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**HL7 Domain Analysis Model: Specimen, Release 1**

May 2014

**HL7 Informative Ballot**

**Sponsored by:
Orders and Observations Work Group**

**Anatomic Pathology Work Group**

**Clinical Genomics Work Group**

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# Revision History

NOTE: Project ID 892

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Date | Name | Comment |
| 1.0 | 3/23/2014 | Riki Merrick / Lorraine Constable | Document for ballot May 2014 |
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# Introduction

This document is intended to present the business requirements for data elements related to specimen for electronic data record systems (Electronic Health Record System, Personal Health Record System or Laboratory Information System).

Scope and goal of the project

Several different domains in HL7 use specimen in their workflow with differing use case requirements. There is need for consolidation of all the requirements across the different use cases for all domains. The resulting domain analysis model (DAM) intends to represent all data elements, regardless of use in data exchange as long as they support workflow in its respective domain – input was provided from several sponsoring Work Groups (Orders and Observations, Clinical Genomics, Interventional Imaging and Anatomic Pathology).

As part of this analysis a review of Specimen V3 models as well as specimen related segments in V2 is included and specific emphasis was placed on support for the Specimen Identifier formats as further established by the Anatomic Pathology Work Group. This work used as its starting point the National Cancer Institute Life Sciences DAM.

Questions for balloters

Specifically we would like feedback on the following:

1. For the attribute definitions - please provide feedback on the appropriateness of all definitions.
2. For the model:
	1. For the StorageEquipment class:
		1. Is there a need to relate specific storage conditions for each instance of the equipment?
		2. Are the storage conditions for each specimen type defined somewhere, and if so, do they need to be referenced for the instance?
	2. For the Specimen class:
		1. Do we have the proper levels of categorization
			1. ClassCode to identify if a specimen is of environmental (or more specifically food, biologics or medical devices), human or animal origin
			2. TypeCode to identify what is being submitted for testing
			3. SubTypeCode to further specify the TypeCode for some laboratory domains like clinical genomics
		2. Several dates related to specimen processing and where best to capture these:
			1. SpecimenReceivedDate
			2. SpecimenExpirationDate
		3. Where best to capture SpecimenAppropriateness as this evaluation is dependent on the test requested
	3. For the PerformedSpecimenCollection class:
		1. We explicitly modeled laterality for TargetSite and TargetApproachSite – is this desirable?
		2. RepetitionNumber is defined as number of collection attempts, but during the discussion we also discussed the possibility of needing to track the position in a series – do we need to add a PositionInSeries attribute?
	4. For the SubjectCharacteristicsAtSpecimenCollection class:
		1. Comment on the decision to represent these as ObservationCode – ObservationValue pairs – essentially mirroring the Ask at Order Entry Approach used in the workflow today
		2. Question on where to place this class as these are often related to the test requested as well as the type of specimen submitted
	5. For the Container and Holder classes:
		1. How to resolve the timing attributes here – should we add just EffectiveTime or are others like Duration also needed?

**Use Cases – copy in here**

# Information Model

Analysis of the described use cases and activity flows resulted in the following conceptual information model. – UPDATE IMAGE!

Figure 4 – Specimen Domain Model

The attributes in the above model use the following conceptual datatypes:



Figure 5 Conceptual Data Types

Definitions of the classes and attributes are documented in subsequent sections.

## Attribute Definitions – copy from other two documents

#### Specimen Container

Physical object that touches and holds specimen.

