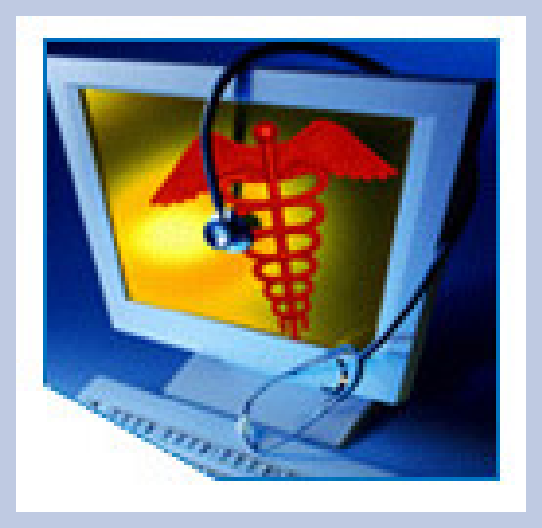
May 11, 2007
Version 2.0

HITSP EHR Lab Result Terminology Component

HITSP/C35



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Population Health Technical Committee
Care Delivery Technical Committee

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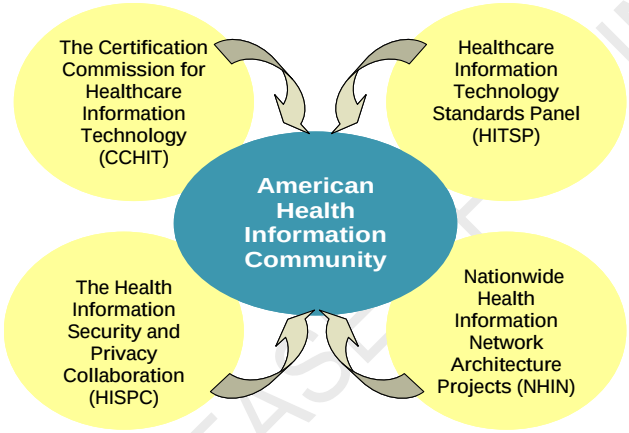
1.0 FOREWORD

This document is referred to as a Component and is an artifact of the Healthcare Information Technology Standards Panel (HITSP).

The following paragraphs provide background information about the HITSP and its role in the overall U.S. efforts to realize large scale interoperability of health information. It also describes the HITSP process for healthcare standards harmonization and explains how to use this document and other related documents to inform your health IT product development or product refinement. If you are familiar with HITSP and HITSP artifacts, please proceed to Section 2.0.

U.S. Nationwide Health Information Interoperability

Studies published by the Institute of Medicine and others have raised awareness of the extent to which the fragmented nature of clinical information adversely impacts the quality of care across the U.S. Health Information Technology (IT) can be used to enable better integration of clinical information. However, as of 2007, only a small number of U.S. healthcare providers have fully adopted health IT due, in part, to technical barriers associated with a lack of unambiguous and nationally recognized interoperability standards.



The American Health Information Community[1] (AHIC), a 2005 federally-chartered commission made up of leaders from public and private health sectors, was formed to provide recommendations on how to make health records digital and interoperable, and assure that the privacy and security of those records are protected, in a smooth, market-led way. At the same time, the Department of Health and Human Services, through the Office of the National Coordinator for Health IT (ONC) awarded contracts to 1) identify Interoperability Standards to facilitate the exchange of patient data (HITSP), 2) define a process for certifying that health IT products comply with appropriate standards through the Certification Commission for Healthcare Information Technology (CCHIT), and 3) develop a series of prototypes to establish the requirements of a Nationwide Health Information Network (NHIN). Under a renewed second year contract, HITSP scheduled activities will include identifying and constraining the standards needed for a standards-based security framework that provides the mechanisms needed to protect patient privacy and maintain confidentiality of information about the patient, as well as further work in additional Use Case priority areas recommended by AHIC. This year, CCHIT is expanding its certification efforts to inpatient, or hospital, electronic health record products. In

[1] http://www.hhs.gov/healthit/ahic.html

January 2007, four NHIN prototypes were delivered based on the requirements for health information exchange. The next phase will be to connect the prototypes and state and regional health information exchange efforts in trial implementations. These activities share the goal of widespread adoption of interoperable electronic health records within 10 years through public-private collaboration.

