7.

Observation Reporting

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7.1 INTRODUCTION AND OVERVIEW

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). However, the transaction set is not limited to such transactions. Observations can be sent from producing systems to archival medical record systems (not necessarily the order placer) and from such medical record 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 any kind of clinical observations including (but not limited to) clinical laboratory results, the results of imaging studies (excluding the image), EKG pulmonary function studies, measures of patient status and condition, vital signs, intake and output, severity and/or frequency of symptoms, drug allergies, problem lists, diagnostic lists, physician and nursing history, physicals, progress notes, operative notes and so on. These transaction sets carry information that is reported as text, numeric or categorical values. These messages do not carry the images themselves. (See ACR NEMA Publication 300-1988 *Digital Imaging and Communications Standard*, for image standards, and ASTM E1467.91 *Standard specification for transferring digital neurophysiological data between independent computer systems*, for transmitting EEG, EMG tracings).

An observation can be one of many data types. The main ones are text, numbers and codes. This provides the flexibility needed to transmit observations that are recorded as continuous values (e.g., glucose, diastolic blood pressure), as categorical values, e.g., patient position (sitting, reclining or standing), VDRL (reactive, weakly reactive or nonreactive), or as text. An entire History and Physical could be transmitted as an observation whose value is one large chunk of formatted text.

This chapter provides mechanisms for transmitting *structured*, record-oriented reports. This means that individual observations are transmitted as separate logical entities (objects), and within this entity, separate fields are defined for identifying the observation, its values, its units, normal ranges, etc., such that the receiving system can "understand," reorganize and/or react to the contents of these messages. Structured reports are to be distinguished from text-oriented reports which can also be transmitted via HL7 using the UDM message described in Chapter 2. The latter are ASCII images of nonstandard printed reports intended for display to humans. For practical purposes their contents are not understandable to the computer.

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 2 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 7.2, "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.

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 and SNOMED 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 CE code.

In past versions of the HL7 standard, Appendix A to Chapter 7 presented suggestions for constructing clinical codes from existing procedure code systems such as CPT4. Appendix A is now part of the Implementation Guide and contains LOINC codes for most laboratory tests and many common clinical variables (e.g., vital signs, intake and output, cardiovascular measurements and others). The most recent version of the LOINC database, which includes records for more than 7,000 observations and includes codes, names, synonyms and other attributes (such as the molecular weights of chemical moieties) for each observation, is available from the HL7 file server at **http://dumccss.mc.duke.edu/standards/termcode/loinclab/loinc.html**. The Implementation Guide provides construction rules for many variables that are not yet covered by LOINC. 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.

7.1.1 Glossary

7.1.1.1 **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*, Section 4.3.1.2, "Placer order number."

7.1.1.2 **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*, Section 4.3.1.3, "Filler order number."

7.1.1.3 **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.

7.1.1.4 **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 7.14, "WAVEFORM SUMMARY," and encapsulated data aggregates using the ED data type described in Section 2.8.14, "ED - encapsulated data," (which can represent actual images, audio data, etc.).

7.1.1.5 **segment (record):** a typed aggregate of fields (fields) describing one complete aspect of a message. For example, the information about one order is sent as type of segment (OBR), the information related to an observation is sent as another segment (OBX).

The segment in a message is analogous to a record in a database, and in previous versions of the Standard we used record in place of the word segment. We have changed the nomenclature to be consistent with HL7 and other standards organizations in this version.

7.1.1.6 **field:** one specific attribute of a segment, for example, patient diagnosis, which may contain aggregates of fields further refining the basic attribute.

7.1.1.7 **repeated value:** some fields may contain many repeat fields. For example, the diagnoses field may contain many different diagnoses.

7.1.1.8 **field components:** a field entry may also have discernible parts or components. For example, the patient's name is recorded as last name, first name, and middle initial, each of which is a distinct entity separated by a component delimiter (sub-subfield in ASTM E1238-94).

7.1.2 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.

We have defined code suffixes for constructing observation IDs for the common components of narrative reports (see *Figure 7-1*). The observation identifier for each such component is obtained by concatenating the observation battery ID (the ID in *OBR-4-universal service ID* of the preceding OBR from any coding system) with the appropriate suffix. The observation ID for a chest X-ray impression, for example, would be the chest X-ray observation ID (if CPT4, it would be 71020), a subcomponent delimiter, and the suffix, IMP, i.e., 71020&IMP.

This same combining rule applies to other coding systems including local and universal procedural codes (see Chapter 4). For example, if a local code for EKG was E793, and the locally agreed upon designation for that local code was EKG, the impression would be identified as E793&IMP^^99EKG.

Note:	The "99EKG" in the 3rd component is included to indicate a local code. The EKG's description, in this case, would be E793&GDT^^99EKG.

Although it is strongly discouraged, the sender and receiver may agree to allow the omission of the observation ID component of a result segment when it is the same as the observation ID of the preceding OBR. In this case, only the ampersand and the suffix would have to be sent, e.g., &IMP or &REC, in *OBX-3-observation identifier* of a result segment. The full code would be assumed as the test identifier (recorded in the order segment) plus the category identifier recorded in the observation segment.

Figure 7-1. Observation ID suffices

Coded Results	Suffix	Type
Diagnostic Impression	IMP	CE
Recommendation	REC	CE
Confirming Procedures	CNP	CE
Procedure Medication	MED	CE
Anatomic Site	ANT	CE
Device/Instrument	DEV	CE
Serial # Device/Instrument	SER	ST
Bulk Text Reports		
Gross Or General Description Of The Study	GDT	TX or FT
Microscopic Or Secondary Description	MDT	TX or FT
Technician's Comment	TCM	TX or FT
Addendum Note	ADT	TX or FT
Other		
Diagnosis Onset Date/Time	ITM	TS
Diagnosis Resolution Date/Time	RTM	TS
Comparison Study	CMS	CE
Comparison Date/Time	CMT	TS
Comparison Results	CMR	CE
Comparison Change	CMC	CE
Predicted Value	PRD	ST
Percent Predicted	PPR	ST
After Drug Observed	AFD	ST
Predicted Value After Drug	ADP	ST
Percent Predicted After Drug	APP	ST
Timing Information	TIM	TS
Channel Definition Data	CHN	CD
Waveform Digital Data	WAS	NA or MA
Waveform Annotation	ANO	CE

7.1.3 Suffixes for defining observation IDs for common components of narrative reports

The following subsections define each of the suffices except for the specialized waveform suffices, which are defined in Section 7.16, "WAVEFORM SPECIFIC OBSERVATION ID SUFFIXES."

7.1.3.1 Diagnostic impressions (IMP)

When the suffix is IMP (*OBX-3-observation identifier*), the result is a diagnosis or finding, stored as a CE data type. Multiple result segments with an IMP suffix can be used if there are multiple parts to the study and each have an associated diagnosis (for example, the awake and sleep portion of an EEG). Each of these would have a different observation sub-ID. Multiple result segments with an IMP suffix can also be used if there are separate diagnoses corresponding to separate anatomic sites; in this case, the site for each diagnosis (each result segment with an IMP suffix) must be specified by an immediately preceding result segment with a suffix of ANT (see Section 7.1.3.5, "Anatomic site (ANT)"), which also has the same observation sub-ID. When multiple distinct diagnostic impressions are being reported, for example, mitral valve prolapse and aortic stenosis, each distinct impression should be sent in a separate OBX segment.

More than one code may be included within one coded result segment, but only when such codes are modifiers of the principal impression, e.g., to report additional detail about the finding, not to report an entirely different finding. In this case, the *OBX-5-observation value* field may repeat, with each instance or repetition specifying one of the related coded impressions.

The coded data type for impressions does not mean that a reporting service must actually code all such impressions. The diagnostic impression can be sent as dictated text, but the text should be sent in the second component of the CE data type without a code to distinguish it from code, i.e. it should be preceded by a component delimiter, e.g., `^congestive heart failure`.

When multiple separate text impressions are being reported, they should be reported in separate OBX segments to indicate that they are distinct impressions.

7.1.3.2 Recommendations (REC)

When the suffix is REC (*OBX-3-observation identifier*), the value is a CE result, representing the reading physician's recommendations about repeat testing, follow up or therapy. For example, when an ambiguous lesion result is seen on a mammogram, the reading physician might recommend a repeat mammogram in six months, or a needle biopsy immediately. The recommended procedures are recorded as codes and/or text descriptions in the coded identifier structure.

If more than one follow up study is recommended, each such recommendation is sent in a separate REC.

7.1.3.3 Confirming procedure (CNP)

The confirming procedure OBX suffix identifies additional studies used to confirm the diagnosis reported in the IMP OBX. If, for example, electron microscopy was done to confirm a surgical pathology diagnosis, the identifier for electron microscopy *OBX-3-observation identifier* would be stored as the value field of an observation ID with a confirming procedure suffix. Confirming procedures are most important in surgical pathology reports. But they might also be used by services such as endoscopy, to record the fact that a biopsy, culture, etc., was taken during the procedure. If more than one confirming procedure was used, each is sent in a separate result segment with observation ID suffix CNP.

7.1.3.4 Procedure medication (MED)

A coded result segment with a suffix of MED (*OBX-3-observation identifier*) indicates that the segment contained information about medication given as part of the procedure -- contrast medication, medication intended to invoke a physiologic response (e.g., to be used in stress testing) or premedication. When patients receive more than one procedure medication, each medication should be reported in a separate OBX medication segment. If the transmitting system has codes available for medications, they would be recorded as the first component of *OBX-3-observation identifier*. The name and/or the dosages could be included in the second component of *OBX-5-observation value*.

A coded result segment with a suffix of MED (procedure medication) may also be used to define a medication administered during recording of digital waveform data or other extended diagnostic procedure, e.g., exercise test. These may be displayed by the receiving system overlaid with the other events reported. The procedure medication is assumed to pertain to and be associated with the data recorded at the time specified in *OBX-14-date/time of the observation*, of the OBX segment labeled with MED, when present.

7.1.3.5 Anatomic site (ANT)

Some diagnostic studies include observations about more than one anatomic site within one report. If, for example, a patient had an appendectomy incidental to gallbladder surgery, the pathologist's assessment of

both specimens would usually be included under a single specimen number in one report. Each distinct anatomic site would be reported as a separate OBX segment with a suffix of ANT (*OBX-3-observation identifier*). More than one coded anatomic location may be included within a single OBX segment only when such additional codes are used to construct an identity for a single site. In this case only, the *OBX-5-observation value* field may repeat, with each instance or repetition specifying one of the related locations. Each OBX segment with an ANT suffix could be followed by one or more OBX segments with an IMP or other suffix to transmit the diagnostic impression(s) associated with the anatomic site. These impressions or recommendations would be associated with a single anatomic site via a common observation ID.

7.1.3.6 Devices (DEV)

When required, the instrument or device which generated an observation can be transmitted as an additional result of the study. In this case, the suffix of *OBX-3-observation identifier* is DEV. Examples include: an automated instrument in the laboratory; an imaging device and model number in radiology; or an automatic blood pressure machine on the ward. The device is specified as a coded entry in anticipation that these identifiers could be specified as codes. Initially, we expect that most of the information about devices will be transmitted as text in the second component of the CE identifier.

7.1.3.7 Gross or general description (GDT)

The general description suffix identifies the description component of a diagnostic studies. In the case of anatomic pathology, it applies to the macroscopic (gross) description of the specimen. If the description consists of multiple paragraphs, the paragraphs should be separated by repeat delimiters so that the receiving computer can display them as paragraphs. It will not be necessary to include a description segment for a report when the impression segment says it all, e.g., for normal studies or studies such as EKG, whose reports are traditionally terse.

7.1.3.8 Secondary or microscopic description (MDT)

For most studies, a secondary description will not be needed. In the case of surgical pathology, however, the microscopic description is a separate part of the report. It describes the histology as seen through the microscope. The microscopic description will be sent in a segment with the suffix MDT in *OBX-3-observation identifier*. If the microscopic description consists of multiple paragraphs, the paragraphs should be separated by repeat delimiters so that the receiving computer can display them as paragraphs.

7.1.3.9 Technician comment (TCM)

This is free text stored in a result segment whose *OBX-3-observation identifier* has a suffix of TCM for technician comment. It is used to record information about technical performance of the procedure, usually recorded by the technician.

7.1.3.10 Addendum note (ADT)

Use to report information that is added as an addendum after the original dictation and sent as a separate labeled section of the report.

7.1.3.11 Diagnosis (problem) onset date-time (ITM)

Use to record the date-time that a problem was first perceived to exist.

7.1.3.12 Diagnosis (problem) resolution date-time (RTM)

Use to record the date-time that a problem became inactive, i.e., the problem was cured or remitted.

7.1.3.13 Comparison study (CMS)

When the reader of a diagnostic report compares the results for the current study with those of a previous study, this suffix allows them to report the nature of the comparison study as a separate result, i.e., an OBX segment with a segment whose observation ID has a suffix of CMS. Ordinarily, this would not be required because the observation ID in the other comparison OBX's would identify the test, if any of the other comparison values were transmitted.

7.1.3.14 Comparison date-time (CMT)

When the reader of a diagnostic procedure compares the current results with a previous study, this suffix allows them to report the date-time of the previous study (time optional) as a separate result within the current report.

7.1.3.15 Comparison results (CMR)

When the reader of a diagnostic procedure compares the current results with those of a previous study on the same patient, this suffix allows them to report the results (impression) of the previous study as a discrete result within the current report.

7.1.3.16 Comparison change (CMC)

When a diagnostic service reports a comparison between the current and a previous study, this suffix is used to report the degree of change (e.g., much worse, worse, minimal worsening, no change, slightly better, better, much better, returned to normal) as a separate result within the report.

In current dictation, information about comparison is usually contained in the descriptions of the study. The provision of the comparison suffixes listed above do not imply a *requirement* to send this information as separate components. The comparison variables are only meant to be enabling. When a system would like to transmit them as discrete report components, these suffixes give them the option.

7.1.3.17 Predicted (PRD)

When an observation has a predicted value as is the case for many spirometry tests, this suffix identifies the predicted observation as distinguished from the actual observation. The AS4 code for forced vital capacity is 94010.1 (see the HL7 Implementation Guide). The predicted forced vital capacity would be 94010.1&PRD.

7.1.3.18 Percent of predicted (PPR)

This is a computed observation `= (actual observation)/(predicted observation.` For forced vital capacity the percent predicted would be identified as 94010.1&PPR.

7.1.3.19 After drug observed (AFD)

An observation might be taken before and after a drug is given. This occurs especially in Spirometry. The predose observation is identified by the base ID. The post drug measure is identified by the AFD suffix. Using the AS4 base code for the forced vital capacity the post drug result would be identified by 94010.1&AFD.

7.1.3.20 Predicted value after drug (ADP)

The post drug predicted value is identified by the suffix, ADP. Following the pattern of the above example, it would be 94010.1&ADP.

7.1.3.21 Percent predicted after drug (APP)

The percent predicted after drug is identified by applying the suffix, APP to the base code -- 94010.1&APP if using the AS4 code for forced vital capacity.

7.1.3.22 Clinical observation codes

In previous version of HL7, AS4 codes[1] have been recommended for identifying clinical observations. The recently introduced LOINC codes (See *Figure 7-2* for full information) may be more useful to many users. Code system information, including LOINC, has been moved from Appendix 7A to the Implementation Guide.

7.1.4 Coding schemes

Various fields of data type CE which are used in segments defined both in the current chapter and other chapters, are used to transmit information about diagnoses, observation results, procedures, health outcomes, and drugs administered. *Figures 7-2* and *7-3* (which were located in Chapter 2 in previous versions) list some common coding schemes for these types of information. The values in the second column of the table would be used in component 3 (and optionally, component 6) of a CE field to identify the coding scheme used.

Figure 7-2. Diagnostic coding schemes (from ASTM 1238-94 Table 3)

Name	Code	Source
American College of Radiology finding codes	ACR	Index for Radiological Diagnosis Revised, 3rd Edition 1986, American College of Radiology, Reston, VA.
AS4 Neurophysiology Codes	AS4E	ASTM's diagnostic codes and test result coding/grading systems for clinical neurophysiology. See ASTM Specification E1467, Appendix 2.
CEN ECG diagnostic codes	CE	CEN PT007. A quite comprehensive set of ECG diagnostic codes (abbreviations) and descriptions published as a pre-standard by CEN TC251. Available from CEN TC251 secretariat, c/o Georges DeMoor, State University Hospital Gent, De Pintelaan 185-5K3, 9000 Gent, Belgium or Jos Willems, University of Gathuisberg, 49 Herestraat, 3000 Leuven, Belgium.
CLIP	CLP	Simon Leeming, Beth Israel Hospital, Boston MA. Codes for radiology reports.
EUCLIDES	E	Available from Euclides Foundation International nv, Excelsiorlaan 4A, B-1930 Zaventem, Belgium; Phone: 32 2 720 90 60.
Home Health Care	HHC	Home Health Care Classification System; Virginia Saba, EdD, RN; Geogetown University School of Nursing; Washington, DC.
ICD9	I9	World Health Publications, Albany, NY.
ICD9-CM	I9C	Commission on Professional and Hospital Activities, 1968 Green Rd., Ann Arbor, MI 48105.
ICD-10	I10	World Health Publications, Albany, NY.
International Classification of Diseases for Oncology	ICDO	International Classification of Diseases for Oncology, 2nd Edition. World Health Organization: Geneva, Switzerland, 1990. Order from: College of American Pathologists, 325 Waukegan Road, Northfield, IL, 60093-2750. (847) 446-8800.
International Classification of Sleep Disorders	ICSD	International Classification of Sleep Disorders Diagnostic and Coding Manual, 1990, available from American Sleep Disorders Association, 604 Second Street SW, Rochester, MN 55902
Local general code	99zzz or L	Locally defined codes for purpose of sender or receiver. Local codes can be identified by L (for backward compatibility) or 99zzz (where z is an alphanumeric character).
Local billing code	LB	Local billing codes/names (with extensions if needed).
Omaha	OHA	Omaha Visiting Nurse Association, Omaha, NB.

1. These AS4 codes are taken directly from ASTM 1238-91, and are printed/adopted with their permission.

Name	Code	Source
NANDA	NDA	North American Nursing Diagnosis Association, Philadelphia, PA.
Read Classification	RC	The Read Clinical Classification of Medicine, Park View Surgery, 26 Leicester Rd., Loughborough LE11 2AG (includes drug procedure and other codes, as well as diagnostic codes).
Systemized Nomenclature of Medicine (SNOMED)	SNM	Systemized Nomenclature of Medicine, 2nd Edition 1984 Vols 1, 2, College of American Pathologists, Skokie, IL.
SNOMED International	SNM3	SNOMED International, 1993 Vols 1-4, College of American Pathologists, Skokie, IL, 60077-1034..
SNOMED- DICOM Microglossary	SDM	College of American Pathologists, Skokie, IL, 60077-1034. (formerly designated as 99SDM).
Unified Medical Language	UML	National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894.

Figure 7-3. Procedure/observation/drug ID/health outcomes coding systems (From ASTM 1238-88 Table 5)

Coding System	Code	Source/Description
ASTM E1238/ E1467 Universal	AS4	American Society for Testing & Materials and CPT4 (see Appendix X1 of Specification E1238 and Appendix X2 of Specification E1467).
American Type Culture Collection	ATC	Reference cultures (microorganisms, tissue cultures, etc.), related biological materials and associated data. American Type Culture Collection, 12301 Parklawn Dr, Rockville MD, 20852. (301) 881-2600. http://www.atcc.org
CPT-4	C4	American Medical Association, P.O. Box 10946, Chicago IL 60610.
CPT-5	C5	(under development - same contact as above)
CDC Surveillance	CDS	CDC Surveillance Codes. For data unique to specific public health surveillance requirements. Epidemiology Program Office, Centers for Disease Control and Prevention, 1600 Clifton Rd, Atlanta, GA, 30333. (404) 639-3661.
DICOM Class Label	DCL	From the Message Standards Classes table of the SNOMED-DICOM-Microglossary. College of American Pathologists, Skokie, IL, 60077-1034
DICOM modality codes	DCM	Dean Bidgood, MD; Duke University Medical Center, Durham NC. Digital Imaging and Communications in Medicine (DICOM) From NEMA Publications PS-3.1 - PS 3.12: The ACR-NEMA DICOM Standard. National Electrical Manufacturers Association (NEMA). Rosslyn, VA, 22209., 1992, 1993, 1995
DICOM Query Label	DQL	HL7 Image Management Special Interest Group, Health Level Seven, Ann Arbor, MI.
Enzyme Codes	ENZC	Enzyme Committee of the International Union of Biochemistry and Molecular Biology. Enzyme Nomenclature: Recommendations on the Nomenclature and Classification of Enzyme-Catalysed Reactions. London: Academic Press, 1992.
EUCLIDES	E	AFP codes. Available from Euclides Foundation International nv, Excelsiorlaan 4A, B-1930 Zaventem, Belgium; Phone: 32 2 720 90 60.
FDA K10	FDK	Dept. of Health & Human Services, Food & Drug Administration, Rockville, MD 20857. (device & analyte process codes).
HCFA Procedure Codes	HPC	Under development as replacement for ICD9 procedure codes. Due out 1997-1998.
UPIN	UPIN	Medicare/HCFA's universal physician identification numbers, available from Health Care Financing Administration, U.S. Dept. of Health and Human Services, Bureau of Program Operations, 6325 Security Blvd., Meadows East Bldg., Room 300, Baltimore, MD 21207
Health Outcomes	HI	Health Outcomes Institute codes for outcome variables available (with responses) from Stratis Health (formerly Foundation for Health Care Evaluation and Health Outcomes Institute), 2901 Metro Drive, Suite 400, Bloomington, MN, 55425-1525; (612) 854-3306 (voice); (612) 853-8503 (fax); dziegen@winternet.com. See examples in the Implementation Guide.
HIBCC	HB	Health Industry Business Communications Council, 5110 N. 40th St., Ste 120, Phoenix, AZ 85018.
Home Health Care	HHC	Home Health Care Classification System; Virginia Saba, EdD, RN; Georgetown University School of Nursing; Washington, DC.
Logical Observation Identifier Names and Codes (LOINC)	LN	Regenstrief Institute, c/o Kathy Hutchins, 1001 West 10th Street RG-5, Indianapolis, IN 46202. 317/630-7433. Also available via HL7 file server: FTP/Gopher (www.mcis.duke.edu/ standards/ termcode/loinclab and www.mcis.duke.edu/standards/termcode/loinclin) and World Wide Web (http:// www.mcis.duke.edu/ standards/termcode/ loincl.htm). January 1997version has

