

2020-08-20 CMHAFF Minutes

Date

20 Aug 2020

Attendees

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

Regrets

Agenda Items

- [Text on cMHAFF in CEN/ISO](#)
- CEN/ISO Gap Analysis a.k.a. cMHAFF - CEN/ISO Harmonization
- Conformity Assessment Ad Hoc Group
- mHealth Hub & HL7 Foundation

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 | | |

- 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"

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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

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|-------|--|-------|--|
| | | | <ul style="list-style-type: none"> • Notes from 7/19 Meeting • Final review of cMHAFf/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 CMHAFf 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 cMHAFf and CEN/ISO and what our views should be on how the CEN/ISO Technical Specification will co-exist with the cMHAFf Framework. <ul style="list-style-type: none"> • As of now cMHAFf 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 cMHAFf as the profiled version - as in realm specific, health topic specific - of the TS • This requires mapping of the TS to cMHAFf and vv • This mapping process is almost finished in the since that where applicable cMHAFf has been incorporated in the TS. In cooperation and adjustment form the TS point of view in cMHAFf has not been undertaken yet. • Basically the main question in the meet was how do we envisage the co-existence of cMHAFf 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 CMHAFf 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 CMHAFf and think we could benefit from some of your background/guidance on this. Would you be available to join the CMHAFf 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

- [Gora Datta](#)- Find out what approvals need to be made (e.g., TSC approval) before submitting NIB on **01 Nov 2020**