Chapter 1 Introduction to the Co-Chair Handbook

FOREWORD

To assist the Accelerators as they develop their projects at HL7 the FHIR Accelerator Home page on confluence was created to provide guidance regarding HL7 processes. Recommendations to improve this confluence page should be directed to the HL7 CTO.

There are numerous responsibilities that you assume as co-chair of an HL7 Work Group (WG) or Board appointed committee. The content of the following pages is provided to assist you with those responsibilities. In addition to this guide, all co-chairs should be familiar with:

- The HL7 Bylaws – which may be updated three times a year
- The HL7 Governance and Operations Manual (GOM) – which may be updated three times a year
  • Special Note on Bylaws and GOM: Currently these are PDF documents on HL7.org. References to these documents will not take you to the section defined in these documents. The hyperlink will take you to the document, then scroll down to the table of contents and hit CNTRL then left click the mouse on the section and it will open that document in another page in HTML directly at the reference.
- The HL7 Essential Requirements: Due Process Requirements for HL7 American National Standards (HL7 ER) – which may be updated three times a year

Throughout this guide, there are links to other documents and material, as an example in the above section, clicking on Bylaws will take you to the Bylaw document. For documents like the Bylaws or the GOM, the link will take you to that document, there will be a reference to the specific area in the document, moving down to the table of contents, then holding the CNTRL key and left clicking on the page number will take you directly to that section of the document.

Suggestions for improvements/corrections to the Co-Chair Handbook should be sent to the Associate Executive Director of HL7 (Karenvan@hl7.org) and the Co-chairs of the Process Improvement WG.

Overview

This guide has the following Chapters:

- Introduction - Chapter 1 provides an overview of the Handbook
- Your Role as Co-Chair - Chapter 2 provides information to help you begin as a new co-chair
- Work Group Planning - Chapter 3 provides guidelines on Work Group (WG) planning and WG Co-chair responsibilities.
- Project Management - Chapter 4 provides information about project planning and updating project plans.
- Balloting – many new co-chairs have questions about balloting. Chapter 5 provides a flowchart of the ballot process for both normative and review documents. There are three types of review ballot: comment only, informative document, and standard for trial use (STU).
- Working Group Meeting Planning - Chapter 6 has information about preparing agendas, hosting meetings for other WGs, scheduling room space and other critical information about the Working Group Meeting (WGM).
- WG Health - Chapter 7 reviews the WG Health requirements including making sure to include updates to WG projects during the WGM.

Available resources:

- Robert's Rules of Order – provides an overview of and tips for conducting meetings using the official Robert's Rules of Order can be found at: Robert's Rules
- Decision Making Practices (DMP) – provides guidance for conducting the business of the WG you are co-chairing. This sections covers areas such as what constitutes a quorum, how to make decision on conference calls, etc. The default DMP can be found at: Default DMP
- HL7 Tools and Resources - Various tools and resources are available for people creating and implementing HL7 standards. The tools and resources that we are aware of are organized below by standards and/or function anc can be found at: Tools and Resources
• **HL7 Standards** - A framework (and related standards) for the exchange, integration, sharing, and retrieval of electronic health information and can be found at: Introduction to Standards.

• **JIRA** - JIRA is the tool currently used to record issues related to HL7 FHIR specifications (both FHIR Core and individual implementation guides). The FHIR Specification Feedback project can be found at: JIRA Issue Tracker.

• **gForge** - the HL7 Project Homebase site is intended to support HL7 Tool Developers (Toolsmiths) and Work Groups in managing their projects. All of the tools available on this Homebase are designed to support the development and publication of HL7 Version 3 Messaging Standards. These tools carry a license that restricts their use to activities that support the development of standards by HL7 and the HL7 International Affiliate Organizations. It can be found at: GForge.

Helpful information:

• **Technical Steering Committee (TSC) Guidance** page has many guidance documents and templates found at: TSC Guidance.

• **ARB’s notes regarding project responsibilities and project workflow** can be found at: BAM Cliffs Notes: Project Responsibilities.

**HL7 International Organization**

A brief overview of the HL7 Organizational Structure.

Overview of the Technical Steering Committee (TSC)

Understanding the structure of HL7 and key players will be helpful in your role at HL7 Work Group (WG) Co-chair. Every effort has been made to make the relations between WGs and Steering Divisions (SD) as logical as possible based on what those WGs intend to accomplish. Using the Administrative Steering Division as example, the WGs in this division provide services that support HL7 in its’ mission to create clinical and administrative messages in the Healthcare environment. These services include Project Management processes, Electronic Services and Tooling and publishing to name a few. Below is a diagram of the TSC organization.
Chapter 2 Your role as Co-chair

Summary of Responsibilities

This section outlines many of the key requirements and responsibilities you have taken on as co-chair. At its core, the co-chair role entails providing the leadership, the stewardship, and the oversight of the workgroup in which you are serving, to help that community achieve its mission. In so doing, there are several competing priorities that will fall within your remit, to include:

• Managing the overall group consistent with the policies documented by the HL7 organization in general, and the Governance and Operations Manual in particular
• Maintaining the integrity and trust of the community, assuring that contributors are able to effectively participate, that all voices are being heard, and that decisions are being made consistent with the decision-making practices that govern the workgroup
• Providing thought leadership to help divergent participants, organizations, and perspectives come together, seeking a consensus whenever possible, on effective work products that advance your mission consistent with your workgroup charter
• Supporting administrative activities to support the needs of the HL7 organization, community, and external stakeholders

Co-Chair Election and Term

Co-chairs are elected to two-year terms and may be re-elected without limit as defined in the GOM (§ 09.02.06 Work Group Co-chairs). When a new WG is formed half the co-chairs will be elected to one-year terms and half the co-chairs will be elected to two-year terms. This ensures that the elections from that point on will be staggered so that there is continuity of leadership.

Key Documents for this chapter

- Co-Chair Training
- Conference Call Center
- GOM (§05.02 §WG Co-chair Nomination and Election, §07.02.02 Representing HL7, 09.02.06 Work Group Co-chairs)
- List Servers
- New Work Group Formation Template
- Relationships with Organizations Outside HL7
- Roberts Rules of Order
- Work Group Meetings
- Work Group Health Components
- World Clock
Prior to the end of your term, HL7 staff will notify you that your term is ending. The HL7 process for electing co-chairs (GOM §05.02 Annual Nomination and Election of HL7 Leadership by Administrative Ballot) involves a 30-day nomination period that is announced to the membership. Anyone who is a current individual member or voting representative of a current organizational or Affiliate member can be nominated or can nominate themselves. HL7 Headquarters will contact all nominees to ensure that they wish to serve if elected. Each nominee will be asked to draft and submit a brief position statement. These statements are published to the membership at large, along with an announcement of the elections.

Starting in 2020, WG Co-Chair elections will be transitioned to an annual schedule matching the current schedule for the Board and Technical Steering Committee elections. The process will follow this format:

- Nominations open May 1 and continue through June 15;
- The election period is July 1 through July 30
- Runoffs, if necessary, are held from August 7 through August 21
- The results are announced during the Plenary Session/September WGM
- Elected individuals are seated January 1 of the following year

Should you or one of the other co-chairs need to resign before your two-year commitment expires, notify HL7 Headquarters by email. HQ will attempt to seek nominees and include the open co-chair position in the next regularly scheduled election. If there is not enough time prior to the WGM, your WG may appoint an interim co-chair (GOM §09.02.06 Work Group Co-chairs) to serve until the next scheduled election. The interim co-chair may be a nominee in the subsequent election. HQ will then formally announce the open co-chair position as part of the normal process and elections will be held at the next WGM.

There is also a link to the most recent Power Point presentation used at the WGM for training new WG co-chairs.

Who can speak on behalf of HL7

Co-chairs cannot speak on behalf of HL7 except where allowed by the policy, as provided in GOM §07.02.02 Representing HL7.

Subscribing to and participating on HL7 Lists

You must read emails sent from the HL7 Co-chairs List. HL7 Headquarters will subscribe you to this list when it learns of your election to a co-chair position. The list is cochair@lists.hl7.org.

Additionally, co-chairs are automatically subscribed to the appropriate SD list server.

You must sign up for and participate in any list servers involving or dedicated to your WG including list servers for projects for which your WG is responsible. A complete list of list servers is available.

Most co-chairs should also sign up for the Modeling and Methodology (MnM) list.

New Co-Chair Updates

HL7 HQ will update the page dedicated to your WG on the HL7 web site to reflect your status as co-chair. HQ staff will not update individual WG Confluence pages. Confluence page edits are the responsibility of the WG co-chairs.

New Co-Chair of a New Work Group

When the TSC approves a new WG, the TSC Program Manager (TSCPM) distributes a task list to HL7 HQ staff to initiate the creation of all the associated web services that will be needed. Review the task to make sure the most current version of your mission/charter statement guidelines and your "New Work Group Formation Template" has been attached to the task. Until both of these documents are available by being attached to the task, the webmaster will not be able to complete the task of making a web presence for your WG. Please allow the webmaster at least 5 business days to complete this task.

A new list server will be created for your WG. The new WG list server will typically be announced via an electronic update from Headquarters that is sent to all members.

