NIST eDOS Test Tool Implementation Decisions

This document clarifies conformance requirements and other aspects of the HL7 Version 2.5.1 Implementation Guide: **S&I Framework Laboratory Test Compendium Framework R2, DSTU Release 1.1 - US Realm (March 2014)** implementation guide (the eDOS Implementation Guide or eDOS IG'). This document does not specify additional requirements. Rather, it clarifies existing requirements given in the eDOS IG. It also identifies areas where the eDOS IG was ambiguous or contradictory for testing tool implementation.

Therefore, this document also lists the implementation decisions made by National Institute of Standards and Technology (NIST) during the creation of the NIST eDOS Conformance Test Tool.

Decision Number	Message Element	Description	Decision
NIST_EDOS-1	NTE segments	NTE is not defined in the eDOS IG. Note : based on the eDOS DSTU comments, the future version of the eDOS guide will include the NTE segment static definition.	All NTE fields are defined as optional for both **context free** and **context based** validation. For **context based** validation, the NIST Test Tool **MAY** require the presence of a particular NTE field, based on the test objectives.
NIST_EDOS-2	Multiple message locations	Element lengths are not clearly defined in the guide and refer to the underlying standard.	At the moment, the eDOS test tool is **NOT** performing any length checks.
NIST_EDOS-3	OM4-6	The content of the 'SNOMED & HL70487' value set is not defined in the tool.	The NIST eDOS Test Tool tool will not perform validation against the 'SNOMED & HL70487' value set in both **context free** and **context based** validation. For **context based** validation, the NIST Test Tool **MAY** require the use of a particular 'SNOMED & HL70487' code in OM4-6, based on the test objectives.
NIST_EDOS-4	OM1-1	There is no explicit requirement in the eDOS IG for the OM1-1 sequence id. The requirement is derived from the HL7 standard, chapter 8. HL7 Definition: "This field [OM1-1] contains the first OM1 segment in a message and is described as 1, the second as 2, and so on."	The NIST Test Tool will validate any message against the following conformance statement in both **context free** and **context based** validation: **NIST-1 :** OM1-1 (Sequence Number - Test/Observation Master File) SHALL be valued sequentially starting with the value '1' within the message.
NIST_EDOS-5	OM2-1	There is no explicit requirement in the eDOS IG for the OM2-1 sequence id. The requirement is derived from the HL7 standard, chapter 8. HL7 Definition: "This field contains the same value as the sequence number of the associated OM1 segment."	The NIST Test Tool will validate any message against the following conformance statement in both **context free** and **context based** validation : **NIST-2 :** OM2-1 (Sequence Number - Test/Observation Master File) SHALL contain the same value as the sequence number of the associated OM1 segment.
NIST_EDOS-6	OM3-1	There is no explicit requirement in the eDOS IG for the OM3-1 sequence id. The requirement is derived from the HL7 standard, chapter 8. HL7 Definition: "This field contains the same value as the sequence number of the associated OM1 segment"	The NIST Test Tool will validate any message against the following conformance statement in both **context free** and **context based** validation: **NIST-3:** OM3-1 (Sequence Number - Test/Observation Master File) SHALL contain the same value as the sequence number of the associated OM1 segment.
NIST_EDOS-7	OM4-1	There is no explicit conformance statement in the eDOS IG to capture the requirements linked to OM4-1 (Sequence Number - Test/Observation Master File). However, the eDOS IG describes how the OM4-1 sequence number must be handled in an example (see Usage Notes in section 5.5.6). eDOG IG definition : The OM1-1 contains a numeric value that indicates a unique set of OM1, OM2, OM3 and OM4 components; each OMn-1 in a set will have the same value as illustrated in the example below. Because the OM4 segment can repeat, but needs to have a unique number for use with OM4-17, the sequence number must be appended with a sequence number as shown in the second example below [...] Note that this definition is in contradiction with the HL7 definition. [HL7 Definition: "This field contains the same value as the sequence number of the associated OM1."]	The NIST Test Tool will validate any message against the following conformance statement in both **context free** and **context based** validation: **NIST-4:** The first part of OM4-1 (Sequence Number - Test/Observation Master File) SHALL contain the same value as the sequence number of the associated OM1 segment. The second part of OM4-1 (Sequence Number - Test/Observation Master File) SHALL be valued sequentially.
NIST_EDOS-8	OM5-1	There is no explicit requirement in the eDOS IG for the OM5-1 sequence id. The requirement is derived from the HL7 standard, chapter 8. HL7 Definition: "This field contains the same value as the sequence number of the associated OM1 segment."	The NIST Test Tool will validate any message against the following conformance statement in both **context free** and **context based** validation: **NIST-5:** OM5-1 (Sequence Number - Test/Observation Master File) SHALL contain the same value as the sequence number of the associated OM1 segment.

