PSS Help and FAQs

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Publication Date: November, 2018

Project Scope Statement Purpose:

This Project Scope Statements is intended for products used outside HL7, such as projects to produce standards or Implementation Guides. **Infrastructure projects** (**the RIM, HL7 maintained vocabulary, wrappers, and methodology**) should also use this scope statement but are not required to complete all sections as noted in the instructions.

The objective of this template is to communicate the type of activities a group is undertaking to achieve specific objectives or to produce specific work products. Project Scopes should provide sufficient information to allow inexperienced individuals to anticipate what a group is working on and decide if they wish to become involved. Project Scope statements should also assist committee chairs to manage the workload of the committee and help to set priorities and recognise inter-dependencies with the work of other committees.

The Steering Divisions, TSC, and other appropriate approval bodies, as defined by the HL7 organization and Project Approval and Initiation Process, review and approve the project request. This includes analysis to avoid project overlaps or dependency gaps. A project not aligned with HL7 strategies established by the HL7 Board, or requiring extensive resources may not be approved. A "hosted" project (funded by an external source) may be approved as long as the sponsors provide adequate resources and the project is not detrimental to HL7 strategy; funding may be in the form of resources or financial support, grants, etc.

Required Information:

The HL7 Project Management Office (PMO) will review project statements to ensure the names and descriptions are clear and unambiguous across all projects and that required information is provided so as to obtain project approval.

Project Insight Note:

The following instructions indicate how the information in this form is mapped to certain fields in Project Insight's project description form. The fields are mapped to specific fields in the project description form available in Project Insight: http://healthlevelseven.projectinsight.net/Login.aspx?ReturnUrl=%2fdefault.aspx

If you need system login setup for Project Insight, contact the HL7 Director of the Project Management Office at pmo@hl7.org

Recommendation for Non-infrastructure Projects:

The HL7 Product Lifecycle recommends ballots proceed through **Informative à STU à Normative** phases, however, HL7 policy allows projects to proceed to normative ballot without an Informative or Draft Standard for Trial Use (STU) in special circumstances, such as such the need to respond to government mandate or resolve a critical issue raised by a stakeholder or noted in an existing American National Standard. Bypassing the Informative and/or STU ballot must be approved by the TSC. Refer to the HL7 Governance and Operations Manual Section 13 – Review Ballot and HL7 Essential Requirements.

Project Name and ID

The name should be concise, based on the objective and unique among all other projects the group takes on; refer to GOM §12.02 Naming Convention for naming convention guidance. ***Project Insight:*** *Enter into "Name".*	Project ID: A project ID will be assigned by Project Insight

TSC Notification Informative/STU to Normative: The Project Facilitator shall complete this section for all "Direct to Normative" ballot projects and when a project proceeds from "Informative to Normative" or "STU to Normative" and send the PSS to the TSC (via the TSC Project Manager). It is not necessary to notify the Steering Division (SD) Co-Chairs to seek re-approval unless there has been a "major" or "significant' change in the project scope (as described in the FAQ section). Since the projected project/ballot dates often change during the course of a project, TSC notification that the project is moving to a normative state is required to fulfill ANSI Project Initiation Notification (PINS) reporting requirements. Please refer to the HL7 Governance and Operations Manual and ANSI Essential Requirements for more detail. ***Project Insight:*** *Enter into "Misc Notes".*

Sponsoring Group(s) / Project Team

Primary Sponsor/Work Group (1 Mandatory): Every project must have only one project sponsor and at least one project facilitator; a multi-disciplinary project team is recommended, e.g. domain expert, UML modeling facilitator, HL7 modeling facilitator, requirements process facilitator, data analyst facilitator, business requirement analyst. Sponsorship may be in the form of resources or funding. ***Project Insight:*** *Enter into "Sponsor(s)".*
Co-Sponsor: When Co-sponsor Work Groups are defined, the Primary Sponsor/Work Group shall negotiate with the Co-Sponsor Work Groups the extent of their involvement; this task may be assigned to the Project Facilitator. Examples of negotiated agreements:·   Request formal content review prior to ballot·   Request period project updates, specify period (for example, monthly, at trimester Working Group Meetings, etc)·   Other agreements***Project Insight:*** *Enter into "Co-Sponsor(s)"*
Project Facilitator (1 Mandatory): This is mandatory for all projects and should be the contact person if there are questions about the Project Scope Statement. The Project Facilitator serves as the Project Lead; the 'go to' person for the project who can answer questions regarding status, scope, objectives, issues, risks, etc. regarding the project. Additional definitions of Project Facilitator responsibilities are at: http://gforge.hl7.org/gf/project/psc/docman/Project%20Facilitator%20Responsibilities. ***Project Insight:*** *Enter into "Project Facilitator".*
Other Interested Parties: This section should also describe other 'interested parties', e.g. anticipated interactions with other committees or other projects. Examples of anticipated interactions that must be negotiated in advance:·   Request content review prior to ballot·   Request period project updates, specify period (for example, monthly, at trimester Working Group Meetings)·   Other agreements
Facilitators: Modeling, Publishing, and Vocabulary facilitators are formal roles recognized by HL7, and highly recommended as project participants. If your project has not filled this role, please indicate a contact person for the role, for example, your project may not have a formal vocabulary facilitator but a committee participate has volunteered to serve as liaison with the Vocabulary Committee. .Descriptions of facilitator roles and their responsibilities can be found on the HL7 Wiki via PIC's Find or Be a Volunteer for an HL7 Work Group .
Infrastructure projects, for example, the RIM, HL7 maintained vocabulary, wrappers, and methodology are required to name only the Primary Sponsor and Project Facilitator.

