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Health Information Technology (HIT)   
Standards Testing Infrastructure

HL7 Version 2.5.1 Implementation Guide: S&I

Framework Laboratory Orders (LOI) from EHR,

Release 1, DSTU Release 2 - US Realm

Draft Standard for Trial Use

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NIST Clarifications and Validation Guidelines

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# 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 Orders (LOI) from EHR, Release 1, DSTU Release 2- US Realm Draft Standard for Trial Use November 2015 (LOI). The policies listed in this document are implemented in the NIST LOI conformance test suite.

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# Validation Policies

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| --- | --- | --- | --- |
| Decision Number | Title | Description | Decision |
| NIST\_LOI-01 | Out of scope conformance statements | The following conformance statements are out of scope in this edition of the NIST LOI Test Tool: - LOI-30 - LOI-31 - LOI-32 - LOI-33 - LOI-34 - LOI-79-a (see decision NIST\_LOI-03) - LOI-80 | ​The NIST LOI Test Tool will **not** validate against the following conformance statements, in both **context free** and **context based** validation: LOI-30, LOI-31, LOI-32, LOI-33, LOI-34, LOI-79-a, LOI-80 |
| NIST\_LOI-02 | Conformance statements applying on optional element or sub-elements are not enforced in the tool | The guide is silent on whether conformance statements applying to complex data element should also apply to underlying optional data elements. | ​For conformance statements that may apply on optional elements or sub elements, the NIST LOI Test tool will **NOT enforce** the checks on optional elements.  For example:  LOI-46 : The value of ORC-12 (Ordering Provider) SHALL be identical to the value of OBR-16 (Ordering Provider) within the same Order Group.  ORC-12/OBR-16 have numerous components that are O (optional). A message that would have a value in ORC-12.4 (Second and Further Given Names or Initials Thereof) and no value or a different value in OBR-16.4 would NOT fail. |
| NIST\_LOI-03 | Duplicate LOI-79 identifier in LOI IG | The same identifier (LOI-79) is used for two different conformance statements in the LOI IG. | ​The NIST Test Tool will differentiate the two conformance statements: **LOI-79-a**: An occurrence of MSH-21 (Message Profile Identifier) SHALL be valued with '2.16.840.1.113883.9.83' **LOI-79-b**: If any OBR-7 (Observation Date/Time), OBR-8 (Observation End Date/Time), SPM-17.1 (Range Start Date/Time) or SPM-17.2 (Range End Date/Time) contain a time zone offset then all SHALL contain a time zone offset. |
| NIST\_LOI-04 | Predicate in Cancel Order message not implementable | The condition predicate for the following elements, in the OML^O21 Cancel Order message structure is not implementable: - PATIENT/NK1 segment - PATIENT/VISIT group - PATIENT/INSURANCE group - PATIENT/GT1 segment - PATIENT/AL1 segment   The condition predicate is defined in the LOI IG as "If ORC-1 (Order Control Code) is valued 'CA' or 'OC'. The OML^O21 Cancel Order message structure allows the ORDER group to repeat (cardinality of [1..\*]) therefore there could be several ORC segments in a valid message and the predicate could not be evaluated because the ORC segment is not uniquely defined. | ​The NIST LOI Test Tool will **not** validate the condition predicate for the following elements, in both **context free** and **context based** validation: - OML^O21 Cancel Order message, PATIENT/NK1 segment - OML^O21 Cancel Order message, PATIENT/VISIT group - OML^O21 Cancel Order message, PATIENT/INSURANCE group - OML^O21 Cancel Order message, PATIENT/GT1 segment - OML^O21 Cancel Order message, PATIENT/AL1 segment |
