HL7 FHIR Repository Governance, Process and Requirements, Release 1
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HL7 Business Process Paper

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Note: name should be changed to “HL7 FHIR Registry/Repository Governance, Process and Requirements”
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I. Foreword

This Guide establishes the governance, process and requirements to manage FHIR artifacts in a repository/registry that is accessible to all users. The goal is to ensure the quality and availability of FHIR artifacts and support adoption of FHIR by the healthcare community and regulators.

II. Introduction

This document describes the business process requirements for a repository/registry that will support FHIR artifacts and associated metadata and help consumers looking for existing FHIR artifacts to rapidly locate them by searching available administrative and classification metadata. The term "FHIR artifacts" is intended to include any of the current FHIR components, including: resources, extensions, profiles, value sets, documentation and examples. In addition, the repository/registry will include implementation guides that provide for a combination of the FHIR artifacts along with testable conformance statements organized around one or more specific use cases. The design and requirements allow for the incorporation of metadata that describes FHIR artifacts, including those stored in one or more non-HL7 repositories. This "registry function" supports an open environment that permits users of the FHIR repository/registry to discover potentially useful artifacts that are maintained elsewhere.

Various users of HL7 standards, as well as HL7 Workgroups, have created a number of FHIR artifacts. Some of these efforts have been coordinated by HL7 and Fire Management Group (FMG) and some have not. Additionally, other groups and companies are also creating FHIR artifacts. There is a need to create a specification for a FHIR artifacts repository/registry that will store FHIR artifacts from various sources, so that the FHIR artifacts themselves can be made accessible to a wide variety of users for a wide variety of purposes. The FHIR artifacts registry is an information system that stores administrative and classification metadata about FHIR artifacts. FHIR artifact metadata is submitted and maintained by one or more custodians.

Once the FHIR artifact repository/registry has received a given FHIR artifact (or group of FHIR artifacts) appropriate change control processes are used. The registry will contain descriptive, structural and administrative information about each FHIR artifacts. It will include information about the FHIR artifact usage, specifically context, scope and adoption for use; inter-relationships: including: parent/child and compositional links; semantic categories; the existence of mappings and transformations between semantically equivalent FHIR artifacts; and, the existence of automated validation and conformance software.2 The repository will also contain reference material and sample FHIR artifact instances. It will support many types of retrieval queries based on structural, semantic, authorship, and other important categories.

The FHIR artifact registry recognizes that metadata, like all repository information, follows a lifecycle and needs to be monitored and maintained over time. The purpose of the repository/registry is to support information sharing and the re-use of FHIR
artifacts. FHIR artifacts and metadata contributions are made by ‘registered’ individuals but submission of actual FHIR artifacts and/or metadata and use of FHIR artifacts will not be an onerous process. The repository/registry relies on contributions from organizations who may delegate authority to submit and comment on their behalf to nominated representatives. A registration process authenticates the nominee and affirms an agreement to abide by the repository’s/registry’s operational policy framework. Registration supports the quality, accuracy and currency of information and enables information consumers to have confidence about statements found in the repository/registry.

The metadata for registering FHIR artifacts will support, at a minimum that mentioned in the HL7 FHIR STU V3. All of the constraint mechanisms supported by the HL7 STU V3 may be used in a given FHIR artifact’s specification, including the derivation path from previously balloted versions and the vocabulary bindings. These vocabulary bindings may also become an important source of metadata that can be used to create an ontological classification for registered FHIR artifacts. The technical staff of a FHIR artifacts repository/registry may create additional structural and semantic links amongst registered FHIR artifacts; they may also use emerging software tools to support this (e.g. the IHTSDO “SNOMED workbench”). This information may be used to support implementation and testing of systems conforming to the registered and approved FHIR artifacts.

The FHIR registry/repository can be integrated with other information systems, such as terminology servers or external FHIR authoring systems. This document is not intended to convey the requirements of these systems.

III. Summary (overview of this document)

This guide specifies the following requirements for and capabilities of the FHIR Repository/Registry:

1. FHIR Artifacts
- Defines the FHIR artifacts that must be supported
- Defines the categories and relationship between the artifacts

2. Repository
- Holds FHIR artifacts with unique reference for each artifact

3. Registry
- Stores metadata for all artifacts in the Repository
- Ability to submit information regarding FHIR artifacts stored in external repositories
- Manages all access to internal and external artifacts
- Maintains relationships between FHIR artifacts
- Maintains statistics on maturity and use

4. Lifecycle/versioning
- Rules / guidelines for the management of versioning of FHIR artifacts throughout their lifecycle
- Defines the lifecycle of an artifact

5. Maturity
- Multiple metrics for measuring maturity of FHIR artifacts

6. Metadata
- Metadata associated with any internal or external FHIR artifact

7. Development and Submission process
- Requirements for tooling to support the development of FHIR artifacts
- Requirement for extraction of FHIR artifacts to common working tools
- Creation of full or partial environment in which to develop and test new functionality
- Testing / validation requirements for submission of new or updated FHIR artifacts
- Submission process depending on maturity of the FHIR artifact

8. Submission/Publication Process
- Ballot or non-ballot publication process

9. Usability
- Defines specific requirements for usability of the Repository / Registry

10. Reporting and Summary
- Minimum requirements for reporting on FHIR artifacts and the associated metadata
- Minimum requirements for summary information that is maintained by the
Repository/Registry system

11. Security
   o Defined minimum security requirements for controlled access to manage updates

12. US Regulatory requirements
   o Reviews US Regulatory requirements
   o Establishes the minimum bar for management of FHIR artifacts that are to be or have been named into US regulation

IV. Intended Audience

The audience for this document includes:

1. Users, implementers and integrators of FHIR based solutions needing to obtain or use the growing body of detailed definitions of clinical and health information that can be represented by FHIR resources, extensions, and profiles. Access to a FHIR repository/registry will greatly enhance the ability to design systems and to share semantically interoperable information between systems, for both clinical and secondary uses.

2. Experts in clinical practice developing guidelines for care, clinical decision support or creating quality measures, who want to understand how to use the structural and ontological definitions of clinical and healthcare information provided by the elements of a FHIR repository to obtain information at the level of FHIR artifacts.

3. Policy-makers and influencers establishing national and regional policies with respect to semantically interoperable information exchange

4. Developers of other FHIR repositories.

5. Developers of other FHIR registries.

6. Creators, distributors and adopters of FHIR based solutions whose artifacts/metadata is stored in this FHIR repository/registry.

V. Scope

This document describes the business process requirements for a repository/registry that will support FHIR artifact creation, management and discovery. The associated metadata will help consumers looking for existing FHIR artifact resources to rapidly locate them by searching available administrative and classification information.

VI. Stakeholders

This section describes the various stakeholders of the FHIR repository/registry and how they interact. Stakeholders are organizations and individuals that benefit from the services provided by a FHIR repository/registry. A FHIR artifact and the associated metadata is a combination of structural, definitional, adoption, relational links and status (e.g. active, under review, inactive, superseded). There will be several revisions of administration status over the course of an artifacts lifecycle.
Stakeholder needs and concerns can be categorized under five main headings:

1. Repository/Registry Administration and Governance
2. FHIR Artifact Creator
3. FHIR Artifact Custodianship
4. FHIR Artifact Adoption
5. FHIR Artifact Information Consumption by an organization or individual
6. Repository/Registry Administration and Governance

The Repository/Registry Administration Governance Organization has responsibilities to:

7. Establish and publish the repository/registry operational procedures and policy framework:
   - Specify the allowable users, accessible content, availability, and the language(s), media, and format in which information is provided
   - Specify the rules by which metadata content is submitted and made available.
8. Administer the registration process.
9. Notify artifact development and metadata submission participants of any decisions according to the procedure specified under the operational policy framework.

FHIR Artifact Creator

The FHIR Artifact Creator is the author of a new or updated FHIR artifact. The original, FHIR artifact developer using a non-HL7 repository, business owner or contributor of FHIR artifact metadata to the registry. The custodian organization remains constant for the lifetime of the FHIR artifact, unless it is contributed to the HL7 Repository and has responsibilities to:

1. Nominate submitters to act on its behalf and advise the Registrar of any nominated representative changes, for example when a nominee retires from their Organization.
2. Submit identifying and structural FHIR artifact metadata to the registry, having first ensured content is not already in the repository.
3. Revise metadata throughout the lifecycle of the FHIR artifact.

FHIR artifact metadata can be recorded by a custodian in two forms – ‘under development’ or ‘published’. This business requirement recognizes a custodian may wish to give formal notice that they are developing a FHIR artifact for a particular purpose. ‘Under development’ may also indicate the custodian wishes to seek editorial advice from FHIR artifact adopters. A FHIR artifact with ‘under development’ status is a work in progress and its definitional and structural details are subject to change and may be incomplete. The FHIR artifact may transition to an ‘under review’ state before publication. The ‘under development’ status is designed to nurture collaboration and awareness by repository/registry users that an organization is developing a FHIR artifact. The FHIR artifact repository equivalent of ‘published’ is ‘active’ and advises the community that a FHIR artifact exists and is available for adoption (use) by a FHIR artifact adopter organization.

FHIR artifact Custodian Organization
The FHIR Artifact Custodian Organization is the original, FHIR artifact developer using a non-HL7 repository, business owner or contributor of FHIR artifact metadata to the registry. The custodian organization remains constant for the lifetime of the FHIR artifact, unless it is contributed to the HL7 Repository and has responsibilities to:

4. Nominate submitters to act on its behalf and advise the Registrar of any nominated representative changes, for example when a nominee retires from their Organization.

5. Submit identifying and structural FHIR artifact metadata to the registry, having first ensured content is not already in the repository.

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For non-HL7 FHIR artifacts that are represented in the registry only, the custodian organization must ensure that both the information content and the technical representation of the FHIR artifact have been validated by the appropriate clinical and technical subject matter experts (SME’s) with the appropriate governance process. SME’s may be staff members of the FHIR artifacts information custodian, or members of organizations with which it has formal agreements. For example, in the case of a non-HL7 clinical FHIR artifact, the accuracy of the clinical content as well as the fact that the FHIR artifact is a set of constraints on a balloted FHIR standard must both be approved by the appropriate SME’s before the status of the FHIR artifact can become the equivalent of an HL7 STU or Normative artifact, at which point the FHIR artifact can be registered in the FHIR artifact repository with the equivalent maturity designation.