Implementers (2 Mandatory): If this project will produce a standard, identify at least two implementers who agree to implement a STU prior to normative ballot (this is a non-binding agreement). Contact information is mandatory. The intended implementers must be identified at project initiation; however, it is a non-binding agreement. Refer to explanation of Candidate Standard validation below for additional information. ***Project Insight:*** *Enter into "Project Implementers".*	

Candidate Standard validation

Candidate Standard validation	Executing the Candidate Standard validation approach. HL7 will have a modified open approach to candidate standard validation. All those participants that made a non-binding commitment when the project was initiated will be included if they choose to honor the commitment. Others may be added to achieve a balance or for other necessities for validation. The previous notwithstanding, HL7 will limit the number of participants to ensure a manageable process and reasonable time frame.
Candidate Standard validation approach	A project step that ensures that the Candidate Standard is validated by external industry resources before it is finalized as a normative standard. Where the standard is for interoperability, it is expected that the validation will include at least two independent entities (vendors, user organizations, etc.) building trial implementations and testing them together. Where the standard serves another purpose the validation approach will involve a trial effort to use the draft standard in the manner for which it was created. At the planning stage the entities willing to test must make a non-binding declaration of their intent to participate in validation. Without such a declaration the project should not be initiated. **Comment:** This is expected to be a significant hurdle for new project initiation. At the same time it helps to assure that HL7 member resources will be concentrated on efforts that have a greater likelihood at industry adoption.

Project Definition

The detail should be sufficient that an individual with no previous exposure to the group (or even HL7) could understand the expected activities and results. The scope description should also include high level expectations for the project and indicate alignment with market demands or other drivers for the project, such as government mandates, requirements from industry interoperability connectathon, etc. Also include if the project is abandoning or replacing anything, as well as if the deliverables are applicable to multiple realms. Be sure to spell out all acronyms which the HL7 community is not familiar with as these are carried forward to the NIB (Notice of Intent to Ballot) for ballot announcements.   Typically projects to produce standards are routinely supported by the volunteer resources committing to complete the project, and HL7 in the form of meeting rooms, conference call facilities, etc. If additional funding is required, you must provide a budget for the project. A proposed budget is required for any project that will be contracted, for example, website redesign or tooling development.   ***Project Insight:*** *Enter into "Description".*
FHIR Project: This project will identify and define the initial set of "key" FHIR resources related to the domain of Your domain name. These resources will be defined using the available FHIR tooling and in accordance with documented quality guidelines and balloted as part of the initial FHIR specification. Expected FHIR resources to be produced include: List expected resource names (need not be all and need not be pre-approved).   In addition, as the committee deems appropriate and time availability permits, it will define a small number of FHIR extensions relevant to domain content and expected to be necessary to support consistent early implementations.

Project Need

Explain the reason behind the need for this project. This may be related to legislative requirements, industry needs or similar justifications.   This section must be completed for projects containing items that are expected to be ANSI approved, as it is an ANSI requirement for all ballots. The information will be used in the NIB form.   ***Project Insight:*** *Enter into "Project Need"*

FHIR Project: FHIR is a major new initiative by HL7 intended to significantly speed and enhance interoperability between healthcare systems. The FHIR methodology is dependent on the existence of a number of discrete data structure definitions called "resources". This project will create the set of essential resource definitions related to the domain of Your domain name here.

Security Risks

If the project is creating implementation/executable deliverables, the Work Group will need to do a Security Risk Analysis prior to submitting a publication request. The Yes/No/Unknown checkbox is informative; changing the response does not require submission of a new scope statement. Updates to the project artifacts in subsequent projects may not require a new security risk assessment with each updated publication, but an umbrella assessment for the standard or for a product family may be required.

Refer to the Cookbook for Security Considerations for additional guidance, including sample spreadsheets that may be used to conduct the security risk assessment.

External Drivers

Describe any external schedules or calendars which may not be known outside of the project team that are driving target dates for this project. These drivers typically stem from other SDOs or governmental agencies or initiatives.

Project Objectives / Deliverables / Target Dates

	Target Dates
Enter a list of objectives the project is trying to meet. If the project is to develop one or more work products, the work products' descriptions should be clear, concise and unambiguous. Work products intended to produce a standard should be in terms of the deliverables: · new elements methodology (e.g. a new way of deriving message specification from a in information model) · new interface specification for services or application roles · new functional models · new message specification (e.g. a new message structure that refers a the state transitions of a new type of clinical act) · new standard profiles (e.g. CDA implementation guide) · new terminology subsets or mapping · new tools intended to improve productivity and support the methodology In those cases where the objectives are not work products, they should be described so that an outside observer can answer "yes" or "no" to the question "has this objective been met?" As the project progresses, objectives and work products can be refined. Target Dates may be updated and typically do not require re-approval unless a major change occurs as defined in the FAQ. Projects that have more than one work product to deliver should list each work product's expected delivery date, taking into consideration expected dependencies among work products. ***Project Insight:*** *Enter into "Pjt Objectives and Deliverables".*	Exact dates are not needed. Enter in WGM or ballot cycle format, e.g. : '2010 Sept WGM' or '2010 Jan Ballot'. Target dates in Project Insight are only provided in the above format. Target dates can be updated.