Roberts Rules of Order

The following documents relate to Robert’s Rules of Order; a guide to parliamentary procedure:

- Robert’s Rules on-line; a link to the complete original 1915 edition of Robert’s Rules
- Robert’s Rules that apply to WG co-chairs; a link to a brief document that outlines the essentials from Robert’s Rules for WG co-chairs.
- Robert’s Rules; a website for co-chairs needing/wanting more in-depth knowledge of Robert’s Rules

Assuming Stewardship for the Work Group Page on the HL7 Web Site
Any updates to your WG page should be conveyed to the webmaster (webmaster@HL7.org). Some guidelines for what information must be kept up-to-date are available from the monitoring done in the WG Health Metrics which includes historical metrics and description of their measures. This includes approved changes to your mission/charter statement (which requires SD approval), changes to your contact information, Decision Making Practices (DMPs).

Use of Confluence

As co-chair of an HL7 WG, you are responsible for posting meeting minutes and documents related to all meetings/business of the WG that you chair. All WGs have moved to using Confluence for their agenda, minutes and documents. A Confluence Space has been set up for each WG. You can work with webmaster@hl7.org if you need help with the set up of your Confluence Space.

There are templates available for Teleconference agenda and minutes as well as WGM agendas and minutes.

To create a new agenda or minutes, go to your WG Confluence space and click on the 3 "dots" to the right of "Create" in the blue bar.

You can select the type of page you want to create:

- Teleconference Agenda/Meeting Notes
- WGM Agenda
- WGM Minutes
- WGM Attendance Log

Co-chair Utility Page

Templates and other helpful instructions are available on the Utilities page of the HL7 website. The page has links and documents related to Balloting, File Maintenance Utilities, Reports, and Robert’s Rules.

Conference Call Center

As a WG Co-chair, you will need to schedule a conference call at some time to discuss WG business.

The conduct of business via conference calls between WGM is a WG Health metric.

Conference Call Center

Conference calls are scheduled via the conference call center. These may be scheduled to discuss business that was left over from the Working Group Meeting, to continue ballot reconciliation, or simply to agree on the agenda for the next meeting. Some groups schedule recurring calls every Monday at 10 am EST, for example, or every other Wednesday at 2 pm EST. The conference call number and access code(s) are included in the meeting invite.

How to schedule your call
Use the on-line conference call center. The call center allows you to schedule single (one time occurrence) or recurring (every week) calls for your WG. You can also edit, cancel and delete calls using the Conference Call Center.

Normally conference calls can only be scheduled through the next two WGMs and should be rescheduled during or immediately following a WGM so they are calendared on a continuous basis. For example, if the next WGM is the first week of May, after January 13th, you can request calls through the first week of October which is one month following the last day of the September WGM.

The Process for Conference Call Center Setup

1. Go to the Conference Call Center
2. Use the navigation to add the type of call you want to request either one time or recurring
3. Make sure to select the list service that will be used by this call for automated messages
4. Your call is now online and will be tied to a dial-in and access number
5. A reminder for each call will automatically be sent to the list associated with the call one to two days (1-2) days prior depending on your time zone.

Conference Call Center Features

On-screen tips are available to help while you learn the new interface for call scheduling. It is a straightforward guided system similar to ones you probably already use.

- You can “name” your call when submitting a request. This enables topic or event driven calls to be obvious on the calendar. You should name a call if the call is just a routine call (or a recurring series of calls) for a group. This is meant as a phrase for WGs (for example the EHR publishing group), not as an agenda description. There is a place provided for agendas.
- If you have the privileges needed to schedule a call, you have an option to “secure” a call. Because everything you see on the calendar is public domain, securing a call is necessary for executive level committees. For WG calls the use of this function is discouraged.
- If there are multiple list services available for the working group you have selected for a call, you can choose the list that reminders will go to.
- Reminders for calls will automatically go out to the assigned list one to two days (1-2) days prior depending on your time zone.
- You can change basic information for an individual call, even if it occurs as part of a series of calls.
- Individual calls can be cancelled and an automatic reminder will go to the list to which that call has been assigned.
- You must have access privileges as a co-chair, Board Member or HQ Staff in order to request a call
- Do not “name” your call if the call is for a WG (see conference call features for information on naming a call) rather than a specific event. There is agenda space provided for these kinds of details
- Do not forward your confirmation of a scheduled call to remind people of the call which happens automatically. Additionally, there is a manual reminder option should events dictate.

Conference Call Reminders

- You must have access privileges as a co-chair, Board Member or HQ Staff in order to request a call
- Do not “name” your call if the call is for a WG (see conference call features for information on naming a call) rather than a specific event. There is agenda space provided for these kinds of details
- Do not forward your confirmation of a scheduled call to remind people of the call which happens automatically. Additionally, there is a manual reminder option should events dictate.

Conference Call Cheat-Sheet

It is difficult, if not impossible, to accommodate everyone’s schedule for a conference call, especially with participants from around the world. If you need to know what time it is in a different country/city, it is suggested that you consult the World Clock.

Provide a desired start time to your call participants along with your access number and participant code which you are provided.

Use of Teleconferencing Services with Screen Sharing

HL7 supports the use of Zoom and Free Conference Call (FCC) for conference calls. Both of these applications support audio (either via by dial in or via your computer) as well as screen sharing.

If your Work Group uses either Zoom or FCC, you can contact webmaster@hl7.org to have the dial in information and web meeting information in Conference Center updated for either Zoom or FCC.

Use of Zoom

For more information on how to use Zoom, see Zoom Tip Sheet on Confluence.

If your Work Group is not currently using Zoom, you can sign up Work Groups Migrating to Zoom

Use of Free Conference Call (FCC)

For more information on how to use FCC, see Free Conference Call Tip Sheet

Co-Chair Expectations

Co-chairs are expected to attend all WGMs. Obviously, there will be occasions when you cannot, for work or personal reasons, attend. But generally you should plan on attending all WGMs.
Refer to the DMP and Robert’s Rules sections of this handbook for tips on ensuring successful meetings.

- Arrive in time to meet all of your commitments as co-chair of your WG and to check over your meeting room.
- Attend your Steering Division meeting on Monday night at the WGM.
- Announce your agenda at your meeting. It is good practice to do introductions each quarter at the WGM. This helps new attendees become familiar with your work group and its members/participants, and allows new attendees to be introduced to the larger group.
- Before adjourning your session at the WGM, work with your group to define a preliminary agenda for the next WGM or conference call; preferably no later than Wednesday of the current WGM.

**Keeping Attendees Updated on Agenda Changes**

Occasionally, WGs need to change their agendas or cancel or add meetings. To ensure that all WGM attendees are kept up to date on these types of changes, co-chairs are required to make announcements regarding these types of changes in a time frame that aligns with the group’s DMP.

To ensure that these types of changes are communicated to all attendees, co-chairs are required to post these announcements:

- to their WG listserv, and
- on the bulletin board near the WGM registration desk.

Additionally, co-chairs may also wish to make these announcements via the HL7 mobile app. You can arrange for this type of announcement by contact HQ staff at the Registration Desk at the WGM. Since all attendees do not use the mobile app, making these types of announcements only via the mobile app is not appropriate.

**Relationships outside HL7**

Relationships with outside organizations are managed by the Board of Directors. Co-chairs should refrain from inviting outside organizations to meet with a particular WG without approval from the HL7 Board of Directors.

**Appointment of Acting Co-Chair as Needed**

Infrequently, there may be occasions when no co-chairs from your WG will be available to attend a WGM. For these occasions, WGs may appoint an acting co-chair by bringing a formal motion to the WG in advance of the WGM. GOM §05.04 Majority Rule allows for any formal motion (including one to appoint an acting co-chair(s)), to be brought for vote to the WG using its DMP.

Acting co-chairs shall have all the powers, privileges, and responsibilities of an elected co-chair for a specific period of time with no expectation of election. An acting co-chair would typically be appointed to preside over the WG sessions at a WGM. The co-chair powers, duties and responsibilities revert back to the elected co-chairs at the conclusion of the WGM.

Selection of HL7 has a formal process for electing co-chairs, which include a 30-day call for nominations and elections at the WGM. Occasionally, a co-chair will resign at a point in time that occurs after the 30-day call for nominations. When this occurs, WGs may select an interim co-chair by a vote of hands during their WG meeting. The interim co-chair will serve until such time as a formal election can be announced and held. Unlike an acting chair, an interim chair has all the powers, privileges and responsibilities until the formal election is held. Many times, the interim chair anticipates being elected during the formal election period. Interim co-chairs will be added to the appropriate list servers and web pages.

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**Chapter 3 Work Group (WG) Planning**

**FOREWORD**

Much of the guidance from the TSC to the Work Group Co-Chairs can be found on HL7.org under resources, then select TSC Guidance.

- For project requirements include links to the Project Insight, Current List of HL7 projects, and a searchable project database.
- Key information there are links to Introducing new processes to HL7, requesting out of cycle ballot, Work Group Health, Ballot Desktop, and Guidelines for 3 year plan (Optional).

