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**HEALTH LEVEL
SEVEN**

Introducing New Processes to HL7 January 2012 Ballot

Project Services Work Group

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<http://www.hl7.org/Special/committees/projectServices/leadership.cfm>

January 2012 Ballot

<http://gforge.hl7.org/gf/project/psc/docman/?action=DocmanFileEdit&id=7225>

For prior versions of this document refer to:

<http://gforge.hl7.org/gf/project/psc/docman/?action=DocmanFileEdit&id=7225>

This document defines the approval and adoption methodology for non-standards process artifacts. It is produced by the Project Services Work Group at the request of the Technical Steering Committee.

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Change Log (to be deleted prior to final publication)

V2	Additions to V1 are redlined and commented
V3	Add Appendix to document decisions Add Appendix – Peer Reviews
V4	Incorporate edits Dave Hamill Added cover page Rearranged appendices
V5	Incorporated edits from review on 5/12/2011 PS call. Saved all revisions and removed comment. Removed Appendices except Appendix A – Peer Review
V6	Added ArB determination and corrected typo re: number phases pg 4
V7	Incorporated revisions discussed with SAIF AP 07/06/2011 including: <ul style="list-style-type: none"> • add mention of Pilot Process under 4c Success criteria and 4d Project Objectives / Deliverables / Target Dates • Add references to Work Group Health Metrics for Encouraged and Managed processes • Add Wiki based Informal Comments for Validation <p>Also need to update the Project Scope Statement template: If non-product project, indicate if it proposing a new or modified process; this could be used for routing to the ArB for their review</p>
V8	Incorporated revisions from 07/14/2011 PS call: <ul style="list-style-type: none"> • Added notes in Initiation Section for discussion with SAIF AP • Revised link to Peer Review forms posted
V9	Incorporated revisions from 07/21/2011 PS call: <ul style="list-style-type: none"> • Revised the Initiation section to describe work efforts not defining a project scope statement per input from the SAIF AP. • Added reference to the Workgroup Scratchpad Webspaces project under Outstanding Issues
V10	Minor edits from 07/28/11 PS call
V11	Edits from 08/10/2011 SAIF Architecture Program call.
V12	Incorporates edits from the TSC (September 10, 2011 meeting at the Plenary WGM.) This version balloted January 2012.

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Overview

HL7 has a well defined methodology for producing standards, but the method to introduce new processes and move them to adoption and deployment throughout the HL7 organization is more obscure/ad hoc. The Technical Steering Committee (TSC) requested Project Services to evaluate this issue.¹ This white paper evaluates the issues and proposes a standard approach to introduce new processes to HL7, pending TSC approval.

This document assumes processes will be documented and will be generically referred to in this document as “Process Artifacts.”

If this adoption process had existed when the following artifacts were created, they exemplify the type of operational items that would follow this process during their initial creation: Project Scope Statement Template, Project Approval Process, and Publishing Facilitator’s Guide. The Security Cookbook is another example, and the Cookbook was the impetus for the TSC to request Project Services to define this new adoption process.

- Related (potentially impacted): Innovation Work Group (WG) and Incubation branding, Services Aware Interoperability Framework (SAIF) Governance, SAIF Implementation Guide, and the [Governance and Operations Manual](#) (GOM)

Initiation

The creation of Process Artifacts may be defined by a Project Scope Statement (PSS) which follows the appropriate approval process:

<http://www.hl7.org/permalink/?ProjectScopeStatement>

If the Architecture Review Board (ArB) is not in the normal approval chain for the project, they must be consulted separately to review the project to determine if there is impact to the Services Aware Interoperability Framework (SAIF) managed by the ArB .

Alternatively, a Work Group/Committee may determine a PSS is not required, for example, if the work effort is contained within the Work Group/Committee with no external coordination required; for example the Common Message Element Types (CMET) Management Process involves facilitators communicating within the Modeling and Methodology (MnM) Work Group, so a PSS was deemed unnecessary. If the work does not follow the PSS process, there may be pushback from the TSC, ArB, or Steering Division (SD) if the work adversely impacts other

¹ Additional information at TSC tracker:

http://gforge.hl7.org/gf/project/tsc/tracker/?action=TrackerItemEdit&tracker_item_id=1681&start=0

This is TSC escalation of PS Tracker # 1591 and Project Insight #740

http://gforge.hl7.org/gf/project/psc/tracker/?action=TrackerItemEdit&tracker_item_id=1591&start=0

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groups. (The adversely affected work group may petition the Steering Division and/or the TSC to recommend that the group create a Project Scope Statement.)

The following lists pros/cons for creating a Project Scope Statement:

Pros	Cons
<ul style="list-style-type: none"> • Communicates work effort (via Project Insight, project page WG webpage, included in PBS metrics, communicate to co-chairs list) • Clearly defines scope and impacts of proposed Process Artifact change 	<ul style="list-style-type: none"> • May not fit formal project definition as defined in the FAQ section of the Project Scope Statement • Perceived as too much work for small item

Development

Once the project is approved, the team responsible for the project follows their normal process to develop Process Artifacts.

- Socializing the initiative as it is in development allows other interested parties to participate in the development and creates awareness for eventual deployment. Socialization Methods include:
 - Brief updates at Working Group Meeting (WGM) Co-Chair Meetings
 - Updates at Steering Division Meetings
 - General Session slides at WGM
 - eNews (weekly)
 - Co-Chair list-serve update (weekly)
 - HL7 Newsletter (Trimester prior to WGM)
- Some Process Artifacts may be subject to annual updates; Project Services recommends including these in your Work Group’s Three Year Plan.