Example of Objectives / Deliverables / Target Dates:

The following attempts to convey how to identify various objectives /deliverables and their target dates.

Objective / Deliverable	Target Date

Complete analysis, design, draft specification work on Standard XYZ	2009 May WGM
Submit for STU Ballot (First Ballot Cycle) First Ballot Cycle" is a prompt for the PMO to create a schedule task in Project Insight to email the Sponsor/Co-Sponsor lists 2 weeks prior to the WGM prior to the first ballot cycle.	2010 May Ballot/ WGM
STU Reconciliation	2010 May Ballot/ WGM
Submit for 2nd STU Ballot	2010 Sept Ballot/ WGM
Request TSC Approval for STU publication	2011 Jan Ballot /WGM
STU Period – 12 months	Jan, 2011 – Jan, 2012
Submit Implementation Guide for Informative Ballot	2011 Jan Ballot/ WGM
Reconcile Informative Ballot	2011 May Ballot/ WGM
Submit Publication Request for Implementation Guide	2012 Sept Ballot/ WGM
Submit Standard XYZ for Normative Ballot	2012 May Ballot/ WGM
Reconcile from Normative Ballot	2012 Sept Ballot/ WGM
Submit Publication Request	2013 Jan Ballot/ WGM
ANSI Approves Standard XYZ	2013 May Ballot/ WGM
Close Project (project end date)	2013 May Ballot/ WGM
FHIR Project: The artifacts produced by this project will be balloted as part of the FHIR STU project (Project Insight ID TBD). Refer to FHIR Ballot Prep wiki page for additional information and dates	

Common Names / Keywords / Aliases

List all common names, aliases, alternative names and keywords related to the product(s) this project is producing.

Common Name - this would be the 'familiar name' or a 'convenience name' of a product, used in place of long and unwieldy names.

Keyword - Any words that would assist a user when searching for the product

Alias - This would be the "also known as" name, or a slant term, or even the old name before it become formal

Project Insight: Enter into "Common Names / Keywords / Aliases"

Lineage

To assist with ballot documentation and cross referencing, for any project creating a subsequent release of a product (i.e. Release 2 or 'higher'), indicate the name of the prior product and if it's supplanting, replacing or coexisting with a previous release.

Project Insight: Enter into "Lineage"

Project Dependencies

This section is not required for Infrastructure Projects.

The dependency may be the work of another project undertaken by this group or by another group. Anticipating dependencies can allow groups to coordinate their effort to ensure the overall objectives of HL7 can be met. An example of a dependency is: The CDA ballot needed the Data Types produced by Infrastructure and Management Project to be through ballot before the CDA ballot could be finalised.

Project Insight: *Enter into "Pjt Dependencies".*

Project Document Repository Location.

Indicate where one can go to find deliverables/documents created by the project team by entering **the EXACT URL(s)** where one can go to find deliverables, documents, artefacts created by the project team for this project. The URL could point to the HL7 Wiki, TSC Wiki, GForge, Project Insight, etc. A template to create a Project Page on the HL7 Wiki is available at: http://wiki.hl7.org/index.php?title=Template:Project_Page

The following summarizes the TSC's guidelines for project document repository locations (these were approved on 2016-04-04):

1. HL7 Projects and External Projects with no formal agreement

a. From the point at which material is ready for ballot all work products SHALL be maintained on HL7 managed platforms.

b. Work groups SHALL maintain all of their development material on HL7 managed platforms so that backup and long-term availability is maintained.

c. Any deviations SHALL require approval by Electronic Services and Tools WG.

2. External projects when formal agreement(s) exist between HL7 and the external organization on document location e.g. National Council for Prescription Drug Programs, (NCPDP)

a. Material SHALL exist at the location defined in the agreement

b. HL7 Participants SHALL have access to the material(s).

3. Work groups SHALL publish the location of their documents on their webpage (which may point to their wiki).

Project Insight: *Enter into "Project Document Repository".*

Backward Compatibility

Indicate the backward compatibility of the expected project artefacts/deliverables, if known. Refer to the Product Family definition of backward compatibility for additional constraints.

Project Insight: *Enter into "Backward Compatibility"; enter additional information into 'Misc. Notes'.*

FHIR Project: Mappings between existing static models and created resources may eventually be defined, but this work is out of scope for this project.

TSC position statement on new projects using R2B

· HL7's primary specification for Data Types to be used in Interoperability is "HL7 Version 3 Standard: Data Types - Abstract Specification, Release 2" Any specification, other than HL7 Version 2 is expected to use or base its data types on this specification (which is also an ISO standard).

· In order to facilitate selected applications originally implemented in Release 1 of this standard, the Implementation Technology Specification Work Group, created an implementation specification "HL7 Version 3 Standard: XML Implementation Technology Specification - Data Types - Abstract DT R2 Implemented in Wire Format Compatible With DT R1, Release 1" This specification is known in short-hand as Data Types R2B.

