Table of Contents

[1 Medical Research Use Case 2](#_Toc413306899)

[1.1 Description 2](#_Toc413306900)

[1.2 Preconditions 2](#_Toc413306901)

[1.3 Use Case Sequence 3](#_Toc413306902)

[1.4 Post Conditions 4](#_Toc413306903)

[1.5 Actors 4](#_Toc413306904)

[1.6 Use Case Scenario 4](#_Toc413306905)

[2 Clinical Genomics Workgroup’s Clinical Sequencing project 4](#_Toc413306906)

[2.1 Description 4](#_Toc413306907)

[2.2 Preconditions 4](#_Toc413306908)

[2.3 Use Case Sequence 4](#_Toc413306909)

[2.4 Post Conditions 4](#_Toc413306910)

[2.5 Actors 4](#_Toc413306911)

[2.6 Use Case Scenario 4](#_Toc413306912)

[3 Specimen Use Case for Isolate Representation 5](#_Toc413306913)

[3.1 Description 5](#_Toc413306914)

[3.2 Preconditions 5](#_Toc413306915)

[3.3 Use Case Sequence Steps 5](#_Toc413306916)

[3.4 Post Conditions 6](#_Toc413306917)

[3.5 Actors 6](#_Toc413306918)

[3.6 Use Case Scenario 6](#_Toc413306919)

[4 Environmental Specimen Use Case 6](#_Toc413306920)

[4.1 Description 6](#_Toc413306921)

[4.2 Preconditions 9](#_Toc413306922)

[4.3 Use Case Sequence 9](#_Toc413306923)

[4.4 Post Conditions 9](#_Toc413306924)

[4.5 Actors 9](#_Toc413306925)

[4.6 Use Case Scenario 9](#_Toc413306926)

[5 Specimen Origin 10](#_Toc413306927)

[5.1 Description 10](#_Toc413306928)

[5.2 Preconditions 10](#_Toc413306929)

[5.3 Use Case Sequence 10](#_Toc413306930)

[5.4 Post Conditions 11](#_Toc413306931)

[5.5 Actors 11](#_Toc413306932)

[5.6 Use Case Scenario 11](#_Toc413306933)

[6 Interventional Imaging 11](#_Toc413306934)

[6.1 Description 11](#_Toc413306935)

[6.2 Preconditions 12](#_Toc413306936)

[6.3 Use Case Sequence 12](#_Toc413306937)

[6.4 Post Conditions 13](#_Toc413306938)

[6.5 Actors 13](#_Toc413306939)

[6.6 Use Case Scenario 13](#_Toc413306940)

Use Cases – copy from other document

Besides relying on the already developed HL7 artifacts, like the SPM segment in V2.x and the Specimen CMET in V3, we collected the following use cases as the basis for creating the domain analysis model:

* Medical Research Use Case and Specimen Core Diagram
* Clinical Genomics Work Group’s Clinical Sequencing project
* [Specimen Use Case for Isolate Representation](http://wiki.hl7.org/index.php?title=Specimen_Use_Case_for_Isolate_Representation)
* Environmental Specimen Use Case
* Specimen Origin Use
* Interventional Imaging

These use cases are further elaborated in subsequent sections.

# Medical Research Use Case

## Description

The research laboratory receives a clinical specimen for research purposes. Often there are several processing steps required prior to performing the actual testing. In order to properly interpret the results at a later time and ensure comparability to other similar results under the same research protocol, all processing steps need to be recorded and identified. Every derived specimen needs to be individually identifiable, while retaining the relationship to its predecessors.

## Preconditions

None

## Use Case Sequence

The activity diagram below represents the processing steps.



Figure Specimen Collection and Handling Activity Diagram

## **Post Conditions**

## Actors

Research Laboratory

## Use Case Scenario

# **Clinical Genomics Workgroup’s Clinical Sequencing project**

## Description

The purpose of this case is to describe the workflow needed for use in clinical genomics testing. Unique to this use case is the requirement for explicate identification of 1 or more specimens to be used in laboratory analysis. This likely necessitates the identification of specimen groups (i.e. separate specimens and associated derivatives) originating from the same patient/subject or related patients/subjects. Derivatives which may be analyzed from the various testing scenarios described in the use cases below include: DNA, RNA, and Protein

## Preconditions

None

## Use Case Sequence

No Sequence Submitted

## **Post Conditions**

Separate specimens and associated derivatives originating from the same patient/subject or related patients/subjects have been prepared and are properly identified with specimen groups.

