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HL7 AUSTRALIA

GOVERNANCE and OPERATIONS

MANUAL (AU-GOM)

Version 0.1

Adopted: TBA

Last Update: 14 May 2025

HL7 Australia Governance and Operations Manual
Table of Contents

Introduction

The HL7 Australia Governance and Operations Manual (AU-GOM) defines standard operating procedures and various policies created to clarify, support, and/or implement the HL7 Australia By-laws[1] and the HL7 Australia Constitution[2].

Like the HL7 International Governance and Operations Manual (HL7-GOM)[3], the AU-GOM is established to assure the uniformity, equity, quality, efficiency, and compliance of administrative and organisational activities through standard methods and guidelines. Maintenance of the AU-GOM shall be proactive, iterative, and broadly engage the membership as defined in §11.

With the adoption of additions or revisions to the AU-GOM, the Company   Secretary shall ensure that these are added to the manual with annotation in the following table reflecting the date adopted or revised. Additions and revisions shall be announced via email to the general membership list within fourteen (14) days of the date on which they were adopted or revised. Periodically the Company Secretary, using their best judgment, may call for ratification of the AU-GOM in its entirety by the Board. Upon ratification of the AU-GOM in its entirety it shall be posted to the HL7 Australia web site with a new adoption date and all internal notations of addition or revision removed.

The AU-GOM will be maintained and distributed electronically via the HL7 Australia web site.

Notes for reading this document

Unless otherwise stated,

- all durations in days refer to calendar days.
- all durations in weeks refer to calendar weeks.
- all references to individual members and organisational members refer to members of HL7 Australia
- all references to Protocol Specifications refer to Protocol Specifications produced by HL7 Australia
- all references to Work Groups refer to HL7 Australia Work Groups.
- all references to the Board refer to the HL7 Australia Board.

Notice of Current Edition

This edition is the current and initial edition of the AU-GOM.

Additions, Deletions and/or Revisions Subsequently Adopted

The following additions, deletions and/or revisions, having been approved by the Board subsequent to adoption of this edition of the AU-GOM, are included by extension. The correction of a typographical or trivial error will not be recorded as a revision in the following table; although such revisions will appear in the mark-up version for reference. Sections that are renumbered as a result of adding or moving a section or subsection, but are not otherwise revised, are not included in the following table.

Designation	Adopted
Initial version	TBA

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[1] https://hl7.com.au/wp-content/uploads/2024/06/20240701-By-laws-v2.20b-Final.pdf
[2] https://hl7.com.au/wp-content/uploads/2023/08/HL7-Australia-Constitution-2022.pdf
[3] https://www.hl7.org/permalink/?GOM

01 Mission and Work Products

01.01 Mission Statement

The company objects for HL7 Australia are to:

- Promote effective use of HL7 International standards and products

- Support and promote interoperability of health information systems

- Promote the widespread, consistent use of standards developed by HL7 International and by HL7 Australia across the Australian health sector

- Be recognised as the principal body in Australia promoting the development, understanding and adoption of standards developed by HL7 International and HL7 Australia

- Be a respected and influential body in Australia and internationally in the health information industry

In support of these, HL7 Australia:

- Develops and publishes Protocol Specifications and various informative documents on a timely basis

- Promotes the use of Protocol Specifications and other documentation within the Australian healthcare community

- Provides information and education:

    o On understanding the Protocol Specifications and their common usage

    o On implementation approaches using the Protocol Specifications

    o On Protocol Specification compliance and analysis approaches

- Collaborates with other developers of healthcare and information technology standards to achieve interoperability.

01.02 Work Products

An HL7 Australia Protocol Specification is a specification, guide, or other material developed by the HL7 Australia Work Group Collective (AU-WGC, defined at section §4 below) in accordance with processes described in the AU-GOM.

HL7 Australia Protocol Specifications encompass the following work products developed and supported by HL7 Australia:

- Technical specifications and Implementation Guides initiated and balloted by the various HL7 Australia Work Groups and based on the

    o Version 2 (V2); and

    o Clinical Document Architecture (CDA); and

    o Fast Healthcare Interoperability Resource (FHIR)

standards from Health Level Seven International.

- Informative documents initiated and balloted by the various HL7 Australia Work Groups.

02 Codes of Ethics, Conduct and Diversity

02.01   Code of Ethics

HL7 Australia participants, including members, non-members and employees or contractors of HL7 Australia shall adhere to the HL7 International HL7 International Code of Ethics[4].

02.02   Code of Conduct

HL7 Australia participants, including members, non-members and employees or contractors of HL7 Australia shall adhere to the HL7 International Code of Conduct[5].

02.03   Diversity, Equity and Inclusion

HL7 Australia is committed to the goals of   diversity, equity, and inclusion that welcomes all participants and provides them with pathways towards understanding and integrating into the HL7 Australia and the broader HL7 community.

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[4] https://www.hl7.org/legal/code-of-ethics.cfm
[5] https://www.hl7.org/about/index.cfm#conduct

03 Intellectual Property

Standards and other intellectual property held by HL7 Australia represent goodwill created by our members, collaborators and stakeholders over many years. To protect the contributions of our stakeholders and the rights of HL7 Australia, the acquisition, use and distribution of HL7 Australia copyright material and trademarks are subject to the HL7 Australia Intellectual Property Policy[6].

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[6] http://hl7.com.au/wp-content/uploads/2024/04/HL7A_IP_Policy_v1.00a_20240429_as_delivered.pdf

04 The HL7 Australia Technical Steering Committee (AU-TSC)

The open, consensus-based development and balloting of Protocol Specifications is primarily the responsibility of HL7 Australia Work Groups. Collectively the various Work Groups shall be known as The HL7 Australia Work Group Collective (AU-WGC). The AU-WGC and Work Groups are described in section §05.

An HL7 Australia Technical Steering Committee (AU-TSC) is established to create, modify or terminate Work Groups and facilitate the coordination and activities of the AU-WGC. Each member of the AU-TSC shall cast an individual vote on formal motions. The TSC shall be comprised of:

- A Chair

- A Deputy Chair, being either the Chair Elect or the Immediate Past Chair. The Chair Elect shall assist the Chair and participate in planning for AU-TSC agendas. The Immediate Past Chair shall assist the incoming Chair, formerly the Chair Elect.

   o Should the AU-TSC Chair be unavailable for any meeting the AU-TSC Deputy Chair will be accorded all rights and privileges of the AU-TSC Chair and shall represent the AU-TSC.

   o If for any reason a Deputy Chair is not available, the AU-TSC may use its decision-making practices to appoint a temporary Deputy Chair until either a Chair Elect or Immediate Past Chair is able to assume the role.

- The Chair of each community process coordination committee [§04.04]

- A Co-chair from each Work Group to represent the AU-WGC.

- Two (2) individuals representing the implementer community

- *Ad hoc* members as appropriate

- The Board Chair and Working Group Liaison Officer (WGLO) shall be *ex officio* members with vote

No organisation shall hold more than one voting position on the AU-TSC. Members of the AU-TSC, except for ex officio members, are defined only by their direct membership status — either as individuals or as representatives of member organisations. Any other organisational connections a member may have through employment or contract work do not affect or determine their AU-TSC participation.

Should a change in membership status during the term of office of any voting member of the AU-TSC result in a violation of this policy, that organisation's representative whose term expires first shall not stand for re-election recognis   ing that the Chair, representing a two (2) year commitment, shall take precedent for retention.

Should the AU-TSC identify an imbalance or the need for specific expertise, they may vote to include *ad hoc* members with vote to correct the situation. Should an *ad hoc* member be elected to or otherwise attain a voting position on the AU-TSC they shall be seated in said position and shall not retain *ad hoc* status.

Additional information on AU-TSC organisation and function, including decision making practices (DMP), can be found on the AU-TSC Home Page[7].

The AU-TSC shall be responsible for product project approval and management oversight including:

- Establishing and maintaining an HL7 Australia architecture, development methodologies, and work processes to be used by the AU-WGC in developing Protocol Specifications

- Establishing the precepts (rules) that Work Groups apply as operational instructions across domains within the scope of the AU-TSC.

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[7] Link to added upon establishment of the AU-TSC.

- Ensuring that the efforts of t   he AU-WGC to produce Protocol Specifications proceed at a pace consistent with project plans.

- Ensuring that The AU-WGC collaborates smoothly and covers its scope of work in a consistent manner.

- Defining and overseeing the ballot and distribution process for those Protocol Specifications identified by the Board as intended to be freely available to the public.

