The Office of the National Coordinator for Health Information Technology

# S&I Framework and Interoperability Standards for Labs Overview

## Laboratory Results Interface (LRI) Initiative, Laboratory Orders Interface (LOI) and Electronic Directory of Services (eDOS)

August 13, 2013

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# Agenda



- What is the S&I Framework
- Laboratory Results Interface (LRI)
- Laboratory Orders Interface (LOI)
- Electronic Directory of Services (eDOS)
- MU2 Final Rule and Certification Criteria for EHR 2014

# Office of Science & Technology

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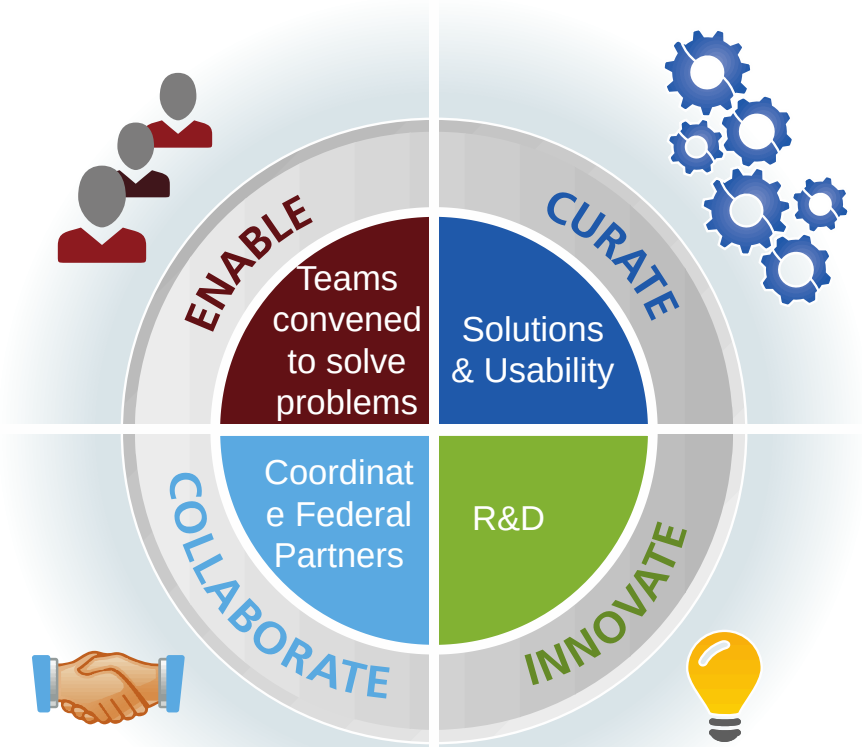
**Enable stakeholders** to come up with simple, shared solutions to common information exchange challenges




**Curate a portfolio** of standards, services, and policies that accelerate information exchange

**Collaborate** with federal agencies to coordinate federal health IT priorities as manager of Federal Health Architecture

**Support Innovation** through SHARP program, Innovation/Challenge Grants, and interfacing with International Standards community

# What is the S&I Framework?

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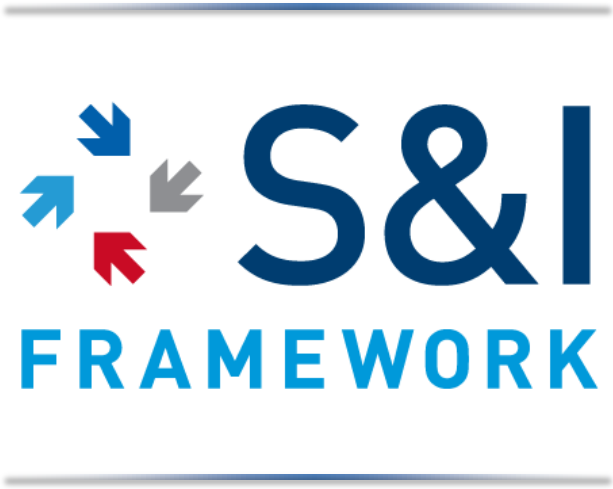
- The Standards and Interoperability (S&I) Framework represents one investment and approach adopted by the Office of Science & Technology (OST) to fulfill its charge of prescribing health IT standards and specifications to support national health outcomes and healthcare priorities
- The S&I Framework is an example of "government as a platform"– enabled by integrated functions, processes, and tools – for the open community* of implementers and experts to work together to standardize