**FHIR Artifact Adopter Organization**

A FHIR Artifact Adopter Organization and its representative may advise the Custodian and Registration Administration and Governance Organizations on FHIR artifact metadata. An adopter makes an assertion that a specific FHIR artifact is in use within its own organization and/or expresses an interest in being notified of future changes to the FHIR artifact or its metadata. The adopter may also advise on the business use case(s) for a FHIR artifact. For example, a cardiology professional society may approve a set of semantically interoperable cardiology FHIR artifacts for use in documenting patient EKG results (primary use) as well as providing data for research on a treatment protocol (secondary use).

An adopter organization may appoint any number of representatives. A registry...
metadata entry may have multiple adopter organizations associated with it but only one person may represent each FHIR Artifact Adopter Organization for each repository item.

A FHIR artifact Adopter Organization may delegate the maintenance of its FHIR artifact adoption details in the repository to another organization. The FHIR artifacts repository must be able to record these types of delegation (and any changes in the delegation specifications). For example, in countries where there are states or provinces, an organization may register at the federal level but delegate responsibilities to states/provinces or other organizations. This document is not concerned with the internal processes associated with such delegation but recognizes and supports them in the repository.

It is conceivable that an Adopter Organization may adopt a FHIR artifact, record details of the adoption in the registry, only to find it needs to adapt/enhance the FHIR artifact to better suit its business needs. Adapting a FHIR artifact in effect creates a new FHIR artifact and the Adopter Organization would become the custodian of a new FHIR artifact with metadata in the repository. The adopter is (1) responsible for acknowledging the history and existence of a relationship between the two FHIR artifacts and (2) for updating the adoption record of the original FHIR artifact to advise details of the adaptation.

FHIR artifact metadata could potentially become ‘orphaned’ if the Custodian Organization ceases to exist or its representative retires without delegating another organization to assume custodian responsibilities. Adopter organizations have a special ‘guardian-like’ interest in FHIR artifact metadata and may assume responsibility for re-assigning FHIR artifact interests if FHIR artifact metadata becomes orphaned.

FHIR ARTIFACTS INFORMATION CONSUMER

A FHIR Artifacts Information Consumer can be a stakeholder per se or can assume other stakeholder roles. All stakeholders need to search, download, compare or analyze information content stored in the FHIR artifacts repository/registry. A consumer may be an individual with their own interests (such as a researcher, configurer or implementer of a clinical system) or they may represent the interests of an organization (such as public health).

VII. Roles and Represented Interests

Within each category are various roles and represented interests. Stakeholders may hold more than one role.

<table>
<thead>
<tr>
<th>Stakeholder Entity</th>
<th>Roles</th>
<th>Represented Interests</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stakeholder Entity</td>
<td>Roles</td>
<td>Represented Interests</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>-------------------------------------------</td>
<td>---------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Repository/Registry Administration/Governance</td>
<td>Executive Committee (Governance)</td>
<td>Oversight and Governance Defines the repository/registry operational procedures and policy framework. Interests: Ensuring the long-term success and performance of the repository/registry; promoting the reuse and sharing of data within and across functional areas, resolving semantic issues associated with conflicting artifacts resources, extensions, profiles</td>
</tr>
<tr>
<td>Repository/Registry Administrator</td>
<td>Main contact for the Repository/Registry</td>
<td>Interests: Expert in FHIR artifacts and repository/registry processes. Enforces policies, procedures, content documentation and validation requirements. Ensures accurate representation of relationships between artifacts</td>
</tr>
<tr>
<td>Registry Metadata Annotator/Approver</td>
<td>Assists Administrator with FHIR artifact registration and maintenance of status information. Adds / verifies metadata associated with a FHIR artifact to make it more useful to others, e.g. keywords</td>
<td></td>
</tr>
<tr>
<td>FHIR artifact Contributor Organization / Governance Group</td>
<td>FHIR artifact Submitter</td>
<td>The original submitter of a FHIR artifact to the repository. Interests: Creates and/or submits the FHIR artifact and assumes responsibility for its support</td>
</tr>
<tr>
<td>FHIR artifact Validator</td>
<td>Validates FHIR artifact. use approved validation tools and submits proof of validation (including any errors)</td>
<td></td>
</tr>
<tr>
<td>FHIR artifact Metadata Submitter</td>
<td>Submits metadata associated with the FHIR artifact: creates and maintains FHIR artifact metadata for the lifecycle of the artifact</td>
<td></td>
</tr>
<tr>
<td>Stakeholder Entity</td>
<td>Roles</td>
<td>Represented Interests</td>
</tr>
<tr>
<td>------------------------------------------</td>
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<td>---------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>FHIR artifact Adopter Organization</td>
<td>FHIR artifact Adopter</td>
<td><strong>Asserts that a specific FHIR artifact is in use within the adopter's organization.</strong> Records usage details in the registry. <strong>Interests:</strong> Sharing implementation experience and contributing to wider knowledge about FHIR artifact's purpose and utilization.</td>
</tr>
<tr>
<td>FHIR artifact Repository/Registry</td>
<td>FHIR artifact Repository/Registry</td>
<td></td>
</tr>
</tbody>
</table>
Notes for comment:

1. The roles and interests of stakeholders are maintained through a simple FHIR artifacts repository/registry user registration process.

2. All stakeholders, except for FHIR artifacts Information Consumers, will nominate representative user(s) who can maintain repository/registry content on their behalf.

3. The repository/registry can be queried by non-registered users.

4. Who can make changes --

5. Keep track of pathway --

6. Track adoption -- author – group - attribution

7. Author / submitter Av0 - Av1 – Av2

8. (adopted/adapted by OO at Av1 now called OOA V0 (with attribution to Av1)

9. Backward compatible – open – can add if not constrained -- if constrained, need new template ID

10. Artifact may need to be tracked to a “source” repository
## VIII. Stakeholder Interaction Through Metadata lifecycle

The table below describes how stakeholders interact with the repository/registry and each other through the metadata lifecycle.

<table>
<thead>
<tr>
<th>Stakeholder Entity:</th>
<th>Stakeholder Entity:</th>
<th>Interactions</th>
<th>Notes:</th>
</tr>
</thead>
<tbody>
<tr>
<td>To FHIR artifacts Repository/Registry:</td>
<td>From FHIR artifact Creator</td>
<td>FHIR artifacts life-cycle status changes and accompanying FHIR artifacts and metadata. Also provides links between individual FHIR artifacts, including replacement links</td>
<td>Each FHIR artifacts life-cycle status change causes appropriate changes in the FHIR artifact’s registry metadata. The changes before the active state are optionally present in the repository/registry. Note also that once a FHIR artifact becomes active it may optionally go through multiple versions. Each version increments the version number, but doesn't change the universally unique FHIR artifact identifier.</td>
</tr>
<tr>
<td>From FHIR artifact Adopter Organization</td>
<td>FHIR artifact Adoption (in process, completed)</td>
<td></td>
<td>A FHIR artifact may have one to many adoptions by one-to many stakeholder organizations. Note that an Adopter Organization may also be a Custodian Organization, in which case it may create adaptations of a given FHIR artifact from another Custodian Organization’s FHIR artifacts. These adaptations (and the links to the adopted FHIR artifact being adapted) will also need to be submitted to the repository and or registry via the Adopter Organization’s custodian role.</td>
</tr>
<tr>
<td>From non-HL7 FHIR artifact repository</td>
<td>A non-HL7 FHIR artifact repository may submit various queries and report requests for FHIR artifacts metadata and FHIR artifacts linked data.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stakeholder Entity: From FHIR Artifacts Registry</td>
<td>Stakeholder Entity: To FHIR artifacts Custodian Organization</td>
<td>Interactions</td>
<td>Notes:</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Transmits requests from FHIR artifact Information Consumers. Makes available FHIR artifact Adaptations and Adoptions metadata, as well as linking data to Custodian Organization.</td>
<td></td>
</tr>
<tr>
<td>To FHIR artifact Adopter Organization</td>
<td></td>
<td>Acknowledges receipt of Adopter Organization metadata.</td>
<td></td>
</tr>
<tr>
<td>To FHIR artifact Information Consumer</td>
<td></td>
<td>Provides metadata on FHIR artifacts, and responds to user queries. Also may transmit to consumers the FHIR Artifact Custodian Organizations responses to specific user queries.</td>
<td></td>
</tr>
</tbody>
</table>
IX. Systems

This section describes the information systems that may communicate or integrate with a FHIR artifacts repository/registry or vice versa.

FHIR artifacts Authoring System
An authoring system is an information system that is used to create FHIR artifacts and the metadata needed to register them.

FHIR artifacts Client System
A client system is a user interface that supports a user’s access to a FHIR artifacts repository.

FHIR artifacts Repository
An information system which stores the FHIR artifacts created by the FHIR artifacts information supplier and which manages their status, life cycle, identification. It may be a separate system or a component of a FHIR artifacts registry. The repository stores the actual FHIR artifacts that are referenced by a FHIR artifacts registry. Recall that a FHIR artifacts registry may register FHIR artifacts from multiple FHIR artifacts repositories. Note that a FHIR artifacts repository must be able to support various state transitions in the life-cycle of a FHIR artifact, including versioning and replacement of one FHIR artifact by another.

FHIR artifacts Registry
The FHIR artifacts registry is a key component of this requirements document. It is an information system maintains metadata about registered FHIR artifacts, such that a pointer to the FHIR artifact’s location and all its metadata can be retrieved as a result of a query. It may be a separate system or a component of a FHIR artifacts repository. A FHIR artifacts registry may contain such information from multiple FHIR artifacts repositories, along with various additional semantic, structural, “contains/contained in” links between registered FHIR artifacts. It may also contain pointers to “transformations” between semantically equivalent FHIR artifacts in the same or different FHIR artifact formalisms.

X. Non-HL7 Repository Artifacts (HL7 FHIR Registry)

Summary

The HL7 FHIR Repository shall also act as a Registry (HL7 FHIR Registry) for artifacts stored in other repositories. This is necessary to provide the broadest resource of FHIR artifacts to HL7 members and the FHIR community. This should be done with maximal reuse of existing/planned FHIR Repository functionality and minimal governance requirements. The focus of the requirements in this section are on the governance issues and the metadata associated with these “external” artifacts.