· The purpose of this specification was to support active projects, with functioning implementations that originated in the R1 data types. Future use of the "R2B" Implementation Technology is limited to projects that:

a) Were originally developed AND implemented in DT R1

b) Are being corrected or extended in the same functional space for use by the original community of implementers.

c) Whose use of the R2B specification is noted in the Project Scope Statement - "Does this project seek to use ITS R2B or its Datatype representations?"

d) Have received permission from the TSC for such use of R2B

External Vocabularies

If the project will reference any external vocabularies, for example SNOMED, LOINC, ICD-10, list the external vocabularies.

Products

Product(s): Indicate the associated Product line(s); check all that apply. Additional information regarding HL7 Products is available at www.HL7.org > Standards > Introduction. For additional information on creating or modifying HL7 processes, refer to the document Introducing New Processes to HL7 posted in the Standards Master Grid.

By selecting the checkbox for "Creating/Using a tool not listed in the HL7 Tool Inventory" (located at HL7.org > Resources > Tools and Resources), it will assist the Electronic Services and Tools Work Group to keep the HL7 Tools and Services Inventory up to date.

Project Insight: Enter into "Product Type".

Project Intent

Indicate if/how this project affects a standard or HL7 policy/procedure/process.

The GOM is available at: http://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf).

The HL7 Essential Requirements are available at: http://www.hl7.org/documentcenter/public/procedures/HL7_Essential_Requirements.pdf.

If the Work Group wants to ballot a White Paper for publication in Master Grid, it shall be balloted as "Informative" per the TSC, and follow the routine ballot naming convention as defined in Section 12.02 of the GOM. Non-balloted Work Group level white papers still require normal PSS approval and are not published in the HL7 Master Grid of Standards. The template for non-balloted WG White Papers is posted at: http://www.hl7.org/permalink/?WGWhitePaperTemplate.*Project Insight:* Enter into "Project Intent".

FHIR Project: Resources will be published as part of the FHIR STU ballot

Ballot Type

If applicable, indicate the type of balloting the deliverables will go through. Additional information in determining the correct ballot strategy can be found in the Technical Steering Committee (TSC) Guidance on Ballot Levels. TSC also offers guidance on balloting and re-balloting. **Project Insight:** *Select a value from the "Type" dropdown.*

FHIR Project: This project will not ballot directly. Instead, content will be combined with resources from other committees and jointly balloted as part of the FHIR STU ballot (managed as a distinct TSC project).

- Joint Copyright Click here to return to this section in the template above

Check this box if you will be pursuing a joint copyright. Note that when this box is checked, a Joint Copyright Letter of Agreement must be submitted to the TSC in order to for the PSS to receive TSC approval.

Project Insight: *Enter into "Joint Copyright".*

Project Logistics

Include SDOs or other external entities you are collaborating with, including government agencies. Indicate the nature and status of the Memorandum of Understanding (MOU) if applicable.

Agreement Status: Memorandum of Understanding (MOU) or Associate Charter Status types are: Negotiating or signed (please indicate the date signed.) Leave blank if there is no agreement in place. Refer to http://www.hl7.org/about/agreements.cfm for a current listing of HL7's agreements.

Project Insight: *Enter into "Collaboration Efforts".*

FHIR Project: In producing resources, the committee will consult specifications from a wide variety of external organizations, including OpenEHR, IHE, various affiliates, government organizations and other SDOs. However, this consultation will not require direct interaction with these other organizations. (Though some may be involved in the ballot review process.)

Feel free to note specific additional collaborations you intend to use in the development of your resources if applicable.

Realm

Indicate whether the project is applicable globally (universal), or intended for a specific country or region (realm). Note that Non-US realm project scope statements should be directed to the appropriate HL7 Affiliate.

Projects meeting one or more of the following guidelines are candidates for being universal realm projects.

·   Stakeholders representing 2 Realms at a minimum, where stakeholder should be interpreted as a specific group or organization listed in the External Project Collaboration section or the Stakeholders / Vendors / Providers section of the project scope statement

·   Requirements coming from a minimum of 2 Realms

·   Project will be implemented in a minimum of 2 Realms

·   Minimum of 2 Realms represented on project team

Also note that if the Realm changes from 'Realm Specific' to 'Universal' additional project resources may be necessary to support that change. This is considered a 'significant' or 'major' change and should go through the project approval process as a Universal Realm project.

If a project is initially proposed as "Realm Specific" but the Work Group participants vote to change the realm to "Universal", the Work Group members supporting "Universal" for use in their country must designate a representative team member (within "Other Interested Party" in the PSS) to participate in the project to insure their requirements are met. Note this is not applicable to Investigative projects (aka PSS-Lite)

If applicable, check the box to indicate that the standard balloted or was previously approved as realm specific standard.

For projects producing both universal and realm specific deliverables, document those details here (specify which deliverables are Universal and which are Realm Specific).

Project Insight: Enter into "Realm" and "HL7 Affiliate" (if applicable).

Stakeholders / Vendors / Providers

This section must be completed for all projects. It is used to determine if a project is a 'US Government Interest' project. It also is an ANSI requirement and is included in the NIB form.

Indicate the associated stakeholders, vendors and providers for which this project is intended. Check all that apply.

