North American Association of Central Cancer Registries, Inc.

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Supplement

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Table of Contents

Volume V	/ Supplement Task Force	iv
Preface		v
	oduction	
1.2	Problem Statement, Goals and Scope of this Document Standards and Guidelines for Electronic Transmission of Reports from Patholog tories to Central Cancer Registries	У
1.3	HIPAA Implications for US Laboratories	2
2 Intro	oduction to HL7 Standard Protocols	
	Introduction	
	Differences Between HL7 Versions 2.3.1 and 2.5.1 Standard Protocols	
2.2.1	HL7 Version Does Matter	6
2.2.2	Optionality, Cardinality and the Addition of Usage	6
2.2.3	Changes in Data Types	
2.2.4	New SPM Segment in HL7 Version 2.5.1 and Volume V Version 4.0	7
2.2.5	Codes, Tables, Value Sets, and Coded Data Types	10
2.2.6	Value Sets Defined in Volume V	10
2.2.7	HL7 Backward-Compatibility Rules	12
2.2.8	Enhancements/Additions to the ORU R01 Message	13
2.2.9	ORU - Unsolicited Transmission of an Observation Message (Event R01)- HL7 V	ersions
	and 2.5.1	
2.3	Differences Between Volume V Versions 2.2 and 4.0	14
2.3.1	Text Based Pathology Reporting	14
2.3.2	Text and Synoptic Based Reporting	
2.3.3	HL7 Backward Compatibility Rules as Applied in Volume V	15
	mary of Updates in Volume V Version 4.0 Recommended for Use by	
	enters of Volume V Version 2.2	
	Introducing New LOINC Codes in Volume V Version 4.0	
3.1.1	Impact of New LOINC Codes on Laboratory Reporting to Cancer Registries	
3.1.2	Forward Adopting of New LOINC Codes in HL7 Version 2.3.1	16
3.1.3	Work in Progress (New Tumor Marker Tests and LOINC Codes)	
3.1.4	Errata in Volume V Version 4.0	17
	eral Notes and Cautions	
	Corrected and Amended Reports	
	Escape Sequences and Text Formatting	
4.3	Use of Strikethrough Characters in Amended/Corrected Reports	21

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Preface

This supplement documents the updates and changes introduced in the North American Association of Central Cancer Registries, Inc. (NAACCR) Standards for Cancer Registries, Pathology Laboratory Electronic Reporting Volume V Version 4.0 (Volume V Version 4.0) and shows through specific examples how they relate to NAACCR Standards for Cancer Registries, Pathology Laboratory Electronic Reporting Volume V Version 2.2 (Volume V Version 2.2). In producing Volume V Version 4.0 the NAACCR Pathology Data Work Group created an implementation guide which contained the standard specifications for electronic pathology reporting using Health Level Seven International (HL7) Version 2.5.1. At that time, it was decided not to update Volume V Version 2.2 (which is based on HL7 Version 2.3.1) because HL7 Version 2.3.1 was no longer actively supported by HL7 and did not contain the robustness to handle specimen specific information.

However, adoption of HL7 Version 2.5.1 has not been as fast as originally anticipated in the U.S., and HL7 Version 2.3.1 continues to be the most widely supported version among pathology laboratory information systems. The aim of this Supplement is to provide potential implementers, such as enterprise architects and interface developers, cancer registry administrators and technical staff with information about the two specifications for electronic pathology reporting to cancer registries to help them decide which version of the reporting standard to select, depending on the capabilities of their systems architecture, and future plan.

It is the hope of the NAACCR Pathology Data Work Group that this Supplement will make it easier and less costly for pathology laboratories, central cancer registries, and software vendors to implement uniform, standard methods for the transmission and receipt of electronic pathology reports, be that using HL7 Version 2.5.1 (as specified in Volume V Version 4.0) or using HL7 Version 2.3.1 (as specified in Volume V Version 2.2). Our goal is to develop resources that will support current and future initiatives toward standardization through the recommended communication protocols that will assure the collection of reliable, accurate, and timely pathology reports of cancer specimens examined by pathology laboratories.

The NAACCR Standardization and Registry Development Steering Committee Chair and the Volume V Supplement Task Force Lead would like to acknowledge the dedicated members of the Pathology Data Work Group (disbanded May 2013), as well as the members of the Volume V Supplement Task Force for their time, effort and dedication in the production of this document.

Sincerely,

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1 Introduction

Cancer surveillance is a cornerstone of cancer control decision-making and can be used to trigger case investigations, follow trends, evaluate the effect of prevention measures, and suggest public health priorities. Since most cancers are definitively diagnosed by histology, cancer surveillance programs use pathology reports to identify new cases and collect information on previously reported cases. This document specifically relates to the electronic transmission of pathology results from the laboratory to a central cancer registry.

1.1 PROBLEM STATEMENT, GOALS AND SCOPE OF THIS DOCUMENT

The Problem

Historically, central cancer registries in the U.S. and Canada have acquired pathology reports through a voluntary manual/paper process. This presents a problem for North American central cancer registries in their quest for complete and accurate case ascertainment since hospital and non-hospital sources are often regionally dispersed and data from non-hospital sources are typically under-reported. There is also considerable variability in sophistication of lab information systems (LIS), which can make interoperability and data transmission (i.e. message content) challenging.

For labs who can transmit electronically and currently do so, there is a fundamental need for the standardization of electronic messages sent to central cancer registries in either HL7 Version 2.3.1 or 2.5.1 to ensure that data transmits completely, accurately and consistently following the same governance, no matter where it is generated in North America, regardless of jurisdictional case ascertainment rules for reportability.

NAACCR is an international standard-setter for the reporting of pathology results to central cancer registries in the U.S. and Canada. Currently there are two accepted NAACCR standards for developers to follow depending on the export capabilities of the LIS and import capabilities of the central cancer registry application database.

It is often difficult for the potential (novice) user to decide which version of the standard to select because there are important differences between the two. The standards are large, detailed volumes, and the differences are not readily apparent. This document provides a user-guide to illustrate the differences so developers clearly understand the requirements when setting up new systems or upgrading existing feeds.

The Proposed Solution

The Volume V Supplement Task Force has developed this Supplement as a companion to the Volume V Version 2.2. This document will assist those engaged in electronic feed planning and/or development at pathology laboratories, cancer registries and software vendors to quickly compare the two NAACCR standards in order to make well informed implementation decisions.

Scope of This Document

The scope of this document is limited to standards and guidelines to transmit cancer information from pathology laboratories to cancer registries, as specified in Volume V Version 2.2 and/or Volume V Version 4.0, mentioned above. The standard format documents address data items, data item definitions, and transmission specifications. Implementation guidelines and business rules are incorporated to help cancer registries, pathology laboratories, and vendors within North America respond to the call for cancer cases in a uniform method.

Reportable tumor definitions are not included in the Scope of this document. Standards for reportability are defined by national standard-setting organizations in NAACCR Standards

Volume II, Data Standards and Data Dictionary, Chapter 3 and are available from the central cancer registry in your region, state or province.

1.2 STANDARDS AND GUIDELINES FOR ELECTRONIC TRANSMISSION OF REPORTS FROM PATHOLOGY LABORATORIES TO CENTRAL CANCER REGISTRIES

The Supplement frequently refers to two versions of NAACCR standards for transmitting electronic pathology laboratory reports to central cancer registries. The NAACCR Standards Volume V documents are designed for those in information technology, and assume a certain level of technical (i.e. HL7) knowledge by the user, which is available on the NAACCR standards website (www.naaccr.org).

