

# HL7<sup>®</sup>

## International

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### **HL7<sup>®</sup> Essential Requirements: Due process requirements for HL7 American National Standards**

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# HL7 Essential Requirements

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# HL7 Essential Requirements

## Introduction

HL7 Essential Requirements (ER) identifies those processes, policies, and procedures designed such that HL7 complies with *ANSI Essential Requirements: Due process requirements for American National Standards* (ANSI ER) supporting continued accreditation as an ANSI-Accredited Standards Developer (ASD). HL7 ER maintenance shall be proactive with a focus on maintaining compliance with the current edition of ANSI ER.

With the adoption of additions or revisions to the HL7 ER, the HL7 Secretary shall cause them to be added to the manual with annotation in the table below reflecting the date adopted or revised. Additions and revisions shall be announced via the general membership list serve within ten working days of the date on which they were adopted or revised.

Periodically the HL7 Secretary, using his or her best judgment, may call for ratification of the HL7 ER in its entirety by the Executive Committee. Upon ratification of the HL7 ER in its entirety it shall be posted to the HL7 web site with a new adoption date and all internal notations of addition or revision removed.

The HL7 ER will be maintained and distributed electronically via the HL7 Web site. A hard copy of the HL7 ER is available upon request to those without electronic access. A processing fee, established by the HL7 Executive Committee, will be assessed to cover printing, postage, and handling.

## Notice of Current Edition

This edition of the HL7 ER, adopted by the Executive Committee in its entirety March 13, 2023, is the current edition, which supersedes and rescinds all previous editions of the HL7 ER.

## Additions and/or Revisions Subsequently Adopted

The following additions and/or revisions, having been approved by the HL7 Executive Committee subsequent to adoption of this edition of the HL7 ER, 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**

# HL7 Essential Requirements

## 01 Due Process

Due process means that any party (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. ANSI ER 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 ER.

### 01.01 Openness

Participation shall be open to all parties who are directly and materially interested in 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 in any organization, 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 the ANSI Executive Standards Council (ExSC), 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 American National Standards and candidate American National Standards.

### 01.05 Notification of Standards Development

Timely and adequate notice of standards development activity shall be announced in media suitable to demonstrate that a meaningful opportunity for participation, debate and deliberation by all directly and materially interested parties in a fair and equitable manner was provided.

### 01.06 Consideration of Views and Objections

Prompt consideration shall be given to the written views and objections of all participants, including those commenting on the PINS announcement or public comment listing in *Standards Action*.

### 01.07 Consensus Vote

Evidence of consensus in accordance with these requirements and the accredited procedures of the standards developer shall be documented.

### 01.08 Appeals

Written procedures of an ASD shall contain an identifiable, realistic, and readily available appeals mechanism for the impartial handling of procedural appeals regarding any action or inaction. Procedural appeals include 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 directly and materially interested party.

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## 01.10 Compliance with Normative ANS Policies and Administrative Procedures

Each ASD is required to comply with the normative policies and administrative procedures established by the ExSC.

## 02 Normative Ballot

A normative ballot is undertaken with the approval of the Technical Steering Committee (TSC). It is intended to process and validate those protocol specifications intended for submission to ANSI for consideration as American National Standards. The normative ballot process shall adhere to the tenets of *ANSI Essential Requirements: Due process requirements for American National Standards*. 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 American National Standard.

### 02.01 Electronic Format

Normative ballots shall be conducted electronically and provide for:

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

#### 02.01.01 Constructing Normative Ballot and Protocol Specification Names

The full document name shall begin with an organizational identifier followed by family name, product type and release number with a subfamily name, product type and release number, if applicable, then the product name and release number followed by the realm designation, if applicable, and the ballot type and number. In the case of a reaffirmation ballot the term “Reaffirmation of” shall precede the organization identifier.