HITSP's Role within Nationwide Interoperability Efforts

The HITSP[2] is a multi-stakeholder coordinating body designed to provide the process within which affected parties can identify, select, and harmonize standards for communicating healthcare information throughout the healthcare spectrum. As used by HITSP, the term "standard" refers, but is not limited to Specifications, Implementation Guides, Code Sets, Terminologies, and Integration Profiles. A standard should be produced through a well defined approach that supports a business process and

1. has been agreed upon by a group of experts
2. has been publicly vetted
3. provides rules, guidelines, or characteristics
4. helps to ensure that materials, products, processes, and services are fit for their intended purpose
5. is available in an accessible format
6. is subject to an ongoing review and revision process

HITSP functions as a partnership of the public and private sectors and operates with a neutral and inclusive governance model administered by the American National Standards Institute. The goal of the Panel is to:

- Facilitate the development of harmonized Interoperability Specifications and information policies, including Standards Development Organization (SDO) work products (e.g., standards, technical reports). These policies, profiles and work products are essential for establishing privacy, security and interoperability among healthcare software applications
- Coordinate, as appropriate, with other national, regional and international groups addressing healthcare information to ensure that the resulting standards are globally relevant
- Be use-case driven, using information from stakeholders and basing decisions on industry needs

The work of the HITSP is conducted through formally chartered Technical Committees and Work Groups. The artifact of the Technical Committee and Work Group activities is an Interoperability Specification (IS) and related constructs referred to as Transaction Packages, Transactions, or Components. For additional information on these constructs, please refer to the HITSP Harmonization Framework.

This HITSP document pertains to the Interoperability Specification for the following:

[2] www.hitsp.org

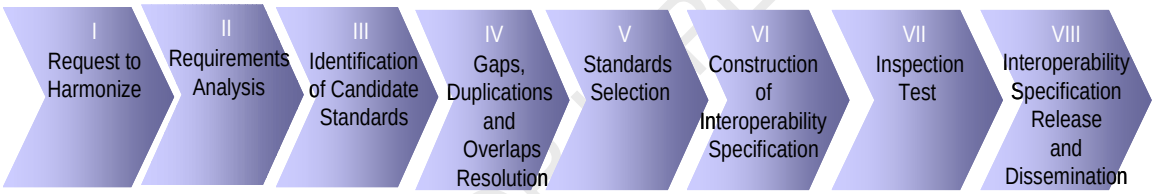
Use Case	Specific Scope of this Use Case
Biosurveillance	Transmit essential ambulatory care and emergency department visit, utilization, and lab result data from electronically enabled healthcare delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time.
Electronic Health Record	Allow ordering clinicians to electronically access laboratory results, and allow non-ordering authorized clinicians to electronically access historical and other laboratory results for clinical care.

In its final state, this Interoperability Specification provides unambiguous instructions for how two or more systems should exchange information within this specific context of the Use Case.

How Use Cases and HITSP Interoperability Specifications are Developed

The American Health Information Community, as the representative of public and private health sector stakeholders, identified the three Use Cases (available at hitsp.org) that drove the initial efforts of the HITSP. Nationwide public and private health sector priorities continue to focus the efforts of the HITSP. The Use Case driven HITSP harmonization process is implemented by formally chartered Technical Committees. The volunteers that comprise a Technical Committee followed an 8 step process, depicted below.

Figure 1.0-1 HITSP Harmonization Process Steps



How to Read this Interoperability Specification

Each Interoperability Specification (IS) is actually a suite of documents that, taken as a whole, provide a detailed map to existing standards and specifications that will satisfy the requirements imposed by a given Use Case. It identifies and constrains standards where necessary, and creates groupings of specific actions and actors to further describe the relevant contexts. Where gaps and overlaps are identified, the Interoperability Specification provides recommendations and a roadmap for corrections to be made. This Interoperability Specification includes the Transaction Packages, Transactions, and Components.

2.0 INTRODUCTION

As an introduction to this EHR Lab Result Terminology Component, this section provides a high level overview of information sharing scenario enabled by following this specification, outlines the technical scope of the specification, describes the intended audience for the technical content of the document, acknowledges the copyright protections that pertain, provides Internet links to the HITSP Acronyms List and an explanation of the conventions used to convey the full descriptions and usage of standards. If you are already familiar with this information, proceed to Section 3.0 Referenced Standards.

