

Conceptual Functional Application Specification

Specimen Resource Locator & Common Biorepository Model

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1 Executive Summary

1.1 Application Description and Purpose

Finding and accessing biospecimens and associated data today is a disintegrated experience. Each institution has its specific biobank management solution. Basic information about specimen collections is rarely shared or easily searchable. The goal for a CBM is to reduce the time and effort required by researchers to locate a biobank that has the specimens they need. The CBM does not seek a full data exchange but to selectively share key information to enable a single search across multiple biobanks. The idea behind a CBM builds on the success of the caBIG® effort and makes it easier for repositories to become caBIG compatible. A CBM supports the idea that data should fit a standardized simple domain model as a means to promote sharing. A CBM would define the infrastructure to enable a dynamically updated repository that can be queried as a service. As data is exchanged using CBM the documentation and quality of biomaterials should by proxy improve. Finally, maintaining a minimal model would support PII compliance. The result is an evolving searchable catalog of basic specimen information that is simple, mutually understood, and community supported.¹

1.2 Scope

*The Office of Biorepositories and Biospecimen Research (OBBR) is **requesting** the Specimen Resource Locator be redesigned and rebuilt. Included in that is scope is addressing the timely update of data provided by this service by designing and building a Common Biorepository Model.*

*CBIIT and OBBR are **paying** to update the Specimen Resource Locator website; however this service is available to the public free of charge. The Common Biorepository Model is being designed and built through a public/private collaboration. Once this is created by CBIIT it too will be available free of charge for biobanking software vendors to adopt and make available to their customers.*

*The **primary users** of the Specimen Resource Locator are researchers whom are looking to search for biospecimens to support their studies. They require an easy, reasonable, and efficient way to use search criteria and locator specimens. The **primary users** of the Common Biorepository Model are biobanking software management vendors and their customers (i.e. biobanks) who wish to use this grid-enabled web service to broadcast summary level information about their collections. The primary subscriber to this service is the Specimen Resource Locator.*

*The **secondary users** of the Specimen Resource Locator would be any other stakeholders who have a need to locate biospecimens to support their studies. The same search criteria and means used by the primary users will suffice. The **secondary users** of the Common Biorepository Model are any other grid-enabled*

¹ Excerpt from abstract to 2009 ISBER conference ["Empowering the search for specimens through a Common Biorepository Model \(CBM\)"](#) by I. Fore, J. Klenk, and A. Breychak

applications who wish to subscribe to and consume summary level information broadcast by biobanks in a meaningful way.

The existing Specimen Resource Locator (SRL) is a product of the precursory organization to CBIIT. The future SRL will be **designed** and **built** by CBIIT. The model that is the Common Biorepository Model is the product of a public/private collaboration among eleven leading biobanking software vendors (including caTissue). This workgroup met on November 3rd, 2008 in a face-to-face meeting to **design** and **build** the original draft of the model. Subsequent community feedback and revisions have been applied to this. The pathway to caBIG silver compatibility review and certification is presently under management by members of the TBPT workspace under advisement of the VCDE/caDSR teams.

The Specimen Resource Locator product is presently **supported** through a contract awarded by the NCI Cancer Detection Program and administered through resources from contractor IMS who provides 1-2 FTEs as "Tissue Expeditors" to respond to inquiries, forward requests to the appropriate parties, and to manage the data content within the application. The Common Biorepository Model (CBM) does not yet exist as a service; however, the existing model is the product the input, participation, and suggestions of eleven leading biobanking software vendors (including caTissue). This workgroup of vendor solutions supports the adoption of the CBM for their software solutions and by extension their customers. Any future support is intended for the vendors who adopt this model; not for the customers of those vendors.

There is no stakeholder with a need for a **regulatory** requirement for either Specimen Resource Locator or the Common Biorepository Model. The implied (but not regulated) need to reconcile with the present 2007 edition and expected update of the "NCI Best Practices for Biospecimen Resources" is one of the drivers of interest for biobanking software vendors to adopt the Common Biorepository Model.²

There are no items being specifically excluded from the Specimen Resource Locator or the Common Biorepository Model.

