ONC's Laboratory Results Interface (LRI) and Laboratory Orders Interface (LOI) Implementation Guides and LIS-EHR Data Exchange

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Outline and Objectives

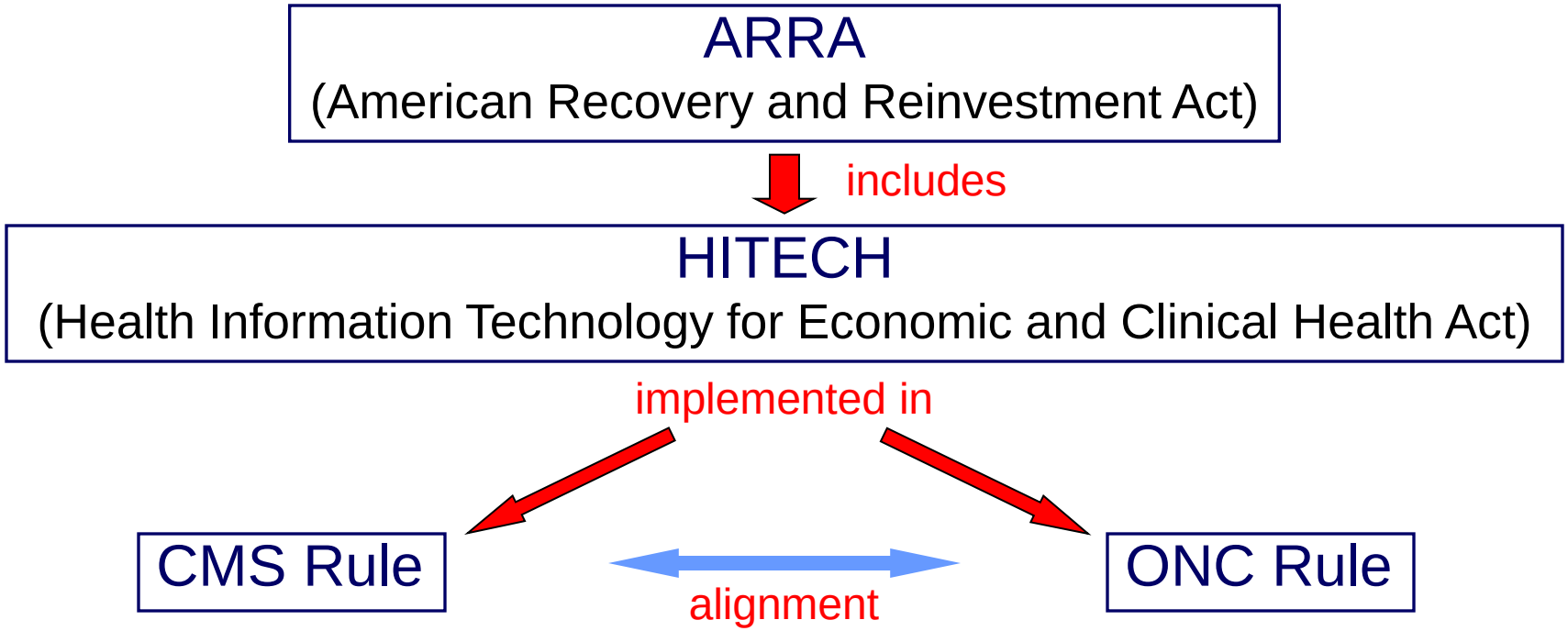
- Describe LRI and LOI and place in regulatory context
- Describe LRI and LOI relevance to laboratories
- Examine ONC's proposed rule for 2015 Edition of Health IT Certification Criteria

What is the Relevance of the LOI, LRI, eDOS Implementation Guides to Laboratories?

- They will determine what the future looks like for laboratory information exchange and LIS interfaces.
- They are woven into the fabric of ONC's emerging, broader framework of "Health IT", which will encompass LISs and other aspects of laboratory information use.
- Laboratories will need to ensure that their systems and interfaces are compliant.
- The IGs will continue to evolve and expand.