- Standards for Cancer Registries Volume V: Pathology Laboratory Electronic Reporting, Version 4.0 (March 2011) for the export of results in HL7 2.5.1
- Standards for Cancer Registries Volume V: Pathology Laboratory Electronic Reporting, Version 2.2 (February 2009) for the export of results in HL7 2.3.1

In addition, the *NAACCR Electronic Pathology* (*E-Path*) *Reporting Guidelines* (*September*, 2011) manual was designed for those in registry and laboratory operations, with the purpose of describing procedural guidelines and business rules for implementing electronic pathology reporting from a pathology laboratory to a cancer registry.

1.3 HIPAA IMPLICATIONS FOR US LABORATORIES

In the U.S., the Health Insurance Portability and Accountability Act (HIPAA, or the Act), P.L. 104-191, enacted on August 21, 1996, includes provisions related to insurance coverage and a section that is relevant to electronic reporting of health care information. HIPAA requires that standards be adopted for certain uniform financial and administrative transactions, data elements, and security of electronic health information systems. It also includes provisions for adopting standards for the privacy of health information. The Act preempts state laws and imposes civil monetary penalties and prison terms for certain violations.

HIPAA also imposes changes in the membership and duties of the National Committee on Vital and Health Statistics (NCVHS). There is a provision that the NCVHS will make recommendations and legislative proposals to the Secretary, Department of Health and Human Services, on the adoption of uniform data standards for patient medical record information and the electronic exchange of such information. HIPAA addresses state regulatory reporting by stating, "[N]othing in this part shall limit the ability of a State to require a health plan to report, or to provide access to, information for management audits, financial audits, program monitoring and evaluation, facility licensure or certification, or individual licensure or certification."

For public health authorities, HIPAA states, "Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention." Covered entities that are named in the HIPAA legislation are "health plans, health care clearinghouses, and health care providers who transmit any health information in electronic form in connection with a transaction referred to in Section 1173(a) of the Act." The regulation implementing the HIPAA privacy provisions allows public health exemptions for disclosure without patient consent of individually identifiable health information for the purposes quoted above.

Under HIPAA, state cancer registries qualify as public health authorities operating as agencies authorized by law to "collect or receive such information for the purposes of preventing or controlling disease... and for the conduct of public health surveillance, public health investigations, and public health interventions" (45 CFR 164.512). As such, public health reporting to state agencies from pathology laboratories is exempt from HIPAA privacy rules. Pathology laboratories, as covered entities, may report this public health information to state cancer registries using the HL7 Standard as described here; HIPAA provisions will not alter these reports.

2 Introduction to HL7 Standard Protocols

HL7 is a standards development organization creating and publishing standards for computer communication of health information, and adopted in dozens of nations around the world. It has been in existence for over 25 years, and has been implemented in almost 100 % of inpatient hospitals in the U.S. and Canada. It has grown over the years to be a large set of specifications covering a broad swath of communication needs in healthcare, and has been adopted officially for various functions by several different countries, including the U.S. and Canada.

HL7 has published standards based upon different technologies and addressing different types of integration architectures. Of the many different types of widely used HL7 standards, those known as "Version 2.x" have been selected for use in cancer registry reporting as described in the Volume V Versions 2.2 and 4.0.

There have been 9 official releases of the Version 2.x standards by HL7 over the past 25 years; the releases explicitly addressed in the Volume V standards are HL7 Versions 2.3.1 and 2.5.1. These standards are available at no cost from HL7 (<u>http://www.hl7.org</u>).

2.1 INTRODUCTION

The HL7 Version 2.x standard is published in pdf (Adobe Acrobat reader) format as a document with multiple chapters (12 plus 5 appendices in HL7 Version 2.3.1, 15 chapters and 5 appendices in HL7 Version 2.5.1) separate pdf files. The total size of the standard is large, in excess of 1000 pages, but only a portion of it is applicable to cancer registry messaging. Therefore relative short excerpts of parts of the HL7 standard have been included in Volume V; it is not the entire standard, nor does it have all of the detailed information contained in the HL7 standard.

HL7 Version 2 is a 7-bit ASCII text-based point-to-point messaging protocol which is intended to be carried on a robust communication infrastructure, such as TCP/IP. HL7 does not specify any details of the physical or base communication infrastructure, but is entirely devoted to healthcare specific data structures, such as Patient (PID), Doctor (ORC or OBR), Lab Result (OBX), etc. As all data are text, any numeric or binary data must be translated to/from text between the HL7 interface and any database or applications. Extended encoding types are supported for things such as 2-byte Asian character sets and binary data, but the techniques are similar to those used in carrying such data in email over SMTP, which is also a text-based protocol. For further details, see Chapter 2 of the HL7 standard.

HL7 Version 2 is a delimited protocol, using special characters to mark the different elements in a transaction. It is also a nested protocol, where large-grained data items (e.g. Patient) contain smaller-grained items (e.g. Patient Address) which in turn contain yet smaller items (e.g. City).

The largest grained structures are defined as "Segments", and they contain "Fields" of data. Each Field is one of several different "Data Types" which may in turn contain finer-grained sub-fields. Each Segment is labeled, and is delimited by a Carriage Return character (13 decimal, 0D hexadecimal). As HL7 is delimited, each of the data items appears in a particular sequence of delimited items; this is also known as "ordinal" (for 'ordered') and the items in HL7 are often referred to by their position (e.g. PID-11.3 is the 3rd component of the 11th field in the PID segment, which is the 'City' of the Patient Address). In other words, messages contain Segments; the hierarchy does not extend below this level however. For more information on encoding and data types, see Chapter 2 of the HL7 Version 2 standard.

HL7 groups these data structures into a "Message", which contains all the information necessary to support a particular business event. Each HL7 message is explicitly associated with a specific business event (e.g. Admit Patient, Send Laboratory Result, etc.). There are hundreds of such events documented in the latest HL7 standard, each with its associated message. The architecture of HL7 Version 2 interoperability is based on the concept that upon the occurrence of a real-world business event in an institution, data are to be transmitted between computer systems in that institution. No HL7 transactions occur without being initiated by an explicit real-world event. HL7 is also designed to provide a handshake mechanism, and every message sent from one system to another is acknowledged with a special acknowledgement message, which can contain information if an error has occurred.

Many HL7 data items are coded, i.e. they are members of a "controlled vocabulary" or "terminology". HL7 defines hundreds of small code sets, which are called 'Tables' in HL7 Version 2. Some of these are required to be used, others are merely suggested values (which are often used as-is in the health information technology community). Still others are drawn from published standards in the community at large, such as the Logical Observation Identifiers Names and Codes (LOINC), SNOMED Clinical Terms (CT), ICD-9-CM, International Organization for Standardization (ISO), and others.

Over the past 25 years as HL7 has improved new releases of the Version 2 standards, the primary changes have been the addition of new messages, new segments, new fields, and new data types. As the data architecture is a delimited protocol, all new items must be added at the end of existing items in order to facilitate backward compatibility. It is the close adherence to these rules and the ability of systems implementing different releases of HL7 Version 2 to operate together that has contributed to the wide acceptance of HL7 Version 2 in the (Health Information Technology) (HIT) community. For more information on the rules governing backward compatibility, see section 2.2.7 below.

2.2 DIFFERENCES BETWEEN HL7 VERSIONS 2.3.1 AND 2.5.1 STANDARD PROTOCOLS

HL7 Version 2.3.1 was released in 1999 and HL7 Version 2.5.1 was released in 2007. During those 8 years, significant enhancements were made to the HL7 Version 2 standards, and the specification itself grew by nearly 30%. In terms of effect for cancer registry messaging however, the changes were smaller; the primary data structures carrying laboratory results from laboratories to registries, and their acknowledgement messages, had only one major change and several minor ones. The larger changes for HL7 Version 2.5.1 are not widely used in cancer registry messaging at this time. Volume V Version 2.2 was based on HL7 Version 2.3.1, and initially released in 2007. Volume V Version 4.0 based on HL7 Version 2.5.1 went through several releases in subsequent years.