** As of August 2013, 2100+ people had registered on the S&I Framework wiki, and 750+ people representing 500+ organizations had committed to the S&I Framework*

# Standards and Interoperability (S&I) Framework



The S&I Framework is a collaborative community of volunteers from the public and private sectors who are focused on providing the tools, services and guidance to facilitate the functional exchange of health information.

Each S&I Initiative tackles a critical interoperability challenge through a rigorous process that typically includes:

- Development of clinically-oriented user stories and robust use cases
- Harmonization of interoperability specifications and implementation guidance
- Provision of real-world experience and implementer support through new initiatives, workgroups and pilot projects
- Mechanisms for feedback and testing of implementations, often in conjunction with ONC partners such as NIST

# S&I Framework Coordination

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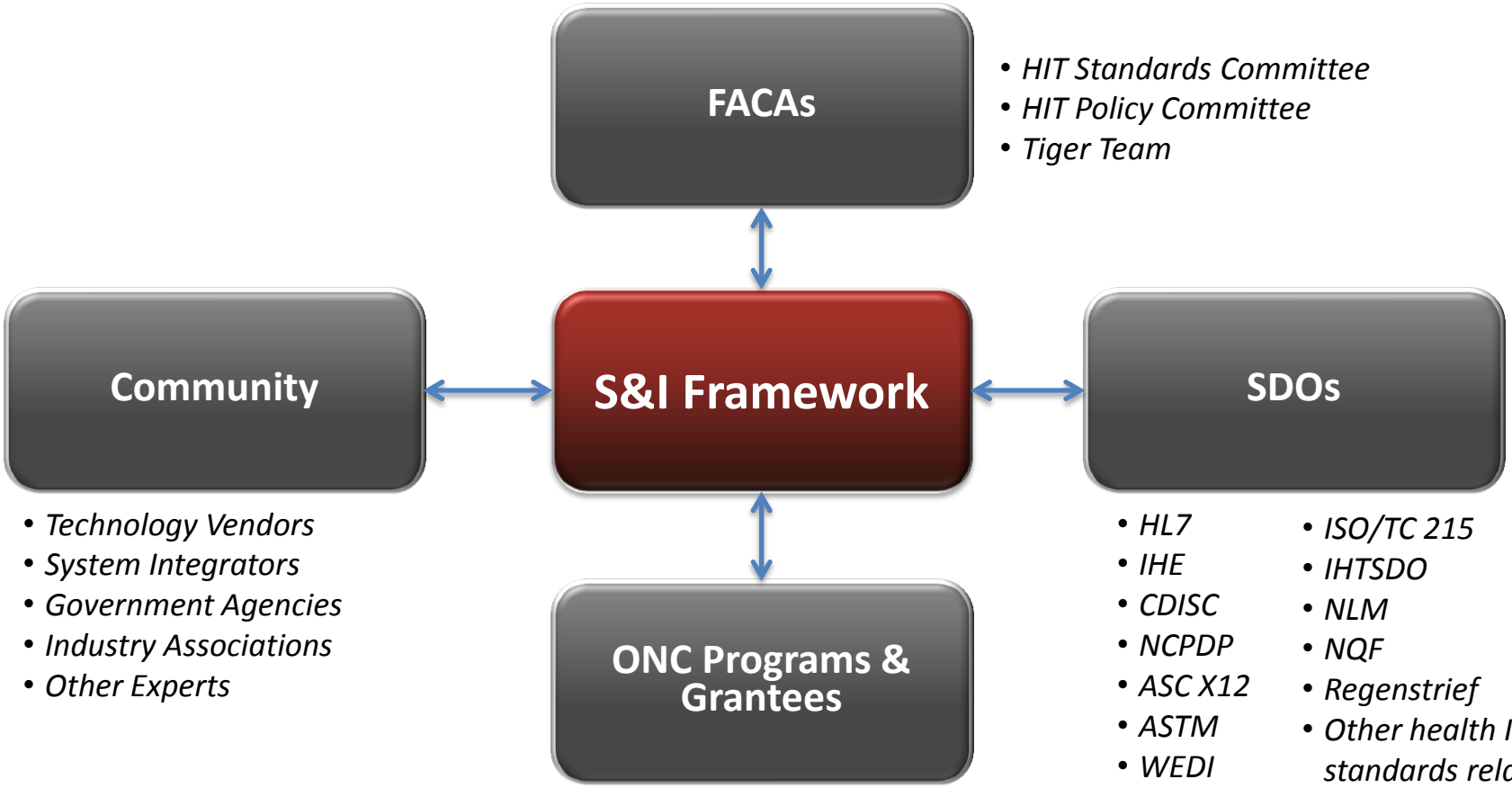
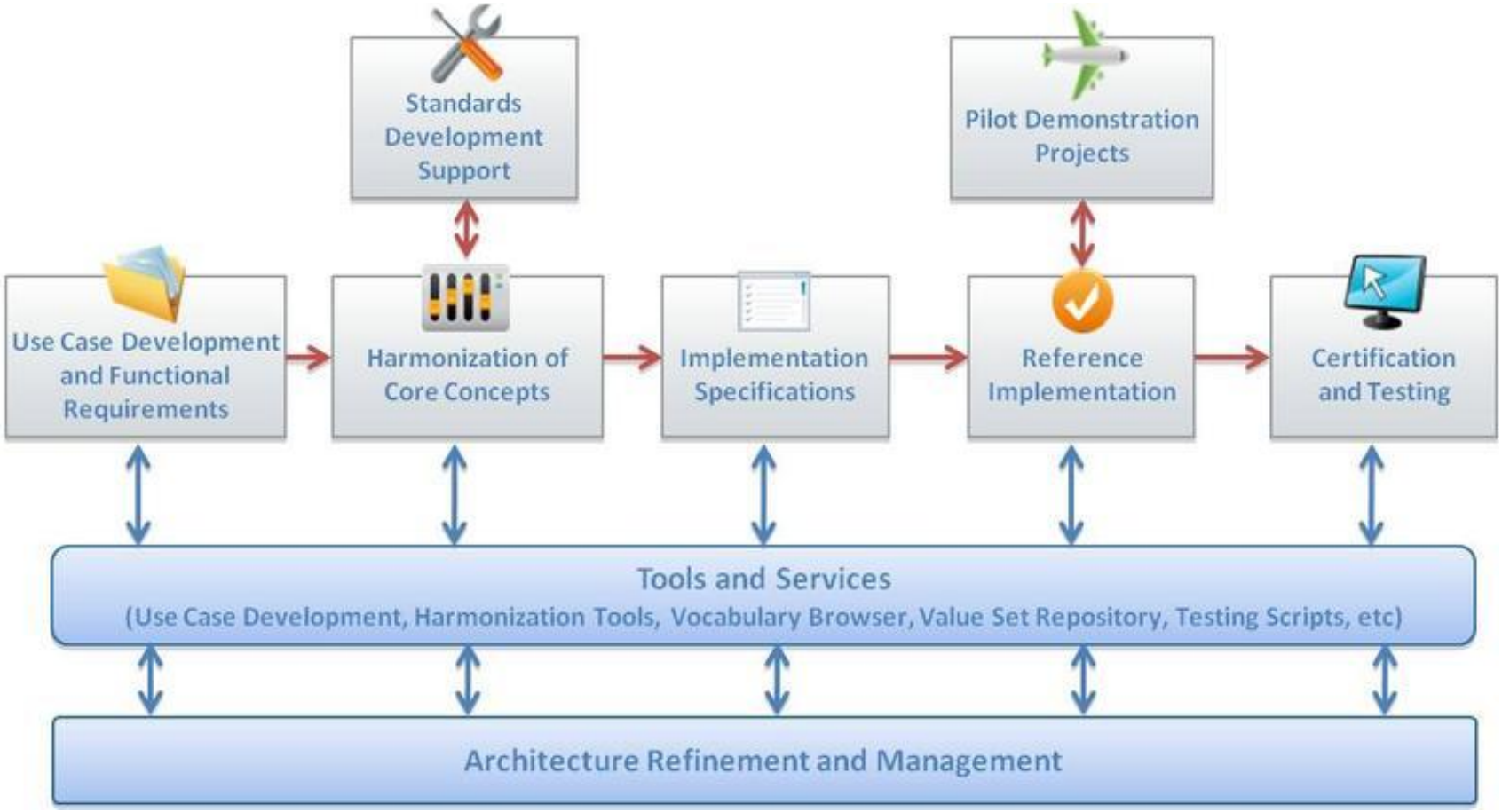


