TO: Consensus Task Force

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RE: Consensus Task Force In-Person Meeting Materials

DA: November 9, 2012

BACKGROUND

The recent hospital-wide readmissions project raised questions about NQF's consensus process for making endorsement decisions. As a result, the Board approved a task force that would review and recommend enhancements for defining and achieving consensus within NQF's consensus development process (CDP). The Consensus Task Force (the "Task Force") is not constrained within the current consensus development process, but will explore the meaning of consensus and different approaches for achieving it.

COMPOSITION AND CHARGE

The NQF Board Executive Committee approved members of the Board of Directors, Consensus Standards Approval Committee (CSAC), and individuals from the NQF membership to serve on this Task Force.

Two non-voting, ex-officio members will also participate in the task force, including Ann Monroe as the CSAC chair, as well as a representative of a standard-setting organization.

The charge to the Consensus Task Force is to:

1) Review different approaches to establishing consensus;
2) Identify the strengths and weaknesses of the current process; and
3) Recommend enhancements to the current process.

The Task Force will seek input from NQF members regarding the current process through a variety of avenues including focus groups and public/member comment, including defining consensus and suggestions for improvement, as well as review approaches used by other standard-setting bodies in establishing consensus. The Task Force will meet in November and provide preliminary recommendations to the NQF Board at the November 29th in-person meeting followed by final recommendations in May 2013. A full timeline can be found in Appendix A.

HISTORY OF THE CONSENSUS DEVELOPMENT PROCESS

As a consensus-based organization, NQF has modeled the CDP to satisfy the requirements of OMB Circular A-119, which establishes policies regarding Federal use and development of voluntary consensus standards, consistent with the National Technology Transfer and Advancement Act of 1995. OMB Circular A-119 defines a consensus-based organization as having the following attributes:

- Openness

- Balance of interest
- Due process
- Appeals process
- Consensus

OMB Circular A-119 defines consensus as "general agreement, but not necessarily unanimity, and includes a process for attempting to resolve objections by interested parties, as long as all comments have been fairly considered, each objector is advised of the disposition of his or her objection(s) and the reasons why, and the consensus body members are given an opportunity to change their votes after reviewing the comments."[1]

NQF satisfies the required attributes of a voluntary consensus standards body through an eight-step process that applies to all NQF CDP projects:

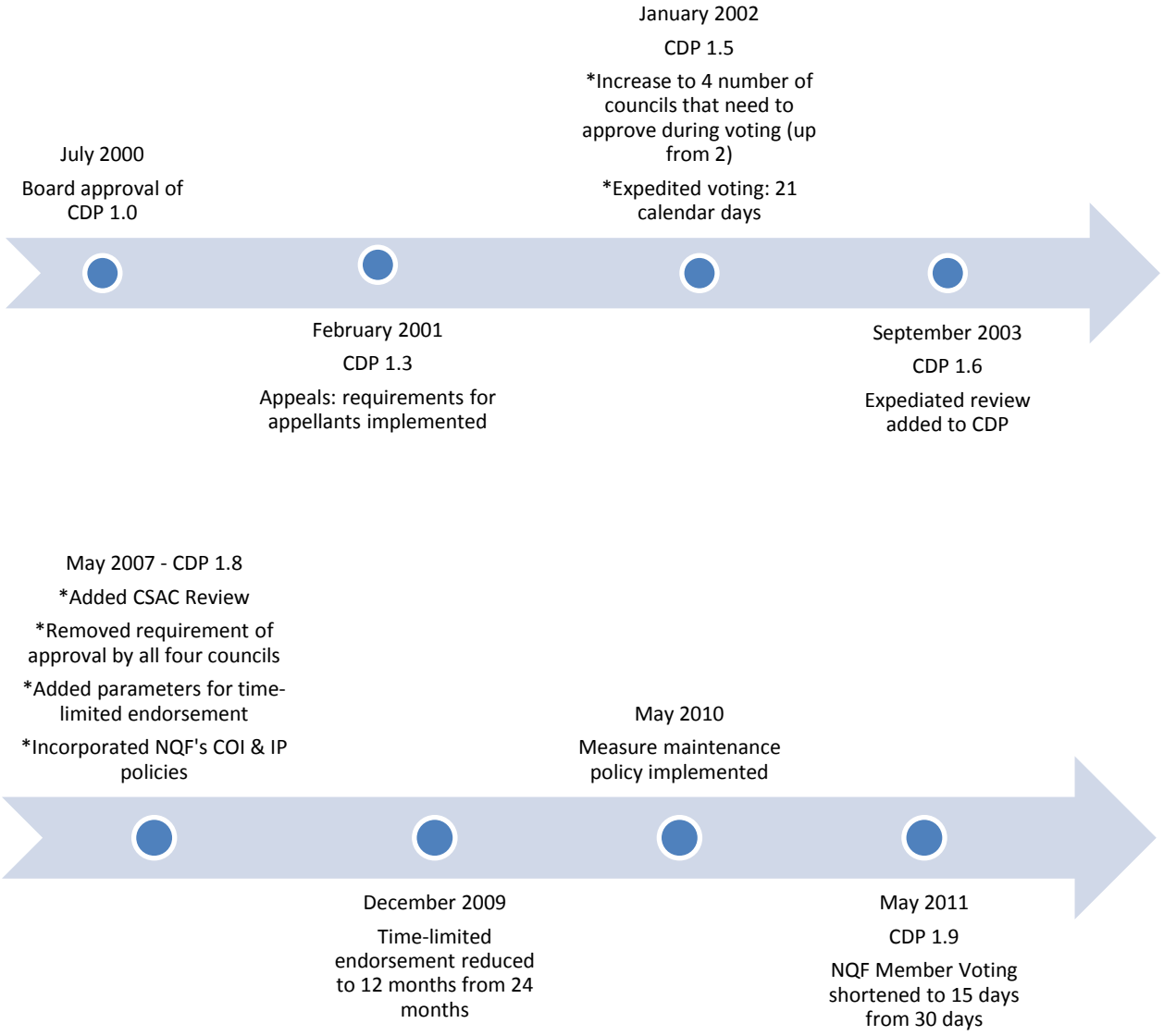
1. Call for Nominations
2. Call for Candidate Standards
3. Candidate Consensus Standard Review
4. Public and Member Comment
5. Member Voting
6. CSAC Decision
7. Board Ratification
8. Appeals

Since the first version of the CDP approved in July 2000, NQF has refined the CDP to address the needs of NQF members and more broadly the needs of the healthcare industry. These refinements include: different types of endorsement, such as time-limited endorsement; efforts to maintain a current NQF-endorsed measures portfolio; and increased efficiency of the CDP (i.e. reducing voting from 30-days to 15-days).