1.3 The reason why the application is necessary

The Specimen Resource Locator and Common Biorepository Model will enable fresh updated searchable content. This will directly address the challenge of the existing content information in Specimen Resource Locator is latent. This resource will increase the ease with which researchers can find biospecimens (i.e. one search for many sources). For biorepositories the resource can be seen as another source of leads for biospecimen inquires. Researchers will now have access to a wider range of sources. There will be less time investment; more time focusing on hypothesis not tracking down specimens. The proposition for biorepositories is there is more to gain from an open index of summary-level inventory information. Finally, there will be more time for the existing Specimen Resource Locator tissue expeditor person to provide higher value-added guidance.

² <http://biospecimens.cancer.gov/practices/default.asp>

2 Business Storyboards

The deliverables for OBBR who is **requesting** this project are: an updated Specimen Resource Locator website (product) and a caBIG silver compliant grid enabled Common Biorepository Model (service).

CBIIT whose is **paying** for the Specimen Resource Locator website (product) is expecting an updated website and a caBIG silver compliant Common Biorepository Model (service) that is widely adopted by biobanking software vendors.

The deliverables for researchers who are the **primary users** is a updated Specimen Resource Locator website that is feed by a timely data updates generated by biobanking software vendors whose customer have adopted the Common Biorepository Model.

The deliverables for **secondary users** would be the same as for primary users

The expectations for stakeholders **designing/building** the Specimen Resource Locator and Common Biorepository Model are an updated website and a caBIG silver compliant model with a test suite to allow validation.

OBBR (and the Cancer Detection Program who is **supporting** this) is expecting an updated website. Vendors who are adopting the Common Biorepository Model are expecting **support** that will allow them to offer to their customer a means to share summary level information that is caBIG silver compliant. The **support** of the Common Biorepository Model is with biobanking software vendors but not with their respective customers.

There are no stakeholders who are **regulating** these products. The expectation for biobanks is adopting a Common Biorepository Model will avail them of implied regulation via the “NCI Best Practices for Biospecimen Research”.

- Include a prioritized list of storyboards illustrating the application and how it will be used
- These should be based upon genuine business need from a stakeholder or reference source (e.g., not “made up”).
- Identified operations in Section 5 need to be directly tied to them. If an operation in Section 5 is not supported by a business storyboard, it will demonstrate a lack of business support for an operation. The same is true for operations omitted or not found in Section 5.
- These should be sufficient to illustrate the main uses of the Application, but not exhaustive.
- For each use case / business case / storyboard describe the dynamics of the application from a requirement-level architectural view and its interactions (with anticipated services/components/applications, etc.)
- Should use any well known, reasonable mechanism for communicating the information (e.g. UML Activity Diagrams or Sequence Diagrams) at a minimum, but rigorous expression (CDL) is preferred.

- Include information from the following table for each enumerated use case / business case:
 - **[Mandatory]** A business-friendly name **describing** the context of the motivating scenario, and is unique within this Functional Model (e.g., “Find a Person” vs. FindPerson)
 - **[Mandatory]** High-level [functional] description of the expected behavior
 - **[Mandatory]** Business **Pre-conditions** [may be null], i.e. what conditions must have been satisfied before the action can be requested or carried out
 - **[Mandatory]** **Inputs** [include both mandatory and optional]
 - **[Mandatory]** **Outputs** [include both mandatory and optional]
 - **[Optional]** Business **Post-conditions**, i.e. what conditions will result from the action being carried out.
 - **[Mandatory]** Business **Exception Conditions** [may be null]
 - **[Mandatory]** Enumeration of **aspects left to the technical** specification [may be null]
 - **[Optional]** **Relationship to levels of conformance** (or other patterns)
 - **[Optional]** **Notes**
 - **[Optional]** **Ties to Requirements** – (Reference Requirement Document in the appendices by URI. Enumerate individual requirements here)

2.1 Summary List of Business Storyboards

2.1.1 Search

Name [M]	<i>Search</i>
High-level description [M]	<i>Research wants to find biospecimens and conducts a search using the Specimen Resource Locator. Using search criteria user specifies criteria, executes query, and is returned actionable list of results.</i>
Pre-Conditions [M]	<i>Researcher is conducting a study and is looking for biospecimens to support said study.</i>
Inputs [M]	<i>Researcher uses web interface search criteria options to prepare and execute a query of the database.</i>
Outputs [M]	<i>Researcher is returned a list of biobanks/biorepositories that match said search criteria.</i>
Post-Conditions [O]	<i>Research contacts one or more biorepositories/biobanks returned from the search query (email or phone) to inquire additional information about biospecimen.</i>