**Co-Chair Division of Labor**

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**Key Documents for this chapter**

- Ballot Desktop
- Decision Making Practices current template
- Governance and Operations Manual (GOM §09.02.04 Dissolution of a WG & §09.02.05 merging two or more Work Groups)
- Guidelines for 3 year plan (Optional)
- Introducing new processes to HL7
- Mission and Charter Template
- Out of cycle ballot
- Publication Request Template
- Standard Withdrawal Template
- TSC Guidance
- WG Dissolution Template
- Work Group Health
Each WG will typically be led by at two or more co-chairs. Each WG has unique projects and needs; the division of responsibilities should be approached with that in mind. For instance, for those WGs whose work involves both V2 and FHIR, it is advisable to divide responsibilities between the co-chairs. One successful model is to specify a V2 co-chair, a FHIR co-chair and an administrative co-chair (who assumes responsibility for meeting minutes and other administrative duties). Dividing the responsibilities in this way ensures that all areas are covered without overburdening a single person. The model of how duties should be divided, should be based on the skill sets of the co-chairs.

Another model, when there are four co-chairs, is to designate/elect both an experienced and new co-chair per version and split administrative duties among the four co-chairs.

Engaging with the Steering Division

In addition to chairing the WG, co-chairs are expected to engage with the Steering Division (SD) to which their WG belongs. The co-chairs that comprise each SD elect the SD co-chairs and vote on projects, proposed changes to work group missions and charters, the dissolution or addition of new work groups, etc. Co-chairs should view their SD as the first point of contact in resolving any number of issues that they or their WG face and/or would like to escalate to the Technical Steering Committee (TSC) for discussion and resolution.

Likewise, the SD co-chairs are the conduits of communication from the TSC to the WG co-chairs. The SD typically schedule regular conference calls and meet immediately following the Monday evening co-chairs’ meeting at each of the three WGM. At least one co-chair from each WG is expected to attend these calls and meetings. Upon your election as co-chair, you will automatically be subscribed to the list server of the Steering Division to which your WG belongs.

Assuming Stewardship for the Work Group Page on the HL7 Web Site

Any updates to your WG page should be conveyed to the webmaster (webmaster@HL7.org). Some guidelines for what information must be kept up-to-date are available from the monitoring done in the WG Health Metrics which includes historical metrics and description of their measures. This includes approved changes to your mission/charter statement (which requires SD approval), changes to your contact information, Decision Making Practices (DMPs), etc.

Keeping WG Mission and Chapter Up to Date

Every 5 years

Co-chairs should ensure that their WG’s mission and charter statement is kept up-to-date. Mission and charter (M&C) statements must be reviewed periodically, at least every five years as reflected in WG Health Metrics, with or without updates made. During this review, the WG M&C should also be compared to the current M&C template to maintain consistency with the current format. Updated M & C are sent to the SD for review and approval. If no updates are made, please indicate to the TSC Project Manager that the M & C was reviewed and no changes made. The review date can then be updated on the WG’s web site. Approved updated M&C should be forwarded to the TSC Project Manager for posting to the WG web site.

A WG may have informal relationships with a number of organizations. For example, a WG may have several active projects, which in turn may identify early adopters or organizations that are working with HL7 to develop a standards document. These are informal relationships that are and should be identified in project scope statements; these should not be listed in the Formal Relationship portion of your WG’s mission and charter statement. Occasionally a WG, such as Imaging Integration, may be formed in collaboration with another standards group or organization. These relationships are formalized with a Statement of Understanding (SOU) or Memorandum of Understanding (MOU). A list of these formal relationships is available. Please note the requirement at relationship

Keeping WG SWOT Statement Up to Date

Every 5 years

Co-chairs should ensure that their WG SWOT (strengths, weaknesses, opportunities and threats) documentation is kept up-to-date, not to exceed five years old. The presence of a current SWOT statement is a Work Group Health Metric

Work Group White Papers

A WG may, on occasion, decide to prepare and publish a white paper; i.e. an authoritative report or guideline informing readers in a concise manner about a complex issue and presenting the issuing body’s philosophy on the matter. A white paper is meant to help readers understand an issue, solve a problem, or make a decision.

A white paper, as with any other HL7 publication, shall be initiated via a Project Scope Statement (PSS) and follow the prescribed project approval process. The scope and intended audience of the white paper are factors that affect its processing and publication.

- A white paper purported to represent a Work Group(s) position on an issue or resolution and intended for a specific interest group may, at the WG’s discretion, be approved following WG peer review, which may be undertaken via the WG list server or Confluence. A Work Group White Paper (WGWP) shall use the WGWP Template and be published on the WG web page under “Documents” and/or the WG Confluence space, but shall not appear in the Master Grid of Standards. Upon Work Group approval, the responsible WG co-chairs shall post the WGWP to the WG web page under <documents>-<white papers>-. The HL7 site will include a new page under <Resources>- that will display WGWP by WG. WGWP shall be subject to reaffirmation or withdrawn within five years of publication, by simple majority vote of the Sponsoring Work Group. Co-chairs shall ensure that appropriate action is taken on or before the five year anniversary.
A white paper purported to represent an HL7 position on an issue, decision, or resolution shall be approved via an Informative Ballot and shall appear on the Master Grid of Standards. Upon Work Group approval, the responsible WG co-chairs shall submit the white paper for consideration for publication using the Publication Request Template. Informative white papers shall be subject to reaffirmation or withdrawal within five years of publication, last update or last reaffirmation following the same process as current balloted HL7 artifacts. Co-chairs shall ensure that appropriate action is taken on or before the five year anniversary.

File Maintenance Utilities

The following utilities are provided to help post minutes and documents to the website.

- **Upload and Catalog Document** - Documents and publications are uploaded using this utility, which is available only to co-chairs and staff.
- **Upload WG Meeting Minutes** - Meeting minutes are uploaded directly on your WG home page where there is a file utility. Alternately, you can use this utility to post minutes. This utility, along with the upload utility on your WG home page, is available only to co-chairs and staff. Other members of your WG do not have access to this utility. Section 2.10.1 above defines the standard HL7 file naming conventions. The minutes will display in date upload order on the web page for your WG.

The Reports

The following reports related to balloting are provided to assist co-chairs in keeping track of the status of their open ballot projects:

- **Active Ballots with no Reconciliation Package Posted** – This report lists active ballots for which a reconciliation package has not been posted. It is ordered by WG and ballot cycle.
- **PBS Metric Guidance** for SD Co-chairs – This document provides guidance for SD Co-chairs on using PBS (Projects, Ballots and Standards) Metrics to evaluate a WG’s capacity to undertake new efforts.
- **PBS Metrics Reports** – This is an archive of PBS metric reports based on WGM meeting cycle.

Chair All Meetings and Conference Calls of Your WG

Refer to the DMP (and your WG’s DMP addendum) and Robert’s Rules sections of this handbook for tips on ensuring successful meetings.

Other Work Group Concerns

Dissolution of a Work Group

GOM §09.02.04 defines the process for Dissolution of a WG. The WG Dissolution Template referenced in the GOM is available online. Additional information is available by clicking below.

Given approval under the Work Group’s documented decision making practices, the co-chairs shall complete and submit a Work Group Change Request to the TSC Chair and CTO for dissolution of the Work Group. Reasons for considering dissolution include lack of interest or expertise as evidenced by participation consistently falling below five members or achievement of the objectives of the Work Group. The request should seek to identify those Work Groups that might assume the work of the dissolving Work Group. The TSC Chair and CTO may propose and seek alternatives to dissolution.

With the concurrence of the TSC Chair and CTO, the dissolving Work Group co-chairs shall seek the approval of the appropriate Work Group(s) to assume responsibility for their work products. The Work Group(s) shall confirm consent by a two-thirds affirmative vote of their members casting a vote. The dissolving Work Group co-chairs shall complete and submit the Work Group Change Request to the parent SD co-chairs. The results of the attempt to achieve consent for the assumption of work products shall be reported on the request.

The parent SD co-chairs shall distribute the request to all other Work Group co-chairs and schedule a vote of the parent SD Work Group co-chairs to consider the request for dissolution within 30 days of submission. If appropriate, all Work Group co-chairs shall petition their Work Group members for candidates to join the affected Work Group in an effort to forestall its dissolution. Should sufficient members come forward, the request to dissolve the Work Group is moot.

Upon an affirmative vote by two-thirds of the parent SD Work Group co-chairs casting votes with at least 60% of the Work Groups returning a vote, the parent SD co-chairs shall submit the request to the TSC Chair who shall advise the TSC members of the intent to review the request for dissolution within thirty days. The TSC shall address the request to dissolve under the tenets of its documented decision-making practices. Upon approval, the TSC Chair shall notify the Board of the dissolution of a Work Group and the disposition of that Work Group’s work products; the HL7 staff representative shall request that Headquarters take the appropriate actions to effectively remove the Work Group from the organization.

Merging Work Groups

GOM §09.02.05 defines the process for merging two or more Work Groups. Additional information is available by clicking below.

Two or more Work Groups (WG) may, for whatever reason and following their documented decision making practices, decide to consolidate their membership and work items. Upon such a decision, the members of the WGs involved shall designate one of the WGs as the surviving WG. Subsequently, the co-chairs of the dissolving WG(s) shall complete and submit a Work Group Change Request for dissolution §09.02.04 citing the proposed merger. Concurrently, the co-chairs of the surviving WG shall complete and submit a Work Group Change Request to change the name of the WG and its mission and charter §09.02.02 citing the proposed merger. Upon approval of the request to dissolve and request for name/mission and charter change, the consolidated WG shall undertake a reconciliation of their former respective DMP with the objective of establishing a comprehensive DMP for the consolidated WG.
Responsibilities for Intellectual Property

HL7 has extended Intellectual Property rights to any HL7 material (Informative, STU, or Normative) that has passed ballot. Beginning with the approval of balloted material and continuing for a period of 90-days from the date of publication access to such material shall, with the exception of that material subject to prior agreement or named in proposed or final rules, be restricted to HL7 International and Affiliate members.