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

STRUCTURE	Comments
[Reaffirmation of]	
{Organization Identifier}	
{	One or more of the 3 following line items required
[Family Name] [Product Type] [ <b><i>Release</i></b> [Release Number]]:	
[Sub-family Name] [Product Type] [ <b><i>Release</i></b> [Release Number]]:	
[Product Name] [ <b><i>Release</i></b> [Release Number]]	
}	
[Realm Designation]	See <a href="#">HL7 Realm</a>
The following elements are specific to ballot names and shall not appear in final document names.	
[Designation] [Ballot Type] <b><i>Ballot</i></b>	Designation shall be 1st, 2nd, etc.
<b><i>PI ID</i></b> {Project Insight ID number}	Ballot metadata; ID number shall have hyperlink to Project Insight

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## 02.01.01.01 Organizational Identifier

The Organizational Identifier shall be:

- ANSI/HL7 indicating an HL7 document that is an ANSI-accredited normative standard
- HL7 indicating an HL7 document other than an ANSI-accredited normative standard
- HL7/Other [such as NCPDP] indicating an HL7 document published in conjunction with another organization

## 02.01.01.02 Family and Subfamily Name

The standard family names are Version 2.x (V2.x); Version 3 (V3) [note: V3 itself does not have a release number, although each of its products typically will]; Clinical Document Architecture® (CDA®) [note: CDA shall be further designated as R1 or R2]; Electronic Health Records System-Functional Model (EHRS-FM); Fast Healthcare Interoperability Resources (FHIR® is the preferred designation); where a document includes reference to two or more family names it may be identified as a Cross Paradigm Specification. Subfamily names are specific to a given family and are not further defined in this document.

## 02.01.01.03 Product Type

Product types are defined as Specification or Standard; Domain Analysis Model (DAM); Service Functional Model (SFM); Functional Model (FM); Functional Profile (FP); Implementation Guide (IG); Logical Model [note: a Logical Model is not a Cross Paradigm Specification]; Profile, White Paper, and Guidance [for documents such as a Cookbook or Companion Guide]. The TSC may, at their discretion, declare additional product types.

## 02.01.01.04 Product Name

The Product Name is specified by the Work Group when they initiate a 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](#)).

## 02.01.01.05 Examples

[NOTE: Hyperlinks illustrated but not included]

HL7 Version 2.8.2 Messaging Standard, Release 1 (2nd Normative Ballot) PI ID [1133](#)

HL7 Version 3 Standard: Regulated Studies; CDISC Content to Message – Study Participation, Release 1 (2nd Normative Ballot) PI ID [205](#)

HL7 Version 3 Standard: Patient Administration; Patient Encounter, Release 1 (1st Normative Ballot) PI ID [1029](#)

HL7 CDA R2 Implementation Guide: Emergency Medical Services; Patient Care Report, Release 2 (1st Normative Ballot) PI ID [677](#)

HL7 Service Functional Model: Care Coordination Services (CCS), Release 1 (1st Normative Ballot) PI ID [924](#)

All the examples shown above reflect ballot names; the ballot designation and Project Insight ID would not appear in the document title used for publication.

## 02.01.01.06 Approving Normative Ballot and Protocol Specification Names

Normative ballot and protocol specification names shall be approved by the TSC. In the case of ballots during the Notice of Intent to Ballot ([NIB](#)) process. In the case of protocol specifications during the review and approval process for the [Publication Request Template](#).

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## 02.02 Ballot Content

### 02.02.01 Consideration of Recommended Actions

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

### 02.02.02 Proposed Normative Content

A Work Group may, with the concurrence of the TSC, 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 co-chairs with the concurrence of the TSC.

The Work Group co-chairs shall present the TSC with the following documentation:

- the publication date of the informative document;
- a log of any post publication comments and subsequent resolution, if such occurred; and
- the rationale for moving the contents to normative ballot.

Subsequent to the successful completion of a normative ballot, the Work Group co-chairs shall issue a statement through HL7 Headquarters withdrawing the Informative Document with reference to the corresponding normative HL7 Protocol Specification.

### 02.02.04 Moving a Standard for Trial Use (STU) 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 an STU appropriately formatted and named as a normative document may, with the concurrence of the TSC, be submitted to a normative ballot.

### 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 TSC, issue a normative ballot without first conducting a review ballot. Although the content may represent a new HL7 American National Standard (ANS), 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 ANS necessary to address the specific requirement.

### 02.02.06 Normative Ballot for Reaffirmation

An HL7 American National Standard, not having been updated in the four years after its publication or date of last revision shall, at the discretion of the Work Group, be submitted to a Normative ballot for reaffirmation at least two ballot cycles prior to the close of the fifth year. A Normative ballot for reaffirmation does not require a PINS form.

