Consensus Report on Emerging Issues (CREI)

Objective:

The objective of a Consensus Report is to provide concise, prompt and practical guidance on narrowly focused topics of high importance to the health technology community. A Consensus Report is intended to respond to an urgent/immediate need for guidance in the following instances:

- While more robust data/information develops on emergent areas
- When variation in the development, implementation or use of a product or process exists
- When existing standards or other documents require additional context/clarification

A Consensus Report is based on the collective knowledge and experience of stakeholders within the healthcare technology community.

Process (13 to 16 weeks):

1. Process for proposal:
   a. An initial concept proposal (NWIP) is developed by an AAMI member or by AAMI staff and submitted to the AAMI SVP, Standards that includes the following:
      i. A well-defined, narrowly focused scope.
      ii. A rationale explaining why the development of a Consensus Report document is appropriate.
      iii. A description of how the topic aligns with AAMI’s Strategic Plan.
      iv. A list of stakeholders in support of or affected by the proposal, including the names/contact information for potential participants.
      v. An outline or rough draft.
      vi. A list or summary of any data/references/other documentation that supports, affects or potentially duplicates any part of the proposed work. This may include suggestion(s) as to where a future version of this work might permanently reside.

2. Process for approval of the proposal and formation of development and consensus bodies (<4 weeks):
   a. Review and approval by the AAMI SVP, Standards.
   b. AAMI Standards Board (SB) is informed and provided a predetermined period in which to raise concerns and/or objections to the development of the document.
   c. A Task Group (preferably 3-9pp) is selected by AAMI staff to develop the document.
   d. A Review Group of stakeholders that represents an appropriate balance of interests is selected by AAMI staff to serve as the consensus body. Note: An existing AAMI standards committee or working group may serve in this capacity.
3. Process for the development and review of the document (6 – 8 weeks):
   a. The Task Group meets (either in person or virtually) to complete and prepare the draft for circulation (within 2 weeks of first meeting).
      i. Document should be ≤10 pages in length (excluding tables/figures/references).
   b. Draft is circulated by AAMI staff to the Review Group for comment (commenting period shall be no more than 2-4 weeks in length).
   c. Adjudication of comments received is carried out by the Task Group virtually and draft finalized (within 2 weeks of receipt of comments).

4. Process for the approval and publication of the document (3-4 weeks):
   a. The proposed draft is sent back to Review Group for up/down approval.
      i. "Substantial agreement" is defined as minimum approval of at least two-thirds of those voting (excluding abstentions), with at least two-thirds of eligible voters returning ballots (including abstentions). However, the voting results of each interest category also may be considered and may override the results at staff’s discretion.
      ii. The Task Group is not required to resolve technical comments received from the Review Group at this stage and can defer such comments to the next iteration. If a technical change is made, a re-ballot of the Review Group is required. Relevant editorial comments can be accepted.
   b. The final draft is sent to the SB (simultaneous with the Review Group) with an opportunity to raise objections to approval. If objections are raised, the final decision on approval will be taken by consensus of the SB (≤2 weeks).
   c. Once approved, the final draft is sent to AAMI production for publication (1 - 2 weeks).

5. Process for post-publication follow-up:
   a. Every 12 – 24 months following publication, the document is reviewed by the Task Group and Review Group and reaffirmed\(^1\), revised, transitioned to a TIR/standard, incorporated into an existing document(s) or withdrawn.
   b. If revised or transitioned, the document can exist until it is superseded.
      i. A New Work Item Proposal (NWIP) is required for converting the document into a TIR or standard and the established AAMI process will be followed.
   c. If determination is made to withdraw the document, withdrawal is immediate
   d. AAMI Staff has the right to administratively withdraw the Consensus Report at any time.

\(^{1}\) Reaffirmation requires an action item; only requires a ballot if any objections are raised.