October 1, 2018

Dr. Donald 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: Request for Public Comments: Interoperability Standards Advisory

Dear Dr. Rucker:

I am submitting the attached comments on behalf of the American Clinical Laboratory Association (ACLA) in response to the *2019 Draft Interoperability Standards Advisory*

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 releasing the Draft 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.

Sincerely,

Thomas B. Sparkman, RPh, MPP, JD
Vice President, Government Relations

ATTACHMENT

Topic: Representing Patient Sex (At Birth)

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

Representing Patient Sex (At Birth)

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
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 II 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 use 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)

ACLA Comment:

We endorse ACLA Best Practice Recommendation for Administrative and Clinical Patient Gender used for Laboratory Testing and Reporting (hyperlink below) and request ONC to add this reference under "Limitations, Dependencies, and Preconditions for Consideration" to provide additional guidance to industry.
http://www.acla.com/acla-best-practice-recommendation-for-administrative-and-clinical-patient-gender-used-for-laboratory-testing-and-reporting/

The adoption level is overstated, many EHR systems are using V2 values; suggest change Adoption Level for observations and observation values to 3 bullets.

Topic: 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

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●○○○	No	Free	No
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

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.

ALCA Comment:
While we recognize 2.5.1 is compliant with the regulatory guidelines for EHR certification, we have not experienced the maturity of adoption stated in this guide.

HL7 published an update to the eDOS Implementation Guide June 20, 2018. We concur with the previously posted comments below:

Please change:

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)

to (updated title and hyperlink)

HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2, STU Release 3 (also referred to as eDOS (Electronic Directory of Service), which is posted at: http://www.hl7.org/documentcenter/public/standards/dstu/V2_IG_LTCF_R2_STU_R3_2018JUN.pdf

Additionally the Value Set Guide referenced in "Limitations, Dependencies, and Preconditions for Consideration" was updated.

Please change:

HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015

to (updated title and hyperlink)

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

Please change:

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

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 current version has been harmonized with the most current suite of Lab US Realm Implementation Guides, published by HL7 June 2018.

Please clarify the intention of the Security and Authentication references in the Applicable Value Set(s) section.

Ordering Labs for a Patient

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

Ordering Labs for a Patient

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●○○○	No	Free	No
Implementation Specification	HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 DSTU Release 2 - 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. ▪ Note that the implementation specification has been harmonized with the most current suite of Lab US Realm Implementation Guides and is scheduled for update in the HL7 January 2017 Ballot Cycle ▪ 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:
While we recognize 2.5.1 is compliant with the regulatory guidelines for EHR certification, we have not experienced the maturity of adoption stated in this guide.

HL7 published an update to the LOI Implementation Guide June 20, 2018, please update to reflect the latest publication.

We suggest the adoption level for LOI should be 1 bullet for the standard and IG.

Please clarify the intention of the Security and Authentication references in the Applicable Value Set(s) section.

Receive Electronic Laboratory Test Results

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

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●○○○	No	Free	No
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 2 - 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:
While we recognize 2.5.1 is compliant with the regulatory guidelines for EHR certification, we have not experienced the maturity of adoption stated in this guide.

HL7 published an update to the LRI Implementation Guide June 20, 2018, please update Emerging Implementation Specification to reflect the latest publication and change the Implementation Maturity to Production.

Please clarify the intention of the Security and Authentication references in the Applicable Value Set(s) section.

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

Text:

Identify Linkages Between Vendor IVD Test Results and Standard Codes

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

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 specification listed has not been vetted through a Voluntary Consensus Standards Body (VCSB) as defined in OMB Circular A-119[1].

Please modify this comment as revision marked:

- 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 result codes. LIVD assures that laboratory personnel select the appropriate LOINC result codes for IVD test(s) used by their laboratory.

Please spell out acronyms at least once on this page:

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

Suggest adding "HL7 FHIR® Implementation Guide: LOINC – IVD Test Code (LIVD) Mapping, Release 1", which is currently being balloted through HL7, as related "Emerging Implementation Specification" with notations in the Standards Process Maturity and Implementation Maturity sections to request additional feedback.

[1] 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

(Vocabulary) Representing Laboratory Tests

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

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	●●●○○	Yes	Free	N/A
Standard for observation values	SNOMED CT®	Final	Feedback requested	Feedback Requested	Yes	Free	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. ▪ See LOINC projects in the Interoperability Proving Ground. ▪ For more information about observations and observation values, see Appendix II 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

ACLA Comment:

- We are aware that some EHR systems assign LOINC or SNOMED CT codes if not provided by the sending laboratory; these mappings should be approved in advance by the Laboratory sending the result.
- Also some EHR systems have asked laboratories not to send SNOMED CT codes, even if they are using a certified interface that supports SNOMED CT, e.g. LRI.
- 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 strongly recommend that CPT codes not be added to the ISA in this section “Representing Laboratory Tests” for lab

tests; CPT codes are not specific enough to represent laboratory tests and are typically used only related to billing for laboratory tests.

- We recommend further discussions be held between ACLA and the Health IT Standards Committee regarding the challenges experienced with adoption and use of these terminologies.

