American Clinical Laboratory Association

September 20, 2019

Dr. Don Rucker
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

DELIVERED ELECTRONICALLY

RE: ACLA Comments on Proposed Rule regarding, 2020 ONC Interoperability Standards Advisory (ISA) [Draft for Comment]

Dear Dr. Rucker:

I am submitting the attached comments on behalf of the American Clinical Laboratory Association (ACLA) in response to the *2020 ONC Interoperability Standards Advisory (ISA) [Draft for Comment]* (hereinafter the "Draft").

ACLA is a non-profit association representing the nation's leading clinical and anatomic pathology laboratories, including national, regional, specialty, end-stage renal disease, hospital, and nursing home laboratories. The clinical laboratory industry employs nearly 277,000 people directly and generates over 115,000 additional jobs in supplier industries. Clinical laboratories are at the forefront of personalized medicine, driving diagnostic innovation and contributing more than $100 billion annually to the nation's economy.

ACLA applauds your leadership in continuing this journey in order to further advance health information technology (HIT) interoperability, a critical and vital goal for improving the quality of care for patients. ACLA member laboratories appreciate the opportunity to comment on the Advisory as a living document and hope these comments serve to continue to move interoperability forward.

If there are any questions regarding these comments, please do not hesitate to contact us by phone (202)-637-9466 or via email at jkegerize@acla.com.

Sincerely,

Joan Kegerize, MS, JD
Vice President, Reimbursement and Scientific Affairs

ATTACHMENT: ACLA COMMENTS

2019-07-23 Announcement

Interoperability Standards Advisory (ISA) – Open for Review and Comment

The Interoperability Standards Advisory (ISA) annual review and comment period is now open! The ISA is an interactive catalog of standards and implementation specifications supporting interoperability in healthcare, and stakeholder input is crucial to ensure it contains the latest standards/specifications and most accurate industry information. **Share your thoughts by Monday, September 23, 2019 at 11:59 pm ET**, at which point ONC will begin to finalize the ISA for the 2020 Reference Edition, to be published in December.

API Resource Collection in Health (ARCH)

https://www.healthit.gov/isa/api-resource-collection-health-arch

Text:

The following resources must be supported from the Health Level Seven (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standard.

FHIR Resource

- AllergyIntolerance
- CarePlan
- Condition
- Device, including representing "Device.udi" element in accordance with the human readable representation of the Unique Device Identifier found in the recommendation, guidance and conformance requirements section for HL7 FHIR of the HL7 Version 3 Cross Paradigm Implementation Guide: Medical Devices and Unique Device Identification (UDI) Pattern, Release 1*
- DiagnosticReport
- DocumentReference, for the purposes of supporting clinical notes
- Goal
- Immunization
- Medication
- MedicationOrder
- MedicationStatement
- Observation
- Patient, including mandatory support for the "patient.address" and "patient.telecom" elements
- Procedure
- Provenance, including mandatory support for "Provenance.agent.actor" (for the author and author's organization) and "Provenance.recorded" elements.

ACLA Comment:

The ARCH indicates the FHIR DocumentReference resource for Clinical Notes referenced in USCDI. If Laboratory Report Narrative and/or Pathology Report Narrative are included in the USCDI as additional clinical note types, we suggest the FHIR Resource used should be the DiagnosticReport[1] if the intent is to include the actual content contained in the laboratory or pathology report, vs. referring to the report(s) using the FHIR DocumentReference resource[2] (i.e. referring to a PDF, C-CDA, etc.)

We suggest the FHIR release supported should be left to trading partners vs. citing a specific FHIR release in the ISA.

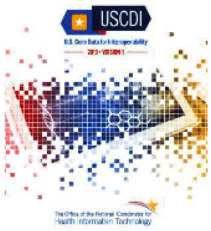
We recommend that patient laboratory results only be rendered to the patient from their ordering/attending provider as their primary health care provider.

[1] http://www.hl7.org/fhir/diagnosticreport.html
[2] http://www.hl7.org/fhir/documentreference.html

U.S. Core Data for Interoperability (USCDI)

https://www.healthit.gov/isa/us-core-data-interoperability-uscdi

Text:



Below is a high-level summary of the data classes and data elements contained in version 1 of the USCDI. For more details, including data class descriptions and applicable standards supporting data elements, view the USCDI v1 in PDF format.

