

1 ***HL7 Templates Business Process***  
2 ***Requirements Analysis***  
3  
4

5 **Comment Only Ballot, Version 2.**  
6

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## 125 1.0 INTRODUCTION

126 This document describes the business process requirements for a registry that will support HL7 v2, v3  
 127 messages and v3 CDA template metadata and help consumers looking for existing template resources to  
 128 rapidly locate them by searching available administrative and classification metadata. The term "Templates"  
 129 is intended to include any coherent static model that is intended to be a constraint on a standardized static  
 130 model. Detailed Clinical Models, HL7 templates as either open or closed models and OpenEHR Archetypes  
 131 are all examples of templates that could be registered in the Templates Registry.

132 Various users of HL7 Standards, as well as HL7 itself, have created a number of templates<sup>1</sup>. Some of these  
 133 efforts have been coordinated and some have not. Additionally other groups and companies are also  
 134 creating templates using other paradigms (e.g. openEHR, Tolven, Ontoreason, DCM, Lanatana Associates,  
 135 IHE, Infoway, NEHTA, NICTIZ etc.) There is a need to create a specification for a templates registry that will  
 136 store "registrations" of templates from various sources, created using various paradigms, so that the  
 137 templates themselves can be made accessible to a wide variety of users for a wide variety of purposes. The  
 138 templates registry is an information system that stores administrative and classification metadata about  
 139 templates. Template metadata is submitted and maintained by a custodian organization that has an  
 140 appropriate legal agreement with the template registry that may include IP rights for the template. Once the  
 141 template registry has received a given template (or group of templates) appropriate change control  
 142 processes are used. The registry will contain descriptive, structural and administrative information about  
 143 templates. It will include information about template usage, specifically context, scope and adoption for use;  
 144 inter-relationships: including: parent/child and compositional links; semantic categories; the existence of  
 145 mappings and transformations between semantically equivalent templates; and, the existence of  
 146 computerized validation and conformance software.<sup>2</sup> The registry will also contain links to reference  
 147 material, such as implementation guides and sample template instances. It will support many types of  
 148 retrieval queries based on structural, semantic, authorship, and other important categories.

149 The template registry recognizes that metadata, like all information, follows a lifecycle and needs to be  
 150 monitored and maintained over time. The purpose of the registry is to support information sharing and the  
 151 re-use of templates. Metadata contributions are made by 'registered' individuals but submission of actual  
 152 template metadata and use of templates will not be an onerous process. The registry relies on contributions  
 153 from organizations who delegate authority to submit and comment on their behalf to nominated  
 154 representatives. A registration process authenticates the nominee and affirms an agreement to abide by the  
 155 registry's operational policy framework. Registration supports the quality, accuracy and currency of  
 156 information to information consumers and enables information consumers to have confidence about  
 157 statements found in the registry.

158 The metadata for the registering templates will support, at a minimum that mentioned in the HL7 Templates  
 159 DSTU. In terms of templates created in the HL7 v3 paradigm, all of the constraint mechanisms supported by  
 160 HL7 v3 may be used in a given template's specification, including the derivation path from balloted static  
 161 models, the Model Interchange Format and the vocabulary bindings supporting the CTS and Terminfo  
 162 specifications. These vocabulary bindings may also become an important source of metadata that can be  
 163 used to create an ontological classification for registered templates. The technical staff of a templates  
 164 registry may create additional structural and semantic links amongst registered templates; they may also use  
 165 emerging software tools to support this (e.g. the IHTSDO "Snomed workbench"). Additionally metadata may  
 166 include the documentation of the availability of software to transform a template created via one formalism

---

<sup>1</sup> See section 3 below for definition of "template."

<sup>2</sup> For example, templates do not exist in the HL7 v2 paradigm, which instead has message profiles detailing constrained value sets and fields. In the future, tools may be able to generate HL7 v2 conformance profiles and the registry will recognize their equivalence to templates and hold information that can assist with migration and conversion.

167 (methodology) to a semantically equivalent template represented in another formalism. This will enable the  
168 retrieval of templates by humans and software applications. This information may be used to support  
169 implementation and testing of systems conforming to the registered and approved templates.

170 Templates registries can be integrated with other information systems, such as terminology servers or  
171 template authoring systems. This document is not intended to convey the requirements of these systems.

## 172 **1.1 INTENDED AUDIENCE**

173 The audience for this document includes:

- 174 • Users, implementers and integrators of systems needing to obtain or use the growing body of  
175 detailed definitions of clinical and health information that can be represented by templates. Access to  
176 a templates registry will greatly enhance the ability to design systems and to share semantically  
177 interoperable information between systems, for both clinical and secondary uses.
- 178 • Experts in clinical practice developing guidelines for care or clinical decision support or creating  
179 quality measures, wanting to understand how to use the structural and ontological definitions of  
180 clinical and healthcare information provided by a templates registry to obtain information at the level  
181 of v3 templates.
- 182 • Policy-makers and influencers establishing national and regional policies with respect to semantically  
183 interoperable information exchange
- 184 • Developers of templates registries.
- 185 • Developers of templates repositories.
- 186 • Creators, distributors and adopters of templates whose metadata is stored in a templates registry.

## 187 **1.2 DOCUMENT ORGANIZATION AND STRUCTURE**

- 188 1. Introduction – This section.
- 189 2. Systems and Stakeholders – Describes the systems and stakeholders (actors in the UML sense)  
190 involved in the use cases described later within this document.
- 191 3. Entities – Describes the entities that are managed by the templates registries.
- 192 4. Registration and Administration Status – Describes the registration status associated with each registry  
193 administered item.
- 194 5. Templates Registry Governance – Describes the principles of governance of templates registries  
195 desirable for HL7 and related stakeholders, including national programs such as HITSP, IHE, NHS,  
196 NEHTA, Infoway and NICTIZ.
- 197 6. Use Cases – Describes the various interactions between systems and stakeholder (actors) and how  
198 those actions impact the entities managed by the templates registry.
- 199 7. Requirements – Specifies the requirements of templates registries.

200  
201  
202

## 203 2.0 SYSTEMS AND STAKEHOLDERS

204

### 205 2.1 Stakeholders

206 This section describes the various stakeholders of the templates registry and how they interact.  
207 Stakeholders are organizations and individuals that benefit from the services provided by a templates  
208 registry. Template metadata is a combination of structural, definitional, adoption, relational links and  
209 administrative registry status (e.g. active, under review, inactive, superseded). There may be several  
210 revisions of administration status over the course of a template's lifecycle.