This provision includes those drafts of such material representing the WG’s effort to prepare the balloted material for final review and subsequent request for publication. WG co-chairs shall ensure that such material is posted to the WG page under “members only” access until such time as Headquarters releases said material.

Chapter 4 - Project Management

WGs are expected to follow HL7’s project management methodology as described in the Project Life Cycle for Product Development (PLCPD). This includes creating project scope statements for WG projects, following the project approval process, and maintaining project status in HL7’s project management tool, Project Insight. Each WG should recruit a project facilitator when possible to assist in these tasks, either for the WG projects in total, or on a project-by-project basis.

Project Services also hosts an “open forum” on scheduled calls and is available to respond to any project-related questions. The Project Services WG maintains the Project Scope Statement, Project Approval Process, PLCPD, and facilitator responsibilities and other project-related artifacts; these documents are hyperlinked below or can be located on the HL7.org website under Resources>Tools & Resources>Project Management and Tracking Tools.

Project Services WG Artifacts

- **HL7 Cover Page Template** – provides a cover page for artifacts produced by your WG (excluding ballots)
- **HL7 Ballot Guide** – The HL7 Ballot Guide was developed as a supplement to the HL7 Co-Chair Handbook to provide a quick reference guide to information related to each level of HL7 balloting.
- **HL7 Project Management Tool Overview** – describes the Project Insight tool
- **Project Approval Process** – describes the steps to take a project through the approval process, which is a requirement to ballot standards. There are different approval paths for different types of projects.
- **Project Life Cycle for Product Development (PLCPD)** – The Project Life Cycle for Product Development (PLCPD) describes the process to produce HL7 ‘products’ including standards and specifications and includes project initiative, analysis and requirements documentation, and specification design. The PLCPD, depicted as a cyclical process flow, presents the HL7 strategy for protocol specification development, enhancement, and management; however, as described in the GOM, it allows WGs flexibility to plan their strategy to produce their artifacts.
- **Project Scope Statement (PSS)** – The PSS is required for project approval as described in the Project Approval Process. It includes a template only version, and a version including the instructions. The PSS is typically updated annually.
- **Project Facilitator Responsibilities** – describes responsibilities of project facilitators, and the traits desired of individuals filling the roles and the tasks expected.
- **Project Services Webinars** - multiple webinars providing instructions on project services products including Project Insight, PBS Metrics Report, Project Management, and Work Group Health Metrics.

Project Insight

Project Insight is HL7’s Project Management System. Each WG has been assigned a log-in available from the WG co-chairs or the HL7 Project Management Office (PMO): PMO@HL7.org.

GForge Homebase

In addition to Project Insight, some Work Groups use GForge Homebase to assist with the management of projects. The HL7 Project Homebase site is intended to support HL7 Tool Developers (Toolsmiths) and WGs in managing their projects. All of the tools available on this Homebase are designed to support the development and publication of HL7 Version 3 Messaging Standards. These tools carry a license that restricts their use to activities that support the development of standards by HL7 International and the HL7 Affiliate Organizations.

Three-year Planning

Three-year planning is optional for each WG, and the future work identified should be listed as three-year planning project placeholders in Project Insight. By using this mechanism, visitors and members using the Project Insight Searchable Database can find reference to upcoming project in which they may be interested. As future development is identified, co-chairs can send their planning project descriptions, which do not require a full project scope statement, to the HL7 PMO office for update. The TSC has provided Three Year Planning Guidelines.
Chapter 5 - Balloting

Co-chairs are ultimately responsible for ensuring that any material that the WG wishes to ballot is completed as required and in a manner that is consistent with procedures upheld by the TSC following Publishing guidelines.

The following publications are very useful for new co-chairs to get a good understanding of the ballot process:

- HL7 Ballots - Voting Made Easy – This document is available for new co-chairs or anyone interested in understanding the HL7 ballot process.
- HL7 Ballot Guide - Provides a quick reference to information related to each level of HL7 ballots.

Participating in Publishing

Each WG is encouraged to select an individual who will function as the WG publishing facilitator or editor and participate in the Publishing WG. A list of current publishing facilitators is available. Please contact Headquarters (HQ@HL7.org) if your WG changes the publishing facilitator so that we can keep this list updated. The individual selected to function as the WG editor should join the editor’s list server and contact the chairs of the Publishing WG for additional instructions.

Participating in Harmonization

Each WG is encouraged to select an individual who will represent any material proposed for sponsored or co-sponsored balloting of V3 material on the Harmonization calls. That individual should join the Harmonization list server or refer to the Harmonization events page for additional instructions. Participation in Harmonization is a WG Health Metric.

Managing Suggested Updates and Modifications to the Standards

Keeping track of suggested enhancements and technical corrections/typographical errors was once a time consuming and often overwhelming task. To assist co-chairs with this task, HL7 developed databases that members use to upload suggested enhancements and corrections to the standards such as the Version 2 Database. Additional databases for tracking changes to other standards may be created as the need arises.

Complete instructions for using the V2 tracking databases are provided on the website (also available as a link from the database page). The databases can also be exported to an Excel spreadsheet for WG preparation.

Co-chairs are encouraged to review the appropriate database(s) and/or Confluence pages regularly to ensure that they have a list of the suggested enhancements/fixes to discuss with the WG and to update the disposition of the line items that have been dealt with.

The current process for conducting Review Ballots is found in GOM §13 while the process for balloting normative documents is provided in the HL7 Essential Requirements (HL7 ER). It is imperative that co-chairs know how to prepare for and conduct ballots. ANSI auditors select a given number of normative ballots for review every five years. The auditors are very thorough and will check to ensure that every negative balloter/commenter has been advised in writing of the status of their negative vote/comments and that each negative vote has either been withdrawn or addressed in a recirculation ballot, and that each negative balloter is informed of the appeals process.

An annual HL7 ballot schedule, based on three ballot cycles per year, is produced by Publishing. All ballot types will adhere to the ballot schedule unless granted an exception by the TSC. The ballot schedule is distributed to all co-chairs and identifies all critical path dates regarding preparation and submission of ballot material. All ballots must be approved by the TSC. A current publishing calendar is available online.

Ballot Desktop

HL7 uses the Ballot Desktop to store votes, comments and reconciliation packages for each of its ballots. The Ballot Desktop enables co-chairs to view ballots related to current and past ballot cycles, send email to voters in the consensus groups related to their WG ballots, and post reconciliation spreadsheets that advise the voters of the status of negative votes. All ballot types, be they Review or Normative, are handled by the Ballot Desktop.

Review Ballots

There are three types of Review Ballot: Informative Documents (GOM §13.01); Standards for Trial Use (STU) (GOM §13.02); and Comment-only (GOM §13.03). The flow involved in the review ballot process is depicted in Appendix B:

Informative Documents explain or support the structure of HL7 standards, or provide detailed information regarding the interpretation or implementation of an HL7 standard.
STU are normally issued as a precursor to a normative ballot. They allow the responsible WG to gather industry input on the completeness and viability of the implementation of a proposed standard. The review ballot allows for validation of the content of the proposed standard prior to release for trial use.

A Comment-only review allows the WG to gather input from a broader audience on documents in process; be they requirements documents, possible informative documents, or candidates for normative status. Comment-only ballots are also used to validate certain administrative actions such as assessing the membership's position on the proposed withdrawal of an informative document or normative standard.

Although the TSC may approve multiple iterations, typically there is a single occurrence of a given Comment-only ballot since the next step for the document under review would be an informative, STU, or normative ballot. An informative document or STU review ballot may remain active until the content is either approved or withdrawn.

HQ notifies all current members at least 30 days prior to scheduled ballot open date of the intent to form a consensus group for Review Ballots. Consensus group signup is allowed until the day prior to the date that the ballot opens.

In the course of the ballot period all comments should be captured via the Ballot Desktop to facilitate later consideration by the WG.

There is no reconciliation of review ballot comments per se. However, WGs are expected to consider all comments with the intent of improving the quality and clarity of the content being reviewed. The results of the WG’s consideration of each comment shall be recorded on the Ballot Desktop. There is no requirement to resolve negative comments.

Substantive change as a result of a review ballot does not cause an arbitrary need to conduct another review ballot. Such changes are the result of identifying obvious shortcomings in the ballot content which is the intent of a review ballot. Having incorporated the change, the WG may move forward with the informative document or STU. However, a WG always has the option to conduct another review if felt necessary.

Quorum and approval levels differ by review ballot type. Please consult the GOM for specifics.

Where the evaluation and comment period of a STU results in a need for substantive changes to the proposed standard, the resulting normative ballot material may embody such changes or a revised STU may be released for further evaluation and trial use without recourse to another review ballot.

Normative Documents

A normative ballot is used to validate and approve proposed American National Standards (ANS). The normative process is driven by American National Standards Institute (ANSI) requirements as implemented by the HL7 Essential Requirements: Due process requirements for HL7 American National Standards (HL7 ER).

