HL7 Balloting

Balloting is the formal process that HL7 uses to vet specifications prior to publication. Rules governing balloting are defined in both HL7’s Governance and Operations Manual and in the HL7 Essential Requirements. These, in turn, are governed by the expectations of the American National Standards Institute (ANSI) which accredits HL7 as a standards development organization and enforces rules around the openness and fairness of approval processes. The objective of balloting is to actively seek feedback on a proposed standard and to ensure that the community that will be governed by that standard is in agreement with the expectations set by the standard.

In the balloting process, a “frozen” version of a specification is subjected to review during a scheduled time window. Reviewers who have registered for the ballot can submit comments about the specification that raise issues and propose changes. They also cast an overall vote indicating whether they believe the specification should be published in its current form. The sponsoring Work Group(s) then review the comments provided and address them through a process called reconciliation. Based on the response of the Work Group(s), the balloter may choose to adjust their vote by “withdrawing” negative votes. The final determination of whether the specification can proceed to publication as a ‘standard’ is driven by the balance of affirmative votes received and varies depending on the type of ballot.

HL7 specifications can be balloted at one of four levels:

- **For Comment** ballots are used early in the development cycle to solicit feedback from the community. Such ballots never result in the authorization to publish a specification. They are intended to give guidance and direction to the Work Group developing the specification by soliciting review from the community outside the participants performing the development work. These ballots have the least onerous requirements in terms of response to feedback. There isn't really a notion of “pass” or “fail” for informative ballots.

- **Informative** ballots are used to vet content that is not intended to be binding on implementers. It is often used for specifications that guide internal HL7 processes or that give non-binding recommendations/guidance to the implementer community. Because the specification resulting from such a process is non-binding, requirements for consensus and limitations on substantive change between review and final publication are lower than other ballot types.

- **Standard for Trial Use (STU)** ballots are used to vet content that is eventually intended to be binding on implementers. It is used to vet content that is deemed “ready to implement” by the sponsoring work group, but where there has not yet been significant implementation experience. STU specifications are time-limited and give an opportunity for the community to exercise the specification in real-world implementation before the specification is “locked down” and forward and backward compatibility rules come into play. STU specifications are also non-binding and therefore requirements for consensus and limitations on substantive change between review and final publication are also lower.

- **Normative** ballots are used for final review of specifications that are intended to be binding on the implementer community and where there are strict rules around future changes to preserve a degree of forward and/or backward compatibility. The specifications that result from this process are considered authoritative. As such, the rules for consensus are highest and any issues raised during the review process receive the greatest degree of scrutiny by the community. There are strict limits on the types of changes that can be made between the ballot review process and eventual publication. It is common for specifications to undergo multiple cycles (where content is submitted for ballot, feedback is received and applied and the content is returned to ballot) before the community is satisfied and the specification can be published as an official standard. If consensus cannot be reached (i.e. agreement between some balloters and the authoring Work Group(s) cannot be achieved), a recirculation ballot is held.

Under ANSI rules, most Normative-balloted content is subject to periodic review to confirm that the specification is still relevant. This review takes the form of a Reafirmation ballot. Such ballots are subject to the same rules as a Normative ballot.

In addition,

- **Recirculation** ballots are a special process invoked at the conclusion of some Normative ballots. They are limited to the pool of voters who submitted votes as part of the original Normative ballot process. They highlight any issues where consensus could not be reached between the authoring Work Group(s) and some members of the ballot pool. They provide the balloters within the pool the chance to adjust their vote based on the outstanding negative comments. Essentially this means that those who voted affirmative have the opportunity to change their vote to negative if they agree with the negative balloters that the specification should not be published “as is.” It also provides those who did not vote or abstained an opportunity to change their vote to either affirmative or negative after reviewing the outstanding negative comments. At the conclusion of the recirculation period, all votes are “locked in” and a final determination is made about whether the ballot passes or not.

In some cases, when dealing with specifications that do not represent a standard or early in the development lifecycle, HL7 may opt to forgo the balloting process and instead use a process of formal Peer Review. As well, feedback can be provided on HL7 published specifications using HL7’s Specification Feedback process even if a ballot is not currently open.

Ballot Process

For a participant, the ballot process works as follows:

1. User signs up to participate in a specific ballot on a specific specification. There may be a cost associated with this if the user is not an HL7 member.
2. During the ballot period, the balloter reviews the specification and provides feedback as ballot comments and marks their comments as either "negative" (the publication should not proceed without change) or "affirmative" (the publication can proceed even if the change isn’t made). These comments get aggregated and determine the balloters **overall vote**:

<table>
<thead>
<tr>
<th>Vote</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>No vote</td>
<td>No vote has been recorded. This is the initial state for the ballot submission. If no action is taken by the voter, this will be the voter’s final submission status. A “no vote” means that the ballot submission won’t count towards quorum.</td>
</tr>
<tr>
<td>Ballot Type</td>
<td>Quorum Requirements</td>
</tr>
<tr>
<td>------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>For Comment</td>
<td>N/A</td>
</tr>
<tr>
<td>Informative</td>
<td>N/A</td>
</tr>
<tr>
<td>STU</td>
<td>N/A</td>
</tr>
<tr>
<td>Normative</td>
<td>50%+1</td>
</tr>
</tbody>
</table>

**Ballot Tooling**

Balloting in HL7 is managed through the use of two tools that work in concert:

- The HL7 Ballot Desktop manages ballot announcement and registration process and captures the formal record of ballot submissions and reconciliation for ANSI audit purposes. It also manages any recirculation ballots.
- The Jira Ballot Process manages the submission of comments, the assignment of ballot weights to comments and the management of the overall vote of each registered balloter.

Specific details on how to use the tools to perform balloting can be found by following the links.