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7. Observation Reporting

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7.1 CHAPTER 7 CONTENTS

7.2 PURPOSE

This chapter describes the transaction set required for sending structured patient-oriented clinical data from one computer system to another. A common use of these transaction sets will be to transmit observations and results of diagnostic studies from the producing system (e.g., clinical laboratory system, EKG system) (the filler), to the ordering system (e.g., HIS order entry, physician's office system) (the placer). Observations can be sent from producing systems to clinical information systems (not necessarily the order placer) and from such systems to other systems that were not part of the ordering loop, e.g., an office practice system of the referring physician for inpatient test results ordered by an inpatient surgeon. This chapter also provides mechanisms for registering clinical trials and methods for linking orders and results to clinical trials and for reporting experiences with drugs and devices.

These transaction sets permit the transmission of clinical observations including (but not limited to) clinical laboratory results, measures of patient status and condition, vital signs, intake and output, severity and/or frequency of symptoms.

If the observation being reported meets one or more of the following criteria, then the content would qualify as a medical document management message (MDM) rather than an observation message (ORU). The reader is referred to the MDM message type in Chapter 9.

- Documents/reports that require succession management to reflect the evolution of both document addenda and replacement documents. Succession management is described in Chapter 9.
- Documents/reports where the Sender wants to indicate the availability of the report for use in patient care using the availability status present in the TXA segment, as described in Chapter 9.

Additional considerations that may affect the appropriateness of using an MDM message:

- Documents/reports where the whole requires a signature as part of the message. While the ORU message does not support the inclusion of signature or authentication, some document content forms support these requirements. Of particular note, CDA documents provide for the inclusion of originator/signature. Thus, if a CDA document requires a signature but does not require succession management or report availability (as described above), then an ORU message may be appropriate. However, if the CDA document requires succession management or report availability, then an MDM message is required.
- Documents/reports where the whole requires authentication as part of the message. As described for signatures, authentication may exist within the document content form. Again, CDA documents provide for the identification of an authenticator. Thus if a CDA document does not require succession management or report availability, then an ORU message may be appropriate. If succession management or report availability are necessary, then an MDM message is required.
- Documents/reports where the content as a whole requires special confidentiality protection using the confidentiality status present in the TXA segment, as described in Chapter 9.
- Documents/reports where document storage status is useful for archival and purging purposes using the storage status present in the TXA segment, as described in Chapter 9.

Using these criteria, the following examples of documents/reports would typically qualify as medical document management (MDM) messages. Note that as clinical content, the following documents/reports typically require succession management and/or report availability thus would require an MDM message even if the payload utilizes CSA.

- History and Physical
- Consultation reports
- Discharge summaries

- Surgical/anatomic pathology reports
- Diagnostic imaging reports
- Cardio-diagnostic reports
- Operative reports
- As an international example, microbiology reports may include clinical interpretation and require authentication. This may not be the case in all jurisdictions, but is an example that the use or requirement of MDM messages may be influenced by local considerations.

Usage Notes:

Transcription is not a defining quality for the selection of an MDM or ORU message. In an MDM message, the document/report is typically dictated or transcribed, but not always. Machine-generated or automated output is an example of a document/report that is appropriate to the MDM but is not transcribed.

Observations may be transmitted in a solicited (in response to a query) or unsolicited mode. In the solicited mode, a user requests a set of observations according to criteria transmitted by the user. The sending system responds with existing data to satisfy the query (subject to access controls). Queries do not elicit new observations by the target system, they simply retrieve old observations. (See Chapter 5 for full discussion of the query transmission.)

The unsolicited mode is used primarily to transmit the values of new observations. It is the mode used by producing services to return the values of observations requested by an ordering system. A laboratory system, for example, would usually send the results of an AM electrolytes to the ordering HIS via the unsolicited mode. An intensive care system would send the blood pressures to the same HIS by the same mode. Calling such transactions unsolicited may sound like a misnomer, but is not. The placing service solicits the producing service to make the observation. It could also (through a query) solicit the value of that observation after it has been made. However, such an approach would demand continuous polling of the producing system until the result was produced. Using the unsolicited mode, the producing service returns the value of an observation as soon as it is available. The unsolicited mode can also be used to transmit new results to a system (e.g., an archival medical record system) that did not order the observation. The transactions that define these modes are more fully described in Section *7.3*, "*General Trigger Events & Message Definitions*."

Observations are usually ordered and reported as sets (batteries) of many separate observations. Physicians order electrolytes (consisting of sodium, potassium, chloride, bicarbonate) or vitals (consisting of diastolic blood pressure, systolic blood pressure, pulse, and temperature). Moreover, tests that we may think of as single entity, e.g., cardiac echo, usually yield multiple separate measurements, e.g., left ventricular diameter, left atrial diameter, etc. Moreover, observations that are usually reported as text (e.g., the review of systems from the history and physical) can also be considered a set of separately analyzable units (e.g., cardiac history, pulmonary history, genito-urinary history, etc.). We strongly suggest that all text clinical reports be broken down into such separate analyzable entities and that these individual entities be transmitted as separate OBX segments. Because many attributes of a set of observations taken at one time will be identical, one OBR segment serves as a header for the report and carries the information that applies to all of the individual observations in the set. In the case of ordered observations, the OBR segment is a "turn-around document" like the manual request forms it replaces. It carries information about the order to the producing service; a copy of the OBR with additional fields completed is returned with the observations to the requesting service. Alternately, text documents can be encoded as a CDA document and sent within a single OBX.

Not all observations are preceded by an order. However, all observations whether explicitly ordered or initiated without an order are reported with an OBR segment as the report header.

The major segments (OBR, OBX) defined in this chapter, their fields, and the code tables have been defined in collaboration with ASTM E31.11 with the goal of keeping HL7 observation transmission the same as ASTM E1238 in pursuit of the goals of ANSI HISPP and the Message Standards Developers Subcommittee. (Some sections of this chapter have been taken with permission directly from the E1238-91 document and vice versa in pursuit of those goals).

The OBR segment provides information that applies to all of the observations that follow. It includes a field that identifies a particular battery (or panel or set) of observations (e.g., electrolytes, vital signs or Admission H&P). For simplicity we will refer to the observation set as the battery. The battery usually corresponds to the entity that is ordered or performed as a unit. (In the case of a query, observation sets may be a more arbitrary collection of observations.) The OBX segment provides information about a single observation, and it includes a field that identifies that single observation (e.g., potassium, diastolic blood pressure or admission diagnosis). Both of these fields assume master tables that define coding systems (the universe of valid identifying codes) for batteries and observations, respectively. These tables will usually be part of the producing and sending services application and (usually) include many other useful pieces of information about the observation or battery. Segments for transmitting such master file information between systems that produce and systems that use clinical information are described in Chapter 8.

This Standard does not require the use of a particular coding system to identify either batteries or single observations In the past, local institutions tended to invent their own unique code systems for identifying test and other clinical observations because standard codes were not available. Such local code systems sufficed for transmitting information within the institutions but presented high barriers to pooling data from many sources for research or for building medical record systems. However, standard code systems such as LOINC® for observation IDs (OBX-3) and SNOMED for coding categorical observations now exist for many of these purposes, and we strongly encourage their use in observation reporting. These codes can be sent either as the only code or they can be sent along with the local historic code as the second code system in a CWE or CNE coded field.

LOINC® codes exist for most laboratory tests and many common clinical variables and codes for reporting observations from the laboratory, 12-lead EKG, cardiac echoes, obstetrical ultrasounds, radiology reports, history and physical findings, tumor registries, vital signs, intake and outputs, UCUM units of measure references and/or answer lists depending on the data type, and descriptions for most variables. Translations of LOINC® descriptions are provided for more than 14 languages. The most recent version of the LOINC® database, which includes records for more than 70,000 observations and includes codes, names, synonyms and other attributes (such as the molecular weights of chemical moieties) for each observation, the LOINC database and a downloadable browser and mapping tool are available at no cost from the Regenstrief Institute at *http://loinc.org/*. A web browser for LOINC is available at https://search.loinc.org. Codes for Neurophysiologic variables (EEG, EMG, Evoked potentials) are provided in Appendix X2 of ASTM E1467. Some parts of this document (the discussion and tables defining units, the discussion of the rules of mapping observations to OBX segments, and some of the examples at the end of the chapter) have been copied (with permission) from ASTM E1238.

As is true throughout this Standard, the emphasis should be on the abstract messages, defined without regard to the encoding rules. The example messages, however, are based upon the HL7 encoding rules.

7.2.1 Snapshot Mode

Chapter 2, Section 2.10.4 defines the meaning of snapshot mode updates and indicates that each chapter or related implementation guides may further refine this definition. The following guidance applies to results messages:

- In some instances there are tests that have a precise relationship between the parent and child to assist the clinician in understanding to which OBX in the parent OBR the child is connected. In

those instances the ORDER_OBSERVATION segment groups of the parent and other children should be included in the snapshot rather than sending the child's ORDER_OBSERVATION segment group (including the OBR/OBX set) by itself. Example: OBRs of the parent OBR (example would be microbiology with culture and Sensitivity Panels (Sensi-Panels)), unless advised otherwise by trading partners, would be included in the snapshot reporting.

7.2.2 Preface (organization of this chapter)

Following this Purpose and general information section, the remainder of this chapter is organized into four main subject areas; General, Clinical Trials, Product Experience and Waveform. Sections 7.1 to 7.5 document the trigger events, message definitions, segment definitions and examples for general observation reporting. Sections 7.6 to 7.9 include all information related to Clinical Trials. Sections 7.10 to 7.13 include all information related to Product Experience messaging, and sections 7.14 to 7.17 include Waveform messaging information. Large tables can be found in section 7.18 and outstanding issues are listed in section 7.19.

7.2.3 Glossary

7.2.3.0 hiddentext

7.2.3.1 Placer:

Person or service that requests (places order for) an observation battery, e.g., the physician, the practice, clinic, or ward service, that orders a lab test, X-ray, vital signs, etc. The meaning is synonymous with, and used interchangeably with, requestor. See *ORC-2-placer order number*, Chapter 4, section 4.5.1.2, "Placer order number."

7.2.3.2 Filler:

Person, or service, who produces the observations (fills the order) requested by the requestor. The word is synonymous with "producer" and includes diagnostic services and clinical services and care providers who report observations about their patients. The clinical laboratory is a producer of lab test results (filler of a lab order), the nursing service is the producer of vital signs observations (the filler of orders to measure vital signs), and so on. See *ORC-3-filler order number*, Chapter 2, section 4.5.1.3, "Filler order number."

7.2.3.3 Battery:

A set of one or more observations identified as by a single name and code number, and treated as a shorthand unit for ordering or retrieving results of the constituent observations. In keeping with the mathematical conventions about set, a battery can be a single observation. Vital signs, electrolytes, routine admission tests, and obstetrical ultrasound are all examples. Vital signs (conventionally) consist of diastolic and systolic blood pressure, pulse, and respiratory rate. Electrolytes usually consist of Na+, K+, Cl-, and HCO3-. Routine admission tests might contain CBC, Electrolytes, SMA12, and Urinalysis. (Note that the elements of a battery for our purposes may also be batteries.) Obstetrical ultrasound is a battery made up of traditional component measurements and the impression, all of which would be returned as separate results when returned to the requestor. A test involving waveform recording (such as an EKG) can be represented as a battery comprised of results of many categories, including digital waveform data, labels and annotations to the data, measurements, and the impression

The word battery is used in this specification synonymously with the word profile or panel. The individual observation elements within a battery may be characteristic of a physiologic system (e.g., liver function tests), or many different physiologic systems.

7.2.3.4 Observation:

A measurement of a single variable or a single value derived logically and/or algebraically from other measured or derived values. A test result, a diastolic blood pressure, and a single chest X-ray impression are examples of observations. In certain circumstances, tracings and images may be treated by HL7 as individual observations and sent as a single OBX. These include waveform data described in section *7.15*, "*Waveform – Trigger Events & Message Definitions*," and encapsulated data aggregates using the ED data

type described in Chapter 2A, section 2.A.24, "ED - encapsulated data," (which can represent actual images, audio data, etc.).

7.2.3.5 Clinical Document Architecture (CDA):

The Health Level 7 Specification (ANSI/HL7 CDA R1.0-2000) for encoding and encapsulating clinical documents.

7.2.4 Narrative Reports as Batteries with Many OBX

Narrative reports from services such as Radiology usually consist of a number of subcomponents (e.g., a chest X-ray report may consist of a description, an impression, and a recommendation). Other studies, such as echocardiograms, contain analogous components, as well as numeric observations (e.g., left ventricular and diastolic diameter). Surgical pathology reports may contain information about multiple specimens and reports: the anatomic source, the gross description, the microscopic description, and a diagnostic impression for each specimen.

The current Standard treats each component of a narrative report as a separate "test" or observation. Just as a CHEM12 is transmitted as an order segment (OBR) plus 12 OBX segments, a chest X-ray would be transmitted as an order (OBR) segment plus three OBX segments, one for the description, one for the impression, and one for the recommendations. Similarly, an EKG report would be transmitted as an order segment (OBR), two OBX segments for the impression and recommendation, and additional OBX segments for each EKG measurement, e.g., the PR interval, QR interval, QRS axis, and so on.

7.2.5 Suffixes for Defining Observation IDs for Common Components of Narrative Reports

Retained for backwards compatability only as of V2.7 and withdrawn as of v2.9, in favor of using LOINC codes that pre-coordinate the appropriate identifiers with the suffices. See Chapter 2.8.4.c.

7.3 GENERAL TRIGGER EVENTS & MESSAGE DEFINITIONS

The triggering events that follow are all served by the ORU (Unsolicited Observation Message, Unsolicited Point-of-Care Observation Message, Unsolicited Alert Observation Message), the OUL (Observational Report – Automated Lab), or the OPU (Observational Report - Population) messages in combination with ACK and ORA (Observational Report - Application Acknowledgement). Each triggering event is listed below, along with the messages exchanged, and the segments that comprise the messages. The notation used to describe the sequence, optionality, and repeating of segments is described in Chapter 2, "Format for defining abstract messages."

7.3.1 ORU – Unsolicited Observation Message (Event R01)

The ORU message is for transmitting observational results, including lab, clinical or other observations, to other systems.. The OUL message is designed to accommodate the laboratory processes of laboratory automation systems.

With the segment (OBX) defined in this chapter, and the OBR defined in Chapter 4, one can construct almost any clinical report as a multi-level hierarchy, with the PID segment defined in Chapter 3 at the upper level, an order record (OBR) at the next level with one or more observation records (OBX), followed by the specimen information (SPM) and one or more observations (OBX) directly associated with the specimen.

One result segment (OBX) is transmitted for each component of a diagnostic report, such as an EKG or obstetrical ultrasound or electrolyte battery.

The CTD segment in this trigger is used to transmit temporary patient contact details specific to this order.

The Device segment (DEV) provides additional device information for a device referenced in one or more of the PRT segments in the message (using PRT-10 Participation Device to match DEV-2 Unique Device Identifier or PRT-22 Participation Device Type using DEV-3 Device Type).

ORU^R01^ORU_R01: Observation Message

Segments	Description	Status	Chapter
MSH	Message Header		2
[{ ARV}]	Access Restrictions		3
[{ SFT }]	Software Segment		2
[UAC]	User Authentication Credential		2
{	--- PATIENT_RESULT begin		
[	--- PATIENT begin		
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[{PRT}]	Participation (for Patient)		7
[{OH1}]	Employment Status		3
[{OH2}]	Past or Present Job		3
[OH3]	Usual Work		3
[{OH4}]	Combat Zone Work		3
[{NTE}]	Notes and Comments		2
[{	--- NEXT_OF_KIN begin		
NK1	Next of Kin/Associated Parties		3
[{OH2}]	Past or Present Job		3
[OH3]	Usual Work		3
}]	--- NEXT_OF_KIN end		
[{ARV}]	For backwards compatibility only as of V2.9	B	3
[{	--- PATIENT_OBSERVATION begin		
OBX	Observation (for Patient ID)		7
[{PRT}]	Participation (Observation Participation)		7
}]	--- PATIENT_OBSERVATION end		
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit - Additional Info		3
[{PRT}]	Participation (for Patient Visit)		7
]	--- VISIT end		
[{	--- INSURANCE begin		
IN1	Insurance		6
[IN2]	Insurance Additional Information		6

Segments	Description	Status	Chapter
[IN3]	Insurance Additional Information, Certification		6
}]	--- INSURANCE end		
]	--- PATIENT end		
{	--- ORDER_OBSERVATION begin		
[	--- COMMON_ORDER begin		
ORC	Order common		4
[{PRT}]	Participation (for Observation)		7
[	--- ORDER_DOCUMENT begin		
OBX	Observation containing Document		7
[{PRT}]	Participation		7
TXA	Transcription Document Header		9
]	--- ORDER_DOCUMENT end		
]	--- COMMON_ORDER end		
OBR	Observations Request		7
[{NTE}]	Notes and comments		2
[{	--- OBSERVATION_PARTICIPATION begin		
PRT	Participation (for Observation)		7
[{DEV}]	Device		17
}]	--- OBSERVATION_PARTICIPATION end		
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		
[CTD]	Contact Data		11
[{	--- OBSERVATION begin		
OBX	Observation related to OBR		7
[{PRT}]	Participation (Observation Participation)		7
{[NTE]}	Notes and comments		2
}]	--- OBSERVATION end		
[{FT1}]	Financial Transaction		6
{[CTI]}	Clinical Trial Identification		7
[{	--- SPECIMEN begin		
SPM	Specimen		

Segments	Description	Status	Chapter
[{	--- SPECIMEN_OBSERVATION begin		
OBX	Observation (for Patient ID)		7
[{PRT}]	Participation (Observation Participation)		7
}]	--- SPECIMEN_OBSERVATION end		
}]	--- SPECIMEN end		
}	--- ORDER_OBSERVATION end		
[{	--- DEVICE begin		
DEV	Device (for Participation)		17
[{OBX}]	Observation/Result		7
}]	--- DEVICE end		
}	--- PATIENT_RESULT end		
[DSC]	Continuation Pointer		2

Acknowledgement Choreography				
ORU^R01^ORU_R01				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^R01^ACK
Application Ack	ACK^R01^ACK	-	ACK^R01^ACK	ACK^R01^ACK

Note: The ORC is permitted but not required in this message. Any information that could be included in either the ORC or the OBR must be included in the OBR on reporting. Notice also that the ORU (and the QRY) messages accommodate reports about many patients.

Many report headers (OBR) may be sent beneath each patient segment, with many separate observation segments (OBX) related to the order / observation request beneath each OBR. OBX segments that are related to specimens immediately follow the SPM segments. Note segments (NTE) may be inserted at different locations in the message. The note segment applies to the entity that immediately precedes it, i.e., the patient if it follows the PID segment, the observation request if it follows the OBR segment, and the individual result if it follows the OBX segment.

ACK^R01^ACK: Observation Message

Segments	Description	Status	Chapter
MSH	Message header		2
[{ SFT }]	Software segment		2
[UAC]	User Authentication Credential		2
MSA	Message acknowledgment		2

Segments	Description	Status	Chapter
[{ ERR }]	Error		2

Acknowledgement Choreography			
ACK^R01^ACK			
Field name	Field Value: Original mode	Field Value: Enhanced Mode	
MSH-15	Blank	NE	AL, ER, SU
MSH-16	Blank	NE	NE
Immediate Ack	-	-	ACK^R01^ACK
Application Ack	-	-	-

There is not supposed to be an Application Level acknowledgement to an Application Level Acknowledgement message. In Enhanced Mode, MSH-16 SHALL always be set to NE (Never).

7.3.2 OUL – Unsolicited Laboratory Observation Message (Event R21)

Attention: ***Retained for backwards compatibility only as of v 2.5 and withdrawn as of v 2.7.***

7.3.3 QRY/ORF - Query for Results of Observation (Events R02, R04)

Attention: ***Retained for backwards compatibility only as of v 2. .and withdrawn as of v 2.7.***

7.3.4 ORU – Unsolicited Point-Of-Care Observation Message without Existing Order – Place an Order (Event R30)

This event trigger instructs the receiving system to create a new order for the observation(s) contained in the message.

One example of this trigger's use case occurs when a Doctor verbally instructs a nurse to perform a test. Looking at this use case from an information management perspective, one might expect that, the nurse would enter an order into laboratory information or ordering system before performing the test. However, there usually isn't time for order entry in these use cases. In fact, it is highly desirable for the POC measurement process to become automated so that the only action a user needs to take is to make a measurement on the POC Device, with all other processes for generating an order and tying it in to the observation handled by the "machines."

In order to allow for the passing of specific information relating to the Patient, responsible Doctor, placing doctor, patient location, etc., there is a requirement for the inclusion of a PV1 and PD1 segment in the ORU message type. One example of this trigger's use case occurs when a Doctor at a remote site without a shared Patient index instructs a nurse to perform a test. The testing is carried out without prior entry of a request into the LIS. Once performed, the results, along with the patient information are transmitted to the LIS. In some circumstances, the LIS may add clinical interpretation to this and report it back to the placing system and/or another system. In order to allow for this to take place, the requester, location, etc., information is required.

To allow the sending system to correlate every result with its associated order, the receiving system will return the placer order number in the ORC segment of the ORA^R33 message. If the receiving system cannot place an order it must returning an application level error description in the Application Acknowledgement Message MSA Text Message field.

The sending system must return a commit-level acknowledgement in response to the ORA^R33 message.

The Device segment (DEV) provides additional device information for a device referenced in one or more of the PRT segments in the message (using PRT-10 Participation Device to match DEV-2 Unique Device Identifier or PRT-22 Participation Device Type using DEV-3 Device Type).

ORU^R30^ORU_R30: Observation Message:

Segments	Description	Status	Chapter
MSH	Message Header		2
[{ ARV}]	Access Restrictions		3
[{ SFT }]	Software Segment		2
[UAC]	User Authentication Credential		2
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[{PRT}]	Participation (for Patient)		7
[{OH1}]	Employment Status		3
[{OH2}]	Past or Present Job		3
[OH3]	Usual Work		3
[{OH4}]	Combat Zone Work		3
[{ARV}]	For backwards compatibility only as of V2.9	B	3
[{	--- PATIENT_OBSERVATION begin		
OBX	Observation (for Patient ID)		7
[{PRT}]	Participation (for Observation)		7
}]	--- PATIENT_OBSERVATION end		
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit – Additional		3
[{PRT}]	Participation (for Patient Visit)		7
]	--- VISIT end		
ORC	Common Order information		4
[{PRT}]	Participation (for common order)		7
OBR	Observation Request		7
{[NTE]}	Notes or Comments for order/result		2
[{PRT}]	Participation (for observation)		7
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		

Segments	Description	Status	Chapter
{	--- OBSERVATION begin		
OBX	Observation Results, one per reported value		7
[{PRT}]	Participation (for Observation)		7
{[NTE]}	Notes or Comments for individual result		2
}	--- OBSERVATION end		
[{	--- DEVICE begin		
DEV	Device (for Participation)		17
[{OBX]]	Observation/Result		7
}]			

Acknowledgement Choreography				
ORU^R30^ORU_R30				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^R30^ACK
Application Ack	ACK^R33^ACK or ORA^R33^ORA_R33	-	ACK^R33^ACK or ORA^R33^ORA_R33	ACK^R33^ACK or ORA^R33^ORA_R33

ACK^R30^ACK: Observation Message

Segments	Description	Status	Chapter
MSH	Message Acknowledgment		2
[{ SFT }]	Software segment		2
[UAC]	User Authentication Credential		2
MSA	Message Acknowledgment		2
[{ ERR }]	Error		2

Acknowledgement Choreography			
ACK^R30^ACK			
Field name	Field Value: Original mode	Field Value: Enhanced Mode	
MSH-15	Blank	NE	AL, ER, SU
MSH-16	Blank	NE	NE
Immediate Ack	-	-	ACK^R30^ACK

Application Ack	-	-	-

There is not supposed to be an Application Level acknowledgement to an Application Level Acknowledgement message. In Enhanced Mode, MSH-16 SHALL always be set to NE (Never).

7.3.5 ORU – Unsolicited New Point-Of-Care Observation Message – Search for an Order (Event R31)

This event trigger instructs the receiving system to search for an existing order for the observation(s) contained in the message.

In this case, the sending system does not know if an order has been placed. This transaction instructs the receiving system to search for an existing order for the associated results. If the receiver finds an existing order, it should return the Placer ID to the sender in the ORC segment of an OML^O21 message. This information allows the Observation Reviewer to correlate every result with its associated order.

The institution's business rules will determine what the receiving system does if it can't find a matching order. Possibilities include automatically placing an order (as in trigger event R30), or returning an application level error description in the Application Acknowledgement MSA Text Message field..

If it is necessary to pass specific information related to the Patient, responsible Doctor, placing doctor, patient location etc, there is a requirement for the inclusion of a PV1 and PD1 segment in the ORU message type (see also ORU^R30 for description).

The Device segment (DEV) provides additional device information for a device referenced in one or more of the PRT segments in the message (using PRT-10 Participation Device to match DEV-2 Unique Device Identifier or PRT-22 Participation Device Type using DEV-3 Device Type).

ORU^R31^ORU_R30: Observation Message

Segments	Description	Status	Chapter
MSH	Message Header		2
[{ARV}]	Access Restrictions		3
[{ SFT }]	Software Segment		2
[UAC]	User Authentication Credential		2
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[{PRT}]	Participation (for Patient)		7
[{OH1}]	Employment Status		3
[{OH2}]	Past or Present Job		3
[OH3]	Usual Work		3
[{OH4}]	Combat Zone Work		3
[{ARV}]	For backwards compatibility only as of V2.9	B	3
[{	--- PATIENT_OBSERVATION begin		
OBX	Observation (for Patient ID)		7
[{PRT}]	Participation (for Observation)		7

Segments	Description	Status	Chapter
}]	--- PATIENT_OBSERVATION end		
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit – Additional		
[{PRT}]	Participation (for Patient Visit)		7
]	--- VISIT end		
ORC	Common Order information		4
[{PRT}]	Participation (for common order)		7
OBR	Observation Request		7
{[NTE]}	Notes or Comments for order/result		2
[{PRT}]	Participation (for observation)		7
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		
{	--- OBSERVATION begin		
OBX	Observation Results, one per reported value		7
[{PRT}]	Participation (for Observation Results)		7
{[NTE]}	Notes or Comments for individual result		2
}	--- OBSERVATION end		
[{	--- DEVICE begin		
DEV	Device (for Participation)		17
[{OBX}]	Observation/Result		7
}]			

Acknowledgement Choreography				
ORU^R31^ORU_R30				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^R31^ACK
Application Ack	ACK^R31^ACK	-	ACK^R31^ACK	ACK^R31^ACK

ACK^R31^ACK: Acknowledgment

Segments	Description	Status	Chapter
MSH	Message Acknowledgment		2
[{ SFT }]	Software segment		2
[UAC]	User Authentication Credential		2
MSA	Message Acknowledgment		2
[{ ERR }]	Error		2

Acknowledgement Choreography			
ACK^R31^ACK			
Field name	Field Value: Original mode	Field Value: Enhanced Mode	
MSH-15	Blank	NE	AL, ER, SU
MSH-16	Blank	NE	NE
Immediate Ack	-	-	ACK^R31^ACK
Application Ack	-	-	-

There is not supposed to be an Application Level acknowledgement to an Application LevelAcknowledgement message. In Enhanced Mode, MSH-16 SHALL always be set to NE (Never).

7.3.6 ORU – Unsolicited Pre-Ordered Point-Of-Care Observation (Event R32)

This event trigger instructs the receiver to place the result with the order information included in the message.

From a traditional clinical laboratory perspective, this event trigger's use case is probably the predominant (if not exclusive) one. However, in the POC environment, it is actually uncommon to have an order already generated when a test is performed. It does happen sometimes, though. If it is necessary to pass specific information related to the Patient, responsible Doctor, placing doctor, patient location, etc., there is a requirement for the inclusion of a PV1 and PD1 segment in the ORU message type (see also ORU^R30 for description).

If the receiving system accepts both the order and the result, it will return an ORA^R33 Application Acknowledgement message with the acknowledgement code of AA. A comment may be included in the Acknowledgement Message MSA Text Message field.

If the receiving system is unable to accept both the order and the result, no order or result should be placed and an ACK^33 Application Acknowledgement message must be returned to the sender with the error identified in the MSA Text Message field.

The sending system must return a commit-level acknowledgement in response to the ORA^R33 message.

The Device segment (DEV) provides additional device information for a device referenced in one or more of the PRT segments in the message (using PRT-10 Participation Device to match DEV-2 Unique Device Identifier or PRT-22 Participation Device Type using DEV-3 Device Type).

ORU^R32^ORU_R30: Observation Message

Segments	Description	Status	Chapter
MSH	Message Header		2

Segments	Description	Status	Chapter
[{ARV}]	Access Restrictions		3
[{ SFT }]	Software Segment		2
[UAC]	User Authentication Credential		2
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[{PRT}]	Participation (for Patient)		7
[{OH1}]	Employment Status		3
[{OH2}]	Past or Present Job		3
[OH3]	Usual Work		3
[{OH4}]	Combat Zone Work		3
[{ARV}]	For backwards compatibility only as of V2.9	B	3
[{	--- PATIENT_OBSERVATION begin		
OBX	Observation (for Patient ID)		7
[{PRT}]	Participation (for Observation)		7
}]	--- PATIENT_OBSERVATION end		
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit – Additional		
[{PRT}]	Participation (for Patient Visit)		7
]	--- VISIT end		
ORC	Common Order information		4
[{PRT}]	Participation (for common order)		7
OBR	Observation Request		7
{[NTE]}	Notes or Comments for order/result		2
[{PRT}]	Participation (for Observation Request)		7
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		
{	--- OBSERVATION begin		
OBX	Observation Results, one per reported value		7
[{PRT}]	Participation (for Observation Results)		7

Segments	Description	Status	Chapter
{[NTE]}	Notes or Comments for individual result		2
}	--- OBSERVATION end		
[{	--- DEVICE begin		
DEV	Device (for Participation)		17
[{OBX}]	Observation/Result		7
}]			

Acknowledgement Choreography				
ORU^R32^ORU_R30				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^R32^ACK
Application Ack	ACK^R32^ACK	-	ACK^R32^ACK	ACK^R32^ACK

ACK^R32^ACK: Observation Message

Segments	Description	Status	Chapter
MSH	Message Acknowledgment		2
[{ SFT }]	Software segment		2
[UAC]	User Authentication Credential		2
MSA	Message Acknowledgment		2
[{ ERR }]	Error		2

Acknowledgement Choreography			
ACK^R32^ACK			
Field name	Field Value: Original mode	Field Value: Enhanced Mode	
MSH-15	Blank	NE	AL, ER, SU
MSH-16	Blank	NE	NE
Immediate Ack	-	-	ACK^R32^ACK
Application Ack	-	-	-

There is not supposed to be an Application Level acknowledgement to an Application Level Acknowledgement message. In Enhanced Mode, MSH-16 SHALL always be set to NE (Never).

7.3.7 ORA – Observation Report Acknowledgement (Event R33)

This message enables a response to the ORU^R30 message to provide an application level acknowledgement that may include a placer order number.

ORA^R33^ORA_R33: Observation Report Acknowledgement

Segments	Description	Status	Chapter
MSH	Message Acknowledgment		2
[{ SFT }]	Software segment		2
[UAC]	User Authentication Credential		2
MSA	Message Acknowledgment		2
[{ ERR }]	Error		2
[	--- ORDER begin		
ORC	Common Order Information		4
[{PRT}]	Participation		7
]	--- ORDER end		

Acknowledgement Choreography			
ORA^R33^ORA_R33			
Field name	Field Value: Original mode	Field Value: Enhanced Mode	
MSH-15	Blank	NE	AL, ER, SU
MSH-16	Blank	NE	NE
Immediate Ack	ACK^R33^ACK	-	ACK^R33^ACK
Application Ack	-	-	-

There is not supposed to be an Application Level acknowledgement to an Application Level Acknowledgement message. In Enhanced Mode, MSH-16 SHALL always be set to NE (Never).

7.3.8 OUL – Unsolicited Specimen Oriented Observation Message (Event R22)

This message was designed to accommodate specimen oriented testing. It should be applicable to container-less testing (e.g., elephant on a table) and laboratory automation systems requiring container.

Generally this construct allows transfer of multiple results related to a specimen from a patient, where this specimen has been in none, one, or multiple containers.

In addition to the patient results themselves it permits the communication of the following kinds of information:

- Analysis results of a non patient related sample (e.g., environmental) – patient related segments (e.g., PID, PD1, PV1, PV2) are optional.
- Analysis results to a particular container with QC sample and the lot and manufacturer information about this sample (SAC-INV segments) – however for this purpose the "Unsolicited Specimen Container Oriented Observation Message" (OUL^R23) is recommended due to explicit relation between the observation and the container.

- Basic identification data (lot, manufacturer, etc.) of the reagents and other substances involved in the generation of analysis results (TCD-SID segments).

Refer to Chapter 13 Laboratory Automation for additional examples of usage of SAC.

The Device segment (DEV) provides additional device information for a device referenced in one or more of the PRT segments in the message (using PRT-10 Participation Device to match DEV-2 Unique Device Identifier or PRT-22 Participation Device Type using DEV-3 Device Type).

OUL^R22^OUL_R22: Observation Message

Segments	Description	Status	Chapter
MSH	Message Header		2
[{ARV}]	Access Restrictions		3
[{SFT}]	Software Segment		2
[UAC]	User Authentication Credential		2
[NTE]	Notes and Comments		2
[	--- PATIENT begin		
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[{PRT}]	Participation (for Patient)		7
[{ARV}]	For backwards compatibility only as of V2.9	B	3
[{NTE}]	Notes and Comments (for Patient ID)		2
[{	--- PATIENT_OBSERVATION begin		
OBX	Observation (for Patient ID)		7
[{PRT}]	Participation (for Observation)		7
}]	--- PATIENT_OBSERVATION end		
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit – Additional Information		3
[{PRT}]	Participation (for Patient Visit)		7
]	--- VISIT end		
]	--- PATIENT end		
[{NK1}]	Next of Kin		3
{	--- SPECIMEN begin		
SPM	Specimen information		7
[{	--- SPECIMEN_OBSERVATION begin		
OBX	Observation Result (for Specimen)		7
[{PRT}]	Participation (for Specimen Observation)		7

Segments	Description	Status	Chapter
}]	--- SPECIMEN_OBSERVATION end		
[{	--- CONTAINER begin		
SAC	Container information		13
[INV]	Detailed Substance information (e.g., id, lot, manufacturer, ... of QC specimen)		13
}]	--- CONTAINER end		
{	--- ORDER begin		
OBR	Observation Order		7
[{PRT}]	Participation (for observation)		7
[	--- COMMON_ORDER begin		
ORC	Common Order		4
[{PRT}]	Participation (for common order)		7
[	--- ORDER_DOCUMENT begin		
OBX	Observation containing Document		7
[{PRT}]	Participation		7
TXA	Transcription Document Header		9
]	--- ORDER_DOCUMENT end		
]	--- COMMON_ORDER end		
[{NTE}]	Notes and Comments (for Detail)		2
[{PRT}]	Deprecated as of V2.8	Deprecated	7
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		
[{	--- RESULT begin		
OBX	Observation Result		7
[{PRT}]	Participation (for Observation Result)		7
[TCD]	Test Code Detail		13
{[SID]}	Substance Identifier (e.g., reagents used for testing)	B	13
{[INV]}	Inventory Detail (Detailed substance data, e.g., reagents used for testing)		13
[{NTE}]	Notes and Comments		2
}]	--- RESULT end		

Segments	Description	Status	Chapter
[{CTI}]	Clinical Trial Identification		7
}	--- ORDER end		
}	--- SPECIMEN end		
[{	--- DEVICE begin		
DEV	Device (for Participation)		17
[{OBX}]	Observation/Result		7
}]			
[DSC]	Continuation Pointer		2

Acknowledgement Choreography				
OUL^R22^OUL_R22				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^R22^ACK
Application Ack	ACK^R22^ACK	-	ACK^R22^ACK	ACK^R22^ACK

7.3.9 OUL – Unsolicited Specimen Container Oriented Observation Message (Event R23)

This message was designed to accommodate specimen oriented testing. It should be applicable to, for example, laboratory automation systems requiring container.

Generally this construct allows **transfer of multiple results related to one or more specific containers with one or more specimens from a patient.**

In addition to the patient results themselves it permits the communication of the following kinds of information:

- Analysis results of a non patient related sample (e.g., environmental) – patient related segments (e.g., PID, PD1, PV1, PV2) are optional.
- Analysis results to a particular container with QC sample and the lot and manufacturer information about this sample (SAC-INV segments).
- Basic identification data (lot, manufacturer, etc.) of the reagents and other substances involved in the generation of analysis results (TCD-SID segments).

Refer to Chapter 13 Laboratory Automation for additional examples of usage of SAC.

The Device segment (DEV) provides additional device information for a device referenced in one or more of the PRT segments in the message (using PRT-10 Participation Device to match DEV-2 Unique Device Identifier or PRT-22 Participation Device Type using DEV-3 Device Type).

OUL^R23^OUL_R23: Observation Message

Segments	Description	Status	Chapter
MSH	Message Header		2

Segments	Description	Status	Chapter
[{ARV}]	Access Restrictions		3
[{ SFT }]	Software Segment		2
[UAC]	User Authentication Credential		2
[NTE]	Notes and Comments		2
[	--- PATIENT begin		
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[{PRT}]	Participation (for Patient)		7
[{OH1}]	Employment Status		3
[{OH2}]	Past or Present Job		3
[OH3]	Usual Work		3
[{OH4}]	Combat Zone Work		3
[{ARV}]	For backwards compatbility ony as of V2.9	B	3
[{NTE}]	Notes and Comments (for Patient ID)		2
[{	--- PATIENT_OBSERVATION begin		
OBX	Observation (for Patient ID)		7
[{PRT}]	Participation (for Observation)		7
}]	--- PATIENT_OBSERVATION end		
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit – Additional Information		3
[{PRT}]	Participation (for Patient Visit)		7
]	--- VISIT end		
]	--- PATIENT end		
[{NK1}]	Next of Kin		3
{	--- SPECIMEN begin		
SPM	Specimen information		7
[{	--- SPECIMEN_OBSERVATION begin		
OBX	Observation (for Specimen)		7
[{PRT}]	Participation (for Observation)		7
}]	--- SPECIMEN_OBSERVATION end		
{	--- CONTAINER begin		
SAC	Container information		13
[INV]	Detailed Substance information (e.g., id,		13

Segments	Description	Status	Chapter
	lot, manufacturer, ... of QC specimen)		
{	--- ORDER begin		
OBR	Observation Order		7
[{PRT}]	Participation (for observation)		7
[	--- COMMON_ORDER begin		
ORC	Common Order		4
[{PRT}]	Participation (for common order)		7
[	--- ORDER_DOCUMENT begin		
OBX	Observation containing Document		7
[{PRT}]	Participation		7
TXA	Transcription Document Header		9
]	--- ORDER_DOCUMENT end		
]	--- COMMON_ORDER end		
[{NTE}]	Notes and Comments (for Detail)		2
[{PRT}]	Deprecated as of V2.8	Deprecated	7
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		
[{	--- RESULT begin		
OBX	Observation Result		7
[{PRT}]	Participation		7
[TCD]	Test Code Detail		13
[{SID}]	Substance Identifier (e.g., reagents used for testing)	B	13
[{INV}]	Inventory Detail (Detailed substance data e.g., reagents used for testing)		13
[{NTE}]	Notes and Comments		2
}]	--- RESULT end		
[{CTI}]	Clinical Trial Identification		7
}	--- ORDER end		
}	--- CONTAINER end		
}	--- SPECIMEN end		
[{	--- DEVICE begin		

Segments	Description	Status	Chapter
DEV	Device (for Participation)		17
[{OBX}]	Observation/Result (for Device)		7
}]			
[DSC]	Continuation Pointer		2

Acknowledgement Choreography				
OUL^R23^OUL_R23				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^R23^ACK
Application Ack	ACK^R23^ACK	-	ACK^R23^ACK	ACK^R23^ACK

7.3.10 OUL – Unsolicited Order Oriented Observation Message (Event R24)

This message was designed to accommodate multi-specimen oriented testing. It should be applicable to, e.g., laboratory automation systems requiring container.

Generally this construct allows **transfer of multiple results, each one related to none, one or more specific containers with one or more specimens from a patient.** (Example: Creatinine Clearance result with detailed information about the urine and serum specimens and their containers.)

In addition to the patient results themselves it permits the communication of the following kinds of information:

- Analysis results of a non patient related sample (e.g., environmental) – patient related segments (e.g., PID, PD1, PV1, PV2) are optional.
- Analysis results to a particular container with QC sample and the lot and manufacturer information about this sample (SAC-INV segments).
- Basic identification data (lot, manufacturer, etc.) of the reagents and other substances involved in the generation of analysis results (TCD-SID segments).

Refer to Chapter 13 Laboratory Automation for additional examples of usage of SAC.

The Device segment (DEV) provides additional device information for a device referenced in one or more of the PRT segments in the message (using PRT-10 Participation Device to match DEV-2 Unique Device Identifier or PRT-22 Participation Device Type using DEV-3 Device Type).

OUL^R24^OUL_R24: Observation Message

Segments	Description	Status	Chapter
MSH	Message Header		2
[{ARV}]	Access Restrictions		3
[{ SFT }]	Software Segment		2
[UAC]	User Authentication Credential		2
[NTE]	Notes and Comments		2

Segments	Description	Status	Chapter
[	--- PATIENT begin		
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[{PRT}]	Participation (for Patient)		7
[{OH1}]	Employment Status		3
[{OH2}]	Past or Present Job		3
[OH3]	Usual Work		3
[{OH4}]	Combat Zone Work		3
[{ARV}]	For backwards compatibility only as of V2.9.	B	3
[{NTE}]	Notes and Comments (for Patient ID)		2
[{	--- PATIENT_OBSERVATION begin		
OBX	Observation (for Patient ID)		7
[{PRT}]	Participation (for Observation)		7
}]	--- PATIENT_OBSERVATION end		
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit – Additional Information		3
[{PRT}]	Participation (for Patient Visit)		7
]	--- VISIT end		
]	--- PATIENT end		
[{NK1}]	Next of Kin		3
{	--- ORDER begin		
OBR	Observation Order		7
[{PRT}]	Participation (for observation)		7
[	--- COMMON_ORDER begin		
ORC	Common Order		4
[{PRT}]	Participation (for common order)		7
[	--- ORDER_DOCUMENT begin		
OBX	Observation containing Document		7
[{PRT}]	Participation		7
TXA	Transcription Document Header		9
]	--- ORDER_DOCUMENT end		
]	--- COMMON_ORDER end		

Segments	Description	Status	Chapter
[{NTE}]	Notes and Comments (for Detail)		2
[{PRT}]	Deprecated as of V2.8	Deprecated	7
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		
[{	--- SPECIMEN begin		
SPM	Specimen information		7
[{	--- SPECIMEN_OBSERVATION begin		
OBX	Observation (for Specimen)		7
[{PRT}]	Participation (for Observation)		7
}]	--- SPECIMEN_OBSERVATION end		
[{	--- CONTAINER begin		
SAC	Container information		13
[INV]	Detailed Substance information (e.g., id, lot, manufacturer, ... of QC specimen)		13
}]	--- CONTAINER end		
}]	--- SPECIMEN end		
[{	--- RESULT begin		
OBX	Observation Result		7
[{PRT}]	Participation		7
[TCD]	Test Code Detail		13
[{SID}]	Substance Identifier (e.g., reagents used for testing)	B	13
[{INV}]	Inventory Detail (Detailed substance data e.g., reagents used for testing)		13
[{NTE}]	Notes and Comments		2
}]	--- RESULT end		
[{CTI}]	Clinical Trial Identification		7
[{	--- DEVICE begin		
DEV	Device (for Participation)		17
[{OBX}]	Observation/Result (for Device)		7
}]			
}	--- ORDER end		

Segments	Description	Status	Chapter
[DSC]	Continuation Pointer		2

Acknowledgement Choreography				
OUL^R24^OUL_R24				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^R24^ACK
Application Ack	ACK^R24^ACK	-	ACK^R24^ACK	ACK^R24^ACK

7.3.11 OPU – Unsolicited Population/Location-Based Laboratory Observation Message (Event R25)

This message supports unsolicited population or location-based surveillance reporting to a central repository where the accession / visit may contain references to multiple patients, multiple specimens, non-patient specimens, and multiple orders per specimen.

This message structure represents the way most submissions to veterinary laboratories occur. There is a multi-tier hierarchy in which a single individual (for example, a veterinarian or an owner of a production facility) submits one or more specimen samples from one or more animals or non-living entity, such as environmental specimens or feed. This grouped submission of specimens from multiple animal 'patients' is usually referred to as an 'accession' which can be considered analogous to a 'visit' in the veterinary laboratory context. This is what accounts for the unusual structure where the PV1 segment precedes a repeatable ACCESSION_DETAIL group.

Since specimens can originate from non-patients the PATIENT group is optional. This allows for specimens that are both associated with patients as well as those associated with non-patients to be included under the same accession (visit). Each specimen may have one or more orders assigned, each of which may have one or more individual results.

The OBX segment at the visit level provides the reason for submission. The repeatable PRT segment at the visit level represents the person(s) or organization submitting the request and other interested parties and locations who (that) play a role in the disposition of the accession/visit.

The NK1 segment contains owner and/or responsible party information for the patient and/or specimen.

OPU^R25^OPU_R25: Observation Message

Segments	Description	Status	Chapter
MSH	Message Header		2
[{ARV}]	Access Restrictions		3
[{SFT}]	Software Segment		2
[UAC]	User Authentication Credential		2
[NTE]	Notes and Comments		2
PV1	Patient Visit		3
[PV2]	Patient Visit – Additional Information		3

Segments	Description	Status	Chapter
[{PRT}]	Participation (for Patient Visit)		7
[{	--- PATIENT_VISIT_OBSERVATION begin		
OBX	Observation on the Visit		7
[{NTE}]	Notes and Comments on Visit		3
[{PRT}]	Participation		7
}]	--- PATIENT_VISIT_OBSERVATION end		
{	--- ACCESSION_DETAIL begin		
{NK1}	Next of Kin		3
[	--- PATIENT begin		
PID	Patient		3
[PD1]	Additional Demographics		7
[{PRT}]	Participation (for Patient)		7
[{OH1}]	Employment Status		3
[{OH2}]	Past or Present Job		3
[OH3]	Usual Work		3
[{OH4}]	Combat Zone Work		3
[{ARV}]	For backwards compatibility only as of V2.9	B	3
[{	--- PATIENT_OBSERVATION begin		
OBX	Observations on Patient		7
[{PRT}]	Participation (for Observation on Patient)		7
[{NTE}]	Notes and Comments for Observation on Patient		2
}]	--- PATIENT_OBSERVATION end		
]	--- PATIENT end		
{	--- SPECIMEN begin		
SPM	Specimen		7
[{	--- SPECIMEN_OBSERVATION begin		
OBX	Observation on Specimen		7
[{PRT}]	Participation (for Observation)		7
[{NTE}]	Notes and Comments for Observation on Specimen		2
}]	--- SPECIMEN_OBSERVATION end		
[{	--- CONTAINER begin		
SAC	Container information		13

Segments	Description	Status	Chapter
[INV]	Detailed Substance information (e.g., id, lot, manufacturer, ... of QC specimen)		13
}]	--- CONTAINER end		
{	--- ORDER begin		
OBR	Observation Order		7
[{PRT}]	Participation (for observation)		7
[	--- COMMON_ORDER begin		
ORC	Common Order		4
[{PRT}]	Participation (for common order)		7
]	--- COMMON_ORDER end		
[{NTE}]	Notes and Comments (for Detail)		2
[{PRT}]	Deprecated as of V2.8	Deprac ted	7
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		
{	--- RESULT begin		
OBX	Observation Result		7
[{PRT}]	Participation		7
[{NTE}]	Notes and Comments		2
}	--- RESULT end		
}	--- ORDER end		
}	--- SPECIMEN end		
}	--- ACCESSION_DETAIL end		

Acknowledgement Choreography				
OPU^R25^OPU_R25				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^R25^ACK
Application Ack	ACK^R25^ACK	-	ACK^R25^ACK	ACK^R25^ACK

7.3.12 ORU – Unsolicited Alert Observation Message (Event R40)

The R40 trigger event is used for observation reports that include an alertable condition, i.e., for which some timely human or application intervention in patient care may be indicated by the findings. The ORA^R41 provides the application level response to the ORU^R40.

