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Health Information Technology (HIT)   
Standards Testing Infrastructure

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Framework Lab Results Interface, 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 Lab Results Interface, Release 1, DSTU Release 2 - US Realm Draft Standard for Trial Use September 2015 (LRI). The policies listed in this document are implemented in the NIST LRI conformance test suite.

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# Validation Policies

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| --- | --- | --- | --- |
| Decision number | Title | Description | Decision |
| NIST\_LRI-01 | LRI-29, LRI-30, LRI-31, LRI-32, LRI-42 not implemented | The following conformance statements are not testable: LRI-29, LRI-30, LRI-31, LRI-32, LRI-42. | Those conformance statements are related to parent/child relationship. The way the conformance statements are written, they are not testable.  The NIST LRI Test Tool will **not** validate against those conformance statements in both **context free** and **context based** validation.  To help the tester with validation errors related to parent/child linking, the NIST LRI Test Tool will validate any message against the following derived conformance statements in both **context free** and **context based** validation:  **FRU and FRN profile components:**  **NIST-021**: If OBR-26 (Parent Result) is valued, then there SHALL be at least one OBX in the message where OBX-3 (Observation Identifier) = OBR-26.1 (Parent Observation Identifier) AND OBX-4 (Observation Sub-ID) = OBR-26.2 (Parent Observation Sub-identifier)  **NIST-022** If OBR-29 (Parent) is valued, then there SHALL be at least one other OBR in the message where OBR-2 (Placer Order Number) = OBR-29.1 (Placer Assigned Identifier) AND OBR-3 (Filler Order Number) = OBR-29.2 (Filler Assigned Identifier)  **FRN profile component only:**  **NIST-023** If OBR-50 (Parent Universal Service Identifier) is valued, then there SHALL be at least one other OBR in the message where OBR-4 (Universal Service Identifier) = OBR-50 (Parent Universal Service Identifier) |
| NIST\_LRI-02 | LRI-58 to LRI-70 not implemented | The following conformance statement are not testable: LRI-58, LRI-59, LRI-60, LRI-61, LRI-62, LRI-63, LRI-64, LRI-65, LRI-66, LRI-67, LRI-68, LRI-69, LRI-70 | Those are functional requirement and cannot be tested at the profile level.  The NIST LRI Test Tool will **not** validate against those conformance statements in both **context free** and **context based** validation. |
| NIST\_LRI-03 | CWE\_\*\*\*.7 condition predicate implementation | The condition predicate "If CWE\_\*\*\*.3 (Name of Coding System) is not an HL7 defined table or user defined." is not clear on how it should be implemented. | This predicate is implemented as "If CWE\_\*\*\*.3 is NOT valued 'L', '99zzz' or 'HL7nnnn'. |
| NIST\_LRI-04 | 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\_LRI-05 | Separation of the "L,M,N" code for locally defined coding schemas in three separate value in value sets HL70301\_USL.5 and HL70301\_USL.6 | The HL70301\_USL value set spreadsheet defines the codes for locally defined coding schemas in a single entry as 'L,M,N'. | The NIST LRI Test Tool will consider the value 'L,M,N' from value set HL70301\_USL as three individual codes : 'L', 'M', 'N'. |
| NIST\_LRI-06 | Format check on TS flavors | The requirements on the TS flavors need to be implemented as conformance statements | The NIST LRI Test Tool will validate any message against the following derived conformance statements in both **context free** and **context based** validation:  **NIST-001**: TS\_0 SHALL be precise to the year **NIST-002**: TS\_1 SHALL be precise to the second **NIST-003**: TS\_2 SHALL be precise to the year **NIST-004**: TS\_3 SHALL be precise to the year **NIST-005**: TS4 SHALL be valued "0000" OR be precise to the day **NIST-006**: TS\_5 SHALL be precise to the day **NIST-007**: TS\_6 SHALL be precise to the minute |