2.1 OVERVIEW

The purpose of this document is to define the vocabulary for either message-based or document-based laboratory results reporting. The goals supported by this terminology component specification are stated in the EHR Use Case:

- Deploy standardized, widely available, secure solutions for accessing laboratory results and interpretations in a patient-centric manner for clinical care by authorized parties
- Provide the following functionality for laboratory results reporting and notification, and is applicable to many types of laboratory tests, including but not limited to: clinical chemistry, hematology, serology, and microbiology

The Use Case notes that there are obstacles to achieving the stated goals. In particular, the following obstacle is delineated:

- Lack of harmonization among data interoperability standards including vocabulary and laboratory and other messaging standards

This EHR Lab Result Terminology Component is the result of a considered assessment of the terminologies available and the current practices in electronic laboratory results reporting for the purpose of moving forward in the harmonization of those terminologies. Without standard terminologies, interoperability is severely limited. This specification describes the vocabularies needed to implement the communication of an electronic standards-based laboratory result. A guiding principle for these selections was to follow Consolidated Heath Informatics Initiative (CHI) standards selections as appropriate. The following sections describe the selected terminologies, the events that are supported by those standards, and the reason for their selection. Also described are the organizations that maintain the standards and where to obtain more information.

This Component specification is part of a series of documents to establish Interoperability Standards for laboratory results reporting. The following documents are related to this specification:

Table 2.1-1 Document Relationships

Related Documents	Document Description
HITSP/C36[3]	HITSP Lab Result Message Component
HITSP/C37	HITSP Lab Report Document Component
HITSP/TP14	HITSP Send Lab Results Message to Ordering Clinician and Providers of Care Transaction Package

2.2 TECHNICAL ASSUMPTIONS AND SCOPE

This Interoperability Specification focuses on a set of constrained standards for information interchange that address the core requirements of the Use Case described above. It may not define all functions, constructs and standards necessary to implement a conforming system in a real world environment. The following paragraphs provide the HITSP principles with regard to several critical topics to ensure consistent interpretation of the Interoperability Specifications.

2.2.1 INTEROPERABILITY SPECIFICATIONS NOT FUNCTIONAL SPECIFICATIONS

The HITSP Interoperability Specification defines how two or more systems exchange standard data content in a standardized manner. Interoperability Specifications define the necessary business and technical actors, the transactions between them including the message, content and terminology standards for the actual information exchange. Interoperability Specifications do not specify the functional requirements or behaviors of the systems or applications.

2.2.2 ARCHITECTURAL NEUTRALITY

HITSP Interoperability Specifications, unless otherwise noted, are not intended to define or prescribe any system architecture or implementation. At the most basic level, the Interoperability Specifications define specific information exchange standards that are to be used by any two systems. Information exchange must be placed within the context of a transaction between defined technical actors which fulfill higher level business requirements derived from the Use Case. In some cases the necessary technical actors may require some architectural structure or make some assumptions involving synchronous or asynchronous data exchanges, or require specific type of exchange, such as a message or document. These requirements may constrain to some degree the total range of choices regarding system architectures. When constraints are necessary to meet the Use Case requirements, the Interoperability Specification will note this and will retain as much architectural neutrality as possible. When appropriate, the Interoperability Specifications may provide architectural examples and discuss considerations of such examples.

[3] The HITSP/C36 Lab Message component is included in this release as a **Review Copy** which outlines the use case and the direction for development of a profile of the HL7 2.5.1 Message specification. The Technical Committees are currently completing the detailed guidance information with an expected **Released for Implementation** in the third quarter of 2007. The HITSP encourages interested parties to become involved and participate in this activity. For information on becoming a member of the HITSP, please contact Jessica Kant for further information at jkant@himss.org.

2.2.3 THE USE OF MESSAGES AND DOCUMENTS AS APPROPRIATE

Within healthcare information there is an ongoing debate concerning the proper role of messages and documents as methods of exchanging data. Messages are typically non-persistent encapsulations of highly structured data that require external context. Documents are persistent encapsulations of both data and context which may be authenticated to insure non-repudiation. Persistence as defined by Health Level Seven (HL7) means that a clinical document continues to exist in an unaltered state for a time period defined by local and regulatory requirements. Non-repudiation, as defined by ISO adapted from ASTM E31, means a service that provides proof of the integrity and origin of data, which can be verified by any party. HITSP recognizes that requirements for both messages and documents exist and where consistent with harmonization will support both. For example, depending on specific phases of the workflow, a laboratory result might be exchanged as a message, as a document, or both. Business requirements may define which format is more effective.