The ORU^R40 message is outside of the order-fulfilling cycle of the ORU and OUL messages with other trigger events, and is supplemental to those order-fulfilling observations. As such, the results conveyed in the ORU^R40 do not replace, edit, or override the results of messages with other trigger events.

The ORU^R40 message represents a unitary alert, which is to be acknowledged as a whole by an ORA message. Multiple alerts requiring separate acknowledgement must be sent as individual messages.

The ORDER_OBSERVATION Segment Group which has OBR-49 value A (Alert provider when abnormal) conveys the alert observation(s). One or more OBX segments in this Segment Group will typically have OBX-8 Interpretation Codes value of LL. HH, or AA. At least one OBR segment shall have OBR-49 value A. Other ORDER_OBSERVATION Segment Groups within the message shall be considered supporting information for the alert observation(s).

An alert observation report may simply replicate observations conveyed in another observation message, e.g., sent in an ORU^R01 (the source observation). In such an instance the ORDER_OBSERVATION Segment Group shall replicate the OBR (and ORC, if present) of the source observation.

An alert observation reporting application may also derive a new alertable observation, e.g., from a combination of other observations from multiple orders, processed by a clinical decision support rule set. In this case, the ORDER_OBSERVATION Segment Group with the alertable observation may use an OBR representing the "order" for clinical decision support, with this instance uniquely identified in the OBR-51 Observation Group ID. Supporting source observations may be conveyed in subsequent ORDER_OBSERVATION Segment Groups in the message using their original OBR information.

If the reporting application can identify a preferred recipient for the alert, that may be conveyed in the PRT segment related to the OBR or OBX (with PRT-4 value RCT "Results Copies To"). This recipient may not be the same as the recipient(s) identified in a source observation. There is no expectation that the reporting application will *a priori* know a preferred recipient, nor that the receiving application will deliver the alert to the identified recipient (e.g., it may be delivered to an "on-call" clinician in lieu of the identified recipient).

ORU^R40^ORU_R01: Observation Message

Segments	Description	Status	Chapter
MSH	Message Header		2
[{ARV}]	Access Restrictions		3
[{ SFT }]	Software Segment		2
[UAC]	User Authentication Credential		2
{	--- PATIENT_RESULT begin		
[	--- PATIENT begin		
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[{PRT}]	Participation (for Patient)		7
[{OH1}]	Employment Status		3
[{OH2}]	Past or Present Job		3
[OH3]	Usual Work		3

Segments	Description	Status	Chapter
[{OH4}]	Combat Zone Work		3
[{NTE}]	Notes and Comments		2
[{	--- NEXT_OF_KIN begin		
NK1	Next of Kin/Associated Parties		3
[{OH2}]	Past or Present Job		3
[OH3]	Usual Work		3
}]	--- NEXT_OF_KIN end		
[{ARV}]	For backwards compatibility only as of V2.9.	B	3
[{	--- PATIENT_OBSERVATION begin		
OBX	Observation (for Patient ID)		7
[{PRT}]	Participation (Observation Participation)		7
}]	--- PATIENT_OBSERVATION end		
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit - Additional Info		3
[{PRT}]	Participation (for Patient Visit)		7
]	--- VISIT end		
[{	--- INSURANCE begin		
IN1	Insurance		6
[IN2]	Insurance Additional Information		6
[IN3]	Insurance Additional Information, Certification		3
}]	--- INSURANCE end		
]	--- PATIENT end		
{	--- ORDER_OBSERVATION begin		
[	--- COMMON_ORDER begin		
ORC	Order common		4
[{PRT}]	Participation (for common order)		7
[	--- ORDER_DOCUMENT begin		
OBX	Observation containing Document		7
[{PRT}]	Participation		7
TXA	Transcription Document Header		9
]	--- ORDER_DOCUMENT end		

Segments	Description	Status	Chapter
]	--- COMMON_ORDER end		
OBR	Observations Request		7
[{NTE}]	Notes and comments		2
[{	--- OBSERVATION_PARTICIPATION begin		
[{PRT}]	Participation (for Observation)		7
[{DEV}]	Device		7
}]	--- OBSERVATION_PARTICIPATION end		17
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		
[CTD]	Contact Data		11
[{	--- OBSERVATION begin		
OBX	Observation related to OBR		7
[{PRT}]	Participation (Observation Participation)		7
{[NTE]}	Notes and comments		2
}]	--- OBSERVATION end		
[{FT1}]	Financial Transaction		6
{[CTI]}	Clinical Trial Identification		7
[{	--- SPECIMEN begin		
SPM	Specimen		
[{	--- SPECIMEN_OBSERVATION begin		
OBX	Observation (for Patient ID)		7
[{PRT}]	Participation (Observation Participation)		7
}]	--- SPECIMEN_OBSERVATION end		
}]	--- SPECIMEN end		
}	--- ORDER_OBSERVATION end		
[{	--- DEVICE begin		
DEV	Device (for Participation)		17
[{OBX}]	Observation/Result		7
}]	--- DEVICE end		
}	--- PATIENT_RESULT end		
[DSC]	Continuation Pointer		2

Acknowledgement Choreography				
ORU^R40^ORU_R01				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^R40^ACK
Application Ack	ORA^R41^ORA_R41	-	ORA^R41^ORA_R41	ORA^R41^ORA_R41

7.3.13 ORA – Observation Report Alert Acknowledgement (Event R41)

This message enables application level acknowledgements in response to the ORU^R40 alert observation message.

The R41 trigger event is used to indicate that the alert observation has been delivered to, and acknowledged by, a clinical user. If the clinical user can be identified, that identity can be conveyed in the PRT segment (with PRT-4 value AAP Alert Acknowledging Provider).

Considering that the alerts may be received by multiple providers, multiple acknowledgements may be returned. The behavior associated with the user acknowledgement may be specified in a local implementation agreement or implementation guide and may be indicated in MSH-21 Message Profile Identifier.

ORA^R41^ORA_R41: Observation Report Alert Acknowledgement

Segments	Description	Status	Chapter
MSH	Message Acknowledgment		2
[{ SFT }]	Software segment		2
[UAC]	User Authentication Credential		2
MSA	Message Acknowledgment		2
[{ ERR }]	Error		2
[{ PRT }]	Participation (Acknowledging User)		7

Acknowledgement Choreography			
ORA^R41^ORA_R41			
Field name	Field Value: Original mode	Field value: Enhanced mode	
MSH-15	Blank	NE	AL, SU, ER
MSH-16	Blank	NE	NE
Immediate Ack	-	-	ACK^R41^ACK
Application Ack	ACK^R41^ACK		

7.3.14 ORU – Unsolicited Device Event Observation Message (Event R42)

The R42 trigger event is used for observation reports that identify a device-sourced event (e.g., transition on an infusion pump between primary and secondary modes of operation) that is relevant to clinical workflow but that does not require a response from a clinician or clinical management system (in which case, an R40 alert message should be used). These events are episodic (vs. periodic), require low latency and appropriate prioritized handling (i.e., should be communicated immediately after the event is signaled), and typically require low transmission bandwidth. R42 messages do not need to provide for an application level response, as does the ORU^R40 message (via the ORA^R41 message).

Use examples of this message include:

- Electronic medication administration record (eMAR) systems that record the pre-programmed transition event of an infusion pump between primary and secondary operational modes, or when it is manually paused and then restarted;
- Clinical decision support systems (CDSS) that track a patient's progress by monitoring, among other events, ventilator transitions from the primary operational mode to a backup mode (e.g., patient triggered to fully mechanical breaths);
- Clinical information systems that note an event when a patient's physiological monitor is placed into Standby Mode;
- Computerized Maintenance Management Systems (CMMS) records usage events and technical (non-alert) maintenance events to determine when a piece of equipment should be evaluated for proper operation.

In contrast to ORU^R42, the ORU^R01 message is typically used to periodically report "bulk" or full-disclosure device data that may include event information, albeit not reported in a timely manner and in a way that requires more processing to identify. As mentioned, the ORU^R40 message supports a class of episodic events, but focuses on those alerts and alarms that require some level of clinical response to resolve. The ORU^R42 message explicitly does not require clinical action to be taken in response to receipt of the message.

The OBX-8 field for these messages should be left blank or set to "N" for normal. Any abnormal or other non-normal indications should result in usage of the ORU^R40 message.

The ORU^R40 message is outside of the order-fulfilling cycle of the ORU and OUL messages with other trigger events, and is supplemental to those order-fulfilling observations. As such, the results conveyed in the ORU^R40 message do not replace, edit, or override the results of messages with other trigger events.

ORU^R42^ORU_R01: Observation Message

Segments	Description	Status	Chapter
MSH	Message Header		2
[{ARV}]	Access Restrictions		3
[{ SFT }]	Software Segment		2
[UAC]	User Authentication Credential		2
{	--- PATIENT_RESULT begin		
[	--- PATIENT begin		
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[{PRT}]	Participation (for Patient)		7
[{OH1}]	Employment Status		3

Segments	Description	Status	Chapter
[{OH2}]	Past or Present Job		3
[OH3]	Usual Work		3
[{OH4}]	Combat Zone Work		3
[{NTE}]	Notes and Comments		2
[{	--- NEXT_OF_KIN begin		
NK1	Next of Kin/Associated Parties		3
[{OH2}]	Past or Prsent Job		3
[OH3]	Usual Work		3
}]	--- NEXT_OF_KIN end		
[{ARV}]	For backwards compatibility only as of V2.9.	B	3
[{	--- PATIENT_OBSERVATION begin		
OBX	Observation (for Patient ID)		7
[{PRT}]	Participation (Observation Participation)		7
}]	--- PATIENT_OBSERVATION end		
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit – Additional Info		3
[{PRT}]	Participation (for Patient Visit)		7
]	--- VISIT end		
[{	--- INSURANCE begin		
IN1	Insurance		6
[IN2]	Insurance Additional Information		6
[IN3]	Insurance Additional Information, Certification		6
}]	--- INSURANCE end		
]	--- PATIENT end		
{	--- ORDER_OBSERVATION begin		
[	--- COMMON_ORDER begin		
ORC	Order common		4
[{PRT}]	Participation (for Observation)		7
[	--- ORDER_DOCUMENT begin		
OBX	Observation containing Document		7
[{PRT}]	Participation		7

Segments	Description	Status	Chapter
TXA	Transcription Document Header		9
]	--- ORDER_DOCUMENT end		
]	--- COMMON_ORDER end		
OBR	Observations Request		7
{[NTE]}	Notes and comments		2
[{	--- OBSERVATION_PARTICIPATION begin		
PRT	Participation (for Observation)		7
[{DEV}]	Device		17
}]	--- OBSERVATION_PARTICIPATION end		
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		
[CTD]	Contact Data		11
[{	--- OBSERVATION begin		
OBX	Observation related to OBR		7
[{PRT}]	Participation (Observation Participation)		7
{[NTE]}	Notes and comments		2
}]	--- OBSERVATION end		
[{FT1}]	Financial Transaction		6
{[CTI]}	Clinical Trial Identification		7
[{	--- SPECIMEN begin		
SPM	Specimen		
[{	--- SPECIMEN_OBSERVATION begin		
OBX	Observation (for Patient ID)		7
[{PRT}]	Participation (Observation Participation)		7
}]	--- SPECIMEN_OBSERVATION end		
}]	--- SPECIMEN end		
}	--- ORDER_OBSERVATION end		
[{	--- DEVICE begin		
DEV	Device (for Participation)		17
[{OBX}]	Observation/Result		7
}]	--- DEVICE end		
}	--- PATIENT_RESULT end		

Segments	Description	Status	Chapter
[DSC]	Continuation Pointer		2

Acknowledgement Choreography				
ORU^R42^ORU_R01				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^R42^ACK
Application Ack	ACK^R42^ACK	-	ACK^R42^ACK	ACK^R42^ACK

7.3.15 ORU – Unsolicited Patient-Device Association Observation Message (Event R43)

The R43 trigger event is used for observation reports that indicate the association of one patient to one or more health care devices. This includes both patient-device association as well as disassociation when a device is removed from active use with a patient. Other messages may be utilized for this purpose (e.g., ADT); however, this message was chosen given the general use of ORU-style messages to communicate device data, including unique device identifiers (e.g., PRT-10 and UDI components), and the possible need to include additional device data such as hardware / software configuration. The R43 trigger provides indication of the specialized usage of this message. Note that OBX-3 Observation Identifier, PRT-4 Participation, and OBX-11 Observation Result Status represent the purpose of the association of the device and the status of that association as further defined through the appropriate implementation guides and/or profiles.

Use cases that this message supports include:

- Simple patient-device association where a system that integrates a bar code or RFID reader is used to capture patient and device identifiers at the point of care and then communicate those to other devices and systems that process device data associated with the same patient.
- When one or more devices are no longer associated with a patient, this message can be used to communicate this change of status
- Systems may not only perform the identifier acquisition from patients and devices, but may also authenticate the identifiers and support cross-referencing (e.g., when there are multiple patient identifiers)

In the latter use case, this message can be used to establish a “source of truth” for patient-device associations. There are many systems in and supportive of the point of care that make associations between patients and health care devices, all of which need to be coordinated to ensure there are no mis-matches between information sources and the patients to which they are associated.

The message shall identify a patient with optional location information, and one or more device observations, each including a unique device identifier along with an indication of whether the device is being associated or disassociated with the specified patient. In addition, a single observation can be specified to disassociate all devices for a given patient.

ORU^R43^ORU_R01: Observation Message

Segments	Description	Status	Chapter
MSH	Message Header		2
[{ARV}]	Access Restrictions		3
[{ SFT }]	Software Segment		2
[UAC]	User Authentication Credential		2
{	--- PATIENT_RESULT begin		
[	--- PATIENT begin		
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[{PRT}]	Participation (for Patient)		7
[{OH1}]	Employment Status		3
[{OH2}]	Past or Present Job		3
[OH3]	Usual Work		3
[{OH4}]	Combat Zone Work		3
[{NTE}]	Notes and Comments		2
[{	--- NEXT_OF_KIN begin		
NK1	Next of Kin/Associated Parties		3
[{OH2}]	Past or Present Job		3
[OH3]	Usual Work		3
}]	--- NEXT_OF_KIN end		
[{ARV}]	For backwards compatibility only as of V2.9.	B	3
[{	--- PATIENT_OBSERVATION begin		
OBX	Observation (for Patient ID)		7
[{PRT}]	Participation (Observation Participation)		7
}]	--- PATIENT_OBSERVATION end		
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit – Additional Info		3
[{PRT}]	Participation (for Patient Visit)		7
]	--- VISIT end		
[{	--- INSURANCE begin		
IN1	Insurance		6
[IN2]	Insurance Additional Information		6

Segments	Description	Status	Chapter
[IN3]	Insurance Additional Information, Certification		6
}]	--- INSURANCE end		
]	--- PATIENT end		
{	--- ORDER_OBSERVATION begin		
[	--- COMMON_ORDER begin		
ORC	Order common		4
[{PRT}]	Participation (for Observation)		7
[	--- ORDER_DOCUMENT begin		
OBX	Observation containing Document		7
[{PRT}]	Participation		7
TXA	Transcription Document Header		9
]	--- ORDER_DOCUMENT end		
]	--- COMMON_ORDER end		
OBR	Observations Request		7
{[NTE]}	Notes and comments		2
[{	--- OBSERVATION_PARTICIPATION begin		
PRT	Participation (for Observation)		7
[{DEV}]	Device		17
}]	--- OBSERVATION_PARTICIPATION end		
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		
[CTD]	Contact Data		11
[{	--- OBSERVATION begin		
OBX	Observation related to OBR		7
[{PRT}]	Participation (Observation Participation)		7
{[NTE]}	Notes and comments		2
}]	--- OBSERVATION end		
[{FT1}]	Financial Transaction		6
[{CTI}]	Clinical Trial Identification		7
[{	--- SPECIMEN begin		
SPM	Specimen		17

Segments	Description	Status	Chapter
[{	--- SPECIMEN_OBSERVATION begin		
OBX	Observation (for Patient ID)		7
[{PRT}]	Participation (Observation Participation)		7
}]	--- SPECIMEN_OBSERVATION end		
}]	--- SPECIMEN end		
}	--- ORDER_OBSERVATION end		
[{	--- DEVICE begin		
DEV	Device (for Participation)		17
[{OBX}]	Observation/Result		7
}]	--- DEVICE end		
}	--- PATIENT_RESULT end		
[DSC]	Continuation Pointer		2

Acknowledgement Choreography				
ORU^R43^ORU_R01				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^R43^ACK
Application Ack	ACK^R43^ACK	-	ACK^R43^ACK	ACK^R43^ACK

7.4 GENERAL SEGMENTS

The full definitions of many segments required for reporting clinical observations are included in other chapters. The patient identifying segment (PID) is provided in Chapter 3. The NTE segment is in Chapter 2.

7.4.1 OBR – Observation Request Segment

General (taken from ASTM E1238)

The Observation Request (OBR) segment is used to transmit information specific to an order for a diagnostic study or observation, physical exam, or assessment.

The Observation Request segment defines the attributes of a particular request for diagnostic services (e.g., laboratory, EKG) or clinical observations (e.g., vital signs or physical exam). When a placer requests a given set of observations, always include an order segment. For lab tests, the information in the order segment usually applies to a single specimen. However, there is not a one-to-one relationship between specimen and tests ordered. Different test batteries will usually require their own order segments even when they can be performed on a single specimen. In this case, the specimen information must be duplicated in each of the order segments that employ that specimen. For other diagnostic studies, e.g., chest X-ray, a separate order segment will usually be generated for each diagnostic study.

Though multiple observation batteries can be ordered on a single order segment, the observation filler shall generate a separate order segment for each battery that it processes independently, e.g., electrolyte, CBC, vital signs. When reporting the observations, the filling service shall copy the appropriate order (specimen) information from the original order segment into each of the new order segments so that a separate "order" segment is returned to the placer as a "header" for each separate battery of observations.

In the event that an ordered battery of observations cannot be performed, e.g., because of hemolysis on a blood sample, an order segment will be returned to the placer with *OBR-25-result status* equal to X (to indicate that the study was not performed). In this case, no observation segments will be transmitted.

When observations are successfully completed, the message returned to the placer will include the order segment (OBR) followed by observation (OBX) segments for each distinct observation generated by the order (see Chapter 7). The number of such observation segments will depend upon the number of individual measurements performed in the process.

OBX segments can be sent by the placer along with an order to provide the filling service with clinical data needed to interpret the results. (See Chapter 7 for OBX details.)

HL7 Attribute Table – OBR – Observation Request

SEQ	LEN	C.LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
1	1..4		SI	O			00237	Set ID – OBR
2			EI	C			00216	Placer Order Number
3			EI	C			00217	Filler Order Number
4			CWE	R		0612	00238	Universal Service Identifier
5				W			00239	Priority
6				W			00240	Requested Date/Time
7			DTM	C			00241	Observation Date/Time #
8			DTM	O			00242	Observation End Date/Time #
9			CQ	B			00243	Collection Volume *
10			XCN	B	Y		00244	Collector Identifier *
11	1..1		ID	O		0065	00245	Specimen Action Code *
12			CWE	O		0613	00246	Danger Code
13		300=	CWE	O	Y	0916	00247	Relevant Clinical Information
14				W			00248	Specimen Received Date/Time *
15				W			00249	Specimen Source
16				W			00226	Ordering Provider
17			XTN	O	Y/2		00250	Order Callback Phone Number
18		199=	ST	O			00251	Placer Field 1
19		199=	ST	O			00252	Placer Field 2
20		199=	ST	O			00253	Filler Field 1 +
21		199=	ST	O			00254	Filler Field 2 +
22			DTM	C			00255	Results Rpt/Status Chng – Date/Time +
23			MOC	O			00256	Charge to Practice +
24	2..3		ID	O		0074	00257	Diagnostic Serv Sect ID
25	1..1		ID	C		0123	00258	Result Status +
26			PRL	O			00259	Parent Result +

SEQ	LEN	C.LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
27				W	Y		00221	Quantity/Timing
28				W			00260	Result Copies To
29			EIP	O			00261	Parent Results Observation Identifier
30	4..4		ID	O		0124	00262	Transportation Mode
31			CWE	O	Y	0951	00263	Reason for Study
32				W			00264	Principal Result Interpreter +
33				W			00265	Assistant Result Interpreter +
34				W			00266	Technician +
35				W			00267	Transcriptionist +
36			DTM	O			00268	Scheduled Date/Time +
37		16=	NM	O			01028	Number of Sample Containers *
38			CWE	O	Y	0614	01029	Transport Logistics of Collected Sample *
39			CWE	O	Y	0619	01030	Collector's Comment *
40			CWE	O		0620	01031	Transport Arrangement Responsibility
41	1..1		ID	O		0224	01032	Transport Arranged
42	1..1		ID	O		0225	01033	Escort Required
43			CWE	O	Y	0621	01034	Planned Patient Transport Comment
44			CNE	O		0088	00393	Procedure Code
45			CNE	O	Y	0340	01316	Procedure Code Modifier
46			CWE	O	Y	0411	01474	Placer Supplemental Service Information
47			CWE	O	Y	0411	01475	Filler Supplemental Service Information
48			CWE	C		0476	01646	Medically Necessary Duplicate Procedure Reason
49			CWE	O		0507	01647	Result Handling
50				W			02286	Parent Universal Service Identifier
51			EI	O			02307	Observation Group ID
52			EI	O			02308	Parent Observation Group ID
53			CX	O	Y		03303	Alternate Placer Order Number
54			EIP	O	Y	0119	00222	Parent Order
55	2..2		ID	O		0206	00816	Action Code

7.4.1.0 OBR field definitions

The daggered (+) items in this segment are created by the filler, not the placer. They are valued by the filler as needed when the OBR segment is returned as part of a report.

The starred (*) fields are only relevant when an observation is associated with a specimen. These are completed by the placer when the placer obtains the specimen. They are completed by the filler when the filler obtains the specimen.

OBR-7-observation date/time and *OBR-8-observation end date/time* (flagged with #) are the physiologically relevant times. In the case of an observation on a specimen, they represent the start and end of the specimen collection. In the case of an observation obtained directly from a subject (e.g., BP, Chest X-ray), they represent the start and end time of the observation.

7.4.1.1 OBR-1 Set ID – OBR (SI) 00237

Definition: For the first order transmitted, the sequence number shall be 1; for the second order, it shall be 2; and so on.

7.4.1.2 OBR-2 Placer order number (EI) 00216

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: This field is identical to *ORC-2-Placer Order Number*.

This field is a special case of the Entity Identifier data type (Chapter 2A, section 2.A.28). The first component is a string that identifies an individual order (i.e., ORC segment and associated order detail segment). A limit of fifteen (15) characters is suggested but not required. It is assigned by the placer (ordering application). An implementation is HL7 compliant when the number of characters for this field is increased to accommodate applications that require a greater number of characters for the Placer order number. It identifies an order uniquely among all orders from a particular ordering application. The second through fourth components contain the application ID of the placing application in the same form as the HD data type (section 2.A.36, "HD – Hierarchic designator"). The second component, namespace ID, is a user-defined coded value that will be uniquely associated with an application. A limit of six (6) characters is suggested but not required. A given institution or group of intercommunicating institutions should establish a unique list of applications that may be potential placers and fillers and assign unique application IDs. The components are separated by component delimiters.

See *ORC-2-placer order number* (section *4.5.1.2*) for information on when this field must be valued.

A given institution or group of intercommunicating institutions should establish a list of applications that may be potential placers and fillers of orders and assign each a unique application ID. The application ID list becomes one of the institution's master dictionary lists that is documented in Chapter 8. Since third-party applications (those other than the placer and filler of an order) can send and receive ORM and ORR messages, the placer application ID in this field may not be the same as any sending and receiving application on the network (as identified in the MSH segment).

The conditions which make this field required are divided into two main issues. The data in *ORC-2* and *OBR-2* are logically the same thing: a placer id. The data in *ORC-3* and *OBR-3* are logically the same thing: the filler id.

From that perspective, each message must have either a placer or a filler id with an exception for the case of a "Send Number" control code since its purpose is to request a placer id.

If both ORC and OBR are present in a message, then only one of the Segments must contain the value(s). If both segments contain either ORC-2/OBR-2 or ORC-3/OBR-3, then each pair must be a matching pair. The sending system can include both the filler and the placer number in both the ORC and OBR segments as long as the data is the same between the two segments.

It is recommended that the initiating system should provide a unique number when a new order or unsolicited result is initially communicated.

These rules apply to the few other fields that are present in both ORC and OBR for upward compatibility (e.g., quantity/timing, parent numbers, ordering provider, and ordering call back numbers).

7.4.1.3 OBR-3 Filler Order Number (EI) 00217

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: This field is the order number associated with the filling application. This is a permanent identifier for an order and its associated observations. It is a special case of the Entity Identifier data type (see Chapter 2, section 2.A.28, "EI – entity identifier").

The first component is a string that identifies an individual order segment (i.e., ORC segment and associated order detail segment). It is assigned by the order filling (receiving) application. It identifies an

order uniquely among all orders from a particular filling application (e.g., clinical laboratory). This uniqueness must persist over time.

The second through fourth components contain the filler application ID, in the form of the HD data type (see section 2.A.36, "HD – hierarchic designator"). The second component is a user-defined coded value that uniquely defines the application from other applications on the network. A limit of six (6) characters is suggested but not required. The second component of the filler order number always identifies the actual filler of an order.

See *ORC-3-filler order number* for information on when this field must be valued.

The conditions which make this field required are divided into two main issues. The data in *ORC-2* and *OBR-2* are logically the same thing: a placer id. The data in *ORC-3* and *OBR-3* are logically the same thing: the filler id.

From that perspective, each message must have either a placer or a filler id with an exception for the case of a "Send Number" control code since its purpose is to request a placer id.

If both ORC and OBR are present in a message, then only one of the Segments must contain the value(s). If both segments contain either ORC-2/OBR-2 or ORC-3/OBR-3, then each pair must be a matching pair. The sending system can include both the filler and the placer number in both the ORC and OBR segments as long as the data is the same between the two segments.

It is recommended that the initiating system should provide a unique number when a new order or unsolicited result is initially communicated.

The filler order number (OBR-3 or ORC-3) also uniquely identifies an order and its associated observations. For example, suppose that an institution collects observations from several ancillary applications into a common database and this common database is queried by yet another application for observations. In this case, the filler order number and placer order number transmitted by the common database application would be that of the original filler and placer, respectively, rather than a new one assigned by the common database application.

Similarly, if a third-party application, not the filler or placer, of an order were authorized to modify the status of an order (say, cancel it), the third-party application would send the filler an ORM message containing an ORC segment with *ORC-1-order control* equal to "CA" and containing the original placer order number and filler order number, rather than assign either itself.

7.4.1.4 OBR-4 Universal Service Identifier (CWE) 00238

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field contains the identifier code for the requested observation/test/battery. The identifier can come from either a local coding system or industry standards. Examples may be LOINC (emerging as the global standard for observation identifiers), JLAC10, or SNOMED CT. Refer to Table 0612 - Universal Service Identifier in Chapter 2C for valid values.

7.4.1.5 OBR-5 Priority

Attention: ***The OBR-5 element was retained for backward compatibility only as of v 2.4 and the detail was withdrawn and removed from the standard as of v 2.7.***

7.4.1.6 OBR-6 Requested Date/Time

Attention: ***The OBR-6 element was retained for backward compatibility only as of v 2.4 and the detail was withdrawn and removed from the standard as of v 2.7.***

7.4.1.7 OBR-7 Observation Date/Time (DTM) 00241

Definition: This field is the clinically relevant date/time of the observation. In the case of observations taken directly from a subject, it is the actual date and time the observation was obtained. In the case of a specimen-associated study, this field shall represent the date and time the specimen was collected or obtained. (This is a results-only field except when the placer or a third party has already drawn the specimen.) This field is conditionally required. When the OBR is transmitted as part of a report message, the field **must** be filled in. If it is transmitted as part of a request **and** a sample has been sent along as part of the request, this field must be filled in because this specimen time is the physiologically relevant date/time of the observation.

7.4.1.8 OBR-8 Observation End Date/Time (DTM) 00242

Definition: This field contains the end date and time of a study or timed specimen collection. If an observation takes place over a substantial period of time, it will indicate when the observation period ended. For observations made at a point in time, it will be null. This is a results field except when the placer or a party other than the filler has already drawn the specimen.

7.4.1.9 OBR-9 Collection Volume (CQ) 00243

```
Components:  <Quantity (NM)> ^ <Units (CWE)>

Subcomponents for Units (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
          System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
          of Alternate Coding System (ID)> & <Coding System Version ID (ST)> &
          <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second
          Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of
          Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>
```

Definition: Deprecated in version 2.9 in favor of SPM-12.

7.4.1.10 OBR-10 Collector Identifier (XCN) 00244

```
Components:  <Person Identifier (ST)> ^ <Family Name (FN)> ^ <Given Name (ST)> ^
          <Second and Further Given Names or Initials Thereof (ST)> ^ <Suffix (e.g.,
          JR or III) (ST)> ^ <Prefix (e.g., DR) (ST)> ^ <WITHDRAWN Constituent> ^
          <DEPRECATED-Source Table (CWE)> ^ <Assigning Authority (HD)> ^ <Name Type
          Code (ID)> ^ <Identifier Check Digit (ST)> ^ <Check Digit Scheme (ID)> ^
          <Identifier Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name
          Representation Code (ID)> ^ <Name Context (CWE)> ^ <WITHDRAWN Constituent>
          ^ <Name Assembly Order (ID)> ^ <Effective Date (DTM)> ^ <Expiration Date
          (DTM)> ^ <Professional Suffix (ST)> ^ <Assigning Jurisdiction (CWE)> ^
          <Assigning Agency or Department (CWE)> ^ <Security Check  (ST)> ^
          <Security Check Scheme (ID)>

Subcomponents for Family Name (FN):  <Surname (ST)> & <Own Surname Prefix (ST)> & <Own
          Surname (ST)> & <Surname Prefix from Partner/Spouse (ST)> & <Surname from
          Partner/Spouse (ST)>

Subcomponents for Source Table (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of
          Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
          & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
          & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
          <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
          of Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Authority (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
          & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
          & <Universal ID Type (ID)>
```

```
Subcomponents for Name Context (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of
          Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
          & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
          & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
          <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
          of Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Jurisdiction (CWE):  <Identifier (ST)> & <Text (ST)> &
          <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
          Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
          Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
          Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text
          (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate
          Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID
          (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)>
          & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)>
          & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Agency or Department (CWE):  <Identifier (ST)> & <Text
          (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> &
          <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding
          System Version ID (ST)> & <Alternate Coding System Version ID (ST)> &
          <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second
          Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> &
          <Second Alternate Coding System Version ID (ST)> & <Coding System OID
          (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate
          Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate
          Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> &
          <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set
          Version ID (DTM)>
```

Definition: ***This field is retained for backward compatibility only as of v 2.7.*** The reader is referred to the PRT segment described in Chapter 7.

When a specimen is required for the study, this field will identify the person, department, or facility that collected the specimen. Either name or ID code, or both, may be present. If the person referenced in this field is also referenced in PRT segment, they must contain the same information. However, if there is a difference, then PRT segment takes precedence.

7.4.1.11 OBR-11 Specimen Action Code (ID) 00245

Definition: This field identifies the action to be taken with respect to the specimens that accompany or precede this order. The purpose of this field is to further qualify (when appropriate) the general action indicated by the order control code contained in the accompanying ORC segment. For example, when a new order (ORC – "NW") is sent to the lab, this field would be used to tell the lab whether or not to collect the specimen ("L" or "O"). Refer to *HL7 Table 0065 – Specimen Action Code* in Chapter 2C, Code Tables, for valid values.

7.4.1.12 OBR-12 Danger Code (CWE) 00246

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
          <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
          Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
          System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
          Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
          Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
          (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
          Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
          Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
          Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
          Alternate Value Set Version ID (DTM)>
```

Definition: This field contains the code and/or text indicating any known or suspected patient or specimen hazards, e.g., patient with active tuberculosis or blood from a hepatitis patient. Either code and/or text may

be absent. However, the code is always placed in the first component position and any free text in the second component. Thus, free text without a code must be preceded by a component delimiter. Refer to Table 0613 - Danger Code in Chapter 2C for valid values.

7.4.1.13 OBR-13 Relevant Clinical Information (CWE) 00247

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field contains additional clinical information about the patient or specimen. This field is used to report the supporting and/or suspected diagnosis and clinical findings on requests for interpreted diagnostic studies where a simple text string or code is sufficient. This field could use all appropriate code sets including SNOMED to message Relevant Clinical Information. If more information is needed, such as date/time of the observation, who observed it, abnormal ranges, etc., or must be provided in further structured format, e.g., structured numeric with units of measure encoded, the Observation/Result group following the OBR should be used. Examples include reporting the amount of inspired carbon dioxide for blood gasses, the point in the menstrual cycle for cervical pap tests, and other conditions that influence test interpretations. Refer to *HL7 Table 0916 – Relevant Clinical Information* in Chapter 2C, Code Tables, for valid values.

7.4.1.14 OBR-14 Specimen Received Date/Time

Attention: ***The OBR-14 element was retained for backward compatibility only as of v 2.5 and the detail was withdrawn and removed from the standard as of v 2.7. See SPM in Chapter 7.***

7.4.1.15 OBR-15 Specimen Source

Attention: ***The OBR-15 element was retained for backward compatibility only as of v 2.5 and the detail was withdrawn and removed from the standard as of v 2.7. See SPM in Chapter 7.***

7.4.1.16 OBR-16 Ordering Provider (XCN) 00226

Definition: ***This field was retained for backward compatibility only as of v 2.7 and the detail was withdrawn and removed from the standard as of v 2.9.*** The reader is referred ot the PRT segment as described in Chapter 7.

7.4.1.17 OBR-17 Order Callback Phone Number (XTN) 00250

```
Components:  <WITHDRAWN Constituent> ^ <Telecommunication Use Code (ID)> ^
             <Telecommunication Equipment Type (ID)> ^ <Communication Address (ST)> ^
             <Country Code (SNM)> ^ <Area/City Code (SNM)> ^ <Local Number (SNM)> ^
             <Extension (SNM)> ^ <Any Text (ST)> ^ <Extension Prefix (ST)> ^ <Speed
             Dial Code (ST)> ^ <Unformatted Telephone number  (ST)> ^ <Effective Start
             Date (DTM)> ^ <Expiration Date (DTM)> ^ <Expiration Reason (CWE)> ^
             <Protection Code (CWE)> ^ <Shared Telecommunication Identifier (EI)> ^
             <Preference Order (NM)>

Subcomponents for Expiration Reason (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of
             Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
             & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
             & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
             <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
             of Second Alternate Coding System (ID)> & <Second Alternate Coding System
             Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
             <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
             <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
             <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
             OID (ST)> & <Second Alternate Value Set Version ID (DTM)>
```

```
Subcomponents for Protection Code (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of
          Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
          & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
          & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
          <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
          of Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Shared Telecommunication Identifier (EI):  <Entity Identifier (ST)>
          & <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>
```

Definition: This field contains the telephone number for reporting a status or a result using the standard format with extension and/or beeper number when applicable.

7.4.1.18 OBR-18 Placer Field 1 (ST) 00251

Definition: This field is user field #1. Text sent by the placer will be returned with the results.

7.4.1.19 OBR-19 Placer Field 2 (ST) 00252

Definition: This field is similar to placer field #1.

7.4.1.20 OBR-20 Filler Field 1 (ST) 00253

Definition: This field is definable for any use by the filler (diagnostic service).

7.4.1.21 OBR-21 Filler Field 2 (ST) 00254

Definition: This field is similar to filler field #1.

7.4.1.22 OBR-22 Results Rpt/Status Chng – Date/Time (DTM) 00255

Definition: This field specifies the date/time when the results were reported or status changed. This conditional field is required whenever the OBR-25 is valued. This field is used to indicate the date and time that the results are composed into a report and released, or that a status, as defined in *ORC-5 order status*, is entered or changed. (This is a results field only.) When other applications (such as office or clinical database applications) query the laboratory application for un-transmitted results, the information in this field may be used to control processing on the communications link. Usually, the ordering service would want only those results for which the reporting date/time is greater than the date/time the inquiring application last received results.

7.4.1.23 OBR-23 Charge to Practice (MOC) 00256

```
Components:  <Monetary Amount (MO)> ^ <Charge Code (CWE)>

Subcomponents for Monetary Amount (MO):  <Quantity (NM)> & <Denomination (ID)>

Subcomponents for Charge Code (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of
          Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
          & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
          & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
          <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
          of Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>
```

Definition: This field is the charge to the ordering entity for the studies performed when applicable. The first component is a dollar amount when known by the filler. The second is a charge code when known by the filler (results only).

7.4.1.24 OBR-24 Diagnostic Serv Sect ID (ID) 00257

Definition: This field is the section of the diagnostic service where the observation was performed. If the study was performed by an outside service, the identification of that service should be recorded here. Refer to *HL7 Table 0074 – Diagnostic Service Section ID* in Chapter 2C, Code Tables, for valid entries.

7.4.1.25 OBR-25 Result Status (ID) 00258

Definition: This field contains the status of results for this order. This conditional field is required whenever the OBR is contained in a report message. It is not required as part of an initial order.

There are two methods of sending status information. If the status is that of the entire order, use *ORC-15-order effective date/time* and *ORC-5-order status*. If the status pertains to the order detail segment, use *OBR-25-result status* and *OBR-22-results rpt/status chng – date/time*. If both are present, the OBR values override the ORC values.

This field would typically be used in a response to an order status query where the level of detail requested does not include the OBX segments. When the individual status of each result is necessary, *OBX-11-observ result status* may be used. Refer to *HL7 Table 0123 – Result Status* in Chapter 2C, Code Tables, for valid entries.

7.4.1.26 OBR-26 Parent Result (PRL) 00259

```
Components:  <Parent Observation Identifier (CWE)> ^ <Parent Observation Sub-
             identifier (OG)> ^ <Parent Observation Value Descriptor (TX)>

Subcomponents for Parent Observation Identifier (CWE):  <Identifier (ST)> & <Text
             (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> &
             <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding
             System Version ID (ST)> & <Alternate Coding System Version ID (ST)> &
             <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second
             Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> &
             <Second Alternate Coding System Version ID (ST)> & <Coding System OID
             (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate
             Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate
             Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> &
             <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set
             Version ID (DTM)>

Subcomponents for Parent Observation Sub-identifier (OG): <Original Sub-Identifier
             (ST)> & <Group (NM)> & <Sequence (NM)> & <Identifier (ST)>
```

Definition: This field is defined to make it available for other types of linkages (e.g., toxicology). This important information, together with the information in *OBR-29-Parent Result Obersvation Identifier* and *OBR-54 Parent Order*, uniquely identifies the parent result's OBX segment related to this order. The value of this OBX segment in the parent result is the organism or chemical species about which this battery reports, or the specific result for which this order or observation is a reflex. For example, if the current battery is an antimicrobial susceptibility, the parent results identified OBX contains a result which identifies the organism on which the susceptibility was run. This indirect linkage is preferred because the name of the organism in the parent result may undergo several preliminary values prior to finalization. In the case of a reflex order, if it is necessary to point to the specific result value for which it is in response, OBR-26 enables pointing to that specific OBX segment.

The third component may be used to record the name of the microorganism identified by the parent result directly. The organism in this case should be identified exactly as it is in the parent culture.

We emphasize that this field does not take the entire result field from the parent. It is meant only for the text name of the organism or chemical subspecies identified. This field is included only to provide a method for linking back to the parent result for those systems that could not generate unambiguous Observation IDs and sub-IDs.

This field is present only when the parent result is identified by *OBR-29-* Result Observation Identifier or OBR-54, Parent Order, and the parent spawns child orders or results for each of many results. (See Chapter 7 for more details about this linkage.)

A second mode of conveying this information is to use a standard observation result segment (OBX). If more than one organism is present, *OBX-4-observation sub-ID* is used to distinguish them. In this case, the first OBX with subID N will contain a value identifying the Nth microorganism, and each additional OBX with subID N will contain susceptibility values for a given antimicrobial test on this organism.

7.4.1.27 OBR-27 Quantity/timing

Attention: ***The OBR-27 element was retained for backward compatibility only as of v 2.5 and the detail was withdrawn and removed from the standard as of v 2.7.***

7.4.1.28 OBR-28 Result Copies To (XCN) 00260

Definition: ***This field was retained for backward compatibility only as of v 2.7 and the detail was withdrawn and removed from the standard as of v 2.9.*** Additional capabilities are now available through thePRT segment following the OBR using the "RCT" (Results Copy To) value in PRT-4 (Participation) from *HL7 Table 912 - Participation* in Chapter 2C, Code Tables, and referencing the appropriate participant information using other PRT Fields. The PRT segment is further described in Chapter 7 Section 7.3.4 "PRT – Participation Information Segment".

7.4.1.29 OBR-29 Parent Result Observation Identifier (EIP) 00261

```
Components:  <Placer Assigned Identifier (EI)> ^ <Filler Assigned Identifier (EI)>

Subcomponents for Placer Assigned Identifier (EI):  <Entity Identifier (ST)> &
           <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Filler Assigned Identifier (EI):  <Entity Identifier (ST)> &
           <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>
```

Definition: This field relates a child result to its parent result when a parent child result relationship exists. This field uniquely identifies the order number of the parent result; no other information is required to link the child result with its parent result.

7.4.1.30 OBR-30 Transportation Mode (ID) 00262

Definition: This field identifies how (or whether) to transport a patient, when applicable. Refer to *HL7 Table 0124 – Transportation Mode* in Chapter 2C, Code Tables, for valid codes.

7.4.1.31 OBR-31 Reason for Study (CWE) 00263

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
           <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
           Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
           System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
           Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
           Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
           (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
           Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
           Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
           Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
           Alternate Value Set Version ID (DTM)>
```

Definition: This field is the code or text using the conventions for coded fields given in the Control chapter (Chapter 2). This is required for some studies to obtain proper reimbursement.

Refer *HL7 Table 0951 – Reason for Study* in Chapter 2C, Code Tables.

7.4.1.32 OBR-32 Principal Result Interpreter (NDL) 00264

Definition: ***This field is retained for backward compatibility only as of v 2.6 and the detail was withdrawn and removed from the standard as of v 2.9..*** The reader is referred to the PRT segment described in Chapter 7.

7.4.1.33 OBR-33 Assistant Result Interpreter (NDL) 00265

Definition: ***This field was retained for backward compatibility only as of v 2.6 and the detail was withdrawn and removed from the standard as of v 2.9..*** The reader is referred to the PRTsegment used relative to OBR as described in section *4.5.3.32*, "*Principal Result Interpreter*."

7.4.1.34 OBR-34 Technician (NDL) 00266

Definition: ***This field was retained for backward compatibility only as of v 2.6 and the detail was withdrawn and removed from the standard as of v 2.9.*** The reader is referred to the PRTsegment used relative to OBR as described in section *4.5.3.32*, "*Principal Result Interpreter*."

7.4.1.35 OBR-35 Transcriptionist (NDL) 00267

Definition: ***This field was retained for backward compatibility only as of v 2.6 and the detail was withdrawn and removed from the standard as of v 2.9.*** The reader is referred to the PRTsegment used relative to OBR as described in section *4.5.3.32*, "*Principal Result Interpreter*."

7.4.1.36 OBR-36 Scheduled Date/Time (DTM) 00268

Definition: This field is the date/time the filler scheduled an observation, when applicable (e.g., action code in *OBR-11-specimen action code* = "S"). This is a result of a request to schedule a particular test and provides a way to inform the placer of the date/time a study is scheduled (result only).

7.4.1.37 OBR-37 Number of Sample Containers (NM) 01028

Definition: This field identifies the number of containers for a given sample. For sample receipt verification purposes; may be different from the total number of samples which accompany the order.

7.4.1.38 OBR-38 Transport Logistics of Collected Sample (CWE) 01029

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field is the means by which a sample reaches the diagnostic service provider. This information is to aid the lab in scheduling or interpretation of results. Possible answers: routine transport van, public postal service, etc. If coded, requires a user-defined table. Refer to Table 0614 - Transport Logistics of Collected Sample in Chapter 2C for valid values.

7.4.1.39 OBR-39 Collector's Comment (CWE) 01030

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field is for reporting additional comments related to the sample. If coded, requires a user-defined table. If only free text is reported, it is placed in the second component with a null in the first component, e.g., ^difficulty clotting after venipuncture and ecchymosis. Refer to Table 0619 - Collector's Comment in Chapter 2C for valid values.

7.4.1.40 OBR-40 Transport Arrangement Responsibility (CWE) 01031

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field is an indicator of who is responsible for arranging transport to the planned diagnostic service. Examples: Requester, Provider, Patient. If coded, requires a user-defined table. Refer to Table 0620 - Transport Arrangement Responsibility in Chapter 2C for valid values.

7.4.1.41 OBR-41 Transport Arranged (ID) 01032

Definition: This field is an indicator of whether transport arrangements are known to have been made. Refer to *HL7 Table 0224 – Transport Arranged* in Chapter 2C, Code Tables, for valid codes.

7.4.1.42 OBR-42 Escort Required (ID) 01033

Definition: This field is an indicator that the patient needs to be escorted to the diagnostic service department. Note: The nature of the escort requirements should be stated in *OBR-43-planned patient transport comment*. See *HL7 Table 0225 – Escort Required* in Chapter 2C, Code Tables, for valid values.

7.4.1.43 OBR-43 Planned Patient Transport Comment (CWE) 01034

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field is the code or free text comments on special requirements for the transport of the patient to the diagnostic service department. If coded, requires a user-defined table. Refer to Table 0621 - Planned Patient Transport Comment in Chapter 2C for valid values.

7.4.1.44 OBR-44 Procedure Code (CNE) 00393

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field contains a unique identifier assigned to the procedure, if any, associated with the charge. Refer to *Externally-defined table 0088 – Procedure code* in Chapter 2C, Code Tables, for suggested values. This field is a coded data type for compatibility with clinical and ancillary systems.

As of version 2.6, applicable external coding systems include those in the referenced table. If the code set used is in the referenced table, then the coding scheme designation in the table shall be used.

7.4.1.45 OBR-45 Procedure Code Modifier (CNE) 01316

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field contains the procedure code modifier to the procedure code reported in *OBR-44-procedure code*, when applicable. Procedure code modifiers are defined by regulatory agencies such as CMS and the AMA. Multiple modifiers may be reported. The modifiers are sequenced in priority according to user entry. In the USA, this is a requirement of the UB and the 1500 claim forms. Multiple modifiers are allowed and the order placed on the form affects reimbursement. Refer to *Externally- defined table 0340 – Procedure code modifier* in Chapter 2C, Code Tables, for suggested values.

Usage Rule: This field can only be used if *OBR-44 – procedure code* contains certain procedure codes that require a modifier in order to be billed or performed. For example, HCPCS codes that require a modifier to be precise.

As of version 2.6, applicable external coding systems include those in the referenced table. If the code set used is in the referenced table, then the coding scheme designation in the table shall be used.

7.4.1.46 OBR-46 Placer Supplemental Service Information (CWE) 01474

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field contains supplemental service information sent from the placer system to the filler system for the universal procedure code reported in *OBR-4 Universal Service ID*. This field will be used to provide ordering information detail that is not available in other specific fields in the OBR segment. Multiple supplemental service information elements may be reported. Refer to *User-defined Table 0411 - Supplemental service information values* in Chapter 2C, Code Tables.