The U.S. Core Data for Interoperability (USCDI) is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange.

- A USCDI "Data Class" is an aggregation of various Data Elements by a common theme or use case.
- A USCDI "Data Element" is the most granular level at which a piece of data is exchanged.
  - For example, Date of Birth is a Data Element rather than its component Day, Month, or Year, because Date of Birth is the unit of exchange.

Clinical Notes

- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

Laboratory

- Tests
- Values/Results

ACLA Comment:

The ARCH indicates the FHIR DocumentReference resource for Clinical Notes referenced in USCDI. If Laboratory Report Narrative and/or Pathology Report Narrative are included in the USCDI as additional clinical note types, we suggest the FHIR Resource used should be the DiagnosticReport[3] if the intent is to include the actual content contained in the laboratory or pathology report, vs. referring to the report(s) using the FHIR DocumentReference resource[4] (i.e. referring to a PDF, C-CDA, etc.).

We recommend that patient laboratory results only be rendered to the patient from their ordering/attending provider as their primary health care provider.

[3] http://www.hl7.org/fhir/diagnosticreport.html
[4] http://www.hl7.org/fhir/documentreference.html

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications

Representing Laboratory Tests

https://www.healthit.gov/isa/representing-laboratory-tests

Representing Laboratory Tests

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Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availabili
Standard for observations	LOINC®	Final	Production	●●●○○	Yes	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	●○○○○	Yes	Free	N/A
Standard	Current Procedural Terminology (CPT)	Final	Production	Feedback Requested	No	$	N/A

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
▪ Laboratory test and observation work in conjunction with values or results which can be answered numerically or categorically. If the value/result/answer to a laboratory test and observation is categorical that answer should be represented with the SNOMED CT® terminology. ▪ A single lab test with a single result will have the same LOINC® term for its order and result answer, but a panel order will have an order LOINC® term and multiple result LOINC® terms for each result in the panel. ▪ A single lab test with a single result may have the same LOINC® code for the order and the result or may have a more specific code in the result (for example if the order code was method less or did not declare the system property). A panel order will have an order LOINC® code and multiple result LOINC® terms for each result in the panel. ▪ Guidance is available for using SNOMED CT® and LOINC® together. ▪ CPT Proprietary Laboratory Analyses (PLA) codes are published quarterly (1/1, 4/1, 7/1, and 10/1) and are available on the AMA website. ▪ See LOINC projects in the Interoperability Proving Ground. ▪ For more information about observations and observation values, see Appendix III for an informational resource developed by the Health IT Standards Committee.	▪ LOINC Top 2000+ Lab Observations - US Version OID: 1.3.6.1.4.1.12009.10.2.3 ▪ CPT: ▪ 80047 - 89398 - including Multianalyte Assays with Algorithmic Analyses (MAAA) codes 81490-81599 ▪ Proprietary Laboratory Analyses (PLA) U codes ▪ MAAA administrative M Codes (0002M-0013M)

ACLA Comment:

- We suggest you remove the 2nd bullet in the "Limitations lll" section (A single lab test with a single result will have the same LOINC® term for its order and result answer, but a panel …); as it is replaced by the 3rd bullet.
- We are aware that some EHR systems assign LOINC if not provided by the sending laboratory; these mappings should be approved in advance by the Laboratory sending the result. We suggest ONC add an EHR certification question to ascertain if the EHR system is assigning LOINC without the sending laboratory's concurrence, e.g. are you consulting with the sending laboratory regarding the assignment of LOINC.
- Some EHR systems want a 1-to-1 SNOMED CT® mapping to each laboratory result, but this not always the case, especially for microbiology. For example, e-coli and Group A Strep (GAS)/Strep pyogenes (STPY) multiple results can have a single SNOMED CT mapping (many results to one SNOMED CT)
- SNOMED CT expertise can be scarce and expensive from resource perspective; SNOMED CT is a very complicated terminology and may be beyond the expertise of a laboratory technologist.
- There is a low adoption of SNOMED CT, which is due to multiple issues. For example, managing the negation aspect, e.g. "no e-coli" could unintentionally be interpreted as "e-coli" if the negation is not interpreted correctly. We suggest ONC work with industry to provide guidance on these issues.
- We strongly recommend that CPT codes not be added to the ISA in this section "Representing Laboratory Tests" for lab tests orders or results; CPT codes are not specific enough to represent laboratory tests and are typically used only related to billing for laboratory tests. Please clarify if CPT is only intended for billing purposes.