HQ notifies all current members at least 30 days prior to scheduled ballot open date of the intent to form a consensus group for normative ballots. Consensus group signup is allowed until the day prior to the date that the ballot opens.

Co-chairs should monitor ballot responses as they are submitted (co-chairs receive copies of all returned ballots related to their WG) and notify the consensus group, especially those who returned negative ballots, when and where their comments will be discussed; e.g., Monday-Wednesday at the next WGM including the location and date.

Prepare a preliminary reconciliation package that is distributed at the meeting, via e-mail or posted to the Ballot Desktop that lists each negative vote/comment and a motion for resolving it. HL7 provides an Amalgamation Macro to aide this process. Hold open discussions to determine the disposition (by WG vote) on all negative comments received in response to the ballot. This may be accomplished at the WGM, via a conference call, etc., but should be consistent with what was announced above. Record the motions and subsequent votes in the disposition section of the Ballot Comment Spreadsheet and include as a zip file with the meeting minutes. The different dispositions are:

- **Persuasive:** A majority of the WG agrees without objection that the position expressed by the negative response is persuasive; the changes recommended by the comment shall be incorporated as reasonable and necessary revisions.
- **Not Persuasive:** A majority of the WG agrees that the comment deals with process or issues not under the control of the WG, or suggests the use of alternate methodologies or solutions which have no advantage over those used, or questions the validity of the approach or the expertise of the developers. Comments declared not persuasive but not withdrawn are reported as unresolved negatives.
- **Not Related:** A majority of the WG agrees that the comment deals with issues or functions beyond the scope of or is clearly not related to the ballot subject matter. Comments declared not related are reported as “negative without comment” and don’t impact the outcome of the ballot.

Once the WG has voted on the dispositions, send an e-mail through the Ballot Desktop to each negative submitter advising them of the status of their negative vote/comment. HL7 headquarters must be able to produce this communication for the ANSI auditor. Using the Ballot Desktop ensures that this requirement is fulfilled and that the communications are captured in a central location.

Follow up with each negative voter to ensure that he/she has been informed of the disposition of their negative vote and given an opportunity to either withdraw the negative vote (which becomes a positive vote) or affirm the negative. To withdraw a negative vote, the voter must advise the co-chair and the appropriate HL7 staff in writing, which is typically done through the Ballot Desktop.

Following reconciliation, determine if the document passed: a majority of the consensus group returned a ballot representative of a majority of HL7 members enrolled and at least 75% of combined affirmative/negative votes are affirmative. Unresolved negative comments do not preclude a document from being submitted to ANSI; however, submission with unresolved negative comments must be preceded by a recirculation ballot to allow consideration of such comments by the entire consensus group.

Make any updates to the document and notify HQ of your intent to re-ballot, if substantive changes merit such, or move forward to ANSI for approval.
For a subsequent normative ballot of the same content, the consensus group shall include those who responded to the previous ballot; whether affirmative, negative, or abstain. Although the TSC may re-open the consensus group to additional registrants, typically the consensus group for subsequent normative ballots of the same content is not open to additional signup.

In the case of a subsequent normative ballot of the same content, a negative vote or comment that has been previously considered and resolved and is resubmitted does not require further consideration.

Reconciliation Activities

Co-chairs are responsible for tracking, completing and posting Ballot reconciliation items using the Ballot Desktop. It is very important that ALL reconciliation activities be recorded on the Ballot Desktop. If at any time you need support in correctly using the Ballot Desktop or in troubleshooting problems you might have, please contact the Technical Publications Manager (ballotmanager@HL7.org) and Webmaster (webmaster@HL7.org) for help. For specific instructions on completing the Excel-based reconciliation spreadsheets, please refer to the instructions in the reconciliation spreadsheet template. In general, co-chairs are responsible for:

- Consolidating all comment spreadsheets submitted on their ballot document during the ballot period before the WGM using the Amalgamation Macro
- Conducting reconciliations during WGMs and conference calls
- Recording and tracking the WG reconciliation decisions and actions in the consolidated spreadsheet
- Posting the completed reconciliation package to the Ballot Desktop
- Notifying all negative voters of the status of their negative votes using the Ballot Desktop

It is recommended that co-chairs post an amalgamated spreadsheet before beginning reconciliation so all participants have access. As reconciliation activity proceeds, post incremental updated spreadsheets using version numbering (V1, V2, etc.) or including the “effective date” in the title. These posting should be to the Ballot Desktop; if not, you must ensure that all participants are aware of their location. When reconciliation is completed, it is recommended that the term “final” be included in the title of the spreadsheet.

Completion of reconciliation activities is required for all Normative Ballots to meet ANSI requirements. Co-chairs may find the reconciliation how-to document helpful when undertaking reconciliation activities.

Consolidation Comments

At the close of the ballot period a co-chair should log in to the Ballot Desktop and consolidate all the comments received from voters during the ballot period. These actions should be completed prior to the upcoming WGM so that WG members have the consolidated comments spreadsheet available for review during your sessions at the WGM.

1) From the Ballot Desktop, click on the Tally tab. When the screen refreshes, you will see a listing of all the consensus groups with each title linking to an individual Tally page.

2) Click the link for your WG’s ballot document. This will load the Tally page for your ballot document. In the left-hand menu section titled “Participation Summary Download” are links to help you download summary information and create a consolidated comment spreadsheet.

3) To begin, click on the Export this Ballot Participation Summary Information link. You will be prompted to open or save a “CSV” file. Click the Save button and save the file to a convenient location, such as an appropriately-named folder on your desktop. (More information on saving and formatting this “CSV” file as an Excel spreadsheet can be found from the Tally page by clicking on the Instructions for Using the Exported data link.)

4) You should also download the Participant Summary Download Macro spreadsheet from the Tally page to the same location you saved the “CSV” file. When you open this spreadsheet it will prompt you to select the “CSV” file. Macros in the spreadsheet will then format it and allow you to save it as an Excel file.

5) Continue to download all the comment spreadsheets submitted by voters to the same download directory. The Tally page will display a link to each of these files in the “Upld?” column.

6) Once you have collected all the Comment spreadsheets, you will need to consolidate them into a single spreadsheet. This is done with the Ballot Amalgamation Macro Spreadsheet. A link to this spreadsheet is available from the main Tally page that lists all the consensus groups. Full directions on performing the consolidation are included in the spreadsheet. Please note that not all voters will provide their comments in a Comment spreadsheet; some may use a Word file or provide comments with their votes. You will need to manually add such comments to your consolidated comment spreadsheet.

7) Use of the Ballot Amalgamation Macro Spreadsheet may result in links from the consolidated spreadsheet back to the original documents. These links are maintained by Excel and may produce annoying notices when opening the spreadsheet regards updating the document from the linked document. If Excel is set to update those links automatically there is the possibility of locking up Excel while it attempts to do the updates. To break the links to the other spreadsheets, open the consolidated spreadsheet and do the following: [IMPORTANT: When a link to a source is broken all formulas that use the source are converted to their current value. For example: the link =SUM([Budget.xls]AnnualC10:C25) would be converted to =45. This action cannot be undone; it is recommended that you save a version of the spreadsheet before you start. NOTE: these links are different from hyperlinks embedded in a cell.]

7.1 On the Edit menu, click Links

7.2 In the Source list, Click the link you want to break or select multiple liked objects hold down CTRL and click each appropriate link or to select all links press CTRL + A

7.3 Click Break Link

Tracking Reconciliation Activities in the Reconciliation Spreadsheet
During your WG sessions or calls, use the consolidated comments spreadsheet to record decisions for each of the comments listed. Information should be as complete as possible because the reconciliation spreadsheets provide the primary means of recording WG decisions, of communicating those decisions and the supporting rationale to negative voters, and of tracking any activities by individuals to resolve those negative comments.

Individual columns in the spreadsheet are provided to, among other things, allow WGs to record their responses to comments, to provide a rationale for a decision, to assign a person responsible for completing a reconciliation action and to record the completion of that action. Please refer to the instructions in the comment spreadsheet for more help on completing the reconciliation spreadsheets correctly and completely filling in column information.

When your reconciliation actions are complete, compress the reconciliation spreadsheet into a zip file along with any other documentation needed to support the reconciliation actions and decisions. This zip file and its contents are now referred to as the Reconciliation Package and will be posted on the ballot document Tally page on the Ballot Desktop.

Posting a completed Reconciliation Package

Once a WG has completed all the necessary reconciliation actions to address all negative comments, the completed spreadsheet needs to be uploaded to the Ballot Desktop.

1) From the Ballot Desktop, click on the Tally tab. When the screen refreshes, you will see a listing of all the consensus groups with each title linking to an individual Tally page.

2) Click the link for your ballot document to view the Tally page for your consensus group.

3) In the left-hand menu, expand the Resolving Negatives header and click on the Upload the Reconciliation Package for the Document Pool link.

4) The Upload page includes a button to allow you to browse to and select your completed Reconciliation Package.

5) Once you have selected the appropriate file click the Upload this Reconciliation Package button. Please note that the web site system will automatically rename your file based on file naming conventions for the ballot pool and the current ballot cycle. You will receive notification when the file upload is complete.

Notifying Negative Voters of the Status of Negative Comments

Once a completed Reconciliation Package has been posted to the Ballot Desktop, co-chairs are responsible for notifying submitters of the status of their negative comments. The Tally page on the Ballot Desktop provides functionality to help you complete these actions.