2.2.4 IMPLEMENTATION TESTING

The 2006 set of Interoperability Specifications were evaluated by inspection testers (desktop review) and reviewed by HITSP members prior to HITSP approval. Although the Interoperability Specifications are based on approved standards, when published, they represent combinations and constraints that have not been tested in actual implementations. HITSP enlisted partners to develop test plans, data and suites to test the implementation and then to support a program for progressive testing, feedback and deployment of implementations. Feedback from test implementers has been used in the revisions in Version 2.0.

2.2.5 SECURITY AND PRIVACY

The Health Insurance Portability and Accountability Act (HIPAA) and its Administrative Simplification sections establish the minimum federal requirements for security and privacy of individually identifiable health information (IIHI). HIPAA requires that “covered entities” establish and maintain secure systems that protect IIHI from unauthorized disclosures while ensuring its availability for authorized uses. Most providers, health plans and intermediaries, and by contract their business associates, are covered by HIPAA regulation. However, HIPAA does not cover personal health records unless they are held by a covered entity, nor an individual’s use of their own health information.

Currently, HITSP is charged by ONC to harmonize standards based on Use Cases derived from AHIC requirements and priorities. Implicitly and in some cases explicitly, the Use Cases require a secure infrastructure and certain security or privacy functions. Because of time and resource constraints and the need for further information as described below, HITSP has decided to defer specifying most security requirements, instead treating these as a pre-condition for implementing the core information exchanges. The underlying premise is that HITSP**,** based upon prioritization by AHIC and ONC, will in the future identify and constrain the standards needed for a standards-based security framework that provides the mechanisms needed to protect patient privacy and maintain confidentiality of information about the patient. This standards-based security framework will need to accommodate federal, state, local, and

healthcare enterprise security and privacy policies and processes. Exceptions to the deferred requirements that are addressed in this first release are secure web-based messaging, pseudonymization and anonymization.

There is a special case for the Consumer Empowerment (CE) Use Case. In the first year of HITSP's work, the Consumer Empowerment TC is to provide an Interoperability Specification for sharing of demographic data, medication lists, and allergies *based on patient consent*. Patient consent is clearly within the scope of the CE Use Case. However, HITSP requires further guidance on patient consent, particularly since patient consent is not addressed by HIPAA in the case of a personal health record (PHR) nor is it established within widely accepted PHR standards. Therefore HITSP identifies patient consent as a necessary pre-condition for successful implementation of a PHR that contains personal demographic data and medication histories. Patient consent will be documented as a pre-condition in the CE Interoperability Specification. Work on patient consent has been deferred until the second year of HITSP work.

2.3 AUDIENCE

The Interoperability Specification is designed to be used by analysts who need to understand the interoperability requirements for the described Use Case, and by implementers working to develop interoperable applications. Understanding and using the relevant set of Interoperability Specifications is a key requirement for establishing interoperability compliance.

2.4 COPYRIGHT PERMISSIONS

the U.K. Department of Health and is a crown copyright. SNOMED is a registered trademark of the College of American Pathologists.

2.5 ACRONYMS

The acronyms used in this document are contained in the HITSP Acronyms List.

2.6 CONVENTIONS

Conventions are used to convey the full descriptions and usage of standards in the Interoperability Specification and are contained in the HITSP Conventions List.

3.0 REFERENCED STANDARDS

It is HITSP's policy to incorporate only standards that have been approved according to the formal policy of standards organization, as defined by HITSP, which publishes the standard. HITSP interprets approval to include Draft Standards for Trial Use. The objective is to incorporate only standards that are managed within a formal life cycle process as defined by the standards organization. In some cases, where we believe a standard that is not yet approved may best meet the requirements of an Interoperability Specification, HITSP may provide a roadmap of its future intent conditional on future actions by either or both the standards organizations and the HITSP Technical Committee. Thus there are four classes of HITSP-committed standards.

- Approved for Use – standards included for unconditional use within a HITSP construct
- Interim – standards included for use now within a HITSP construct but for a defined time period or conditional on future actions, e.g., "Intended for Use" standard is available
- Provisional - standards that are not yet but are expected to be approved by the Standards Organization by the time the Interoperability Specification is released by HITSP. A "Provisional" standard becomes an "Approved for Use" standard only if:
  - It is approved by the Standards Organization by the time that the Interoperability Specification is released by HITSP and
  - It is substantially the same as it was when it was provisionally used and
  - It requires no further action by the Technical Committee
- Intended for Use – proposed standards that are roadmapped for future use pending actions by the TC and/or the standards organization. Therefore a standard is defined as "Intended for Use" because it will not be approved by the time that the HITSP construct is released but is sufficiently defined to enable detailed evaluation of how well it will meet technical and business requirements

HITSP may continue to use "Provisional" or "Interim" standards as they existed when incorporated into the HITSP construct if the expected conditions are not satisfied until such time as HITSP can replace it with a more suitable standard. In this circumstance, the Standards Organization would have no responsibility to maintain or correct this artifact. If a standard "Intended for Use" is not developed and approved in terms of time frame or content as expected by the TC at the time of its initial selection, it may be replaced. All standards used by HITSP must meet the HITSP selection criteria. The use of "Interim" and "Intended for Use" standards will be weighed against the alternative of simply declaring a gap for HITSP and the Standards Organizations to resolve.