These changes were themselves part of a broader process of continuous improvement in the structure and governance of NQF to reflect what we learned as the organization grew and to respond to concerns and requests of NQF members and more broadly of NQF's multi-stakeholder constituencies – hospitals, physicians and other clinicians, consumers, purchasers, health plans, public health organizations and agencies, suppliers and health industry companies, and quality improvement organizations.

[1] OMB Circular A-119, § 4(a)(1)(v) (1998).

Material changes to the CDP



<u>Versions of the CDP:</u>

July 2000 – Board approval of CDP version 1.0

August 2000 – CDP version 1.1 approved, incorporating changes in response to comments received from member organizations (overall structure and approach did not change)

November 2000 – CDP version 1.2 approved with the following material changes:

- Language inserted into the introduction to clarify the purpose of the document and the kinds of NQF products[2] to which the formal process applies;

[2] The term "NQF Products" appears to be a term of art used in prior versions of the CDP. We believe that NQF products in this context refers to endorsed measures, frameworks, and preferred practices.

- Language inserted regarding priority-setting for project topic areas and NQF members' role in this activity;
- Emphasis on NQF member role/privileges in this process; and
- Language clarifying the circumstances under which a draft product would be forwarded to the Board to consider even if majority agreement had not been obtained by all four councils (requirement of a majority of voting members on each of at least two councils the first round of voting introduced).

February 2001 – CDP version 1.3 approved with more specificity regarding appeals:

- Requirement that the appellant must demonstrate that interests are directly and materially affected and that the decision has or will have an adverse effect on those interests.

November 2001 – CDP version 1.4 approved with the following material changes:

- Language inserted under IV. Product Review clarifying the role of individual member organizations vs. member councils in the review process, specifying how member and member council comments during this phase should be submitted and handled, and how information about their disposition should be presented;
- Inserted text in the same section specifying that public comments (or a summary of comments) will be made available to the membership before the formal voting process begins;
- Inserted text in the same section clarifying pre-voting review, voting, and a second round of voting if necessary;
- Inserted language under V. Product Endorsement, specifying major elements of the voting process, including mailing and confirmation of ballots; reminders; handling of non-responders; and clarifying the specific elements for which formal consensus vote is being solicited and specifying how comments submitted during vote should be submitted and disseminated; and
- Changed the designation of the committees overseeing minor projects from "Executive Committee" to Review Committee and change the designation of Strategic Framework Board to Strategic Advisory Council.

January 2002 – CDP version 1.5 approved with the following material changes:

- Language added to allow expedited voting of 21 calendar days;
- Language added to clarify how abstentions would be not be counted in votes; and
- Revised the requirement of the number of councils needed to approve in the first round of voting from at least two councils to all four councils.

September 2003 – CDP version 1.6 approved with the following materials changes:

- The opening "Purpose" and "Background and Context" were significantly revised;
- Addition of a new section detailing "Expedited Consideration" (now referred to as the expedited review); and
- Addition of a new section on "Evaluation" outlining monitoring for implementation issues.

August 2004 – CDP version 1.7 approved; no material changes made to the document

May 2007 – CDP version 1.8 approved with the following material changes:

- Clarified NQF's core activities to include priority setting and conducting educational and award activities;
- Removed any requirement for a majority of members from all four councils approve a standard in order to move forward to the Board for ratification;
- Increased the number of councils from four to eight;
- Added the Consensus Standards Approval Committee (CSAC) and described its role in endorsing consensus standards and in making recommendations for measure maintenance;
- Referenced and incorporated NQF's Conflict of Interest Guidelines and Intellectual Property Policy;
- Described the parameters for time-limited endorsement for measures not fully field tested; and
- Clarified the measure steward's role in measure development.

Changes made to the CDP between 1.8 and 1.9 that did not receive a new version number:

- December 2009 – Time-limited endorsement addendum: the time period for the temporary endorsement of untested measures was shortened to 12 months (from 24 months).
- May 2010 – Measure maintenance policy implemented: each measure scheduled to undergo re-review every three years, to assure measure still meets criteria.
- September 2010 – Expedited review criteria revised

May 2011 – CDP version 1.9

- NQF Member Voting period shortened to 15 days from 30 days

Over the life of the CDP, the most significant refinements to the process have focused on being responsive to an increased desire for member involvement and input into the process. For example, the number of councils required to approve a consensus standard evolved from a majority of members from two of the four councils to all four councils and finally to no minimum threshold or simple majority required from the councils.

In addition, when requirements for a simple majority from two or more of the councils existed, it often resulted in Board consideration of the potential need for NQF staff work to identify how consensus could be reached and may have led to a second round of voting. Examples of where a second round of voting or additional consideration or analyses was considered was sent previously (CDP Second Round Voting from 2002 to Present.pdf).

In the last five years, the most notable changes have occurred including a restructuring of the NQF membership and governance in 2007 as well as the addition of endorsement maintenance, time-limited endorsement, and reduction of the member voting period.

Specifically, NQF's 2007 restructuring eliminated a consensus threshold requiring that all four councils approve a measure prior to a final endorsement decision by the Board. The 2007 restructuring also created the CSAC, a multi-stakeholder standing committee with specialized expertise to oversee the endorsement process and to make recommendations to the NQF Board, which serves as the final decision-making body for endorsement decisions. In addition to its role in review and approval of proposed consensus standards, the CSAC is charged with serving in an advisory capacity to the Board of Directors and NQF management on ongoing enhancements to the consensus development process and

emerging issues in performance measurement. Since 2007, all candidate consensus standards move forward to the CSAC after one round of traditional member voting, along with information on the concerns raised by the Members and the Steering Committee. NQF member voting results are summarized for each of the eight councils for consideration by the CSAC in making endorsement decisions. The CSAC has the option of calling for a second round of voting if it is unclear whether member concerns have been adequately addressed.

