HL7 IMPLEMENTATION GUIDE: S&I FRAMEWORK EHR-S FUNCTIONAL REQUIREMENTS FOR LABORATORY RESULTS INTERFACE (LRI), RELEASE 1- US REALM

January 2015

1st DSTU Ballot

Sponsored by:
Orders and Observations
in collaboration with the Health and Human Services Standards
and Interoperability Framework Laboratory Result Interface Working Group

LRI Work Group Co-chair:	Hans Buitendijk, Siemens Healthcare
LRI Work Group Co-chair:	Ken McCaslin, Quest Diagnostics
EHR-S Functional Requirements IG-Labs Work Group Co-chair:	Riki Merrick, Vernetzt, LLC
EHR-S Functional Requirements IG-Labs Work Group Co-chair:	Robert Dieterle, Enablecare

Questions or comments regarding this document should be directed to the Orders and Observations Workgroup (ord@lists.hl7.org).

1 IMPORTANT NOTES

HL7 licenses its standards and select IP free of charge. **If you did not acquire a free license from HL7 for this document,** you are not authorized to access or make any use of it. To obtain a free license, please visit http://www.HL7.org/implement/standards/index.cfm.

If you are the individual that obtained the license for this HL7 Standard, specification or other freely licensed work (in each and every instance "Specified Material"), the following describes the permitted uses of the Material.

A. HL7 INDIVIDUAL, STUDENT AND HEALTH PROFESSIONAL MEMBERS, who register and agree to the terms of HL7's license, are authorized, without additional charge, to read, and to use Specified Material to develop and sell products and services that implement, but do not directly incorporate, the Specified Material in whole or in part without paying license fees to HL7.

INDIVIDUAL, STUDENT AND HEALTH PROFESSIONAL MEMBERS wishing to incorporate additional items of Special Material in whole or part, into products and services, or to enjoy additional authorizations granted to HL7 ORGANIZATIONAL MEMBERS as noted below, must become ORGANIZATIONAL MEMBERS of HL7.

B. HL7 ORGANIZATION MEMBERS, who register and agree to the terms of HL7's License, are authorized, without additional charge, on a perpetual (except as provided for in the full license terms governing the Material), non-exclusive and worldwide basis, the right to (a) download, copy (for internal purposes only) and share this Material with your employees and consultants for study purposes, and (b) utilize the Material for the purpose of developing, making, having made, using, marketing, importing, offering to sell or license, and selling or licensing, and to otherwise distribute, Compliant Products, in all cases subject to the conditions set forth in this Agreement and any relevant patent and other intellectual property rights of third parties (which may include members of HL7). No other license, sublicense, or other rights of any kind are granted under this Agreement.

C. NON-MEMBERS, who register and agree to the terms of HL7's IP policy for Specified Material, are authorized, without additional charge, to read and use the Specified Material for evaluating whether to implement, or in implementing, the Specified Material, and to use Specified Material to develop and sell products and services that implement, but do not directly incorporate, the Specified Material in whole or in part.

NON-MEMBERS wishing to incorporate additional items of Specified Material in whole or part, into products and services, or to enjoy the additional authorizations granted to HL7 ORGANIZATIONAL MEMBERS, as noted above, must become ORGANIZATIONAL MEMBERS of HL7.

Please see http://www.HL7.org/legal/ippolicy.cfm for the full license terms governing the Material.

Ownership. Licensee agrees and acknowledges that **HL7 owns** all right, title, and interest, in and to the Trademark. Licensee shall **take no action contrary to, or inconsistent with**, the foregoing.

Licensee agrees and acknowledges that HL7 may not own all right, title, and interest, in and to the Materials and that the Materials may contain and/or reference intellectual property owned by third parties ("Third Party IP"). Acceptance of these License Terms does not grant Licensee any rights with respect to Third Party IP. Licensee alone is responsible for identifying and obtaining any necessary licenses or authorizations to utilize Third Party IP in connection with the Materials or otherwise. Any actions, claims or suits brought by a third party resulting from a breach of any Third Party IP right by the Licensee remains the Licensee's liability.

Following is a non-exhaustive list of third-party terminologies that may require a separate license:

Terminology	Owner/Contact
Current Procedures Terminology (CPT) code set	American Medical Association http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/cpt-products-services/licensing.page?
SNOMED CT	International Healthcare Terminology Standards Developing Organization (IHTSDO) http://www.ihtsdo.org/snomed-ct/get-snomed-ct or info@ihtsdo.org
Logical Observation Identifiers Names & Codes (LOINC)	Regenstrief Institute
International Classification of Diseases (ICD) codes	World Health Organization (WHO)

Acknowledgments

The authors of this document wish to recognize the following participants who contributed their time and expertise to the development of this guide.

Alexis Carter	Emory
Andrea Pitkus	Intelligent Medical Objects, Inc.
Anne Pollock	Centers for Disease Control and Prevention
Bill Ormerod	Siemens
Bob Yencha	RTY LLC
Carolyn Knapik	College of American Pathologists (CAP)
Cindy Johns	LabCorp
Craig Krause	Epic
Craig Newman	Epic
David Burgess	LabCorp
Diane Amerault	Meditech
Elizabeth Hough	
Eric Haas	Health eData Inc
Ern Grove	SHAPE HITECH, LLC
Freida Hall	Quest Diagnostics
Gai Elhanan	Epic
Gary Dickenson	Centrihealth
Gil Shohamy	Epic
Heather Patrick	Centers for Disease Control and Prevention
John Daly	
John Feikema	Feikema and Associates, LLC
John Ritter	
Karen Dyer	Centers for Medicare & Medicaid Services
Kathy Walsh	LabCorp
Kristie Gill	LabCorp
Lauren Niles	
Lenel James	Blue Cross, Blue Shield
Lester Keepper	SHAPE HITECH, LLC
Maggie Wright	McKesson
Maribeth Gagnon	Vermont Information Technology Leaders
Mark Jones	Orchard Software
Mary Kennedy	College of American Pathologists
Megan Sawchuck	Centers for Disease Control and Prevention
Nathan Bunker	Open Immunizations Software
Penny Probst	Highmark
Riki Merrick	Vernetzt, LLC
Robert Dieterle	EnableCare, LLC
Robert Snelick	National Institute of Standards and Technology

Ron van Duyne	Centers for Disease Control and Prevention
Serafina Versaggi	Adavanta Healthcare Partners, LLC
Sheryl Taylor	Booz Allen Hamilton
Sony Varghese	
Steve Groskreutz	University of Pittsburgh
Susan Eben	McKesson
Tawni Reller	Tawni Reller Consulting

Copyrights

This document is © 2015 Health Level Seven International, All rights reserved.

This material includes SNOMED Clinical Terms ® (SNOMED CT®) which is used by permission of the International Health Terminology Standards Development Organization (IHTSDO). All rights reserved. SNOMED CT was originally created by The College of American Pathologists. "SNOMED ®" and "SNOMED CT ®" are registered trademarks of the IHTSDO.

This material contains content from LOINC® (http://loinc.org). The LOINC table, LOINC codes, and LOINC panels and forms file are copyright © 1995-2011, Regenstrief Institute, Inc. and the Logical Observation Identifiers Names and Codes (LOINC) Committee and available at no cost under the license at http://loinc.org/terms-of-use.

This material contains references and citations to various publications from the Health Level Seven International (HL7). Members may obtain a copy of the referenced materials without charge in the Members-only area of the site. Non-members are referred to the HL7 Intellectual Property Policy to determine if a no-cost license is available, otherwise a copy can be obtained for a nominal fee via the HL7 Store at www.hl7.org.

Notes to Balloters

We are seeking input specifically in the following areas:

1. Overall format of this document as well as the presentation of the detail in the spreadsheet format. In particular this document gives some background on the Electronic Health Record system (EHR-S) Functional Model (FM) and established this documents relationship to it (Section 2.4.1.3 Functional Profiles) as well as an overall introduction to the subject matter of this document, including the scope, pre-and post-conditions and user stories with the respective functional requirements (Section 3 Functional and Behavioral Requirements). The following sections describe in detail the requirements for different scenarios (Section 4 Requirements for Laboratory Report Data Integrity, Section 5 Report and Result Status and Succession, Section 6 EHR Error). Finally the data element level requirements are described in Section 7 Understanding Incorporation Requirements. An effort was made to align with the format of the existing Laboratory Implementation guides as well as that of the Functional Profile documents, but we are unsure, if we succeed, so please provide input.

2. The action verbs used to describe the detailed functionality for incorporate and use still need to be synchronized with the action verbs in use in the parent normative standard of this implementation guide, the Electronic Health Record system (EHR-S) Functional Model (FM) and we seek input on the best fit. The action of verbs used here are:

   a. Associate

   b. Display

   c. Incorporate

   d. Log

   e. Make available

   f. Process

   g. Receive

   h. Store

   i. Translate

   j. Use

   Please refer to Section 2.4.1.4 Language for a brief introduction to the relationship between the action verbs here and in the EHR-S FM.

3. Application of rules for error handling (Section 6 EHR Error) – is the section on error handling clear enough to implement? A few conformance statements for this section are listed, but the full list will need to be developed with more group input.

4. Data succession – is the section on result progression (Section 5 Report and Result Status and Succession), dealing with updates to lab results and ancillary data clear enough to implement? Does the way result statuses are used to drive EHR-S functionality in regards to Clinical Laboratory Improvement Amendments (CLIA) requirements and nomenclature make sense? A few conformance statements for this section are listed, but the full list will need to be developed with more group input.

5. Question regarding time over which there is requirement to provide corrected reports based on any criteria (analytic, demographic, interpretation, etc.) – when is it automatic and when does it require manual review (1 day, 1 week, ...) - or should it just be listed as to be arranged by partner agreement?

We acknowledge that at this time this guide may have more information than needed to describe the functional requirements on the EHR-S side of the LRI transaction only, which is due to the lack of a Laboratory Information System (LIS) Functional Model document, where some of these elements would otherwise be described. They are included here, as the development of data elements in the message will help explain the reasoning behind some of the functional requirements.

TABLE OF CONTENTS

TABLE OF CONTENTS

INDEX OF TABLES

INDEX OF FIGURES

2 INTRODUCTION

2.1 Purpose

This document has been developed through the Standards and Interoperability (S&I) Framework EHR-S Functional Requirements IG-Labs Work Group. The intention is for this implementation guide to be part of the Lab related implementation guides for the US Realm as an ANSI-approved normative standard.

This work is part of a larger current project, whose goal it is to create a suite of functional requirements documents for Electronic Health Record System (EHR-S) technology for laboratory orders and results.

The focus here is on creating EHR-S Functional Requirements Implementation Guide for laboratory results compatible with the S&I Laboratory Results Interface (S&I LRI) guide. Additional regulatory requirements Clinical Laboratory Improvement Amendments (CLIA) and clinical best practices beyond the LRI IG have been considered in the development of this guide.

This document is intended to bridge the gap and harmonize between the LRI and LOI IGs and the yet to be developed EHR-S Functional Profile for Laboratory (being developed via another project (Project Insight ID#1097 specifically for the Laboratory Results Interface (LRI) with the goal to inform testing for Meaningful Use (MU) certification.

2.2 Audience

This guide is designed for use by analysts and developers, who require guidance on the storage and processing (incorporation) of data elements and components of the *HL7 Version 2.5.1 ORU Unsolicited Observation Message* as defined by the Laboratory Results Interface (LRI) initiative, see Section 2.2.2 Requisite Knowledge. Users of this guide must be familiar with the details of HL7 message construction and processing. This guide is not intended to be a tutorial on that subject.

2.2.1 RELEVANT LABORATORY IMPLEMENTATION GUIDES

There are multiple Implementation Guides in support of the Office of the National Coordinator (ONC) that have been developed under the Standards and Interoperability Framework Initiative (S&I Framework). These guides have been created using the same processes, are stylistically similar and designed to work together. The set includes but is not limited to:

- This publication; EHR-S Functional Requirements For Laboratory Results Messages

- HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 2- US Realm [HL7 Version 2.5.1 ORU^R01] Draft Standard for Trial Use, August 2014

- HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 2, US Realm [HL7 Version 2.5.1: OML^O21] Draft Standard for Trial Use, August 2014

- HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, R2, DSTU Release 1.1 US Realm March 2014 (eDOS)

- The profiles that make up modifications of both the LRI (HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm) Draft Standard for Trial Use, November 2013) and LOI IG to support the Electronic Laboratory Reporting (ELR) or the addendum to those guides.

As part of that design, some components are prefaced by LAB_, LOI_ or LRI_, which indicates the following use:

- LAB_*xxx* – the component declares behaviors and constraints that apply to all guides.

- LOI_*xxx* – the component declares behaviors and constraints that apply specifically to laboratory orders.

- LRI_*xxx* – the component declares behaviors and constraints that apply specifically to laboratory results.

- PH-*xxx* - the component declares behaviors and constraints that apply specifically to reporting for public health (ELR)

LRI-EHR-S-FR-*xxx* - the component declares behaviors and constraints that apply specifically to the EHR-S in regards to handling LRI transactions. The EHR System and LIS will conform to this family of implementation guides.

2.2.2 REQUISITE KNOWLEDGE

This guide is constructed assuming the implementer has prior knowledge and understanding of and access to the following relevant documents:

- [HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1- US Realm (S&I LRI IG)](#)

- [HL7 EHR-System Functional Model, Release 2 (EHR-S FM)](#)

Another related document is the HL7 EHR-System Meaningful Use Functional Profile, Release 1 – US Realm (MU-FP), Informative Ballot, September 2014 currently being prepared for publication that aimed to identify the EHR-S FM functions used in named MU certification requirements.

2.3 Key Technical Decisions

- **Error definitions** – this document defines the meaning of hard and soft errors in the context of processing laboratory results messages conformant to the LRI IG; see Section 6 EHR Error .

- **Storage and Processing Requirements Criteria** – this document defines a scheme whereby the storage and subsequent processing requirements are declared at the most atomic level; see Section 7.4 Detailed Requirements for In-scope Data Elements .

2.4 Functional Model and Functional Profiles

A brief summary of the organization of the HL7 EHR-S Functional Model is presented here to provide context for the specific Use Cases defined elsewhere in this document.

The EHR-S Functional Model is composed of the Function List, which is divided into seven sections shown in Figure 2-1. Functional List Sections.
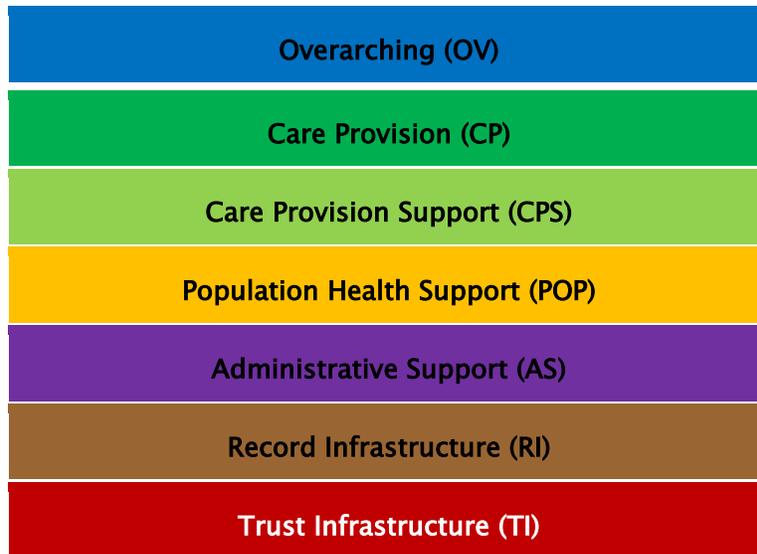
Figure 2-1. Functional List Sections

Within the seven Sections of the Functional List the functions are grouped under header functions which each have one or more sub-functions in a hierarchical structure. Each function in the HL7 EHR-S Functional Model is identified by a function ID and a name, and a statement describing the purpose and scope of the function which is further elaborated on in the longer description. Each function is associated with one or more conformance criteria that can be used to verify that the function has been implemented.

2.4.1.1   CONFORMANCE CLAUSE

This IG is based on the HL7 EHR-S Functional Model, Release 2 April 2014.

Key to the Functional Model and derived profiles is the concept of *conformance,* which is defined as *"The fulfillment of specified requirements by a product, process, or service".* [1] In the Functional Model and in derived profiles, the general concept of conformance may be expressed in a number of forms. For instance, a profile can be said to conform to the Functional Model if it adheres to the defined rules specified by the Functional Model specification. Similarly, an EHR system, to exchange data with a LIS, may claim conformance to one of these profiles if it meets all the requirements outlined in the profile.

2.4.1.2   CONFORMANCE CRITERIA

Each function defined in the Functional Model or profiles is associated with specific *conformance criteria,* which are statements used to determine if a particular function is met (i.e., "the system SHALL capture, display and report all hearing tests associated with a patient"). Conformance criteria have been developed in accordance with the standards set forth by the EHR Work Group. In order to ensure

---

[1] HL7. Electronic Health Record-System Functional Model, Release 2. 2014. URL: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=269

consistent, unambiguous understanding and application of the Functional Profile, a consistent set of keywords (normative verbs) has been employed to describe conformance requirements.

The key words SHALL, SHALL NOT, SHOULD, and MAY in this document are to be interpreted as described in HL7 EHR-S Functional Model, Release 2, May 2013 Conformance Clause:

> **"SHALL"** Indicates a mandatory requirement to be followed (implemented) in order to conform. Synonymous with 'is required to' and 'must'.

> **"SHALL NOT"** Indicates a prohibited action. Synonymous with 'prohibited' and 'must not'.

> **"SHOULD"** Indicates an optional recommended action, one that is particularly suitable, without mentioning or excluding others. Synonymous with 'is permitted and recommended'.

> **"MAY"** Indicates an optional, permissible action. Synonymous with 'is permitted'.

2.4.1.3   FUNCTIONAL PROFILES

A "Functional Profile" is a selected set of functions that are applicable for a particular purpose, user, care setting, domain, etc. Functional profiles help to manage the master list of functions. It is not anticipated that the full Functional Model will apply to any single EHR-S implementation. As such, an EHR system does not conform directly to the Functional Model; rather, it conforms to one or more Functional Profiles.

