FHIR Registry Requirements and Gap-Assessment

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This document provides a summarized extract of the requirements proposed by the [*HL7 International Repository Governance Process and Requirements*](http://wiki.hl7.org/index.php?title=FHIR_Repository_Process) document. Although this title refers to “Repository” the actual business need was primarily for a registry – though registry.fhir.org can serve as a repository for certain artifacts, it was never intended to be a document management system or universal repository of all content, so the term “Registry” will be used for the purposes of this document. Requirements that would be intrinsic to any registry product such as the ability for a repository to store, search and support download of artifacts are not listed (and, in most cases, are already part of v1 of registry.fhir.org). As well, requirements that deal with business process or for tooling separate from the registry tool (e.g. related to authoring or balloting) are not included or in scope of the FHIR registry system.

For each candidate requirement, an assessment is made as to whether there is a gap with the capabilities of the planned FHIR registry. The assessment is color-coded as follows:

* Green indicates that the proposed requirement is met by the existing [registry.fhir.org](http://registry.fhir.org/) tool
* Blue indicates that the proposed requirement is not met but is either not deemed to be necessary or will be sufficiently satisfied by means other than incorporation in the registry
* Red indicates that the requirement is unmet and should be considered as a potential future enhancement of HL7’s registry.

Red requirements are further broken down into three categories:

*Immediate* requirements should be in place as soon as possible. Failing to meet these requirements will either have a significant negative impact on the usefulness of the registry or will create a risk for users and/or HL7.

*Medium* requirements are desirable features that will significantly enhance the utility of the registry, but aren’t so important that it would make sense to delay registry access. Ideally these requirements would be met in the first year or so of operation.

Low requirements are not deemed to be necessary and likely to be deferred.

Decisions on whether or when these proposed requirements will be met will be handled as part of discussions between HL7 and Furore, the supplier of registry.fhir.org.

The requirements below were adapted (with page number references) from *HL7 FHIR Repository Governance, Process and Requirements, Release 1, August 2017,* available at <http://wiki.hl7.org/index.php?title=FHIR_Repository_Process>.