EXAMPLES:

slide, tube, box, jar

Attributes

| **Name** | **Type** | **Definition** |
| --- | --- | --- |
| name | String | A non-unique textual identifier for the specimen container.  |
| containerIdentifier | Identifier | The alphanumeric sequence that uniquely defines the container. Label can be linear or 2 dimensional bar code, RFID. Example(S): In Pathology a tissue specimen or part would have a Unique identifier and one or more blocks may result from a single part with each block having their own Unique Identifier. This would also accommodate clinical specimens such as CSF. |
| containerTypeCode | Code | Coded representation of the categorization of a container. Example(s): model number used to order the same kind of tube |
| containerMaterialCode | Code | Coded representation of the material composition of the container.Example(s): codes for glass, plastic, metal |
| containerCapCode | Code | Coded representation of the type of container cap. Container caps may be used to identify differences in container attributes to facilitate tracking and processingExample(s): red top, tiger top, purple, blue |
| position | Coordinates | Coordinates of specimen container relative to the holder. |
| separatorType | Code | A material in a fluid collection container that facilities the separation of cellular or solid material from liquid.Example(s): SST, buffy cell layer |
| additive | Code | Substances introduced in order to preserve, maintain or enhance the particular nature or component of the specimen.Example(s): Formalin, Citrate, EDTA |
| containerCondition | Code | A textual note or description regarding discrepancies or anomalies observed about a container. Example(s): Cap not sealed, label not firmly attached, tube received broken |
| identifierLocation | Code | Placement of the identifier on or in the container. |
| barrierDeltaQuantity | Quantity | Distance from the Point of Reference to the separator material (barrier) within the container in units specified below.Example(s): Serum gel tube, tubes that are being centrifuged |
| bottomDeltaQuantity | Quantity | Thickness of the container at the bottom of the container.Example(S): Adjustment to make to the drop distance based on the container parameter (tube height) and the thickness of the container wall at the bottom - idea is to not break the tip off the pipette. |

#### Specimen Processing Activity

Description of procedure.

Attributes

| **Name** | **Type** | **Definition** |
| --- | --- | --- |
| description | String | Textual explanation of procedure. |
| processingProcedure | Code | Coded representation of a step in the procedure. |
| processingAdditive | Code | Substance added to a specimen for preservation or to aid in the process as required by the procedure. EXAMPLE(s): Anticoagulant, Separator, stabilizer |
| statusCode | Code | Coded representation of the state of the processing step in the procedure.Example(S): completed, in progress, scheduled |
| processing DateTime | Range:timestamp | Start and, if needed, end time for the processing step. Example(S): In Clinical Genomics, the time of freezing of the sample. |
| temperature | Quantity | The temperature at which the processing occurred. |

#### Storage Equipment

DEFINITION: A physical item which is used for holding or containment of something such as materials or samples and from which the items it contains can be retrieved at a later time.

Attributes

| **Name** | **Type** | **Definition** |
| --- | --- | --- |
| name | String | A word or a combination of words, numbers or identifiers by which a specific instance of storage equipment is designated, called, or known. |
| locationIdentifier | Identifier | A word or a combination of words, numbers or identifiers that uniquely defines the location of the single instance of equipment.Example(S): barcode, RFID, alphanumeric |
| locationNamespace | Identifier | A word or a combination of words, numbers or identifiers by which the location is defined. |
| equipmentType | Code | Coded representation of the category of equipment used.Example(S): Refrigerator, nitrogen freezer, shelving |
| geographicalLocation | GeographicLocation | Alphanumeric sequence, term or symbols used to identify a point or an area where the equipment is physically located. |

#### Subject

The person, non-living or living non-human material on which a procedure is performed to obtain a specimen.

Attributes

|  |  |  |
| --- | --- | --- |
| **Name** | **Type** | **Definition** |
| name | String | Linguistic designation of an individual subject. |
| subjectLocation | String | The geographic place where the subject is when a specimen is obtained. |

#### Subject Characteristics at Collection

Ask at Order Entry questions about the subject at time of collection, important for proper interpretation of test results.

Example(s):

Weight / Vaccination Status / ethnicity / fasting Status/ Age

Attributes

|  |  |  |
| --- | --- | --- |
| **Name** | **Type** | **Definition** |
| ObservationTypeCode | Code | Coded representation for the Ask at Order Entry (AOE) question conveying information about the subject, that may be important for the interpretation of the testing performed on the specimen. |
| ObservationValue | ANY | Answer to the AOE - may be any format, but format, but is pre-defined for each question. |