211 Stakeholder needs and concerns can be categorized under four main headings:

- 212 • Registry Administration and Governance
  - 213 • Template Custodianship
  - 214 • Template Adoption
  - 215 • Template Information Consumption by an organization or individual
- 216

### 217 2.2 Stakeholder Responsibilities

#### 218 2.2.1 Registration Administration and Governance

219 The Registry Administration Governance Organization has responsibilities to:

- 220 • Establish and publish the registry operational procedures and policy framework:
    - 221 ○ Specify the allowable users, accessible content, frequency of availability, and the
    - 222 language(s), media, and format in which information is provided.
    - 223 ○ Specify the rules by which metadata content is submitted and made available.
  - 224 • Administer the registration process.
  - 225 • Notify metadata development participants of any decisions according to the procedure specified under
  - 226 the operational policy framework.
- 227

#### 228 2.2.2 Template Custodian Organization

229 The Template Custodian Organization is the original template developer, business owner or contributor of  
230 template metadata to the registry. The organization may be an information broker (distributor of authoritative  
231 information but not otherwise responsible for the template). The custodian organization remains constant for  
232 the lifetime of the template and has responsibilities to:

- 233 • Nominate submitters to act on its behalf and advise the Registrar of any nominated representative  
234 changes, for example when a nominee retires from their Organization.
  - 235 • Submit identifying and structural template metadata to the registry, having first ensured content is not  
236 already in the registry.
  - 237 • Revise metadata throughout the lifecycle of the template.
- 238

239 Template metadata can be recorded by a custodian in two forms – ‘under development’ or ‘published’. This  
240 business requirement recognizes a custodian may wish to give formal advance notice that they are  
241 developing a template for a particular purpose. ‘Under development’ may also indicate the custodian wishes  
242 to seek editorial advice from template adopters. A template with ‘under development’ status is formative, a  
243 work in progress, its definitional and structural details are subject to change and may be incomplete. The  
244 template may transition to an ‘under review’ state before publication. The ‘under development’ status is  
245 designed to nurture collaboration and awareness by registry users that an organization is developing a

246 template. The template registry equivalent of 'published' is 'active' and advises the registry community that a  
247 template exists and is available for adoption (use) by a template adopter organization.

248

249 Depending on the information domain of the template (e.g. administrative, financial, clinical, research, etc.)  
250 the custodian organization must ensure that both the information content and the technical representation of  
251 the template have been validated by the appropriate clinical and technical subject matter experts (SME's)  
252 with the appropriate governance process. SME's may be staff members of the templates information  
253 custodian, or members of organizations with which it has formal agreements. For example, in the case of an  
254 HL7 v3 clinical template, the accuracy of the clinical content as well as the fact that the template is a set of  
255 constraints on a balloted v3 static model must both be approved by the appropriate SME's before the status  
256 of the template can become "final", at which point the template can be registered in a template registry.  
257 Templates that are standards or draft standards for trial use can be immediately registered.

### 258 **2.2.3 Template Adopter Organization**

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

266 An adopter organization may appoint any number of representatives. A registry metadata entry may have  
267 multiple adopter organizations associated with it but only one person may represent each template adopter  
268 organization for each registry item.

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

275

276 It is conceivable that an adopter organization may adopt a template, record details of the adoption in the  
277 registry, only to find it needs to adapt/enhance the template to better suit its business needs. Adapting a  
278 template in effect creates a new template and the adopter organization would become the custodian of a  
279 new template with metadata in the registry. The adopter is (1) Responsible for acknowledging the history  
280 and existence of a relationship between the two templates and (2) for updating the adoption record of the  
281 original template to advise details of the adaptation.

282

283 Template metadata could potentially become 'orphaned' if the custodian organization ceases to exist or its  
284 representative retires without delegating another organization to assume custodian responsibilities. Adopter  
285 organizations have a special 'guardian-like' interest in template metadata and may assume responsibility for  
286 re-assigning template interests if template metadata becomes orphaned.

287

### 288 **2.2.4 Templates Information Consumer**

289 A templates information consumer can be a stakeholder per se or can assume other stakeholder roles. All  
290 stakeholders need to search, download, compare or analyze information content stored in the templates

291 registry. A consumer may be an individual with their own interests (such as a researcher, configurer or  
 292 implementer of a clinical system) or they may represent the interests of an organization (such as public or  
 293 population health).

294 A consumer can also be an interface to a system that is referenced to the Templates Registry.

295 2.2.5 Roles and Represented Interests

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

298

Stakeholder Entity	Roles	Represented Interests
Registry Administration/Governance	Executive Committee (Governance)	<b>Oversight and Governance</b> Defines the registry operational procedures and policy framework. <b>Interests:</b> Ensuring the long-term success and performance of the registry; promoting the reuse and sharing of data within and across functional-areas, resolving semantic issues associated with registered items.
	Registrar (Administration)	<b>Main contact for the Registry</b> <b>Interests:</b> Expert in registration processes. Enforces user policies, procedures and formats. Ensures accurate representation of relationships between external registers or dictionaries.
	Templates Registry Administrator, Metadata Annotator	<b>Assists Registrar with user registration and maintenance of template registration status information.</b> <b>Adds metadata to a template to make it more useful to others, e.g. keywords</b> <b>Interests:</b> Administrative workflow and process co-ordination; stakeholder communication and co-ordination; annotating content to enhance its business usefulness
	Templates Registry Supplier	<b>Owner or maintainer of the registry infrastructure</b> , including the hardware and software and the administrative management resources. <b>Interests:</b> Operational infrastructure of the registry.
Template Custodian Organization	Template Metadata Creator	<b>The original submitter of template metadata to the registry.</b> <b>Interests:</b> Defines and maintains structural and definitional metadata about the template.
	Template Metadata Annotator	<b>Tracks metadata changes made by the submitting organization</b> until the template metadata is 'retired' from the registry.
	Template Metadata Distributor	<b>Distributes authoritative information</b> that it is not otherwise responsible for creating (information broker).
Template Adopter Organization	Template Adopter	<b>Asserts that a specific template is in use within the adopter's organization.</b> Records usage details in the registry. <b>Interests:</b> Sharing implementation experience and contributing to wider knowledge about template's purpose and

		utilization. Assuming responsibility for a template if the custodian organization ceases to exist and the template becomes orphaned.
Templates Information Consumer	Templates Metadata Consumer	Uses “adopted” templates to support consumer’s designated use cases

299  
300 The roles and interests of stakeholders are maintained through a simple templates registry user registration  
301 process. All stakeholders, except for Templates Information Consumers, will nominate representative  
302 user(s) who can maintain registry content on their behalf. The registry can be queried by non registered  
303 users.

304 2.2.6 Stakeholder Interaction through Metadata Lifecycle

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

Stakeholder Entity :	Stakeholder Entity:	Interactions	Notes:
To Templates Registry:	From Templates Custodian Organization	Templates life-cycle status changes and accompanying template metadata. (See section 6.3). Also provides links between individual templates, including replacement links	Each templates life-cycle status change causes appropriate changes in the template’s registry metadata. The changes before the active state are optionally present in the registry. Note also that once a template becomes active it may optionally go through multiple versions Each version increments the version number, but doesn’t change the universally unique template identifier).
	From Template Adopter Organization	Template Adoption (in process, completed)	A template 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 template from another custodian organization’s templates. These adaptations (and the links to the adopted template being adapted) will also need to be submitted to the registry via the adopter organization’s custodian role.

	From Template Information Consumer	<p>May request via the registry, that a templates custodian make changes in templates registry statuses and/or the various types of links between templates and/or the creation of new versions of templates, and/or new templates.</p> <p>A template information consumer may also submit various queries and report requests for templates metadata and templates link data.</p>	
	From "other" Template Registries.	May request available template registration metadata and links from other template registries.	
From Templates Registry	To Templates Custodian Organization	Transmits requests from Template Information Consumers. Makes available Template Adaptations and Adoptions metadata, as well as linking data to Custodian Organization.	
	To Template Adopter Organization	Acknowledges receipt of Adopter Organization metadata.	
	To Template Information Consumer	Provides metadata on templates, and responds to user queries. Also may transmit to consumers the template custodian organizations responses to specific user queries.	
	To Other Template Registries.	May make available template metadata and links to other template registries.	