The ballot cover or title page shall clearly state that it is for reaffirmation. Ballot content shall include a reference to the published version of the ANS to be reaffirmed without any substantive change to the main text of the standard. Any non-substantive changes to the standard shall be explained or noted in a foreword.

### 02.02.07 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.” The objective of the submitting Work Group 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 reconciliation.



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## 02.02.08 Confirm Reconciliation of Previous Ballot of Same Content

A subsequent normative ballot of the same content 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 ballots of the same content. The required documentation includes:

- Reconciliation packages uploaded to the Ballot Desktop
- The Ballot Desktop reflecting that all negative voters have been sent notice of the dispositions of their negative votes
- The Ballot Desktop reflecting that all unresolved negative voters and submitters of unresolved negative public comments have been notified of the right to appeal (§02.13)
- The Ballot Desktop 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.
- The Ballot Desktop 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 Headquarters shall provide a list of items submitted for the current ballot cycle to the TSC.

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 TSC 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 Ballot Desktop.

## 02.03 Notice of Intent to Ballot

The notice of normative ballot shall be provided to the membership and the headquarters or secretariat of cooperating ANSI Accredited Standards Developers (ASD) via e-mail announcements. This notice shall be released at least thirty (30) 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 Ballot Desktop found in the Members Only section of the website. 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].

### 02.03.01 PINS Form

With the exception of Reaffirmation, a PINS form shall be submitted to ANSI upon notification from the TSC that a Project Scope Statement indicating the intent to ballot Normative as its next milestone has been approved.

#### 02.03.01.01 Requests for Additional Information or Opportunity to Discuss

Should HL7 receive a written request for additional information or for the opportunity to discuss the proposal from a directly and materially interested outside party or current consensus body member, during the 30-day PINS comment period, it shall respond in writing within 30 days of the comment deadline. The response shall include the individual's right to appeal (§02.13).

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### 02.03.01.02 Assertion of Duplication of or Conflict with an Existing or Announced ANS

Should HL7 receive written comments within 30 days of the publication date of a PINS announcement in *ANSI Standards Action* which assert that a proposed standard duplicates or conflicts with an existing ANS or a candidate ANS previously announced in *ANSI Standards Action* it shall comply with the process to address said assertions as defined in the current edition of *ANSI Essential Requirements: Due process requirements for American National Standards §2.5.1.2*.

### 02.04 Forming the Consensus Group

A normative ballot shall be open to all directly and materially interested parties; however, quorum shall be defined as a simple majority (50% + 1) of a consensus group comprised of more than 50% HL7 International members. There shall be no constraints on or requirements for participation of non-members other than the assessment of an administrative processing fee to be established by the Executive Committee, but in no case to exceed the individual membership fee.

#### 02.04.01 Interest Categories

The consensus group may be composed of the following interest categories; however, all interest categories may not be represented in any given consensus group:

**Vendors/Manufacturers** shall include those participating in the consensus group who represent an organization, typically a member of HL7, which produces or sells products or systems incorporating HL7 Standards.

**Healthcare Providers/Users** shall include those participating in the consensus group who represent an organization, typically a member of HL7, which purchases and uses products or systems incorporating HL7 Standards.

**Government Agencies/Universities** shall include those individuals participating in the consensus group who represent various government agencies and universities which may or may not be members of HL7.

**Payers/Third Party Administrators** shall include those participating in the consensus group who represent an organization, typically an HL7 member, which deals with managed care reimbursement, insurance, and fiscal management.

**Pharmaceuticals** shall include those participating in the consensus group who represent pharmaceutical companies, which are typically HL7 members.

**General Interest** shall include those participating in the consensus group whose business or other interests are not covered by another discretely defined category. This category may include members of Professional Societies and Trade Associations as well as any Consultant or Affiliate Member participating in the consensus group as an individual, for professional growth, or solely as a representative of their employer versus a client or constituency.

#### 02.04.02 Member Participation

The notice of normative ballot [§02.03] shall serve as the mechanism by which HL7 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 organizational and Affiliate members; the specific number allowed being defined by organizational membership level or the tenets of the Affiliate agreement respectively.

Given that an organizational or Affiliate 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 Affiliate member in any given consensus group each being recognized as an individual participant and reported as such in the summary of voting activity.