| NIST\_LOI-05 | Missing conformance statements in ORL message | Some conformance statements are only defined under the LOI\_Common\_Component but should also be applied to LOI\_ORL\_Acknowledgement\_Component. | ​The NIST LOI Test Tool will validate ORL messages against the following derived conformance statements in both **context free** and **context based** validation: **NIST-09**: MSH-1 (Field Separator SHALL contain the constant value '|'. **NIST-10**: MSH-2 (Encoding Characters) SHALL contain the constant value '^~\&' or the constant value '^~\&#' **NIST-11**: MSH-12.1 (Version ID) SHALL contain the constant value '2.5.1'. |
| NIST\_LOI-06 | PID-8 in ORL^O22 value set undefined in HL70001\_USL | The value set binding for PID-8 (Administrative Sex) in not defined in the HL70001\_USL spreadsheet for the ORL^O22 message structure. | ​The NIST LOI Test Tool will validate PID-8 (Administrative Sex) in ORL^O22 messages against the same value set as in the OML^O21 message, HL70001\_USL.3, in both **context free** and **context based** validation. |
| NIST\_LOI-07 | PID-11 predicate not implementable in ORL^O22 (no PV1 segment in message structure) | PV1 segment is not part of the ORL^O22 message structure therefore the PID-11 (Patient Address) condition predicate is not implementable in ORL^O22 messages. | ​The NIST LOI Test Tool will validate PID-11 (Patient Address) as an **C usage** with no condition predicate in both **context free** and **context based** validation for **ORL^O22** messages. |
| NIST\_LOI-08 | Separation of the "L,M,N" code for locally defined coding schemas in three separate values in value sets HL70301\_USL.3 and HL70301\_USL.4 | The HL70301\_USL value set spreadsheet defines the codes for locally defined coding schemas in a single entry as 'L,M,N'. | ​The NIST LOI Test Tool will consider the value 'L,M,N' from value set HL70301\_USL as three individual codes : 'L', 'M', 'N'. |
| NIST\_LOI-09 | Use HL70396 online version for optional fields | The LOI NIST Test Tool uses the HL7 tables defined in the standard to validate optional (O) data elements. However, HL70396 is a dynamic table and therefore the NIST LOI Test Tool should not use a static version of that table. | ​The online version of HL7 table HL70396 will be used to validate optional fields.  http://www.hl7.org/special/committees/vocab/table\_0396/index.cfm The concept of usage is not defined in the online version of HL70396, the NIST validation tool will use the following convention: - all codes marked as "obsolete" are treated as E (excluded) usage - all other codes are treated as P ("permitted") usage |
| NIST\_LOI-10 | CWE\_\*\*\*.7 condition predicate clarification | The LOI IG defines the condition predicate on CWE\_\*\*\*.7 as "If CWE\_\*\*\*.3 (Name of coding System) is not an HL7 defined table or user defined." | ​The NIST LOI Test Tool will consider, in both **context free** and **context based** validation, that: - "HL7 defined table" is a table that starts with the "HL7" prefix, followed by the four digits identifying the table number. - "user defined" is a code system represented by either 'L' or '99zzz' where  z is an alphanumeric character. |
| NIST\_LOI-11 | MSG conformance statements and value sets | The value of MSH-9.1 (MSG.1) is already checked by conformance statements (LOI-9, LOI-20, LOI-69). The value of MSH-9.2 (MSG.2) is already checked by conformance statements (LOI-10, LOI-65, LOI-70). The value of MSH-9.3 (MSG.3) is already checked by conformance statements (LOI-11, LOI-66, LOI-71). | ​The NIST LOI Test Tool will **not** validate MSG.1 (Message Code) against HL70076\_USL in both **context free** and **context based** validation. The NIST LOI Test Tool will **not** validate MSG.2 (Trigger Event) against HL70003\_USL in both **context free** and **context based** validation. The NIST LOI Test Tool will **not** validate MSG.3 (Message Structure) against HL70354\_USL in both **context free** and **context based** validation. |
| NIST\_LOI-12 | Format check on 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 derived conformance statements in both **context free** and **context based** validation:  **NIST-01** : TS\_0 SHALL be precise to the year. **NIST-02** : TS\_1 SHALL be precise to the second. **NIST-03** : TS\_2 SHALL be precise to the year. **NIST-04** : TS\_3 SHALL be precise to the year. **NIST-05** : TS\_4 SHALL be precise to the day OR be valued '0000'. **NIST-06** : TS\_5 SHALL be precise to the day. **NIST-07 :** TS\_7 SHALL be precise to the day. |