## 308 **2.3 SYSTEMS**

309 This section describes the information systems that may communicate or integrate with a templates registry  
310 or vice versa.

### 311 **Templates Authoring Tool**

312 An authoring tool is an information system that is used to create templates and the metadata needed to  
313 register them. This is a type of client system.

### 314 **Templates Client System**

315 A client system is a user interface that supports a user's access to a templates registry.

### 316 **Templates Repository**

317 An information system which stores the templates created by the templates information supplier and which  
318 manages their status, life cycle, identification and the basic registration metadata. It may be a separate  
319 system or a component of a templates registry. The repository stores the actual templates that are  
320 referenced by a templates registry. Recall that a templates registry may register templates from multiple  
321 templates repositories. Note that a templates registry must be able to support various state transitions in the  
322 life-cycle of a template, including versioning and replacement of one template by another.<sup>3</sup>

323  
324 **Templates Registry**  
325 The templates registry is the principle focus of this requirements document. It is an information system  
326 whereby metadata about registered templates can be stored, such that a pointer to the template's location  
327 and all its metadata can be retrieved as a result of a query. A templates registry may contain such  
328 information from multiple templates repositories in various template formalisms, along with various additional  
329 semantic, structural, "contains/contained in" links between registered templates. It may also contain pointers  
330 to "transformations" between semantically equivalent templates in the same or different template formalisms.

331 A template formalism defines the information architecture used to define a given template, along with its  
332 vocabulary bindings, as well as one or more implementable technology specifications (ITS's). Examples  
333 include healthcare standards based templates such as HL7 v3 templates (including CDA r-2 templates), ISO  
334 13606 archetypes and templates, Tolven open source HL7 v3-based templates, as well as non-healthcare  
335 standards based templates such as openEHR archetypes and templates, IHE, detailed clinical models etc.

### 336 **Federated Templates Registries**

337 A templates registry can be integrated with other templates registries so as to "federate" access to templates  
338 across a set of registries.

339  
340 Note that the federated access to templates across various registries must also support the multiple  
341 adoptions across registries that apply to a given template or set of templates. This may increase the  
342 complexity of the governance aspects of the template adopter organizations.

### 343 344 **Web Browser**

345 A web browser is a user interface that supports a user's access to a templates registry over the web. This is  
346 a type of client system.

### 347 348 **Web Server**

349 A web server is an information system that supports a user's access to a template registry over the web.  
350

351

---

<sup>3</sup> See section 6.3 for details.

## 352 3.0 ENTITIES, CATEGORIES OF OBJECT TYPES AND INSTANCES

353 This section describes the various information entities that the templates registry manages.

354 Types:

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

361 **Adoption** An adoption is an assertion by an organization that a specific published template is in use  
362 within the organization and a notice that the organization would have an interest in any  
363 changes to the template or to the template's metadata.

364 **Publication** A publication is an acknowledgement by a custodian organization that a template or a  
365 group of templates is ready for use. The set of publication status changes associated with  
366 a template are part of that template's metadata. The custodian organization may also  
367 create an "unpublished" template which may be registered as a template "under  
368 development" or in "pre-publication review status."

369 **Registration** A template is registered when its metadata and status are added to the registry and the  
370 registry assigns it a unique identifier. When the registry status is changed to "active"<sup>4</sup>, the  
371 template may be used by any template adopter stakeholder.<sup>5</sup> The basic metadata (the  
372 template's authorship and "authoring system status") is created by the authoring system  
373 and instantiated when the template is registered by the custodian organization. As  
374 mentioned above, other additional metadata may be added via adoption and the various  
375 types of annotations and grouping mechanisms described in sections 3.0 and 6.8 of the  
376 document. Note that 'publication' often means that the registry status of a template has  
377 been changed to "active", rather than other changes in the template's registry status.

378 **Template** HL7 v3 technical definition: a uniquely identified set of formal constraints on a normative  
379 static model.<sup>6</sup>

380 Generic definition: A template is a formal structured (modeled) representation of an  
381 independent clinical information concept, or a structured compositional group of such  
382 concepts. Note that the compositional group may contain other compositional groups as  
383 well as independent clinical information model specification. A template structure is made  
384 up of multiple attributes (data elements) organized according to the template formalism  
385 (methodology) being used. In healthcare standards, templates primarily refer to reusable  
386 models of clinical information, but they may also refer to models of administrative or  
387 research or financial information.. Their main purpose is to enable the sharing and re-use  
388 of information via the sharing and re-use of the template definitions which enable the  
389 semantic interoperability of data instantiated via those definitions.

390 In addition to their definitional aspects, templates are also important in "run-time" use to  
391 exchange information. At "run-time", templates are instantiated with specific data, and may

---

<sup>4</sup> See section 2.2.5 and section 6.3.

<sup>5</sup> See section 6.5 below.

<sup>6</sup> See the HL7 Templates DSTU for further details (*HL7 Version 3 Standard: Specification and Use of Reusable Information Constraint Templates, DSTU Release 1*).

392 be combined in many different ways to support a variety of standards-based documents,  
393 messages, and services.

394 There are several different standard and standards-based template architectures, with  
395 varying degrees of semantic interoperability and varying degrees of support for vocabulary  
396 services (e.g. HL7's Common Terminology Services (CTS1 and CTS2) and Terminology  
397 specifications). One of the important purposes for a templates registry is to be able to  
398 support the registration of templates created with various template architectures, and the  
399 creation of various structural links and semantic links between templates created using  
400 various architectures. (See below.)

401 **Group** A group is a collection of templates. It provides a mechanism to manage the registrations  
402 of all the members of the group. The action specified for an individual template's  
403 registration is to be repeated for all members of a specific group.

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

407 Groups are defined by templates adopter organizations, or templates custodian  
408 organizations through their template adopter roles.

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

411 **Right** A right is the authority to perform a specified action or group of actions on a template  
412 registration or group of template registrations within the templates registry system.

413 **Group metadata**

414 Templates can belong to one or more adoption groups, and as such, this must be  
415 supported by appropriate template metadata.

416 **User Credential** An authorized individual is represented by a User Credential in the Templates registry  
417 system. A user's credential denotes which actions a templates registry user may perform.

418 **Structural Link** A link between two templates based on their respective information models.

419 An example in HL7 v3 is a v3 template formally derived by the addition of an explicit set  
420 constraints to an existing HL7 v3 template (a template of a template). The two templates  
421 will have a structural link documenting this fact. Note that there may be multiple individual  
422 templates defined as different explicit sets of constraints on an existing template.

423 Another type of structural link is the link that defines a specific template as part of a specific  
424 compositional template (or vice versa). I.e. a template may contain other template, or a  
425 template may be contained by another template.

426 **Transformational Links**

427 A link that references the existence of an explicit representation transformation that exists  
428 between two registered templates (usually created via different template architectural  
429 methodologies). The transformation may or may not support semantic interoperability  
430 between the two templates.