The major change is the addition of a segment known as the SPM (Specimen Segment). This is entirely new in HL7 Version 2.5.1, and contains a myriad of details of collected specimens on which analyses have been performed. This segment did not exist in 1999 when HL7

Version 2.3.1 was released. For more information on the SPM segment, see section 2.2.4 below.

The minor changes from HL7 Version 2.3.1 to HL7 Version 2.5.1 are listed in Table 1 below.

	NAACCR Standards	NAACCR Standards	
	Volume V Version 2.2	Volume V Version 4.0	T.T.
HL7 Field	HL7 Version 2.3.1	HL7 Version 2.5.1	Usage
	(Data Type)	(Data Type)	
Field, sub-field		Increased	
length			
MSH-21	Conformance Stmt ID (ID)	Message Profile Identifier (EI)	RE
PID-31	n/a	Identify Unknown Indicator (ID)	RE
PID-32 new	n/a	Identity Reliability Code (IS)	RE
PID-39 new	n/a	Tribal Citizenship (CWE)	RE
NK1			these fields are not used
ORC-28 new		2 additional fields added to end of segment	RE
ORC-31 new	n/a	Confidentiality Code (CWE)	CE
OBR-49 new	n/a	Parent Universal Service Identifier (CWE)	RE
OBR-50 new	n/a	Result handling (IS)	CE
OBX-23 new	n/a	Parent Universal Service Identifier (CWE)	RE
OBX-24 new	n/a	Performing Organization Name (XON)	RE
OBX-25 new	n/a	Performing Organization Address (XAD)	Х
SPM 1-31 new	n/a	Ability to collect additional detail about a specimen upon which analysis has been performed	*see section 2.2.4
Data type	n/a	Performing Organization Director (XCN)	*see section 2.2.3 for additional information
		multiple new fields added to end of many data types	*see section 2.2.2 for additional information
Data tables		explicit definition of conformance usage for all data	*see sections 2.2.5 & 2.2.6
		items & components of data	for further
		types	discussion of
			vocabulary differences
			between the
			versions.

	Table 1. Differences between HL7 Versions 2.3.1 and 2.5.1 reflected in the NAACCRStandards Volume V Versions 2.2 and 4.0				
HL7 Field	HL7 FieldNAACCR Standards Volume V Version 2.2 HL7 Version 2.3.1 (Data Type)NAACCR Standards Volume V Version 4.0 HL7 Version 2.5.1 (Data Type)Use		Usage		
		multiple new values added to many of the data tables	*see section 3.1 for additional information		
ORU R01		explicit list of new LOINC codes is defined specifically for use in Cancer Registry Messaging	*see section 2.2.8 for additional information		

2.2.1 HL7 Version Does Matter

A receiving system at a cancer registry which has implemented HL7 Version 2.3.1 may be able to accept and process HL7 Version 2.5.1 messages. However, if certain key pieces of information in the cancer report are contained in data items that are only specified in HL7 Version 2.5.1, the cancer registry system will not be able to receive or process that information. Backward compatibility merely ensures that the interface will not generate fatal errors and fail.

The version of HL7 used to construct the message must be declared in MSH-12 for correct message processing at the receiving facility.

Lab and registry teams will need to engage in thorough testing during the feed development phase to flag and resolve data transmission errors and/or omissions.

2.2.2 Optionality, Cardinality and the Addition of Usage

Optionality	A property defined in early iterations of the HL7 standard (e,g., HL7 Version 2.3.1) to provide maximum implementation flexibility between systems.
Cardinality	Governance regarding which segments within HL7 standard messages are allowed to repeat, and to what extent.
Usage (new in HL7 Version 2.5.1)	Explicitly identifies whether a sending system is required to populate a particular data item if the data are available, and whether a receiving system is required to be capable of processing the data, if contained in a message.

As of HL7 Version 2.5.1, an extensive set of specifications for documenting conformance to HL7 interfaces was introduced. This is described in detail in HL7 Version 2 Chapter 2.12, and is now widely referenced and used to improve ability to interface HL7 systems. One of the key provisions is the introduction of the concepts of "Usage" and "Cardinality" to augment the standard "Optionality".

The original published HL7 standards defined a property known as "Optionality" to every field in a segment. This was done because many of the data fields in a particular message may not be appropriate for use in a specific set of applications. However, this results in a specification that is overly vague and difficult for IT professionals to implement consistently. The new "Usage" property is a constraint on the existing optionality, and explicitly identifies whether a sending system is required to populate a particular data item if the data are

available, and whether a receiving system is required to be capable of processing the data if it is in a message. This directly informs developers as to the necessary software to be implemented. In addition, for those fields that may repeat, "Cardinality" places an upper bound on the number of repetitions that a receiving system is required to accept and process.

Both Cardinality and Usage are applied to Fields in Segments, and Components of Fields (those of complex data types with multiple components). HL7 has stated that these are required elements of HL7 Version 2 Implementation Guides for those interfaces based on HL7 Version 2.5.1 and later.

2.2.3 **Changes in Data Types**

The HL7 Version 2.x messaging protocol specifies how the message should be constructed using "segments", "fields", "components", and "sub-components" and each field, component or sub-component will have a defined data type, which defines the format and the type of data to be used. Examples of data types are: text string (ST), number (NM), date and time typically sent in a "time-stamp" (TS) or the complex data type (XPN) used to code all the parts that make up a person's name. Defined data types facilitate interoperability.

Data types used in Volume V are included in Version 2.2, Section 2.8, while Version 4.0 lists data types in Appendix B. Please note, if a field is not supported (i.e. not used), then that data type is not included in either version of Volume V.

	The provide state of the provi				
Standards Volun	ne V Versions 2.2 and	d 4.0		-	
	NAACCR		NAACCR		
	Standards Volume		Standards Volume		
HL7 Field	V Version 2.2	Description	V Version 4.0	Description	
	HL7 Version 2.3.1		HL7 Version 2.5.1		
	(Data Type)		(Data Type)		
MSH-9 Message	СМ	Composite data	MSG	Message type	
Туре		(a combination of			
		other meaningful			
		data fields)			
MSH-21	ID	ID value is drawn	EI	Entity identifier	
Conformance		from a table of			
Statement ID		legal values			
OBR-15	СМ	See above	SPS	Specimen source	
Specimen					
Source					
OBR-32	СМ	See above	NDL	Name with date	
Principal Result				and location	
Interpreter					

Table 2. Differences between HL7 Versions 2.3.1 and 2.5.1 reflected in the NAACCR

New SPM Segment in HL7 Version 2.5.1 and Volume V Version 4.0 2.2.4

A major change from HL7 Version 2.3.1 to Version 2.5.1 was the addition of a new segment, SPM, to carry specimen information. In Volume V Version 2.2, specimen information is carried in different segments: OBR-3 Filler Order Number/Accession Number, OBR-10 Collector Identifier, OBR-14 Specimen Received Date/Time, and OBR-15 Specimen Source. However, for complex cases involving multiple specimens (such as a 12-point prostate biopsy with 12 samples tracked separately), results involving multiple laboratories and/or different studies conducted on the same specimen, this set of fields has proven insufficient. There is no standard way to carry this level of detail in HL7 Version 2.3.1 segments.

