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**HL7® Australia Standards Development Practices:
Due process requirements for HL7 Australia
National Standards**

Adopted: **To be added post AGM**
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HL7 Australia Essential Requirements

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Introduction

HL7 Australia Standards Development Practices identifies those processes, policies, and procedures designed to ensure HL7 Australia aligns with its parent standards development organization, HL7 International, which is itself in compliance with *ANSI Essential Requirements: Due process requirements for American National Standards* (ANSI ER). Standards Development Practices maintenance shall be proactive with a focus on maintaining compliance with the current edition of HL7 International Essential Requirements and other standards accreditation requirements.

With the adoption of additions or revisions to the Standards Development Practices, the HL7 Australia Secretary shall cause them to be added to an updated version of this document with annotation in the table below reflecting the date adopted or revised. Additions and revisions will be posted within ten working days of the date on which they were adopted.

Periodically the HL7 Australia Secretary, using his or her best judgment, may call for ratification of the Standards Development Practices in its entirety by the HL7 Australia Board. Upon ratification of the Standards Development Practices in its entirety it shall be posted with a new adoption date and all internal notations of addition or revision removed.

The Standards Development Practices will be maintained and distributed electronically via the HL7 Australia Web site. A hard copy of the Standards Development Practices is available upon request to those without electronic access. A processing fee, established by the HL7 Australia Board, may be applied to cover printing, postage, and handling.

Notice of Current Edition

This edition of the Standards Development Practices, adopted in its entirety in 2015, is the current edition, which supersedes and rescinds all previous editions of the Standards Development Practices.

Additions and/or Revisions Subsequently Adopted

The following additions and/or revisions, having been approved by the HL7 Australia Board subsequent to adoption of this edition of the Standards Development Practices, are included by extension. The correction of a typographical or trivial error, captured as a standing work item, 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.

| <u>Designation</u> | <u>Adopted</u> |
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HL7 Australia Essential Requirements

01 Due Process

Due process means that any entity (organization, company, government agency, individual, etc.) with a direct and material interest has a right to participate by: a) expressing a position and its basis, b) having that position considered, and c) having the right to appeal. Due process allows for equity and fair play. HL7 International defines the following as constituting the minimum acceptable due process requirements for the development of consensus for approval, revision, reaffirmation, or withdrawal of HL7 American National Standards (ANS). As such these represent the guiding principles for the HL7 Australia Standards Development Practices.

01.01 Openness

Participation shall be open to all persons who are directly and materially affected by the activity in question. There shall be no undue financial barriers to participation. Voting membership in the consensus body shall not be conditional upon membership of HL7 Australia, nor unreasonably restricted on the basis of technical qualifications or other such requirements.

01.02 Lack of Dominance

The standards development process shall not be dominated by any single interest category, individual or organization. Dominance means a position or exercise of dominant authority, leadership, or influence by reason of superior leverage, strength, or representation to the exclusion of fair and equitable consideration of other viewpoints.

01.03 Balance

The standards development process should have a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving balance. If a consensus body lacks balance in accordance with the historical criteria for balance, and no specific alternative formulation of balance was approved by NAME, outreach to achieve balance shall be undertaken.

01.04 Coordination and Harmonization

Good faith efforts shall be made to resolve potential conflicts between and among existing Australian Standards and candidate HL7 Australia Standards.

01.05 Notification of Standards Development

Notification of standards activity shall be announced on the HL7info Community email list (which is open to subscription independent of membership) and the HL7 Australia web site as appropriate to demonstrate an opportunity for participation by all directly and materially affected persons.

01.06 Consideration of Views and Objections

Consideration shall be given to the written views and objections of all participants, including those commenting on the public announcement.

01.07 Consensus Vote

Evidence of consensus in accordance with these requirements and the procedures of the HL7 Australia shall be documented.

01.08 Appeals

HL7 Australia written procedures shall contain an identifiable, realistic, and readily available appeals mechanism for the impartial handling of procedural appeals regarding any action or inaction. Procedural appeals may include, for instance, whether a technical issue was afforded due process.

01.09 Written Procedures

Written procedures shall govern the methods used for standards development and shall be available to any interested person.