# S&I Functions





# Laboratory Results Interface - LRI



## User Story:

A Provider *(order placer)* may enter a laboratory order into an ambulatory EHR. A laboratory requisition is generated (paper or electronic) and is communicated to the laboratory. The information in the laboratory requisition is entered manually or captured electronically into the Laboratory Information System (LIS). After the specimen(s) have been collected and, if necessary, shipped or delivered to the laboratory, the laboratory processes the specimen(s). The laboratory performs or attempts to perform the test(s). If testing is successful, results are obtained and entered/released in the laboratory information system. An authorized person at the laboratory reviews and approves the laboratory test results to be sent to the ordering provider.

The laboratory's LIS system *(results sender)* transmits the results to the Provider's Electronic Health Record system *(results receiver).* The EHR incorporates the results into the patient's electronic record. The Provider logs into his/her EHR and views the laboratory results in order to inform patient care decisions.

# Laboratory Results Interface - LRI



**Mission:** To address the challenges of laboratory reporting to ambulatory primary care providers. Primarily driven by the needs of internal medicine, family practice and pediatrics, but may also be leveraged by other providers and settings.

**Summary of Accomplishments**: The Laboratory Results Interface Initiative analyzed two identified HL7 implementation guides that were under consideration for the Lab Reporting Interface specification, and evaluated the content of the guides against the Lab Reporting Interface Use Case Requirements. This enabled the Workgroup to write an Lab Results Implementation Guide that was submitted and balloted through HL7.

**Main Deliverable(s):**

*HL7 Version 2.5.1 Implementation Guide :Laboratory Results Interface for US Realm, Release 1* - The Laboratory Results Interface implementation guidance for electronic reporting of laboratory test results to ambulatory care providers in the US Realm.

# LRI Vocabulary Considerations



- Must use LOINC code if it exists for the test
- Must use SNOMED-CT for microbiology
- Optional use of UCUM for units of measure
- Optional use of OIDs for unique identifiers (e.g. Performing Laboratory)

# Laboratory Orders Interface - LOI

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**User Story:** A Provider (*Order Placer)* enters into an ambulatory EHR system a new or scheduled laboratory order and indicates whether or not they would like to receive ongoing status updates on the order.
Scheduled orders enable Providers *(Order Placers)* to order laboratory tests and/or panels for a patient, which are scheduled to be performed at a future date. A laboratory requisition is generated for the new or scheduled laboratory order in electronic form and is electronically transmitted to the selected Laboratory. An electronic notification will be sent from the Laboratory (*Order Filler*) to the Provider (*Order Placer)* acknowledging that the laboratory requisition has been received.
The information from laboratory requisition is electronically captured by the Laboratory
After the specimen(s) has been collected at either the Provider, testing center, or at the Laboratory and, if necessary, shipped or delivered to the Laboratory, the Laboratory receives and processes the specimen(s). The Laboratory (*Order Filler)* performs or attempts to perform the test(s).
As the test is being resulted, a report is sent back electronically in a standardized, structured format (use of the LRI IG is recommended).