Exception Conditions [M]	<i>If a search criterion returns no match records in the database the researcher is returned existing statement “There are no resources in the database that meet your search criteria.” The user is additionally given existing prompt to enter information in order to contact the Tissue Expeditor for additional help.</i>
Aspects left for Technical Bindings [O]	
Relationship to levels of conformance [O]	
Notes [O]	
Links to Requirements [O]	

2.1.2 Update SRL database by CBM

Name [M]	<i>Update SRL database by CBM</i>
High-level description [M]	<i>Administrator of SRL wants to update the SRL database through a query to the CBM grid nodes.</i>
Pre-Conditions [M]	<i>There are active CBM grid nodes available.</i>
Inputs [M]	<i>Administrator queries CBM grid nodes for availability and is returned list of avail nodes.</i>
Outputs [M]	<i>Any data available from each CBM grid node is downloaded into a queue in the SRL database.</i>
Post-Conditions [O]	<i>The SRL administrator reviews the queue of record updates from the CBM grid nodes and elects to selectively post updates to the public SRL database and web application.</i>
Exception Conditions [M]	<i>If a CBM grid node is active for the 1st query and inactive the 2nd query then the Administrator is given the choice to: a) do nothing; not change the public SRL posting b) is given email link to query administrator/owner of CBM grid node c) is [alternatively] given option to delete public SRL posting for that specific CBM grid node.</i>
Aspects left for	

Technical Bindings [O]	
Relationship to levels of conformance [O]	
Notes [O]	
Links to Requirements [O]	

2.1.3 Update SRL database (manual and semi-manual)

Name [M]	<i>Update SRL database (manual and semi-manual)</i>
High-level description [M]	<i>Administrator wants to update the SRL database but the biobank/institution/collection does not use CBM.</i>
Pre-Conditions [M]	<i>Biobank has been added to SRL in the past or wants to be added to SRL in the future as a new entry.</i>
Inputs [M]	<i>Either a) Data is entered into the SRL queue as new (non-CBM) record by Administrator or b) Administrator elects to conduct periodic electronic request for update to non-CBM biobanks.</i>
Outputs [M]	<i>Any data captured through (a) or (b) inputs is fed into the SRL queue.</i>
Post-Conditions [O]	<i>The SRL administrator reviews the queue of record updates and elects to selectively post updates to the public SRL database and web application.</i>
Exception Conditions [M]	<i>Any data entered through this use case will be subject to the same screening for semantic interoperability as the incoming feeds from the CBM grid nodes by using the CBM test suite for data validation.</i>
Aspects left for Technical Bindings [O]	
Relationship to levels of conformance [O]	
Notes [O]	

Links to Requirements [O]	
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2.1.4 Establish a CBM grid node

Name [M]	<i>Establish a CBM grid node</i>
High-level description [M]	<i>Biobank wishes to share their data on the grid using the CBM.</i>
Pre-Conditions [M]	<i>Biobank has established contact with SRL Administrator/Tissue Expeditor notifying them they wish to join the network.</i>
Inputs [M]	<i>Biobank works with their BSMS vendor to establish a CBM grid node and a test. Biobank establishes ETL from their data to local CBM grid node. Biobank applies for membership by 1st validation against a CBM test suite.</i>
Outputs [M]	<i>Biobank is now an active CBM grid node.</i>
Post-Conditions [O]	<i>Biobank can now participant in "Update the SRL by CBM" as a member.</i>
Exception Conditions [M]	<i>If biobank does not pass 1st validation they are returned a electronic report that notes what is not CBM compliant. If biobank CBM grid node is a validated member but fails to maintain grid node they will be contacted by automated email notification.</i>
Aspects left for Technical Bindings [O]	
Relationship to levels of conformance [O]	
Notes [O]	
Links to Requirements [O]	

2.1.5 Validate against a test suite

Name [M]	<i>Validate against a test suite</i>
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High-level description [M]	<i>Prospective or existing CBM grid node wishes to validate data against a test suite.</i>
Pre-Conditions [M]	<i>Biobank has established (or is establishing for the 1st time) a CBM grid node.</i>
Inputs [M]	<i>Data entered in a CBM grid node at a local biobank and made available in a DMZ.</i>
Outputs [M]	<i>Biobank attains (or maintains) CBM membership.</i>
Post-Conditions [O]	<i>Report issued to prospective/existing CBM grid node of success/fail and itemization.</i>
Exception Conditions [M]	<i>If validation fails then both SRL Administrator and local biobank are notified by email.</i>
Aspects left for Technical Bindings [O]	
Relationship to levels of conformance [O]	
Notes [O]	
Links to Requirements [O]	