As noted above, consensus is defined as "general agreement, but not necessarily unanimity." Member engagement in the voting process has always been challenging, but it has decreased somewhat in recent years. Many factors have likely contributed to this decrease, including: an increase in the volume and technical/clinical complexity of measures; competing demands on members; whether a given topic is relevant and of interest to the member organization; and possibly a perception that member voting is less important since the elimination of the threshold requiring that all of the councils support a measure to move it forward. NQF has also expanded its mission and focus over the years and organizations join NQF for different reasons (e.g., NPP, MAP, and HIT).

NQF staff have conducted an analysis of the number of reports/projects, participation by both the membership and the public in the commenting process across all projects since NQF's inception as well as the voting participation from the membership (sent previously: NQF Participation Trend 2002 – 2012 Final.xls). The number of projects for the first five years of NQF's work specific to endorsement of consensus standards averaged approximately 5 projects a year and in the last few years this average has doubled to 11-12 projects. In this last year alone, the membership has been asked to comment and vote on at least 19 reports – a significant increase. Commenting continues to be an integral input in the consensus development process as the number of organizations that have provided comments ranges from three to 200 with an average of roughly 30 organizations commenting per project. Voting participation rates have dropped throughout the 11 years of data analyzed with the percent of membership participation averaging approximately 40% on each project in the first five years and approximately 5% in 2012. While some of this may be attributed to the increase in membership (141 members in 2002 and 419 in 2012) and the volume of reports and projects, the number of members who voted from 2002 to 2007 dropped by roughly 15% and subsequently 10% from 2007 to 2010.

Input from Standard Setting Organizations

NQF staff collected information from other consensus-based standard setting organizations. NQF is exploring processes used by other organizations, particularly American National Standards Institute (ANSI) as most of the standard setting bodies in the United States are ANSI-accredited. As of October 2012, there are 228 ANSI-accredited standards organizations[i], all of which meet the guidelines for achieving consensus outlined in a document sent previously (NQF Consensus v ANSI Consensus.pdf). The majority of the ANSI-accredited organizations reviewed by NQF staff had flexible timelines for approving a standard, allowing for increased time for public input and a more iterative process for modifying standards than NQF's current process.

Other notable process points that vary from the NQF process include:

- Consensus is defined as "substantial agreement has been reached by directly and materially affected interests. This signifies the concurrence of more than a simple majority, but not

necessarily unanimity. Consensus requires that all views and objections be considered, **and that an effort be made toward their resolution."** [ii] NQF currently requires a simple majority.

- Voting must meet numerical requirements for consensus as described in a standard developer's accredited procedures. An example of the criteria for consensus includes a requirement that a majority of the consensus body cast a vote (counting abstentions) and at least two-thirds of those voting approve (not counting abstentions). [iii] NQF currently has no requirements on what percentage of votes from eligible members are required, and requires that a simple majority of those voting approve (abstentions are omitted from the voting percentage calculation entirely).
- ANSI guidance places an emphasis on staff training, maintaining a basic training guide for new staff and for volunteers on committees.
- ANSI has several checks and balances in place, including:
    - An audit program to ensure procedures are consistent and a checklist which is submitted to demonstrate that process has been followed;
    - An annual review cycle to ensure compliance with processes and to provide any updates to the processes; and
    - Recommendations for efficient standards are provided to all standards organizations, emphasizing consistency in process and in implementation of process.[iv]

Focus Groups

NQF contracted with an external consultant to conduct focus groups with members to better understand the factors that facilitate or impede member participation in the CDP including commenting and voting. The week of October 29th, four in-person focus groups and one virtual session were conducted in Washington, DC and Chicago. The focus groups included those organizations that typically participate in the CDP as well as those organizations that do not regularly participate in voting or other CDP activities such as commenting or nominating for Steering Committees.

Two in-person focus group sessions were held in Washington, DC, and targeted the Provider, Purchaser, and Consumer councils. The other two in-person focus group sessions were held in Chicago, IL, and targeted the Quality Measurement, Research and Improvement and Health Professional councils. The virtual session included the Health Plan, Public and Community Health Agencies, and the Supplier and Industry councils. The organizations that participated in the focus groups and discussion guide appear in Appendix XX.

The results of the focus groups are currently being compiled and themes and recommendations will be presented at the in-person meeting.

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[i] http://publicaa.ansi.org/sites/apdl/Documents/Standards%20Activities/American%20National%20Standards/ANSI%20Accredited%20Standards%20Developers/OCT12ASD_basic.pdf

[ii] http://publicaa.ansi.org/sites/apdl/Documents/Standards%20Activities/American%20National%20Standards/Procedures,%20Guides,%20and%20Forms/2012%20ANSI%20Essential%20Requirements%20and%20other%20Updated%20Procedures/2012_ANSI_Essential_Requirements.pdf

[iii] *IBID*

[iv] http://publicaa.ansi.org/sites/apdl/Documents/Standards%20Activities/American%20National%20Standards/Proc

edures,%20Guides,%20and%20Forms/Recommendations%20for%20Efficient%20Standards%20Development%20FINAL.pdf

Appendix A: Consensus Task Force Timeline

Activity	Timeline
Conduct Focus Group Sessions	October 29-November 2, 2012
Task Force In-Person Meeting	November 13, 2012
Preliminary Board Review of Recommendations	November 29, 2012
Follow Up to In-Person Meeting	December 2012
45 day Public Comment on Draft Recommendations	*January 15, 2013 through February 2013
Task Force Review of Comments and Finalization of Recommendations	*March 2013
CSAC Review of Final Recommendations	*April 2013
Board Review of Final Recommendations	*May 2013

Balance of interest

- 1 organization, 1 vote during the member voting process; everyone should have an equal voice at the table; concern that 1 or 2 orgs may have undue influence
- Key is having composition on SC be balanced
- Need to consider the council vote AND the popular vote
- It isn't clear to members if the CDP adequately balances the input of stakeholders
- Request for increased transparency
- End use of the measure is important in determining the balance of interest