04.01   Standards Development Methodology

The AU-TSC shall be responsible for the development and maintenance of a standards development methodology to define, clarify, and delineate the processes employed by HL7 Australia. The following, at minimum, shall be addressed:

- overall governance of the methodology,

- common processes,

- specific process and procedures applicable to individual products and services e.g. rules for variances, naming and labelling, maturity models, copyright and licensing, and strategic alignment,

- support processes, and

- performance checkpoints.

These elements should be described in sufficient detail to act as a guide to both experienced standard developers as well as those new to the HL7 Australia process. Certain artefacts which articulate this methodology may be balloted to formalis   e and promote the good practices inherent in the HL7 Australia process.

04.02   Interpretation of Non-normative HL7 Protocol Specifications

The AU-TSC shall be responsible for the official interpretation of all non-normative Protocol Specifications (§01.02).

Requests for interpretation of a Protocol Specification shall be submitted by letter to the Board. In addition to the specific query, the request shall include the submitter's name, affiliation, address, telephone, and email address. Such submissions shall be routed to the WGLO and AU-TSC Chair who may refer the request to the appropriate HL7 Australia Work Group for consideration.

The WGLO in collaboration with the AU-TSC, shall respond in kind to written requests for interpretation. These written interpretations shall be retained on file and made available electronically.

When determined by the WGLO or AU-TSC Chair to be of value to the membership, reference to a current interpretation may be included in the next updates to the membership.

04.03   Tools Created by HL7 Australia for Standards Development

The AU-TSC shall be responsible for ensuring that any tools created by HL7 Australia for the development of Protocol Specifications (§01.02) have met design specifications, are thoroughly documented and tested, and that such tools have established maintenance and support mechanisms. Upon such assurance, the Board shall notify the membership of the availability of such tools.

04.04   Community Process Coordination Committees

The Board may establish a community process   for the purpose of engaging additional individuals and organisations, whether or not they are members, in effective development of open specifications based on HL7 International primary standards[8] in the community (i.e. outside of HL7 Australia).

These community processes shall include the establishment of an associated coordination committee in HL7 Australia. The coordination committee shall provide coordination related to community adoption of

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[8] https://www.hl7.org/implement/standards/product_section.cfm?section=1&ref=nav

the relevant standard which includes defining and establishing the community processes and ensuring its ongoing and efficient operation on behalf of the Board. All coordination committees will have a Chair appointed by the Board and a committee-specific terms of reference approved by the Board.

Parties following a community process develop specifications which adhere to the rules of the community process but are not bound by the rules of the AU-GOM.

05   The HL7 Australia Work Group Collective (AU-WGC)

05.01   Establishing a Work Group

05.01.01   Criteria

Individuals interested in establishing a new HL7 Australia Work Group (AU-WG) shall liaise   with the AU-TSC Chair and the WGLO to establish their conformance to the following criteria:

- There is a demonstrated need for the creation of a Work Group such as a government mandate, the results of "gap" analysis, or a stakeholder imperative and such need is of a scope that precludes it being addressed as a project by an existing Work Group.

- The expressed need is within the scope of HL7 Australia and creation of the proposed Work Group shall facilitate HL7 Australia accomplishing its objects.

- A minimum of five members have agreed to active participation in the proposed Work Group, and collectively they possess the necessary expertise and commitment to accomplish its goals.

Should the AU-TSC Chair and WGLO concur on the creation of a new Work Group they shall advise on appropriate collaboration with existing Work Groups. As a pre-cursor to Work Group establishment, the interested individuals may request that the AU-TSC provide a Confluence page and email distribution list for support during the formation period; said Confluence page and email distribution list to be deactivated should the new Work Group not be subsequently approved by the AU-TSC.

Otherwise, the AU-TSC Chair and WGLO shall recommend the appropriate Work Group for the interested individuals to approach the AU-TSC with a project proposal.

05.01.02   Process

With the concurrence of the AU-TSC Chair and the WGLO, the individuals proposing a new Work Group shall complete and submit a *Work Group Proposal Template*[9] to the AU-TSC who shall distribute it to the Co-chairs of all existing Work Groups in the AU-WGC. Within thirty (30) days of receipt of the template the AU-TSC shall schedule a vote for the purpose of accepting or rejecting the proposal.

The proposal shall be moved to the AU-TSC for consideration upon a two-thirds affirmative vote by those Work Groups placing a vote with at least fifty percent (50%) of the Work Groups returning a vote. Failure to achieve quorum (50% of AU-WGC Co-chairs) shall result in the proposal and record of votes cast moving forward to the AU-TSC for consideration. Given quorum, failure to receive a 50% affirmative vote shall cause the proposal to be rejected. A rejected proposal may be appealed to the AU-TSC up to thirty (30) days from the date of rejection. The AU-TSC shall resolve an appeal within thirty (30) days of submission.

The AU-TSC shall address the Work Group proposal under the tenets of its documented decision-making practices. If approved, the AU-TSC Chair shall inform the Board of the creation of a new Work Group and all necessary infrastructure activity appropriate to the creation of a new Work Group shall be initiated by the WGLO. The Board shall determine whether the formation of this Work Group is deserving of a press release or other external communications.

An AU-TSC decision to reject the proposal may be appealed to the Board within thirty (30) days of the AU-TSC decision. The Board shall set a date to resolve the appeal and notify the appellant. The decision of the Board shall be final.

05.01.03   Metrics for Viability

In order for an HL7 Australia Work Group to be considered viable the AU-TSC requires the following criteria be met:

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[9] Link to template to be added upon establishment of the AU-TSC

- Ensure that Work Group's Mission & Charter (M&C) align with HL7 Australia's prevailing strategic direction as defined by the Board.
- Have at least 1 active sponsored or co-sponsored projects that are consistent with Work Group's M&C
- Hold at least two meetings every Work Group cycle (four months).

Failure to ensure these criteria are met may result in the AU-TSC contacting the Work Group to discuss viability.

05.01.04   Lack of Viability

Should the criteria in §05.01.03 not be met for two Work Group cycles, the AU- TSC will attempt communications with the Work Group to resolve such issues.

Should the AU-TSC encounter no active Work Group participants and be unable to reach a Work Group Co-chair, the AU-TSC shall issue a call to the Work Group's email distribution list for a special meeting between the AU-TSC and the Work Group to discuss issues and possible resolutions. Following the initial meeting, a Work Group Co-chair (or representative) shall meet monthly with the WGLO and the AU-TSC Chair (or representative) with proposed resolutions being presented to the AU-TSC for consideration.

Should the issues not be resolved to the satisfaction of the AU-TSC or there has been no response to the call for a meeting with three months, the AU-TSC shall inform the Work Group's email distribution list of the intent to dissolve the Work Group in question in ninety (90) days per §05.02.03. The Work Group in question may appeal the declaration of dissolution to the AU-TSC. Further, the Work Group may appeal the subsequent decision of the AU-TSC to the Board, whose decision shall be final.

05.02   Work Group Change, Merger or Dissolution

05.02.01   Changing Name or Mission & Charter

Given approval under the Work Group's documented decision-making practices, the Work Group Co-chairs shall complete and submit a *Work Group Change Request*[10] to change the name of the Work Group or revise its Mission & Charter. The request shall be presented to the AU-TSC and will include a draft Work Group charter citing the proposed name and including any proposed revisions.

Upon approval by the AU-TSC, using its documented decision-making practices, the revised Work Group charter shall be distributed to the Co-chairs of all Work Groups. Further, the WGLO shall initiate all necessary changes to the infrastructure to reflect the Work Group's new name and Mission & charter.

An AU-TSC decision to deny or approve the proposal may be appealed to the Board within thirty (30) days of the AU-TSC decision. The Board shall set a date to resolve the appeal and notify the appellant. Should the appellant be a member of the Board, they shall recuse themselves from resolution of the appeal. The decision of the Board shall be final. Should the approval of the Work Group's new name or Mission & Charter be overturned on appeal, the WGLO shall initiate all necessary changes to the infrastructure to reinstate the Work Group's previous name and Mission & Charter.

05.02.02   Merger of Two or More Work Groups

Two or more Work Groups 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 Work Groups involved shall designate one of the Work Groups as the surviving Work Group. Subsequently, the Co-chairs of the dissolving Work Group(s) shall complete and submit a *Work Group Change Request*[11] for dissolution [§05.02.03] citing the proposed merger.

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[10] Link to request template to be added upon establishment of the AU-TSC
[11] Link to request template to be added upon establishment of the AU-TSC

Concurrently, the Co-chairs of the surviving Work Group shall complete and submit a *Work Group Change Request[12]* to change the name of the Work Group (if required) and its Mission & Charter [§05.02.01] citing the proposed merger. Upon approval of the request to dissolve and request for name/mission and charter change, the consolidated Work Group shall undertake a reconciliation of their former respective decision-making practices with the objective of establishing comprehensive decision-making practices for the consolidated Work Group.