## Actors

Genomics Laboratory

## Use Case Scenario

In particular the following use case subtypes need to be captured:

1. Germline testing for biomarkers/mutations (usually inherited)
2. Tumor testing for somatic (tumor specific biomarkers/mutations)
   1. Matched specimens for germline and somatic analysis, where comparison will result in the identification of tumor specific mutations/biomarkers
   2. Tumor specimen without a matched germline specimen, where mutations/biomarkers are believed to be specific to tumors.
3. Pediatric testing for biomarkers/mutations causal to rare early childhood conditions
   1. Matched specimens of patient and maternal and paternal specimens, where comparison aids in identification of original biomarkers/mutations within the patient
4. Prenatal testing which may be reported on the maternal medical record (and should be identified as separate from germline testing
   1. Often have matched fetal and maternal specimens for analysis
5. Infectious disease testing, where the biomarker/mutation identified within the disease causing organism is reported into the patient medical record following similar data standards as used for other testing scenarios above.
6. Microbiome analysis of a the patient
   1. Includes analysis of microorganisms living in the patients gastrointestinal tract or Genitourinary system

# [Specimen Use Case for Isolate Representation](http://wiki.hl7.org/index.php?title=Specimen_Use_Case_for_Isolate_Representation)

## Description

Public Health Labs often receive isolates submitted for reference testing. The specimen type for that ordered test is the isolate, but information about the original clinical sample the isolate was grown from is important, so it also needs to be conveyed. A related use case is the testing of nucleic acid extracted from a sample, either submitted that way, or processed at the lab. Where would the following attributes about that original specimen be conveyed?

Not all of these would be required every time:

1. Original clinical specimen type (at minimum)
2. Original clinical specimen source site
3. Original clinical specimen collection method (if important)
4. Original clinical specimen additives / transport media (if important)

## Preconditions

Clinical sample has been submitted and a derived specimen has been created for submission to another lab for further testing

## Use Case Sequence Steps

1. A clinical sample is submitted to the testing laboratory.
2. The testing laboratory provides testing on the clinical sample and in the process it creates a derived specimen.
3. The testing laboratory does not have the capacity to complete testing on the derived specimen.
4. The derived specimen is forwarded to the reference laboratory for further testing.
5. The reference laboratory receives the derived specimen and all information required to properly interpret the requested test.
6. The reference laboratory completes testing and provides the result to the testing laboratory, who forwards it to the original ordering provider.

## Post Conditions

1. Testing on the derived specimen is completed by the reference laboratory.
2. The result is sent to the testing laboratory.
3. The testing laboratory reports the results of its own testing along with the results from the reference lab to the original ordering provider.

## Actors

Testing laboratory

Reference laboratory

## Use Case Scenario

Patient John Q. Doe, a 45 year old white Hispanic male is seen by Dr. Mark A. Jones for severe diarrhea, who collects a stool sample and send that to his usual testing laboratory, ACME Laboratory. During the testing process ACME Laboratory isolates Salmonella from the stool specimen and sends the isolate on the state Public Health Laboratory, where it is identified as *Salmonella enterica subspecies enterica*. The state Public Health Laboratory does not have the capacity for further subtyping and forwards the isolate to the Centers for Disease Control and Prevention’s National Salmonella Reference Laboratory for identification and subtyping.

# [Environmental Specimen](http://wiki.hl7.org/index.php?title=Specimen_Use_Case_for_Environmental_Specimen) Use Case

## Description

Public Health Environmental samples cover a broad spectrum of programs, matrixes, and methods. This spectrum continues to expand frustrating efforts to harmonize data elements for both the data generator and the data consumer. When defining the data elements that are necessary to characterize environmental samples for submission to a Public Health Laboratory it is useful to take a step back and seek opportunities to define these data elements in a such a way that they are agnostic to programs, matrixes, and methods and provide the ability to expand. Such an approach also makes data exchange between sample submissions easier to map and harmonize. Starting with a domain model that first looks at the organization of data elements is one approach.

As an example, Figure 1 is a domain model used for data exchange and data element organization for public and private health laboratory sample submittal and collection of results for environmental emergency response. This domain model is more inclusive than needed for this discussion, since this domain model also includes data elements associated with sample analysis and results.