Coding System	Code	Source/Description
		identifiers, synonyms and cross-reference codes for reporting over 8,500 laboratory and related observations and 1,500 clinical measures.
ICCS	ICS	Commission on Professional and Hospital Activities, 1968 Green Road, Ann Arbor, MI 48105.
ICD-9CM	I9C	Commission on Professional and Hospital Activities, 1968 Green Road, Ann Arbor, MI 48105 (includes all procedures and diagnostic tests).
ICHPPC-2	IC2	International Classification of Health Problems in Primary Care, Classification Committee of World Organization of National Colleges, Academies and Academic Associations of General Practitioners (WONCA), 3rd edition. An adaptation of ICD9 intended for use in General Medicine, Oxford University Press.
ISBT	IBT	International Society of Blood Transfusion. Blood Group Terminology 1990. VOX Sanquines 1990 58(2):152-169.
IUPAC/IFCC Property Codes	IUC IUPP	International Union of Pure and Applied Chemistry/International Federation of Clinical Chemistry. The Silver Book: Compendium of terminology and nomenclature of properties in clinical laboratory sciences. Oxford: Blackwell Scientific Publishers, 1995. Henrik Olesen, M.D., D.M.Sc., Chairperson, Department of Clinical Chemistry, KK76.4.2, Rigshospitalet, University Hospital of Copenhagen, DK-2200, Copenhagen. http://inet.uni-c.dk/~qukb7642/
IUPAC/IFCC Component Codes	IUPC	Codes used by IUPAC/IFF to identify the component (analyte) measured. Contact Henrik Olesen, as above for IUPP.
Japanese Chemistry	JC8	Clinical examination classification code. Japan Association of Clinical Pathology. Version 8, 1990. A multiaxial code including a subject code (e.g., Rubella = 5f395, identification code (e.g., virus ab IGG), a specimen code (e.g., serum =023) and a method code (e.g., ELISA = 022)
Local	99zzz or L	Locally defined codes for purpose of sender or receiver. If multiple local codes exist, the format should be 99zzz, where z is an alphanumeric character.
Medicare	MCR	Medicare billing codes/names.
Medicaid	MCD	Medicaid billing codes/names.
Nursing Interventions Classification	NIC	Iowa Intervention Project, College of Nursing, University of Iowa, Iowa City, Iowa
National Provider Identifier	NPI	Health Care Finance Administration, US Dep't. of Health and Human Services, 7500 Security Blcd., Baltimore, MD 21244.
Omaha System	OHA	Omaha Visiting Nurse Association, Omaha, NB.
UCDS	UC	Uniform Clinical Data Systems. Ms. Michael McMullan, Office of Peer Review Health Care Finance Administration, The Meadows East Bldg., 6325 Security Blvd., Baltimore, MD 21207; (301) 966 6851.
Universal Product Code	UPC	The Uniform Code Council. 8163 Old Yankee Road, Suite J, Dayton, OH 45458; (513) 435 3070
Euclides Lab method codes	E6	Available from Euclides Foundation International nv, Excelsiorlaan 4A, B-1930 Zaventem, Belgium; Phone: 32 2 720 90 60.
Euclides Lab equipment codes	E7	Available from Euclides Foundation International nv (see above)
SNOMED topology codes (anatomic sites)	SNT	College of American Pathologists, 5202 Old Orchard Road, Skokie, IL 60077-1034.
Euclides quantity codes	E5	Available from Euclides Foundation International nv (see above)
Drug codes:		
CDC Vaccine Codes	CVX	National Immunization Program, Centers for Disease Control and Prevention, 1660 Clifton Road, Atlanta, GA, 30333
CDC Vaccine Manufacturer Codes	MVX	As above, for CVX
CDC Methods/Instruments Codes	CDCM	Public Health Practice Program Office, Centers for Disease Control and Prevention, 4770 Buford Highway, Atlanta, GA, 30421. Also available via FTP: ftp.cdc.gov/pub/laboratory_info/CLIA and Gopher: gopher.cdc.gov:70/11/laboratory_info/CLIA
CDC Analyte Codes	CDCA	As above, for CDCM
First DataBank Drug Codes	FDDC	National Drug Data File. Proprietary product of First DataBank, Inc. (800) 633-3453, or http://www.firstdatabank.com.
First DataBank Diagnostic Codes	FDDX	Used for drug-diagnosis interaction checking. Proprietary product of First DataBank, Inc. As above for FDDC.
Medispan GPI	MGPI	Medispan hHierarchical drug codes for identifying drugs down to manufacturer and pill size. Proprietary product of MediSpan, Inc.l 8425 Woodfield Crossing Boulevard,

Coding System	Code	Source/Description
		Indianapolis, IN 46240. Tel: (800)428-4495.
Medispan Diagnostic Codes	MDDX	Codes Used for drug-diagnosis interaction checking. Proprietary product. Hierarchical drug codes for identifying drugs down to manufacturer and pill size. MediSpan, Inc.l 8425 Woodfield Crossing Boulevard, Indianapolis, IN 46240. Tel: (800)428-4495. WWW: http://www.espan.com/medispan/pages/ medhome.html As above for MGPI.
Medical Economics Drug Codes	MEDC	Proprietary Codes for identifying drugs. Proprietary product of Medical Economics Data, Inc. (800) 223-0581.
Medical Economics Diagnostic Codes	MEDX	Used for drug-diagnosis interaction checking. Proprietary product of Medical Economics Data, Inc. (800) 223-0581.
Chemical abstract codes	CAS	These include unique codes for each unique chemical, including all generic drugs. The codes do not distinguish among different dosing forms. When multiple equivalent CAS numbers exist, use the first one listed in USAN. USAN 1990 and the USP dictionary of drug names, William M. Heller, Ph.D., Executive Editor, United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.
National drug codes	NDC	These provide unique codes for each distinct drug, dosing form, manufacturer, and packaging. (Available from the National Drug Code Directory, FDA, Rockville, MD, and other sources.)
COSTART	CST	International coding system for adverse drug reactions. In the USA, maintained by the FDA, Rockville, MD.
Medical Dictionary for Drug Regulatory Affairs (MEDDRA)	MEDR	Dr. Louise Wood, Medicines Control Agency, Market Towers, 1 Nine Elms Lane, London SW85NQ, UK Tel: (44)0 171-273-0000 WWW: http://www.open.gov.uk/mca/mcahome.htm
WHO rec# drug codes	W1, W2	World Health organization record number code. A unique sequential number is assigned to each unique single component drug and to each multi-component drug. Eight digits are allotted to each such code, six to identify the active agent, and 2 to identify the salt, of single content drugs. Six digits are assigned to each unique combination of drugs in a dispensing unit. The six digit code is identified by W1, the 8 digit code by W2.
WHO rec# code with ASTM extension	W4	With ASTM extensions (see Implementation Guide), the WHO codes can be used to report serum (and other) levels, patient compliance with drug usage instructions, average daily doses and more (see Appendix X1 the Implementation Guide).
WHO ATC	WC	WHO's ATC codes provide a hierarchical classification of drugs by therapeutic class. They are linked to the record number codes listed above.
WHO Adverse Reaction Terms	ART	WHO Collaborating Centre for International Drug Monitoring, Box 26, S-751 03, Uppsala, Sweden.
Note: The Read and NLM (National Library of Medicine) codes in Table 3 also include drugs. A number of sources of unique drug names exist: British Approved Names (BAN), French-approved nonproprietary names (DCF), and International Nonproprietary name (INN). These sources are now being reviewed. Those that also provide unique codes will be added to the registry of coding systems, using the abbreviations given in parentheses.		
Device code:		
MDNS	UMD	Universal Medical Device Nomenclature System. ECRI, 5200 Butler Pike, Plymouth Meeting, PA 19462 USA. Phone: 215-825-6000, Fax: 215-834-1275.

7.2 MESSAGE DEFINITIONS

The triggering events that follow are all served by the ORU (Observational report - Unsolicited) or the ORF (Observational Report Response) messages in combination with ACK and QRY. 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."

7.2.1 ORU/ACK - unsolicited transmission of an observation message (event R01)

With the type (OBX) defined in this chapter, and the OBR defined in Chapter 4, one can construct almost any clinical report as a three-level hierarchy, with the PID segment defined in Chapter 3 at the upper level, an order record (OBR) at the next level and one or more observation records (OBX) at the bottom.

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

ORU	Observational Results (Unsolicited)	Chapter
MSH	Message Header	2
{		
[		
PID	Patient Identification	3
[PD1]	Additional Demographics	3
[{NTE}]	Notes and Comments	2
[PV1	Patient Visit	3
[PV2]]	Patient Visit - Additional Info	3
]		
{		
[ORC]	Order common	4
OBR	Observations Report ID	7
{[NTE]}	Notes and comments	2
{		
[OBX]	Observation/Result	7
{[NTE]}	Notes and comments	2
}		
{[CTI]}	Clinical Trial Identification	7
}		
}		
[DSC]	Continuation Pointer	2

ACK	Acknowledgment	Chapter
MSH	Message header	2
MSA	Message acknowledgment	2

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) beneath each OBR. Note segments (NTE) may be inserted after any of the above segments. The note segment applies to the entity that immediately precedes it, i.e., the patient if it follows the PID segment, the observation if it follows the OBR segment, and the individual result if it follows the OBX segment.

7.2.2 QRY/ORF - query for results of observation (events R02, R04)

QRY	Query	Chapter
MSH	Message Header	2
QRD	Query Definition	2
QRF	Query Filter	2

ORF	Observational Report	Chapter
MSH	Message Header	2
MSA	Message Acknowledgment	2
QRD	Query Definition	2
[QRF]	Query Filter	2
{ [PID	Patient ID	3
[{NTE}]]	Notes and Comments	3
{		
[ORC]	Order common	
OBR	Observation request	7
{[NTE]}	Notes and comments	2
{		
[OBX]	Observation/Result	7
{[NTE]}	Notes and comments	2
}		
{[CTI]}	Clinical Trial Identification	7
} }		
[DSC]	Continuation Pointer	2

7.2.2.1 Query usage notes

Display-oriented results reporting is described in Chapter 2, Section 2.14.1, “Display vs. record-oriented messages.” The QRD and QRF segments are defined in Chapter 2, Section 2.24, “Messages Control Segments.” Event R05 is used for queries for display results; event R06 is used in the unsolicited message for reporting display results.

The subject filters contained in the QRD and QRF segments are defined by local agreement between the inquiring system and the ancillary system.

The Set ID fields in the various segments (including PID) are used to count the number of segments of one kind transmitted at one level of the hierarchy.

The Query Result Level field of the QRD determines the amount of data requested. See Chapter 2, Section 2.24.4, “QRD - original style query definition segment.”

7.3 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.

7.3.1 OBR - observation request segment

In the reporting of clinical data, the OBR serves as the report header. It identifies the observation set represented by the following atomic observations. It includes the relevant ordering information when that applies. It contains many of the attributes that usually apply to all of the included observations.

When a set of observations is ordered, the order message contains an OBR segment. However, observations can be collected and reported without an antecedent order. When observations are reported, the report message also includes one or more OBR segments. So, the OBR segment is like a turn-around

document. Some fields in the OBR segment apply only to the ordering message and some to the reporting message. To those familiar with healthcare procedures, these should be obvious from their names (e.g., transcriptionist or principal result interpreter could only apply to the reporting phase). However, we have also flagged them in *Figure 7-4* to indicate whether placer, filler, or both may send data in a given field.

Figure 7-4. OBR attributes

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM #	ELEMENT NAME
1	4	SI	C			00237	Set ID - OBR
2	22	EI	C			00216	Placer Order Number
3	22	EI	C			00217	Filler Order Number +
4	200	CE	R			00238	Universal Service ID
5	2	ID	X			00239	Priority
6	26	TS	X			00240	Requested Date/time
7	26	TS	C			00241	Observation Date/Time #
8	26	TS	O			00242	Observation End Date/Time #
9	20	CQ	O			00243	Collection Volume *
10	60	XCN	O	Y		00244	Collector Identifier *
11	1	ID	O		0065	00245	Specimen Action Code *
12	60	CE	O			00246	Danger Code
13	300	ST	O			00247	Relevant Clinical Info.
14	26	TS	C			00248	Specimen Received Date/Time *
15	300	CM	O		0070	00249	Specimen Source *
16	80	XCN	O	Y		00226	Ordering Provider
17	40	XTN	O	Y/2		00250	Order Callback Phone Number
18	60	ST	O			00251	Placer field 1
19	60	ST	O			00252	Placer field 2
20	60	ST	O			00253	Filler Field 1 +
21	60	ST	O			00254	Filler Field 2 +
22	26	TS	C			00255	Results Rpt/Status Chng - Date/Time +
23	40	CM	O			00256	Charge to Practice +
24	10	ID	O		0074	00257	Diagnostic Serv Sect ID
25	1	ID	C		0123	00258	Result Status +
26	400	CM	O			00259	Parent Result +
27	200	TQ	O	Y		00221	Quantity/Timing
28	150	XCN	O	Y/5		00260	Result Copies To
29	150	CM	O			00261	Parent *
30	20	ID	O		0124	00262	Transportation Mode
31	300	CE	O	Y		00263	Reason for Study
32	200	CM	O			00264	Principal Result Interpreter +
33	200	CM	O	Y		00265	Assistant Result Interpreter +
34	200	CM	O	Y		00266	Technician +
35	200	CM	O	Y		00267	Transcriptionist +
36	26	TS	O			00268	Scheduled Date/Time +
37	4	NM	O			01028	Number of Sample Containers *
38	60	CE	O	Y		01029	Transport Logistics of Collected Sample *
39	200	CE	O	Y		01030	Collector's Comment *
40	60	CE	O			01031	Transport Arrangement Responsibility
41	30	ID	O		0224	01032	Transport Arranged
42	1	ID	O		0225	01033	Escort Required
43	200	CE	O	Y		01034	Planned Patient Transport Comment

The complete description of these fields is provided below as well as in Chapter 4.

7.3.1.0 OBR field definitions

The daggered (+) items in this segment are not created by the placer known to the filler, not the placer. They are created by the filler and valued as needed when the OBR segment is returned as part of a report. Hence on a new order sent to the filler, they are not valued. There is an exception when the filler initiates the order. In that case, the filler order number is valued and the placer order number may be blank. 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 collector. 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.

7.3.1.1 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.

7.3.1.2 Placer order number (EI) 00216

```
Components:  <entity identifier (ST)> ^ <namespace ID (IS)> ^ <universal ID (ST)> ^ <universal ID type (ID)>
```

Definition: This field is a case of the Entity Identifier data type (See 2.8.13, “EI - Entity identifier”). The first component is a string that identifies an individual order (e.g., OBR). A limit of fifteen (15) characters is suggested but not required. It is assigned by the place (ordering application). 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 2.8.18, “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.

There are three situations in which the true placer is somewhat arbitrary (and thus not unique):

a) in *ORC-1-order control* value of RO, following an RU replacement;

b) in *ORC-1-order control* value of CH (child orders); and

c) in *ORC-1-order control* value of SN (send number).

See the Table Notes under *ORC-1-order control* for the details of how the *ORC-2-placer order number* is assigned in these cases.

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).

ORC-2-placer order number is the same as *OBR-2-placer order number*. If the placer order number is not present in the ORC, it must be present in the associated OBR and vice versa. If both fields, *ORC-2-placer order number* and *OBR-2-placer order number,* are valued, they must contain the same value. When results are transmitted in an ORU message, an ORC is not required, and the identifying placer order number must be present in the OBR segments.

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).

7.3.1.3 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. It is a case of the Entity Identifier data type (Section 2.8.13, "EI - Entity Identifier"). Its first component is a string that identifies an order detail segment (e.g., OBR). A limit of fifteen (15) characters is suggested but not required. It is assigned by the order filler (receiving) application. This string must uniquely identify the order (as specified in the order detail segment) from other orders in 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 2.8.18, "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.

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 filler 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).

ORC-3-filler order number is the same as *OBR-3-filler order number*. If the filler order number is not present in the ORC, it must be present in the associated OBR. (This rule is the same for other identical fields in the ORC and OBR and promotes upward and ASTM compatibility.) This is particularly important when results are transmitted in an ORU message. In this case, the ORC is not required and the identifying filler order number must be present in the OBR segments.

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.

7.3.1.4 Universal service ID (CE) 00238

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^<alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

Definition: This field is the identifier code for the requested observation/test/battery. This can be based on local and/or "universal" codes. We recommend the "universal" procedure identifier. The structure of this CE data type is described in the control section.

7.3.1.5 Priority (ID) 00239

Definition: ***This field has been retained for backward compatibility only***. It is not used. Previously priority (e.g., STAT, ASAP), but that information is carried as the sixth component of *OBR-27-quantity/timing*.

7.3.1.6 Requested date/time (TS) 00240

Definition: ***This field has been retained for backward compatibility only***. This is not used. Previously requested date/time. That information is now carried in the fourth component of the *OBR-27-quantity/timing*.

7.3.1.7 Observation date/time (TS) 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.

7.3.1.8 Observation end date/time (TS) 00242

Definition: This field is 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.

7.3.1.9 Collection volume (CQ) 00243

```
Components:  <quantity (NM)> ^ <units (CE)>

Subcomponents of units: <identifier (ST)> & <test (ST)> & <name of coding system (ST)> & <alternate identifier
              (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>
```

Definition: For laboratory tests, the collection volume is the volume of a specimen. The default unit is ML. 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. (See Chapter 7 for full details about units.)

7.3.1.10 Collector identifier (XCN) 00244

```
Components: <ID number (ST)> ^ <family name (ST)> ^ <given name (ST)> ^ <middle initial or name (ST)> ^
             <suffix (e.g., JR or III) (ST)> ^ <prefix (e.g., DR) (ST)> ^ <degree (e.g., MD) (ST)> ^ <source
             table (IS)> ^ <assigning authority (HD)> ^ <name type code (ID)> ^ <identifier check digit (ST)>
             ^ <code identifying the check digit scheme employed (ID )> ^ <identifier type code (IS)> ^
             <assigning facility (HD)>

Subcomponents of assigning authority:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>

Subcomponents of assigning facility ID:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>
```

Definition: 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.

7.3.1.11 Specimen action code (ID) 00245

Definition: This field is 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* for valid values.

Table 0065 - Specimen action code

Value	Description
A	Add ordered tests to the existing specimen
G	Generated order; reflex order
L	Lab to obtain specimen from patient
O	Specimen obtained by service other than Lab
P	Pending specimen; Order sent prior to delivery
R	Revised order
S	Schedule the tests specified below

7.3.1.12 Danger code (CE) 00535

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

Definition: This field is 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.

7.3.1.13 Relevant clinical information (ST) 00247

Definition: This field contains any additional clinical information about the patient or specimen. This field is used to report the suspected diagnosis and clinical findings on requests for interpreted diagnostic studies. 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. For some orders this information may be sent on a more structured form as a series of OBX segments (see Chapter 7) that immediately follow the order segment.

7.3.1.14 Specimen received date/time (TS) 00248

Definition: For observations requiring a specimen, the specimen received date/time is the actual login time at the diagnostic service. This field must contain a value when the order is accompanied by a specimen, or when the observation required a specimen **and** the message is a report.

7.3.1.15 Specimen source (CM) 00249

```
Components:  <specimen source name or code (CE)> ^ <additives (TX)> ^ <freetext (TX)> ^ <body site (CE)> ^
             <site modifier (CE)> ^ <collection method modifier code (CE)>

Subcomponents of specimen source name or doe: <identifier (ST)> & <test (ST)> & <name of coding system (ST)> &
             <alternate identifier (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>

Subcomponents of body site: <identifier (ST)> & <test (ST)> & <name of coding system (ST)> & <alternate
             identifier (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>

Subcomponents of site modifier: <identifier (ST)> & <test (ST)> & <name of coding system (ST)> & <alternate
             identifier (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>

Subcomponents of collection method modifier code: <identifier (ST)> & <test (ST)> & <name of coding system
             (ST)> & <alternate identifier (ST)> & <alternate text (ST)> & <name of alternate coding system
             (ST)>
```

Definition: This field identifies the site where the specimen should be obtained or where the service should be performed.

The first component contains the specimen source name or code (as a CE data type component). (Even in the case of observations whose name implies the source, a source may be required, e.g., blood culture-heart blood.) Refer *to HL7 table 0070 - Source of specimen* for valid entries.

The second component should include free text additives to the specimen such as Heparin, EDTA, or Oxlate, when applicable.

The third is a free text component describing the method of collection when that information is a part of the order. When the method of collection is logically an observation result, it should be included as a result segment.

The fourth component specifies the body site from which the specimen was obtained, and the fifth is the site modifier. For example, the site could be anticubital foss, and the site modifier “right.” The components of the CE fields become subcomponents. Refer to *HL7 table 0163 - Administrative site* for valid entries.

Table 0163 - Administrative site

Value	Description	Value	Description
BE	Bilateral Ears	LVL	Left Vastus Lateralis
OU	Bilateral Eyes	NB	Nebulized
BN	Bilateral Nares	PA	Perianal
BU	Buttock	PERIN	Perineal
CT	Chest Tube	RA	Right Arm
LA	Left Arm	RAC	Right Anterior Chest
LAC	Left Anterior Chest	RACF	Right Antecubital Fossa
LACF	Left Antecubital Fossa	RD	Right Deltoid
LD	Left Deltoid	RE	Right Ear
LE	Left Ear	REJ	Right External Jugular
LEJ	Left External Jugular	OD	Right Eye
OS	Left Eye	RF	Right Foot
LF	Left Foot	RG	Right Gluteus Medius
LG	Left Gluteus Medius	RH	Right Hand
LH	Left Hand	RIJ	Right Internal Jugular
LIJ	Left Internal Jugular	RLAQ	Rt Lower Abd Quadrant
LLAQ	Left Low er Abd Quadrant	RLFA	Right Lower Forearm
LLFA	Left Lower Forearm	RMFA	Right Mid Forearm
LMFA	Left Mid Forearm	RN	Right Naris
LN	Left Naris	RPC	Right Posterior Chest
LPC	Left Posterior Chest	RSC	Right Subclavian
LSC	Left Subclavian	RT	Right Thigh
LT	Left Thigh	RUA	Right Upper Arm
LUA	Left Upper Arm	RUAQ	Right Upper Abd Quadrant
LUAQ	Left Upper Abd Quadrant	RUFA	Right Upper Forearm
LUFA	Left Upper Forearm	RVL	Right Vastus Lateralis
LVG	Left Ventragluteal	RVG	Right Ventragluteal

The fifth component indicates whether the specimen is frozen as part of the collection method. Suggested values are F (Frozen); R (Refrigerated). If the component is blank, the specimen is assumed to be at room temperature.