05.02.03 Dissolution

05.02.03.01 At the Request of the Work Group

Given approval under the Work Group's documented decision-making practices, the Work Group's Co-chairs shall complete and submit a *Work Group Change Request[13]* to the AU-TSC Chair and WGLO 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 AU-TSC Chair and WGLO may propose and seek alternatives to dissolution.

With the concurrence of the AU-TSC Chair and WGLO, 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 AU-TSC. The results of the attempt to achieve consent for the assumption of work products shall be reported on the request.

The AU-TSC Chair shall distribute the request to all other Work Group Co-chairs and schedule a vote of the Work Group Co-chairs to consider the request for dissolution within thirty (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 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 Work Group Co-chairs casting votes with all the Work Groups returning a vote, the AU-TSC Chair shall submit the request to the AU-TSC for review of the request for dissolution within thirty (30) days. The AU-TSC shall address the request to dissolve under the tenets of its documented decision-making practices.

Upon approval, the AU-TSC Chair shall notify the Board of the dissolution of the Work Group and the disposition of that Work Group's work products. The WGLO shall take the appropriate actions to effectively remove the Work Group from the organisation.

05.02.03.02 Initiated by the HL7 Australia Technical Steering Committee (AU-TSC)

Should the declaration of intent to dissolve the Work Group [§05.01.04] not be rescinded within ninety (90) days subsequent to any appeal time, the AU-TSC shall initiate the dissolution process including the distribution of any Work Group projects or artifacts to alternative Work Groups willing to accept such projects and/or artifacts. Once all projects and artifacts associated with the Work Group to be dissolved have been redistributed to the appropriate Work Groups or assigned to the AU-TSC for further action, the AU-TSC shall:

- Inform the Board of the dissolution of the Work Group in question
- Notify the AU-WGC of said dissolution
- Update the HL7 Australia web and Confluence site to reflect dissolution and redistribution of projects and artifacts

05.03 Work Group Co-Chairs

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[12] Link to request template to be added upon establishment of the AU-TSC
[13] Link to request template to be added upon establishment of the AU-TSC

In general, the following points summarise the responsibilities various HL7 Australia groups have in relation to co-chairs:

- The AU-TSC is responsible for

    o   removal of co-chairs

    o   maining the default Decision Making Practices (DMP) document and the DMP Modification Template.

- The Board is responsible for

    o   conducting co-chair elections.

    o   maintaining the official lists of co-chairs

    o   considering appeals against AU-TSC decisions.

    o   Maintaining the AU-GOM

Each Work Group shall have a minimum of two Co-chairs to ensure leadership in the event that one or the other is unable to attend a Work Group meeting with the actual number of Co-chairs determined by the Work Group using their decision-making practices.

The Board shall be informed upon a decision by a Work Group to increase the number of Co-chairs which shall result in the subsequent call for nominations and annual election for such additional positions. The Work Group may, using their decision-making practices, designate an individual to fill the additional position interim to the seating of a duly elected Co-chair or for such period as stipulated by vote of the Work Group. The designated interim Co-chair shall be identified to the AU-TSC and the Board and may be nominated for election.

Additionally, Temporary Work Group Co-chairs may also be appointed as part of an active HL7 Australia Accelerator (AU Accelerator) [§10.02.03.01]. These Work Group Co-chairs have terms restricted to the duration of the AU Accelerator and carry out Work Group Co-chair responsibilities as part of the AU Accelerator's standards development activities in the relevant Work Group.

Likewise, the Board shall be informed upon a decision by a Work Group to decrease the number of active Co-chairs. Those individuals in positions being eliminated shall serve the remainder of their term, if possible. The newly authorised number of active Co-chairs shall constitute the basis for eligible positions during subsequent elections.

05.03.01   Responsibilities

Work Group Co-chairs are responsible for:

- the conduct of the Work Group in the development of Protocol Specifications in the designated domain;

- collecting and publishing the minutes of all the Work Group meetings including teleconferences and in-person meetings;

- encouraging the submission of minutes or notes from all meetings of any sub-groups, task forces, or project teams related to the Work Group;

- ensuring that the portion of the Protocol Specifications for which they are responsible is properly balloted; for resolving negative normative ballot comments appropriately;

- reporting compliance with established procedures to the AU-TSC.

Guidance on Co-chair responsibilities can be found in the HL7 International *Co-chair's Handbook*[14].

05.03.02   Term of Office

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[14] https://confluence.hl7.org/display/CH/Co-Chair+Handbook

Co-chairs shall serve two-year terms without term limits. Terms shall be staggered to ensure continuity of leadership, with half the Co-chairs of a Work Group being elected in even numbered years and half elected in odd numbered years. Upon establishment of a new Work Group, an appropriate number of Co-chairs shall be elected to an initial one-year term to establish staggered terms.

05.03.03 Removal from Office

At any time, a Work Group that judges the performance of a Co-chair egregious may, using their decision-making practices, make a motion to the AU-TSC for removal of that Co-chair.

Criteria for removal shall include:

● failure to participate in at least 60% of the Work Group teleconferences held in the preceding calendar year;

● undesirable or disruptive behaviour that deviates from the HL7 International Code of Conduct[15]; or

● failure to fulfill the responsibilities set forth in §05.03.01

Upon receipt of a motion for removal of a Co-chair the AU-TSC shall take appropriate action which may range from counselling to removal of non-participating or non-performing Co-chairs following sufficient fact gathering to ensure due process.

The decision to remove a Co-chair shall result in that individual immediately stepping down from the position of Co-chair and notification to the WGLO for the removal of that individual from the list of active Co-chairs on the HL7 Australia website and Confluence spaces. The Work Group may, using their decision-making practices, designate an individual to serve as Co-chair interim to the seating of a duly elected Co-chair or for such period as stipulated by vote of the Work Group. The designated interim Co-chair shall be identified to the AU-TSC and the Board and may be nominated for election.

Alternatively, the Work Group, using their decision-making practices, may decide to eliminate rather than fill the vacated position. The Board shall be informed of said decision resulting in a reduction of the number of active Co-chairs for that Work Group.

05.03.04 Co-chair Vacancy due to Change in Membership Status

Should a seated Co-chair be notified of a change in membership status due to either the loss of individual membership or loss of membership by their organisation, that individual shall have thirty (30) days from the date of notification to reinstate membership by submitting or having their organisation submit payment in full. Requests to extend the 30-day period shall be considered on a case-by-case basis by the Board. If unresolved by the end of that period, that individual shall immediately step down from the position of Co-chair.

The Work Group shall notify the Board of the loss of a Co-chair and request a subsequent election. Resolution of the individual's membership status subsequent to stepping down would allow them to seek nomination for election as a Co-chair. The Work Group may, using their decision-making practices, designate an individual other than the individual who stepped down to serve as a Co-chair interim to the seating of a duly elected Co-chair or for such period as stipulated by vote of the Work Group. The designated interim Co-chair shall be identified to the Board and may be nominated for election.

05.03.05 Voluntary Co-chair Vacancy

Should a seated Co-chair voluntarily vacate their position, for whatever reason, the Work Group shall notify the Board of the loss of a Co-chair and request a subsequent election. The Work Group may, using their decision-making practices, designate an individual to serve as a Co-chair interim to the seating of a duly elected Co-chair or for such period as stipulated by vote of the Work Group. The designated interim Co-chair shall be identified to the Board and may be nominated for election.

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[15] https://www.hl7.org/about/index.cfm#conduct

Should the Work Group, using their decision-making practices, decide to eliminate rather than fill the vacant position, they shall inform the Board of said decision resulting in a reduction of the number of active Co-chairs for that Work Group.

05.04   Decision-Making Practices

All Work Groups shall follow a documented set of decision-making practices (DMP)[16]. The DMP is written from the point of view of a group with open membership. Most sections apply to all groups and committees and are not modifiable. Sections that may be modified via the *DMP Modification Template*[17] include §5.1 Quorum Definition; §7 Electronic Voting; and §8 Proxy Participation (for closed committees). Proposed modifications shall be made via the *DMP Modification Template* and submitted to the AU-TSC.

The practices in effect in each Work Group shall be adopted by majority vote of that Work Group and shall not conflict with HL7 Australia's Constitution, Bylaws, Policies and the AU-GOM. Working sessions of each Work Group shall be governed by the rules set forth in the DMP. Meetings hosted jointly shall follow the DMP of the host Work Group.

There is no requirement for Work Group proceedings to be overly formal; although situations may arise that require such formality. If a situation occurs that mandates the use of formal procedures or for situations not otherwise addressed in the DMP, Robert's Rules of Order shall govern. As situations demand, a Work Group may force the institution of this formality through a majority vote of the Work Group.