Commented [TW1]: I find this paragraph confusing – does it mean that you do not need to be a member to participate? How are we checking that the people participating are directly and materially affected by the activity?

Commented [PF2R1]: Yes. Wording copied from HL7 International. With regards to checking the directly and materially affected I think we would have to judge that on a case by case basis. One would hope that in most circumstances any participation of this nature would be well meaning and from a known entity. Depending on the nature and intent of any input we could ask for justification of direct and material interest if required – though one would hope that to be a rare exception.

Commented [TW3]: Do we want to add government to this list?

Commented [PF4R3]: My view is that they are an organisation and therefore covered.

Commented [PF5]: HL7 Australia will require to nominate an approving entity

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01.10 Compliance with Normative Policies and Administrative Procedures

HL7 Australia will comply with the normative policies and administrative procedures established by HL7 International.

02 Normative Ballot

A normative ballot is undertaken with the approval of the HL7 Australia Board. It is intended to process and validate those protocol specifications intended for adoption as HL7 Australia standards. The normative ballot process shall adhere to the tenets of HL7 International Essential Requirements. Under normal circumstances the subject matter of a normative ballot will have at some point been subjected to a review ballot; however, there are a number of scenarios where material may need to move directly to normative ballot, such as the need to respond to government mandate or to resolve a critical issue raised by a stakeholder or noted in an existing HL7 Australia Standard.

02.01 Electronic Format

Normative ballots shall be conducted electronically and provide for:

- a) The means to form a consensus group and provide necessary notifications.
- b) The means to capture the vote and associated comments.
- c) The means to capture disposition of negative comments.

02.02 Normative Ballot Content

02.02.01 Consideration of Recommended Actions

Prompt consideration shall be given to proposals made for developing new or revising existing HL7 Australia Standards. The HL7 Australia Board shall approve recommendations for all actions pertaining to approval or adoption of HL7 Australia Standard, or any portion thereof, prior to submission for ballot.

02.02.02 Proposed Normative Content

A Work Group may, with the concurrence of the HL7 Australia Board, submit proposed normative content to a normative ballot.

02.02.03 Moving an Informative Document to Normative Ballot

An Informative Document, representing the consensus of the issuing Work Group on a given subject area, may be submitted for normative ballot by the issuing Work Group chair with the concurrence of the HL7 Australia Board. The Work Group chair shall present the HL7 Australia Board with the following documentation: (1) the publication date of the informative document; (2) a log of any post publication comments and subsequent resolution, if such occurred; and (3) the rationale for moving the contents to normative ballot. Subsequent to the successful completion of a normative ballot, the Work Group chair shall issue a statement through HL7 Australia withdrawing the Informative Document with reference to the corresponding normative HL7 Australia Standard.

02.02.04 Moving a Draft Standard to Normative Ballot

Following the close of the trial use period and the application of revisions resulting from comments received and practical experience gained during the trial use period, if any, the subject matter of a draft standard appropriately formatted and named as a normative document may, with the concurrence of the HL7 Australia Board, be submitted to a normative ballot.

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02.02.05 Normative Ballot Resulting from External Requirements

In order to provide timely compliance with regulatory or other governmental mandates and/or a timely response to industry or market demand, a Work Group may, with the concurrence of the HL7 Australia Board, issue a normative ballot without first conducting a review ballot. Although the content may represent a new HL7 Australia Standard, generally the content of the normative ballot resulting from an external requirement will be restricted to those changes and/or additions to an existing HL7 Australia Standard necessary to address the specific requirement.

02.02.06 Components Labeled “For Comment Only”

Certain components of a normative ballot may be labeled as “reference material” or “informative content” and are not considered normative content. Such components may be included in normative ballot material “for comment only.” In such instances, the objective is to gather input from the membership on the appropriateness and accuracy of the material in question. There is no vote per se on such material and comments are not subject to formal reconciliation.