| NIST\_LOI-13 | Exclusion and replacement of USPS\_USL value set | The USPS\_USL value set spreadsheet does not contain an explicit list of USPS state or province codes allowed. | The NIST LOI Test Tool will **not** validate XAD.4 (State or Province) against USPS\_USL value set in both **context free** and **context based** validation. The NIST LOI Test Tool will validate XAD.4 (State or Province) against a custom value set, NIST\_USPS\_USL, that explicitely ​contains all the required and permitted values in both **context free** and **context based** ​validation. |
| NIST\_LOI-14 | Format check on XAD-5 | There is no requirement regarding the format of XAD-5 (Zip or Postal Code) in the LOI IG. | The NIST LOI Test Tool will validate any message against the following derived conformance statements in both **context free** and **context based** validation: **NIST-08**: If XAD-6 (Country Code) is valued 'USA' or not valued, then XAD-5 (Zip or Postal Code) SHALL be a valid USPS postal code.​ |
| NIST\_LOI-15 | Locally defined value sets excluded from validation | The following vale sets are locally defined and must be completed by trading partners: HL70361\_USL.2 HL70362\_USL.3 HL70362\_USL.4 | ​The NIST LOI Test Tool will **not** validate MSH-3 (Sending Application) against HL70361\_USL.2 in both **context free** and **context based** validation. The NIST LOI Test Tool will **not** validate MSH-4 (Sending Facility) against HL70362\_USL.3 in both **context free** and **context based** validation. The NIST LOI Test Tool will **not** validate MSH-6 (Receiving Facility) against HL70362\_USL.4 in both **context free** and **context based** validation. |
| NIST\_LOI-16 | MSH-5 value set undefined in HL70361\_USL | The value set binding for MSH-5 is not defined in the HL70361\_USL spreadsheet. | The NIST test tool will not validate MSH-5 (Receiving Application) against HL70361\_USL in both **context free** and **context based** validation.​ |
| NIST\_LOI-17 | LOI-44, LOI-45 & LOI-46 clarification | The OML^O21 message structure contains two ORC segments and two OBR segments : - one ORC segment is directly nested under the ORDER group -one ORC segment is nested under the ORDER/OBSERVATION\_REQUEST/PRIOR\_RESULT/ORDER\_PRIOR group - one OBR segment is nested under the ORDER/OBSERVATIOB\_REQUEST group - one OBR segment is nested under the ORDER/OBSERVATION\_REQUEST/PRIOR\_RESULT/ORDER\_PRIOR group Because the message structure contains several ORC and OBR segments (all said segments are in the ORDER group), the LOI-44, LOI-45 and LOI-46 conformance statements are ambiguous (ORC and OBR that are affected by the conformance statements are not clearly identified). | ​​The NIST LOI Test Tool will validate against LOI-44, LOI-45 and LOI-46 assuming that the ORC and OBR segments are the following: - the ORC segment directly nested under the ORDER group - the OBR segment directly nested under the ORDER/OBSERVATION\_REQUEST group.   No additional checks related to LOI-44, LOI-45 and LOI-46 will be performed on ORC and OBR segments nested under the PRIOR\_RESULT group. |
| NIST\_LOI-18 | Exclusion of LOINC\_USL value set | The LOINC\_USL value set spreadsheet does not contain an explicit list of LOINC codes allowed. The NIST LOI Test Tool still needs to be able to check that a provided code is valid when the LOINC code system is used. | ​The NIST LOI Test Tool will **not** validate OBR-4 (Universal Service Identifier) or OBX-3 (Observation Identifier) against LOINC\_USL in both **context free** and **context based** validation. |