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[16] https://confluence.hl7.org/spaces/HA/pages/184912137/Process+AU+Decision+Making+Practices

[17]

https://confluence.hl7.org/spaces/HA/pages/184912137/Process+AU+Decision+Making+Practices?preview=%2F184912137%2F184912896%2FDMP+Modification+Template_HL7AU.docx

06   Electronic Ballots

All HL7 Australia ballots, be they administrative, review, or normative, shall be conducted electronically by the Board. Electronic ballots shall provide, as appropriate:

- The means to form a consensus group and provide necessary notifications.

- The means to capture the vote and associated comments.

- A method for resolving negative comments and reconciling the normative ballot.

06.01   Consideration of Recommended Actions

Prompt consideration shall be given to proposals made for developing new or revising existing Protocol Specifications. The AU-TSC shall approve recommendations for all actions pertaining to approval or adoption of Protocol Specifications, or any portion thereof, prior to submission for ballot.

06.02   Naming Convention

A naming convention has several basic objectives:

- Provide a concise way of identifying a publication in a human-meaningful way

- Help the target user locate a document in a hierarchy of documents

- Help the target user determine the purpose of a document

06.03   Constructing Protocol Specification Names

There are three variations on naming convention for Protocol Specifications, all described below. The first is for naming releases of a product family. The second is for naming products derived from a product family. The final syntax is for artifacts that are not part of a product family or that span product families.

The naming construct is described below using a notation of {required} or [optional] with literals expressed in **_bold italics_**.

STRUCTURE	Comments
{Organisation Identifier}	
<	One or more of the following three options required
{Family Name} {Product Type}: {Product Name}, {Release } {Release Number}	
{Family Name} {Product Type}: {Product Name}, {**_R_**}{Release Number}	
[Product Type:] {Product Name}, {Release {Release Number}]	
[Product Type:] {Product Name}, {**_R_**}{Release Number}	
>	

06.03.01   Organisation Identifier

The Organisation Identifier shall be:

- `HL7 Australia` indicating an HL7 Australia document

- `HL7 Australia/[Other]` where `[Other]` is the abbreviated/short name for the other organisation, such as AIHW, indicating an HL7 Australia document published in conjunction with another organisation

06.03.02   Family Name

The standard family names from Health Level Seven International are Version 2 (V2); Version 3 (V3); Clinical Document Architecture® (CDA®); Electronic Health Records System-Functional Model

(EHRS-FM); Fast Healthcare Interoperability Resource (FHIR®); Conceptual Model; or DAM. Where a specification is based on two or more product families the Family Name naming option cannot be used, instead the work program shall submit a standalone title for AU-TSC approval

The Family Name acronym may be used for all specification names. Specifications shall document the full family name as part of the specification text. However, with the exception of FHIR®, a Standard or Standard for Trial Use (STU) shall use the full family name. In lieu of the full family name the appropriate acronym may be used for Implementation Guides, Profiles, and other documentation.

Subfamily names are specific to a given family and are not further defined in this document.

06.03.03   Release Number

The Release Number is a unique identifier for a particular product family or stand-alone primary Protocol Specification.

The AU-TSC defines the Release Number format for Protocol Specifications; however, they are generally expressed as a number with the syntax {major} dot {minor} dot {patch} – e.g., 3.2.1. It reflects the number of the final publication of the artifact intended for use by implementers. It remains the same across all ballots until the specification is published. The major number can be used alone if there is no minor release. The release number is not reset when a product transitions from working standard to normative or at any other point. Those work standard updates not balloted must be a minor release.

The AU-TSC may approve alternate release number syntaxes – for example year-based identifiers. The release number must be specified when naming derived specifications unless the specification applies to multiple releases of the base product family in which case it must be omitted.

06.03.04   Product Type

Product types are defined as Specification or Standard; Domain Analysis Model; Service Functional Model; Functional Model; Functional Profile; Implementation Guide; Logical Model; Profile, White Paper, and Guidance [for documents such as a Cookbook or Companion Guide]. The AU-TSC may, at their discretion, declare additional product types.

06.03.05   Product Name

The Product Name is specified by the Work Group when they initiate a Project Scope State (PSS) to create a new or update an existing Protocol Specification; however, the Product Name may be revised upon submission of the Notice of Intent to Ballot (NIB).

If a product is based on higher-level derived artifacts (e.g., an implementation guide based on another implementation guide, a services functional model based on a higher-level model) the product name may include references to one or more of those higher-level artifacts, including their versions. This should only be done if it is a necessary part of the descriptive name to ensure uniqueness or to ensure implementers understand what the artifact is. Detailed metadata should be provided in the artifact itself. All efforts should be made to keep the product name concise and easy to use.

06.03.06   Edition Number

Where required, the Edition Number format shall be defined by the AU-TSC as a unique number for the Product Name within the scope of the product family. The term "Edition" is used to avoid confusion with the "Release Number" of the product family on which the Edition is based. The term Edition is used for all artifacts derived from a based product family publication – even if there is a hierarchy of artifacts. For example, Edition 1 of implementation guide B, might depend on Edition 3.1 of implementation guide A, which in turn depends on R4 of the product family specification. Edition Numbers follow the same format as the Release Number with respect to major and minor version numbers.

The Edition Number does **not** reset when a derived publication advances to a newer release of the same product family. Multiple publications with different release numbers for the base specification and the same edition number and product name are possible if multiple publications are produced with essentially the same content for different releases of the underlying product family.

06.03.07　　Ballot Level

Ballot level information may be provided as metadata distinct from the name but shall not be part of the name.

06.03.08　　Examples

Protocol Specification naming convention examples are available at the following link[18].

06.04　Constructing HL7 Australia Ballot Names

The ballot naming construct is described below using a notation of {required} or [optional] with literals expressed in **bold italics**.

STRUCTURE　　　Comments

{Ballot Cycle}

{Specification Name}

[- Qualifier]

{Ballot Level} **ballot**

06.04.01　　Ballot Cycle

The "closing month" of the ballot cycle that includes this ballot, expressed as YYYY-mmm e.g. `2025-JAN`. Note that the ballot cycle date remains the same for those ballots that have alternate opening dates within the same ballot cycle.

06.04.02　　Specification Name

The name for the Protocol Specification as defined in §06.03 (to include Release Number, Edition Number, etc.) to be balloted. It will remain the same for all ballots targeting the same Protocol Specification publication.

06.04.03　　Qualifier

A Qualifier shall be used when the Specification Name does not clearly identify the ballot content as a subset of the base Protocol Specification. The Qualifier should be a few words identifying the ballot content as a subset of the target publication; such as Vocabulary only or Terminology only.

Note that the published Protocol Specification will only include the Specification Name without any qualifier. Information about the approval status of the limited subset will be conveyed in metadata of the resulting published Protocol Specification.

06.04.04　　Ballot Level

The Ballot Level identifies the type of Review Ballot (Informative, Working Standard, or Comment-only) being undertaken.

06.04.05　　Examples

HL7 Australia ballot naming convention examples are available at the following link[19].

06.05　Approving Review Ballot and Protocol Specification Names

06.05.01　　Informative Documents and Working Standard:

Ballot and Protocol Specification names shall be approved by the AU-TSC.

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[18] Link to examples to be added upon establishment of the AU-TSC
[19] Link to examples to be added upon establishment of the AU-TSC

In the case of ballot naming approval occurs during the Notice of Intent to Ballot process.

In the case of Protocol Specification naming approval occurs during the review and approval process of the *Publication Request Template*[20].

06.05.02   Other Documents

The Work Group proposing a new document title or a change to an existing document title, for other documents published as official HL7 Australia documents (carrying an HL7 Australia copyright and logo) shall obtain approval from the AU-TSC as early as possible; preferably before the document is circulated widely for review, but certainly prior to publication.

06.05.03   Documents in Progress

The AU-TSC may require a change to the title of documents already in progress, in ballot, or in technical editing after ballot for conformance with an established convention.

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[20] Link to template to be added upon establishment of the AU-TSC

07 Review Ballots

A review ballot shall be used to review and validate the content of informative documents, the subject matter of proposed working standard publications, and other items that, after due consideration of the AU-TSC, are not yet deemed appropriate for a normative ballot. All review ballot types (Informative, Working Standard, and Comment-only) require a project scope statement (PSS) and must comply with the HL7 Australia project approval process[21].

The AU-TSC, in compliance with its defined processes, may approve the release of a review ballot. Once initiated, a review ballot shall remain active until such time as the subject matter of the ballot has been approved or withdrawn from consideration. At its discretion, the AU-TSC may allow a Work Group to conduct multiple comment-only review cycles.