Project Insight: *Enter into "Stakeholders / Vendors / Providers"; enter additional information into 'Misc. Notes'.*

Project Approval Dates

Approvals are by simple majority vote of the approving body.

Sponsoring Work Group Approval Date: The date the sponsoring Work Group approved the project. Following Work Group Approval, forward the PSS to the PMO (pmo@hl7.org):
Project Insight: Enter into "Start Date".

Co-Sponsor Group Approval Date(s): The dates that each of the co-sponsors approved the project.
Project Insight: Select appropriate dropdown value.

Family Management Group Approval Dates(s): Based on the project's products, the dates that each of the Management Groups approved the project

Project Insight: Select appropriate dropdown value.

US Realm Steering Committee (USRSC) Approval Date: Forward the PSS to the TSC Project Manager and request a time to review the project with the US Realm Steering Committee (USRSC).
Project Insight: Select appropriate dropdown value.

Affiliate Approval Date: The date the sponsoring HL7 Affiliate approved the project. Following Affiliate Approval, forward the PSS to the PMO (pmo@hl7.org):
Project Insight: Enter into "Start Date".

SD Approval Date: The date the sponsor's Steering Division approved the project. When multiple WGs co-sponsor a project, it's the "Primary Sponsor/Work Group" Steering Division that must approve the project. *Project Insight:* Enter into "SD Approval Date".

The "PBS Metrics Reviewed?" checkbox is a reminder for the Steering Divisions to look at the Work Group's PBS Metrics during their SD review process to insure that the Work Group has the bandwidth to take on additional project work.

PBS Metrics Reviewed? (required for SD Approval): Additional information regarding this task can be found via www.HL7.org > Resources > Tools and Resources > Project Management and Tracking Tools > Guidance for Steering Division Co-Chairs to Evaluate Work Group Capacity to Undertake New Effort

ARB Approval Date: Submit your PSS for ARB approval when creating or modifying an HL7 Policy/Procedure/Process or content is being externally developed. Work Groups should include the ARB when sending the PSS to their Steering Division for review/approval. For additional information on creating or modifying HL7 processes, refer to the document Introducing New Processes to HL7.

Joint Copyright Letter of Agreement received? (req'd for Joint Copyrighted material): When the Joint Copyright box is checked; a Joint Copyright Letter of Agreement that contains the verbiage outlined within the SOU must be signed by both parties and submitted to the TSC in order for the PSS to receive TSC approval.

TSC Approval Date: The date the Technical Steering Committee approved the project. *Project Insight:* Enter into "TSC Approval Date".

Frequently Asked Questions

Q: What is the definition of a project?

A: From the HL7 Development Framework, Section 2.2.1, HL7 Work Effort:

An HL7 work effort represents an activity being undertaken by an existing Work Group or Board appointed committee to achieve specific objectives or to produce specific work products.

A Work Group shall consider a work effort to be a project if one or more of the following is true of that work effort:

- involves a group outside of HL7 (may require Board approval)
- requires external funding (may require Board approval)
- is going to be balloted
- requires cross-committee participation
- is determined to be a project by the committee

An HL7 project:

- has an objective (statement of what is going to be produced),
- will have a finite existence (the end date to be determined by the resources available and the start date), and
- if additional funding is required, it will have a budget (including resources and funding sources)
- will have at least one participant available to contribute and must have a project leader, if only an interim to get the project started
- will have at least two implementers (unless the project is intended to support the HL7 infrastructure)
- will have an estimated schedule

Project Management Institute's PMBOK Guide and the publication "The Fast Forward MBA in Project Management" indicate the following:

Typically, a project is a temporary endeavor undertaken to create a unique product or service. All projects have two essential characteristics. (1) Every project has a beginning and an end. (2) Every project produces a unique product. HL7 also recognizes 'Maintenance' projects which usually repeat on an annual basis; these maintenance projects do not need to be re-submitted or have a definite end date.

Temporary means that every project has a definite beginning and a definite end. Temporary does not necessarily mean short in duration, it just means that projects are not ongoing efforts. Furthermore, projects involve something that has not been done before and which is, therefore, unique.

Projects shouldn't be confused with ongoing operations. Ongoing operations have the opposite characteristics of projects in that they have no defined end and they produce similar, often identical, products. Examples of ongoing operations are (a) an insurance company processes thousands of claims every day; (b) a bank teller serves over 100 customers daily, providing a few dozen specific services.

The objective of a project is to attain the objective and close the project. The objective of an ongoing operation is typically to sustain the business.

Q: Do I need to create a Project Scope Statement if my project isn't going through the ballot process?

A: Yes, all projects need to have a Project Scope Statement completed and submitted to the HL7 PMO. A lot of work done by Education, Marketing, Electronic Services, ArB, PIC, etc. does not need to go through the ballot process; however, visibility of that work is necessary. Project Scope Statements are the foundation for communicating project information. They also serve as a tool for Project Facilitators to gather the right information to begin a project as well as track the project's progress.

Q: Do I need to create separate Project Scope Statements for each Implementation Guide or other support documents?

A: A single PSS can indicate multiple deliverables for the standard being addressed, so, no, a separate PSS does not need to be created for each Implementation Guide or support document for that standard. Simply identify all of the Implementation Guides and documents in the Project Objectives and Deliverables section that are to be produced for the project.

