observers in the meetings of the Subgroup on Standards of the Medical Device Coordination Group (MDCG). And of course, they can also attend TC/WG meetings, if justified by the agenda (so, there must be a clear connection to their assessment work, attending for information purposes only would not be allowed).
2	Is the internal quality check included in the 5 weeks the HAS consultants have time for the Assessment?	Yes. By the way, this Quality Review was already happening under the previous HAS contract.
3	300-person days seems very few regarding the list of standards included in M575 and the need to have a larger participation of HAS consultant during meetings. Is there a way to have more resources allocated (if needed) for meeting M575 objectives and milestones?	300 working days per year is much more than was used for the medical devices sector in the previous 4 years. However, should we see that this is not enough, at the end of each 12 month-period we can reallocate resources from one sector to another.
4	Why are assessments of standards at formal vote stage (submitted at the beginning of last year) still pending while others at enquiry stage have been assessed?	Normally, requests are processed as they come in. For those pending which accumulated in the time between the two contracts, we agreed with CCMC which ones to prioritise. Nevertheless, it is possible to have cases like that but it would depend on the development of assessments with the different HAS consultants. But indeed, we make all the effort to keep an adequate and reasonable pace for all.
5	Where do I find the "normal assessment tasks" of a HAS consultant in the contract?	In the Technical Specifications of the call for tenders for the HAS service contract, and to which the slides contain a link, you will find a detailed description. All the information on the specific role and tasks of the HAS Consultants is contained in part 1.4.2

		of the Technical Specifications (these are 16 pages in total).
6	Is the HAS platform to check the state of the Assessments out of order?	If by HAS platform it was meant the "HAS Database", this is an internal Commission IT-tool with no connection whatsoever with the work of the HAS Consultants. No information on the assessments is stored there. Actually, the HAS Database as such is used by the Commission and CEN-CENELEC to submit harmonised standards proposed to be referred in the OJEU, and it is not open to the public. In the medical device sector, we are studying the possibility to share more information on the state of assessments to give a more precise idea of the timing of possible publications in the OJEU. At the moment, CCMC is forwarding the HAS assessment reports to the concerned Technical Committee leadership.
7	General note on HAS meeting request based on initial experience: E&Y's application to request a meeting with the HAS consultant does not provide feedback that the request has been received or whether the HAS consultant can attend the meeting. This could be improved. Likewise, it should be clarified in the application how many days there should be between the request and the meeting.	Thank you for the feedback, we will look into this. A revision to improve the user-friendliness of this application is already being carried out by EY.
8	What happens when 2 versions of the same normative are still applicable because of grace period, e.g. IEC norms?	In that case, I would recommend you to use the latest edition available.
9	What is the European Commission's legal basis for only allowing Normative References of EN/ISO/IEC standards?	It is related to the legal presumption of conformity that harmonised European standards confer when referred to in the OJEU. So in this sense, normative references should be standards issued by the standardisation organisations mentioned in the Standardisation Regulation (EU) No 1025/2012: CEN, CENELEC and ETSI for EN standards, and ISO, IEC and ITU for international standards. This is the general

		rule, however in some specific and justified cases it could be possible to use also other standards. To be noted: this is not a new requirement, already the Vademecum from 2015 specified this aspect. In addition, this requirement applies only to clauses which provide presumption of conformity.
10	Why can normative references not refer to TS or TR? If parts of them are made normative in the international version (e.g. IEC or ISO), in accordance with ISO/IEC directives, how to manage in ENs?	Because TS or TR are not properly standards, but standardisation deliverables that are not suitable to confer presumption of conformity. Nevertheless indeed, parts of them can be inserted in harmonised standards to become normative - but directly using its relevant text, not through a reference, to avoid confusion and problems in management of the standard itself. It is important to bear in mind that, TRs are informative documents, so completely not appropriate to generate a legal effect (only normative documents can generate presumption of conformity). As for TS, they are a normative document, but their level of technical harmonisation is not sufficient (conflicting national standards can remain in place and do not need to be withdrawn, contrary to European standards). In the end, only standards provide the necessary normative and harmonising strength that documents need to generate in order to have a legal effect.
11	Follow up question, what about all of the standards currently published in the OJEU that contain Normative References to non-EN/ISO/IEC?	What is already cited in the OJEU will not be touched by the EC (unless of course there is e.g. a formal objection by a Member State, or similar exceptional situations). However, when these standards will be revised, this issue will have to be addressed and solved in order to have citation of the new version in the OJEU.
12	What happens if we would like to add an Annex ZA as A11 (European amendment) to an EN ISO standard where a normative reference is dated but a new version is already available? How can we address	A11 are still possible. And you could amend the normative references through that A11. For more specific guidance, I would invite you to contact your sectorial CCMC Project Manager.