431

## 432 Validation Link

433 A validation link is a link to an annotation specifying the algorithm that would validate that an  
434 instance produced by applying the template is accurately populated according to the  
435 constraints defined by the template. The validation algorithm may only be useful to a  
436 particular technical platform and therefore, more than one validation algorithm may be linked  
437 to a given template.  
438

## 439 Semantic links and tags

440 A registered template may be assigned a semantic tag which classifies it according to a  
441 specific ontology (e.g. MESH tags, Snomed codes, Loinc codes). Depending on the  
442 standard vocabulary, compositional coded expressions may also be used, and semantic  
443 links may also be created that describe the semantic relationships between templates  
444 according to the supported ontology.

## 445 Registration status and links

446 Each registration of a template shall have a 'status code' (see *template metadata lifecycle*  
447 *management* in section 6.3 and *template custodian functions* in section 6.4 below).

448 Template Registry item status values shall include provisional, final, nullified, obsolete, plus  
449 there shall be links between multiple versions of templates, as well as between a replacing  
450 and replaced template. These item status values must be accepted by the templates  
451 registry, and no template that does not have a 'final' item status can be published.

452

## 453 4.0 REGISTRATION PROCESSES

454 The Templates Registry has a formal registration process to register a user to contribute to metadata  
455 content. Users are nominated to represent organizations.

456 Registration recognizes a(n):

- 457 • Independent assessment of the custodian organization's qualification/subject matter expertise to  
458 contribute metadata
- 459 • Designation by an organization of an individual to represent the organization at a point of time and  
460 within a specified scope  
461

## 462 5.0 REGISTRY GOVERNANCE

463 Procedures are required to define the processes of:

- 464 • Managing/administering the registry
- 465 • Submission of metadata
- 466 • Maintaining subject matter responsibility for metadata already submitted.  
467

468 The following principles of governance apply and are based upon various metadata registry standards, as  
469 well as on the specific functionality needed to support a templates registry.

470

## 471 **5.1 RIGHTS TO INFORMATION**

472 The Templates Registry is a place to register templates from a variety of sources. The custodian  
473 organization or agency of origin of the registered template shall remain the authoritative source for the data,  
474 and shall retain any rights to such data, whether in paper or digital form. This is true for HL7 Templates and  
475 also for any SDO and SDO-related templates that are contained in the registry.

476 The Templates registry needs to have written and publicly available policies and procedures that govern the  
477 use and access to content. These policies must indicate how the rights of the organization or agency of  
478 origin are protected. The registry must clearly document the intellectual property rights asserted by the  
479 Custodian organization, and make that information available to users of those templates. The registry must  
480 also provide contact information for the originators of the templates. The registry must have processes in  
481 place to identify authorized representatives of information originators and to make agreements with  
482 information originators to maintain data within the registry.

## 483 **5.2 LACK OF BARRIERS AND EASE OF ACCESS**

484 Use of the templates registry shall be open to all persons and organizations that have requirements to use  
485 the material that is maintained within the templates registry. There must be no undue financial barriers to use  
486 of the templates registry. Use of the templates registry shall not be conditional upon membership in any  
487 organization or unreasonably restricted on the basis of technical qualifications or any other such  
488 requirements.

489 Template Custodian Organizations (see section 2.2.2) must be able to supply the templates registry with  
490 information in a computable format for upload and download. The templates registry shall clearly document  
491 the computable formats it supports. Similarly, Templates Information Consumers must be able to download  
492 information in a computable format.

493 Information exchanges with the templates registry should be based upon standards, for example, ISO 15000  
494 (EBXML). For specific SDO's and Standards-based organizations, the relevant template architectures and  
495 Implementable Technology Specifications (ITS's) should be used, e.g. HL7 Version 3: Specification and Use  
496 of Reusable Constraint Templates (the Templates DSTU)).

497 These exchanges must be vendor and implementation neutral with respect to the exchange of templates  
498 registry metadata (for example, the templates registry shall not require a specific operating system or  
499 programming language be used by an information consumer or originator to make use of the information).

500 Templates Registries should to support information access by people with disabilities according to applicable  
501 laws and policies of their country or jurisdiction.

## 502 **5.3 MAINTENANCE**

503 The templates registry supplier has a responsibility to maintain the templates registry infrastructure. This  
504 requires customary maintenance associated with the registry information systems, including such things as  
505 backup, technical support, bug reporting and fixes, and predictable update and maintenance schedules.

506 In addition to the normal maintenance responsibilities, registries act as an intermediary between templates  
507 information consumers and originators (custodian organizations). It will not always be possible for consumers  
508 to determine whether the source of an issue is the templates registry supplier or the custodian organization  
509 (originator). The templates registry must therefore have processes in place that support the communication  
510 of templates information consumer issues to the custodian organization (originators). Likewise the custodian  
511 organization (originators) must have the ability to communicate changes to the templates registry, as  
512 denoted by changes to the template's metadata. Anonymous comments are not permitted.

513 Template registries will be key components for information consumers and originators. Template registries  
514 must therefore take into account the business requirements of those stakeholders to support scheduled  
515 updates of templates registry information. For example, a given template custodian organization may update  
516 its templates on an annual basis, and consumers and originators will have times of peak need with respect to  
517 those annual cycles. Thus, in the case of an annual publication cycle, the updates to the templates registry  
518 must align with “industry best practices” for such annual cycles.

519 Template registries will also need a mechanism to test and validate that the metadata describing their  
520 templates is accurate before it is made publicly available. The registry must therefore document the  
521 mechanisms or processes by which it supports such efforts. Such efforts could for example, be supported by  
522 having multiple versions of the templates registry available for staging and production. This document does  
523 not identify a preferred process; only that such a process must exist.

524 In addition to templates registry responsibilities, custodian organizations (originators) and consumers also  
525 have certain responsibilities. Templates information consumers must agree to use templates registry  
526 metadata only in ways that are described in the registries published policies for use. Custodian organizations  
527 (originators) must agree to maintain the data that they supply to the registry, and make corrections or  
528 updates to it in a timely fashion.

#### 529 **5.4 VERSIONING**

530 Specifications may be superseded over time; the registry should maintain templates registrations of past  
531 versions online for research and reference purposes. There should be a mechanism to uniquely identify each  
532 distinct version of template metadata, and to link each version with its prior version. Templates registries  
533 shall also document the process used to remove or revise information about the registered templates once it  
534 has been published.

535

### 536 **6.0 USE CASES**

537 This section describes the various interactions between stakeholders and systems and the impact of those  
538 interactions on the entities that are managed by the templates registry. It does not provided details on how  
539 the interactions are performed because we have not found any specific requirements that require that level of  
540 detail to be included.

541 Of particular interest to the templates registry are use cases between templates registries, a templates  
542 registry and a templates repository, a templates registry and a set of web and/or service methodologies.

#### 543 **6.1 POLICIES**

544 This section describes use cases around templates registry governance and availability of policy information  
545 to users.