Balance of interest

- Patient-centered approach – where is the patient in our balance of interest?
- Objections need to be couched in evidence or criteria

Order/weight

- Credibility of clinical expertise is essential; importance of the SC in the process
- including understanding of end user early in the process; feedback loops
- Need for technical experts for testing, etc.
- SC has the most power in the process
- What is the role of the council vs. individual stakeholder? Does a council vote as a whole? Does it facilitate the vote? Council should probably step back from voting?
- By rolling the votes into 1 council, assume speak as one voice…

Order/weight

- Does commenting happen early enough to have an impact?
- Disconnect between the membership and the CSAC
- Opportunity to vote while commenting

Composition of SC

- Unclear who gets on a committee and how they are seated
- What are conflicts of interest
- Issue occasionally where SC is not best equipped to deal with a measure in a project
- To have real balance of interest, felt the needs to really ensure that everyone has their own way but that it is open dialogue of differing opinions
  - Minority report
  - Ok with outcome if feel that they are heard, fairness of process, clarify and transparency of process
  - True opportunity toward consensus building

Composition of SC

- equipped to deal with a measure in a project
- Given concerns around politics around SC seating and deliberations, perhaps should not have as much power in the process
- What role can membership play in the process
- Checks and balances for the SC
- SC selection is extremely important
- Need a requirement of SC participation

Composition of SC

- Limited consumer/purchaser members
- Often only one representative for a clinical area or specialty – can sway the committee based on one opinion

End user

- Do you prioritize those who will be paid vs. the consumer/purchaser?
  - Scientific acceptability of the measures is paramount; however, different stakeholders have varying thresholds of what uncertainty is acceptable. How good is good enough?
- Need to take time to think of the unintended consequences

CSAC and Board

- Collective understanding of moving forward
- Want transparency of term limits for CSAC and Board
- CSAC and Board should not have a stakeholder view; it should be an interest in policy being followed
- Also question whether same old people all the time does not encourage balance of interest
- More engagement during the development of the measure?
- Iterative process for measure developers?
- CSAC is simple majority of consumer and purchaser – should their input occur early in the process

Priorities under balance of interest

- CSAC has too much power too late in the process; if want consumer/purchaser input, early in process
- Use other input rather than CSAC; go broader leverage CVEs, etc.; blow up the building
- Need commitment to use measures after endorsement; happen up front
- Need to keep in mind all of the interests in the stakeholders and end users; CMS is not the only group using measures

Priorities under balance of interest

- Value proposition of being an NQF member
  - Asked to work but vote doesn't count
- Need for SC to be transparently selected, consistently engaged
- Enhancing member engagement
- Increasing weight of member vote without marginalizing the smaller councils
  - Cannot have one group driving the bus

Priorities under balance of interest

- Need new faces in NQF leadership
- CSAC and BOD are duplicative – who takes ownership of the process?
  - CSAC has disproportionate influence and seems to be more political
  - BOD should be accountable for the endorsed measures
  - If consensus is working well, the role of the CSAC should be as a rubber stamp.
- Is it still appropriate to have a majority consumer/purchaser influence on the CSAC and Board?

Member Engagement

- Need to reach out to members and identify by interest groups if not participating in the process – ensure input from those of interest
  - Majority or near unanimity of those being measures including consumers, those who have to report
  - Draw stakeholder attention to projects that should be of particular interest to them.
- Currently vote doesn't count – should be a membership consensus
- Not enough time to vote
- Need a quorum of each council in order to participate

Consensus

- Real consensus process – ability to understand, come together and share perspectives both in the council and across councils
- Consensus does not mean simple majority
- Overwhelming response that 51% is not consensus
  - General agreement that somewhere between 66 and 75% is their starting point for consensus (only at committee level?)
  - Membership agreement/vote would be ideal; allow them to vote couched in the criteria
- Consensus of the steering committee should be higher than other steps in the process
- Process for mediation to allow give and take and presenting of different perspectives
  - Need a forum for hashing out the issues

Consensus

- Current process alienates stakeholder groups – feel like you cannot win; feels political
- Currently no hard stop on what is adequate input/participation – consensus threshold theme
- Groups need to be led by facilitator; cannot have one member dominating and swaying; work needs to be around gaining understanding, investigating divergent opinions, and reaching consensus
- Not a loudest voice gets their way – this is the current perception

Consensus

- Perception that the process is inconsistently applied; feels unjust; feels like there are favorites; many questions around how do you get on the committee, CSAC, and Board; inside track that gets you in the running. Do not trust that it is fair and balanced.
- Our ability to define and consistently and transparently follow our process will ultimately be how our members and the public determine the value of endorsement and whether consensus was really achieved. Must say what we are going to do and do what we say under all circumstances.

Consensus

- CSAC is the only vote that seems to count; really CSAC should be there to assess whether it was a fair process
- CSAC has differing weight of representations than the committees; giving the feeling to those involved early in the process that they could be blindsided later in the process
  - Defined criteria on when they can re-hash measure vs. oversee process
- CSAC representation is not believed to adequately/fairly represent the membership

Consensus

- Balance of NQF of being an neutral convener
- SC concern when groups are appointed vs. nominated
  - Clarify on who and how selected
  - 50% +1 is not general agreement
  - Physician representation is heavily weighted
- Concern that appeals are only for those endorsed
  - Process for requesting additional consideration when not recommended not clear

Foundational

- Consistency of application of criteria by the committees
- Getting the right members; Balanced committee
  - Concern that members are acting on behalf of their stakeholder/organization rather than individual
- Early on define what is the end use/who is impacted
- Different defined needs based on purpose/science
- Identify key stakeholders needed to participate in the process and if not received, then need to stop the process
- Member requirements for a certain level of voting for topics specific to their areas of expertise/interest
- Designations – voting vs. non-voting members

Foundational

- Standard criteria of what a good measure looks like
- How do we learn based on past experiences to become more useful in the future
- Identify how the measures endorsed fill gaps/fill out the portfolio of measures

