

OASIS eTMF Standard Technical Committee  
Summary of Changes  
OASIS Electronic Trial Master File (eTMF) Specification  
CSD Draft 03 201607

Date: Oct 16 2016

Below is the list of requests made by OASIS staff to the Spec WD 3, posted on OASIS as 'OASIS-eTMF-Standard-CSD-V3-201607', for the spec titled 'Committee Specification Draft 03, 201607-R03, dated 28 July 2016'

Please note Chet Ensign's request numbers, followed in **RED** with the summary of changes made.

Per Chet Ensign, OASIS (Sept 15 2016 email):

Members of the eTMF TC,  
TC Administration provides the following comments for the public review of the above Committee Specification Drafts. These are editorial / production items we noted during publication.

1. For section 1.1 Terminology, we added "RFC2119" to the end of the sentence as it was missing. Please include the reference to RFC2119 as a normative reference next time as well next time. Also, we didn't see that the capitalized key words were used in the spec. **[Done]**
2. The final two references in sect. 1.2 ([19] and [20]) are formatted differently from the first 18, leading to misalignment in both the text and HTML versions. **[Done]**
3. In Appendix B.2 Content Item Numbering, there is a reference to C93816. Given the way it is used it can probably be listed as a non-normative reference. In any case though, any references made should be listed in section 1.2 References. **[Done]**
4. Likewise please make sure that all the references in Appendix C. Glossary are listed in section 1.2
5. Appendix D uses "Oasis" in place of "OASIS" in titles and captions. **[Done]**
6. The captions for Figures 1, 12 and 13 are handled differently from the others. The captions themselves seem to be actual graphic elements, instead of being linked to their diagrams normally. This causes their numbering to come out wrong in the HTML. E.g. Figures 12 and 13 show up as "Figure 1" in the HTML version. **[Done]**
7. Figures 12 and 13 are very done in a way such that they become corrupted when we save the document as HTML. They seem to consist of multiple graphic elements overlaid. It would help if they can be done as single images that can be inserted into the document. **[Done]**
8. The "schema" spreadsheets are named with "V3". That seems confusing when the spec itself is version 1.0. We suggest using "wd03" for the working draft number instead or even just drop the version number. **[Done]**

Please let us know if you have any questions on any of these items.

/chet

-----

Chet Ensign  
Director of Standards Development and TC Administration  
OASIS: Advancing open standards for the information society  
<http://www.oasis-open.org>