Table 0070 - Specimen source codes

Value	Description	Value	Description	Value	Description
ABS	Abscess	FLU	Body fluid, unsp	SER	Serum
AMN	Amniotic fluid	GAS	Gas	SKN	Skin
ASP	Aspirate	GAST	Gastric fluid/contents	SKM	Skeletal muscle
BPH	Basophils	GEN	Genital	SPRM	Spermatozoa
BIFL	Bile fluid	GENC	Genital cervix	SPT	Sputum
BLDA	Blood arterial	GENL	Genital lochia	SPTC	Sputum - coughed
BBL	Blood bag	GENV	Genital vaginal	SPTT	Sputum - tracheal aspirate
BLDC	Blood capillary	HAR	Hair	STON	Stone (use CALC)
BPU	Blood product unit	IHG	Inhaled Gas	STL	Stool = Fecal
BLDV	Blood venous	IT	Intubation tube	SWT	Sweat
BON	Bone	ISLT	Isolate	SNV	Synovial fluid (Joint fluid)
BRTH	Breath (use EXHLD)	LAM	Lamella	TEAR	Tears
BRO	Bronchial	WBC	Leukocytes	THRT	Throat
BRN	Burn	LN	Line	THRB	Thrombocyte (platelet)
CALC	Calculus (=Stone)	LNA	Line arterial	TISS	Tissue
CDM	Cardiac muscle	LNV	Line venous	TISG	Tissue gall bladder
CNL	Cannula	LIQ	Liquid NOS	TLGI	Tissue large intestine
CTP	Catheter tip	LYM	Lymphocytes	TLNG	Tissue lung
CSF	Cerebral spinal fluid	MAC	Macrophages	TISPL	Tissue placenta
CVM	Cervical mucus	MAR	Marrow	TSMI	Tissue small intestine
CVX	Cervix	MEC	Meconium	TISU	Tissue ulcer
COL	Colostrum	MBLD	Menstrual blood	TUB	Tube NOS
CBLD	Cord blood	MLK	Milk	ULC	Ulcer
CNJT	Conjunctiva	MILK	Breast milk	UMB	Umbilical blood
CUR	Curettage	NAIL	Nail	UMED	Unknown medicine
CYST	Cyst	NOS	Nose (nasal passage)	URTH	Urethra
DIAF	Dialysis fluid	ORH	Other	UR	Urine
DOSE	Dose med or substance	PAFL	Pancreatic fluid	URC	Urine clean catch
DRN	Drain	PAT	Patient	URT	Urine catheter
DUFL	Duodenal fluid	PRT	Peritoneal fluid /ascites	URNS	Urine sediment
EAR	Ear	PLC	Placenta	USUB	Unknown substance
EARW	Ear wax (cerumen)	PLAS	Plasma	VOM	Vomitus
ELT	Electrode	PLB	Plasma bag	BLD	Whole blood
ENDC	Endocardium	PLR	Pleural fluid (thoracentesis fld)	BDY	Whole body
ENDM	Endometrium	PMN	Polymorphonuclear neutrophils	WAT	Water
EOS	Eosinophils	PPP	Patelet poor plasma	WICK	Wick
RBC	Erythrocytes	PRP	Platelet rich plasma	WND	Wound
EYE	Eye	PUS	Pus	WNDA	Wound abscess
EXHLD	Exhaled gas (=breath)	RT	Route of medicine	WNDE	Wound exudate
FIB	Fibroblasts	SAL	Saliva	WNDD	Wound drainage
FLT	Filter	SEM	Seminal fluid	XXX	To be specified in another part of the message
FIST	Fistula				

7.3.1.16 Ordering provider (XCN) 00226

```
Components: <ID number (ST)> ^ <family name (ST)> ^ <given name (ST)> ^ <middle initial or name (ST)> ^
            <suffix (e.g., JR or III) (ST)> ^ <prefix (e.g., DR) (ST)> ^ <degree (e.g., MD) (ST)> ^ <source
```

```
                    table (IS)> ^ <assigning authority (HD)> ^ <name type code(ID)> ^ <identifier check digit (ST)>
                    ^ <code identifying the check digit scheme employed (ID )> ^ <identifier type code (IS)> ^
                    <assigning facility (HD)>

Subcomponents of assigning authority:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>

Subcomponents of assigning facility ID:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>
```

Definition: This field identifies the provider who ordered the test. Either the ID code or the name, or both, may be present. This is the same as *ORC-12-ordering provider*.

7.3.1.17 Order callback phone number (XTN) 00250

```
Components:  [NNN] [(999)]999-9999 [X99999] [B99999] [C any text] ^ <telecommunication use code (ID)> ^
              <telecommunication equipment type (ID)> ^ <email address (ST)> ^ <country code (NM)> ^
              <area/city code (NM)> ^ <phone number (NM)> ^ <extension (NM)> ^ <any text (ST)>
```

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

7.3.1.18 Placer field #1 (ST) 00251

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

7.3.1.19 Placer field #2 (ST) 00252

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

7.3.1.20 Filler field #1 (ST) 00253

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

7.3.1.21 Filler field #2 (ST) 00254

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

7.3.1.22 Results rpt/status chng - date/time (TS) 00255

Definition: This field specifies the date/time results reported or status changed. 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 untransmitted 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.

7.3.1.23 Charge to practice (CM) 00256

```
Components:  <dollar amount (MO)> ^ <charge code (CE)>

Subcomponents of dollar amount:  <quantity (NM)> & <denomination (ID)>

Subcomponents of charge code: <identifier (ST)> & <test (ST)> & <name of coding system (ST)> & <alternate
              identifier (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>
```

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).

7.3.1.24 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* for valid entries.

Table 0074 - Diagnostic service section ID

Value	Description	Value	Description
AU	Audiology	OUS	OB Ultrasound
BG	Blood gases	OT	Occupational Therapy
BLB	Blood bank	OTH	Other
CUS	Cardiac Ultrasound	OSL	Outside Lab
CTH	Cardiac catheterization	PHR	Pharmacy
CT	CAT scan	PT	Physical Therapy
CH	Chemistry	PHY	Physician (Hx. Dx, admission note, etc.l)
CP	Cytopathology	PF	Pulmonary function
EC	Electrocardiac (e.g., EKG, EEC, Holter)	RAD	Radiology
EN	Electroneuro (EEG, EMG,EP,PSG)	RX	Radiograph
HM	Hematology	RUS	Radiology ultrasound
ICU	Bedside ICU Monitoring	RC	Respiratory Care (therapy)
IMM	Immunology	RT	Radiation therapy
LAB	Laboratory	SR	Serology
MB	Microbiology	SP	Surgical Pathology
MCB	Mycobacteriology	TX	Toxicology
MYC	Mycology	VUS	Vascular Ultrasound
NMS	Nuclear medicine scan	VR	Virology
NMR	Nuclear magnetic resonance	XRC	Cineradiograph
NRS	Nursing service measures		

7.3.1.25 Result status (ID) 00258

Definition: This field is 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 report/status change - 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* for valid entries.

Table 0123 - Result status

Value	Description	Value	Description
O	Order received; specimen not yet received	R	Results stored; not yet verified
I	No results available; specimen received, procedure incomplete	F	Final results; results stored and verified. Can only be changed with a corrected result.
S	No results available; procedure scheduled, but not done	X	No results available; Order canceled.
A	Some, but not all, results available	Y	No order on record for this test. (Used only on queries)
P	Preliminary: A verified early result is available, final results not yet obtained	Z	No record of this patient. (Used only on queries)
C	Correction to results		

7.3.1.26 Parent result (CM) 00259

```
Components:  <OBX-3-observation identifier of parent result (CE)> ^ <OBX-4-sub-ID of parent result (ST)> ^
              <part of OBX-5 observation result from parent (TX) see discussion>

Subcomponents of OBX-3-observation identifier or parent result: <identifier (ST)> & <test (ST)> & <name of
              coding system (ST)> & <alternate identifier (ST)> & <alternate text (ST)> & <name of alternate
              coding system (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 number,* 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. For example, if the current battery is an antimicrobial susceptibility, the parent result's identified OBX contains a result which identifies the organism on which the susceptibility were run. This indirect linkage is preferred because the name of the organism in the parent result may undergo several preliminary values prior to finalization.

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 which could not generate unambiguous Observation IDs and sub-IDs.

This field is present only when the parent result is identified by *OBR-29-parent number* and the parent spawn child orders 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-subID* 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.

7.3.1.27 Quantity/timing (TQ) 00221

```
Components:  <quantity (CQ)> ^ <interval (CM)> ^ <duration> ^ <start date/time (TS)> ^ <end date/time (TS)> ^
              <priority (ID)> ^ <condition (ST)> ^ <text (TX)> ^ <conjunction (ID)> ^ <order sequencing>
```

Definition: This field contains information about how many services to perform at one service time and how often the service times are repeated, and to fix duration of the request. See Section 4.4, "Quantity/Timing (TQ) Definition."

7.3.1.28 Result copies to (XCN) 00260

```
Components: <ID number (ST)> ^ <family name (ST)> ^ <given name (ST)> ^ <middle initial or name (ST)> ^
            <suffix (e.g., JR or III) (ST)> ^ <prefix (e.g., DR) (ST)> ^ <degree (e.g., MD) (ST)> ^ <source
            table (IS)> ^ <assigning authority (HD)> ^ <name type code(ID)>  ^ <identifier check digit (ST)>
            ^ <code identifying the check digit scheme employed (ID )> ^ <identifier type code (IS)> ^
            <assigning facility (HD)>

Subcomponents of assigning authority:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>

Subcomponents of assigning facility ID:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>
```

Definition: This field is the people who are to receive copies of the results. By local convention, either the ID number or the name may be absent.

7.3.1.29 Parent (CM) 00261

```
Components:  <parent's placer order number (EI)> ^ <parent's filler order number (EI)>

Subcomponents of parent's placer order number:  <entity identifier (ST)> & <namespace ID (IS)> & <universal ID
            (ST)> & <universal ID type (IS)>

Subcomponents of parent's filler order number:  <entity identifier (ST)> & < <namespace ID (IS)> & <universal
            ID (ST)> & <universal ID type (IS)>
```

Definition: This field is identical to *ORC-8-parent*. This field relates a child to its parent when a parent/child relationship exists. For example, observations that are spawned by previous observations, e.g., antimicrobial susceptibilities spawned by blood cultures, need to record the parent (blood culture) filler order number here. The parent/child mechanism is described under the order control field notes (see Segment ORC field notes in Section 4.3.1.1.1, "Table notes for order control codes of ORC." It is required when the order is a child.

Parent is a two-component field. The first component contains the parent's placer order number. The second component is optional and contains the parent's filler order number. The components of the placer order number and the filler order number are transmitted in subcomponents of the two components of this field.

7.3.1.30 Transportation mode (ID) 00262

Definition: This field identifies how (or whether) to transport a patient, when applicable. Refer to *HL7 table 0124 - Transportation mode* for valid codes.

Table 0124 - Transportation mode

Value	Description
CART	Cart - patient travels on cart or gurney
PORT	The examining device goes to patient's location
WALK	Patient walks to diagnostic service
WHLC	Wheelchair

7.3.1.31 Reason for study (CE) 00263

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
            <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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

7.3.1.32 Principal result interpreter (CM) 00264

```
Components:  <name (CN)> ^ <start date/time (TS)> ^ <end date/time (TS)> ^ <point of care (IS)> ^ <room (IS)>
             ^ <bed (IS)> ^ <facility (HD)> ^ <location status (IS)> ^ <patient location type (IS)> ^
             <building (IS)> ^ <floor (IS)>

Subcomponents of name :  <ID number (ST)> & <family name (ST)> & <given name (ST)> & <middle initial or name
             (ST)> & <suffix (e.g., JR. III) (ST)> & <prefix (e.g., DR)> & <degree (e.g., MD) (ST)> & <source
             table (IS)> & <assigning authority (HD)>

Subcomponents of facility:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>
```

Definition: This field identifies the physician or other clinician who interpreted the observation and is responsible for the report content.

7.3.1.33 Assistant result interpreter (CM) 00265

```
Components:  <name (CN)> ^ <start date/time (TS)> ^ <end date/time (TS)> ^ <point of care (IS)> ^ <room (IS)>
             ^ <bed (IS)> ^ <facility (HD)> ^ <location status (IS)> ^ <patient location type (IS)> ^
             <building (IS)> ^ <floor (IS)>

Subcomponents of name :  <ID number (ST)> & <family name (ST)> & <given name (ST)> & <middle initial or name
             (ST)> & <suffix (e.g., JR. III) (ST)> & <prefix (e.g., DR)> & <degree (e.g., MD) (ST)> & <source
             table (IS)> & <assigning authority (HD)>

Subcomponents of facility:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>
```

Definition: This field identifies the clinical observer who assisted with the interpretation of this study.

7.3.1.34 Technician (CM) 00266

```
Components:  <name (CN)> ^ <start date/time (TS)> ^ <end date/time (TS)> ^ <point of care (IS)> ^ <room (IS)>
             ^ <bed (IS)> ^ <facility (HD)> ^ <location status (IS)> ^ <patient location type (IS)> ^
             <building (IS)> ^ <floor (IS)>

Subcomponents of name :  <ID number (ST)> & <family name (ST)> & <given name (ST)> & <middle initial or name
             (ST)> & <suffix (e.g., JR. III) (ST)> & <prefix (e.g., DR)> & <degree (e.g., MD) (ST)> & <source
             table (IS)> & <assigning authority (HD)>

Subcomponents of facility:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>
```

Definition: This field identifies the performing technician.

7.3.1.35 Transcriptionist (CM) 00267

```
Components:  <name (CN)> ^ <start date/time (TS)> ^ <end date/time (TS)> ^ <point of care (IS)> ^ <room (IS)>
             ^ <bed (IS)> ^ <facility (HD)> ^ <location status (IS)> ^ <patient location type (IS)> ^
             <building (IS)> ^ <floor (IS)>

Subcomponents of name :  <ID number (ST)> & <family name (ST)> & <given name (ST)> & <middle initial or name
             (ST)> & <suffix (e.g., JR. III) (ST)> & <prefix (e.g., DR)> & <degree (e.g., MD) (ST)> & <source
             table (IS)> & <assigning authority (HD)>

Subcomponents of facility:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>
```

Definition: This field identifies the report transcriber.

7.3.1.36 Scheduled - date/time (TS) 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).

7.3.1.37 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.

7.3.1.38 Transport logistics of collected sample (CE) 01029

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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.

7.3.1.39 Collector's comment (CE) 01030

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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., ^difficult clotting after venepuncture and echymosis ..

7.3.1.40 Transport arrangement responsibility (CE) 01031

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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.

7.3.1.41 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* for valid codes.

Table 0224 - Transport arranged

Value	Description
A	Arranged
N	Not Arranged
U	Unknown

7.3.1.42 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 the *OBR-43-planned patient transport comment* field. See *HL7 table 0225 - Escort required* for valid values.

Table 0225 - Escort required

Value	Description
R	Required
N	Not Required
U	Unknown

7.3.1.43 Planned patient transport comment (CE) 01034

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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.

7.3.2 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. Its structure is summarized in *Figure 7-5*.

Its principal mission is to carry information about observations in report messages. But the OBX can also be part of an observation order (see Section 4.2, "Order 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 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.

Figure 7-5. OBX attributes

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1	10	SI	O			00569	Set ID - OBX
2	2	ID	C		0125	00570	Value Type
3	590	CE	R			00571	Observation Identifier
4	20	ST	C			00572	Observation Sub-ID
5	65536[2]	*	C	Y[3]		00573	Observation Value
6	60	CE	O			00574	Units
7	10	ST	O			00575	References Range
8	5	ID	O	Y/5	0078	00576	Abnormal Flags
9	5	NM	O			00577	Probability
10	2	ID	O	Y	0080	00578	Nature of Abnormal Test
11	1	ID	R		0085	00579	Observ Result Status
12	26	TS	O			00580	Date Last Obs Normal Values
13	20	ST	O			00581	User Defined Access Checks
14	26	TS	O			00582	Date/Time of the Observation
15	60	CE	O			00583	Producer's ID
16	80	XCN	O			00584	Responsible Observer
17	60	CE	O	Y		00936	Observation Method

7.3.2.0 OBX field definitions

7.3.2.1 Set ID - observation simple (SI) 00569

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

7.3.2.2 Value type (ID) 00570

Definition: This field contains the format of the observation value in OBX. It must be valued if *OBX-11-Observation result status* is not valued with an 'X". If the value is CE then the result must be a coded entry. When the value type is TX or FT then the results are bulk text. The valid values for the value type of an observation are listed in *HL7 table 0125 - Value type*.

The observation value must be represented according to the format for the data type defined in Chapter 2, Section 2.8, "Data Types." For example, a PN consists of 6 components, separated by component delimiters.

Although NM is a valid type, observations which are usually reported as numbers will sometimes have the string (ST) data type because non-numeric characters are often reported as part of the result, e.g., >300 to indicate the result was off-scale for the instrument. In the example, ">300", ">" is a symbol and the digits are considered a numeric value. However, this usage of the ST type should be discouraged since the SN (structured numeric) data type now accommodates such reporting and, in addition, permits the receiving system to interpret the magnitude.

All HL7 data types are valid, and are included in Table 0125 except CM, CQ, SI, and ID. For a CM definition to have meaning, the specifics about the CM must be included in the field definition. *OBX-5-observation value* is a general field definition that is influenced by the data type *OBX-3*, so CMs are undefined in this context. CQ is invalid because units for *OBX-5-observation value* are always specified explicitly in an OBX

2 The length of the observation value field is variable, depending upon value type. See *OBX-2-value type*.

3 May repeat for multipart, single answer results with appropriate data types, e.g., CE, TX, and FT data types.

segment with *OBX-6 units*. SI is invalid because it only applied to HL7 message segments, and ID because it requires a constant field definition.

The RP value (reference pointer) must be used if the actual observation value is not sent in OBX but exists somewhere else. For example, if the observation consists of an image (document or medical), the image itself cannot be sent in OBX. The sending system may in that case opt to send a reference pointer. The receiving system can use this reference pointer whenever it needs access to the actual image through other interface standards, e.g., DICOM, or through appropriate data base servers.

Table 0125 - Value type

Value	Description
AD	Address
CE	Coded Entry
CF	Coded Element With Formatted Values
CK	Composite ID With Check Digit
CN	Composite ID And Name
CP	Composite Price
CX	Extended Composite ID With Check Digit
DT	Date
ED	Encapsulated Data
FT	Formatted Text (Display)
MO	Money
NM	Numeric
PN	Person Name
RP	Reference Pointer
SN	Structured Numeric
ST	String Data.
TM	Time
TN	Telephone Number
TS	Time Stamp (Date & Time)
TX	Text Data (Display)
XAD	Extended Address
XCN	Extended Composite Name And Number For Persons
XON	Extended Composite Name And Number For Organizations
XPN	Extended Person Number
XTN	Extended Telecommunications Number

The full definition of these data types is given in Chapter 2, Section 2.8, "Data Types." The structured numeric (SN) data type, new to version 2.3, 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.

7.3.2.3 Observation identifier (CE) 00571

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

Definition: This field contains a unique identifier for the observation. The format is that of the Coded Element (CE). Example: 93000.3^P-R interval^A34.

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). One possible **universal** identifier is LOINC codes for laboratory and clinical measurements (see *Figure 7-3* and the HL7 www list server); see Section 7.15, "WAVEFORM RESULT DATA TYPES," and Appendix X2 of ASTM E1467 for neurophysiology tests.

7.3.2.4 Observation sub-ID (ST) 00572

Definition: This field is used to distinguish between multiple OBX segments with the same observation ID organized under one OBR. 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 7-6*.

Figure 7-6. Example of sub-identifier usage

```
OBR|1|||88304&SURG PATH REPORT...
OBX|1|CE|88304&ANT|1|T57000^GALLBLADDER^SNM...
OBX|2|TX|88304&GDT|1|THIS IS A NORMAL GALLBLADDER...
OBX|3|TX|88304&MDT|1|MICROSCOPIC EXAM SHOWS HISTOLOGICALLY
   NORMAL GALLBLADDER TISSUE...
OBX|4|CE|88304&IMP|1|M-00100^NML^SNM...
OBX|5|CE|88304&ANT|2|T66000^APPENDIX^SNM...
OBX|6|TX|88304&GDT|2|THIS IS A RED, INFLAMED, SWOLLEN, BOGGY
APPENDIX...
OBX|7|TX|88304&MDT|2|INFILTRATION WITH MANY PMN's - INDICATING
INFLAMATORY CHANGE...
OBX|8|CE|88304&IMP|2|M-40000^INFLAMMATION NOS^SNM...
```

The example in *Figure 7-6* has two segments for each component of the report, one for each of the two tissues. Thus, there are two 88304&ANT segments; there are two 88304&GDT segments, and there are two 88304&MDT 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 7-6* 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	88304&GDT	80304&MDT	80304&IMP
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 7-7*. This really represents the existence of a row nested within a single cell of the table given above.

Figure 7-7. Example of sub-identifier usage

```
OBX|1|CE|880304&ANT|1|T57000^GALLBLADDER^SNM...
OBX|2|TX|880304&GDT|1|THIS IS A NORMAL GALL BLADDER...
OBX|3|TX|880304&MDT|1|MICROSCOPIC EXAMINATION SHOWS HISTOLOGICALLY
   NORMAL GALLBLADDER TISSUE...
OBX|4|CE|880304&IMP|1|M-00100^NML^SNM...
OBX|5|CE|880304&ANT|2|T57000^APPENDIX^SNM...
OBX|6|TX|880304&GDT|2|THIS IS A RED, INFLAMED APPENDIX...
OBX|7|TX|880304&MDT|2|INFLAMMATION WITH MANY PUS CELLS-ACUTE
INFLAMMATION...
OBX|8|CE|880304&IMP|2|M-40000^INFLAMMATION NOS^SNM...
OBX|9|CE|880304&IMP|2|M-30280^FECALITH^SNM...
```

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 are to be combined into one composite observation in the receiving system. We suggest the use of a dot and a string (similar to the Dewey Decimal system) 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 7-7* would become *7-8*. If there are cases where such nesting occurs at even deeper levels, this approach could be extended.

Figure 7-8. Example of sub-identifier usage

```
OBX|1|CE|880304&ANT|1|T57000^GALLBLADDER^SNM...
OBX|2|TX|880304&GDT|1|THIS IS A NORMAL GALL BLADDER...
OBX|3|TX|880304&MDT|1|MICROSCOPIC EXAMINATION SHOWS HISTOLOGICALLY
   NORMAL GALLBLADDER TISSUE...
OBX|4|CE|880304&IMP|1|M-00100^NML^SNM...
OBX|5|CE|880304&ANT|2|T57000^APPENDIX^SNM...
OBX|6|TX|880304&GDT|2|THIS IS A RED, INFLAMED APPENDIX...
OBX|7|TX|880304&MDT|2|INFLAMMATION WITH MANY PUS CELLS-ACUTE
INFLAMMATION...
OBX|8|CE|880304&IMP|2.1|M-40000^INFLAMMATION NOS^SNM...
OBX|9|CE|880304&IMP|2.2|M-30280^FECALITH^SNM...
```

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. This is in fact the case of the repeats depicted in Figure 7-8, but without any need to group sets of OBXs. Three such OBXs could be distinguished by using sub-IDs 1,2,e; alternatively, sub-IDs 1.1, 1.2, 1.3 could be used, as shown in *Figure 7-8*. *Figure 7-9* shows and example 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 7-9 Example of Sub-ID used to distinguish three independent results with the same observation ID

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

7.3.2.5 Observation value (*) 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 normalcy/abnormalcy (*OBX-8*), especially in product experience reporting.

Representation

This field contains the value of *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. This requirement is included to assure that the contents of *OBX-6-units*, *OBX-8-abnormal flags*, and *OBX-9-probability* can be interpreted unambiguously. 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, multiple categorical responses are allowed (usually as CE 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.

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 (CE). In this case, the logical observation can be sent in more than one OBX segment. For example, one segment of numeric or string data type for the numeric result and another segment of CE 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 CE data types, the observations are stored as a combination of codes and/or text. In Section 7.4.4, "Example of narrative report messages," examples of results that are represented as CE 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 CE data type. In this case, the test must be recorded as the second component of the **result code,** e.g.,