Foundational

- The use of the measure:
  - Appropriateness of the measure across the different accountability purposes
    - Endorsement for different uses
    - Perhaps more categories are needed
- Two different kinds of consensus:
  - technical/scientific vs. usability

Transparency/consistency

- Consistent evaluation of the measures within and across projects
  - Doing so will allow for easier acceptance of consensus if transparent
  - Hashing out – making sure the right people are at the table
- 60-90 day notice on upcoming votes
- Clear communications on key milestones and criteria of the milestone
- Noted in previous discussions that it might help to pick a day of the week for when comment/vote released

Transparency

- Perception is that comments go into a black hole and that certain member voices have no weight
- Comments do not matter (health professional and providers)
- Need for transparency of process, reports, SC member selection, SC discussion, SC recommendations
- Unclear whether measures are recommended or not based on favorites, who the developer is vs. criteria

Ease of communication

- Ease of accessing information
- Translation of the information into a language that all stakeholders understand
- Simpler ways to indicate issues/concerns with measures – provide more detailed sorting or categorization of the measures by criteria
- Need defined criteria around pre-work prior to steering committee on what is provided to public/membership

Ease of communication

- High-level overview of the measures in the project and issues addressed
- Can the web site have an actionable column focused on CDP activities
- Clarify of reports – committee recommendations and this is why
  - Need to capture the story and description of the committee's deliberations
- Be able to know/track when a specific measure is in the process and to know what measure are within which topic area

Ease of communication

- Website difficult to find things; difficult to engage; impacts level of involvement

Voting

- Bicameral House and Senate model – balance between CSAC (senate) and member voting (house); broad membership vs. the councils
- Difficult to determine if consensus reached with low voting participation
  - What does one vote in a council indicate?
- 50% +1 is not acceptable

Other models

- What needs to come through NQF?
  - Accreditation of other developers/models
- How do you create a larger or multiple pipelines to increase capacity?
  - Ensure NQF maintains key role of harmonization

Priorities under achieving consensus

- Transparency
- SC credibility and composition (selection and consistency)
- Consensus in 2 ways, 1. scientific acceptability and 2. importance, usability, feasibility
- Timeline for the year so orgs can prioritize/plan and ultimately vote
- Member engagement – outreach, education
- Clear and consistent pathways of what happens and when consensus is or is not reached – no one-offs
- One vote per council is not representative

Consensus Task Force
Focus Group Survey Questions

Balance of Interest

1. Do you feel the consensus development process (CDP) currently balances the interest of the different stakeholders?

   Yes No

   Please explain:

2. Do you feel CDP currently balances your interest?

   Yes No

   Please explain:

3. Do you believe that NQF appropriately considers input from all stakeholders?

   Yes No

   Please explain:

4. Do you have ideas or suggestions on how the process could be changed to better include the interests of different stakeholders?

5. Is calculating votes by each council the best way to balance the interests of multiple stakeholders?

   Yes No

6. Are there other ways to represent votes that should be considered?

7. How should abstentions be counted (currently they are not included in the calculations)?

8. What else would you like to tell us related to balance of interest?

Consensus

1. What do you feel are the essential elements/steps in the CDP to achieve consensus?

2. At what agreement threshold do you consider consensus achieved?
   i. 50%
   ii. 51%
   iii. 75%
   iv. ___

3. What should happen when the consensus threshold is not met?

4. Do you feel that there are step(s) in the CDP that have an inappropriately large representation or influence on the process?

   Yes No

   If yes, what step(s) and why is it of concern to you?

5. Do you feel that there is enough transparency into CSAC and BOD deliberations and that decisions are transparent?

   Yes No

   If no, why?

6. My vote matters?

   Yes No

   If no, why?

7. I feel that commenting has the most impact when the committee considers it:

   ___ Before making endorsement recommendation

   ___ After making preliminary endorsement recommendation (current process)

   ___Other_____

8. Did you used to vote and stop voting?

   Yes No

   If yes, why?

9. What else would like to tell us related to consensus?

General questions

1. I participate in voting.

   Yes No

   Why?

2. I participate in commenting.

   Yes No

   Why?

3. I feel like the current projects include the right number of measures for me to review and make an informed comment/vote?

   _____Too few measures are included for review
   _____Too many measures are provided
   _____I am able to review current projects with the current number of measures included
   _____Other:

4. How many projects are too many to vote on at one time?

   _____1 project a month
   _____2-3 projects a month
   _____4-5 projects a month
   _____Other:

5. Is the voting process easy for you to use?

   Yes No

   If no, why?

6. Are project reports presented in a way that is easy to understand?

____Too much detail provided
____Too little detail provided
____Information provided is on target and useful
____Information provided is not useful at all
____The report format is clear and useful
____The report format is not clear and useful

Please explain.

7. How do you decide what project to comment or vote on?

_____

_____

_____

Focus group experience

1. I was able to share my thoughts and ideas regarding the Consensus Development process.

1	2	3	4	5
Strongly Disagree	Disagree	Neither agree or disagree	Agree	Strongly Agree

2. The facilitator ensured everyone had a chance to participate in discussion of the focus group topics.

1	2	3	4	5
Strongly Disagree	Disagree	Neither agree or disagree	Agree	Strongly Agree

3. I would be willing to participate in another NQF focus group in the future.

   Yes No

   Please explain:

4. Any additional comments

_____

_____

_____

CDP projects where measures were released for a second round of voting

Project	CDP version	Reason	Outcome
2002			
Safe Practices	1.5	In response to comments received during the Member and public comment period, the practices have been revised. At least one council had not supported these 4 Safe Practices.	All 4 Safe Practices were approved by the 4 councils and subsequently endorsed.
2003			
Hospital Care, Group 2	1.5	Five Group 2 measures were not approved by all Councils on the first round of voting. Given that previous comments generally reflected fundamental disagreements with the measures, rather than specific reconcilable differences, the four Member Council Chairs and NQF staff agreed that another review period would not be useful, since no apparent changes could be made to the measure specifications themselves that would address Member concerns. Instead, an all-Council conference call was held on February 28, 2003, to allow Members of all four Councils to interact, discuss the pros and cons of the measures, and attempt to reach greater agreement around the collective NQF Membership's position.	All 5 measures were not recommended for endorsement (2 councils approved three of the measures, no councils supported the other two measures).
Nursing Homes	1.5	In the first round of voting, the chronic care measure "residents who lost too much weight" was not approved by the Provider and Health Plan Council. During review and voting, a number of NQF Members identified the lack of "obvious" exclusions (e.g., hospice patients and patients on weight loss programs) as the reason for not supporting the draft consensus standard. NQF staff worked with the measure developer, researchers, and the project Steering Committee to consider possible revisions to the measure, which resulted in a hospice exclusion, only. All four Member Councils approved the staffing measure in the first round of voting. In response to concerns raised by the Centers for Medicare and Medicaid Services, however, the NQF Board did not	All 4 councils approved weight loss measure and the staffing measure was endorsed.