3.1 LIST OF STANDARDS

It is important to understand that the standards selected here are within the context of the specific Use Case requirements and do not necessarily reflect selection in other contexts. The following standards form the basis of this terminology component:

Table 3.1-1 List of Standards

Standard	Description
College of American Pathologists Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	SNOMED CT consists of a technical design, core content architecture, and Core content. SNOMED CT Core content includes the technical specification of SNOMED CT and fully integrated multi-specialty clinical content. The Core content also includes a concepts table, description table, relationships table, history table, ICD-9-CM mapping, and Technical Reference Guide. Additionally, SNOMED CT provides a framework to manage language dialects, clinically relevant subsets, qualifiers and extensions, as well as concepts and terms unique to particular organizations or localities. Visit www.snomed.org for more information.
Health Level Seven (HL7) Version 2.5/2.5.1[4]	The HL7 Version 2.5 and 2.5.1 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets / code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 5, and 7 including patient demographic (ADT) and lab result reporting. These are also used within composite standards from IHE for Patient Identity Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), and Acknowledgements. Visit www.hl7.org for more information.
Health Level Seven (HL7) Version 3.0	The HL7 Version 3.0 Messaging Standard is an application protocol for electronic data exchange in healthcare. Version 3.0 is based on a Reference Information Model (RIM); which is used to instantiate various message formats. Value sets / code tables are contained in the standard. Visit www.hl7.org for more information.
Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2)	The HL7 Clinical Document Architecture is an XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA is one instantiation of HL7's Version 3.0 Reference Information Model (RIM) into a specific message format. Of particular focus for HITSP Interoperability Specifications are message formats for Laboratory Results and Continuity of Care (CCD) documents. Release 2 of the HL7 Clinical Document Architecture (CDA) is an extension to the original CDA document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. CDA R2 further builds upon other HL7 standards beyond just the Version 3.0 Reference Information Model (RIM) and incorporates Version 3.0 Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and Structures. Visit www.hl7.org for more information.

[4] HITSP references HL7 2.5.1 messaging for lab results reporting and HL7 2.5 for other messages. Future maintenance work will move toward referencing a single HL7 version across HITSP documents.

Standard	Description
Logical Observation Identifiers Names and Codes (LOINC®)	A database of universal identifiers for laboratory and other clinical observations. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), and toxicology; as well as categories for drugs and the cell counts typically reported on a complete blood count or a cerebrospinal fluid cell count. Antibiotic susceptibilities are a separate category. The clinical portion of the LOINC database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, selected survey instruments, and other clinical observations. Visit www.loinc.org for more information.
Unified Code for Units of Measure (UCUM)	A code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units. The focus is on electronic communication, as opposed to communication between humans. Visit aurora.regenstrief.org for more information.

NOTE: While HL7 V2.5 and 3.0 are messaging standards, they include value sets for many of the coded attributes in a message that do not involve external standards.

4.0 COMPONENTS

4.1 CONTEXT OVERVIEW

This component defines the vocabularies and terminologies utilized by laboratories and clinicians to report the findings from laboratory tests. The context is defined by a common scenario where a laboratory has received an order to perform routine tests involving a specimen taken from a patient during an inpatient or outpatient encounter. The laboratory performs the tests. Electronic results are coded according to these specifications for electronic transmission. The sender could be the laboratory or an intermediary such as a clinical repository. The recipient could be an authorized public health agency, an EHR system, or a non-EHR clinical system.

4.1.1 CONTEXTUAL CONSTRAINTS

The constraints on this terminology component are imposed for the sake of defining a path to the future for healthcare interoperability. The lack of consistent terminologies across laboratories and institutions is well known. These inconsistent terminologies pose an obstacle to interoperability and must be addressed before universal roll-out of the HITSP recommended Interoperability Specifications, but early adopters can use this specification by aligning with the recommended vocabularies and implement the supported scenarios sooner. A standard terminology must be defined for Service Identifiers (a code for the type of test). For this Interoperability Specification, the terminology for the Observation Identifier must be LOINC, and the terminology for the observation value should be SNOMED-CT for coding microbiology results.