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The TSC shall be informed of any normative ballot where, not later than three (3) days prior to the closing of the enrollment period, the ballot pool includes fewer than ten (10) current individual members or 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 simple majority of those enrolled returning a ballot response where the consensus group is comprised of more than 50% HL7 International members.

### **02.04.03 Nonmember Participation**

A nonmember who is directly and materially interested 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 through the HL7 Desktop or by contacting HL7 Headquarters by telephone or email providing information supporting their status as nonmembers; as being directly and materially interested 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 Ballot Desktop. They shall be notified that participation in the ballot implies adherence to the tenets of the HL7 intellectual property policies. Nonmembers must adhere to all ballot instructions and respond by the ballot closing date.

HL7 shall assess an administrative fee for providing access to the ballot desktop for nonmembers. Said fee, to be determined by the Executive Committee, shall not exceed the fee associated with an individual membership in HL7. The fee, at the discretion of HL7 Headquarters, 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, but are not refundable.

### **02.04.04 Seeking Balance**

Not later than three (3) days prior to the closing of the enrollment period for a given specification, HL7 Headquarters shall review the consensus group to ascertain if a single interest category constitutes a majority. In addition to its Affiliate organizations, which represent an interest category, HL7 also recognizes the various classifications of Organizational Membership [GOM §03.04.01] as interest categories.

If a disparity is found, HL7 Headquarters 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.

### **02.04.05 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 Project Initiation Notification System (PINS) form submitted to ANSI, 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.

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## **02.04.06 Consensus Group Variance Process**

Any Affiliate or organizational member experiencing a change in voting representatives or any other situation which impacts current consensus groups shall request a variance of process from the Chief Standards Development Officer (CSDO) or, in his or her absence, the TSC Chair. A request for variance of process shall include a detailed explanation for such a request and clearly identify the individuals involved. The CSDO or, in his or her absence, the TSC Chair 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 the ANSI audit process.

## **02.05 Issuing the Ballot**

### **02.05.01 Authority**

The TSC 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 30 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 ANSI ASD**

Normative ballots shall be routinely provided to the headquarters or secretariat of cooperating ANSI ASD.

## **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).

### **02.06.01 Achieving the Necessary Ballot Response Level**

On or about seven (7) days prior to the close of a normative ballot, HL7 staff shall, at their convenience, issue a reminder email message to those individuals in the consensus group who have not yet submitted a ballot response. On or about three (3) days prior to the close of a normative ballot, at the convenience of HL7 staff, the Work Group co-chairs 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 members participating, the Work Group co-chairs having jurisdiction may choose to:

- execute a single extension of the normative ballot closing date for a period not to exceed two (2) weeks (fourteen (14) calendar days) with the objective of achieving the required majority response level and/or majority response of the participating HL7 members; or
- 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.

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In the event that a normative ballot is closed with a declaration of “for comment only,” HL7 staff shall inform the participants of that decision by email message stipulating the failure to achieve the required response levels. The Work Group co-chairs having jurisdiction shall consider revising the materials involved in the normative ballot based on any comments received but are not required to conduct ballot reconciliation. Said 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**

Submission to ANSI for consideration as an American National Standard is not contingent on the withdrawal of all negative ballots. The existence of unresolved negatives shall not preclude the submission 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 TSC, be moved forward by the Work Group having jurisdiction for publication and submission for consideration as an American National 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 consensus group shall report the issue to HL7 Headquarters. HL7 staff shall investigate the reported incident, assess its impact on the outcome of the ballot and prepare recommendations for correcting the situation. The Technical Steering Committee (TSC) 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 ballot process, Headquarters notifies ANSI of normative action to create a new or revise, reaffirm, or withdraw an existing American National Standard (ANS). This action causes publication of a notification of activity in ANSI *Standards Action* which initiates a public review period during which members of the general public, who are directly and materially interested 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 (WG) shall capture all ballot and public review comments using the HL7 Ballot Reconciliation Report unless the WG has petitioned for and been granted a waiver of such use by the Technical Steering Committee (TSC).

### **02.07.01 Affirmative Ballots or Public Review Comments**

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

### **02.07.02 Negative Ballot or Public Review Comments**

#### **02.07.02.01 Submission of Negative Ballot with Comments**

Comments accompanying negative ballot votes shall be submitted in writing and clearly reference the particular standards(s) to which it pertains.