1) From the Ballot Desktop, click on the Tally tab. When the screen refreshes, you will see a listing of all the consensus groups with each title linking to an individual Tally page.

2) Click the link for your ballot document to view the Tally page for your document pool.

3) In the left-hand menu, expand the Resolving Negatives header and click on the Request Withdrawal by Emailing All Negative Voters link. This page allows you to email all or select negative voters in the consensus group. Please note that you either need to select the Send to All Names checkbox or check individual names. If you don’t check any box, the message has no recipients. This page also allows you to customize the notification email and to include a link to the reconciliation package in the email. Co-chairs can use this page to send out several notification emails at different points in the process of completing a ballot. Such notification might include an initial notification that a reconciliation package is available, follow-up notices if the information in a reconciliation package changes, or requests for additional information from voters who fail to withdraw their negatives.

The completion and posting of reconciliation actions and the recording of reconciliation activities is a very important part of a co-chair’s responsibilities and helps us to comply with the requirements of an ANSI-accredited standards development organization.

Escalating and Resolving Requests to Withdraw Negative Votes

As noted above, normative documents can progress to ANSI as long as 75% of the affirmative and negative votes cast on the document are affirmative. However, unresolved negative votes must be subject to a re-circulation ballot, which presents the members of the consensus group an opportunity to change their vote if desired. To request a recirculation ballot, complete the Recirculation Request Template and send it to both the Director of Technical Publications and the Associate Executive Director. If the recirculation ballot concludes with at least 75% affirmative votes, the document can be submitted to ANSI for approval.

Many times, negative voters do not respond to repeated requests to withdraw negative votes or engage with the committee on resolving negative votes. The following steps are recommended to keep the ballot process moving forward:

• Provide each negative voter with two (2) requests, sent through the Ballot Desktop, to withdraw their negative votes, providing a week or two for a response.
• If the negative voter fails to respond to those requests, call the HL7 Associate Executive Director (734-677-7777 x104), who will phone the key contact at the appropriate organization and ask the key member to resolve the issue.
• If the key member fails to respond within a week or two, co-chairs should reassess how many affirmative votes have been received. If less than 75% of the combined affirmative and negative votes are affirmative, the document may need to be re-balloted. If at least 75% of the combined affirmative and negative votes are affirmative, the co-chair shall advise the Director of Technical Publications that a recirculation ballot is necessary.
• If at least 75% of the combined affirmative and negative votes returned for the re-circulation ballot are affirmative, the document will be submitted to ANSI for approval. If the document failed to pass the recirculation ballot with at least 75% affirmative vote, it is a candidate for re-ballot or withdrawal.
Substantive Change

What is a substantive change? According to ANSI a Substantive Change is one that directly and materially affects the use of the standard. The ANSI definition includes changes that would break solutions that were implemented using the specification as it existed before the change. As an ANSI-accredited Standards Development Organization (SDO), HL7 must be guided by the ANSI definition provided in *ANSI Essential Requirements* and reiterated in the HL7 ER.

According to ANSI a Substantive Change to a proposed American National Standard is one that directly and materially affects the use of the standard. Examples of Substantive Changes are:

- Changing “shall” to “should” or “should” to “shall”;
- Addition, deletion or revision of requirements, regardless of the number of the changes.
- Addition of mandatory compliance with referenced standards

The Architectural Review Board (ARB) describes substantive changes as those changes which modify the standard by adding or removing capabilities. Any change that damages the integrity of semantics as well as the validity of syntax is a substantive change. A change that materially affects the contents of exchanged messages is substantive. For example, the addition of a new trigger event is substantive; adding fields to an existing message type is substantive. On the other hand, the correction of a typographical error, or the addition of an example message is not considered substantive.

The ARB considers a change to the standard to be substantive if an interface would fail when a message composed with the change is built, sent or received. This is similar to, but more expansive than, the definition of backwards compatibility. A change that creates a backwards compatibility problem is substantive by definition.

Role of Substantive Change in Balloting

The goals of the HL7 ballot process are to:

- Meet its members' needs for specifications that are responsive to conditions. Timeliness is important.
- Develop specifications that permit any interested HL7 member to participate and make their views known.
- Encourage early implementation of specifications to ensure that final specifications are used and useful.
- Publish high quality specifications that are accurate, clear, coherent, and consistent across the full set of specifications.
- Adhere to *ANSI Essential Requirements* that are focused on ensuring that a consensus is achieved within the entire industry without any "special interests" skewing the results.
- Abide by the HL7 Bylaws, *Essential Requirements* (HL7 ER) and Governance and Operations Manual (GOM) to achieve these goals.

The definition of "substantive" changes must be interpreted within this context.

In a perfect world, every specification submitted for ballot would be complete, coherent, clearly expressed, consistent with all related specifications and delivered "just in time" for its intended use. Normative ballot reviewers would represent the full spectrum of affected parties and would vote in the affirmative with the only comments being small suggestions to add "polish" before publication. Additionally, many people would implement the specifications and actively provide feedback to continue to extend and enhance the specifications.

We realize that we do not live in a perfect world. Each of us juggles many objectives. The tradeoffs are tough and it is the Architecture Review Board's responsibility to provide guidance to the WGs so that the overall set of Version 3 specifications approaches this ideal. The ARB has been approached by WGs for interpretation when they cannot clearly delineate changes as either "substantive" or "non-substantive". The 2.x concept of substantive change is based on the premise that changes that would "break" solutions implemented using the specifications are substantive. The ARB will apply this principle to Version 3.

Since the goal of Version 3 Standards is semantic interoperability, the overriding principle for determining if a change is substantive will be whether the change damages the integrity of semantics or the validity of syntax. A primary Version 3 principle is the use of constraints as the delineation of correctness. The Version 3 specifications are model driven, so changes to any of the structural properties that would alter the constraints contained in the source models would be substantive changes.

Effect of Substantive Change

HL7 ER §02.09.04 stipulates that substantive change introduced as a result of comments received on a normative ballot will result in a subsequent normative ballot of the same content.

The Importance of Substantive Change

Why is the distinction between substantive and non-substantive important? ANSI rules and HL7 process require that all substantive changes to normative material be balloted.

The identification and designation of changes as substantive or non-substantive plays an important role in the balloting process. When a WG creates a ballot package, the package should include a list of all changes from the previous version of the document. This list should indicate which changes are considered to be substantive, and which are not. When a chapter or other section of a standard goes through successive ballots, this list should indicate changes from the prior ballot, not from the beginning of the balloting process.

V2 Substantive Changes description can be found by clicking below.

The following constitute substantive V2 changes:
• Addition or deletion of a trigger event - This implies the definition of an abstract message corresponding to the trigger event.
• Addition or deletion of an abstract message or change to an existing one - This includes addition or deletion of segments or segment groups, changes in segment or segment group repetition and changes to segment or segment group optionality.
• Addition of a segment - This implies the use of the segment in an abstract message.
• Addition of a data element within a segment.
• Changes to an existing data element - This includes addition or deletion of components, and changes to component order, optionality, or repetition. It includes changes to the data type assigned to a component, and/or changes in the maximum length of a component.
• Changes to an HL7 defined table - This implies that the code table is assigned to at least one data element. Substantive changes include the addition or subtraction of code values.
• Change to a definition that changes how a receiving system has to manage the received message.
• Changes to chapter text that change the rules for when a trigger event is used.

V2 Non-Substantive Changes description can be found by clicking below.

The following constitute non-substantive V2 changes:

• Changes to the codes in user defined and externally defined tables.
• Changes to definitions (segment, element, trigger event, data type, etc.) that clarify the WG’s intent rather than changing subsequent processing.
• Technical corrections that implement the original intent of the WG. For example, if a WG meant to add an attribute to one segment, and it was mistakenly added to another; this can be corrected without an additional ballot.
• Changes to the HL7 assigned ID for an element when it is realized that what appears to be a new element is an existing one.

V3 Substantive Changes description can be found by clicking below.

V3 Substantive Changes

The objective is the same as for V2 – anyone materially affected by a change in the normative specification should have an opportunity to make their opinion of the change known, and have that opinion taken into consideration, before a change is adopted.

Those potentially materially affected are not just senders and receivers of messages – but consumers of ANY HL7 specification. Operationally, if implementing against the specification as previously communicated does not accomplish the same objective as implementing against the current specification, the introduced change is substantive.

Substantive differs between Version 2 and Version 3 in the increased emphasis on the “semantics” of the interaction, not just the syntax. Therefore, if any system participating in an interoperable function cannot meet its contractual obligations, the introduced change is substantive.

Because V3 has more artifacts and is more explicit, there is more probability that ANY introduced change will be substantive, unless it was just a change to definition to improve clarity. The following are examples of substantive changes:

• Changing constraints on data.
• Changing the properties of an existing data type - For example, Add a property to AD to indicate the parts are unordered.
• Changing the value set assigned to a structural table - For example, Use of an HL7 defined vocabulary instead of xml:lang for coding languages. This is non-controversial, but substantive.
• Changing definitions that change receiving system behavior.

V3 Non-Substantive Changes description can be found by clicking below.

V3 Non-Substantive Changes

Changes to descriptive text that clarify, but do not change meaning, are considered non-substantive:

• Typographical corrections.
• Formatting corrections.
• Changes made to graphics.