Context for LOI, LRI, eDOS IGs

- HITECH Act
- “Meaningful Use”
- EHR Standards and Certification Criteria
- ONC Standards and Interoperability (S&I) Framework



- **EHR Incentive Program** ("Meaningful Use"; MU)

- HOW providers and hospitals must use EHRs

- **EHR Standards and Certification Criteria** (SCC)

- WHAT EHRs must be able to do

(ONC = Office of the National Coordinator for Health Information Technology in HHS)

Brief Regulatory History of EHRs

- July 2010: Stage 1 MU; 2011 Edition SCC
- Sept. 2012: Stage 2 MU; 2014 Edition SCC
- Sept. 2014: CEHRT Flexibility Rule
  - Allowed for delays in EHRs meeting 2014 Edition
- Sept. 2014: 2014 Edition SCC Release 2
  - Added flexibility; promoted interoperability; set stage for 2015 Edition SCC
- **March 30, 2015:** *Proposed Rules* – Stage 3 MU and 2015 Edition SCC

MU=Meaningful Use; SCC=Standards and Certification Criteria
CEHRT=Certified Electronic Health Record Technology

ONC Health IT Certification Criteria

"…incorporated by reference"

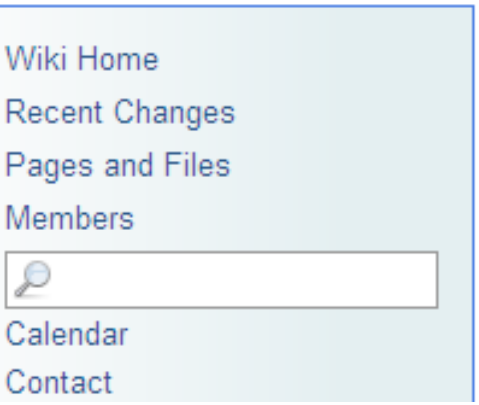
- **Content exchange standards** for exchanging electronic health information
  - **LRI**
  - **LRI Public Health**
  - **LOI**
  - **eDOS**
  - (others – CDA, etc.)
- **Vocabulary standards** for representing electronic health information
  - LOINC
  - SNOMED-CT
  - UCUM (Unified Code for Units of Measure)
  - (others – RxNorm, etc.)

How great is this?

ONC Standards and Interoperability Framework

S&I FRAMEWORK

- Public and private sector community effort
- Adopted by ONC to enable harmonized interoperability specifications
- Creation of tools, services, and guidance to facilitate exchange of health information
- Set of integrated functions, processes, and tools
- Specific initiatives focused on real world challenges (e.g. lab orders)



Laboratory Orders Interface Initiative

Initiative Home | Join the Initiative | Charter & Members | S&I Phases | Materials

Edit PageTabs

Table of Contents

Each S&I Initiative has a Wiki

The Path to S&I IG

S&I Initiatives
(Laboratory)