02.02.07 Confirmation of Previous Ballot Reconciliation

A normative ballot shall not include content from a previous normative ballot that has not been fully reconciled. The responsible Work Group must ensure the completeness of required documentation for all previous normative ballot cycles of the same content. The required documentation includes:

- a) Reconciliation packages uploaded to the Collaborative Workspace
- b) The Collaborative Workspace reflecting that all negative voters have been notified of the dispositions of their negative votes
- c) The Collaborative Workspace reflecting that all negative voters have been notified of the right to appeal (§02.13)
- d) The Collaborative Workspace reflecting that an email has been sent to those negative voters who have verbally agreed to withdraw their negative vote. This email shall seek confirmation of the voter’s decision and allow the voter five days in which to respond. Further, the email shall indicate the date on which this verbal agreement occurred which shall be documented in the Work Group minutes for future reference. During the subsequent five day period the negative voter may either confirm the withdrawal or state that the negative stands.
- e) The Collaborative Workspace reflecting that quorum was achieved and affirmative votes were handled appropriately.

The deadline for completing required documentation is the *Supporting Content Deadline* which is scheduled two weeks prior to ballot opening. At least two weeks prior to the *Ballot Announcement Date* HL7 Australia shall provide a list of items submitted for the current ballot cycle to the HL7 Australia Board. This list shall include those items submitted but not eligible to proceed due to outstanding reconciliation issues on a prior Normative Ballot of the same content. While the HL7 Australia Board may waive the issue and allow an item to move to ballot, a Normative Ballot is not considered complete until the final reconciliation package has been posted to the Collaborative Workspace.

02.03 Notice of Normative Ballot

The notice of normative ballot shall be provided to the membership, the headquarters or secretariat of cooperating Australian Standards Developers, and the general public via the HL7info Community email list (which is open to subscription independent of membership) and the HL7 Australia web site. This notice shall be released at least thirty days prior to the start of a normative ballot period.

For an initial normative ballot and for those subsequent normative ballots of the same content the notice of normative ballot shall include the dates that enrollment in the consensus group will be available. Interested parties may indicate their intent to participate in a normative ballot by enrolling in the appropriate consensus group via the HL7 Collaborative Workspace. Enrollment shall close with the opening of the normative ballot period. In the case of a recirculation ballot [§02.12] the notice of ballot shall include notification of the right to appeal an unresolved negative comment [§02.13].

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02.04 Forming the Consensus Group

A normative ballot shall be open to all interested and materially affected parties; however, quorum shall be defined relative to the number of HL7 Australia members in the consensus group. There shall be no constraints on or requirements for participation of non-members other than a charge for administrative processing. Such a fee is to be established by the HL7 Australia Board, not exceeding the individual membership fee.

02.04.01 Member Participation

The notice of normative ballot [§02.03] shall serve as the mechanism by which HL7 Australia shall canvass its membership to identify those members willing to participate in the consensus group for a normative ballot.

Participation shall include both individual members and those individuals designated as voting representatives of organisational and benefactor members; the specific number allowed being defined by membership level. Given that an organizational or benefactor member may be represented by multiple individuals who are at liberty to enroll in any given consensus group, there may be multiple representatives of any given organizational or benefactor member in any given consensus group each being recognized as an individual participant and reported as such in the summary of voting activity.

The HL7 Australia board shall be informed of any normative ballot where, not later than three days prior to the closing of the enrollment period, the ballot pool includes fewer than ten current individual members or separate individuals representing at least three current organizational members. Unless the consensus group has met this criterion by the close of the enrollment period the ballot period shall not commence. Quorum shall be determined by a majority of those HL7 members enrolled returning a ballot response.

Commented [PF6]: The HL7 Australia Board may wish to review this figure prior to approval.

Commented [PF7]: Ditto above.

02.04.02 Nonmember Participation

A nonmember who is directly and materially affected by a ballot proposal may request to join the consensus group specific to the normative ballot of a given specification. Nonmembers shall register their intent by completing the Non-Member Enrollment process by contacting the HL7 Australia Secretary by telephone or email providing information supporting their status as nonmembers; as being directly and materially affected and full contact information including name, address, telephone, and email address if appropriate. Nonmember participation is by definition at the individual level. A nonmember may register their intent to join the consensus group during the enrollment period.

Upon validation of status the nonmember shall be provided access to the ballot via the HL7 Collaborative Workspace. They shall be notified that participation in the ballot implies adherence to the tenets of the HL7 Australia intellectual property policies. Nonmembers must adhere to all ballot instructions and respond by the ballot closing date.