| NIST\_LRI-07 | Exclusion and replacement of USPS\_USL value set in XAD datatype | The USPS\_USL value set spreadsheet does not contain an explicit list of USPS state or province codes allowed. | The NIST LRI Test Tool will **not** validate OBX-5.4 (XAD datatype) and OBX-24.4 against USPS\_USL in both **context free** and **context based** validation.  The NIST LRI Test Tool will validate XAD-4 (State or Province) against a custom value set, NIST\_USPS\_USL, that explicitly contains all the required and permitted values in both **context free** and **context based** validation. |
| NIST\_LRI-08 | Format check on XAD-5 | There is no requirement regarding the format of XAD-5 (Zip or Postal Code) in the LRI IG. | The NIST LRI Test Tool will validate any message against the following derived conformance statement in both **context free** and **context based** validation:  **NIST-009**: 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\_LRI-09 | Exclusion and replacement of the HL70399\_USL value set in XAD datatype | The HL70399\_USL value set spreadsheet does not contain an explicit list of codes excluded. | The NIST LRI Test Tool will **not** validate XAD-6 against the HL70399\_USL value set in both **context free** and **context based** validation.  The NIST LRI 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\_LRI-10 | Exclusion of FIPS64\_USL value set | The FIPS64\_USL value set spreadsheet does not contain an explicit list of FIPS64 codes allowed.   The NIST test tool still needs to be able to check that a provided FIPS64 code is valid. | The NIST LRI Test Tool will **not** validate XAD-9 against FIPS64\_USL in both **context free** and **context based** validation.  The NIST test tool will validate any message against the following derived conformance statement in both **context free** and **context based** validation:  **NIST-008**: XAD-9 (County/Parish Code) SHALL be a five-digit code. |
| NIST\_LRI-11 | Locally defined value sets excluded from validation | The following value sets are locally defined and must be completed by trading partners:   * HL70361.3 * HL70362.5 * HL70362.6 | The NIST LRI Test Tool will **not** validate MSH-3 against HL70361\_USL.3 in both **context free** and **context based** validation.  The NIST LRI Test Tool will **not** validate MSH-4 against HL70362\_USL.5 in both **context free** and **context based** validation.  The NIST LRI Test Tool will **not** validate MSH-6 against HL70362\_USL.6 in both **context free** and **context based** validation. |
| NIST\_LRI-12 | Wrong value in LRI-72 conformance statement | The value "ORU\_R01" in LRI-72 [MSH-9.1 (Message Type.Message Code) SHALL contain the constant value ‘ORU\_R01’ drawn from the code systems HL70076.] is incorrect. The value should be "ORU". | The NIST LRI Test Tool will validate against the following derived conformance statement in both **context free** and **context based** validation:  **LRI-72**: MSH-9.1 (Message Type.Message Code) SHALL contain the constant value 'ORU' drawn from the code systems HL70076. |
| NIST\_LRI-13 | MSG conformance statements and value sets | The value of MSH-9.1 (MSG.1) is already checked by conformance statements (LRI-72, LRI-15).  The value of MSH-9.2 (MSG.2) is already checked by conformance statements (LRI-73, LRI-15).  The value of MSH-9.3 (MSG.3) is already checked by conformance statements (LRI-8, LRI-15). | The NIST LRI Test Tool will **not** validate MSG.1 against HL70076\_USL in both **context free** and **context based** validation.  The NIST LRI Test Tool will **not** validate MSG.2 against HL70003\_USL in both **context free** and **context based** validation.  The NIST LRI Test Tool will **not** validate MSG.3 against HL70354\_USL in both **context free** and **context based** validation. |
| NIST\_LRI-14 | MSH-12.1 conformance statement and value set | The value of MSH-12.1 (VID.1) is already checked by conformance statements (LRI-9 and LRI-16). | The NIST LRI Test Tool will **not** validate MSH-12.1 against HL70104\_USL in both **context free** and **context based** validation. |
| NIST\_LRI-15 | PID-18 is missing CX datatype flavor | The flavor of CX is not defined for PID-18 (Patient Account Number). | The NIST LRI Test Tool will validate the datatype of PID-18 (Patient Account Number) against the CX\_GU flavor for GU profile and against the CX\_NG flavor for NG profile in both **context free** and **context based** validation. |
