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Health Information Technology (HIT)   
Standards Testing Infrastructure

HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework R2, DSTU Release 2 - US Realm Also referred to as eDOS (Electronic Directory Of Service) Draft Standard for Trial Use September 2015

NIST Clarifications and Validation Guidelines

Version 1.0

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**TABLE OF CONTENTS**

[1.0 Introduction 3](#_Toc464053720)

[2.0 Validation Policies 5](#_Toc464053721)

[3.0 errata 23](#_Toc464053722)

# Introduction

This document lists conformance testing issues and associated policies derived by NIST based on a review of the HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework R2, DSTU Release 2 - US Draft Standard for Trial Use September 2015 (EDOS). The policies listed in this document are implemented in the NIST EDOS conformance test suite.

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# Validation Policies

|  |  |  |  |
| --- | --- | --- | --- |
| Decision Number | Title | Description | Decision |
| NIST\_EDOS-01 | Length checks | Element lengths are not clearly defined in the guide and refer to the underlying standard. | At the moment, the NIST eDOS Test Tool is **NOT** performing any length checks. |
| NIST\_EDOS-02 | OM1-1 sequence check (derived from HL7) | 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 eDOS Test Tool will validate any message against the following derived conformance statement in both **context free** and **context based** validation:  **NIST-001 :** OM1-1 (Sequence Number - Test/Observation Master File) SHALL be valued sequentially starting with the value '1' within the message. |
| NIST\_EDOS-03 | OM2-1 sequence check (derived from HL7) | 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 eDOS Test Tool will validate any message against the following derived conformance statement in both **context free** and **context based** validation:  **NIST-002** : OM2-1 (Sequence Number - Test/Observation Master File) SHALL contain the same value as the sequence number of the associated OM1 segment. |
| NIST\_EDOS-04 | OM3-1 sequence check (derived from HL7) | 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 eDOS Test Tool will validate any message against the following derived conformance statement in both **context free** and **context based** validation:  **NIST-003:** OM3-1 (Sequence Number - Test/Observation Master File) SHALL contain the same value as the sequence number of the associated OM1 segment. |
| NIST\_EDOS-05 | OM4-1 sequence check | 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 eDOS Test Tool will validate any message against the following derived conformance statement in both **context free** and **context based** validation:  **NIST-004:** 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-06 | OM5-1 sequence check (derived from HL7) | 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 eDOS Test Tool will validate any message against the following derived conformance statement in both **context free** and **context based** validation:  **NIST-005:** OM5-1 (Sequence Number - Test/Observation Master File) SHALL contain the same value as the sequence number of the associated OM1 segment. |
| NIST\_EDOS-07 | Format check on TS flavors | The requirements on the TS flavors need to be implemented as conformance statements. | ​​​The NIST eDOS Test Tool will validate any message against the following derived conformance statements in both **context free** and **context based** validation :  **NIST-016:** TS\_1 SHALL be precise to the second. |
| NIST\_EDOS-08 | ALL subcomponents of the CWE datatype SHALL match | 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 eDOS 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-09 | eDOS-6 & eDOS-7 should apply to eDOS\_Acknowledgment\_Component | The eDOS-6 and eDOS-7 conformance statements are only nested under eDOS\_Common\_Component. NIST believes those conformance statements should also apply to the MSH segment present in MFK (all message types) messages. | The NIST eDOS Test Tool will validate MFN and MFK message against the following conformance statement in both **context free** and **context based** validation:  **eDOS-6**: MSH-1 (Field Separator) SHALL contain the constant value ‘|’. **eDOS-7**: MSH-2 (Encoding Characters) SHALL contain the constant value ‘^~\&’ or the constant value ‘^~\&#’. |