Project	CDP version	Reason	Outcome
		approve the measure. Rather, given the Board's view on the importance of staffing, it asked the Steering Committee to reconsider the staffing measure and any additional approaches that might be appropriate. The Steering Committee did not reach consensus on a recommendation to the Board regarding the staffing measure; it split evenly on whether it should recommend the specifications approved by the four Member Councils versus continuing to recommend against it. Given no change was recommended to the specifications already approved by all Councils, reconsideration of the proposed voluntary consensus standard for staffing was considered directly by the Board. Note: the spreadsheet of results includes 2 sets of voting results as CMS requested deferral of the Board final action to allow them to provide additional analyses; not related to voting results.	
2004			
Nursing Sensitive	1.6	Some Board members raised concerns about two proposed consensus standards that had been approved by all four Councils (i.e., pneumonia prevalence, urinary tract infection (UTI) prevalence) and requested further consideration of these, along with two that were not approved by all four Councils. For the four proposed consensus standards, an all-Council conference call was held to allow Members of all four Councils to interact, discuss the pros and cons of the measures, ask specific questions of the measure developers, and attempt to reach greater agreement around the collective NQF Membership's position.	Two measures were endorsed (UTI Prevalence and Pneumonia Prevalence) and two were not (Restraint Prevalence and Nurses' Educational Preparation).
2005			
Hospital Care, Round 1, Recommendation	1.7	The Board agreed to submit the two care coordination measures and the recommendation regarding risk adjustment modeling to Members for a second ballot after NQF staff attempted to resolve	Recommendation was approved with revised language.

Project	CDP version	Reason	Outcome
		competing views about these items. For the care coordination measures in particular, staff were directed to consult with the measure developer regarding additional specifications for the measure and, based on the timing, include it immediately or do so when the revised specifications were available. The developer of the care coordination measures advised that the additional specifications were being refined and tested, but were not available for immediate (in time for December 2005 Board meeting) reconsideration. Thus, only a revised hierarchical modeling recommendation was forwarded to Members for the second round of voting.	
Diabetes Care 2005 update	1.7	In response to Board and Member support for additional measures, the 37 proposed measures designated for internal quality improvement and community-level reporting only, and a revised recommendation reflecting the various purposes of these measures, were forwarded for a first round of NQF Member voting on June 2005. Only three Member Councils approved all items, with the Consumer Council voting to approve all the measures and the revised recommendation contingent upon the work of the NQF Ad Hoc Advisory Committee on Performance Measure Criteria.	All were approved assuming no redundancies across this project and Ambulatory Care following the ad hoc committee's input.
Home health	1.7	The seven proposed ACOVE-derived consensus standards passed two of the four NQF Member Councils. Many Members raised concerns about the small size of the home health population used in the testing of the measures, questioning their evidence, reliability, and validity for the home health population; some Board members expressed similar concerns. At its meeting on February 7, 2005, the NQF Board decided against a second round of voting for the proposed ACOVE measures, but, importantly, it did not reject the ACOVE measures per se based on the voting results, comments received, and Board discussion. Instead, given the important areas these measures encompass, the Board requested that we contact you to inquire about the potential for RAND to undertake further	Second round of voting did not occur.

Project	CDP version	Reason	Outcome
		testing of the ACOVE measures with a larger home health patient population, with the hope that after further validation they can be again considered.	
Ambulatory Care, Phase 2	1.7	Of the eight measures that were not approved on the first ballot, six are measures developed by the National Committee for Quality Assurance (NCQA) contained "optional exclusions" as part of the measure specifications. NQF staff had recommended approval of the six measures, conditional on the developer agreeing to change the "optional exclusions" to mandatory exclusions because measure specifications that allow exclusions to be included in some instances and not in others fail to meet one of the primary goals of NQF—achieving standardization in measurement so as to make comparisons through public reporting valid. NCQA submitted modified specifications to remove the "optional" exclusions. The Executive Committee of the NQF Board of Directors approved a second round of voting for the six measures with the modified measure specifications, rather than have the measures re-evaluated in Phase 3 of the ambulatory care project.	All six measures were approved by the 4 councils and endorsed by the Board.
2006			
Hospital Care, CTM3	1.7	The two performance measures that were not approved on the first ballot addressed hospital care coordination. On the initial ballot, NQF staff recommended the two different versions of the CTM be disapproved at that time, but be reconsidered immediately once the detailed sampling and administrative specifications became available—an outcome that prevailed on the first ballot and was ratified by the Board. The measure developer withdrew one of the candidates (the 15-item CTM) from further consideration and modified the remaining measure (the 3-item CTM) to address concerns raised during the review and first voting period. This measure was released for a second round of voting.	Measure was endorsed.
Ambulatory Care,	1.7	Three measures were not supported by one or more of the councils.	Second round of voting did not occur.