- LRI
- LRI PH
- LOI
- eDOS
- EHR-S

Participants

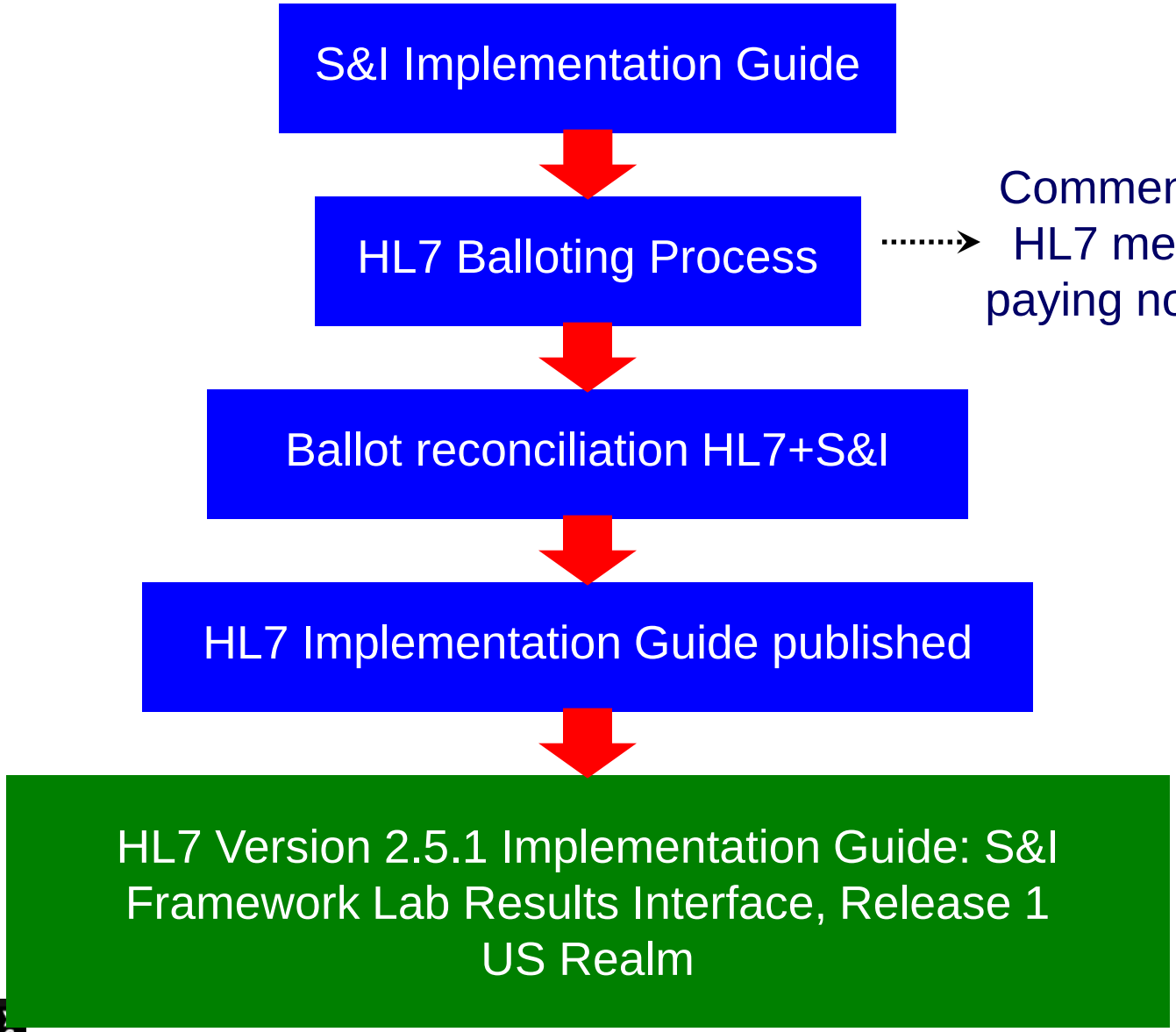
- Health IT developers
- Gov't agencies
- Consulting groups
- Professional societies
- Commercial labs
- Individuals, etc.