This field can be used to describe details such as whether study is to be done on the right or left, for example, where the study is of the arm and the order master file does not distinguish right from left, or whether the study is to be done with or without contrast (when the order master file does not make such distinctions).

7.4.1.47 OBR-47 Filler Supplemental Service Information (CWE) 01475

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field contains supplemental service information sent from the filler system to the placer system for the procedure code reported in *OBR-4 Universal Service ID*. This field will be used to report ordering information detail that is not available in other specific fields in the OBR segment. Typically it will reflect the same information as was sent to the filler system in *OBR-46-Placer supplemental service information* unless the order was modified, in which case the filler system will report what was actually performed using this field. Multiple supplemental service information elements may be reported. Refer to *User-Defined Table 0411 - Supplemental Service Information Values* in Chapter 2C, Code Tables.

This field can be used to describe details such as whether study is to be done on the right or left, for example, where the study is of the arm and the order master file does not distinguish right from left, or whether the study is to be done with or without contrast (when the order master file does not make such distinctions).

7.4.1.48 OBR-48 Medically Necessary Duplicate Procedure Reason (CWE) 01646

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field is used to document why the procedure found in *OBR-44 - Procedure Code* is a duplicate of one ordered/charged previously for the same patient within the same date of service and has been determined to be medically necessary. The reason may be coded or it may be a free text entry.

This field is intended to provide financial systems information on who to bill for duplicate procedures.

Refer to *User-Defined Table 0476 – Medically Necessary Duplicate Procedure Reason* in Chapter 2C, Code Tables, for suggested values.

7.4.1.49 OBR-49 Result Handling (CWE) 01647

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: Transmits information regarding the handling of the result. For example, an order may specify that the result (e.g., an x-ray film) should be given to the patient for return to the requestor. Refer to *HL7 Table 0507 - Observation Result Handling* in Chapter 2C, Code Tables, for values. If this field is not populated or if it includes value "CC^Copies Requested", then routine handling is implied and PRT segments assocatied with this OBR with PRT-4 value of "RCT^Result Copies To" identify additional recipients for the results. When this field includes the value "BCC^Blind Copy", those PRT segments, which are included in the order message and in the observation result message sent to the requestor, shall not be included in the observation result messages sent to the copied recipients.

7.4.1.50 OBR-50 Parent Universal Service Identifier (CWE) 02286

Definition: ***This field is retained for backward compatibility only as of v 2.7 and withdrawn as of v2.9.***

7.4.1.51 OBR-51 Observation Group ID (EI) 02307

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: The Observation Group ID is the identifier assigned by the producer of a result to uniquely identify the results associated with this OBR segment. The Observation Group ID is intended to remain the same regardless of the change in status to the result (i.e., it is not a snapshot ID). This field is intended to promote forward compatibility with HL7 V3.

7.4.1.52 OBR-52 Parent Observation Group ID (EI) 02308

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
           <Universal ID Type (ID)>
```

Definition: The Parent Observation Group ID field relates this child OBR to its parent OBR segment using the Observation Group ID of the parent result.

7.4.1.53 OBR-53 Alternate Placer Order Number (CX) 03303

```
Components:  <ID Number (ST)> ^ <Identifier Check Digit (ST)> ^ <Check Digit Scheme
           (ID)> ^ <Assigning Authority (HD)> ^ <Identifier Type Code (ID)> ^
           <Assigning Facility (HD)> ^ <Effective Date (DT)> ^ <Expiration Date (DT)>
           ^ <Assigning Jurisdiction (CWE)> ^ <Assigning Agency or Department (CWE)>
           ^ <Security Check (ST)> ^ <Security Check Scheme (ID)>

Subcomponents for Assigning Authority (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
           & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
           & <Universal ID Type (ID)>

Subcomponents for Assigning Jurisdiction (CWE):  <Identifier (ST)> & <Text (ST)> &
           <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
           Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
           Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
           Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text
           (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate
           Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID
           (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)>
           & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)>
           & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
           OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Agency or Department (CWE):  <Identifier (ST)> & <Text
           (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> &
           <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding
           System Version ID (ST)> & <Alternate Coding System Version ID (ST)> &
           <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second
           Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> &
           <Second Alternate Coding System Version ID (ST)> & <Coding System OID
           (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate
           Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate
           Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> &
           <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set
           Version ID (DTM)>
```

Definition: This field enables a shorter number to be communicated that is unique within other identifiers.

7.4.1.54 OBR-54 Parent Order (EIP) 00222

```
Components:  <Placer Assigned Identifier (EI)> ^ <Filler Assigned Identifier (EI)>

Subcomponents for Placer Assigned Identifier (EI):  <Entity Identifier (ST)> &
           <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Filler Assigned Identifier (EI):  <Entity Identifier (ST)> &
           <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>
```

Definition: This field relates a child order to its parent order when a parent child order relationship exists. The parent child order mechanism is described in *HL7 Table 0119 – Order Control Codes* in Chapter 2C, Code Tables, under order control code PA. This field uniquely identifies the parent orders; no other information is required to link the child order with its parent orders. It can be used to express that this order is a reflex being a consequence of original results referred here.

The first component has the same format as *ORC-2-placer order number* (Section *4.5.3.2*, "*Placer Order Number* (EI) 00216"). The second component has the same format as *ORC-3-filler order number*

(Section *4.5.3.3*, "*Filler Order Number* (EI) 00217"). The components of the placer order number and the filler order number are transmitted in sub-components of the two components of this field.

Note that ORC-8 – Parent Order is equivalent to OBR-54-Parent Order, but neither one is the same as *OBR-29-Parent Result Obersvation Identifier* .

Condition: Where the message has matching ORC/OBR pairs, ORC-8 and OBR-54 must carry the same value.

7.4.1.55 OBR-55 Action Code (ID) 00816

Definition: This field reveals the intent of the message. Refer to *HL7 Table 0206 - Segment Action Code* for valid values.

The action code can only be used when an either OBR-2 and/or OBR-3 is valued with unique identifier in accordance with Chapter 2, Section 2.10.4.2.

7.4.2 OBX - Observation/Result Segment

The OBX segment is used to transmit a single observation or observation fragment. It represents the smallest indivisible unit of a report. The OBX segment can also contain encapsulated data, e.g., a CDA document or a DICOM image.

Its principal mission is to carry information about observations in report messages. But the OBX can also be part of an observation order (see Chapter 4, section 4.4, "General Trigger Events & Message Definitions"). In this case, the OBX carries clinical information needed by the filler to interpret the observation the filler makes. For example, an OBX is needed to report the inspired oxygen on an order for a blood oxygen to a blood gas lab, or to report the menstrual phase information which should be included on an order for a pap smear to a cytology lab. Appendix 7A includes codes for identifying many of the pieces of information needed by observation producing services to properly interpret a test result. OBX is also found in other HL7 messages that need to include patient clinical information.

HL7 Attribute Table – OBX – Observation/Result

SEQ	LEN	C.LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1	1..4		SI	O			00569	Set ID – OBX
2	2..3		ID	C		0125	00570	Value Type
3			CWE	R		0622	00571	Observation Identifier
4		20=	OG	C			00572	Observation Sub-ID
5			varies	C	Y		00573	Observation Value
6			CWE	O		0623	00574	Units
7		60=	ST	O			00575	Reference Range
8			CWE	O	Y	0078	00576	Interpretation Codes
9		5#	NM	O			00577	Probability
10	1..2		ID	O	Y	0080	00578	Nature of Abnormal Test
11	1..1		ID	R		0085	00579	Observation Result Status
12			DTM	O			00580	Effective Date of Reference Range
13		20=	ST	O			00581	User Defined Access Checks
14			DTM	O			00582	Date/Time of the Observation
15			CWE	B		0624	00583	Producer's ID
16			XCN	B	Y		00584	Responsible Observer
17			CWE	O	Y	0626	00936	Observation Method
18			EI	B	Y		01479	Equipment Instance Identifier

SEQ	LEN	C.LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
19			DTM	O			01480	Date/Time of the Analysis
20			CWE	O	Y	0163	02179	Observation Site
21			EI	O			02180	Observation Instance Identifier
22			CNE	C		0725	02182	Mood Code
23			XON	B	N		02283	Performing Organization Name
24			XAD	B	N		02284	Performing Organization Address
25			XCN	B	N		02285	Performing Organization Medical Director
26	1..10		ID	O	N	0909	02313	Patient Results Release Category
27			CWE	O		0914	03308	Root Cause
28			CWE	O	Y	0915	03309	Local Process Control
29			ID	O	N	0936	03432	Observation Type
30			ID	O	N	0937	03475	Observation Sub-Type
31	2..2		ID	O		0206	00816	Action Code
32			CWE	C	Y	0960	03510	Observation Value Absent Reason
33			EIP	O	Y		02454	Observation Related Specimen Identifier

7.4.2.0 OBX field definitions

7.4.2.1 OBX-1 Set ID - OBX (SI) 00569

Definition: This field contains the sequence number. For compatibility with ASTM.

7.4.2.2 OBX-2 Value Type (ID) 00570

Definition: This field defines the data type of OBX-5, Observation Value. If OBX-5, Observation Value, is valued then OBX-2, Value Type, SHALL be valued. When OBX-5, Observation Value, is not valued, OBX-2 Value Type MAY be valued to represent a data type used to value the observation expressed in OBX-3, Observation Identifier. See *HL7 Table 0125 – Value Types* for valid values.

Condition: This field is required if OBX-5, Observation Value, is valued.

For example, if the value is 'CWE' then the result in OBX-5 must be a coded entry or text or both. As of v 2.7, the ST data type may not be used to transmit data that can be more precisely transmitted using other data types, e.g. SN when comparative symbols are needed.

The RP value (reference pointer) must be used if the OBX-5 contains a pointer to the data e.g., a URL of an image. The receiving system can use this reference pointer whenever it needs access to the actual data through other interface standards, e.g., DICOM, or through appropriate data base servers.

The structured numeric (SN) data type provides for reporting ranges (e.g., 3-5 or 10-20), titres (e.g., 1:10), and out-of-range indicators (e.g., >50) in a structured and computer-interpretable way.

We allow the FT data type in the OBX segment, but its use is discouraged. Formatted text usually implies a meaningful structure, e.g., a list of three independent diagnoses reported on different lines. But ideally, the structure in three independent diagnostic statements would be reported as three separate OBX segments.

TX should **not** be used except to send large amounts of text. In the TX data type, the repeat delimiter can only be used to identify paragraph breaks. Use ST to send short, and possibly encodable, text strings.

CDA documents are to be exchanged in the OBX segment in any message that can exchange documents (such as MDM or ORU). Within the OBX segment, the MIME package is encoded as an encapsulated (ED) data type.

7.4.2.3 OBX-3 Observation Identifier (CWE) 00571

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field contains a unique identifier for the observation. The format is that of the Coded Element (CWE). Example: "8625-6^P-R interval^LN". Refer to Table 0622 - Observation Identifier in Chapter 2C for valid values.

In most systems the identifier will **point** to a master observation table that will provide other attributes of the observation that may be used by the receiving system to process the observations it receives. A set of message segments for transmitting such master observation tables is described in Chapter 8. The relation of an observation ID to a master observation table is analogous to the relationship between a charge code (in a billing record) and the charge master.

When local codes are used as the first identifier in this field we strongly encourage sending a universal identifier as well to permit receivers to equivalence results from different providers of the same service (e.g., a hospital lab and commercial lab that provides serum potassium to a nursing home). LOINC® is one possible universal and HL7-approved code system for the Observation identifier. It covers observations and measurements, such as laboratory tests, physical findings, radiology studies, and claims attachments. See *HL7 Table 0396 – Coding System*, the HL7 www list server and Appendix X2 of ASTM E1467 for neurophysiology tests, or it can be obtained from www.regenstrief.org/loinc/loinc.htm.

The use of suffixes as described in section *7.2.4* and section *7.2.5* has been deprecated as of v 2.7.

7.4.2.4 OBX-4 Observation Sub-ID (OG) 00572

```
Components:  <Original Sub-Identifier (ST)> ^ <Group (NM)> ^ <Sequence (NM)> ^
             <Identifier (ST)>
```

Definition: This field is used to distinguish between multiple OBX segments with the same observation ID organized under one OBR. Starting with V2.8.2 the data type was changed from ST to OG to enable improved structured grouping of observation segments. In this enhanced mode, the first component provides backwards compatibility with existing grouping schemes, while the additional components can be used for improved structures as defined in specific conformance profiles. For example, a chest X-ray report might include three separate diagnostic impressions. The standard requires three OBX segments, one for each impression. By putting a 1 in the Sub-ID of the first of these OBX segments, 2 in the second, and 3 in the third, we can uniquely identify each OBX segment for editing or replacement.

The sub-identifier is also used to group related components in reports such as surgical pathology. It is traditional for surgical pathology reports to include all the tissues taken from one surgical procedure in one report. Consider, for example, a single surgical pathology report that describes the examination of gallbladder and appendix tissue. This report would be transmitted roughly as shown in Figure 7-2.

Figure 7-2. Example of sub-identifier usage – enhanced mode

```
OBR|1||1234^LAB|11529-5^Study report^LN|...<cr>

OBX|1|CWE|31208-2^Specimen source [Identifier] of Unspecified
    specimen^LN|^1^1^1|8231008^Gallbladder structure (body structure)^SCT|...<cr>

OBX|2|TX|22634-0^Path report.gross observation^LN|^1^2^1|THIS IS A NORMAL
    GALLBLADDER|...<cr>

OBX|3|TX|22635-7^Path report.microscopic observation^LN|^1^3^1|MICROSCOPIC EXAM
    SHOWS HISTOLOGICALLY  NORMAL GALLBLADDER TISSUE|...<cr>

OBX|4|CWE|34574-4^Path report.final diagnosis^LN|^1^4^1|300355005^Gallbladder
    normal (finding)^SCT|...<cr>

OBX|5|CWE|31208-2^Specimen source [Identifier] of Unspecified
    specimen^LN|^2^1^1|66754008^Appendix structure (body structure)^SCT|...<cr>

OBX|6|TX|22634-0^Path report.gross observation^LN|^2^2^1|THIS IS A RED, INFLAMED,
    SWOLLEN, BOGGY APPENDIX|...<cr>

OBX|7|TX|22635-7^Path report.microscopic observation^LN|^2^3^1|INFILTRATION WITH
    MANY PMN's - INDICATING INFLAMATORY CHANGE|...<cr>

OBX|8|CWE|34574-4^Path report.final diagnosis^LN|^2^4^1|M-40000^INFLAMMATION
    NOS^SNM|...<cr>
```

The example in Figure 7-2 has two segments for each component of the report, one for each of the two tissues. Thus, there are two "31208-2^Specimen source [Identifier] of Unspecified specimen^LN" segments; there are two "22634-0^Path report.gross observation^LN" segments, and there are two "22635-7^Path report.microscopic observation^LN" segments. Segments that apply to the gallbladder all have the sub-identifier 1. Segments that apply to the appendix all have sub-identifier 2.

The observation sub ID has other grouping uses. It can be used to organize the reporting of some kinds of fluid intakes and outputs. For example, when intake occurs through multiple intravenous lines, a number of separate observations (OBX segments), the intake volume, the type of intake (Blood, D5W, Plasma, etc.), the site of the IV line, etc. may be needed for each intravenous line, each requiring a separate OBX segment. If more than one IV line is running, we can logically link all of the OBX segments that pertain to the first IV line by assigning them an observation sub ID of 1. We can do the same with the second IV line by assigning them a sub ID 2 and so on. The same would apply to the outputs of surgical drains when there are multiple such drains.

The use of the sub ID to distinguish repeating OBXs for the same observation ID is really a special case of using the sub ID to group, as can be seen if we picture the OBX segments in Figure 7-2 as part of a table where the rows correspond to a particular species of observation and the cells correspond to the sub ID numbers that would be associated with each corresponding OBX.

Distinct Observations	88304&ANT	22634-0^Path report.gross observation^LN	22635-7^Path report.microscopic observation^LN	34574-4^Path report.final diagnosis^LN
Sub ID 1st Group	1	1	1	1
Sub ID 2nd Group	2	2	2	2

The use of Sub IDs to group results is equivalent to defining a table, and the use of sub IDs to distinguish repeats is just a special case, represented by one column in this table.

However, this approach introduces ambiguities if we have a set of repeating observations within a group, e.g., if the appendix observations include two impressions as in the 8th and 9th OBXs shown in Figure 7-3. This really represents the existence of a row nested within a single cell of the table given above.

Figure 7-3. Example of sub-identifier usage – original mode

```
OBX|1|CWE|880304&ANT|1|T57000^GALLBLADDER^SNM|...<cr>

OBX|2|TX|22634-0^Path report.gross observation^LN|1|THIS IS A NORMAL GALL
    BLADDER|...<cr>

OBX|3|TX|22635-7^Path report.microscopic observation^LN|1|MICROSCOPIC EXAMINATION
    SHOWS HISTOLOGICALLY

    NORMAL GALLBLADDER TISSUE|...<cr>

OBX|4|CWE|34574-4^Path report.final diagnosis^LN|1|M-00100^NML^SNM|...<cr>

OBX|5|CWE|880304&ANT|2|T57000^APPENDIX^SNM|...<cr>

OBX|6|TX|22634-0^Path report.gross observation^LN|2|THIS IS A RED, INFLAMED
    APPENDIX|...<cr>

OBX|7|TX|22635-7^Path report.microscopic observation^LN|2|INFLAMMATION WITH MANY
    PUS CELLS-ACUTE INFLAMMATION|...<cr>

OBX|8|CWE|34574-4^Path report.final diagnosis^LN|2|M-40000^INFLAMMATION
    NOS^SNM|...<cr>

OBX|9|CWE|34574-4^Path report.final diagnosis^LN|2|M-30280^FECALITH^SNM|...<cr>
```

The text under *OBX-5-observation value* provides guidance about dealing with two OBXs with the same observation ID and observation sub IDs. They are sent and replaced as a unit. However, some systems will take this to mean that the set of OBXs is to be combined into one composite observation in the receiving system. In original mode, this could use a dot and a string (similar to the Dewey Decimal system) notation that would be used when users wish to distinguish each of the repeats within one type, or results within a cell for editing and correction purposes. Using this system, Figure 7-3 would become 7-4. If there are cases where such nesting occurs at even deeper levels, this approach could be extended, although with the introduction of the OG data type we suggest the use of components 2-4 as described in Figure 7-2.

Figure 7-4. Example of sub-identifier usage – original mode with nesting

```
OBX|1|CWE||31208-2^Specimen source [Identifier] of Unspecified
    specimen^LN|1|28231008^Gallbladder structure (body structure)^SCT|...<cr>

OBX|2|TX|22634-0^Path report.gross observation^LN|1|THIS IS A NORMAL GALL
    BLADDER|...<cr>

OBX|3|TX|22635-7^Path report.microscopic observation^LN|1|MICROSCOPIC EXAMINATION
    SHOWS HISTOLOGICALLY

    NORMAL GALLBLADDER TISSUE|...<cr>

OBX|4|CWE|34574-4^Path report.final diagnosis^LN|1|300355005^Gallbladder normal
    (finding)^SCT|...<cr>

OBX|5|CWE|31208-2^Specimen source [Identifier] of Unspecified
    specimen^LN|2|66754008^Appendix structure (body structure)^SCT|...<cr>

OBX|6|TX|22634-0^Path report.gross observation^LN|2|THIS IS A RED, INFLAMED
    APPENDIX|...<cr>

OBX|7|TX|22635-7^Path report.microscopic observation^LN|2|INFLAMMATION WITH MANY
    PUS CELLS-ACUTE INFLAMMATION|...<cr>

OBX|8|CWE|34574-4^Path report.final diagnosis^LN|2.1|M-40000^INFLAMMATION
    NOS^SNM|...<cr>

OBX|9|CWE|34574-4^Path report.final diagnosis^LN|2.2|M-30280^FECALITH^SNM|...<cr>
```

Use a null or 1 when there is no need for multiples.

If the observation includes a number of OBXs with the same value for the observation ID OBX-3, then one must use different values for the sub-ID. If there is no need to group or sequence any further, the original mode can continue to be used to ensure uniqueness of OBX as shown in the example below of an electrocardiograph chest radiograph report with three diagnostic impressions, using 1,2,3 in the sub-ID field to distinguish the three separate results.

Figure 7-5. Example of Sub-ID used to distinguish three independent results with the same observation ID – without grouping/sequencing

```
OBX|1|CWE|8601-7^EKG IMPRESSION ^LN|1|^atrial fibrillation|...<cr>
OBX|2|CWE|8601-7^EKG IMPRESSION ^LN|2|^OLD SEPTAL MYOCARDIAL INFARCT|...<cr>
OBX|3|CWE|8601-7^EKG IMPRESSION ^LN|3|^poor R wave progression|...<cr>
```

7.4.2.5 OBX-5 Observation Value (varies) 00573

Definition: This field contains the value observed by the observation producer. *OBX-2-value type* contains the data type for this field according to which observation value is formatted. It is not a required field because some systems will report only the Interpretation Codes (*OBX-8*), especially in product experience reporting. The length of the observation field is variable, depending upon *OBX-2-value type*. This field may repeat for multipart, single answer results.

Representation

This field contains the value related to the *OBX-3-observation identifier* of the same segment. Depending upon the observation, the data type may be a number (e.g., a respiratory rate), a coded answer (e.g., a pathology impression recorded as SNOMED), or a date/time (the date/time that a unit of blood is sent to the ward). An observation value is always represented as the data type specified in *OBX-2-value type* of the same segment. Whether numeric or short text, the answer shall be recorded in ASCII text.

Reporting logically independent observations

The main sections of dictated reports, such as radiologic studies or history and physicals, are reported as separate OBX segments. In addition, each logically independent observation should be reported in a separate OBX segment, i.e., one OBX segment should not contain the **result** of more than one logically independent observation, unless it is part of a list of like concepts that belong together (e.g., a list of conditions tested for in newborn screening or mutations looked for in genomic testing). This requirement is included to assure that the contents of *OBX-6-units*, *OBX-8-interpretation codes*, and *OBX-9-probability* can be interpreted unambiguously. This means that all other OBX field values apply equally to the whole of OBX-5 noting that OBX-6 does not apply in the case of coded values. The electrolytes and vital signs batteries, for example, would each be reported as four separate OBX segments. Two diagnostic impressions, e.g., congestive heart failure and pneumonia, would also be reported as two separate OBX segments whether reported as part of a discharge summary or chest X-ray report. Similarly, two bacterial organisms isolated in a single bacterial culture would be reported as two separate OBX segments.

Though two independent diagnostic **statements** cannot be reported in one OBX segment, unless they represent elements of a single list to which all other OBX field values apply equally, multiple categorical responses are allowed (usually as CWE data types separated by repeat delimiters), so long as they are fragments (modifiers) that together construct one diagnostic statement. Right upper lobe (recorded as one code) and pneumonia (recorded as another code), for example, could be both reported in one OBX segment. Such multiple "values" would be separated by repeat delimiters. The other example where use of repeat delimiters is allowed for coded values would be a list of conditions or mutations tested for to provide reference for the test results reported in related, but independent OBX segments. Multiple answers to a single question (for example mark all that apply type questions) could also be handled using this approach. It is important to state that ANY independent observation, that may require parent-child linking to additional tests, such as reflex testing, SHALL NOT be included in a single OBX-5 field using repeat delimiters, nor any list elements that require variations in the values of other OBX field values.

The following provides an example of how this may be communicated for 10 Cystic Fibrosis mutations, where the mutations are highlighted in red font (note that some labs test for as many as 140 mutations):

```
OBX|1|CWE|21656-4^CFTR gene mutations tested for in Blood or Tissue by Molecular
    genetics method Nominal
    ^LN|1|c.254G>A^^HGVS~c.350G>A^^HGVS~c.489+1G>T^^HGVS~c.579+1G>T^^HGVS~c.1000C
    >T^^HGVS~c.1040G>C^^HGVS~c.1364C>A^^HGVS~c.1519_1521del^^HGVS~c.1521_1523del^
    ^HGVS~c.1585-1G>A^^HGVS|||N|||F
```

Multiple OBX segments with the same observation ID and Sub ID

In some systems, a single observation may include **fragments** of more than one data type. The most common example is a numeric result followed by coded comments (CWE). In this case, the logical observation can be sent in more than one OBX segment. For example, one segment of numeric data type for the numeric result and another segment of CWE data type for coded comments. If the producer was reporting multiple coded comments they would all be sent in one OBX segment separated by repeat delimiters because they all modified a single logical observation. Multiple OBX segments with the same observation ID and sub ID should always be sent in sequence with the most significant OBX segment (the one that has the normal flag/units and or reference range and status flag) first. The value of *OBX-6 through 12* should be null in any following OBX segments with the same *OBX-3-observation identifier* and *OBX-4-observation sub-ID*. For the purpose of replacement or deletion, multiple OBX segments with the same observation ID and sub ID are treated as a unit. If any are replaced or deleted, they all are replaced.

Coded values

When an OBX segment contains values of CWE data types, the observations are stored as a combination of codes and/or text. In Section *7.8.3*, "*CSS - Clinical Study Data Schedule Segment*," examples of results that are represented as CWE data types are shown in the first and second OBX segments of OBR 1 and the first and second OBX segments of OBR 2. The observation may be an observation battery ID (for recommended studies), a diagnostic code or finding (for a diagnostic impression), or an anatomic site for a pathology report, or any of the other kinds of coded results.

It is not necessary to always encode the information stored within a coded observation. For example, a chest X-ray impression could be transmitted as pure text even though it has a CWE data type. In this case, the test must be recorded as the second component of the **result code,** e.g.,

```
OBX|1|CWE|19005^X-Ray Impression^LN|1|^CONGESTIVE HEART FAILURE.|...<cr>
```

However, separate impressions, recommendations, etc., even if recorded as pure text, should be recorded in separate result segments. That is, congestive heart failure and pneumonia should not be sent as:

```
OBX|1|CWE|19005^X-Ray Impression^LN|1|^CONGESTIVE HEART FAILURE AND PNEUMONIA|...<cr>
```

but as:

```
OBX|1|CWE|19005^X-Ray Impression^LN|1|^CONGESTIVE HEART FAILURE|...<cr>
OBX|2|CWE|19005^X-Ray Impression^LN|2|^PNEUMONIA|....<cr>
```

Even better would be fully-coded results that include computer understandable codes (component 1) instead of, or in addition to, the text description (component 2). One may include multiple values in a CWE value and these can be mixtures of code and text, but only when they are needed to construct one diagnosis, impression, or concept. When text follows codes as an independent value it would be taken as a modifier or addenda to the codes. E.g.,

```
OBX|1|CWE|19005-8^X-ray impression^LN~29548-5^DiagnosisImpPatient^LN
    |1|428.0^CONGESTIVE HEART FAILURE^I9C~^MASSIVE HEART|...<cr>
```

The text in component 2 should be an accurate description of the code in component 1. Likewise, if used, the text in component 5 should be an accurate description of the code in component 4.

Insertion of CDA within an OBX:

CDA documents are to be exchanged in the OBX segment. The value of *OBX-2-Value Type* should be set to 'ED'. *OBX-5-Observation Value* contains the MIME package encoded as an encapsulated data type. The components should be valued as follows:

- Set the value of *OBX-5.2-Type of Data* to 'multipart.'

- Set the value of *OBX-5.3-Data Subtype* to '-hl7-cda-level-one.'
- Set the value of *OBX-5.4-Encoding* to 'A'. (Note that a MIME package is not itself Base64-encoded. Rather entities within the MIME package are Base64-encoded. A MIME package is sent as ASCII text. Therefore, the correct value is 'A' not 'Base64.'
- Set the value of *OBX-5.5-Data* to equal the MIME package. Every entity within the MIME package must be Base64-encoded. As stated in Chapter 2, "the data component must be scanned before transmission for HL7 delimiter characters (and other non-printing ASCII or non-ASCII characters such as LineFeed), and any found must be escaped by using the HL7 escape sequences defined in Section 2.7 'Use of escape sequences in text fields.' On the receiving application, the data field must be de-escaped after being parsed." As a result, CR/LF sequences required in the MIME package need to be escaped (i.e., converted to '\X0D0A\') prior to transmission. The content type of the first MIME entity is set to 'application/x-hl7-cda-level-one+xml', and should contain the CDA document itself. Multimedia objects referenced by the CDA document that need to be transmitted within the CDA document are to be placed in successive entities of the MIME package.

7.4.2.6 OBX-6 Units (CWE) 00574

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
           <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
           Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
           System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
           Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
           Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
           (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
           Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
           Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
           Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
           Alternate Value Set Version ID (DTM)>
```

Definition: This field contains the units of measurement for the value in *OBX-5, Observation Value*. Coding system from which the values may be drawn include, UCUM, ISO+, ANSI X3.50 - 1986 and site specific (local) coding systems. Considering Version 3 direction and consistent use of V2 and V3 messages/documents within an organization, use of UCUM is strongly recommended. Refer to Table 0623 - Units in Chapter 2C for valid values.

Note that OBX-6 applies to both OBX-5.2 and OBX-5.4 if OBX-2 = “SN”.

7.4.2.7 OBX-7 Reference Range (ST) 00575

Components: for numeric values in the format:

a) lower limit-upper limit (when both lower and upper limits are defined, e.g., for potassium 3.5 - 4.5)

b) > lower limit (if no upper limit, e.g., >10)

c) < upper limit (if no lower limit, e.g., <15)

alphabetical values: the normal value may be reported in this location

Definition: When the observation quantifies the amount of a toxic substance, then the upper limit of the range identifies the toxic limit. If the observation quantifies a drug, the lower limits identify the lower therapeutic bounds and the upper limits represent the upper therapeutic bounds above which toxic side effects are common.

7.4.2.8 OBX-8 Interpretation Codes (CWE) 00576

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: One or more codes specifying a categorical assessment of the observation value (OBX.5), such as "Normal", "Abnormal", "Positive", "Negative", "Resistant", "Susceptible", etc.

This field may also be used to convey an assessment of an observation where no legitimate result may be obtained. This includes laboratory assays that are rejected due to the presence of interfering substances, specimen toxicity or failure of quality control.

As a CWE data type, this field may be populated with either HL7-defined codes or codes derived from other code systems (such as SNOMED). See *User-defined Table 0078 – Interpretation Code* for potential entries.

When the filler can discern the normal status of a textual report, such as chest X-ray reports or microbiologic culture, these should be reported as "N" when normal and "A"when abnormal. Multiple codes, e.g., abnormal and worse, would be separated by a repeat delimiter, e.g., "A~W".

Results may also be reported in **shorthand** by reporting the normalcy status without specifying the exact numeric value of the result. Such shorthand is quite common in clinical notes, where physicians will simply say that **the glucose result was normal.** Such shorthand reporting is also seen in drug experience reporting. In such cases, the result can be reported in the OBX by reporting the interpretation code in *OBX-8-Interpretation Codes* without specifying any value in *OBX-5-observation value.*

7.4.2.9 OBX-9 Probability (NM) 00577

Definition: This field contains the probability of a result being true for results with categorical values. It mainly applies to discrete coded results. It is a decimal number represented as an ASCII string that must be between 0 and 1, inclusive.

7.4.2.10 OBX-10 Nature of abnormal test (ID) 00578

Definition: This field contains the nature of the abnormal test. Refer to *HL7 Table 0080 - Nature of abnormal testing* for valid values. As many of the codes as apply may be included, separated by repeat delimiters. For example, normal values based on age, sex, and race would be codes as "A~S~R".

The constraints on the use of the codes in this table must be consistent with those defined in the PID segment, specifically *PID-35-Species Code*, *PID-36-Breed Code* and *PID-37-Strain*.

7.4.2.11 OBX-11 Observation Result Status (ID) 00579

Definition: This field contains the observation result status. Refer to *HL7 table 0085 - Observation result status codes interpretation* for valid values. This field reflects the current completion status of the results for one Observation Identifier.

It is a required field. Previous versions of HL7 stated this implicitly by defining a default value of "F." Code **F** indicates that the result has been verified to be correct and final. Code **W** indicates that the result has been verified to be wrong (incorrect); a replacement (corrected) result may be transmitted later. Code **C** indicates that data contained in the *OBX-5-observation value* field are to replace previously transmitted (verified and) final result data with the same observation ID (including suffix, if applicable) and observation sub-ID usually because the previous results were wrong. Code **D** indicates that data previously transmitted in a result segment with the same observation ID (including suffix) and observation sub-ID should be deleted. When changing or deleting a result, multiple OBX segments with the same observation ID and observation sub-ID are replaced or deleted as a unit. Normal progression of results through

intermediate (e.g., 'gram positive cocci') to final (e.g., 'staphylococcus aureus') should not be transmitted as **C** (correction); they should be transmitted as **P** (depending upon the specific case) until they are final.

If an observation involves multiple OBX segments with the same observation ID (including suffix) and observation sub-ID, the observation result status applies to all OBX segments, except where the value is D or X. The value of D or X is applicable only to the individual OBX. All other OBX segments with the same Observation ID and observation sub-ID must have the same value.

In the case of coding systems such as LOINC, the preceding rules typically mean that this field applies to a single OBX segment.

There are situations where the observation battery required for the order needs to be dynamically specified at the time of ordering. That is, this battery is then defined by the set of OBX segments transmitted along with the order and generated by the placing system. For example, timed measurements of serum glucose challenge tests may vary among laboratories. One institution may report them at –30, -15, 0, 30, 60, and 120 minutes, while another may report them at –30, 0, 30, 60, 90, and 120 minutes. Master file entries may exist for each individual element of the battery but not for the battery itself. Another example may be Renin Studies where the specification may be done upon ordering without having a master file definition for each permutation of the possible element. The OBX segments in the ORM message can be used to create dynamic specifications to accommodate these permutations without defining pre-existing master file definitions for the battery itself. The result status field in the OBX can be used to indicate whether the OBX in the ORM message is used to provide a dynamic specification or is used to communicate a result as context to the order. The status of O shall be used to indicate that the OBX segment is used for a dynamic specification of the required result. An OBX used for a dynamic specification must contain the detailed examination code, units, etc., with *OBX-11* valued with O, and *OBX-2* and *OBX-5* valued with null.

7.4.2.12 OBX-12 Effective Date of Reference Range (DTM) 00580

Definition: This field contains the date (and, optionally, the time) on which the values in *OBX-7-reference range* went into effect.

Usage Rule: This field can be valued only if *OBX-7-reference range* is populated.

When this field is present, it facilitates comparison between identical results with different reference ranges. Reference range values may vary because of changes in laboratory practice over time. Such variances could reflect updated practice in laboratory medicine, or the use of updated instrumentation.

7.4.2.13 OBX-13 User Defined Access Checks (ST) 00581

Definition: This field permits the producer to record results-dependent codes for classifying the observation at the receiving system. This field should be needed only rarely, because most classifications are fixed attributes of the observation ID and can be defined in the associated observation master file (see description in Chapter 8).

However, there are a few cases when such controls vary with the value of the observation in a complex way that the receiving system would not want to re-calculate. An example is an antimicrobial susceptibility result. Some systems prefer to display only the susceptibility results of inexpensive antimicrobials depending upon the organism, the source of the specimen and the patient's allergy status. The sending service wants to send all of the susceptibilities so that certain privileged users (e.g., Infectious Disease specialists) can review all of the results but non-privileged users would see only the "preferred" antimicrobials to which the organism was susceptible. We expect that other cases also occur.

7.4.2.14 OBX-14 Date/Time of the Observation (DTM) 00582

Definition: This field is needed in two circumstances. The first is when the observations reported beneath one report header (OBR) have different dates/times. This could occur in the case of queries, timed test sequences, or clearance studies where one measurement within a battery may have a different time than another measurement.

It is also needed in the case of OBX segments that are being sent by the placer to the filler, in which case the date of the observation being transmitted is likely to have no relation to the date of the requested

observation. In France, requesting services routinely send a set of the last observations along with the request for a new set of observations. The date of these observations is important to the filler laboratories.

In all cases, the observation date-time is the physiologically relevant date-time or the closest approximation to that date-time. In the case of tests performed on specimens, the relevant date-time is the specimen's collection date-time. In the case of observations taken directly on the patient (e.g., X-ray images, history and physical), the observation date-time is the date-time that the observation was performed.

The Date/Time of observation can be used to identify when the answer was determined, i.e., when the answer to an Ask at Order Entry question was acquired.

7.4.2.15 OBX-15 Producer's ID (CWE) 00583

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
          <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
          Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
          System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
          Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
          Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
          (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
          Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
          Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
          Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
          Alternate Value Set Version ID (DTM)>
```

Definition: ***Retained for backwards compatibility as of v 2.7 only. This field is now represented through the PRT segment.*** This field contains a unique identifier of the responsible producing service. It should be reported explicitly when the test results are produced at outside laboratories, for example. When this field is null, the receiving system assumes that the observations were produced by the sending organization. This information supports CLIA regulations in the US. The code for producer ID is recorded as a CWE data type. In the US, the Medicare number of the producing service is suggested as the identifier. Refer to Table 0624 - Producer's ID in Chapter 2C for valid values.

7.4.2.16 OBX-16 Responsible Observer (XCN) 00584

```
Components:  <Person Identifier (ST)> ^ <Family Name (FN)> ^ <Given Name (ST)> ^
          <Second and Further Given Names or Initials Thereof (ST)> ^ <Suffix (e.g.,
          JR or III) (ST)> ^ <Prefix (e.g., DR) (ST)> ^ <WITHDRAWN Constituent> ^
          <DEPRECATED-Source Table (CWE)> ^ <Assigning Authority (HD)> ^ <Name Type
          Code (ID)> ^ <Identifier Check Digit (ST)> ^ <Check Digit Scheme (ID)> ^
          <Identifier Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name
          Representation Code (ID)> ^ <Name Context (CWE)> ^ <WITHDRAWN Constituent>
          ^ <Name Assembly Order (ID)> ^ <Effective Date (DTM)> ^ <Expiration Date
          (DTM)> ^ <Professional Suffix (ST)> ^ <Assigning Jurisdiction (CWE)> ^
          <Assigning Agency or Department (CWE)> ^ <Security Check  (ST)> ^
          <Security Check Scheme (ID)>

Subcomponents for Family Name (FN):  <Surname (ST)> & <Own Surname Prefix (ST)> & <Own
          Surname (ST)> & <Surname Prefix from Partner/Spouse (ST)> & <Surname from
          Partner/Spouse (ST)>

Subcomponents for Source Table (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of
          Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
          & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
          & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
          <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
          of Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Authority (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
          & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
          & <Universal ID Type (ID)>
```

```
Subcomponents for Name Context (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of
          Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
          & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
          & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
          <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
          of Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Jurisdiction (CWE):  <Identifier (ST)> & <Text (ST)> &
          <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
          Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
          Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
          Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text
          (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate
          Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID
          (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)>
          & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)>
          & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Agency or Department (CWE):  <Identifier (ST)> & <Text
          (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> &
          <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding
          System Version ID (ST)> & <Alternate Coding System Version ID (ST)> &
          <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second
          Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> &
          <Second Alternate Coding System Version ID (ST)> & <Coding System OID
          (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate
          Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate
          Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> &
          <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set
          Version ID (DTM)>
```

Definition: ***Retained for backwards compatibility as of v 2.7 only. This field is now represented through the PRT segment.*** When required, this field contains the identifier of the individual directly responsible for the observation (i.e., the person who either performed or verified it). In a nursing service, the observer is usually the professional who performed the observation (e.g., took the blood pressure). In a laboratory, the observer is the technician who performed or verified the analysis. The code for the observer is recorded as a CWE data type. If the code is sent as a local code, it should be unique and unambiguous when combined with *OBX-15-producer ID*.

7.4.2.17 OBX-17 Observation Method (CWE) 00936

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
          <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
          Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
          System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
          Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
          Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
          (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
          Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
          Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
          Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
          Alternate Value Set Version ID (DTM)>
```

This optional field can be used to transmit the method or procedure by which an observation was obtained when the sending system wishes to distinguish among one measurement obtained by different methods and the distinction is not implicit in the test ID. Chemistry laboratories do not usually distinguish between two different methods used to measure a given serum constituent (e.g., serum potassium) as part of the test name. See the LOINC® Users Manual[1] for a more complete discussion of these distinctions. If an

[1] 1. McDonald CJ, Huff SM, Deckard J, Armson S, Abhyankar S, Vreeman DJ, eds. Logical Observation Identifiers Names and Codes (LOINC®) Users' Guide. Indianapolis: Regenstrief Institute; 2016. http://loinc.org/downloads
2. LOINC, a universal standard for identifying laboratory observations: a 5-year update.

observation producing service wanted to report the method used to obtain a particular observation, and the method was NOT embedded in the test name, they can use this field. Refer to Table 0626 - Observation Method in Chapter 2C for valid values.

7.4.2.18 OBX-18 Equipment Instance Identifier (EI) 01479

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: ***Retained for backwards compatibility as of v 2.7 only. This field is now represented through the PRT segment.*** This field identifies the Equipment Instance (e.g., Analyzer, Analyzer module, group of Analyzers, etc.) responsible for the production of the observation. This is the identifier from an institution's master list of equipment, where the institution is specified by the *namespace ID* or if it is blank, then by the "Producer's ID" (OBX-15). It should be possible to retrieve from this master list the equipment type, serial number, etc., however it is not planned to transfer this information with every OBX. The repeating of this field allows for the hierarchical representation of the equipment (lowest level first), e.g., module of an instrument, instrument consisting of modules, cluster of multiple instruments, etc.

7.4.2.19 OBX-19 Date/Time of the Analysis (DTM) 01480

Definition: This field is used to transfer the time stamp associated with generation of the analytical result by the instrument specified in Equipment Instance Identifier (see above).

7.4.2.20 OBX-20 Observation Site (CWE) 02179

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field typically contains the body site(s) where the measurement being reported was obtained. This field should not be used for a specimen source or specimen collection site.

This information is of particular importance if the clinical meaning of a value is modified either directly by the site (for example, is the temperature central or peripheral?) or if the site of one measurement impacts the value of another measurement (for example, is the finger SpO2 probe on the same arm as the NIBP cuff?). In most cases these observations are performed directly upon the patient and do not involve a specimen.

Any nationally recognized coding system might be used for this field including SNOMED or MDC; alternatively the *HL7 Table 0163 – Body Site* may be used. Veterinary medicine may choose the tables supported for the components of this field as decided by their industry.

7.4.2.21 OBX-21 Observation Instance Identifier (EI) 02180

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: This field contains a unique identifier for this observation. This instance identifier is persistent between messages.

Note: OBX-21 Observation Instance Identifier was introduced in v 2.6 to support Patient Care messaging concepts and constructs. At this time, there are no documented use cases for this field in the context of messages as described in this chapter. This statement does not preclude the use of OBX-21, but implementers should exercise caution in using this field outside of the Patient Care context until the appropriate use cases are established. This

McDonald CJ, Huff SM, Suico JG, Hill G, Leavelle D, Aller R, Forrey A, Mercer K, DeMoor G, Hook J, Williams W, Case J, Maloney P. Clin Chem. 2003 Apr;49(4):624-33.
PMID: 12651816 Free Article:

identifier provides persistent reference to an object within or outside the message and represents an identifier established by external applications rather than temporal message considerations.

7.4.2.22 OBX-22 Mood Code (CNE) 02182

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field identifies the actuality of the observation (e.g., intent, request, promise, event). Refer to HL7 Table 0725 – Mood Codes for valid values. This field may only be used with new trigger events and new messages from v 2.6 onward. When this field is not valued in a message that qualifies, then the Value is assumed to be 'EVN'.

Note: OBX-22 Mood Code was introduced in v 2.6 to support Patient Care messaging concepts and constructs. At this time, there are no documented use cases for this field in the context messages as described in this chapter. This statement does not preclude the use of OBX-22, but implementers should exercise caution in using this field outside of the Patient Care context until appropriate use cases are established. While a similar note exists for OBX-21 Observation Instance Identifier, particular care should be taken with OBX-22 as this could modify the intent of the segment/message and create backward compatibility problems.

7.4.2.23 OBX-23 Performing Organization Name (XON) 02283

```
Components:  <Organization Name (ST)> ^ <Organization Name Type Code (CWE)> ^
             <WITHDRAWN Constituent> ^ <WITHDRAWN Constituent> ^ <WITHDRAWN
             Constituent> ^ <Assigning Authority (HD)> ^ <Identifier Type Code (ID)> ^
             <Assigning Facility (HD)> ^ <Name Representation Code (ID)> ^
             <Organization Identifier (ST)>

Subcomponents for Organization Name Type Code (CWE):  <Identifier (ST)> & <Text (ST)>
             & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
             Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
             Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
             Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text
             (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate
             Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID
             (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)>
             & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)>
             & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
             OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Authority (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
             & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
             & <Universal ID Type (ID)>
```

Definition: ***Retained for backwards compatibility as of v 2.7 only. This field is now represented through the PRT segment.*** This field contains the name of the organization/service responsible for performing the service. When this field is null, the receiving system assumes that the observations were produced by the sending organization. The information for performing organization is recorded as an XON data type. In the US, the Medicare number of the performing organization is suggested as the identifier (component 10).

For lab, this field specifies the laboratory that produced the test result described in this OBX segment. It should be reported explicitly when the test results are produced at outside laboratories, for example. This information supports CLIA regulations in the US. For the US producing laboratories, which are CLIA certified, the CLIA identifier should be used for the organization identifier (component 10).

7.4.2.24 OBX-24 Performing Organization Address (XAD) 02284

Components: <Street Address (SAD)> ^ <Other Designation (ST)> ^ <City (ST)> ^ <State or Province (ST)> ^ <Zip or Postal Code (ST)> ^ <Country (ID)> ^ <Address Type (ID)> ^ <Other Geographic Designation (ST)> ^ <County/Parish Code (CWE)> ^ <Census Tract (CWE)> ^ <Address Representation Code (ID)> ^ <WITHDRAWN Constituent> ^ <Effective Date (DTM)> ^ <Expiration Date (DTM)> ^ <Expiration Reason (CWE)> ^ <Temporary Indicator (ID)> ^ <Bad Address Indicator (ID)> ^ <Address Usage (ID)> ^ <Addressee (ST)> ^ <Comment (ST)> ^ <Preference Order (NM)> ^ <Protection Code (CWE)> ^ <Address Identifier (EI)>

Subcomponents for Street Address (SAD): <Street or Mailing Address (ST)> & <Street Name (ST)> & <Dwelling Number (ST)>

Subcomponents for County/Parish Code (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Census Tract (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Expiration Reason (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Protection Code (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Address Identifier (EI): <Entity Identifier (ST)> & <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Definition: ***Retained for backwards compatibility as of v 2.7 only. This field is now represented through the PRT segment.*** This field contains the address of the organization/service responsible for performing the service.

For labs, this field specifies the address of the laboratory that produced the test result described in this OBX segment. It should be reported explicitly when the test results are produced at outside laboratories, for example. This information supports CLIA regulations in the US.

7.4.2.25 OBX-25 Performing Organization Medical Director (XCN) 02285

Components: <Person Identifier (ST)> ^ <Family Name (FN)> ^ <Given Name (ST)> ^ <Second and Further Given Names or Initials Thereof (ST)> ^ <Suffix (e.g., JR or III) (ST)> ^ <Prefix (e.g., DR) (ST)> ^ <WITHDRAWN Constituent> ^ <DEPRECATED-Source Table (CWE)> ^ <Assigning Authority (HD)> ^ <Name Type Code (ID)> ^ <Identifier Check Digit (ST)> ^ <Check Digit Scheme (ID)> ^ <Identifier Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name Representation Code (ID)> ^ <Name Context (CWE)> ^ <WITHDRAWN Constituent> ^ <Name Assembly Order (ID)> ^ <Effective Date (DTM)> ^ <Expiration Date (DTM)> ^ <Professional Suffix (ST)> ^ <Assigning Jurisdiction (CWE)> ^ <Assigning Agency or Department (CWE)> ^ <Security Check (ST)> ^ <Security Check Scheme (ID)>

Subcomponents for Family Name (FN): <Surname (ST)> & <Own Surname Prefix (ST)> & <Own Surname (ST)> & <Surname Prefix from Partner/Spouse (ST)> & <Surname from Partner/Spouse (ST)>

Subcomponents for Source Table (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Authority (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Name Context (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Jurisdiction (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

```
Subcomponents for Assigning Agency or Department (CWE):  <Identifier (ST)> & <Text
          (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> &
          <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding
          System Version ID (ST)> & <Alternate Coding System Version ID (ST)> &
          <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second
          Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> &
          <Second Alternate Coding System Version ID (ST)> & <Coding System OID
          (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate
          Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate
          Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> &
          <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set
          Version ID (DTM)>
```

Definition: ***Retained for backwards compatibility as of v 2.7 only. This field is now represented through the PRT segment.*** This field contains the medical director of the organization/service responsible for performing the service.