All HL7 Australia work products, whether Informative [§07.01.05 Lifetime Review], Working Standard [§07.02.07 Lifetime Review], or Normative, are subject to periodic review by the appropriate Work Group to ascertain timeliness and relevance. The AU-TSC has provided a table as a quick reference to the process and requirements for Standards Lifetime Review[22].

07.01 Informative Documents

An Informative Document is the product of a Work Group that is not currently deemed normative but nonetheless is intended for general publication. It explains or supports the structure of Protocol Specifications (§01.02) or provides detailed information regarding the interpretation or implementation of a Protocol Specification. The AU-TSC holds the authority to approve the issuance of an informative document ballot.

07.01.01 Forming the Consensus Group

All current members shall be notified of the intent to form a consensus group and ballot an informative document at least thirty (30) days prior to the start of the ballot period.   This notification shall occur via the various HL7 Australia newsletters and member email distribution lists and shall include the dates of enrolment in the consensus group. Members shall indicate their interest by enrolling in the appropriate consensus group via the indicated mechanisms during the enrolment period which shall end with the opening of the ballot period.

Non-members who wish to participate in an Informative Document consensus group must register their intent with the Board via an email to the WGLO. Non-members shall be assessed a fee established by the Board for such participation.

07.01.02 Ballot Package

The ballot package shall be available to all members of the consensus group for thirty (30) days following the opening of the ballot period. Participants are encouraged to provide constructive comments for improving the content or language of the subject matter under review.

07.01.03 Handling Comments

At the close of the ballot the responsible Work Group shall capture all comments using the HL7 Australia Ballot Reconciliation Report unless the Work Group has petitioned for and been granted a waiver of such use by the AU-TSC. The responsible Work Group shall consider all comments with the intent of improving the quality and clarity of the informative document. While not on a par with a normative reconciliation package, the results of the Work Group's consideration of the comments submitted as recorded on the Ballot Reconciliation Report shall be posted on either the HL7 Australia web site or Confluence space.

21

https://confluence.hl7.org/spaces/HA/pages/265095995/Process+Project+Proposal+Project+Scope+Statement

[22] Link to be added upon establishment of the AU-TSC

A negative without comment shall be considered as "no response" and shall not be factored into the numerical requirements for approval. No effort shall be made to solicit comments from the submitter of a negative without comment.

The process of consideration of the comments is not synonymous with nor shall it assume the rigor of normative reconciliation. There is no requirement to resolve negative comments and seek withdrawal of the negative.

Nevertheless, the responsible Work Group is encouraged to annotate each negative comment on the reconciliation report with a disposition of "Persuasive", "Not Persuasive", "Considered for Future Use", or "Not Related" with a recorded vote and an explanation for the Work Group's decision in accordance with the Work Group's decision-making practices to maintain transparency on decisions made. A negative ballot withdrawn at the request of the submitter shall be recorded as an affirmative.

The issue of substantive change shall not be applicable to an informative document. In the instance of an approved informative document with substantive change resulting from review, it is left to the discretion of the responsible Work Group to either submit to another ballot or move forward with the revised informative document.

If the informative document fails to be approved, it again falls to the discretion of the responsible Work Group, after appropriate revision, if necessary, to either submit to another review ballot, withdraw the document from consideration, or repackage the content and submit it to the AU-TSC for consideration of submission to a normative ballot.

07.01.04   Approval and Publication

There is no quorum required for an informative document. The informative document shall be considered approved if, following ballot review, sixty percent (60%) of the combined affirmative and negative votes cast are affirmative.

Upon approval and posting of the ballot reconciliation report the responsible Work Group shall vote to submit a Publication Request[23] to the AU-TSC Chair, who shall include an item on the agenda of the next AU-TSC meeting for the consideration of affirmation of release for publication. The Work Group vote shall be recorded in the minutes and reported on the Publication Request (to include the Work Group making this request and date/URL of approval minutes).

Following approval of the informative document the submitting Work Group may, with the concurrence of the AU-TSC, submit the document to a normative ballot for subsequent consideration as an HL7 Australia normative standard.

07.01.05   Lifetime Review

One year prior to the fifth anniversary of any action (publication, update or extension) related to an Informative Document the Board shall notify the AU-TSC and the responsible Work Group of the requirement to review said document with the objective of determining its ongoing status.

The responsible Work Group shall, having conferred with any co-sponsoring Work Groups and using its established decision-making practices, determine whether to:

- Update and re-ballot the document at least two ballot cycles prior to the anniversary date; or
- Submit a request to the AU-TSC at least two ballot cycles prior to the anniversary date to extend the existing document for up to five (5) years; or
- Retire the document.

A successful ballot and publication of the updated document shall reset the required review date. Likewise, an AU-TSC decision to extend the current document shall reset the review date based on the requested and approved extension period.

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[23] Link to template be added upon establishment of the AU-TSC

Should the responsible Work Group decide to retire a published Informative Document it shall conduct a 30-day Comment-only ballot soliciting feedback on the decision to retire the document at least two ballot cycles prior to the anniversary date.

Should the responsible Work Group take no action by two ballot cycles prior to the anniversary date, the Board, having notified the Work Group, shall initiate the Comment-only ballot soliciting feedback related to the retirement of the document

The Comment-only ballot need not contain the contents of the document but shall include at least the document title and the question "Should this Informative Document be retired?". Having considered any comments received, the responsible Work Group shall reassess its decision to retire versus update or extend the document.

07.01.06   Retirement of an Informative Document

A Work Group that, through its decision-making practices, identifies an Informative Document to be retired shall submit a Notice of Withdrawal of a Protocol Specification[24] form to the AU-TSC. This form will identify the subject Protocol Specification and provides the process to request input, review and approval of the request to retire the document from various HL7 Australia entities. Upon retirement, the Informative Document shall be retained in the registry of HL7 Australian publications with a status of retired.

07.02   Working Standards

HL7 Australia Working Standards may be considered as standards for trial use and are synonymous with HL7 International's Standard for Trial Use (STU).

Given that the ultimate objective is the creation of a normative standard, it is appropriate to validate the content of a Working Standard by subjecting it to review prior to its release for use.

Should the content of the proposed standard not be approved, for whatever reason, it may simply be withdrawn from consideration. Following a successful review, the proposed standard, in the appropriate form, may be presented to the AU-TSC for release as a Working Standard.

07.02.01   Forming the Consensus Group

All current members shall be notified of the intent to form a consensus group and ballot the content of a proposed standard for trial use at least thirty (30) days prior to the start of the ballot period. This notification shall occur via the various HL7 Australia newsletters and member email distribution lists and shall include the dates of enrolment in the consensus group. Members shall indicate their interest by enrolling in the appropriate consensus group via the indicated mechanisms during the enrolment period which shall end with the opening of the ballot period.

The minimum consensus group shall be ten current individual members or individuals representing at least three current organisational members. The ballot shall not commence if the minimum consensus group requirement is not met.

Non-members who wish to participate in a Working Standard consensus group must register their intent with the Board during the stated enrolment period via an email to the WGLO. Non-members shall be assessed a fee established by the Board for such participation.

07.02.02   Ballot Package

The ballot package shall be available to all members of the consensus group for thirty (30) days following the opening of the ballot period. Reviewers are encouraged to provide constructive comments for improving the content or language of the subject matter under review.

07.02.03   Handling Comments

At the close of the review ballot the responsible Work Group shall capture all comments using the HL7 Australia Ballot Reconciliation Report unless the work has petitioned for and been granted a waiver of such use by the AU-TSC. The responsible Work Group shall consider all comments with the

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[24] Link to be added upon establishment of the AU-TSC

intent of improving the quality and clarity of the proposed standard. While not on a par with a normative reconciliation package, the results of the Work Group's consideration of the comments submitted as recorded on the Ballot Reconciliation Report shall be posted on either the HL7 Australia web site or Confluence space.

A negative without comment shall be considered as "no response" and shall not be factored into the numerical requirements for approval. No effort shall be made to solicit comments from the submitter of a negative without comment.

The process of consideration of the comments is not as complete or rigorous as normative reconciliation. There is no requirement to resolve negative comments and seek withdrawal of the negative. Nevertheless, the responsible Work Group is expected to annotate each negative comment on the reconciliation report with a disposition of "Persuasive", "Not Persuasive", "Considered for Future Use", or "Not Related" with a recorded vote and an explanation for the Work Group's decision in accordance with the Work Group's decision-making practices (DMP) to maintain transparency on decisions made. A negative ballot withdrawn at the request of the submitter shall be recorded as an affirmative.

The issue of substantive change shall not be applicable to a Working Standard. In the instance of an approved Working Standard with substantive change resulting from review, it is left to the discretion of the responsible Work Group to either submit to another review ballot or move forward with a request to the AU-TSC to release the revised content as a Working Standard.