Phases

- Charter
- Use cases
- Implementation Guide (IG)
- Pilots
- Evaluation

- "Artifacts"
- HL7 Balloted

S&I and HL7 Collaboration to Create IGs



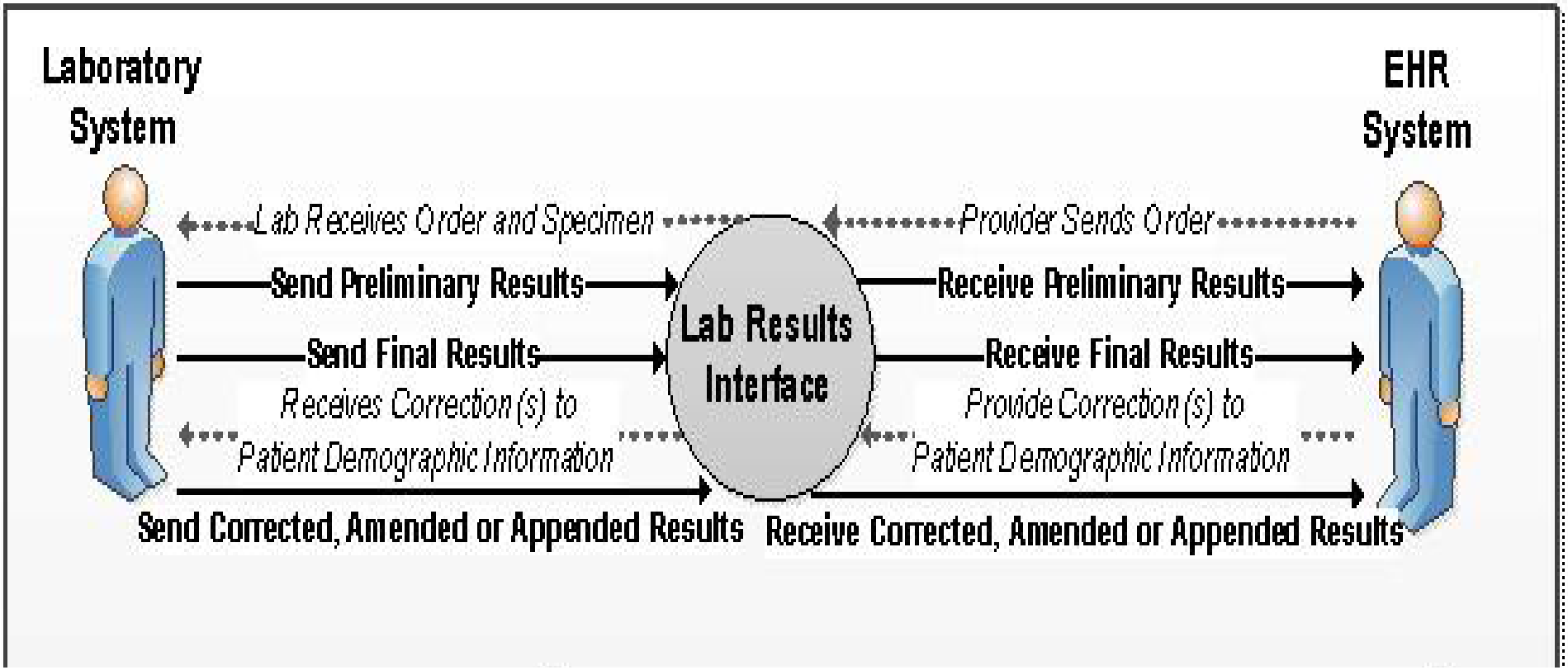
HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 - US Realm

Draft Standard for Trial Use

Laboratory Results Initiative (LRI) Implementation Guide (IG)

- Requirements, specifications, standards, and implementation guidance for electronic reporting of laboratory test results to *ambulatory* care providers
- Use Cases directed at reporting between LIS and EHR
- Balloted and approved through HL7
- HL7 V2.5.1 ORU^R01 Message as basis for IG

LRI Context Diagram



OBX Segment Table in HL7 IG

TABLE 3-13. OBSERVATION RESULT SEGMENT (OBX)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
6	Units	CWE_CRE	C(R/RE)	[0..1]		Condition Predicate: If OBX-2 (Value Type) is valued "NM" or "SN" and OBX-11 is not valued "X" or "N" **Note:** If there is not a unit of measure available while the Condition Predicate is True, the value "NA" shall be used in CWE_CRE.1 and "HL70353" in CWE_CRE.3 **Note:** UCUM (Unified Code for Units of Measure) will be evaluated during the pilot for potential subsequent inclusion. As part of the pilot test, for dimensionless units the UCUM representation could be {string}, e.g., for titer the pilot might use {titer} to test feasibility. When sending units of measure as text, they must be placed in the correct component of OBX-6 (CWE_CRE.9).
7	References Range	ST	RE	[0..1]		Guidance: It is not appropriate to send the reference range for a result in an associated NTE segment. It would be appropriate to send additional information clarifying the reference range in an NTE associated with this OBX-
8	Abnormal Flags	IS	RE	[0..*]	HL70078 (2.5.1)	Microbiology example: Ceftazidime susceptibility (LOINC 133-9) value = |<=^1|, units = ug/ml, Abnormal flag = S Note that this IG is adopting HL70078 from 2.5.1, see Section 4.7.3 for value set.
9	Probability		O			
10	Nature of Abnormal Test		O			
11	Observation Result Status	ID	R	[1..1]	HL70085	
12	Effective Date of Reference Range		O			
13	User-Defined Access Checks		O			
14	Date/Time of the Observation	TS_5	RE	[0..1]		For specimen based test, if it is valued it must be the same as SPM-17 If SPM-17 is present and relates to the same observation, then OBX-14 must be within the DR range.
15	Producer's Reference		O			
16	Responsible Observer		O			