```
OBX|1|CE|71020&IMP|1|^CONGESTIVE HEART FAILURE.
```

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|CE|71020&IMP|1|^CONGESTIVE HEART FAILURE AND PNEUMONIA|
```

but as:

```
OBX|1|CE|71020&IMP|1|^CONGESTIVE HEART FAILURE|
OBX|2|CE|71020&IMP|2|^PNEUMONIA|.
```

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 CE 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|CE|710120&IMP^CXR|1|428.0^CONGESTIVE HEART FAILURE^I9C~^MASSIVE
```

HEART

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.

7.3.2.6 Units (CE) 00574

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

Definition: This field contains the units that have a data type of CE. The default coding system for the units codes consists of the ISO+ abbreviation for a single case unit (ISO 2955-83) plus extensions, that do not collide with ISO abbreviations (see introductory section to this chapter). We designate this coding system as ISO+. Both the ISO unit's abbreviations and the extensions are defined in Section 7.3.2.6.1.2, "ISO and ANSI customary units abbreviations," and listed in *Figure 7-13*. The ISO+ abbreviations *are* the codes for the default coding system. Consequently, when ISO+ units are being used, only ISO+ abbreviations need be sent, and the contents of the units field will be backward compatible to HL7 Version. 2.1.

7.3.2.6.1 Identifying reporting units

7.3.2.6.1.1 Background

When an observation's value is measured on a continuous scale, one must report the measurement units within the units field of the OBX segment. Since in HL7 Version 2.2 of the specification, all fields that report units are of data type CE. The default coding system for the units codes consists of the ISO abbreviation for a single case unit (ISO 2955-83) plus extensions that do not collide with ISO abbreviations. We designate this coding system as ISO+ (see *Figure 7-13*). Both the ISO unit's abbreviations and the extensions are defined in Section 7.3.2.6.1.2, "ISO and ANSI customary units abbreviations." The ISO+ abbreviations *are* the codes for the default coding system. Consequently, when ISO+ units are being used, only ISO+ abbreviations need be sent, and the contents of the units field will be backward compatible to HL7 Version 2.1 and ASTM 1238-88.

We strongly encourage observation producers to use ISO+ abbreviated units exclusively, but permit the use of other code systems, including US customary units (ANSI X3.50) and locally defined codes where necessary. Local units are designated **L** or 99zzz where z is an alpha numeric character (see *Figures 7-2* and *73*). ANSI X3.50 -1986 provides an excellent description of these standards, as well as a table of single case abbreviations for US customary units such as foot or gallon.

We had originally intended to include the ANSI X3.50 - 1986 US customary units in the default ISO+ coding system. However, there are overlaps between ISO's abbreviations and the abbreviations for US customary units. For example, **ft** is the abbreviation for foot in US customary units and for femtotesla in ISO; **pt** is the abbreviation for pint in US customary and for picotesla in ISO. (Be aware that the ANSI document also differs from the ISO document regarding the abbreviation of a few ISO units, as well.) In order to avoid potential ambiguity, we have defined another coding system, designated ANS+. It includes the US customary units (e.g., feet, pounds) and **ISO** abbreviations defined in ANSI X3.50-1986, as well as other non-metric units listed in *Figure 7-13* and the ISO combinations of these units. Be aware that a few of the ANSI **ISO** unit abbreviations differ from their abbreviations in ISO (see note at bottom of *Figure 7-13*).

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 avoiding ANS+ unit codes when possible.

When ANS+ units codes (abbreviations) are being transmitted, **ANS+** must be included in the third (sixth) component of the field. If the units of distance were transmitted as meters (ISO+) it would be transmitted as **m** because ISO+ is the default coding system for units. However, if transmitted in the US customary units of feet, the units would be transmitted as **ft^^ANS+.** When required, the full text of the units can be sent as the second component in keeping with the CE data type conventions.

Both ISO and ANSI also provide a set of mixed case abbreviations, but these abbreviations cannot be translated to single case without loss of meaning, and should not be used in this specification whose content is required to be case insensitive.

7.3.2.6.1.2 ISO and ANSI customary units abbreviations

ISO builds its units from seven base dimensions measured as meters, kilograms, seconds, amperes, kelvins, moles and candelas (see *Figure 7-10*). Other units can be derived from these by adding a prefix to change the scale and/or by creating an algebraic combination of two or more base or derived units. However, some derived units have acquired their own abbreviations (see *Figure 7-10*). Abbreviations for U.S. customary units are given in *Figure 7-11*.

The ISO rules, well explained in ANSI X3.50, provide a way to create units of different scales by adding **multiplier** prefixes. These prefixes can be expressed as **words** or abbreviations. In this Standard we are only concerned with the abbreviations.

Figure 7-10. 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 ISA 2955-1983 for full set					

The ISO abbreviations for multiplier prefixes are given in *Figure 7-12*. 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/m^2** 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 7-11. 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".					
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					

Figure 7-12. 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 7-13 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 Version 2.2.

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.

Figure 7-13. 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 $\times$ 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

Code/Abbr.	Name
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 Per Minute
bq	Becquerel
(bdsk_u)	*Bodansky Units
(bsa)	*Body surface area
(cal)	*Calorie
1	*Catalytic Fraction
/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
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

Code/Abbr.	Name
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 × 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 × 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 × 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
ug/hr	*Microgram / Hour
ug(8hr)	Microgram / 8 Hour Shift
ug/kg	Microgram / Kilogram
mg/(kg.d)	(Microgram / Kilogram) /Day = microgram / (kilogram × day) (e.g., mass dose of medication per patient body weight per day)
mg/(kg.hr)	(Microgram / Kilogram) / Hour = microgram / (kilogram × hours) (e.g., mass dose of medication per patient body weight per hour)
mg/(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)
mg/(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

Code/Abbr.	Name
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)
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
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)

Code/Abbr.	Name
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
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
w b	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

7.3.2.6.1.3 Local unit codes

Local codes can be used for the units by indicating the code source of **99zzz** in the third component (where 99zzz is an alpha-numeric string). In the case of local codes, the text name of the codes or the description of the units should also be transmitted (in the second component), so that the receiving system can compare the results with results for the same measurement sent by another service (refer to Chapter 2, Section 2.8, "Data Types"). An "L" should be stored in the third component to indicate that the code is locally defined. More specialized local code designations, as specified in the CE data type definition, can also be employed.

7.3.2.7 References 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.

7.3.2.8 Abnormal flags (ID) 00576

Definition: This field contains a table lookup indicating the normalcy status of the result. We strongly recommend sending this value when applicable. If the observation is an antimicrobial susceptibility, the interpretation codes are: S=susceptible; R=resistant; I=intermediate; MS=moderately susceptible; VS=very susceptible. (See ASTM 1238 - review for more details). Refer to *HL7 table 0078 - Abnormal flags* for valid entries.

When the laboratory 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.

Table 0078 Abnormal flags

Value	Description
L	Below low normal
H	Above high normal
LL	Below lower panic limits
HH	Above upper panic limits
<	Below absolute low-off instrument scale
>	Above absolute high-off instrument scale
N	Normal (applies to non-numeric results)
A	Abnormal (applies to non-numeric results)
AA	Very abnormal (applies to non-numeric units, analogous to panic limits for numeric units)
null	No range defined, or normal ranges don't apply
U	Significant change up
D	Significant change down
B	Better--use when direction not relevant
W	Worse--use when direction not relevant
For microbiology susceptibilities only:	
S	Susceptible
R	Resistant
I	Intermediate
MS	Moderately susceptible
VS	Very susceptible

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 normalcy code in *OBX-8-abnormal flags* without specifying any value in *OBX-5-observation value*.

7.3.2.9 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.

7.3.2.10 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.

Table 0080 Nature of abnormal testing

Value	Description
A	An age-based population
N	None - generic normal range
R	A race-based population
S	A sex-based population

7.3.2.11 Observ result status (ID) 00579

Definition: This field contains the observation result status. Refer to *HL7 table 0085 - Observation result status* 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** or **S** (depending upon the specific case) until they are final.

Table 0085 - Observation result status codes interpretation

Value	Description
C	Record coming over is a correction and thus replaces a final result
D	Deletes the OBX record
F	Final results; Can only be changed with a corrected result.
I	Specimen in lab; results pending
P	Preliminary results
R	Results entered -- not verified
S	Partial results
X	Results cannot be obtained for this observation
U	Results status change to Final. without retransmitting results already sent as 'preliminary.' E.g., radiology changes status from preliminary to final
W	Post original as wrong, e.g., transmitted for wrong patient

7.3.2.12 Effective date last obs normal value (TS) 00580

Definition: This field contains the changes in the observation methods that would make values obtained from the old method not comparable with those obtained from the new method.

Null if there are no normals or units. If present, a change in this date compared to date-time recorded, the receiving system's test dictionary should trigger a manual review of the results to determine whether the new observation ID should be assigned a new ID in the local system to distinguish the new results from the old.

7.3.2.13 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 nonprivileged users would see only the "preferred" antimicrobials to which the organism was susceptible. We expect that other cases also occur.

7.3.2.14 Date-time of the observation (TS) 00582

Definition: This field is required in two circumstances. The first is when the observations reported beneath one report header (OBR) have different dates. 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.

7.3.2.15 Producer's ID (CE) 00583

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

Definition: 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 CE data type. In the US, the Medicare number of the producing service is suggested as the identifier.

7.3.2.16 Responsible observer (XCN) 00584

```
Components:  <ID number (ST)> ^ <family name (ST)> ^ <given name (ST)> ^ <middle initial or name (ST)> ^
              <suffix (e.g., JR or III) (ST)> ^ <prefix (e.g., DR) (ST)> ^ <degree (e.g., MD) (ST)> ^ <source
              table (IS)> ^ <assigning authority (HD)> ^ <name type (ID)>  ^<identifier check digit (ST)> ^
              <code identifying the check digit scheme employed (ID)> ^ <identifier type code (IS)> ^
              <assigning facility ID (HD)>

Subcomponents of assigning authority:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>

Subcomponents of assigning facility ID:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>
```

Definition: 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 CE data type. If the code is sent as a local code, it should be unique and unambiguous when combined with *OBX-15-producer ID.*

7.3.2.17 Observation method (CE) 00936

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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[4] for a more complete discussion of these distinctions. If an 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.

The Centers for Disease Control and Prevention (CDC) Method Code (CDCM) (see *Figure 7-3*) is one candidate code system for reporting methods/instruments. EUCLIDES method codes are another. User-defined tables are an alternative.

7.4 EXAMPLE TRANSACTIONS

7.4.1 Query/response

The following is a query of the EKG system for the data for a particular patient number 0123456-1 for reports that have been modified or created since 1/1/88. The response ends with a continuation pointer. A continuation query follows, in reply to which a continuation response is sent.

Query (QRY)

```
MSH|^~\&|CBD||EKG||||QRY^R02|CDB22222|P<cr>
QRD|198904180943|R|I|Q4412|||10|RD|0123456-1|RES<cr>
QRF|EKG||198801010000<cr>
```

Response

```
MSH|^~\&|EKG||CDB||||ORF^R04|X981672|P<cr>
MSA|AA|CDB22222|P<cr>
QRD|198904180943|R|I|Q4412|||10|RD|0123456-1|RES<cr>
QRF|EKG||198804010000<cr>
PID|1|0123456-1||ROBERTSON^JOHN^H||||||9821111<cr>
OBR|1|43215^OE|98765^EKG|93000^EKG
```

[4] LOINC Committee. Logical Observation Identifier Names and Codes. Indianapolis: Regenstrief Institute and LOINC Committee, 1995. c/o Kathy Hutchins, 1001 West 10th Street RG-5, Indianapolis, IN 46202. 317/630-7433. Available via FTP/Gopher (dumccss.mc.duke.edu/standards/HL7/ termcode/ loinclab) and World Wide Web (http://dumccss.mc.duke.edu/standards HL7/termcode/ loinclab/). The LOINC Code System is described in Forrey AW, McDonald CJ, DeMoor G, Huff SM, Leavelle D, Leland D, et.al. Logical Observation Identifier Names and Codes (LOINC) database: a public use set of codes and names for electronic reporting of clinical laboratory test results. Clinical Chemistry 1996;42:81-90

```
REPORT|R|198801111000|198801111330|||RMT||||
   ... 1988011 11330|?|P030||||||198801120930||||||88-126666|A111|
   ... VIRANYI ^ANDREW<cr>

OBX|1|ST|8897-1^QRS COMPLEX:^LN||91|/MIN|60-100||||F<cr>
OBX|2|ST|8894-8^P WAVE:^LN|||/MIN|60-100||||F<cr>
OBX|3|ST|8625-6^P-R INTERVAL:^LN||0|/MSEC|1.06-.10||||F<cr>
OBX|4|ST|8633-0^QRS DURATION:^LN||368|/MSEC|.18-.22||||F<cr>
               ...
               ...
               ...
OBX|8|CE|8601-7^EKG IMPRESSION:^LN|1|^ATRIAL FIBRILATION||||||F<cr>
OBX|9|CE|8601-7^EKG IMPRESSION:^LN|2|^ST DEPRESSION||||||F<cr>
OBX|109|FT||93000&ADT^EKG COMMENT||\.in+4\\.ti-4\ 1. When compared with
EKG of
   ... 31-oct-88 ventricular rate has increased by 30 bpm.\.sp\\.ti-4\
   ... 2. Criteria for Lateral infarct are no longer present.|||||F<cr>

OBR|2|43217^OE|98767^EKG|93000^EKG
REPORT||198810311004|198810311004||||?|||198810311004|?|P030||||||19881
0311744||||||
   ... 88-126689|A122|BREAL|WILLIAM<cr>
               ...
               ...
               ...
DSC|1896X22;0123456-1<cr>
```

Continuation query

```
MSH|^~\&|CDB||EKG||||QRY^R02|CDB22289|P<cr>
QRD|198904180943|R|I|Q4412|||10|RD|0123456-1|RES<cr>
QRF|EKG||1988040100000<cr>
DSC|1896X22;0123456-1<cr>
```

Continuation response

```
MSH|^~\&|EKG||CDB||||ORF^R04|X981672|P<cr>
MSA|AA|CDB22289|P<cr>
QRD|198904180943|R|I|Q4412|||10|RD|0123456-1RES<cr>
QRF|EKG||198804010000<cr>
PID||0123456-1||ROBERTSON^JOHN^H|||||||9821111<cr>
OBR| ...
     ...
     ...
```

7.4.2 Unsolicited

The following is an unsolicited transmission of radiology data.

```
MSH|^~\&|XRAY||CDB||||ORU^R01|K172|P<cr>
PID|1|0123456-1||ROBERTSON^JOHN^H|||||||9821111<cr>
OBR|1|X89-1501^OE|78912^RD|71020^CHEST XRAY AP &
```

```
LATERAL|R|198703291530|19873290800|||JBM|N <cr>
OBX|1|CE|71020&IMP^RADIOLOGIST'S IMPRESSION|4||^MASS LEFT LOWER
LOBE|1||A||F<cr>
OBX|2|CE|71020&IMP|2|^INFILTRATE RIGHT LOWER LOBE|||A||F<cr>
OBX|3|CE|71020&IMP|3|^HEART SIZE NORMAL|||N||F<cr>
OBX|4|FT|71020&GDT|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|CE|71020&REC||71020^Follow up CXR 1 month||30-45||||F<cr>
```

7.4.3 Example message

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

```
MSH|...
PID|...
```

Electrolytes:

```
OBR|1|870930010^OE|CM3562^LAB|80004^ELECTROLYTES|R|198703281530|1987032
90800|||
   401-
0^INTERN^JOE^^^^MD^L|N|||||SER|^SMITH^RICHARD^W.^^^DR.|(319)377-4400|
   This is requestor field #1. Requestor field #2|Diag.serv.field #1.|
   Diag.serv.field #2.|198703311400|||F<cr>
OBX|1|ST|84295^NA||150|mmol/l|136-148|H||A|F|19850301<cr>
OBX|2|ST|84132^K+||4.5|mmol/l|3.5-5|N||N|F|19850301<cr>
OBX|3|ST|82435^CL||102|mmol/l|94-105|N||N|F|19850301<cr>
OBX|4|ST|82374^CO2||27|mmol/l|24-31|N||N|F|19850301<cr>
```

CBC:

```
OBR|2|870930011^OE|HEM3268^LAB|85022^CBC|R|198703281530|198703290800|||
401-0 ^
   INTERN^JOE^^^^MD^L|N||||BLD|^SMITH^RICHARD^W.^^^DR.|(319)377-4400|Th
is is
   requestor field #1.|This is Requestor field #2.|This is lab field
#1.|Lab
   field #2.|198703311400|||F<cr>

OBX|1|ST|718-7^HEMOGLOBIN:^LN||13.4|GM/DL|14-18|N||S|F|19860522<cr>
OBX|2|ST|4544-3^HEMOATOCRIT:^LN||40.3|%|42-52|L||S|F|19860522<cr>
OBX|3|ST|789-8^ERYTHROCYTES:^LN||4.56|10*6/ml|4.7-
6.1|L||S|F|19860522<cr>
OBX|4|ST|787-2^ERYTHROCYTE MEAN CORPUSCULAR VOLUME:^LN
   ||88|fl|80-94|N||S|F|19860522<cr>
OBX|5|ST|785-6^ERYTHROCYTE MEAN CORPUSCULAR HEMOGLOBIN:^LN
   ||29.5|pg|27-31|N||N|F|19860522<cr>
OBX|6|ST|786-4^ERYTHROCYTE MEAN CORPUSCULAR HEMOGLOBIN
CONCENTRATION:^LN
   ||33|%|33-37|N||N|F|19860522<cr>
OBX|7|ST|6690-2^LEUKOCYTES:^LN||10.7|10*3/ml|4.8-
10.8|N||N|F|19860522<cr>
OBX|8|ST|764-1^NEUTROPHILS BAND FORM/100 LEUKOCYTES:^LN||2|%||||F<cr>
OBX|9|ST|769-0^NEUTROPHILS SEGMENTED/100 LEUKOCYTES:^LN||67|%||||F<cr>
OBX|10|ST|736-9^LYMPHOCYTES/100 LEUKOCYTES:^LN||29|%||||F<cr>
OBX|11|ST|5905-5^MONOCYTES/100 LEUKOCYTES:^LN||1|%||||F<cr>
OBX|12|ST|713-8^EOSINOPHILS/100 LEUKOCYTES:^LN||2|%||||F<cr>
```

Sed rate:

```
OBR|3|870930011^OE|HEM3269^LAB|4537-7^ERYTHROCYTE SEDIMENTATION
RATE:^LN
   |R|198703281530|198703290800|||
   401-0^INTERN^JOE^^^^MD^L|N||||BLD|^SMITH^RICHARD^W.^^^DR.|(319)377-
4400|
   This is requestor field #1.|This is Requestor field #2.|This is lab
field
   #1.|Lab field #2.|198703311400|||F<cr>
OBX|1|ST|4537-7^ERYTHROCYTE SEDIMENTATION RATE:^LN|
   |7|MM/HR|0-10|N||S|F|19860522|E|1|1792|27<cr>
Parent micro result, identifies organism
OBR|4|2740X^OE|BC376^MIC|87040^Blood
culture|R|198703280600|198703290800|||
   99-2^JONES&COLLECTOR|N|Hepatitis risk||198703290830|Bld|
   4010^INTERN^JOE^^^^MD^L|X3472|Requestor field 1|Requestor field 2|
   Producer's field 1|Producer's field 2|198703301000|35.00|MB|F|<cr>
OBX|1|CE|600-7^MICROORGANISM IDENTIFIED:^LN|1|^E Coli|||A||F<cr>
OBX|2|CE|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|R|198703281230
   |198703290800||||G|Hepatitis Risk||198703290830|Bld
   |401.0^INTERN^JOE^^^^MD^L|X3472|||||198703310900|40.00
   |MB|F|87040^1|||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^AMAKACIN: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|140-4^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|R|198703281230|198703290800||||G|
   Hepatitis risk||198703290830|Bld|401.0^INTERN^JOE^^^^MD^L|X3472|||||
   198703310900|40.00|MB|F|87040^2|||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>
```

7.4.4 Example of 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) EKG order record (OBR)

c) EKG coded result record (OBX)

d) EKG result records (OBX):

1) ventricular rate

2) atrial rate

3) QRS width

4) PR interval

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

f) two diagnostic impressions for CXR (OBX)

g) description record for CXR (OBX)

h) a recommendation record for CXR (OBX)

i) an order record for surgical pathology (OBR)

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

k) a microscopic description record for pathology (OBX)

l) vital signs request (OBR)

m) six vital signs (OBX)

n) part of the physical history (OBR & OBX)

o) end record

```
MSH|...
PID|...
**--Order record for EKG--**
OBR|1|P8753^OE|EK5230^EKG|93000^EKG|R|198703281530|198703290800|||401
0^INTERN^JOE^^^^MD^L|N <cr>


**--Two interpretation records for EKG--**
**--[In this case, the result observation ID assumes the observation
code in the order
record.]--**
OBX|1|CE|&IMP|1|^Sinus bradycardia|||A|||F <cr>
OBX|2|CE|&IMP|2|^Occasional PVCs|||A|||F <cr>


**--Four numeric results for EKG--**
**--[The AS4 code is an extension of the CPT4 code (93000) for EKG plus
extension .1,
.2, etc., as detailed in the Implementation Guide.]--**

OBX|3|ST|8897-1^QRS COMPLEX:NRAT:PT:CARDIAC VENTRICLES:QN:EKG^LN|
   |80|/min|60-100||||F <cr>
OBX|4|ST|8894-8^P WAVE:NRAT:PT:CARDIAC ATRIA:QN:^LN||80|/min
   |60-100||||F <cr>
OBX|5|ST|8633-0^QRS DURATION:TIM:PT:HEART:QN:EKG^LN||.08|msec
   |.06-.10||||F <cr>
OBX|6|ST|8625-6^P-R INTERVAL:TIM:OT:HEART:QN:EKG^LN||.22|msec
   |.18-.22||||F <cr>



**--Order record for CXR--**
OBR|2|P8754^OE|XR1501^XR|71020^Chest X-ray AP &
Lateral|R|198703281530|198703290800|||
   401-0^INTERN^JOE^^^^MD^L|N <cr>


**--Two CXR diagnostic impressions--**
OBX|1|CE|71020&IMP^Radiologist's
Impression|1|.61^RUL^ACR~.212^Bronchopneumonia^ACR|||A|||F<cr>
OBX|2|CE|71020&IMP|2|51.71^Congestive heart failure^ACR|||A|||F<cr>
```

```
**--CXR Description with continuation records--**
OBX|3|TX|71020&GDT||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|CE|71020&REC||71020^Followup CXR 1 month^AS4||||||F<cr>


**--Order record for pathology report--**
OBR|3|P8755^OE|SP89-739^SP|88304^Surgical Path
Report|R|198703281530|198703290800|||401-0^INTERN^JOE^^^^MD^L|N<cr>

OBX|1|CE|&ANT|1|Y0480-912001^orbital region^SNM||||||F<cr>


**--Gross description record (with overflow) for pathology--**
OBX|2|TX|&GDT^GrossSpecimenDescription|1|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|&MDT^MicroscopicDescription|1|A|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--**
OBR|4|P8756^OE|N2345^NR|3000.02^VITAL
SIGNS|R|198703281530|198703290800|||401-0^INTERN^JOE^^^^MD^L|N<cr>


OBX|1|ST|8462-4^INTRAVASCULAR DIASTOLIC:PRES:^LN||90|mm(hg)|60-
90||||F<cr>
OBX|2|ST|8479-8^INTRAVASCULAR SYSTOLIC:PRES:^LN||120|mm(hg)
   |100-160||||F<cr>
OBX|3|ST|8478-0^INTRAVASCULAR MEAN:PRES:^LN||100|mm(hg)|80-
120|N|||F<cr>
OBX|4|ST|8867-4^HEART BEAT:NRAT:^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|R|198703281530|198703290800|401
0^INTERN^JOE^^^^MD^L|N<cr>

OBX|1|CE|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 & SOB.  NO RELIEF WITH ANTACIDS
   OR NTG. NO OTHER SX. NOT PREVIOUSLY ILL.||||||F<cr>
   .
   .
and so on.
```

7.4.5 Reporting cultures and susceptibilities

7.4.5.1 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||CE|organism^413^L|1|^E. Coli||||||F <cr>
OBX||CE|organism^413^L|2|^S. Aureus||||||F <cr>
```

Not recommended:

```
OBX||CE|organism1^413^L|1|^E. Coli||||||F <cr>
OBX||CE|organism2^413^L|1|^S. Aureus||||||F <cr>
```

7.4.5.2 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 an MIC value (in *OBX-5-observation value* (results)) and *OBX-8-abnormal flag* that indicates whether the organism is sensitive, resistant, or intermediate (see *HL7 table 0078- Abnormal flags* 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-abnormal flags* (e.g., **S**).

