

2020-09-10 CMHAFF Minutes

Date

10 Sep 2020

Attendees

- [Nathan Botts](#)
- [Frank Ploeg](#)
- [Gora Datta](#)

Regrets

Agenda Items

- Review of near final draft of **EN-ISO DTS 82304-2:2020**
- [Text on cMHAFF in CEN/ISO](#)
- CEN/ISO Gap Analysis a.k.a. cMHAFF - CEN/ISO Harmonization
- HITEQ Health App Analyzer

Discussion items

Time	Item	Who	Notes
3 min	Introductions	All	<ul style="list-style-type: none">• No new attendees
50 min	CEN/ISO Gap Analysis a.k.a. cMHAFF - CEN/ISO Harmonization & Conformity Assessment Ad Hoc Group		<ul style="list-style-type: none">• Review of CEN-ISO DTS 82304-2:2020 near final draft for ballot<ul style="list-style-type: none">• Discussion of gap analysis for next CMHAFF ballot• Plan to break up gap findings, conduct review, and add conformance updates or changes to language as appropriate• HL7 WGM Meeting Planning<ul style="list-style-type: none">• Updating slide deck• CEN/ISO Progress<ul style="list-style-type: none">• Frank to follow-up with the meeting request with Charlie• Response from Charlie:<ul style="list-style-type: none">• Many thanks I look forwards to working with HL7, ISO, IEC, CEN and others to avoid fragmentation in this space.• How do we progress the statement on differences? -- maybe we could discuss on the monday call and then schedule a call sometime next week with petra to finalise the detail?• Frank still working on gap analysis between HaWa and CMHAFF• HITEQ Health App Analyzer Review<ul style="list-style-type: none">• Overview of presentation and current draft of HITEQ HAA• Nathan Botts to send Frank Ploeg an account for testing

- **Notes from 8/27/2020**

- General discussion on how best to leverage the CEN/ISO HaWa gap analysis conducted by [Frank Ploeg](#)
- Work toward response to Charlie McCays proposal for collaboration
- Charlie McCay email text:

"I think that there is a case for separating the statements describing what cMHAFf is and how it is being maintained alongside 82304-2 from the statements about the relationship between the two specifications from a user perspective.

These reads to me as an excellent way to frame the need for HL7/ISO/CEN/IEC to collaborate going forwards, and I would suggest that we take the statement forwards in that context, developing a proposal for the relevant HL7/ISO/CEN/IEC/CENELEC leaderships for how the specifications can be taken forwards.

It seems to me that the situation is as follows:

[1] both specifications have been developed to support the assessment of health apps.

[2] where possible they use common definitions and criteria

[3] there are differences in the number of criteria, and focus of the criteria, so a direct mapping between the criteria is not possible in the current versions of the specifications

[4] the PSDO relationship between HL7 and ISO opens up opportunities for more direct and formal collaboration in the maintenance of the specifications going forwards

I suggest that in the TS we include (a paraphrasing of) the statements [1], [2] and [3] with a reference to the HL7 cMHAFf product page.

fwiw my preference for a future collaboration would be:

[1] ISO/IEC is the home for a base set of criteria

[1.1] ISO/IEC maintain the links into the suite of health software and software-as-a-medical-device standards

[1.2] HL7 maintains the links through to the HL7 functional specification frameworks

[1.3] HL7 maintains the links through to SMART on FHIR and similar relevant interoperability specifications

[2] HL7, HL7 Affiliates, CEN, and National Member bodies can define and ballot profiles for specific geographies or usecases. This may be done collaboratively between HL7 national affiliates and national member bodies.

Both specifications are in a "pre-standard" state... 82304-2 is a TS, and cMHAFf and STU .. and it is clear that there is more to learn about what the market needs and how to best drive adoption at scale... and I think that we need to keep the momentum up on those conversations"

Response to email:

- Overall agreement with statements outlined in the email
- Need to work on the description of differences as discussed in [3](#)
- In principle, we fully agree with this proposed way forward. Discussion on the obvious need to walkout the proposed collaboration elements and work through the respective procedures for each organization.
- Plan to circle back to discuss next steps in the future collaboration after the respective products are in the public domain

			<ul style="list-style-type: none"> • Notes from 7/19 Meeting • Final review of cMHAF/ISO harmonization text for inclusion within ISO TS82304-2 <ul style="list-style-type: none"> • Approved by subworkgroup 16 Jul 2020 • Need to get ballot NIB in order by 01 Nov 2020 to meet the January 2021 WGM deadline. <ul style="list-style-type: none"> • Need to get the workgroup vote on approval to ballot by early October so that it has time to be passed on to the steering division for approval afterwards • For projects other than investigative and reaffirmations, to submit a NIB, your PSS must have been approved by TSC a minimum of four weeks before the start of the WGM that precedes the NIB deadline. • Notes from 6/25 Meeting <ul style="list-style-type: none"> • CEN/ISO and CMHAF Inclusion Discussion <ul style="list-style-type: none"> • Discussion on certification need and impact in relation to global software as a medical device • First step in integration between ISO and HL7 - How to collaborate? <ul style="list-style-type: none"> • As the two efforts evolve within standardization cycles each will benefit from each others formal progress • Notes from 6/11 Meeting <ul style="list-style-type: none"> • Focused this meeting primarily on how to harmonize cMHAF and CEN/ISO and what our views should be on how the CEN/ISO Technical Specification will co-exist with the cMHAF Framework. <ul style="list-style-type: none"> • As of now cMHAF is referenced in the TS in Annex E (Informative) "relationship to HL7 Consumer Mobile Health Application Functional Framework" • The idea was to have the CEN/ISO specs as a overall TS and cMHAF as the profiled version - as in realm specific, health topic specific - of the TS • This requires mapping of the TS to cMHAF and vv • This mapping process is almost finished in the since that where applicable cMHAF has been incorporated in the TS. In cooperation and adjustment form the TS point of view in cMHAF has not been undertaken yet. • Basically the main question in the meet was how do we envisage the co-existence of cMHAF to the CEN/ISO specs. This led to an invitation to Gora to help us define this co-existence, also in relation to the <i>Conformity Assessment Ad Hoc Group</i> which is founded by the initiative of Gora (which is the understanding by Frank). Ther invite to Gora reads as follows: <ul style="list-style-type: none"> • Hi Gora, From the CEN/ISO perspective (as relayed by Frank) it sounds as though there are some questions on the ongoing "relationship" between HaWa and CMHAF and how formal that continues to be moving forward. Members of the conformance assessment adhoc group (that you helped to initiate as we understand it) seem to be having questions about this and the benefits or not. We are not completely sure we understand all of the implications/politics involved between CEN/ISO and HL7 CMHAF and think we could benefit from some of your background/guidance on this. Would you be available to join the CMHAF meeting next week (6/18) to discuss this and formulate a position of sorts that can be communicated to that team. Thanks, -Nathan
2 min	New Business: mHealth Hub and HL7 Foundation involvement	Frank	<ul style="list-style-type: none"> • Frank informed the team about HL7 foundation joining in with the mHealth Hub. By the initiative of Catherine Chronaki, Giorgio Cangioli, Gora Datta & Frank have been asked to join the initiative (and have accepted 😊).

Action items

- [Frank Ploeg](#) to provide slide updates of HaWa work
- [Nathan Botts](#) to provide slide updates of HITEQ