Governance Implications

Providing a registry for foreign FHIR artifacts poses some unique governance challenges. To minimize the potential for conflict with organizations external to HL7 and limit the investment of time, the following governance standards shall be observed:

1. An organization using the Registry capability of the HL7 FHIR Repository must be a paid HL7 member and maintain its membership for the organization’s artifacts to be included in the HL7 FHIR Registry.
   Note: this may require a new type of membership if the rights are restricted to use (submission and maintenance) of artifacts to the HL7 FHIR Registry only.

2. Each HL7 FHIR Registry contributing organization shall identify a contact person who is responsible for all artifacts contributed and the attestations for each of the artifacts.

3. All external artifacts shall be openly accessible and available to the public without need for external repository accounts or logon.

4. External artifacts shall be restricted to an HL7 Maturity Level of Proposed
   Note: if an external organization wishes to move to a higher HL7 Maturity Level, they must submit the artifacts to the HL7 FHIR Repository and follow the HL7 Maturity Process

5. Access to all HL7 FHIR Registry artifacts shall require an HL7 account (which shall be available at no charge).

6. Conformance to HL7 FHIR Repository standards shall be via attestation by the contributing organization and violation of the standards shall be grounds for removal of the artifacts from the HL7 FHIR Registry and revocation of the special HL7 membership.
Note: need to define appropriate process for notification of violation(s) and provide for a remediation capability to avoid removal of artifacts and cancellation of special membership.
Note: if we have automated validation tools that produce a defined output, include output as part of artifact evaluation.

Operational Requirements

Specific operational requirements to support the Registry functionality are focused on access to and validation of the FHIR artifacts stored in the external registry’s functions:

2. Validation (using standard validation tools or via attestation) of FHIR artifacts on initial “incorporation” in the HL7 FHIR Registry.
3. Automated, recurring, verification of access to externally hosted artifacts to verify availability.
4. Support for both the contributing organization and users
   - Access to help desk
   - Access to standards and tools
   - Ability to report issues with registry or contributed artifacts
   - Ability to manage contributed artifact metadata
   - Access to registry for all contributed artifacts and

Functional Requirements

The HL7 FHIR Registry shall provide the following functional capability for FHIR artifacts held in external repositories (e.g. non-HL7 FHIR Repositories). This shall include both portal and Restful transaction oriented (FHIR based) ability to perform the following functions where appropriate:

1. Support registration of an External Repository in the HL7 FHIR Registry
   - Organization
   - Contact Information (including email)
   - URL for repository
   - Status (inactive, active, suspended)
   - Other information as required to enable/enforce HL7 FHIR Registry requirements
2. Support contribution of FHIR Artifact Metadata for FHIR artifacts in External Repositories
3. Automatic validation that artifacts are publicly accessible without need for accounts or logon to the External Repository
4. Provide for external Attestations regarding all validation, quality and completeness metrics that require administrative support by HL7 corporate staff or HL7 workgroups.
5. Support links to artifacts in external repositories
6. Verify that artifacts in external repositories are publicly available
7. Provide a process to validate all links for a contributing organization or for all contributing organizations
8. Provide the ability to “remove” artifacts that are no longer available.

9. Integrate with HL7 membership process to only allow individual(s) from the contributing organization to update that organization’s metadata and attestations.

10. Additional metadata for external artifact shall include all of the HL7 FHIR Repository artifact metadata, with the following qualifications or extensions:
   - Contributing Organization (in addition to “ownership”)
   - External Repository Location (URL)
   - Contact information
   - Status for artifact – attested but not HL7 validated
   - Contributing organization maturation metrics

11. Support all access based tracking and maturation metrics for HL7 FHIR Registry artifacts.

12. Ability to automate move to HL7 Repository controlled by contributor

Other Functional Requirements

The HL7 FHIR Registry requires changes to current practices and technical support. These changes are summarized as follows:

- **Policy**
  - HL7 FHIR Registry Organization Memberships (limited membership?)
  - Open source licensing for contributed material

- **Operations**
  - Review (spot check HL7 FHIR Registry Organization Attestations)
  - Support/train HL7 FHIR Registry Organization Representative
  - Respond to and follow-up on communications (email, …) regarding HL7 FHIR Registry Organization issues

- **Technology**
  - Support membership for HL7 FHIR Registry Organization – e.g. rights to maintain artifacts

XI. FHIR Artifacts, Categorization and Views

This section describes the various FHIR artifacts that the repository/registry manages.

Basic Structures

**Resources** – the basic building block of FHIR – and entity that:

- has a known identity (a URL) by which it can be addressed
- identifies itself as one of the types of resource defined in this specification
- contains a set of structured data items as described by the definition of the resource type
- has an identified version that changes if the contents of the resource changes
- has a common way to define and represent them, building them from data types that define common reusable patterns of elements
• has a common set of metadata
• has a human readable part

Extensions

• Every element in a resource can have extension child elements to represent additional information that is not part of the basic definition of the resource. The use of extensions is what allows the FHIR specification to retain a core simplicity for everyone.

• There is strict governance applied to the definition and use of extensions. Although any implementer can define and use extensions, there is a set of requirements that must be met as part of their use and definition.

Structure Definition (Profiles)

• provide additional rules that serve to constrain the optionality, cardinality, terminology bindings, data types and extensions defined in the resources used by the implementation

Core Definitions

Data Types

The FHIR specification defines a set of data types that are used for the resource elements. There are four categories of data types:

• Simple / primitive types, which are single elements with a primitive value (below)
• General purpose complex types, which are re-usable clusters of elements (below)
• Complex data types for metadata
• Special purpose data types: Reference, Narrative, Extension, Meta, and Dosage

Code System and Value Set

• code system - defines a set of codes with meanings (also known as enumeration, terminology, classification, and/or ontology)
• value set - selects a set of codes from those defined by one or more code systems
• Code systems define which codes (symbols and/or expressions) exist, and how they are understood. Value Sets select a set of codes from one or more code systems to specify which codes can be used in a specific context.
• The CodeSystem resource is used to declare the existence of a code system, and its key properties:
  o Identifying URL and version
  o Description, Copyright, publication date, and other metadata
  o Some key properties of the code system itself - whether it's case sensitive, version safe, and whether it defines a compositional grammar
  o What filters can be used in value sets that use the code system in a ValueSet.compose element
  o What properties the concepts defined by the code system

Categories

The registry shall support categorization of the FHIR artifacts based on multiple independent hierarchies. The current frameworks support the following categories:
Framework 1

Basic Framework
  o Foundation

Supporting Implementation
  o Implementation Support
  o Security and Privacy
  o Conformance
  o Terminology
  o Linked Data

Real world health care concepts
  o Administration

Record-keeping and Data Exchange
  o Clinical
  o Diagnostics
  o Medications
  o Workflow
  o Financial

Clinical Reasoning

Framework 2

Foundation
  o Conformance
  o Terminology
  o Security
  o Documents
  o Other

Basic
  o Individuals
  o Entities
  o Workflow
  o Management

Clinical
  o Summary
  o Diagnostics
  o Medications
  o Care-Provision
  o Request & Response

Financial
  o Support
  o Billing
  o Payment
  o General

Specialized
  o Public Health & Research
  o Definitional Artifacts
  o Clinical Decision Support
  o Quality Reporting
  o Testing

Framework 3 – by HL7 Working Group
  • Community Based Collaborative Care
• Clinical Decision Support
• Clinical Genomics
• Clinical Quality Information
• Health Care Devices
• FHIR Infrastructure
• Financial Management
• Imaging Integration
• Infrastructure And Messaging
• Orders and Observations
• Patient Administration
• Patient Care
• Public Health and Emergency Response
• Pharmacy
• Regulated Clinical Research Information Management
• Structured Documents
• Security
• Vocabulary

Views of Resources (all include name, link, and maturity level)

The registry shall support views of all FHIR artifacts based on each of the categorization frameworks and basic naming / layout information. The current views that must be supported are:

• Categorized
• Alphabetical
• R2 Layout
• By Maturity (highest to lowest – level 5 to level 1) and by other maturity metrics
• By Committee
The FHIR specification development and submission process applies to FHIR artifacts the base standard (e.g. FHIR STU 4.0, any balloted FHIR implementation guides, and non-balloted FHIR artifacts submitted to the FHIR repository. While it does not apply specifically to FHIR artifacts in external repositories with information in the FHIR registry, it does provide the requirement for rigorous testing / validation prior to submit
registry information for externally held FHIR artifacts at maturity levels above level zero (0). The goal is to create a static, but renewable view of all FHIR artifacts, if any, associated with the development process. In addition, it provides for a build and test, validation, reconciliation and submission tool set to allow all developers to effectively create, modify, extend, constrain, test, validation and ultimately, submit FHIR artifacts.

The system should provide for the following capability:

1) Development artifact selection tool.
   a) Simple user and API interface to select FHIR artifacts for the development environment
   b) Allow selection at any level of detail and include all relevant items (e.g. as course as an implementation guide or as fine grained as a resource or data type
   c) Tooling shall automatically create a development environment for the selected artifacts
   d) If the user is creating an implementation guide, all of the necessary artifacts and documentation templates should be created.

2) Relevant FHIR artifacts
   a) The system shall create a repository / registry of the FHIR artifacts needed for the development project that isolated from all other users (except as authorized by the individual that creates the development environment.
   b) This repository / registry may be contained in the existing repository/registry as a separate named space or created as a new instance

3) Development usability tools / interface
   a) The system should provide the ability to export to a third-party development environments, or generate a development environment using tooling provided as part of the registry/repository.
   b) Regardless of the tooling, the ability to export to and consume information from Excel based worksheets and Word based documentation shall be supported

4) Build and Test;
   a) Provide the ability to take the newly developed/updated artifacts and automatically build a test environment

5) Validation and Reconciliation
   a) As part of the development / submission process, the tooling should include the ability to validate conformance of the new /updated FHIR artifacts with established requirements – this includes conformance for/to:
      1. relevant FHIR specifications for resources, elements and backbone elements
      2. all datatypes
3. extensions
4. vocabularies and value sets
5. conformance statement standards
6. documentation requirements

6) Artifact submission process tools
   a) The tooling shall automate the submission process for new and updated FHIR artifacts and assist in the generation of appropriate metadata for insertion in the registry

XIII. Balloting and Publication Process

The FHIR publication process applies to both publication of the base standard (e.g. FHIR STU 3.0 and any balloted FHIR implementation guides). The goal is to create a static view of all FHIR artifacts associated with the ballot for review and comment. The process requires that the specific artifacts stay static (other than changes applied during the comment reconciliation and disposition process) during the entire ballot process. This needs to be done without impacting the ability to continue to evolve the base standard create new implementation guides.