A susceptibility battery may only contain results corresponding to a single organism that has been previously reported in a culture battery.

7.4.5.3 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 number* (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^R03|LAB1003929
PID|||900329493||PETRSN~DAVID|||927
PV1||I|
ORC|NW|
OBR||A485388^OE|H29847^LAB1|BLOOD CULTURE|||
```

Result for culture

```
ORC|RE...
OBR||A485388^OE|H29847^LAB1|BLOOD CULTURE||...
OBX||FT|SDES^SOURCE||BLOOD-RAPID|||||F <cr>
OBX||FT|EXAM^MICROSCOPIC||GRAM POSITIVE COCCI IN GROUPS|||||F <cr>
OBX||FT|ORGANISM^IDENTIFIER|1|ISOLATE 1|||||F <cr>
```

Result for susceptibility

```
ORC|RE...
OBR||A485388^OE|H29848^LAB1|BT1^SUSCEPTIBILITY BATTERY|||||MC|to field
   ... 26|ORGANISM^1|||A485388&OE^H29847&LAB1|
OBX||CE|ACAPEN^PENICILLIN||0.5|R|||||F <cr>
OBX||CE|ACHNAF^NAICILLIN||1|R|||||F <cr>
OBX||CE|ACHCCLI^CLINDAMYCIN||<=0.1|S|||||F <cr>
```

Result for Culture ID

```
ORC|RE...
OBR||A485388^OE|H29847^LAB1|BLOOD CULTURE||...
OBX||FT|ORGANISM^IDENTIFIER|1|STAPH EPI||||||F <cr>
```

New result for culture ID

```
ORC|RE...
OBR||A485388^OE|H29847^LAB1|BLOOD CULTURE||...
OBX||FT|ORGANISM^IDENTIFIER|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.

7.4.6 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|...
PID|...
OBR|||89-551^EKG|93000^EKG REPORT|...         // 1ST child OBR.
OBX||ST|93000.1^VENTRICULAR RATE (EKG)|...
OBX||ST|93000.2^...
   ...
   ...
OBX||FT|93000.14^EKG COMMENT|...
OBR|...                                        // other observation
segments to follow
```

- 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) are carried in the OBR segment.

2. 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|...
PID|...
ORC|PA|A226677^OE|89-450^EKG|...          // original order's ORC.
OBR||||93000^EKG REPORT|...         // original order segment
ORC|CH|A226677^OE|89-451^EKG<cr>          // 1st child ORC.
OBR||||93000^EKG REPORT|...         // 1st EKG child OBR.
OBX||ST...                          // 1st EKG report
OBX||ST...
   ...
OBX||FT...
ORC|CH|A226677^OE|89-452^EKG<cr>          // 2nd child ORC.
OBR||||93000^EKG REPORT|...         // 2nd EKG child OBR.
OBX||ST...                          // 2nd EKG report
OBX||ST...
   ...
OBX||FT...
ORC|CH|A226677^OE|89-453^EKG<cr>          // 3rd child ORC.
OBR||||93000^EKG REPORT|...         // 3rd EKG child OBR.
OBX||ST...                          // 3rd EKG report
OBX||ST...
   ...
OBX||FT...
    ...                             // 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.

7.4.7 Patient-specific clinical data with an order

Reporting body weight and height with a creatinine clearance.

```
MSH|...
PID|...
ORC|NW|...                          // New order.

OBR||P42^PC||2164-2^CREATININE RENAL CLEARANCE:VRAT:24H:UR:QN^LN|...
OBX||ST|3141-9^BODY WEIGHT:MASS:^LN||62|kg<cr>
OBX||ST|3137-7^BODY HEIGHT:LEN:^LN||190|cm<cr>

ORC|NW|...                          // Next order.
```

7.5 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 4.5.1, ""OBR - observation request segment"), OBX (Section 7.3.2, "OBX - observation/result segment"), RXA (Section 4.8.14, "RXA - pharmacy /treatment administration segment"), and RXR (Section 4.8.3, "RXR - pharmacy/treatment order 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.

7.5.1 Terminology and concepts

7.5.1.1 **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.

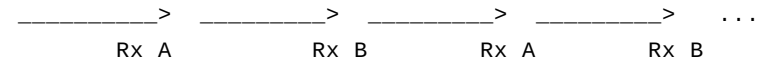
7.5.1.2 **phase of a clinical trial:** a treatment and/or observation interval of a clinical trial. A phase may represent an interval with a specific treatment regimen assigned randomly or otherwise, with each regimen of a progression of treatments, or with an evaluation component only. Generally, for 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.

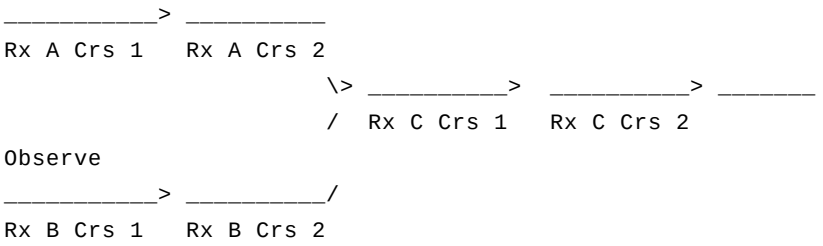
7.5.1.2.1 Example 1

Alternating treatment plus observation intervals:



7.5.1.2.2 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:



7.5.1.2.3 Example 3

Random assignment to placebo or treatment A, both taken daily and evaluated monthly.

```
_____________> _____________> _____________> _____________>  . . .
  Month 1       Month 2       Month 3       Month 4
```

7.5.1.3 **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:

7.5.1.3.1 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																

7.5.1.3.2 Schedule for a cancer chemotherapy trial

		Prior to Each Cycle		Every 3 Cycles	
	Prestudy		During Cycle		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 radionuclide 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.

* Radionuclide scan and X-ray of the bones, CT scans of the chest, pelvis, and brain only when clinically indicated.

7.5.1.3.3 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-opiod 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

7.6 CLINICAL TRIALS - TRIGGER EVENTS AND MESSAGE DEFINITIONS

The event type will be carried in the message header segment.

7.6.1 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.

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)
C07	Correct/update phase information
C08	Patient has gone off phase of clinical trial

CRM	Clinical Study Registration Message	Chapter
MSH	Message Header	2
{PID	Patient Identification	3
[PV1]	Patient Visit	3
CSR	Clinical Study Registration	7
{[CSP]}	Clinical Study Phase	7
}		

7.6.2 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.

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	Unsolicited Study Data Message	Chapter
MSH	Message Header	2
{		
PID	Patient Identification	3
[PD1]	Additional Demographics	3
[{NTE}]	Notes and comments	2
[PV1	Patient Visit	3
[PV2]	Patient Visit - Additional Info	3
]		
CSR	Clinical Study Registration	7
{[CSP]	Clinical Study Phase	7
{[CSS]	Clinical Study Data Schedule	7
{[[ORC]	Common Order	4
OBR	Observation Battery	7
{OBX}	Observation Results	7
}]		
{[ORC]	Common Order	4
{RXA	Pharmacy Administration	4
RXR	Pharmacy Route	4
}		
}		
}		
}		
}		

7.6.3 CM0, CM1, CM2 - clinical trials master file messages

The master file definition segments are defined in Chapter 8.

7.7 CLINICAL TRIALS - SEGMENT DEFINITIONS

7.7.1 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.

Figure 7-14. CSR attributes

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1	60	EI	R			01035	Sponsor Study ID
2	60	EI	O			01036	Alternate Study ID
3	60	CE	O			01037	Institution Registering the Patient
4	30	CX	R			01038	Sponsor Patient ID
5	30	CX	O			01039	Alternate Patient ID - CSR
6	26	TS	R			01040	Date/Time Of Patient Study Registration
7	60	XCN	O			01041	Person Performing Study Registration
8	60	XCN	R			01042	Study Authorizing Provider
9	26	TS	C			01043	Date/time Patient Study Consent Signed
10	60	CE	C			01044	Patient Study Eligibility Status
11	26	TS	O	Y/3		01045	Study Randomization Date/time
12	200	CE	O	Y/3		01046	Randomized Study Arm
13	200	CE	O	Y/3		01047	Stratum for Study Randomization
14	60	CE	C			01048	Patient Evaluability Status
15	26	TS	C			01049	Date/time Ended Study
16	60	CE	C			01050	Reason Ended Study

7.7.1.0 CSR field definitions

7.7.1.1 Sponsor study ID (EI) 01035

```
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).
```

7.7.1.2 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.

7.7.1.3 Institution registering the patient (CE) 01037

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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.

7.7.1.4 Sponsor patient ID (CX) 01038

```
Components:  <ID (ST)> ^ <check digit (ST)> ^ <code identifying the check digit scheme employed (ID)> ^ <
              assigning authority (HD)> ^ <identifier type code (IS)> ^ < assigning facility (HD)>

Subcomponets of assigning authority:  <namespace ID (IS)> & <universal ID (ST)> * <universal ID type (ID)>

Subcomponents of assigning facility: <namespace ID (IS)> & <universal ID (ST)> * <universal ID type (ID)>
```

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*.

7.7.1.5 Alternate patient ID - CSR (CX) 01039

```
Components:  <ID (ST)> ^ <check digit (ST)> ^ <code identifying the check digit scheme employed (ID)> ^ <
              assigning authority (HD)  )> ^ <identifier type code (IS)> ^ < assigning facility (HD)>

Subcomponets of assigning authority:  <namespace ID (IS)> & <universal ID (ST)> * <universal ID type (ID)>

Subcomponents of assigning facility: <namespace ID (IS)> & <universal ID (ST)> * <universal ID type (ID)>
```

Definition: This field may be the sending application's patient identification. Coding conventions may be used as agreed upon by users.

7.7.1.6 Date/time patient of patient study registration (TS) 01040

Definition: This field contains 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.

7.7.1.7 Person performing study registration (XCN) 01041

```
Components:  <ID number (ST)> ^ <family name (ST)> ^ <given name (ST)> ^ <middle initial or name (ST)> ^
              <suffix (e.g., JR or III) (ST)> ^ <prefix (e.g., DR) (ST)> ^ <degree (e.g., MD) (ST)> ^ <source
              table (IS)> ^ <assigning authority (HD)> ^ <name type (ID)>  ^<identifier check digit (ST)> ^
              <code identifying the check digit scheme employed (ID)> ^ <identifier type code (IS)> ^
              <assigning facility ID (HD)>

Subcomponents of assigning authority:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>

Subcomponents of assigning facility ID:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>
```

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.

7.7.1.8 Study authorizing provider (XCN) 01042

```
Components:  <ID number (ST)> ^ <family name (ST)> ^ <given name (ST)> ^ <middle initial or name (ST)> ^
              <suffix (e.g., JR or III) (ST)> ^ <prefix (e.g., DR) (ST)> ^ <degree (e.g., MD) (ST)> ^ <source
              table (IS)> ^ <assigning authority (HD)> ^ <name type (ID)>  ^<identifier check digit (ST)> ^
              <code identifying the check digit scheme employed (ID)> ^ <identifier type code (IS)> ^
              <assigning facility ID (HD)>

Subcomponents of assigning authority:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>
```

```
Subcomponents of assigning facility ID:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>
```

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).

7.7.1.9 Date patient study consent signed (TS) 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.

7.7.1.10 Patient study eligibility status (CE) 01044

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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).

7.7.1.11 Study randomization date/time (TS) 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 chronologic order.

7.7.1.12 Randomized study arm (CE) 01046

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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.

7.7.1.13 Stratum for study randomization (CE) 01047

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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.

7.7.1.14 Patient evaluability status (CE) 01048

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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).

7.7.1.15 Date/time ended study (TS) 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.

7.7.1.16 Reason ended study (CE) 01050

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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).

7.7.2 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 7.5.1.2, "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.

Figure 7-15. CSP attributes

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1	60	CE	R			01051	Study Phase Identifier
2	26	TS	R			01052	Date/time Study Phase Began
3	26	TS	O			01053	Date/time Study Phase Ended
4	60	CE	C			01054	Study Phase Evaluability

7.7.2.0 CSP field definitions

7.7.2.1 Study phase Identifier (CE) 01051

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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. Example: `2^Init Rx, Crs 1^NCI T93-0807 Phases`

7.7.2.2 Date/time study phase began (TS) 01052

Definition: This field contains the date the patient began this phase interval. The time is optional.

7.7.2.3 Date/time study phase ended (TS) 01053

Definition: This field contains the date the patient ended this phase interval.

7.7.2.4 Study phase evaluability (CE) 01054

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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**.

7.7.3 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 7.5.1.3, "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.

Figure 7-16. CSS attributes

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1	60	CE	R			01055	Study Scheduled Time Point
2	26	TS	O			01056	Study Scheduled Patient Time Point
3	60	CE	O	Y/3		01057	Study Quality Control Codes

7.7.3.0 CSS field definitions

7.7.3.1 Study scheduled time point (CE) 01055

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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 4.4.2, "Interval component (CM)," (the Interval component of the TQ Timing/Quantity data type could be used.) Time point naming conventions and usage must be specified by implementors.

7.7.3.2 Study scheduled patient time point (TS) 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.

7.7.3.3 Study quality control codes (CE) 01057

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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.

7.7.4 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.

Figure 7-17. CTI attributes

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1	60	EI	R			01058	Sponsor Study Identifier
2	60	CE	C			01051	Study Phase Identifier
3	60	CE	O			01055	Study Scheduled Time Point

7.7.4.0 CTI field definitions

7.7.4.1 Sponsor study identifier (EI) 01058

```
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-study ID*.

7.7.4.2 Study phase identifier (CE) 01051

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

Definition: This field identifies the phase of the study that a patient has entered. See *CSP-1-study phase ID* for details of coding systems.

7.7.4.3 Study scheduled time point (CE) 01055

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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-scheduled time point*.

7.7.5 CM0 clinical study master segment

The clinical study master segment (CMO) is described in Chapter 8.

7.7.6 CM1 clinical study phase master segment

The clinical study phase master segment (CMI) is described in Chapter 8.

7.7.7 CM2 clinical study schedule master segment

The clinical study schedule master segment is described in Chapter 8.

7.8 CLINICAL TRIALS - EXAMPLES

7.8.1 CRM - message when patient registered on a clinical trial

```
MSH|^~\&|PDMS|MDACC|ORDER ENTRY|MDACC|||CRM^C01 <cr>
CMO|1|DM90-004^Didemnin Small Cell Lung^MDACC||
     Phase II Study of Didemnin in Early Stage Small Cell Lung Cancer|
     31^Smith^Joan ^^^^MD^MDACC|19941001|12|19941013 <cr>
PID|1||223892||King^Sally^Brown||19530117 <cr>
CSR|1|DM94-004^MDACC||MDACC|3||19941013||342^^^^^^^PDMS|
.....1005^^^^^^^MDACC| 19941013|Y^Meets All Requirements^PDMS <cr>
```

7.8.2 CRM - message when patient begins a phase of a clinical trial

```
MSH|^~\&|PDMS|MDACC|PHARM|MDACC|||CRM^C05 <cr>
CMO|1|ID91-025^MDACC||Double Blind, Multicenter Study of 13-Cis
.....Retinoic Acid to Prevent Secondary Primary Tumors^MDACC|
.....863^McDougall^Lester^^^^MD^MDACC|19940701|312|19941227 <cr>
CM1|1|2^Treatment^PDMS|Daily Drug/Placebo Treatment|3^YEARS <cr>
PID|1||352352||West^Mary^L.||19230213 <cr>
CSR||ID91-025^MDACC||MDACC|301||19941005|||||19941201|2^blind^PDMS|
     12^Smoker,Stage II,<60^PDMS <cr>
CSP||2^Treatment^PDMS|19941201 <cr>
```

7.8.3 CSU - message reporting monthly patient data updates to the sponsor

```
MSH|^~\&|PDMS|MDACC|CTMS|NCI|||CSU^C09 <cr>
CMO|1|T93-0800^NCI|ID93-030^Ph I Study of Oral Fostriecin^MDACC|
     |235^Alexander^Susan^B.^^^MD^MDACC|19940801|14|19941205|^Sam Smith
<cr>
CM2|1|^Prestudy^NCI|Prestudy Eligibility and Baseline Clinical Params|
     ^CBC~^SMA12~^Pathology~^Elig.checklist~^Prestudy Form~^
     Imaging procedures as indicated <cr>
CM2|2|^Course Completion^NCI|Course Completion Toxicity and Response
.....Evaluation|Adverse Events Form~^Course Completion Form~^CEA <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|||3^EligibilChecklist^StudyFormsList|||19941205 <cr>
OBX|1|CE|ELIG1^Elig Crit 1^NCI|Text Elig Crit 1|Y <cr>
OBX|2|CE|ELIG2^Elig Crit 2^NCI||Y <cr>
OBR|2|||4^Prestudy Form^StudyFormsList|||19941205 <cr>
OBX|1|CE|QOL^Quality of Life^NCI||2&3&2&4&2^SPITZER <cr>
OBX|2|CE|PRICHEM^Prior Chemo^NCI||Yes <cr>
OBX|3|CE|PRIBIOL^Prior Biologics^NCI||No <cr>
OBX|4|NM|NUMREM^Number Prior Remissions^NCI||2 <cr>
```

```
OBR|3|||88304^SURG PATH REPORT|||19940101 <cr>
OBX|1|CE|88304&ANT|1|9999^PANCREAS^SNM <cr>
OBX|2|CE|88304&IMP|2|9999^ADENOCARCINOMA^SNM <cr>
OBR|4|||85022^CBC|||199412050800 <cr>
OBX|1|ST|718-7^HEMOGLOBIN:^LN||13.4|GM/DL|14-18|N||S|F|19860522<cr>
[cbc values]

OBX|2|ST|4544-3^HEMATOCRIT:^LN||40.3|%|42-52|L||S|F|19860522 <cr>
OBX|3|ST|789-8^ERYTHROCYTES:^LN||4.56|10*6/ml|4.7-6.1|L||S|F|19860522
<cr>
OBX|4|ST|787-22^ERYTHROCYTE MEAN CORPUSCULAR VOLUME:^LN||88|fl
   |80-94|N||S|F|19860522 <cr>
OBX|5|ST|785-6^ERYTHROCYTE MEAN CORPUSCULAR HEMOGLOBIN:^LN||29.5|pg
   |27-31|N||N|F|19860522 <cr>
OBX|6|ST|786-4^ERYTHROCYTE MEAN CORPUSCULAR HEMOGLOBIN
CONCENTRATION:^LN|
   |33|%|33-37|N||N|F|19860522 <cr>
OBX|7|ST|6690-2^LEUKOCYTES:^LN||10.7|10*3/ml|4.8-10.8|N||N|F|19860522
<cr>
OBX|8|ST|764-1^NEUTROPHILS BAND FORM/100 LEUKOCYTES:^LN||2|%|||F <cr>
OBX|9|ST|769-0^NEUTROPHILS SEGMENTED/100 LEUKOCYTES:^LN||67|%|||F <cr>
OBX|10|ST|736-9^LYMPHOCYTES/100 LEUKOCYTES:^LN||29|%|||F <cr>
OBX|11|ST|5905-5^MONOCYTES/100 LEUKOCYTES:^LN||1|%|||F <cr>
OBX|12|ST|713-8^EOSINOPHILS/100 LEUKOCYTES:^LN||2|%|||F <cr>
OBR|5|||80004^ELECTROLYTES|||199412050800 <cr>
OBX|1|ST|2947-0^SODIUM:^LN||150|mmol/l|136-148|H||A|F|19850301 <cr>
OBX|2|ST|2823-3^POTASSIUM:^LN||4.5|mmol/l|3.5-5|N||N|F|19850301 <cr>
[electrolytes values]

OBX|3|ST|2069-3^CHLORIDE:^LN||102|mmol/l|94-105|N||N|F|19850301 <cr>
OBX|4|ST|2028-9^CARBON DIOXIDE.TOTAL:^LN||27|mmol/l|24-31|N||N|F
   |19850301<cr>
CSP|1|^Course 1|19941205|19950120|Y^Toxicity and Response^NCI <cr>
CSS|1|^Course Completion|19950120| <cr>
OBR|1|||2039-6^CARCINOEMBRYONIC AG:^LN|||19941008 <cr>
   OBX|1|NM|2039-6^CARCINOEMBRYONIC AG:^LN||15.2|IU <cr>
OBR|2|||10^Course Completion Form^StudyPhaseFormsList|||19950120 <cr>
OBX|1|CE|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|CE|PERSTAT^Performance Status^NCI||3^ZUBRODS <cr>
OBR|3|||9999^Adverse Events <cr>
OBX|1|CE|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|ID|9999&GRADE|1|M^MODERATE <cr>
OBX|5|ID|9999&RELATION_TO_RX|1|L^LIKELY <cr>
OBX|6|CE|9999&EVENT|2|303^Dyspnea^NCI <cr>
OBX|7|DT|9999&ONSET|2|19941231 <cr>
OBX|8|DT|9999&RESOLUTION|2 <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,