Value Sets for Interpretive Codes in HL7 IG

TABLE 4–5. HL7 TABLE 0078 INTERPRETATION CODES (V2.5.1)		
Value	Description	Comment
L	Below low normal	
H	Above high normal	
LU	Low Urgent	Between L and LL
HU	High Urgent	Between H and HH
LL	Below lower panic limits	
HH	Above upper panic limits	
<	Below absolute low-off instrument scale	
>	Above absolute high-off instrument scale	
N	Normal (applies to non-numeric results)	
A	Abnormal (applies to non-numeric results)	
AA	Very abnormal (applies to non-numeric units, analogous to panic limits for numeric units)	
null	No range defined, or normal ranges don't apply	
U	Significant change up	
D	Significant change down	
B	Better—use when direction not relevant	
W	Worse—use when direction not relevant	
S	Susceptible. Indicates for microbiology susceptibilities only.	
R	Resistant. Indicates for microbiology susceptibilities only.	
I	Intermediate. Indicates for microbiology susceptibilities only.	
MS	Moderately susceptible. Indicates for microbiology susceptibilities only.	

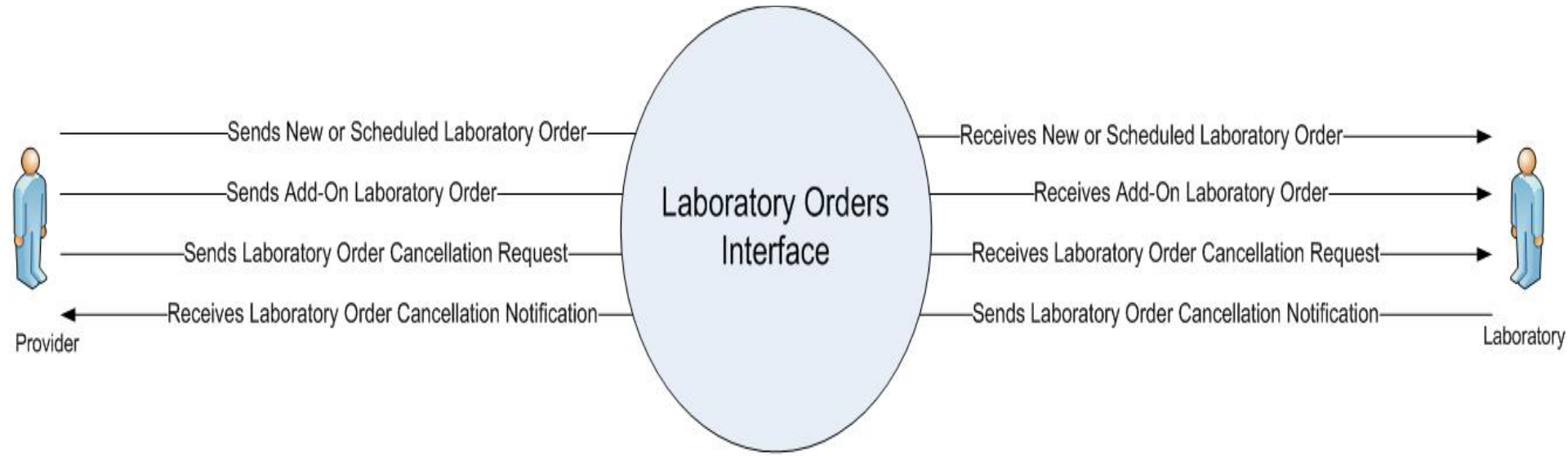
LRI IG Vocabulary Standards

- LOINC vocabulary required where a LOINC code is available
- For receivers, SNOMED CT vocabulary required for certain Microbiology related results
- For senders, SNOMED CT recommended
- UCUM (Unified Code for Units of Measure) recommended

Laboratory Orders Initiative (LOI) Implementation Guide (IG)

- Requirements, specifications, standards, and implementation guidance for electronic ordering of laboratory tests in *ambulatory* settings
- Use Case directed at test ordering between EHR-S and LIS
- HL7 V2.5.1 OML^O21 Message as basis for IG

LOI Context Diagram



LOI IG – Order Entry Challenges Addressed

- Add on test orders
- Cancel test request by provider
- Cancel test by laboratory
- Ask at Order Entry responses
  - Information needed for interpretation of results
  - Data required for state/federal agency mandates
  - Information at time of specimen collection (e.g. fasting)

LOI IG Vocabulary Standards

- LOINC vocabulary where a LOINC code is available AND provided by the laboratory
- SNOMED-CT strongly recommended
- UCUM recommended