##### 546 1. Review Policies

547 Enables users to review the templates registry policies.

##### 548 2. Accept Policies

549 Enables users to note acceptance of templates registry policies.

##### 550 3. Notification of Policy Changes

551 Used to notify authorized users of changes in policy.

552

## 553 6.2 SECURITY

### 554 6.2.1 Authorization

#### 555 1. Create User Credentials

556 Used to create a user login necessary to modify information maintained in the templates registry.

#### 557 2. Communicate Credentials to Users

558 Used to convey details necessary to log in to the templates registry to the user.

#### 559 3. Activate User Credentials

560 Used to enable the credentials for log in.

#### 561 4. Deactivate User Credentials

562 Used to disable the credentials for log in, without removing them.

563 Note: different classes of users may require different levels of credentials. I.e. a user may only be allowed to  
564 access a certain group of templates according to the custodian organization's authorizing processes. Also,  
565 one organization may be allowed to delegate its authorizing privileges to another organization.

### 566 6.2.2 Authentication

#### 567 1. User Login

568 Used to identify an authorized user of the system.

#### 569 2. Change Password

570 Used to change password.

#### 571 3. User Logout

572 Used to prevent unauthorized use of the system.

#### 573 4. Automated Logout (e.g., Timeout)

574 Used to prevent unauthorized use of the system.

### 575 6.2.3 Audit

#### 576 1. Audit Activity

577 Used to ensure that changes to the information maintained by the templates registry are tracked.

#### 578 2. Review Audit Logs

579 Used to review changes made to ensure appropriate use of the templates registry.

#### 580 3. Request audit report

581 Used by a custodian organization to request an audit activity report of all activity involving their templates  
582 metadata.

### 583 6.2.4 Access Control

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

#### 587 1. Grant New User Access

588 Used to enable a user to access, create or change the metadata associated with a template or group of  
589 templates. . The access may be limited to the registration metadata, the adoption metadata and/or the  
590 various types of annotation metadata.

- 591 2. Modify Access  
592 Used to modify an authorized user's fine-grained access control.
- 593 3. Revoke Access  
594 Permanently remove access, for example when a representative leaves the employment of an  
595 organization.
- 596 4. Permit Access (system function)  
597 Used to permit user access to a specific authorized function. System records user function.
- 598 5. Deny Access (system function)  
599 Used to prevent fine-grained access control. System records user's attempt to perform a function.

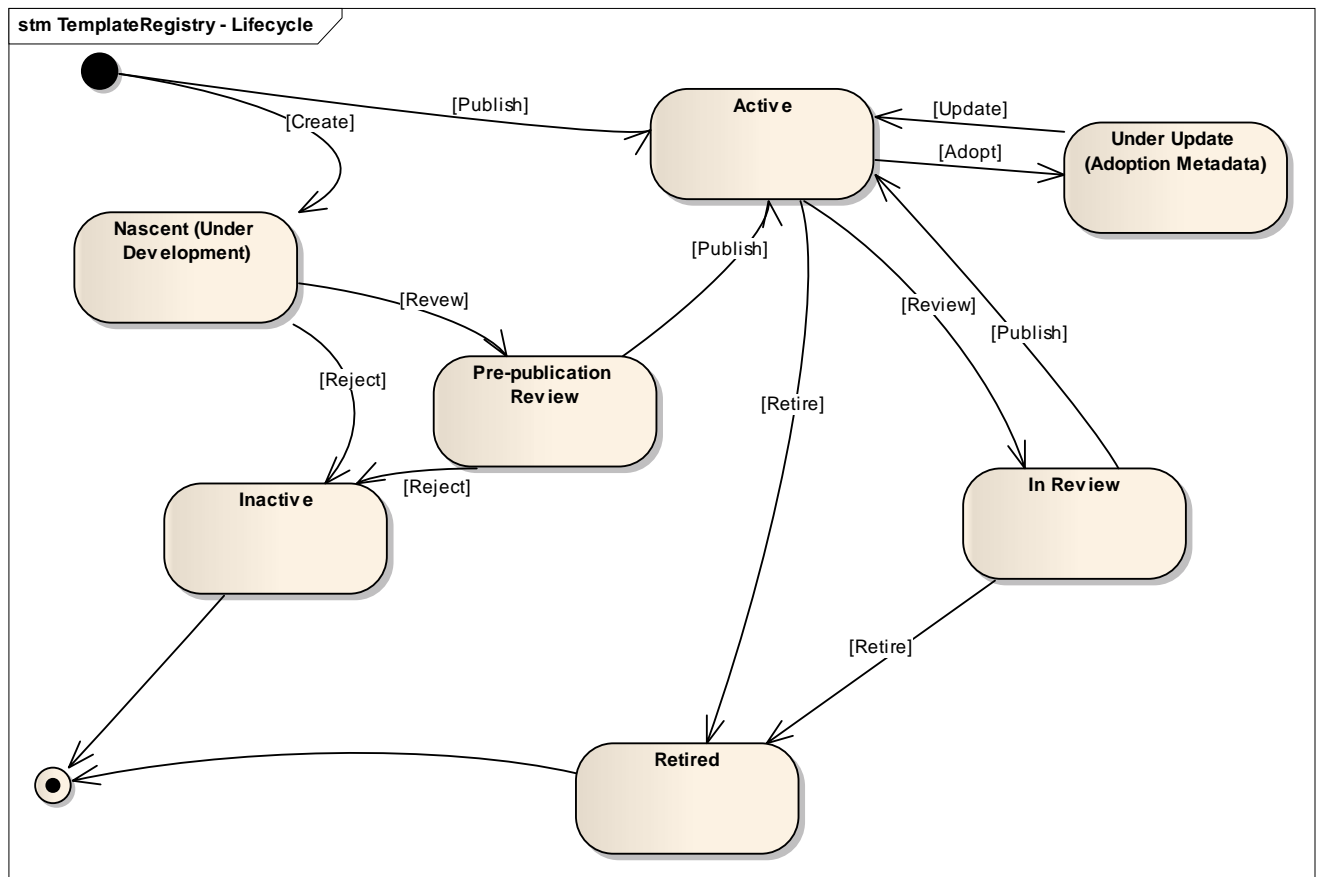
### 600 **6.3 TEMPLATE METADATA INFORMATION LIFECYCLE MANAGEMENT**

601 Template metadata information is contributed by custodian and adopter organizations through a dynamic  
602 and iterative set of business workflow processes. It may also be added via annotations created by registry-  
603 designated annotators.

604 Recall ( section 2.2.2), that the basic metadata (the template's authorship and "authoring system status") is  
605 created by the template authoring system and instantiated in the registry when template metadata is initially  
606 submitted by the custodian organization to the registry. Additional metadata can then be added by the  
607 adopting organization(s), the custodian organization, and the registry organization's annotators.

608 The state diagram below shows the lifecycle of a registration, including the status changes in the registration  
609 itself.

610



611

612 **States**

613 Nascent: Under development. Metadata and template may be incomplete. Entered primarily to encourage  
 614 other users to be aware of ongoing process.