As a response to this issue, HL7 introduced the SPM Specimen segment in HL7 Version 2.5, and NAACCR incorporated the use of the SPM segment into the Volume V Version 4.0 as an optional component. Recognizing that many laboratories may lack the ability to populate and send SPM segments, careful guidance was put in place by NAACCR to describe complex case encoding using both the HL7 Version 2.5.1 messages with the SPM and/or without it. Over time, it is hoped that more laboratories will use the SPM segment for complex multi-specimen cases as they upgrade the HL7 interfaces in their systems and tie-in complex data from their lab information systems.

			ing in HL7 Versions ne V Versions 2.2 an	
HL7 Field	NAACCR Standards Volume V Version 2.2 HL7 Version 2.3.1 (Data Type)	Description	NAACCR Standards Volume V Version 4.0 HL7 Version 2.5.1 (Data Type)	Description
OBR-3 Filler order number (Accession number) - R	EI	Entity identifier	EI	Entity identifier
OBR-10 Collector Identifier - RE	XCN	Extended composite ID # and name	XCN	Extended composite ID # and name
OBR-14 Specimen Received Date - RE	TS	Time Stamp	TS	Time Stamp
OBR-15 Specimen Source - R	СМ	Composite	SPS	Specimen source
SPM-1 Set ID- SPM - RE			SI	Sequence ID
SPM-2 Specimen ID - R			EIP	Entity identifier pair
SPM-3 Specimen Parent IDs - RE			EIP	Entity identifier pair
SPM-4 Specimen Type - R			CWE	Coded with exceptions
SPM-17 Specimen Collection Date/Time - RE			DR	Date/time range
SPM-18 Specimen Received Date/Time - RE			TS	Time Stamp
SPM-21 Reject Reason - RE			CWE	Coded with exceptions
SPM-26 Number of specimen containers – RE			NM	Numeric
SPM-29 Specimen Child Role – C			CWE	Coded with exceptions
SPM-31 Accession ID			CX	Extended composite ID with check digit
SPM-31 Other Specimen ID - RE			CS	Coded simple value

Implementing the SPM Segment in HL7 Version 2.5.1

As illustrated in Table 3, when the SPM segment is used, the SPM-2 Specimen ID field is required. This will carry the accession number and be the same as OBR-3 Filler Order Number for simple single specimen cases.

However in multi-specimen cases, or where the specimen has been subdivided and the individual parts tracked, this field will contain the unique identifier for the specimen associated with the result set. Note that the structure of the HL7 Version 2.5.1 ORU_R01 message allows multiple SPM segments, each with its own associated set of specimen-specific results, to be carried in the message.

When a specimen is divided into pieces and each part is tracked separately with its own set of results, the SPM-3 Specimen Parent ID is used to carry the identifier of the specimen that each part was taken from. For cancer reporting, this field does not repeat. When parts of specimens are sent to reference laboratories (ie. if Lab A sends a sample to Lab B for further analysis) the SPM-31 Other Specimen ID field may contain a list of other specimen identifiers related to this case that were assigned by other organizations. This helps registries associate all relevant data to specific cases.

The segment SPM-30 Accession ID explicitly holds the accession number for the specimen; this is especially important for circumstances where the OBR-3 Filler Order Number contains a number that is a key to the report but may not be the accession number. **NOTE: When these numbers are different the accession number must be transmitted in SPM-30**. The SPM-30 segment may repeat, and therefore include the list of all accession numbers related to the case that the result may contain (which occasionally happens when multiple specimens for the same case arrive at different times at the laboratory).

There are separate fields for SPM-17 Specimen Collection Date/Time and SPM-18 Specimen Received Date/Time. Occasionally these are important to know, as the collection time is the clinically relevant time for interpreting the results, but on occasion a late received date/time can inform degradation issues from specimens too long in transit.

The final additional fields of information carried in the SPM segment for NAACCR reporting are SPM-21 Specimen Reject Reason and SPM-26 Number of Specimen Containers. These fields are less relevant for cancer registries, but when the HL7 message is used to transmit information from the laboratory back to the hospital where the specimen was collected, these fields can inform cases where something was not analyzed by the laboratory for some reason. In cases where the test could not be performed due to the condition of the specimen, SPM-21 can hold up to two reasons for the laboratory rejection of the specimen. When one or more containers are not processed for some reason, SPM-26 can be used to determine the reason for potentially incomplete case results.

It is recommended that laboratories use the SPM segment when the specimen information is detailed and complex. Volume V Version 4.0 has simple and complex multi-specimen case examples illustrating how this additional information may be transmitted in the SPM segment (see Appendix D, section D.1.3 and section D1.4).

2.2.5 Codes, Tables, Value Sets, and Coded Data Types

Many data items carried in cancer registry messages are drawn from limited numbers of specific values. Each of these specific values has a particular meaning, and is usually referred to as a 'code'. Some of these are used widely, such as ICD-O-3 (International Classification of Diseases, Oncology, 3rd Edition), the codes employed to indicate site, histology, behavior and grade. Others are less widely known, such as the HL7 codes for types of identifiers (HL7 Table 0203 Identifier Type). A common understanding and use of the codes in the messages are critical to correct transmission of meaning, as these codes provide much of the underlying vocabulary in the communication. Shared vocabulary is the key to interoperability.

Code values are carried in fields of data types such as, ID (coded values for HL7 tables), IS (coded values for user-defined tables), CWE (coded with exceptions), and CNE (coded with no exceptions), and have historically been listed in tables in HL7 v.2.x standards. Increasingly however, the North American health information technology sector is making use of the concept of 'Value Sets' to define collections of coded values to be used in one data field or another. These 'Value Sets' are typically a subset of the larger number of codes published by HL7 and others.

In its simplest form, a Value Set is a list of coded values similar to a table. However, a Value Set explicitly references its underlying code system so that users of the codes have access to additional properties of the coded values, such as their positions in hierarchies (for values that are in a hierarchy), or other relationships for complex terminologies, such as SNOMED CT. More complex representations of Value Sets are currently in use in North America, but discussions of those are out of scope for the use of Volume V cancer registry messaging.

Value Sets are important when other related standards are used to transmit information. For example, a central cancer registry may need to transform or convert an HL7 CDA message (used by physicians for cancer reporting) into a Volume V Version 2.2 compliant message. In this case, Value Sets are crucial for such translation/transformation. NAACCR code tables (Value Sets) are included in Volume V Version 2.2, Chapter 2 and Volume V Version 4.0, Appendix A.

2.2.6 Value Sets Defined in Volume V

The code tables in Volume V contains only the coded concepts that are part of the Value Sets used in Volume V messaging. The HL7 standard will usually have more values than the Value Set listed in Volume V. In some cases, HL7 has suggested values to be used whereas in other cases there are no suggested values.

The values listed in Volume V Version 4.0, Appendix A have been approved by the NAACCR Volume V Work Group and must be used for cancer registry messaging; the values listed are considered to be the most commonly used set for most cancer registries and/or jurisdictions. All tables with values should be treated as if they are HL7-defined tables. This means that if the concept to be conveyed has a code listed in Appendix A for the table in question, that code must be used.

Appendix A of Volume V Version 4.0 contains updated HL7-defined tables as well as User-defined tables.

Adding Unique Codes to NAACCR Value Sets

Developers are asked to check whether the concept of interest exists in the standard code system from which the Volume V Versions 2.2 and 4.0 set of values has been drawn, before creating local codes and attempting to send those to the cancer registry.

However, if this route proves unsuccessful, a local code may be created by the sender (e.g. the lab), but the receiving cancer registry *must approve* the use of the additional code before any message can be transmitted to that registry.

Subsequently, it is incumbent on the cancer registry to communicate the new code(s) to NAACCR so that they may be evaluated for inclusion in future revisions of the Volume V standard.

Example 1. PID-10 Adding a new race indicator from a different code system

How does a jurisdiction encode a race in PID-10 which is not currently included in the code table? For example, the American Indian 'Pawnee' tribe?

Appendix A, Table 0005 - Race lists a number of race codes values. If it isn't desirable to 'roll-up' the detailed concept into the higher level concept "1002-5 American Indian or Alaskan Native" in the published list of codes, the code for 'Pawnee' (defined as 1445-6) could be suggested to the receiving cancer registry.