LOINC in LOI IG

- Test order consisting of both the laboratory's local order code and the corresponding LOINC order code:

```
|BMP^Basic Metabolic Panel^99LAB^24321-2^Bas Metab 2000 Pnl
SerP^LN^20120731^2.40|
```

- Test order using only the laboratory's local order code:

```
|CA125^CA-125^99LAB^^^^20120731|
```

Laboratory Test Compendium Framework (eDOS) Implementation Guide (IG)

- Standardized means of electronically communicating a laboratory's **Directory of Services** (eDOS)
- Defined format to deliver laboratory test menu offerings and related information to systems that support electronic laboratory ordering, results reporting, and other functionality
- Support of initial eDOS build for each new client and ongoing maintenance updates
- Laboratory = Compendium Producer
- EHR (or other system) = Compendium Consumer

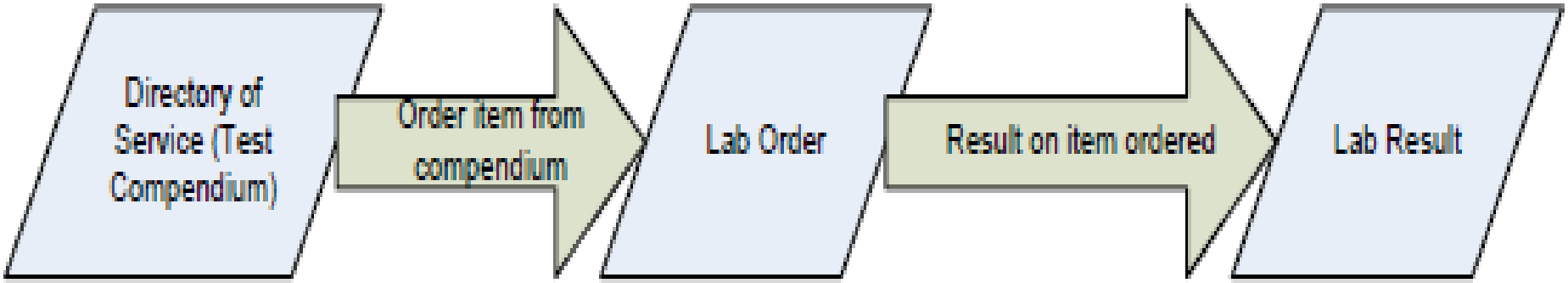
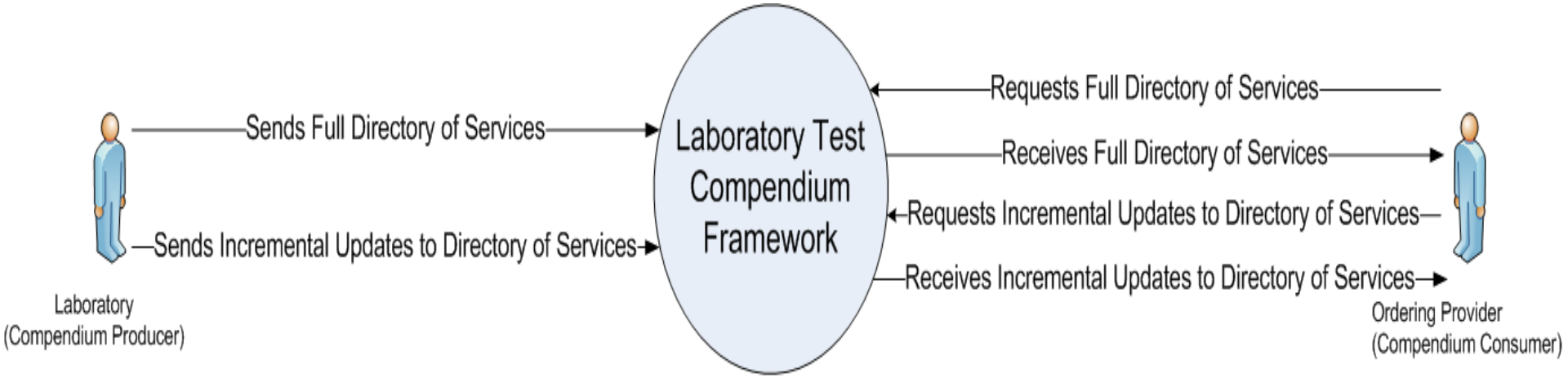