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NIST_EDOS-9	OM1-7 OM1-31 OM1-34 OM1-52 OM1-56 OM5-2	The NIST eDOSTest Tool is not validating OM1-7 (Other Service/Test/Observation IDs for the Observation) and OM1-56 (Observation Identifier associated with Producer's Service/Test/Observation ID) against the LOINC value set. The tool still needs to be able to check that a provided code is valid when the LOINC code system is used.	The NIST Test Tool will validate any message against the following conformance statements in both **context free** and **context based** validation: **NIST-6:** If OM1-7.3 (Name of Coding System) value is 'LN', OM1-7.1 (Identifier) SHALL be a valid LOINC code identifier format. **NIST-7:** If OM1-7.6 (Name of Alternate Coding System) value is 'LN', OM1-7.4 (Alternate Identifier) SHALL be a valid LOINC code identifier format. **NIST-8:** If OM1-31.3 (Name of Coding System) value is "LN", OM1-31.1 (Identifier) SHALL be a valid LOINC code identifier format. **NIST-9:** If OM1-31.6 (Name of Alternate Coding System) value is "LN", OM1-31.4 (Alternate Identifier) SHALL be a valid LOINC code identifier format. **NIST-10:** If OM1-34.3 (Name of Coding System) value is "LN", OM1-34.1 (Identifier) SHALL be a valid LOINC code identifier format. **NIST-11:** If OM1-34.6 (Name of Alternate Coding System) value is "LN", OM1-34.4 (Alternate Identifier) SHALL be a valid LOINC code identifier format. **NIST-12:** If OM1-52.3 (Name of Coding System) value is "LN", OM1-52.1 (Identifier) SHALL be a valid LOINC code identifier format. **NIST-13:** If OM1-52.6 (Name of Alternate Coding System) value is "LN", OM1-52.4 (Alternate Identifier) SHALL be a valid LOINC code identifier format. **NIST-14:** If OM1-56.3 (Name of Coding System) value is "LN", OM1-56.1 (Identifier) SHALL be a valid LOINC code identifier format. **NIST-15:** If OM1-56.6 (Name of Alternate Coding System) value is "LN", OM1-56.4 (Alternate Identifier) SHALL be a valid LOINC code identifier format.
NIST_EDOS-10	All TS flavors	The requirements on the TS flavors need to be implemented as conformance statements.	The NIST Test Tool will validate any message against the following conformance statements in both **context free** and **context based** validation **NIST-18:** TS_1 SHALL be precise to the second.
NIST_EDOS-11	CDM-1	There is no explicit requirement in the eDOS IG for the CDM-1 (Primary Key Value - CDM). The requirement is derived from the HL7 standard, chapter 8. HL7 Definition: "This field [CDM-1] contains the code assigned by the institution for the purpose of uniquely identifying the thing that can be charged. The key field of the entry. For example, this field would be used to uniquely identify a procedure, item, or test for charging purposes. Probably the same set of values as used in FT1-7-Transaction Code in financial messages. Must match MFE-4 - Primary Key Value - MFE. [...]"	The NIST Test Tool will validate any message against the following conformance statement in both **context free** and **context based** validation: **NIST-19:** CDM-1 (Primary Key Value - CDM) SHALL match MFE-4 (Primary Key Value - MFE).
NIST_EDOS-12	OM4-6	The NIST eDOS Test Tool does not perform validation agaisnst the 'SCT & HL70487' value set (implementation choice #NIST_EDOS-XXX). The following conformance statement was added to ensure the SCT or HL70487 code system is used in the element OM4-6.	The NIST Test Tool will validate any message against the following conformance statement in both **context free** and **context based** validation: **NIST-20**: When present, either OM4-6.3 (Specimen.Name of Coding System) or OM4-6.6 (Specimen.Name of Alternate Coding System) SHALL be valued 'SCT' or 'HL70487'.
NIST_EDOS-13	OM1-2	There is no explicit conformance statment in the eDOS IG related to the relation between MFE-4 & OM1-2. The requirement is described in the comment section on table TABLE 5-10. MASTER FILE ENTRY (MFE) : "MFE-4 (Primary Key Value – MFE) shall match OM1-2 (Producer's Service/Test/Observation ID)." Note that this can only apply to M08 and M10 message since there is no OM1 segment in the M04 message structure.	The NIST Test Tool will validate any message against the following conformance statement in both **context free** and **context based** validation: **NIST-21:** OM1-2 (Producer's Service/Test/Observation ID) SHALL match MFE-4 (Primary Key Value - MFE).