| NIST\_LOI-19 | Added format check for LOINC codes | The NIST LOI Test Tool is not validating OBR-4 and OBX-3 against the LOINC value set (see item NIST\_LOI-18). The tool still needs to be able to check that a provided code is valid when the LOINC code system is used. | The NIST LOI Test Tool will validate any message against the following derived conformance statements in both **context free** and **context based** validation : **NIST-10:** If OBR-4.3 (Name of Coding System) value is valued 'LN', OBR-4.1 (Identifier) SHALL be a valid LOINC code identifier format.  **NIST-11:** If OBR-4.6 (Name of Coding System) value is valued 'LN', OBR-4.4 (Identifier) SHALL be a valid LOINC code identifier format.  **NIST-12:** If OBX-3.3 (Name of Coding System) value is valued 'LN', OBX-3.1 (Identifier) SHALL be a valid LOINC code identifier format.  **NIST-13:** If OBX-3.6 (Name of Coding System) value is valued 'LN', OBX-3.4 (Identifier) SHALL be a valid LOINC code identifier format. |
| NIST\_LOI-20 | OBX-4 predicate not implementable (tool limitation) | The condition predicate on OBX-4 (Observation Sub-ID) cannot be implemented as such (validation engine limitation) | ​The NIST LOI Test Tool will **not** validate against the OBX-4 (Observation Sub-ID) condition predicate in both **context free** and **context based** validation. |
| NIST\_LOI-21 | Incorrect value set for OBX-5 in LOI IG | The LOI IG defines the value set for OBX-5 (Observation value) as HL70125\_USL. As OBX-5 is a "varies" datatype, it does not make sense to assign a value set to all possible datatypes. | ​The NIST LOI Test Tool will **not** validate OBX-5 (Observation value) against HL70125\_USL in both **context free** and **context based** validation. |
| NIST\_LOI-22 | OBX-5.10 (XCN) value set undefined in HL70200\_USL | The value set binding for OBX-5.10 (XCN datatype) is not defined in the HL70200\_USL spreadsheet. | ​The NIST LOI Test Tool will **not** validate OBX-5.10 (XCN datatype) against HL70200\_USL in both **context free** and **context based** validation. |
| NIST\_LOI-23 | OBX-5 (XAD) values sets undefined in USPS\_USL, HL70399\_USL, HL701090\_USL | The value set binding for OBX-5.4 (XAD datatype) is not defined in the USPS\_USL spreadsheet. The value set binding for OBX-5.6 (XAD datatype) is not defined in the HL70399\_USL spreadsheet. The value set binding for OBX-5.7 (XAD datatype) is not defined in the HL701090\_USL spreadsheet. | ​The NIST LOI Test Tool will **not** validate OBX-5.4 (XAD datatype) against USPS\_USL in both **context free** and **context based** validation. The NIST LOI Test Tool will **not** validate OBX-5.6 (XAD datatype) against HL70399\_USL in both **context free** and **context based** validation. The NIST LOI Test Tool will **not** validate OBX-5.7 (XAD datatype) against HL70190\_USL in both **context free** and **context based** validation. |
| NIST\_LOI-24 | XPN datatype for OBX-5 undefined | The flavor of the XPN datatype to be used in OBX-5 is not defined in the LOI IG. | ​The NIST LOI Test Tool will validate OBX-5 (XPN datatype) against the flavor defined in the LOI IG as "XPN - EXTENDED PERSON NAME - BASE", chapter 4.19.1 in both **context free** and **context based** validation. |
| NIST\_LOI-25 | OBX-5.7 (XPN) value set undefined in HL70200\_USL | The value set binding for OBX-5.7 (XPN datatype) is not defined in the HL70200\_USL spreadsheet. | ​The NIST LOI Test Tool will **not** validate OBX-5.7 (XPN datatype) against HL70200\_USL in both **context free** and **context based** validation. |
| NIST\_LOI-26 | Exclusion of the HL70291\_USL value set | The HL70291\_USL value set spreadsheet does not contain an explicit list of codes allowed. | ​The NIST test tool will not validate OBX-5.3 (ED datatype) against HL70291\_USL value set in both **context free** and **context based** validation.​ |
| NIST\_LOI-27 | Exclusion of the UCUM\_USL value set | The UCUM\_USL value set spreadsheet does not contain an explicit list of codes. | ​The NIST LOI Test Tool will **not** validate OBX-6 (Units) against the UCUM\_USL value set in both **context free** and **context based** validation. |
| NIST\_LOI-28 | Exclusion of ICD-9CM ICD-10CM value set | The 'ICD-9CM ICD-10CM' is not defined in the value set spreadsheets. | ​​The NIST LOI Test Tool will not perform validation against the 'ICD-9CM & ICD-10CM' 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 'ICD-9CM & ICD-10CM' code in DG1-3 (Diagnosis Code), based on the test objectives.​​ |