Prior to ballot, the system will provide for:

1) Selection and creation of a static version of all artifact that will be balloted together (“ballot contents”)
2) Publishing the ballot contents so HL7 member can review and provide ballot comments during the comment portion of the process.
3) Each item in the ballot contents shall have a unique designation to permit specific comments that clearly identify the particular FHIR artifact and the individual “element” that is the subject of the comment.

As part of the comment and comment resolution process

7) Each comment shall be attributed to the comment author and shall be associated, here possible with unique target of the comment.
8) The system shall automatically allow for aggregation of comments by:
   b) Author
   c) Artifact
   d) Type of comment
   e) Categories provided for selection as part of the comment process
f) Status (provisional, submitted, in process, withdrawn, disposed, applied, …)

9) The system shall support recording dispositions and pointing directly to their application in the specific FHIR artifacts where possible

10) The authoring system shall be used to apply the updates to the affected FHIR artifacts. (This includes the ability to validate and test as frequently as required)

11) The system shall provide the ability for the comment author (or any other authorized user else) to review the disposition of their / specific comments and trance the result directly to the modified artifact (including documentation).

12) The comment author shall have the ability to withdraw their negative comment at any time in the ballot process.

13) Final statistics shall be created, kept and made available.

14) The ability to review any FHIR artifact and track comments, dispositions and applies changes shall be supported

15) After all changes are applies to the balloted version, reconciliation, validation and testing performed, the systems shall create a publication version of all of the related artifacts for approval by the TSC and publication by HL7

16) Upon final approval, the metadata for all affected artifacts shall be updated with a reference to the specific ballot number and type (e.g. STUn / Normative )

XIV. Artifact Maturity Process

Concepts:

1) Each artifact has its own maturity level based on a defined process
   a. Maturity metrics
      i. FHIR maturity process
      ii. HL7 / ANSI process for all subsidiary standards
      iii. Regulatory Process
      iv. Use based
      v. User feedback
      vi. Frequency of changes

2) Promotion of artifacts in Repository levels/requirements are based
   a. Specified requirement for the level (independent of the “maturity of the artifact”)  
   b. Based on highest level of the associates set of artifacts (all must meet any objective conformance criteria – e.g. pass conformance testing)

3) Conclusion
   a. Maturity process for artifacts and artifact level assignment are orthogonal
   b. Level assignment may use maturity metrics as part of its formal process, but is allowed to have any defined exceptions

4) Adoption into regulation fixes all components of the adopted IG at level 4 or 5 but maturity metrics of involved artifacts continues to evolve based on metric criteria.
Questions:

1) Dependent artifacts (e.g. extensions) have maturity level based on?
   a. The resource (Yes – initial assumption)
   b. Process for extension is independent of the resource

2) What effect do elements of a profile have maturity based on …?
   a. Lowest level of any element
   b. Highest level of any element
   c. Process starts over with the profile

3) What happens when a change is made as part “normal” evolution of an artifact?
   a. Add new extension
   b. Change constraints in a profile
   c. Add new element to a resource
   d. Add new profile to an IG
   e. Update any element in an IG

4) Role of code systems and value sets in maturity process

<table>
<thead>
<tr>
<th>Artifact Types</th>
<th>Maturity Indicators / Metrics</th>
</tr>
</thead>
<tbody>
<tr>
<td>FHIR Artifact</td>
<td></td>
</tr>
<tr>
<td>Resources</td>
<td>WG support and incorporation in implementation guides</td>
</tr>
<tr>
<td>Extensions</td>
<td>Use in Connectathons and ongoing need for change</td>
</tr>
<tr>
<td>Data Types</td>
<td>Utilization of artifacts (play, pilot, production)</td>
</tr>
<tr>
<td>Terminology/Value Set</td>
<td>Rating of artifact maturity by users (e.g. Amazon, ebay approach)</td>
</tr>
</tbody>
</table>

Note: Each of the Maturity Indicators / Metrics can apply to each Artifact Type
Comments

1) Recognize non-HL7 connectathons as metrics
2) Open or Closed regarding templates as guide to approach?
3) Support current C-CDA approach to “open” and conformance testing for the published portion of any “extended” template
4) Profiles have their only maturity level
5) IGs have their own maturity levels
6) Can you change the

Maturity Levels (HL7 definition)

From HL7 All resources in this specification are assigned a "Maturity Level", known as FMM (after the well-known CMMI grades). The FMM level can be used by implementers to judge how advanced - and therefore stable - a resource is. The following FMM levels are defined:

1) the resource or profile (artifact) has been published on the current build
2) FMM0 + the artifact produces no warnings during the build process and the responsible WG has indicated that they consider the artifact substantially complete and ready for implementation

1. FMM1 + the artifact has been tested and successfully exchanged between at least three independently developed systems at a connectathon whose results have been reported to the FHIR Management Group
2. FMM2 + the artifact has been verified by the work group as meeting the DSTU Quality Guidelines and has been subject to a round of formal balloting with at least 10 implementer comments drawn from at least 3 organizations resulting in at least one substantive change
3. FMM3 + the artifact has been tested across its scope (see below), published in a formal publication (e.g. DSTU), and implemented in multiple prototype projects. As well, the responsible work group agrees the resource is sufficiently stable to require implementer consensus for subsequent non-backward compatible changes.
4. FMM4 + the artifact has been published in two formal publication release cycles at FMM1+ (i.e. DSTU level) and has been implemented in at least 5 independent production systems in

HL7 Formal FHIR Artifact “maturity” Level (0-5)
FHIR Maturity Model

This page describes the 5 level FHIR maturity model for resources. It's based on the CMM (Capability Maturity Model) framework, and the intention is to give implementers a sense of how mature a resource is based on the level and types of review it has been subject to. These criteria may evolve over time.

Any of the criteria can be waived provided the sponsoring WG can convince the FMG that that criteria should not apply in the case of a specific artifact.

Tested across scope means:

- The FMG has signed off on the list of "example contexts" defined for the artifact
- For each example context, the artifact has either been: reviewed and approved by a domain expert for that scope area, mapped to an existing implemented scope-area-specific standard or tested in an implementation

FMM1 and higher will be published as STU level rather than draft. FMM 5 is a pre-requisite (but not sufficient) to be published as Normative. i.e. Normative is a step beyond

In some cases, a resource may have components or dependencies that are a lower level than the resource overall. For example, a resource may have been well tested, with the exception of one or two data elements which are "new" or that have limited production use due to the distribution of early adopters. In these cases, a "maturity note" will be provided that highlights areas of the resource that are considered "less mature" than the resource as a whole.

Other Maturity Models

Capability Maturity Model was originally developed as a tool for objectively assessing the ability of government contractors' processes to implement a contracted software project. The model is based on the process maturity framework first described in the 1989 book Managing the Software Process by Watts.
Humphrey. It was later published in a report in 1993 and as a book by the same authors in 1995.

Structure

The model involves five aspects:

- **Maturity Levels**: a 5-level process maturity continuum - where the uppermost (5th) level is a notional ideal state where processes would be systematically managed by a combination of process optimization and continuous process improvement.
- **Key Process Areas**: a Key Process Area identifies a cluster of related activities that, when performed together, achieve a set of goals considered important.
- **Goals**: the goals of a key process area summarize the states that must exist for that key process area to have been implemented in an effective and lasting way. The extent to which the goals have been accomplished is an indicator of how much capability the organization has established at that maturity level. The goals signify the scope, boundaries, and intent of each key process area.
- **Common Features**: common features include practices that implement and institutionalize a key process area. There are five types of common features: commitment to perform, ability to perform, activities performed, measurement and analysis, and verifying implementation.
- **Key Practices**: The key practices describe the elements of infrastructure and practice that contribute most effectively to the implementation and institutionalization of the area.

Levels

There are five levels defined along the continuum of the model and, according to the SEI: "Predictability, effectiveness, and control of an organization's software processes are believed to improve as the organization moves up these five levels. While not rigorous, the empirical evidence to date supports this belief".

1. **Initial** (chaotic, ad hoc, individual heroics) - the starting point for use of a new or undocumented repeat process.
2. **Repeatable** - the process is at least documented sufficiently such that repeating the same steps may be attempted.
3. **Defined** - the process is defined/confirmed as a standard business process.
4. **Managed** - the process is quantitatively managed in accordance with agreed-upon metrics.
5. **Optimizing** - process management includes deliberate process optimization/improvement.

Within each of these maturity levels are Key Process Areas which characterize that level, and for each such area there are five factors: goals, commitment, ability, measurement, and verification. These are not necessarily unique to CMM, representing — as they do — the stages that organizations must go through on the way to becoming mature.

The model provides a theoretical continuum along which process maturity can be developed incrementally from one level to the next. Skipping levels is not
allowed/feasible.

Level 1 - Initial (Chaotic)
It is characteristic of processes at this level that they are (typically) undocumented and in a state of dynamic change, tending to be driven in an ad hoc, uncontrolled and reactive manner by users or events. This provides a chaotic or unstable environment for the processes.

Level 2 - Repeatable
It is characteristic of processes at this level that some processes are repeatable, possibly with consistent results. Process discipline is unlikely to be rigorous, but where it exists it may help to ensure that existing processes are maintained during times of stress.

Level 3 - Defined
It is characteristic of processes at this level that there are sets of defined and documented standard processes established and subject to some degree of improvement over time. These standard processes are in place (i.e. they are the AS-IS processes) and used to establish consistency of process performance across the organization.

Level 4 - Managed
It is characteristic of processes at this level that, using process metrics, management can effectively control the AS-IS process (e.g. for software development). In particular, management can identify ways to adjust and adapt the process to particular projects without measurable losses of quality or deviations from specifications. Process Capability is established from this level.