| NIST\_EDOS-10 | Conformance statement eDOS-8 should be removed | The conformance statement: eDOS-8: MSH-12.1 (Version ID.Version ID) SHALL contain the constant value ‘2.5.1’. can be removed because there is already a conformance statement similar in the VID datatype: eDOS-5: VID.1 (Version Identifier) SHALL be valued ‘2.5.1’ drawn from the HL7 Table HL70104. | The NIST eDOS Test Tool will **not** validate message against eDOS-8 in both **context free** and **context based** validation. |
| NIST\_EDOS-11 | eDOS-25, eDOS-26, eDOS-27 & eDOS-28 should apply to eDOS\_Acknowledgment\_Component | The eDOS-25, eDOS-26, eDOS-27 & eDOS-28 conformance statements are only nested under eDOS\_Common\_Component. NIST believes those conformance statements should also apply to the MFI segment present in MFK (all message types) messages. | The NIST eDOS Test Tool will validate MFN and MFK messages against the following conformance statement in both **context free** and **context based** validation:  **(M04 only) eDOS-25:** MFI-1.1 (Identifier) **SHALL** be valued 'CDM' drawn from the HL7 Table HL70175. **(M08 only) eDOS-26:** MFI-1.1 (Identifier) **SHALL** be valued 'OMA' or 'OMM' drawn from the HL7 Table HL70175. **(M10 only) eDOS-27:** MFI-1.1 (Identifier) **SHALL** be valued 'OMC' or 'OMM' drawn from the HL7 Table HL70175. **(M18 only) eDOS-28:** MFI-1.1 (Identifier) **SHALL** be valued 'MLCP' or 'MACP' drawn from the HL7 Table HL70175. |
| NIST\_EDOS-12 | Numbering of eDOS conformance statements. | Some conformance statements were not assigned a unique identifier in the eDOS IG. The last used identifier from the eDOS IG is eDOS-37. NIST has decided to assign identifiers starting at eDOS-38. | **eDOS-38**: MO.2 (Denomination) SHALL be valued ‘USD’ drawn from the HL7 Table HL70913.  Conformance Statements Conformance Statements eDOS\_Common\_Component (M04 Message only):  **eDOS-39**: MSH-9.1 (Message Code) SHALL be valued ‘MFN’ drawn from the HL7 Table HL70076. **eDOS-40**: MSH-9.2 (Trigger Event) SHALL be valued ‘M04” drawn from the HL7 Table HL70003. **eDOS-41**: MSH-9.3 (Message Structure) SHALL be valued ‘MFN\_M04’ drawn from HL7 Table HL70354.  Conformance Statements eDOS\_Common\_Component (M08 Message only):  **eDOS-42**: MSH-9.1 (Message Code) SHALL be valued ‘MFN’ drawn from the HL7 Table HL7 0076. **eDOS-43**: MSH-9.2 (Trigger Event) SHALL be valued ‘M08’ drawn from the HL7 Table HL70003. **eDOS-44**: MSH-9.3 (Message Structure) SHALL be valued “MFN\_M08” drawn from the HL7 Table HL70354.  Conformance Statements eDOS\_Common\_Component (M10 Message only):  **eDOS-45**: MSH-9.1 (Message Code) SHALL be valued ‘MFN’ drawn from the HL7 Table HL7 0076. **eDOS-46**: MSH-9.2 (Trigger Event) SHALL be valued ‘M10’ drawn from the HL7 Table “HL70003. **eDOS-47**: MSH-9.3 (Message Structure) SHALL be valued ‘MFN\_M10’ drawn from the HL7 Table HL70354.  Conformance Statements eDOS\_Common\_Component: (M18 Message only):  **eDOS-48**: MSH-9.1 (Message Code) SHALL be valued ‘MFN’ drawn from the HL7 Table HL70076. **eDOS-49**: MSH-9.2 (Trigger Event) SHALL be valued ‘M18’ drawn from the HL7 Table HL70003. **eDOS-50**: MSH-9.3 (Message Structure) SHALL be valued ‘MFN\_M18’ drawn from the HL7 Table HL70354.  Conformance Statements eDOS\_Acknowledgement\_Component (M04 Acknowledgement Message only):  **eDOS-51**: MSH-9.1 (Message Code) SHALL be valued ‘MFK’ drawn from the HL7 Table HL70076. **eDOS-52**: MSH-9.2 (Trigger Event) SHALL be valued ‘M04’ drawn from the HL7 Table HL70003. **eDOS-53**: MSH-9.3 (Message Structure) SHALL be valued ‘MFK\_M01’ drawn from the HL7 Table HL70354.  Conformance Statements eDOS\_Acknowledgement\_Component (M08 Acknowledgement Message only):  **eDOS-54**: MSH-9.1 (Message Code) SHALL be valued ‘MFK’ drawn from the HL7 Table HL70076. **eDOS-55**: MSH-9.2 (Trigger Event) SHALL be valued ‘M08’ drawn from the HL7 Table HL70003. **eDOS-56**: MSH-9.3 (Message Structure) SHALL be valued ‘MFK\_M01’ drawn from the HL7 Table HL70354.  