	this? or is in this case an A11 not possible anymore?	
13	How should one proceed if the referred standard is only harmonised to the old MDD or has a reference in itself to an historic document and it is not possible to cite it as an informative standard?	In principle it is not necessary that in a harmonised standard under the new MDR/IVDR a referred standard is harmonised under the same Regulations - see the case of normative references to international standards. If it is necessary also other EN standards may be referred, even if they are harmonised under old legislation.
14	Is the new HAS platform for submitting assessment request, especially for first working draft, now operational? Having assessment at early stage is really important especially for standards draft at ISO level under Vienne agreement.	On the side of EC and EY everything is in place, and in fact we have received already assessment requests from other sectors also for first working draft versions.
15	Why are we not always submitting the Annex ZA to CCMC?	For EN ISO standards, at Enquiry and Formal Vote, the TC secretaries are to submit the Annexes Z directly to ISO via the ISO submission interface tool. This will then be circulated for parallel DIS and FDIS.
16	Thank you very much for your explanation and problem resolution approach. Does that mean that the European version of the ISO/IEC standard, then, has to include those referenced parts in its normative body, while the international version just has a normative reference there?	This would be the ideal solution, even if we understand that it is not easy to modify the normative part of an international standard going to become a EN standard. We should check on a case-by-case approach.
17	Is it correct that a Notified Body asks to the manufacturer that use a non-harmonised standard (because do not exist yet for MDR) to build/justify in the GSPR table the reference to the specific points of the standard that cover each GSPR? We receive this as non-conformity of technical file.	Yes, it is correct. If the manufacturer uses a harmonised standard referred in the OJEU, the presumption of conformity is "automatic" without any need for further explanations
18	Is the EC accepting the normative reference to ISO 14971?	In principle yes, even if the European version currently harmonised and cited in the OJEU is EN ISO 14971:2019 plus its amendment A11:2021.
19	HAS consultants do not assess candidate hENs at PUB stage under the new HAS	Correct

	contract. This has been removed from the scope of the contract. TCs are allowed to request a "Last Conformity Assessment" before 2nd Formal Vote in case the 1st FV was non-compliant.	
20	Is there a specific transition period between the previous version and a newly published standard? Or does the three-year transition period is still valid?	It is a 6-month implementation period and not technically a transition period for CEN. Often the date of withdrawal (DOW) of a standard on the CEN CENELEC website is interpreted/used as the implementation date. For harmonised standards referred to in the OJEU, a "transition period" is provided and indicated in the OJEU itself when a new version of a harmonised standard supersedes a previous version. We had not yet a case like that in support of the MDR and IVDR but we will do that when necessary. Such a transition period is usually proposed by CEN-CENELEC when submitting the standard for reference in the OJEU and the Commission may modify it if necessary. Normally, the Commission gives an 18-month transitional period for all sectors and all standards. Derogations (shorter or longer periods) are possible but must be duly justified.
21	Why do some standards define requirements for compliance (shall) and others are recommendations only (should)?	It happens that there are different wordings in English, however the general principle is that "requirements" as such binding are established by legislation only.
22	It is still unclear to me if from a CCMC point of view, assessment (submission platform or internal CCCMC tool?) for FWD is operational. Could you clarify that? Thank you. We expected such evaluation for pr EN ISO 23908 and it was submitted by DIN the 31 October 2022.	The Submission interface is operational. The Technical Committees are to use the tool for the submission of documents to CCMC.