Topic: Representing Patient Sex (At Birth)

https://www.healthit.gov/isa/representing-patient-sex-birth

Representing Patient Sex (At Birth)

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Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availab
Standard for observations	LOINC®	Final	Production	●●●●●	No	Free	N/A
Standard for observation values	For Male and Female, HL7 Version 3 Value Set; for Administrative Gender Unknown, HL7 Version 3 Null Flavor	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
▪ HL7 Version 2 and 3 need to be harmonized. ▪ See LOINC projects in the Interoperability Proving Ground. ▪ For more information about observations and observation values, see Appendix III for an informational resource developed by the Health IT Standards Committee.	▪ LOINC® code: 76689-9 Sex assigned at birth ▪ Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1 ▪ ONC's 2015 Edition certification requirements reference the following value set for birth sex that a combination of HL7 Version 3 (V3) Standard value set for Administrative Gender and NullFlavor: (1) M ("Male") (2) F ("Female") (3) UNK ("Unknown") (HL7 V3 NullFlavor code)

Comment:

This continues to be an ongoing challenge to laboratories and potentially impacts patient safety. Laboratories need the patient's chromosomal gender to be separate from a patient's identity gender as certain reference ranges are dependent on this information. We recommend ONC assess the various state laws as some states are permitting residents to legally change their birth sex. With these changes being allowed on birth certificates, we recommend ONC consider changing this section from Representing Patient's Sex (at birth) to something like Patient's Biological / Chromosomal Sex.

Additionally, the representation of the patient's biological gender should be similar across all various industries including Lab, Clinician, Pharmacy, etc.

This may require additional LOINC codes.

While the adoption level may be accurate for capturing this data since it is an EHR certification requirement, as a large commercial laboratory, we can assert we are not seeing this data reported from EHR systems, and laboratories may not be ready to accept Sex assigned at Birth because they are currently supporting only HL7 V2 "Administrative Sex".

Topic: Representing Units of Measure (For Use with Numerical References and Values)

https://www.healthit.gov/isa/representing-units-measure-use-numerical-references-and-values

Representing Units of Measure (For Use with Numerical References and Values)

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Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	The Unified Code for Units of Measure	Final	Production	●●●○○	Yes	Free	Yes Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
▪ UCUM is a syntax for representing units of measure for use with numerical references and values. It is not an enumerated set of codes. ▪ The case sensitive version is the correct unit string to be used for interoperability purposes. ▪ Per public comments received, there may be some limitations with UCUM in the laboratory domain that remain unresolved. ▪ The abbreviations used for a few of the units of measure listed in the UCUM standard are currently on lists of prohibited abbreviations from the Institute for Safe Medication Practice (ISMP). ▪ Some abbreviations for units of measure include symbols which may be in conflict with other HL7 standards. ▪ Some abbreviations for units are nonstandard for human understanding.(For example, if a result for a White Blood Cell count is 9.6 x 103/µL, the UCUM recommendation for rendering this value in a legacy character application is 9.6 x 10*3/uL. Because the "*" is a symbol for multiplication in some systems.) This recommendation may result in errors either by the information system or the human reading the result. ▪ Some abbreviations used in UCUM are not industry standard for the tests that use these units of measure.	▪ Units Of Measure Case Sensitive 2.16.840.1.113883.1.11.12839 (most frequently used codes) ▪ "Table of Example UCUM Codes for Electronic Messaging" published by the Regenstrief Institute, Inc. Value set is made available at http://loinc.org/usage/units and identified by the OID 1.3.6.1.4.1.12009.10.3.1

ACLA Comment:
You have indicated UCUM is Federally required; please provide the hyperlink to the applicable regulation as you have in other federally required sections of the ISA.