Functional profiles are the expression of usable subsets of functions from the EHR-S Functional Model. The act of creating a Functional Profile is to support a business case for EHR-S use by selecting an applicable subset of functions from the EHR-S Functional Model list of functions, in effect constraining the model to meet specific requirements. The yet to be developed Lab-Functional Profile (Lab-FP) will specify EHR-S functionality that is necessary to exchange and utilize the following data content:

- Laboratory Test Order and related information

- Laboratory Test Result

- Information allowing the proper association or integration into the health record for the correct patient

- Jurisdictional guidelines for clinicians on public health lab result reporting, e.g., newborn screening, infectious diseases, chronic diseases and other

- Educational materials for providers regarding PHL testing, e.g., infectious diseases

- Error handling of exchange transactions

This implementation guide is further constraining the Lab-FP.

2.4.1.4   LANGUAGE

Additional clarification is necessary to understand the standardized nomenclature used to describe the actions performed by a system. The following adapted excerpt from the EHR-S FM R2 Glossary, illustrates the hierarchical nature of the nomenclature. For example, the term "Capture" is used to describe a function that includes both direct data entry ("Enter") and indirect data entry (e.g., "Import" from another system. Similarly, "Maintain" is used to describe a function that entails storing, updating, and/or removing data.

Table 2–1. Manage (Data) Action Verbs										
Capture		**Maintain**			**Render**		**Determine**		**Manage-Data-Visibility**	
Input (External)	Create (internal)	Store	Update	Remove Access	Read (Internal)	Output (External)	Analyze	Decide	De-Identify Hide	
Accept Download Import Receive	Auto-Populate Compute Enter Record	Archive Backup Compact Decrypt Encrypt Recover Restore Save	Annotate Attest Augment Edit Harmonize Integrate Link Tag	Destroy Inactivate Nullify Purge	Extract Present	Send Upload Export Synchronize Transmit			Mask Re-Identify Unhide Unmask	

In the final version of this guide this section will include a mapping between the verbs used in this IG and the conformance verbs as defined in the EHR-S FM.

As a starting point we have identified the following conformance verbs from the EHR-S FM, and their relationship to the verbs currently used in this guide and will be further constrained in this guide:

CAPTURE (or more specifically RECEIVE) – currently listed as "receive" in the pre-condition, also referred to as "log", describes receipt of the LRI HL7 message and part of the processing of its content

STORE (or more specifically SAVE) – currently listed as "store" with several variations

INTEGRATE – currently listed as "incorporate", is used in the user stories, as part of the process of storing message content after it was associated with the correct record

LINK - currently listed as "associate", is used in the user stories, as part of the process of storing message content after it was associated with the correct record

PRESENT – currently listed as "use" or "display" with several variations

NEED VERB – currently listed as "translate to equivalent concept" (mapped) as part of the store action

NEED VERB – currently listed as "process" as part of the store action

NEED VERB – currently listed as "made available" as part of the store action

2.5 Referenced Profiles - Antecedents

Figure 2-2 illustrates the relationship between the EHR-S FM, the Lab-FP and this guide.
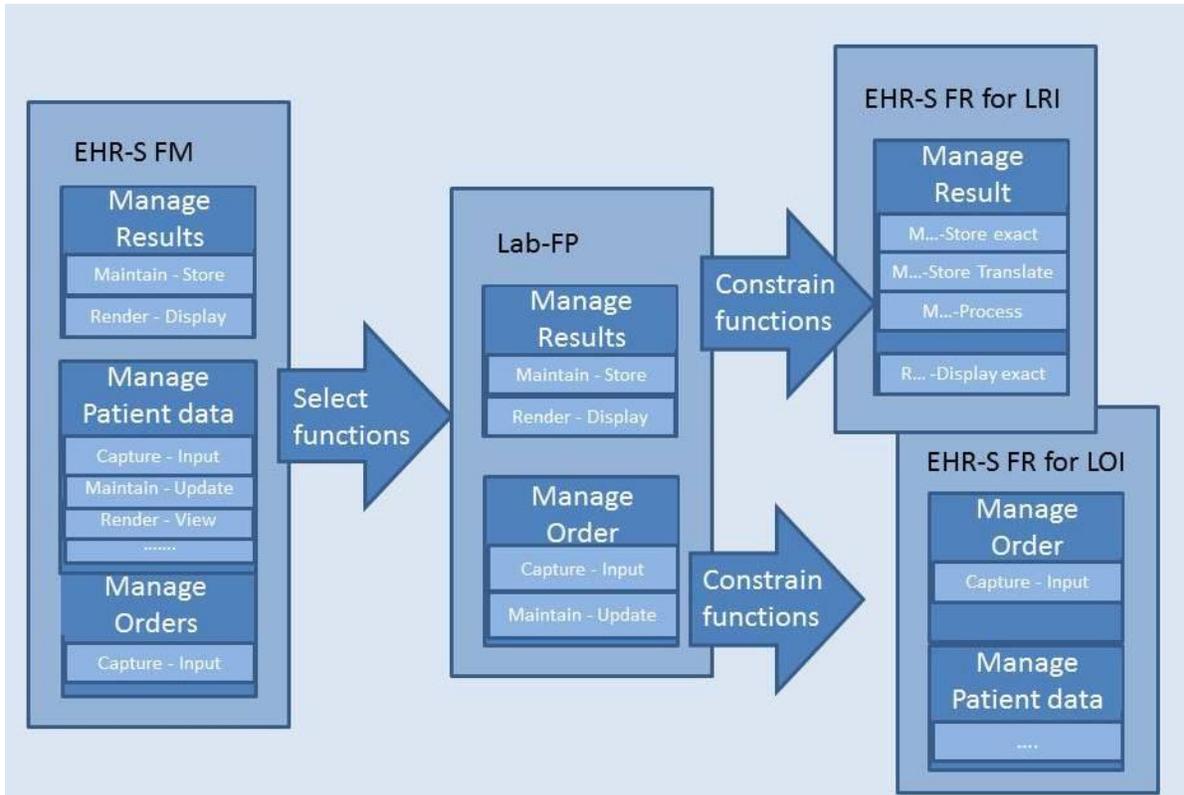
Figure 2-2. Relationship between the EHR-S FM, the Lab-FP and this guide

3 FUNCTIONAL AND BEHAVIORAL REQUIREMENTS

3.1.1 INCORPORATE AND DISPLAY LABORATORY RESULTS

The Incorporate and Display Laboratory Results functional requirements specify in what ways laboratory results data may be shown to be (1) imported, attributed, associated, or stored such that the data are subsequently available for use and (2) displayed such that the laboratory results can be appropriately interpreted by clinicians for making clinical decisions. The requirements describe in this guide are based on US realm specific regulation like Clinical Laboratory Improvement Amendments (CLIA), related guidance documents at the federal and state level as well as clinical best practice based on rules from several national laboratory oversight agencies.

3.1.2 INCORPORATION PROCESS

The Laboratory Results Interface (LRI) Implementation Guide is created to assist EHR technology vendors with developing systems capable of meeting standard interoperability requirements to facilitate the sharing (sending and receiving) of laboratory results data with providers at points of service across the continuum. The data elements required to be supported for lab results messages are specified in the LRI Implementation Guide. As shown in Figure 3-1. Processing of LRI Message with Incorporation and Display of Data Elements, incorporation of data elements received in a laboratory results message via an interface is a part of the processing performed by the receiver of the message. Once processed and incorporated, a set of related data elements that constitutes the laboratory report is subject to display and other uses.

3.1.3 CONFORMANCE DEFINITIONS FOR INCORPORATE: STORE AND USE

Various definitions of "incorporate" are used to convey the meaning of and objectives for this action in the context of EHR technology. Two of these definitions from the Edition 2014 certification criterion published by the Office of the National Coordinator for Health Information Technology (ONC)[2] are provided below as examples:

1) "'Incorporate' is used to mean to electronically import, attribute, associate, or link information in EHR technology."

2) "…to electronically process structured information from another source such that it is combined (in structured form) with information maintained by EHR technology and is subsequently available for use within the EHR technology by a user."

---

[2] From Section A.3. "Explanation and Revision of Terms Used in Certification Criteria", Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule (September 4, 2012)
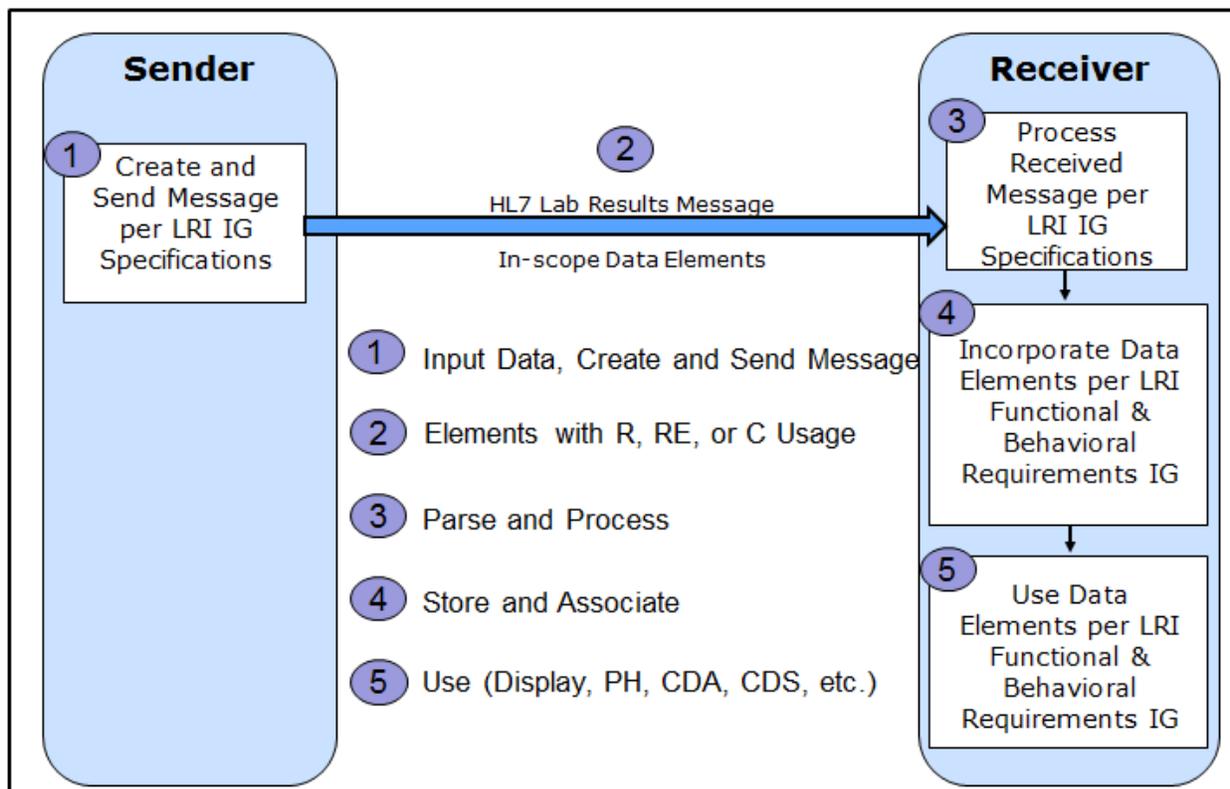
Figure 3-1. Processing of LRI Message with Incorporation and Display of Data Elements

To clarify for EHR technology vendors the precise expectations for incorporation of data elements sent with a lab results message, each of the laboratory message data elements designated in the LRI Implementation Guide as "R" (Required), "RE" (Required, but may be empty), and "C" (Conditional)[3] (these data elements hereafter are referred as "in-scope") has been analyzed by subject matter experts (SMEs) to determine how their incorporation best serves the needs of clinical users of the EHR technology in providing safe patient care. These data elements have been assigned a conformance level that indicates the degree in which they must be incorporated. Additionally, certain data elements have been identified and assigned a conformance level that indicates the degree in which they must be displayed.

3.2 Scope

The scope of this guide is the receipt, incorporation and presentation of laboratory test results by an EHR-system from a laboratory in a structured electronic format based on the LRI transaction specification.

In Scope

1. Defining the functional requirements for incorporation and presentation of core data elements required for clinical laboratory test results within the environment of the EHR-S.

---

[3] Provided one of the conditional usages is an R or RE

2. Clinical laboratory test results in the US Realm.

3. Test results for an order that was placed either manually or electronically.

4. Use of order specific data included in the result transaction to enable the receiving EHR-S to associate the test results with the originating order and related patient.

5. All CLIA reporting requirements and clinical best practice.

6. Receipt, incorporation and presentation of laboratory results by both the order placer and non-order placer's EHR-S.

7. Incorporating clinical laboratory test results as standardized structured (or unstructured, if received as part of the LRI transaction, e.g. pdf document, images) data into an EHR-S.

8. Supporting Stage 2 certification criteria and Meaningful Use (MU) requirements for the *HL7 VERSION 2.5.1 IMPLEMENTATION GUIDE: S&I FRAMEWORK LAB RESULTS INTERFACE, RELEASE 1, US REALM* by developing requirements for the incorporation of clinical laboratory test results into an EHR-S when data is sent as standardized structured data.

9. Intra- and inter-organizational exchanges of laboratory test results between clinical laboratories and EHR-Ss.

10. Where an LIS is the sender of laboratory test results and an EHR is the receiver of results.

Out of Scope

1. Specifications and implementation guidance for EHR-S functional requirements related to laboratory ordering transactions. However, the establishment of requirements for the incorporation of laboratory results that will allow the matching of the reported test result to an existing order initiated from the ordering clinician's EHR-S is within the scope of this effort.

2. Secondary use of laboratory data (i.e., public health or bio surveillance uses of the reported laboratory results, use in clinical decision support, report to patient electronic health record systems, etc.) shall be deferred to a future version of this IG. General requirements for secondary uses are considered in scope.

3. Results received not using the LRI specification.

4. Requirements from accrediting bodies (e.g., Joint Commission) that are beyond laboratory accreditation requirements.

3.3 Pre-Conditions

1. An order has been generated manually or electronically by an Ordering Provider for one or more laboratory test results to be produced.

2. When indicated, the Laboratory receives a request to send laboratory results to one or more non-order placer(s).

3. The Laboratory receives an order (manual or electronic) or the Laboratory receives a request to re-run (repeat) a test, or determines a need to re-run a test for possible correction, or determines that reflex testing (which is based on criteria set by the medical review board) is required or determines the need to amend a test result based on erroneous information.

4. The laboratory enters manually, or received through an electronic interface, the appropriate patient and ordering provider information as required by CLIA or the performing laboratory

including the information required to associate the laboratory results to the correct patient and original order.

5. The Laboratory receives the appropriate clinical information as required by CLIA or the performing laboratory for the ordered test.

6. Laboratory has entered manually, or received through an electronic interface, pertinent (or corrected) data for a laboratory test order into the LIS.

7. Laboratory has received and processed properly identified specimen(s) related to the ordered test(s).

8. Laboratory entered manually, or received through an electronic interface, pertinent data about the specimen(s) into the LIS.

9. Laboratory performed the ordered test(s) on received specimen(s) and/or incorporated calculated and reference data to produce the result(s) to be returned to the ordering provider and requested non-order placer(s).

10. The laboratory result message contains both the appropriate patient and provider information and the originating order information to associate the laboratory results to the correct patient and original order.

11. The LIS is capable of and ready to send laboratory results electronically and in standardized format using LRI specification.

12. EHR-S is in place and capable of receiving laboratory results electronically and in standardized format using LRI specification.

13. The laboratory result(s) is/are verified and ready for release.

14. The laboratory result(s) is/are released for reporting.

15. The laboratory transmitted the result message to the appropriate EHR-Ss using LRI specification.

16. The EHR-S received the result and verified that the message is intact and conformant with the LRI specification.

17. The EHR-S has replied to the laboratory with any response messages (including error responses) required prior to incorporation.

3.4 Post-Conditions

1. Laboratory results are made available to the authorized provider and any provider using the laboratory results in a timely, accurate, reliable manner, consistent with CLIA requirements and clinical best practice.

2. Laboratory test result information is correctly associated with the appropriate order, patient, and provider when the information to do so exists in the EHR-S and the received test result information.

3. All EHR-S functions related to the receipt, incorporation and presentation of clinical laboratory test results are capable of conformance testing and certification, if required.

4. Information required for auditing the receipt, incorporation and presentation of clinical laboratory result information is available.

3.5 Use Case Assumptions

1. Providers securely access clinical information through an EHR-S.

2. Appropriate security and transport protocols; time synchronization; patient identification methodology; order identification methodology and optionally requisition identification methodology; consent; privacy and security procedures; coding, vocabulary and normalization standards have been agreed to by all relevant participants.

3. This Use Case only addresses the receipt, incorporation and presentation of clinical laboratory test results that are considered In Scope.

4. All relevant parties have agreed on a structured laboratory test results message format based on LRI specifications.

5. This Use Case covers CLIA regulations and guidance in effect at time of publication of this IG as well as clinical best practice.

6. Legal and governance issues regarding data access authorizations, data ownership, and data use are in effect.

    a. Established network and policy infrastructure to enable consistent, appropriate, and accurate information exchange across provider systems, data repositories and locator services. This includes, but is not limited to:

        i. Methods to identify and authenticate users;

        ii. Methods to identify and determine Providers of care;

        iii. Methods to enforce data access authorization policies;

        iv. Methods to ensure the veracity of data;

    b. Detailed audit trails are kept as necessary by all participating systems.

7. Security and privacy policies, procedures and practices are commonly implemented to support acceptable levels of patient privacy and security; i.e. HIPAA, HITECH and EHR certification criteria.

8. The transport mechanism will provide guaranteed delivery and error handling.

9. This Use Case acknowledges the variations in requirements for reporting across local, state, tribal, and territorial boundaries as well as voluntary versus mandatory requirements.

10. Laboratories meet accreditation criteria according to jurisdiction requirements or agency criteria.

11. For the purposes of the user stories, all legal result types are included

12. All messages are sent in snapshot mode as defined in the LRI IG

3.6 Receiving Results Use Case and Context Diagram

---- begin citation ----

"A laboratory is defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health."[4].