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

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

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

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

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

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

## 632 **6.4 Template Custodian Functions**

- 633 1. Create Item (registry state="Nascent, Under Development")  
634 Create a metadata record for a template that is under development. May solicit advice from all  
635 stakeholders on metadata (registry state = "open for comments").
- 636 2. Create Item (registry state="Active")  
637 Create a metadata record in final form and submit as published.
- 638 3. Review Nascent (Under Development) Item (registry state="Pre-Publication Review")  
639 Users may view submission either on its own or as part of a group of submissions (registry state="Pre-  
640 publication review")
- 641 4. Reject Item (registry state = "Inactive")  
642 Used to remove a submission or a group of submissions (registry state="inactive")
- 643 5. Review Item (registry state = "Under Review")  
644 Used to update published metadata. May result in a new version, or may result in a retired template.
- 645 6. Publish Under Development Item (registry state = "Active")  
646 Used to make an item or all items in a group available to other users of the registry. Prior to publication,  
647 the metadata may only be accessible to certain authorized users of the template custodian organization..
- 648 7. Retire Item (registry state = "Retired")  
649 Used to mark an item or all published items in a group as being retired, an indication that the template  
650 should no longer be used. The metadata is still "published" for research and for historical purposes (and  
651 applies to previous instantiations of the template) and contains valid information, but the template is no  
652 longer recommended for use. Can only be done on the basis of information received from the custodian  
653 organization. An example is the receipt at the registry of a new version of a template or group of  
654 templates from a custodian organization.
- 655 8. Link Item  
656 Used to record an association between two templates in the registry. The link can be structural,  
657 replacement, semantic, validation etc. Can only be done by the custodian of either template but may  
658 also be done on the basis of information received from an adopter organization, or created by a template  
659 annotator. E.g. used when a post-publication review results in the retirement of a template, which is then  
660 replaced by a new template (with a different template identifier).

## 661 **6.5 Template Adopter Functions**

662 Additional metadata may be recorded by a template adopter organization once a template has been  
663 published to assert that that organization is using a template or has a special interest in it (see section  
664 2.2.3 above) and wishes to be notified of future changes to the template's metadata.

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

- 674  
675 1. Adopt  
676 Marks a template registration or group of template registrations as being under adoption update by a  
677 Templates Adopter.
- 678 2. Publish: submits the adoption metadata to the registry.
- 679 3. Adapt (Structural and definitional, adoptive, relational/link).  
680 An adopter organization may adapt (change) an existing template and become the custodian of the new  
681 template (which has a new identifier attribute). It then has responsibility to acknowledge the existing  
682 template as the source/basis of the new template via an appropriate link type. The new template may or  
683 may not supersede an existing template. Linking recognizes there is an adapted/familial relationship  
684 between two templates and that the linked template is not a version of the adopted template.  
685

## 686 **6.6 VERSIONING**

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

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

- 694 1. Create New Version  
695 Used to create a new version of a registration from an existing registration or group. Each version is  
696 maintained as a separate registration with an appropriate link as noted above.
- 697 2. Identify Differences Between Versions  
698 Allows a user to see changes between two different registered templates.

## 699 **6.7 NOTIFICATION**

- 700 1. Notify a templates information consumer of changes to a template or a group of templates. Changes may  
701 be in registration metadata including registration status changes and/or versioning, annotations, or  
702 adoptions.. Also, notify user of updates made in the templates registry software and system  
703 maintenance, update, and testing cycles..
- 704 2. Update Topics of Interest for Notification  
705 Allows a templates information consumer to indicate which topics are of interest with respect to  
706 notifications.

## 707 **6.8 GROUPING**

708 Template registrations may be managed in groups related to the active (published) template. The group of  
709 template registrations may be used, adopted, versioned, implemented, et cetera, as a set as well as  
710 individually. Templates groups may be created by a templates custodian stakeholder or a templates adoption  
711 stakeholder.

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

715 2. Add Template Registration to a Group  
716 Marks a specific template registration as being a member of a specific group.

717 3. Remove a Template Registration from a Group  
718 Removes a specific Template registration from a group.

## 719 **6.9 INTEGRATION**

### 720 6.9.1 Linking Between Template Registries

721 This can be implemented with several common architectural approaches.

722 Users of one registry are able only to view/read another registry

723 Users can have a single sign on to more than one registry. There are several types available on the  
724 web (e.g. Google)

725 Appropriate users (see above) can register templates from another registry. Appropriate users can  
726 just 'quote' registrations, and/or could create 'new registrations', local to this (linked) registry.

### 727 6.9.2 Linking Between Template Registries and Template Repositories

728 A given template registry can be linked to more than one template repository. A given template  
729 repository can be linked to more than one template registry. The relationship between any template  
730 registry/template repository pair will be the same as the relationship between a single template  
731 registry and a single template repository, as previously defined in 5.4, 5.5 and 5.6 above.  
732

## 733 **7.0 REQUIREMENTS**

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

### 738 **7.1 USER INTERFACE REQUIREMENTS**

739 1. Users of the templates registry shall be able to access navigation, search, reporting and download  
740 functions within a web browser.

741 See section 7.8 for Search, Browse and Reporting requirements that users must have access to,  
742 according to their credentials.

743 See section 5.2 for governance requirements affecting the web browser user interface.

744 2. The user interface should support information access by people with disabilities. These standards  
745 vary according to country of use. See section 5.2

### 746 **7.2 COMMUNICATION OF POLICY**

747 This section describes the requirements for templates registry governance and availability of policy  
748 information to users. See sections 5.1 and 6.1.

749 1. The templates registry shall to have written and publicly available policies and procedures that  
750 govern the use and access to content. These policies must indicate how the rights of the  
751 organization or agency of origin are protected.

752 2. The templates registry shall clearly document the intellectual property rights asserted by the owners  
753 of the information they retain, and make that information available to users of that information.

- 754 3. The templates registry shall provide contact information for the originators of information they  
755 maintain.
- 756 4. The templates registry must have processes in place to identify authorized representatives of  
757 information originators and to make agreements with information originators to maintain data within  
758 the templates registry.
- 759 5. The templates registry shall provide a mechanism to allow a user to review the policies prior to  
760 obtaining credentials to use the templates registry.
- 761 6. The templates registry should have a mechanism to note the user's acceptance of the policies  
762 established for its use.
- 763 7. The templates registry should have a mechanism to notify authorized users of any changes in  
764 policies.

### 765 **7.3 Security Requirements**

#### 766 7.3.1 Authorization

767 Authorization is necessary to identify users that make changes to information in the templates registry.  
768 These requirements may not apply to users who are just viewing templates registry content. See section  
769 6.2.1.

- 770 1. The templates registry custodian shall have a process to establish the identity of an authorized user.
- 771 2. There shall be a way for the templates registry supplier to create a set of user credentials for an  
772 authorized user.
- 773 3. There shall be a way for the templates registry supplier to securely establish or communicate the user  
774 credentials to the authorized user.
- 775 4. The system shall have a mechanism to activate and deactivate a user's credentials.
- 776 5. When a user's credentials have been deactivated, the system shall not allow her to log in. It may report  
777 the reason for not allowing her to log in.
- 778 6. The system should have a mechanism to allow a user to have his credentials communicated to him on  
779 demand (e.g., lost log-in or password).
- 780 7. The system should have a mechanism to allow the user to change or reset her password.

#### 781 7.3.2 Authentication

782 Authentication is necessary to identify users that make changes to information in the templates registry.  
783 These requirements may not apply to users who are just viewing templates registry content. See section  
784 6.2.2.