| NIST\_LRI-16 | PID-22 usage is optional | The usage of PID-22 (Ethnic group) is O (optional). The element will be validated against the base standard. | The NIST LRI Test Tool will **not** validate PID-22 against the value set HL70189\_USL.2 in both **context free** and **context based** validation. |
| NIST\_LRI-17 | Exclusion of LOINC\_USL value set | The LOINC\_USL value set spreadsheet does not contain an explicit list of LOINC codes allowed. | The NIST LRI Test Tool will **not** validate OBR-4 and OBX-3 against LOINC\_USL in both **context free** and **context based** validation. |
| NIST\_LRI-18 | Added format check for LOINC codes | The NIST LRI Test Tool is not validating OBR-4 and OBX-3 against the LOINC value set (see item NIST\_LRI-17). The tool still needs to be able to check that a provided code is valid when the LOINC code system is used. | The NIST LRI Test Tool will validate any message against the following derived conformance statements in both **context free** and **context based** validation:  **NIST-010**: If OBR-4.3(Name of Coding System) is valued 'LN', OBR-4.1 (Identifier) SHALL be a valid LOINC code identifier format.  **NIST-011**: If OBR-4.6 (Name of Alternate Coding System) is valued 'LN', OBR-4.4 (Alternate Identifier) SHALL be a valid LOINC code identifier format.  **NIST-012**: If OBX-3.3 (Name of Coding System) is valued 'LN', OBX-3.1 (Identifier) SHALL be a valid LOINC code identifier format.  **NIST-013**: If OBX-3.6 (Name of Alternate Coding System) is valued 'LN', OBX-3.4 (Alternate Identifier) SHALL be a valid LOINC code identifier format. |
| NIST\_LRI-19 | OBX-4 condition predicate implementation | The condition predicate on OBX-4 cannot be implemented as such (validation engine limitation). | The NIST LRI Test Tool will **not** validate against the OBX-4 condition predicate in both **context free** and **context based** validation. |
| NIST\_LRI-20 | LRI-45 not implemented | The following conformance statement is not testable: LRI-45: The value of OBX-5 (Observation Value) SHALL NOT be truncated. | The NIST LRI Test Tool will **not** validate against LRI-45 in both **context free** and **context based** validation. |
| NIST\_LRI-21 | LRI-48 is captured by structure validation | LRI-48: If OBX-2 (Value Type) is valued, then the data type format for OBX-5 (Observation Value) SHALL conform to the corresponding constrained data type identified in the "comment" column of HL70125\_USL. This conformance statement cannot be tested as a constraint, but the requirement will be tested by the structure validation. | The NIST LRI Test Tool will **not** validate against LRI-48; however, the requirement will be part of the test tool structure validation. If a message does not conform to the requirement, the tool will issue an error. |
| NIST\_LRI-22 | OBX-5.10 (XCN) value set undefined in HL70200\_USL | The value set binding for OBX-5.10 is not defined in the HL70200\_USL spreadsheet. | The NIST LRI Test Tool will **not** validate OBX-5.10 (when the datatype is XCN) against HL70200\_USL in both **context free** and **context based** validation. |
| NIST\_LRI-23 | Exclusion of the HL70291\_USL value set | The HL70291\_USL value set spreadsheet does not contain an explicit list of codes allowed. | The NIST LRI Test Tool will **not** validate OBX-5.3 (ED datatype) against HL70291\_USL value set in both **context free** and **context based** validation. |
| NIST\_LRI-24 | Exclusion of SNOMED\_CT\_USL value set | The SNOMED\_CT\_USL value set spreadsheet does not contain an explicit of SNOMED CT codes allowed. | The NIST LRI Test Tool will **not** validate OBX-5 (CWE\_CR datatype) or SPM-4 against SNOMED\_CT\_USL in both **context free** and **context based** validation. |
| NIST\_LRI-25 | Code system check for OBX-5 (CWE) | The NIST LRI Test Tool does not perform validation against the SNOMED\_CT\_USL value set (see item NIST\_LRI-24). The following conformance statement was added to ensure the SCT code system is used in the element OBX-5. | The NIST LRI Test Tool will validate any message against the following derived conformance statements in both **context free** and **context based** validation:  **NIST-014**: If OBX-2 is valued 'CWE' and OBX-5.3 (Name of Coding System) is valued 'SCT', OBX-5.1 (Identifier) SHALL be a valid SNOMED CT code identifier format.  **NIST-015**: If OBX-2 is value 'CWE' and OBX-5.6 (Name of Alternate Coding System) is valued 'SCT', OBX-5.4 (Alternate Identifier) SHALL be a valid SNOMED CT code identifier format. |