# Laboratory Orders Interface - LOI



**Mission:** The Laboratory Orders Interface Initiative is focused on the creation of an Implementation Guide (IG) for the ambulatory setting that builds on the architecture and design of the California HealthCare Foundation's (CHCF) EHR-Lab Interoperability and Connectivity Specification (ELINCS) Laboratory Orders and the Health Level Seven (HL7) Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 - US Realm (July 2012)(LRI IG).

**Summary of Accomplishments**: The Laboratory Orders Initiative has developed an IG that, when broadly adopted by clinical laboratories and ambulatory EHR systems, will obviate the requirement to define a new specification each time an EHR system-LIS orders interface is implemented.

**Main Deliverables:** *HL7 V 2.5.1 Implementation Guide: S&I Framework Lab Orders Interface, Release 1 – US Realm DSTU* - The Laboratory Orders Interface implementation guidance for electronic ordering of laboratory tests in the US Realm.

# Laboratory Orders Interface - eDOS



**User Story:**

A Laboratory (*Compendium Producer*) and an Ordering Provider and/or the Ordering Provider's EHR Vendor (*Compendium Consumer*) agree to automate the process of delivering the Laboratory's Directory of Services. The initial Laboratory Test Compendium build for a Compendium Consumer includes the electronic delivery of either the entire DOS or a subset, based on the Ordering Provider's ordering history, specialty, etc., as agreed to between the Compendium Consumer and the Compendium Producer.

As scheduled or as requested, a Compendium Producer electronically sends the complete laboratory test compendium or subset. The compendium is received and processed by a Compendium Consumer.

# Laboratory Orders Interface - eDOS

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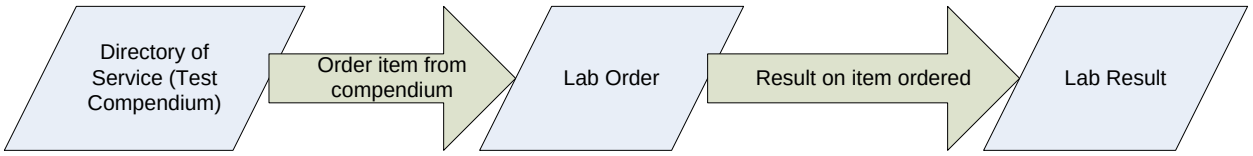
**Mission:** The eDOS sub workgroup is focussed in providing an electronic interchange of a laboratory's Directory of Services (DOS) in a structured format. This implementation guide, is intended to provide all necessary information to help an Ordering Provider properly request laboratory tests consistent to aide patient diagnosis.

The eDOS work effort will:

- Validate that the current Informative Implementation Guide meets the objective through a pilot of eDOS
- Align the IG with the in-scope tests in the Lab Result Interface (LRI) IG



# Status of Laboratory IGs



- **HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 – US Realm (LRI IG)**
  - *Published July 2012, In MU 2014 Edition*

- **HL7 Version 2.5.1 Implementation Guide: Laboratory Orders Interface for US Realm, Release 1 – US Realm (LOI IG)**
  - *2nd ballot reconciliation is in progress now*
  - *Target to publish this fall*

- **HL7 Version 2 Implementation Guide: Laboratory Test Compendium Framework, Release 2 – US Realm (eDOS IG)**
  - *1st ballot reconciliation is in progress now*
  - *Target to publish this fall w/LOI*

# Laboratory Initiatives NIST Testing



- NIST has released the test framework for LRI for compliance testing
- NIST is extending this tool/environment to include compliance testing for LOI and eDOS
- These should be released for testing in ~4 weeks
- The intention is time the final release in concert with the LOI and eDOS IGs releases