- 785 1. The system shall not allow a user to perform any alterations to templates registry content without first  
786 communicating his credentials (logging in).
- 787 2. The system shall allow the user to log out manually.
- 788 3. The system should automatically log a user out at after a preset time of no activity.

789

### 790 7.3.3 Audit

791 See section 6.2.3.

- 792 1. All activity that changes the content of the templates registry shall be audited, storing the date, time (at  
793 least to the second), and authorized user who changed the information and the identity of the workstation  
794 that he was using.
- 795 2. Upon review of any information in the templates registry, a user shall be able to identify when the  
796 information being shown was last changed. More detailed information may be shown depending upon  
797 the policies of the templates registry (e.g., identity or location of the user making the change).
- 798 3. Template Registry Administrators shall be able to view the complete audit record of changes made to the  
799 content of the templates registry.
- 800 4. Template Registry Administrators shall be able to organize and filter the audit information by the  
801 date/time of the record, the identity of the user making the change, or location where the change was  
802 made, or the type of change made.

### 803 7.3.4 Access Control

804 This section specifies that users other than Templates Registry Administrators could manage access rights,  
805 but does not require that capability. See section 6.2.4.

- 806 1. An authorized user shall be able to grant, revoke, or explicitly deny access rights to change or view (write  
807 or read) information in the templates registry to other authorized users.

## 808 7.4 Versioning

- 809 1. The templates registry shall support registration of multiple versions of a template (or group of  
810 templates), and also of the adoption of a template (or group of templates).
- 811 2. The templates registry should have the ability to identify the differences in the metadata between two  
812 versions of a template (or group of templates) or two versions of an adoption (or group of adoptions)

813 See section 6.6 for further details.

## 814 7.5 Notification

- 815 3. See section 6.7 and section 5 (Registry Maintenance) for notification use cases and governance  
816 aspects. Note that in the case of federated registries or registries with multiple templates repository  
817 sources, notification requirements need to address coordination issues. The templates registry shall  
818 have a way to notify users of updates to its content.
- 819 4. The templates registry should support a mechanism for users to indicate which topics are of interest with  
820 respect to updates.
- 821 5. Updates should be delivered using well-established industry standards (e.g., e-Mail, List Servers, or  
822 subscription feeds such as ATOM or RSS).
- 823 6. The templates registry should provide a mechanism to group notification updates so that a single user  
824 does not get a large number of update notifications at the same time.
- 825 7. The templates registry may provide the user with a mechanism to indicate the frequency at which  
826 updates will be reported (e.g., daily, weekly, monthly, et cetera).

827 8. The templates registry shall have the ability to notify users of updates made in software and system  
828 maintenance and testing cycles

829 9. The templates registry shall have the ability to notify users of a pre-release, use test environment for a  
830 template or group of templates.

## 831 7.6 TEMPLATES REGISTRATION AND MANAGEMENT

832 See Section 6.3. for the Template Registration state transition diagram.

833 The templates registry shall provide a mechanism to allow an authorized user and/or stakeholder to  
834 create and revise an artifact's registration as follows:

835 1. The templates registry shall provide a mechanism to group a collection of registrations so that they can  
836 be managed as a unit for the purpose of managing their lifecycle.

837 • E.g. This allows different groups of templates, approved for different organization's use cases, to be  
838 versioned, adopted, updated replaced asynchronously.

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

844 3. The templates registry shall provide a mechanism to mark an artifact's registration state as *active*,  
845 *nascent (under development)*, *inactive*, *in pre-publication review*, *in review*, *under update (in process of*  
846 *being adopted)*, *retired*.

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

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

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

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

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

857 • A template in *post-publication review* may transition to *active* (with a new version number, but the  
858 same template identifier), or to *retired* after appropriate review by registry stakeholders.

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

862 4. The templates registry should support partitioning of information so that different authorized users can be  
863 responsible for the management of different artifacts without interfering with each other. This capability  
864 is needed because different people within an organization may be responsible for different groups of  
865 metadata maintained within the templates registry.

- 866 5. Partitioning of information described above shall not interfere with searching information within the  
867 templates registry.
- 868 6. The templates registry shall support the metadata specified for the registered artifacts in TN903 (HITSP  
869 specified metadata) and the HL7 Templates DSTU <sup>7</sup>
- 870 7. The templates registry shall provide a mechanism to upload registered artifacts in bulk.
- 871 8. The templates registry shall provide a mechanism to update a single registration.
- 872 9. The templates registry shall provide a mechanism to annotate registrations with supportive metadata of  
873 the types mentioned in section 3 (semantic tags and links, structural links & transformational links), as  
874 well as adoption metadata (see next section).

## 875 **7.7 ADOPTIONS**

876 A registered artifact can be approved before or after publication, and may be approved by one or more  
877 approving organizations. See section 6.5.

- 878 1. The templates registry shall support recording adoptions that have been provided for a template or a  
879 group of templates.
- 880 2. The templates registry shall support expiration or withdrawal of adoptions for a template or a group of  
881 templates
- 882 3. The templates registry shall support the ability for the delegation of adoptions from one Templates  
883 Adoption stakeholder to 1 to many other Templates Adoption Stakeholders.

## 884 **7.8 Search And Browse**

### 885 7.8.1 Search

886 Search capabilities described below are assumed to be performed as user specified “queries” upon the  
887 templates registry. This is not, however, intended to restrict the user interface for the implementation of  
888 these capabilities. Note that unless specified otherwise, search fields are any of the fields in the 3 types of  
889 template metadata: registration, adoption or annotation metadata.

890 The templates registry shall support search for registrations by the registration metadata specified for these  
891 templates in update by reference<sup>8</sup>

- 892 1. The templates registry shall support search for registrations for templates by the content of the adoptions  
893 received or the contents of the registration for those templates.
- 894 2. Search capabilities shall include searches on the content of the various annotation types mentioned in  
895 section 3 (semantic tags and links, structural links & transformational links), as well as adoption  
896 metadata.
- 897 3. Search capabilities shall include search by template registration metadata including: name, identifier,  
898 source, purpose, definition, type, version, status, creation, revision, effective or expiration dates,  
899 associated metadata (e.g., code system for a value set or value set for a template registry metadata  
900 attribute, related templates for a template, etc.), and classifications within external ontology.

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<sup>7</sup> See <http://wiki.hitsp.org/docs/TN903/TN903-1.html>, Table 4-10 and also HL7 Templates DSTU (add references)

<sup>8</sup> See <http://wiki.hitsp.org/docs/TN903/TN903-1.html>, Table 4-10 and also HL7 Templates DSTU (add references)

- 901 4. Registries should support Exact, Full Word, Contains, Begins-with, Ends-with and Wild cards on the  
902 name, purpose and definition fields of the registration, adoption or annotation metadata.
- 903 5. Search capabilities on text fields in the registration, adoption or annotation metadata (e.g., name,  
904 purpose, definition) should support some degree of approximate matching.
- 905 6. Search capabilities on classification fields in any of the 3 types of metadata (registration, adoption or  
906 annotation metadata) (e.g., keywords or other ontological associations) should support search based  
907 upon inclusion in a hierarchy.
- 908 7. Search capabilities on date fields in all metadata should support date ranges.
- 909 8. Search capabilities on identifier and version template registration metadata fields shall support exact  
910 match, and need not support any more complex capability.
- 911 9. Searching shall support at least complex and/or logic and grouping <'level1'>, but need not support full  
912 Boolean expressions <more advanced claim>. It is acceptable to support finding all metadata records  
913 meeting all user specified criteria, or meeting at least one of the user specified criteria.
- 914 10. Searching using an external ontology should support search by the semantic links supported by the  
915 external ontology (e.g. the ontology-based searches supported by IHTSDO.)
- 916 11. Users should be able to search within previously returned search results.
- 917 12. The templates registry should support both summary and detailed views of the results returned from a  
918 search.
- 919 13. The templates registry shall be able to query the registrations from a web browser.