The preferred code system for race indicators is the Centers for Disease Control and Prevention (CDC) Race and Ethnicity code system 2.16.840.1.113883.6.238 ph-RaceAndEthnicity-CDC which has a Table 0396 mnemonic to use – "CDCREC". The resulting PID-10 field should therefore be encoded:

... |1445-6^Pawnee^CDCREC|...

Example 2. PID-16 Adding a new local value for Marital Status in Table 0002

Some jurisdictions may want to transmit marital status as 'civil union', which is a legal status in some jurisdictions.

Appendix A, Table 0002 - Marital Status (used in PID-16) lists 5 coded concepts but there is no code for 'civil union'. So the sending system must contact the cancer registry with a request to use a custom or locally-defined code for this concept, such as 'C – civil union'.

Upon approval from the cancer registry, the code 'C' may be transmitted in PID-16 for marital status, and this code is then communicated by the cancer registry to NAACCR for future evaluation and potential inclusion in Volume V.

The resulting PID-16 field should therefore be encoded as:

...|C^Civil union^L|...

where the code system is sent as "L" indicating a local value that has been added.

There are a number of fields used in the cancer registry message which are of data type ID (coded values for HL7 tables) or IS (coded values for user-defined tables).

These data types include only the code value, and do not include the code system mnemonic or table number in the field itself; the code system or table the code is drawn from is indicated only in the Volume V specification. For fields of this type, only the code is transmitted, not the display name or the code system. An example of such a field is PID-8 Sex, which is used to indicate the gender of the patient, and is data type IS. This field is drawn from table 0001. For a patient who is male, this field would be encoded as:

...|M|...

Another field of this type is OBX-2 Value Type, which is of data type ID. The values to be used in this field are drawn from table 0125, as shown in the segment layout, in the column labeled 'Tbl#'. A typical example of this is:

 $\dots |FT| \dots$

indicating that the OBX carries Formatted Text data.

Variation in Code Table Usage Between Volume V Versions 2.2 and 4.0

In Volume V Version 2.2 User-defined Table 0171 is referenced in PID-26 [Citizenship] a CE (coded element) data type, using ISO Table 3166 as the suggested values.

However, PID-26 Citizenship is not supported in Volume V Version 4.0. Instead, the reference to User-defined Table 0171 is with respect to PID-39 [Tribal Citizenship], a CWE (coded with exceptions) data type. The preferred HL7 code set is the U.S. Bureau of Indian Affairs (BIA) Tribal Identity List, but when this is not sufficient, coders may create a local definition in User-defined Table 0171, as illustrated in Table 4, which follows.

Table 4. Compari	Table 4. Comparison of User-defined Table 0171 Reference in NAACCR Standards Volume					
	NAACC		rsions 2.2 and 4 Is Volume V 2.2	4.0 NAACCR Standards Volume V Version 4.0		Volume V
	Н	L7 Version (Data Typ		HL7 Version 2.5.1 (Data Type)		
HL7 Field	Data Type	Status	Reference	Data Type	Status	Reference
PID-26 Citizenship	CE	Not supported	Use ISO Table 3166 as the suggested values in User- defined Table 0171 – Citizenship. See page 29.	CE	Not Supported	
PID-39 Tribal Citizenship				CWE	RE	BIA Tribal ID List (USA) or local definition using User- defined Table 0171 (see p. 71)

Note that user-defined table 0171 is used in Volume V Version 4.0 only for PID-39 Tribal Citizenship.

2.2.7 HL7 Backward-Compatibility Rules

The concept of backward compatibility as outlined in the HL7 Standard is summarized in this section. This section is to be used in conjunction with Volume V Versions 2.2 and 4.0, which include HL7 Versions 2.3.1 and 2.5.1 respectively. The objective of backward compatibility is to ensure that HL7 message interpreters (i.e. parsers) that have been programmed for a

given (newer) version of a message format continue to function unabated when a message formatted in an older version is received.

The messages, segments, fields, and components are modular; in that they can be modified when the need arises. This can cause havoc for receiving applications, if they do not follow the backward compatibility rules for HL7. The sending applications must also follow guidelines to allow receivers to properly interpret the messages.

The main principles receivers must follow are:

- to process new versions of messages
- to ignore any information they cannot interpret, while continuing to process older version of messages, as stated above.

If a sending application upgrades an electronic pathology feed from HL7 Version 2.3.1 to Version 2.5.1, subsequently moving from Volume V Version 2.2 to Volume V Version 4.0 message structure, in order to ensure compatibility at the receiving facility, developers must ensure that:

- newly added segments do not disturb the original content of the message, and must follow the original message data layout (e.g., the data layout of an ORU),
- new fields are added at the end of a segment,
- new components are added after the last component of an existing data type, and
- required segments are never removed from a later version of the same message but may be marked as no longer used.

2.2.8 Enhancements/Additions to the ORU R01 Message Introduction- Unsolicited Trigger Events

Observations, such as for example, pathology results, or other laboratory test results, may be transmitted in a solicited (in response to a query) or unsolicited mode. **Reporting to central cancer registries by pathology laboratories is an example of observations transmitted in the unsolicited mode.** These are new observations, the results of which are sent to the registry based on an agreed upon schedule (for example, daily, weekly, monthly, quarterly). The solicited mode is in response to a query, which polls the system based on specific criteria and permissions, retrieving 'old' observations.

Trigger events: The HL7 standard is written with the assumption that an event in the real world of health care delivery creates the need for data to flow between systems. The real world event is called the trigger event. An example of a trigger event: a patient is admitted to the physician office or hospital, this in turn 'triggers', i.e., causes the need for data about that event (and patient) to be sent to a number of other systems. Another trigger event could be the patient's elevated CBC result, which may cause the need for that observation to be sent to a number of other systems. When the transfer of information is initiated by the application system that deals with the triggering event, the transaction is called an unsolicited message or unsolicited update.

2.2.9 ORU - Unsolicited Transmission of an Observation Message (Event R01)- HL7 Versions 2.3.1 and 2.5.1

The table below shows the ORU (Observational report - Unsolicited) message, as described in the HL7 Versions 2.3.1 and 2.5.1 standards. These are shown side by side, in order to better illustrate any changes from HL7 Version 2.3.1 to Version 2.5.1. (Primarily the introduction of the SPM segment).

ORU^R01	ORU^R01	Observational Results	HL7 Standard	HL7 Standard
HL7 Version	HL7 Version	(Unsolicited)	Version 2.3.1	Version 2.5.1
2.3.1	2.5.1	(Onsolicited)	Chapter	Chapter
MSH	MSH	Message Header segment	2	2
WISH	[{SFT}]	Software segment	<u>ک</u>	2
([{3F1}]	-Patient Result begin		2
<u>۱</u>	{ 	0		
		Patient begin	2	2
PID	PID	Patient Identification	3	3
(5) 17(1)	(1) 12 (1)	segment	2	2
{[NK1]}	{[NK1]}	Next of Kin segment	3	3
[PV1]	[PV1]	Patient Visit segment	3	3
]]	Patient end		
{	{	Order Result begin		
[ORC]	[ORC]	Common Order segment	4	4
OBR	OBR	Observations Report ID	4	4
		segment		
{[NTE]}	{[NTE]}	Notes and Comments	2	2
		segment		
{	{	Results begin		
[OBX]	OBX	Observation/Result	7	7
		segment		
{[NTE]}	{[NTE]}	Notes and Comments	2	2
		segment		
}	}	Results end		
	[{	Specimen Information		
		begin		
	SPM	Specimen segment		7
		Observation Related to		7
	{[OBX]}	Specimen		
	}]	Specimen Information	1	
		end		
}	}	Order Result end	1	
}	}	-Patient Result end	1	
[DSC]	[DSC]	Continuation Pointer	2	2

Notations:

{ } This segment or group may repeat.