#### **02.07.02.02 Submission of Negative Ballot without Comments**

A negative ballot not accompanied by comments shall not be considered. Such ballots will be recorded as a “negative without comment” for the purposes of establishing a quorum and reporting to ANSI. 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 vote returned without comment.

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## 02.07.02.03 Submission of Public Review Comments

Public review comments should be submitted in writing and clearly reference the particular standard(s) to which it pertains.

## 02.07.03 Retraction

The submitter may, of their own volition, retract an accompanying 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 statement shall be considered to have been submitted in error and shall not be retained as part of the ballot material.

## 02.08 Reconciliation

The responsible Work Group (WG) shall make every effort to complete all actions related to the disposition of comments received during the ballot or public review period, otherwise known as reconciliation, in a timely manner.

## 02.09 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-chairs 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.

## 02.10 Negative Ballot Comments and Public Review Comments Not Previously Considered

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

### 02.10.01 Motions for Handling Negative Ballot and Public Review Comments

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

#### 02.10.01.01 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 vote responses declared 'not related' shall be recorded and reported to ANSI as a "negative without comment" and shall not impede progress of the ballot. The submitter of a negative response declared 'not related' shall be advised of the disposition of their response and the reasons therefore in writing, which includes electronic communications. No further action is required.

Negative public review comments declared "not related" shall be recorded as such and the submitter notified in writing, which includes electronic communications. No further action is required.

Those items declared 'not related', whether from ballot or public review, may become recommended actions for the development of new or revision of existing HL7 ANS.

#### 02.10.01.01.01 Considered for Future Use

As a clarification of the decision of the responsible Work Group to declare a negative response Not Related, a disposition of Considered for Future Use may be applied to ensure the submitter is aware that the response, though deemed not relevant to current ballot material, may be considered a recommended action for the development of new or the revision of existing HL7 ANS.

For ANSI reporting purposes, this disposition of such a negative comment shall be synonymous with Not Related.

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## 02.10.01.02 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 and reported to ANSI as an unresolved negative.

## 02.10.01.03 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.

## 02.10.02 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.

## 02.10.03 Effect of Withdrawn Negative Ballot

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

## 02.10.04 Substantive Change

ANSI Essential Requirements defines substantive change as “one that directly and materially affects the use of the standard.” [Annex A: Definitions]

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 ANS 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.

## 02.11 Notification of Disposition of Negative Ballots and Public Comments

With the exception of those negative public reviews 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, and shall include the right to appeal (§02.13).

### 02.11.01 Individual Members

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

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## **02.11.02 Organizational or Affiliate Member's Voting Representatives**

If the attempt to notify an organization or Affiliate member's voting representative of the disposition of their negative comments via the Ballot Desktop is unsuccessful, the responsible WG co-chair shall notify HL7 Headquarters who shall forward such notification to the organization or Affiliate's Key Voting Representative.

The Key Voting Representative shall, if unable after a reasonable attempt to engage their respective voting representative, forward a copy of said voting representative's signed proxy statement, if available, to HL7 Headquarters. Upon submission of the voting representative's proxy statement, the named proxy shall respond to the disposition of negative comments. Proxy statements shall be retained with the ballot material for audit purposes.

## **02.12 Re-circulation of Unresolved Negative Comments**

In the case of a normative ballot reconciled by the Work Groups 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 report 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 Right to Appeal**

Any individual, whether participating in a ballot or via public review, who has been or will be adversely affected by any procedural action or inaction by HL7 with regard to the development and subsequent approval by normative ballot of a proposed American National Standard (ANS) or the revision and subsequent approval by normative ballot of an existing ANS, 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 (30) days of the purported infraction; inactions may be identified at any time but shall be appealed within thirty (30) days of the date the purported inaction is identified.

The HL7 Associate Executive Director or designee, with the assistance of the HL7 CSDO if appropriate, shall engage the appellant to discuss the issue with the intent of resolving the appeal informally. These discussions may include clarification of HL7 process or procedure as well as next steps for the ANS in question. The appellant shall have ten (10) business days to request a hearing of the appeal after being advised of the disposition of the appeal. If no hearing is requested, the appeal is considered closed.

Failing an informal resolution, the Associate Executive Director shall notify the appellant in writing, which includes electronic means, that their appeal is being processed. If the investigation shall take longer than sixty (60) days, the Associate Executive Director shall inform the appellant in writing of the reason for a delay and the expected date of response.