Level 5 - Optimizing
It is a characteristic of processes at this level that the focus is on continually improving process performance through both incremental and innovative technological changes/improvements.

At maturity level 5, processes are concerned with addressing statistical common causes of process variation and changing the process (for example, to shift the mean of the process performance) to improve process performance. This would be done at the same time as maintaining the likelihood of achieving the established quantitative process-improvement objectives. There are only a few companies in the world that have attained this level 51.

Critique
The model was originally intended to evaluate the ability of government contractors to perform a software project. It has been used for and may be suited to that purpose, but critics pointed out that process maturity according to the CMM was not necessarily mandatory for successful software development.

Software process framework
The software process framework documented is intended to guide those wishing to
assess an organization's or project's consistency with the Key Process Areas. For each maturity level there are five checklist types:

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy</td>
<td>Describes the policy contents and KPA goals recommended by the Key Process Areas.</td>
</tr>
<tr>
<td>Standard</td>
<td>Describes the recommended content of select work products described in the Key Process Areas.</td>
</tr>
<tr>
<td></td>
<td>Describes the process information content recommended by the Key Process Areas. These are refined into checklists for:</td>
</tr>
<tr>
<td>Process</td>
<td>• Roles, entry criteria, inputs, activities, outputs, exit criteria, reviews and audits, work products managed and controlled, measurements, documented procedures, training, and tools</td>
</tr>
<tr>
<td>Procedure</td>
<td>Describes the recommended content of documented procedures described in the Key Process Areas.</td>
</tr>
<tr>
<td></td>
<td>Provides an overview of an entire maturity level. These are further refined into checklists for:</td>
</tr>
<tr>
<td>Level overview</td>
<td>• Key Process Areas purposes, goals, policies, and standards; process descriptions; procedures; training; tools; reviews and audits; work products; measurements</td>
</tr>
</tbody>
</table>
XV. **FHIR Artifact Metadata**

FHIR artifact metadata information is contributed by custodian and adopter organizations through a dynamic and iterative set of business workflow processes. It may also be added via annotations created by registry/repository-designated annotators.

Recall (section xxx), that the basic metadata (the FHIR artifact’s authorship and “authoring system status”) is created by the FHIR artifact authoring system and instantiated in the registry/repository when FHIR artifact metadata is initially submitted by the custodian organization to the registry/repository. Additional metadata can then be added by the adopting organization(s), the custodian organization, and the registry/repository organization’s annotators.

**Annotation** An annotation is a collection of metadata for a FHIR artifact that makes it more accessible to others but does not alter the meaning of the FHIR artifact itself. An example would be keywords associated with a FHIR artifact. Annotations are distinct from the FHIR artifact registration metadata, FHIR artifact adoption data, and FHIR artifact group data. Types of annotations may include semantic links and tags, structural links, transformational links, (see below).

**Adoption** An adoption is an assertion by an organization that a specific published FHIR artifact is in use within the organization and a notice that the organization would have an interest in any changes to the FHIR artifact or to the FHIR artifact’s metadata.

**Publication** A publication is an acknowledgement by a custodian organization that a FHIR artifact or a group of FHIR artifacts is ready for use. The set of publication status changes associated with a FHIR artifact are part of that FHIR artifact’s metadata. The custodian organization may also create an “unpublished” FHIR artifact which may be registered as a FHIR artifact “under development” or in “pre-publication review status.”

**Unique Id** A FHIR artifact is registered when its metadata and status are added to the registry/repository and the registry/repository assigns it a unique identifier. When the registry/repository status is changed to “active”, the FHIR artifact may be used by any FHIR artifact adopter stakeholder. The basic metadata (the FHIR artifact’s authorship and “authoring system status”) is created by the authoring system and instantiated when the FHIR artifact is registered by the custodian organization. As
mentioned above, other additional metadata may be added via adoption and the various types of annotations and grouping mechanisms. Note that ‘publication’ often means that the registry/repository status of a FHIR artifact has been changed to “active”, rather than other changes in the FHIR artifact’s registry/repository status.

**Group**

A group is a collection of FHIR artifacts. It provides a mechanism to manage the registrations of all the members of the group. The action specified for an individual FHIR artifact’s registration is to be repeated for all members of a specific group.

A group is merely a convenience functionality for registration actions to be applied to all the members of the group. It does not function to categorize FHIR artifacts but to manage them as an identified set.

Groups are defined by FHIR artifacts adopter organizations, or FHIR artifacts custodian organizations through their FHIR artifact adopter roles.

After the initial creation of a group, individual FHIR artifacts within the group may be managed as individuals as well as through their group membership.

**Right**

A right is the authority to perform a specified action or group of actions on a FHIR artifact registration or group of FHIR artifact registrations within the FHIR artifacts registry/repository system.

**Group metadata**

FHIR artifacts can belong to one or more adoption groups, and as such, this must be supported by appropriate FHIR artifact metadata.

**User Credential**

An authorized individual is represented by a User Credential in the FHIR artifacts registry/repository system. A user’s credential denotes which actions a FHIR artifacts registry/repository user may perform.

**Structural Link**

A link between two FHIR artifacts based on their respective information models.

A type of structural link is the link that defines a specific FHIR artifact as part of a specific compositional FHIR artifact (or vice versa). I.e. a FHIR artifact may contain other FHIR artifact, or a FHIR artifact may
be contained by another FHIR artifact.

Validation Link

A validation link is a link to an annotation specifying the algorithm that would validate that an instance produced by applying the FHIR artifact is accurately populated according to the constraints defined by the FHIR artifact. The validation algorithm may only be useful to a particular technical platform and therefore, more than one validation algorithm may be linked to a given FHIR artifact.

Semantic links and tags

A registered FHIR artifact may be assigned a semantic tag which classifies it according to a specific ontology (e.g. MESH tags, SNOMED codes, LOINC codes). Depending on the standard vocabulary, compositional coded expressions may also be used, and semantic links may also be created that describe the semantic relationships between FHIR artifacts according to the supported ontology.

Registration status and links

Each registration of a FHIR artifact shall have a ‘status code’

FHIR artifact Registry/repository item status values shall include provisional, final, nullified, obsolete, plus there shall be links between multiple versions of FHIR artifacts, as well as between a replacing and replaced FHIR artifact. These item status values must be accepted by the FHIR artifacts registry/repository, and no FHIR artifact that does not have a ‘final’ item status can be published.

States

**Nascent**: Under development. Metadata and FHIR artifact may be incomplete. Entered primarily to encourage other users to be aware of ongoing process.

**Active**: Has been published by the custodian organization and deemed fit for use. May have associated adoption and annotation metadata.

**Inactive**: Never recommended for use. For example, rejected, withdrawn or found another FHIR artifact fit for use of the one under development. Will not have associated adoption metadata.

**Under Update** (adoption metadata): adopter adds adoption metadata and/or
grouping metadata: these are the only actions an adopter organization can perform. The FHIR artifact(s) in the “under update (adoption metadata)” status are unavailable for any other status or metadata changes until the “under update (adoption metadata)” action has been completed.

**Pre-publication review:** the FHIR artifact is complete, pending appropriate review. Entered primarily to encourage other users to be aware of and/or participate in the review process. The custodian organization has not given it an “Active” status (i.e. it has not been published); and it may still be rejected (transitioned to an inactive status). E.g. the FHIR artifact may be under ballot by an SDO.

**In Review:** a post-publication state; may result in a new version or a retirement or no change at all. A new version is one that adds clarity but not new intent; the version number is incremented by one, but the identifier is unchanged. A retirement is a FHIR artifact that is no longer fit for purpose, and which may be replaced by a different a FHIR artifact with a different identifier, which is linked to the retired FHIR artifact.

**Retired:** No longer fit for use. Information available for historical reference.

**FHIR artifact Custodian Information**

1. **Create Item (registry/repository state=“Nascent, Under Development”)**
   Create a metadata record for a FHIR artifact that is under development. May solicit advice from all stakeholders on metadata (registry/repository state = “open for comments”).

2. **Create Item (registry/repository state=“Active”)**
   Create a metadata record in final form and submit as published.

3. **Review Nascent (Under Development) Item (registry/repository state=“Pre-Publication Review”)**
   Users may view submission either on its own or as part of a group of submissions (registry/repository state=“Pre-publication review”)

4. **Reject Item (registry/repository state = “Inactive”)**
   Used to remove a submission or a group of submissions (registry/repository state=“inactive”)

5. **Review Item (registry/repository state = “Under Review”)**
   Used to update published metadata. May result in a new version, or may result in a retired FHIR artifact.

6. **Publish Under Development Item (registry/repository state = “Active”)**
   Used to make an item or all items in a group available to other users of the registry/repository. Prior to publication, the metadata may only be accessible to
certain authorized users of the FHIR artifact custodian organization..

7. Retire Item (registry/repository state = "Retired")

Used to mark an item or all published items in a group as being retired, an indication that the FHIR artifact should no longer be used. The metadata is still “published” for research and for historical purposes (and applies to previous instantiations of the FHIR artifact) and contains valid information, but the FHIR artifact is no longer recommended for use. Can only be done on the basis of information received from the custodian organization. An example is the receipt at the registry/repository of a new version of a FHIR artifact or group of FHIR artifacts from a custodian organization.

8. Link Item

Used to record an association between two FHIR artifacts in the registry/repository. The link can be structural, replacement, semantic, validation etc. Can only be done by the custodian of either FHIR artifact but may also be done on the basis of information received from an adopter organization, or created by a FHIR artifact annotator. E.g. used when a post-publication review results in the retirement of a FHIR artifact, which is then replaced by a new FHIR artifact (with a different FHIR artifact identifier).

FHIR artifact publication information

Additional metadata may be recorded by a FHIR artifact adopter organization once a FHIR artifact has been published to assert that that organization is using a FHIR artifact or has a special interest in it and wishes to be notified of future changes to the FHIR artifact’s metadata.

Adoption metadata is different metadata to the structural and definitional detail supplied by the custodian organization. It is expected that a custodian will record its own adoption metadata. A FHIR artifact can have zero or many adopters and each adoption must have its own unique identifier/identity. Adoption of a FHIR artifact by an organization is the use of a FHIR artifact for one or more specified use cases; if the adopting organization later 'adapts' (creates) a new FHIR artifact, it becomes the custodian of the new FHIR artifact and needs to give feedback to the original organization via the registry/repository: it must adopt a FHIR artifact before it can adapt. The adopter organization becomes the custodian for the adapted FHIR artifact, and must provide the registry/repository with an appropriate type of link between the adopted FHIR artifact and the adapted FHIR artifact.