07.02.04 Approval

The proposed Working Standard shall be considered approved if sixty percent (60%) of the combined affirmative and negative votes cast by the review group are affirmative.

Upon approval and posting of the ballot reconciliation report the responsible Work Group shall vote to submit a Publication Request[25] to the AU-TSC Chair, who shall include an item on the agenda of the next scheduled AU-TSC meeting for the consideration of affirmation of release for publication. The Work Group vote shall be recorded in the minutes and reported on the Publication Request (to include the Work Group making this request and date/URL of approval minutes).

If the proposed Working Standard fails to be approved, it again falls to the discretion of the responsible Work Group, after appropriate revision, if necessary, to either submit to another review ballot, withdraw the document from consideration, or repackage the content and submit it to the AU-TSC for consideration as a normative ballot.

07.02.05 Trial use

Once approved a Working Standard shall be released for use to refine and enhance its content through demonstrations of interoperability. Due consideration should be given to the need for timeliness in moving the Working Standard into the normative process. Therefore, the trial use period should be of sufficient duration to provide for viable proof of concept yet not so long as to unnecessarily delay the initiation of the normative ballot process.

A guideline for the trial use period is from one to two years for trial use and comment which should be followed by one year or less for completion of the normative ballot period. The Working Standard shall be viable for the specified trial use period, the subsequent normative ballot process, and up to six months following publication of the normative Protocol Specification. The Board may, at its discretion, extend the viability of a Working Standard for up to five years beyond the close of the trial use period.

07.02.05.01 Working Standard Front Matter

The front cover of a Working Standard shall include the following statement.

"Publication of this Working Standard has been approved by HL7 Australia Ltd. This Working Standard is not an accredited Australian national standard. The feedback period on the use of

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[25] Link to template be added upon establishment of the AU-TSC

this STU shall end *[indicate the number of months allocated for evaluation, review and feedback]* months from the date of publication. For information on submitting feedback see Specification Feedback[26].

Following this *[the number of months shown above]* month feedback period, this Working Standard, revised as necessary, may be resubmitted for further feedback or submitted to a normative ballot in preparation for approval as a normative standard. Implementations of this Working Standard shall be viable throughout any subsequent normative ballot process and for up to six months after publication of the relevant normative standard."

The use of the logo or trademark from

● Standards Australia; or

● any organisation accredited by Standards Australia[27] to develop Australian Standard® brand standards

on a Working Standard is strictly prohibited and **at no time** shall the Working Standard be referred to as an Australian Working Standard.

07.02.05.02   Extending the Trial Use Period or Reopening a Working Standard for Trial Use

A Work Group may petition the AU-TSC to extend the trial use period of a Working Standard typically for up to one year from the end of the existing period. Longer duration or subsequent extensions may be granted by the AU-TSC, but at no point shall a Working Standard be extended beyond 5 years from its original release for comment date without the express approval of the Board.

The request for extension shall stipulate the reason an extension is needed; the proposed length of the extension; what actions the Work Group will take to facilitate a normative ballot of the proposed standard following the trial use period; and whether the request for extension is supported by the current and any additional organisations committed to implementation. The decision of the AU-TSC or, in the case cited above, the Boards regarding the approval and length of an extension is final.

A Work Group may petition the AU-TSC to reopen the trial use period for an expired Work Group. The request to reopen the trial use period shall stipulate:

● the reason for reopening the trial use period;

● the proposed length of the new trial use period;

● what actions the Work Group will take to facilitate a normative ballot of the proposed standard following the trial use period;

● and whether the request it reopen the trial use period is supported by the current and any additional organisations committed to implementation.

The decision of the AU-TSC regarding the approval and length of the new trial use period is final.

07.02.05.03   Extended Trial Use Period Related to a Regulatory Issue

A Working Standard that has been extended in response to a regulatory issue shall only be available for comment if it is the current version of the Standard. Participants may submit comments for consideration for a next release, be it another Working Standard or a Normative version. Such comments shall only be submitted for the most current published version of the Working Standard in question.

07.02.06   Results of the Trial Use Period

Where the evaluation and comment period results in a need for substantive changes to the Working Standard, the resulting content for normative ballot may embody such changes or a revised Working Standard may be released for further evaluation without recourse to a review ballot. In either case,

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[26] Link to be added upon establishment of the AU-TSC
[27] https://www.standards.org.au/standards-development/accreditation

should there be a need for substantive changes, the normative ballot content or the subsequent revised Working Standard is not bound to maintain compatibility with the initial Working Standard. Under such circumstances, given that the intent of a Working Standard is to improve the viability of the subsequent normative Protocol Specification (§01.02), it is the obligation of the responsible Work Group to select enhancement over compatibility with the initial Working Standard.

07.02.07   Lifetime Review

One year prior to the expiration date of either the publication, extension or update of a Working Standard the Board shall notify the AU-TSC and the responsible Work Group of the requirement to review said Working Standard with the objective of determining its ongoing status.

The responsible Work Group shall, having conferred with any co-sponsoring Work Groups and using its established decision-making practices, determine whether to:

- Move the Working Standard to Normative ballot at least two ballot cycles prior to the anniversary date, or
- Update and re-ballot the Working Standard at least two ballot cycles prior to the anniversary date; or
- Submit a request to the AU-TSC at least two ballot cycles prior to the anniversary date to extend the existing Working Standard for up to three (3) years by default or up to five (5) years with AU-TSC approval; or
- Retire the Working Standard upon the end of the feedback period on its anniversary.

A successful ballot and publication of the updated Working Standard shall reset the required review date. Likewise, an AU-TSC decision to extend the current document shall reset the review date based on the requested and approved extension period.

Should the responsible Work Group decide to retire a published Working Standard that is currently accepting feedback it shall conduct a 30-day Comment-only ballot soliciting feedback on the decision to retire the Working Standard at least two ballot cycles prior to the anniversary date.

The Comment-only ballot need not contain the contents of the Working Standard but shall include at least the Working Standard title and the question "Should this Working Standard be retired?". Having considered any comments received, the responsible Work Group shall reassess its decision to retire versus move to Normative, update or extend the document.

Should the responsible Work Group take no action by two ballot cycles prior to the anniversary date, HL7 HQ, having notified the Work Group, shall retire the STU upon the completion of its feedback period.

07.02.08   Retirement of a Working Standard

A Work Group that, through its decision-making practices, identifies a Working Standard to be retired shall submit a Notice of Withdrawal of a Protocol Specification[28] form to the AU-TSC. This form will identify the subject Protocol Specification and provides the process to request input, review and approval of the request to retire the document from various HL7 Australia entities. Upon retirement, the Working Standard shall be retained in the registry of HL7 Australian publications with a status of retired.

07.03   Publishing Technical Corrections as Errata

A publication request[29] for errata addressing either an informative document or a Standard for Trial Use (STU) shall comply with AU-TSC guidance on technical corrections[30] and be accompanied by a cover letter drafted by the responsible Work Group. The cover letter shall cite the rationale

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[28] Link to template be added upon establishment of the AU-TSC
[29] Link to template be added upon establishment of the AU-TSC
[30] Link to be added upon establishment of the AU-TSC

supporting such a request and be submitted for the approval of the WGLO. Refer to the WGLO errata cover letter template[31] for guidance.

07.04   Comment-only Ballot

A Work Group, with the concurrence of the AU-TSC, may submit proposed content or requirements documents to comment-only review. The intent is to gather input from members outside of the Work Group on the viability and clarity of the proposed content or requirements document. The review of proposed content or requirements documents does not seek a vote, per se, but will capture all comments.

07.04.01   Forming the Consensus Group

All current members shall be notified of the intent to form a consensus group for comment-only review at least thirty (30) days prior to the opening of the review period. This notification shall occur via the various HL7 Australia newsletters and member email distribution lists and shall include the dates of enrolment in the consensus group. Members shall indicate their interest by enrolling in the appropriate consensus group via the indicated mechanisms during the enrolment period which shall end with the opening of the review period.

Non-members who wish to participate in a Working Standard consensus group must register their intent with the Board during the stated enrolment period via an email to the WGLO. Non-members shall be assessed a fee established by the Board for such participation.

07.04.02   Ballot Package

The ballot material shall be available for thirty (30) days following the opening of the comment-only review period. Participants are encouraged to provide constructive comments for improving the content or clarity of the ballot material.

07.04.03   Results of the Review

At the close of the comment-only review period the responsible Work Group shall capture all comments using the HL7 Australia Ballot Reconciliation Report unless the Work Group has petitioned for and been granted a waiver of such use by the AU-TSC. The responsible Work Group shall consider all comments received during the review period with the intent of improving the quality and clarity of the submitted content before seeking the approval of the AU-TSC for submission to a subsequent ballot.