Section II: Content/Structure Standards and Implementation Specifications

Support the Transmission of a Laboratory's Directory of Services to Provider's Health IT or EHR System

https://www.healthit.gov/isa/support-transmission-a-laboratorys-directory-services-providers-health-it-or-ehr-system

Support the Transmission of a Laboratory's Directory of Services to Provider's Health IT or EHR System

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Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availabilit
Implementation Specification	HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2, DSTU Release 2 (also referred to as eDOS (Electronic Directory of Service)	Balloted Draft	Production	●○○○○	No	Free	No
Emerging Implementation Specification	*HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework (eDOS) Release 2, STU Release 3 (US Realm)*	*Balloted Draft*	*Feedback requested*	*Feedback Requested*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
▪ HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements. ▪ Note that the current version has been harmonized with the most current suite of Lab US Realm Implementation Guides, was updated in the HL7 January 2017 Ballot Cycle, and is pending publication. ▪ See HL7 V2 projects in the Interoperability Proving Ground.	▪ **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. ▪ **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. ▪ **Authentication Enforcer** – centralized authentication processes. ▪ **Authorization Enforcer** – specifies access control policies. ▪ **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). ▪ **Assertion Builder** – define processing logic for identity, authorization and attribute statements. ▪ **User Role** – identifies the role asserted by the individual initiating the transaction. ▪ **Purpose of Use** - Identifies the purpose for the transaction.

ACLA Comment:

In response to your request for feedback re: the "Emerging Implementation Specification," we support Release 2, STU Release 3 published in 2018 which has been updated based on STU comments, and harmonized with other 2018 Laboratory Implementation Guides (LRI, LOI).

It may be premature to include in the ISA, unless as "In Development" status, but there is another "Emerging Implementation Specification" project at HL7, developing resources to express the V2 eDOS content in FHIR resources, referred to as the Order Catalog Interface. It was balloted in 2018 and has been tested in several FHIR connectathons.

Please update the text below in "Limitations, Dependencies, and Preconditions for Consideration"

From:

- HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements.

To (updated text and hyperlink):

- HL7 Version 2 Implementation Guide: Laboratory Value Set Companion Guide Release 1, STU Release 3 - US Realm, June 2018 which is posted at: http://www.hl7.org/documentcenter/public/standards/dstu/V2_IG_VALUESETS_R1_STU3_2018JUN.zip

From:

- Note that the current version has been harmonized with the most current suite of Lab US Realm Implementation Guides, was updated in the HL7 January 2017 Ballot Cycle, and is pending publication

To (updated text):

- Note that the Emerging Implementation Specification has been harmonized with the most current suite of Lab US Realm Implementation Guides, published by HL7 in June 2018.

Identify Linkages Between Vendor IVD Test Results and Standard Codes

https://www.healthit.gov/isa/identify-linkages-between-vendor-ivd-test-results-and-standard-codes

Identify Linkages Between Vendor IVD Test Results and Standard Codes

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Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	LIVD – Digital Format for Publication of LOINC to Vendor IVD Test Results	Final	Production	●○○○○	No	Free	No
Emerging Implementation Specification	*HL7® FHIR® Implementation Guide - LOINC/IVD Mapping (LIVD) R1 (STU)*	*In Development*	*Pilot*	*Feedback Requested*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
▪ The LIVD - Digital Format for Publication of LOINC to Vendor IVD Test results defines the digital publication of LOINC using vendor defined IVD tests associated with a set of predefined LOINC codes. LIVD assures that laboratory personnel select the appropriate LOINC codes for IVD test used by their laboratory. It also allows LIS systems to automatically map the correct IVD vendor test result to a LOINC code. LIVD was developed in collaboration with the members of the FDA IVD Semantic workgroup.	▪ Feedback Requested.

ACLA Comment:

Please add comment to "Limitations, Dependencies, and Preconditions for Consideration":

- Note that the LIVD Implementation Specification (LIVD – Digital Format for Publication of LOINC to Vendor IVD Test Results) has not been vetted through a Voluntary Consensus Standards Body (VCSB) as defined in OMB Circular A-119[5].

Please spell out acronyms at least once on this page:

- in vitro diagnostic (IVD)
- LOINC to IVD (LIVD)

[5] https://www.whitehouse.gov/omb/circulars/ and https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A119/revised_circular_a-119_as_of_1_22.pdf

Ordering Labs for a Patient

https://www.healthit.gov/isa/ordering-labs-a-patient

Ordering Labs for a Patient

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Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availabilit
Implementation Specification	HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 DSTU Release 3 - US Realm	Balloted Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
▪ HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements. ▪ See HL7 V2 projects in the Interoperability Proving Ground.	▪ **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. ▪ **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. ▪ **Authentication Enforcer** – centralized authentication processes. ▪ **Authorization Enforcer** – specifies access control policies. ▪ **Credential Tokenizer** – encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). ▪ **Assertion Builder** – define processing logic for identity, authorization and attribute statements. ▪ **User Role** – identifies the role asserted by the individual initiating the transaction. ▪ **Purpose of Use** - Identifies the purpose for the transaction.