HL7 Australia may charge an administrative fee for providing access to the Collaborative Workspace for nonmembers. The fee, to be determined by the HL7 Australia board, shall not exceed the fee for an individual membership of HL7 Australia. The fee, at the discretion of the HL7 Australia Board, may be requested in advance. The fee shall support and provide for participation in all subsequent ballots specific to the initial issue. Nonmember administrative fees may be applied to membership in the year collected, however, this fee is not refundable.

02.04.03 Seeking Balance

Not later than three days prior to the closing of the enrollment period for a given specification, the HL7 Australia Board shall review the consensus group to ascertain if a single interest category constitutes a majority. If a disparity is found, the HL7 Australia Board shall engage members of underrepresented interest categories through electronic means seeking their participation in the consensus group. A record of such action, if it proves necessary, shall be part of the ballot record.

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02.04.04 The Consensus Group

The consensus group for the initial and subsequent normative ballots of the same content, that being an iterative ballot of material specific to the project defined by the HL7 Australia Board, shall consist of those individuals, members or nonmembers, who expressed an interest by enrolling for a given ballot.

Those registrants, be they member or nonmember, who return an affirmative, negative with comment or abstention shall be registered as continuing participants in the consensus group of subsequent normative ballots of the same content. No additional fees shall be assessed for nonmembers who qualify to participate in subsequent normative ballots of the same content.

Those registrants, be they member or nonmember, who do not return a ballot or return a negative ballot without comment shall be reported as such and shall not participate in any subsequent normative ballot of the same content subject to their electing to reenroll in the consensus group of a subsequent normative ballot of the same content.

02.04.05 Consensus Group Variance Process

Any organizational or benefactor member experiencing a change in voting representatives or any other situation which impacts current consensus groups shall request a variance of process from the HL7 Australia Chair, in his or her absence, the HL7 Secretary. A request for variance of process shall include a detailed explanation for such a request and clearly identify the individuals involved. The HL7 Australia Chair or, in his or her absence, the HL7 Secretary shall triage the issue, engage the appropriate parties, and assure resolution of the issue. Documentation of the variance and its resolution will be retained with the ballot material for review during any external audit process.

02.05 Issuing a Normative Ballot

02.05.01 Authority

The HL7 Australia Board is empowered to initiate and conduct a normative ballot on those items properly submitted by a Work Group.

02.05.02 Return Date

The ballot shall indicate a return date, which shall not be less than thirty days after the date that the ballot commences or opens.

02.05.03 Reason

The ballot shall include the information supporting the submission of the item to ballot.

02.05.04 Instructions

The ballot package shall include clear and conspicuous instructions that negative responses submitted without comment will not be factored into the numerical requirements for approval and will be recorded as "negative without comment" without further notice to the submitter.

02.05.05 Cooperating Australian Standards Developers

Normative ballots shall be routinely provided to the headquarters or secretariat of cooperating Australian Standards Developers.

02.06 Approval

A 75% affirmative response of the combined affirmative and negative votes cast shall be required for approval with a majority of the consensus group returning ballots (affirmatives, negatives with comment, or abstentions) and representative of a majority of the HL7Australia members participating.

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02.06.01 Achieving the Necessary Ballot Response Level

Seven days prior to the close of a normative ballot, HL7 Australia shall, at its convenience, issue a reminder email message to those individuals in the consensus group who have not yet submitted a ballot response. Three days prior to the close of a normative ballot, at the convenience of HL7 Australia, the Work Group co-chair having jurisdiction shall be notified of the status of the consensus group response level.

If the required majority response has not been achieved or the response is not inclusive of the majority of HL7 Australia members participating, the Work Group co-chair having jurisdiction may choose to:

- a) execute a single extension of the normative ballot closing date for a period not to exceed two weeks (fourteen calendar days) with the objective of achieving the required majority response level and/or majority response of the participating HL7 Australia members; or
- b) close the normative ballot on the date originally stipulated and declare the ballot “for comment only” if the required response levels have not been achieved by that date.