---- end citation -----

In this Use Case, the Laboratory provides results based on a request for laboratory services from an authorized Provider. It is assumed that the receiving system is an EHR-S that can receive lab results even if it is not aware of the request (order), as there is no assumption that the receiving EHR-S provided the request for lab services. Figure 3-2. Context Diagram depicts the context of the data transaction.

The following are variations under this use case:

1) Results received - first report for an ordered test (ORC/OBR pair)

   a. Includes all possible initial reports (partial, preliminary, final)

   b. Results received that were forwarded from a reference lab

   c. Results of specific types (quantitative, qualitative, documents)

   d. Results from specific lab domains (Chemistry, Micro, Anatomic Pathology)

2) Results received – update to the initial report

   a. Includes all possible updates (preliminary to final, partial to final, final to corrected, preliminary to corrected, corrected to corrected)

   b. Demographic updates

      i. Includes all possible changes affecting the result, abnormal flag or reference range

      ii. Includes all possible changes not affecting result, abnormal flag or reference range

   c. Specimen updates

3) Results received – duplicate report

   a. Includes all possible situations where the report was retransmitted

   b. Includes retransmission of a transaction to manage error conditions with a prior transmission

4) Results received – exception (error) handling

   a. Includes all situations in report updates, where the report date/time is prior to the most recently received report date/time

---

[4] Derived from the CLIA definition (https://www.cms.gov/CLIA/07_Program_Descriptions_Projects.asp - TopOfPage). Future Use Cases may require expansion to include non-human subjects.

b. Includes all possible situations, where the message cannot be consumed (Hard error)

c. Includes all possible situations, where a message can be consumed, but errors have occurred
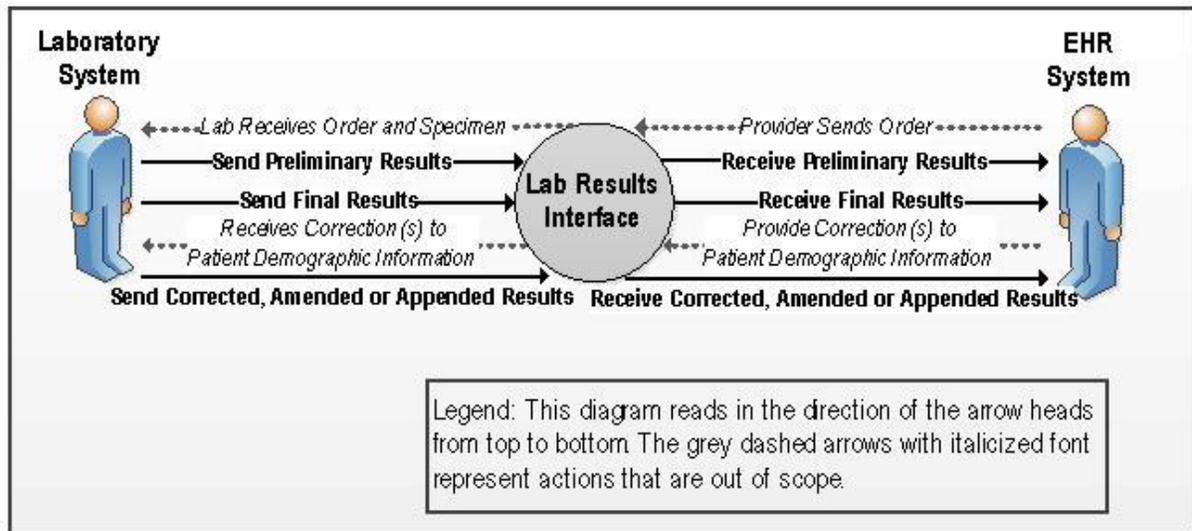
Figure 3-2. Context Diagram for Incorporating Results

3.7 Transactions related to Cancellations Use Case

In this Use Case, either the Provider or the Laboratory decides that a previously ordered test needs to be canceled. This use case describes the variations under this scenario, where LRI messages may be used for communication.

The following are variations under this use case:

1) Cancellation by the laboratory

   a. Included when reported via LRI

2) Cancellation by the provider is EXCLUDED, as LRI is not an allowed mechanism

3) Responses to provider cancelations

   a. The most common EXCLUDED,

   b. Included when reported via LRI

3.8 User Stories

3.8.1 USER STORY FOR RESULTS RECEIVED - GENERAL

A Provider *(order placer)* enters a laboratory order into an EHR-S. A laboratory requisition is generated (paper or electronic) and is communicated to the laboratory. The information in the laboratory requisition is entered manually, or received through an electronic interface, into the LIS. After the specimen(s) is(are) collected and, if necessary, shipped or delivered to the laboratory, the laboratory processes the specimen(s). If the specimen(s) is satisfactory for testing the laboratory performs the test(s). If testing is successful, and results are obtained they are entered in the LIS. An authorized person at the laboratory or the certifying laboratory reviewer of record, in the case of an auto-verification

process, reviews, approves and releases the laboratory test result(s) to send to the ordering provider as well as any provider identified as needing to be copied (copy-to provider).

The following specific requirements apply for the EHR-S of the ordering provider as well as the copy-to provider, except where marked ** to indicate not applicable for copy to providers.

The general EHR-S Requirements for all user stories about receiving results are:

1) Log the results transaction

2) Associate the results with the correct

   a. Order**;

   b. Patient (name and ID or 2 IDs);

   c. Physician (Ordering** and/or Copy-to);

   d. Performing laboratory (name and address).

3) Examine if the Results Report/ Status Change Date/Time (OBR-22) in the current transaction is later than the stored value for the respective ordered test, if it exists.

4) Incorporate the individual observations (OBXs) into the patient record with information that clearly indicates the following (required, but not limited to):

   a. The observation information:

      i. the performed test (OBX-3);

      ii. the result value (OBX-5) and its units (OBX-6), if provided;

      iii. the reference range (OBX-7), if provided;

      iv. the abnormal flag or interpretation (OBX-8), if provided;

      v. The date/time of each observation (OBX-19);

   b. The status of each observation as indicated by Observation Result Status (OBX-11);

   c. Any comments sent in Notes and Comments segment(s) (NTE) immediately following the Observation segment (OBX), if provided.

5) Record information about the specimen:

   a. the Specimen Collection Date and Time (SPM-17);

   b. the Specimen Condition (SPM-24), if provided;

   c. the Specimen Type (SPM-4), if appropriate;

6) Integrate or update the ordered test information with:

   a. the Results Report/ Status Change Date/Time (OBR-22);

   b. the Results Status (OBR-25) summarized at the order level;

   c. Any comments sent in Notes and Comments segment(s) (NTE) immediately following the order (OBR), if provided;

7) If the Order Status (ORC-5) is reported as complete:

   a. the EHR-S clearly indicates that the order is complete.

8) If the Order Status (ORC-5) is reported as not complete;

    a. the EHR-S clearly indicates that the order is incomplete.

3.8.2 USER STORY FOR INITIAL RESULTS RECEIVED

Pre-requisites:

1) General user story

The results are sent from the laboratory LIS *(results sender)* to the provider EHR-S *(results receiver)*. The EHR-S incorporates the results into the patient's electronic record, including information about the status of the order and each of the results for this order. The provider logs into his/her EHR-S and views the laboratory results in order to inform patient care decisions.

This is the first time results are received on a specific ordered test (as defined by an ORC/OBR pair) and the message has the following characteristics:

1) There is no previous order report date/time (OBR-22) in the EHR-S

2) The order level Result Status (OBR-25) may be any valid value from LRI constrained Table HL7 0123 (V2.5.1) except for:

    a. Corrected (C), which is considered an error for an initial report.

3) The Observation Result Status (OBX-11) may be any valid value from the Table HL7 0085 (V2.8) except for:

    a. Corrected (C), Amended (A), Appended (B), Post Original as Wrong (W), which are considered an error for an initial report.

4) The Order Status (ORC-5) may be any valid value from the constrained LRI Table HL70038 (v2.5.1) except for:

    a. In process, unspecified (IP), as that indicates no results available and Order was canceled (CA), which are considered an error for an initial report.

There are NO exceptions to the general EHR-S Requirements for all user stories about receiving results as described in Section 3.8.1 User Story for Results received - General.

3.8.3 USER STORY FOR UPDATED RESULTS RECEIVED

Pre-requisites

1) General user story

2) Initial Results Received user story.

An updated report is sent from the laboratory LIS *(results sender)* to the provider EHR-S *(results receiver).* The EHR-S incorporates the results into the patient's electronic record, including information about the status of the order and each of the results for this order. The provider logs into his/her EHR-S and views the updated laboratory results in order to inform patient care decisions. Differences to the general EHR-S Requirements for all user stories about receiving results as described in Section 3.8.1 User Story for Results received - General:

1) In addition to all requirements listed in Section 3.8.1 User Story for Results received - General the following applies:

a. Only the latest information shall be used for display.

b. Existing Order and Observation information must be retained as a prior version of the laboratory report.

There are several reasons for an update:

1) The laboratory had to revise a previously sent result, for example after discovering a calibration error in the instrument.

2) Additional preliminary results are available, so the previously sent preliminary report is being updated.

3) After a preliminary report has been sent, the laboratory finalizes the result and sends a final report.

4) The laboratory finalizes all results under a panel, so that a previously reported partial report can be replaced with a final.

This is an updated report and the message has the following characteristics:

a. The Order Report Date/Time (OBR-22) is greater than the date/time from the previously received transaction, currently stored in the EHR-S, for the same ORC/OBR

b. The order level Result Status (OBR-25) may be any valid value from LRI constrained Table HL7 0123 (V2.5.1) except for:

   i. In Progress (I), which is considered an error for an updated report.

b. The Observation Result Status (OBX-11) may be any valid value from the Table HL7 0085 (V2.8) except for:

   i. Post Original as Wrong (W), which are considered an error for an updated report.

c. The Order Status (ORC-5) may be any valid value from the constrained LRI Table HL70038 (v2.5.1) except for:

   i. In process, unspecified (IP), as that indicates no results available and Order was canceled (CA), which are considered an error for an updated report.

3.8.4 USER STORY FOR PATIENT DEMOGRAPHIC CHANGES

Pre-requisites

1) General user story

2) Initial Results Received user story.

The ordering provider reviews the result(s) received and they don't correspond to the clinical presentation of the patient, so he reviews the patient demographic information and finds an error in the DOB of the patient. The provider notifies the laboratory to correct the patient's DOB, which triggers a re-evaluation of the result interpretation.

3.8.4.1 AFFECTING THE RESULT OR RELATED FIELDS LIKE REFERENCE RANGE AND ABNORMAL FLAG

An authorized person at the laboratory or the certifying laboratory reviewer of record, in the case of an auto-verification process, reviews the results and applies new age based reference ranges to the result,

which triggers a change in the interpretation, enters a comment describing the reason for the change and then approves and releases the laboratory test result(s) with an updated status to send to the ordering provider.

This is a corrected report and the message has the following characteristics:

1) The Order Report Date/Time (OBR-22) is greater than the date/time from the previously received transaction, currently stored in the EHR-S, for the same ORC/OBR

2) The order level Result Status (OBR-25) must be Corrected (C). Any other valid value from LRI constrained Table HL7 0123 (V2.5.1) is considered an error for the corrected report.

3) The Observation Result Status (OBX-11) of at least one Observation under that ordered test MUST be Amended (A) and may be any valid value from the Table HL7 0085 (V2.8) except for:

   a. Post Original as Wrong (W), which are considered an error for the corrected report.

4) The Order Status (ORC-5) may be any valid value from the constrained LRI Table HL70038 (v2.5.1) except for:

   a. In process, unspecified (IP), as that indicates no results available and Order was canceled (CA), which are considered an error for the corrected report.

There are no differences to the EHR-S Requirements for updated results as described in Section 3.8.3 User Story for Updated Results Received.

3.8.4.2   NOT AFFECTING THE RESULT OR RELATED FIELDS LIKE REFERENCE RANGE AND ABNORMAL FLAG

An authorized person at the laboratory or the certifying laboratory reviewer of record, in the case of an auto-verification process, reviews the results, but the reference range for this test is not age based, so no changes to the result and related fields are needed. The person approves and re-releases the laboratory test result(s) to send to the ordering provider.

This is an updated report and the message has the following characteristics:

1) The Order Report Date/Time (OBR-22) is greater than the date/time from the previously received transaction, currently stored in the EHR-S, for the same ORC/OBR

2) The order level Result Status (OBR-25) must be Corrected (C). Any other valid value from LRI constrained Table HL7 0123 (V2.51) is considered an error for the corrected report.

3) The Observation Result Status (OBX-11) of at least one Observation under that ordered test MUST be Appended (B) and may be any valid value from the Table HL7 0085 (V2.8) except for:

   a. Post Original as Wrong (W), which are considered an error for the corrected report.

4) The Order Status (ORC-5) may be any valid value from the constrained LRI Table HL70038 (v2.5.1) except for:

   a. In process, unspecified (IP), as that indicates no results available and Order was canceled (CA), which are considered an error for the corrected report.

There are no differences to the EHR-S Requirements for updated results as described in Section 3.8.3 User Story for Updated Results Received.

3.8.5 USER STORY FOR SPECIMEN CONDITION CHANGES

Pre-requisites

2) General user story

3) Initial Results Received user story.

After the report has been sent, the testing personnel realize the specimen condition was not appropriate for the test and could have interfered with testing. Following standard operating procedure, an aliquot of the specimen was re-run under conditions to offset the interference and new results are obtained. A comment was entered about the specimen condition of the original result report and the corrective measures taken for the re-testing. An authorized person at the laboratory or the certifying laboratory reviewer of record, in the case of an auto-verification process, reviews, approves and releases the laboratory test result(s) to send to the ordering provider.

This is an updated report and the message has the following characteristics:

1) The Order Report Date/Time (OBR-22) is greater than the date/time from the previously received transaction, currently stored in the EHR-S, for the same ORC/OBR

2) The order level Result Status (OBR-25) must be Corrected (C). Any other valid value from LRI constrained Table HL7 0123 (V2.5.1) is considered an error for the corrected report.

3) The Observation Result Status (OBX-11) of at least one Observation under that ordered test MUST be Corrected (C). and may be any valid value from the Table HL7 0085 (V2.8) except for:

   a. Post Original as Wrong (W), which are considered an error for the corrected report.

4) The Order Status (ORC-5) may be any valid value from the constrained LRI Table HL70038 (v2.5.1) except for:

   a. In process, unspecified (IP), as that indicates no results available and Order was canceled (CA), which are considered an error for the corrected report.

There are no differences to the EHR-S Requirements for updated results as described in Section 3.8.3 User Story for Updated Results Received.

3.8.6 USER STORY FOR WRONG PATIENT

Pre-requisites

1) General user story

2) Initial Results Received user story.

After the report is finalized, the testing personnel is informed, that the patient information on the tested specimen was incorrect. The result reported does not belong to the patient for whom it was reported. The laboratorian subsequently cancels the wrongly ordered test in their system and releases the updated report.

The important part here is that the results no longer show up on the patient's record, but they need to be accessible, if searched, for, because they may have been used in care decisions, so they cannot be deleted from the underlying data base.

This is an updated report and the message has the following characteristics:

1) The Order Report Date/Time (OBR-22) is greater than the date/time from the previously received transaction, currently stored in the EHR-S, for the same ORC/OBR

2) The order level Result Status (OBR-25) used for this use case still needs to be determined.

3) The Observation Result Status (OBX-11) of all Observations under that ordered test MUST be Post Original as Wrong (W). Any other valid value from LRI constrained Table HL7 0085 (V2.8) is considered an error.

4) The Order Status (ORC-5) MUST be Order was canceled (CA). Any other valid value from LRI constrained Table HL70038 (v2.5.1) is considered an error.

Differences to the EHR-S Requirements for updated results as described in Section 3.8.3 User Story for Updated Results Received:

As a variation to the additional requirements listed in Section 3.8.3 User Story for Updated Results Received the following applies:

1) In this scenario no results will be displayed.

2) At the order level there needs to be an indication that this order was on the wrong patient

3) Existing Order and Observation information must be retained as a prior version of the laboratory report, but must be clearly marked as reported in error

3.8.7 USER STORY FOR DUPLICATE RESULTS RECEIVED

Pre-requisites

1) General user story

2) Initial Results Received user story.

The following conditions could contribute to the duplicate report scenario:

1) All ordered test are retransmitted by the LIS until the entire "requisition is complete"

2) Retransmission of a number of transaction by an intermediary system (e.g. gateway)

3) Retransmission of one or more transactions by the LIS

4) Requested retransmission of a transaction by the provider to solve an incorporation error on the EHR-S side.

This is an updated report and the message has the following characteristics:

(1) The Order Report Date/Time (OBR-22) is equal to the date/time from the previously received transaction, currently stored in the EHR-S, for the same ORC/OBR

(2) The order level Result Status (OBR-25) may be any valid value from LRI constrained Table HL7 0123 (V2.5.1).

(3) The Observation Result Status (OBX-11) of Observations under that ordered test may be any valid value from the Table HL7 0085 (V2.8).

(4) The Order Status (ORC-5) may be any valid value from the constrained LRI Table HL70038 (v2.5.1).

Differences to the EHR-S Requirements for updated results as described in Section 3.8.3 User Story for Updated Results Received:

1) For conditions (1) to (3) above, the newly received transaction for the ORC/OBR, where OBR-22 is the same, should be logged for audit purposes and ignored

2) For condition (4) it should be treated as an update

    a. To do this, the EHR-S should not save the OBR-22 date/time unless it has completely and successfully incorporated the entire set of observations associated with an ORC/OBR.

3.8.8 USER STORY FOR RESULTS RECEIVED IN INCORRECT CHRONOLOGICAL ORDER

Pre-requisites

1) General user story

2) Initial Results Received user story.

In this user story, results are received from the laboratory for an ordered test with an Order Report Date/Time (OBR-22) that is less than the previously received LRI transaction for the same ORC/OBR.

This is an error and should never occur if the LIS-EHR interface is functioning properly. Since all ordered tests are reported in snapshot mode, the more recent transaction (as identified by OBR-22) will have all of the observations for the specific ORC/OBR and this transaction should be considered an error.