2.1.6 ETL from BSMS to CBM grid node (out of scope)

Name [M]	<i>ETL from BSMS to CBM grid node (out of scope)</i>
High-level description [M]	<i>Biobank electively loads data from their BSMS into local CBM grid node.</i>
Pre-Conditions [M]	<i>A locally established CBM grid node.</i>
Inputs [M]	<i>A script provided by BSMS vendor to perform ETL of data from their system into CBM grid node.</i>
Outputs [M]	<i>A CBM grid node populated with data.</i>
Post-Conditions [O]	<i>Use case "Validation against a test suite" is executed.</i>
Exception Conditions [M]	<i>If ETL from BSMS to CBM grid node is unsuccessful then biobank works with their BSMS provider to address.</i>

Aspects left for Technical Bindings [O]	
Relationship to levels of conformance [O]	
Notes [O]	
Links to Requirements [O]	

2.1.7 Contact Tissue Expeditor (out of scope)

Name [M]	<i>Contact Tissue Expeditor (out of scope)</i>
High-level description [M]	<i>Researcher/visitor to SRL wishes to contact Tissue Expeditor directly.</i>
Pre-Conditions [M]	<i>Visiting the SRL website to find link to contact Tissue Expeditor.</i>
Inputs [M]	<i>Researcher/visitor enters information into form on SRL website to send pertinent information on to Tissue Expeditor.</i>
Outputs [M]	<i>Email/notification to queue sent to Tissue Expeditor that contains entered information.</i>
Post-Conditions [O]	<i>Tissue Expeditor triages request and responds with the appropriate contact (voice, email).</i>
Exception Conditions [M]	
Aspects left for Technical Bindings [O]	
Relationship to levels of conformance [O]	
Notes [O]	
Links to Requirements [O]	

2.1.8 Query SRL grid node (out of scope)

Name [M]	<i>Query SRL grid node (out of scope)</i>
High-level description [M]	<i>Establish centralized SRL database as a caBIG grid node.</i>
Pre-Conditions [M]	<i>A SRL database being regularly and consistently being populated by CBM grid nodes.</i>
Inputs [M]	<i>A grid query.</i>
Outputs [M]	<i>A grid query result.</i>
Post-Conditions [O]	<i>Grid query results consumed by application(s).</i>
Exception Conditions [M]	<i>SRL grid node is unavailable and query returns no results.</i>
Aspects left for Technical Bindings [O]	
Relationship to levels of conformance [O]	
Notes [O]	
Links to Requirements [O]	

3 Structure of the Application

In macro the Specimen Resource Locator is an existing website created and deployed in 2002 under the guidance of the NCI Cancer Detection Program. In 2008, the future ownership and direction of this website was transferred to the OBBR who is now setting the direction and goals for this resource. The existing site built using ColdFusion is available here: <http://biospecimens.cancer.gov/locator>. It has a number of search criteria that allows a visitor to specify a query on the associated database and return a short list of matching results. The goal is to update this website and the associated data.

The single driver to ensuring a revitalized resource is to enable a re-occurring reasonable means to update the data. This is where the proposed structure as seen in figure 1 will enable periodic updates using a Common Biorepository Model service. This service will take de-identified summary level information from a biospecimen

management system installation and make it available through ETL into a CBM database residing the DMZ of a client site. This database and service in the DMZ will enable synoptic interoperability using caBIG caGRID services. The data within the local Common Biorepository Model database will fit an established form that will enable semantic interoperability using a caBIG silver compliant model.

Referencing the numbers in figure 1 the overall application workflow is: step 1 = research/visitor queries the Specimen Resource Locator website using pre-defined choices from a web user interface; step 2 = the Specimen Resource Locator database queries for updates (at pre-determined periodic intervals) using caGRID services; step 3 = local exposed grid nodes using the Common Biorepository Model are updated at periodic intervals determined by local instance; step 4 = the queries from {step 2} return updated data over the grid and collect them into the local database associated with the Specimen Resource Locator; step 5 = researcher/visitor uses the results return from their query to identify a short actionable list of possible biobanks/collections that may be able to meet the biospecimen needs for their studies.