The Work Group shall post the results of their consideration of the comments submitted as recorded on either the HL7 Australia web site or Confluence space. There is no requirement to respond to any comment or advise any submitter of the disposition of their comments. Given that this is a comment-only review; the issue of substantive change is moot.

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[31] Link to be added upon establishment of the AU-TSC

08   Normative Ballot

A normative ballot is undertaken with the approval of the AU-TSC. The rules for HL7 Australia normative ballots will be included in future versions of the AU-GOM.

09 Governance

09.01 Participation in Standards Development and Maintenance

Each individual present in a Work Group shall have the right to participate and cast their vote specific to development and maintenance of Protocol Specifications (§01.02), whether at in-person meetings, connectathons, special meetings, teleconferences, or other forums.

09.02 Annual Nomination and Election of HL7 Australia Leadership Positions by Administrative Ballot

Key leadership positions in HL7 Australia are open to nomination and election on an annual basis.

The rules governing the nomination, election and appointment of Board directors are stated in the HL7 Australia Constitution[32] and HL7 the Australia By-laws[33].

Other positions subject to annual nomination and election by the general membership, or some designated portion thereof, shall occur annually by electronic administrative ballot. These include:

- the AU-TSC Chair
- AU-TSC Representatives
- Work Group Co-chairs.

Every effort shall be made to present at least two candidates for each position.

Nomination as the AU-TSC Chair or a AU-TSC Representative carries with it the responsibility to attend AU-TSC meetings, whether in person or conducted via teleconference. Nominees from organisational members acknowledge that they have the support of their organisations in seeking a position on the AU-TSC and agree that they, either individually or through their organisations, will be responsible for the expenses associated with participation as a representative to the AU-TSC.

The call for nominations for the AU-TSC Chair, AU-TSC Representatives and Work Group Co-chairs positions occurs at the same as the call for nominations for the Board and shall include instructions for acquiring nomination packets. Nomination packets for these positions shall be accepted from May 1 through June 15 of each year. No nominations shall be accepted after the close of the nomination period. Nominees shall be either

- a current individual member; or
- a designated voting representative of a current organisational member.

Nominations may come from individuals (including the nominee themselves) who are either

- an individual member; or
- a designated voting representative of an organisational member of HL7 Australia on behalf of that organisation.

An individual who is nominated for or appointed to more than one position on the AU-TSC (e.g. Chair and Representative) must state which position on the AU-TSC they wish to seek and reject other AU-TSC nominations and appointments. Individuals may serve concurrently on the Board, a community process coordination committee, and the AU-TSC. Likewise, an individual may Co-chair one or more Work Groups while holding other HL7 Australia leadership positions.

There shall be no campaigning conducted using any HL7 Australia, HL7 International or other HL7-related (e.g. HL7 Affiliate) managed electronic communications (e.g., email list servers, chat forums, wiki pages, etc.). Any such activity shall be cause for disqualification.

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[32] http://hl7.com.au/wp-content/uploads/2023/08/HL7-Australia-Constitution-2022.pdf
[33] https://hl7.com.au/wp-content/uploads/2024/06/20240701-By-laws-v2.20b-Final.pdf

Elections shall occur at the same period as Board elections each year. The ballot for leadership positions is necessarily electronic with no proxy voting allowed. The ballot shall not support write-in votes.

At the conclusion of the election period the HL7 Australia Returning Officer will review the tally of the returned ballots.

Run-off elections, if necessary, shall occur at a time agreed by the Board each year. In lieu of run-off elections, candidates involved in a tie vote may opt to resolve the issue by drawing lots or one candidate may choose to defer to the other.

The results of the elections shall remain on file for two (2) years and shall be produced upon submission of a written request for results identifying a specific election by a current individual member or a designated voting representative of a current organisational member.

09.02.01   HL7 Australia Technical Steering Committee (AU-TSC) Chair

To be considered "nominated" the candidate must:

- be a current individual member or a designated voting representative of a current organisational member for at least the last two years
- have demonstrated prior leadership experience in HL7 Australia or HL7 International within the past five years such as
    - Work Group Co-chair, AU-TSC member, community process coordination committee member, or Board director
    - HL7 International Work Group Co-chair, Technical Steering Committee (TSC) member, Management Group Co-chair, International Council member, community process coordination committee member, Committee member, or Board director
- have demonstrated knowledge of existing AU-TSC practices by either being[34]:
    - a current member of the AU-TSC
    - a former member of the AU-TSC in the past five years
- have the endorsement of at least one current AU-TSC member or a Board director.

The Board appointed Returning Officer shall provide the official AU-TSC Chair ballot to current individual members and designated voting representatives of current organisational members reflecting those individuals who have nominated themselves or accepted a peer nomination. The winner of the election shall be announced at the HL7 Australia Annual General Meeting (AGM).

The AU-TSC Chair Elect shall be seated January 1 of the following year.

09.02.02   HL7 Australia Technical Steering Committee (AU-TSC) Representatives

AU-TSC representative nominees acknowledge that they have the support of their organisations (if they are a designated voting representative of an organisational member) in seeking a position on the AU-TSC and agree that they, either individually or through their organisations, will be responsible for the expenses associated with participation as an AU-TSC Representative. Election to the AU-TSC carries with it the responsibility to attend AU-TSC meetings, whether held in conjunction with the in-person events or conducted via teleconference.

09.02.03   HL7 Australia Work Group Co-chairs

Nominations for Work Group Co-chairs shall be open to members of the Work Group's primary email distribution list one week prior to the start of the nomination period. Self-nominations shall be accepted.

Nominees for Work Group Co-chair must be current individual members or individuals who represent a current organisational member although not necessarily as a designated voting representative.

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[34] This requirement will be waived for the initial establishment of the AU-TSC

An incumbent Work Group Co-chair seeking re-election shall include in their nomination submitted to the HL7 Australia Returning Officer a statement reaffirming the ability to fulfill their duties.

All other nominees must submit a statement from an existing Work Group Co-chair and another member of the Work Group in question supporting their nomination and stipulating that they are an active member of the Work Group in question and have affirmed they have the capacity to fulfill the Co-chair duties as required if elected. Active working group members participate in consensus building discussions, contribute to resolution of issues, and are recognised by their peers within the Work Group.

The HL7 Australia Returning Officer shall provide an official Work Group Co-chair ballot to those eligible members of each Work Group holding Co-chair elections reflecting those individuals nominated by their peers or themselves.

Eligible voters shall be those members subscribed to the Work Group's primary email distribution list one week prior to the start of the nomination period who:

- are current individual members, or

- have a domain name reflecting the name of a current organisational member.

A list of those elected to Co-chair Work Groups shall be provided to the Work Groups and posted during the AGM with newly elected Co-chairs assuming their duties on 1 January of the following year.

09.03   Majority Rule

All formal motions made within Work Groups shall be decided by simple majority of the quorum of that Work Group, unless otherwise specified in documented Work Group decision-making practices (DMPs). Work Groups may, at their discretion, adopt practices requiring thresholds higher than simple majority as long as those practices are documented and adopted by two-thirds vote of the members of the Work Group present and voting at the time.

09.04   Submitting and Resolving Motions under Robert's Rules of Order When Not in Session

The following process adheres to parliamentary procedure as defined by Robert's Rules of Order related to the submission and resolution of motions using collaborative tools. It is not intended to replace or deny other means, methods, or processes employing collaborative tools for the purpose of e-voting.

Motions may be submitted, discussed, and resolved electronically using a group's collaborative platform. As with face-to-face meetings certain rules of order apply to motions.

The motion shall be posted to the group platform seeking a second.

The second shall be recorded on the group platform initiating a discussion period to be determined by the group; typical guidelines suggest five (5) days, but not less than three (3) days.

Comments submitted and subsequent responses during the discussion period shall be recorded on the group platform. The chair of the group may move (post a comment) to "call the question", essentially ending the discussion, at their discretion depending on the volume of comments or lack thereof and subject to the approval of the group.

Voting shall commence at the close of the discussion period. The voting period is at the discretion of the group, typical guidelines suggest three (3) days.

Votes shall be recorded on the group platform with the final tally shown including abstentions.

While voting may continue to the close of the voting period, the motion may be declared as passed or failed given the results of a majority of quorum where quorum is defined by the group's DMPs.

10 External engagement

10.01   HL7 International

10.01.01   Participation in HL7 International voting

As the official HL7 International Affiliate for Australia and in accordance with the HL7 International Affiliate Agreement[35], HL7 Australia has the right for its members to participate in HL7 International votes.

Specifically, under the 2024-2025 Affiliate Agreement:

- For HL7 International Review and Normative Ballots and the election of Technical Steering Committee members, the number of votes allotted to the Affiliate is 10% of the number of dues-paying named members in the Affiliate.