The error may be caused by:

1) Transactions delivered out of order by intermediary systems (e.g. gateways)

2) Incorrect transaction resent by the LIS

Differences to the EHR-S Requirements for updated results as described in Section 3.8.3 User Story for Updated Results Received:

1) Log the results transaction for audit purposes

2) The EHR-S must not replace/update any observations with the "new" results

3) The EHR-S must not replace/update any order information

4) Clearly indicate in an appropriate error log that results were received with a date/time prior to the current results for the same ordered test

3.8.9 USER STORY FOR CANCEL LAB TEST - PROVIDER

Modified general user story as follows:

A Provider (order placer) enters a laboratory order into an ambulatory EHR-S. A laboratory requisition is generated (paper or electronic) and is communicated to the laboratory. The information in the laboratory requisition is entered manually, or received through an electronic interface, into the LIS. After the specimen(s) is (are) collected and, if necessary, shipped or delivered to the laboratory, the laboratory processes the specimen(s). The provider decided the test was ordered in error and sends a cancelation request to the laboratory (electronic, verbal (or paper)).

3.8.9.1   CANCELATION SUCCESSFUL

The laboratory has not yet begun testing on the specimen and can accommodate the cancelation request. The laboratory's LIS *(results sender)* transmits the order cancelation notification message to the ordering provider. The EHR-S incorporates the order cancelation into the patient's electronic record, including information about the status of the results for the order and the reason for order cancelation. The provider logs into his/her EHR-S and views the appropriate information related to this canceled laboratory order.

In this scenario, no result message (LRI) is produced, but instead the response will be an OML message, which is described in Section 4.3 of the LOI guide.

3.8.9.2   CANCELATION NOT SUCCESSFUL

The laboratory performs or attempts to perform the test(s). If testing is successful, and final results are obtained they are entered in the LIS. An authorized person at the laboratory or the certifying laboratory reviewer of record, in the case of an auto-verification process, reviews, approves and releases the laboratory test result(s) to send to the ordering provider.

The laboratory's LIS *(results sender)* transmits the results to the provider's EHR-S *(results receiver).* The EHR-S incorporates the results into the patient's electronic record, including information about the status of the results for the order. The provider logs into his/her EHR-S and views the laboratory results in order to inform patient care decisions.

This scenario describes the use of the ORL message as described in Section 4.4 in the LOI guide.

However, since the testing has been completed and results have been obtained, that part of this scenario follows the expectations as described in Section 3.8.1 User Story for Results received - General.

3.8.10 USER STORY FOR CANCEL LAB TEST - LABORATORY

Modified general user story as follows:

A Provider (order placer) enters a laboratory order into an ambulatory EHR-S. A laboratory requisition is generated (paper or electronic) and is communicated to the laboratory. The information in the laboratory requisition is entered manually, or received through an electronic interface, into the LIS. After the specimen(s) is (are) collected and, if necessary, shipped or delivered to the laboratory.

3.8.10.1   SPECIMEN REJECTION

The laboratory processes the specimen(s) and identifies a broken container, with leaked specimen, so there is not enough specimen available for testing and cancels the order. An authorized person at the laboratory or the certifying laboratory reviewer of record, in the case of an auto-verification process, reviews, approves and releases the laboratory test information about the rejected specimen to send to the ordering provider.

The laboratory's LIS *(results sender)* transmits the result message to the provider's EHR-S *(results receiver).* The EHR-S incorporates the specimen rejection information into the patient's electronic record, including information about the reason for cancelation and the subsequent result of the order. The provider logs into his/her EHR-S and tries to view the laboratory results in order to inform patient care decisions, but realizes he has no results, due to insufficient specimen.

In this scenario, an LRI message is expected. The LRI guide describes the two scenarios in Section 5.3.9.

1) For the preferred reporting scenario the message has the following characteristics:

   a. There is no previous order report date/time (OBR-22) in the EHR-S

   b. The order level Result Status (OBR-25) MUST be No results available; Order canceled (X). Any other value is considered an error for a cancelation.

   c. There will be Notes and Comments (NTE) segment(s) following that order (OBR), describing the reason for the cancelation.

   d. There will be NO OBX segments following this order.

   e. The Order Status (ORC-5) MUST be Order was canceled (CA). Any other value is considered an error for a cancelation.

Differences to the general EHR-S Requirements for all user stories about receiving results as described in Section 3.8.1 User Story for Results received - General are as follows:

1) Since No OBX segment(s) are following the OBR, no information will be available to incorporate any observation information.

2) In addition to recording the information about the specimen as described in Section 3.8.1 User Story for Results received - General:

   a. the Specimen Reject Reason (SPM-21) must also be recorded and displayed with the order.

3) The Order Status (ORC-5) of Order was canceled (CA) must be clearly indicated.

4) For the alternate reporting scenario, when Specimen reject reason is not communicated in the Specimen segment (SPM), the message has the following characteristics:

   a. There is no previous order report date/time (OBR-22) in the EHR-S

   b. The order level Result Status (OBR-25) MUST be Final results (F). Any other value is considered an error for a rejected specimen reported this way

   c. The OBX segment following this order will

      i. in the Observation Value (OBX-5) either have a previously negotiated coded value or a string indicating that the test could not be performed

      ii. the Observation Result Status (OBX-11) MUST be Final result (F). Any other value is considered an error for a rejected specimen reported this way

   d. There will be Notes and Comments (NTE) segment(s) following this Observation (OBX), describing the reason for the specimen rejection

      i. The Order Status (ORC-5) MUST be Order was canceled (CA). Any other value is considered an error for a rejected specimen reported this way

Differences to the general EHR-S Requirements for all user stories about receiving results as described in Section 3.8.1 User Story for Results received - General are as follows:

1) The Order Status (ORC-5) of Order was canceled (CA) must be clearly indicated

3.8.11 OTHER REASON TO CANCEL

Pre-requisites:

Modified general user story as described in Section 3.8.10 User Story for Cancel Lab Test - Laboratory

The laboratory processes the specimen(s) and realizes the test(s) ordered cannot be completed, because the equipment is not properly functioning. The laboratory cancels the test(s). An authorized person at the laboratory or the certifying laboratory reviewer of record, in the case of an auto-verification process, reviews, approves and releases the laboratory cancelation to send to the ordering provider.

The laboratory's LIS *(results sender)* transmits the order cancelation notification message to the ordering provider. The EHR-S incorporates the order cancelation into the patient's electronic record, including information about the status of the results for the order and the reason for order cancelation. The provider logs into his/her EHR-S and views the appropriate information related to this canceled laboratory order.

This scenario describes the use of the ORL message as described in the LOI guide in Section 4.4

Or

Modified general user story as described in Section 3.8.10 User Story for Cancel Lab Test - Laboratory

The laboratory processes the specimen(s) and realizes the test(s) ordered cannot be completed, because the equipment is not properly functioning. The laboratory cancels the test(s). An authorized person at the laboratory or the certifying laboratory reviewer of record, in the case of an auto-verification process, reviews, approves and releases the laboratory cancelation to send to the ordering provider.

The laboratory's LIS *(results sender)* transmits the result message to the provider's EHR-S *(results receiver).* The EHR-S incorporates the specimen rejection information into the patient's electronic record, including information about the reason for cancelation and the subsequent result of the order. The provider logs into his/her EHR-S and tries to view the laboratory results in order to inform patient care decisions, but realizes he has no results, due to insufficient specimen.

In this scenario, an LRI message is expected. The LRI guide describes the two scenarios in Section 5.3.9.

1) For the preferred reporting scenario the message has the following characteristics:

   a. There is no previous order report date/time (OBR-22) in the EHR-S

   b. The order level Result Status (OBR-25) MUST be No results available; Order canceled (X). Any other value is considered an error for a cancelation

   c. There will be Notes and Comments (NTE) segment(s) following this order (OBR), describing the reason for the specimen rejection

   d. There will be NO OBX segments following this order

   e. The Order Status (ORC-5) MUST be Order was canceled (CA). Any other value is considered an error for a cancelation

Differences to the general EHR-S Requirements for all user stories about receiving results as described in Section 3.8.1 User Story for Results received - General are as follows:

1) Since No OBX segment(s) are following the OBR, no information will be available to incorporate any observation information.

2) The Order Status (ORC-5) of Order was canceled (CA) must be clearly indicated.

4 REQUIREMENTS FOR LABORATORY REPORT DATA INTEGRITY

The lab result message includes a set of related data that must be preserved in order to maintain the integrity of the laboratory testing. This section of the implementation guide lists these requirements, which go beyond the individual data element incorporation conformance requirements. These requirements define the Laboratory Reference Report (LRR) that is the required representation of an individual laboratory report. Note: other methods of displaying laboratory information are usually available in an EHR (summary report, flow sheet, graphs, etc.) these reports are considered, for the purpose of this guide, Connected Laboratory Displays (CLDs). The store actions requirements are the same for both the LRR and CLDs, but the display options may be quite different. Four key categories of laboratory information have been identified for review in this section: patient demographics, ordering provider, performing organization, and the actual laboratory results.

4.1 Requirements for the Laboratory Reference Report

4.1.1 PATIENT DEMOGRAPHICS

4.1.1.1 PATIENT IDENTIFIER

The Patient Identifier (ID#) (PID-3) from the HL7 lab result message is normally used for matching patient records in the EHR technology. The following guidelines are provided for use of the Patient ID#:

- For a match to occur between the LIS and the EHR-S based on the Patient Identifier, the ID# in the EHR and the ID# received in the LRI transaction SHALL be identical not "equivalent"

- The patient may have more than one ID# in the EHR. For example, an "Enterprise" ID# plus one or more local ID#s ; the local ID# would normally be used by a provider or provider office practice; the Enterprise ID# would be used across the system of which the provider or provider office practice was a part to uniquely identify the patient.

- If the patient ID# in the lab Test Report does not match the appropriate ID information in the EHR, then the Patient ID# from PID-3 SHALL be stored with the result in the EHR and a matching error SHALL occur if this is the ordering system and MAY occur if this is a COPY to system.

4.1.1.2 PATIENT NAME

The Patient Name received in the LRI transaction must be displayed on the LRR whether it matches the EHR Patient Name or not (assuming a match with PID-3 is determined). It is *critical* that the laboratory's Patient Name data be stored and displayed with the laboratory result in the EHR.

Example Scenario: Results are sent from LIS to EHR for a female under her maiden name; then, the next day she gets married and the EHR is updated with her new name. Yesterday the "current" patient name at that time was a perfect match, and the EHR must display the patient's name in the results report as transmitted.

Conformance Statements

LRI-EHR-S-FR-1: The Patient Name (PID-5) data element from the HL7 laboratory result message SHALL be stored with the lab result data and SHALL be displayed on the laboratory reference report in the receiving EHR technology.

4.1.1.3   PATIENT DATE OF BIRTH

The EHR-S must not modify the Patient Date of Birth data received in the LRI message.

The laboratorian uses the patient's "Date and Time of Birth" data provided with the order to establish the age range when interpreting results against age specific reference ranges.

When "Date and Time of Birth" data is not provided with the order, but an age is provided, it should be the age "at the time of the lab processing", i.e. at specimen collection.

Conformance Statements

LRI-EHR-S-FR-2: The Patient Date and Time of Birth (PID-7) data element from the HL7 lab result message SHALL be stored with the lab result data and SHALL be displayed on the lab reference report in the receiving EHR technology.

4.1.1.4   PATIENT GENDER

- The Patient Gender (PID-8) data element from the HL7 lab result message used only for administrative purposes. When the lab needs to use Gender data provided with the order for interpreting certain gender-specific results, and those should be communicated as part of the Ask at Order Entry Questions, not drawn from administrative gender (PID-8). If provided as Ask at Order Entry Question with the order, this data must be stored and displayed with the laboratory result data on the laboratory Test Report in the receiving EHR technology.

4.1.1.5   PATIENT RACE

Labs use very nuanced data for Patient Race and Ethnicity related to needs for specific laboratory tests – these will be solicited as Ask at Order Entry questions when they are required for proper interpretation of test results.

- Race and Ethnicity terms from the OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997 SHALL be used for lab results messaging in the LRI message:

- Race: Native Hawaiian or Other Pacific Islander, American Indian or Alaska, Asian, Black or African American, White

- Ethnicity: Hispanic or Latino, Not Hispanic or Latino

- Note: Other ethnicities may be required by the laboratory for use in processing special types of tests: Ashkenazi Jewish, Romani)

If provided as Ask at Order Entry Question with the order, this data must be stored and displayed with the laboratory result data on the laboratory Test Report in the receiving EHR technology.

The receiving EHR technology (e.g., ambulatory EHR) must not over-write its patient demographic data with the demographic data sent by the sending LIS. Demographic data provided in OBX segments are not necessarily the same as the demographic data provided in the PID segment; PID demographic data

are intended to be data given by the patient, whereas OBX demographic data likely are data given by the provider based on their examination of the patient.

Conformance Statements

>**LRI-EHR-S-FR-3:** Answers to Ask at Order Entry questions (AOEs) from the HL7 laboratory result message **SHALL** be stored with the laboratory result data and **SHALL** be displayed on the laboratory Test Report in the receiving EHR technology.

4.1.2 ORDERING PROVIDER

If a match occurs between the LIS and the EHR-S for the Ordering Provider, then the EHR-S can (but does not need to) store the Ordering Provider data sent by the LIS with the test result.

If no match occurs based on the ID Number (ID#) of a specific Ordering Provider, then the EHR-S must store the Ordering Provider Name (ORC-12.2.1, 12.3, 12.4, 12.5, 12.6/OBR-16.2.1, 16.3, 16.4, 16.5, 16.6), ID# (ORC-12.1/OBR-16.1) with Assigning Authority (ORC-12.9/OBR-16.9) with the test result for reference. The name of the ordering provider must be displayed on the LRR.

4.1.3 PERFORMING ORGANIZATION

If more than one Performing Organization is responsible for a result on the laboratory reference report, then the name and address information for each of the Performing Organizations must be stored and displayed along with, at a minimum, an indicator that is stored and displayed with each test result on the LRR that is capable of identifying the responsible Performing Organization directly or by reference.

4.1.4 LABORATORY RESULTS

Laboratory results consist of the following components:

Each order is identified in the EHR-S by a placer order number (ORC-2/OBR-2) and contains the ordered test (OBR-4), which may lead to one or more performed tests, and the status of all results under that order (OBR-25). From an HL7 message perspective, this is considered a report unit and requires the use of the report date (OBR-22). As described in Section 5.1 Determining Chronological Order the report date (OBR-22) is used to identify if the data in the HL7 message is an update to already existing information or not and is used to trigger the replacement of data whereas the status flags (ORC-5, OBR-25 and OBX-11) are only used to display the status of the report and the individual results.

For each performed test, the test identifier and name (OBX-3), the result (OBX-5), with units (OBX-6) where applicable, reference range(s) (OBX-7), abnormal flag(s) (OBX-8), result status (OBX-11) and any notes (NTE immediately following that OBX) related to the result must all be displayed in the LRR.

4.2 Requirements for Connected Laboratory Displays

Connected Laboratory Displays (CLDs) are displays in the EHR, other than the LRR, that have direct access to the EHR database. These CLD always reflect the status of the laboratory results at the time the display is generated and have the ability to interact directly with the EHR database in real-time (e.g. query for additional information).

Conformance Statements

>**LRI-EHR-S-FR-4:** All CLDs SHALL support the display actions as defined later in this guide.

>**LRI-EHR-S-FR-5:** All CLDs SHALL provide the ability to display the LRR corresponding to any visible (in the CLD) laboratory information with a single action

As an example, a flow sheet display of a single laboratory test results such as a White Blood Cell (WBC) count will allow access to the LRR from which the WBC is derived (e.g. CBC) with a single action (e.g. hyperlink).

5 REPORT AND RESULT STATUS AND SUCCESSION

5.1 Determining Chronological Order

EHR-S must be able to update lab results over time. The following rules apply, since per LRI guide OBR-22 must be updated by the laboratory with any change in the respective OBR segment or any associated segment under that OBR:

1. OBR-22 is solely used to determine report succession by the EHR

2. ORC-5, OBR-25 and OBX-11 are only used to display the status of the order and result respectively on the current version of the report in the EHR.

5.1.1 LAB_REQ_COMPONENT – ID: 2.16.840.1.113883.9.AA

When this component is declared, the lab will always send all orders and their respective results for the entire requisition, regardless if changes have been made in a specific order or result.

The previous OBR-22 value is

greater than the current OBR-22 associated with a previously received report, then the EHR **SHALL** replace the report with the new version

less than the current OBR-22 associated with a previously received report, then this is an error and **SHOULD** be evaluated as soon as possible to determine the cause.

equal to the current OBR-22 associated with a previously received report, then the EHR **SHOULD** ignore the received report and not update it in the system.

5.1.2 LAB_NONREQ_COMPONENT – ID: 2.16.840.1.113883.9.BB

When this component is declared, the lab will only send orders and their respective results for those where changes have been made in the OBR or its subsequent segments.

The previous OBR-22 value is:

greater than or equal to the current OBR-22 associated with a previously received report, then the EHR **SHALL** replace the report with the new version

less than the current OBR-22 associated with a previously received report, then this is an error and **SHOULD** be evaluated as soon as possible to determine the cause.

The EHR-S **SHALL** always display the most recent version of a laboratory order and its results.

The EHR-S shall use the result status codes to properly identify the CLIA required status of the report and the result(s) for the currently displayed report.

5.2 Handling of Status Codes

Status codes for results (OBXs), and Orders (ORC/OBRs) are highly constrained and SHALL only be created by the LIS and exchanged using the LRI IG according to the following restrictions on allowed code values for ORC-5, OBR-25 and OBX-11. The following table defines the allowed code values.

TABLE 4–1. ALLOWED STATUS CODE VALUES			
Element	Type of Value	Value	Definition
OBX–11			
	Typical	I	Specimen in lab, results pending
		P	Preliminary results
		F	Final results
		C	Record coming over is a correction and thus replaces a final result (aka Corrected)
	Alternative with result	A	Amended
		B	Appended
	Service not Delivered	N	Not Asked
		X	Results cannot be obtained for this observation
		D	Deletes the OBX record
	Wrong Patient	W	Post original as wrong
ORC–25			
	Typical	I	No results available, specimen received
		A	Some, but not all, results available (aka Partial)
		P	Preliminary: A verified early result is available; final results not yet obtained
		F	Final results
		C	Correction to results
	Service not Delivered	X	No results available; Order canceled
ORC–5			
	Limited to	IP	In Process, unspecified
		A	Some, but not all results available (aka Partial)
		CM	Order is completed
		CA	Order was canceled

5.2.1 ALLOWED OBX-11 TRANSITIONS

This is the status on one OBX, depending on changes being applied – when an OBX is sent unaltered in an update message the status remains the same.