Conformance Statements eDOS\_Acknowledgement\_Component (M10 Acknowledgement Message only):  **eDOS-57**: MSH-9.1 (Message Code) SHALL be valued ‘MFK’ drawn from the HL7 Table HL70076. **eDOS-58**: MSH-9.2 (Trigger Event) SHALL be valued ‘M10’ drawn from the HL7 Table HL70003. **eDOS-59**: MSH-9.3 (Message Structure) SHALL be valued ‘MFK\_M01’ drawn from the HL7 Table HL70354.  Conformance Statements eDOS\_Acknowledgement\_Component (M18 Acknowledgement Message only):  **eDOS-60**: MSH-9.1 (Message Code) SHALL be valued ‘MFK’ drawn from the HL7 Table HL70076. **eDOS-61**: MSH-9.2 (Trigger Event) SHALL be valued ‘M18’ drawn from the HL7 Table HL70003. **eDOS-62**: MSH-9.3 (Message Structure) SHALL be valued ‘MFK\_M01’ drawn from the HL7 Table HL70354.  **eDOS-63**: CDM-7.3 (Procedure Code.Code system) SHALL be valued ‘C4’ drawn from the HL7 table 0088.  **eDOS-64**: NTE-1 (Set ID – NTE) SHALL be sequentially numbered starting with the value '1' for each segment it is following.  **eDOS-65**: MCP-1 (Set ID – MCP) SHALL be sequentially numbered starting with the value '1' within a given PAYER MF Entry group. |
| NIST\_EDOS-13 | Exclusion of value sets when requirement is checked by a conformance statement | The following value sets are not defined:   * HL70076\_USL (MSH-9.1) * HL70003\_USL (MSH-9.2) * HL70354\_USL (MSH-9.3) * HL70132\_USL (CDM-1)   The values of those element are checked by conformance statements. | The NIST eDOS Test Tool will **not** perform validation against the following value sets:   * HL70076\_USL (MSH-9.1) * HL70003\_USL (MSH-9.2) * HL70354\_USL (MSH-9.3) * HL70132\_USL (CDM-1)   in both **context free** and **context based** validation. The NIST eDOS Test Tool tool will perform validation against the conformance statements associated to those elements in both **context free** and **context based** validation. |
| NIST\_EDOS-14 | Locally defined value sets excluded from validation | The following value sets are locally defined and must be completed by trading partners:   * HL70361\_USL.1 * HL70362\_USL.1 * HL70362\_USL.2 | The NIST eDOS Test Tool will **not** validate MSH-3 (Sending Application) against HL70361\_USL.1 in both **context free** and **context based** validation.  The NIST eDOS Test Tool will **not** validate MSH-4 (Sending Facility) against HL70362\_USL.1 in both **context free** and **context based** validation.  The NIST eDOS Test Tool will **not** validate MSH-6 (Receiving Facility) against HL70362\_USL.2 in both **context free** and **context based** validation. |
| NIST\_EDOS-15 | Exclusion of '9999' value set for context based & context free | The value set '9999' is defined as 'Externally or Locally defined'. | The NIST eDOS Test 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 | Exclusion of 'HL70103\_USL' value set | The HL70103\_USL spreadsheet does not define the se of required/permitted/excluded codes for eDOS messages. | The NIST eDOS Test Tool will **not** validate MSH-11.1 against the HL70103\_USL value set in both **context free** and **context based** validation. |
| NIST\_EDOS-17 | Exclusion of the HL70190\_USL value set | The binding to element XAD.7 (Address type) is undefined in HL70190\_USL. | The NIST eDOS Test Tool will not validate XAD.7 (Address type) against HL70190\_USL in both **context free** and **context based** validation.​ |
| NIST\_EDOS-18 | Exclusion and replacement of the HL70399\_USL value set | The binding to element XAD.6 (Country code) is undefined in HL70399\_USL.  The HL70399\_USL value set spreadsheet does not contain an explicit list of codes excluded. | The NIST eDOS Test Tool will **not** validate XAD.6 (Country code) against the HL70399\_USL value set in both **context free** and **context based** validation.  The NIST eDOS Test Tool will validate XAD-6 against a custom value set, **NIST\_HL70399\_USL​**, that explicitly contains all the required and permitted values in both **context free** and **context based** validation. |