- For election of Affiliate Directors to the HL7 International Board of Directors the Affiliate is allotted one (1) vote.

- For election to the HL7 International Council Co-Chair positions, the Affiliate is allotted one (1) vote.

10.01.01.01   Participation in HL7 International Review and Normative Ballots and election of Technical Steering Committee members

Following advice from HL7 International on how many votes are allocated to HL7 Australia and within thirty (30) days, the Board will contact all active members via an email and posting to the #Australia stream in FHIR Community Chat[36] to invite them to indicate their interest in being appointed as a voter. HL7 Australia members who are eligible to vote in HL7 International Review and Normative ballots through means other than their HL7 Australia membership (e.g. a membership of HL7 International) need to declare this when registering their interest to participate as an HL7 Australia member.

Following the deadline, the Board will distribute the votes as follows:

- One vote will be retained for use by the WGLO as a voter able to submit ballot comments and votes in review and normative ballots on behalf of the whole HL7 Australia membership. To facilitate this, the WGLO will register themselves for all HL7 International review and normative ballots.

- The remaining votes will be distributed to those who have indicated their interest with preference given to individuals who:

  o   are currently HL7 Australia Work Group Co-chairs and AU-TSC members.

  o   are currently in leadership positions in HL7 International including HL7 International Work Group Co-chairs, Management Group members and Co-chairs, and committee members.

  o   have prior experience in participating in HL7 International ballots.

  o   have previously been allocated a vote and effectively exercised it through meaningful participation.

- If fewer HL7 Australia members indicate their interest to participate than the number of allocated votes, the remaining votes will be distributed by the Board in the following order with individual allowed to decline if they do not wish to participate:

  o   The AU-TSC Chair

  o   The AU-TSC Representatives (following a meeting to decide allocation)

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[35] https://confluence.hl7.org/spaces/IC/pages/77367025/Master+Affiliate+Agreement
[36] https://chat.fhir.org

- The HL7 Australia Work Group Co-chairs chosen at random
- Other active HL7 Australia members chosen at the Board's discretion.

10.01.01.02 Participation in election of Affiliate Directors to the HL7 International Board of Directors

This single vote will be held by the current Board Chair.

10.01.01.03 Participation in election of HL7 International Council Co-Chair positions

This single vote will be held by the current Board Chair.

10.02 Australian Accelerators

An Australian Accelerator is a uniquely named program of work undertaken by one or more HL7 Australia members (individuals or organisations) with projects which includes amongst their deliverables open technical specifications which are:

- based on HL7 International or HL7 Australia standards or specifications; and
- are intended for adoption globally or by the Australian healthcare sector

Australian accelerators may be established through the following pathways:

- HL7 Australia Accelerators (AU Accelerators): Accelerators established with HL7 Australia as a partner and whereby the open technical specifications are developed through HL7 Australia's Work Groups under the governance of the AU-GOM;
- Community-aligned Accelerators: Accelerators established independently of HL7 Australia where open technical specifications are developed outside of Work Groups, align with the requirements of an HL7 Australia community process (e.g. the Australian FHIR Community Process), and are not subject to the AU-GOM.

10.02.01 HL7 Australia Accelerators (AU Accelerators)

10.02.01.01 Establishment

A single Benefactor organisational member; or a group of organisational members with at least one Benefactor member (the AU Accelerator Partner/s) may submit a proposal to establish an AU Accelerator to the Board for consideration and approval. The proposal should address the following:

- The proposed name of the AU Accelerator
- Relevant HL7 Australia and HL7 International standards
- The HL7 Australia Work Group/s through which the AU Accelerator   will develop Protocol Specifications
- Deliverables of the AU Accelerator
- Resources provided by the members
- Governance arrangements
- Funding and other arrangements

If the Board approves of the proposal, the AU Accelerator can proceed to be established through a legally binding contract (the AU Accelerator Contract) between HL7 Australia and the Accelerator Partner/s.

10.02.02 HL7 Australia Accelerator Leadership

The accelerator must have an overall decision-making committee which includes amongst its voting members at least two current HL7 Australia Board directors.

10.02.03 Standards development arrangements

10.02.03.01 Temporary Work Group Co-chairs

The AU Accelerator's overall decision-making committee may nominate up to three individuals in total who are designated voting representatives of the AU Accelerator Partner organisation/s for consideration to become Temporary Work Group Co-chairs of the relevant Work Group. Temporary Co-chairs are still meet the criteria to become a Work Group Co-chair [§09.02.03].

Temporary Work Group Co-chairs shall only carry out Work Group Co-chair responsibilities

- for the duration of the AU Accelerator;
- related to standards development associated with the AU Accelerator.

Appointment of these Work Group Co-chairs will be based on the relevant Work Group:

- using its decision-making practices to increase the number of required Co-chairs; and
- seeking nominations from Work Group members who wish to become Temporary Work Group Co-chairs; and
- conducting an election if required and appointing the Temporary Work Group Co-chairs.

10.02.03.02   Work Group projects

Single or multiple Work Group projects with names that includes the AU Accelerator name will be established in the relevant Work Group or Work Groups for coordination of the standards development activities of the AU Accelerator.

The AU Accelerator's technical specifications will be developed Protocol Specifications in these projects and following the standard development processes and practices of the AU-GOM.

10.02.04   Termination

HL7 Australia Accelerators may cease for reasons as stipulated in the Accelerator Contract. Following termination of the contract the following activities are expected to be undertaken as soon as possible:

- Temporary Work Group Co-chair appointments for the AU Accelerator will cease.
- AU Accelerator Work Group projects will be terminated.
- The relevant Work Groups through their decision-making practices shall decide whether any incomplete specifications will be progressed through new Work Group projects or not.

11 Maintenance of the HL7 Australia Governance and Operations Manual (AU-GOM)

The HL7 Australia Governance and Operations Manual (AU-GOM) shall be a dynamic document with proactive, iterative, and participatory maintenance designed to keep the manual current with HL7 operational requirements.

Those entities tasked with implementation of HL7 Australia process and procedure may, in the course of normal operations, identify a need to deviate from those processes and procedures documented in the AU-GOM.

In such circumstances, the responsible entity my make a request for deviation directly to the Board rather than deferring until a suitable revision to the AU-GOM adopted by the Board. The requests for deviation may be submitted to the Board for consideration and approval.

Subsequently, should the action taken rise to the level of an organisational change rather than a one-off deviation, the responsible entity shall then submit a request for revision of the AU-GOM to the Board for consideration and approval.

11.01 Membership Participation

The membership shall be an active participant in maintenance of the GOM. They will be engaged through

- the ability to submit comments and recommendations[37] for maintenance of the AU-GOM, and
- participation in the peer reviews of AU-GOM changes.

11.02 Concurrent Processes

11.02.01 Developing the AU-GOM Revisions between AGMs

At regular intervals the Board shall prepare documentation with markup reflecting the revision proposals received from members. This documentation shall be submitted to a peer review process. Peer review will engage the membership via the AU-GOM email distribution list and posting to the #Australia stream in FHIR Community Chat[38].

The peer review period shall be scheduled for thirty (30) days. Following the review period the Board will schedule a meeting to resolve the comments as received, finalise the revisions, and either adopt or reject them. The outcomes of the meetings will be posted on the HL7 Australia web site.

11.02.02 Exceptional Revision Requests

Exceptional revision requests may result from ongoing process review, or the comments received during the peer review of revision proposals. The Board shall assess the criticality of the exceptional revision request. If deemed necessary and given sufficient time to conduct a focused peer review of at least two (2) weeks duration, the Board will meet to finalise the revisions, and either adopt or reject it. The outcomes of the meeting will be posted on the HL7 Australia web site. Otherwise, the revision request shall become a candidate for the next revision cycle.

11.03 Effective Date of Revision or Adoption

Revisions or additions to the GOM shall be effective on the date stipulated upon adoption by the Board.

An updated AU-GOM shall be posted to the HL7 Australia web site within fourteen (14) days of revisions being adopted.

11.04 Periodic Adoption in its Entirety

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[37] Link be added upon establishment of the AU-TSC
[38] https://chat.fhir.org

The HL7 Australia Secretary may periodically call for the Board to ratify the AU-GOM in its entirety. Upon approval motion to adopt the AU-GOM in its entirety:

- The AU-GOM shall, within fourteen (14) days, be posted to the HL7 Australia web site with an adoption date reflecting the decision of the Board and with all notations of addition or revision removed.

- The Secretary shall institute a call for review of all current organisational documentation to ensure compliance with the procedures defined in and the terminology used by the current AU-GOM as adopted by the Board.