For labs, this field specifies the medical director of the laboratory that produced the test result described in this OBX segment. This field is different than OBX-16 in that OBX-16 identifies the individual who performed the lab test (made the observation) whereas this field identifies the individual who is the medical director of the organization responsible for the result. It should be reported explicitly when the test results are produced at outside laboratories, for example. This information supports CLIA regulations in the US.

7.4.2.26 OBX-26 Patient Results Release Category (ID) 02313

Definition: This field contains instructions on whether to share the results with the patient, and if so how.

Valid values are provided in *HL7 Table 0909 – Patient Results Release Categorization Scheme*.

7.4.2.27 OBX-27 Root Cause (CWE) 03308

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
          <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
          Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
          System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
          Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
          Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
          (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
          Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
          Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
          Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
          Alternate Value Set Version ID (DTM)>
```

Definition: This element contains the reason code indicating the root cause for the reissue of a previously released lab report. This element is used in conjunction with *OBX-11 Observation Result Status* to define the root cause for a reissued laboratory result in the case of a corrected, amended, appended, or revised result. For example, if the laboratory result was reissued due to an equipment malfunction.

Refer to *User-defined Table 0914 – Root Cause* in Chapter 2C, Code Tables, for potential values.

7.4.2.28 OBX-28 Local Process Control (CWE) 03309

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
          <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
          Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
          System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
          Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
          Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
          (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
          Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
          Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
          Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
          Alternate Value Set Version ID (DTM)>
```

Definition: This element contains information intended to be used for locally defined processing, particularly process control/status type information. It is defined as repeating and as a CWE data type to provide flexibility. The specific use may be specified in a message profile or implementation guide (see Chapter 2.B), or use may be specified by local agreement internally within an organization.

For example, a laboratory information system might use this element to convey an internal status during processing before the result is communicated outside the organization, such as revision previously reported, revision report pending.

See *User-Defined Table 0915 – Process Control Code* in Chapter 2C, Code Tables, for a list of suggested values.

7.4.2.29 OBX-29 Observation Type (ID) 03432

Definition: This field indicates the type of observation to enable systems to distinguish between observations sent along with an order, versus observations sent as the result to an order. See *HL7 Table 0936 – Observation Type* in Chapter 2C, Code Tables, for valid values.

7.4.2.30 OBX-30 Observation Sub-Type (ID) 03475

Definition: The result sub-type provides further classification of OBX-29 Observation Type. This may aid in the grouping of OBX-segments. See *HL7-defined Table 0937 – Observation Sub-Type* in Chapter 2C, Code Tables, for a set of valid values.

7.4.2.31 OBX-31 Action Code (ID) 00816

Definition: This field reveals the intent of the message. Refer to *HL7 Table 0206 - Segment Action Code* for valid values.

The action code can only be used when an OBX-21 is valued in accordance with guidance in Chapter 2, Section 2.10.4.2.

7.4.2.32 OBX-32 Observation Value Absent Reason (CWE) 03510

Definition: This field reports the reason(s) why there is no value reported in the Observation Value (OBX-5) field. This field can be used when *OBX-5-Observation Value* is empty.

See *HL7 Table 0960 – Observation Value Absent Reason* for valid values.

Condition: This field must be blank if OBX-5, Observation Value, is valued.

7.4.2.33 OBX-33 Observation Related Specimen Identifier (EIP) 02454

```
Components:  <Placer Assigned Identifier (EI)> ^ <Filler Assigned Identifier (EI)>

Subcomponents for Placer Assigned Identifier (EI):  <Entity Identifier (ST)> &
           <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Filler Assigned Identifier (EI):  <Entity Identifier (ST)> &
           <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>
```

Definition: This field contains the unique identifier for the specimen as referenced by the Placer application, the Filler application, or both in the SPM segment that describes the specimen this observation is related to, allowing an explicit linkage between the two.

7.4.3 SPM – Specimen Segment

The intent of this segment is to describe the characteristics of a specimen. It differs from the intent of the OBR in that the OBR addresses order-specific information. It differs from the SAC segment in that the SAC addresses specimen container attributes. An advantage afforded by a separate specimen segment is that it generalizes the multiple relationships among order(s), results, specimen(s) and specimen container(s).

A specimen is defined as "A physical entity that is an individual, a group, an item, or a part representative of a larger group, class or whole that is the target of an observation or analysis for the purpose of drawing conclusions about the group, class, or whole." Note that any physical entity in the universe has the potential to become a specimen

A specimen is collected or obtained from a source and may be representative of the source, or may represent a deviation within the source. A specimen may be wholly or partially consumed during an observation and any remaining portion of the specimen is persistent and can be stored.

This segment may also be used in limited cases to describe a "virtual" specimen. In particular, to identify the characteristics required for a specimen in the context of a specific observation or test.

In summary, SPM represents the attributes specific and unique to a specimen.

HL7 Attribute Table – SPM – Specimen

SEQ	LEN	C.LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
1	1..4		SI	O			01754	Set ID - SPM
2			EIP	O			01755	Specimen Identifier
3			EIP	O	Y		01756	Specimen Parent IDs
4			CWE	R		0487	01900	Specimen Type
5			CWE	O	Y	0541	01757	Specimen Type Modifier
6			CWE	O	Y	0371	01758	Specimen Additives
7			CWE	O		0488	01759	Specimen Collection Method
8			CWE	O		0784	01901	Specimen Source Site
9			CWE	O	Y	0542	01760	Specimen Source Site Modifier
10			CWE	O		0543	01761	Specimen Collection Site
11			CWE	O	Y	0369	01762	Specimen Role
12			CQ	O			01902	Specimen Collection Amount
13		6=	NM	C			01763	Grouped Specimen Count
14			ST	O	Y		01764	Specimen Description
15			CWE	O	Y	0376	01908	Specimen Handling Code
16			CWE	O	Y	0489	01903	Specimen Risk Code
17			DR	O			01765	Specimen Collection Date/Time
18			DTM	O			00248	Specimen Received Date/Time
19			DTM	O			01904	Specimen Expiration Date/Time
20	1..1		ID	O		0136	01766	Specimen Availability
21			CWE	O	Y	0490	01767	Specimen Reject Reason
22			CWE	O		0491	01768	Specimen Quality
23			CWE	O		0492	01769	Specimen Appropriateness
24			CWE	O	Y	0493	01770	Specimen Condition
25			CQ	O			01771	Specimen Current Quantity
26		4=	NM	O			01772	Number of Specimen Containers
27			CWE	O		0785	01773	Container Type
28			CWE	O		0544	01774	Container Condition
29			CWE	O		0494	01775	Specimen Child Role
30			CX	O	Y		02314	Accession ID
31			CX	O	Y		02315	Other Specimen ID
32			EI	O	N		02316	Shipment ID

SEQ	LEN	C.LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
33			DTM	O	N		3485	Culture Start Date/Time
34			DTM	O	N		3486	Culture Final Date/Time
35	2..2		ID	O		0206	00816	Action Code

7.4.3.0 SPM field definitions

7.4.3.1 SPM -1 Set ID - SPM (SI) 01754

Definition: This field contains the sequence number. This field is used to identify SPM segment instances in message structures where the SPM segment repeats.

7.4.3.2 SPM-2 Specimen Identifier (EIP) 01755

```
Components:  <Placer Assigned Identifier (EI)> ^ <Filler Assigned Identifier (EI)>

Subcomponents for Placer Assigned Identifier (EI):  <Entity Identifier (ST)> &
           <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Filler Assigned Identifier (EI):  <Entity Identifier (ST)> &
           <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>
```

Definition: This field contains a unique identifier for the specimen as referenced by the Placer application, the Filler application, or both.

This field is not required, as there are use cases in which a unique specimen identifier may not exist. In the first scenario, a placer application may initiate an observation request against an existing specimen without uniquely identifying the specimen. Additionally, in the case of the TCU_U10 message structure, used in Automated equipment test code settings messages, the SPM segment is used to define required characteristics of the specimen. As such, TCU_U10 uses SPM to define a virtual specimen, and a specific specimen identifier would not exist. Filler applications would be expected to assign a Specimen Identifier and populate this field accordingly.

7.4.3.3 SPM-3 Specimen Parent IDs (EIP) 01756

```
Components:  <Placer Assigned Identifier (EI)> ^ <Filler Assigned Identifier (EI)>

Subcomponents for Placer Assigned Identifier (EI):  <Entity Identifier (ST)> &
           <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Filler Assigned Identifier (EI):  <Entity Identifier (ST)> &
           <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>
```

Definition: This field contains the identifiers for the specimen or specimens that contributed to the specimen that is described by the segment instance.

If this field repeats, then *SPM-11-Specimen Role* should be valued with "L" (pooled). The repetitions of this field then carry the specimen IDs of the parent specimens contributing to the pool.

7.4.3.4 SPM-4 Specimen Type (CWE) 01900

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
           <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
           Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
           System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
           Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
           Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
           (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
           Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
           Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
           Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
           Alternate Value Set Version ID (DTM)>
```

Definition: This field describes the precise nature of the entity that will be the source material for the observation.

Any physical entity that may have observations made about it may qualify as a specimen. The entry in this attribute describes the specific entity as precisely as possible, whether that is a complex organism (e.g., an ostrich) or a specific cellular mass (e.g., a specific muscle biopsy).

A nationally recognized coding system is to be used for this field. Valid coding sources for this field include:

- *HL7 Table 0487 – Specimen Type* (replaces *HL7 Table 0070 – Specimen source codes*)
- SNOMED, etc.
- Veterinary medicine may choose the tables supported for the components of this field as decided by their industry.

7.4.3.5 SPM-5 Specimen Type Modifier (CWE) 01757

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field contains modifying or qualifying description(s) about the specimen type

The use of this attribute is to modify, qualify or further specify, the entity described by *SPM-4 -Specimen Type*. This is particularly useful when the code set used in *SPM-4-Specimen Type* does not provide the precision required to fully describe the specimen. For example, if the specimen was precisely described as 'capillary venous blood' but the code set employed only provided 'venous blood,' this attribute could be employed to add the modifier 'capillary.'

Refer to *User-Defined Table 0541 Specimen Type Modifier* for suggested values.

7.4.3.6 SPM-6 Specimen Additives (CWE) 01758

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field identifies any additives introduced to the specimen before or at the time of collection. These additives may be introduced in order to preserve, maintain or enhance the particular nature or component of the specimen. Refer to *HL7 Table 0371 – Additive/Preservative* for valid values. When multiple additives are introduced and valid individual additive codes exist but a valid value for the combination does not exist, repeating the field with individual values is most appropriate.

7.4.3.7 SPM-7 Specimen Collection Method (CWE) 01759

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: Describes the procedure or process by which the specimen was collected.

Any nationally recognized coding system might be used for this field including SNOMED; alternatively the *HL7 Table 0488 – Specimen Collection Method* may be used. Veterinary medicine may choose the tables supported for the components of this field as decided by their industry.

7.4.3.8 SPM-8 Specimen Source Site (CWE) 01901

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: specifies the source from which the specimen was obtained. For example, in the case where a liver biopsy is obtained via a percutaneous needle, the source would be 'liver'. Refer to Table 0784 - Specimen Source Site in Chapter 2C for valid values.Any nationally recognized coding system might be used for this field including SNOMED; alternatively the *HL7 Table 0163 – Body Site* may be used. Veterinary medicine may choose the tables supported for the components of this field as decided by their industry.

7.4.3.9 SPM-9 Specimen Source Site Modifier (CWE) 01760

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field contains modifying or qualifying description(s) about the specimen source site

The use of this attribute is to modify, qualify or further specify, the entity described by *SPM-8 – Specimen Source Site*. This is particularly useful when the code set used in *SPM-8* does not provide the precision required to fully describe the site from which the specimen originated. For example, if the specimen source site was precisely described as 'left radial vein' but the code set employed only provided 'radial vein,' this attribute could be employed to add the modifier 'left.'

Veterinary medicine may choose the tables supported for the components of this field as decided by their industry. Refer to *User-Defined Table 0542 – Specimen Source Type Modifier* for suggested values.

7.4.3.10 SPM-10 Specimen Collection Site (CWE) 01761

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field differs from *SPM-8-Specimen Source Site* in those cases where the source site must be approached via a particular site (e.g., anatomic location). For example, in the case where a liver biopsy is obtained via a percutaneous needle, the collection site would be the point of entry of the needle. For venous blood collected from the left radial vein, the collection site could be "antecubital fossa".

Veterinary medicine may choose the tables supported for the components of this field as decided by their industry.

Refer to *User-Defined Table 0543 – Specimen Collection Site* for suggested values.

7.4.3.11 SPM-11 Specimen Role (CWE) 01762

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

This field indicates the role of the sample. Refer to *User-defined Table 0369 – Specimen role* for suggested values. Each of these values is normally identifiable by the systems and its components and can influence processing and data management related to the specimen.

If this field is not populated, then the specimen described has no special, or specific, role other than serving as the focus of the observation. Such specimens include patient, environmental and other specimens that are intended for analysis.

A grouped specimen consists of identical specimen types from multiple individuals that do not have individual identifiers and upon which the same services will be performed. If the specimen role value is "G" then the Grouped Specimen Count (*SPM-13*) must be valued with the total number of specimens contained in the group.

If the specimen role is "L", the repetitions of Parent Specimen ID (SPM-4) represent the individual parent specimens that contribute to the pooled specimen.

7.4.3.12 SPM-12 Specimen Collection Amount (CQ) 01902

```
Components:  <Quantity (NM)> ^ <Units (CWE)>

Subcomponents for Units (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
             System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
             of Alternate Coding System (ID)> & <Coding System Version ID (ST)> &
             <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second
             Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of
             Second Alternate Coding System (ID)> & <Second Alternate Coding System
             Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
             <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
             <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
             <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
             OID (ST)> & <Second Alternate Value Set Version ID (DTM)>
```

Definition: This field specifies the volume or mass of the collected specimen. For laboratory tests, the collection volume is the volume of a specimen. Specifically, units should be expressed in the ISO Standard unit abbreviations (ISO-2955, 1977). This is a results-only field except when the placer or a party has already drawn the specimen. Use of UCUM is strongly recommended as one of the delivered units (could be in addition to the local units). (See Chapter 7 Section 7.4.2.6 for a full discussion regarding units.)

7.4.3.13 SPM-13 Grouped Specimen Count (NM) 01763

Definition: This field refers to the number of individual specimens of a particular type represented by this instance of a specimen. The use of this field is restricted to specimens upon which all specimen related attributes are identical. This field would only be valued if SPM-11 Specimen Role has the value "G" or “L”.

7.4.3.14 SPM-14 Specimen Description (ST) 01764

Definition: This is a text field that allows additional information **specifically about the specimen** to be sent in the message

7.4.3.15 SPM-15 Specimen Handling Code (CWE) 01908

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
           <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
           Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
           System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
           Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
           Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
           (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
           Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
           Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
           Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
           Alternate Value Set Version ID (DTM)>
```

Definition: This describes how the specimen and/or container need to be handled from the time of collection through the initiation of testing. As this field is not required, no assumptions can be made as to meaning when this field is not populated.

Refer to *User-defined Table 0376 – Special Handling Code* for suggested values.

7.4.3.16 SPM-16 Specimen Risk Code (CWE) 01903

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
           <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
           Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
           System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
           Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
           Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
           (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
           Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
           Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
           Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
           Alternate Value Set Version ID (DTM)>
```

Definition: This field contains any known or suspected specimen hazards, e.g., exceptionally infectious agent or blood from a hepatitis patient. Either code and/or text may be absent. However, the code is always placed in the first component position and any free text in the second component. Thus, a component delimiter must precede free text without a code. Refer to *User-defined Table 0489 – Risk Codes* for suggested entries

7.4.3.17 SPM-17 Specimen Collection Date/Time (DR) 01765

```
Components:  <Range Start Date/Time (DTM)> ^ <Range End Date/Time (DTM)>
```

Definition: The date and time when the specimen was acquired from the source. The use of the Date Range data type allows for description of specimens collected over a period of time, for example, 24-hour urine collection. For specimens collected at a point in time, only the first component (start date/time) will be populated.

7.4.3.18 SPM-18 Specimen Received Date/Time (DTM) 00248

Definition: The specimen received date/time is the time that the specimen is received at the diagnostic service facility. The actual time that is recorded is based on how specimen receipt is managed and may correspond to the time the sample is logged in. This is fundamentally different from *SPM-17 Specimen Collection date/time*.

7.4.3.19 SPM-19 Specimen Expiration Date/Time (DTM) 01904

Definition: This field is the date and time the specimen can no longer be used for the purpose implied by the order. For example, in the Blood Banking environment the specimen can no longer be used for pre-transfusion compatibility testing. The specimen segment will include a *SPM-21-Specimen Reject Reason* of 'EX' indicating 'Expired' for message instances created after this date and time.

7.4.3.20 SPM-20 Specimen Availability (ID) 01766

Definition: This describes whether the specimen, as it exists, is currently available to use in an analysis. Refer to *HL7 Table 0136 – Yes/No Indicator* for valid values.

7.4.3.21 SPM-21 Specimen Reject Reason (CWE) 01767

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This describes one or more reasons the specimen is rejected for the specified observation/result/analysis. Refer to *HL7 Table 0490 – Specimen Reject Reason* for valid values.

7.4.3.22 SPM-22 Specimen Quality (CWE) 01768

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: The degree or grade of excellence of the specimen at receipt. The filler populates this attribute. Refer to *User-defined Table 0491 – Specimen Quality* for suggested entries.

7.4.3.23 SPM-23 Specimen Appropriateness (CWE) 01769

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: The suitability of the specimen for the particular planned use as determined by the filler. Refer to *User-defined Table 0492 – Specimen Appropriateness* for suggested entries.

7.4.3.24 SPM-24 Specimen Condition (CWE) 01770

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
           <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
           Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
           System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
           Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
           Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
           (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
           Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
           Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
           Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
           Alternate Value Set Version ID (DTM)>
```

Definition: A mode or state of being that describes the nature of the specimen. Refer to *User-defined Table 0493 – Specimen Condition* for suggested entries.

7.4.3.25 SPM-25 Specimen Current Quantity (CQ) 01771

```
Components:  <Quantity (NM)> ^ <Units (CWE)>

Subcomponents for Units (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
           System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
           of Alternate Coding System (ID)> & <Coding System Version ID (ST)> &
           <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second
           Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of
           Second Alternate Coding System (ID)> & <Second Alternate Coding System
           Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
           <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
           <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
           <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
           OID (ST)> & <Second Alternate Value Set Version ID (DTM)>
```

Definition: This attributes contains the amount of specimen that currently exists or is available for use in further testing.

7.4.3.26 SPM-26 Number of Specimen Containers (NM) 01772

Definition: This field identifies the number of containers for a given sample. For sample receipt verification purposes; may be different from the total number of samples that accompany the order.

7.4.3.27 SPM-27 Container Type (CWE) 01773

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
           <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
           Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
           System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
           Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
           Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
           (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
           Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
           Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
           Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
           Alternate Value Set Version ID (DTM)>
```

Definition: The container in or on which a specimen is transported. Refer to Table 0785 - Container Type in Chapter 2C for valid values.

Note: If the container type is categorized (e.g., FBT (false-bottom-tube), Cup, …), the specific codes should be transferred in the SPM-27 field "Container Type". If the container is characterized by dimensions and other characteristics this information should be transferred as specific values in the SAC segment (fields: SAC-16 … SAC-21).

7.4.3.28 SPM-28 Container Condition (CWE) 01774

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
           <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
           Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
           System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
           Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
           Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
           (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
           Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
           Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
           Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
           Alternate Value Set Version ID (DTM)>
```

Definition: In chain of custody cases where specimens are moved from lab to lab, the status of the container that the specimen is shipped in must be recorded at each receipt. If the container is compromised in any way (seal broken, container cracked or leaking, etc) then this needs to be recorded for legal reasons.

Refer to *HL7 Table 0544 – Container Condition* for suggested values.

7.4.3.29 SPM-29 Specimen Child Role (CWE) 01775

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
           <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
           Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
           System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
           Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
           Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
           (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
           Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
           Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
           Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
           Alternate Value Set Version ID (DTM)>
```

Definition: For child specimens, this field identifies the relationship between this specimen and the parent specimen. If this field is populated, then *SPM-3-Specimen Parent ID* must be populated. This field differs from *SPM-15-Specimen Role* in that this field refers to the role of this specimen relative to a parent role rather than the role of this specimen to the ordered service.

Refer to *HL7 Table 0494 – Specimen Child Role* for valid values.

7.4.3.30 SPM-30 Accession ID (CX) 02314

```
Components:  <ID Number (ST)> ^ <Identifier Check Digit (ST)> ^ <Check Digit Scheme
           (ID)> ^ <Assigning Authority (HD)> ^ <Identifier Type Code (ID)> ^
           <Assigning Facility (HD)> ^ <Effective Date (DT)> ^ <Expiration Date (DT)>
           ^ <Assigning Jurisdiction (CWE)> ^ <Assigning Agency or Department (CWE)>
           ^ <Security Check (ST)> ^ <Security Check Scheme (ID)>

Subcomponents for Assigning Authority (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
           & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
           & <Universal ID Type (ID)>

Subcomponents for Assigning Jurisdiction (CWE):  <Identifier (ST)> & <Text (ST)> &
           <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
           Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
           Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
           Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text
           (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate
           Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID
           (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)>
           & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)>
           & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
           OID (ST)> & <Second Alternate Value Set Version ID (DTM)>
```

```
Subcomponents for Assigning Agency or Department (CWE):  <Identifier (ST)> & <Text
          (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> &
          <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding
          System Version ID (ST)> & <Alternate Coding System Version ID (ST)> &
          <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second
          Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> &
          <Second Alternate Coding System Version ID (ST)> & <Coding System OID
          (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate
          Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate
          Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> &
          <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set
          Version ID (DTM)>
```

Definition: This field contains accession identifier(s) associated with the specimen. In many cases, applications involved in the collection, transportation or testing of the specimen will assign their own accession identifiers. This field allows communication of these accession identifiers.

An accession id may or may not, depending up laboratory practice, identify a single specimen. Best practice is to use accession identifiers that are globally unique (typically ID Number + Assigning Facility components). However, an accession id may or may not, depending up laboratory practice, identify a single specimen. In addition, accession ids are commonly re-used over time, so the accession id may not uniquely identify a specimen.

7.4.3.31 SPM-31 Other Specimen ID (CX) 02315

```
Components:  <ID Number (ST)> ^ <Identifier Check Digit (ST)> ^ <Check Digit Scheme
          (ID)> ^ <Assigning Authority (HD)> ^ <Identifier Type Code (ID)> ^
          <Assigning Facility (HD)> ^ <Effective Date (DT)> ^ <Expiration Date (DT)>
          ^ <Assigning Jurisdiction (CWE)> ^ <Assigning Agency or Department (CWE)>
          ^ <Security Check (ST)> ^ <Security Check Scheme (ID)>

Subcomponents for Assigning Authority (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
          & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
          & <Universal ID Type (ID)>

Subcomponents for Assigning Jurisdiction (CWE):  <Identifier (ST)> & <Text (ST)> &
          <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
          Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
          Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
          Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text
          (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate
          Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID
          (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)>
          & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)>
          & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Agency or Department (CWE):  <Identifier (ST)> & <Text
          (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> &
          <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding
          System Version ID (ST)> & <Alternate Coding System Version ID (ST)> &
          <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second
          Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> &
          <Second Alternate Coding System Version ID (ST)> & <Coding System OID
          (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate
          Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate
          Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> &
          <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set
          Version ID (DTM)>
```

Definition: This field contains other identifier(s) for the specimen as referenced in an application. Normally this field is used to carry additional identifiers for the specimen in addition to those identified in *SPM-2, Specimen ID*. In may cases other applications involved in the collection, transportation or testing of the specimen will assign additional specimen identifiers. This field allows communication of those other specimen identifiers.

7.4.3.32 SPM-32 Shipment ID (EI) 02316

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: The shipment identifier is the identifier assigned by the shipment transportation provider that uniquely identifies this shipment from all other shipments by the same provider. The addressee for the shipment should be able to use this identifier to match a physical shipment with the electronic manifest for the shipment.

7.4.3.33 SPM-33 Culture Start Date/Time (DTM) 3485

Definition: The Culture Start date/time is the time that the specimen is plated, or inoculated to selective and differential growth mediums that are used in organism identification in microbiology. This is the start of differential diagnosis and is a clinically relevant date and time. The actual time that is recorded is based on when specimen is directly inoculated onto growth media and may correspond to the time the sample is logged in or received.

7.4.3.34 SPM-34 Culture Final Date/Time (DTM) 3486

Definition: The Culture Final date/time is the time in which the order filler is communicating to the clinician that all work on a cultured specimen is completed and no further updates will be received. All work, including determination of growth, Organism Identification, and sensitivity testing are completed. The clinician should expect no further updates on this cultured specimen.

7.4.3.35 SPM-35 Action Code (ID) 00816

Definition: This field reveals the intent of the message. Refer to *HL7 Table 0206 - Segment Action Code* for valid values.

The action code can only be used when an SPM-2 or SPM-31 is valued in accordance with the guidance in Chapter 2, Section 2.10.4.2.

7.4.4 PRT – Participation Information Segment

The Participation Information segment contains the data necessary to add, update, correct, and delete from the record persons, organizations, devices, or locations (participants) participating in the activity being transmitted.

In general, the PRT segment is used to describe a participant playing a particular role within the context of the message. In OO, for example, in the results messages the PRT segment may be used to provide the performing provider, whether a person or organization. In a specimen shipment message it may be the waypoint location relevant for the shipment.

The positional location of the PRT segment indicates the relationship. When the segment is used following the OBX segment, then the participations relate to that OBX addressing participations such as responsible observer.

The PRT segment may be used to communicate U.S. FDA Unique Device Identifier (UDI[2]) information, with the PRT-10 field containing the UDI and additional fields added to contain UDI elements, when it is advised to communicate these individually (see Guidance in PRT-10 definition). These identifiers are intended to cover a wide variety of devices. When representing a UDI, PRT-4 would be “EQUIP”.

HL7 Attribute Table - PRT – Participation Information

SEQ	LEN	C.LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
1	1..4		EI	C	N		02379	Participation Instance ID
2	2..2		ID	R		0287	00816	Action Code

[2] See www.fda.gov/udi.

SEQ	LEN	C.LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
3			CWE	O			02380	Action Reason
4			CWE	R		0912	02381	Role of Participation
5			XCN	C	Y		02382	Person
6			CWE	C			02383	Person Provider Type
7			CWE	C		0406	02384	Organization Unit Type
8			XON	C	Y		02385	Organization
9			PL	C	Y		02386	Location
10			EI	C	Y		02348	Device
11			DTM	O			02387	Begin Date/Time (arrival time)
12			DTM	O			02388	End Date/Time (departure time)
13			CWE	O			02389	Qualitative Duration
14			XAD	C	Y		02390	Address
15			XTN	O	Y		02391	Telecommunication Address
16			EI	O			03476	UDI Device Identifier
17			DTM	O			03477	Device Manufacture Date
18			DTM	O			03478	Device Expiry Date
19			ST	O			03479	Device Lot Number
20			ST	O			03480	Device Serial Number
21			EI	O			03481	Device Donation Identification
22			CNE	C		0961	03483	Device Type
23			CWE	O		0185	00684	Preferred Method of Contact
24			PLN	O	Y	0328	01171	Contact Identifiers

7.4.4.0 PRT field definitions

7.4.4.1 PRT-1 Participation Instance ID (EI) 02379

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: This field contains a unique identifier of the specific participation record.

In the case of waypoints tracked for a shipment, it identifies the waypoint.

Condition: The identifier is required when known, but there are times we may only know a name but do not have an identifier.

7.4.4.2 PRT-2 Action Code (ID) 00816

Definition: This field reveals the intent of the message. Refer to *HL7 Table 0287 – Problem/goal action code* for valid values.

7.4.4.3 PRT-3 Action Reason (CWE) 02380

Components: <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^ <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second Alternate Value Set Version ID (DTM)>

Definition: This field indicates the reason why the person, organization, location, or device is assuming (or changing) the role (e.g., shift change, new primary nurse, etc.).

7.4.4.4 PRT-4 Role of Participation (CWE) 02381

Components: <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^ <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second Alternate Value Set Version ID (DTM)>

Definition: This field indicates the functional involvement with the activity being transmitted (e.g., Case Manager, Evaluator, Transcriber, Nurse Care Practitioner, Midwife, Physician Assistant, etc.). Refer to *HL7 Table 0912 – Participation* for valid values.

7.4.4.5 PRT-5 Person (XCN) 02382

Components: <Person Identifier (ST)> ^ <Family Name (FN)> ^ <Given Name (ST)> ^ <Second and Further Given Names or Initials Thereof (ST)> ^ <Suffix (e.g., JR or III) (ST)> ^ <Prefix (e.g., DR) (ST)> ^ <WITHDRAWN Constituent> ^ <DEPRECATED-Source Table (CWE)> ^ <Assigning Authority (HD)> ^ <Name Type Code (ID)> ^ <Identifier Check Digit (ST)> ^ <Check Digit Scheme (ID)> ^ <Identifier Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name Representation Code (ID)> ^ <Name Context (CWE)> ^ <WITHDRAWN Constituent> ^ <Name Assembly Order (ID)> ^ <Effective Date (DTM)> ^ <Expiration Date (DTM)> ^ <Professional Suffix (ST)> ^ <Assigning Jurisdiction (CWE)> ^ <Assigning Agency or Department (CWE)> ^ <Security Check (ST)> ^ <Security Check Scheme (ID)>

Subcomponents for Family Name (FN): <Surname (ST)> & <Own Surname Prefix (ST)> & <Own Surname (ST)> & <Surname Prefix from Partner/Spouse (ST)> & <Surname from Partner/Spouse (ST)>

Subcomponents for Source Table (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Authority (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

```
Subcomponents for Name Context (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of
          Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
          & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
          & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
          <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
          of Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Jurisdiction (CWE):  <Identifier (ST)> & <Text (ST)> &
          <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
          Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
          Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
          Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text
          (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate
          Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID
          (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)>
          & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)>
          & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Agency or Department (CWE):  <Identifier (ST)> & <Text
          (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> &
          <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding
          System Version ID (ST)> & <Alternate Coding System Version ID (ST)> &
          <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second
          Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> &
          <Second Alternate Coding System Version ID (ST)> & <Coding System OID
          (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate
          Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate
          Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> &
          <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set
          Version ID (DTM)>
```

Definition: This field contains the identity of the person who is represented in the participation that is being transmitted.

If this attribute repeats, all instances must represent the same person.

Condition: At least one of PRT-5 Person, PRT-8 Organization, PRT-9 Location, or PRT-10 Device or PRT-22 Device Type fields must be valued.

7.4.4.6 PRT-6 Person Provider Type (CWE) 02383

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
          <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
          Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
          System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
          Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
          Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
          (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
          Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
          Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
          Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
          Alternate Value Set Version ID (DTM)>
```

Definition: This field contains a code identifying the provider type for the participating person. This attribute correlates to the following master file attribute: *STF-4 Staff Type*. Coded values from the correlated master file table are used; the user defined master file table is used as the coding system for this attribute. For example, if you are using values from *STF-2 Staff Type*, the coding system would be HL70182 which is the table number for the user defined Staff Type table. This field is included in this segment to support international requirements. When ROL is used in an encounter message, it is not intended as a master file update.

Condition: This field may only be valued if *PRT-5 Person* is valued.

7.4.4.7 PRT-7 Organization Unit Type (CWE) 02384

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field identifies the environment in which the participant acts in the role specified in *PRT-3 Action Reason*. In the case of a person, the environment is not the specialty for the provider. The specialty information for the provider is defined in the PRA segment.

This attribute is included in the PRT segment to allow communication of this data when the participant information may not have been communicated previously in a master file or to provide better context. Refer to *User-defined table 0406 - Organization unit type*. This field is included in this segment to support international requirements, and is not intended as a master file update.

Condition: This field may only be valued if PRT-5 Person is valued.

7.4.4.8 PRT-8 Organization (XON) 02385

```
Components:  <Organization Name (ST)> ^ <Organization Name Type Code (CWE)> ^
             <WITHDRAWN Constituent> ^ <WITHDRAWN Constituent> ^ <WITHDRAWN
             Constituent> ^ <Assigning Authority (HD)> ^ <Identifier Type Code (ID)> ^
             <Assigning Facility (HD)> ^ <Name Representation Code (ID)> ^
             <Organization Identifier (ST)>

Subcomponents for Organization Name Type Code (CWE):  <Identifier (ST)> & <Text (ST)>
             & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
             Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
             Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
             Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text
             (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate
             Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID
             (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)>
             & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)>
             & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
             OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Authority (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
             & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
             & <Universal ID Type (ID)>
```

Definition: The organization that is involved in the participation. If *PRT-5 Person* is valued, it reflects the affiliation of the individual participating as identified in *PRT-4 Role of Participation*. Otherwise the organization is directly participating as identified in *PRT-4 Role of Participation*.

If this attribute repeats, all instances must represent the same organization.

Condition: At least one of the PRT-5 Person, PRT-8 Organization, PRT-9 Location, or PRT-10 Device or PRT-22 Device Type fields must be valued.

7.4.4.9 PRT-9 Location (PL) 02386

```
Components:  <Point of Care (HD)> ^ <Room (HD)> ^ <Bed (HD)> ^ <Facility (HD)> ^
             <Location Status (IS)> ^ <Person Location Type (IS)> ^ <Building (HD)> ^
             <Floor (HD)> ^ <Location Description (ST)> ^ <Comprehensive Location
             Identifier (EI)> ^ <Assigning Authority for Location (HD)>

Subcomponents for Point of Care (HD):  <Namespace ID (IS)> & <Universal ID (ST)> &
             <Universal ID Type (ID)>

Subcomponents for Room (HD):  <Namespace ID (IS)> & <Universal ID (ST)> & <Universal
             ID Type (ID)>
```

```
Subcomponents for Bed (HD):  <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID
          Type (ID)>

Subcomponents for Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)> &
          <Universal ID Type (ID)>

Subcomponents for Building (HD):  <Namespace ID (IS)> & <Universal ID (ST)> &
          <Universal ID Type (ID)>

Subcomponents for Floor (HD):  <Namespace ID (IS)> & <Universal ID (ST)> & <Universal
          ID Type (ID)>

Subcomponents for Comprehensive Location Identifier (EI):  <Entity Identifier (ST)> &
          <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Assigning Authority for Location (HD):  <Namespace ID (IS)> &
          <Universal ID (ST)> & <Universal ID Type (ID)>
```

Definition: This field specifies the physical location (e.g., nurse station, ancillary service location, clinic, or floor) that is participating. If either *PRT-5 Person* or *PRT-8 Organization* is valued, it reflects the location of the individual or organization participating as identified in *PRT-4 Role of Participation*. Otherwise the location is directly participating as identified in *PRT-4 Role of Participation*.

If this attribute repeats, all instances must represent the same organization.

Condition: At least one of the PRT-5 Person, PRT-8 Organization, PRT-9 Location, or PRT-10 Device or PRT-22 Device Type fields must be valued.

7.4.4.10 PRT-10 Device (EI) 02348

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
          <Universal ID Type (ID)>
```

Definition: Identifier for the device participating. This may reflect an unstructured or a structured identifier such as FDA UDI, RFID, IEEE EUI-64 identifiers, or bar codes.

Example: The device used to register the shipment at the waypoint.

If this attribute repeats, all instances must represent the same device.

Condition: At least one of the PRT-5 Person, PRT-8 Organization, PRT-9 Location, or PRT-10 Device or PRT-22 Device Type fields must be valued.

If this field contains an FDA UDI, it shall contain the entire Human Readable Form of the UDI. For example, a GS1-based UDI would be represented as follows:

|(01)00643169001763(17)160712(21)21A11F4855^^2.16.840.1.113883.3.3719^ISO|

A HIBCC-based example would be represented as follows:

|+H123PARTNO1234567890120/$$420020216LOT123456789012345/SXYZ456789012345678/16D20130202C^^2.16.840.1.113883.3.3719^ISO

An ICCBBA-based example would be represented as follows:

|=/A9999XYZ100T0944=,000025=A99971312345600=>014032=}013032\T\,1000000000000XYZ123^^2.16.840.1.113883.3.3719^ISO|

Or for ICCBBA (for blood bags only) an example would be represented as follows:

|=)1TE123456A\T\)RZ12345678^^2.16.840.1.113883.3.3719^ISO|

The identifier root shall be the OID assigned to UDI. For example, for FDA UDIs the root shall be 2.16.840.1.113883.3.3719, and the extension shall be the Human Readable Form appropriate for the style of content. When captured as a simple string, the string shall be the Human Readable Form appropriate for the style of content. The content style can be determined from the leading characters of the content:

UDIs beginning with:

'(' are in the GS1 Human Readable style;

'0-9' are a GS1 DI (containing only the DI value, no PI or GS1 AI);

'+' are in the HIBCC Human Readable style;

'=' or '&' are in the ICCBBA Human Readable style.

Note: If "&" is used in the UDI while one of the delimiters in MSH.2 includes "&" as well, it must be properly escaped per Chapter 2.7.

The exchange of UDI sub-elements in PRT-16 through PRT-21 is not required when the full UDI string is provided in PRT-10. Whether to include some or all these fields as well when PRT-10 is present with a UDI that the rules are subject to specific implementation guides that will have to consider the patient safety implications of potentially conflicting data.

When a UDI is provided and sub-elements are also provided, then for those sub-elements that are valued, the content must match the content encoded in the UDI if it is encoded within the UDI.

When communicating a UDI, the UDI may either be uniquely identifying an instance of a device, or a type of device. This can be asserted based on the inclusion or absence of a serial number in the Product Identifier section of the UDI. When the serial number is present, PRT-10 must be used, while if it is absent, PRT-22 must be used.

Caution: The UDI may contain personally identifying information in the form of the device **serial number** which may be used to link to other information on a patient. Security and privacy consideration should be addressed, particularly when sending a UDI with a serial number, as that may inadvertently be able to identify a patient. Note: In the US realm that would be addressed by HIPAA.

Note: PRT-10 Device is a repeating field. Additional device identifiers, such as an IEEE EUI-64 may also be contained in this field.

7.4.4.11 PRT-11 Begin Date/Time (DTM) 02387

Definition: This field contains the date/time when the participation began.

In the case of waypoints, this reflects the time a shipment arrives at the waypoint.

7.4.4.12 PRT-12 End Date/Time (DTM) 02388

Definition: This field contains the date/time when the participation ended.

In the case of waypoints, this reflects the time a shipment departs from the waypoint.

7.4.4.13 PRT-13 Qualitative Duration (CWE) 02389

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field contains the qualitative length of time for participation (e.g., until the next assessment, four days, until discharge, etc.).

7.4.4.14 PRT-14 Address (XAD) 02390

Components: <Street Address (SAD)> ^ <Other Designation (ST)> ^ <City (ST)> ^ <State or Province (ST)> ^ <Zip or Postal Code (ST)> ^ <Country (ID)> ^ <Address Type (ID)> ^ <Other Geographic Designation (ST)> ^ <County/Parish Code (CWE)> ^ <Census Tract (CWE)> ^ <Address Representation Code (ID)> ^ <WITHDRAWN Constituent> ^ <Effective Date (DTM)> ^ <Expiration Date (DTM)> ^ <Expiration Reason (CWE)> ^ <Temporary Indicator (ID)> ^ <Bad Address Indicator (ID)> ^ <Address Usage (ID)> ^ <Addressee (ST)> ^ <Comment (ST)> ^ <Preference Order (NM)> ^ <Protection Code (CWE)> ^ <Address Identifier (EI)>

Subcomponents for Street Address (SAD): <Street or Mailing Address (ST)> & <Street Name (ST)> & <Dwelling Number (ST)>

Subcomponents for County/Parish Code (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Census Tract (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Expiration Reason (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Protection Code (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Address Identifier (EI): <Entity Identifier (ST)> & <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Definition: This field contains addresses associated with the participation. The address can repeat to indicate alternate addresses or an alternate expression of the same address.

Condition: The address must be present if the Participation is Performing Organization Medical Director.

7.4.4.15 PRT-15 Telecommunication Address (XTN) 02391

```
Components:  <WITHDRAWN Constituent> ^ <Telecommunication Use Code (ID)> ^
          <Telecommunication Equipment Type (ID)> ^ <Communication Address (ST)> ^
          <Country Code (SNM)> ^ <Area/City Code (SNM)> ^ <Local Number (SNM)> ^
          <Extension (SNM)> ^ <Any Text (ST)> ^ <Extension Prefix (ST)> ^ <Speed
          Dial Code (ST)> ^ <Unformatted Telephone number  (ST)> ^ <Effective Start
          Date (DTM)> ^ <Expiration Date (DTM)> ^ <Expiration Reason (CWE)> ^
          <Protection Code (CWE)> ^ <Shared Telecommunication Identifier (EI)> ^
          <Preference Order (NM)>

Subcomponents for Expiration Reason (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of
          Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
          & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
          & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
          <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
          of Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Protection Code (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of
          Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
          & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
          & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
          <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
          of Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Shared Telecommunication Identifier (EI):  <Entity Identifier (ST)>
          & <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>
```

Definition: The waypoint telecommunication address field carries telecommunications addresses for the waypoint. These telecommunications addresses are used to contact the waypoint for additional information regarding the receipt of the shipment. The address can repeat to indicate alternate addresses or an alternate expression of the same address.

7.4.4.16 PRT-16 UDI Device Identifier (EI) 03476

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
          <Universal ID Type (ID)>
```

Definition: Provides the U.S. FDA UDI *device identifier* (DI) element.

This is the first component in the UDI and acts as the look up key for the Global Unique Device Identification Database (GUDID[3]), and may be used for retrieving additional attributes.

When exchanging Device Identifiers (DI) the root shall be the OID, or standards' appropriate corollary to the OID, assigned to DI and the extension shall be the Human Readable Form of the content. For example, for DIs the root shall be:

GS1 DIs:	2.51.1.1
HIBCC DIs:	1.0.15961.10.816
ICCBBA DIs:	2.16.840.1.113883.6.18.1.17 for Blood containers and 2.16.840.1.113883.6.18.1.34 otherwise.

Example: |00643169001763^^2.51.1.1^ISO|

[3] See www.fda.gov/udi

7.4.4.17 PRT-17 Device Manufacture Date (DTM) 03477

Definition: Date and time when the device was manufacturered.

Note: The user system may need to convert the date and optional hour from the UDI Human Readable Form to a timestamp style data type, augmenting the date as required to provide for a complete date and optionally the hour.

Example: |20140401|

7.4.4.18 PRT-18 Device Expiry Date (DTM) 03478

Definition: Date and time when the device is no longer approved for use.

Note: The user system may need to convert the date and optional hour from the UDI Human Readable Form to a timestamp style data type, augmenting the date as required to provide for a complete date and optionally the hour.

Example: |20160712|

7.4.4.19 PRT-19 Device Lot Number (ST) 03479

Definition: Alphanumeric string that identifies the device's production lot number.

Example: |123ABC|

7.4.4.20 PRT-20 Device Serial Number (ST) 03480

Definition: Manufacturer's serial number for this device.

CAUTION: See the related privacy considerations discussion in PRT-10.

Example: |21A11F4855|

7.4.4.21 PRT-21 Device Donation Identification (EI) 03481

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: Identifies a device related to a donation (e.g., whole blood).

When exchanging Donation Identification Numbers (DIN) the root shall be the OID assigned to DIN and the extension shall be the Human Readable Form of the content. For example, for DINs the root shall be:

ICCBBA DINs: 2.16.840.1.113883.6.18.2.1

An ICCBBA DIN OID is available for reference where required, but is not required when the specific data element is scoped to ICCBBA DINs.

Example: | RA12345678BA123^^2.16.840.1.113883.6.18.1.34^ISO|

7.4.4.22 PRT-22 Device Type (CNE) 03483

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field contains the type of device used in the participation.

When communicating a UDI, the UDI may either be uniquely identifying an instance of a device, or a type of device. This can be asserted based on the inclusion or absence of a serial number in the Product Identifier section of the UDI. When the serial number is present, PRT-10 must be used, while if it is absent, PRT-22 must be used.

When communicating a UDI in this field, the coding system used is limited to FDA (FDAUDI), HIBCC (HIBUDI), ICCBBA (ICCUDI), and GS1 (GS1UDI) coding systems defined in HL7 Table 0396.

Condition: At least one of the PRT-5 Person, PRT-8 Organization, PRT-9 Location, or PRT-10 Device or PRT-22 Device Type fields must be valued.

See Externally HL7 defined HL70961 in Chapter 2C for suggested values.

7.4.4.23 PRT-23 Preferred Method of Contact (CWE) 00684

```
Components: <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
            <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
            Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
            System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
            Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
            Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
            (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
            Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
            Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
            Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
            Alternate Value Set Version ID (DTM)>
```

Definition: This field contains the preferred method to use when communicating particularly when the contact is a person or organization This is typically used in combination with PRT-5 Person, and/or PRT-8 Organization. Refer to User-defined Table 0185 - Preferred Method of Contact in Chapter 2C, "Code Tables", for suggested values.

7.4.4.24 PRT-24 Contact Identifiers (PLN) 01171

```
Components: <ID Number (ST)> ^ <Type of ID Number (CWE)> ^ <State/other Qualifying
            Information (ST)> ^ <Expiration Date (DT)>

Subcomponents for Type of ID Number (CWE): <Identifier (ST)> & <Text (ST)> & <Name of
            Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
            & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
            & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
            <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
            of Second Alternate Coding System (ID)> & <Second Alternate Coding System
            Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
            <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
            <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
            <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
            OID (ST)> & <Second Alternate Value Set Version ID (DTM)>
```

Definition: This field contains the contact identifier to use when communicating particularly when the contact is a person or organization This is typically used in combination with PRT-5 Person, and/or PRT-8 Organization. This repeating field contains the contact's unique identifiers such as UPIN, Medicare and Medicaid numbers. Refer to User-defined Table 0338 – Practitioner.