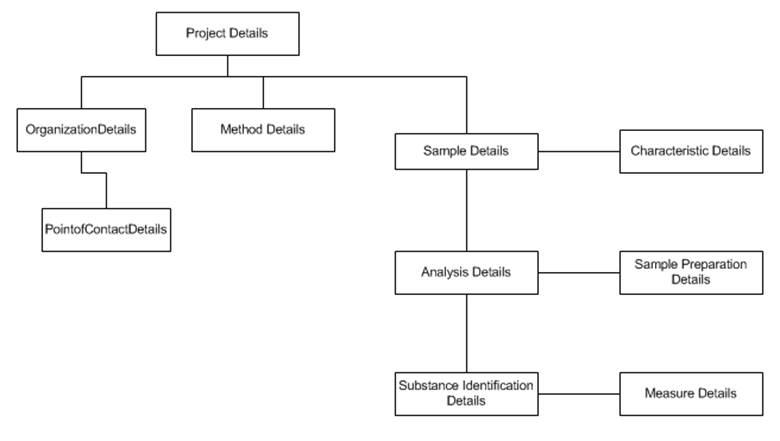


Figure - Domain Model for a Comprehensive Data Exchange and Data Element Organization of Environmental Samples

At this time, the discussion is focused on the data elements associated with sample submittal; an abbreviated domain model is appropriate.

Listed below are data element groups with example data elements that reflect multiple programs, matrixes (referred to as specimen type in the clinical domain), and methods associated with environmental health sample submissions.

For consideration in the DAM we are mostly interested in items #1, #2, #3, and #4. Some of the elements included in the DAM can also be used to address chain of custody requirements.

1. Sample Collection Information
   1. Unique Sample Identifier supplied by Sampler; if a regulatory sample the sample license or regulatory identifier for the sample = format of ID plus assigning authority
   2. Sample Matrix (soil, water, air) = coded format with a sub matrix to reflect additional information as separate matrix modifier = coded format or text
      1. E.g. for water: well, lake, river, reservoir
      2. E.g. for soil: sand, clay, humus, landfill
      3. E.g. for food: fresh, cooked, commercial, home-made, fermented, pickled
   3. Sample Type to reflect the growing interest to capture measurement of quality objectives used for data validation such as:
      1. Test sample
      2. Field Spike and Laboratory Spike
      3. Field Blank and Laboratory Blank
      4. Field Duplicate and Laboratory Duplicate
      5. sampler/requestor name = name format
      6. date collected (range) = date/time format, include start and end date time, if applicable
      7. additional information specific to the program the sample is collected for
2. Sample Subject Information
   1. Type of Object, if applicable (for example the medical device) = coded format
   2. Manufacturer = text format
   3. Model = text format
   4. Lot Number = text format
   5. Service Date (or Prepared Date for food) = date/time format
   6. Expiration Date = date/time format
   7. Relationship to Human Sample = ID and assigning authority format (or name format?)
3. Sample Location
   1. GIS
   2. Text Location = address format (street, town, state, zip etc)
   3. Name or Identifier for the location (e.g. well ID, or name of lake) = format of ID and assigning authority or name (or would this be the sample subject?)
   4. Additional Information about the location of the sample (e.g. shore of the lake, close to house, playground) = text format
   5. Coordinates of sample collection (including depth)
4. Sample Characteristics that may affect analysis
   1. pH = number and units format
   2. Turbidity
   3. Temperature = number and units format
   4. Preservative = coded format
   5. Sample container = coded format
   6. Sample Batch Identifier = ID format with assigning authority
   7. Number of Samples in the Batch = number format
5. Sample Analysis Requested
   1. Sample Method = coded format
   2. Sample Results Point of Contact = name format and possibly ID format with assigning authority
   3. Other information such as turnaround time, requested detection limits, result data formats, data report format, etc.
6. Chain of Custody
   1. Chain of Custody Identifier needed = Boolean – if checked, then:
      1. Time Sample Delivered to Lab = date/time format
      2. Any other Sample Collectors = name format and possibly ID format with assigning authority
      3. Additional Sample Identifier = ID format with assigning authority

## Preconditions

None

## Use Case Sequence

No sequence submitted

## **Post Conditions**

## Actors

1. Organizational Requestor Type
2. Homeowner
3. Regulatory Program Associated with sample
4. FDA Program
   1. eLexnet (https://www.elexnet.com/elex/login/elexnethome.jsp)
5. EPA Program
   1. Safe Drinking Water Information System SDWIS (http://water.epa.gov/scitech/datait/databases/drink/sdwisfed)
   2. Air Quality System AQS (http://www.epa.gov/ttn/airs/aqsdatamart/)
   3. National Pollutant Discharge Elimination System NPDES (http://cfpub.epa.gov/npdes/home.cfm?program\_id=45)
6. Centers for Disease Control and Prevention CDC
   1. LRN-C
7. Environmental Public Health Tracking
8. Environmental Childhood Lead
9. Public Health Environmental Laboratory

## Use Case Scenario

1. Water testing:
   1. Surface water testing for coliform bacteria:

Every month the Public Health Laboratory receives water samples collected from the local lake that is used as a swimming facility during the summer and determines the number of coliform bacteria in order to evaluate, if the lake is still safe for public use.