| NIST\_EDOS-19 | Exclusion of HL70088\_USL value set (CDM-7) for context based & context free | The value set 'HL70088\_USL' is only composed of one value, 'C4'. This value is actually the code system for CPT-4. Since does not contain any of the actual CPT-4 codes, the NIST validation tool is not capable of validating against this value set. | The NIST eDOS Test Tool will **not** perform validation against the HL70088\_USL value set in both **context free** and **context based** validation. |
| NIST\_EDOS-20 | Exclusion of UCUM\_USL value set | The UCUM\_USL value set spreadsheet does not contain an explicit list of codes allowed. | The NIST eDOS Test Tool will **not** validate OM2-2 (Unit of Measure) and OM4-5 (Container Units) against the UCUM\_USL value set in both **context free** and **context based** validation. |
| NIST\_EDOS-21 | Exclusion of the SNOMED\_CT\_USL value set | The SNOMED\_CT\_USL value set spreadsheet does not contain an explicit list of SNOMED CT codes allowed. The NIST eDOS Test Tool still needs to be able to check that a provided code is valid when the SNOMED CT code system is used. | The NIST eDOS Test Tool will **not** validate OM4-6 (Specimen), OM3-4 (Normal Text/Codes for Categorical Observations), OM3-5 (Abnormal Text/Codes for Categorical Observations), OMC-11 (Answer Choices) against SNOMED\_CT\_USL in both **context free** and **context based** validation.  The NIST eDOS Test Tool will validate any message against the following derived conformance statements in both **context free** and **context-based** validation:  **NIST-017**: If OM4-6.3 (Name of Coding System) is valued 'SCT' OM4-6.1 (Identifier) SHALL be a valid SNOMED CT code identifier format. **NIST-018**: If OM4-6.6 (Name of Alternate Coding System) is valued 'SCT' OM4-6.4 (Alternate Identifier) SHALL be a valid SNOMED CT code identifier format. **NIST-019**: If OM3-4.3 (Name of Coding System) is valued 'SCT' OM3-4.1 (Identifier) SHALL be a valid SNOMED CT code identifier format. **NIST-020**: If OM3-5.3 (Name of Coding System) is valued 'SCT' OM3-5.1 (Identifier) SHALL be a valid SNOMED CT code identifier format. **NIST-021​** : If OMC-11.3 (Name of Coding System) is valued 'SCT' OMC-11.1 (Identifier) SHALL be a valid SNOMED CT code identifier format. |
| NIST\_EDOS-22 | Exclusion of LOINC\_USL value set | The LOINC\_USL value set spreadsheet does not contain an explicit list of LOINC codes allowed. The NIST eDOS Test Tool still needs to be able to check that a provided code is valid when the LOINC code system is used. | The NIST eDOS Test Tool will **not** validate OM1-7 (Other Service/Test/Observation IDs for the Observation), OM1-34 (Reflex Tests/Observations), OM1-52 (Replacement Producer's Service/Test/Observation ID), OM1-56 (Observation Identifier associated with Producer's Service/Test/Observation ID), OM5-2 (Test/Observations Included Within an Ordered Test Battery) or OMC-4 (Clinical Information Request) against LOINC\_USL in both **context free** and **context based** validation.   The NIST eDOS Test Tool will validate any message against the following derived conformance statements in both **context free** and **context based** validation: **NIST-006:** If OM1-7.3 (Name of Coding System) value is 'LN', OM1-7.1 (Identifier) SHALL be a valid LOINC code identifier format.  **NIST-007:** If OM1-34.3 (Name of Coding System) value is "LN", OM1-34.1 (Identifier) SHALL be a valid LOINC code identifier format. **NIST-008:** 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-009:** If OM1-52.3 (Name of Coding System) value is "LN", OM1-52.1 (Identifier) SHALL be a valid LOINC code identifier format.  **NIST-010:** If OM1-56.3 (Name of Coding System) value is "LN", OM1-56.1 (Identifier) SHALL be a valid LOINC code identifier format. **NIST-011:** 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-012:** If OM5-2.3 (Name of Coding System) value is "LN", OM5-2.1 (Identifier) SHALL be a valid LOINC code identifier format. **NIST-013:** If OM5-2.6 (Name of Alternate Coding System) value is "LN", OM5-2.4 (Alternate Identifier) SHALL be a valid LOINC code identifier format.  **NIST-014:** If OMC-4.3 (Name of Coding System) value is "LN", OMC-4.1 (Identifier) SHALL be a valid LOINC code identifier format. **NIST-015:** If OMC-4.6 (Name of Alternate Coding System) value is "LN", OMC-4.4 (Alternate Identifier) SHALL be a valid LOINC code identifier format. |