V3 Elements and Substantive Change
This section lists elements of a Version 3 Standard with rules and examples of substantive and non-substantive changes. See the Version 3 Guide in the HL7 Ballot document for more information on each element. As a general rule, changes that are made to non-normative elements are not substantive. Changes to normative elements may be substantive.

**Storyboards**

A storyboard consists of a short description of its purpose and an interaction diagram that shows the progression of interactions between application roles. A storyboard narrative is a description of a real-life event that provides the necessary context for the development of a specific interaction described in the storyboard. The process of storyboarding lays the foundation for describing HL7 messages and their content. Storyboards are not normative. Therefore, changes to Storyboards are not substantive.

**Application Roles**

Application Roles represent a set of communication responsibilities that might be implemented by an application. They describe system components or sub-components that send or receive interactions. Application Roles are not normative. Therefore, changes to Application Roles are not substantive.

**Trigger Events**

A Trigger Event is an explicit set of conditions that initiate the transfer of information between system components (application roles). Trigger Events are normative. Changes to normative elements may be substantive.

Here are some examples:

- Adding or deleting a Trigger Event is a substantive change.
- Changing descriptive text that alters Trigger Event rules is a substantive change.

**Domain Message Information Models**

The Domain Message Information Model (D-MIM) is a subset of the Reference Information Model (RIM) that includes a fully expanded set of class clones, attributes and relationships that are used to create messages for a particular domain. D-MIMs are not Normative. Therefore, changes to D-MIMs are not substantive. However, a change to an R-MIM not supported in the D-MIM is Substantive, because messages will fail.

**Definitions**

**Backwards Compatibility:** A change that would create a backward compatibility problem is a substantive change. For backwards compatibility, a message recipient is expected to process a new message and ignore added material. If there is new material that needs to be parsed in order to process the message given its new definition, the change is substantive.

Some general rules for a Backwards Compatibility are:

- From the V3 perspective, the focus is on message types. As long as there is a set of message types that do what was done before, the contents of a ballot are backwards compatible.
- Neither attributes nor associations can be removed from a message type.
- Association cardinality cannot be tightened.
- You can change attribute conformance from Mandatory to Required, and from Required to Optional, but not the reverse.
- You cannot remove values from the HL7 defined value sets for structural codes. This includes all attributes with CS data types.
- If a particular coding system is associated with a domain within the ballot, it may not be removed.
- If a particular value set is associated with a domain within a ballot, the value set reference may not be removed, nor may any code be removed from the value set.
- No interaction may be removed that existed in the prior ballot. This precludes removal or redefinition of a trigger event.
- Receiver responsibilities may not be removed from interactions.

**Non-substantive:** A change is considered to be non-substantive if it would not cause an interface to fail when a message was sent or received. All technical corrections are non-substantive changes. Changes made to non-Normative material are not substantive.

**Substantive:** Substantive changes modify the standard by adding or removing capabilities. A change is considered to be substantive if it would cause an interface to fail when a message was sent or received. This is similar to, but more expansive than, the definition of backwards compatibility. A change that creates a backwards compatibility problem is substantive by definition.

**Technical Corrections**

A technical correction is a type of non-substantive change. A technical correction is a non-controversial change that alters a document so that it says what the WG intended to say. Technical corrections typically involve correcting changes to normative content that were not made, were incorrectly made, or were inconsistently made during the editing process.

When there is doubt, a WG may ask the TSC to rule whether a change is a technical correction. In this case, the TSC will ask for documentation that the WG intended to make the change and evidence that the change is non-controversial, such as:

- A reconciliation package or meeting minutes that document the WG’s intent to make a change.
- Meeting minutes that document a discussion of the change and record a unanimous vote to make the correction.

Here are some examples of technical corrections:

- The CDA document refers and links to RFC 2557 "MIME Encapsulation of Aggregate Documents, such as HTML (MHTML)" If the RFC moves, the hyperlink would break. Fixing a broken hyperlink is a technical correction and a non-substantive change.
The RMIM Design tool never correctly named the associations to or from a role clone when that clone is a CMET. The tool was corrected. A process was run on existing material to correct the naming error. This is a technical correction and a non-substantive change.

In ebXML, the WG neglected to add the type attribute used in the OASIS original. The type element could be ISO OID, DUNS Number, etc. Making this change, which makes ebXML consistent with the underlying OASIS standard, is a technical correction and a non-substantive change.

### Managing Substantive Change

The TSC will play the following role in the management of substantive change:

- Define the criteria for substantive changes.
- Review, upon request, proposed changes to determine whether they are substantive.
- Act, as a general matter, in the role of an auditor. It is important to recognize that the TSC may need to discuss changes with the WG, because the application of the rules needs to consider the context.

### Submitting ANSI-approved HL7 Standards for ISO Approval

Once an HL7 standard is ANSI-approved or is published as a Standard for Trial Use (STU), it can be submitted for approval by the International Organization for Standardization (ISO) under a special agreement. Please review information and complete instructions to follow this process.

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### Chapter 6 Working Group Meeting Planning

#### Responsibilities at the WGM

Co-chairs are expected to attend all WGMs. Obviously, there will be occasions when you cannot, for work or personal reasons, attend. But generally you should plan on attending all WGMs. Arrive in time to meet all of your commitments as co-chair of your WG and to check over your meeting room. This will certainly include attending the co-chairs’ meeting on Monday evening as well as attending the SD meeting for your WG, which is a WG Health Metric. Announce your agenda at your meeting. It is good practice to do introductions each quarter at the WGM. This helps new attendees become familiar with your work group and its members/participants, and allows new attendees to be introduced to the larger group. Before adjourning your session at the WGM, work with your group to define a preliminary agenda for the next WGM or conference call; preferably no later than Wednesday of the current WGM.

#### WGM Checklist

A generic checklist, including the items discussed above, that WG co-chairs need to coordinate both before and after the WGM is available online.

#### Work Group Health Metrics

There is an ongoing effort to ensure that WGs are open, active and effective within each SD. The measures of perceived WG health include a few simple items identified to better align the WGs with HL7 expectations for effective WGs. WG Health Metrics are produced before each WGM. The following TSC Confluence page includes the details on what is measured in the WG Health Metrics as well as approval requirements for the Work Group Mission and Charter Statement (M&C), Decision Making Practices (DMP), and Strength/Weakness/Opportunity/Threat (SWOT) analysis.

#### Co-Chair Dinner - Monday night of the Working Group Meeting

The co-chairs dinner/meeting is composed of the co-chairs of all WGs and committees within HL7, HL7 leadership, and staff. Additionally, any WGM attendees are allowed to observe but not actively participate in discussion or decision making unless they have been invited to participate on specific topics. While registering for the WG, co-chairs should indicate their intent to attend this meeting. It is typically scheduled for Monday evening during each WGM. Check the meeting brochure to confirm the date/time and location of this meeting. While all co-chairs are encouraged to attend the meeting, only one co-chair per WG is required to attend. The SD should be notified if this is not possible. Each WG will designate one co-chair from among the co-chairs to represent their interests at the co-chairs dinner/meeting. They are the official spokesperson and voting co-chair for their WG. The co-chairs dinner/meeting is typically followed by the SD meetings. Co-chair representation from each WG is required at the SD meeting. Both the WG and SD should be notified if this is not possible. SD meeting attendance by a co-chair representative from each WG is a WG Health Metric.

#### Keep Attendees Apprised of Agenda Changes

Occasionally, WGs need to change their agendas or cancel or add meetings. To ensure that all WGM attendees are kept up to date on these types of changes, co-chairs are required to make announcements regarding these types of changes in a timeframe that aligns with the group's DMP. To
ensure that these types of changes are communicated to all attendees, co-chairs are required to post these announcements to their WG listserv, and on the bulletin board near the WGM registration desk. Additionally, co-chairs may also wish to make these announcements via the HL7 mobile app. Since all attendees do not use the mobile app, making these types of announcements only via the mobile app is not appropriate.

Preparing for the WGM

Appoint an Acting Co-chair as Needed

Infrequently, there may be occasions when no co-chairs from your WG will be available to attend a WGM. For these occasions, WGs may appoint an acting co-chair by bringing a formal motion to the WG in advance of the WGM. GOM §05.04 Majority Rule allows for any formal motion (including one to appoint an acting co-chair(s)), to be brought for vote to the WG using its DMP.

Acting co-chairs shall have all the powers, privileges, and responsibilities of an elected co-chair for a specific period of time with no expectation of election. An acting co-chair would typically be appointed to preside over the WG sessions at a WGM. The co-chair powers, duties and responsibilities revert back to the elected co-chairs at the conclusion of the WGM.

Select an Interim Co-chair

HL7 has a formal process for electing co-chairs, which include a 30-day call for nominations and elections at the WGM. Occasionally, a co-chair will resign at a point in time that occurs after the 30-day call for nominations. When this occurs, WGs may select an interim co-chair by a vote of hands during their WG meeting. The interim co-chair will serve until such time as a formal election can be announced and held. Unlike an acting chair, an interim chair has all the powers, privileges and responsibilities until the formal election is held. Many times, the interim chair anticipates being elected during the formal election period. Interim co-chairs will be added to the appropriate list servers and web pages.