Upon the receipt of the investigator's report, the Executive Committee will provide a written decision to the appellant within 30 days.

The Associate Executive Director or their designated individual conducting the investigation shall prepare a report for the consideration of the Executive Committee, who shall adjudicate the appeal.



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All members of the Executive Committee involved in hearing the appeal shall be unbiased and shall not be directly and materially affected by the decision. Additionally, any member of the Executive Committee who was a member of the consensus group of the ANS cited in the appeal shall recuse themselves from hearing any appeal related to that ANS. The appellant shall be advised in writing of the disposition of the appeal.

The appeals process shall be concluded prior to the time that final submittal of evidence of consensus is made to ANSI in support of the approval of a standard as an American National Standard.

### 02.14 Post 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 Reconciliation Report must be posted to the Ballot Desktop.

### 02.15 Request for Publication

Upon approval and posting of the final reconciliation package, the responsible WG shall vote to submit a [Publication Request Template](#) to the TSC Project Manager. The results of the vote shall be recorded in the WG minutes with subsequent annotation in the appropriate section of the Publication Request <HL7 Work Group making this request and date/URL of approval minutes>.

Upon receipt of the Publication Request the TSC Project Manager shall include an item on the agenda of the next scheduled TSC meeting for the consideration of approval of release for publication.

### 02.16 Publishing Technical Corrections as Errata

A publication request for errata shall comply with TSC guidance on technical corrections and be accompanied by a cover letter drafted by the responsible Work Group. The cover letter shall cite the rationale supporting such a request and be submitted for the approval of the Chief Standards Development Officer (CSDO). Refer to the *CSDO errata cover letter template* for guidance.

### 02.17 Discontinuance of a Standards Project

Given approval by three quarters (75%) of those in session when the motion is addressed, a Work Group may petition the TSC 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 TSC shall have the final decision on a request to discontinue a standards project.

The TSC may consider the discontinuance of a project involving a proposed HL7 ANS or revision to an existing HL7 ANS or portion thereof (a standards project) if the initiating Work Group has been unable to either:

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

Upon a decision by the TSC to discontinue a standards project, HL7 Headquarters shall notify ANSI of the discontinuance of said project in a timely manner.

## 03 Submission of American National Standards

Having previously reported project initiation and upon approval by normative ballot, the TSC shall cause the subject protocol specifications to be submitted to ANSI as a candidate for acceptance and acknowledgment as an American National Standard in compliance with then applicable ANSI requirements. Subsequent public review comments received in response to announcements in the media shall be addressed in writing in a timely fashion and shall be subject to the ANSI procedures for handling such comments.

# HL7 Essential Requirements

## 03.01 Prerequisites for Submission

### 03.01.01 BSR-8 Form

A BSR-8 form may be submitted to ANSI at any time following the PINS submission and may be concurrent with the final normative ballot. Any subsequent substantive change would require the submission of an additional BSR-8 form.

### 03.01.02 Adherence to ANSI Patent Policy

HL7 shall adhere to the ANSI patent policy relevant to the submission of American National Standards as defined in the current edition of *ANSI Essential Requirements: Due process requirements for American National Standards*.

### 03.01.03 Adherence to ANSI Metric Policy

HL7 uses Unified Codes for Units and Measures (UCUM) which includes the International System of Units (SI); the ANSI preferred units of measure in American National Standards.

### 03.01.04 Adherence to ANSI Antitrust Policy

HL7 shall adhere to the ANSI antitrust policy relevant to the submission of American National Standards as defined in the current edition of *ANSI Essential Requirements: Due process requirements for American National Standards*.

### 03.01.05 Exclusion of Commercial Terms and Conditions

HL7 shall adhere to the restrictions on the use of Commercial Terms and Conditions stipulated in the current edition of *ANSI Essential Requirements: Due Process Requirements for American National Standards*.

### 03.01.06 Records Retention as Evidence of Compliance

Records related to new, revised, or reaffirmed American National Standards (ANS) maintained under periodic maintenance shall be retained for one standards-cycle or until the standard is revised as specified in §3.4 [Evidence of Compliance] of *ANSI Essential Requirements: Due process requirements for American National Standards*.