Q: I have many related projects, should I include them all within one PSS or complete a PSS for each subordinate project?

A: The Project Services Work Group discourages creating a 'Master Project containing many subordinate projects'. Instead, multiple individual projects should be created, using the Dependency field to refer to the other related projects.

Q: The scope or objective of my project changed. Do I need to create a new PSS?

A: You may or may not have to as it depends on the change. Oftentimes, the scope or objectives of a project may change during its lifecycle, perhaps due to regulatory changes or tying back to a different standard. When the scope changes, it is preferred that a new Project Scope Statement NOT be created. By keeping the same Project ID, the ballot site can readily point the same project ID to both STU and Normative ballots.

If the change in scope or objectives is minor, simply update the existing project scope statement, and within Project Insight, indicate the modifications in the appropriate fields. You can also use the 'Misc. Notes' text box for documentation.

However, if the change in scope or objectives is major, the Project Facilitator should submit a new Project Scope Statement, as many of the original information won't accurately reflect what is being done anymore.

Q: What defines a 'major' or 'significant' change in scope?

A: Since 'major' and 'significant' are subjective terms, examples may provide better comprehension of a "major" or "significant" change to a project scope statement.

A "major" or "significant change" in project scope includes the following:

- Creating a new Release of a Normative or Informative artifact (excludes STU, refer to TSC Policy and Guidance to Work Groups on STU Updates vs. STU Ballots)
- The Project End date extends by 24+ months
- Additional HL7 funds are required
- The Project Intent changes (i.e. the project changes from "Revising a Standard" to "Creating a Standard")
- The change in scope will result in an item that qualifies as 'substantive change' as defined in HL7 Essential Requirements. (Normative ballot)
- The Realm changes from 'Realm Specific' to 'Universal' (since additional project resources may be necessary to support that change)
- The deliverable's backwards compatibility changes from 'Yes' to 'No' (excludes STU, refer to TSC guidance documents on the TSC Wiki Main Page)

Q: I'm taking my project from STU to Normative or Informative to Normative, what should I do first?

A: Prior to submitting a NIB, notify the TSC (via the TSC Project Manager) that you plan to bring something to Normative ballot by modifying Section 1 of the PSS with the following information and including the current date in the date field. There is no need to contact the Steering Division of this action.

For existing projects, if there isn't a major change in scope, there is no need to fill out a new PSS; simply add the Normative notification date information below to Section 1 to the PSS document was previously approved by the TSC. The TSC approval triggers a notification to ANSI of a new standard coming. It also begins a countdown clock where the project item(s) need to complete balloting within 18 months and then be published within 12 months.

Q: Are special considerations for FHIR projects?

A: There is a FHIR Ballot Prep wiki page which provides guidance on ballot dates; these dates will impact the "Project Objectives/Deliverables/ Target Dates" section of the project scope statement. Additional instructions for FHIR projects are contained in Appendix A – Instructions.

Q: Do I need to include budget figures in my scope?

A: Typically projects to produce standards are routinely supported by the volunteer resources committing to complete the project, and HL7 in the form of meeting rooms, conference call facilities, etc. If additional funding is required from HL7, you must provide a budget for the project.   A proposed budget is required for any project that will be contracted, for example, website redesign.

Q: Do I need to update the PSS if I discover after it's approved that I need to coordinate ballots with other HL7 Work Groups?

A: Yes, we recommend updating the Ballot Strategy section of the Project Scope Statement as well as Project Insight. Include the ballot name and release/version your project is coordinating with.

Q: Are there special considerations for STU ballots

A: Refer to TSC guidance documents on the TSC Wiki Main Page for additional information on STUs available at: http://gforge.hl7.org/gf/download /docmanfileversion/7482/10824/Guidance-to-Work-Groups-on-DSTU-Updates20130819.docx.

Q: When withdrawing a published standard or a standard that has gone through balloting, does a PSS need to be created and go through the review/approval process?

A: In most cases, a PSS is not required. However a Notice of Withdrawal of a Protocol Specification form must be completed, approved by the Work Group and submitted to the TSC for their approval, following HL7 Essential Requirements. This form can be found via www.HL7.org > Resources > Templates > Notice of Withdrawal of a Protocol Specification .

In this case 'withdrawing a standard' refers to many things, such as choosing not to extend a standard that has reached its 5 year end-of-life or identifying the need to sunset a standard.

A PSS does need to be created if the standard being withdrawn is intertwined/intermingled with other standards. The PSS provides visibility so dependencies in other standards can be changed.

Q: Do I need to go through the project approval process if a standard has expired and will not be reaffirmed?

A: No. When a work group has balloted a standard at STU, informative, or normative ballot, and decides the standard will be withdrawn, the withdrawal form at www.HL7.org > Resources > Templates > Notice of Withdrawal of a Protocol Specification must be approved by the Work Group and then submitted to and approved by the TSC.

Q: Should a Work Group create a new PSS when creating a new Release of a Standard?

A: This is required for Normative and Informative artifacts only. In most all cases, there will be a significant enough change in the newer Release of the Standard to warrant a new PSS. New balloted products require a PSS, for example, adding ITS to an existing project creating a DAM (Domain Analysis Model). Also, a new PSS helps for tracking and historical purposes, as a new PSS assists HQ in keeping a one-to-one relationship of standards to projects (refer to TSC guidance documents on the TSC Wiki Main Page for additional information on STUs; STUs do not require a new PSS for a new release).