7.5 EXAMPLES OF USE

7.5.1 Query/response

Attention: ***Retained for backwards compatibility only as of v 2.4 and withdrawn as of v 2.7.***

7.5.2 Unsolicited

The following is an unsolicited transmission of radiology data.

```
MSH|^~\&|XRAY||CDB||200006021411||ORU^R01^ORU_R01|K172|P|...<cr>

PID|...<cr>

OBR|1|X89-1501^OE|78912^RD|71020^CHEST XRAY AP \T\
    LATERAL|||198703290800||||...<cr>

OBX|1|CWE|19005-8^X-ray impression^LN|4|^MASS LEFT LOWER LOBE|||A|||F|...<cr>

OBX|2|CWE|19005-8^X-ray impression^LN|2|^INFILTRATE RIGHT LOWER
    LOBE|||A|||F|...<cr>

OBX|3|CWE|19005-8^X-ray impression^LN|3|^HEART SIZE NORMAL|||N|||F|...<cr>

OBX|4|FT|36687-2^Chest XR AP+Lat ^LN|1|circular density (2 x 2 cm) is seen in the
    posterior segment of

    the LLL.  A second, less well-defined infiltrated circulation density is

    seen in the R mid lung field and appears to cross the minor
    fissure#||||||F|...<cr>

OBX|5|CWE|71020&REC|5|71020^Follow up CXR 1 month||30-45||||F|...<cr>
```

7.5.3 Laboratory

Laboratory message: electrolytes, CBC, sed rate, blood cultures and susceptibilities

```
MSH|...<cr>
PID|...<cr>
```

Electrolytes:

```
OBR|1|870930010^OE|CM3562^LAB|2432-6^ELECTROLYTES HCFA 98 PANEL^LN|
    ||198703290800|||
    401-0^INTERN^IRVING^I^^^MD^L| ||||SER|^HIPPOCRATES^HAROLD^H^^DR|(555)555-1003|
    This is requestor field #1.|Requestor field #2|Diag.serv.field #1.|
    Diag.serv.field #2.|198703311400|||F|...<cr>
OBX|1|NM|2951-2^SODIUM^LN||150|mmol/L|136-148|H||A|F|19850301|...<cr>
OBX|2|NM|2823-3^POTASSIUM^LN||4.5|mmol/L|3.5-5|N||N|F|19850301|...<cr>
OBX|3|NM|2075-0^CHLORIDE^LN||102|mmol/L|94-105|N||N|F|19850301|...<cr>
OBX|4|NM|2028-9^CARBON DIOXIDE^LN||27|mmol/L|24-31|N||N|F|19850301|...<cr>
```

CBC:

```
OBR|2|870930011^OE|HEM3268^LAB|24359-2^HEMOGRAM+DIFFERENTIAL PANEL^LN|
    ||198703290800|||401-0 ^
    INTERN^IRVING^I^^^MD^L|||||BLDV|^HIPPOCRATES^HAROLD^H^^DR|(555)555-1003|This is
        requestor field #1.|This is Requestor field #2.|This is lab field #1.|Lab
        field #2.|198703311400|||F|...<cr>
OBX|1|NM|718-7^HEMOGLOBIN^LN||13.4|GM/DL|14-18|N||S|F|19860522|...<cr>
OBX|2|NM|4544-3^HEMATOCRIT^LN||40.3|%|42-52|L||S|F|19860522|...<cr>
OBX|3|NM|789-8^ERYTHROCYTES^LN||4.56|10*6/ml|4.7-6.1|L||S|F|19860522|...<cr>
OBX|4|NM|787-2^ERYTHROCYTE MEAN CORPUSCULAR VOLUME:^LN
   ||88|fl|80-94|N||S|F|19860522|...<cr>
OBX|5|NM|785-6^ERYTHROCYTE MEAN CORPUSCULAR HEMOGLOBIN:^LN
   ||29.5|pg|27-31|N||N|F|19860522|...<cr>
OBX|6|NM|786-4^ERYTHROCYTE MEAN CORPUSCULAR HEMOGLOBIN CONCENTRATION:^LN
   ||33|%|33-37|N||N|F|19860522|...<cr>
OBX|7|NM|6690-2^LEUKOCYTES^LN||10.7|10*3/ml|4.8-10.8|N||N|F|19860522|...<cr>
OBX|8|NM|770-8^NEUTROPHILS/100 LEUKOCYTES^LN||68|%||||F|...<cr>
OBX|9|NM|736-9^LYMPHOCYTES/100 LEUKOCYTES:^LN||29|%||||F|...<cr>
OBX|10|NM|5905-5^MONOCYTES/100 LEUKOCYTES:^LN||1|%||||F|...<cr>
OBX|11|NM|713-8^EOSINOPHILS/100 LEUKOCYTES:^LN||2|%||||F|...<cr>
```

Sed rate:

```
OBR|3|870930011^OE|HEM3269^LAB|4537-7^ERYTHROCYTE SEDIMENTATION RATE^LN
   |||198703290800|||
    401-0^INTERN^IRVING^I^^^MD^L|||||BLDV|^HIPPOCRATES^HAROLD^H^^DR|(555)555-1003|
    This is requestor field #1.|This is Requestor field #2.|This is lab field
    #1.|Lab field #2.|198703311400|||F|...<cr>
OBX|1|NM|4537-7^ERYTHROCYTE SEDIMENTATION RATE:^LN|
   |7|MM/HR|0-10|N||S|F|19860522|...<cr>
```

Parent micro result, identifies organism

```
OBR|4|2740X^OE|BC376^MIC|87040^Blood culture| ||198703290800|||
    99-2^SPINNER^SAM^S||^Hepatitis risk||198703290830|BLDV|
    4010^INTERN^IRVING^I^^^MD^L|555-1022 X3472^^^^^^^3472|Requestor field
    1|Requestor field 2|
    Producer's field 1|Producer's field 2|198703301000|35.00|MB|F|...<cr>
OBX|1|CWE|600-7^MICROORGANISM IDENTIFIED^LN|1|^E Coli|||A|||F|...<cr>
OBX|2|CWE|600-7^MICROORGANISM IDENTIFIED^LN|2|^S Aureus|||A|||F|...<cr>
```

Child micro result, gives antimicrobials susceptibilities for organism identified in first OBX of parent

```
OBR|5|2740X^OE|BC402^MIC|87186^Antibiotic MIC||
   |198703290800||||G|^Hepatitis Risk||198703290830|BLDB
   |401.0^INTERN^IRVING^I^^^MD^L|555-1022 X3472^^^^^^^3472|||||198703310900|40.00
   |MB|F|600-7&MICROORGANISM IDENTIFIED&LN^1|||2740X&OE^BC376&MIC|...<cr>
OBX|1|ST|28-1^AMIPICILLIN:SUSC:PT:ISLT:QN:MIC^LN||<2|ug/ml||S|||F|...<cr>
OBX|2|ST|60-4^CARBENICILLIN:SUSC:PT:ISLT:QN:MIC^LN||<16|ug/ml||S|||F|...<cr>
OBX|3|ST|267-5^GENTAMICIN:SUSC:PT:ISLT:QN:MIC^LN||<2|ug/ml||S|||F|...<cr>
OBX|4|ST|496-0^TETRACYCLINE:SUSC:PT:ISLT:QN:MIC^LN||<1|ug/ml||S|||F|...<cr>
OBX|5|ST|408-5^PIPERACILLIN:SUSC:PT:ISLT:QN:MIC^LN||<8|ug/ml||S|||F|...<cr>
OBX|6|ST|145-3^CEFUROXIME:SUSC:PT:ISLT:QN:MIC^LN||<2|ug/ml||S|||F|...<cr>
OBX|7|ST|161-0^CEPHALOTHIN:SUSC:PT:ISLT:QN:MIC^LN||<8|ug/ml||S|||F|...<cr>
OBX|8|ST|20-8^AMOXICILLIN+CLAVULANATE:SUSC:PT:ISLT:QN:MIC^LN
   ||<4|ug/ml||S|||F|...<cr>
OBX|9|ST|173-5^CHLORAMPHENICOL:SUSC:PT:ISLT:QN:MIC^LN||<4|ug/ml||S|||F|...<cr>
OBX|10|ST|508-2^TOBRAMYCIN:SUSC:PT:ISLT:QN:MIC^LN||<2|ug/ml||S|||F|...<cr>
OBX|11|ST|12-5^AMIKACIN:SUSC:PT:ISLT:QN:MIC^LN||<4|ug/ml||S|||F|...<cr>
OBX|12|ST|516-5^TRIMETHOPRIM+SULFMOETHOXAZOLE:SUSC:PT:ISLT:QN:MIC^LN|
   |<2/38|ug/ml||S|||F|...<cr>
OBX|13|ST|76-0^CEFAZOLIN:SUSC:PT:ISLT:QN:MIC^LN||<2|ug/ml||S|||F|...<cr>
OBX|14|ST|116-4^CEFOXITIN:SUSC:PT:ISLT:QN:MIC^LN||<2|ug/ml||S|||F|...<cr>
OBX|15|ST|141-2^CEFTRIAXONE:SUSC:PT:ISLT:QN:MIC^LN||<4|ug/ml||S|||F|...<cr>
OBX|16|ST|133-9^CEFTAZIDIME:SUSC:PT:ISLT:QN:MIC^LN||<2|ug/ml||S|||F|...<cr>
OBX|17|ST|185-9^CIPROFLOXACIN:SUSC:PT:ISLT:QN:MIC^LN||<1|ug/ml||S|||F|...<cr>
```

Second micro child result, gives susceptibilities or organism identified by Second OBX of parent

```
OBR|6|2740X^OE|BC403^MIC|87186^Antibiotic MIC| ||198703290800||||G|
    ^Hepatitis risk||198703290830|BLDV|401.0^INTERN^IRVING^I^^^MD^L|321-4321
    X3472^^^^^^^3472|||||
    198703310900|40.00|MB|F|600-7&MICROORGANISM IDENTIFIED &LN^2|
   ||2740X&OE^BC376&MIC|...<cr>
OBX|1|ST|28-1^AMPICILLIN:SUSC:PT:ISLT:QN:MIC^LN||<8|ug/ml||R|||F|...<cr>
OBX|2|ST|193-3^CLINDAMYCIN:SUSC:PT:ISLT:QN:MIC^LN||<.25|ug/ml||S|||F|...<cr>
OBX|3|ST|267-5^GENTAMICIN:SUSC:PT:ISLT:QN:MIC^LN||<1|ug/ml||S|||F|...<cr>
OBX|4|ST|233-7^ERYTHROMYCIN:SUSC:PT:ISLT:QN:MIC^LN||<.5|ug/ml||S|||F|...<cr>
OBX|5|ST|383-0^OXACILLIN:SUSC:PT:ISLT:QN:MIC^LN||<.5|ug/ml||S|||F|...<cr>
OBX|6|ST|524-9^VANCOMYCIN:SUSC:PT:ISLT:QN:MIC^LN||<2|ug/ml||S|||F|...<cr>
OBX|7|ST|6932-8^PENICILLIN:SUSC:PT:ISLT:QN:MIC^LN||<8|ug/ml||R|||F|...<cr>
OBX|8|ST|161-0^CEPHALOTHIN:SUSC:PT:ISLT:QN:MIC^LN||<2|ug/ml||S|||F|...<cr>
OBX|9|ST|173-5^CHLORAMPHENICOL:SUSC:PT:ISLT:QN:MIC^LN||<4|ug/ml||S|||F|...<cr>
OBX|10|ST|12-5^AMIKACIN:SUSC:PT:ISLT:QN:MIC^LN||<16|ug/ml||S|||F|...<cr>
OBX|11|ST|185-9^CIPROFLOXACIN:SUSC:PT:ISLT:QN:MIC^LN||<1|ug/ml||S|||F|...<cr>
OBX|12|ST|428-3^RIFAMPIN:SUSC:PT:ISLT:QN:MIC^LN||<1|ug/ml||S|||F|...<cr>
```

7.5.4 Narrative report messages

This example of the body of reports shows the following observation from what are usually free text reports. The text within these examples that begins with **-- and ends with --** are explanatory comments, not a formal part of the message. The following outline shows the segments that are included in this example message.

a) patient identifying record (PID)

b) order record for chest x-ray (OBR)

c) two diagnostic impressions for CXR (OBX)

d) description record for CXR (OBX)

e) a recommendation record for CXR (OBX)

f) an order record for surgical pathology (OBR)

g) a gross description record for pathology showing use of anatomy fields (OBX)

h) a microscopic description record for pathology (OBX)

i) vital signs request (OBR)

j) six vital signs (OBX)

k) part of the physical history (OBR & OBX)

l) end record

```
MSH|...<cr>
PID|...<cr>
```

Order record for CXR

```
OBR|2|P8754^OE|XR1501^XR|24646-2^CXR PA+LAT^LN|||198703290800|||
   401-0^INTERN^IRVING^I^^^MD^L|...<cr>
```

Two CXR diagnostic impressions

```
OBX|1|CWE|24646-2&IMP^CXR PA+LAT^LN

|1|.61^RUL^ACR~.212^Bronchopneumonia^ACR|||A|||F|...<cr>

OBX|2|CWE|24646-2&IMP^CXR PA+LAT^LN |2|51.71^Congestive heart
    failure^ACR|||A|||F|...<cr>
```

CXR Description with continuation records

```
OBX|3|TX|24646-2&GDT^CXR PA+LAT^LN||Infiltrate probably representing
    bronchopneumonia in the right lower lobe.  Also pulmonary venous congestion
    cardiomegaly and cephalization, indicating early congestive heart
    failure.|...<cr>
```

Recommendations about CXR report to follow up one month with a repeat CXR

```
OBX|4|CWE|24646-2&REC^CXR PA+LAT^LN||71020^Followup CXR 1 month^AS4||||||F|...<cr>
```

Order record for pathology report

```
OBR|3|P8755^OE|SP89-739^SP|11529-5^Surgical Path

Report^LN|||198703290800|||401-0^INTERN^IRVING^I^^^MD^L|...<cr>

OBX|1|CWE|11529-5&ANT^Surgical Path Report^LN|1|Y0480-912001^orbital
    region^SNM||||||F|...<cr>
```

Gross description record (with overflow) for pathology

```
OBX|2|TX|22634-0^Path report.gross observation^LN||The specimen is received in four
    containers.  The first is labeled with the patient's name and consists of three
    fragments of reddish-brown tissue each of which measures 2 mm in greatest
    dimension.  They are wrapped in tissue paper and submitted in toto in a single
    cassette|...<cr>
```

Microscopic description record for pathology

```
OBX|3|TX|22635-7^Path report.microscopic observation^LN|1|Sections of the first
    specimen received for frozen section diagnosis reveal thick walled, ramifying
    vessels lined by a single layer of flattened endothelial cells.  The thick
    smooth muscle walls exhibit no malignant cytologic features nor do the
    endothelial lining cells.  Within the same specimen are also found fragments of
    fibrous connective tissue, bone, and nerve which are histologically
    unremarkable||||||F|...<cr>
```

Vital signs using LOINC® codes as observation identifiers

```
OBR|4|P8756^OE|N2345^NR|29274-8^VITAL SIGNS^LN| ||198703290800|||401-
    0^INTERN^IRVING^I^^^MD^L|...<cr>
OBX|1|NM|8462-4^INTRAVASCULAR DIASTOLIC:PRES^LN||90|mm(hg)|60-90||||F|...<cr>
OBX|2|NM|8479-8^INTRAVASCULAR SYSTOLIC:PRES^LN||120|mm(hg)
   |100-160||||F|...<cr>
OBX|3|NM|8478-0^INTRAVASCULAR MEAN:PRES^LN||100|mm(hg)|80-120|N|||F|...<cr>
OBX|4|NM|8867-4^HEART BEAT RATE^LN||74|/min|60-100|N|||F|...<cr>
OBX|5|ST|8357-6^BLOOD PRESSURE METHOD^LN||MANUAL BY CUFF||||||F|...<cr>
OBX|6|ST|8886-4^HEART RATE METHOD^LN||MANUAL BY PALP||||||F|...<cr>
```

Part of the patient's history

```
OBR|5|P8568^OE|HX2230^^CLN||2000^HISTORY| ||198703290800||401
0^INTERN^IRVING^I^^^MD^L||...<cr>
OBX|1|CWE|8661-1^CHIEF COMPLAINT^LN||...<cr>
OBX|2|ST|8674-4^HISTORY SOURCE^LN||PATIENT||||||F|...<cr>
OBX|3|TX|8684-3^PRESENT ILLNESS^LN||SUDDEN ONSET OF CHEST PAIN. 2 DAYS,
   PTA ASSOCIATED WITH NAUSEA, VOMITING \T\ SOB.  NO RELIEF WITH ANTACIDS
   OR NTG. NO OTHER SX. NOT PREVIOUSLY ILL.||||||F|...<cr>
    .
    .
```

and so on.

7.5.5 Reporting Cultures and Susceptibilities

7.5.5.0

7.5.5.1 Culture battery/report representation

Organisms and other observations/tests are reported using multiple OBX segments. The granularity expected for HL7culture reports is one observation per organism.

All OBX segments which have the same observation ID and sub-ID are part of a single observation.

Each organism in a culture battery is assigned a unique *OBX-4 Observation Sub-ID* (and is therefore a separate observation). The organism name is given in *OBX-5 Observation Value* (results). It is recommended, but not required, that the organism name may change over time, but the corresponding observation sub-ID never changes. (The observation ID will be identical for all organisms reported.)

Recommended:

```
OBX|1|CWE|600-7^Micro Organism Identified^LN|1|^E. Coli|||||F|...<cr>
OBX|2|CWE|600-7^Micro Organism Identified^LN |2|^S. Aureus|||||F|...<cr>
```

Not recommended:

```
OBX|1|CWE|600-7^Micro Organism Identified^LN |1|^E. Coli|||||F|...<cr>
OBX|2|CWE|600-7^Micro Organism Identified^LN |1|^S. Aureus|||||F|...<cr>
```

7.5.5.2 Susceptibility battery/report representation

Each antimicrobial should be reported as a separate (OBX) observation where the Observation ID is a code for the antimicrobial. (OBXs for non-antimicrobials observations and related information may be present in the same battery.)

MIC and disk diffusion (Kirby Bauer) susceptibility results can be combined in the same OBX segment. An OBX can contain a MIC value (in *OBX-5 Observation Value* (results)) and *OBX-8 Interpretation Codes*

that indicates whether the organism is sensitive, resistant, or intermediate (see *HL7 Table 0078 - Interpretation Codes* under abnormal flag fields).

Or, an OBX can contain a disk diffusion result string (e.g., **sensitive**) in the Observation Results field and the disk diffusion interpretation in *OBX-8 Interpretation Codes* (e.g., **S**).

A susceptibility battery may only contain results corresponding to a single organism that has been previously reported in a culture battery.

7.5.5.3 Identification of the organism for a susceptibility battery

The following is the preferred, but not required method of organizing data about antimicrobial susceptibility.

A susceptibility battery may only contain results corresponding to a single organism that has been previously reported in a culture battery.

A susceptibility battery is always a child order to a culture battery. *OBR-29 Parent* (parent's filler order number) in the susceptibility OBR is equal *to OBR-3 Filler Order Number* in the parent culture OBR and is used to link the two batteries logically.

The susceptibility battery also contains a linkage back to a particular organism in the culture battery. *OBR-26 Parent Result* of the susceptibility OBR contains two components--*OBX-3 Observation Identifier* (code only) and *OBX -4 Observation Sub-ID* of the OBX in the culture battery which contains the organism name.

The identity of an organism/isolate is expected to be refined over time. When an organism identification changes, the parent culture battery can be resent without resending the child susceptibility battery.

The case may occur where a susceptibility battery is reported on an organism which has not yet been identified. In this case, it is required that a placeholder OBX for the organism name be reported in the corresponding culture battery so that *OBR-26 Parent Result* in the susceptibility OBR will point to a valid organism OBX in the culture battery. Transmission of an organism OBX (in the culture battery) with the Sub-ID field valued must precede the susceptibility battery which uses the identical Sub-ID in *OBR-26 Parent Result*.

Discussion and examples:

Order micro results (blood culture)

```
MSH|^~\&|LAB1||DESTINATION||19910127105114||ORU^R01^ORU_R01|LAB1003929|...<cr>
PID|...<cr>
PV1|...<cr>
ORC|NW|...<cr>
OBR|1|A485388^OE|H29847^LAB1|17928-3^BLOOD CULTURE^LN|||...<cr>
```

Result for culture

```
ORC|RE|...<cr>
OBR|1|A485388^OE|H29847^LAB1|17928-3^BLOOD CULTURE ^LN||...<cr>
OBX|1|FT|SDES^SOURCE||BLOOD-RAPID||||||F|...<cr>
OBX|2|FT|664-3^GRAM STAIN SMEAR^LN||GRAM POSITIVE COCCI IN GROUPS||||||F|...<cr>
OBX|3|FT|600-7^MICROORGANISM IDENTIFIED^LN|1|ISOLATE 1||||||F|...<cr>
```

Result for susceptibility

```
ORC|RE|...<cr>
OBR|1|A485388^OE|H29848^LAB1|BT1^SUSCEPTIBILITY BATTERY||||||123^MANSFIELD^CHARLES|
    ||||||||||||||600-7&MICROORGANISM IDENTIFIED&LN
    ^1|||A485388&OE^H29847&LAB1|...<cr>
OBX|1|NM|6932-8^PENICILLIN MIC^LN||0.5|||R|||F|...<cr>
OBX|2|NM|347-5^NAFCILLIN MIC^LN||1|||R|||F|...<cr>
OBX|3|ST|193-3^CLINDAMYCIN MIC^LN||<=0.1|||S|||F|...<cr>
```

Result for Culture ID

```
ORC|RE|...<cr>
OBR|1|A485388^OE|H29847^LAB1|17928-3^BLOOD CULTURE ^LN||...<cr>
OBX|1|FT|600-7^ MICROORGANISM IDENTIFIED^LN |1|STAPH EPI||||||F|...<cr>
```

New result for culture ID

```
ORC|RE|...<cr>
OBR|1|A485388^OE|H29847^LAB1|17928-3^BLOOD CULTURE ^LN||...<cr>
OBX|1|FT|600-7^MICROORGANISM IDENTIFIED^LN|1|STAPH EPI SERO TYPE 3||||||F|...<cr>
```

Assumptions

1) All OBXs in the parent order must employ the same coding scheme.
2) The Sub-ID of the parent OBXs (result) cannot change.

7.5.6 EKG Results Reporting

Suppose an order has been placed to the EKG system for three EKGs to be performed on successive days. These results can be reported in various ways.

1) The EKG application needs to communicate to anyone the results of the 1st EKG:

ORU message:

```
MSH|...<cr>
PID|...<cr>
```

Order record for EKG

```
OBR|1|P8753^OE|EK5230^EKG|8601-7^EKG impression^LN|||198703290800|||401
0^INTERN^IRVING^I^^^MD^L|...<cr>
```

Two interpretation records for EKG

```
OBX|1|CWE|8601-7^EKG impression^LN|1|^Sinus bradycardia|||A|||F|...<cr>
OBX|2|CWE|8601-7^EKG impression^LN |2|^Occasional PVCs|||A|||F|...<cr>
```

Four numeric results for EKG

```
OBX|3|NM|8897-1^QRS COMPLEX RATE ^LN|
   |80|/min|60-100|||||F|...<cr>
OBX|4|NM|8894-8^PULSE RATE^LN||80|/min
   |60-100||||F|...<cr>
OBX|5|NM|8633-0^QRS DURATION ^LN||.08|msec
   |.06-.10||||F|...<cr>
OBX|6|NM|8625-6^P-R INTERVAL ^LN||.22|msec
   |.18-.22||||F|...<cr>
```

- Notice that this report is without reference to the original order.

- No ORC is required because the identifying Fillers Order Number (and other ORC fields) is carried in the OBR segment.
- The EKG application needs to communicate to anyone the original order information, the details of the child orders, the fact of the child spin off, and the results of all three EKGs:

ORU message:

```
MSH|...<cr>
PID|...<cr>
ORC|PA|A226677^OE|89-450^EKG|...<cr>          // original order's ORC.
OBR|1|||8601-7^EKG REPORT|...<cr>        // original order segment
ORC|CH|A226677^OE|89-451^EKG|...<cr>          // 1st child ORC.
OBR|1|||8601-7^EKG REPORT|...<cr>        // 1st EKG child OBR.
OBX|1|ST|...<cr>                         // 1st EKG report
OBX|2|ST|...<cr>
    ...
OBX|14|FT|...<cr>
ORC|CH|A226677^OE|89-452^EKG|...<cr>          // 2nd child ORC.
OBR|1|||8601-7^EKG REPORT|...<cr>        // 2nd EKG child OBR.
OBX|1|ST|...<cr>                         // 2nd EKG report
OBX|2|ST|...<cr>
    ...
OBX|14|FT|...<cr>
ORC|CH|A226677^OE|89-453^EKG|...<cr>          // 3rd child ORC.
OBR|1|||8601-7^EKG REPORT|...<cr>        // 3rd EKG child OBR.
OBX|1|ST|...<cr>                         // 3rd EKG report
OBX|2|ST|...<cr>
    ...
OBX|14|FT|...<cr>
    ...                              // Other parts of message might follow.
```

In this case, we are transmitting the information about the fact of child spin off, the original order and the results all at the same time. Thus, this form of the ORU message reports not only the results of an order, but all of its associated ordering information including the original OBR for three EKGs that was replaced by three separate OBR EKG segments.

7.5.7 Patient-Specific Clinical Data with an Order

Reporting body weight and height with a creatinine clearance.

```
MSH|...<cr>
PID|...<cr>
ORC|NW|...<cr>                          // New order.
OBR|1|P42^PC||2164-2^CREATININE RENAL CLEARANCE: QN^LN|...<cr>
OBX|1|NM|3141-9^BODY WEIGHT^LN||62|kg|...<cr>
OBX|2|NM|3137-7^BODY HEIGHT^LN||190|cm|...<cr>
ORC|NW|...<cr>                          // Next order.
```

7.5.8 Patient-connected medical device reporting

Information acquired from patient-connected medical devices may be relatively simple, such as monitored values from a pulse-oximeter or infusion pump, or highly complex and rich such as comprehensive data from a multi-parameter physiological monitor or ventilator. In acute care contexts, many devices may be associated with a single patient and are often added and removed during an episode of care. Though point-of-care devices typically use non-HL7 protocols for their communication interfaces, data acquired from these devices are often aggregated and periodically published to enterprise applications using an HL7-based interface.

In order to enhance interoperability between point-of-care medical device systems and enterprise applications, there have been a number of collaborative projects to establish a consistent mapping of information acquired from these devices to HL7 messages. This clause provides an overview and examples of such a project by the IHE Patient Care Device ("PCD") group[4] that defines a consistent mapping from specialized device semantics to HL7 messages.

Standardized representation of device semantics is provided by the ISO/IEEE 11073 ("X73") family of standards. Specifically the ISO/IEEE 11073-10101 standard[5] provides a nomenclature or terminology for the representation of device information and is referenced in *HL7 Table 0396 – Coding System* as "MDC."

Additionally, a device-specific information model is defined, ISO/IEEE 11073-10201 Domain Information Model ("DIM"), to support the specialized, real-time communication needs of medical devices. The following diagram presents a simplified example of the X73 objects in which a given observation or Metric::Numeric are contained. The MDS, VMD, and Channel objects provide the information that is often necessary to identify specific devices and their configuration (e.g., serial numbers or internal time settings), as well as the association of data items that come from the same device subsystem (VMD or Channel) and shouldn't be confused with other observations that may have the same identifier.

[4] Information on Integrating the Healthcare Enterprise (“IHE”), including PCD message profiles are available at www.IHE.net.

[5] Additional ISO/IEEE 11073-1010x standards may be used to represent abstract device semantics, such as ISO/IEEE 11073-10102 Annotated ECG.

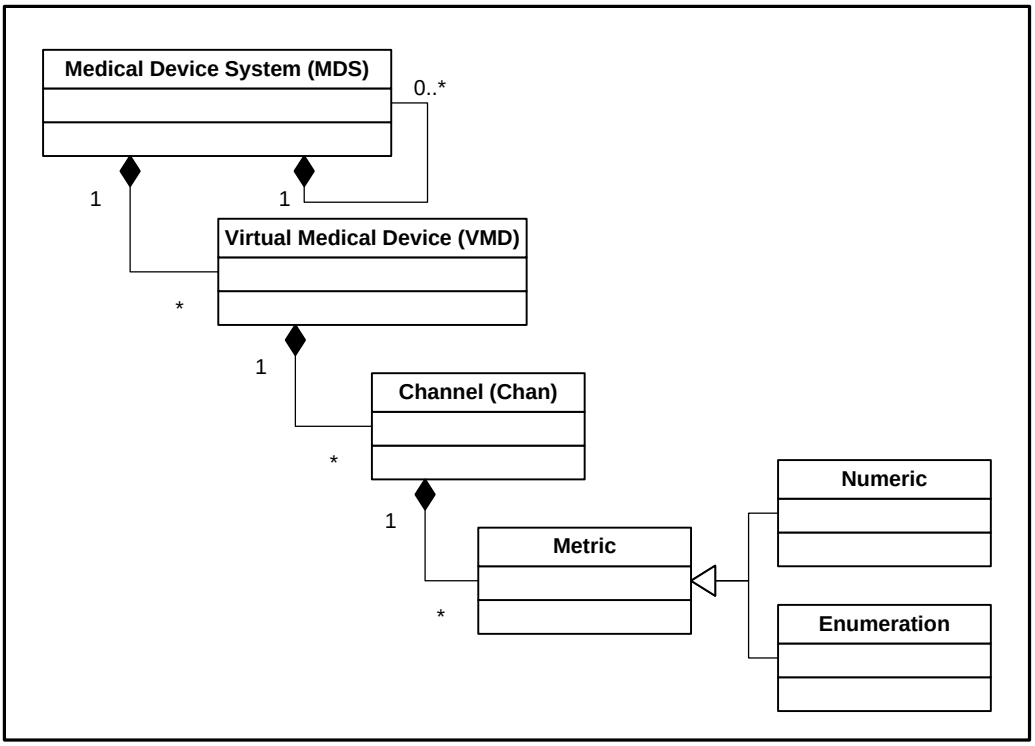


Figure 7-5 Basic ISO/IEEE 11073-10201 Containment Tree

The IHE PDC Device-to-Enterprise ("DEC") profile defines a single HL7 message, ORU^R01, that maps X73 abstract device semantics to specific message segments and fields. The message specification includes the following:

- Device terms should be communicated using their "MDC" code within and among devices. Between devices and medical record systems other standard vocabulary, e.g., LOINC (emerging as the global standard) and SNOMED, may be used.
- Units of measurement may be either those defined in the ISO/IEEE 11073-10101 Nomenclature, or UCUM. Carrying both is recommended.
- Devices and device-related applications and systems are identified using the 64-bit IEEE EUI-64 identifier (Table 0301) that is specified in the X73 standards.
- OBX-4 is used with a dotted nomenclature[6] to indicate containment of specific measurements within Channels, Virtual Medical Devices and Medical Device Systems.

Complete details of this message profile are defined in the IHE PCD DEC framework. The following message examples illustrate how device information is communicated using this profile.

[6] See section 7.4.2.5 OBX-4 Observation Sub-ID discussion, including Figure 7-4 Example of sub-identifier usage.

Message Example from a Single Simple Device

```
MSH|^~\&|PAT_DEVICE_PUMPCO^0012210000000001^EUI-
    64|PUMPCO|CIS_HITCO|HITCO|20071204153604-
    0600||ORU^R01^ORU_R01|11|P|2.8|||NE|AL||ASCII|EN^English^ISO659||IHE PCD ORU-
    R01 2006^HL7^2.16.840.1.113883.9.n.m^HL7

PID|||CD60002^^^IHE^PI||Darwin^Charles^^^^^L|Emerine|19620101000000-0600|M

PV1||I|3 West ICU^3002^1

OBR|0|AB12345^HL7^ACDE48234567ABCD^EUI-64|CD12345^HL7^ACDE48234567ABCD^EUI-
    64|69985^MDC_DEV_PUMP_INFUS_MDS^MDC|||20071204153602-0600

OBX|1||69985^MDC_DEV_PUMP_INFUS_MDS^MDC|1000002.0.0.0||||||X|||||N60002||^^A0002^P
    UMPCO

OBX|2||69986^MDC_DEV_PUMP_INFUS_VMD^MDC|1000002.1.0.0||||||X

OBX|3||126978^MDC_DEV_PUMP_INFUS_CHAN_DELIVERY^MDC|1000002.1.1.0||||||X

OBX|4||126977^MDC_DEV_PUMP_INFUS_CHAN_SOURCE^MDC|1000002.1.2.0||||||X

OBX|5||126977^MDC_DEV_PUMP_INFUS_CHAN_SOURCE^MDC|1000002.1.3.0||||||X

OBX|6|NM|68063^MDC_ATTR_PT_WEIGHT^MDC|1000002.0.0.2|95.0|1731^kg^UCUM^263875^MDC_DI
    M_X_KILO_G^MDC|||||R|||20071204153602-0600|||||20071204153602-0600

OBX|7|ST|184504^MDC_PUMP_MODE^MDC|1000002.1.1.101|pump-mode-drug-
    dosing||||||R|||20071204153602-0600|||||20071204153602-0600

OBX|8|ST|184508^MDC_PUMP_STAT^MDC|1000002.1.1.102|pump-status-
    infusing||||||R|||20071204153602-0600|||||20071204153602-0600

OBX|9|NM|157784^MDC_FLOW_FLUID_PUMP^MDC|1000002.1.1.103|24.9|3122^mL/h^UCUM^265266^
    MDC_DIM_MILLI_L_PER_HR^MDC|||||R|||20071204153602-0600|||||20071204153602-0600

OBX|10|NM|157784^MDC_FLOW_FLUID_PUMP^MDC|1000002.1.2.201|24.9|3122^mL/h^UCUM^265266
    ^MDC_DIM_MILLI_L_PER_HR^MDC|||||R|||20071204153602-0600|||||20071204153602-0600

OBX|11|NM|157872^MDC_VOL_FLUID_TBI_REMAIN^MDC|1000002.1.2.202|250.0|1618^mL^UCUM^26
    3762^MDC_DIM_MILLI_L^MDC|||||R|||20071204153602-0600|||||20071204153602-0600

OBX|12|NM|157916^MDC_TIME_PD_REMAIN^MDC|1000002.1.2.203|601|2208^min^UCUM^264352^MD
    C_DIM_MIN^MDC|||||R|||20071204153602-0600|||||20071204153602-0600

OBX|13|ST|184330^MDC_DRUG_NAME_TYPE^MDC|1000002.1.2.204|DOPamine||||||R|||200712041
    53602-0600|||||20071204153602-0600

OBX|14|NM|157760^MDC_CONC_DRUG^MDC|1000002.1.2.205|1.6|2162^mg/mL^UCUM^264306^MDC_D
    IM_MILLI_G_PER_ML^MDC|||||R|||20071204153602-0600|||||20071204153602-0600

OBX|15|NM|157924^MDC_RATE_DOSE^MDC|1000002.1.2.206|7.00|3475^ug/kg/min^UCUM^265619^
    MDC_DIM_MICRO_G_PER_KG_PER_MIN^MDC|1-20||||R|||20071204153602-
    0600|||||20071204153602-0600
```

Message Example for Multiple Devices

```
MSH|^~\&|CIS_HITCO ^ACDE48234567ABCD^EUI-64||||20061220214210-
    0500||ORU^R01^ORU_R01|D1220214210609b5f9aa|P|2.8|||NE|AL

PID|||LM60005^^^Health IT Co^PI||Montgomery^Larry^^^^^L||19560101000000|M

PV1||I|UNIT_1^^Bed1

OBR|1|D1220214210609b5f9aa^CIS_HITCO^ACDE48234567ABCD^EUI-
    64|D1220214210609b5f9aa^CIS_HITCO^ACDE48234567ABCD^EUI-
    64|69640^MDC_DEV_ANALY_SAT_O2^MDC|||20061220213500

OBX|1|NM|150456^MDC_PULS_OXIM_SAT_O2^MDC|1.1.1.150456|99|262688^MDC_DIM_PERCENT^MDC
    ||N|||F|||20061220213500

OBR|2|D1220214210609b5f9aa^CIS_HITCO^ACDE48234567ABCD^EUI-
    64|D12202214210609b5f9aa^CIS_HITCO^ACDE48234567ABCD^EUI-
    64|69636^MDC_DEV_ANALY^MDC|||20061220213500

OBX|1|NM|147842^MDC_ECG_HEART_RATE^MDC|1.1.1.147842|133|264864^MDC_DIM_BEAT_PER_MIN
    ^MDC||A|||F|||20061220213500
```

```
OBR|3|D1220214210609b5f9aa^CIS_HITCO^ACDE48234567ABCD^EUI-
    64|D1220214210609b5f9aa^CIS_HITCO^ACDE48234567ABCD^EUI-
    64|69708^MDC_DEV_ANALY_PRESS_BLD^MDC|||20061220213500

OBX|1|NM|150037^MDC_PRESS_BLD_ART_ABP_SYS^MDC|1.1.1.150037|126|266016^MDC_DIM_MMHG^
    MDC||N|||F|||20061220213500

OBX|2|NM|150038^MDC_PRESS_BLD_ART_ABP_DIA^MDC|1.1.1.150038|76|266016^MDC_DIM_MMHG^M
    DC||N|||F|||20061220213500

OBX|3|NM|150039^MDC_PRESS_BLD_ART_ABP_MEAN^MDC|1.1.1.150039|92|266016^MDC_DIM_MMHG^
    MDC||N|||F|||20061220213500

OBR|4|D1220214210609b5f9aa^CIS_HITCO^ACDE48234567ABCD^EUI-
    64|D1220214210609b5f9aa^CIS_HITCO^ACDE48234567ABCD^EUI-
    64|69708^MDC_DEV_ANALY_PRESS_BLD^MDC|||20061220213500

OBX|1|NM|150087^MDC_PRESS_BLD_VEN_CENT_MEAN^MDC|1.1.1.150087|12|266048^MDC_DIM_CM_H
    2O^MDC||N|||F|||20061220213500

OBR|5|D1220214210609b5f9aa^CIS_HITCO^ACDE48234567ABCD^EUI-
    64|D1220214210609b5f9aa^CIS_HITCO^ACDE48234567ABCD^EUI-
    64|69708^MDC_DEV_ANALY_PRESS_BLD^MDC|||20061220213500

OBX|1|NM|150045^MDC_PRESS_BLD_ART_PULM_SYS^MDC|1.1.1.150045|26|266016^MDC_DIM_MMHG^
    MDC||A|||F|||20061220213500

OBX|2|NM|150046^MDC_PRESS_BLD_ART_PULM_DIA^MDC|1.1.1.150046|9|266016^MDC_DIM_MMHG^M
    DC||A|||F|||20061220213500

OBX|3|NM|150047^MDC_PRESS_BLD_ART_PULM_MEAN^MDC|1.1.1.150047|14|266016^MDC_DIM_MMHG
    ^MDC||A|||F|||20061220213500
```

7.6 CLINICAL TRIALS

Academic medical institutions, academic research coordinating centers, and industry-based research organizations often have computer systems that support registration, compliance and safety monitoring, and outcomes analysis for clinical trials. Patients on these trials may receive their treatment and evaluation at one research facility or at many different medical facilities. Clinical trials systems could message other applications that a patient is registered on a clinical trial. Several functional examples follow:

(1) Some of the data required to monitor or analyze outcomes on the trial are generated in other medical computer systems, such as pharmacy, laboratory, or clinical applications. These applications may tag patients on clinical trials so that data may be sent back to the clinical trials system.

(2) Order entry systems could also use patient registration information: they could display standard order sets for the protocol or particular treatment/evaluation phases of a complex protocol. They could pass the clinical trials status on to service provider applications to initiate a results report to the clinical trials system. It could also be passed to billing applications that may use specialized procedures for research-related costs.

(3) Nursing and pharmacy systems can use information on patients' clinical trials status for care plans or dispensing authorization (auxiliary to the physician's prescription), respectively. There could be many other uses of this message since a patient's involvement on a clinical trial affects all concurrent medical care.

To meet monitoring and analysis requirements, patient registration, treatment, diagnostic, and study summary data are reported to study sponsors like pharmaceutical or medical device companies, regulatory agencies, and data management centers for collaborative studies. Automated procedures must be used to transfer these voluminous data among the participant computer systems in a cost-efficient and timely manner. The following additions to HL7 aim to specify standard messaging transactions to automate such reporting as well as to enable communication of clinical trials registration data to relevant medical applications as described above.

The objectives of the clinical trials messages and segments are to identify that patients are registered on clinical trials, have entered a study-specific phase of treatment or evaluation, or to indicate the study protocol's data

schedule. Messages include OBR (section 4.5.3, "OBR - Observation Request Segment"), OBX (section 7.4.2, "OBX - Observation/Result Segment"), RXA (section 4.14.7, "RXA - Pharmacy /Treatment Administration Segment"), and RXR (section 4.14.2, "RXR - pharmacy/Treatment Route Segment") segments to report observations or drug administration that are relevant to the study. In addition to study-related clinical data, OBX segments may contain the results of study variables according to master code tables such as the Health Outcomes Variables (HL7 Implementation Guide). There are also master segments to describe the clinical trial, its treatment phases, and its scheduled date-time points for message recipients. These are analogous to the Test/Observation Master Segments (Chapter 8), with the trials, phases, or scheduled time points treated as the OMX treats observation identifiers.

7.6.1 Glossary

7.6.1.0 hiddentext

7.6.1.1 Clinical trial:

A scientifically rigorous study of individual outcomes to some process of healthcare intervention. Clinical trials usually involve medical treatments so this document will use the term *treatment*, rather than the broader term *intervention*. A clinical trial design may randomly assign and compare one treatment approach with another, or generate safety and efficacy data on a single treatment approach. The clinical trial has a protocol for the patient's course of treatment and/or evaluation. There is usually a schedule for collection of data to measure compliance, safety, and outcomes.

7.6.1.2 Phase of a clinical trial:

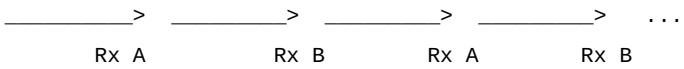
A treatment and/or observation interval of a clinical trial. A phase may represent an interval with a specific treatment regimen assigned randomly or otherwise, with each regimen of a progression of treatments, or with an evaluation component only. Generally, for each phase, there is an explicit patient management, evaluation, and data collection schedule. Each of these phases may have associated safety, outcome, and quality-control variables. A simpler study design need not use the phase structures.

The phase structure serves several purposes in the clinical trials messages. Other computer systems may need to know that the patient has begun a phase with a particular treatment regimen or diagnostic schedule, such as the pharmacy or order entry systems. When reporting study data, observations and variables often describe particular phase instances. For example, each course of treatment may have its own values for the same set of observations or variables. Phase instances may also have distinct data schedules that need to be linked to submitted data.

Several examples follow with each line depicting a phase.

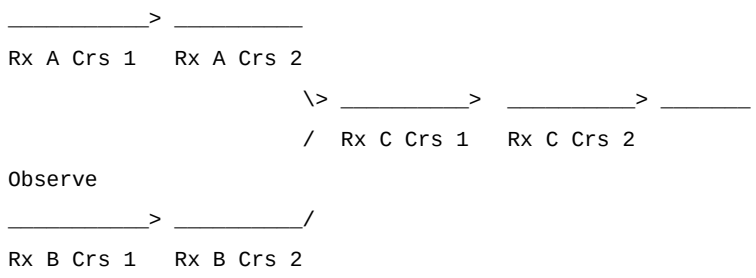
7.6.1.2.1 Example 1

Alternating treatment plus observation intervals:



7.6.1.2.2 Example 2

Random assignment to two courses each of treatment A or B, all responding patients to treatment C, continue with observation and a diagnostic regimen after all treatment phases are completed. Treatment phases include the evaluation component for that course of treatment:



7.6.1.2.3 Example 3

Random assignment to placebo or treatment A, both taken daily and evaluated monthly.

7.6.1.3 Data schedule:

The treatment, diagnostic, and procedural requirements, as well as data collection due dates, scheduled on a timeline for most clinical trials. As data are reported, they may need to reflect the scheduled time point that they satisfy. Clinical trials quality control requires attention to compliance between the protocol's schedule and patient data records.

The data schedule will be keyed by time points relative to the study. Some data may be due prior to and at the conclusion of the study and/or one or more of its phases. Some are interim within the study or its phases depending on protocol events such as administration of treatment, arbitrary time intervals instated to make and record assessments, or some clinical milestone such as relapse of disease. Often, multiple data parameters are scheduled at the same time point. Several examples follow:

7.6.1.3.1 Schedule for a randomized cancer prevention trial

		Treatment 1st - 3rd Years																
	Reg	Rand	Months															
			3	6	9	12	18	24	30	36	42	48	54	60	66	72	78	84
Disease Staging	X																	
H & P	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Assess Adverse Events and Outcome Variables	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Chest PAL X-ray	X			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
CBC, Diff, Plt	X			X	X	X	X	X	X	X		X		X		X		X
SMA 12	X		X	X	X	X	X	X	X	X		X		X		X		X
Cholesterol and Triglyceride	X		X	X	X	X	X	X	X	X								
Electrolytes	X																	
Plasma Retinoic Acid	X	X																
Cotinine Level (nonsmokers)		X																

7.6.1.3.2 Schedule for a cancer chemotherapy trial

	Prestudy	Prior to Each Cycle	During Cycle	Every 3 Cycles	End Study
Informed Consent	X	X			
H & P Neurologic	X1				X
Vital Signs	X1		X2		X
Disease Staging	X	X3			X
ECG	X1		X4		
Radiology*		X		X5	X
Chest X-ray	X	X			X
Bone Marrow Bx.	X6				
HCG	X1				
Assess Adverse Events		X			X
CBC, Diff, Plt	X1			X7	X

UA, PT, PTT	X1			X
SMA12, Mg, CEA	X1	X		X

1) Within 3 days prior to start of infusion.

2) At 0,10,30, and 60 minutes after start of drug administration and one-half hour after test drug infusion ends for cycles 1 and 2. For subsequent cycles at 0 and 10 minutes after start of drug administration, and at the end of infusion.

3) Record tumor measurements at the end of every cycle if assessable clinically by physical examination or with simple X-ray.

4) Continuous ECG monitoring during infusion if necessary, due to bradycardia (<50 beats/min) or other significant cardiac findings.

5) When measurable disease requires complex radiologic studies such as CT or radionucleide scans.

6) To be done at baseline (if clinically indicated) at the option of the investigator and also during study if patient has prolonged myelosuppression (WBC<2000 cells/mm3>14 days).

7) Blood counts will be done twice weekly during cycles 1 and 2, then weekly.

8) * Radionucleide scan and X-ray of the bones, CT scans of the chest, pelvis, and brain only when clinically indicated.

7.6.1.3.3 Schedule for a randomized pain medication trial

	Day 1 Before RX	Day 1 After RX	Daily	Day 30
H & P	X			X
Creat, Bili, SGOT	X			
Urinalysis	X			
Pain Diagnosis	X			
Opioid Dose Strand	X	X	X	X
Non-opioid Analgesic		X	X	X
Medications for Side Effects		X	X	X
Phone Report: Pain and Side Effects			X	
Visual Analog Scales	X	X	X	X
Pain Evaluation Form	X			X

7.7 CLINICAL TRIALS - TRIGGER EVENTS AND MESSAGE DEFINITIONS

The event type will be carried in the message header segment.

7.7.1 CRM - Clinical Study Registration Message (Events C01-C08)

The data are entered in a clinical trials or other patient data system and broadcast to other facility systems such as order entry, pharmacy, accounting, and nursing systems. They can be transmitted in batch mode or broadcast to outside-facility computer systems, including diagnostic and patient management systems. It is assumed that proper routing and security mechanisms are in place.

The general acknowledgement message as defined in Chapter 2 should be used for any acknowledgements.