In the event that a normative ballot is closed with a declaration of “for comment only,” HL7 Australia shall inform the participants of that decision by email message stipulating the failure to achieve the required response levels. The Work Group co-chair having jurisdiction shall consider revising the materials involved in the normative ballot based on any comments received, but is not required to conduct ballot reconciliation. These materials, whether revised or not, may be submitted for the next normative ballot cycle. Information regarding closing date extensions shall be included in the ballot report.

02.06.02 Unresolved Negatives

Approval of an HL7 Australia Standard is not contingent on the withdrawal of all negative ballots. The existence of unresolved negatives shall not preclude the publication of a protocol specification that meets the approval criteria.

02.06.03 Approved Components

Those components of a normative ballot which receive approval, and are easily delineated and shown to not adversely affect any other component of the same ballot, may, with the concurrence of the HL7 Australia Board, be moved forward by the relevant Work Group, to publication and submission for consideration as an HL7 Australia Standard, regardless of the approval or disapproval of other components of the same ballot.

02.06.04 Reporting Concerns in the Voting Process

Any individual who becomes aware of any issue related to the submission of a vote by any member of the ballot pool shall report the issue to a board member. HL7 Australia shall investigate the reported incident, assess its impact on the outcome of the ballot and prepare recommendations for correcting the situation. The HL7 Australia Board shall review the recommendations and take such action as appropriate. The reporting individual may, at their discretion, appeal [§02.13] any action or inaction which they feel adversely affects the normative ballot.

02.07 Accompanying Comments

As a function of the HL7 Australia ballot process, HL7 Australia will publish notice of normative action to create a new or revise, reaffirm, or withdraw an existing HL7 Australia Standard in the HL7Info Community email list (which is open to subscription independent of membership) and the HL7 Australia web site. This action initiates a public review period during which members of the general public, who are interested or materially affected parties, may submit comments to the standards developer. Such public review comments shall be considered on a par with ballot comments.

At the close of the ballot period the responsible Work Group shall capture all ballot and public review comments in the HL7 Australia Collaborative Workspace unless the responsible Work Group has petitioned for and been granted a waiver of such use by the HL7 Australia Board.

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02.07.01 Retraction

A submitter may, of their own volition, retract a comment, whether associated with public review or a ballot, either negative or affirmative, at any time by providing written notice of such action in a letter, memorandum, or e-mail. A retracted comment shall be considered to have been submitted in error and shall not be retained as part of the ballot material.

02.07.02 Affirmative Ballots

All affirmative public review comments or comments accompanying affirmative ballots shall be considered by the appropriate Work Group.

02.07.03 Negative Ballots or Public Review Comments

02.07.03.01 Submission with Comments

Negative public review comments or comments accompanying negative ballots shall be submitted as an attachment and clearly reference the particular ballot item(s) to which it pertains.

02.07.03.02 Submission without Comments

A negative public review submitted without rationale or a negative ballot not accompanied by comments shall not be considered. Such ballots or public review comments will be recorded as a "negative without comment" for the purposes of establishing a quorum. However, these ballots shall not be factored into the numerical requirements for approval. No effort shall be made to solicit comments from the submitter of a negative public review or ballot submitted without comment.

02.08 Completion of Disposition Action

The responsible Work Group shall attempt to complete all actions related to the disposition of comments received during the ballot or public review period, otherwise known as reconciliation, within ten months of the close of the respective ballot cycle. If reconciliation cannot be completed by the end of the tenth month following the close of the respective normative ballot cycle, the responsible Work Group may submit a request for extension to the HL7 Australia Board or simply submit the document as revised to another ballot cycle.

02.09 Negative Ballots Not Previously Considered

All negative ballots not disposed in an earlier normative ballot cycle shall be considered by the responsible Work Group.

02.09.01 Motions for Handling Negative Ballots

All motions for handling negative comments shall include an explanation of the reason for the action.

02.09.01.01 Not Related

A negative response should be considered not related if it deals with issues or functionality that is beyond the scope of or is, in the considered opinion of the Work Group, clearly not related to the ballot subject matter. Approval of a motion to declare a negative response not related shall require an affirmative majority vote of the combined affirmative and negative votes cast by the Work Group during reconciliation. Negative responses declared not related shall be recorded as a "negative without comment" and shall not impede progress of the ballot.