Typically, laboratories use local codes for Observation IDs and Values. To communicate results according to this Interoperability Specification, the results need to be transmitted in the specified vocabularies. This may be done using mapping tools available today. This mapping process is a constraint for this terminology component.

Universal Service Identifier is a major gap in healthcare interoperability today. While acceptable standards exist for Observation ID and Observation Value, no complete terminology exists for Service Identifier. LOINC offers some coverage, but currently laboratory interfaces require a synchronization of master files to code and interpret the test being requested and performed.

Some implementers of electronic laboratory results reporting today utilize some form of translation between terminologies, especially for Observation Value. It is recognized that the National Library of Medicine (NLM) maintains cross-maps of terms for some of the major coding systems. A subset of these cross-maps can be utilized by a Common Terminology Service (CTS) to provide an equivalent term for a concept in a different terminology.

4.1.2 TERMINOLOGY COMPONENTS: RULES FOR IMPLEMENTING

This EHR Lab Result Terminology Component Specification supports the reporting of laboratory results. The value sets or Code Systems selected for each selected coded attribute in the laboratory results message are shown in the HL7 V2.5.1 Standard. Tables are included here that constrain or vary from HL7 published standards.

The terminologies in this component apply equally to both the HITSP ISC-36 Lab Result Message and the HITSP ISC-37 Lab Report Document. The Care Delivery TC is constructing a mapping between these two representations to make the correspondence between data elements explicit. This mapping will be presented to the HL7 committees that publish the two representations with the expectation that HL7 will maintain the mapping.

HL7 V2.5 OBR - Observation Request Segment

Table 4.1.2-1 HL7 V2.5 OBR – Observation Request segment

Message Element	Terminology	Comments
OBR-4 Universal Service Identifier	(Noted terminology gap)	See discussion under Section 4.1.1

NOTE: The VA/KP Problem List Subset of SNOMED CT should be used in the OBR 31 Reason for Study field.

HL7 V2.5 OBX – Observation Segment

Table 4.1.2-2 HL7 V2.5 OBX – Observation segment

Message Element	Terminology	Comments
OBX-3 Observation Identifier	LAB LOINC	
OBX-15 Producer ID	CLIA ID	May include allowed exceptions.

4.1.3 TERMINOLOGY CONSTRAINTS

Terminologies have subsets for each specific type of laboratory result. In particular, the Laboratory subsets of LOINC and SNOMED, which are used to identify the type of result, have subsets defined by numerous private and public organizations in addition to the subsets defined within the terminology.

Lab LOINC

Table 4.1.3-1 Lab LOINC

Code sets, vocabularies, terminologies and nomenclatures that need to be constrained:	All LOINC lab result codes
Minimum attributes of the component:	Minimum data set = HEDIS (Health plan Employer Data and Information Set) reported tests accounting for 95% of routine Lab orders (Note: ELINCS selections refer to 90% of HEDIS) Category A, B, & C bioterrorism agents/diseases Public Health jurisdiction and Federal reportable disease conditions. Minimum requirements to satisfy CLIA
Other Comments:	We are spelling out what we need to have for today, but need to capture what future considerations are also desirable. Consider requirements for identifying subsets

SNOMED-CT

Table 4.1.3-2 SNOMED-CT

Code sets, vocabularies, terminologies and nomenclatures that need to be constrained:	SNOMED-CT
Minimum attributes of the component:	SNOMED-CT VA Problem List Subset SNOMED-CT Lab Test Findings Table SNOMED-CT Organisms
Other Comments:	VA Problem List Subset same as FDA/DoD/KP subset list

Note: PAP Smears / Bethesda Terminology

5.0 CONSTRAINTS FOR REUSE

This EHR Lab Terminology Component can be reused for a variety of scenarios in addition to laboratory results reporting. The only constraints for reuse are the applicability of the described vocabulary for fields not currently selected for transmission.

5.1 GAPS

There may be need for additional specialized terminologies for particular uses that require further analysis. Candidates previously selected as provisional requiring further analysis include:

- CPT
- ICD-9 CM
- NDF-RT
- COAS
- RxNorm
- HCPCS

6.0 CHANGE HISTORY

6.1 MAY 11, 2007

This document is now Released for Implementation.