```
OBX|9|ID|9999&GRADE|2|MI^MILD <cr>
OBX|10|ID|9999&RELATION_TO_RX|2|U^UNLIKELY <cr>
```

RECHALLENGE.]

7.9 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.

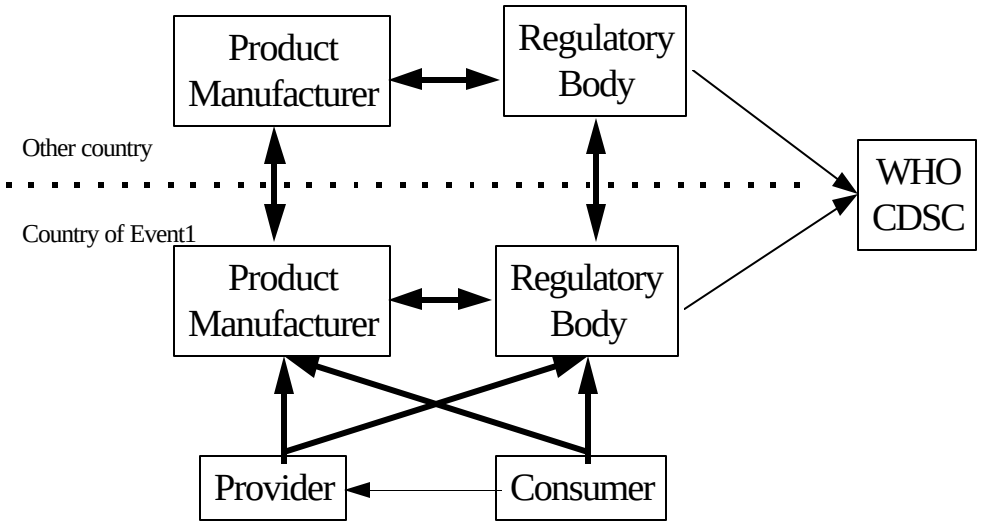
Reporting has usually focused on *serious* and *unexpected* events. Serious, if defined unambiguously, focuses attention on those events of most importance to the patient and practitioner. Expected events are those which prior experience has demonstrated to be probabilistically linked to the product 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 7-18. - 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.

7.9.1 Terminology and concepts

7.9.1.1 **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 physiologic condition (Dorland's Illustrated Medical Dictionary 27th edition).

7.9.1.2 **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)

7.9.1.3 **product:** a drug or medical device.

7.9.1.4 **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.

7.9.1.5 **trade (brand) name:** proprietary names that are registered to protect the name for the sole use of the manufacturer holding the trademark.

7.9.1.6 **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.

7.9.1.7 **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.

7.9.1.8 **causation:** an exposure which truly does increase or decrease the probability of a certain outcome.

7.9.1.9 **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 believe in a causal relationship between the product and the event while others can decrease the probability that there is a causal relationship.

7.9.1.10 **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.

7.9.1.11 **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.

7.9.1.12 **Holder of marketing authorization (HMA):** the organization which holds the authority to market a product. This will often be the organization which manufactures the product.

7.9.1.13 **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.

7.9.1.14 **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 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

7.10.1 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	Product Experience Message	Chapter
MSH	Message Header	2
EVN	Event Type	3
PID	Patient Identification	3
[PD1]	Additional Demographics	3
[{NTE}]	Notes and comments	2
[PV1	Patient Visit	3
[PV2]]	Patient Visit - Additional Info	3
{ PES	Product Experience Sender	7
{ PEO	Product Experience Observation	7
{ PCR	Potential Causal Relationship	7
[RXE	Pharmacy/Treatment Encoded Order	4
[{RXR}]	Pharmacy/Treatment Route	4
]		
[{RXA	Pharmacy/Treatment Administration	4
[RXR]	Pharmacy/Treatment Route	4
}]		
[{PRB}]	Detail problem segment	12
[{OBX}]	Observation/Result Segment	7
[{NTE}]	Notes and comments	2
[NK1	Associated parties segment	2
[RXE	Pharmacy/Treatment Encoded Order	4
[{RXR}]	Pharmacy/Treatment Route	4
]		
[{RXA	Pharmacy/Treatment Administration	4
[RXR]	Pharmacy/Treatment Route	4
}]		
[{PRB}]	Detail Problem Segment	12
[{OBX}]	Observation/Results Segment	7
]		
[{CSR	Clinical study registration	7
[{CSP}]	Clinical study phase segment	7
}]		
}}}		

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 were 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.

7.10.2 SUR - summary product experience report (event P09)

Sending summary reports related to products constitutes a P09 event.

SUR	Summary Product Experience Report	Chapter
MSH	Message Header	2
{		
FAC	Facility	7
{PSH	Product Summary Header	7
PDC	Product Detail Country	7
}		
PSH	Product Summary Header	7
{FAC	Facility	7
PDC	Product Detail Country	7
NTE	Notes (for PCR)	2
}		
ED	Encapsulated Data	2
}		

The Summary Product Experience Report message can be divided into two separate parts. Part 1 consists of a Facility segment which identifies the reporting organization, a Product Summary Header segment which provides summary information about the products and manufacturers, and a Product Detail Country segment which provides country specific product identification and marketing information. Part 2 consists of a repeating series of segments. These segments could be used to represent data about each model of a medical device (Part 2 of FDA Form 3417, for example). The Product Summary Header segment provides manufacturer's data, under which repeating sets of Facility segments (representing multiple manufacturing sites), a Product Detail Country segment (representing marketing and product identification data) and the Note segment (for other commentary) may follow. Finally, the Encapsulated Data (ED) segment can be used to transmit images of documents, including any of the MIME (Multimedia Internet Mail Extension) support formats such as JPEG, GIF, and FAX.

Regulatory agencies require a variety of reports that are centered on the product, not on a single patient. Some of these reports request information just about the product, and some request information about the

product combined with a summary of the product experience reports on that product. These are used by regulatory agencies to provide totals against which they can verify that they have received and processed all of the relevant reports, and to calculate denominators for computing event rates. If manufacturers begin to transmit these reports electronically and regulatory agencies in turn electronically confirm the receipt of such reports, the need for some of these summary reports will decline.

The SUR message provides a mechanism for sending a variety of different summary reports. In the United States, the Medical Device Reporting Annual Certification and the Medical Device Reporting Baseline Report are examples of such reports. Below, we use these two medical device reports to illustrate how one would map the contents of this kind of report to the SUR message.

Manufacturers are required to submit a Baseline Report (FDA Form 3417 of October, 1995 (when a device is first released. The focus of this report is a single product. The first part requests information about the manufacturer of the product (Questions 2a through 2g), e.g., the firm's name, street address, city, country, type of firm (e.g., manufacturer, distributor, both); the manufacturer's contact (Questions 3a through 3g). e.g., title, street address, city, state, phone number, and whether the firm is an organization of a foreign manufacturer. Most of this information can be transmitted as fields within the FAC (Facility segment - the first segment in the SUR message following the MSH). Question 1 (which asks the type of baseline report - initial or annual update) and Question 7 (the date of the report) are reported in the PSH (Product Summary Header) segment that follows the FAC segment in the SUR message. The second part of the Baseline Report form also includes information about the device name (Question 2), generic name (Question 3), device model number (Question 4), device catalogue number (Question 5), other device identifier (Question 6), product code (Question 7), and device family (Question 8), related device information (Question 9), the basis for marketing the device (Question 10), device life (Question 11), the date the device was first marketed (Question 12), the date the device ceased being marketed (Question 13), whether the device was the subject of a 522 study (Question 14), and the number of devices manufactured, distributed, and in current use (Question 15). All of these questions with the exception of #9 are represented in the PDC segment. Questions 16a and 16b are represented by nested PSH segments.

The Medical Device Reporting Annual Certification form consists of two parts. Part 12 transmits information describing the firm submitting the report (Questions 2a through 2h) and the individual who completed the report (Questions 3a through 3g). These questions are represented in the FAC segment. Question 1 (period covered by the certification) corresponds to the PSH segment. Part 2, Question 3, which details one or more individual devices, can be transmitted in the repeating FAC and PSH segments. *Figure 7-19* summarizes the mapping between questions on these two FDA forms and the SUR message.

Figure 7-19. Mapping of FDA medical device reports to SUR message

Baseline Report	**Annual Certification**	**SUR**
		MSH
Part 1 Questions 2a-2g, 3a-3g	Part 1 Questions 2,3	{ FAC
Part 1 Questions 1, 7	Part 1 Question 1	{PSH
		PDC
		}

Part 2 Questions 16a, 16b Part 2 Questions 1a, 1b Part 2 Questions 2-15 Part 2 Alternative transmission method - image file rather than text	Part 2 Question 3 Part 2 Question 3	PSH { FAC PDC NTE } ED }

7.11 PRODUCT EXPERIENCE - SEGMENTS DEFINITIONS

7.11.1 PES - product experience sender segment

Figure 7-20. PES attributes

SEQ	LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
1	80	XON	O			01059	Sender Organization Name
2	60	XCN	O	Y		01060	Sender Individual Name
3	200	XAD	O	Y		01062	Sender Address
4	44	XTN	O	Y		01063	Sender Telephone
5	75	EI	O			01064	Sender Event Identifier
6	2	NM	O			01065	Sender Sequence Number
7	600	FT	O	Y		01066	Sender Event Description
8	600	FT	O			01067	Sender Comment
9	26	TS	O			01068	Sender Aware Date/Time
10	26	TS	R			01069	Event Report Date
11	3	ID	O	Y/2	0234	01070	Event Report Timing/Type
12	1	ID	O		0235	01071	Event Report Source
13	1	ID	O	Y	0236	01072	Event Reported To

7.11.1.0 PES - field definitions

7.11.1.1 Sender organization name (XON) 01059

```
Components:  <organization name (ST)> ^ <organization name type code (IS)> ^ <ID Number (NM)> ^ <check digit
             (NM)> ^ <code identifying the check digit scheme employed (ID)> ^ <assigning authority  (HD)> ^
             <identifier type code (IS)> ^ <assigning facility ID (HD)>

Subcomponents of assigning authority: <namespace ID (IS)> & <universal ID (ST)> * <universal ID type (ID)>

Subcomponents of assigning facility: <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.

7.11.1.2 Sender individual name (XCN) 01060

```
Components:  <ID number (ST)> ^ <family name (ST)> ^ <given name (ST)> ^ <middle initial or name (ST)> ^
             <suffix (e.g., JR or III) (ST)> ^ <prefix (e.g., DR) (ST)> ^ <degree (e.g., MD) (ST)> ^ <source
             table (IS)> ^ <assigning authority (HD)> ^ <name type (ID)>  ^<identifier check digit (ST)> ^
             <code identifying the check digit scheme employed (ID)> ^ <identifier type code (IS)> ^
             <assigning facility ID (HD)>

Subcomponents of assigning authority:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>

Subcomponents of assigning facility ID:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>
```

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.

7.11.1.3 Sender address (XAD) 01062

```
Components:  <street address (ST)> ^ <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 (IS)> ^ <census tract (IS)>
```

Definition: This field contains the postal address of the message sender to which correspondence regarding the experience being reported should be directed.

7.11.1.4 Sender telephone (XTN) 01063

```
Components:  [NNN] [(999)]999-9999 [X99999] [B99999] [C any text] ^ <telecommunication use code (ID)> ^
             <telecommunication equipment type (ID)> ^ <email address (ST)> ^ <country code (NM)> ^
             <area/city code (NM)> ^ phone number (NM)> ^ <extension (NM)> ^ <any text (ST)>
```

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.

7.11.1.5 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 an 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").

7.11.1.6 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.

7.11.1.7 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.

7.11.1.8 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.

7.11.1.9 Sender aware date/time (TS)

Definition: This field identifies the date the sender became aware of the event.

7.11.1.10 Event report date (TS) 01069

Definition: This field contains the date the message was originally sent to the regulatory agency.

7.11.1.11 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.

Table 0234 - Report timing

Value	Description
CO	Correction
AD	Additional information
RQ	Requested information
DE	Device evaluation
PD	Periodic
3D	3 day report
7D	7 day report
10D	10 day report
15D	15 day report
30D	30 day report

7.11.1.12 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.

Table 0235 - Report source

Value	Description
C	Clinical trial
L	Literature
H	Health professional
R	Regulatory agency
D	Database/registry/poison control center
N	Non-healthcare professional
P	Patient
M	Manufacturer/marketing authority holder
E	Distributor
O	Other

7.11.1.13 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.

Table 0236 - Event reported to

Value	Description
M	Manufacturer
L	Local facility/user facility
R	Regulatory agency
D	Distributor

7.11.2 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.

Figure 7-21. PEO attributes

SEQ	LEN	DT	OPT/C	RP/ #	TBL #	ITEM #	ELEMENT NAME
1	60	CE	O	Y		01073	Event Identifiers Used
2	60	CE	O	Y		01074	Event Symptom/Diagnosis Code
3	26	TS	R			01075	Event Onset Date/Time
4	26	TS	O			01076	Event Exacerbation Date/Time
5	26	TS	O			01077	Event Improved Date/Time
6	26	TS	O			01078	Event Ended Data/Time
7	106	XAD	O			01079	Event Location Occurred Address
8	1	ID	O	Y	0237	01080	Event Qualification
9	1	ID	O		0238	01081	Event Serious
10	1	ID	O		0239	01082	Event Expected
11	1	ID	O	Y	0240	01083	Event Outcome
12	1	ID	O		0241	01084	Patient Outcome
13	600	FT	O	Y		01085	Event Description From Others
14	600	FT	O	Y		01086	Event 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	60	CE	O	Y		01090	Cause Of Death
19	46	XPN	O			01091	Primary Observer Name
20	106	XAD	O	Y		01092	Primary Observer Address
21	40	XTN	O	Y		01093	Primary Observer Telephone
22	1	ID	O		0242	01094	Primary Observer's Qualification
23	1	ID	O		0242	01095	Confirmation Provided By
24	26	TS	O			01096	Primary Observer Aware Date/Time
25	1	ID	O		0243	01097	Primary Observer's identity May Be Divulged

7.11.2.0 PEO field definitions

7.11.2.1 Event identifiers used (CE) 01073

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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.

7.11.2.2 Event symptom/diagnosis code (CE) 01074

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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.

7.11.2.3 Event onset date/time (TS) 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).

7.11.2.4 Event exacerbation date/time (TS) 01076

Definition: This field identifies the best estimate of the date/time the event was exacerbated.

7.11.2.5 Event improved date/time (TS) 01077

Definition: This field identifies the best estimate of the date/time the event improved.

7.11.2.6 Event ended data/time (TS) 01078

Definition: This field identifies the best estimate of the date/time the event resolved.

7.11.2.7 Event location occurred address (XAD) 01079

```
Components:  <street address (ST)> ^ <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 (IS)> ^ <census tract (IS)>
```

Definition: This field identifies the location at which the event started. Often this will specify only the country in which the event started.

7.11.2.8 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.

Table 0237 - Event qualification

Value	Description
I	Interaction
O	Overdose
A	Abuse
M	Misuse
D	Dependency
L	Lack of expect therapeutic effect
W	Drug withdrawal
B	Unexpected beneficial effect

Unexpected beneficial effects would not often be reported but are required by certain countries.

7.11.2.9 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.

Table 0238 - Event seriousness

Value	Description
Y	Yes
S	Significant
N	No

7.11.2.10 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.

Table 0239 - Event expected

Value	Description
Y	Yes
N	No
U	Unknown

7.11.2.11 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 consequences* for valid values.

Table 0240 - Event consequence

Value	Description
D	Death
L	Life threatening
H	Caused hospitalized
P	Prolonged hospitalization
C	Congenital anomaly/birth defect
I	Incapacity which is significant, persistent or permanent
J	Disability which is significant, persistent or permanent
R	Required intervention to prevent permanent impairment/damage
O	Other

7.11.2.12 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.

Table 0241 - Patient outcome

Value	Description
D	Died
R	Recovering
N	Not recovering/unchanged
W	Worsening
S	Sequelae
F	Fully recovered
U	Unknown

7.11.2.13 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.

7.11.2.14 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.

7.11.2.15 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.

7.11.2.16 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.

7.11.2.17 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.

7.11.2.18 Cause of death (CE) 01090

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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.

7.11.2.19 Primary observer name (XPN) 01091

```
Components:  <family name (ST)> ^ <given name (ST)> ^ <middle initial or name (ST)> ^ <suffix (e.g., JR or
              III) (ST)> ^ <prefix (e.g., DR) (ST)> ^ <degree (e.g., MD) (ST)> ^ <name type code (ID) >
```

Definition: This field identifies the name of the person who initially described the event.

7.11.2.20 Primary observer address (XAD) 01092

```
Components:  <street address (ST)> ^ <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 (IS)> ^ <census tract (IS)>
```

Definition: This field identifies the address of the person who initially described the event.

7.11.2.21 Primary observer telephone (XTN) 01093

```
Components:  [NNN] [(999)]999-9999 [X99999] [B99999] [C any text] ^ <telecommunication use code (ID)> ^
              <telecommunication equipment type (ID)> ^ <email address (ST)> ^ <country code (NM)> ^
              <area/city code (NM)> ^ phone number (NM)> ^ <extension (NM)> ^ <any text (ST)>
```

Definition: This field identifies the telephone number of the person who initially described the event.

7.11.2.22 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.

Table 0242 - Primary observer's qualification

Value	Description
P	Physician (osteopath, homeopath)
R	Pharmacist
M	Mid-level professional (nurse, nurse practitioner, physician's assistant)
H	Other health professional
C	Health care consumer/patient
L	Lawyer/attorney
O	Other non-health professional

7.11.2.23 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.

7.11.2.24 Primary observer aware date/time (TS) 01096

Definition: This field identifies the date/time the primary observer became aware of event.

7.11.2.25 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.

Table 0243 - Identity may be divulged

Value	Description
Y	Yes
N	No
NA	Not applicable

7.11.3 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.

Figure 7-22. PCR attributes

SEQ	LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
1	60	CE	R			01098	Implicated Product
2	1	IS	O		0239	01099	Generic Product
3	60	CE	O			01100	Product Class
4	8	CQ	O			01101	Total Duration Of Therapy
5	26	TS	O			01102	Product Manufacture Date
6	26	TS	O			01103	Product Expiration Date
7	26	TS	O			01104	Product Implantation Date
8	26	TS	O			01105	Product Explantation Date
9	8	IS	O		0239	01106	Single Use Device
10	60	CE	O			01107	Indication For Product Use
11	8	IS	O		0239	01108	Product Problem
12	30	ST	O	Y/3		01109	Product Serial/Lot Number
13	1	IS	O		0239	01110	Product Available For Inspection
14	60	CE	O			01111	Product Evaluation Performed
15	60	CE	O		0247	01112	Product Evaluation Status
16	60	CE	O			01113	Product Evaluation Results
17	8	ID	O		0248	01114	Evaluated Product Source
18	26	TS	O			01115	Date Product Returned To Manufacturer
19	1	ID	O		0242	01116	Device Operator Qualifications
20	1	ID	O		0250	01117	Relatedness Assessment
21	2	ID	O	Y/6	0251	01118	Action Taken In Response To The Event
22	2	ID	O	Y/6	0232	01119	Event Causality Observations
23	1	ID	O	Y/3	0253	01120	Indirect Exposure Mechanism

7.11.3.0 PCR field definitions

7.11.3.1 Implicated product (CE) 01098

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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 CE data. See Chapter 2 for a listing of some recognized coding systems for drugs and devices.

7.11.3.2 Generic product (IS) 01099

Definition: This field indicates whether the product used was a generic or a branded product. Refer to *user-defined table 0239 - Event expected* for suggested values.

7.11.3.3 Product class (CE) 01100

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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.

7.11.3.4 Total duration of therapy (CQ) 01101

```
Components:  <quantity (NM)> ^ <units (CE)>

Subcomponents of units: <identifier (ST)> & <test (ST)> & <name of coding system (ST)> & <alternate identifier
             (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>
```

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.

7.11.3.5 Product manufacture date (DT) 01102

Definition: This field indicates the date the product was manufactured.

7.11.3.6 Product expiration date (DT) 01103

Definition: This field contains the expiration date indicated on the product packaging.

7.11.3.7 Product implantation date (DT) 01104

Definition: If an implantable medical device, this field identifies the date device was implanted.

7.11.3.8 Product explantation date (DT) 01105

Definition: If an implantable medical device and it was removed, the field identifies the date it was removed.

7.11.3.9 Single use device (IS) 01106

Definition: This field indicates whether the product was designed for a single use. Refer to *user-defined table 0239 - Event expected* for suggested values.

7.11.3.10 Indication for product use (CE) 01107

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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.

7.11.3.11 Product problem (IS) 01108

Definition: A product problem would exist if a product malfunction could lead to death or serious injury. Refer to *user-defined table 0239 - Event expected* for suggested values.

7.11.3.12 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.

7.11.3.13 Product available for inspection (IS) 01110

Definition: This field indicates that the product is available for analysis. Refer to *user-defined table 0239 - Event expected* for suggested values. 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.

7.11.3.14 Product evaluation performed (CE) 01111

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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.

7.11.3.15 Product evaluation status (CE) 01112

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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.

Table 0247 - Status of evaluation

Value	Description
Y	Evaluation completed
P	Evaluation in progress
K	Problem already known, no evaluation necessary
X	Product not made by company
A	Evaluation anticipated, but not yet begun
D	Product discarded -- unable to follow up
C	Product received in condition which made analysis
I	Product remains implanted -- unable to follow up
U	Product unavailable for follow up investigation
Q	Product under quarantine -- unable to follow up
R	Product under recall/corrective action
O	Other

7.11.3.16 Product evaluation results (CE) 01113

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

Definition: This field contains the results of the product evaluation.

7.11.3.17 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.

Table 0248 - Product source

Value	Description
A	Actual product involved in incident was evaluated
L	A product from the same lot as the actual product
R	A product from a reserve sample was evaluated
N	A product from a controlled/non-related inventory was

7.11.3.18 Date product returned to manufacturer (TS) 01115

Definition: If the product was returned to the manufacturer, this field contains the date it was returned may be reported.

7.11.3.19 Device operator qualification (ID) 01116

Definition: This field identifies the qualification of the person operating the device when the event occurred. Refer to *HL7 table 0242 - Primary observers qualification* for valid values.

7.11.3.20 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.

Table 0250 - Relatedness assessment

Value	Description
H	Highly probable
M	Moderately probable
S	Somewhat probable
I	Improbable
N	Not related

7.11.3.21 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.

Table 0251 - Action taken in response to the event

Value	Description
WP	Product withdrawn permanently
WT	Product withdrawn temporarily
DR	Product dose or frequency of use reduced
DI	Product dose or frequency of use increased
OT	Other
N	None

7.11.3.22 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.

Table 0252 - Causality observations

Value	Description
AW	Abatement of event after product withdrawr
BE	Event recurred after product reintroduced
LI	Literature reports association of product with event
IN	Event occurred after product introduced
EX	Alternative explanations for the event available
PL	Effect observed when patient receives placebo
TC	Toxic levels of product documented in blood or body
DR	Dose response observed
SE	Similar events in past for this patient
OE	Occurrence of event was confirmed by objective
OT	Other

7.11.3.23 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.