Example: If an OBX has been reported with an OBX-11 status of P (Preliminary), then the next time it is reported with any changes, the allowed OBX-11 status may be I, P, F, D or W, but not C, A, B, N or X.

Legend for the following two tables:

Not Allowed
A=Allowed
R=Required

Note: [1] requires at least one of the OBXes under the order to be present, in order to affect the order level result status (OBR-25).

TABLE 4–2. ALLOWED OBX–11 TRANSITIONS										
From OBX–11 (existing result)		To OBX–11 (new result)								
		I	P	F	C	A	B	N	X	D	W
I	In Process	A	A	A				A	A	A	A
P	Preliminary		A	A						A	A
F	Final				A	A	A			A	A
C	Corrected				A	A	A			A	A
A	Amended				A	A	A			A	A
B	Appended				A	A	A			A	A
N	Not Asked									A	A
X	Not Possible									A	A
D	Delete									A	A
W	Wrong										A

5.2.2 ALLOWED STATUS CODES (OBR-25, OBX-11 AND ORC-5 COMPLETION) FOR ORDERS AND RESULTS

The table below should be read as follows:
1) OBX-11 status combination for all OBXs results in the OBR-25 status
2) The status of the order is indicated in ORC-5 status – not all OBX-11 / OBR-25 code combinations are allowed for all order statuses

Note to readers: Need to propose handling of OBX-11, OBR-25 and ORC-5 when the lab has determined, or been informed, that the results are for the wrong patient (e.g. mismatch in the patient demographics and the specimen source).

TABLE 4–3. ALLOWED OBX–11, OBR–25 AND ORC–5 VALUES IN SAME ORDER							
From OBX–11		OBR–25					
		I	A	P	F	C	X
I	In Process	R	A	A		A	A
P	Preliminary			R		A	

TABLE 4–3. ALLOWED OBX–11, OBR–25 AND ORC–5 VALUES IN SAME ORDER							
From OBX–11	**OBR–25**						
	I	A	P	F	C		X
F Final		A	A	R	A	A	
C Corrected					R1	R1	
A Amended					R1	R1	
B Appended					R1	R1	
N Not Asked		A	A	A	A	A	
X Not Possible		A	A	A	A	A	
D Delete					R1	R1	
W Wrong							
ORC–5							
IP In Process	R						
A Partial		R	R		R		
CM Completed				R		R	
CA Canceled							R

1) An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI where one or more OBX has the OBX-11 status F (final) and the other OBXs have a status that indicates either a preliminary result (OBX-11 = P) or does not have a result at this time (OBX-11 = I). None of the OBXs have an OBX-11 status that indicated a corrected (C), amended (A), appended (B), deleted (D) or wrong patient (W). The status for the order should be Partial (OBR-25 = A) and the ORC indicates partial completion (ORC-5 = A).

2) An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI where one or more OBX has been corrected, amended, appended or deleted (after reporting a result) [OBX-11 is C, A, B, or X]. At least one of the other OBXs has a status that indicates either a preliminary result (OBX-11 = P) or does not have a result at this time (OBX-11 = I). The status for the order should be Corrected (OBR-25 = C) and the ORC indicates partial completion (ORC-5 = A).

2) An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI where one or more OBX has been corrected, amended, appended or deleted (after reporting a result) [OBX-11 is C, A, B, or X]. **No** OBX has a status indicating either a preliminary result (OBX-11 = P) or does not have a result at this

time (OBX-11 = I). The status for the order should be Corrected (OBR-25 = C) and the ORC indicates completion (ORC-5 = CM).

Conformance Statements

Transition: a change in the current LRI element relative to the same LRI element in the immediately prior transaction for the same ORC and its related segments.

LRI-EHR-S-FR-6: ORC-5 transition from CM or CA to IP or A **SHALL** be a hard error.

LRI-EHR-S-FR-7: ORC-5 transition from CM or CA or A to IP **SHALL** be a hard error.

LRI-EHR-S-FR-8: ORC-5 transition from CM to CA **SHALL** be a hard error.

LRI-EHR-S-FR-9: ORB-25 transition from C to F or P or A or I **SHALL** be a hard error.

LRI-EHR-S-FR-10: ORB-25 transition from F to A or I **SHALL** be a hard error.

LRI-EHR-S-FR-11: ORB-25 transition from A to I **SHALL** be a hard error.

LRI-EHR-S-FR-12: OBX-11 transition from W to any other status **SHALL** be a hard error.

Note to readers: Need to complete the full list in publication version.

5.2.3 USER STORY MAPPING TO STATUS CODES

The following provides examples of user story use of specific combinations of the status codes in the OBX, OBR and ORC segments:

1) Initial Results Received – any valid combination in Table 3-3 except where the value of OBR-25 is "C".

2) Updated Results – any valid combination in Table 4-3. Allowed OBX-11, OBR-25 and ORC-5 values in same Order, except where OBR-25 is "I"

3) Corrected Results – only valid combinations in Table 4-3. Allowed OBX-11, OBR-25 and ORC-5 values in same Order, where OBR-25 is "C".

4) Patient Demographic changes resulting in result interpretation changes – only valid combination is where OBR-25 is "C" and the OBX-11 is "C" or "A".

5) Specimen Conditions that require cancellation of the order – only valid where the value of OBR-25 is "X".

6) Requirements for Wrong patient will have to be determined.

7) Duplicate Results – any valid combination in Table 4-3. Allowed OBX-11, OBR-25 and ORC-5 values in same Order

6 EHR ERROR RESPONSES

The EHR is required to be able to respond to an LRI transaction with one or more success or failure responses. In most cases, the EHR will provide two responses; the first in a System acknowledgement (MSA-1 = CR or CA) to indicated that it has received the LRI transaction from the previous sender (this may be a gateway or HIE) and the second is an application level response to indicate the success (MSA-1 = AA or AE) or failure (MSA-1 = AR) of the transaction to meet the standards for the LRI guide and application requirement specified in this guide. Soft errors (MSA-1 = AE) or hard errors (MSA-1 = AR) are communicate through the use of the appropriate ERR segment elements (ERR-3 and/or ERR-5) as defined in the LRI IG.
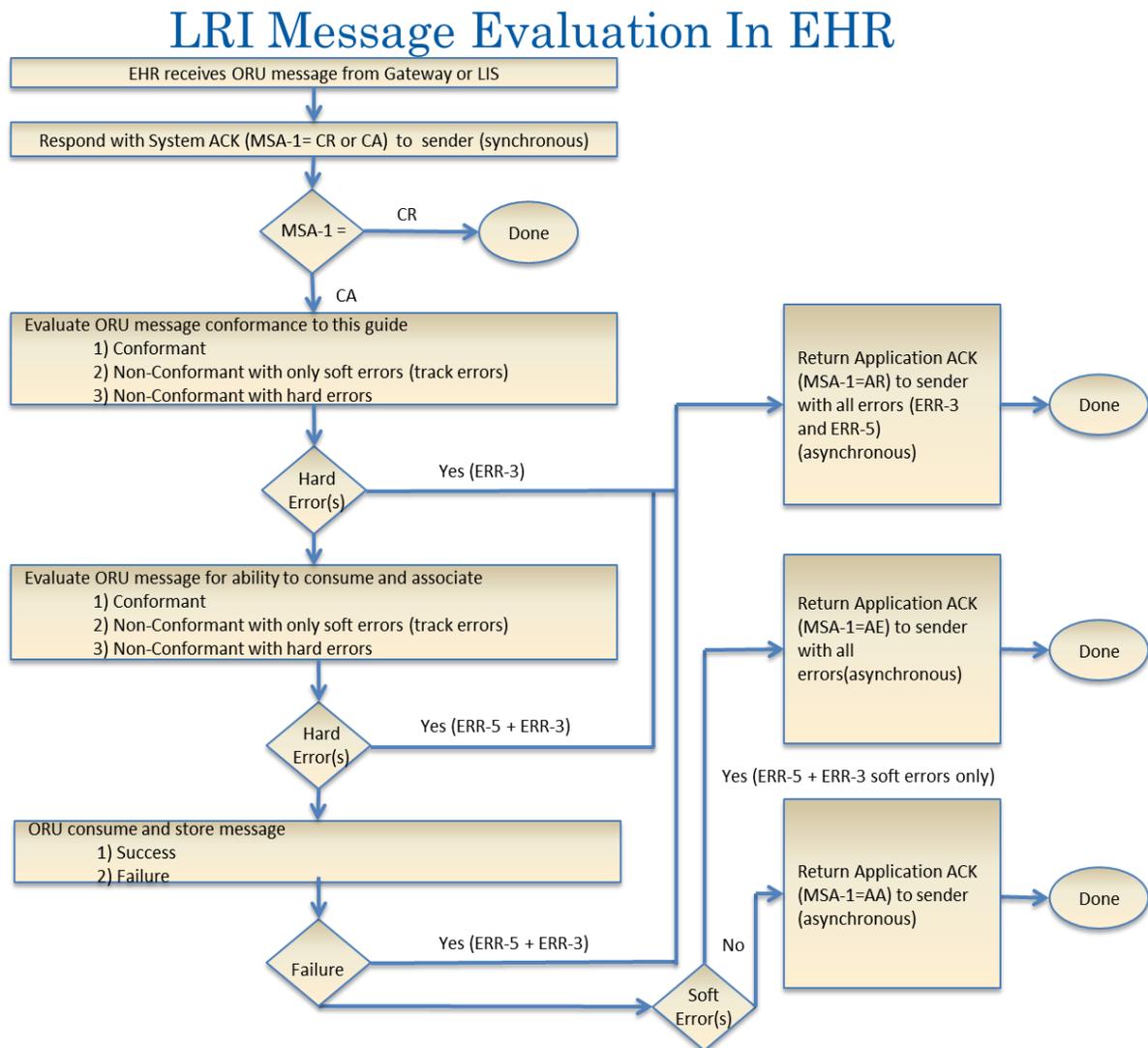

Figure 5-1. LRI Message Evaluation and Application Acknowledgement

6.1 Definitions

6.1.1 ERROR TYPE DEFINITIONS

System Error - These are errors in the structure or the message content that can be identified during validation against the guide profile. They can result in hard or soft errors.

Application Error – These are errors related to the message content that are not computable form the guide profile, but related to the receiving application's functionality. They can result in hard or soft errors.

6.1.2 ERROR SEVERITY DEFINITIONS

Hard Error – stop; suspend processing and notify sender, do not commit info to patient record

Soft Error – notify (as directed) but can continue to process message unless a hard error is encountered prior to end of message processing; may commit data to patient record while informing sender of soft errors.

6.1.3 CONDITIONS RESULTING IN A HARD ERROR AND REQUIRED EHR BEHAVIOR

For HL7 errors (reported in ERR-3) the following are defined as hard errors, which mean the message cannot be committed to the patient record:

- System level errors as defined by the base standard (MSH-9, MSH-11, MSH-12) – MSA-1 = AR or CR
- Message conformance errors that prohibit proper parsing – MSA-1 = CE if part of system level ACK, or AR if part of Application level ACK
- Missing or incorrect segments required by the LRI IG (usage is R)
- Missing or incorrect elements required by the LRI IG (usage is R)
- Missing or incorrect fields required by the LRI IG (usage is R)
- Missing data where usage is R
- Cardinality errors defined as hard errors in _____
- Field truncation for any CLIA required field or fields that are required for association
- Code values restricted by the applicable value set where usage is R

For application errors the following are defined as hard errors, which mean the message content cannot be committed to the patient record (ordering system only) :

- Order (ORC/OBR)
  - Placer Order Number – local decision on level of error
  - OBR–4 – service identifier – hard error for this pair in the event that it is not on the patient record, can continue with other pairs
  - Does not apply when specimen action code is 'G' for reflex testing

- Patient not found ordering provider system
- Ordering provider not found in ordering system (may be defined as soft error locally)
- Cannot store ALL OBX segments under one ORC/OBR-pair
- Cannot store ALL NTE segments under one OBX segment

6.1.4 CONDITIONS RESULTING IN A SOFT ERROR AND REQUIRED EHR BEHAVIOR

For HL7 errors the following are defined as soft errors, which mean that parts of the message do not comply fully with the guide, but the message can still be processed and stored – continue processing and report as soft error unless otherwise indicated below:

- Unexpected segments not required by the LRI IG
- Elements defined as optional in the LRI IG – ignore only
- Fields defined as optional in the LRI IG – ignore only
- Cardinality errors defined as soft errors in _____
- Field truncation for fields that are not required by CLIA or necessary for association of the results with an order/patient/provider
- Code values defined as optional or not found (if open) in the applicable value set

For application errors the following are defined as soft errors, which mean that the EHR shall process the message and store it associated with the appropriate patient:

- Need to define soft application error for publication version

Note to readers: Need to define soft and hard error for copy to receivers for publication version.

Note to readers: Need to define conformance statements for publication version.

7 UNDERSTANDING INCORPORATION REQUIREMENTS

Each in-scope data element is assigned a store and use conformance requirement drawn from Tables 4 (Incorporation) and 5 (Use Action). The incorporation and display requirements indicate what the EHR system must do with the data element. The *LRI_Functional_BehavioralRequirementsIG.xlsx* (see Section 7.4 Detailed Requirements for In-scope Data Elements) provides a list of all in-scope data elements and the associated incorporation and display bindings. The rules laid out in *LRI_Functional_BehavioralRequirementsIG.xlsx* implicitly provide an expansion of explicit requirement statements. For example, if the surname of a patient (PID-5.1.1) is assigned an incorporation requirement of "Store Exact" (S-EX), this requirement can be expanded as "The Patient Surname (PID-5.1.1) SHALL BE stored exactly as received and SHALL NOT be translated when stored".

Table 7-1. Requirements for Incorporation shows the formal levels of incorporation requirements, including the store action, implementation description, and impact on implementers.

This does not include the *LOG* functionality, i.e. saving information for the purpose of audit.

TABLE 7–1. REQUIREMENTS FOR INCORPORATION			
Requirement	Store Action	Implementation	Impact on Implementers
Store	S-EX – Store Exact	The implementation SHALL "store" exactly and SHALL NOT "translate".	EHR must be designed to store only exact data received in the message. Example: Result data in text form is stored unaltered (including typos, if those are sent).
Store	S-EX-A – Store exact by association	The implementation SHALL "store" the data by using a pointer to the local representation, ELSE use S-EX.	EHR must be designed to retain the exact data received in the message by associating it with the same local value OR may be designed to store exact data received. Example: Placer Order number is the key in an internal table and the lab results received are linked to that specific entry.
Store	S-EQ – Store equivalent	The implementation SHALL "transform" to equivalent value and "store" that equivalent value ELSE use S-EX.	EHR must be designed to reformat data received in the message, and store the reformatted form of the data OR may be designed to store exact data received OR may be designed to do both. Example: Any date received in the message can be stored in the internal date time format in use in the EHR-S.
Store	S-EX-TR – Store exactly; translation allowed, and if translated store translation	The implementation SHALL "store" exactly and MAY "translate" and if translated SHALL store translation.	EHR must be designed to store exact data received in the message, and may be designed to translate the data and store the translated version. Example: Observation Identifier for the performed test may be stored as sent as well as translated to a local code.

TABLE 7−1. REQUIREMENTS FOR INCORPORATION			
Requirement	Store Action	Implementation	Impact on Implementers
Store	S-TR-R – Translate and store translation (exact value can be re-created from translation any time)	The implementation SHALL implement one of the following: 1) "store" exact, or 2) "translate" and SHALL store translation, where a re-creation of the original exact data is possible, or 3) 1 and 2.	EHR may be designed to translate data received and store translated version (translated version must be able to be converted back to originally sent data) OR may be designed to store exact data received OR may be designed to do both. Example: Abnormal flag code sent in the message does not need to be stored exactly, but can be stored as its translated value only.
Store	S-RC – Process and re-create	The implementation SHALL have the capability to store the data element in an abstract manner and re-create the data from the system's data model (this option is allowed as long as the original data sent in the message can be re-created, if needed) ELSE use S-EX.	EHR may be designed EITHER to store the exact data received, OR to use the EHR's data model to store the data so the exact original data received can be abstracted and re-created if needed. Example: Identifier Type has a separate location to store a Social Security number vs an internal medical record number, then there is no need to retain the identifier type code.
Store Permitted	S-MA – Made Available	The implementation SHALL make the data element available for use to accomplish the stated tasks defined by the use case (e.g., incorporation of laboratory results). There is no requirement to store the element. Implementation of any store option is also allowed.	EHR shall be designed to provide the data such that the logical operation defined in the use case can be performed. There is no requirement to persist the data; however, the EHR may be designed to persist the data in whatever manner it desires (e.g., it may choose to store the data). Example: In order to relate a reflex test to the result that caused the reflex, OBR-29 (Parent) lists the placer and filler order number of the order that caused the parent result – this number already exists in the system, so it just needs to be used to relate the two tests, but does not need to be stored.,
Store Permitted	S-PR – Processed	The implementation can process or store the data element in accordance with their business rules; this guide places no requirements on these elements.	EHR may be designed in any manner the vendor chooses to process these data elements. Note: other functional specifications may include processing or storage requirements for these elements, but these are out-of-scope for this use case. Example: The value in the MSH-9 (Message Type) is needed to process the incoming message, but it need not be retained, nor linked to the patient result in any way.

Important: Since the incorporation requirements form a hierarchy, an implementer has the option of implementing to a higher incorporation requirement. For example, if a data element is assigned a

requirement of "S-TR = Translate and store translation OR store exactly OR both" the implementer may elect to implement a conformance level of "S-EX store exact" (i.e., store, directly). This approach would be considered conformant.

For all store conformance requirements the association with the correct patient record applies, even though not explicitly stated (i.e. "SHALL BE associated to the appropriate patient record"). The requirement levels differentiate the degree to which the data are processed or maintained, but incorporate always means to associate as intended.