[] This segment or group is optional.

2.3 DIFFERENCES BETWEEN VOLUME V VERSIONS 2.2 AND 4.0

2.3.1 Text Based Pathology Reporting

Pathology data are traditionally captured and reported in a text-based format. A text-based pathology report is a narrative that includes a block of text that describes specific information from the pathologist's review of the case. In many laboratories, pathologists dictate their findings for transcriptionists to enter the textual case findings into the laboratory information system. These textual data are not easily used or analyzed. Processing of these data requires sophisticated algorithms to automate searching the text to identify key words to assist the certified tumor registrar with processing the case. There are limitations to the sensitivity and specificity of these tools, so human intervention is necessary to process the case. Please refer to the <u>NAACCR Volume V: Pathology Laboratory Electronic Reporting, Version 2.2</u> and the <u>NAACCR Electronic Pathology Reporting Guidelines</u> documents for additional information.

2.3.2 Text and Synoptic Based Reporting

With the movement to standardize electronic health records for meaningful use and the work underway with the College of American Pathologists (CAP), laboratories are slowly moving toward a more standardized, coded pathology report format. The traditional narrative reports are being structured to formally divide the information into explicit items for a specific observation on a specimen. CAP's ultimate goal is to have fully encoded synoptic reports that have information fully separated into explicit data items with a set of defined question and answer pairs that are coded using a consistent standard across all laboratories in the United States.

LOINC codes are standard codes used by laboratories and data exchange partners to identify a piece of information in a consistent way. These codes are used in both synoptically structured narrative reports and fully encoded synoptic reports. Please refer to the <u>NAACCR Volume V:</u> <u>Pathology Laboratory Electronic Reporting, Version 4.0</u> and the <u>NAACCR Electronic</u> <u>Pathology Reporting Guidelines</u> documents for additional information.

2.3.3 HL7 Backward Compatibility Rules as Applied in Volume V

Each revision of the HL7 Version 2.x standard updates can bring changes to the elements such as fields, segments, and data types. These changes must be indicated, within the standards, to allow senders and receivers to be backward compatible.

The Volume V Versions 2.2 and 4.0 explicitly indicate when a field does not need to be included in a message. Sometimes a data item of a later version of HL7 has a new preferred location in a different field or segment. However, older systems continue to expect the data item in its original location. Such data items are marked with a "B" (backwards compatible) in the column for "Optionality/Cardinality" of the "Segment Attribute Table". These fields are kept for backward compatibility, and need not be populated once two revisions of the standard have past (i.e., 2.1 to 2.3).

An example of a backward compatible field is PID-19 Social Security Number (HL7 Version 2.3.1). If the sending system has capability to do so, this information should be sent in PID-3, in HL7 Version 2.5.1. PID-3 has been identified as a better location to insert all patient identifiers, and thus PID-19 has been identified as a backward compatible field. Volume V Version 2.2 states PID-19 and PID-3 cannot both contain the social security number. However, in Volume V Version 4.0, both fields may contain the social security number to allow receivers running either HL7 Versions 2.3.1 or 2.5.1 to parse correctly. Note: in such a case the second component of PID-3 must contain the social security number.

An example of a data type change has occurred to MSH-21. The data type in Volume V Version 2.2 was ID (Coded values for HL7 tables), while Volume V Version 4.0 uses EI (Entity identifier). The data type, ID was used to populate values obtained from a table. The formatting rules for this field were similar to the ST (String) data type, which is described in Volume V Version 4.0. The data type, EI, contains an additional three components to ID. The first component is of importance because a receiver using the previous version of the standard must be able to interpret the data. This component, in EI, has a data type of ST, which is of a similar data type to the one used in ID. The following three components must be ignored by the receiver. The component(s) being shared between the previous and new field, containing the new data type, must provide the same usage, factual description, and properties to a receiver that is using the previous version.

3 Summary of Updates in Volume V Version 4.0 Recommended for Use by Implementers of Volume V Version 2.2

3.1 INTRODUCING NEW LOINC CODES IN VOLUME V VERSION 4.0

As of the Volume V Version 4.0 release, a number of new LOINC codes have been created in LOINC to support labeling of the different kinds of pathology reports, and the different styles

of reporting. In addition, specific LOINC codes for synoptic reporting using the College of American Pathologists Electronic Cancer Checklists (eCC) have also been introduced. These new LOINC codes are summarized in the following tables.

K	Kinds and Styles of reports (for use in OBR-4)					
Kind of Report	Style of Reporting	LOINC	LOINC Component			
		code				
Primary Report	Narrative Text	11529-5	Study report			
Consult Report	Narrative Text	60570-9	Consultation note			
Addendum	Narrative Text	35265-8	Path report.addendum			
Autopsy Report	Narrative Text	18743-5	Autopsy note			
Primary Report	Synoptic	60568-3	Synoptic report			
Consult Report	Synoptic	60571-7	Consultation note.synoptic			
Addendum	Synoptic	60569-1	Report addendum.synoptic			
Pathology Report	any	60567-5	Comprehensive pathology report			
Collection			panel			

Identification for Synoptic Reports (for use in OBX-3)				
LOINC code LOINC Component				
60573-3	Report template source			
60572-5	Report template ID			
60574-1	Report template version ID			

3.1.1 Impact of New LOINC Codes on Laboratory Reporting to Cancer Registries

Messages built according to the specifications in Volume V Version 2.2 labeled all pathology reports with the single general LOINC code 11529-5 study report. With the addition of types and styles of reports, including synoptic reporting (both synoptically structured and fully encoded), the new LOINC codes disambiguate these and facilitate processing at the registry. For any pathology case report that is not unstructured narrative text, these new codes must be utilized.

3.1.2 Forward Adopting of New LOINC Codes in HL7 Version 2.3.1

As LOINC coding is fully supported in HL7 Version 2.3.1 messages, and is also recommended for use in later versions as described in Volume V, these new LOINC codes may be used in interfaces based on Volume V Version 2.2, which implements HL7 Version 2.3.1. LOINC codes are recommended for any report types or styles identified in the tables above that are carried in Volume V Version 2.2 messages.

3.1.3 Work in Progress (New Tumor Marker Tests and LOINC Codes)

The use of molecular genetics and other biomarkers in the clinical setting is dynamic and rapidly evolving. The scientific methodologies, units of measure, and interpretation of these complex molecular tests present challenges to the cancer surveillance community. These challenges are multiple and include: identifying the clinically relevant tests for the diagnosis, prognosis, prediction and staging of cancer patients that need to be included in the cancer surveillance data set, identifying where the testing is being performed, the variations in the methods and interpretation of these tests, and the associated vocabularies used to transmit and store the results electronically.

Obtaining data from clinical settings is a major challenge for cancer registries. The current processes used to collect this information are resource-intensive, time-consuming, and error-prone potentially leading to incomplete or inaccurate reporting for cancers diagnosed in both hospital and non-hospital settings. Standardized reporting of anatomic and clinical laboratory reports to facilitate electronic reporting of data from biomarker/molecular tests are needed to assess stage and appropriate treatment.

CDC collaborated with several national laboratories to explore the feasibility of capturing and reporting biomarker/molecular test data for diagnosed cancer patients. Tests included: BCR-ABL, JAK2, HER2, KRAS, Microsatellite Instability, ER, PgR, etc. This review of biomarker test reports from several major laboratories identified large variations in: the test procedures, lab value sets, variation in vocabularies used, utilization of reference ranges, and the types of laboratory reports transmitted to hospitals and cancer registries. The vast majority of these data are prepared in narrative format and lacks standardized data elements and value sets (e.g. LOINC, SNOMED, etc.) making analysis of such data subject to misclassification and misinterpretation. Further, information captured from these molecular/biomarker tests are required to complete the coding of collaborative stage as defined by the American Joint Commission on Cancer (AJCC).