| NIST\_LOI-29 | Code system check for DG1-3 | The NIST LOI Test Tool does not perform validation against the 'ICD-9CM & ICD-10CM' value set (see item NIST\_LOI-28). | ​The NIST Test Tool will validate any message against the following derived conformance statement in both **context free** and **context based** validation : **NIST-09**: Either DG1-3.3 (Diagnosis Code - DG1.Name of Coding System) or DG1-3.6 (Diagnosis Code - DG1.Name of Alternate Coding System) SHALL be valued 'I9C' or 'I10C'. |
| NIST\_LOI-30 | Exclusion and replacement of HL70359\_USL.1 | The HL70359\_USL value set spreadsheet does not contain an explicit list of codes required and/or permitted. | ​The NIST Test Tool will **not** validate DG1-15 (Diagnosis Priority) against HL70359\_USL value set in both **context free** and **context based** validation. The NIST LOI Test Tool will validate DG1-15 against a custom value set, **NIST\_HL70359\_USL.1​**, that explicitely contains all the required and permitted values in both **context free** and **context based** validation. |
| NIST\_LOI-31 | DG1-20 & DG1-21 usage | The usage of DG1-20 (Diagnosis Identifier) and DG1-21 (Diagnosis Action Code) is defined as C(X/X) and the condition predicate is not defined. | ​The usage of DG1-20 (Diagnosis Identifier) and DG1-21 (Diagnosis Action Code) is set to "X" ("Not supported") in the NIST LOI Test Tool for both **context free** and **context based** validation. |
| NIST\_LOI-32 | Exclusion of SNOMED\_CT\_USL | The SNOMED\_CT\_USL value set spreadsheet does not contain an explicit list of SNOMED CT codes allowed. The NIST LOI 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 LOI Test Tool will **not** validate SPM-4 (Specimen type), SPM-5 (Specimen Type Modifier) against SNOMED\_CT\_USL in both **context free** and **context based** validation. The NIST LOI Test Tool will validate any message against the following derived conformance statement in both context free and context based validation: **NIST-14**: If SPM-4.3 (Name of Coding system) is valued 'SCT', SPM-4.1 (Identifier) SHALL be a valid SNOMED CT code identifier format. **NIST-15**: If SPM-4.6 (Name of Alternate Coding System) is valued 'SCT', SPM-4.4 (Alternate Identifier) SHALL be a valid SNOMED CT code identifier format. **NIST-17**: If SPM-5.3 (Name of Coding System) is valued 'SCT', SPM-5.1 (Identifier) SHALL be a valid SNOMED CT code identifier format. **NIST-18**: If SPM-5.6 (Name of Alternate Coding System) is valued 'SCT', SPM-5.4 (Alternate Identifier) SHALL be a valid SNOMED CT code identifier format. |
| NIST\_LOI-33 | Exclusion of multiple binding value set for SPM-4 | The NIST test tool does not support, at the moment, the validation against multiple binding of value sets, when one of the value set has been excluded from validation. The value set bindings for SPM-4 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\_LOI-32. | The NIST test tool will not validate SPM-4 against the SNOMED CT and/or HL70487\_USL value set in both **context free** and **context based** validation.​     For context based validation, the NIST LOI Test Tool MAY require the use of a particular 'SNOMED & HL70487\_USL' code in SPM-4, based on the test objectives.​ |
| NIST\_LOI-34 | Code system check for SPM-4 | The NIST LOI Test Tool does not perform validation against the 'SCT & HL70487\_USL' value set (see item NIST\_LOI-33). The following conformance statement was added to ensure the SCT or HL70487 code system is used in the element SPM-4. | ​The NIST Test Tool will validate any message against the following derived conformance statement in both **context free** and **context based** validation:  **NIST-16** : When present, either SPM-4.3 (Specimen Type.Name of Coding System) or SPM-4.6 (Specimen Type.Name of Alternate Coding System) SHALL be valued 'SCT', 'HL70487', 'L' or '​99zzz' for a local code system​. |

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# errata

For a current list of errata see the [HL7 LOI R2 DSTU site](http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=180).