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

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

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:

We recommend further discussions be held between ACLA and the Health IT Standards Committee regarding the challenges experienced with adoption and use of these terminologies.

Electronic Transmission of Reportable Lab Results to Public Health Agencies

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

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●○○○	Yes	Free	No
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
Emerging Implementation Specification	*HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm), Draft Standard for Trial Use, Release 1.1*	*Balloted Draft*	*Pilot*	*Feedback Requested*	*No*	*Free*	*No*
Emerging Implementation Specification	*HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 2 - US Realm*	*In Developement*	*Pilot*	●○○○○	*No*	*Free*	*Yes*

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 ELR as there may be jurisdictional variation or requirements. ▪ The Emerging Implementation Specification: "HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public health, Release 2 (US REALM), Draft Standard for Trial Use, Release 1.1" listed above was in a Draft Standard for Trial use status, but was not renewed or balloted as normative. However, a recommendation was received to leave it listed here until there is wider adoption/experience with other listed specifications. ▪ 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:
While we recognize 2.5.1 is compliant with the regulatory guidelines for EHR certification, we have not experienced the maturity of adoption stated in this guide.

HL7 published an update to the ELR Implementation Guide in May 2014 please update Emerging Implementation Specification to reflect the latest publication and change the Implementation Maturity to Production.

HL7 published an update to the LRI Implementation Guide June 20, 2018, please update Emerging Implementation Specification to reflect the latest publication and change the Implementation Maturity to Production.

Please clarify the intention of the Security and Authentication references in the Applicable Value Set(s) section.

Reporting Cancer Cases to Public Health Agencies

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.

ACLA Comment:

Feedback on the NAACR Implementation Specification:

We suggest that NAACCR develop a profile in the HL7 V2.5.1 LRI IG (cited under Receive Electronic Laboratory Test Results and required for 2014 Edition Certification), vs. continued support of a separate implementation specification. We understand that NAACCR is already considering this option.

IHE Emerging Implementation specification: *IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation*

We suggest this specification should be balloted through an established Voluntary Consensus Standards Body (VCSB) as defined in OMB Circular A-119[2], preferably HL7 since IHE has a Memorandum of Understanding (MOU) with HL7. Laboratories that might be impacted should have the opportunity to comment on the specifications following the American National Standards Institute (ANSI) due process.

Please clarify the intention of the Security and Authentication references in the Applicable Value Set(s) section.

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

Text:

Lab Tests

Lab Tests

Representing Laboratory Tests

Limitations, Dependencies, and Preconditions for Consideration

- 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

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

ACLA Comment:

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

Section VI: Questions and Requests for Stakeholder Feedback (18-1 to 18-4)

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

[2] 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

Updated questions for the 2018 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. While more limited in scope this year to general high-level questions, 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.

18-1

Text:
18-1. 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:
In our experience, the ISA has served as a single source guideline; however it has not been instrumental (*consistently leveraged*) in encouraging adoption of new or emerging standards within healthcare IT where standards bodies and associated regulations are primary drivers.

18-2

Text:
18-2. Over the course of 2018, some new functionality has been added to the ISA, with more enhancements expected through 2018 and 2019. Are there additional features or functionality that would enhance the user experience?

ACLA Comment:

18-3

Text:
18-3. Is the existing ISA format used for listing standards and implementation specifications applicable for listing Models and Profiles? Are there additional or different attributes that should be collected for them? Are there additional models and/or profiles that should be listed? Are models and profiles useful for inclusion in the ISA?

ACLA Comment:
This is dependent on the standard, for example several HL7 V2 Implementation Guides (IGs) cited in the ISA contain profiles in the IG (LRI, LOI, eDOS), vs. (for example) separate profiles defined in FHIR. Models are more useful in the

context of the standard referencing, and not necessarily needed in ISA; could also be a synchronization maintenance issue.

18-4

Text:
18-4. Are there additional informative or educational resources that can be provided to help stakeholders better understand the ISA, health IT standards, interoperability, etc?

ACLA Comment:
Existing information is acceptable.

ACLA Comments in response to IVD Industry Connectivity Consortium: see Appendix A

The following comments are in response to IVD Industry Connectivity Comments posted 2017-11-14 on the Introduction to the ISA webpage: https://www.healthit.gov/isa/

IVD Industry Connectivity Consortium (IICC) comment

IICC comment text:

The IVD Industry Connectivity Consortium finds that it would be beneficial if ONC would add the LAW – Laboratory Analytical Workflow Profile and LIVD – Digital Format for Publication of LOINC to Vendor IVD Test Results standards to the following proposed new sections:

ACLA Comment:
LAW has not been vetted through Voluntary Consensus Standards Body (VCSB) as defined in OMB Circular A-119[3]. We suggest this specification should be balloted through HL7 since LIVD is currently being balloted by HL7. This would give laboratories opportunity to comment.

IVD Industry Connectivity Consortium (IICC) comment

IICC comment text:

[3] 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

The IVD Industry Connectivity Consortium (IICC) would also ask ONC's support to make both standards "Federally Required" for federal agencies as well as commercial entities.