1. Differentiate an artifact into “nascent/under development”, “pre-publication review”, “under review”, “inactive”, under update”, “active/published”, “retired” states (p9, p10, p34, p42#3)
   1. Review processes will not be managed through the registry. Reviews will be handled through a separate tracker mechanism. Resources will therefore stick with the standard FHIR conformance statuses of draft, active and retired.
2. Identify submitters who can act on behalf of a custodian or adopter organization (p10)
   1. Furore’s Forge tool will allow users to be associated with organizations and with projects. There will not be a mechanism to automatically authorize one organization’s users to manage another organization’s content – for now the relevant users will need to be added to the organization whose content is to be managed.
3. Allow individuals to “subscribe” to an artifact to receive notifications of updates to the artifact and registry information with bulk notifications at a requested frequency (p10, p39, p41n#1-5)
   1. Medium: It would be very useful for the registry to support Subscription – both to be able to subscribe to other registries to automatically retrieve content as well as to allow other registries to retrieve content from it.
4. Allow individuals to note that a specific artifact version has been adopted for use and how (p10, p34, p41v#1)
   1. Medium: Simplifier is proposed to support a Thumbs up/Thumbs down notion, but changing this requirement to be based on “use” and capturing a couple of simple elements around type of use would be better, though it is unclear how this would be maintained.
5. Allow organizations to delegate their rights to another organization (p11, p14)
   1. This can be handled by adding the relevant users to the delegating organization
6. Support indicating that one artifact is derived from another artifact (p11, p15)
   1. This is captured in the derived artifact, but an artifact does not track if other artifacts are derived from it.
7. Allow organizations to take on the rights of another organization if the initial organization is no longer able to meet its responsibilities (p11)
   1. This can be handled by adding the relevant users to the delegating organization
8. Control update privileges such that only submitters and their designates/replacements can maintain a submitted artifact (p14, p43m#4)
   1. Submitters can control who can maintain their content. Notion of designates/replacements doesn’t need to be supported in an automated fashion.
9. Control update privileges such that only users and associated organizations/designates/replacements can maintain adoption notes for an artifact (p14)
   1. This would need to be part of adding support for adoption tracking (see 4) above)
10. Allow linking an artifact back to its “source” repository (p14)
    1. Supported
11. Supports queries from other registries (not just users) (p15)
    1. Supported: RESTful interface will support any authorized user. A system can be a user
12. Provides a conduit for queries (questions) from users to custodian organizations (p16)
    1. This will be handled by placing relevant contact information on the project page and having users visit the relevant website or use the associated email address.
13. Support noting that one artifact has been replaced by another artifact – this is distinct from versioning (p17)
    1. Low: Would be nice to have this exposed in the interface, though presently there’s no mechanism to support declaring it in the conformance resources, so it would need to be added in the future
14. Support registration of an External Repository in the HL7 FHIR Registry (p19#1) (Organization, contact information, URL, status, other information)
    1. For most of this, it should be sufficient to just follow a link included in the registry (see 15)) or just have a wiki page listing other registries and/or repositories. See above for support for subscribing to other registries.
15. Support contribution of FHIR Artifact Metadata for and links to FHIR artifacts in External Repositories (p19#2, p19#5)
    1. Supported
16. Automatic validation that artifacts are publicly accessible without need for accounts or logon to the External Repository (p19#3, p19#6)
    1. This is outside the scope of the registry and isn’t terribly useful – even if a link might be valid at the time content is registered, it may break in the future. As well, it’s possible the registry may point to content that isn’t available without some sort of registration. It will be a policy question whether HL7 chooses to support such links, but this is currently considered out of scope.
17. Provide for external Attestations regarding all validation, quality and completeness metrics that require administrative support by HL7 corporate staff or HL7 workgroups. (p19#4)
    1. For content that has undergone HL7 ballot, the loading process will only post content that has passed ballot. Vetting of resources posted by others is subject to their own processes.
    2. There are no plans, as yet, for HL7 to vet materials except through balloting. So requirements around mechanisms for managing this are premature and out of scope.
18. Provide a process to validate all links for a contributing organization or for all contributing organizations (p19#7)
    1. This would be a nice-to-have, but it’s actually a hard thing to do. Checking that links resolve to **something** is possible, but checking that what’s resolved to aligns with the metadata and doesn’t change over time is difficult/impossible. Also, it’s not r within the scope of the registry
    2. Low: Consider this as a future add-on that could be run against content exported from the registry
19. Provide the ability to “remove” artifacts that are no longer available. (p20#8)
    1. Supported
20. Integrate with HL7 membership process to only allow individual(s) from the contributing organization to update that organization’s metadata and attestations. (p20#9)
    1. It’s not clear that this will be desired behavior for all (or even many) organizational members. Organizational membership association is maintained for voting purposes. Rights for maintaining metadata are quite different. Also, this is difficult to integrate with HL7’s membership system, so it is currently out of scope.
21. Additional metadata for external artifact shall include all the HL7 FHIR Registry 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 (p20#10)
    1. Repository location and status are supported as is contact information as part of the description
    2. Contributing organization is not tracked or considered essential to HL7 and is currently out of scope
    3. Medium: Supporting exposing artifact maturity and ability to search on it would be useful, but it is not yet clear how such information would be collected and maintained.
22. Support all access based tracking and maturation metrics for HL7 FHIR Registry artifacts. (p20#11, p54f#5)
    1. Not clear what “access-based-tracking metrics” are. Maturity metrics addressed above in 21).
    2. Registry does track access by users.
23. Ability to automate move to HL7 Repository controlled by contributor (p20#12)
    1. Registry includes an export capability.
    2. Medium: Need an ability to download content in IGPack format to enable subsequent upload to a separate server.