Validation

After completion of the Process Artifact, the validation phase elicits feedback from the HL7 community.

- Based on the nature of the artifact, it may be validated through one of three methods:
 - Comment Only Ballot – this is discouraged because of the timing associated with a ballot cycle (minimum 60 days for announcement and comment period) and required review as defined in GOM 13.03.04.
 - Wiki based Informal Comments - this method can use a simplified version of the familiar ballot comment spreadsheet, or informal comments entered directly on the wiki. Details on the format/location of the wiki access will be determined by each project team.
 - Peer Review² process – this method collects comments using a variety of simplified forms, with an individual, or task force, reviewing/applying updates.
- It is at the discretion of the sponsoring group(s) which validation method to use. All have pros and cons discussed on the following page:

² Refer to Appendix A for additional information on Peer Reviews.

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Comment Only Ballot		Wiki based Informal Comments		Peer Review	
Pros	Cons	Pros	Cons	Pros	Cons
Community more familiar with ballot review process	Competing with other ballots	Community more familiar with ballot review process; can use simplified ballot spreadsheet for comments	Possibility of less security of comments if wiki edits are supported	Can be scheduled out of cycle with ballots to ease “ballot fatigue”	Community is less familiar with peer reviews
Methodology to track and reconcile comments	Reconciliation required as defined in GOM 13.03.04	Can be scheduled out of cycle with ballots to ease “ballot fatigue	May not get people’s attention	Methodology to track and reconcile comments; multiple formats available	May not get people’s attention
		Methodology to track and reconcile comments if using simplified ballot spreadsheet		Faster to produce iterations of artifacts since formal reconciliation not required	
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Adoption

Adoption will follow three phases:

Piloted:

A couple of projects will pilot the new process defined by the Process Artifact and report back on experience. The sponsoring group, with input of the Technical Steering Committee or other governance, will determine the number of pilots required. Typically one (alpha) or two (beta) are adequate to test the process. During this step, contact the SAIF Architecture Program (AP) for input on the Pilot; the SAIF AP may determine the pilot impacts their process and may incorporate it into their processes.

Endorsed:

Work Groups are informed about the new Process Artifact and can chose to use it if they want to.

- At least three methods will be used to inform the HL7 community about the new process:
 - Announce to Co-Chairs list
 - Announce at WGM Co-Chairs Monday Meeting
 - Article in HL7 eNews
 - Article in HL7 Newsletter
 - Offer free information forum (to be coordinated with Education WG)
 - Offer recorded education session
 - Twitter
- Dependent on the process, a registry tracking usage may be needed, with a defined feedback loop, similar to the Draft Standard for Trial Use (DSTU) process.

Implemented

Finalized Process Artifacts are deployed in one of two ways:

a. Encouraged:

Projects must either use the Process Artifact, or document why they are diverging from the guidance. The sponsor group should state the reason for the divergence, for example to allow experimentation with different process, or to allow for unforeseen circumstances. Encouraged processes may be added to the Work Group Health metrics at the discretion of the TSC.

b. Mandated:

The Process Artifact process must be followed by the stated deadline. Mandated processes may be added to the Work Group Health metrics at the discretion of the TSC.

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Appendix A - Peer Review³

Peer Reviews are used in many settings, particularly academic and professional settings, with the first known Peer Review dating back to 1665.⁴

As adapted in HL7, a peer review can be used by HL7 Work Groups and committees to perform quality assurance on artifacts and solicit additional input. The purpose of the peer review is to help encourage a more complete review without necessarily going through the rigor of a complete ballot process. The review can also cover "partial" or incomplete artifacts

Peer Reviews can be scheduled outside the ballot review schedule to avoid "ballot fatigue." Some Work Groups have used the Peer Review process to ready the content so their ballots passed in single cycle.

Peer Reviews involves up to 6 steps:

1. An artifact is produced to a level that is deemed to be "as complete as possible without review" or ready for review outside the authoring group. For example:
 - A task force group solicits input from the sponsoring Work Group
 - A sponsoring Work Group solicits input from other co-sponsoring Work Groups for specific project artifact deliverables
2. Upon agreement from the respective Work Group the author of the artifact distributes the artifact, together with the announcement and a peer review form; multiple options for the peer review comment collection are available.⁵
 - Optionally, the author can schedule a Question & Answer (Q&A) meeting scheduled to walk through the artifact or otherwise assist reviewers in their review
 - The announcement includes the review period and instructions for posting comments.
3. Reviewers go through the artifact identifying issues and concerns, capturing each one as a distinct row in the peer review form
 - The peer review form is similar to a ballot comment spreadsheet, but with less information and not subject to formal reconciliation requirements
4. Reviewers submit their peer review forms as directed in the announcement; forms must be submitted by the submission deadline.
5. The author(s) reviews the peer review forms, identifying proposed dispositions (accepted, rejected, clarification)
6. The author(s) finalizes the Peer Review by either:
 - Scheduling a Peer review call to lead the Work Group (and other reviewers) in a walkthrough of the review comments, confirming resolutions, answering questions, identifying rationale for rejections, etc.
 - Applying comments to the artifact and publishing the next version. The subsequent version may be ready for another round of Peer Review, possibly widening the

³ Adapted from http://wiki.hl7.org/index.php?title=Peer_review. The Peer Review process above is recommended by the Project Services Work Group.

⁴ http://en.wikipedia.org/wiki/Peer_review

⁵ Peer Review forms are available at: <http://gforge.hl7.org/gf/project/psc/docman/admin/?subdir=340>

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targeted reviewers, or submitted for ballot with concurrence of the sponsoring Work Group.

DRAFT