7.1.1 UNDERSTANDING STORE EXACT INCORPORATION REQUIREMENT

Figure 6-1. Store Exact: S-EX illustrates the "Store Exact" incorporation requirement where data received in the message are stored unaltered in the EHR technology and are related to the appropriate patient record.

In this example, John Cohen is a patient whose laboratory result value (OBX.5) is "10". When this laboratory result is received in the message, it is stored as is in the patient's record in the EHR. For any field except for result, capitalization may be altered, but no other alterations to the received data are allowed, including fixing typos. In the result field NO alteration is allowed – so if OBX-5.1 is "This pAthologist report ...", then that is what is stored.
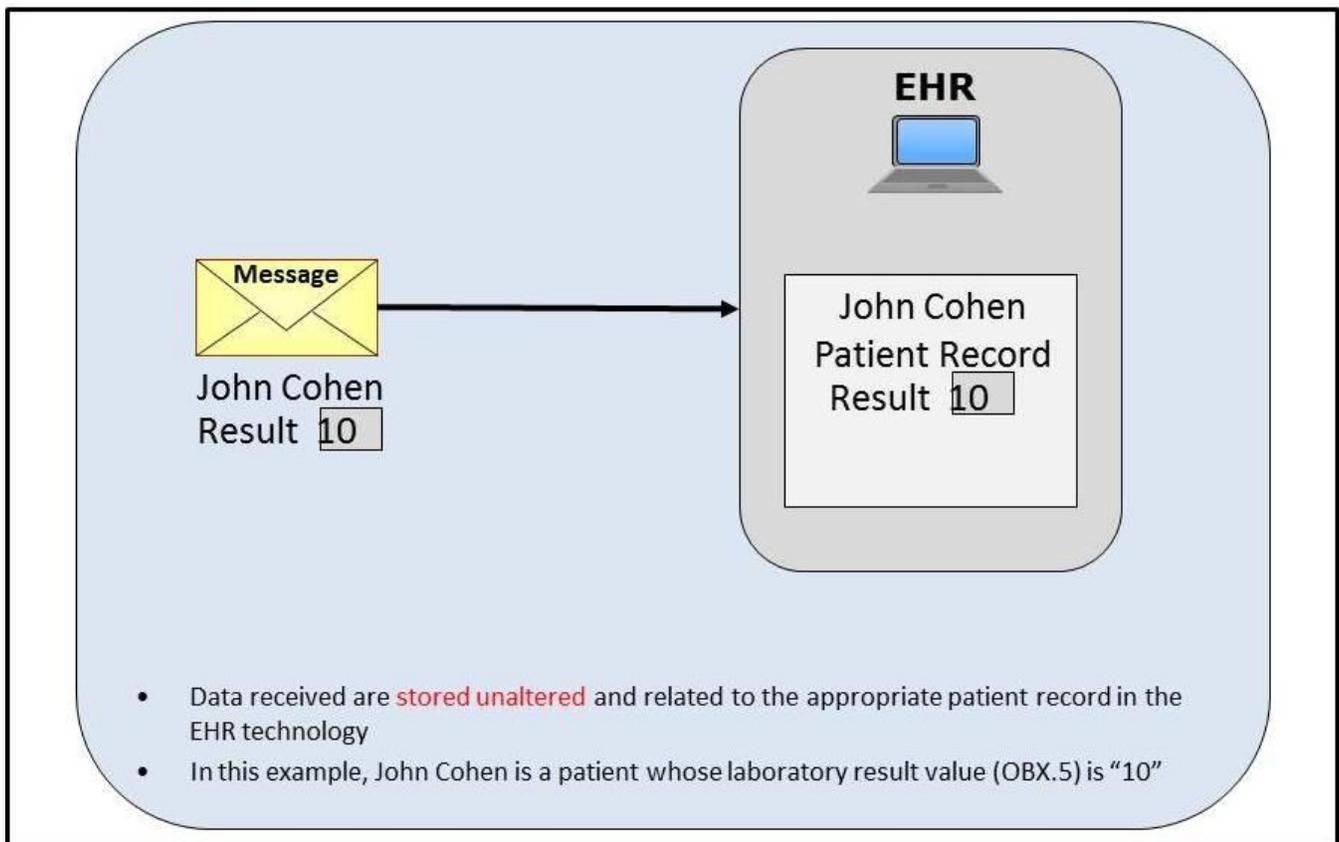

Figure 6-1. Store Exact: S-EX

7.1.2 UNDERSTANDING STORE EXACT BY ASSOCIATION INCORPORATION REQUIREMENT

Figure 6-2. Store Exact, Translation Allowed And Stored illustrates the "Store Exact by Association" incorporation requirement where data received matches existing data exactly and can be stored by associating the existing data to the correct record. Store Exact by Association is what establishes the relationship between new data and existing data. This requirement identifies the elements in the message used to establish relationships.
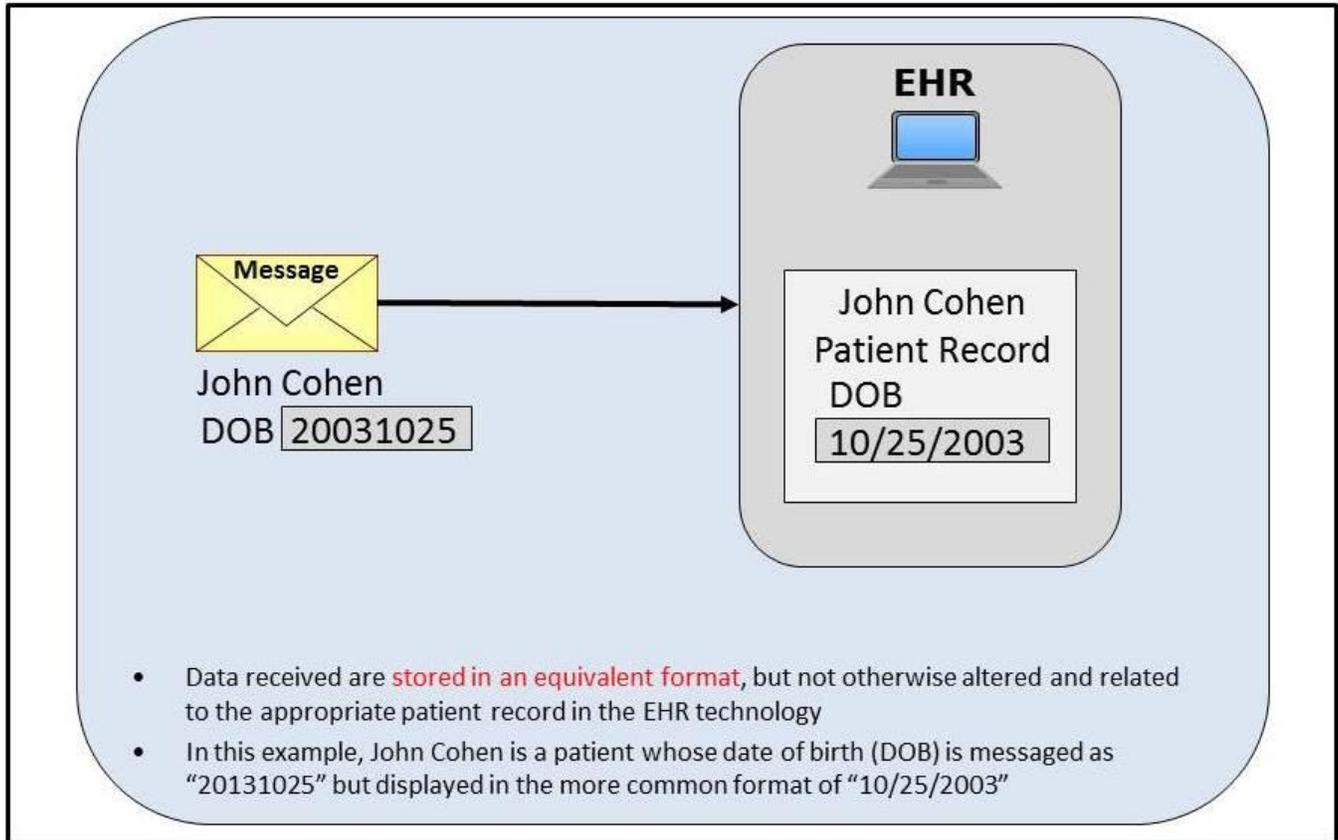

Figure 6-2. Store Exact, Translation Allowed And Stored: S-EX-A

7.1.3 UNDERSTANDING STORE EQUIVALENT INCORPORATION REQUIREMENT

Figure 6-3. Store Equivalent: S-EQ illustrates the "Store Equivalent" incorporation requirement where data received in the message are stored in an equivalent format. In this case the format of the data is changed, BUT no other translation or transformations have occurred – the most common example will be the date – in HL7 messages it is sent in the format of YYYYMMDDHHMM +/-0000 (Y = Year, M = Month, D = Day, H = hour, second M = Minute, where +/- is the time zone offset from Universal Time), which is hard to read and should be stored as commonly done in the system.
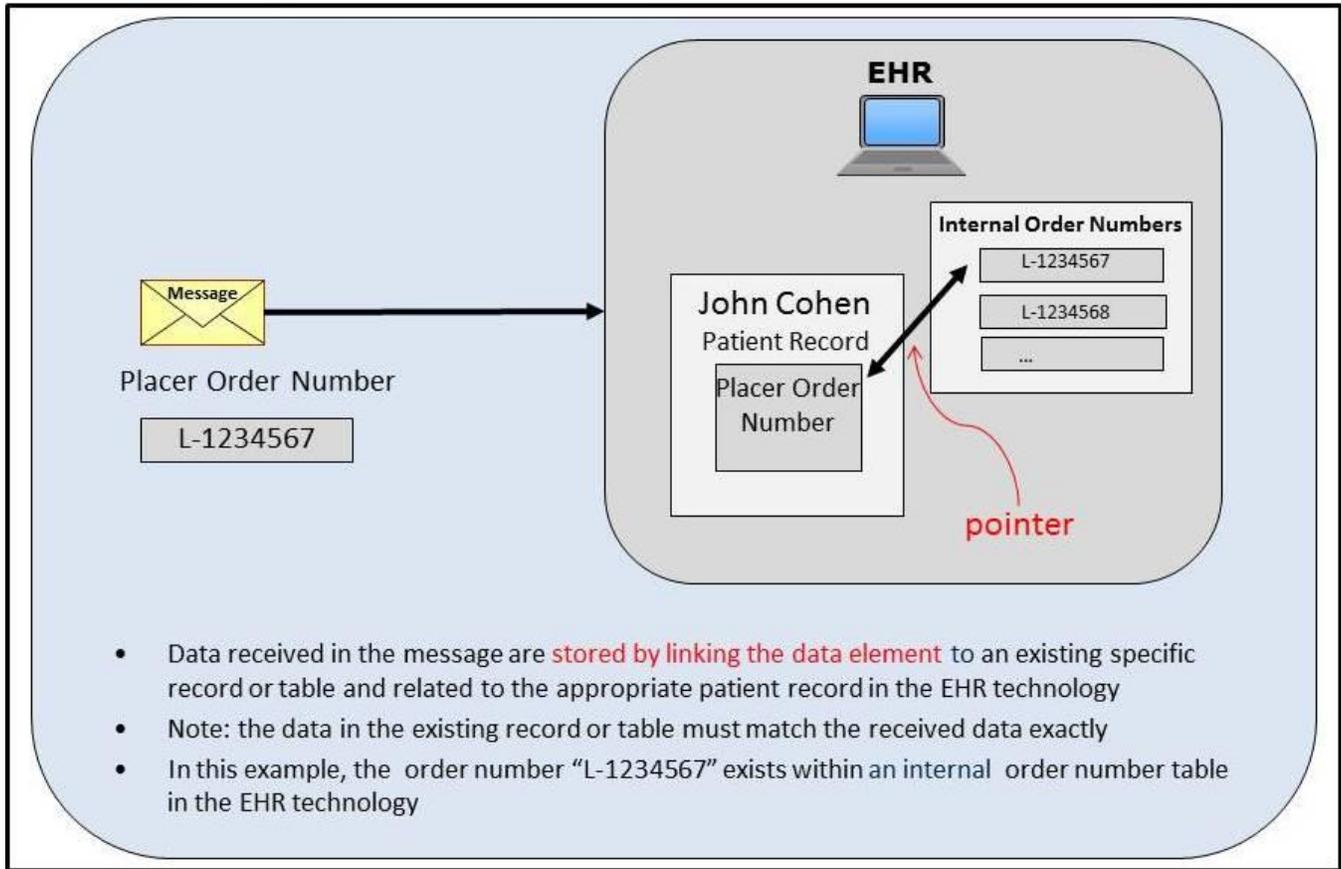
Figure 6-3. Store Equivalent: S-EQ

7.1.4 UNDERSTANDING STORE EXACT, TRANSLATION ALLOWED AND STORED INCORPORATION REQUIREMENT

Figure 6-4. Store Exact and Translated: S-EX-TR illustrates the "Store Exact and Translated" incorporation requirement where data received in the message are mapped to the "local" representation of the same data concept, i.e., internal values in the EHR technology. In this example, a laboratory test with a specific LOINC code is received in the message. This LOINC code is mapped to an internal (local) code in the EHR technology, and this local code – along with a pointer to the LOINC code and the LOINC code – is stored in the patient record.
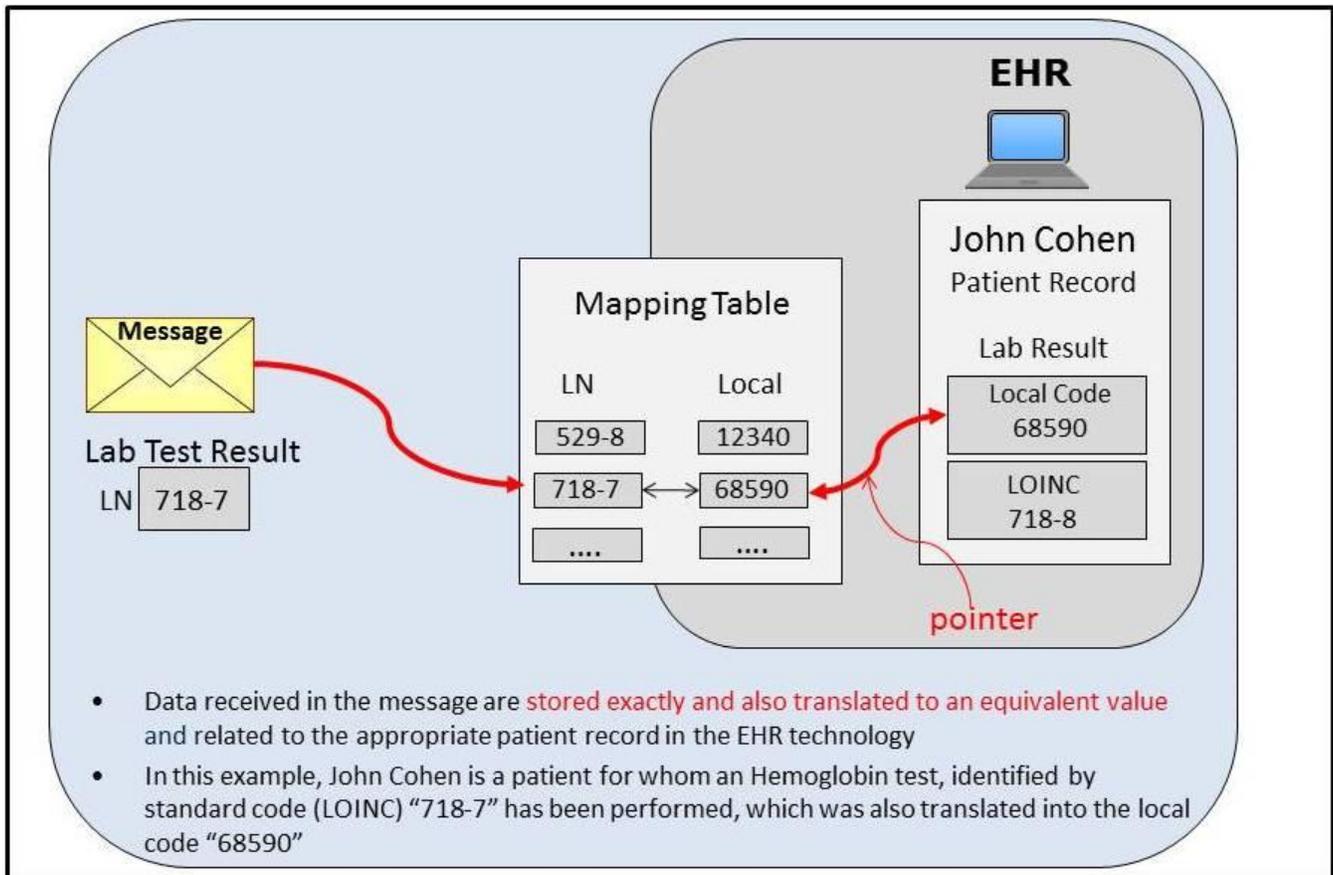
Figure 6-4. Store Exact and Translated: S-EX-TR