| NIST\_EDOS-23 | Exclusion of SNOMED & HL70487 value set (OM4-6) for context based & context free | The NIST eDOS Test Tool does not support, at the moment, the validation against multiple binding of value sets, when one of the value set bindings has been excluded from validation. The value set bindings for OM4-6 (Specimen) is defined as SNOMED CT and/or HL70487\_USL. The SNOMED CT value set (SNOMED\_CT\_USL) has been excluded from the validation per decision NIST\_EDOS-21**.** | 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 (Specimen), based on the test objectives.  Additionally, the NIST eDOS Test Tool will validate any message against the following derived conformance statement in both **context free** and **context based** validation:  **NIST-022**: If OM4-6.3 (Name of Coding system) is valued 'HL70487', OM4-6.1 (Identifier) SHALL be a valid code drawn from the HL70487\_USL.1 value set.  **NIST-023**: If OM4-6.6 (Name of Alternate Coding System) is valued 'HL70487', OM4-6.4 (Alternate Identifier) SHALL be a valid code drawn from the HL70487\_USL.1 value set. |
| NIST\_EDOS-24 | Code system check for OM4-6 | The NIST eDOS Test Tool does not perform validation against the 'SCT & HL70487\_USL' value set (see item NIST\_EDOS-23). The following conformance statement was added to ensure the SCT or HL70487 code system is used in the element OM4-6 (Specimen). | The NIST eDOS Test Tool will validate any message against the following derived conformance statement in both **context free** and **context based** validation:  **NIST-024**: 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', 'HL70487', 'L' or '99zzz' for a local code system. |
| NIST\_EDOS-25 | Changing OM1-34 Value Set from '9999' to 'LOINC\_USL' | NIST recommends the use of the LOINC value set for element OM1-34 (Reflex Tests/Observations) instead of '9999' | The value set binding for element OM1-34 (Reflex Tests/Observations) is set to "LOINC\_USL".  The NIST eDOS Test Tool will **not** validate OM1-34 against the LOINC\_USL value set as LOINC\_USL has been excluded from validation per decision NIST\_EDOS-22. |
| NIST\_EDOS-26 | Changing OM1-52 Value Set from '9999' to 'LOINC\_USL' | NIST recommends the use of the LOINC value set for element OM1-52 (Replacement Producer’s Service/Test/Observation ID) instead of '9999' | The value set binding for element OM1-52 (Replacement Producer’s Service/Test/Observation ID) is set to "LOINC\_USL".  The NIST eDOS Test Tool will **not** validate OM1-52 against the LOINC\_USL value set as LOINC\_USL has been excluded from validation per decision NIST\_EDOS-22. |
| NIST\_EDOS-27 | Changing OM1-56 Value Set from '9999' to 'LOINC\_USL' | NIST recommends the use of the LOINC value set for element OM1-56 (Observation Identifier associated with Producer's Service/Test/Observation ID) instead of '9999' | The value set binding for element OM1-56 (Observation Identifier associated with Producer's Service/Test/Observation ID) is set to "LOINC\_USL".  The NIST eDOS Test Tool will **not** validate OM1-56​ against the LOINC\_USL value set as LOINC\_USL has been excluded from validation per decision NIST\_EDOS-22. |
| NIST\_EDOS-28 | Changing OM2-2 Value Set from '9999' to 'UCUM\_USL' | According to the note in the eDOS IG note on OM2-2 (Units of Measure), the recommended value set for that element is UCUM. | The value set binding for element OM2-2(Units of Measure) is set to "UCUM\_USL.4".  The NIST eDOS Test Tool will **not** validate OM2-2 against the UCUM\_USL.4 value set as UCUM\_USL has been excluded from validation per decision NIST\_EDOS-20. |
| NIST\_EDOS-29 | Changing OM4-5 Value Set from '9999' to 'UCUM\_USL' | NIST recommends the use of the UCUM value set for element OM4-5 (Container Units) instead of '9999' | The value set binding for element OM4-5 (Container Units) is set to "UCUM\_USL".  The NIST eDOS Test Tool will **not** validate OM4-5 against the UCUM\_USL value set as UCUM\_USL has been excluded from validation per decision NIST\_EDOS-20. |

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# errata

For a current list of errata see the [HL7 EDOS R2 DSTU site](http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=172).