Q: How do I know the approval status of my project?

A: Look up your project using the HL7 Searchable Project Database (http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm), located on the www.HL7.org Homepage). The search results will reflect SD and TSC approval statuses either by reflecting the date the group approved the project or indicated 'Awaiting Approval' if the group has not approved the project.

Q: I've submitted my PSS to my Steering Division for approval but haven't heard anything from them. What should I do?

A: First, check the Steering Division's meeting minutes. Look to see if your project was on one of their agendas, and if so, if it was approved or the SD had further questions. Your first point of contact with the SD should be their Project Facilitator. If you can't contact them, contact the Steering Division Representative and Alternate.

If the SD has approved your project, they will submit it to the TSC for approval via GForge's tracker system. To view which approvals your project has gathered, find your project by using the HL7 Searchable Project Database (http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm), located on the www.HL7.org Homepage).

Q: When reaffirming a standard, does a PSS need to be created and go through the review/approval process? What sections need to be filled out?

A: Yes. Reaffirmation of a standard requires a normative ballot. The areas on the PSS that need to be filled out are:

- Project Name (should be something like: Reaffirmation of Standard XYZ, Release 123)
- Check the box labeled "TSC Notification Informative/STU to Normative" (since all reaffirmations are direct to Normative projects)
- Primary Sponsor/Work Group
- Project Facilitator
- Project Scope (can be as simple as 'Reaffirmation of Standard XYZ, Release 123', which is expiring as of YYYY-MM-DD)
- Project Objectives / Deliverables / Target Dates (indicate the ballot cycle that the standard will go through its Normative ballot)
- Products
- Project Intent (select Reaffirmation of a Standard)
- Ballot Type (select Normative (no STU))
- Realm
- Approval Dates (Reaffirmation projects do need to gather the appropriate approvals -- e.g. Work Group, USRSC (for US Realm projects), Steering Division, TSC, etc.)

Q: What approvals are needed if I revise my existing PSS, say the project's scope changes?

A: The same approval process should be followed whether it's a new project or a scope change to an existing project.

When the scope is changed in a project, the modified Project Scope Statement will be approved by the primary WG and the SD, providing the TSC using the same time line and deadlines as submissions for new projects. When the scope changes, it is recommended that a new Project Scope Statement NOT be created. By keeping the same Project ID, the ballot site can readily point the same project ID to both STU and Normative ballots.

Q: What ballot types are required to go through the project approval process?

A: All ballot types (Comment-Only, Informative, Normative, STU) need to go through the project approval process, however, as identified in the Project Scope Statement, a single project can define ballot plans for multiple types of ballots for the project, for example, Comment Only > STU > Normative or Informative > Normative.

Q: What is the approval process for HL7 projects that collaborate with ISO or the JIC?

A: Follow the process documented on via www.HL7.org > Participate > Balloting > HL7's Collaboration with ISO and JIC .

Q: Do I need additional approvals when creating or modifying an HL7 Policy/Procedure/Process?

A: Yes. Work Groups should also have the Architectural Review Board review/approve the PSS. Work Groups should include the ArB when sending the PSS to their Steering Division for review/approval. For additional information on creating or modifying HL7 processes, refer to the document Introducing New Processes to HL7.

Q: How should a Work Group document the voting results after seeking approval for the PSS?

A: The ideal way is to post it in meeting minutes, so that they are documented and easily referenced. If that's not possible, an email to the Listserv will suffice.

Q: Why does the USRSC review/approval occur before the Work Group review/approval?

A: One of the tasks of the USRSC is to review and recommend which Work Groups are the best sponsor and cosponsors, hence a review by the USRSC will aid in determining these.

Q: Define 'task' and 'activity' as related to project management.

A: Theoretically, 'activity' is the action verb within a 'task'. However, for HL7 projects, 'task' and 'activity' can be considered synonymous terms.

Task/activities should be:

- Specific - a single, well defined, discrete activity. The 8/80 is a good guideline -- no task should be smaller than 8 hours or larger than 80 hours.
- Achievable - it should be something that can be done as a single deliverable and can be defined as being completed or done such as a document being produced.
- Measurable - it should be an activity that can be measured such as a deliverable produced, an elapsed period of time or number of iterations

Q: How should a Work Group document annual work/maintenance within Project Insight?

A: A project entry should be opened in Project Insight indicating the annual work and the respective years. This project should have a Project Status of '3 Year Plan Item'; note that a Project Scope Statement isn't needed for this entry because it's a 3 Year Plan item and only high level information is necessary.   This project can then remain 'as-is', or modified so it indicates accurate future years.

When the Work Group actually begins the annual work, they should complete a PSS indicating the scope of work involved and gather the necessary approvals for the PSS. A new project in Project Insight will be created (and will have a Project Status of 'Active Project'). Once the scope of work has been completed for this project, it will be closed/archived.

Hence, the 3-Year Plan project always remains open; the 'Active Project' PSS will be the project reflecting the specific annual maintenance being done.