7.1.5 UNDERSTANDING STORE TRANSLATED INCORPORATION REQUIREMENT

Figure 7-5. Store Translated illustrates the "Store Translated" incorporation requirement where data received in the message are mapped to the "local" representation of the same data concept, i.e., internal values in the EHR technology. The EHR internal value, which is mapped to a record in an external table that contains the received value, is stored in the patient record. The received version of the data must be derivable for use via the mapping function, and the derived version of the data must match exactly the original data received in the message. In this example, a laboratory test with the abnormal flag of critically high (HH) is received in the message. This abnormal flag code is mapped to an internal (local) code in the EHR technology, and this local code – along with a pointer to the abnormal flag code and version in the external table – is stored in the patient record. When the abnormal flag code that was received in the message needs to be utilized, it is derived by the EHR technology via the mapping to the external LOINC table
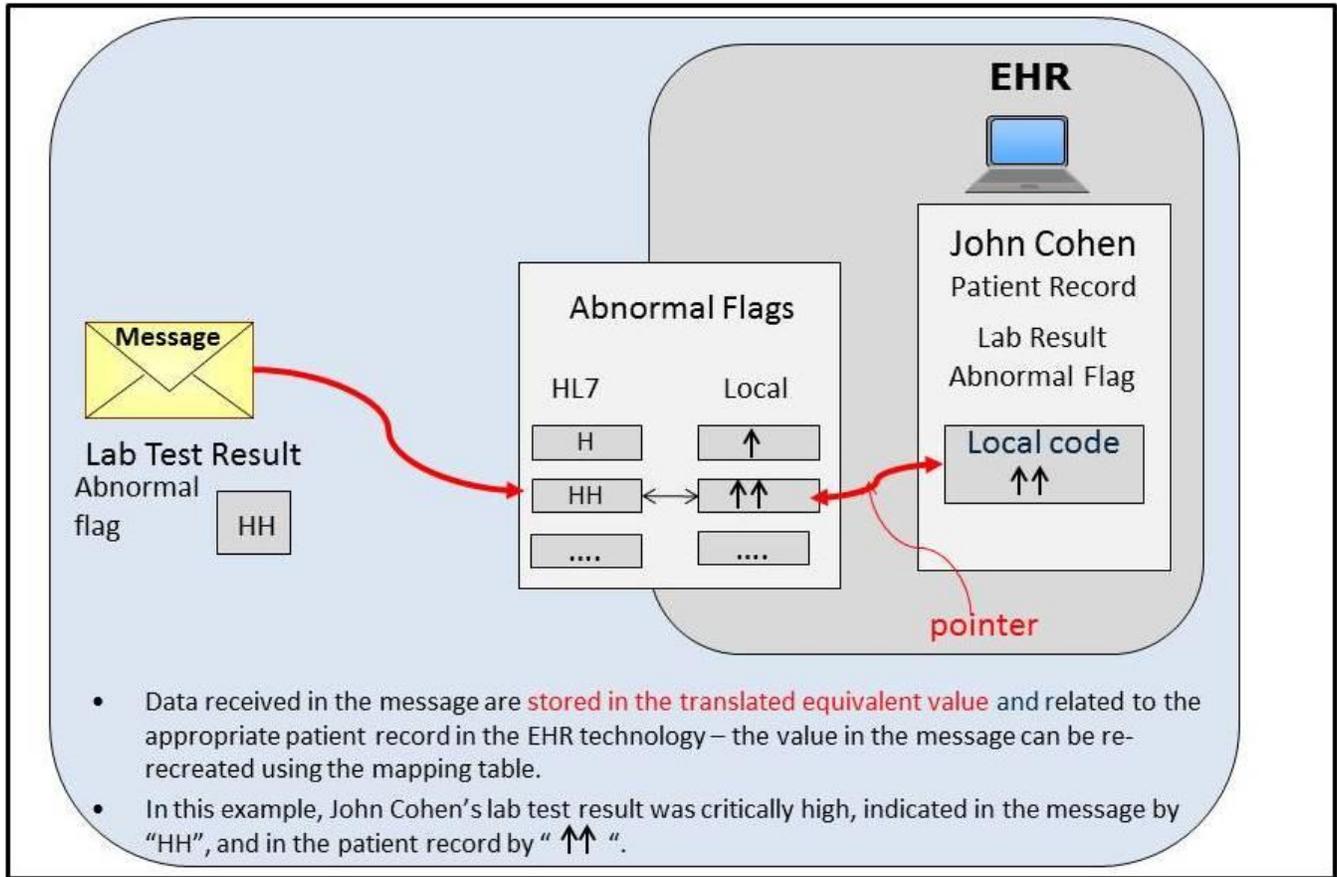
Figure 7-5. Store Translated: S-TR-R

7.1.6 UNDERSTANDING PROCESS AND RECREATE INCORPORATION REQUIREMENT

Figure 6-6. Process and Recreate: S-RC illustrates the "Process and Recreate: S-RC" incorporation requirement where data received in the message are processed and made available for operational purposes (such as placing an identifier into the correct field in the data base) as indicated by relevant functional requirements. Once the data are utilized for the operational purpose, they do not need to be stored, associated, or displayed though storage is allowed. These data may be discarded by the EHR technology.

In this example, a patient identification number of the type internal Identifier is received in the message. This information is used to place or link John Cohen's internal patient record number in the EHR technology.
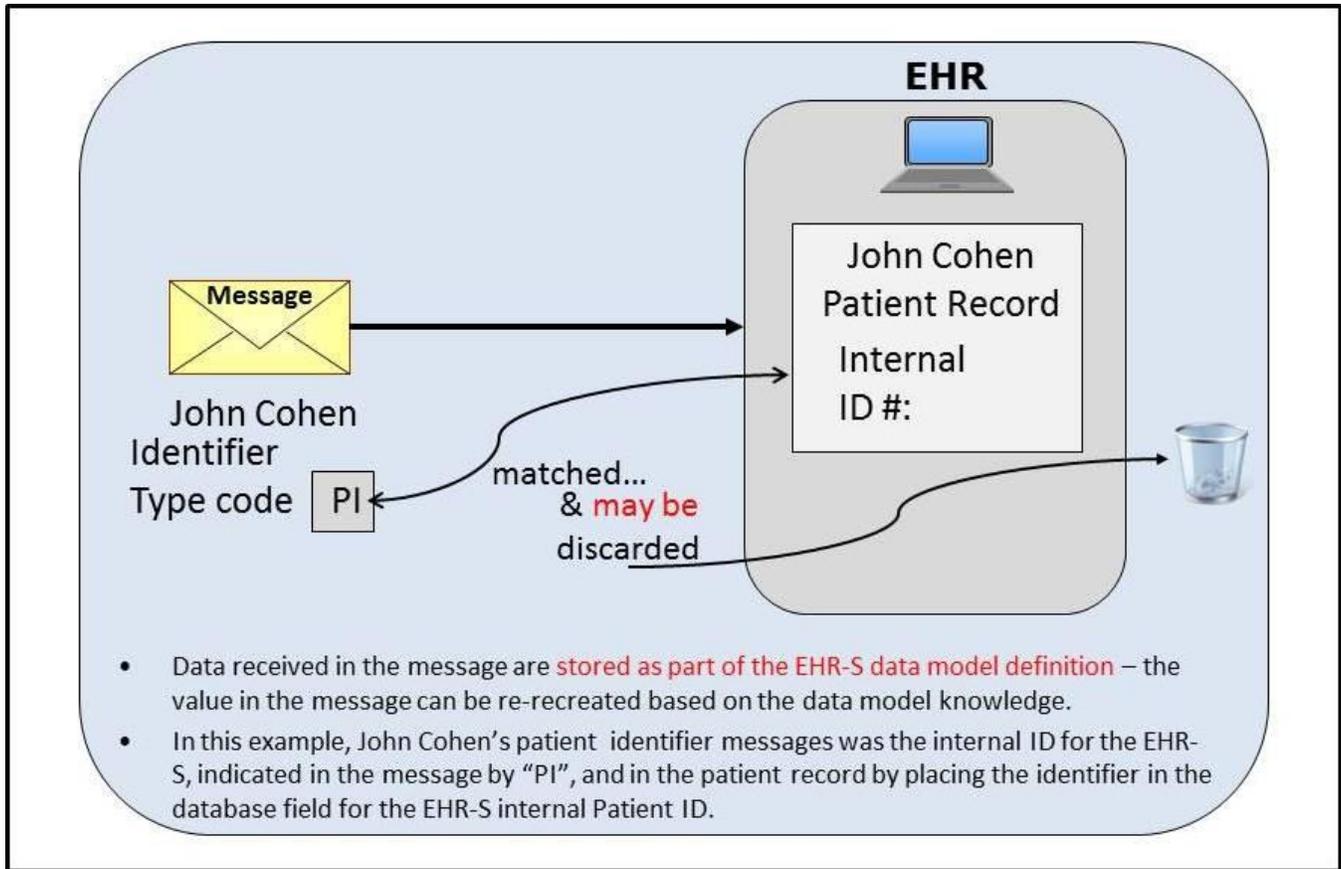
Figure 6-6. Process and Recreate: S-RC

7.1.7 UNDERSTANDING MADE AVAILABLE INCORPORATION REQUIREMENT

Figure 6-7. Made Available: S-MA illustrates the "Made Available Version: S-MA" incorporation requirement where data received in the message are processed and made available for operational purposes (such as matching related data) as indicated by relevant functional requirements. Once the data are utilized for the operational purpose, they may be but do not need to be stored, associated, or displayed. These data may be discarded by the EHR technology.

In this example the message contains the parent number (OBR-29) for a reflex test. This number is used for relating the reflex order to the order whose result spawned it, in order to associate the lab results data from both orders in the EHR technology. Once the exact match is made, the patient identification number data received in the message is discarded.
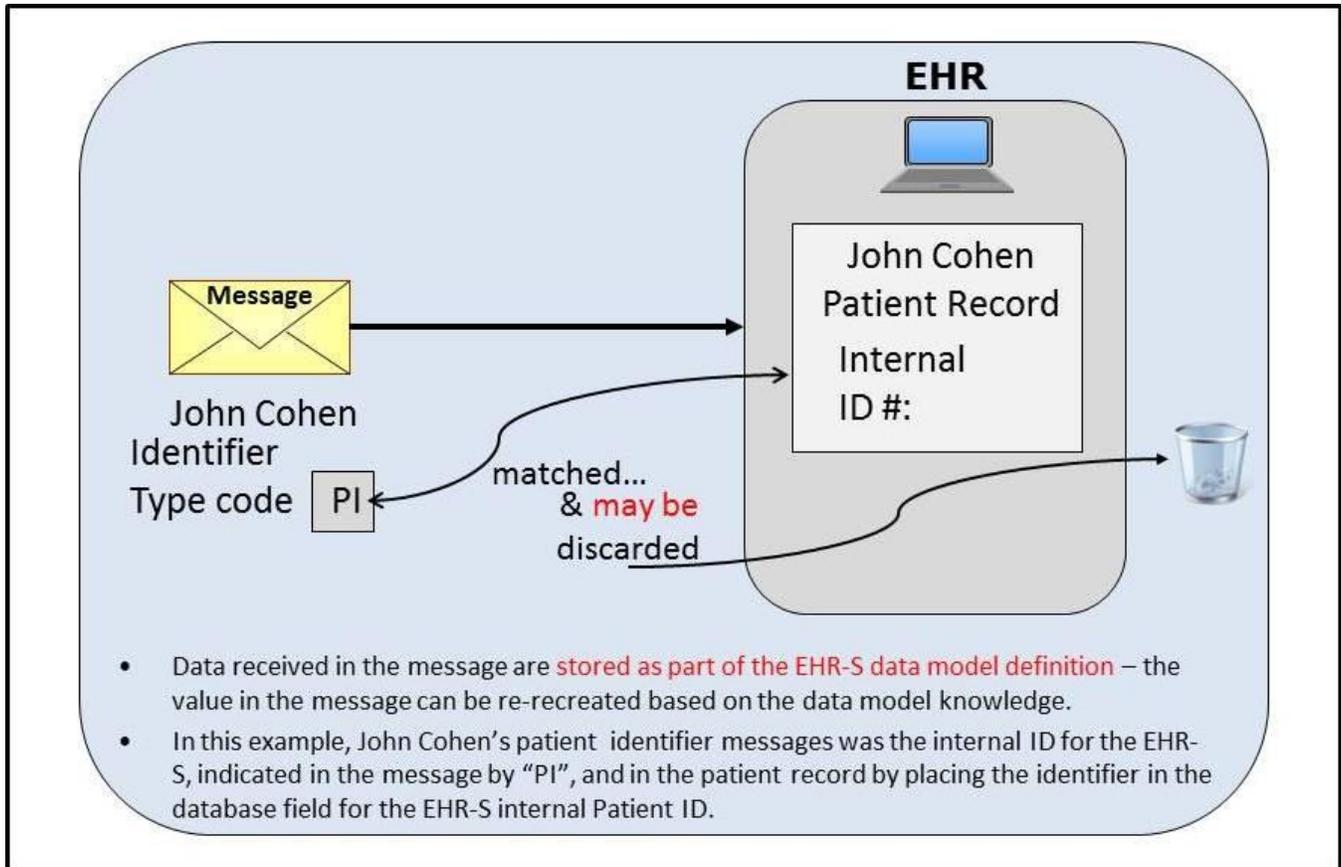
Figure 6-7. Made Available: S-MA

7.1.8 UNDERSTANDING PROCESS INCORPORATION REQUIREMENT

Figure 6-8. Process: S-PR illustrates the "Process Version: S-PR" incorporation requirement where data received in the message are processed and made available for operational purposes (such as parsing the message) as indicated by relevant functional requirements. Once the data are utilized for the operational purpose, they may be but do not need to be stored, associated, or displayed. These data may be discarded by the EHR technology.

In this example the message is identified as an ORU^R01 message, which is used to properly parse the content in the message. Once the message is successfully parsed, that data received in the message is discarded.
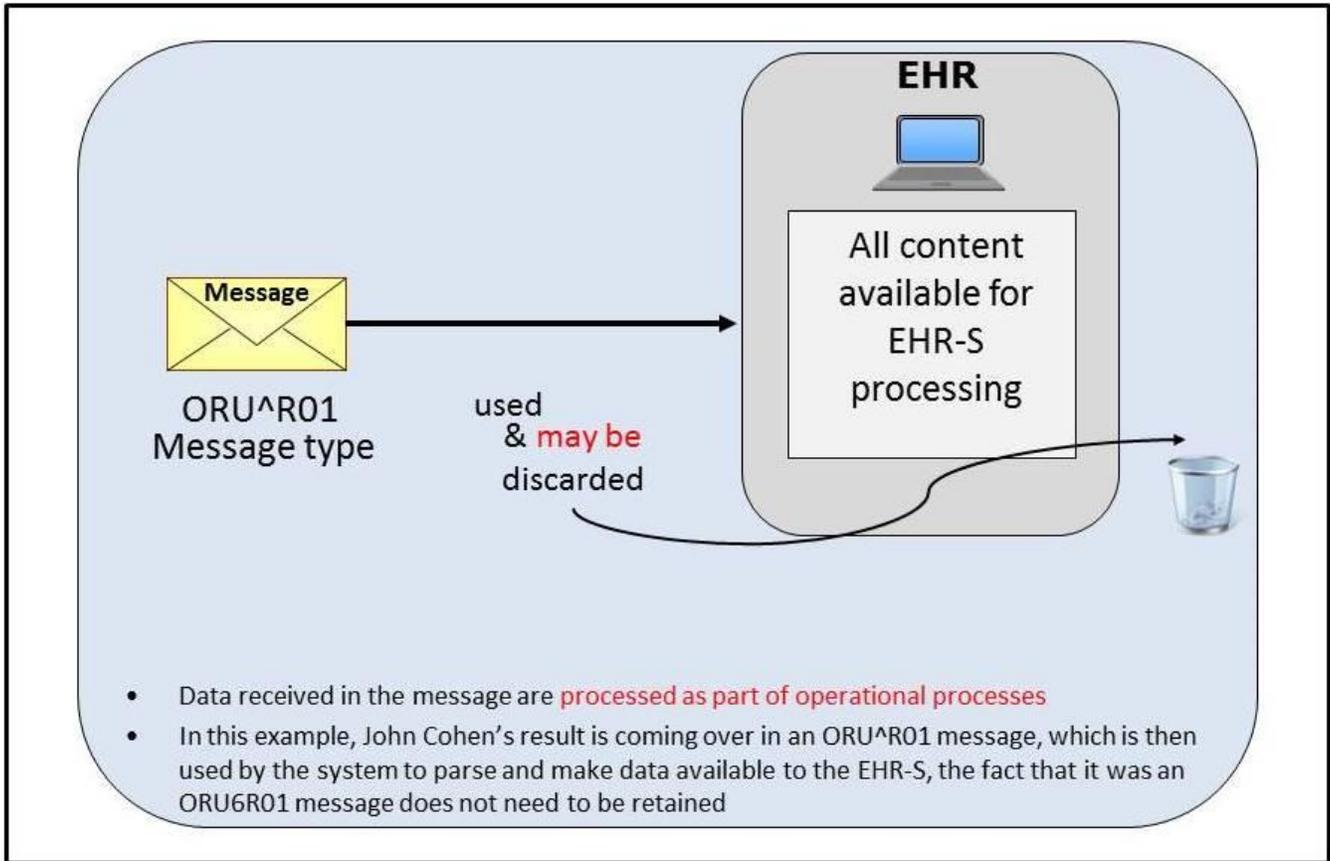
Figure 6-8. Process: S-PR

7.2 Understanding Display Requirements

Once data are incorporated into the EHR technology in the required manner, two levels of use requirements are identified for displaying the data to the user. Table 7-2 shows the levels of the display use requirements and the associated display action and implementation requirements.

TABLE 7–2. REQUIREMENTS FOR USE			
Requirement	Display Action	Implementation	Impact on Implementers
Display Required	U-EX Use exact version of stored data	Data SHALL BE displayed to the user by the EHR technology, and what is displayed SHALL BE exactly the same as the text stored.	EHR must be designed to display only exact stored data. With the exception of Results, exact capitalization is not required. Example: If "ABC" is stored, then "ABC" must be displayed
Display Required	U-EQ Use of equivalent version of stored data	Data SHALL BE displayed to the user by the EHR technology, and these displayed data MAY BE the equivalent of the stored data.	EHR must be designed to display data exact stored data, and also may be designed to display the reformatted version of the data. Example: Date/Time can always be shown as an equivalent – in the format familiar to the user.

TABLE 7–2. REQUIREMENTS FOR USE			
Requirement	Display Action	Implementation	Impact on Implementers
Display Required	U-TR Translate exact stored data to equivalent concept	Data SHALL BE displayed to the user by the EHR technology, and these displayed data MAY BE a translation to an equivalent concept rather than exactly the same.	EHR must be designed to display exact stored data, and also may be designed to display a translated concept (not data) of the exact data that was stored). Example: If "M" is the exact data, "Male" or "male" may be displayed to the user
Display Required	U-REF Use referenced data based on stored pointer	Data SHALL BE displayed to the user by the EHR technology, and these displayed data MAY BE referenced data based on stored pointer	EHR must be designed to display exact stored data, and also may be designed to display referenced data using a stored pointer to those data. Example: Administrative Sex may be displayed by linking to the locally stored value
Display Permitted	U-PR Use permitted	Data MAY BE displayed to the user by the EHR technology at the discretion of the EHR vendor.	EHR may be designed to display exact stored data. Example: The EHR vendor may design their system to display to the user the LOINC code for a laboratory test
Display Permitted	U-NR Use not recommended	Data SHOULD NOT be displayed to the user by the EHR technology.	EHR may be designed to display data to the user, however in this use case that is NOT recommended. Example: Metadata about an identifier, like the identifier type code or the universal identifier itself.
N/A	U-NA Use not applicable	Data may not be stored nor otherwise used in this use case, so there is nothing to display.	Example: The Set ID of each segment is used in parsing the message, but not retained.