24. The registry shall support categorization of the FHIR artifacts based on multiple independent hierarchies (ballot organization hierarchy, responsible WG). (p21)
    1. Ballot organization hierarchy is dynamic and changes from ballot to ballot. It has little search utility. And for most users, searching by WG won’t be relevant either. The WG will be exposed in the artifact and can be identified through the HL7 website.
25. Support views of all FHIR artifacts based on each of the categorization frameworks and basic naming / layout information (categorized, alphabetical, R2 layout, by maturity, by WG) (p23)
    1. There’s no need for these views to exist in the registry – the ballot handles that. Registry is for searching, not presentation, and is not intended to replace HL7 ballot processes.
26. Support Grouping of resources for submission, maintenance and rights management (p35, p42#1, p43m#7)
    1. The Project capability supports this
27. Expose and allow navigation of links between resources (p35, p43#2)
    1. This is supported, though only in the forward direction (as references are shown in FHIR publications)
    2. Medium: It would be useful to allow navigation of reverse links – “What artifacts use this artifact?”
28. Expose and allow searching by associated coded terminologies (p36, p42#2, p43#2)
    1. While supported, this is not commonly done in existing FHIR artifacts now.
29. The user interface should support information access by people with disabilities. These standards vary according to country of use. (p40UI#2)
    1. Medium: It would be good to audit the tool against disability access requirements. I don’t believe HL7 is legislatively bound to adhere to any specific guidelines, but we should take what reasonable steps we can to support broad access.
30. All activity that changes the content of the FHIR registry 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. (p40Audit#1)
    1. Immediate: Audit information is essential. We need to be able to figure out how data was changed, by whom and when as well as so it’s possible to analyze how the registry is being used for query, etc.
    2. Medium: Capturing and exposing Provenance for records would be useful so that system users can also see information about data creation.
31. Upon review of any information in the FHIR artifacts registry, 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 registry (e.g., identity or location of the user making the change). (p40Audit#2)
    1. Date of change is shown
    2. User/location making the change can be gleaned from audit
32. FHIR Registry Administrators shall be able to view the complete audit record of changes made to the content of the FHIR artifacts registry. (p41Audit#3)
    1. Audit information would be available as FHIR AuditEvent records. There is currently no expectation for a user interface for examining audit information within the registry tool
33. FHIR 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. (p41Audit#4)
    1. User interface for audit information is out of scope – audit information will be managed using FHIR’s standard query interface
34. 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 registry to other authorized users. (p41AC#1)
    1. Any information in the FHIR registry can be viewed by anyone – we will not have “private” projects.
    2. Access rights are already maintained at a project level, not at an artifact level
35. 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) (p41v#2)
    1. Not clear what the use-case for this would be. Users are free to download what artifacts they wish and compare them using tools appropriate to the type of comparison they’re interested in.
36. Shall support searching based on adoption (p43s#1,2)
    1. Medium: There would be utility to be able to search for artifacts in use in production, in use in a specific geography or possibly in use by a specified organization. Unclear how information would be collected or maintained.
37. 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 metadata attribute, related FHIR artifacts for a FHIR artifact, etc.), and classifications within external ontology. (p44#3)
    1. Searching by type, FHIR version & status are supported
    2. Medium: Finding artifacts by organization is possible, but not searching across all of an organization’s artifacts. This would be useful. E.g. “only show me contents from HL7 Int’l” or “only show me contents from NHS”
    3. Conformance artifacts don’t currently have effective or expiry dates. Such dates would typically be tied to a particular use of an artifact, not necessarily the artifact itself. This could be considered for a future requirement if adequately defined.
    4. Free text search matching is available for name, identifier, source, purpose and definition are supported, but not searching by individual elements. It’s not clear that searching by individual elements is useful/necessary
    5. Medium: Searching by last changed date could be useful to see what’s new as well as to look for “actively maintained” artifacts
38. 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. (p44#4)
    1. Not clear how critical this capability is
39. Search capabilities on text fields in the registration, adoption or annotation metadata (e.g., name, purpose, definition) should support some degree of approximate matching. (p44#5)
    1. Not clear of the business case and how critical this capability is; not currently in scope.
40. 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. (p44#6)
    1. Not clear how critical this capability is; not currently in scope.
41. Search capabilities on date fields in all metadata should support date ranges. (p44#7)
    1. Not clear if this will be relevant for “last updated” – which will generally just be “find me records that have been changed on or after date x.
42. Search capabilities on identifier and version FHIR artifact registration metadata fields shall support exact match, and need not support any more complex capability. (p44#8)
    1. Partial matches can be relevant for version searching. Searching by business identifiers other than canonical URL is uncommon
    2. Medium: Would be useful to allow exact match searching based on canonical URLs
43. 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. (p44#9)
    1. Currently support “or” searches for values for status, FHIR version, etc. and “and” between those filters. Can also support “and” for free-text searches.
44. 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.) (p44#10)
    1. No clear use-case for this capability; not currently in scope.
45. Users should be able to search within previously returned search results. (p44#11)
    1. Not clear how critical this capability is; not currently in scope.
46. The FHIR registry should support both summary and detailed views of the results returned from a search. (p44#12, p45#4)
    1. Supported
47. The FHIR registry shall be able to query the registrations from a web browser (p44#13, p45$5)
    1. Supported
48. The FHIR registry may support preset or custom configured user specific views of registrations based upon user preferences. E.g. researchers, implementers, standards developers, educators, etc. (p45#1)