One standards-cycle is the period between updates to an ANS, not to exceed five years from publication or last update at which point said standard must be reaffirmed, updated, or withdrawn. Update or reaffirmation initiates a new standards-cycle.

Records related to new, revised, or reaffirmed American National Standards (ANS) maintained under continuous maintenance shall be retained for a minimum of five years or until the approval of the subsequent revision or reaffirmation of the complete standard as specified in §3.4 [Evidence of Compliance] of *ANSI Essential Requirements: Due process requirements for American National Standards*.

Records concerning withdrawn ANS shall be retained for at least five years from the date of withdrawal or a period consistent with the ANSI audit schedule.

## 03.02 Required Information

HL7 Headquarters shall be responsible for the timely submission of the required information to ANSI.

### 03.02.01 BSR-9 Form

The BSR-9 form shall be submitted to ANSI upon approval of the proposed HL7 ANS via normative ballot and the close of the public review comment period initiated by the BSR-8 form, but not more than one year following the close of said public comment period.

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### 03.03 Submission of HL7 American National Standards for ISO Approval

The submission of HL7 American National Standards (ANS) to ISO must be reviewed by the HL7 ISO liaison and approved by TSC. The recommended HL7 ANS, in ISO-acceptable format, and the appropriate ISO forms must be submitted electronically to HL7 Headquarters, which will forward them to the ISO liaison. The ISO liaison will either return the documentation to the submitter for additional action or forward it to the Secretary of the Board with a recommendation for action.

### 03.04 Maintenance of HL7 American National Standards (ANS)

HL7 American National Standards (ANS) shall be kept current and relevant by means of timely review and revision. Procedures shall be established which ensure a process in which requests for change are received and dealt with in a timely fashion.

If no revisions are issued for a period of four years from its publication as an ANS or date of last revision, the TSC shall notify the appropriate Work Group that on or before the beginning of the fifth year it must either

- initiate revision of the ANS at least two ballot cycles prior to the close of the fifth year or
- seek reaffirmation [§02.02.06] of the ANS at least two ballot cycles prior to the close of the fifth year or,
- with the concurrence of a majority of the Work Group voting in session, seek retirement of the HL7 ANS from ANSI and retirement of the HL7 Standard [§ 03.04.01].

Should the responsible Work Group take no action by two ballot cycles prior to the close of the fifth year, HL7 Headquarters (HQ), having notified the Work Group, shall initiate the Comment-only ballot soliciting feedback related to the withdrawal of the HL7 ANS and retirement of the HL7 Standard.

#### 03.04.01 Withdrawal and Retirement of an HL7 American National Standard (ANS)

Upon a decision by the responsible Work Group to withdraw an HL7 ANS with retirement of the HL7 Standard, whether of its own volition or as a result of the failure of a Normative Ballot for reaffirmation, a Comment-only Ballot to solicit feedback on the proposed withdrawal and retirement shall be conducted during the next scheduled ballot cycle ; preferably two ballot cycles prior to the close of the fifth year.

Should the responsible Work Group take no action by two ballot cycles prior to the close of the fifth year, HL7 Headquarters (HQ), having notified the Work Group, shall initiate the Comment-only ballot soliciting feedback related to the withdrawal of the HL7 ANS and retirement of the HL7 Standard.

Following completion of the Comment-only Ballot and consideration of any comments received, the Work Group shall submit a [Notice of Withdrawal of a Protocol Specification](#) form to the Technical Steering Committee. Any public comments received as a result of the notification of retirement posted in ANSI Standards Action shall be duly noted.

The withdrawn ANS shall be retained in the Standards Grid with a status of Retired. The Notice of Withdrawal form and any subsequent reconciliation of associated comments shall be retained at least through a subsequent ANSI audit, but no longer than seven (7) years.

### 03.05 Interpretation of HL7 American National Standards

The Chief Standards Development Officer (CSDO) or, in his or her absence, the TSC Chair shall be responsible for official interpretation of any existing or proposed HL7 American National Standard (ANS). Requests for interpretation of an existing or proposed HL7 ANS shall be submitted letter to HL7 Headquarters. 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 CSDO and TSC Chair who may refer the request to the appropriate Work Group for consideration. The CSDO or TSC Chair, in collaboration with the TSC, shall respond in writing to written requests for interpretation. These written interpretations shall be retained on file and made available electronically. When determined by the CSDO or TSC Chair to be of value to the membership, reference to a current interpretation may be included in the next TSC Update to the membership.