ACLA Comment:

HL7 published an update to the LOI Implementation Guide (IG) and Value Set Companion Guide June 20, 2018, please update to reflect the latest publications:

- "HL7 Version 2.5.1 Implementation Guide: Laboratory Orders from EHR (LOI) Release 1, STU Release 3 - US Realm"

Link to specification =
http://www.hl7.org/documentcenter/public/standards/dstu/V251_IG_LABORDERS_R1_STU_R3_2018JUN.pdf

Please update the Value Set IG which specifies the vocabulary used in the IGs and is 'companion' to the LOI IG:
"HL7 Version 2 Implementation Guide: Laboratory Value Set Companion Guide Release 1, STU Release 3 - US Realm HL7 Standard for Trial Use"
Link to specification =
http://www.hl7.org/documentcenter/public/standards/dstu/V2_IG_VALUESETS_R1_STU3_2018JUN.zip

Receive Electronic Laboratory Test Results

https://www.healthit.gov/isa/receive-electronic-laboratory-test-results

Receive Electronic Laboratory Test Results

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Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availabili
Implementation Specification	HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1—US Realm [HL7 Version 2.5.1: ORU_R01] Draft Standard for Trial Use, July 2012	Balloted Draft	Production	●○○○○	Yes	Free	Yes
Emerging Implementation Specification	*HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 3 - US Realm*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
▪ HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements. ▪ The HL7 EHR-S Functional Requirements: S&I Framework Laboratory Results Messages, Release 1 - US Realm further clarifies sender/receiver responsibilities to achieve end-to-end interoperability for this interoperability need. ▪ See HL7 V2 projects in the Interoperability Proving Ground.	▪ **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. ▪ **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. ▪ **Authentication Enforcer** – centralized authentication processes. ▪ **Authorization Enforcer** – specifies access control policies. ▪ **Credential Tokenizer** – encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). ▪ **Assertion Builder** – define processing logic for identity, authorization and attribute statements. ▪ **User Role** – identifies the role asserted by the individual initiating the transaction. ▪ **Purpose of Use** - Identifies the purpose for the transaction.

ACLA Comment:

Emerging Implementation Specification, correct the title to: "HL7 Version 2.5.1 Implementation Guide: Lab Results Interface (LRI) Release 1, STU Release 3 - US Realm HL7 Standard for Trial Use"

In Limitations, Dependencies…, please update the Value Set IG which specifies the vocabulary used in the IGs and is 'companion' to the LOI IG:
Link to specification =
http://www.hl7.org/documentcenter/public/standards/dstu/V2_IG_VALUESETS_R1_STU3_2018JUN.zip

Electronic Transmission of Reportable Lab Results to Public Health Agencies

https://www.healthit.gov/isa/electronic-transmission-reportable-lab-results-public-health-agencies

Electronic Transmission of Reportable Lab Results to Public Health Agencies

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Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	HL7 Version 2.5.1: Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 with Errata and Clarifications and ELR 2.5.1 Clarification Document for EHR Technology Certification	Final	Production	●●●●○	Yes	Free	Yes
Implementation Specification	HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm)	Balloted Draft	Production	●○○○○	No	Free	No
Implementation Specification	HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 3 - US Realm	Balloted Draft	Production	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
▪ Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting ELR as there may be jurisdictional variation or requirements. ▪ See HL7 V2 projects in the Interoperability Proving Ground.	▪ **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. ▪ **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. ▪ **Authentication Enforcer** – centralized authentication processes. ▪ **Authorization Enforcer** – specifies access control policies. ▪ **Credential Tokenizer** – encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). ▪ **Assertion Builder** – define processing logic for identity, authorization and attribute statements. ▪ **User Role** – identifies the role asserted by the individual initiating the transaction. ▪ **Purpose of Use** - Identifies the purpose for the transaction.

