eTMF Exchange Mechanism

Release Notes r19.1.5

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Identification

Authors

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Version History

Version	Release Date	Change Requests
19.1.5	31-MAY-2019	CR: 3, 4, 6, 7, 8, 9, 10

Table of Contents

1 Introduction

These Release Notes relate to changes and updates to the *Specification for the eTMF Exchange Mechanism Standard (eTMF-EMS)* that are included in the minor release 19.1.5.

A minor update is defined as a release that requires no substantial change to the specification, and for which changes are unlikely to cause incompatibility issues with previous releases of the eTMF-EMS and/or no significant technical changes to implement the update for electronic TMF solutions.

Examples of changes that would require a minor release include:
- Bug changes
- Changes to the alignment of artifacts with filing level (study, country and site)

This minor release also includes maintenance changes, defined as having no significant impact on adoption or implementation of the Specification. Examples of changes that would require a maintenance release include:
- Exchange process
- eTMF Exchange agreement
- Correction of typographical errors

An outline of the release process and release plan are detailed under sections 3 and 4 and the link to the changes incorporated in the current release are under section 5.

2 Context

The specification of the eTMF Exchange Mechanism Standard was created to bridge an existing gap by enabling easy transfer of eTMF documents between key stakeholders. The specification is an organic document that will go through changes to improve the exchange process and comply with evolving standards. Details on scope and purpose of the EMS can be found in *Specification for the eTMF Exchange Mechanism Standard (eTMF-EMS) Version: 1.0 14-Jun-2018*, https://tmfrefmodel.com/wp-content/uploads/2018/06/etmf-ems-v1-0.pdf.

3   EMS Release Process

A layout of the release steps:
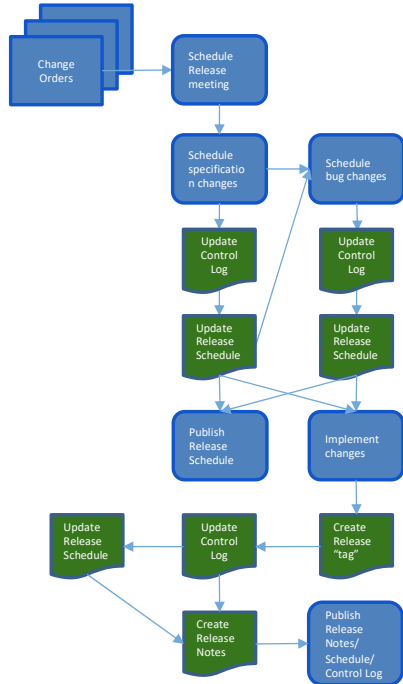
Release Process

- **Schedule release meeting**
  - If there is no or few Change orders this can be done by email
- Schedule specification changes
  - Negotiate when different specification changes should be implemented
- Schedule bug changes
  - Negotiate when different bug changes should be implemented
    - There is no need to hold a bug to a later release, as there is no requirement for a vendor to take a release. Testing can be bulk.
  - Assign change to develope.
- **Implement changes**
  - Implement specification changes
  - Implement XML/XSD changes
    - If specification changes are made, wait for approval
    - Create Release "tag"
    - Update Control Log and Release Schedule
- **Create release notes**
  - Include changes, known issues and link to Release Schedule
  - Afer review publish Release Notes, Schedule and Control Log

4   EMS Release Plan for 2019

Bug release date	Release type	Development name	XSD version	Specification version	Github hash	Release version
6/14/2018	Initial		1.0	1.0	1124ec3	1.0
6/21/2018	Bug		1.0.01	Pending	9b6e259	1.0.01
1/11/2019	Bug	18.4.1				No release
1/25/2019	Bug	18.4.2				No release
2/8/2019	Bug	18.4.3				No release
2/22/2019	Bug	18.4.4				No release
3/8/2019	Bug	18.4.5				No release
3/29/2019	Major/Bug	19.1				No release
4/12/2019	Bug	19.1.1				No release
4/24/2019	Bug	19.1.2				No release
5/6/2019	Bug	19.1.3				No release
5/18/2019	Bug	19.1.4				No release
5/30/2019	Bug	19.1.5	19.1.5	1.0	5350831	19.1.5
6/28/2019	Major/Bug	19.2				
7/12/2019	Bug	19.2.1				
7/26/2019	Bug	19.2.2				
8/9/2019	Bug	19.2.3				
8/23/2019	Bug	19.2.4				
9/6/2019	Bug	19.2.5				
9/27/2019	Major/Bug	19.3				
10/11/2019	Bug	19.3.1				
10/25/2019	Bug	19.3.2				
11/8/2019	Bug	19.3.3				
11/22/2019	Bug	19.3.4				
12/6/2019	Bug	19.3.5				
12/27/2019	Major/Bug	19.4				
1/10/2020	Bug	19.4.1				
1/24/2020	Bug	19.4.2				
2/7/2020	Bug	19.4.3				
2/21/2020	Bug	19.4.4				
3/6/2020	Bug	19.4.5				
3/27/2020	Major/Bug	19.5				

5 General and Bug Changes in the Release 19.1.5

All change requests (CR) in this release are detailed in the table extracted from the EMS Change Control Log below.

CR#	Change Request Description	Link to the issue
3	The string used to match ArtifactNumber is: [0-9]{2}.[0-9]{2}.[0-9]{2} I believe those "." need to be escaped or else it will match on any character? Meaning 01-44-66 and 44566788 and 33#56u88 will all be seen as valid ArtifactNumbers. The below should fix I think... [0-9]{2}.[0-9]{2}.[0-9]{2}	https://github.com/TmfRef/exchange-framework/issues/8
4	1.0.01 changes - remove CHKSUMSTD, change capitalization on AUDITENTR... (...YTYPE values)	https://github.com/TmfRef/exchange-framework/commit/9b6e259fd10ff8611fed58ba96a7213472902fd8
6	Update Schema to support multiple <PERSONNAME> tags	https://github.com/TmfRef/exchange-framework/issues/7
7	Update Schema To Support Multiple AuditRecords Per File	https://github.com/TmfRef/exchange-framework/issues/10
8	According to Tmf specification I've found a bug inside .xsd file. Tmf specification allows to put multiple OBJECT tags inside produced .xlm export file. If we run validation against current .xsd file , it will only validate values from first OBJECT tag from exported file, and skip validation for others. I suggest to add 2 additional attributes to OBJECT tag minOccurs="1" and maxOccurs="unbounded"	https://github.com/TmfRef/exchange-framework/issues/13
9	There are 3 tags which should be optional, but now those fields are mandatory in .xsd file: -RENTENTIONDATE -ARTIFACTDATE -SIGNATURE	https://github.com/TmfRef/exchange-framework/issues/15
10	UNIQUEID field is a number with leading zeros Most programming languages treat a number as is, without tracking leading zeroes. Could we not simplify this field by making it a simple integer? Proposed change is: #18 The UNIQUEID field should be be a true integer (no leading zeros), as the UNIQUEID field is to support technical integration, so you want to minimize the risk for ambiguity and make coding simpler. Whereas the ARTIFACTNUMBER is for business integration.	https://github.com/TmfRef/exchange-framework/issues/19