# HL7 Essential Requirements

## 03.06 Maintaining ANSI Membership

The Associate Executive Director shall ensure timely remittance of all dues necessary for maintenance of ANSI membership.

## 04 Maintenance of Essential Requirements

HL7 Essential Requirements (ER) shall be a dynamic document with proactive, iterative, and participatory maintenance designed to keep the document current with HL7 operational requirements in support of *ANSI Essential Requirements: Due process requirements for American National Standards*.

### 04.01 Membership Participation

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

- an open forum at each WGM to collect comments and recommendations for maintenance of the ER,
- the ability to [submit comments and recommendations](#) for maintenance of the ER interim to the WGM, and
- participation in the Revision Cycle peer review process

### 04.02 During the Working Group Meeting

To ensure that all members are aware of current ER 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 subscribers of the HL7 list server before or during each Working Group Meeting (WGM). A revision cycle (RC) shall commence concurrent with each WGM. A RC shall be designated by the two-digit calendar year and the typical month WGMs occur; i.e., YY01, YY05, YY09.

The Governance and Operations Committee (GOC) shall conduct an Open Forum during each WGM. GOC members will be available during the open forum to:

- Answer questions related to any revisions to the ER announced at that WGM
- Capture issues for revision proposals to be considered by the Executive Committee

### 04.03 Concurrent Processes Interim to Working Group Meetings

#### 04.03.01 Developing ER Revisions

The GOC shall prepare documentation with markup reflecting the revision proposals adopted by the EC. This documentation shall be submitted to a peer review process. Peer review will engage the membership via the general membership list serve and posting to the #announce stream in Zulip.

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 WGM. The GOC shall resolve any comments as received and finalize the revisions for consideration and adoption by the Executive Committee prior to the opening of the next WGM.

#### 04.03.02 Exceptional Revision Requests

Exceptional revision requests may result from ongoing process review or the comments received during the peer review of revision proposals for the current revision cycle. The GOC 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 weeks duration, the GOC may seek the approval of the Executive Committee to include the request in the current revision cycle. Otherwise, the request shall become a candidate for the next revision cycle.

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## **04.03.03 Developing the Revision List for the Next Cycle**

Following any given WGM, the GOC shall consolidate all comments and recommendations collected during the previous WGM or captured since the last revision cycle into a proposed revisions list for consideration for adoption by the Executive Committee (EC). Any proposed revision not adopted by the EC shall be deferred for consideration in the next revision cycle or, if so directed, removed from further consideration.

Correction of any typographical or other trivial errors; any items addressing ANSI audit report results; and any items resulting from changes to *ANSI Essential Requirements* shall be considered adopted proposed revisions and processed accordingly.

## **04.04 Executive Committee Action**

Following any given WGM, the GOC shall prepare a motion for the Executive Committee to consider those issues captured by the GOC in the current revision cycle for adoption as proposed revisions.

Upon completion of peer review, preferably at least two weeks prior to any given WGM, the GOC shall prepare a motion for the Executive Committee to consider adoption of the proposed revisions resulting from the current revision cycle. The Executive Committee proceedings shall include notice of those revisions subsequently adopted. Those revisions not adopted shall be returned to the GOC for additional work during the next revision cycle or, if so directed, not further considered.

## **04.05 Effective Date of Revision or Addition**

Revisions or additions to the ER shall be effective on the date stipulated upon adoption by the Executive Committee. An updated ER shall be posted to the HL7 Web site within ten working days of the closing date of each WGM.

## **04.06 Periodic Adoption in its Entirety**

The Secretary, with the concurrence of the Governance and Operations Committee (GOC), may periodically call for the Executive Committee (EC) to ratify the ER in its entirety.

Upon approval of the Secretary's motion to adopt the ER in its entirety:

- The ER shall, within ten working days, be posted to the HL7 web site with an adoption date reflecting the decision of the EC and with all notation of addition or revision removed
- 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 ER as adopted by the EC.

## **04.07 ANSI Review and Accreditation**

HL7 Headquarters shall establish a schedule for periodic review and accreditation of the ER by ANSI. In no case should a year elapse since the last revision without an ANSI review.