- Adopt
  
  Marks a FHIR artifact registration or group of FHIR artifact registrations as being under adoption update by a FHIR artifacts Adopter.

- Publish: submits the adoption metadata to the registry/repository.
• Adapt (Structural and definitional, adoptive, relational/link).

An adopter organization may adapt (change) an existing FHIR artifact and become the custodian of the new FHIR artifact (which has a new identifier attribute). It then has responsibility to acknowledge the existing FHIR artifact as the source/basis of the new FHIR artifact via an appropriate link type. The new FHIR artifact may or may not supersede an existing FHIR artifact. Linking recognizes there is an adapted/familial relationship between two FHIR artifacts and that the linked FHIR artifact is not a version of the adopted FHIR artifact.

Versioning Metadata

A distinct sub-type of “revise registration” is the use case defined as follows: the FHIR artifacts registry/repository receives a new version of a given FHIR artifact from a FHIR artifacts information supplier (via a custodian organization) and replaces the prior version, which becomes ‘retired.’ The new version has a 'publish' link to the prior version.

Note that adoptions can also be versioned, and that the state change on the new and previous version of an adopted FHIR artifact is parallel to those used for versioning a registration: the prior version becomes 'updated', the new version becomes “active” and there is a “update adoption metadata” link from the prior to the new version.

1. Create New Version
   Used to create a new version of a registration from an existing registration or group. Each version is maintained as a separate registration with an appropriate link as noted above.

2. Identify Differences Between Versions
   Allows a user to see changes between two different registered FHIR artifacts.

NOTIFICATION Metadata

1. Notify a FHIR artifacts information consumer of changes to a FHIR artifact or a group of FHIR artifacts. Changes may be in registration metadata including registration status changes and/or versioning, annotations, or adoptions. Also, notify user of updates made in the FHIR artifacts registry/repository software and system maintenance, update, and testing cycles.

2. Update Topics of Interest for Notification
   Allows a FHIR artifacts information consumer to indicate which topics are of interest with respect to notifications.
GROUPING

FHIR artifact registrations may be managed in groups related to the active (published) FHIR artifact. The group of FHIR artifact registrations may be used, adopted, versioned, implemented, et cetera, as a set as well as individually. FHIR artifacts groups may be created by a FHIR artifacts custodian stakeholder or a FHIR artifacts adoption stakeholder.

1. Create a Group
   Allow an authorized user to create a group that contains multiple FHIR artifact registrations associated with it. Common metadata for these FHIR artifact registrations may be maintained within the group.

2. Add FHIR artifact registration to a Group
   Marks a specific FHIR artifact registration as being a member of a specific group.

3. Add FHIR artifact registration to a Group
   Removing a FHIR artifact registration from a group, removes the specific FHIR artifact registration from a group.

XVI. Usability Requirements

Note: different classes of users may require different levels of these requirements, as specified by the user’s credentials. E.g. a user may only be allowed to authorize a certain group of FHIR artifacts according to the authorizing organization that the user represents; one organization may be allowed to delegate its authorizing privileges to another organization; et cetera.

User Interface Requirements

1. Users of the FHIR artifacts registry/repository shall be able to access navigation, search, reporting and download functions within a web browser.

2. The user interface should support information access by people with disabilities. These standards vary according to country of use.

Audit

1. All activity that changes the content of the FHIR artifacts registry/repository shall be audited, storing the date, time (at least to the second), and authorized user who changed the information and the identity of the workstation that he was using.

2. Upon review of any information in the FHIR artifacts registry/repository, a user shall be able to identify when the information being shown was last changed. More detailed information may be shown depending upon the policies of the FHIR artifacts registry/repository (e.g., identity or location of the user making the change).
3. FHIR Repository/Registry Administrators shall be able to view the complete audit record of changes made to the content of the FHIR artifacts registry/repository.

4. FHIR Repository/Registry Administrators shall be able to organize and filter the audit information by the date/time of the record, the identity of the user making the change, or location where the change was made, or the type of change made.

Access Control

This section specifies that users other than FHIR artifacts Repository Administrators could manage access rights, but does not require that capability.

1. An authorized user shall be able to grant, revoke, or explicitly deny access rights to change or view (write or read) information in the FHIR artifacts registry/repository to other authorized users.

Versioning

1. The FHIR artifacts registry shall support registration of multiple versions of a FHIR artifact (or group of FHIR artifacts), and also of the adoption of a FHIR artifact (or group of FHIR artifacts).

2. The FHIR artifacts registry should have the ability to identify the differences in the metadata between two versions of a FHIR artifact (or group of FHIR artifacts) or two versions of an adoption (or group of adoptions).

Notification

1. The FHIR artifacts registry/repository shall have a way to notify users of updates to its content.

2. The FHIR artifacts registry/repository should support a mechanism for users to indicate which topics are of interest with respect to updates.

3. Updates should be delivered using well-established industry standards (e.g., e-Mail, List Servers, or subscription feeds).

4. The FHIR artifacts registry/repository should provide a mechanism to group notification updates so that a single user does not get a large number of update notifications at the same time.

5. The FHIR artifacts registry/repository may provide the user with a mechanism to indicate the frequency at which updates will be reported (e.g., daily, weekly, monthly, etcetera).

FHIR artifacts registration and management

The FHIR artifacts registry/repository shall provide a mechanism to allow an authorized user and/or stakeholder to create and revise an artifact’s registration as follows:
1. The FHIR artifacts registry/repository shall provide a mechanism to group a collection of registrations so that they can be managed as a unit for the purpose of managing their lifecycle.

E.g. This allows different groups of FHIR artifacts, approved for different organization’s use cases, to be versioned, adopted, updated replaced asynchronously.

2. The FHIR artifacts registry/repository shall provide mechanisms to allow an artifact’s registration to be classified using one or more external ontologies. This may be used to associate keywords with an artifact, classify it according to a code system such as MESH, identify where the metadata artifact fits into an information model, identify exchange standards utilized and record version specific data structures (e.g., HL7 v3 observations vs. encounters vs. SubstanceAdministration, Eligibility vs. Prior Authorization, et cetera).

3. The FHIR artifacts registry/repository shall provide a mechanism to mark an artifact’s registration state as active, nascent (under development), inactive, in pre-publication review, in review, under update (in process of being adopted), retired.

   - An **active** registration is one that is current and available for use. It may transition to **retired**, **under update** (of adoption metadata), in **review** (post-publication).

   - A **nascent** registration is one that is available for review in a **pre-publication review** state, or for a transition to **inactive**.

   - An inactive registration is one that has been either nascent (**under development**), or in **pre-publication review**, and is no longer available for use.

   - A **pre-publication review** state may transition either to an **active** state (published) or an **inactive** state after appropriate review by registry/repository stakeholders.

   - A **retired** registration identifies a registration that is no longer available for use, but that was previously either **active** or in **review** (post-publication).

   - A FHIR artifact in **post-publication review** may transition to **active** (with a new version number, but the same FHIR artifact identifier), or to **retired** after appropriate review by registry/repository stakeholders.

   - A FHIR artifact in **under adoption** (Adoption Metadata) state has transitioned from an **active** state to a state of being adopted (**adoption metadata** added...
by the adopter stakeholder). It transitions back to an active state after the adoption metadata update is completed.

4. The FHIR artifacts registry/repository should support partitioning of information so that different authorized users can be responsible for the management of different artifacts without interfering with each other.

5. Partitioning of information described above shall not interfere with searching information within the FHIR artifacts registry/repository.

6. The FHIR artifacts registry/repository shall support the metadata specified for the registered artifacts in TN903 (HITSP specified metadata) and the HL7 FHIR artifacts DSTU 7.

7. The FHIR artifacts registry/repository shall provide a mechanism to upload and register artifacts in bulk.

8. The FHIR artifacts registry/repository shall provide a mechanism to update a single registration.

9. The FHIR artifacts registry/repository shall provide a mechanism to annotate registrations with supportive metadata of the types mentioned in the Metadata section of this guide (semantic tags and links, structural links & transformational links), as well as adoption metadata.

Search

Search capabilities described below are assumed to be performed as user specified “queries” upon the FHIR artifacts registry/repository. This is not, however, intended to restrict the user interface for the implementation of these capabilities. Note that unless specified otherwise, search fields are any of the fields in the FHIR artifact metadata: registration, adoption or annotation metadata.

The FHIR artifacts registry/repository shall support search for registrations by the registration metadata specified for these FHIR artifacts in update by reference

1. The FHIR artifacts registry/repository shall support search for registrations for FHIR artifacts by the content of the adoptions received or the contents of the registration for those FHIR artifacts.

2. Search capabilities shall include searches on the content of the various annotation types (semantic tags and links, structural links & transformational links), as well as adoption metadata.

3. Search capabilities shall include search by FHIR artifact registration metadata including: name, identifier, source, purpose, definition, type, version, status, creation, revision, effective or expiration dates, associated metadata (e.g., code
system for a value set or value set for a FHIR artifact registry/repository metadata attribute, related FHIR artifacts for a FHIR artifact, etc.), and classifications within external ontology.

4. Registries should support Exact, Full Word, Contains, Begins-with, Ends-with and Wild cards on the name, purpose and definition fields of the registration, adoption or annotation metadata.

5. Search capabilities on text fields in the registration, adoption or annotation metadata (e.g., name, purpose, definition) should support some degree of approximate matching.

6. Search capabilities on classification fields in any of the 3 types of metadata (registration, adoption or annotation metadata) (e.g., keywords or other ontological associations) should support search based upon inclusion in a hierarchy.

7. Search capabilities on date fields in all metadata should support date ranges.

8. Search capabilities on identifier and version FHIR artifact registration metadata fields shall support exact match, and need not support any more complex capability.

9. Searching shall support at least complex and/or logic and grouping, but need not support full Boolean expressions. It is acceptable to support finding all metadata records meeting all user specified criteria, or meeting at least one of the user specified criteria.

10. Searching using an external ontology should support search by the semantic links supported by the external ontology (e.g. the ontology-based searches supported by IHTSDO.)