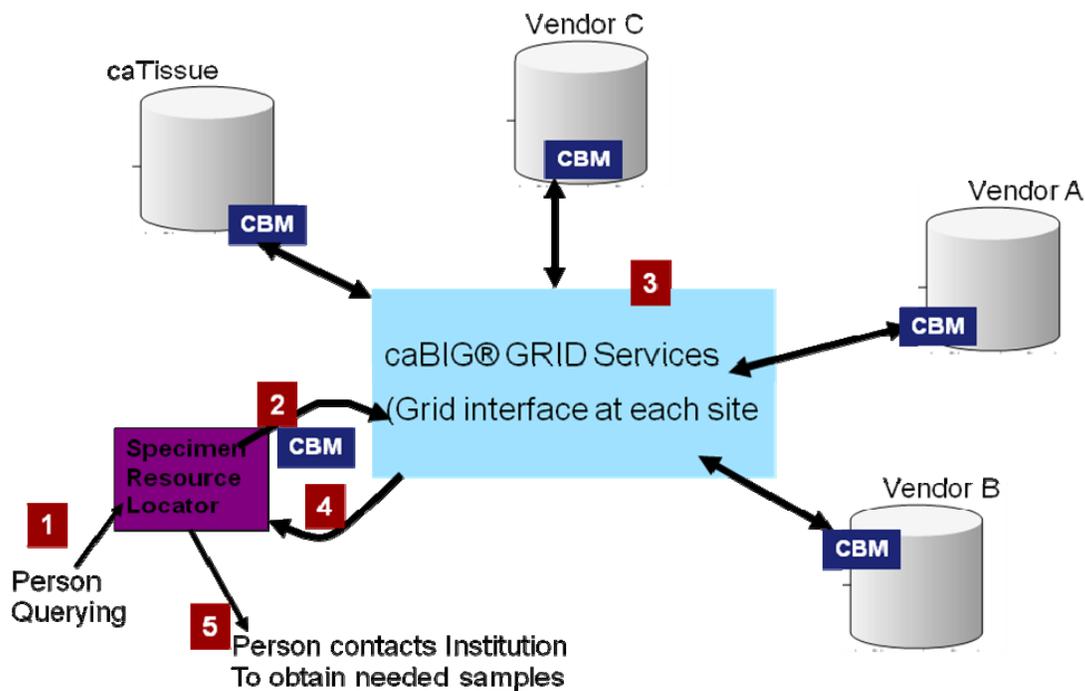


Figure 1: Specimen Resource Locator & Common Biorepository Model summary interaction

3.1 Implementation Considerations

In figure 2 below is a proposed architecture that would be representative of an implementation from the perspective of a biorepository management software vendor and their respective customer(s).

- Relevant and representative examples of deployment scenarios
- Consider representation formalism and the intended audience, not necessarily rigorously expressing the content in UML

- This specification in the real world (e.g., relationships to existing infrastructure, other deployed services, dependencies, etc.)