Those items declared not related shall become recommended actions for the development of new or revision of existing HL7 Australia Standard. The submitter of a negative response declared not related shall be advised of the disposition of their response and the reasons therefore. No further action is required.

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02.09.01.02 Not Persuasive

A negative response should be considered not persuasive if it deals with processes or issues not in the purview of the Work Group responsible for ballot content; suggests the use of alternate methodologies or solutions; or questions the validity of the approach or the expertise of the developers.

Approval of a motion to declare a negative response not persuasive shall require an affirmative majority vote of the combined affirmative and negative votes cast by the Work Group during reconciliation. The submitter of a negative response declared not persuasive shall be advised of the disposition of their response and the reasons therefore. The submitter may choose to withdraw their negative in favor of an affirmative or abstention; otherwise, the response shall be recorded as an unresolved negative.

02.09.01.03 Persuasive

Where a majority of the Work Group voting on reconciliation agrees that the position expressed by the negative response is persuasive, the changes recommended by the comment shall be incorporated into the specification as reasonable and necessary revisions. The submitter may choose to withdraw their negative in favor of an affirmative; if not, the response shall be recorded as a resolved negative given that the submitter's concern has been satisfied by the adoption of their recommended solution.

02.09.02 Confirmation of Withdrawn Negative Ballot

Those negative ballots recorded as resolved and withdrawn at the request of the submitter during a working group reconciliation session or teleconference shall be affirmed via email. No response to the email within five working days shall be considered a de facto affirmation of withdrawal.

02.09.03 Effect of Withdrawn Negative

A negative ballot withdrawn at the request of the submitter shall be recorded as an affirmative vote.

02.09.04 Substantive Change

HL7 International Essential Requirements defines substantive change as "one that directly and materially affects the use of the standard." Examples of substantive change include:

- "shall" to "should" or "should" to "shall"
- addition, deletion or revision of requirements, regardless of the number of changes
- addition of mandatory compliance with referenced standards

A substantive change is any change that materially affects the intent or content of the proposed HL7 Australia Standard as balloted; e.g., alters the information content of a message, the circumstances under which it would be sent, or the interpretation of its content. Any substantive change shall necessitate a subsequent normative ballot of the same content; allowing the consensus group [§02.04.04] to respond, reaffirm, or change their vote due to the substantive change.

02.10 Negative Ballots Previously Considered

When a negative response to a normative ballot raises virtually the same issues as those contained in a negative response disposed as not related or not persuasive in a previous normative ballot cycle of the same subject matter, the Work Group co-chair may move that the negative ballot be given no further consideration and cite the results of the previous reconciliation action. Approval of this motion shall require an affirmative vote of at least sixty percent (60%) of the combined affirmative and negative votes cast by the Work Group during reconciliation.

02.11 Notification of Disposition of Negative Ballots

With the exception of those negative public reviews submitted without rationale or negative ballots submitted without comment, those individuals submitting negative ballots or public review comments shall be notified as to the disposition of their negative ballots or comments and the reasons therefore. Notification of the disposition of negative comments submitted during the ballot or public comment period shall be in writing which includes electronic communications.

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02.11.01 Fulfilling Notification of Disposition Requirements

If the attempt to notify an organization or benefactor member representative of the disposition of their negative comments via the Collaborative Workspace is unsuccessful, the responsible Work Group chair will notify a board member who shall forward such notification to the organization or benefactor's nominated Representative fulfilling the requirement of notification.

If the attempt to notify an individual member of the disposition of their negative comments via the Collaborative Workspace is unsuccessful, the attempt shall be considered reasonable and prudent and shall fulfill the requirement of notification of disposition.

02.12 Re-circulation of Unresolved Negative Comments

In the case of a normative ballot reconciled by the Work Group with no substantive change and otherwise receiving approval, all unresolved negative comments shall be reported back to all members of the consensus group approving the ballot, including those who did not respond, allowing them the opportunity to respond, reaffirm, or change their vote based on the content of the unresolved negative comments. The report of unresolved negative comments shall be an amalgamated ballot reconciliation table in the Collaborative Workspace including only those negative comments not withdrawn and documenting any attempts at resolution.