# Resources



- LRI: http://wiki.siframework.org/Lab+Results+Interface+%28LRI%29+Initiative

- LRI IG Overview: http://hitrc-collaborative.org/confluence/download/attachments/54329605/LRI+IG+Overview.pdf?version=1&modificationDate=1354548834000

- LOI and eDOS (sub-workgroup under LOI): http://wiki.siframework.org/Laboratory+Orders+Interface+Initiative

# Thank You

# Backup Reference Slides

- MU Stage 2 requirements for Lab
- Certification Criteria for EHR Technology 2014 (relevant to lab)

# 42 CFR Part 495 MU Stage 2 Final Rule



**Stage 2 Core Criteria for Eligible Providers**

(7)(i) Objective. Incorporate clinical lab test results into Certified EHR Technology as structured data.

(ii) Measure. Subject to paragraph (c) of this section, more than 55 percent of all clinical lab tests results ordered by the EP during the EHR reporting period whose results are either in a positive/negative affirmation or numerical format are incorporated in Certified EHR Technology as structured data.

**Stage 2 Core Criteria for Eligible Hospitals or CAH**

(6)(i) Objective. Incorporate clinical lab test results into Certified EHR Technology as structured data.

(ii) Measure. More than 55 percent of all clinical lab tests results ordered by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative affirmation or numerical format are incorporated in Certified EHR Technology as structured data.

**Stage 2 Menu Set Criteria for Eligible Hospitals or CAH**

(6)(i) Objective. Provide structured electronic lab results to ambulatory providers.

(ii) Measure. Hospital labs send structured electronic clinical lab results to the ordering provider for more than 20 percent of electronic lab orders received.

**§ 170.102 Definitions.**

Common MU Data Set means the following data expressed, where indicated, according to the specified standard(s):

…

(11) Laboratory test(s) – at a minimum, the version of the standard specified in § 170.207(c)(2).

(12) Laboratory value(s)/result(s).

…

**§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.**

(j) Electronic incorporation and transmission of lab results. Standard. HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, (incorporated by reference in § 170.299).

**§ 170.207 Vocabulary standards for representing electronic health information.**

(c) Laboratory tests.

(1) Standard. Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, when such codes were received within an electronic transaction from a laboratory (incorporated by reference in § 170.299).

(2) Standard. Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc. (incorporated by reference in § 170.299).

**§ 170.299 Incorporation by reference.**

(f) Health Level Seven, 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104; Telephone (734) 677–7777 or http://www.hl7.org/

(10) 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, IBR approved for § 170.205.

(l) Regenstrief Institute, Inc., LOINC® c/o Medical Informatics The Regenstrief Institute, Inc 410 West 10th Street, Suite 2000 Indianapolis, IN 46202-3012; Telephone (317) http://loinc.org/. Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, June 15, 2009, IBR approved for § 170.207.

(2) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40**,** Released June 2012, IBR approved for § 170.207.

**170.314(b)(5) Incorporate laboratory tests and values/results.**

(i) Receive results.

(A) Ambulatory setting only.

(1) Electronically receive and incorporate clinical laboratory tests and values/results in accordance with the standard specified in § 170.205(j) and, at a minimum, the version of the standard specified in § 170.207(c)(2).

(2) Electronically display the tests and values/results received in human readable format.

(B) Inpatient setting only. Electronically receive clinical laboratory tests and values/results in a structured format and electronically display such tests and values/results in human readable format.

(ii) Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).

(iii) Electronically attribute, associate, or link a laboratory test and value/result with a laboratory order or patient record.

**§ 170.314 2014 Edition electronic health record certification criteria.**

(6) Inpatient setting only – transmission of electronic laboratory tests and values/results to ambulatory providers. EHR technology must be able to electronically create laboratory test reports for electronic transmission in accordance with the standard specified in § 170.205(j) and with laboratory tests expressed in accordance with, at a minimum, the version of the standard specified in § 170.207(c)(2).