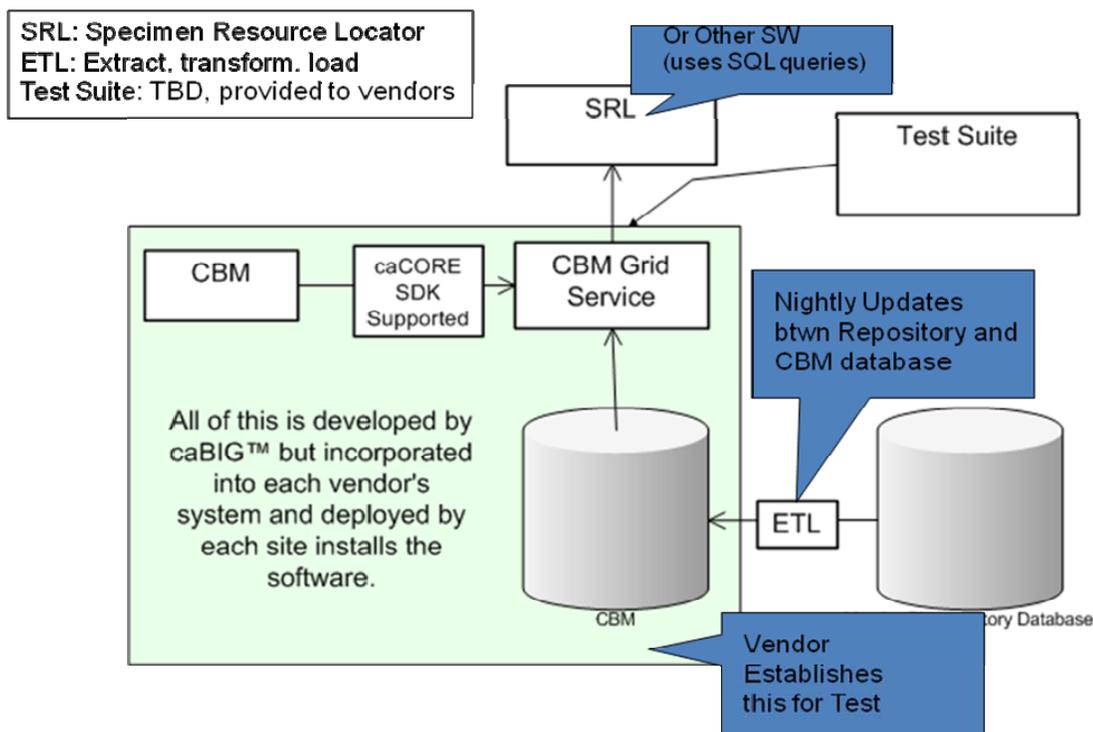


Figure 2: SRL/CBM proposed architecture

3.2 Assumptions and Dependencies

It is assumed that the specification and availability of caGRID will be the means to support syntactic interoperability between disparate biobanking software vendors using a Common Biorepository Model. Furthermore, semantic interoperability will be achieved by said Common Biorepository Model confirming with caBIG silver-level compatibility.³

It is assumed that the location and inventory information from biobanks will be available and consumable via a Common Biorepository Model for the Specimen Resource Locator to be effective. It is assumed biobanks and their customers will find sharing information through a Common Biorepository Model to be a distinct risk-free advantage to warrant the effort to implement this.

There is a dependency on the development of a standard format or Common Biorepository Model for data to be sharable in this manner. A constraint will be the resources and effort required to rebuild the Specimen Resource Locator and to develop the Common Biorepository Model.

³ Silver-level compatibility implies the model has been reviewed and approved by VCDE and caDSR teams and the Common Biorepository Model is registered as caBIG Silver Level compliant.

3.3 Detailed Functional Dependencies for the Application

List of capabilities (aka responsibilities or actions) that the application's workflow depends on and description on what it does in business terms.

Description	Doc Title	Doc Version
<business friendly description>	<document title>	<document version>

4 Profiles

4.1 Introduction

A profile is a named set of cohesive capabilities. A profile enables an application to be used at different levels and allows implementers to provide different levels of capabilities in differing contexts. Whereas interoperability is the metric with services, applications focus on usability (from a user's perspective) and reusability (from an implementer's).

Include the following three components in each profile:

- Information Profile: identification of a named set of information descriptions (e.g. semantic signifiers) that are supported by one or more operations.
- Functional Profile: a named list of a subset of the operations defined as dependencies within this specification which must be supported in order to claim conformance to the profile.
- Behavioral Profile: the business workflow context (choreography) that fulfills one or more business purposes for this application. This may optionally include additional constraints where relevant.

Fully define the profiles being defined by this version of the application.

When appropriate, a minimum profile should be defined. For example, if an application provides access to several business workflows, then one or more should be deemed essential to the purpose of the application.

Each functional profile must identify which interfaces are required, and when relevant, where specific data groupings, etc... are covered etc.

When profiling, consider the use of your application in:

- Differing business contexts
- Different localizations
- Different information models
- Partner-to-Partner Interoperability contexts
- Product packaging and offerings

Profiles themselves are optional components of application specifications, not necessarily defining dependencies as they define usage with services. Nevertheless, profiles may be an effective means of creating groupings of components that make sense within the larger application concept.

4.2 Information Profiles

Identify a named set of information descriptions (e.g. semantic signifiers) that are supported by one or more operations.

4.3 Functional Profiles

A named list of a subset of the operations, defined as dependencies within this specification, which must be supported in order to claim conformance to the profile.

4.4 Behavioral Profiles

The business workflow context (choreography) that fulfills one or more business purposes for this application. This may optionally include additional constraints where relevant.