The College of American Pathologists formed a multi-organizational workgroup named Cancer Biomarker Reporting Workgroup (CBRW) to address the needs of pathologists, and others, in the reporting of results of molecular genetic and other biomarker testing on cancer specimens, as well as to make recommendations on ways in which to help standardize laboratory cancer biomarker reporting. CBRW membership includes a wide range of backgrounds and key stakeholder organizations involved in cancer care, including pathologists, oncologists, cancer registrars, and public health professionals. The CBRW has created standardized pathology biomarker reporting templates for Breast, Lung and Colorectal specimens and incorporated recommendations that would standardize laboratory reporting to cancer registries.

The existing health care coding systems that are used internationally to standardize test and observation data include: LOINC, which provides extensive coverage of laboratory tests and some types of clinical measurements; and SNOMED CT, which provides a very rich clinical semantics for use by health care systems. Currently these two coding systems do not adequately support molecular genetic and other biomarker data for cancer specimens.

A coding system for commonly tested genetic biomarkers is needed in order to increase the computability of genetic test results. The College of American Pathologists, CDC, American Society of Clinical Oncology (ASCO), NAACCR, and several other key organizations will work with Regenstrief Institute Inc. to extend the LOINC model to provide a coding system that will be hierarchical and include common protein-level and RNA level cancer biomarkers of clinical relevance.

The International Health Terminology Standards Development Organization (IHTSDO) and Regenstrief Institute, Inc. have a formal agreement in place to work together to link their global health care terminologies: LOINC and SNOMED CT. This collaboration will provide users with a common framework within which to use LOINC and SNOMED CT.

3.1.4 Errata in Volume V Version 4.0

This document records known errors in the above noted document, located on-line at: http://www.naaccr.org/LinkClick.aspx?fileticket=KA9zQRZ5Vn8=&tabid=136&mid=476

Appendix A User-defined Table 0005 Page 133Value 2034-7 Description Chinese(update) [2013-10-17]Rationale: Table did not include Chinese Race code.(update) [2013-10-17]Rationale: Table did not include Chinese Race code.PID-26In Appendix A: Code Tables User Defined Table 171, the table has been changed to:Appendix A User-defined Table 0171 Page 142User-defined Table 0171 - Citizenship (Use in PID-26 and PID-39)Rationale: Table did not include use in PID-39.Rationale: Table did not include use in PID-39.OBR-4, 26 OBX-3, 5, 17In Appendix A: Code Tables User Defined Table 0396, the table has been changed to:Appendix A User-defined Table 0396User-defined Table 0396 - Coding system [Only selected values listed] [From HL7 Standard, Version 2.5.1] (Use in OBR-4, 26, OBX-3, 5, 17.) For the published latest version of this table, see the page on Table 0396 at http://www.hl7.org/Special/committees/vocab/table_0396/index.cfm under Tools and Resources.	DID 15	In Annuality A. Code Tables Hear Defined Table 0005 the table has
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[2013-10-17]In Appendix A: Code Tables User Defined Table 171, the table has been changed to:Appendix A User-defined Table 0171 Page 142User-defined Table 0171 - Citizenship (Use in PID-26 and PID-39)Rationale: Table did not include use in PID-39.Rationale: Table did not include use in PID-39.(update) [2013-10-17]In Appendix A: Code Tables User Defined Table 0396, the table has been changed to:OBR-4, 26 OBX-3, 5, 17In Appendix A: Code Tables User Defined Table 0396, the table has been changed to:Appendix A User-defined Table 0396 Page 154User-defined Table 0396 - Coding system [Only selected values listed] [From HL7 Standard, Version 2.5.1] (Use in OBR-4, 26, OBX-3, 5, 17.) For the published latest version of this table, see the page on Table 0396 at http://www.hl7.org/Special/committees/vocab/table_0396/index.cfm under Tools and Resources.	1 age 155	
Appendix A User-defined Table 0171 Page 142User-defined Table 0171 - Citizenship (Use in PID-26 and PID-39)Rationale: Table did not include use in PID-39.(update) [2013-10-17]OBR-4, 26 OBX-3, 5, 17In Appendix A: Code Tables User Defined Table 0396, the table has been changed to:Appendix A User-defined Table 0396 Page 154(update) [2013-05-29](update) [2013-05-29]	· •	Rationale: Table did not include Chinese Race code.
User-defined Table 0171 Page 142User-defined Table 0171 - Citizenship (Use in PID-26 and PID-39)Rationale: Table did not include use in PID-39.(update) [2013-10-17]OBR-4, 26 OBX-3, 5, 17In Appendix A: Code Tables User Defined Table 0396, the table has been changed to:Appendix A User-defined Table 0396 Page 154Iser-defined Table 0396 - Coding system [Only selected values listed] [From HL7 Standard, Version 2.5.1] (Use in OBR-4, 26, OBX-3, 5, 17). For the published latest version of this table, see the page on Table 0396 at http://www.hl7.org/Special/committees/vocab/table_0396/index.cfm under Tools and Resources.	PID-26	
Table 0171 Page 142Rationale: Table did not include use in PID-39.(update) [2013-10-17]In Appendix A: Code Tables User Defined Table 0396, the table has been changed to:OBR-4, 26 OBX-3, 5, 17In Appendix A: Code Tables User Defined Table 0396, the table has been changed to:Appendix A User-defined Table 0396 Page 154User-defined Table 0396 - Coding system [Only selected values listed] [From HL7 Standard, Version 2.5.1] (Use in OBR-4, 26, OBX-3, 5,17.) For the published latest version of this table, see the page on Table 0396 at http://www.hl7.org/Special/committees/vocab/table_0396/index.cfm under Tools and Resources.		User defined Table 0171 Citizenship (Use in DID 26 and DID 20)
Page 142Rationale: Table did not include use in PID-39.(update) [2013-10-17]In Appendix A: Code Tables User Defined Table 0396, the table has been changed to:OBR-4, 26 OBX-3, 5, 17In Appendix A: Code Tables User Defined Table 0396, the table has been changed to:Appendix A User-defined Table 0396 Page 154User-defined Table 0396 - Coding system [Only selected values listed] [From HL7 Standard, Version 2.5.1] (Use in OBR-4, 26, OBX-3, 5,17.) For the published latest version of this table, see the page on Table 0396 at http://www.hl7.org/Special/committees/vocab/table_0396/index.cfm under Tools and Resources.		User-defined Table 01/1 - Citizenship (Use in FiD-20 and FiD-39)
[2013-10-17]OBR-4, 26 OBX-3, 5, 17In Appendix A: Code Tables User Defined Table 0396, the table has been changed to:Appendix A User-defined Table 0396 Page 154User-defined Table 0396 - Coding system [Only selected values listed] [From HL7 Standard, Version 2.5.1] (Use in OBR-4, 26, OBX-3, 5,17.) For the published latest version of this table, see the page on Table 0396 at http://www.hl7.org/Special/committees/vocab/table_0396/index.cfm under Tools and Resources.		Rationale: Table did not include use in PID-39.
OBX-3, 5, 17been changed to:Appendix A User-defined Table 0396 Page 154User-defined Table 0396 - Coding system [Only selected values listed] [From HL7 Standard, Version 2.5.1] (Use in OBR-4, 26, OBX-3, 5,17.) For the published latest version of this table, see the page on Table 0396 at http://www.hl7.org/Special/committees/vocab/table_0396/index.cfm under Tools and Resources.	· • ·	
OBX-3, 5, 17been changed to:Appendix A User-defined Table 0396 Page 154User-defined Table 0396 - Coding system [Only selected values listed] [From HL7 Standard, Version 2.5.1] (Use in OBR-4, 26, OBX-3, 5,17.) For the published latest version of this table, see the page on Table 0396 at http://www.hl7.org/Special/committees/vocab/table_0396/index.cfm under Tools and Resources.	OBR-4 26	In Appendix A: Code Tables User Defined Table 0396, the table has
Appendix A User-defined Table 0396 Page 154User-defined Table 0396 - Coding system [Only selected values listed] [From HL7 Standard, Version 2.5.1] (Use in OBR-4, 26, OBX-3, 5,17.) For the published latest version of this table, see the page on Table 0396 at http://www.hl7.org/Special/committees/vocab/table_0396/index.cfm under Tools and Resources.	· · ·	
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User-defined Table 0396 Page 154listed] [From HL7 Standard, Version 2.5.1] (Use in OBR-4, 26, OBX-3, 5,17.) For the published latest version of this table, see the page on Table 0396 at http://www.hl7.org/Special/committees/vocab/table_0396/index.cfm under Tools and Resources.(update) [2013-05-29]	Appendix A	
Page 154page on Table 0396 at http://www.hl7.org/Special/committees/vocab/table_0396/index.cfm under Tools and Resources.[2013-05-29]	. .	
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		under lools and Resources.
Rationale: Document/link change on HI 7 International web site	[2013-05-29]	
Rationale. Document, mix change on meriational web site.		Rationale: Document/link change on HL7 International web site.