Figure 1-1. eDOS Data Flow

eDOS works in concert with LRI and LOI:

Several elements in the laboratory's test compendium are subsequently used in the lab order and lab result

eDOS Context Diagram



Laboratory Test Compendium Framework (eDOS) IG – Expectations for Exchange

- Complete eDOS delivered to initialize an interface.
- Delivery of complete eDOS available at any time upon request.
- Delivery of eDOS, full or partial, should be automated process between Compendium Producer and Consumer
- eDOS to be processed by Consumer upon receipt

Laboratory Test Compendium Framework (eDOS) IG Vocabulary Standards

- Laboratory's *local* test code to be used to identify orderable test in its eDOS
- LOINC as standard alternate vocabulary to identify an orderable test.
  - Performing laboratory determines applicable LOINC order code.
  - If no applicable LOINC code, local code may be only code defined in eDOS.
- SNOMED CT recommended
- UCUM recommended

Proposed Rule
Federal Register
March 30, 2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 170

RIN 0991–AB93

2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking with comment period.

ONC Health IT Certification Criteria

"…incorporated by reference"

- **Content exchange standards** for *exchanging* electronic health information
  - **LRI**
  - **LRI Public Health**
  - **LOI**
  - **eDOS**
  - (others – CDA, etc.)
- **Vocabulary standards** for *representing* electronic health information
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  - (others – RxNorm, etc.)

Proposed ONC 2015 Edition marks a shift that has implications for laboratories

ONC 2015 Edition Marks Significant Shift

- "EHR", "EHR Technology" → **Health IT**
- "EHR Module" → **Health IT Module**
- "The term **health IT** is reflective of the scope of ONC's authority…and represents a broad range of technology..."
- "Our proposals…would permit other types of health IT (*e.g.*, ***laboratory information systems (LISs)***), …to receive appropriate attribution and not be referenced by a certificate with 'EHR' in it."

170.315(a)(2) Computerized Provider Order Entry – Laboratory

- HL7 v2.5.1 Implementation Guide: Laboratory Orders from EHR, Release 2 (LOI IG)
- HL7 v2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2, v1.2 (eDOS IG)
- LOINC v2.50 or newer
- LOI R2 IG – test requisition information specified in CLIA (42 CFR 493.1241) required in message
- "Therefore, inclusion of this standard for certification *may also facilitate laboratory compliance with CLIA*."

170.315(b)(4) Incorporate Laboratory Tests and Values/Results

170.315(b)(5) Transmission of Laboratory Test Reports

- HL7 v2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 2 (LRI IG)
- More specific requirements for display of information included in a test report.
- "…*which would also assist with laboratory compliance with CLIA*."
- Reference ranges, critical values, delays, corrected reports
- LOINC v2.50 or newer

170.315(f)(3) Transmission to Public Health Agencies – reportable laboratory tests and values/results

- HL7 v2.5.1 Implementation Guide: Electronic Reporting to Public Health, Release 2
- LOINC v2.50 or newer
- SNOMED-CT September 2014 release

Other "Pearls" from (proposed) ONC 2015 Edition

- "…framework [that is]open and accessible to more types of health IT"
- Emphasis on interoperability
- Supports Stage 3 MU
- 170.315(e)(1) (View, download, and transmit to 3rd party) – "VDT"
  - "We seek to ensure that the test reports that are delivered by providers to patients *through the VDT capabilities* adhere to the *CLIA test reporting requirements*."

One more thing…EHR-S Functional Requirements IG

- Definition of EHR system functional requirements related to the receipt of laboratory results compliant with the LRI Release 2.
- Additional requirements as set forth in CLIA *as well as clinical best practices beyond the scope of LRI Release 2*.
- ONC seeking comment in the proposed rule

Summary

- ONC's (proposed) 2015 Edition Health IT Certification Criteria signal a shift to broader framework of "Health IT", which will encompass LISs and other aspects of laboratory information use.
- LRI, LOI, eDOS are key elements of ONC's 2015 Edition
- These efforts will determine the future for laboratory information exchange and LIS interfaces.
- IGs will continue to evolve and expand.
- Laboratories will need to ensure that their systems and interfaces are compliant.