* 1. Well water testing for toxic contaminants:
     + 1. A homeowner collects water from a well to check for contaminants to determine, if it is still safe to drink.
       2. As part of the Safe Drinking Water Act all public water agencies have to regularly submit samples from their public water supply samples for contaminants testing

1. Soil sampling:
   1. Testing for lead in soil:

After an elevated blood lead level is reported to the Public Health Agency a case worker collects soil samples at the playground of the child care center and at the home of the child. These soil samples are then tested to determine the lead content to help locate the source of the lead contamination.

1. Environmental Swab
   1. Routine Infection Control:

As part of infection control the laboratory performs routine swabs of hospital equipment used in the Intensive Care Unit and sends to the laboratory for culture.

1. Food
   1. A patient has been diagnosed with Salmonella typhi and this result has been reported to the Public Health Agency. A case investigation is started and based on the interview with the patient several food items are selected as possible sources and are sent to the Public Health Laboratory for testing.

# [Specimen Origin](http://wiki.hl7.org/index.php?title=Specimen_Use_Case_for_Environmental_Specimen)

## Description

Public health laboratories that handle a variety of sample types, not just human clinical samples, need an easy was to identify the category of specimen, also referred to as origin. As demonstrated in the Environmental Specimen Use case described above, the data elements required to be provided in order to properly interpret test results differs quite considerably from those needed for clinical samples depending on the category of specimen submitted.

## Preconditions

Sample collected from human or non-human origin.

## Use Case Sequence

N/A

## **Post Conditions**

Data related to specimen clearly indicates the origin of the specimen.

## Actors

Public Health Laboratory

## Use Case Scenario

See Environmental Specimen Use Case Scenario, Section 4.6.

# Interventional Imaging

## Description

Interventional Imaging is part of the anatomical pathology workflow when examining specimen.

The specimen model needs to accommodate the identification of

* Case
* Part
* Block
* Slide or similar entities derived by processing steps – each can be generalized as “Container”.

Digital Imaging and Communications in Medicine (DICOM) [[1]](#footnote-1)defines formal attributes for the identification and description of the specimen that is subject of a DICOM image – these are necessary to understand and interpret the image. They cover the following classes:

* Specimen
* Container
* Specimen Collection
* Specimen Sampling
* Specimen Processing
* Specimen Ancestor(s)

## Preconditions

None

## Use Case Sequence



Figure – Sampling for one specimen for one container [ftp://medical.nema.org/medical/dicom/2011/11\_17pu.pdf – Figure NN.4-1page 315]

## **Post Conditions**

Components of a single case are correctly identified at a specimen, part, block and section level.

## Actors

Surgeon

Interventional Radiology Staff

Anatomic Pathology Staff

## Use Case Scenario

Interventional Imaging is part of the anatomical pathology workflow when examining specimen.

1. Case: As part of the typical anatomic pathology workflow all samples removed in a single collection procedure, be they biologic (e.g. tissue) or non-biologic (e.g. orthopedic hardware) are considered a single “Case” and given a single identifier, often referred to as an accession.
2. Specimen = Part: The surgeon may label and send one or more discrete collections of material (specimens) to pathology for analysis, which are expected to be both identified as being part of the “Case”, while at the same time being treated as a separate entity as well. Each “Part” is a logical component of the laboratory workflow and is managed separately.
3. Blocks = Each “Part” can be further processed into smaller sections called “Blocks” treated with different materials (e.g. embedded in a paraffin block or epoxy resin) for further examination.
4. Sections = This “Block” can be further sliced into thin “Sections” and one or more “Sections” will be placed on slides for histological examination.

1. From: Digital Imaging and Communications in Medicine (DICOM)

   Part 17: Explanatory Information, Published by National Electrical Manufacturers Association, 2011 pages 301-327; <ftp://medical.nema.org/medical/dicom/2011/11_17pu.pdf>

   Detailed specimen information can be found in DICOM Part 3; <ftp://medical.nema.org/medical/dicom/2011/11_03pu.pdf>).

   This information that has been specified by DICOM WG26 "Pathology" (DICOM Supplement 122 "Specimen Identification and Revised Pathology" Project) [↑](#footnote-ref-1)