The re-circulation period shall not exceed two weeks and is solely for the purpose of allowing those in the approving consensus group to reconsider their vote in light of the content of any unresolved negative comments. While there is no requirement to include comments for votes that are changed from negative to affirmative or from either negative or affirmative to abstain, participants who choose to change an affirmative to a negative must cite the unresolved negative comment that prompted that decision. Anyone enrolled in the approving consensus group who did not submit a ballot response and, subsequently, responds to the recirculation ballot with a negative shall cite the negative comment(s) that caused their response. At the close of the re-circulation period, the votes shall be tallied and the results of the ballot reported to the membership. The results of the recirculation ballot shall constitute the final tally of the normative ballot.

02.13 Appeal

Any individual who has been or will be adversely affected by any procedural action or inaction by HL7 Australia with regard to the development and subsequent approval by normative ballot of a proposed HL7 Australia Standard or the revision and subsequent approval by normative ballot of an existing HL7 Australia Standard, shall have the right to appeal. The burden of proof to show adverse effect shall be on the appellant. Appeals of actions shall be made within thirty days of the purported infraction; inactions may be identified at any time but shall be appealed within thirty days of the date the purported inaction is identified.

The appellant shall state their case in writing and deliver the appeal including all appropriate contact information to HL7 Australia addressed to the attention of the HL7 Australia Chair. Upon receipt the HL7 Australia Chair shall immediately notify the HL7 Australia Board of the submission of an appeal by providing them a copy of the appellant's correspondence. The board shall identify a disinterested third party, who may or may not be a member of HL7 Australia, and instruct them to conduct an audit of the process and records related to the action or inaction in question.

The HL7 Australia Chair shall notify the appellant in writing, which includes electronic means, that their appeal is being processed. If the investigation shall take longer than sixty (days, the HL7 Australia Chair shall inform the appellant in writing of the reason for a delay and the expected date of response. The individual conducting the investigation shall prepare a report for the consideration of the Executive Committee, who shall resolve the appeal. The decision of the HL7 Australia Board is final. The appellant shall be advised in writing of the disposition of the appeal.

02.14 Posting the Reconciliation Package

In order for a Normative Ballot to be considered completed and prior to the initiation of a Normative Ballot of the same content the reconciliation package addressing the disposition of all comments as recorded on the ballot table in the Collaborative Workspace.

HL7 Australia Essential Requirements

02.15 Discontinuance of a Standards Project

The HL7 Australia Board may discontinue a project involving a proposed HL7 Australia Standard or revision to an existing HL7 Australia Standard or portion thereof (a standards project) if the initiating Work Group has been:

- a) unable to reach consensus necessary to bring the proposed HL7 Australia Standard to normative ballot within a year of project initiation; or
- b) unable to successfully complete a normative ballot and move the proposed HL7 Australia Standard to publication within a year of initiation of a normative ballot

Given approval by three quarters (75%) of those in session when the motion is addressed, a Work Group may petition the HL7 Australia Board to discontinue a standards project regardless of its current status. The Work Group has the discretion to take this action for whatever reason it deems appropriate. The HL7 Australia board shall have the final decision on a request to discontinue a standards project.

Upon a decision by the HL7 Australia Board to discontinue a standards project, HL7 Australia shall publish notice of the discontinuance of the project via the HL7info Community email list (which is open to subscription independent of membership) and the HL7 Australia website in a timely manner.

03 Interpretation of HL7 Australia Standards

The HL7 Australia Chair or, in his or her absence, the HL7 Australia Secretary shall be responsible for official interpretation of any existing or proposed HL7 Australia Standard (ANS). Requests for interpretation of an existing or proposed HL7 Australia Standards shall be submitted email to the HL7 Australia Secretary (secretary@hl7.org.au). In addition to the specific query, the request shall include the submitter's name, address, affiliation, telephone, and email address. Such submissions shall be routed to the HL7 Australia Chair who may refer the request to the appropriate Work Group for consideration. The HL7 Australia Chair or Secretary, in collaboration with the HL7 Australia Board, 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 HL7 Australia Chair or Secretary to be of value to the membership, reference to a current interpretation may be included on the HL7 Australia website.