An example of the above situation can be found for Project Service's annual updates to the PSS Template. Project 531 is the 3YP entry indicating the need for the work in 2010, 2011, 2012, 2013 and beyond. Project 581 was created to identify the specific work that would be done for the 2010 updated template. In January, 2010, project 581 was closed because the new PSS template was released to membership, however project 531 was modified to remove references to '2010' and remains open to indicate the need for the work each year.

Q: Should a project remain open/active during its STU Test Period?

A: Yes, it should. This means that the project will continue to show up in the Searchable Project Database and on Project Insight reports.

Q: Why was I asked to Disable or Enable a macro when I opened this document?

A: This document contains a macro that, when run by the user, removes the green 'help' text within the template portion of this document and provides a cleaner version of their project scope statement. To run the macro, select Tools > Macro > Macros… > Run.

Note that the macro will NOT remove the Appendices; the user must remove the Appendix verbiage on their own.

Q: How do I search/view HL7 Projects?

A: There are three ways to view HL7 projects, all located at www.HL7.org > Participate > Tools and Resources > Project Management and Tracking Tools (http://www.hl7.org/participate/toolsandresources.cfm):

1. The Searchable Project Database (http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm, located on the www.HL7.org Homepage and titled 'H7 Project Database'.
2. An Excel spreadsheet of all HL7 projects is available via GForge > Projects » TSC > Releases > HL7 Project List (http://gforge.hl7.org/gf/project/tsc/frs/?action=FrsReleaseBrowse&frs_package_id=98).
3. Project Insight (a Project Insight User ID and Password is required – this differs from your HL7 User ID and Password). Contact the HL7 PMO for more information (pmo@hl7.org). The URL is: http://healthlevelseven.projectinsight.net/l.aspx?ReturnUrl=%2fdefault.aspx.

Q: How can I view projects which my Work Group is a co-sponsor?

A: Look up your project using the Searchable Project Database (http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm), located on the www.HL7.org Homepage). Select your Work Group in the "Sponsor" dropdown field. The search results will reflect projects which your Work Group is sponsoring and co-sponsoring.

Q: What should I do if an approval group is unresponsive?

A: For an unresponsive co-sponsor, raise the issue to the co-sponsor's Steering Division, indicating that if the co-sponsor is unable to review the PSS in an acceptable time period (~2 weeks), that they will be removed.

For other unresponsive groups, raise the issue to the TSC.

Q: Do I need to specify a Reference Information Model (RIM) version in the V3 standard I am developing?

A: Unless specified, it is assumed that a project incorporates the current version of HL7 infrastructure (RIM, Datatypes and Vocabulary).

Project Services recommends that your Work Group's modeling facilitator monitor proposed RIM changes that may impact the standards you are developing for the duration of your project. The modeling facilitator can do this by subscribing to the harmonization@lists.hl7.org listerv. For more information on RIM change proposals, contact the MnM Work Group.

Q: What do I need to do if I want a project document to be publically available outside of HL7?

A: It's a rare instance that a project will create and distribute a public document in accordance to the GOM's ruling. In the instance that a project deliverable does adhere to it, the project team will need to present a proposal to the Executive Committee to provide funding to create and distribute a document publicly. GOM Sections 09.01(d) and 16.01 indicate that the Executive Committee determines what is publically available. More information can be found at: http://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf.

Q: Do white papers need to be balloted?

A: White papers can either be balloted informative or just reviewed/approved by the Work group. If the Work Group wants to ballot a White Paper for publication in the Master Grid, it shall be balloted as "Informative" per the TSC, and follow the routine ballot naming convention as defined in Section 12 of the GOM.   Non-balloted Work Group level reviewed/approved white papers will not published in the HL7 Master Grid of Standards nor contain any type of 'HL7 Stamp'.

Q: What do I need to do to advance or move an Investigative project (PSS-Lite) to a full project?

A: A new PSS form needs to be completed (you can use the original form since a lot of the fields will already be filled in). The new PSS must go through the normal approval process. The PMO will assign a new project number to it.

Q: While in the middle of an investigative project (which used a PSS-Lite template), the scope or objective of my project changed. Do I need to create a new PSS (using the PSS-Lite template)?

A: No, a new PSS does not need to be created during the investigative period. Since investigative projects are short term in nature and have the purpose of investigation, research and analysis, it's quite likely that their scope/objectives could change as information is gathered. Hence even if the scope's change is 'major' or 'significant' as described above in this appendix, a new PSS-Lite template does not need to be created.

Q: What are the Intellectual Protection requirements for protecting balloted HL7 material (Informative, DSTU, or Normative)?

A: §16 of the Governance and Operations Manual (GOM) defines Intellectual Property restrictions. Material that has passed ballot, and continuing for a period of 90 days from the date of publication, is restricted to HL7 International and Affiliate members (unless exception is granted per GOM §16.01.10). During this "protected period" balloted material can be posted for "Members Only" access to HL7.org, but should not be distributed to non-members, e.g. via the Work Group's list or wiki. For example, Work Group votes to approve ballot reconciliation January 15; editor incorporates reconciliation edits and submits for publication January 30; item approved for publication by TSC, and published by HL7 HQ February 15. The "protected period" is from January 15 through May 15 (e.g. beginning on the ballot reconciliation approval date and concluding 90 days after the publication date).

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