#### 920 7.8.2 Browse

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

- 924 1. The templates registry may support preset or custom configured user specific views of registrations  
925 based upon user preferences. These views should incorporate the needs of users in various roles:
- 926 ▪ Health Information Technology (HIT) system users interested in the meaning and context of  
927 templates used in standards, regulations, policies, reports, and application systems
  - 928 ▪ Researchers requiring an understanding of the meaning over time of the templates in the registries  
929 for use in longitudinal studies or the development of quality measures.
  - 930 ▪ Implementers of HL7 templates registry specifications interested in the meaning, context, and  
931 representation, including domain values, of artifacts used in HL7 templates registry specification for  
932 use in the development of the application systems or commercial-off-the-shelf products.
  - 933 ▪ Developers of standards and implementation guides or HL7 templates registry specifications  
934 reviewing artifacts that may be incorporated into those publications.
  - 935 ▪ Adopters reviewing artifacts and related registrations for adoption for regulation or other uses.
  - 936 ▪ Educators and students engaged in the study of health informatics to understand the use of the  
937 registered artifacts in information systems and research.

- 938 2. The templates registry shall support browse or preconfigured queries that enable users to locate  
939 registrations by the attributes in any of the three types of metadata: registration, adoption and  
940 annotations. (see section 3.0)
- 941 3. The templates registry should support navigation of registrations by classification schemes or  
942 ontologies associated with any of the coded attributes in any of the three types of metadata:  
943 registration, adoption and annotations. (See section 3.0).
- 944 4. The templates registry should support navigation of registrations by the health information standards  
945 categories where the metadata artifact fits into a standard's information model. I.e. it should support  
946 navigation based on identifying various information exchange standards utilized and standard  
947 specific data structures (e.g., HL7 v3 observations vs. encounters vs. SubstanceAdministration,  
948 Eligibility vs. Prior Authorization, HL7 v3 CDA templates et cetera).
- 949 5. The templates registry should support both summary and detailed views of the results returned from  
950 navigation.
- 951 6. The templates registry shall be able to navigate the registrations in a web browser.

### 952 7.8.3 Reporting

- 953 1. The templates registry shall be able to produce reports of registered artifacts associated with a  
954 particular HL7 publication (i.e. Standard or implementation guide, or conformance specification). The  
955 same requirement applies to registered templates created by other SDO's or SDO-related  
956 organizations.
- 957 2. Reports shall be viewable in a web browser.
- 958 3. Information contained in reports shall be downloadable in a format suitable for import into a database  
959 or spreadsheet application (e.g., Comma Separated Values as specified in [RFC 4180](#)).
- 960 4. Information contained in reports should be downloadable in a standards-based XML format (e.g., as  
961 specified in ISO 15000<sup>9</sup> or ISO 11179 Part 3 Edition 3<sup>10</sup>).
- 962 5. Specifications of the file formats used for downloading reports shall be documented and accessible  
963 to users of the templates registry.
- 964 6. The templates registry shall be able to indicate all HL7 templates registry publications associated  
965 with a particular registration. The same requirement applies to registered templates created by other  
966 SDO's or SDO-related organizations.
- 967 7. The templates registry should be able to report on associations between different artifacts and the  
968 types of associations between them. E.g., Value sets used by a template attribute; template  
969 attributes using a particular value set; templates requiring or using other templates, et cetera.
- 970 8. The templates registry shall provide a mechanism to view the reports in a web browser.
- 971 9. Detailed reports shall be available that support download of all metadata for the any template in the  
972 templates registry.

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<sup>9</sup> This specification has been published and contains a schema to record registration information.

<sup>10</sup> Note that Edition 3 of ISO-11179-3 is not yet published and it is not clear that an XML schema will be published in it.

## 973 7.9 INTEGRATION REQUIREMENTS

974 This section describes requirements that entail integration between different types of templates registries and  
975 a templates registry and its associated template information sources (templates repositories). See section  
976 6.9.

- 977 1. A templates registry should be able to show the relationships between registered HL7 templates and  
978 registered templates using methodologies of other standards development organizations (SDO's) or  
979 SDO-related organizations.
- 980 2. A templates registry should be able to show the formal constrained vocabulary bindings for each of  
981 its metadata attributes (including intentional value sets). This ability will vary with the coding system,  
982 and the types of vocabulary bindings supported (e.g. CTS1, CTS2 (under development), Terminfo,  
983 Snomed Workbench, OWL2-based, etc.)
- 984 3. A templates registry should be able to show the containing/contained by relationships between  
985 templates.
- 986 4. A value set templates registry should be able to show the derivation relationships between  
987 templates. I.e. Template "X" is derived by constraints (allowed by the template methodology) from  
988 Template "Y".
- 989 5. A value set templates registry should be able to show the relationships between a value set and the  
990 templates that bind that value set to a metadata attribute, or non-metadata attribute managed by the  
991 template information supplier (repository).
- 992 6. A template templates registry should be able to show the relationships between a template and the  
993 template metadata attribute (or a non-metadata attribute managed by the template information  
994 supplier (repository) that are constrained by that template.

## 995 7.10 UPLOAD

996 A single publication may specify metadata for a number of artifacts that could be registered. This section  
997 describes requirements for uploading the metadata for a single publication.

- 998 1. The templates registry shall support the creation of registration artifacts by upload of the metadata in  
999 a single transaction's payload (for message, service or document). Such transactions can be created  
1000 using standards such as HL7, XML and/or other relevant SDO or ISO standards (e.g. ISO 15000 and  
1001 ISO 11179 part 3 rev 3).
- 1002 2. Classifications are supported by ISO 15000.
- 1003 3. The payload description format shall be standards based and should be identical to one of the  
1004 formats used for download of registration information.
- 1005 4. The format shall support grouping of the registrations.

## 1006 7.11 SYSTEM TO SYSTEM COMMUNICATION

1007 The specific use cases mentioned in sections 5.8.1 (Linking between templates registries) and 5.8.2 (linking  
1008 between template registries and template repositories) shall be supported.

1009 This needs to be followed up on jointly by HL7 Tooling Work Group in order to understand the specific  
1010 requirements between Information Systems being able to implement semantically interoperable  
1011 communication based on existing registry standards.

1012 **7.12 AUTHORIZING TOOLS**

1013 The templates authoring tools shall support the templates registry information and communication and  
1014 integration requirements expressed in this document.

1015 This business process analysis needs to be followed up on jointly by the HL7 Tooling WG and OHT in order  
1016 to understand what specific requirements are shared between HL7 Tooling WG and the parallel group in  
1017 OHT.