ACLA Comment:

Since the 3rd implementation specification is a different title, suggest you add a bullet explaining the content in the first two Electronic Laboratory Reporting (ELR) implementation specifications are now handled as a profile in the third listing, e.g. the Laboratory Results Interface (LRI) implementation specification, using the "LRI_PH_COMPONENT – ID: 2.16.840.1.113883.9.195.3.5" Result Profile Component.

Public Health Reporting/Reporting Cancer Cases to Public Health Agencies

https://www.healthit.gov/isa/reporting-cancer-cases-public-health-agencies

Reporting Cancer Cases to Public Health Agencies

Printer Friendly, PDF & Email

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, August 2012	Final	Production	●●○○○	Yes	Free	Yes
Implementation Specification	HL7 CDA ® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 – US Realm	Balloted Draft	Production	●○○○○	Yes	Free	Yes
Implementation Specification	North American Association of Central Cancer Registries, Inc. (NAACCR), Standards for Cancer Registries, Volume V, Pathology Laboratory Electronic Reporting, Version 4.0, published April 2011	Final	Production	●●●●○	Yes	Free	Yes Yes
Emerging Implementation Specification	*IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
▪ Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting cancer reporting date as there may be jurisdictional variation or requirements. Some jurisdictions may not support cancer case reporting at this time. ▪ Note that the NAACCR specification listed has not been vetted through a Voluntary Consensus Standards Body (VSCB), however it references the HL7 V 2.5.1 standard and LOINC, and has been sponsored by a number of organizations working in the cancer registry space. ▪ See CDA and IHE projects in the Interoperability Proving Ground.	▪ **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. ▪ **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. ▪ **Authentication Enforcer** – centralized authentication processes. ▪ **Authorization Enforcer** – specifies access control policies. ▪ **Credential Tokenizer** – encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). ▪ **Assertion Builder** – define processing logic for identity, authorization and attribute statements. ▪ **User Role** – identifies the role asserted by the individual initiating the transaction. ▪ **Purpose of Use** - Identifies the purpose for the transaction.

ACLA Comment:

In the 2020 ISA update, the NAACCR implementation specification has been changed to “Federally required” and “Yes”. Please add a hyperlink indiciating the source of federal requirement which has apparently changed since the 2019 publication of the ISA (see screen print below).

2019 Reference

Text:

Reporting Cancer Cases to Public Health Agencies

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	Yes	Free	No
Implementation Specification	Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, August 2012	Final	Production	●●○○○	Yes	Free	Yes
Implementation Specification	HL7 CDA ® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 – US Realm	Balloted Draft	Production	●○○○○	Yes	Free	Yes
Implementation Specification	North American Association of Central Cancer Registries, Inc. (NAACCR), Standards for Cancer Registries, Volume V, Pathology Laboratory Electronic Reporting, Version 4.0, published April 2011	Final	Production	Feedback Requested	No	Free	No
Emerging Implementation Specification	*IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
▪ Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting cancer reporting date as there may be jurisdictional variation or requirements. Some jurisdictions may not support cancer case reporting at this time. ▪ Note that the NAACCR specification listed has not been vetted through a Voluntary Consensus Standards Body (VSCB), however it references the HL7 V 2.5.1 standard and LOINC, and has been sponsored by a number of organizations working in the cancer registry space. ▪ See CDA and IHE projects in the Interoperability Proving Ground.	▪ **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. ▪ **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. ▪ **Authentication Enforcer** – centralized authentication processes. ▪ **Authorization Enforcer** – specifies access control policies. ▪ **Credential Tokenizer** – encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). ▪ **Assertion Builder** – define processing logic for identity, authorization and attribute statements. ▪ **User Role** – identifies the role asserted by the individual initiating the transaction. ▪ **Purpose of Use** - Identifies the purpose for the transaction.

Questions and Requests for Stakeholder Feedback

https://www.healthit.gov/isa/questions-and-requests-stakeholder-feedback

Updated questions for the 2019 Review and Comment Period

As with the previous iterations of the Interoperability Standards Advisory (ISA), posing questions has served as a valuable way to prompt continued dialogue with stakeholders for continuous improvement of the ISA. In addition to the questions and requests for feedback below, stakeholders are encouraged to review content within the sections and specific Interoperability Needs to provide feedback, or submit requests for new Interoperability Needs, as necessary.

Historical questions and requests for stakeholder feedback have been moved for viewing history, but comments on and responses to these questions remain on this page, or may be included in comment letters received posted as comments elsewhere on the ISA.