Event	Description
C01	Register a patient on a clinical trial
C02	Cancel a patient registration on clinical trial (for clerical mistakes since an intended registration should not be canceled)
C03	Correct/update registration information
C04	Patient has gone off a clinical trial
C05	Patient enters phase of clinical trial
C06	Cancel patient entering a phase (clerical mistake)

Event	Description
C07	Correct/update phase information
C08	Patient has gone off phase of clinical trial

CRM^C01-C08^CRM_C01: Clinical Trial Message

Segments	Description	Status	Chapter
MSH	Message Header		2
[{ARV}]	Access Restrictions		3
[{ SFT }]	Software Segment		2
[UAC]	User Authentication Credential		2
{	--- PATIENT begin		
PID	Patient Identification		3
[{PRT}]	Participation (for Patient		7
[{ARV}]	For backwards compatibility only as of V2.9.	B	3
[	--- PATIENT_VISIT begin		
PV1	Patient Visit		3
[{PRT}]	Participation (for Patient Visit		7
]	--- PATIENT_VISIT end		
CSR	Clinical Study Registration		7
[{CSP}]	Clinical Study Phase		7
}	--- PATIENT end		

Acknowledgement Choreography				
CRM^C01^CRM_C01				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^C01^ACK
Application Ack	ACK^C01^ACK	-	ACK^C01^ACK	ACK^C01^ACK

Acknowledgement Choreography				
CRM^C02^CRM_C01				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER

Immediate Ack	-	-	-	ACK^C02^ACK
Application Ack	ACK^C02^ACK	-	ACK^C02^ACK	ACK^C02^ACK

Acknowledgement Choreography				
CRM^C03^CRM_C01				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^C03^ACK
Application Ack	ACK^C03^ACK	-	ACK^C03^ACK	ACK^C03^ACK

Acknowledgement Choreography				
CRM^C04^CRM_C01				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^C04^ACK
Application Ack	ACK^C04^ACK	-	ACK^C04^ACK	ACK^C04^ACK

Acknowledgement Choreography				
CRM^C05^CRM_C01				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^C05^ACK
Application Ack	ACK^C05^ACK	-	ACK^C05^ACK	ACK^C05^ACK

Acknowledgement Choreography				
CRM^C06^CRM_C01				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^C06^ACK
Application Ack	ACK^C06^ACK	-	ACK^C06^ACK	ACK^C06^ACK

Acknowledgement Choreography				
CRM^C07^CRM_C01				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^C07^ACK
Application Ack	ACK^C07^ACK	-	ACK^C07^ACK	ACK^C07^ACK

Acknowledgement Choreography				
CRM^C08^CRM_C01				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^C08^ACK
Application Ack	ACK^C08^ACK	-	ACK^C08^ACK	ACK^C08^ACK

7.7.2 CSU - Unsolicited Study Data Message (Events C09-C12)

Data are entered in the clinical trials system or may reside in laboratory, pathology, radiology, pharmacy and/or other clinical applications. Most clinical trials data - clinical observations and study variables - will be communicated in OBR and OBX segments. The CSR, CSP, and CSS segments will identify the specific association these OBR and OBX have to the clinical trial. Data can be broadcast or transmitted in batch mode to study sponsors or the data management center for collaborative studies.

The general acknowledgement message as defined in Chapter 2 should be used for any acknowledgements.

Event	Description
C09	Automated time intervals for reporting, like monthly
C10	Patient completes the clinical trial
C11	Patient completes a phase of the clinical trial
C12	Update/correction of patient order/result information

CSU^C09-C12^CSU_C09: Clinical Trial Message

Segments	Description	Status	Chapter
MSH	Message Header		2
[{ARV}]	Access Restrictions		3
[{SFT}]	Software Segment		2
[UAC]	User Authentication Credential		2
{	--- PATIENT begin		
PID	Patient Identification		3
[PD1]	Additional Demographics		3

Segments	Description	Status	Chapter
[{PRT}]	Participation (for Patient)		7
[{ARV}]	For backwards compatibility only as of V2.9.	B	3
[{NTE}]	Notes and comments		2
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit - Additional Info		3
[{PRT}]	Participation (for Patient Visit)		7
]	--- VISIT end		
CSR	Clinical Study Registration		7
{	--- STUDY_PHASE begin		
[CSP]	Clinical Study Phase		7
{	--- STUDY_SCHEDULE begin		
[CSS]	Clinical Study Data Schedule		7
{	--- STUDY_OBSERVATION begin		
[			
ORC	Common Order		4
[{PRT}]	Participation (for common order)		7
]			
OBR	Observation Battery		7
[{PRT}]	Participation (for observation)		7
[{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}]	--- TIMING_QTY end		
OBX	Observation Results		7
[{PRT}]	Participaton (for Observation Results)		7
}	--- STUDY_OBSERVATION end		
{	--- STUDY_PHARM begin		
[	--- COMMON_ORDER begin		
ORC	Common Order		4
[{PRT}]	Participation (for Common Order)		7
]	--- COMMON_ORDER end		
{	--- RX_ADMIN begin		

Segments	Description	Status	Chapter
RXA	Pharmacy Administration		4
RXR	Pharmacy Route		4
[{PRT}]	Participation (for Pharmacy Administration)		7
}	--- RX_ADMIN end		
}	--- STUDY_PHARM end		
}	--- STUDY_SCHEDULE end		
}	--- STUDY_PHASE end		
}	--- PATIENT end		

Acknowledgement Choreography				
CSU^C09^CSU_C09				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^C09^ACK
Application Ack	ACK^C09^ACK	-	ACK^C09^ACK	ACK^C09^ACK

Acknowledgement Choreography				
CSU^C10^CSU_C09				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^C10^ACK
Application Ack	ACK^C10^ACK	-	ACK^C10^ACK	ACK^C10^ACK

Acknowledgement Choreography				
CSU^C11^CSU_C09				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^C11^ACK
Application Ack	ACK^C11^ACK	-	ACK^C11^ACK	ACK^C11^ACK

Acknowledgement Choreography				
CSU^C12^CSU_C09				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^C12^ACK
Application Ack	ACK^C12^ACK	-	ACK^C12^ACK	ACK^C12^ACK

7.8 CLINICAL TRIALS – SEGMENT DEFINITIONS

7.8.1 CSR - Clinical Study Registration Segment

The CSR segment will contain fundamental administrative and regulatory information required to document a patient's enrollment on a clinical trial. This segment is all that is required if one needs to message another system that an enrollment has taken place, i.e., from clinical trials to pharmacy, accounting, or order entry systems. The CSR segment may also be used to identify that OBR, OBX, RXA, and RXR segments that follow represent data applicable to the identified study.

HL7 Attribute Table – CSR – Clinical Study Registration

SEQ	LEN	C.LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1			EI	R			01011	Sponsor Study ID
2			EI	O			01036	Alternate Study ID
3			CWE	O		0589	01037	Institution Registering the Patient
4			CX	R			01038	Sponsor Patient ID
5			CX	O			01039	Alternate Patient ID - CSR
6			DTM	R			01040	Date/Time of Patient Study Registration
7			XCN	O	Y		01041	Person Performing Study Registration
8			XCN	R	Y		01042	Study Authorizing Provider
9			DTM	C			01043	Date/Time Patient Study Consent Signed
10			CWE	C		0590	01044	Patient Study Eligibility Status
11			DTM	O	Y/3		01045	Study Randomization Date/time
12			CWE	O	Y/3	0591	01046	Randomized Study Arm
13			CWE	O	Y/3	0592	01047	Stratum for Study Randomization
14			CWE	C		0593	01048	Patient Evaluability Status
15			DTM	C			01049	Date/Time Ended Study
16			CWE	C		0594	01050	Reason Ended Study
17	2..2		ID	O		0206	00816	Action Code

7.8.1.0 CSR field definitions

7.8.1.1 CSR-1 Sponsor Study ID (EI) 01011

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: The field contains the universal identifier for the clinical trial. Since many clinical trials are collaborative and multi-centered, and since one goal of these standards is to promote automated data exchange among sites, the primary identifier should come from the sponsor. The coding system component may reference the sponsor. Example:

```
T93-0807^NCI (where NCI refers to the National Cancer Institute).
```

7.8.1.2 CSR-2 Alternate Study ID (EI) 01036

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
          <Universal ID Type (ID)>
```

Definition: This field contains an alternate identifier that may be used as agreed upon by messaging parties. For example, the sending application may code its internal study number here.

7.8.1.3 CSR-3 Institution Registering the Patient (CWE) 01037

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
          <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
          Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
          System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
          Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
          Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
          (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
          Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
          Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
          Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
          Alternate Value Set Version ID (DTM)>
```

Definition: This field distinguishes the institution where registration occurred. The legal approval to give patients access to a trial lies with the Internal Review Board for the institution. Universal healthcare provider facility codes should be used when they exist. Currently coding systems must be devised by users. Refer to Table 0589 - Institution Registering the Patient in Chapter 2C for valid values.

7.8.1.4 CSR-4 Sponsor Patient ID (CX) 01038

```
Components:  <ID Number (ST)> ^ <Identifier Check Digit (ST)> ^ <Check Digit Scheme
          (ID)> ^ <Assigning Authority (HD)> ^ <Identifier Type Code (ID)> ^
          <Assigning Facility (HD)> ^ <Effective Date (DT)> ^ <Expiration Date (DT)>
          ^ <Assigning Jurisdiction (CWE)> ^ <Assigning Agency or Department (CWE)>
          ^ <Security Check (ST)> ^ <Security Check Scheme (ID)>

Subcomponents for Assigning Authority (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
          & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
          & <Universal ID Type (ID)>

Subcomponents for Assigning Jurisdiction (CWE):  <Identifier (ST)> & <Text (ST)> &
          <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
          Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
          Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
          Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text
          (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate
          Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID
          (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)>
          & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)>
          & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Agency or Department (CWE):  <Identifier (ST)> & <Text
          (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> &
          <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding
          System Version ID (ST)> & <Alternate Coding System Version ID (ST)> &
          <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second
          Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> &
          <Second Alternate Coding System Version ID (ST)> & <Coding System OID
          (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate
          Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate
          Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> &
          <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set
          Version ID (DTM)>
```

Definition: This field contains the main patient identification for the study. The sponsor patient ID allows automation of records on patients treated at various institutions. The sponsor patient ID should be unique for each patient participating on the study identified in *CSR-1 Sponsor Study ID*.

7.8.1.5 CSR-5 Alternate Patient ID - CSR (CX) 01039

```
Components:  <ID Number (ST)> ^ <Identifier Check Digit (ST)> ^ <Check Digit Scheme
          (ID)> ^ <Assigning Authority (HD)> ^ <Identifier Type Code (ID)> ^
          <Assigning Facility (HD)> ^ <Effective Date (DT)> ^ <Expiration Date (DT)>
          ^ <Assigning Jurisdiction (CWE)> ^ <Assigning Agency or Department (CWE)>
          ^ <Security Check (ST)> ^ <Security Check Scheme (ID)>

Subcomponents for Assigning Authority (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
          & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
          & <Universal ID Type (ID)>

Subcomponents for Assigning Jurisdiction (CWE):  <Identifier (ST)> & <Text (ST)> &
          <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
          Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
          Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
          Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text
          (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate
          Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID
          (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)>
          & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)>
          & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Agency or Department (CWE):  <Identifier (ST)> & <Text
          (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> &
          <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding
          System Version ID (ST)> & <Alternate Coding System Version ID (ST)> &
          <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second
          Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> &
          <Second Alternate Coding System Version ID (ST)> & <Coding System OID
          (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate
          Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate
          Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> &
          <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set
          Version ID (DTM)>
```

Definition: This field may be the sending application's patient identification. Coding conventions may be used as agreed upon by users.

7.8.1.6 CSR-6 Date/Time Patient of Patient Study Registration (DTM) 01040

Definition: This field containing the date of the patient registration is mandatory. The time component is optional. The time stamp for a registration may be useful. For example, patients may be randomized at the pharmacy according to the order in which they were registered.

7.8.1.7 CSR-7 Person Performing Study Registration (XCN) 01041

```
Components:  <Person Identifier (ST)> ^ <Family Name (FN)> ^ <Given Name (ST)> ^
          <Second and Further Given Names or Initials Thereof (ST)> ^ <Suffix (e.g.,
          JR or III) (ST)> ^ <Prefix (e.g., DR) (ST)> ^ <WITHDRAWN Constituent> ^
          <DEPRECATED-Source Table (CWE)> ^ <Assigning Authority (HD)> ^ <Name Type
          Code (ID)> ^ <Identifier Check Digit (ST)> ^ <Check Digit Scheme (ID)> ^
          <Identifier Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name
          Representation Code (ID)> ^ <Name Context (CWE)> ^ <WITHDRAWN Constituent>
          ^ <Name Assembly Order (ID)> ^ <Effective Date (DTM)> ^ <Expiration Date
          (DTM)> ^ <Professional Suffix (ST)> ^ <Assigning Jurisdiction (CWE)> ^
          <Assigning Agency or Department (CWE)> ^ <Security Check  (ST)> ^
          <Security Check Scheme (ID)>

Subcomponents for Family Name (FN):  <Surname (ST)> & <Own Surname Prefix (ST)> & <Own
          Surname (ST)> & <Surname Prefix from Partner/Spouse (ST)> & <Surname from
          Partner/Spouse (ST)>
```

Subcomponents for Source Table (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Authority (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Name Context (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Jurisdiction (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Agency or Department (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Definition: This field contains the healthcare facility employee who actually phoned, submitted a form, or interactively registered the patient on the clinical trial. This is generally done under authorization from the attending physician or a principal or collaborating investigator.

7.8.1.8 CSR-8 Study Authorizing Provider (XCN) 01042

Components: <Person Identifier (ST)> ^ <Family Name (FN)> ^ <Given Name (ST)> ^ <Second and Further Given Names or Initials Thereof (ST)> ^ <Suffix (e.g., JR or III) (ST)> ^ <Prefix (e.g., DR) (ST)> ^ <WITHDRAWN Constituent> ^ <DEPRECATED-Source Table (CWE)> ^ <Assigning Authority (HD)> ^ <Name Type Code (ID)> ^ <Identifier Check Digit (ST)> ^ <Check Digit Scheme (ID)> ^ <Identifier Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name Representation Code (ID)> ^ <Name Context (CWE)> ^ <WITHDRAWN Constituent> ^ <Name Assembly Order (ID)> ^ <Effective Date (DTM)> ^ <Expiration Date (DTM)> ^ <Professional Suffix (ST)> ^ <Assigning Jurisdiction (CWE)> ^ <Assigning Agency or Department (CWE)> ^ <Security Check (ST)> ^ <Security Check Scheme (ID)>

```
Subcomponents for Family Name (FN):  <Surname (ST)> & <Own Surname Prefix (ST)> & <Own
          Surname (ST)> & <Surname Prefix from Partner/Spouse (ST)> & <Surname from
          Partner/Spouse (ST)>

Subcomponents for Source Table (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of
          Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
          & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
          & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
          <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
          of Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Authority (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
          & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
          & <Universal ID Type (ID)>

Subcomponents for Name Context (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of
          Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
          & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
          & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
          <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
          of Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Jurisdiction (CWE):  <Identifier (ST)> & <Text (ST)> &
          <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
          Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
          Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
          Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text
          (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate
          Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID
          (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)>
          & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)>
          & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Agency or Department (CWE):  <Identifier (ST)> & <Text
          (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> &
          <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding
          System Version ID (ST)> & <Alternate Coding System Version ID (ST)> &
          <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second
          Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> &
          <Second Alternate Coding System Version ID (ST)> & <Coding System OID
          (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate
          Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate
          Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> &
          <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set
          Version ID (DTM)>
```

Definition: This field contains the healthcare provider, generally the attending physician, who is accountable that the patient is eligible for the trial and has signed an informed consent. National standard healthcare provider codes should be used when they exist. This field is required for the patient registration trigger event (C01).

7.8.1.9 CSR-9 Date/Time Patient Study Consent Signed (DTM) 01043

Definition: This field contains the consent form signing date is collected to provide a checkpoint that the consent form was obtained. Since many trials involve unapproved drugs and other treatment modalities, the consent form is highly important to document and store. This field is required for the patient registration trigger event (C01). The time component is optional.

7.8.1.10 CSR-10 Patient Study Eligibility Status (CWE) 01044

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field indicates whether the patient was an appropriate candidate for the trial. It is important for quality control and data analysis. The code set will vary among clinical trials. An example answer set is: ***Yes, No, By Approval, Not Assessed, Unknown***. This field is required for the patient registration trigger event (C01). Refer to Table 0590 - Patient Study Eligibility Status in Chapter 2C for valid values.

7.8.1.11 CSR-11 Study Randomization Date/Time (DTM) 01045

Definition: This field contains the date the patient was randomized. The time component is optional. Up to three randomizations are supported. Sequential randomizations are listed in chronological order.

7.8.1.12 CSR-12 Randomized Study Arm (CWE) 01046

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field contains codes that must be developed by users. The blind treatment assignment may be communicated as a dummy text: **^blind** or if a coded treatment assignment must also be communicated**: 1^blind^local_code**. If more than one randomization occurs, the second and third repetitions will correspond to the second and third repetitions of *CSR-11 Study Randomization Date/Time*, if they exist. Refer to Table 0591 - Randomized Study Arm in Chapter 2C for valid values.

7.8.1.13 CSR-13 Stratum for Study Randomization (CWE) 01047

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: Many studies have stratified randomization schemas. The strata codes must be developed for each clinical trial. This field is important for statistical analysis of the study results. The second and third repetitions will correspond to the second and third repetitions of *CSR-11 Study Randomization Date/Time* and *CSR-12 Randomized Study Arm*, if they exist. Refer to Table 0592 - Stratum for Study Randomization in Chapter 2C for valid values.

7.8.1.14 CSR-14 Patient Evaluability Status (CWE) 01048

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field categorizes the inclusion of this patient's data for various analyses. The patient's data may be evaluable for analysis of adverse events but not for outcomes. Or it may be evaluable for some outcomes and not others. The coding systems will vary among trials. This field is required for the off-study trigger event (C04). Refer to Table 0593 - Patient Evaluability Status in Chapter 2C for valid values.

7.8.1.15 CSR-15 Date/Time Ended Study (DTM) 01049

Definition: This field contains the date the patient completes or is otherwise removed from the study. This field is required for the off-study event (C04). The time component is optional.

7.8.1.16 CSR-16 Reason Ended Study (CWE) 01050

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This information is important for quality control and data analysis. The coding systems will vary among trials. An example answer set is: **Adverse Events, Completed Trial, Death, Drug Resistance, Intercurrent Illness, Lost to Follow up, No Response to Therapy, Noncompliance, Progression of Disease, Protocol Violation, Refused Further Therapy.** This field is required for the off-study trigger event (C04). Refer to Table 0594 - Reason Ended Study in Chapter 2C for valid values.

7.8.1.17 CSR-17 Action Code (ID) 00816

Definition: This field reveals the intent of the message. Refer to *HL7 Table 0206 - Segment Action Code* for valid values.

The action code can only be used when CSR-1 and CSR-4, or CSR-2 and CSR-5 are valued as agreed to by the trading partners in accordance with the guidance in Chapter 2, Section 2.10.4.2.

7.8.2 CSP - Clinical Study Phase Segment

The CSP segment contains information on a patient's status for a particular phase of the study. This segment is optional and is useful when a study has different evaluation intervals within it. (See section *7.8.1*, "*HL7 Attribute Table – CSR – Clinical Study Registration*," and section *7.6.1.2*, "*Phase of a clinical trial:*.") The CSP segment is implemented on a study-specific basis for messaging purposes. The fact that the patient has entered a phase of the study that represents a certain treatment approach may need to be messaged to other systems, like pharmacy, nursing, or order entry. It is also important to sponsors and data management centers for tracking patient progress through the study and monitoring the data schedule defined for each phase. It may subsume OBR and OBX segments that follow it to indicate that these data describe the phase.

HL7 Attribute Table – CSP – Clinical Study Phase

SEQ	LEN	C.LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1			CWE	R		0587	01022	Study Phase Identifier
2			DTM	R			01052	Date/time Study Phase Began
3			DTM	O			01053	Date/time Study Phase Ended
4			CWE	C		0588	01054	Study Phase Evaluability

7.8.2.0 CSP field definitions

7.8.2.1 CSP-1 Study Phase Identifier (CWE) 01022

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field identifies the phase of the study that a patient has entered. The set of codes will generally be developed for each clinical trial, although there are patterns that trials in particular disease or prevention categories may follow. The phase structure will be based on data collation and reporting needs for the study. It is an operational structure and need not be discussed in the clinical trial protocol documentation or even made known to patient care or data collection personnel. The coding system will usually be developed by the sponsor for multicentered clinical trials to standardize the receipt of automated data. Local codes could be added if an additional local message is desired. Otherwise, local coding conventions will be used. Refer to Table 0587 - Study Phase Identifier in Chapter 2C for valid values.

Example:

```
2^Init Rx, Crs 1^NCI T93-0807 Phases
```

7.8.2.2 CSP-2 Date/Time Study Phase Began (DTM) 01052

Definition: This field contains the date the patient began this phase interval. The time is optional.

7.8.2.3 CSP-3 Date/Time Study Phase Ended (DTM) 01053

Definition: This field contains the date the patient ended this phase interval.

7.8.2.4 CSP-4 Study Phase Evaluability (CWE) 01054

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field contains the disposition of the patient's data for this phase interval for quality control and data analysis purposes. The set of codes will vary across clinical trials. An example answer set: **Complete, Adverse Events Only, Outcome Only, None, Unknown**. Refer to Table 0588 - Study Phase Evaluability in Chapter 2C for valid values.

7.8.3 CSS - Clinical Study Data Schedule Segment

The Clinical Study Data Schedule (CSS) segment is optional depending on whether messaging of study data needs to be linked to the scheduled data time points for the study. (See Section *7.6.1.3*, "*Data schedule:*".) The CSS segment enables communication of data schedules and adherence that ranges from the basic to the elaborate. Use of the segment must be planned for each implementation. Each CSS segment will subsume observation and drug administration segments that follow, indicating that they satisfy this scheduled time point.

HL7 Attribute Table – CSS – Clinical Study Data Schedule Segment

SEQ	LEN	C.LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1			CWE	R		0595	01055	Study Scheduled Time Point
2			DTM	O			01056	Study Scheduled Patient Time Point
3			CWE	O	Y/3	0596	01057	Study Quality Control Codes

7.8.3.0 CSS field definitions

7.8.3.1 CSS-1 Study Scheduled Time Point (CWE) 01055

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field contains the time point for which some instance of data for the clinical trial was scheduled. The time point may be expressed in any coded format. Some examples of time point values are: **Prestudy, Pretreatment, 4 times/day, Weekly, Every 3 days, Every course, At Relapse, At Off Study.** Alternatively, frequency values from Section 2.A.81.2, "Interval component (RI)," (the Interval component of the TQ Timing/Quantity data type could be used; however, note that as of version 2.5, the TQ data type is retained only for backward compatibility). Time point naming conventions and usage must be specified by implementers. Refer to Table 0595 - Study Scheduled Time Point in Chapter 2C for valid values.

7.8.3.2 CSS-2 Study Scheduled Patient Time Point (DTM) 01056

Definition: This field contains the date/time that the scheduled time point should occur for this patient. The date/time may be used for a reference in reviewing the actual dates on which scheduled items that follow in OBR segments occur for the patient. The time component is optional.

7.8.3.3 CSS-3 Study Quality Control Codes (CWE) 01057

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: In clinical settings, the **actual** date of a treatment or procedure may vary considerably from the **due** date. Various coding systems may be used to evaluate the adherence to the schedule or acceptability of the data. Coding systems will vary among trials. Refer to Table 0596 - Study Quality Control Codes in Chapter 2C for valid values.

7.8.4 CTI - Clinical Trial Identification Segment

The CTI segment is an optional segment that contains information to identify the clinical trial, phase and time point with which an order or result is associated.

HL7 Attribute Table – CTI – Clinical Trial Identification

SEQ	LEN	C.LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1			EI	R			01011	Sponsor Study ID
2			CWE	C		0597	01022	Study Phase Identifier
3			CWE	O		0598	01055	Study Scheduled Time Point
4	2..2		ID	O		0206	00816	Action Code

7.8.4.0 CTI field definitions

7.8.4.1 CTI-1 Sponsor Study ID (EI) 01011

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: This field contains the universal identifier for the clinical trial. The coding system is as described in *CSR-1 Sponsor Study ID*.

7.8.4.2 CTI-2 Study Phase Identifier (CWE) 01022

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field identifies the phase of the study that a patient has entered. See *CSP-1 Study Phase Identifier* for details of coding systems. Refer to Table 0597 - Study Phase Identifier in Chapter 2C for valid values.

7.8.4.3 CTI-3 Study Scheduled Time Point (CWE) 01055

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field identifies a time point in the clinical trial phase. *CTI-2 Study Phase Identifier* must be valued if *CTI-3 Study Scheduled Time Point* is valued. Should correspond to *CSS-1 Study Scheduled Time Point*. Refer to Table 0598 - Study Scheduled Time Point in Chapter 2C for valid values.

7.8.4.4 CTI-4 Action Code (ID) 00816

Definition: This field reveals the intent of the message. Refer to *HL7 Table 0206 - Segment Action Code* for valid values.

The action code can only be used when CTI-1 is valued in accordance with the guidance in Chapter 2, Section 2.10.4.2.

7.8.5 CM0 Clinical Study Master Segment

The clinical study master segment (CMO) is described in Chapter 8 section 8.11.2.

7.8.6 CM1 Clinical Study Phase Master Segment

The clinical study phase master segment (CMI) is described in Chapter 8, section 8.11.3.

7.8.7 CM2 Clinical Study Schedule Master Segment

The clinical study schedule master segment is described in Chapter 8, section 8.11.4.

7.9 CLINICAL TRIALS – EXAMPLES OF USE

7.9.1 CRM - Message When Patient Registered on a Clinical Trial

```
MSH|^~\&|PDMS|MDACC|ORDER ENTRY|MDACC|200006021649||CRM^C01^CRM_C01|...<cr>

PID|1||2222||Everywoman^Eve^E||19530117|...<cr>

CSR|DM94-004^MDACC||MDACC|3||19941013||342^^^^^^^PDMS|
    |||||1005^^^^^^^MDACC|19941013|Y^Meets All Requirements^PDMS|...<cr>
```

7.9.2 CRM - Message When Patient Begins a Phase of a Clinical Trial

```
MSH|^~\&|PDMS|MDACC|PHARM|MDACC|200006050925||CRM^C05^CRM_C05|...<cr>

PID|1||2222||Everywoman^Eve^E||19230213|...<cr>

CSR|ID91-025^MDACC||MDACC|301||19941005||342^^^^^^^PDMS |||19941201|2^blind^PDMS|
        12^Smoker,Stage II,<60^PDMS|...<cr>

CSP|2^Treatment^PDMS|19941201|...<cr>
```

7.9.3 CSU - Message Reporting Monthly Patient Data Updates to the Sponsor

```
MSH|^~\&|PDMS|MDACC|CTMS|NCI|200006050927||CSU^C09^CRM_C09|...<cr>

PID|1||235925||J^F^M||19350616|...<cr>
             [note:anonymous]

CSR|T93-080^NCI|ID93-030^^MDACC|MDACC|14||19941205|...<cr>

CSS|^Prestudy|19941204|C^compliant^NCI<cr>

OBR|1|1234|1234|3^EligibilChecklist^StudyFormsList|||19941205|...<cr>
```

Note: The clinical trials section probably needs its own definition of OBR. OBR-2&3 have condition rules indicating that the placer and filler numbers must be present in either the ORC or the OBR. Since an ORC is not present, then these fields must be populated in the OBR. My guess is that clinical trials aren't interested in the placer and filler number.

```
OBX|1|CWE|ELIG1^Elig Crit 1^NCI|Text Elig Crit 1|Y|...<cr>

OBX|2|CWE|ELIG2^Elig Crit 2^NCI||Y|...<cr>

OBR|2|1235|1235|4^Prestudy Form^StudyFormsList|||19941205|...<cr>

OBX|1|CWE|QOL^Quality of Life^NCI||2\T\3\T\2\T\4\T\2^SPITZER|...<cr>

OBX|2|CWE|PRICHEM^Prior Chemo^NCI||Yes|...<cr>

OBX|3|CWE|PRIBIOL^Prior Biologics^NCI||No|...<cr>

OBX|4|NM|NUMREM^Number Prior Remissions^NCI||2|...<cr>

OBR|3|932^OE|243789^LAB|88304^SURG PATH REPORT|||19940101|...<cr>

OBX|1|CWE|88304&ANT|1|9999^PANCREAS^SNM|...<cr>

OBX|2|CWE|88304&IMP|2|9999^ADENOCARCINOMA^SNM|...<cr>

OBR|4|933^OE|243790^LAB|85022^CBC|||199412050800|...<cr>

OBX|1|NM|718-7^HEMOGLOBIN:^LN||13.4|GM/DL|14-18|N||S|F|19860522|...<cr>
```

[cbc values]

```
OBX|2|NM|4544-3^HEMATOCRIT:^LN||40.3|%|42-52|L||S|F|19860522|...<cr>

OBX|3|NM|789-8^ERYTHROCYTES:^LN||4.56|10*6/ml|4.7-6.1|L||S|F|19860522|...<cr>

OBX|4|NM|787-22^ERYTHROCYTE MEAN CORPUSCULAR VOLUME:^LN||88|fl   |80-
    94|N||S|F|19860522|...<cr>

OBX|5|NM|785-6^ERYTHROCYTE MEAN CORPUSCULAR HEMOGLOBIN:^LN||29.5|pg   |27-
    31|N||N|F|19860522|...<cr>

OBX|6|NM|786-4^ERYTHROCYTE MEAN CORPUSCULAR HEMOGLOBIN
    CONCENTRATION:^LN||33|%|33-37|N||N|F|19860522|...<cr>

OBX|7|NM|6690-2^LEUKOCYTES:^LN||10.7|10*3/ml|4.8-10.8|N||N|F|19860522|...<cr>

OBX|8|NM|764-1^NEUTROPHILS BAND FORM/100 LEUKOCYTES:^LN||2|%||||F|...<cr>

OBX|9|NM|769-0^NEUTROPHILS SEGMENTED/100 LEUKOCYTES:^LN||67|%||||F |...<cr>

OBX|10|NM|736-9^LYMPHOCYTES/100 LEUKOCYTES:^LN||29|%||||F|...<cr>

OBX|11|NM|5905-5^MONOCYTES/100 LEUKOCYTES:^LN||1|%||||F|...<cr>

OBX|12|NM|713-8^EOSINOPHILS/100 LEUKOCYTES:^LN||2|%||||F|...<cr>

OBR|5|934^OE|243791^LAB|80004^ELECTROLYTES|||199412050800|...<cr>

OBX|1|NM|2947-0^SODIUM:^LN||150|mmol/l|136-148|H||A|F|19850301 |...<cr>

OBX|2|NM|2823-3^POTASSIUM:^LN||4.5|mmol/l|3.5-5|N||N|F|19850301|...<cr>
```

[electrolytes values]

```
OBX|3|NM|2069-3^CHLORIDE:^LN||102|mmol/l|94-105|N||N|F|19850301|...<cr>

OBX|4|NM|2028-9^CARBON DIOXIDE.TOTAL:^LN||27|mmol/l|24-31|N||N|F
    |19850301|...<cr>

CSP|^Course 1|19941205|19950120|Y^Toxicity and Response^NCI |...<cr>

CSS|^Course Completion|19950120|...<cr>

OBR|1|935^OE|243791^LAB|2039-6^CARCINOEMBRYONIC AG:^LN|||19941008|...<cr>

OBX|1|NM|2039-6^CARCINOEMBRYONIC AG:^LN||15.2|IU |...<cr>

OBR|2|1236|1236|10^Course Completion Form^StudyPhaseFormsList|||19950120 |...<cr>

OBX|1|CWE|CRSRESP^Course Response^NCI||4^Partial Response|...<cr>

OBX|2|NM|DRUGDISP^Capsules Dispensed^NCI||60|...<cr>

OBX|3|NM|DRUGRETN^Capsules Returned^NCI||5|...<cr>

OBX|4|ID|DXCOMP^Diagnostic Tests Compliance^NCI||Y|...<cr>

OBX|5|CWE|PERSTAT^Performance Status^NCI||3^ZUBRODS|...<cr>

OBR|3|1237|1237|9999^Adverse Events|...<cr>

OBX|1|CWE|9999&EVENT|1|45^Vomiting^NCI|...<cr>

OBX|2|DT|9999&ONSET|1|19941215|...<cr>

OBX|3|DT|9999&RESOLUTION|1|19941217|...<cr>

OBX|4|CWE|9999&GRADE|1|M^MODERATE|...<cr>

OBX|5|CWE|9999&RELATION_TO_RX|1|L^LIKELY|...<cr>

OBX|6|CWE|9999&EVENT|2|303^Dyspnea^NCI|...<cr>

OBX|7|DT|9999&ONSET|2|19941231|...<cr>

OBX|8|DT|9999&RESOLUTION|2|...<cr>

OBX|9|CWE|9999&GRADE|2|MI^MILD|...<cr>

OBX|10|CWE|9999&RELATION_TO_RX|2|U^UNLIKELY|...<cr>
```

[Note: Needs to maintain compatibility with ongoing product experience message efforts.]

[Note2: There are other possible OBX suffixes defined by FDA: APEX/ NADIR, ACTION, THERAPY, OUTCOME, RECHALLENGE.]

7.10 PRODUCT EXPERIENCE

Patients experience symptoms, manifest signs or develop diseases or syndromes while exposed to medical devices and/or drugs. Evidence suggests that some of these symptoms, signs, diseases or syndromes may develop as a consequence of the products used. Examples include the development of clear cell adenocarcinoma of the vagina in the daughters of mothers treated with diethylstilbestrol during pregnancy and gastrointestinal bleeding in patients treated with non-steroidal anti-inflammatory drugs. While it is difficult to prove causality, strong evidence exists in many cases.

It is important to document such experiences during the development and testing of products to identify potential adverse effects but also during routine use of the product to identify serious adverse effects which occur infrequently. The latter is the realm of pharmacoepidemiology and post-marketing surveillance.

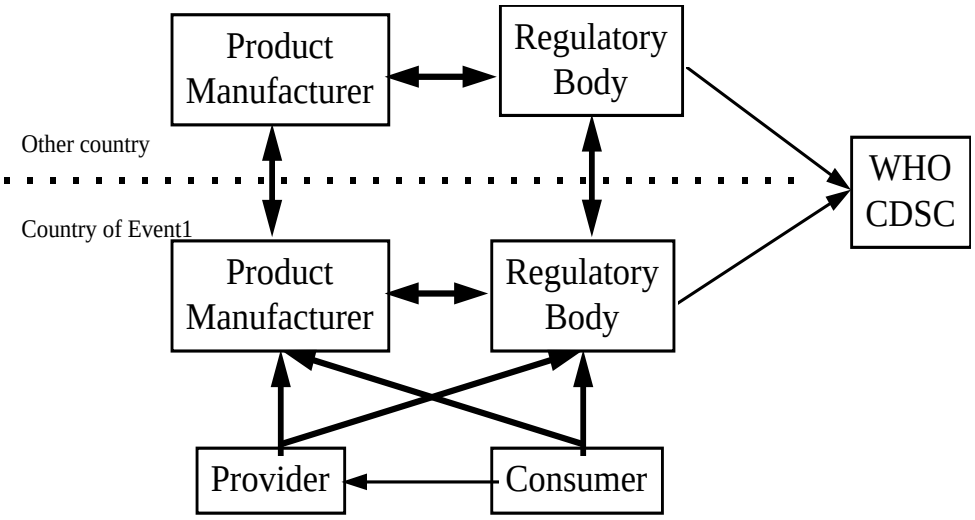
Adverse events are important for product manufacturers as signal generating hypotheses concerning drug kinetics or dynamics, often in special populations of patients. Adverse events are important for regulators in ensuring that manufacturers protect the public health in assessments of risk and benefits, including special populations, and that they promptly and thoroughly investigate individual events and clusters of events. Adverse events are especially important for practitioners and patients who always deal with a special population of one individual who may be having an event and a practitioner seeking information about related events seen with the same or similar products.

Reporting has usually focused on *serious* and *unexpected* events. Serious, if defined unambiguously, focuses attention on those events of most importance to the patient and practitioner. Expected events are those which prior experience has demonstrated to be probabilistically linked to the product and are generally included in product labeling.

Because of the risks associated with the uses of drugs and medical devices, a system of surveillance has been established in most developed countries. With globalization of the marketplace, the need to share this information across national boundaries has increased. Currently most reporting is performed using a series of forms, including CIOMS, yellow cards, the FDA's 1639 and MedWatch forms and the Japanese form, which are sent:

- from identified reporting sources to regulatory bodies
- from identified reporting sources to product manufacturers
- between regulatory bodies
- within product manufacturers
- within regulatory bodies
- from product manufacturers to regulatory bodies
- from regulatory bodies to the WHO Collaborative Drug Surveillance Center

Figure 7-6. - Flow of product experience information



Regardless of who originates a drug experience report, documentation of the experience eventually reaches the regulatory agencies. The manufacturer is mandated to alert the regulatory agency.

Electronic interchange of these data would reduce errors, decrease costs and speed communications.

7.10.1 Glossary

7.10.1.0 hiddentext

7.10.1.1 Drug:

Any chemical compound that may be used on or administered to humans or animals as an aid in the diagnosis, treatment or prevention of disease or other abnormal condition, for the relief of pain or suffering, or to control or improve any physiological condition (Dorland's Illustrated Medical Dictionary 27th edition).

7.10.1.2 Medical device:

Something contrived for or used in the diagnosis (vascular catheters), treatment (thermotherapy units) or prevention of disease or other abnormal condition, for the relief of pain or suffering or to control or improve any physiologic condition, including instrumentation and implanted devices (prosthetic cardiac valves, pacemakers, hip prostheses).

7.10.1.3 Product:

A drug or medical device.

7.10.1.4 Non-proprietary (generic) name:

Drug name that is not protected by a trademark, usually descriptive of its chemical structure; sometimes called a public name. In the US, most generic drug names are assigned by the US Adopted Name Council (USAN). Other generic names in common use are the National Formulary (NF) and the US Pharmacopoeia (USP) names. Figure 7-3 lists other available drug coding systems.

7.10.1.5 Trade (brand) name:

Proprietary names that are registered to protect the name for the sole use of the manufacturer holding the trademark.

7.10.1.6 Adverse event/adverse experience:

- Pre-marketing: Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment.

- Post-marketing/European Union: Any undesirable experience occurring to a patient treated with a pharmaceutical product whether or not considered related to the medicinal product.
- Post-marketing/US: Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: An adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose; an adverse event occurring from drug withdrawal; and any failure of expected pharmacologic action.
- WHO: Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this product.

7.10.1.7 Adverse drug reaction:

- Pre-marketing: All noxious and unintended responses to a medicinal product related to any dose.
- Post-marketing/WHO: A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function
- Post-marketing/European Union: A reaction which is harmful and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis, or treatment of disease or the modification of physiological function.
- Post-marketing/US: Any undesirable effect reasonably associated with the use of the drug that may occur as part of the pharmacological action of the drug or may be unpredictable.

7.10.1.8 Causation:

An exposure which truly does increase or decrease the probability of a certain outcome.

7.10.1.9 Causal relationship:

When an event occurs a product may be suspected as causing the event but rarely can it be proven particularly at an early stage of the product's life. Certain information about the relationship between the product and the event can reinforce the belief in a causal relationship between the product and the event while others can decrease the probability that there is a causal relationship.

7.10.1.10 Regulatory agency:

Many geopolitical entities have established agencies/authority responsible for regulating products used in health care. The agencies are collectively referred to as regulatory agencies.

7.10.1.11 Product manufacturer:

The organization which is responsible for the manufacture of a product. This will usually be the entity, which holds the marketing authorization for the product.

7.10.1.12 Holder of marketing authorization:

The organization which holds the authority to market a product. This will often be the organization, which manufactures the product.

7.10.1.13 Serious adverse product reaction:

An adverse product reaction which:

- is fatal (results in death)
- is life threatening
- requires hospitalization or prolongation of a hospitalization
- results in persistent or significant disability/incapacity
- results in a congenital anomaly/birth defect.

Medical and scientific judgment should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life threatening or result

in hospitalization but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These should also be considered serious.

7.10.1.14 Expected adverse product reaction:

Expected events are those which prior experience has demonstrated to be probabilistically linked to the product and are generally included in product labeling.

Pre-marketing: An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product).

Post-marketing/European Union: This relates to an adverse reaction which is not mentioned in any EC summary of product characteristics (SPC). In the absence of any European SPC, an international document prepared by the marketing authorization holder containing all relevant safety information which the marketing authorization holder considers should be listed for the medicinal product in all countries where the medicinal product is marketed (Care Data Sheet).

Post-marketing/US current: Unexpected means an adverse drug experience that is not listed in the current labeling for the drug product and includes an event that may be symptomatically and pathophysiologically related to an event listed in the labeling but differs from the event because of greater severity or specificity.

Post-marketing/US (proposed): The applicant's core safety data sheet shall be a document prepared by the applicant that contains all relevant safety information, including adverse drug experiences, which the applicant believes should e listed for the drug in all countries where the drug is marketed. It may be used by the applicant as the reference document by which an adverse drug experience is judged to be expected or unexpected for purposes of this post-marketing periodic report.

Post-marketing/WHO: An adverse reaction, the nature or severity of which is not consistent with domestic labeling or market authorization, or expected from characteristics of the drug.

7.10.2 References

Gabrielli ER. Standard specification for drug therapy documentation. ASTM Committee E31.12 July (1993).

Kessler DA. Introducing MEDWatch. JAMA 269: 2765-2768(1993).

Kurata JH, Overhage JM, Gabrielli E, Jones JK. International Data Standards for Hospital-based Drug Surveillance. M.D. Computing 12(1) 50-57 (1995).

Moore N, Montera d, Coulson R, DeAbajo F, Kreft-Jais C, Biron A, Monteaugudo J. The single case format: proposal for a structured message for the telematic transmission of information on individual case reports in pharmacovigilance. Pharmacoepidemiology and Drug Safety 3: 157-162 (1994)

Thompson WL. A modest proposal for enhancing the safety and effectiveness of use of human drugs, biologics and devices and animal health products with human health implications through cost-effective health informatics tools supporting a global database of safety reports as a joint ICH E2, M1 and M2 initiative. Private communication. March (1995)

7.11 PRODUCT EXPERIENCE - TRIGGER EVENTS AND MESSAGE DEFINITIONS

The message header segment will care one of three event types at *MSH-9-message type*.

Event	Description
P07	PEX - Unsolicited initial individual product experience report
P08	PEX - Unsolicited update individual product experience report
P09	SUR - Summary product experience report

7.11.1 PEX - Product Experience Message (Events P07, P08)

The primary application of this message is to transfer information related to an adverse event occurring while a patient was exposed to a product.

PEX^P07-P08^PEX_P07: Product Experience Message

Segments	Description	Status	Chapter
MSH	Message Header		2
[{ARV}]	Access Restrictions		3
[{SFT}]	Software Segment		2
[UAC]	User Authentication Credential		2
EVN	Event Type		3
PID	Patient Identification		3
[PD1]	Additional Demographics		3
[{PRT}]	Participation (for Patient)		7
[{ARV}]	For backwards compatibility only as of V2.9.	B	3
[{NTE}]	Notes and comments		2
[	--- VISIT begin		
PV1	Patient Visit		3
[PV2]	Patient Visit - Additional Info		3
[{PRT}]	Participation (for Patient Visit)		7
]	--- VISIT end		
{	--- EXPERIENCE begin		
PES	Product Experience Sender		7
{	--- PEX_OBSERVATION begin		
PEO	Product Experience Observation		7
{	--- PEX_CAUSE begin		
PCR	Potential Causal Relationship		7
[	--- RX_ORDER begin		
RXE	Pharmacy/Treatment Encoded Order		4A
[{PRT}]	Participation (for Pharmacy/Treatment)		7
{	--- TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}	--- TIMING_QTY end		
[{RXR}]	Pharmacy/Treatment Route		4A

Segments	Description	Status	Chapter
]	--- RX_ORDER end		
[{	--- RX_ADMINISTRATION begin		
RXA	Pharmacy/Treatment Administration		4A
[RXR]	Pharmacy/Treatment Route		4A
[{PRT}]	Participation (for Pharmacy Administration)		7
}]	--- RX_ADMINISTRATION end		
[{PRB}]	Detail problem segment		12
[{	--- OBSERVATION begin		
OBX	Observation/Result Segment		7
[{PRT}]	Participation (for Observation Result)		7
}]	--- OBSERVATION end		
[{NTE}]	Notes and comments		2
[	--- ASSOCIATED_PERSON begin		
NK1	Associated parties segment		2
[	--- ASSOCIATED_RX_ORDER begin		
RXE	Pharmacy/Treatment Encoded Order		4A
[{PRT}]	Participation (for Pharmacy/Treatment)		7
{	--- NK1_TIMING_QTY begin		
TQ1	Timing/Quantity		4
[{TQ2}]	Timing/Quantity Order Sequence		4
}	--- NK1_TIMING_QTY end		
[{RXR}]	Pharmacy/Treatment Route		4
]	--- ASSOCIATED_RX_ORDER end		
[{	--- ASSOCIATED_RX_ADMIN begin		
RXA	Pharmacy/Treatment Administration		4A
[RXR]	Pharmacy/Treatment Route		4A
[{PRT}]	Participation (for Pharmacy Administration)		7
}]	--- ASSOCIATED_RX_ADMIN end		
[{PRB}]	Detail Problem Segment		12
[{	--- ASSOCIATED_OBSERVATION begin		
OBX	Observation/Results Segment		7
[{PRT}]	Participation (for Observation Result)		7

Segments	Description	Status	Chapter
}]	--- ASSOCIATED_OBSERVATION end		
]	--- ASSOCIATED_PERSON end		
[{	--- STUDY begin		
CSR	Clinical study registration		7
[{CSP}]	Clinical study phase segment		7
}]	--- STUDY end		
}	--- PEX_CAUSE end		
}	--- PEX_OBSERVATION end		
}	--- EXPERIENCE end		

The PID segment provides the patient identification information including institutional identification numbers, date of birth and in the case of patients who die, information about their death. Patients are frequently identified only by their initials which can be represented in the PID segment, e.g., the initials JMO would appear as J^M^O in the name field of the PID segment. The EVN segment identifies the type of transaction that is being sent -- primarily it specifies who the sender is and implies which information is expected to be included in the message. A message sent from a healthcare provider, for example, might contain minimal information, while a message from a pharmaceutical manufacturer might contain nearly complete information.

The PES or Product Experience Sender segment provides information about the message sender and its knowledge of the event. The heart of the product experience message is the product experience observation (PEO) segment and the PCR segments clustered under it. The PEO segment identifies a clinical event and the PCR segments identify products which are potentially causally related to the event. There may be more than one product which is potentially related to the event so multiple PCR segments can be included. RXE and RXR segments can be repeated and provide information about the products the patient was exposed to at the time of the event (typically excluding those used to treat the event). Details about the administration of the products identified in the PCR segments should be described with RXE and RXR segments. Repeated PRB segments provide information about diagnoses which represent comorbid conditions. The repeated OBX segments are used to send patient observations such as height, weight, last menstrual period, and laboratory results. Analytical commentary can be included in the NTE segment. This commentary will typically be the sender's analysis of the event and the potentially causally related products. Finally, the CSR and CSP segments can optionally be included if the event occurred during a formal clinical trial in order to describe the trial.

When a product experience relates to an exposure which occurred indirectly (transmammary or transplacentally for example), the individual experiencing the adverse effect — the fetus or child — would be described in the PID segment and the individual via which they are exposed in the NK1 segment. The first set of RXE segments would typically indicate the drugs which to which the fetus or child was exposed. Additional codes for the route are defined in this Appendix to allow the suspected routes of exposure to be represented. The second set of RXE/RXR segment - those clustered under the NK1 segment - would represent the route by which the mother or father was exposed to the drug. Early spontaneous abortion would normally be treated as an adverse effect on the mother rather than on the fetus, and the PID would refer to the mother. The second set of PRB/OBX segments reflects the problems/observations associated with the individual via which they were exposed.

Each message contains information about a single case including one patient (PID), at least one sender (PES), one or more events (PEO) and one or more suspected products (PCR and RXE/RXA) for a minimal message. The structure of the message allows actual administration information to be sent in the RXA if known; if administration information is unavailable, or the adverse reaction cannot be related to a single administration event, the RXE segment can be used to send prescription level information. Additional information may be included based on availability and regulatory requirements.

The MSH segment specifies the character set (*MSH-18*) and the language (*MSH-19*) used in the PEX message.

The PEX message is designed to accommodate required reporting of adverse product events to the responsible regulatory agencies. In the United States, the paper version of this report is Medwatch.