    1. Not clear what the differences in preferences would be. This level of customization is costly to develop and maintain
49. The FHIR registry 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 (p45#2)
    1. No obvious need for pre-defined searches. Search capabilities already discussed above
50. The FHIR registry 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. (p45#3)
    1. Search by codes is used in limited places, but not full ontologies like SNOMED or LOINC – no obvious need
51. The FHIR registry shall provide the ability to create reports on demand that include current status and history of any artifact or artifact group; list of artifacts by metadata information; usage history for any artifact or group (p46#1)
    1. Report generation is currently out of scope for the tool. There will be support for querying resources. The results of those can be used to create reports locally.
    2. Medium: Tool should support exporting search results to allow local report generation
52. The FHIR artifacts registry 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. (p46#2)
    1. Artifacts associated with a publication are already included within the publication. That’s not a function of the registry. If necessary, the content can be downloaded and used to generate a report
53. Reports shall be viewable in a web browser. (p46#3, p47#9, p47#11)
    1. No report generation is expected; not currently in scope.
54. 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). (p46#4)
    1. No report generation is expected. CSV can be locally generated from XML/JSON if needed (presuming XML/JSON is supported)
55. Information contained in reports should be downloadable in a standards-based XML format (e.g., as specified in ISO 15000). (p46#5)
    1. Medium: It would be helpful if query data can be downloaded as a bundle of artifacts (DocumentReferences for registry entries, actual artifacts for repository entries)
56. Specifications of the file formats used for downloading reports shall be documented and accessible to users of the FHIR artifacts registry. (p46#6)
    1. These would be FHIR resources, so no need for documentation; reports are not currently in scope.
57. The FHIR artifacts registry shall be able to indicate all HL7 FHIR artifacts publications associated with a particular registration. The same requirement applies to registered FHIR artifacts created by other SDO’s or SDO-related organizations. (p46#7)
    1. What was submitted together is generally only relevant from an audit perspective. Tool is capable of representing all artifacts in a project, which should cover most needs.
58. The FHIR artifacts registry 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. (p47#8)
    1. Medium: Reporting is out of scope, but it might be useful to be able to trace dependencies and request a download of all dependencies of a selected artifact or those artifacts in a search result.
59. Detailed reports shall be available that support download of all metadata for artifacts in the FHIR registry . (p47#10)
    1. Reporting is out of scope
60. The FHIR artifacts registry shall provide a mechanism to view the reports in a web browser. (p47#11)
    1. Reporting is out of scope
61. All statistics should be available for the following time periods or user selected time periods (daily, weekly, monthly, YTD, prior years) (p47#1)
    1. Statistics could potentially be extracted from the Audit log – but would generally only be available/relevant to HL7. HL7 could choose which statistics it wanted to publish/share, but generation of these would not be the responsibility of the registry.
62. All statistics should be segmented/segmentable by contributing source, repository location, artifact type (p48#2)
    1. Statistics are out of scope for registry
63. 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 (p48#3)
    1. Statistics are out of scope for registry
64. The Registry shall not allow changes to the version of FHIR artifacts that are referenced in regulation (p53)
    1. The registry cannot be aware of all possible uses of artifacts in regulation and, even when aware, use in regulation does not govern the artifact evolution process – that’s determined by the artifact lifecycle. If regulation chooses to reference an artifact that is not yet normative, then the jurisdiction that made that choice will have to deal with the consequences of substantive changes if those changes occur.
65. 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 (p54f#1)
    1. Consistency of use is hard to define and evaluate by humans, let alone by automated means. And this would not be a registry function – it would apply to artifact development which occurs before submission to the registry.
66. All artifacts included in any release of a FHIR standard must pass all validation tool tests (see chapter on validation) (p54f#2)
    1. This is a publication process requirement, not a registry requirement. Registry can impose syntactic validation (necessary to parse resources for metadata), but can’t really impose anything else.
67. 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) (p54f#3)
    1. Backward compatibility can’t be fully verified by automated means. As well, backwards compatibility expectations are by policy and can’t be enforced by the registry as different policies will exist. Backwards compatibility rules won’t be driven by inclusion in regulation, they’ll be driven by artifact life-cycle. Backwards compatibility rules should and will be handled during development process, not registration.
68. Provide capability to clearly document changes and incompatibilities when a new major version is released (p54f#4)
    1. This is handled by publication process, not registry process
69. Support automated logout (p56)
    1. Medium: This is a good security practice. It’s possible that a malicious actor could upload content to the registry that would result in harm, given HL7’s role as a “trusted source”. We should probably set minimum rules for passwords too.

Additional requirements not addressed in *HL7 International Repository Governance Process and Requirements* document:

1. 70) There needs to be a distinction between “source” artifacts and “published” artifacts – these are not the same thing. The registry may need to point to both.
2. There is a need for grouping of artifacts – i.e., IGs
3. Support for dependencies - Some artifacts may be used by other artifacts (this is different than derivation). E.g. static model bound to separately published value set.
4. The document focuses on StructureDefinitions (and a limited subset of those) and doesn’t sufficiently address other types of Conformance artifacts that may need to be registered.
5. A requirement about checking stored content for malicious content should be considered as a medium priority (e.g. virus checking) so the registry is less likely to be a vector of attack.

Other comments:

There is an implication that FMM level is automatically changed based on use in regulations which is not consistent with the FMM. (FMM criteria must be met to change levels – inclusion in regulation for one country could influence implementers and thus result in FMM criteria being met sooner, but this is not guaranteed on a global level.)

The concept of “validation link” is not defined, so cannot be addressed in the requirements.