19-1

Text:
19-1: In what ways has the ISA been useful for you/your organization as a resource? ONC seeks to better understand how the ISA is being used, by whom, and the type of support it may be providing for implementers and policy-makers.

ACLA Comment:
The American Clinical Laboratory Association reviews and comments annually for laboratory impacts.

19-2

Text:
19-2: Are there additional features or functionality ONC could make to the ISA website that would enhance the user experience?

ACLA Comment:
We appreciate having all of the information in the same location for quick searches and references. Would it be possible to provide a full document to easily use during the review period, similar to the published Reference Edition?

19-3

Text:
19-3: The adoption level, along with other informative characteristics about standards/implementation specifications, was introduced to the ISA in August, 2015, and currently represents ONC's "best guess" at current adoption based on a number of factors. Is the adoption level characteristic as it stands valuable information for stakeholders, or should it be retired or replaced with other information?

ACLA Comment:
We suggest you retire the adoption level since, as you say, it is a "best guess" and not really based on quantifiable data. Additionally, you may rate an item at a high level of adoption because it is required for EHR certification, but it is not being electronically exchanged so it is not contributing to interoperability at a high level (for example, gender identity.)

Ultimately, removing this will help resolve the misconceptions of usage and maturity in the industry.

Appendix I – Sources of Security Standards and Security Patterns

https://www.healthit.gov/isa/appendix-i-sources-security-standards-and-security-patterns

Text:
4th bullet: ASTM

ACLA Comment:
This hyperlink returns error: 404: Page Not Found
Suggest you remove this entry since it does not indicate a specific ASTM standard with functional hyperlink, or correct the hyperlink.

Appendix II - Models and Profiles

https://www.healthit.gov/isa/appendix-ii-models-and-profiles

HL7 Standards - Section 1: Primary Standards

Text:

HL7 Standards - Section 1: Primary Standards

SECTION 1 Primary standards are the most popular standards integral for system integrations, and interoperability. Our most frequently used and in-demand standards are in this category. (This section also includes the Version 2 and Version 3 solution sets, which encompass all standards relative to that version. Individual V2 and V3 standards are sold independently in the corresponding categories.)

ACLA Comment:
Most HL7 standards are licensed at no cost. Rather than stating "…standards are sold independently…" we suggest you refer the reader to HL7's Standards Licensed At No Cost policy statement at:
http://www.hl7.org/implement/standards/nocost.cfm

IHE Profiles

- IHE Profiles describe specific solutions to integration problems. A profile documents how standards will be used by each system's Actors to cooperate to address the problem.

Text: (example)
Laboratory Testing Workflow

This profile is part of the Pathology and Laboratory Medicine (PaLM) domain, which merged the former AP and LAB domains since 2016, January 4th.

Laboratory Testing Workflow (LTW) integrates the ordering, scheduling, processing, and result reporting activities associated with in vitro diagnostic tests performed by clinical laboratories in healthcare institutions.

ACLA Comment:

In order to avoid potentially conflicting requirements, please add a general statement (perhaps as an introductory section to Appendix II) that standards, implementation guides (IGs), profiles, etc. developed/sponsored by the Office of National Coordinator (ONC) or previously cited by a federal agency in a Final Rule supersede other standards, (IGs), profiles, etc. included in the ISA.

For example, the ONC Standards & Interoperability Framework sponsored a suite of HL7 V2.5.1 laboratory implementation guides (LOI, LRI and associated value set companion guide) which may conflict with the IHE Laboratory Testing Workflow based on HL7 V2.5 and V2.5.1.

Multiple Sections including Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications

General ACLA Comments:

- Suggest retitling all references to 'lab' (or 'Lab') to 'laboratory' (or 'Laboratory') for consistency throughout the ISA.

  Examples:

  Representing Laboratory Tests

  Limitations, Dependencies, and Preconditions for Consideration

  - A single lab test with a single result may have the same LOINC® code for the order and the result or may have a more specific code in the result (for example if the order code was method less or did not declare the system property). A panel order will have an order LOINC® code and multiple result LOINC® terms for each result in the panel

  Interoperability Need: Electronic Transmission of Reportable Lab Results to Public Health Agencies

  Electronic Transmission of Reportable Lab Results to Public Health Agencies

- Suggest replacing references for LOINC code or LOIN code to LOINC or LOINC (code).