Project	CDP version	Reason	Outcome
Phase 3, Cycle 1		All dealt with tobacco use that were either condition-specific or redundant to previously endorsed measures. NQF staff recommended that the Board not endorse the measures and not require a second round of voting.	
2007			
Ambulatory Care Phase III, Clinician Specialty	1.7	Majority of members of the Consumer and Purchaser Councils conditionally approved the measure only if endorsement is limited to a two-year time period due to lack of testing for reliability and validity. Note: in December 2006, the Board had approved the time-limited endorsement policy with implementation in the fall of 2007	The measures were endorsed as time-limited.
2008			
ESRD Measures	1.8	Mortality Measure: The CSAC did not approve the ESRD facility mortality measure because of methodological issues and inconsistency with other NQF-endorsed mortality measures. As submitted, the mortality measure included cut points and levels of statistical significance that the CSAC identified as reporting parameters that should not be part of the measure specifications. The measure also was inconsistent with CMS' hospital mortality measures. CMS decided to resubmit the mortality measure without the reporting specifications to be consistent with other CMS mortality measures. The CSAC submitted this measure for a second round of voting and the membership was asked to vote on the revised measure. Hemoglobin Measures: In the first round of voting, the hemoglobin measures were not included in the ESRD set because of the controversy regarding safe hemoglobin levels associated with erythropoiesis-stimulating agents	Both measures were endorsed.

Project	CDP version	Reason	Outcome
		(ESA) therapy and ongoing discussions by the FDA regarding label warnings. At that time, the ESRD Steering Committee was equally divided on what hemoglobin levels should be reflected in the measures. On November 8, 2007, the FDA issued its final label warning for ESA therapy and CMS submitted revised facility hemoglobin measures.	
2009			
Hospital outcomes & efficiency	1.8	The votes for the six Leapfrog Survival Predictors on surgical procedures for which NQF had previously endorsed mortality measures were divided by council. The measures received less than 50% approval by both the Health Professional and Provider Organization councils and 100% approval by the Consumer, Public/Community Health Agency, and Purchaser councils; with overall approval less than 60%. In October 2009 the NQF Board deferred action on the six candidate standards. Although the six Leapfrog Survival Predictors passed through each step of the CDP, there was a noticeable division of support along stakeholder lines. The primary issues raised about the Survival Predictors were variability in the evidence of the volume-mortality relationship across procedures and lack of risk adjustment. To conduct the re-assessment of the Leapfrog Survival Predictors, NQF sponsored an independent evidence review by ECRI on the strength of the volume/mortality relationship for each of the six measures; collected risk model performance for each of the measures; and assessed the current and future state of public reporting for each of the currently endorsed measures.	Following CSAC and Board review of the evidence review by ECRI, three of the measures were endorsed.
2010			
Patient Outcomes, Phases I& II	1.8	The STS CABG Composite measure *did not* go out for a second round of voting; however, while the measure was supported by the membership and the Steering Committee, there was concern about	The measure was endorsed without the star rating system. Policy guidance was issued stating that embedded scoring

Project	CDP version	Reason	Outcome
		the inclusion of an embedded scoring mechanism, a star rating system, in the measure submission. The Steering Committee reviewed the measure and voted to recommend the measure for endorsement, without the embedded scoring mechanism as part of the measure stemming from the belief that this addresses implementation of the measure and is inappropriate for endorsement. The measure went out for comment and vote and received member support. The CSAC and Board pulled the topic to discuss, at a policy level, whether NQF should endorse a measure that essentially has embedded in it a presentation format or whether the measure should be limited to the numerical score, allowing users to decide how to present the results. Endorsement of the measure was delayed in this process, but it never went out for a repeat comment or voting period.	presentation formats are not part of the endorsed measure.
2012			
All-Cause readmissions	1.9	The CSAC reviewed the NQF Member voting results where members from 7 of the 8 councils participated in the voting (there were no votes from members of the supplier/industry council), and four out of seven councils supported the two measures under consideration. The CSAC was concerned about the lack of support for the measures in the health professional, provider, and QMRI councils. The primary concern of these councils related to the lack of adequate adjustment for socioeconomic status. After extensive discussion, the CSAC considered and subsequently voted on whether there was any additional information that could be provided to address this concern, and concluded there was not. The CSAC then voted to recommend both measures for endorsement. The Board then reviewed the measures, process followed as well as additional analyses.	The measure was endorsed with guidance and a task force was approved that would review and recommend enhancements for defining and achieving consensus within NQF's consensus development process.

SUMMARY OF CONSENSUS PROCESSES

	NQF	ANSI
Focus	NQF uses its formal Consensus Development Process (CDP) to evaluate and endorse consensus standards for public reporting on the performance of the US health care system including: • performance measures • best practices • frameworks • reporting guidelines[i]	Primary administrator and coordinator of US private sector voluntary standards program to enhance global competitiveness of business and US quality of life; accredits qualified standards development organizations (SDOs) developing American National Standards (ANS).[ii] Currently there are approximately 226 SDOs accredited by ANSI.
Transparency; Public Participation	Materials posted; meetings open; comments elicited both from members and public at large; members given preference in committees; members only participate in voting.	SDOs must open the process to all directly and materially affected with no undue financial barrier; ANSI publishes weekly proposals for new and proposed standards. Public can comment; participation not dependent on membership.
Criteria for Decision	Importance, scientific acceptability, feasibility and usability.	N/A[iii]
Standard for Approval	Majority votes	Dependent upon the action being considered, the concurrence of more than a simple majority of votes or 2/3 of eligible voters may be the standard for approval
Consensus Body	Volunteers, multi-stakeholders; individual project committees to recommend with standing Committee to decide.	Appointed, term limited expert volunteers (generalists vs. specialists on a particular topic).
Management of Bias	Conflict of interest policy with management to minimize conflict.	Conflict of interest policy required of SDOs and ANSI; ANSI operates final level of appeal.
Consensus Process Summary	• Call for Nominations • Call for Candidate Standards • Candidate Consensus Standard Review • Public and Member Comment • Member Voting • CSAC Decision • Board Ratification • Appeals	• Consensus on a proposed standard by a group or consensus body that includes representatives from materially affected and interested parties • Broad-based public review and comment on draft standards • Consideration of and response to comments submitted by voting members of the relevant consensus body and by public review commenters • Incorporation of approved changes into a draft standard • Right to appeal by any participant that believes that due process principles were not sufficiently respected during the standards development in accordance with the ANSI-accredited procedures of the standards developer.[iv]