11. Users should be able to search within previously returned search results.

12. The FHIR artifacts registry/repository should support both summary and detailed views of the results returned from a search.

13. The FHIR artifacts registry/repository shall be able to query the registrations from a web browser.

**Browse**

The browsing or navigation capabilities described below are expected to allow a user to navigate through information by traversing the registrations using the external ontology that organizes registrations. These may be delivered as links, visual navigation aids, preconfigured queries, et cetera.

1. The FHIR artifacts registry/repository may support preset or custom configured
user specific views of registrations based upon user preferences. These views should incorporate the needs of users in various roles:

- Health Information Technology (HIT) system users interested in the meaning and context of FHIR artifacts used in standards, regulations, policies, reports, and application systems.
- Researchers requiring an understanding of the meaning over time of the FHIR artifacts in the registries for use in longitudinal studies or the development of quality measures.
- Implementers of HL7 FHIR artifacts registry/repository specifications interested in the meaning, context, and representation, including domain values, of artifacts used in HL7 FHIR artifacts registry/repository specification for use in the development of the application systems or commercial-off-the-shelf products.
- Developers of standards and implementation guides or HL7 FHIR artifacts registry/repository specifications reviewing artifacts that may be incorporated into those publications.
- Adopters reviewing artifacts and related registrations for adoption for regulation or other uses.
- Educators and students engaged in the study of health informatics to understand the use of the registered artifacts in information systems and research.

2. The FHIR artifacts registry/repository shall support browse or preconfigured queries that enable users to locate registrations by the attributes in any of the three types of metadata: registration, adoption and annotations.

3. The FHIR artifacts registry/repository should support navigation of registrations by classification schemes or ontologies associated with any of the coded attributes in any of the three types of metadata: registration, adoption and annotations.

4. The FHIR artifacts registry/repository should support both summary and detailed views of the results returned from navigation.

5. The FHIR artifacts registry/repository shall be able to navigate the registrations in a web browser.

XVII. Reporting capability
1. The FHIR repository/registry shall provide the ability to create reports on demand that include the following criteria:
   - Current status and history of any specific artifact or related group of artifacts
   - List of artifacts by any of the metadata information including (type, status, owner, maturity level, dates). List should include query specified metadata.
   - Usage history for any artifact or group of artifacts
2. The FHIR artifacts repository shall be able to produce reports of registered artifacts associated with a particular HL7 publication (i.e. Standard or implementation guide, or conformance specification). The same requirement applies to registered FHIR artifacts created by other SDO’s or SDO-related organizations.
3. Reports shall be viewable in a web browser.
4. Information contained in reports shall be downloadable in a format suitable for import into a database or spreadsheet application (e.g., Comma Separated Values as specified in RFC 4180).
5. Information contained in reports should be downloadable in a standards-based XML format (e.g., as specified in ISO 15000 9).
6. Specifications of the file formats used for downloading reports shall be documented and accessible to users of the FHIR artifacts repository.
7. The FHIR artifacts repository shall be able to indicate all HL7 FHIR artifacts repository publications associated with a particular registration. The same
requirement applies to registered FHIR artifacts created by other SDO’s or SDO-related organizations.

8. The FHIR artifacts repository should be able to report on associations between different artifacts and the types of associations between them. E.g., Value sets used by a FHIR artifact attribute; FHIR artifact attributes using a particular value set; FHIR artifacts requiring or using other FHIR artifacts, et cetera.

9. The FHIR artifacts repository shall provide a mechanism to view the reports in a web browser.

10. Detailed reports shall be available that support download of all metadata for artifacts in the FHIR repository/registry.

11. The FHIR artifacts repository shall provide a mechanism to view the reports in a web browser.

XVIII. Summary capability

Summary Information

<table>
<thead>
<tr>
<th>User configurable view</th>
<th>Stats</th>
<th>Registry</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

This section describes requirements for registry summary/statistical information regarding artifacts and their metadata. The statistics should be immediately available and kept up to date as the various actions occur.

1. All statistics should be available for the following time periods or user selected time periods
   - Daily
   - Weekly
   - Monthly
• Year to Date (YTD)
• Prior Year(s)

2. All statistics should be segmented/segmentable by
   • Contributing source
   • Repository location
   • FHIR artifact type (resources, extension, dataTypes, ...)

3. Statistics should be captured and maintained for:
   • Artifacts (creation, update, use, view, annotation)
   • Feedback
   • General access by unique address
   • Login
   • Connectathon (including use of each artifact)
   • Builds

XIX. Other Requirements

The following principles of governance apply and are based upon various metadata repository standards, as well as on the specific functionality needed to support a FHIR artifacts repository.

Versioning all components for federal regulations
Key requirements for standards name by US regulations:

1) Regulations must cite a specific version of a standard

2) That standard must not undergo any substantive changes (other than errata corrections) during the time the regulation is in effect

FHIR Repository/Registry requirements:

1) To accomplish this, FHIR must provide the ability to maintain the version of any "resources, extensions, structure definitions, bundles, implementation guides, profiles and static vocabulary, conformance statements and all documentation regarding the requirements for implementing the "standard" that is to be named or has been named in regulation.

2) The Repository/Registry shall not allow changes to the version of the above FHIR artifacts. This does not prohibit continued evolution of the FHIR artifacts for other or future uses (regulatory or not), but does protect the integrity of the published standard.

Standard maturity requirements:

1) In general, standards named into regulations should be Normative standards. However, there are situations where Standards for Trial Use (STU) may be named into regulation when it is deemed appropriate to adopt non-normative standards of reasonable quality to move the industry
forward by encouraging or requiring specific entities and technologies to adopt and utilize a trial standard.

2) Regardless of the maturity of the named standard, the specific version must be maintained for the time the regulation is in place and enforceable.

Backward Compatibility for incremental adoption of functionality

The following is a proposed process to address evolution of named standards in a controlled manner. It relies on a combination of additional optional capability that includes backward compatibility with the named standard and periodic update of the regulations.
Once a regulation names a version of a standard, all changes to the named standard (other than errata corrections) are prohibited to ensure uniformity of adoption. This has the impact of stifling innovation and enhancements that adopters need to advance the standard. This guide suggests that there is an alternative that meets both the regulatory goals and yet provides for the incorporation of new functionality in a controlled fashion.

Let’s assume, as the drawing indicates, that we have named a FHIR implementation guide or base standard. This would normally fix the functionality allowed for the duration of the regulation (e.g. until a new version is named). However, this guide proposes that the regulations should allow for additional versions that provide for optional enhancements as long as the version ensures full backward compatibility:

1) New capability is completely optional and may be implemented and made available, but not required under the regulation.
2) All required functionality of the named version must be supported with each incremental version that is implemented.
3) Any exchange that includes only the named version requirements must be accepted and considered fully valid for the name purpose.

On a periodic basis, the regulation should be updated to include a new version where optional features are now required with a reasonable time to implement. In general the standard should provide for backward compatibility with the new version or allow for transition to incompatible features over a controlled number of releases of the standard.
XX. US Regulatory Requirements

US regulations have an impact on the governance, policies and functional requirements for the HL7 FHIR repository. The following are the most significant regulations that impact adoption of technical standards by US Federal Agencies:

Relevant Policy
1. National Technology Transfer and Advance Act (NTTAA) (law)
2. OMB Circular A-119
3. Federal Register Rules: 1 CFR 51.1 (f)
4. Administrative Procedure Act

Note: For links to the specific laws, excerpts, summaries, and regulations, see Appendix A: US Regulatory References

NTTAA Summary
The National Technology and Transfer Act (P.L. 104-113) signed into law in March 7, 1996, gives NIST the responsibility to coordinate standards and conformity assessment activities with other Federal agencies, state and local governments, and with the private sector. The Act directs NIST to coordinate with other federal government agencies to achieve greater reliance on voluntary standards and conformity assessment bodies with lessened dependence on in-house regulations.

1. All Federal agencies and departments shall use technical standards that are developed or adopted by the voluntary consensus standards bodies, unless compliance is inconsistent with applicable law or otherwise impractical
2. Federal agencies are encouraged to participate in the voluntary consensus standards process.

Revised OMB Circular A-119 Summary
OMB Circular A-119 establishes policies to improve the internal management of the Executive Branch with respect to the U.S. Government’s role in the development
Many voluntary consensus standards are appropriate or adaptable for the Federal government's purposes. Such standards should be used whenever practicable and provide:

1. additional guidance for agency participation in standards development activities, including with respect to serving on standards technical committees as well as the boards of standards developing bodies;
2. guidance to agencies on what factors to consider when incorporating standards by reference in regulation;
3. encourages agencies to work together to reference the same version of standards in regulation and procurements and coordinate on conformity assessment requirements, where feasible;
4. maintains a strong preference for using voluntary consensus standards over government-unique standards in Federal regulation and procurement.

Administrative Procedures Act Summary

The Administrative Procedures Act governs the process required to create Federal regulation. It specifically establishes the notice and comment regulatory process that all agencies (including ONC) must follow when proposing/establishing new regulations.

Federal Register Rules: 1 CFR 51.1 (f) Summary

The single most significant regulation with respect to adoption of standards is the Federal Register Rules: 1 CFR 51.1 (f) that state:

“Incorporation by reference of a publication is limited to the edition of the publication that is approved.”

Based on this regulation, future amendments or revision of the publication are not included. This limits the ability to adopt future changes to the version of the standard and requires, in effect, that the adopted version of the standard must be maintained as it was at the time of the final rule.

Governance Implications

1. Ensure that the FHIR Repository governance process supports an open consensus standards process including the creation and maintenance of published standards that have been adopted in regulation.
2. FHIR Standards must be developed by an open consensus process in which the Federal agencies have an opportunity to participate.
3. FHIR Standards must be published and available to all potential adopters.
4. External artifacts (e.g. registry only entries where artifacts are maintained in external repositories), other than education and testing, shall not be incorporated in published FHIR standards and Implementation Guides intended for adoption in US regulation.

Operational Requirements

Specific operational requirements to support the US Regulatory environment regarding standards and technology are focused on the standards process and maintenance of published standards that have been adopted in regulation.
1. Support for controlled management of published version FHIR standards and implementation guides.

2. Quality control process to ensure that all FHIR artifacts that are part of a standard are appropriately versioned and available for the lifetime of the standard.