Table 0253 - Indirect exposure mechanism

Value	Description
B	Breast milk
P	Transplacental
F	Father
X	Blood product
O	Other

7.11.4 PSH - product summary header segment

Figure 7-23. PSH attributes

SEQ	LEN	DT	OPT	RP/#	TBL #	ITEM #	ELEMENT NAME
1	60	ST	R			01233	Report Type
2	60	ST	O			01297	Report Form Identifier
3	26	TS	R			01235	Report Date
4	26	TS	O			01236	Report Interval Start Date
5	26	TS	O			01294	Report Interval End Date
6	12	CQ	O			01238	Quantity Manufactured
7	12	CQ	O			01239	Quantity Distributed
8	1	ID	O		0329	01240	Quantity Distributed Method
9	600	FT	O			01241	Quantity Distributed Comment
10	12	CQ	O			01242	Quantity in Use
11	1	ID	O		0329	01243	Quantity in Use Method
12	600	FT	O			01244	Quantity in Use Comment
13	2	NM	O	Y/8		01245	Number of Product Experience Reports Filed by Facility
14	2	NM	O	Y/8		01246	Number of Product Experience Reports Filed by Distributor

7.11.4.0 PSH field definitions

7.11.4.1 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).

7.11.4.2 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).

7.11.4.3 Report date (TS) 01235

Definition: This field contains the date as assigned by the sender.

7.11.4.4 Report interval start date (TS) 01236

Definition: This field contains the date which marks the beginning of the time interval covered by the current report.

7.11.4.5 Report interval end date (TS) 01294

Definition: This field contains the date which marks the inclusive end of the time interval covered by the current report.

7.11.4.6 Quantity Manufactured (CQ) 01238

```
Components:  <quantity (NM)> ^ <units (CE)>

Subcomponents of units: <identifier (ST)> & <test (ST)> & <name of coding system (ST)> & <alternate identifier
              (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>
```

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.

7.11.4.7 Quantity Distributed (CQ) 01239

```
Components:  <quantity (NM)> ^ <units (CE)>

Subcomponents of units: <identifier (ST)> & <test (ST)> & <name of coding system (ST)> & <alternate identifier
              (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>
```

Definition: This field is used to send the number of units of the product which were distributed during the reporting interval. The second component can be used to specify the units for the quantity.

7.11.4.8 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.

Table 0329 - Quantity method

Value	Description
A	Actual count
E	Estimated (see comment_

7.11.4.9 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.

7.11.4.10 Quantity in use (CQ) 01242

```
Components:  <quantity (NM)> ^ <units (CE)>

Subcomponents of units: <identifier (ST)> & <test (ST)> & <name of coding system (ST)> & <alternate identifier
              (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>
```

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.

7.11.4.11 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.

7.11.4.12 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.

7.11.4.13 Number of product experience reports filed by facility (NM) 01245

Definition: The field contains the number of product experience reports filed by facility.

7.11.4.14 Number of product experience reports filed by distributor (NM) 01246

Definition: This field contains the number of product experience reports filed by distributor.

7.11.5 PDC - product detail country segment

Figure 7-24. PDC attributes

SEQ	LEN	DT	OPT	RP/ #	TBL #	ITEM #	ELEMENT NAME
1	80	XON	R			01247	Manufacturer/Distributor
2	60	CE	R			01248	Country
3	60	ST	R			01249	Brand Name
4	60	ST	O			01250	Device Family Name
5	60	CE	O			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	60	CE	O			01255	Product Code
10	4	ID	O		0330	01256	Marketing Basis
11	60	ST	O			01257	Marketing Approval ID
12	12	CQ	O			01258	Labeled Shelf Life
13	12	CQ	O			01259	Expected Shelf Life
14	26	TS	O			01260	Date First Marked
15	26	TS	O			01261	Date Last Marked

7.11.5.0 PDC field definitions

7.11.5.1 Manufacturer/distributor (XON) 01247

```
Components:  <organization name (ST)> ^ <organization name type code (IS)> ^<ID Number (NM)> ^ <check digit
              (NM)> ^ <code identifying the check digit scheme employed (ID)> ^ <assigning authority  (HD)> ^
              <identifier type code (IS)> ^ <assigning facility ID (HD)>

Subcomponents of assigning authority: <namespace ID (IS)> & <universal ID (ST)> * <universal ID type (ID)>

Subcomponents of assigning facility: <namespace ID (IS)> & <universal ID (ST)> * <universal ID type (ID)>
```

Definition: This field contains the identity of the manufacturer/distributor.

7.11.5.2 Country (CE) 01248

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

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.

7.11.5.3 Brand name (ST) 01249

Definition: This field contains the name under which the product is marketed by this manufacturer.

7.11.5.4 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.

7.11.5.5 Generic name (CE) 01251

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

Definition: This field contains the name generically used to identify the product.

7.11.5.6 Model identifier (ST) 01252

Definition: This field contains the manufacturer's model identifier for the product.

7.11.5.7 Catalogue identifier (ST) 01253

Definition: This field contains the manufacturer's catalogue identifier for the product.

7.11.5.8 Other identifier (ST) 01254

Definition: This field contains any other identifier used to for the product.

7.11.5.9 Product code (CE) 01255

```
Components:  <identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^
              <alternate text (ST)> ^ <name of alternate coding system (ST)>
```

Definition: This field contains the product code from an external coding system such as that used by the CDRH at the FDA.

7.11.5.10 Marketing basis (ID) 01256

Definition: This field contains the basis for marketing approval. Refer to *HL7 table 0330 - Marketing basis* for valid values.

Table 0330 - Marketing basis

Value	Description
510K	510 (K)
510E	510 (K) exempt
PMA	Premarketing authorization
PRE	Preamendment
TXN	Transitional
522S	Post marketing study (522)

7.11.5.11 Marketing approval ID (ST) 01257

Definition: This field contains the designation or description of the marketing basis.

7.11.5.12 Labeled shelf life (CQ) 01258

```
Components:  <quantity (NM)> ^ <units (CE)>

Subcomponents of units: <identifier (ST)> & <test (ST)> & <name of coding system (ST)> & <alternate identifier
             (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>
```

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.

7.11.5.13 Expected shelf life (CQ) 01259

```
Components:  <quantity (NM)> ^ <units (CE)>

Subcomponents of units: <identifier (ST)> & <test (ST)> & <name of coding system (ST)> & <alternate identifier
             (ST)> & <alternate text (ST)> & <name of alternate coding system (ST)>
```

Definition: This field contains the shelf life of the product expected by the manufacturer. This will usually be in months or years.

7.11.5.14 Date First Marked (TS) 01260

Definition: This field contains the date the product was first marketed in the country.

7.11.5.15 Date Last Marked (TS) 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.

7.11.6 FAC - facility segment

Figure 7-25. FAC attributes

SEQ	LEN	DT	OPT	RP/	TBL #	ITEM #	ELEMENT NAME
1	20	EI	R			01262	Facility ID
2	1	ID	O		0331	01263	Facility Type
3	200	XAD	R			01264	Facility Address
4	44	XTN	R			01265	Facility Telecommunication
5	60	XCN	O	Y		01266	Contact Person
6	60	ST	O	Y		01267	Contact Title
7	200	XAD	O	Y		01268	Contact Address
8	44	XTN	O	Y		01269	Contact Telecommunication
9	60	XCN	R			01270	Signature Authority
10	60	ST	O			01271	Signature Authority Title
11	200	XAD	O			01272	Signature Authority Address
12	44	XTN	O			01273	Signature Authority Telecommunication

7.11.6.0 PCR field definitions

7.11.6.1 Facility ID (EI) 01262

```
Components:  <entity identifier (ST)> ^ <namespace ID (IS)> ^ <universal ID (ST)> ^ <universal ID type (ID)>
```

Definition: This field contains the facility identifier.

7.11.6.2 Facility type (ID) 01263

Definition: This field contains the type of facility. Refer to HL7 table 0331 - Facility type for valid values.

Table 0331 - Facility type

Value	Description
U	User
M	Manufacturer
D	Distributor
A	Agent for a foreign manufacturer

7.11.6.3 Facility address (XAD) 01264

```
Components:  <street address (ST)> ^ <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 (IS)> ^ <census tract (IS)>
```

Definition: This field contains the facility's address.

7.11.6.4 Facility telecommunication (XTN) 01265

```
Components:  [NNN] [(999)]999-9999 [X99999] [B99999] [C any text] ^ <telecommunication use code (ID)> ^
              <telecommunication equipment type (ID)> ^ <email address (ST)> ^ <country code (NM)> ^
              <area/city code (NM)> ^ phone number (NM)> ^ <extension (NM)> ^ <any text (ST)>
```

Definition: This field contains the facility's telecommunication information.

7.11.6.5 Contact person (XCN) 01266

```
Components: <ID number (ST)> ^ <family name (ST)> ^ <given name (ST)> ^ <middle initial or name (ST)> ^
              <suffix (e.g., JR or III) (ST)> ^ <prefix (e.g., DR) (ST)> ^ <degree (e.g., MD) (ST)> ^ <source
              table (IS)> ^ <assigning authority (HD)> ^ <name type code(ID)> ^ <identifier check digit (ST)>
              ^ <code identifying the check digit scheme employed (ID )> ^ <identifier type code (IS)> ^
              <assigning facility (HD)>

Subcomponents of assigning authority:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>

Subcomponents of assigning facility ID:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>
```

Definition: This field contains the primary contact person's name.

7.11.6.6 Contact title (ST) 01267

Definition: This field contains the primary contact person's title.

7.11.6.7 Contact address (XAD) 01268

```
Components:  <street address (ST)> ^ <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 (IS)> ^ <census tract (IS)>
```

Definition: This field contains the primary contact person's address.

7.11.6.8 Contact telecommunication (XTN) 01269

```
Components:  [NNN] [(999)]999-9999 [X99999] [B99999] [C any text] ^ <telecommunication use code (ID)> ^
              <telecommunication equipment type (ID)> ^ <email address (ST)> ^ <country code (NM)> ^
              <area/city code (NM)> ^ phone number (NM)> ^ <extension (NM)> ^ <any text (ST)>
```

Definition: This field contains the primary contact person's telecommunication information.

7.11.6.9 Signature authority (XCN) 01270

```
Components: <ID number (ST)> ^ <family name (ST)> ^ <given name (ST)> ^ <middle initial or name (ST)> ^
            <suffix (e.g., JR or III) (ST)> ^ <prefix (e.g., DR) (ST)> ^ <degree (e.g., MD) (ST)> ^ <source
            table (IS)> ^ <assigning authority (HD)> ^ <name type code(ID)>  ^<identifier check digit (ST)>
            ^ <code identifying the check digit scheme employed (ID )> ^ <identifier type code (IS)> ^
            <assigning facility (HD)>

Subcomponents of assigning authority:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>

Subcomponents of assigning facility ID:  <namespace ID (IS)> & <universal ID (ST)> & <universal ID type (ID)>
```

Definition: This field contains the name of the individual with signature authority or who is responsible for the report.

7.11.6.10 Signature authority title (ST) 01271

Definition: This field contains the title of the individual with signature authority or who is responsible for this report.

7.11.6.11 Signature authority address (XAD) 01272

```
Components:  <street address (ST)> ^ <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 (IS)> ^ <census tract (IS)>
```

Definition: This field contains the address of the individual with signature authority or who is responsible for this report.

7.11.6.12 Signature authority telecommunication (XTN) 01273

```
Components:  [NNN] [(999)]999-9999 [X99999] [B99999] [C any text] ^ <telecommunication use code (ID)> ^
             <telecommunication equipment type (ID)> ^ <email address (ST)> ^ <country code (NM)> ^
             <area/city code (NM)> ^ phone number (NM)> ^ <extension (NM)> ^ <any text (ST)>
```

Definition: This field contains the telecommunication information of the individual with signature authority of who is responsible for this report.

7.12 PRODUCT EXPERIENCE - EXAMPLE MESSAGES

The RXE segments in this message include a proposed change in RXE to include an element to transmit the indication as a coded entity (CE).

```
MSH|^-&|...
EVN|...
PID|1|||A^A^A||19230616|F|||||||||||||||19950710|Y<cr>
PES|^Eli Lilly and Company^||Lilly Corporate
Center^Indianapolis^IN^46285||
GB95070448A|0|||19950704|19950710|10D<cr>
PEO||^Awaiting results of
autopsy^|19950704||||^^^^^GB||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^^^06/29/95^07/10/95|*xxxxx*^Wonder Drug 1^ATC|||||||||||||||||||||M1|3||NON SMALL CELL LUNG CANCER<cr>

RXR|PO<cr>

RXE|1|NO2AA^DIHYDROCODEINE^ATC|||||||||||||||||||||D1|120|MG^MG^L|PAIN<cr>

RXR|PO<cr>

RXE|1^^^06/27/95^|GO3AC^MEGESTROL^ATC|||||||||||||||||||||D1|320|MG^MG^L|DECREASED APPETITE<cr>

RXR|PO<cr>

RXE|1|AO2BC^OMEPRAZOLE^ATC|||||||||||||||||||||D1|20|MG^MG^L|PAST HX<cr>

RXR|PO<cr>

RXE|1|AO7EC^SULPHASALAZINE^ATC|||||||||||||||||||||D1|1000|MG^MG^L|RHEUMAT<cr>

RXR|PO<cr>

RXE|1^^^06/27/95^|A11GA^ASCORBIC ACID^ATC|||||||||||||||||||||D1|1|TAB^TAB^L|DECREASED APPETITE<cr>

RXR|PO<cr>

RXE|1^^^06/27/95^|A11DA^THIAMINE^ATC|||||||||||||||||||||D1|1|TAB^TAB^L|DECREASED APPETITE<cr>

RXR|PO<cr>

RXE|1^^^06/29/95^|AO3FA^METOCLOPRAMIDE^ATC|||||||||||||||||||||D1|60|MG^MG^L|NAUSEA<cr>

RXR|PO<cr>

RXE|1|BO3A^IRON^ATC|||||||||||||||||||||D1|600|MG^MG^L|ANEMIA<cr>

RXR|PO<cr>

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|CE|804-5^lEUKOCYTES^LN||2300|10*3/ml||||||19940704<cr>

OBX|2|CE|770-8^NEUTROPHILS/100 LEUKOCYTES^LN||1.9|%||||||19950704<cr>

OBX|2|CE|6299-2^UREA NITROGEN^LN||22.3|mg%||||||19950709<cr>

OBX|2|CE|2160-0^CREATININE^LN||247|mmole||||||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>

7.13 PRODUCT EXPERIENCE - 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)

7.14 WAVEFORM SUMMARY

HL7 support for waveform data is intended to provide access to waveform data in a variety of situations. Needs include remote access to waveform data, research, and input to clinical decision making, as well as obtaining snippets of waveform data to complete waveform data sets. In some cases, predominantly in research oriented environments, a physician may want to manually interpret, scale the raw data, and/or apply alternative algorithms to the raw data values. In these environments, the review of waveform data includes the processing of the raw data. The HL7 waveform data capabilities allow for these applications, including data collection information such as skew between channels, in-band with the waveform.

Waveform observations, like other results, can be transmitted in solicited mode (in response to a query) or in unsolicited mode - see Section 7.2, "MESSAGE DEFINITIONS ," for discussion. In either mode of transmission the timing information, channel definition, annotations, and digital time series data in the waveform recording are treated as individual "observations" within a result "battery." For a given "battery," each of the result fragments is transmitted in a separate OBX segment, where the Observation ID suffix for the OBX is used to identify the result fragment. To reduce ambiguity, an explicit framework for defining the structure of waveform result messages is provided. The elements of that framework include the following:

- Waveform specific data types which enable transmission of channel definition and waveform data
- Waveform specific Observation ID suffixes (*OBX-3-observation identifier*) which uniquely identify the category of waveform result in a given OBX segment
- Fixed rules for combining OBX segments of each category in the waveform response messages
- Explicit definition of which OBX fields may be populated for each category of waveform result
- Unique trigger events which identify result messages which contain batteries of waveform result OBX segments

7.15 WAVEFORM RESULT DATA TYPES

Three waveform specific data types have been defined to enable transmission of waveform results.

7.15.1 NA - numeric array

```
<value1> ^ <value2> ^ <value3> ^ <value4> ^ ...
```

This data type is used to represent a series (array) of numeric values, each one having a data type of NM. A field of this type may contain a one-dimensional array (vector or row) of numbers. Also, by allowing the

field to repeat, a two-dimensional array (table) of numbers may be transmitted using this format, with each row of the table represented as one repetition of the field. Arrays which have one or more values not present may be transmitted using this data type. "Not present" values are represented as two adjacent component delimiters. If the absent values occur at the end of a row, the trailing component delimiters may be omitted. If an entire row of a table has no values, no component delimiters are necessary (in this case, there will be two adjacent repetition delimiters). The maximum number of values in one repetition of an NA format field is determined by the maximum field length.

Examples:

```
|125^34^-22^-234^569^442^-212^6|            vector of 8 numbers
|1.2^-3.5^5.2~2.0^3.1^-6.2~3.5^7.8^-1.3|    3 x 3 array of numbers
|^2^3^4~5^^^8~9^10~~17^18^19^20|            5 x 4 array of numbers with
                                        the values in positions
                                        (1,1), (2,2), (2,3), (3,3),
                                        (3,4), (4,1), (4,2), (4,3),
                                        and (4,4) not present
```

7.15.2 MA - multiplexed array

```
<sample 1 from channel 1>^<sample 1 from channel 2>^<sample 1 from channel 3> ...~

<sample 2 from channel 1>^<sample 2 from channel 2>^<sample 2 from channel 3> ...~

 ...
```

This data type is used to represent channel-multiplexed waveform data, (e.g., the digitized values from an analog-to-digital converter or other digital data source). Each value is of type NM, and represents a time sample from a channel. This segment may contain data from one or more channels. The waveform data is in channel-multiplexed format (that is, the values for all channels for the first time sample are transmitted, then the values for the next time sample, and so on until the requisite number of time samples have been transmitted). Time samples are separated by repeat delimiters (~), and channels within a sample are separated by component delimiters (^). The time between samples (the sampling interval) is the reciprocal of the digitization frequency as specified using the CD data type.

Examples:

```
|0^0^0~1^1^1~2^2^2~3^3^3~4^4^4~5^5^5|       3 channels (identical), 5
time-samples
|0~1~2~3~4~5~6~7~8~9~10|                    1 channel, 11 time-samples
```

7.15.3 CD - channel definition