Acknowledgement Choreography				
PEX^P07^PEX_P07				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^P07^ACK
Application Ack	ACK^P07^ACK	-	ACK^P07^ACK	ACK^P07^ACK

Acknowledgement Choreography				
PEX^P08^PEX_P07				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^P08^ACK
Application Ack	ACK^P08^ACK	-	ACK^P08^ACK	ACK^P08^ACK

7.11.2 SUR - Summary Product Experience Report (Event P09)

Retained for backwards compatibility only as of v 2.5 and withdrawn as of v 2.7.

7.12 PRODUCT EXPERIENCE – SEGMENT DEFINITIONS

7.12.1 PES - Product Experience Sender Segment

HL7 Attribute Table - PES – Product Experience Sender

SEQ	LEN	C.LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
1			XON	O	Y		01059	Sender Organization Name
2			XCN	O	Y		01060	Sender Individual Name
3			XAD	O	Y		01062	Sender Address
4			XTN	O	Y		01063	Sender Telephone
5			EI	O			01064	Sender Event Identifier
6		16=	NM	O			01065	Sender Sequence Number
7		600=	FT	O	Y		01066	Sender Event Description
8		600=	FT	O			01067	Sender Comment

SEQ	LEN	C.LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
9			DTM	O			01068	Sender Aware Date/Time
10			DTM	R			01069	Event Report Date
11	2..3		ID	O	Y/2	0234	01070	Event Report Timing/Type
12	1..1		ID	O		0235	01071	Event Report Source
13	1..1		ID	O	Y	0236	01072	Event Reported To

7.12.1.0 PES - field definitions

7.12.1.1 PES-1 Sender Organization Name (XON) 01059

Components: <Organization Name (ST)> ^ <Organization Name Type Code (CWE)> ^ <WITHDRAWN Constituent> ^ <WITHDRAWN Constituent> ^ <WITHDRAWN Constituent> ^ <Assigning Authority (HD)> ^ <Identifier Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name Representation Code (ID)> ^ <Organization Identifier (ST)>

Subcomponents for Organization Name Type Code (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Authority (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Definition: This field contains the name of the organization sending the message. Coded lists of manufacturers such as that from the World Health Organization database might be used in the component of the coded name to identify the source code type. If sent from an individual, this field may not be sent.

7.12.1.2 PES-2 Sender Individual Name (XCN) 01060

Components: <Person Identifier (ST)> ^ <Family Name (FN)> ^ <Given Name (ST)> ^ <Second and Further Given Names or Initials Thereof (ST)> ^ <Suffix (e.g., JR or III) (ST)> ^ <Prefix (e.g., DR) (ST)> ^ <WITHDRAWN Constituent> ^ <DEPRECATED-Source Table (CWE)> ^ <Assigning Authority (HD)> ^ <Name Type Code (ID)> ^ <Identifier Check Digit (ST)> ^ <Check Digit Scheme (ID)> ^ <Identifier Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name Representation Code (ID)> ^ <Name Context (CWE)> ^ <WITHDRAWN Constituent> ^ <Name Assembly Order (ID)> ^ <Effective Date (DTM)> ^ <Expiration Date (DTM)> ^ <Professional Suffix (ST)> ^ <Assigning Jurisdiction (CWE)> ^ <Assigning Agency or Department (CWE)> ^ <Security Check (ST)> ^ <Security Check Scheme (ID)>

Subcomponents for Family Name (FN): <Surname (ST)> & <Own Surname Prefix (ST)> & <Own Surname (ST)> & <Surname Prefix from Partner/Spouse (ST)> & <Surname from Partner/Spouse (ST)>

Subcomponents for Source Table (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Authority (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Name Context (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Jurisdiction (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Agency or Department (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Definition: This field contains the name of the contact individual. If sent by an organization, the individuals in the organization who serve as primary contact points correspondence regarding this event.

7.12.1.3 PES-3 Sender Address (XAD) 01062

Components: <Street Address (SAD)> ^ <Other Designation (ST)> ^ <City (ST)> ^ <State or Province (ST)> ^ <Zip or Postal Code (ST)> ^ <Country (ID)> ^ <Address Type (ID)> ^ <Other Geographic Designation (ST)> ^ <County/Parish Code (CWE)> ^ <Census Tract (CWE)> ^ <Address Representation Code (ID)> ^ <WITHDRAWN Constituent> ^ <Effective Date (DTM)> ^ <Expiration Date (DTM)> ^ <Expiration Reason (CWE)> ^ <Temporary Indicator (ID)> ^ <Bad Address Indicator (ID)> ^ <Address Usage (ID)> ^ <Addressee (ST)> ^ <Comment (ST)> ^ <Preference Order (NM)> ^ <Protection Code (CWE)> ^ <Address Identifier (EI)>

Subcomponents for Street Address (SAD): <Street or Mailing Address (ST)> & <Street Name (ST)> & <Dwelling Number (ST)>

Subcomponents for County/Parish Code (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Census Tract (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Expiration Reason (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Protection Code (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Address Identifier (EI): <Entity Identifier (ST)> & <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Definition: This field contains the postal address of the message sender to which correspondence regarding the experience being reported should be directed.

7.12.1.4 PES-4 Sender Telephone (XTN) 01063

Components: <WITHDRAWN Constituent> ^ <Telecommunication Use Code (ID)> ^ <Telecommunication Equipment Type (ID)> ^ <Communication Address (ST)> ^ <Country Code (SNM)> ^ <Area/City Code (SNM)> ^ <Local Number (SNM)> ^ <Extension (SNM)> ^ <Any Text (ST)> ^ <Extension Prefix (ST)> ^ <Speed Dial Code (ST)> ^ <Unformatted Telephone number (ST)> ^ <Effective Start Date (DTM)> ^ <Expiration Date (DTM)> ^ <Expiration Reason (CWE)> ^ <Protection Code (CWE)> ^ <Shared Telecommunication Identifier (EI)> ^ <Preference Order (NM)>

Subcomponents for Expiration Reason (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

```
Subcomponents for Protection Code (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of
          Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
          & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
          & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
          <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
          of Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Shared Telecommunication Identifier (EI):  <Entity Identifier (ST)>
          & <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>
```

Definition: This field contains the telephone number of the message sender to which telephone communications regarding the experience being reported should be directed. An electronic mail address can be specified in this field.

7.12.1.5 PES-5 Sender Event Identifier (EI) 01064

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
          <Universal ID Type (ID)>
```

Definition: The first component of this field contains the product manufacturer's unique alphanumeric identifier for this specific event. This identifier will be used on all subsequent communications regarding this event. For events reported to the FDA, the identifier is: the FDA assigned manufacturer or distributor number; a hyphen; the 4-digit year; a hyphen; and a consecutive 5-digit sequence number for each report filled by the sender that year. For example, the event identifier for the third event reported in 1996 by a manufacturer whose FDA-assigned registration number is 1234567 would be 1234567-1993-3. Organizations without a FDA-assigned registration number should use 0000000 until assigned a number. Reports from other facilities should use the 10-digit HCFA number left padded with zeros in place of the FDA-assigned registration number. The second through fourth components are defined in exactly the same way as the three components of the hierarchic designator (HD) data type (Section 2.8.18, "HD - hierarchic designator").

7.12.1.6 PES-6 Sender Sequence Number (NM) 01065

Definition: This field contains sequentially assigned integer values which distinguish messages which share the same sender event identification element. 0 for initial report, 1 for second, and so on.

7.12.1.7 PES-7 Sender Event Description (FT) 01066

Definition: This field contains the summary narrative text description of the event that occurred written by the sender, which may include a description of the nature of the event, how the product was involved, any environmental conditions that may have influenced the event, and patient follow-up or required treatment. Note that laboratory results can be encoded as OBX segments rather then including them in the narrative. By representing clinical information in OBX segments rather than in the narrative, these data become much more useful and flexible.

7.12.1.8 PES-8 Sender Comment (FT) 01067

Definition: This field contains the text commentary regarding the report being made, such as disclaimers, which is not necessarily part of the report.

7.12.1.9 PES-9 Sender Aware Date/Time (DTM) 01068

Definition: This field identifies the date the sender became aware of the event.

7.12.1.10 PES-10 Event Report Date (DTM) 01069

Definition: This field contains the date the message was originally sent to the regulatory agency.

7.12.1.11 PES-11 Event Report Timing/Type (ID) 01070

Definition: This field contains the timing type of report as required by regulatory agency. Refer to *HL7 Table 0234 - Report Timing* for valid values.

7.12.1.12 PES-12 Event Report Source (ID) 01071

Definition: This field identifies the source from which the sender learned about the event. Multiple sources may be reported by repeating the element.

If the source of the report is a clinical trial, the CSR and CSP segments can be included to define the study. Refer to *HL7 Table 0235 - Report Source* for valid values.

7.12.1.13 PES-13 Event Reported To (ID) 01072

Definition: This field indicates all the entities to whom the entity submitting the report has reported the event. Repeat the element if the report was submitted to more than one entity. Refer to *HL7 Table 0236 - Event reported to* for valid values.

7.12.2 PEO - Product Experience Observation Segment

Details related to a particular clinical experience or event are embodied in the PEO segment. This segment can be used to characterize an event which might be attributed to a product to which the patient was exposed. Products with a possible causal relationship to the observed experience are described in the following PCR (possible causal relationship) segments. The message format was designed to be robust and includes many optional elements which may not be required for a particular regulatory purpose but allow a complete representation of the drug experience if needed.

A PEX message can contain multiple PEO segments if the patient experienced more than one event but must contain at least one PEO segment.

HL7 Attribute Table – PEO – Product Experience Observation

SEQ	LEN	C.LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
1			CWE	O	Y	0678	01073	Event Identifiers Used
2			CWE	O	Y	0679	01074	Event Symptom/Diagnosis Code
3			DTM	R			01075	Event Onset Date/Time
4			DTM	O			01076	Event Exacerbation Date/Time
5			DTM	O			01077	Event Improved Date/Time
6			DTM	O			01078	Event Ended Data/Time
7			XAD	O	Y		01079	Event Location Occurred Address
8	1..1		ID	O	Y	0237	01080	Event Qualification
9	1..1		ID	O		0238	01081	Event Serious
10	1..1		ID	O		0239	01082	Event Expected
11	1..1		ID	O	Y	0240	01083	Event Outcome
12	1..1		ID	O		0241	01084	Patient Outcome
13		600=	FT	O	Y		01085	Event Description from Others
14		600=	FT	O	Y		01086	Event Description from Original Reporter
15		600=	FT	O	Y		01087	Event Description from Patient
16		600=	FT	O	Y		01088	Event Description from Practitioner
17		600=	FT	O	Y		01089	Event Description from Autopsy
18			CWE	O	Y	0680	01090	Cause Of Death
19			XPN	O	Y		01091	Primary Observer Name
20			XAD	O	Y		01092	Primary Observer Address
21			XTN	O	Y		01093	Primary Observer Telephone
22	1..1		ID	O		0242	01094	Primary Observer's Qualification

SEQ	LEN	C.LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
23	1..1		ID	O		0242	01095	Confirmation Provided By
24			DTM	O			01096	Primary Observer Aware Date/Time
25	1..2		ID	O		0243	01097	Primary Observer's identity May Be Divulged

7.12.2.0 PEO field definitions

7.12.2.1 PEO-1 Event Identifiers Used (CWE) 01073

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field may be used to transmit the event identifier used by other entities for this event. The entry would typically contain a unique alphanumeric identifier assigned by an entity with the text component null or repeating the unique alphanumeric identifier followed by the organization's identifier. An event identifier might be GB1234^GB1234^PharmaGiant for example. Refer to Table 0678 - Event Identifiers Used in Chapter 2C for valid values.

7.12.2.2 PEO-2 Event Symptom/Diagnosis Code (CWE) 01074

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field is the coded diagnosis or problem description which best describes the event. A text representation of the coded item should routinely be included. MEDDRA and WHO-ART are examples of appropriate coding schemes, as are the patient and device codes included in the FDA Center for Devices and Radiologic Health's coding manual for Form 3500A. Refer to Table 0679 - Event Symptom/Diagnosis Code in Chapter 2C for valid values.

7.12.2.3 PEO-3 Event Onset Date/Time (DTM) 01075

Definition: This field contains a report or best estimate of the date/time of onset of the event. The date/time can be recorded to any level of precision it is known (hour, day, month, year).

7.12.2.4 PEO-4 Event Exacerbation Date/Time (DTM) 01076

Definition: This field identifies the best estimate of the date/time the event was exacerbated.

7.12.2.5 PEO-5 Event Improved Date/Time (DTM) 01077

Definition: This field identifies the best estimate of the date/time the event improved.

7.12.2.6 PEO-6 Event Ended Data/Time (DTM) 01078

Definition: This field identifies the best estimate of the date/time the event resolved.

7.12.2.7 PEO-7 Event Location Occurred Address (XAD) 01079

Components: <Street Address (SAD)> ^ <Other Designation (ST)> ^ <City (ST)> ^ <State or Province (ST)> ^ <Zip or Postal Code (ST)> ^ <Country (ID)> ^ <Address Type (ID)> ^ <Other Geographic Designation (ST)> ^ <County/Parish Code (CWE)> ^ <Census Tract (CWE)> ^ <Address Representation Code (ID)> ^ <WITHDRAWN Constituent> ^ <Effective Date (DTM)> ^ <Expiration Date (DTM)> ^ <Expiration Reason (CWE)> ^ <Temporary Indicator (ID)> ^ <Bad Address Indicator (ID)> ^ <Address Usage (ID)> ^ <Addressee (ST)> ^ <Comment (ST)> ^ <Preference Order (NM)> ^ <Protection Code (CWE)> ^ <Address Identifier (EI)>

Subcomponents for Street Address (SAD): <Street or Mailing Address (ST)> & <Street Name (ST)> & <Dwelling Number (ST)>

Subcomponents for County/Parish Code (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Census Tract (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Expiration Reason (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Protection Code (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Address Identifier (EI): <Entity Identifier (ST)> & <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Definition: This field identifies the location at which the event started. Often this will specify only the country in which the event started.

7.12.2.8 PEO-8 Event Qualification (ID) 01080

Definition: This field is contains a classification of the type of product experience this event is considered to represent. Refer to *HL7 Table 0237 - Event Qualification* for valid values.

Unexpected beneficial effects would not often be reported but are required by certain countries.

7.12.2.9 PEO-9 Event Serious (ID) 01081

Definition: This field indicates whether the event was judged as serious. If the event did not meet the criteria for seriousness but the sender judges the event significant on other grounds, the event can be identified as significant [*but not serious*]. Refer to *HL7 Table 0238 - Event Seriousness* for valid values.

7.12.2.10 PEO-10 Event Expected (ID) 01082

Definition: This field indicates whether the observed event was expected or unexpected as judged. Refer to *HL7 Table 0239 - Event Expected* for valid values.

7.12.2.11 PEO-11 Event Outcome (ID) 01083

Definition: This field identifies the consequence of the event on the patient. If the consequence of the event is not understood or not available, the patient outcome element may be used although neither is required. May be repeated if more than one is appropriate. Refer to *HL7 Table 0240 - Event Consequence* for valid values.

7.12.2.12 PEO-12 Patient Outcome (ID) 01084

When an event specific outcome is not available, the patient outcome element may be used to represent the patient's overall outcome if that information is known. Refer to *HL7 Table 0241 - Patient Outcome* for valid values.

7.12.2.13 PEO-13 Event Description from Others (FT) 01085

Definition: This field contains a summary narrative text description of the event that occurred written by the sender. Note that laboratory results can be encoded as OBX segments rather then including them in the narrative. By representing clinical information in OBX segments rather than in the narrative, these data become much more useful and flexible.

7.12.2.14 PEO-14 Event Description from Original Reporter (FT) 01086

Definition: This field contains a summary narrative text description of the event provided by the original reporter. Note that laboratory results can be encoded as OBX segments rather then including them in the narrative.

7.12.2.15 PEO-15 Event Description from Patient (FT) 01087

Definition: This field contains a summary narrative text description of the event obtained directly from the patient. Note that laboratory results can be encoded as OBX segments rather then including them in the narrative, which will allow the data to be more readily represented and manipulated.

7.12.2.16 PEO-16 Event Description from Practitioner (FT) 01088

Definition: This field contains a summary narrative text description of the event provided by the practitioner most familiar with the event. Note that laboratory results can be encoded as OBX segments rather then including them in the narrative.

7.12.2.17 PEO-17 Event Description from Autopsy (FT) 01089

Definition: This field contains a summary narrative text description of the autopsy results. Note that laboratory results can be encoded as OBX segments rather then including them in the narrative.

7.12.2.18 PEO-18 Cause of Death (CWE) 01090

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field identifies the coded cause of death. May be repeated as necessary to list multiple contributing causes. A text description can be included by including text but no code or coding system. For example, if the cause of death is to be determined at autopsy but results are not yet available, the cause of death element could be ^Pending autopsy^. The date/time of death can be sent in the PID and the autopsy results sent in the event description from autopsy element of the PEO segment. Refer to Table 0680 - Cause Of Death in Chapter 2C for valid values.

7.12.2.19 PEO-19 Primary Observer Name (XPN) 01091

Components: <Family Name (FN)> ^ <Given Name (ST)> ^ <Second and Further Given Names or Initials Thereof (ST)> ^ <Suffix (e.g., JR or III) (ST)> ^ <Prefix (e.g., DR) (ST)> ^ <WITHDRAWN Constituent> ^ <Name Type Code (ID)> ^ <Name Representation Code (ID)> ^ <Name Context (CWE)> ^ <WITHDRAWN Constituent> ^ <Name Assembly Order (ID)> ^ <Effective Date (DTM)> ^ <Expiration Date (DTM)> ^ <Professional Suffix (ST)> ^ <Called By (ST)>

Subcomponents for Family Name (FN): <Surname (ST)> & <Own Surname Prefix (ST)> & <Own Surname (ST)> & <Surname Prefix from Partner/Spouse (ST)> & <Surname from Partner/Spouse (ST)>

Subcomponents for Name Context (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Definition: This field identifies the name of the person who initially described the event.

7.12.2.20 PEO-20 Primary Observer Address (XAD) 01092

Components: <Street Address (SAD)> ^ <Other Designation (ST)> ^ <City (ST)> ^ <State or Province (ST)> ^ <Zip or Postal Code (ST)> ^ <Country (ID)> ^ <Address Type (ID)> ^ <Other Geographic Designation (ST)> ^ <County/Parish Code (CWE)> ^ <Census Tract (CWE)> ^ <Address Representation Code (ID)> ^ <WITHDRAWN Constituent> ^ <Effective Date (DTM)> ^ <Expiration Date (DTM)> ^ <Expiration Reason (CWE)> ^ <Temporary Indicator (ID)> ^ <Bad Address Indicator (ID)> ^ <Address Usage (ID)> ^ <Addressee (ST)> ^ <Comment (ST)> ^ <Preference Order (NM)> ^ <Protection Code (CWE)> ^ <Address Identifier (EI)>

Subcomponents for Street Address (SAD): <Street or Mailing Address (ST)> & <Street Name (ST)> & <Dwelling Number (ST)>

Subcomponents for County/Parish Code (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Census Tract (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Expiration Reason (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Protection Code (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Address Identifier (EI): <Entity Identifier (ST)> & <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Definition: This field identifies the address of the person who initially described the event.

7.12.2.21 PEO-21 Primary Observer Telephone (XTN) 01093

Components: <WITHDRAWN Constituent> ^ <Telecommunication Use Code (ID)> ^ <Telecommunication Equipment Type (ID)> ^ <Communication Address (ST)> ^ <Country Code (SNM)> ^ <Area/City Code (SNM)> ^ <Local Number (SNM)> ^ <Extension (SNM)> ^ <Any Text (ST)> ^ <Extension Prefix (ST)> ^ <Speed Dial Code (ST)> ^ <Unformatted Telephone number (ST)> ^ <Effective Start Date (DTM)> ^ <Expiration Date (DTM)> ^ <Expiration Reason (CWE)> ^ <Protection Code (CWE)> ^ <Shared Telecommunication Identifier (EI)> ^ <Preference Order (NM)>

Subcomponents for Expiration Reason (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Protection Code (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Shared Telecommunication Identifier (EI): <Entity Identifier (ST)> & <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Definition: This field identifies the telephone number of the person who initially described the event.

7.12.2.22 PEO-22 Primary Observer's Qualification (ID) 01094

Definition: This field contains the qualification of the primary observer which may assist in assessing the validity of the observations. Refer to *HL7 Table 0242 - Primary Observer's Qualification* for valid values.

7.12.2.23 PEO-23 Confirmation Provided By (ID) 01095

Definition: This field contains the qualification of the health professional who confirmed the observation if the primary observer was not a health professional. Refer to *HL7 Table 0242 - Primary Observer's Qualification* for valid values.

7.12.2.24 PEO-24 Primary Observer Aware Date/Time (DTM) 01096

Definition: This field identifies the date/time the primary observer became aware of event.

7.12.2.25 PEO-25 Primary Observer's Identity May Be Divulged (ID) 01097

Definition: Indicates whether or not the primary observer, if known to the sender, grants permission to disclose his or her identity to the product manufacturer for the purpose of further investigating the event. If the element is absent, the assumption should be made that permission is not granted. Refer to *HL7 Table 0243 - Identity May Be Divulged* for valid values.

7.12.3 PCR - Possible Causal Relationship Segment

The PCR segment is used to communicate a potential or suspected relationship between a product (drug or device) or test and an event with detrimental effect on a patient. This segment identifies a potential causal relationship between the product identified in this segment and the event identified in the PEO segment.

More than one PCR segment can be included in the message if more than one product is possibly causally related to the event.

HL7 Attribute Table – PCR – Possible Causal Relationship

SEQ	LEN	C.LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
1			CWE	R		0670	01098	Implicated Product
2		1=	IS	O		0249	01099	Generic Product
3			CWE	O		0671	01100	Product Class
4			CQ	O			01101	Total Duration Of Therapy
5			DTM	O			01102	Product Manufacture Date
6			DTM	O			01103	Product Expiration Date
7			DTM	O			01104	Product Implantation Date
8			DTM	O			01105	Product Explantation Date
9			CWE	O		0244	01106	Single Use Device
10			CWE	O		0672	01107	Indication For Product Use
11			CWE	O		0245	01108	Product Problem
12		199=	ST	O	Y/3		01109	Product Serial/Lot Number
13			CWE	O		0246	01110	Product Available For Inspection
14			CWE	O		0673	01111	Product Evaluation Performed
15			CWE	O		0247	01112	Product Evaluation Status
16			CWE	O		0674	01113	Product Evaluation Results
17	1..1		ID	O		0248	01114	Evaluated Product Source
18			DTM	O			01115	Date Product Returned To Manufacturer
19	1..1		ID	O		0242	01116	Device Operator Qualifications
20	1..1		ID	O		0250	01117	Relatedness Assessment
21	1..2		ID	O	Y/6	0251	01118	Action Taken In Response To The Event
22	2..2		ID	O	Y/6	0252	01119	Event Causality Observations

SEQ	LEN	C.LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
23	1..1		ID	O	Y/3	0253	01120	Indirect Exposure Mechanism

7.12.3.0 PCR field definitions

7.12.3.1 PCR-1 Implicated Product (CWE) 01098

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field contains the coded identity of the product (drug, device, etc.) which is possibly causally related to the event. Includes the product identity number such as NDC, model or catalogue numbers. If a coded value is not available for the product a text description can be included as the second component of the CWE data. See Chapter 2 for a listing of some recognized coding systems for drugs and devices. Refer to Table 0670 - Implicated Product in Chapter 2C for valid values.

7.12.3.2 PCR-2 Generic Product (IS) 01099

Definition: This field indicates whether the product used was a generic or a branded product. Refer to *User-defined Table 0249 – Generic Product* for suggested values.

7.12.3.3 PCR-3 Product Class (CWE) 01100

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field contains the coded classification of the implicated product. For drugs, this would usually be the drug class - calcium channel blocking agents for nifedipine, for example. For other products it would be the generic type of device, e.g., urinary catheter, cardiac pacemaker. If a coded value is not available for the class, a text description can be included. Refer to Table 0671 - Product Class in Chapter 2C for valid values.

7.12.3.4 PCR-4 Total Duration of Therapy (CQ) 01101

```
Components:  <Quantity (NM)> ^ <Units (CWE)>

Subcomponents for Units (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
             System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
             of Alternate Coding System (ID)> & <Coding System Version ID (ST)> &
             <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second
             Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of
             Second Alternate Coding System (ID)> & <Second Alternate Coding System
             Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
             <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
             <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
             <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
             OID (ST)> & <Second Alternate Value Set Version ID (DTM)>
```

Definition: This field represents the total duration of therapy with product listed. The treatment at the current dose and schedule are indicted in the quantity timing attribute of the RXE segment but the patient

may have been treated for some time previously at a different dose or on a different schedule. The quantity in the second component of the CQ should be a time quantity.

7.12.3.5 PCR-5 Product Manufacture Date (DTM) 01102

Definition: This field indicates the date the product was manufactured.

7.12.3.6 PCR-6 Product Expiration Date (DTM) 01103

Definition: This field contains the expiration date indicated on the product packaging.

7.12.3.7 PCR-7 Product Implantation Date (DTM) 01104

Definition: If an implantable medical device, this field identifies the date device was implanted.

7.12.3.8 PCR-8 Product Explantation Date (DTM) 01105

Definition: If an implantable medical device and it was removed, the field identifies the date it was removed.

7.12.3.9 PCR-9 Single Use Device (CWE) 01106

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field indicates whether the product was designed for a single use. Refer to *User-defined Table 0244 – Single Use Device* for suggested values.

7.12.3.10 PCR-10 Indication for Product Use (CWE) 01107

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field contains coded representation of the problem or diagnosis for which the product was used. See Chapter 2 for some coding systems which might be chosen to transmit diagnoses or problems. Refer to Table 0672 - Indication For Product Use in Chapter 2C for valid values.

7.12.3.11 PCR-11 Product Problem (CWE) 01108

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: A product problem would exist if a product malfunction could lead to death or serious injury. Refer to *User-defined Table 0245 - Product Problem* for suggested values.

7.12.3.12 PCR-12 Product Serial/Lot Number (ST) 01109

Definition: This field is an alphanumeric descriptor which identifies the specific item or lot of drug. This descriptor would normally be obtained from the package labeling or item itself.

7.12.3.13 PCR-13 Product Available for Inspection (CWE) 01110

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field indicates that the product is available for analysis. *User-defined Table 0246 -Product Available for Inspection* is used as the HL7 identifier for the user-defined table of values for this field. If the product was returned to the manufacturer, this would be indicated by including the date it was returned in the date product returned to manufacturer element.

7.12.3.14 PCR-14 Product Evaluation Performed (CWE) 01111

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field indicates the type of product evaluation performed. The evaluation codes listed in SubPart B of the Coding Manual for FDA Form 3500A, "Type of Evaluation Performed," may be used. If no codes are available, text may be sent in the second component of the field. Refer to Table 0673 - Product Evaluation Performed in Chapter 2C for valid values.

7.12.3.15 PCR-15 Product Evaluation Status (CWE) 01112

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field identifies the status of product evaluation. Subpart A Item H.3 of the Coding Manual for FDA Form 3500A may also be used. If no codes are available, text may be sent in the second component of the field. Refer to *HL7 Table 0247 - Status of Evaluation* for valid values.

7.12.3.16 PCR-16 Product Evaluation Results (CWE) 01113

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field contains the results of the product evaluation. Refer to Table 0674 - Product Evaluation Results in Chapter 2C for valid values.

7.12.3.17 PCR-17 Evaluated Product Source (ID) 01114

Definition: This field contains the source of the product evaluated. Refer to *HL7 Table 0248 - Product Source* for valid values.

7.12.3.18 PCR-18 Date Product Returned to Manufacturer (DTM) 01115

Definition: If the product was returned to the manufacturer, this field contains the date it was returned.

7.12.3.19 PCR-19 Device Operator Qualifications (ID) 01116

Definition: This field identifies the qualification of the person operating the device when the event occurred. Refer to *HL7 Table 0242 - Primary Observer's Qualification* for valid values.

7.12.3.20 PCR-20 Relatedness Assessment (ID) 01117

Definition: This field represents the assessment of relatedness of the product to the event. Refer to *HL7 Table 0250 - Relatedness Assessment* for valid values.

7.12.3.21 PCR-21 Action Taken in Response to the Event (ID) 01118

Definition: This field indicates the action taken as a result of the event. Segment may repeat if multiple categories of evidence are relevant. Refer to *HL7 Table 0251 - Action Taken in Response to the Event* for valid values.

7.12.3.22 PCR-22 Event Causality Observations (ID) 01119

Definition: This field contains observations made about the event which may bear on causality. Refer to *HL7 Table 0252 - Causality Observations* for valid values. Segment may repeat if multiple categories of evidence are relevant.

7.12.3.23 PCR-23 Indirect Exposure Mechanism (ID) 01120

Definition: The patient identified in the PID segment, who experienced the event, might have been exposed to the potential causal product via an intermediary, e.g., a child might be exposed to a product through the placenta or in breast milk, or a transfusion recipient might be exposed via a blood product. If this is the case, the mechanism of product transmission is identified in this field, using the valid values in *HL7 Table 0253 - Indirect Exposure Mechanism*. If this field is populated, the identity of the person through whom the product was transmitted is contained in NK1 and RXE segments which follow.

7.12.4 PSH - Product Summary Header Segment

This segment is maintained for backwards compatibility only as of v 2.7.

HL7 Attribute Table – PSH –Product Summary Header

SEQ	LEN	C.LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
1		60=	ST	R			01233	Report Type
2		60=	ST	O			01297	Report Form Identifier

SEQ	LEN	C.LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
3			DTM	R			01235	Report Date
4			DTM	O			01236	Report Interval Start Date
5			DTM	O			01237	Report Interval End Date
6			CQ	O			01238	Quantity Manufactured
7			CQ	O			01239	Quantity Distributed
8	1..1		ID	O		0329	01240	Quantity Distributed Method
9		600=	FT	O			01241	Quantity Distributed Comment
10			CQ	O			01242	Quantity in Use
11	1..1		ID	O		0329	01243	Quantity in Use Method
12		600=	FT	O			01244	Quantity in Use Comment
13		16=	NM	O	Y/8		01245	Number of Product Experience Reports Filed by Facility
14		16=	NM	O	Y/8		01246	Number of Product Experience Reports Filed by Distributor

7.12.4.0 PSH field definitions

7.12.4.1 PSH-1 Report Type (ST) 01233

Definition: This field contains the name, title, or other description of the report. Typically, the field will include the agency name (e.g., FDA), agency component if applicable (e.g., CDRH) and the report type (e.g., Medical Device Reporting Baseline Report).

7.12.4.2 PSH-2 Report Form Identifier (ST) 01297

Definition: This field contains the form descriptor which describes the report. Typically, the field will include the agency name (e.g., FDA), agency component if applicable (e.g., CDRH) and the form number (e.g., 3417).

7.12.4.3 PSH-3 Report Date (DTM) 01235

Definition: This field contains the date as assigned by the sender.

7.12.4.4 PSH-4 Report Interval Start Date (DTM) 01236

Definition: This field contains the date that marks the beginning of the time interval covered by the current report.

7.12.4.5 PSH-5 Report Interval End Date (DTM) 01237

Definition: This field contains the date which marks the inclusive end of the time interval covered by the current report.

7.12.4.6 PSH-6 Quantity Manufactured (CQ) 01238

```
Components:  <Quantity (NM)> ^ <Units (CWE)>

Subcomponents for Units (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
           System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
           of Alternate Coding System (ID)> & <Coding System Version ID (ST)> &
           <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second
           Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of
           Second Alternate Coding System (ID)> & <Second Alternate Coding System
           Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
           <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
           <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
           <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
           OID (ST)> & <Second Alternate Value Set Version ID (DTM)>
```

Definition: This field is used to send the number of units of the product manufactured during the reporting interval. The second component can be used to specify the units for the quantity.

7.12.4.7 PSH-7 Quantity Distributed (CQ) 01239

```
Components:  <Quantity (NM)> ^ <Units (CWE)>

Subcomponents for Units (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
          System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
          of Alternate Coding System (ID)> & <Coding System Version ID (ST)> &
          <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second
          Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of
          Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>
```

Definition: This field is used to send the number of units of the product which was distributed during the reporting interval. The second component can be used to specify the units for the quantity.

7.12.4.8 PSH-8 Quantity Distributed Method (ID) 01240

Definition: This field is used for measuring the quantity distributed. An explanation of the method used for estimation can be included in *PSH-9 Quantity Distributed Comment*. Refer to *HL7 Table 0329 - Quantity Method* for valid values.

7.12.4.9 PSH-9 Quantity Distributed Comment (FT) 01241

Definition: This field is used for any explanatory text needed but in particular should provide a description of the estimation method used. If referring to the description used in a previous report, the comment should include the product identifier and data of that report.

7.12.4.10 PSH-10 Quantity in Use (CQ) 01242

```
Components:  <Quantity (NM)> ^ <Units (CWE)>

Subcomponents for Units (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
          System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
          of Alternate Coding System (ID)> & <Coding System Version ID (ST)> &
          <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second
          Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of
          Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>
```

Definition: This field is used to send the number of units of the product which were in use during the reporting interval. The second component can be used to specify the units for the quantity.

7.12.4.11 PSH-11 Quantity in Use Method (ID) 01243

Definition: This field contains the method used for measuring the quantity in use. An explanation of the method used for estimation can be included in *PSH-12-quantity in use comment*. Refer to *HL7 Table 0329 - Quantity Method* for valid values.

7.12.4.12 PSH-12 Quantity in Use Comment (FT) 01244

Definition: This field can be used for any explanatory text needed but in particular should provide a description of the estimation method used. If referring to the description used in a previous report, the comment should include the product identifier and data of the report.

7.12.4.13 PSH-13 Number of Product Experience Reports Filed by Facility (NM) 01245

Definition: The field contains the number of product experience reports filed by facility.

7.12.4.14 PSH-14 Number of Product Experience Reports Filed by Distributor (NM) 01246

Definition: This field contains the number of product experience reports filed by distributor.

7.12.5 PDC - Product Detail Country Segment

This segment is maintained for backwards compatibility only as of v 2.7.

HL7 Attribute Table – PDC – Product Detail Country

SEQ	LEN	C.LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
1			XON	R	Y		01247	Manufacturer/Distributor
2			CWE	R		0675	01248	Country
3		60=	ST	R			01249	Brand Name
4		60=	ST	O			01250	Device Family Name
5			CWE	O		0676	01251	Generic Name
6		60=	ST	O	Y		01252	Model Identifier
7		60=	ST	O			01253	Catalogue Identifier
8		60=	ST	O	Y		01254	Other Identifier
9			CWE	O		0677	01255	Product Code
10	3..4		ID	O		0330	01256	Marketing Basis
11		60=	ST	O			01257	Marketing Approval ID
12			CQ	O			01258	Labeled Shelf Life
13			CQ	O			01259	Expected Shelf Life
14			DTM	O			01260	Date First Marketed
15			DTM	O			01261	Date Last Marketed

7.12.5.0 PDC field definitions

7.12.5.1 PDC-1 Manufacturer/Distributor (XON) 01247

```
Components:  <Organization Name (ST)> ^ <Organization Name Type Code (CWE)> ^
             <WITHDRAWN Constituent> ^ <WITHDRAWN Constituent> ^ <WITHDRAWN
             Constituent> ^ <Assigning Authority (HD)> ^ <Identifier Type Code (ID)> ^
             <Assigning Facility (HD)> ^ <Name Representation Code (ID)> ^
             <Organization Identifier (ST)>

Subcomponents for Organization Name Type Code (CWE):  <Identifier (ST)> & <Text (ST)>
             & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
             Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
             Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
             Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text
             (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate
             Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID
             (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)>
             & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)>
             & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
             OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Authority (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
             & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
             & <Universal ID Type (ID)>
```

Definition: This field contains the identity of the manufacturer/distributor.

7.12.5.2 PDC-2 Country (CWE) 01248

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
           <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
           Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
           System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
           Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
           Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
           (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
           Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
           Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
           Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
           Alternate Value Set Version ID (DTM)>
```

Definition: This field contains the country to which this product detail is relevant. ISO 3166 provides a list of country codes that may be used. Refer to Table 0675 - Country in Chapter 2C for valid values.

7.12.5.3 PDC-3 Brand Name (ST) 01249

Definition: This field contains the name under which the product is marketed by this manufacturer.

7.12.5.4 PDC-4 Device Family Name (ST) 01250

Definition: This field contains the name used by the manufacturer to describe the family of products to which this product belongs.

7.12.5.5 PDC-5 Generic Name (CWE) 01251

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
           <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
           Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
           System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
           Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
           Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
           (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
           Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
           Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
           Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
           Alternate Value Set Version ID (DTM)>
```

Definition: This field contains the name generically used to identify the product. Refer to Table 0676 - Generic Name in Chapter 2C for valid values.

7.12.5.6 PDC-6 Model Identifier (ST) 01252

Definition: This field contains the manufacturer's model identifier for the product.

7.12.5.7 PDC-7 Catalogue Identifier (ST) 01253

Definition: This field contains the manufacturer's catalogue identifier for the product.

7.12.5.8 PDC-8 Other Identifier (ST) 01254

Definition: This field contains any other identifier used to for the product.

7.12.5.9 PDC-9 Product Code (CWE) 01255

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
           <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
           Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
           System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
           Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
           Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
           (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
           Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
           Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
           Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
           Alternate Value Set Version ID (DTM)>
```

Definition: This field contains the product code from an external coding system such as that used by the CDRH at the FDA. Refer to Table 0677 - Product Code in Chapter 2C for valid values.PDC-10 Marketing Basis (ID) 01256

Definition: This field contains the basis for marketing approval. Refer to *HL7 Table 0330 - Marketing Basis* for valid values.

7.12.5.10 PDC-11 Marketing Approval ID (ST) 01257

Definition: This field contains the designation or description of the marketing basis.

7.12.5.11 PDC-12 Labeled Shelf Life (CQ) 01258

```
Components:  <Quantity (NM)> ^ <Units (CWE)>

Subcomponents for Units (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
          System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
          of Alternate Coding System (ID)> & <Coding System Version ID (ST)> &
          <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second
          Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of
          Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>
```

Definition: This field contains the shelf life of the product as labeled. This will usually be in months or years. If there is no shelf life indicated in the product labeling, this field will be empty.

7.12.5.12 PDC-13 Expected Shelf Life (CQ) 01259

```
Components:  <Quantity (NM)> ^ <Units (CWE)>

Subcomponents for Units (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of Coding
          System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name
          of Alternate Coding System (ID)> & <Coding System Version ID (ST)> &
          <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second
          Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of
          Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>
```

Definition: This field contains the shelf life of the product expected by the manufacturer. This will usually be in months or years.

7.12.5.13 PDC-14 Date First Marketed (DTM) 01260

Definition: This field contains the date the product was first marketed in the country.

7.12.5.14 PDC-15 Date Last Marketed (DTM) 01261

Definition: This field contains the date the product was last marketed in the country. This field will be omitted if the product is still being marketed.

7.12.6 FAC - Facility Segment

This segment is maintained for backwards compatibility only as of V2.7.

HL7 Attribute Table – FAC – Facility

SEQ	LEN	C.LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
1			EI	R			01262	Facility ID-FAC
2	1..1		ID	O		0331	01263	Facility Type
3			XAD	R	Y		01264	Facility Address
4			XTN	R			01265	Facility Telecommunication
5			XCN	O	Y		01266	Contact Person

SEQ	LEN	C.LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
6		60=	ST	O	Y		01267	Contact Title
7			XAD	O	Y		01166	Contact Address
8			XTN	O	Y		01269	Contact Telecommunication
9			XCN	R	Y		01270	Signature Authority
10		199=	ST	O			01271	Signature Authority Title
11			XAD	O	Y		01272	Signature Authority Address
12			XTN	O			01273	Signature Authority Telecommunication

7.12.6.0 FAC field definitions

7.12.6.1 FAC-1 Facility ID-FAC (EI) 01262

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: This field contains the facility identifier.

7.12.6.2 FAC-2 Facility Type (ID) 01263

Definition: This field contains the type of facility. Refer to *HL7 Table 0331 - Facility Type* for valid values.

7.12.6.3 FAC-3 Facility Address (XAD) 01264

```
Components:  <Street Address (SAD)> ^ <Other Designation (ST)> ^ <City (ST)> ^ <State
             or Province (ST)> ^ <Zip or Postal Code (ST)> ^ <Country (ID)> ^ <Address
             Type (ID)> ^ <Other Geographic Designation (ST)> ^ <County/Parish Code
             (CWE)> ^ <Census Tract (CWE)> ^ <Address Representation Code (ID)> ^
             <WITHDRAWN Constituent> ^ <Effective Date (DTM)> ^ <Expiration Date (DTM)>
             ^ <Expiration Reason (CWE)> ^ <Temporary Indicator (ID)> ^ <Bad Address
             Indicator (ID)> ^ <Address Usage (ID)> ^ <Addressee (ST)> ^ <Comment (ST)>
             ^ <Preference Order (NM)> ^ <Protection Code (CWE)> ^ <Address Identifier
             (EI)>

Subcomponents for Street Address (SAD):  <Street or Mailing Address (ST)> & <Street
             Name (ST)> & <Dwelling Number (ST)>

Subcomponents for County/Parish Code (CWE):  <Identifier (ST)> & <Text (ST)> & <Name
             of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text
             (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID
             (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
             <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
             of Second Alternate Coding System (ID)> & <Second Alternate Coding System
             Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
             <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
             <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
             <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
             OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Census Tract (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of
             Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
             & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
             & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
             <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
             of Second Alternate Coding System (ID)> & <Second Alternate Coding System
             Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
             <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
             <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
             <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
             OID (ST)> & <Second Alternate Value Set Version ID (DTM)>
```

Subcomponents for Expiration Reason (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Protection Code (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Address Identifier (EI): <Entity Identifier (ST)> & <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Definition: This field contains the facility's address.

7.12.6.4 FAC-4 Facility Telecommunication (XTN) 01265

Components: <WITHDRAWN Constituent> ^ <Telecommunication Use Code (ID)> ^ <Telecommunication Equipment Type (ID)> ^ <Communication Address (ST)> ^ <Country Code (SNM)> ^ <Area/City Code (SNM)> ^ <Local Number (SNM)> ^ <Extension (SNM)> ^ <Any Text (ST)> ^ <Extension Prefix (ST)> ^ <Speed Dial Code (ST)> ^ <Unformatted Telephone number (ST)> ^ <Effective Start Date (DTM)> ^ <Expiration Date (DTM)> ^ <Expiration Reason (CWE)> ^ <Protection Code (CWE)> ^ <Shared Telecommunication Identifier (EI)> ^ <Preference Order (NM)>

Subcomponents for Expiration Reason (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Protection Code (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Shared Telecommunication Identifier (EI): <Entity Identifier (ST)> & <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Definition: This field contains the facility's telecommunication information.

7.12.6.5 FAC-5 Contact Person (XCN) 01266

Components: <Person Identifier (ST)> ^ <Family Name (FN)> ^ <Given Name (ST)> ^ <Second and Further Given Names or Initials Thereof (ST)> ^ <Suffix (e.g., JR or III) (ST)> ^ <Prefix (e.g., DR) (ST)> ^ <WITHDRAWN Constituent> ^ <DEPRECATED-Source Table (CWE)> ^ <Assigning Authority (HD)> ^ <Name Type Code (ID)> ^ <Identifier Check Digit (ST)> ^ <Check Digit Scheme (ID)> ^ <Identifier Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name Representation Code (ID)> ^ <Name Context (CWE)> ^ <WITHDRAWN Constituent> ^ <Name Assembly Order (ID)> ^ <Effective Date (DTM)> ^ <Expiration Date (DTM)> ^ <Professional Suffix (ST)> ^ <Assigning Jurisdiction (CWE)> ^ <Assigning Agency or Department (CWE)> ^ <Security Check (ST)> ^ <Security Check Scheme (ID)>

Subcomponents for Family Name (FN): <Surname (ST)> & <Own Surname Prefix (ST)> & <Own Surname (ST)> & <Surname Prefix from Partner/Spouse (ST)> & <Surname from Partner/Spouse (ST)>

Subcomponents for Source Table (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Authority (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Name Context (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Jurisdiction (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Agency or Department (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Definition: This field contains the primary contact person's name.

7.12.6.6 FAC-6 Contact Title (ST) 01267

Definition: This field contains the primary contact person's title.

7.12.6.7 FAC-7 Contact Address (XAD) 01166

```
Components:  <Street Address (SAD)> ^ <Other Designation (ST)> ^ <City (ST)> ^ <State
          or Province (ST)> ^ <Zip or Postal Code (ST)> ^ <Country (ID)> ^ <Address
          Type (ID)> ^ <Other Geographic Designation (ST)> ^ <County/Parish Code
          (CWE)> ^ <Census Tract (CWE)> ^ <Address Representation Code (ID)> ^
          <WITHDRAWN Constituent> ^ <Effective Date (DTM)> ^ <Expiration Date (DTM)>
          ^ <Expiration Reason (CWE)> ^ <Temporary Indicator (ID)> ^ <Bad Address
          Indicator (ID)> ^ <Address Usage (ID)> ^ <Addressee (ST)> ^ <Comment (ST)>
          ^ <Preference Order (NM)> ^ <Protection Code (CWE)> ^ <Address Identifier
          (EI)>

Subcomponents for Street Address (SAD):  <Street or Mailing Address (ST)> & <Street
          Name (ST)> & <Dwelling Number (ST)>

Subcomponents for County/Parish Code (CWE):  <Identifier (ST)> & <Text (ST)> & <Name
          of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text
          (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID
          (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
          <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
          of Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Census Tract (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of
          Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
          & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
          & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
          <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
          of Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Expiration Reason (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of
          Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
          & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
          & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
          <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
          of Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Protection Code (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of
          Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
          & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
          & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
          <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
          of Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Address Identifier (EI):  <Entity Identifier (ST)> & <Namespace ID
          (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>
```

Definition: This field contains the primary contact person's address.

7.12.6.8 FAC-8 Contact Telecommunication (XTN) 01269

Components: <WITHDRAWN Constituent> ^ <Telecommunication Use Code (ID)> ^ <Telecommunication Equipment Type (ID)> ^ <Communication Address (ST)> ^ <Country Code (SNM)> ^ <Area/City Code (SNM)> ^ <Local Number (SNM)> ^ <Extension (SNM)> ^ <Any Text (ST)> ^ <Extension Prefix (ST)> ^ <Speed Dial Code (ST)> ^ <Unformatted Telephone number (ST)> ^ <Effective Start Date (DTM)> ^ <Expiration Date (DTM)> ^ <Expiration Reason (CWE)> ^ <Protection Code (CWE)> ^ <Shared Telecommunication Identifier (EI)> ^ <Preference Order (NM)>

Subcomponents for Expiration Reason (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Protection Code (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Shared Telecommunication Identifier (EI): <Entity Identifier (ST)> & <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Definition: This field contains the primary contact person's telecommunication information.