3. As part of lifecycle management, establish a process that allows for “sun setting”/retiring of older standards once they have been replaced, in regulation, by newer standards and any “phase in” period has expired. The artifacts that are retired should still be available in an historical archive for users that have adopted them under prior regulation and the change to new standards does not apply.

**Functional Requirements**

The HL7 FHIR Repository shall provide the following functional capability to support the US Regulatory environment regarding standards and technology. Functionality is focused on the standards process and maintenance of published standards that may be or have been adopted in regulation.

1. Version control for all artifacts that are included in any release of a FHIR standard or implementation guide

2. Provide ability to easily validate consistency in use (versions) of resources, extensions, value sets and profiles between multiple implementation guides that may logically be adopted as a family in regulation

3. All artifacts included in any release of a FHIR standard must pass all validation tool tests (see chapter on validation)

4. Provide capability to verify backward compatibility of all “minor” versions of the standard. (While especially true for normative release, it is also required for any release adopted into US regulation)

5. Provide capability to clearly document changes and incompatibilities when a new major version is released

6. Support all access based tracking and maturation metrics for HL7 FHIR Registry artifacts.

**Other Requirements**

The US Regulatory environment regarding standards and technology may require clarification or changes to current practices. These changes are summarized as follows:

**Policy (part of existing TSC process or additional policy for consideration)**

1. Establish policy to recognize and support US Realm regulatory requirements with regard to open (includes opportunity for participation by Federal agencies) consensus based standards development.

2. Establish policy to ensure that standards (underlying and implementation guides) that are adopted into regulation are maintained, without substantive changes for the duration of the regulations.

3. Establish policy to provide an orderly evolution of the standard where minor version releases are fully backward compatible (with the exception of errata that clarifies errors and omission but does not add new functionality or change exiting functionality) and new features are considered optional to provide the ability for US entities to adopt the new version and still be compliant with existing regulations regarding the adopted version of the standard.
XXI. Security

Overview

The security service provides for authentication of various stakeholders including

3) Administrators
4) Contributors
5) Custodians
6) Artifact Adopters
7) API to accomplish both submission and retrieval of FHIR artifacts

- The ability to authenticate the individual or application that wishes to access the repository/registry is fundamental to the ability manage the FHIR artifacts.
- Each user shall be assigned specific rights based on the role they are authorized to play

AUTHORIZATION

1. Create User Credentials
   Used to create a user login necessary to modify information maintained in the FHIR artifacts repository/registry.
2. Communicate Credentials to Users
3. Activate User Credentials
   Used to enable the credentials for log in.

4. Deactivate User Credentials
   Used to disable the credentials for log in, without removing them.

Note: different classes of users may require different levels of credentials. e.g. a user may only be allowed to perform certain capability based on their role (e.g. create/update metadata, promote the maturity level of a FHIR artifact).

**Authentication**

1. User Login
   Used to identify an authorized user of the system.

2. Change Password
   Used to change password.

3. User Logout
   Used to prevent unauthorized use of the system.

4. Automated Logout (e.g., Timeout)
   Used to prevent unauthorized use of the system.

**Audit**

1. Audit Activity
   Used to ensure that changes to the information maintained by the FHIR artifacts repository/registry are tracked.

2. Review Audit Logs
   Used to review changes made to ensure appropriate use of the FHIR artifacts repository/registry.

3. Request audit report
   Used by a custodian organization to request an audit of all activity involving their FHIR artifacts metadata.

**Access Control**

Note: different classes of users may require different levels of access. I.e. A user may only be allowed to access a certain group of FHIR artifacts according to the authorizing organization that the user represents. Also, one organization may be allowed to delegate its access privileges to another organization.

1. Use of Open ID or other trust framework to identify applications

2. Use of OAuth 2.0 or above to provide for access by registered applications to perform the following authorized activities:
Application Access Control

Notes:

- Applications may be used to automate the submission, management and/or retrieval of metadata and artifacts from the registry and repository (respectively).
- Use of OAuth, Open ID Connect and OpenID should be supported

The repository shall provide the capability to support authorized access by these apps to perform the following functions:

1. Submit artifacts to the repository at level 1 and enter their metadata in the registry
2. Submit registry metadata and links to artifacts in external repositories
3. Retrieve metadata (based on supported search criteria) and where appropriate, the associated FHIR artifacts
4. Perform artifact and metadata versioning and update of appropriate maturity indicators
5. Perform management activities on both the repository and registry

XXII. Appendix A: US Regulatory References

National Technology Transfer and Advance Act (NTTAA) (law)

Public Law 104-113 establishing the NTTAA

NTTAA (National Technology Transfer and Advance Act) and A-119

NTTAA (Partially excerpted from published documents)

The National Technology and Transfer Act (P.L. 104-113) signed into law on March 7, 1996, gives NIST responsibility to coordinate standards and conformity assessment activities with other Federal agencies, state and local governments, and with the private sector. The Act directs NIST to coordinate with other federal government agencies to achieve greater reliance on voluntary standards and conformity assessment bodies with lessened dependence on in-house regulations.

The Act also tasks NIST with coordinating with state and local agencies on standards matters, and gives NIST a central role in coordinating conformity assessment activities with government agencies and the private sector.

Finally, the Act requires NIST to report this plan to Congress by June 1996 for work with other government agencies and the private sector, to build workable systems for standards and conformity assessment that meet the needs of U.S. industry in a global market.

The specific provisions for standards-related activities contained in the Act are the following:
To compare standards used in scientific investigations, engineering, manufacturing, commerce, industry, and educational institutions with the standards adopted or recognized by the Federal Government and to coordinate the use by Federal agencies of private sector standards, emphasizing where possible the use of standards developed by private, consensus organizations.

NIST will - coordinate Federal, State, and local technical standards activities and conformity assessment activities, with private sector technical standards activities and conformity assessment activities, with the goal of eliminating unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures;

Use of Consensus Technical Standards means:

- All Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments;
- Federal agencies and departments shall consult with voluntary, private sector, consensus standards bodies and shall, when such participation is in the public interest and is compatible with agency and departmental missions, authorities, priorities, and budget resources, participate with such bodies in the development of technical standards;
- Exception - If compliance is inconsistent with applicable law or otherwise impractical, a Federal agency or department may elect to use technical standards that are not developed or adopted by voluntary consensus standards bodies if the head of each such agency or department transmits to the Office of Management and Budget an explanation of the reasons for using such standards. Each year, beginning with fiscal year 1997, the Office of Management and Budget shall transmit to Congress and its committees a report summarizing all explanations received in the preceding year under this paragraph;
- "Technical standards" means performance-based or design-specific technical specifications and related management systems practices.

**OMB A-119 (links to documents)**

Federal Register Announcement re A-119


Federal Register Notice: Vol 81, No 17 /Wednesday, January 27, 2016

[https://www.gsa.gov/portal/mediaId/146959/fileName/OMB_Circular_A-119_(1).action](https://www.gsa.gov/portal/mediaId/146959/fileName/OMB_Circular_A-119_(1).action)

**Revised OMB Circular A-119 (Partially excerpted from published documents)**

OMB Circular A-119 establishes policies to improve the internal management of the Executive Branch with respect to the U.S. Government’s role in the development and use of standards and conformity assessment. Consistent with section 12(d) of
P.L. 104-113, the “National Technology Transfer and Advancement Act of 1995,” as amended (hereinafter “the NTTAA”), and U.S. Government executive orders, this Circular directs agencies to use standards developed or adopted by voluntary consensus standards bodies rather than government-unique standards, except where inconsistent with applicable law or otherwise impractical. The policies in this Circular are intended to facilitate agencies’ compliance with obligations under U.S. trade statutes and trade agreements. U.S. Federal law (19 U.S.C. § 2532) specifically prohibits any U.S. Government agency from engaging in standards-related activities that create unnecessary obstacles to the foreign commerce of the United States.

This Circular provides guidance for agencies participating in the work of voluntary consensus standards bodies and describes procedures for satisfying the reporting requirements of the NTTAA. The policies in this Circular are intended to minimize the reliance by agencies on government-unique standards. The Circular also provides policy guidance to agencies on the use of conformity assessment in procurement, regulatory, and program activities. This Circular replaces Office of Management and Budget (OMB) Circular No. A-119, dated February 10, 1998.

Many voluntary consensus standards are appropriate or adaptable for the Federal government's purposes. The use of such standards, whenever practicable and appropriate, is intended to achieve the following goals:

4. eliminating the cost to the Federal government of developing its own standards and decreasing the cost of goods procured and the burden of complying with agency regulation;
5. providing incentives and opportunities to establish standards that serve national needs, encouraging long-term growth for U.S. enterprises and promoting efficiency, economic competition, and trade; and
6. furthering the reliance upon private sector expertise to supply the Federal government with cost-efficient goods and services.

The revised Circular A-119:

7. provides additional guidance for agency participation in standards development activities, with respect to serving on standards technical committees as well as the boards of standards developing bodies;
8. encourages each agency to alert the public through the Federal Register or the agency’s webpage when the agency is considering whether to participate in the standards development process of a particular body. Such notification would give the public notice that the agency may use the resulting standard in support of significant regulatory action, international regulatory cooperation activities or to otherwise address issues of national priority;
9. provides guidance to agencies on what factors to consider when incorporating standards by reference in regulation;
10. encourages agencies to work together to reference the same version of standards in regulation and procurements and coordinate on conformity assessment requirements, where feasible;
11. maintains a strong preference for using voluntary consensus standards over government-unique standards in Federal regulation and procurement.

The Circular does not preclude the use of standards other than voluntary consensus
standards in rulemaking, procurement or other program activities in cases where voluntary consensus standards do not exist or where use of existing voluntary consensus standards would be inconsistent with law or otherwise impractical, including where use of a voluntary consensus standard would not be as effective at meeting the agency’s regulatory, procurement, or program needs. The Circular also recommends that the agency consider allowing the use of other standards as alternative means for complying with agency regulatory, procurement, or program requirements based on voluntary consensus standards where such other standards are also found to be suitable under the agency’s analysis.

Federal Register Rules: 1 CFR 51.1 (f)
Federal Register rules regarding incorporation by reference

Administrative Procedure Act
Administrative Procedure Act – governs regulatory process