ACLA Comment:
We suggest that both 'standards' should be balloted through an established VCSB, e.g. HL7, before consideration of citing as "Federally Required". Laboratories that might be impacted should have the opportunity to comment on the specifications following ANSI due process.

Appendix A

IVD Industry Connectivity Consortium –

https://www.healthit.gov/isa/

Submitted by sjonnaert **on 2017-11-14**

Dear Madam,

Dear Sir,

On behalf of the IVD Industry Connectivity Consortium we are pleased to provide written comments to the Office of the National Coordinator for Health Information Technology (ONC) in response to the 2017 Interoperability Standards Advisory (ISA).

The IVD Industry Connectivity Consortium (IICC) is a global, nonprofit organization dedicated to creating and encouraging adoption of a unified connectivity standard to reduce the cost and variability of data exchange between IVD devices and healthcare informatics in clinical laboratories. This will improve healthcare efficiency and patient care.

The IICC has collaborated with several government bodies, including the US Food and Drug Administration (DMD/OIR/CDRH), US Centers for Disease Control and Prevention, and US Department of Health and Human Services (HHS) (ONC), National Institutes of Health (NIH), and industry organizations such as IHE International, HL7, Clinical & Laboratory Standards Institute, the College of American Pathologists, the Association of Public Health Laboratories (APHL), the Medical Device Innovation Consortium (MDIC), and the Regenstrief Institute to develop two standards that **together allow for true Plug & Play connectivity of IVD instruments to Middleware and Laboratory Information Systems (LIS)**.

The IVD Industry Connectivity Consortium appreciates the opportunity to leverage our volunteers' expertise in commenting on the Standards Advisory, and we look forward to continuing our dialogue with ONC on identifying, assessing, and determining the best available interoperability standards and implementation specifications. We feel that this effort will provide the necessary foundation for more rapidly advancing interoperability.

The IVD Industry Connectivity Consortium finds that it would be beneficial if ONC would add the LAW – Laboratory Analytical Workflow Profile and LIVD – Digital Format for Publication of LOINC to Vendor IVD Test Results standards to the following proposed new sections:

- Section II: Content/Structure Standards and Implementation Specifications > Interoperability Need: Identify linkages between vendor IVD test results and standard codes

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	LIVD – Digital Format for Publication of LOINC to Vendor IVD Test Results	Final	Production	1	No	Free	No

- Section II: Content/Structure Standards and Implementation Specifications > Interoperability Need: Connectivity between instruments, middleware, and LIS systems

Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	LAW – Laboratory Analytical Workflow Profile	Final	Production	3	No	Free	Yes

- **LAW – Laboratory Analytical Workflow Profile** – The LAW Profile defines the physical connection, message definitions (based on the HL7 Messaging Standard v2.5.1), and workflow definitions between instruments, middleware, and LIS systems in the laboratory. IICC collaborated with the IHE Pathology and Laboratory Medicine (PaLM) domain to develop the LAW Profile. LAW is already implemented by all major IVD companies, including Abbott Laboratories, Beckman Coulter, BD, bioMerieux, Data Innovations, Orchard Software, Ortho Clinical Diagnostics, Roche, Siemens Healthineers, Systelab, Sunquest, and Werfen Group.

  For more information on LAW **[click here]**

- **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.

  For more information on LIVD **[click here]**

  Why are LAW and LIVD important for clinical laboratories?

  The LAW Profile and LIVD specifications should have a significant positive impact on laboratory operations. Clinical laboratories are encouraged to ask their instrument, middleware, and LIS vendors about their current or planned support for the IICC/IHE Laboratory Analytical Workflow (LAW) and LIVD. The LAW Profile is currently being implemented by all major IVD companies.

- LAW and LIVD will significantly reduce the time and cost involved with deploying, connecting, and updating instruments in the laboratory by eliminating the need for vendor customized connectivity implementations, favoring vendors that adopt the specifications and pass the savings to their customers.
- Addresses all the shortcomings of outdated laboratory connectivity standards such as CLSI LIS1-A (ASTM 1391) and CLSI LIS2 (ASTM E1394).
- LAW will be a global standard (CLSI AUTO16).
- LAW and LIVD support federal guidelines on Meaningful Use.
- Improves the integrity of patient data.
- The LAW and LIVD specifications are available for download **and do not require any licensing or fees for implementation**.

The IVD Industry Connectivity Consortium (IICC) would also ask ONC's support to make both standards "Federally Required" for federal agencies as well as commercial entities.

We appreciate the opportunity to submit comments on the 2017 ISA. Our comments are intended to recognize the importance of each stakeholder's role in advancing standards-based interoperability and health information exchange, and ensuring that each domain is invested in overcoming the inherent challenges, while further enhancing health IT's pivotal role in enabling healthcare transformation.

Please feel free to contact me if you have any questions or to obtain more information.

Sincerely,

Serge Jonnaert, BiD
President, IVD Industry Connectivity Consortium - ivdconnectivity.org
serge.jonnaert@ivdconnectivity.org
+1.949.259.3807
/ Board Member, At-Large - IHE International - ihe.net
/ President, AERTWORKS® LLC – www.aertworks.com