5 Recommendations for Technical Realization

- Identification of topics requiring elaboration in candidate solutions. This may be application-specific, deployment related, or non-functional

5.1 Conformance Assertions

- List any Conformance Assertions that emerge from this specification

6 Appendix A - Glossary

SRL = Specimen Resource Locator

CBM = Common Biorepository Model

BRD = Biospecimen Research Database

BSMS = Biospecimen Management System (generic)

ETL = Extract, Transform, Load

DMZ = Semi-public region exposed outside a company's firewall

OBRR = Office of Biorepositories and Biospecimen Research

ORDR = Office of Rare Diseases

CDP = Cancer Diagnosis Program

CHTN = Cooperative Human Tissue Network

ATCC = American Type Culture Collection

DTP = Developmental Therapeutics Program

TARP = Tissue Array Research Program

CBIIT = Center for Bioinformatics and Information Technology

Biospecimen or specimen: A quantity of tissue, blood, urine, or other biologically derived material used for diagnosis and analysis. A single biopsy may generate several specimens, including multiple paraffin blocks or frozen specimens. A specimen can include everything from subcellular structures (DNA) to cells, tissue (bone, muscle, connective tissue, and skin), organs (e.g., liver, bladder, heart, and kidney), blood, gametes (sperm and ova), embryos, fetal tissue, and waste (urine, feces, sweat, hair and nail clippings, shed epithelial cells, and placenta).⁴

⁴ <http://biospecimens.cancer.gov/patientcorner/glossary.asp>

7 Appendix B – Conceptual Models and Application Specification

7.1 Introduction and Scope

The NCI CBIIT Development Framework Methodology is the methodology followed to define NCI specifications for applications. The methodology sets out an overall process, and also defines the separation of responsibilities of the Conceptual Functional Model (CFM) for services and the Functional Specifications for Applications. It is important to note that a strong dependency exists between applications and services in the NCI Service Oriented Architecture, and that these dependencies should emerge in the process of creating this Functional Specification.

7.1.1 Application Definition Principles

The high level principles regarding the definition of applications that are deployed within the caBIG are:

- Applications shall be well defined and clearly scoped and with well understood requirements and responsibilities.
- Applications shall realize one or more workflows. These workflows may cross domains.
- Applications shall specify their own workflows, but shall, to whatever extent possible, utilize existing services, capabilities, and other architecture as has been defined by the Composite Architecture Teams.
- Applications may, in their conceptual specification, only be tightly coupled to other conceptual specifications. This allows implementations to be derived and conformant to an architecture rather than specified in the absence thereof.

An application at the CFS level is regarded as a business process that is bound to other capabilities. It is intended to trace requirements (both functional and non-functional) and to ultimately meet a user's (or users') defined business needs. It is intended to aggregate and use aggregations of modular services and workflows that exist elsewhere in the architecture. Wherever possible, it should not contain business logic, but should rely on services and other architectural components to realize the business logic for it.

Each Conceptual Functional Specification defines the workflows, depends on services, and utilizes information constructs to realize its business purpose or purposes. Dependencies in the Functional Specification relate to services that have or may in future have a Functional Model at a similar level; detailed dependencies on low-level utility services or on technology bindings should not be included, as that level of design is not in scope for the Functional Specification.

The detailed manner in which services and interfaces are deployed, discovered, and so forth is outside the scope of the Functional Specification. However, Functional Models may reference content from other areas of CAT work that deals with architecture,

deployment, naming and so forth. Except where explicitly specified, these references are to be considered informative only. All other interactions within the scope of the scenarios identified above are in the scope of the Functional Specification.

Reference may be made to other specifications for interface descriptions, for example where an interface is governed by an existing standard.

8 Appendix

8.1 Conformance Assertions

Conformance Assertions are testable, verifiable statements made in the context of a single RM-ODP Viewpoint (ISO Standard Reference Model for Open Distributed Processing, ISO/IEC IS 10746|ITU-T X.900). They may be made in four of the five RM-ODP Viewpoints, i.e. *Enterprise, Information, Computational, and/or Engineering*. The *Technology Viewpoint* specifies a particular implementation /technology binding that is run within a ‘test harness’ to establish the degree to which the implementation is conformant with a given set of Conformance Assertions made in the other RM-ODP Viewpoints. Conformance Assertions are conceptually *non-hierarchical*. However, Conformance Assertions *may have hierarchical relationships to other Conformance Assertions within the same Viewpoint* (i.e. be increasingly specific). *They are not, however, extensible in and of themselves.*

8.1.1 Enterprise

8.1.2 Informational

8.1.3 Computational

8.1.4 Engineering (Optional)