Chapter 2	OBR-15 has been changed to:			
Section 2.8.2	Non-Coded Specimen Sources: If coded text is not available,			
Page 91	then the information is provided as either:			
(error) [2013-06-19]	 the uncoded value in the second subcomponent of the first component of the SPS, as: &free text un coded data use the original text in the CWE, which is the ninth subcomponent, as: &&&&&&free text un coded data use the HL7 code "TISS" to indicate the specimen type is tissue, and encode OBR-15 as: TISS&Tissue&HL70070 			

Rationale: The data type for OBR-15 is SPS, which has 7 components and the third component is "Specimen Collection Method".

4 General Notes and Cautions

4.1 CORRECTED AND AMENDED REPORTS

Frequently laboratory reports that have already been released and transmitted to a registry are later modified with corrected or additional/alternative information than originally transmitted. In the case when a report that has already been sent, is sent again, the Report Status flag in OBR-25 (values drawn from table 0123) must be set to 'C' to indicate that there is a correction to the results. The correction is to the entire report, not to the individual OBX segments that may make up the report. Registries that receive corrected reports may process them in whatever manner matches their workflow requirements. Some systems may save the prior and the current version, and use a compare function to explicitly indicate the differences; there are other strategies used by various registries. The sending laboratory does not mark the individual OBX segments as being corrected, the entire report is amended. Note that the correction indicator in OBR-25 may only be set on reports that have previously been sent to the registry. The first time the report is sent to the registry the OBR-25 is set to F. When a correction is sent, the OBR-25 is then set to C and the entire corrected report is included in the message. Each individual OBX segment may be marked with the appropriate flag in OBX-11 Observation Result Status field.

4.2 ESCAPE SEQUENCES AND TEXT FORMATTING

The text within HL7 fields can be inserted as formatted text and characters with special meanings. The characters that allow for such meanings are referred to as escape sequences. Fields that allow for such operations must be of data type CF, FT, ST, or TX. Rules must be followed to ensure parsers function as expected, and the original formatting is kept. If HL7 delimiter characters are included in text fields without using escape characters the message cannot be parsed. When the rules are not followed, special formatting will be lost, and it is possible the system receiving the

message will not be able to reproduce the message during parsing. Escape sequences cannot be nested within each other.

Escape Sequences

The beginning and end of the escape sequences are defined by the encoding characters within MSH-2-encoding characters. Only the encoding characters can also be used in ST data type fields. The examples provided within Volume V use the escape character "\" (backslash). The beginning and end of all escape sequences must be contained within the backslash. The following escape sequences are employed within the HL7 Version 2.5.1 standard:

\E\	Escape Character	\mathbf{F}	Field Separator
H	Start Highlighting	\mathbf{N}	Normal Text (End highlight)
\mathbf{R}	Repetition Separator	S	Component Separator
T	Subcomponent Separator	Xdddd	Hexadecimal Data
Zdddd	Locally Defined Sequence		

Example:

OBXI1|FT|22638-1^Comment Section^LN||\H\Satisfactory\N\ for evaluation.||||||F

Output: **Satisfactory** for evaluation.

Where, *Satisfactory for evaluation* can be in yellow, bold, or any other property that would highlight the text. The example above incorporates bolding.

Character Sets

Escape sequences are used to identify different character sets appearing within the text. These can be found within the data types FT, ST, and TX. The following character set escape sequences are to be used:

Character Set Escape Sequence	Examples	Character Set Representation
\Cxxyy\ Used to represent single-	\C2842\	ISO-IR6 G0 (ISO 646: ASCII)
byte character sets.	C2D41	ISO-IR100 (ISO 8859: Latin Alphabet 1)
\Mxxyyzz\ Used to represent multi-	\M2442\	ISO-IR87 (JIS X 0208: Kanji, hiragana and
byte character sets.		katakana
	\M242844\	ISO-IR159 (JIS X 0212: Supplementary Kanji)

Where the xx, yy, and zz variables represent hexadecimal values.

Text Formatting

Formatted text can also appear within the text, and must appear in the data type FT. The following commands allow for this functionality:

Command	Description	
.sp <number></number>	End the current output line, and create <number> of new lines, where <number> must be positive</number></number>	
	integers only. If no number is inserted, a single new line is inserted.	
.br	Create a new output line. This is equivalent to \.sp\	
.fi	Use word wrap, following this command.	

Command	Description
.nf	End word wrap, following this command.
.in <number></number>	Indent <number> of spaces, where <number> can be a positive or negative integer. This command</number></number>
	can only be used at the beginning of a new line, when no printable characters are present.
.ti <number></number>	Temporarily indent <number> of spaces, where <number> can be a positive or negative integer.</number></number>
	This command can only be used at the beginning of a new line, when no printable characters are
	present.
.sk <number></number>	Skip <number> of spaces to the right.</number>
.ce	End the current output line, and start at the center of a new line.

Example:

Output:

- A POLYP AT DESCENDING COLON BIOPSY:
- B POLYP AT PROXIMAL TRANSVERSE COLON BIOPSY:
- C PROXIMAL DESCENDING COLON POLYP BIOPSY:

The example above represents data all on one line, without any spaces. Using the commands embedded within the data, the output will appear on separate lines, due to the \black commands.

4.3 USE OF STRIKETHROUGH CHARACTERS IN AMENDED/CORRECTED REPORTS

In certain laboratories, it is still customary to use strikethrough in narrative Amended/Corrected AP or Cytology Reports to distinguish between errant (original) text and correct (revised) text. Depending on circumstances, these modifications could occur in any/all of the Specimen, History, Notes, Gross Description or Diagnosis sections of a report.

While it is possible to create inline mark-up elements for strikethrough in other electronic languages (e.g., HTML, CSS), this is not possible in HL7 using UTF-8, the standard encoding for version 2 messages in North America.

Recommendation: Although the HL7 standard does support the use of extended character sets <u>Volume V registry messaging does not</u>. Information engineers strongly discourage meaning conveyed through display characteristics, because differences in system rendering behavior may change conveyed meaning. A corrected report should only include the changed wording that represents the corrections to the original; if the original strikethrough text must be displayed, it must be computed by comparing the corrected report with the original.

The strikethrough practice is strongly discouraged because it only works properly using traditional (historic) technology such as printed documents and faxes, and has been shown to fail in the modern technical milieu.