| NIST\_LRI-26 | Exclusion of the UCUM\_USL value set | The UCUM\_USL value set spreadsheet does not contain an explicit list of codes. | The NIST LRI Test Tool will **not** validate OBX-6 (Units) against the UCUM\_USL value set in both **context free** and **context based** validation. |
| NIST\_LRI-27 | Exclusion of multiple binding value set for SPM-4 | The NIST LRI 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\_LRI-24. | The NIST LRI 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 LRI Test Tool **MAY** require the use of a particular 'SNOMED & HL70487\_USL' code in SPM-4, based on the test objectives.  Additionally, the NIST LRI Test Tool will validate any message against the following derived conformance statements in both **context free** and **context based** validation:  **NIST-016**: 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-017**: 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-018**: If SPM-4.3 (Name of Coding system) is valued 'HL70487', SPM-4.1 (Identifier) SHALL be a valid code drawn from the HL70487\_USL.3 value set.  **NIST-019**: If SPM-4.6 (Name of Alternate Coding System) is valued 'HL70487', SPM-4.4 (Alternate Identifier) SHALL be a valid code drawn from the HL70487\_USL.3 value set. |
| NIST\_LRI-28 | Code system check for SPM-4 | The NIST LRI Test Tool does not perform validation against the 'SCT & HL70487\_USL' value set (see item NIST\_LRI-27). The following conformance statement was added to ensure the SCT or HL70487 code system is used in the element SPM-4. | The NIST LRI Test Tool will validate any message against the following derived conformance statements in both **context free** and **context based** validation:  **NIST-020**: 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. |
| NIST\_LRI-29 | NTE segment listed twice in "view all" of profile viewer | In Profile viewer the NIST LRI Test Tool shows 2 versions of the NTE segment - one following the LRI guide for use when and as defined in the LRI guide and one based on the base standard for groups, where NTE is marked as optional in the LRI guide. | In Profile viewer the tool shows 2 versions of the NTE segment - one following the LRI guide for use when and as defined in the LRI guide and one based on the base standard for groups, where NTE is marked as optional in the LRI guide. |
| NIST\_LRI-30 | OBX Segment listed twice in "view" all choice in profile viewer | In Profile viewer the NIST LRI Test Tool shows 2 versions of the OBX segment - one following the LRI guide for use when and as defined in the LRI guide and one based on the base standard for groups, where OBX is marked as optional in the LRI guide. | In Profile viewer the tool shows 2 versions of the OBX segment - one following the LRI guide for use when and as defined in the LRI guide and one based on the base standard for groups, where OBX is marked as optional in the LRI guide. |
| NIST\_LRI-31 | No requirements defined for TQ1-9 (Priority) in the EHR-S Functional Requirements guide | The field TQ1-9 (Priority) is required in the LRI implementation guide but there is no functional requirement associated with that field in the EHR-S Functional Requirements guide | The juror document in the NIST LRI Test Tool will include the data from TQ1-9 in both Display and Incorporate verification sections, when applicable. |
| NIST\_LRI-32 | No requirements defined for ED datatype in the EHR-S Functional Requirements guide | The datatype ED (Encapsulated Data) is defined in the LRI implementation guide and can be used in OBX-5 (Observation Value), but there is no functional requirement associated with that datatype in the EHR-S Functional Requirements guide. | The juror document in the NIST LRI Test Tool will include instructions such as “PDF is created” or “PDF is stored”. The base 64 encoding data and the PDF to be created will be available in the NIST LRI Test Tool, under the Supplements section of the test case. |

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# errata

For a current list of errata see the [HL7 LRI R2 DSTU site](http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=171).