7.12.6.9 FAC-9 Signature Authority (XCN) 01270

Components: <Person Identifier (ST)> ^ <Family Name (FN)> ^ <Given Name (ST)> ^ <Second and Further Given Names or Initials Thereof (ST)> ^ <Suffix (e.g., JR or III) (ST)> ^ <Prefix (e.g., DR) (ST)> ^ <WITHDRAWN Constituent> ^ <DEPRECATED-Source Table (CWE)> ^ <Assigning Authority (HD)> ^ <Name Type Code (ID)> ^ <Identifier Check Digit (ST)> ^ <Check Digit Scheme (ID)> ^ <Identifier Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name Representation Code (ID)> ^ <Name Context (CWE)> ^ <WITHDRAWN Constituent> ^ <Name Assembly Order (ID)> ^ <Effective Date (DTM)> ^ <Expiration Date (DTM)> ^ <Professional Suffix (ST)> ^ <Assigning Jurisdiction (CWE)> ^ <Assigning Agency or Department (CWE)> ^ <Security Check (ST)> ^ <Security Check Scheme (ID)>

Subcomponents for Family Name (FN): <Surname (ST)> & <Own Surname Prefix (ST)> & <Own Surname (ST)> & <Surname Prefix from Partner/Spouse (ST)> & <Surname from Partner/Spouse (ST)>

Subcomponents for Source Table (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Authority (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

```
Subcomponents for Assigning Facility (HD):  <Namespace ID (IS)> & <Universal ID (ST)>
          & <Universal ID Type (ID)>

Subcomponents for Name Context (CWE):  <Identifier (ST)> & <Text (ST)> & <Name of
          Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)>
          & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)>
          & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> &
          <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name
          of Second Alternate Coding System (ID)> & <Second Alternate Coding System
          Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> &
          <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> &
          <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> &
          <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Jurisdiction (CWE):  <Identifier (ST)> & <Text (ST)> &
          <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate
          Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System
          Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original
          Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text
          (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate
          Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID
          (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)>
          & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)>
          & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set
          OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Agency or Department (CWE):  <Identifier (ST)> & <Text
          (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> &
          <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding
          System Version ID (ST)> & <Alternate Coding System Version ID (ST)> &
          <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second
          Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> &
          <Second Alternate Coding System Version ID (ST)> & <Coding System OID
          (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate
          Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate
          Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> &
          <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set
          Version ID (DTM)>
```

Definition: This field contains the name of the individual with signature authority or who is responsible for the report.

7.12.6.10 FAC-10 Signature Authority Title (ST) 01271

Definition: This field contains the title of the individual with signature authority or who is responsible for this report.

7.12.6.11 FAC-11 Signature Authority Address (XAD) 01272

```
Components:  <Street Address (SAD)> ^ <Other Designation (ST)> ^ <City (ST)> ^ <State
          or Province (ST)> ^ <Zip or Postal Code (ST)> ^ <Country (ID)> ^ <Address
          Type (ID)> ^ <Other Geographic Designation (ST)> ^ <County/Parish Code
          (CWE)> ^ <Census Tract (CWE)> ^ <Address Representation Code (ID)> ^
          <WITHDRAWN Constituent> ^ <Effective Date (DTM)> ^ <Expiration Date (DTM)>
          ^ <Expiration Reason (CWE)> ^ <Temporary Indicator (ID)> ^ <Bad Address
          Indicator (ID)> ^ <Address Usage (ID)> ^ <Addressee (ST)> ^ <Comment (ST)>
          ^ <Preference Order (NM)> ^ <Protection Code (CWE)> ^ <Address Identifier
          (EI)>

Subcomponents for Street Address (SAD):  <Street or Mailing Address (ST)> & <Street
          Name (ST)> & <Dwelling Number (ST)>
```

Subcomponents for County/Parish Code (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Census Tract (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Expiration Reason (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Protection Code (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Address Identifier (EI): <Entity Identifier (ST)> & <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Definition: This field contains the address of the individual with signature authority or who is responsible for this report.

7.12.6.12 FAC-12 Signature Authority Telecommunication (XTN) 01273

Components: <WITHDRAWN Constituent> ^ <Telecommunication Use Code (ID)> ^ <Telecommunication Equipment Type (ID)> ^ <Communication Address (ST)> ^ <Country Code (SNM)> ^ <Area/City Code (SNM)> ^ <Local Number (SNM)> ^ <Extension (SNM)> ^ <Any Text (ST)> ^ <Extension Prefix (ST)> ^ <Speed Dial Code (ST)> ^ <Unformatted Telephone number (ST)> ^ <Effective Start Date (DTM)> ^ <Expiration Date (DTM)> ^ <Expiration Reason (CWE)> ^ <Protection Code (CWE)> ^ <Shared Telecommunication Identifier (EI)> ^ <Preference Order (NM)>

Subcomponents for Expiration Reason (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Protection Code (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Shared Telecommunication Identifier (EI): <Entity Identifier (ST)> & <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Definition: This field contains the telecommunication information of the individual with signature authority of who is responsible for this report.

7.13 PRODUCT EXPERIENCE – EXAMPLES OF USE

```
MSH|^-&|SAP||RAP||200006051512||PEX^P07|...<cr>

EVN|...<cr>

PID||1||A^A^A||19230616|F|||||||||||||||Y|...<cr>
```

Note: This section probably needs to have its own definition of the PID. PID-3 is a required field in chapter 3, but in the context of this section probably shouldn't be required. I also removed PID-23, Birthplace (19950710). A date is not a birthplace.

```
PES|MakeADrug, Inc||Manufacturer Mall^^Ann Arbor^MI^99999||
    GB95070448A|0|||19950704|19950710|10D|...<cr>

PEO||^Awaiting results of autopsy|19950704||||^^^^^GBR||S|N|D~H~O||Patient
    admitted via casualty with increased shortness of breath and left sided chest
    pain on 04 JUL 95 for assessment.~11-JUL-95 Patient admitted 09-JUL-95 at
    11:30 PM with an 18 hour history of diarrhoea followed by collapse. On
    admission, patient was exhausted and dehydrated. She had a rash on both
    breasts and abdomen. Patient found to have deteriorating renal function.
    Patient commenced IV fluid, however patient was found dead on 10-JUL-95
    morning. Query vomited and aspirated. Post mortem requested. Events possibly
    related to study drug.|...<cr>

PCR|xxxxx^Wonder Drug 1^ATC|N|^antineoplastic|||||||^NON SMALL CELL LUNG
    CANCER|...<cr>

RXE|1^^^19950629^19950710|xxxxx^Wonder Drug
    1^ATC|1||TAB|||||||||||||||||M1|3||||NON SMALL CELL LUNG CANCER|...<cr>

RXR|PO|...<cr>
```

Note: The message structure for the PEX does not allow repeating RXE/RXR groups within a PCR group. This is probably a mistake in the message definition table for the PEX messages.

```
PRB|AD|19950704|705^DYSPNEA^MEDR|...<cr>
PRB|AD|19950710|20143^DEATH^MEDR|...<cr>
PRB|AD|19950704|18330^CHEST PAIN^MEDR|...<cr>
PRB|AD|19950709|21197^DIARRHEA^MEDR|...<cr>
PRB|AD|19950709|6432^SYNCOPE^MEDR|...<cr>
PRB|AD|19950709|4966^DEHYDRATION^MEDR|...<cr>
PRB|AD|19950709|20544^KIDNEY FUNCTION ABNORMAL^MEDR|...<cr>
OBX|1|NM|804-5^lEUKOCYTES^LN||2300|10*3/ml|||||F|19940704|...<cr>
OBX|2|NM|770-8^NEUTROPHILS/100 LEUKOCYTES^LN||1.9|%|||||F|19950704|...<cr>
OBX|3|NM|6299-2^UREA NITROGEN^LN||22.3|mg%|||||F|19950709|...<cr>
OBX|4|NM|2160-0^CREATININE^LN||247|mmole|||||F|19950709|...<cr>
NTE|||Additional details must be obtained from the affiliate in order to assess
    causality. A three day alert phone call was made to the FDA on 12-JUL-
    95|...<cr>
```

7.14 WAVEFORM

Retained for backwards compatibility only in v 2.7 and withdrawn as of v2.9. Implementers are encouraged to use other V2 guidance (e.g., IHE's PCD profile) or V3 constructs to support waveform messages.

7.15 WAVEFORM – TRIGGER EVENTS & MESSAGE DEFINITIONS

Retained for backwards compatibility only in v 2.7 and withdrawm as of v2.9. Implementers are encouraged to use other V2 guidance (e.g., IHE's PCD profile) or V3 as it expands its use cases in this space, while using older V2 versions until that point.

7.16 SPECIMEN SHIPMENT MANIFEST

7.16.1 OSM - Unsolicited Specimen Shipment Manifest Message (Event R26)

The OSM^R26 Unsolicited Specimen Shipment Manifest message is used to communicate the contents of a specimen shipment to a specimen receiver (typically a laboratory). The message documents details regarding the following:

- Shipment information including sender, receiver, shipper, shipping container, etc.;
- Specimens in the shipment;
- Specimen containers; and,
- Identification of persons/places/things associated with the specimens.

OSM^R26^OSM_R26: Specimen Shipment Message

Segments	Description	Status	Chapter
MSH	Message Header		2
{[ARV}]	Access Restrictions		3
[{SFT}]	Software Segment		2
[UAC]	User Authentication Credential		2
{	--- SHIPMENT begin		

Segments	Description	Status	Chapter
SHP	Shipment Segment		7
{PRT}	Participation (for Shipment)		7
[{	--- SHIPPING_OBSERVATION begin		
OBX	Observation/Result Segment (Additional Shipping Information)		7
[{PRT}]	Participation (for Shipping Observation)		7
}]	--- SHIPPING_OBSERVATION end		
{	--- PACKAGE begin		
PAC	Shipping Package Segment		7
[{PRT}]	Participation (for Shipping Package)		7
[{	--- SPECIMEN begin		
SPM	Specimen Information		7
[{PRT}]	Participation (for Specimen)		7
[{	--- SPECIMEN_OBSERVATION begin		
OBX	Observation/Result Segment (For Specimen)		7
[{PRT}]	Participation (for Specimen Observation)		7
}]	--- SPECIMEN_OBSERVATION end		
[{	--- CONTAINER begin		
SAC	Container Information		13
[{	--- CONTAINER_OBSERVATION begin		
OBX	Observation/Result Segment (For Container)		7
[{PRT}]	Participation (for Container Observation Result)		7
}]	--- CONTAINER_OBSERVATION end		
}]	--- CONTAINER end		
[	--- SUBJECT_PERSON_OR_ANIMAL_IDENTIFICATION begin		
PID	Patient Identification (For Person/Animal)		3
[{PRT}]	Participation (for Patient)		7
[{ARV}]	For backwards compability only as of V2.9.	B	3
[{	--- PATIENT_OBSERVATION begin		
OBX	Observation/Result Segment (For Patient)		7
[{PRT}]	Participation (for Observation)		7
}]	--- PATIENT_OBSERVATION end		

Segments	Description	Status	Chapter
[{NK1}]	Next of Kin/Associated Parties (For Person/Animal)		
]	--- SUBJECT_PERSON_OR_ANIMAL_IDENTIFICATION end		
[	--- SUBJECT_POPULATION_OR_LOCATION_IDENTIFICATION begin		
PV1	Patient Visit (For Population/Location)		3
[{PRT}]	Participation (for Patient Visit)		7
[{	--- PATIENT_VISIT_OBSERVATION begin		
OBX	Observation/Result Segment (For Visit)		7
[{PRT}]	Participation (for Patient Visit Observation)		7
}]	--- PATIENT_VISIT_OBSERVATION end		
[PID]	Patient Identification (For Population)		3
[{PRT}]	Participation (for Patient)		7
[{NK1}]	Next of Kin/Associated Parties (For Population/Location)		3
]	--- SUBJECT_POPULATION_OR_LOCATION_IDENTIFICATION end		
}]	--- SPECIMEN end		
}	--- PACKAGE end		
}	--- SHIPMENT end		

Acknowledgement Choreography				
OSM^R26^OSM_R26				
Field name	Field Value: Original mode	Field value: Enhanced mode		
MSH-15	Blank	NE	NE	AL, SU, ER
MSH-16	Blank	NE	AL, SU, ER	AL, SU, ER
Immediate Ack	-	-	-	ACK^R26^ACK
Application Ack	ACK^R26^ACK	-	ACK^R26^ACK	ACK^R26^ACK

7.16.1.0 Segment Notes

The Participation (PRT) segment following the Shipment (SHP) segment is used to document participants in a shipment. A minimum of one Participation segment is required for documenting the destination of the

shipment. Other participants including shipment originator, shipment packer, shipment waypoints, etc. can also be documented using the Participation segment.

The Observation/Result (OBX) segment in the SHIPPING_OBSERVATION segment group is used to carry any additional shipping information or observations that are not carried in the Shipment segment.

The Participation (PRT) segment following the Specimen (SPM) segment is used to identify the person(s) who collected the specimen.

The Observation/Result (OBX) segment in the SPECIMEN_OBSERVATION segment group is used to document any additional shipping information that is not conveyed in the Specimen (SPM) segment.

The Container (SAC) segment is used to document the containers for a specimen. If it is necessary to document where in a package a particular specimen container is found, use SAC-11 (Position in Carrier) to convey this position. SAC-10 (Carrier Identifier) can be used to carry the identifier of the package within which the specimen container is located.

The Observation/Result (OBX) segment in the CONTAINER_OBSERVATION segment group is used to document observations regarding the specimen container.

The SUBJECT_PERSON/ANIMAL_IDENTIFICATION segment group is used to associate a specimen with the person or animal the specimen was obtained from. If the subject of the testing is something other than a person, the Next of Kin/Associated Parties (NK1) segment will document the person or organization responsible or owning the subject. For patients who are persons, the NK1 segment documents the next of kin of the patient.

If the specimen was obtained from a population of animals or a location then the SUBJECT_POPULATION/LOCATION_IDENTIFICATION segment group should be used instead. The Patient Identification (PID) segment in this segment group is used to carry the species, breed and strain information for a population. The Next of Kin (NK1) segment in this segment group is used to convey information regarding the owner or responsible party for a population of animals or a location.

The Patient Visit (PV1) segment is used to provide basic information about a patient encounter where the specimen was taken.

The Observation/Result (OBX) segment in the PATIENT_VISIT_OBSERVATION segment group is used to document observations regarding the visit.

7.16.1.1 Actors

7.16.1.1.1 Specimen Shipper

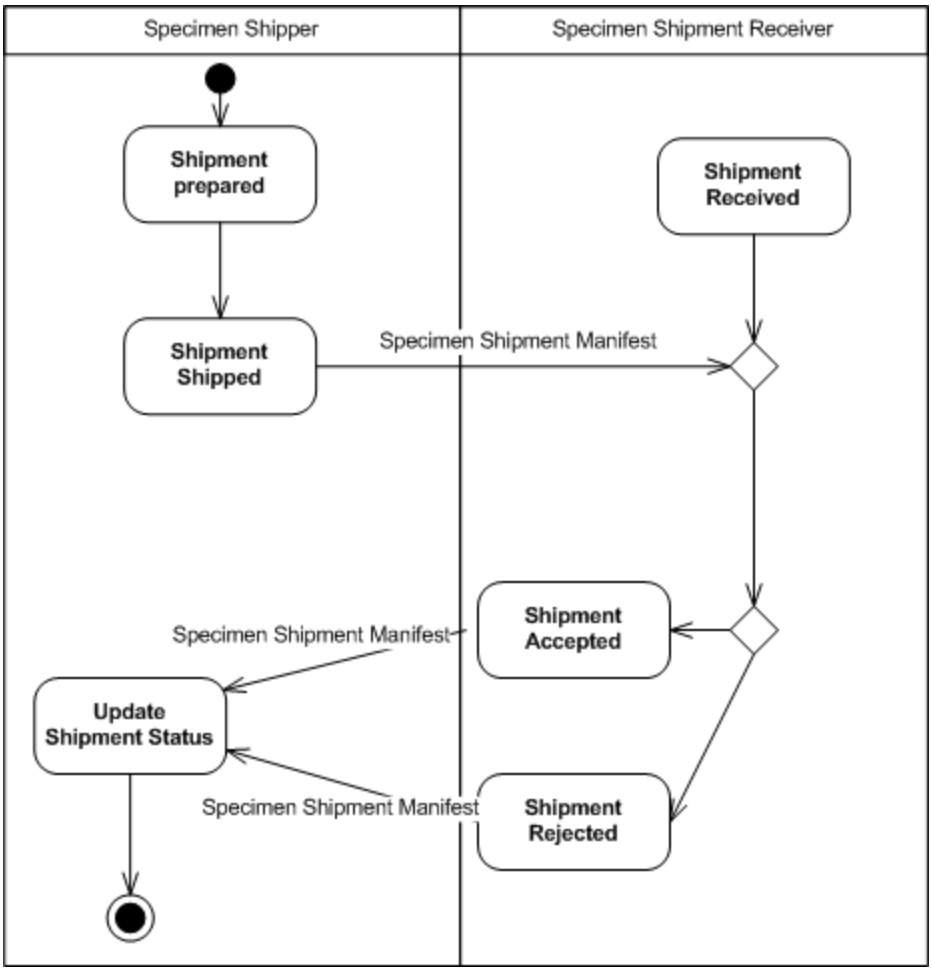
The Specimen Shipper actor is an application capable of sending specimen shipments and transmitting the specimen shipment manifest message.

7.16.1.1.2 Specimen Shipment Receiver

The Specimen Shipment Receiver actor is an application capable of receiving specimen shipments as well as specimen shipment manifest messages. Typically this application is associated with a Laboratory.

7.16.1.2 Activity Diagram

The following activity diagram illustrates the usage of this message. The message is initially sent from the Specimen Shipper at the point the specimen is shipped. The actual point of transmission of the message could occur as soon as all the contents of the shipment have been identified, and the transporters shipment id has been assigned to the shipment. The specimen shipment receiver will send back transaction using the Specimen Shipment Manifest message indicating the specimen shipment has been accepted or rejected. This normally will occur after the shipment has been physically received and evaluated. Note that this response back is not considered an application acknowledgment, and is certainly not required. Its purpose is to update the shipper with the status of the shipment.



7.16.2 SHP - Shipment Segment

The intent of this segment is to describe the information associated with the transportation of the shipment.

HL7 Attribute Table – SHP – Shipment

SEQ	LEN	C.LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
1			EI	R	N		02317	Shipment ID
2			EI	O	Y		02318	Internal Shipment ID
3			CWE	O	N	0905	02319	Shipment Status
4			DTM	R	N		02320	Shipment Status Date/Time
5			TX	O	N		02321	Shipment Status Reason
6			CWE	O	N	0906	02322	Shipment Priority
7			CWE	O	Y	0907	02323	Shipment Confidentiality
8		4=	NM	O	N		02324	Number of Packages in Shipment
9			CWE	O	Y	0544	02325	Shipment Condition
10			CWE	O	Y	0376	02326	Shipment Handling Code
11			CWE	O	Y	0489	02327	Shipment Risk Code
12	2..2		ID	O		0206	00816	Action Code

7.16.2.0 SHP Field Definitions

7.16.2.1 SHP-1 Shipment ID (EI) 02317

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: The shipment id is the identifier assigned by the shipment transportation provider that uniquely identifies this shipment from all other shipments by the same provider. The addressee for the shipment should be able to use this identifier to match a physical shipment with the electronic manifest for the shipment.

7.16.2.2 SHP-2 Internal Shipment ID (EI) 02318

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: The internal shipment id is an identifier assigned to the shipment by the sender or addressee of the shipment. The field repeats allowing multiple identifiers to be transmitted.

7.16.2.3 SHP-3 Shipment Status (CWE) 02319

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: The shipment status specifies where in the shipment process the package is at the time of messaging. Refer to *HL7 Table 0905 – Shipment Status* for specific values:

7.16.2.4 SHP-4 Shipment Status Date/Time (DTM) 02320

Definition: The shipment status date/time carries the date and time the status in *SHP-3 Shipment Status* occurred.

7.16.2.5 SHP-5 Shipment Status Reason (TX) 02321

Definition: The shipment status reason is used to document the reason for the status in *SHP-3 Shipment Status*. This reason field is of particular importance when a shipment is rejected.

7.16.2.6 SHP-6 Shipment Priority (CWE) 02322

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: The shipment priority documents the priority the shipment has been given by the sender. Refer to *HL7 Table 0906 - ActPriority* for specific values.

7.16.2.7 SHP-7 Shipment Confidentiality (CWE) 02323

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: The shipment confidentiality documents any confidentiality that may be associated with this particular shipment. Refer to *HL7 Table 0907 – Confidentiality* for specific values.

7.16.2.8 SHP-8 Number of Packages in Shipment (NM) 02324

Definition: The number of packages in shipment field documents the total number of separate packages that are contained in the shipment. This total should not include packages that are nested inside of one another. For instance if a shipment consisted of 3 separate boxes, this field would contain the value

"…|3|…".

7.16.2.9 SHP-9 Shipment Condition (CWE) 02325

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: The shipment condition field allows the receiver of the shipment to document the condition of the shipment when it was received. Refer to *HL7 Table 0544 – Container Condition* for suggested values. Many of the values found in Table 0544 are associated with values found in Table 0376 (Special Handling Codes). Values from Table 0376 have had an X placed in front of them, and the meaning of the code has been changed to indicate that the type of handling has failed during shipment. For instance if a handling code indicated that the shipment was to be kept at body temperature (C37), and the shipment arrived at some other temperature, the XC37 condition code would be used to indicate the shipment arrived with a temperature outside the range indicated by the handling code.

7.16.2.10 SHP-10 Shipment Handling Code (CWE) 02326

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This describes how the shipment needs to be handled during transport. Refer to *User-defined Table 0376 – Special Handling Code* for suggested values.

7.16.2.11 SHP-11 Shipment Risk Code (CWE) 02327

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field contains any known or suspected hazards associated with this shipment, e.g., exceptionally infectious agent or blood from a hepatitis patient. Refer to *User-defined Table 0489 – Risk Codes* for suggested values.

7.16.2.12 SHP-12 Action Code (ID) 00816

Definition: This field reveals the intent of the message. Refer to *HL7 Table 0206 - Segment Action Code* for valid values.

The action code can only be used when SHP-1 is valued in accordance with the guidance in Chapter 2, Section 2.10.4.2.

7.16.3 PAC – Shipment Package Segment

The intent of this segment is to describe the information associated with the shipping package specimens are sent in.

HL7 Attribute Table – PAC – Shipment Package

SEQ	LEN	C.LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
1	1..4		SI	R	N		02350	Set Id – PAC
2			EI	C	N		02351	Package ID
3			EI	O	N		02352	Parent Package ID
4			NA	O	N		02353	Position in Parent Package
5			CWE	R	N	0908	02354	Package Type
6			CWE	O	Y	0544	02355	Package Condition
7			CWE	O	Y	0376	02356	Package Handling Code
8			CWE	O	Y	0489	02357	Package Risk Code
9	2..2		ID	O		0206	00816	Action Code

7.16.3.0 PAC Field Definitions

7.16.3.1 PAC-1 Set Id – PAC (SI) 02350

Definition: This field contains the sequence number. This field is used to identify PAC segment instances in message structures where the PAC segment repeats

7.16.3.2 PAC-2 Package ID (EI) 02351

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: The Package ID uniquely identifies this package from all other packages within its shipment.

Condition: If *SHP-8 Number of Packages in Shipment* is greater then 1, then Package ID must be valued.

7.16.3.3 PAC-3 Parent Package ID (EI) 02352

```
Components:  <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^
             <Universal ID Type (ID)>
```

Definition: The parent package id identifies the package which contains this package. This is used to link a nested set of packages. For instance a shipping container may itself contain several smaller packages. These contained packages would identify the shipping container as their parent package. Multiple layers of nested packaging can be documented in this fashion.

7.16.3.4 PAC-4 Position in Parent Package (NA) 02353

```
Components:  <Value1 (NM)> ^ <Value2 (NM)> ^ <Value3 (NM)> ^ <Value4 (NM)> ^ < ()>
```

Definition: The position in parent package field is used when it is important to communicate specifically where in the parent package this package resides. Each position is identified with a position number. The NA (numeric array) data type is used to allow, if necessary, to transfer multiple axis information, e.g., 2-dimensional tray (X^Y).

7.16.3.5 PAC-5 Package Type (CWE) 02354

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: The package type field identifies the type of container. See *User-defined Table 0908 – Package Type* for values.

7.16.3.6 PAC-6 Package Condition (CWE) 02355

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: The package condition field describes the condition of the package at the time of the message. Refer to *HL7 Table 0544 – Container Condition* for suggested values.

7.16.3.7 PAC-7 Package Handling Code (CWE) 02356

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This describes how the package needs to be handled during transport. Refer to *User-defined Table 0376 – Special Handling Code* for suggested values.

7.16.3.8 PAC-8 Package Risk Code (CWE) 02357

```
Components:  <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^
             <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate
             Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding
             System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate
             Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second
             Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID
             (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set
             Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value
             Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate
             Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second
             Alternate Value Set Version ID (DTM)>
```

Definition: This field contains any known or suspected hazards associated with this package, e.g., exceptionally infectious agent or blood from a hepatitis patient. Refer to *User-defined Table 0489 – Risk Codes* for suggested values.

7.16.3.9 PAC-9 Action Code (ID) 00816

Definition: This field reveals the intent of the message. Refer to *HL7 Table 0206 - Segment Action Code* for valid values.

The action code can only be used when PAC-2 is valued in accordance with the guidance in Chapter 2, Section 2.10.4.2.

7.17 TABLES LISTINGS

7.17.1 Common ISO Derived Units & ISO+ Extensions

Figure 7-10. Common ISO derived units and ISO+ extensions

Code/Abbr.	Name
/(arb_u)	*1 / arbitrary unit
/iu	*1 / international unit
/kg	*1 / kilogram
/L	1 / liter
1/mL	*1 / milliliter
10.L/min	*10 x liter / minute
10.L /(min.m2)	*10 x (liter / minute) / meter^2 = liter / (minute × meter^2)
10*3/mm3	*10^3 / cubic millimeter (e.g., white blood cell count)
10*3/L	*10^3 / Liter
10*3/mL	*10^3 / milliliter
10*6/mm3	*10^6 / millimeter^3
10*6/L	*10^6 / Liter
10*6/mL	*10^6 / milliliter
10*9/mm3	*10^9 / millimeter^3
10*9/L	*10^9 / Liter
10*9/mL	*10^9 / milliliter
10*12/L	*10^{12} / Liter
10*3(rbc)	*1000 red blood cells†
a/m	Ampere per meter
(arb_u)	*Arbitrary unit
bar	Bar (pressure; 1 bar = 100 kilopascals)
/min	Beats or Other Events Per Minute
bq	Becquerel
(bdsk_u)	*Bodansky Units
(bsa)	*Body surface area
(cal)	*Calorie
1	*Catalytic Fraction

Code/Abbr.	Name
/L	Cells / Liter
cm	Centimeter
cm_h20	* Centimeters of water =H_20 (pressure)
cm_h20.s/L	Centimeters H_20 / (liter / second) = (centimeters H_20 × second) / liter (e.g., mean pulmonary resistance)
cm_h20/(s.m)	(Centimeters H_20 / second) / meter = centimeters H_20 / (second × meter) (e.g., pulmonary pressure time product)
(cfu)	*Colony Forming Units
m3/s	Cubic meter per second
d	Day
db	Decibels
dba	*Decibels a Scale
cel	Degrees Celsius
deg	Degrees of Angle
(drop)	Drop
10.un.s/cm5	Dyne × Second / centimeter^5 (1 dyne = 10 micronewton = 10 un) (e.g., systemic vascular resistance)
10.un.s/(cm5.m2)	((Dyne × second) / centimeter^5) / meter^2 = (Dyne × second) / (centimeter^5 × meter^2) (1 dyne = 10 micronewton = 10 un) (e.g., systemic vascular resistance/body surface area)
ev	Electron volts (1 electron volt = 160.217 zeptojoules)
eq	Equivalent
f	Farad (capacitance)
fg	Femtogram
fL	Femtoliter
fmol	Femtomole
/mL	*Fibers / milliliter
g	Gram
g/d	*Gram / Day
g/dL	Gram / Deciliter
g/hr	Gram / Hour
g/(8.hr)	*Gram / 8 Hour Shift
g/kg	Gram / Kilogram (e.g., mass dose of medication per body weight)
g/(kg.d)	(Gram / Kilogram) / Day = gram / (kilogram × day) (e.g., mass dose of medication per body weight per day)
g/(kg.hr)	(Gram / Kilogram) / Hour = gram / (kilogram × hour) (e.g., mass dose of medication per body weight per hour)
g/(8.kg.hr)	(Gram / Kilogram) /8 Hour Shift = gram / (kilogram × 8 hour shift) (e.g., mass dose of medication per body weight per 8 hour shift)
g/(kg.min)	(Gram / Kilogram) / Minute = gram / (kilogram × minute) (e.g., mass dose of medication per body weight per minute)
g/L	Gram / Liter
g/m2	Gram / Meter^2 (e.g., mass does of medication per body surface area)
g/min	Gram / Minute
g.m/(hb)	Gram × meter / heart beat (e.g., ventricular stroke work)
g.m/((hb).m2)	(Gram × meter/ heartbeat) / meter^2 = (gram × meter) / (heartbeat × meter^2) (e.g., ventricular stroke work/body surface area, ventricular stroke work index)
g(creat)	*Gram creatinine
g(hgb)	*Gram hemoglobin
g.m	Gram meter
g(tot_nit)	*Gram total nitrogen
g(tot_prot)	*Gram total protein
g(wet_tis)	*Gram wet weight tissue
gy	Grey (absorbed radiation dose)
hL	Hectaliter = 10^2 liter
h	Henry
in	Inches

Code/Abbr.	Name
in_hg	Inches of Mercury (=Hg)
iu	*International Unit
iu/d	*International Unit / Day
iu/hr	*International Unit / Hour
iu/kg	International Unit / Kilogram
iu/L	*International Unit / Liter
iu/mL	*International Unit / Milliliter
iu/min	*International Unit / Minute
j/L	Joule/liter (e.g., work of breathing)
kat	*Katal
kat/kg	*Katal / Kilogram
kat/L	*Katal / Liter
k/watt	Kelvin per watt
(kcal)	Kilocalorie (1 kcal = 6.693 kilojoule)
(kcal)/d	*Kilocalorie / Day
(kcal)/hr	*Kilocalorie / Hour
(kcal)/(8.hr)	*Kilocalorie / 8 Hours Shift
kg	Kilogram
kg(body_wt)	* kilogram body weight
kg/m3	Kilogram per cubic meter
kh/h	Kilogram per hour
kg/L	Kilogram / liter
kg/min	Kilogram per minute
kg/mol	Kilogram / mole
kg/s	Kilogram / second
kg/(s.m2)	(Kilogram / second)/ meter^2 = kilogram / (second $\times$ meter^2)
kg/ms	Kilogram per square meter
kg.m/s	Kilogram meter per second
kpa	Kilopascal (1 mmHg = 0.1333 kilopascals)
ks	Kilosecond
(ka_u)	King-Armstrong Unit
(knk_u)	*Kunkel Units
L	Liter
L/d	*Liter / Day
L/hr	Liter / hour
L/(8.hr)	*Liter / 8 hour shift
L/kg	Liter / kilogram
L/min	Liter / minute
L/(min.m2)	(Liter / minute) / meter^2 = liter / (minute $\times$ meter^2) (e.g., cardiac output/body surface area = cardiac index)
L/s	Liter / second (e.g., peak expiratory flow)
L.s	Liter / second / second^2 = liter $\times$ second
lm	Lumen
lm/m2	Lumen / Meter^2
(mclg_u)	*MacLagan Units
mas	Megasecond
m	Meter
m2	Meter^2 (e.g., body surface area)
m/s	Meter / Second
m/s2	Meter / Second^2
ueq	*Microequivalents
ug	Microgram
ug/d	Microgram / Day
ug/dL	Microgram / Deciliter
ug/g	Microgram / Gram

Code/Abbr.	Name
ug/hr	*Microgram / Hour
ug(8hr)	Microgram / 8 Hour Shift
ug/kg	Microgram / Kilogram
ug/(kg.d)	(Microgram / Kilogram) /Day = microgram / (kilogram × day) (e.g., mass dose of medication per patient body weight per day)
ug/(kg.hr)	(Microgram / Kilogram) / Hour = microgram / (kilogram × hours) (e.g., mass dose of medication per patient body weight per hour)
ug/(8.hr.kg)	(Microgram / Kilogram) / 8 hour shift = microgram / (kilogram × 8 hour shift) (e.g., mass dose of medication per patient body weight per 8 hour shift)
ug/(kg.min)	(Microgram / Kilogram) / Minute = microgram / (kilogram × minute) (e.g., mass dose of medication per patient body weight per minute)
ug/L	Microgram / Liter
ug/m2	Microgram / Meter^2 (e.g., mass dose of medication per patient body surface area)
ug/min	Microgram / Minute
uiu	*Micro international unit
ukat	*Microkatel
um	Micrometer (Micron)
umol	Micromole
umol/d	Micromole / Day
umol/L	Micromole / Liter
umol/min	Micromole / Minute
us	Microsecond
uv	Microvolt
mbar	Millibar (1 millibar = 100 pascals)
mbar.s/L	Millibar / (liter / second) =(millibar × second) / liter (e.g., expiratory resistance)
meq	*Milliequivalent
meq/d	*Milliequivalent / Day
meq/hr	*Milliequivalent / Hour
meq/(8.hr)	Milliequivalent / 8 Hour Shift
meq/kg	Milliequivalent / Kilogram (e.g., dose of medication in milliequivalents per patient body weight)
meq/(kg.d)	(Milliequivalents / Kilogram) / Day = milliequivalents / (kilogram × day) (e.g., dose of medication in milliequivalents per patient body weight per day)
meq/(kg.hr)	(Milliequivalents / Kilogram) / Hour = milliequivalents / (kilogram × hour) (e.g., dose of medication in milliequivalents per patient body weight per hour)
meq/(8.hr.kg)	(Milliequivalents / Kilogram) / 8 Hour Shift = milliequivalents / (kilogram × 8 hour shift) (e.g., dose of medication in milliequivalents per patient body weight per 8 hour shift)
meq/(kg.min)	(Milliequivalents / Kilogram) / Minute = milliequivalents / (kilogram × minute) (e.g., dose of medication in milliequivalents per patient body weight per minute)
meq/L	Milliequivalent / Liter
	Milliequivalent / Meter^2 (e.g., dose of medication in milliequivalents per patient body surface area)
meq/min	Milliequivalent / Minute
mg	Milligram
mg/m3	Milligram / Meter^3
mg/d	Milligram / Day
mg/dL	Milligram / Deciliter
mg/hr	Milligram / Hour
mg/(8.hr)	Milligram / 8 Hour shift
mg/kg	Milligram / Kilogram
mg/(kg.d)	(Milligram / Kilogram) / Day = milligram / (kilogram × day) (e.g., mass dose of medication per patient body weight per day)
mg/(kg.hr)	(Milligram / Kilogram) / Hour = milligram/ (kilogram × hour) (e.g., mass dose of medication per patient body weight per hour)
mg/(8.hr.kg)	(Milligram / Kilogram) /8 Hour Shift = milligram / (kilogram × 8 hour shift) (e.g., mass dose of medication per patient body weight per 8 hour shift)

Code/Abbr.	Name
mg/(kg.min)	(Milligram / Kilogram) / Minute = milligram / (kilogram × minute) (e.g., mass dose of medication per patient body weight per hour)
mg/L	Milligram / Liter
mg/m2	Milligram / Meter^2 (e.g., mass dose of medication per patient body surface area)
mg/min	Milligram / Minute
mL	Milliliter
mL/cm_h20	Milliliter / Centimeters of Water (H_20) (e.g., dynamic lung compliance)
mL/d	*Milliliter / Day
mL/(hb)	Milliliter / Heart Beat (e.g., stroke volume)
mL/((hb).m2)	(Milliliter / Heart Beat) / Meter^2 = Milliliter / (Heart Beat × Meter^2) (e.g., ventricular stroke volume index)
mL/hr	*Milliliter / Hour
mL/(8.hr)	*Milliliter / 8 Hour Shift
mL/kg	Milliliter / Kilogram (e.g., volume dose of medication or treatment per patient body weight)
mL/(kg.d)	(Milliliter / Kilogram) / Day = milliliter / (kilogram × day) (e.g., volume dose of medication or treatment per patient body weight per day)
mL/(kg.hr)	(Milliliter / Kilogram) / Hour = milliliter / (kilogram × hour) (e.g., volume dose of medication or treatment per patient body weight per hour)
mL/(8.hr.kg)	(Milliliter / Kilogram) / 8 Hour Shift = milliliter / (kilogram × 8 hour shift) (e.g., volume dose of medication or treatment per body weight per 8 hour shift)
mL/(kg.min)	(Milliliter / Kilogram) / Minute = milliliter / (kilogram × minute) (e.g., volume dose of medication or treatment per patient body weight per minute)
mL/m2	Milliliter / Meter^2 (e.g., volume of medication or other treatment per patient body surface area)
mL/mbar	Milliliter / Millibar (e.g., dynamic lung compliance)
mL/min	Milliliter / Minute
mL/(min.m2)	(Milliliter / Minute) / Meter^2 = milliliter / (minute × meter^2) (e.g., milliliters of prescribed infusion per body surface area; oxygen consumption index)
mL/s	Milliliter / Second
mm	Millimeter
mm(hg)	*Millimeter (HG) (1 mm Hg = 133.322 kilopascals)
mm/hr	Millimeter/ Hour
mmol/kg	Millimole / Kilogram (e.g., molar dose of medication per patient body weight)
mmol/(kg.d)	(Millimole / Kilogram) / Day = millimole / (kilogram × day) (e.g., molar dose of medication per patient body weight per day)
mmol/(kg.hr)	(Millimole / Kilogram) / Hour = millimole / (kilogram × hour) (e.g., molar dose of medication per patient body weight per hour)
mmol/(8.hr.kg)	(Millimole / Kilogram) / 8 Hour Shift = millimole / (kilogram × 8 hour shift) (e.g., molar dose of medication per patient body weight per 8 hour shift)
mmol/(kg.min)	(Millimole / Kilogram) / Minute = millimole / (kilogram × minute) (e.g., molar dose of medication per patient body weight per minute)
mmol/L	Millimole / Liter
mmol/hr	Millimole / Hour
mmol/(8hr)	Millimole / 8 Hour Shift
mmol/min	Millimole / Minute
mmol/m2	Millimole / Meter^2 (e.g., molar dose of medication per patient body surface area)
mosm/L	*Milliosmole / Liter
ms	Milliseconds
mv	Millivolts
miu/mL	*Milliunit / Milliliter
mol/m3	Mole per cubic meter
mol/kg	Mole / Kilogram
mol/(kg.s)	(Mole / Kilogram) / Second = mole / (kilogram × second)
mol/L	Mole / Liter
mol/s	Mole / Second
ng	Nanogram

Code/Abbr.	Name
ng/d	Nanogram / Day
ng/hr	*Nanogram / Hour
ng/(8.hr)	Nanogram / 8 Hour shift
ng/L	Nanogram / Liter
ng/kg	Nanogram / Kilogram (e.g., mass dose of medication per patient body weight)
ng/(kg.d)	(Nanogram / Kilogram) / Day = nanogram / (kilogram × day) (e.g., mass dose of medication per patient body weight per day)
ng/(kg.hr)	(Nanogram / Kilogram) / Hour = nanogram / (kilogram × hour) (e.g., mass dose of medication per patient body weight per hour)
ng/(8.hr.kg)	(Nanogram / Kilogram) / 8 Hour Shift = nanogram / (kilogram × 8 hour shift) (e.g., mass dose of medication per patient body weight per 8 hour shift)
ng/(kg.min)	(Nanogram / Kilogram) / Minute = nanogram / (kilogram × minute) (e.g., mass dose of medication per patient body weight per minute)
ng/m2	Nanogram / Meter^2 (e.g., mass dose of medication per patient body surface area)
ng/mL	Nanogram / Milliliter
ng/min	*Nanogram / Minute
ng/s	*Nanogram / Second
nkat	*Nanokatel
nm	Nanometer
nmol/s	Nanomole / Second
ns	Nanosecond
n	Newton (force)
n.s	Newton second
(od)	*O.D. (optical density)
ohm	Ohm (electrical resistance)
ohm.m	Ohm meter
osmol	Osmole
osmol/kg	Osmole per kilogram
osmol/L	Osmole per liter
/m3	*Particles / Meter^3
/L	*Particles / Liter
/(tot)	*Particles / Total Count
(ppb)	*Parts Per Billion
(ppm)	*Parts Per Million
(ppth)	Parts per thousand
(ppt)	Parts per trillion (10^12)
pal	Pascal (pressure)
/(hpf)	*Per High Power Field
(ph)	*pH
pa	Picoampere
pg	Picogram
pg/L	Picogram / Liter
pg/mL	Picogram / Milliliter
pkat	*Picokatel
pm	Picometer
pmol	*Picomole
ps	Picosecond
pt	Picotesla
(pu)	*P.U.
%	Percent
dm2/s2	Rem (roentgen equivalent man) = 10^{-2} meter^2 / second^2 = decimeter^2 / second^2 Dose of ionizing radiation equivalent to 1 rad of x-ray or gamma ray) [From Dorland's Medical Dictionary]
sec	Seconds of arc
sie	Siemens (electrical conductance)
sv	Sievert

Code/Abbr.	Name
m2/s	Square meter / second
cm2/s	Square centimeter / second
t	Tesla (magnetic flux density)
(td_u)	Todd Unit
v	Volt (electric potential difference)
1	Volume Fraction
wb	Weber (magnetic flux)
*Starred items are not genuine ISO, but do not conflict. †This approach to units is discouraged by IUPAC. We leave them solely for backward compatibility	

7.17.2 External Units of Measure Examples

Figure 7-11. ISO single case units abbreviations

Units	Abbreviation	Units	Abbreviation	Units	Abbreviation
Base units code/abbreviations					
Ampere	a	kelvin	K	meter	m
Candela	cd	Kilogram	Kg	mole	mol
				second	s
Derived units with specified name and abbreviation					
coulomb	c	hour	Hr	pascal	pal
day	d	joule	J	volt	v
degree Celsius	cel	minute (ti)	Min	watt	w
farad	f	newton	N	weber	wb
hertz	hz	ohm	Ohm	year	ann
Other units					
atomic mass unit	u	grey	gy	minute of arc	mnt
Bel	b	henry	h	radian	rad
Decibel	db	liter	l	siemens	sie
Degree	deg	lumen	Lm	steradian	sr
Gram	g	lux	Lx	tesla	t
See ISO 2955-1983 for full set					

Figure 7-12. ANSI+ unit codes for some U.S. customary units

Units	Abbreviation	Units	Abbreviation	Units	Abbreviation
LENGTH		VOLUME		TIME	
Inch	In	cubic foot	Cft	Year	yr
Foot	Ft	cubic inch	Cin	Month	mo
Mile (statute)	Mi	cubic yard	Cyd	Week	wk
nautical mile	Nmi	tablespoon	Tbs	Day	d
Rod	Rod	teaspoon	Tsp	Hour	hr
Yard	Yd	pint	Pt	minute	min
		quart	Qt	second	sec
		gallon	Gal		
		ounce (fluid)	Foz		
AREA		MASS			
square foot	Sqf	dram	Dr		
square inch	Sin	grain	gr (avoir)		
square yard	Syd	ounce (weight)	Oz		
		pound	Lb		
Other ANSI units, derived units, and miscellaneous					
**British thermal unit	Btu	**degrees Fahrenheit	Degf	**millirad	mrad
cubic feet/minute	cft/min	**feet/minute	ft/min	**RAD	rad
Note: The abbreviations for conventional U.S. units of time are the same as ISO, except for year. ISO = ANN,					

AMSI = yr. The metric units in X3.50 are the same as ISO, except for: pascal ("pa" in ANSI, "pal" in ISO); ANSI uses "min" for both time and arc while ISO uses "mnt" for minutes of arc; and in ISA seconds are abbreviated "s", in ANSI, "sec".
Caution: Because the ANS+ specification includes both ISO and US customary units, as well as miscellaneous non-metric units, some of the abbreviations are ambiguous. Although there should be little confusion, in the context of a particular observation, this ambiguity is a good reason for a voiding ANS+ unit codes when possible.
This list is not exhaustive. Refer to ANSI X3.50-1986, Table 1, for other metric and standard U.S. units.
**Non-metric units not explicitly listed in ANSI

The ISO abbreviations for multiplier prefixes are given in Figure 7-13. Prefixes ranging from 10^{-24} (1/billion billionth) to 10^{24} (a billion billion) are available. The single case abbreviation for kilo (x1000) is **k**. A unit consisting of 1000 seconds would be abbreviated as **ks**, 1000 grams as **kg**, 1000 meters as **km**, and so on. Some prefixes share the abbreviation of a base unit. Farad and femto, for example, (10^{-18}) both have the abbreviation of **f**. To avoid confusion, ISO forbids the use of solitary prefixes. It also deprecates the use of two prefixes in one complex unit. Thus, **f** always means farad, **ff** would mean 1 million billionth of a farad. Compound prefixes are not allowed.

A unit can be raised to an exponential power. Positive exponents are represented by a number immediately following a unit's abbreviation, i.e., a square meter would be denoted by m2. Negative exponents are signified by a negative number following the base unit, e.g., **1/m2** would be represented **as m-2.** Fractional exponents are expressed by a numeric fraction in parentheses: the square root of a meter would be expressed as m(1/2). The multiplication of units is signified by a period (.) between the units, e.g., meters X seconds would be denoted **m.s**. Notice that spaces are not permitted. Division is signified by a slash (/) between two units, e.g. meters per second would be denoted as **m/s**. Algebraic combinations of ISO unit abbreviations constructed by dividing, multiplying, or exponentiating base ISO units, are also valid ISO abbreviations units. Exponentiation has precedence over multiplication or division. For example, microvolts squared per hertz (a unit of spectral power) would be denoted **uv2/hz** and evaluated as uv ^{2}/hz while microvolts per square root of hertz (a unit of spectral amplitude) would be denoted uv/hz(1/2) and evaluated as uv/hz^{½}. If more than one division operator is included in the expression the associations should be parenthesized to avoid any ambiguity, but the best approach is to convert a/(b/c) to a.c/b or a.c.b-1 to simplify the expression.

Figure 7-13. Single case ISO abbreviations for multiplier prefixes

Prefix		Code	Prefix		Code
yotta*	10^{24}	ya	yocto	10^{-24}	Y
zetta*	10^{21}	za	zepto	10^{-21}	Z
exa	10^{18}	ex	atto	10^{-18}	A
peta	10^{15}	pe	femto	10^{-15}	F
tera	10^{12}	t	pico	10^{-12}	p
giga	10^{9}	g	nano	10^{-9}	n
mega	10^{6}	ma	micro	10^{-6}	u
kilo	10^{3}	k	milli	10^{-3}	m
hecto	10^{2}	h	centi	10^{-2}	c
deca	10^{1}	da	deci	10^{-1}	d
*These abbreviations are not defined in the ISO specification for single case abbreviations.					

Figure 7-9 lists the abbreviations for common ISO derived units. It also includes standard unit abbreviations for common units, e.g., Milliequivalents, and international units, mm(Hg), and for counting per which we denote by a division sign, a denominator, but no numerator, e.g., /c, that are not part of the above referenced ISO standards. We have extended the units table to better accommodate drug routes and physiologic measures, and otherwise fill in gaps in v2.2.

We have generally followed the IUPAC 1995 Silver Book[2] in the definitions of units. However, IUPAC specifies standards for reporting or displaying units and employs 8-bit data sets to distinguish them. This Standard is concerned with the *transmission* of patient information. Therefore, we have restricted ourselves

to case insensitive alphabetic characters and a few special characters (e.g., ".", "/", "(", ")", "*", and "_") to avoid any possible confusion in the transmission. Therefore, we use ISO 2955-1983 (Information processing -- representation of SI and other units in systems with limited character sets) and ANSI X3.50-1986 (Representations for U.S. customary, SI, and other units to be used in systems with limited character sets) case insensitive units abbreviations where they are defined. This means that in some cases, IUPAC abbreviations have different abbreviations in ISO+ even when the IUPAC abbreviations use only standard alphabetic characters. For example, **Pascal** is abbreviated **Pa** in IUPAC but **PAL** in ISO+ (following ISO 2955) because **Pa** in a case insensitive context also means **Picoampere**. However, the requirements for transmission do not preclude usage of IUPAC standards for presentation on paper or video display reports to end-users.

All unit abbreviations are case insensitive. One could write milliliters as ML, ml, or mL. In this table we have used lower case for all of the abbreviations except for the letter **L** which we represent in upper case so that readers will not confuse it with the numeral one (1). This is just a change in presentation, not a change in the Standard. Systems should continue to send the codes as upper or lower case as they always have.

7.18 OUTSTANDING ISSUES

None.