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NIST_EDOS-14	CDM-7	The content of the 'HL70088' value set is not defined in the tool.	The NIST eDOS Test Tool tool will not perform validation against the 'HL70088' value set in both **context free** and **context based** validation. For **context based** validation, the NIST Test Tool **MAY** require the use of a particular 'HL70088' code in CDM-7, based on the test objectives.
NIST_EDOS-15	MFE-4 OM1-2 OM1-5 OM1-7 OM1-27 OM1-31 OM1-33 OM1-34 OM1-52 OM1-56 OM2-2 OM3-4 OM3-5 OM4-5 OM5-2	The value set '9999' is defined as 'Externally or Locally defined'.	The NIST eDOS Test Tool tool will not perform validation against the '9999' value set in both **context free** and **context based** validation. For **context based** validation, the NIST Test Tool **MAY** require the use of a particular code and/or code system in elements linked to the '9999' value set, based on the test objectives.
NIST_EDOS-16	MFE-2 OM1-2 CDM-1	Pending a DSTU comment to the eDOS WG, ALL components of the CWE datatype SHALL match. This is a functional requirement and at a minimum the code and code system should match, but depending upon implementation the text components may be used for display purpose and in those cases they should match as well to avoid confusion. Therefore unless the eDOS workgroup and/or the LRI functional requirements workgroup clarifies these requirements a "match" on the CWE datatype shall mean all components must be identical.	When comparing CWE elements (this includes any datatype flavor derived from CWE), the NIST test tool will check for an **exact match** for ALL components and subcomponents that are NOT optional. This rule applies for both **context free** and **context based**.
NIST_EDOS-17	MSH-21	The eDOS IG does not include any requirement on MSH-21 in regards to the use of the correct profile identifier for the GU or NG profiles.	The NIST Test Tool will validate any message against the following conformance statement in both **context free** and **context based** validation for the GU Profile : **NIST-22** : An occurrence of MSH-21 (Message Profile Identifier) SHALL be valued with '2.16.840.1.113883.9.70' (eDOS_GU_Profile) or two occurrences SHALL be valued with '2.16.840.1.113883.9.67' (eDOS_Common_Component) and '2.16.840.1.113883.9.68' (eDOS_GU_Component) in any order. The NIST Test Tool will validate any message against the following conformance statement in both **context free** and **context based** validation for the NG Profile : **NIST-23** : An occurrence of MSH-21 (Message Profile Identifier) SHALL be valued with '2.16.840.1.113883.9.71' (eDOS_NG_Profile) or two occurrences SHALL be valued with '2.16.840.1.113883.9.67' (eDOS_Common_Component) and '2.16.840.1.113883.9.69' (eDOS_NG_Component) in any order.

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