Figure 6-9. Use Conformance Requirements illustrates the use conformance requirements of incorporated data elements that are received by an EHR technology.
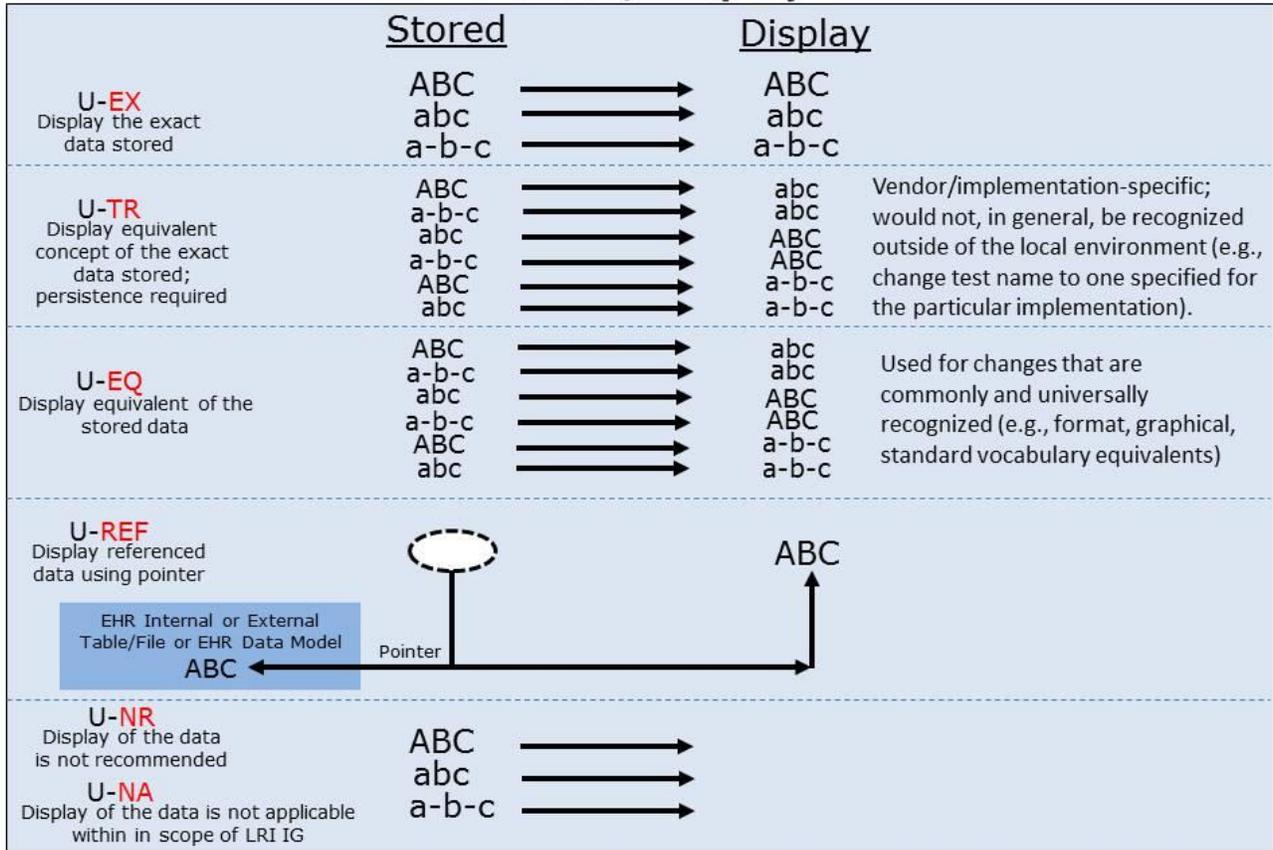
Figure 6-9. Use Conformance Requirements

7.3 Process for Assigning the Store and USE Conformance Requirements

As illustrated in Figure 6-10. Method used for Assigning Store and Use Requirements, each in-scope data element is assigned a conformance requirement selected from the options defined for store and use (for example, display) respectively. Refer to Section 7.4 Detailed Requirements for In-scope Data Elements for actual conformance requirement assignments for in-scope data elements.

The process of assigning the conformance requirement includes review of each data element and selection of a store conformance requirement and a use conformance requirement.

For example, Figure 6-10 shows that data element OBX-3.1 is assigned a store conformance requirement of "Store Exact; Translate and Store Translation" and a use conformance requirement of "Translated". Note that the usage for OBX-17 is Optional, therefore this data element is out of scope and the conformance requirements are listed as "Indifferent".
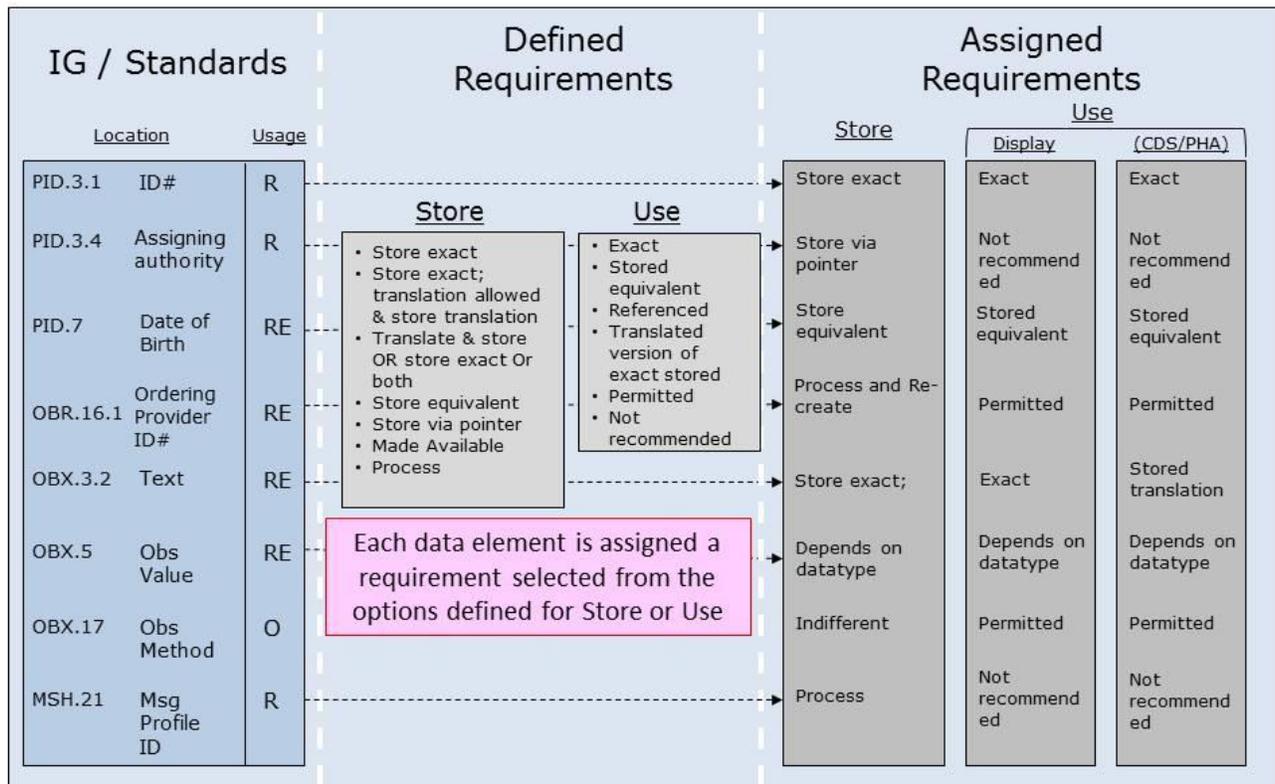
Figure 6-10. Method used for Assigning Store and Use Requirements

The assignment of the incorporate requirements drives the content of the Juror Document used for EHR technology certification testing. Figure 6-11 illustrates the use of the Juror Document in the testing process of the system under test (SUT).
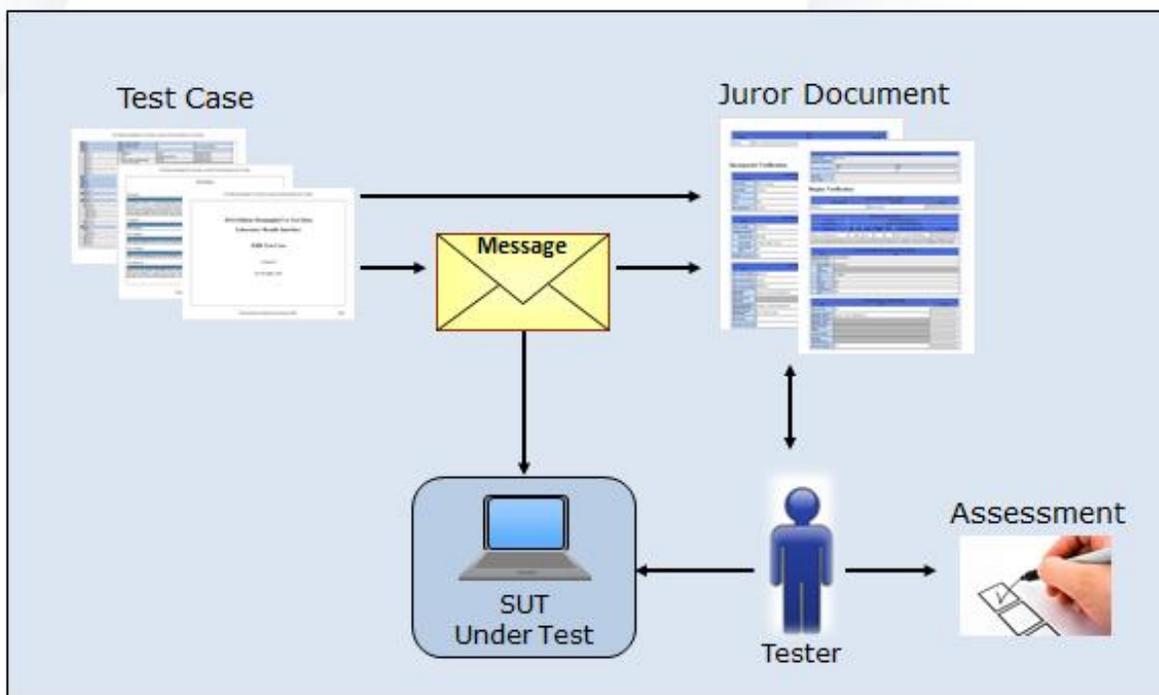
Figure 6-11. Use of the Juror Document in the Testing Process

7.4 Detailed Requirements for In-scope Data Elements

This information is currently contained in the related spreadsheet file that is part of this ballot package titled *LRI_Functional_BehavioralRequirementsIG.xlsx*. It is organized in the following tabs:

KEY: Displays the conformance requirements abbreviations and their names as used in the subsequent tabs. Also describes the color coding and its meaning used to create the conformance level assignment tables in the following sheets.

Tabs labeled MSH – PID – ORC – OBR- NTE – TQ1 – SPM – OBX-All except OBX-5 – OBX-5: Each row represents an in-scope data element (as defined in LRI transaction) and its respective store and use conformance requirement. The first two columns describe the data element as identified in the LRI message, the third column assigns the conformance requirement for store action, the forth column assigns the use action requirement for the reference report (to satisfy CLIA regulation), the fifth column assigns the use action requirement for any other connected environment, where results are displayed or used. The sixth column lists comments specific to the data element, if needed.

Menu Options: Collection of restricted values usable on the conformance level tabs for each column.

7.5 Required Functionality for Display of Results Data by EHR Technology

Based on discussions with clinical informatics subject matter experts, the following display practices are recommended when applied to the "laboratory reference report", which is the report received from the laboratory that falls under CLIA regulation:

"…These data are meant to be displayed concurrently in their entirety by the EHR technology under test, and the content must be presented in a human readable format[5].

When all of the required data elements cannot be displayed concurrently in their entirety (for example, due to complexity or IT limitations), additional electronic display screens are to be permitted. When multi-page electronic display screens are utilized, they should follow these characteristics:

- Identify individual electronic display screens unambiguously as part of the same report and as belonging to the specific patient

- Indicate on each electronic display screen the continuation of the report on additional display screens

- Provide additional information with ideally no more than two motions for electronic displays, e.g., hover, click, scroll, pan, zoom

Other presentations of laboratory information may be present in the EHR technology such as a flow sheet or summary reports."[6]

---

[5] *Human readable format* means a format that enables a human to read and easily comprehend the information presented to him or her regardless of the method of presentation. [45 CFR 170.102]

[6] 2014 Edition Test Procedure for §170.314(b)(5)(A) Incorporate laboratory tests and values/results, Approved Test Procedure Version 1.4, February 26, 2013, page 8.

8 APPENDIX

8.1 ONC Incorporate Lab Results Certification Criterion

The Office of the National Coordinator for Health Information Technology (ONC) published the *Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule* in September of 2012. One of the certification criteria included in the Final Rule addressed incorporation of laboratory tests and results:

§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.3

> (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.

The metrics to be used to measure successful incorporation of lab tests and results are not named in this criterion. These metrics, determined through analysis discussions with numerous clinical laboratory stakeholders and subject matter experts, are explained in the Incorporate Laboratory Results section of this Functional Requirements Behaviors Implementation Guide.

8.2 Descriptions and Definitions

The definitions for "incorporate" are provided in the Final Rule published by the ONC in September 2012.

TABLE 8–1. DEFINITIONS OF INCORPORATE	
Definition	Source
" 'Incorporate' is used to mean to electronically import, attribute, associate, or link information in EHR technology. With the exception of import, we previously used these terms to describe the 'incorporate' capability included in certification criteria as illustrated by the capability specified at § 170.302(h)(3). We only propose to revise its unique meaning for the 2014 Edition EHR certification criteria and the purposes of certification to account for the ability to electronically import information."	From Section A.3. "Explanation and Revision of Terms Used in Certification Criteria", *Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule* (September 4, 2012).

TABLE 8-1. DEFINITIONS OF INCORPORATE	
Definition	Source
"…when the term incorporate is used within a certification criterion it is intended to mean to electronically process structured information from another source such that it is combined (in structured form) with information maintained by EHR technology and is subsequently available for use within the EHR technology by a user."	From Section A.3. "Explanation and Revision of Terms Used in Certification Criteria", *Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule* (September 4, 2012).
"…by requiring ambulatory EHR technology to be capable of receiving laboratory tests and values/results formatted in accordance with the HL7 2.5.1 standard and the LRI implementation guide, it would be significantly easier and more cost effective for electronic laboratory results interfaces to be set up in an ambulatory setting (that is, minimal additional configuration and little to no additional/custom mapping). Moreover, we stated that it would increase the likelihood that data would be properly incorporated into ambulatory EHR technology upon receipt and thus, facilitate the subsequent use of the data by the EHR technology for other purposes, such as CDS."	From Section III.A of the preamble of the *Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule (September 4, 2012)* where the incorporate laboratory tests and values/results certification criterion is discussed.
"Because we have specified a standard by which EHR technology designed for an ambulatory setting must be capable of receiving lab results, we clarify that testing and certification for this setting will examine whether EHR technology can properly extract lab tests results/values and incorporate the data from the LRI specification for subsequent use."	From Section III.A of the preamble of the *Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule (September 4, 2012)* where the incorporate laboratory tests and values/results certification criterion is discussed.
"…the only additional modification we have made in response to public comment was to reinsert the phrase 'attribute, associate, or link' in 170.314(b)(5)(iii) to reflect the 2011 Edition version of this certification criterion due to the confusion we caused by overloading the term 'incorporate'."	From Section III.A of the preamble of the *Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule (September 4, 2012)* where the incorporate laboratory tests and values/results certification criterion is discussed.

8.3 Example Testing Scenarios

1. Results are sent from LIS to EHR for a female under her Maiden name; then, the next day she gets married and the EHR is updated with her new name

   - Yesterday the "current" patient name at that time was a perfect match, and the EHR should be able to recreate what the patient's name was at the time the results report was transmitted (the EHR audit trail should list the patient's name at the time of the lab result)

2. Final result message is transmitted to the EHR with the patient's DOB demographic information as it was provided with the lab order; DOB on Final result report matches DOB in EHR; then DOB is modified in the EHR, and a Corrected result message is transmitted to the EHR with the patient's

EHR-S Functional Requirements For Laboratory Results Messages, DSTU R1 – US Realm
January 2015 Ballot

DOB demographic information as it was provided with the lab order; DOB on Corrected result report does not match the DOB in EHR

- The EHR should have the ability to show (display) the name, DOB and gender as it was at the time the test report was transmitted. How this is accomplished is up to the EHR system.

- During certification testing, the Tester should have the EHR Vendor

    o Show the Final results and the patient name, DOB, and gender received with these results

    o Change the DOB for this patient in the EHR

    o Transmit a Corrected result message and then inspect the EHR again to view the patient name, DOB, and gender received with these Corrected results

- One way the EHR could demonstrate the above scenario would be to receive the transmitted lab result, create a PDF of the Test Report with DOB, gender, and anything else, and then store the PDF. Then the EHR vendor recalls this PDF as the display (for display of lab results).

    Note: Use of PDF documents for storing the Test Report raises the issue of storing discrete or non-discrete data (ONC likely wants discrete data so it can be processed for clinical quality measures, for clinical decision support, and to forward on downstream (e.g., for ELR).

3. In the situation where the patient demographic data in the LRI results message differs from the patient demographic data in the EHR, the tester verifies that

- the data sent with the result are stored with/associated with the results and are not overwritten with the data in the EHR

- the data sent with the result do not overwrite the data in the EHR