04 Maintenance of Standards Development Practices

HL7 Australia Standards Development Practices shall be a dynamic document with proactive, iterative, and participatory maintenance designed to keep the document current with HL7 Australia operational requirements in support of HL7 International Essential Requirements and other standards accreditation requirements that may be required.

04.01 Membership Participation

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

- a) a suggestion box openly displayed at each Annual General Meeting
- b) a standing agenda item at each Annual General Meeting to collect comments and recommendations for maintenance of the Standards Development Practices,
- c) an email address [secretary@hl7.org.au] for the submissions of comments and recommendations for maintenance of the Essential Requirement interim to the AGM, and
- d) peer review of all proposed revisions to the Standards Development Practices

04.02 During the Annual General Meeting

To ensure that all members are aware of current Standards Development Practices revisions, an extract of the table of "Additions and/or Revisions Subsequently Adopted" reflecting the results of the most recent revision shall be sent to all members seven days before the Annual General Meeting.

HL7 Australia Essential Requirements

04.03 Concurrent Processes Interim to Annual General Meetings

04.03.01 Developing Standards Development Practices Revisions

HL7 Australia shall prepare documentation with markup reflecting any proposed revisions identified in a work item list. This documentation shall be submitted to a peer review process. While a particular revision may dictate additional peer review resources, generally peer review will engage the following: HL7 Australia Board, Work Group chairs and self-identified HL7 Australia members with an expressed interest in the governance of standards.

The peer review period shall be scheduled for thirty days with a closing date preferably at least ten days prior to the opening date of the next Annual General Meeting. The HL7 Australia Board shall resolve any comments as received such that the revisions can be published in accordance with the publication requirements of the Annual General Meeting [§04.02].

04.03.02 Exceptional Work Item Requests

Exceptional work items may result from ongoing process review or the comments received during the peer review of work items ratified for the current revision cycle. The HL7 Australia Board shall assess the criticality of the exceptional work item request. If deemed necessary and given sufficient time to conduct a focused peer review of at least two weeks duration, the HL7 Australia Board may include the work item in the current revision cycle. Otherwise, the work item shall become a candidate for the next revision cycle.

04.03.03 Developing the Work Item List for the Next Cycle

Following any given Annual General Meeting, the HL7 Australia Board shall consolidate all comments and recommendations collected during the previous Annual General Meeting or received via email since the last revision cycle into an issues list for consideration for adoption as work items by the board. There shall be standing work items to capture correction of any typographical or other trivial errors and any items resulting from changes to HL7 International Essential Requirements and other standards accreditation requirements. Any issues not adopted as work items by the HL7 Australia Board will be reworked for consideration in the next cycle or, if so directed, removed from the list and not further considered.

04.04 HL7 Australia Board Action

Following any given Annual General Meeting, the HL7 Australia Board shall prepare and consider a motion to consider those issues captured by the membership in the current revision cycle for adoption as work items. At least two weeks prior to any given Annual General Meeting, the HL7 Australia Board shall prepare and consider a motion to consider adoption of the proposed revisions resulting from the work items in the current revision cycle. The HL7 Australia Board proceedings shall include notice of those revisions subsequently adopted. Those revisions not adopted shall be returned to the issues list for additional work during the next revision cycle or, if so directed, dropped as a work item and not further considered.

04.05 Effective Date of Revision or Addition

Revisions or additions to the Standards Development Practices shall be effective on the date stipulated upon adoption by the HL7 Australia Board. An updated Essential Rules shall be posted to the HL7 Australia Web site within ten working days of the closing date of each Annual General Meeting.

04.06 Periodic Adoption in its Entirety

The Secretary, may periodically call for the HL7 Australia Board to ratify the Standards Development Practices in its entirety. Upon approval of the Secretary's motion to adopt the Essential Rules in its entirety:

- 1) The Standards Development Practices shall, within ten working days, be posted with an adoption date reflecting the decision of the HL7 Australia Board and with all notation of addition or revision removed.

HL7 Australia Essential Requirements

2) The Secretary shall institute a call for review of all current organizational documentation to ensure compliance with the procedures defined in and the terminology used by the current Standards Development Practices as adopted by the HL7 Australia Board.

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