```
Components:  <channel identifier> ^ <waveform source> ^ <channel sensitivity/units> ^ <calibration parameters>
              ^ <sampling frequency> ^ <minimum/maximum data values>
```

This data type is used for labeling of digital waveform data. It defines a recording channel which is associated with one of the values in each time sample of waveform data. Each channel has a number (which generally defines its position in a multichannel display) and an optional name or label (also used in displays). One or two named waveform sources may also be associated with a channel (providing for the use of differential amplifiers with two inputs). The other components of the channel definition data type are optional. The individual components are defined as follows:

7.15.3.1 Channel identifier

Two subcomponents separated by subcomponent delimiters (&) which identify the channel, consisting of a channel number (required, maximum 4 characters, data type NM)and a channel name (optional, maximum 17 characters, data type ST). The channel name is a text string used as a label in waveform data displays. If this name is not present, the channel label displayed is <source1>-<source2>, where <source1> and <source2> are the names of the two waveform sources connected to this channel, or, if only one waveform sources <source1> is specified, the channel label displayed when the channel name is not given is <source1>.

7.15.3.2 Waveform source

Identifies the source of the waveform connected to the channel. Two names (each maximum of 8 characters, data type ST) separated by a subcomponent delimiter (&) may be specified if it is necessary to individually identify the two inputs for a waveform. Only one name need be specified if the channel is connected to a single input. For example, in EKG recordings typically only one name is used (such as I or II); in electroencephalography, two names are typically used, one for each input of the differential amplifier (such as F3 and C3)..*(NOTE: Although the committee voted in Denver to make waveform source a coded entry, this is not syntactically possible. We do not have a sub-sub-component delimiter available to separate the sub-fields of the proposed coded entry. Therefore, waveform source remains a string data type.).*

7.15.3.3 Channel sensitivity and units (CM)

This CM data type defines the channel sensitivity (gain) and the units in which it is measured. This component consists of up to seven subcomponents, separated from each other by subcomponent delimiters (&). The first subcomponent specifies the sensitivity, while the remaining six subcomponents are used to specify the units of the sensitivity, using a format similar to the components of the coded entry (CE) data type. The subcomponents of the channel sensitivity and units are as follows:

7.15.3.3.1 Sensitivity (NM)

Defines the nominal value (maximum 20 characters, data type NM) that corresponds to one unit in the waveform data, that is, the effective resolution of the least significant bit of the ADC, and the polarity of the channel. The sensitivity incorporates both the amplifier gain and the actual ADC resolution. It does not, however, relate to the vertical scaling of a waveform display (it is, for example, a measure of voltage, not voltage per unit distance). For channels recording potential differences between two electrodes using a differential amplifier, a positive sensitivity indicates that a number in the waveform data which is greater than the channel baseline represents a potential at the first electrode which is more positive than that at the second electrode. A negative sensitivity indicates that a number in the waveform data which is greater than the channel baseline corresponds to a potential at the first electrode which is more negative than that at the second electrode.

7.15.3.3.2 Units

A units designation (for example, uv = microvolt, mv = millivolt, v = volt, pal = pascal, or mm(hg) = millimeters of mercury) from a designated system of units, such as the ISO+ extension of the standard SI single case unit abbreviations presented as *Figure 7-13* in Section 7.3.2.6.1, "Identifying reporting units," or the ANSI+ U.S. customary unit abbreviations, a superset of the ANSI standard which appears in *Figure 7-10*. Other unit systems can be used as well.

7.15.3.4 Channel calibration parameters (NM)

This component consists of three optional subcomponents (each a maximum of 20 characters, data type NM), separated from each other by subcomponent delimiters (&), which define corrections to channel sensitivity, baseline, and channel time skew which may be derived from a calibration procedure. The three subcomponents are as follows:

7.15.3.4.1 Sensitivity correction factor

Defines a correction factor for channel sensitivity which may be derived from the last calibration procedure performed. The actual channel sensitivity is the nominal channel sensitivity given in the previous component multiplied by the unitless correction factor.

7.15.3.4.2 Baseline

Defines the actual channel baseline (the data value which corresponds to a nominal input signal of zero). The actual baseline may differ from the ideal because of a dc offset in the amplifier connected to the ADC. The actual baseline values for all channels (which need not be integers) may be determined at the time of calibration as the average digitized values obtained when a zero input signal is connected to each channel.

7.15.3.4.3 Time skew

Defines the time difference between the nominal sampling (digitization) time (which would be the same for all channels) and the actual sampling time of the channel, in seconds (or fractions thereof). This value will differ from zero when all channels in the montage are not sampled simultaneously, as occurs in systems which sample successive channels at regular time intervals. This value may be determined from a calibration procedure in which an identical time-varying signal is applied to all channels and interchannel time differences are estimated, or more commonly it may be taken from the manufacturer's specifications for the digitizing system used. For example, for a system which samples successive channels at regular time intervals t, the time skew of channel number n would be $(n-1)t$. The actual time of sampling (digitization) of sample number m of channel number n in such a system would be $R + (m-1)/f + (n-1)t$, where R is the reference time at the start of the epoch and f is the channel sampling frequency ($t < 1/f$).

7.15.3.5 Channel sampling frequency

Defines the sampling frequency in hertz of the channel, that is, the reciprocal of the time in seconds between successive samples (maximum 20 characters, data type NM). Note that this is the frequency of transmitted data, which may or may not be the actual frequency at which the data was acquired by an analog-to-digital converter or other digital data source (i.e. the data transmitted may be subsampled, or interpolated, from the originally acquired data.)

7.15.3.6 Minimum and maximum data values (NM)

Defines the minimum and maximum data values which can occur in this channel in the digital waveform data, that is, the range of the ADC (each maximum of 20 characters, data type NM), and also specifies whether or not nonintegral data values may occur in this channel in the waveform data. If the minimum and maximum values are both integers (or not present), only integral data values may be used in this channel. If either the minimum or the maximum value contains a decimal point, then nonintegral as well as integral data values may be used in this channel. The minimum and maximum data values are separated by a component delimiter (&). For an n-bit signed ADC, the nominal baseline $B = 0$, and the minimum (L) and maximum (H) values may be calculated as follows:

$$L = -2^{n-1}$$

$$H = 2^{n-1} - 1$$

For an unsigned *n*-bit ADC, the minimum value $L = 0$, and the nominal baseline value (*B*) and maximum value (*H*) may be calculated from the formulas,

$$B = 2^{n-1}$$

$$H = 2^{n} - 1$$

The actual signal amplitude *A* (for differentially amplified potential measurements, the potential at electrode number one minus that at electrode number two) may be calculated from the value *D* (range *L* to *H*) in the waveform data using the actual baseline value *B* and the nominal sensitivity *S* and actual sensitivity correction factor *C* by the formula,

$$A = SC(D-B)$$

7.16 WAVEFORM SPECIFIC OBSERVATION ID SUFFIXES

Each waveform channel in a recording contains timing, channel definition and digital time series data. The category of waveform result transmitted in a given OBX segment is determined by the Observation ID Suffix contained in *OBX-3-observation identifier*. Four suffixes are provided for the different categories of waveform result:

Observation	Suffix	Data Type
Timing Information	TIM	TS
Channel Definition	CHN	CD
Waveform Data	WAV	NA or MA
Waveform Annotation	ANO	CE

The Observation Sub-ID is used to associate the TIM, CHN, and subsequent WAV, and ANO category result segments for a given channel or channels in a waveform response message.

7.16.1 Timing information (TIM)

The TIM category OBX result segment establishes the date and time of the first data point in a given Observation Sub-ID grouping of waveform channels. If there is a gap in the time sequence of waveform data, this should be indicated by the transmission of a new TIM category result segment prior to subsequent WAV category result segments with the same Observation Sub-ID. The data type is TS.

7.16.2 Channel definition data (CHN)

The CHN category OBX result segment defines recording channels for digitally sampled time-series waveforms. Subsequent WAV category result segments carry the actual waveform samples. Each CHN category result segment defines one or more channels; the *OBX-5-Observation Value* field may repeat to define additional channels. Each instance or repetition is formatted as a CD data type.

Each channel has a number (which generally defines its position in a multichannel display) and an optional name or label (also used in displays). One or two named waveform sources may also be associated with a

channel (providing for the use of differential amplifiers with two inputs). A channel also has an associated sensitivity, calibration parameters (sensitivity correction factor, baseline, and time skew), sampling frequency, and minimum and maximum values. The sampling frequency refers to the number of samples per unit time for the data reported in the subsequent WAV category result segments.

When multiple channels are defined within a single CHN category result segment, if the channel sensitivity/units (third component), sensitivity correction factor (first subcomponent of component 4), baseline (second subcomponent), time skew (third subcomponent), sampling frequency (fifth component), minimum data value (first subcomponent of component 6), or maximum data value (second subcomponent) is not present in any repetition of the *OBX-5-observation value* field, the value given in the last repetition in which the item *was* present may used by the receiver system. This is referred to as a "sticky default." For example, if all channels have the same sensitivity, sensitivity correction factor/baseline/time skew, sampling frequency, and minimum/maximum data values, these may be specified for the first channel but omitted in all subsequent channel definitions in the same CHN category result segment, thus reducing the length of the segment. If the sensitivity correction factor, baseline, or time skew is not present in the first channel being defined, values of 1, 0, and 0 (respectively) may be used. No other default values are assumed for components which are not present.

7.16.3 Waveform digital data (WAV)

The WAV category OBX result segment is used to transmit the actual waveform data (the time-series digitized values from an analog-to-digital converter (ADC) or other source of sampled digital data). WAV category result segments are associated with their corresponding channel definitions (CHN category OBX result segment) via the Observation Sub-ID. The number of channels defined in the CHN category result segment specifies the number of channels of multiplexed data contained in the WAV category result segments associated with it. For example, if a CHN category result segment contains only a single channel definition, then each WAV category result segment with the same Observation Sub-ID contains only one channel of data. However, if a CHN category result segment contains three channel definitions then each WAV category result segment with the same Observation Sub-ID must contain three channels of data. A given set of waveform data for all channels and at multiple successive times may be transmitted in a single WAV category result segment (provided that the length of the observation value field does not exceed the maximum defined field length for OBX segments, 65536), or in multiple successive WAV category result segments, possibly with interspersed result segments of other types (for example, containing annotations, or comments).

The data type of the WAV category result segment can be NA (Numeric Array) or MA (Multiplexed Array). Using the NA data type, the data values are formatted in "channel-block", or "unmultiplexed" format. The digital samples for each channel are separated using component delimiters, and successive channels are separated using the repeat delimiter. Using the MA data type, the data values are formatted in "channel multiplexed" format, i.e., the values for the first time sample (all channels) are transmitted first, then the values for the second time sample (all channels) are transmitted, and so on until all samples have been transmitted. The digital samples for each channel are separated by the component delimiter, and successive samples are separated by the repeat delimiter. Channel multiplexed format can only be used if all of the multiplexed channels have the same effective sampling frequency.

7.16.4 Waveform annotation (ANO)

The ANO category OBX segment is used to transmit waveform annotations (coded entry associated with a given point in time during the waveform recording). The ANO category result segments are referenced to their corresponding channel definitions (CHN category OBX result segment) via the Observation Sub-ID. The number of channels defined in the CHN category result segment specifies the number of channels of

annotation contained in any ANO category result segments associated with it. For example, if a CHN category result segment contains only a single channel definition, then any ANO category result segments with the same Observation Sub-ID will contain only one annotation coded entry. However, if a CHN category result segment contains three channel definitions then any ANO category result segments with the same Observation Sub-ID must contain three separate annotation coded entries.

The data type of the ANO category result segment is CE. The annotation coded entries for successive channels are separated using the repeat delimiter. Adjacent repeat delimiters are used when there is no annotation coded entry for a channel in a multichannel result segment. Refer to *user defined table 0317 - Annotations* for suggested values.

User-defined table 0317 - Annotations

Value	Description
9900	Pace spike
9901	SAS marker
9902	Sense marker
9903	Beat marker
9904	etc.

7.17 COMBINING RULES FOR WAVEFORM OBX SEGMENTS

A waveform result "battery" may contain one or more channels of digital waveform data. The Observation Sub-ID is used to logically associate the TIM, CHN and WAV category OBX segments which pertain to a given set of channels in the result "battery." Each Sub-ID group must contain at least one TIM, one CHN and one WAV category segment and at least one of the TIM category result segments must precede the first WAV category result segment in that group.

7.18 RESTRICTIONS ON VALUATION OF OBX SEGMENT FIELDS

The result category for a given OBX segment determines how specific fields in that segment are valued. The following tables define field requirements for each category of OBX segment. The OPT/X column can take the values of R = Required, O = Optional, or X = Ignored and not valued. **OBX Fields marked with an X should not be valued in Waveform response messages of specified Suffix type.** Valuation of the fields must match the value provided in the associated wave category OBX segments, i.e., OBX with the same sub-ID must share the same result status.

7.18.1 OBX segment - TIM category

Figure 7-26. OBX attributes - TIM category

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1	4	SI	O			00569	Set ID - Observational Simple
2	2	ID	R		0125	00570	Value Type
3	80	CE	R			00571	Observation Identifier
4	20	ST	R			00572	Observation Sub-ID
5	26	TS	R			00573	Observation Value
6	60	CE	X			00574	Units
7	60	ST	X			00575	References Range
8	10	ID	X		0078	00576	Abnormal Flags
9	5	NM	X	Y/5		00577	Probability
10	5	ID	X		0080	00578	Nature of Abnormal Test
11	2	ID	R		0085	00579	Observ Result Status
12	26	TS	X			00580	Date Last Obs Normal Values
13	20	ST	X			00581	User Defined Access Checks
14	26	TS	X			00582	Date/Time of the Observation
15	60	CE	X			00583	Producer's ID
16	60	CN	X			00584	Responsible Observer
17	80	CE	X	Y		00936	Observation Method

7.18.2 OBX segment - CHN category

Figure 7-27. OBX attributes - CHN category

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1	4	SI	O			00569	Set ID - Observational Simple
2	2	ID	R		0125	00570	Value Type
3	80	CE	R			00571	Observation Identifier
4	20	ST	R			00572	Observation Sub-ID
5	65536	CD	R			00573	Observation Value
6	60	CE	X			00574	Units
7	60	ST	X			00575	References Range
8	10	ID	X		0078	00576	Abnormal Flags
9	5	NM	X	Y/5		00577	Probability
10	5	ID	X		0080	00578	Nature of Abnormal Test
11	2	ID	R		0085	00579	Observ Result Status
12	26	TS	X			00580	Date Last Obs Normal Values
13	20	ST	X			00581	User Defined Access Checks
14	26	TS	X			00582	Date/Time of the Observation
15	60	CE	X			00583	Producer's ID
16	60	CN	X			00584	Responsible Observer
17	80	CE	X	Y		00936	Observation Method

Note: The length of the observation value field is variable, depending upon number of channels defined.

7.18.3 OBX segment - WAV category

Figure 7-28. OBX attributes - WAV category

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1	4	SI	O			00569	Set ID - Observational Simple
2	2	ID	R		0125	00570	Value Type
3	80	CE	R			00571	Observation Identifier
4	20	ST	R			00572	Observation Sub-ID
5	65536	NA or MA	C			00573	Observation Value
6	60	CE	X			00574	Units
7	60	ST	X			00575	References Range
8	10	ID	O		0078	00576	Abnormal Flags
9	5	NM	X	Y/5		00577	Probability
10	5	ID	X		0080	00578	Nature of Abnormal Test
11	2	ID	R		0085	00579	Observ Result Status
12	26	TS	X			00580	Date Last Obs Normal Values
13	20	ST	X			00581	User Defined Access Checks
14	26	TS	X			00582	Date/Time of the Observation
15	60	CE	X			00583	Producer's ID
16	60	CN	O			00584	Responsible Observer
17	80	CE	X			00936	Observation Method

Notes:

1. The length of the observation value field is variable, depending upon number of channels and number of data points sampled.

2. Fields 8, 11 and 16 apply exclusively to the set of data points in the OBX. They do not map to a particular data point or channel.

7.18.4 ANO category OBX segment

Figure 7-29. OBX segment - ANO category

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
1	4	SI	O			00569	Set ID - Observational Simple
2	2	ID	R		0125	00570	Value Type
3	80	CE	R			00571	Observation Identifier
4	20	ST	R			00572	Observation Sub-ID
5	65535	CE	C			00573	Observation Value
6	60	CE	X			00574	Units
7	60	ST	X			00575	References Range
8	10	ID	O	Y/5	0078	00576	Abnormal Flags
9	5	NM	X			00577	Probability
10	5	ID	X		0080	00578	Nature of Abnormal Test
11	2	ID	R		0085	00579	Observ Result Status
12	26	TS	X			00580	Date Last Obs Normal Values
13	20	ST	X			00581	User Defined Access Checks
14	26	TS	O			00582	Date/Time of the Observation
15	60	CE	X			00583	Producer's ID
16	60	CN	O			00584	Responsible Observer
17	80	CE	X	Y		00936	Observation Method

Note: The length of the observation value field is variable, depending upon number of channels defined.

7.19 WAVEFORM RESPONSE TRIGGER EVENTS

Response messages containing waveform results are identified by the trigger event provided in the message header segment (MSH-09, second component of message type). Separate trigger events have been defined to differentiate the solicited and unsolicited modes of transmission.

7.19.1 W01 - waveform result, unsolicited transmission of requested information

The waveform response unsolicited trigger event identifies ORU messages used to transmit waveform data which are results of an ordered test or series of observations. The W01 trigger event may also be used to identify ORU messages sent as the eventual response to a QRY message specifying a deferred mode query for waveform results/observations with record-oriented format (similar to the deferred response display mode DSR message type described in Chapter 2). One or more ORU messages with the W01 trigger event may result from this type of QRY message.

7.19.2 W02 - waveform result, response to query

The W02 trigger event identifies QRF messages which are a response to a QRY message specifying an immediate mode query for waveform results/observations with record-oriented format.

7.20 EXAMPLE MESSAGES FOR GENERIC WAVEFORM DATA

This section gives four example messages of type ORU (unsolicited) that each contain a three-channel waveform recording, with the same waveform in each channel. These examples contain data for one patient. In these example message transmissions, **<cr>** indicates an ASCII carriage return character (ASCII 13).

The following is a detailed explanation of each of the segments contained in the example messages:

Message Header (MSH) Segment - This specifies the delimiters (**|^~\&**), sending application (**SVL,** meaning Sunnyville Laboratory), receiving application (**SVC**, meaning Sunnyville Clinic), date and time of transmission (March 24, 1990 at 10:12:15), message type (**ORU**) and trigger event (**W01**), a message control ID that identifies this message uniquely among all messages transmitted by this sender (**19264**), processing ID (**P**, meaning production), and specification version ID (**2.3**).

Patient ID (PID) Segment - This contains a sequence number (**1**), external and internal patient IDs (both **4567890**), and a patient name (**Mr. John Q Doe, Jr**).

Order (OBR) Segment - This contains a sequence number (**1**), placer order number (**5678**) and placer ID (**SVC**, meaning Sunnyville Clinic), filler order number (**1234**) and filler ID (**SVL**, meaning Sunnyville Laboratory), and test/observation ID (**5**, using a local coding system that is known to the intended receiver, meaning a three-channel waveform recording).

CHN Category Result (OBX) Segments - Using a value type of **CD** (channel definition), these define each of the three data channels by number and specify a label (waveform source) for each. The channel sensitivity (**0.5 mV**), sampling frequency (**200**), and minimum and maximum data values (**-2048** to **2047**) are specified for each channel in examples 1 and 2 and 4. In example 3, these are specified only for channel 1, but apply by default to all subsequent channels. No baseline or calibration parameters are specified, so defaults are used for all channels.

TIM Category Result (OBX) Segments - Using the data type TS (time stamp), these define the start of the waveform data at a time 525 ms past 8:12:37 on March 24, 1990.

WAV Category Result (OBX) Segments - The data may be transmitted in either "channel-block" (unmultiplexed) format using the NA data type, or in "channel-multiplexed" format using the MA data type. The three examples demonstrate different ways of transmitting 3 waveform channels, with 25 samples from each waveform channel. Note that in these examples, each waveform channel is identical.

ANO Category Result (OBX) Segments - Annotation segments with a single channel definition contain a single annotation string. Annotation segments with multiple channel definitions contain a separate annotation string for each defined channel - successive annotation strings are separated from each other by the repeat delimiter. In the following examples, channel 1 has been annotated at a time 565 ms past 8:12:37 on March 24, 1990; channel 3 has been annotated at a time 605 ms past 8:12:37 on March 24, 1990.

7.20.1 Example 1: "channel-block" format, using three separate sets of TIM, CHN, WAV and category OBX segments:

```
MSH|^~\&|SVL||SVC||19900324101215||ORU^W01|19264|P|2.3<cr>
PID|1|4567890|4567890||Doe^John^Q^Jr^Mr<cr>
OBR|1|5678^SVC|1234^SVL|5^three-channel waveform recording^L<cr>
OBX|1|CD|5&CHN^^L|1|1^ONE^0.5&mv^^200^-2048&2047|||||F<cr>
OBX|2|TS|5&TIM^^L|1|19900324081237.525||||||F<cr>
OBX|3|NA|5&WAV^^L|1|0^1^2^3^4^5^6^7^8^7^6^5^4^3^2^1^0^-1^-2^-3^-4^-5^-
6^-7^-8||||||F<cr>
OBX|4|CE|5&ANO^^L|1|^Channel passing through
maxima|||||F||19900324081237.565<cr>
OBX|5|CD|5&CHN^^L|2|2^TWO^0.5&mv^^200^-2048&2047|||||F<cr>
OBX|6|TS|5&TIM^^L|2|19900324081237.525||||||F<cr>
OBX|7|NA|5&WAV^^L|2|0^1^2^3^4^5^6^7^8^7^6^5^4^3^2^1^0^-1^-2^-3^-4^-5^-
6^-7^-8||||||F <cr>
OBX|8|CD|5&CHN^^L|3|3^THREE^0.5&mv^^200^-2048&2047|||||F<cr>
OBX|9|TS|5&TIM^^L|3|19900324081237.525||||||F<cr>
OBX|10|NA|5&WAV^^L|3|0^1^2^3^4^5^6^7^8^7^6^5^4^3^2^1^0^-1^-2^-3^-4^-5^-
6^-7^-8||||||F <cr>
OBX|11|CE|5&ANO^^L|3|^Channel passing through
zero|||||F||19900324081237.605<cr>
...
```

7.20.2 Example 2: “channel-block” format, using a single set of TIM, CHN, WAV and category OBX segments, with multiple channels within the one WAV category result segment:

```
MSH|^~\&|SVL||SVC||19900324101215||ORU^W01|19264|P|2.3<cr>
PID|1|4567890|4567890||Doe^John^Q^Jr^Mr<cr>
OBR|1|5678^SVC|1234^SVL|5^three-channel waveform recording^L<cr>
OBX|1|CD|5&CHN^^L|1|1^ONE^0.5&mv^^200^-2048&2047~2^TWO^0.5&mv^^200^
2048&2047~3^THREE^0.5&mv^^200^-2048&2047||||||F<cr>
OBX|2|TS|5&TIM^^L|1|19900324081237.525||||||F<cr>
OBX|3|NA|5&WAV^^L|1|
0^1^2^3^4^5^6^7^8^7^6^5^4^3^2^1^0^-1^-2^-3^-4^-5^-6^-7^-8~
0^1^2^3^4^5^6^7^8^7^6^5^4^3^2^1^0^-1^-2^-3^-4^-5^-6^-7^-8~
0^1^2^3^4^5^6^7^8^7^6^5^4^3^2^1^0^-1^-2^-3^-4^-5^-6^-7^-8||||||F <cr>
OBX|4|CE|5&ANO^^L|1|^Channel passing through
maxima||||||F||19900324081237.565<cr>
OBX|5|CE|5&ANO^^L|1|~~^Channel passing through
zero||||||F||19900324081237.605<cr>
...
```

7.20.3 Example 3: “channel-multiplexed” format, with multiple channels within the one WAV category result segment:

```
MSH|^~\&|SVL||SVC||19900324101215||ORU^W01|19264|P|2.3<cr>
PID|1|4567890|4567890||Doe^John^Q^Jr^Mr<cr>
OBR|1|5678^SVC|1234^SVL|5^three-channel waveform recording^L<cr>
OBX|1|CD|5&CHN^^L|1|1^ONE^0.5&mv^^200^-
2048&2047~2^TWO^~3^THREE^||||||F<cr>
OBX|2|TS|5&TIM^^L|1|19900324081237.525||||||F<cr>
OBX|3|MA|5&WAV^^L|1|0^0^0~1^1^1~2^2^2~3^3^3~4^4^4~5^5^5~6^6^6~7^7^7~8^8
^8~7^7^7~6^6^6~5^5^5~4^4^4~3^3^3~2^2^2~1^1^1~0^0^0~-1^-1^-1~-2^-2^-2~-
3^-3^-3~-4^-4^-4~-5^-5^-5~-6^-6^-6~-7^-7^-7~-8^-8^-8||||||F <cr>
OBX|4|CE|5&ANO^^L|1|^Channel passing through
maxima||||||F||19900324081237.565<cr>
OBX|5|CE|5&ANO^^L|1|~~^Channel passing through
zero||||||F||19900324081237.605<cr>
...
```

7.20.4 Example 4: “channel-block” format, using three separate sets of TIM, CHN, WAV and category OBX segments with a break in waveform data used to pinpoint waveform annotations for channels one and three:

```
MSH|^~\&|SVL||SVC||19900324101215||ORU^W01|19264|P|2.3<cr>
PID|1|4567890|4567890||Doe^John^Q^Jr^Mr<cr>
OBR|1|5678^SVC|1234^SVL|5^three-channel waveform recording^L<cr>
OBX|1|CD|5&CHN^^L|1|1^ONE^0.5&mv^^200^-2048&2047||||F<cr>
OBX|2|TS|5&TIM^^L|1|19900324081237.525||||F<cr>
OBX|3|NA|5&WAV^^L|1|0^1^2^3^4^5^6^7^8||||||F<cr>
```

```
OBX|4|CE|5&ANO^^L|1|^Channel passing through
maxima||||||F||19900324081237.565<cr>
OBX|5|NA|5&WAV^^L|1|7^6^5^4^3^2^1^0^-1^-2^-3^-4^-5^-6^-7^-8||||||F<cr>
OBX|6|CD|5&CHN^^L|2|2^TWO^0.5&mv^^200^-2048&2047||||||F<cr>
OBX|7|TS|5&TIM^^L|2|19900324081237.525||||||F<cr>
OBX|8|NA|5&WAV^^L|2|0^1^2^3^4^5^6^7^8^7^6^5^4^3^2^1^0^-1^-2^-3^-4^-5^-
6^-7^-8||||||F <cr>
OBX|9|CD|5&CHN^^L|3|3^THREE^0.5&mv^^200^-2048&2047||||||F<cr>
OBX|10|TS|5&TIM^^L|3|19900324081237.525||||||F<cr>
OBX|11|NA|5&WAV^^L|3|0^1^2^3^4^5^6^7^8^7^6^5^4^3^2^1^0||||||F <cr>
OBX|12|CE|5&ANO^^L|3|^Channel passing through
zero||||||F||19900324081237.605<cr>
OBX|13|NA|5&WAV^^L|3|-1^-2^-3^-4^-5^-6^-7^-8||||||F <cr>
...
```

7.21 OUTSTANDING ISSUES

None.