Ensure that Meeting Minutes are Taken

If you have a WG secretary or a co-chair who is responsible for taking minutes, verify that he or she will be in attendance. Otherwise, ask for a volunteer to provide notes or minutes in electronic form so you can focus on chairing the meeting.

Minutes can vary widely in their depth of coverage. WGs should use the RTF minutes template or the Wiki minutes template. These templates provide an empty file (no words) with the appropriate styles for taking meeting minutes. A style guide is included with the templates to assist co-chairs with the look/feel of meeting minutes. Also available is the Meeting Attendee template which can be posted with the minutes.

The minutes should include:

1) A list of attendees
2) Precisely worded motions that were made along with indication of how successful they were (passed unanimously, passed without objection, or the actual number of votes for, against, and abstentions). Motions and tallies related to ballot reconciliation can, instead, be recorded in the reconciliation spreadsheet, and posted as noted under item 5 below.
3) Descriptions of any associated work products (white papers, draft documents, presentations, etc.).
4) The agenda for the next meeting
5) Electronic copies of all work products of the WG including papers that were presented at the meetings, overheads, etc. Text files, Microsoft Word documents and PowerPoint documents are the three most common ways of providing information. Combine the minutes and all related documents in a single .ZIP archive and upload it to the website.

If your WG did not achieve quorum, post a document stating that fact and that no business was conducted. While there can be no binding decisions on calls that do not achieve quorum, minutes of the discussions, should there be any, should be taken and posted to the website.

Your WGM meeting minutes are expected to be posted within two weeks following the WGM. Conference call minutes should be posted as defined in the Decision Making Practices document.

Note that meeting minutes must be accessible from the Work Group's "Minutes" tab whether posted to the Work Group's page on the HL7 website or to the WG Confluence Space. Work Groups posting minutes to a location other than the WG page on the HL7 website should include links under the "Minutes" tab to direct visitors to the appropriate location. Notify the webmaster if you have alternate locations for Conference Call Notices, Documents, Issues/Hot Topics, Meeting Agendas, Meeting minutes, other links, Presentations, Project Documents, or a Confluence space. The posting of minutes is a WG Health Metric.

At the Work Group Meeting

Meeting Room and AV Requirements

Instructions for requesting meeting rooms for the next WGM are distributed at the co-chairs' dinner meeting held on Monday evening of the current WGM. Co-chairs will also receive a reminder email from the Director of Meetings with instructions and the URL for room scheduling for the next WGM.

Rooms are assigned in the following priority, based on room size and availability:

1) Work Groups
2) Board-appointed Committees
3) HL7 Special Projects Groups
4) Ancillary Groups

Request only the space you will need and indicate the numbers of attendees you expect at the WG meeting. In the event more participants attend than were planned for, the HL7 Director of Meetings can have additional chairs brought in.

Meeting space for the next WGM is requested online. Room requests for all joint WGMs planned for the next WGM must be submitted to the HL7 Director of Meetings no later than the Friday following the WGM as specified in the section below.

**WGM Room Requests**

Meeting room requests for the next WGM are submitted online no later than Friday of the week following the most recent WGM, (7 calendar days). You must include your AV requirements in the online form.

Requests for meeting rooms for joint WG meetings are made after the co-chairs of the WGs determine a day and quarter(s) which they would like to meet. The co-chairs determine which WG will be designated as the Host. One of the co-chairs of the Host WG will submit the meeting room request for the joint meeting when they submit the meeting room request for the next WGM. The non-Host WG(s) **WILL NOT** request meeting room for the quarters when they are meeting jointly and should not include any reference to it in their WGM request.

For assistance using the WGM Room Request Application, please take the opportunity to view a short webinar targeted to co-chairs demonstrating the use of the application to request conference rooms for upcoming WGM.

**AV Requests**

When requesting AV support, consider your needs carefully and request only the items needed. The following items should be considered: LCD projector; screen; power requirements (strips); and sound system for large groups and special presentations.

**Photocopy Requests**

HL7, like many organizations, is “green” and therefore encourages the use of electronic rather than hardcopy documents. If you need photocopies during the WGM you will need to obtain them through the meeting venue business support office or contract for photocopy services with an off-site provider.

**Meeting Change Notification**

Notify the WGM registration desk of any changes to your scheduled WG sessions. The headquarters staff posts changes to scheduled WG sessions to a bulletin board near the registration desk and can ensure the changes are posted to HL7 mobile app. This alerts interested attendees of the changes and advises the staff of changes. You may also need to announce meeting changes on your WG’s list server or via other means as defined in your WG’s DMP.

**Prepare a Detail Meeting Agenda**

WGs should plan the agenda for the following WGM by Wednesday of the current WGM in order to determine room requirements and joint meetings for the following WGM. Agendas for upcoming WGM are to be posted as soon as possible to the WGM Confluence page for the appropriate meeting so that WG attendees can plan their participation well in advance of the meeting.

HQ will send several emails to co-chairs reminding them to post their agendas. Agendas can be updated as needed and reposted to the Confluence space. Once an agenda is set you should consult with your WG prior to changing the agenda, particularly for items that might impact travel schedules. For example, some organizations have different representatives for V2 and V3 work so changing those agenda items could adversely impact travel plans.

If the agenda is changed after the WGM has started, post those changes on the bulletin board near the WGM registration desk and announce the change on the WG list service. Additionally, co-chairs may also wish to make these announcements via the HL7 mobile app. Since all attendees do not use the mobile app, making these types of announcements only via the mobile app is not appropriate.

Agendas should be brief but cover the major topics including, but not limited to, votes or elections that may be coming up. The Plenary meeting (usually in September) has a general session Monday morning (Q1, Q2) with the WG sessions beginning after lunch (Q3). Plan your agenda accordingly. An agenda template is provided on the website along with agenda icons.

**Responsibilities after the WGM**

**Submit Meeting Room Requests for the Next WGM**

Within one week following the end of the most recent WGM you must submit your request for your regular meeting room for the next WGM via the web form announced at the TSC meeting during the most recent WGM as indicated in GOM §2.12.6.1 WGM Scheduling.

**WGM Posted within 2 weeks**

Submit minutes and associated work products within two (2) weeks following the end of the most recent WGM. Get the minutes from your secretary or the person who took notes for you. Review, edit and have the WG vote to approve them. Note that minutes may be approved by “general consent”
when there are no corrections; the co-chair states “You have received the minutes. Are there any corrections to the minutes? Hearing none, if there are no objections the minutes are approved as posted.” Once approved, upload them directly to the website by going to the Minutes repository for the individual WG located on the WG page. You can upload your minutes in Word, PDF or Zip file format. You are encouraged to include machine-readable diagrams in your minutes. Should you choose to post meeting minutes to the WG Confluence Space, a link to the location must be included in the “Minutes” tab of the WG’s website.

Communicate with your WG members via teleconference or by e-mail; monitor and facilitate any work towards deliverables that are due before or at the next WGM.

Submit Post WGM Survey

One of the co-chairs of each WG must complete and submit the post-WGM co-chair survey providing feedback on the WGM. This survey will be available the week of the WGM. Many WGs complete the survey as they are concluding their WGM sessions. Several emails will be distributed to the co-chairs listserv reminding co-chairs of the survey, its location, and date by which responses are due. Completion of this survey is a WG Health Metric; WGs are encouraged to complete the survey on time.

Chapter 7 - Work Group Health

There is an ongoing effort to ensure that WGs are open, active and effective within each SD. The measures of perceived WG health include a few simple items identified to better align the WGs with HL7 expectations for effective WGs. WG Health Metrics are produced before each WGM. The following TSC Confluence page includes the details on what is measured in the WG Health Metrics as well as approval requirements for:

- Work Group Mission and Charter Statement (M&C),
- Decision Making Practices (DMP), and
- Strength/Weakness/Opportunity/Threat (SWOT) analysis.

The Work Group mission and charter statement must be reviewed periodically, at least every five years as reflected in WG Health Metrics, with or without updates made. During this review, the WG M&C should also be compared to the current M&C template to maintain consistency with the current format. Updated M & C are sent to the Steering Division for review and approval. If no updates are made, please indicate to the TSC Project Manager that the M & C was reviewed and no changes made. The review date can then be updated on the WG's website. Approved updated M&C should be forwarded to the TSC Project Manager for posting to the WG website.

Decision Making Practices (DMP) are written from the point of view of a group with an open membership and reviewed every 3 years. Most sections of the default DMP apply to all groups and are not modifiable. Sections that can be modified via the HL7 DMP Addendum are:

- 5 - Quorum Requirements
- 7 – Electronic Voting (particularly items c, d and e)

Strength/Weakness/Opportunity/Threat Analysis is to be reviewed every 3 years.

This page contains the links and charts for the latest Work Group Health (WGH) information by Steering Division.

2019May Interim cycle Projects, Ballots and Standards (PBS) Metrics report is available HERE

Current WGH Snapshots: Browse all packages or see the latest releases for 2019Jan:

There are several aspects to Work Group Health besides key functional documents outlined above and can be viewed in the Work Group Health Table.

For those WGs that maintain green for the period between WGMs are awarded Gold Stars for all of their members. For WGs that maintain Gold Stars for all period in a year are awarded a trophy that is displayed on their WG website. This is certainly the benefit of keep all aspects of WG Health up to date; however, the real value is the ability of our membership to learn timely what is happening at HL7 so that they can get involved where they see the most benefit for themselves and the companies they represent.