COMPARISON CONSENSUS PROCESS STANDARDS-SETTING ORGANIZATIONS[v]

	NQF	ANSI
Definition of Consensus	Consensus is defined as general agreement, but not necessarily unanimity, and includes a process for attempting to resolve objections by interested parties, as long as all comments have been fairly considered, **each objector is advised of the disposition of his or her objection(s) and the reasons why, and the consensus body members are given an opportunity to change their votes after reviewing the comments**.[vi]	Consensus means substantial agreement has been reached by directly and materially affected interests. This signifies the concurrence of more than a simple majority, but not necessarily unanimity. Consensus requires that all views and objections be considered, **and that an effort be made toward their resolution.**[vii]
	CONSENSUS PROCESS	
1. Call for Panel Nominations (Focused on Steering Committees)	As a consensus development project begins, NQF issues a call for nominations for the project's steering committee. **Timing** The call for nominations is open for 30 days. Public comment on a proposed steering committee roster is open for 15 days. **Eligibility** Any interested party can electronically submit one or more nominations for the steering committee. **Transparency** The call for nominations is posted on the website. Proposed steering committee rosters, with member names, organizations, affiliations and biographies are posted on the website for public comment. Final steering committee rosters, with member names, organizations, affiliations and biographies are posted on the website.	Call for members – applies to the ANS consensus bodies: the group that approves the content of a standard and whose vote demonstrates evidence of consensus. **Timing** Varies: directly and materially affected interested parties must contact the sponsoring standards developer "in a timely manner". **Eligibility** Directly and materially affected parties. **Transparency** Establishment of a new consensus body must be provided to all known directly and materially affected interests, including announcement of a call for members in Standards Action (www.ansi.org/standardsaction). Upon request of interested parties, the member's name (or if membership is by organization, the name of the organization with a point of contact), affiliation, and interest category of each member of the consensus body must be made available upon request.
2. Call for Proposed Standards (Focused on initiation of a process for review of new or existing standards)	**Timing** The call for candidate standards within a specific topic area opens at least 60 days prior to project start. **Eligibility** Any interested party, who will serve as steward of the candidate measure, meaning they assume responsibility for the submission of the measure for potential endorsement to NQF. **Transparency**	Stage 1: A Project Initiation Notice (PINS) is sent to ANSI by an ANS consensus body. A PINS is not required for revisions of ANS that are under continuous or stabilized maintenance. **Timing** The public comment period for a PINS is one of the following, depending on ease of availability/accessibility of documentation supporting the proposed ANS: 30, 45 or 60 days. **Eligibility**

	NQF	ANSI
	Submitted standards posted on the public website to obtain ongoing public input during the consensus standards review process, and become part of the historical project documentation, remaining on NQF's website after the endorsement decision.	Only ANSI accredited standards developers are eligible to submit candidate standards for consideration as American National Standards (ANS). Specific forms/data must be submitted to ANSI at various points in the development cycle of each standard. When a standard is ready for final consideration, a formal submittal including **evidence of consensus**, is required: that is, requirements related to the balance of the consensus body, deliberations, resolution of objections and voting have been met. A tally of the final consensus body vote is required. [viii] **Transparency** All candidate standards, and proposals to revise, reaffirm, or withdraw approval of existing standards are published in Standards Action to provide an opportunity for public comment.
3. Comments on Proposals for Standards	**N/A**	A **PINS deliberation** is required if claim of conflict or duplication of an existing ANS is raised. **Timing** If a developer receives written comments within **30 days from the publication date of a PINS announcement** stating that a proposed standard duplicates or conflicts with an existing or candidate ANS, a mandatory deliberation of representatives from the relevant stakeholder groups must usually be held within **90 days from the comment deadline**.[ix] **Process** All claims must be addressed and good faith efforts must be made to resolve potential conflicts. There are no specific requirements for deliberations. But the outcome must be conveyed in writing by the developer and commenter (ideally as a joint submission) to the ANSI Board of Standards Review (BSR) for consideration **should the developer ultimately submit the related candidate standard to ANSI for approval**.[x]
4. Proposed Standards Review	Review of candidate consensus standards by the steering committee begins after the close of the project call for standards. **Timing** The duration of a steering committee's review varies depending on the scope of the project, the number of standards under review, and the relative complexity of the standards.	Stage 2: Approval of draft standard **Criteria and Process** An ANS consensus body approves the text of draft standards by following the requirements set out in the *ANSI Essential Requirements* related to the balance of the consensus body, deliberations, resolution of objections and voting.

	NQF	ANSI
	Criteria All candidate consensus measures are evaluated against NQF's Measure Evaluation Criteria. **Transparency** Deliberations and materials are open to members and the public **Process** The steering committee is expected to reach consensus and may either recommend: • A candidate consensus standard continue through the consensus development process toward possible endorsement by NQF; or • A candidate standard be returned to the steward and/or developer for further development and/or refinement. Sometimes a technical advisory panel will assist the steering committee as it deliberates. Link	**Transparency** Participation is open to all persons directly and materially affected by the activity in question. There shall be no undue financial barriers to participation.
5. Comments on Proposed Standards under Review	When the steering committee completes initial review of the submitted candidate standards, a draft of the committee's recommendations is posted on the NQF website for review and comment by members and the public. **Timing** The comment period is open for 30 days. **Eligibility** NQF members and the public may comment on the steering committee's draft recommendations via the NQF website. **Transparency** Notification of the commenting period is posted on the NQF website. NQF also sends an email notification to NQF members and the public who have signed up for these notifications. During a commenting period, documents related to the project and the steering committee's evaluation and recommendations are posted on the NQF website for members and the public to review. All submitted comments are posted on the NQF website.	Stage 3: Public Review (2&3 may be concurrent) Proposals for new ANS and proposals to revise, reaffirm, or withdraw approval of existing ANS are published in Standards Action to provide an opportunity for public comment. The developer is also expected to announce in industry publications, etc. (multiple public reviews are possible). **Timing** The public comment period for a PINS published in Standards Action is one of the following, depending on ease of availability/accessibility of documentation supporting the proposed ANS: 30, 45, or 60 days. **Eligibility** Any member of the public may comment on the proposals. **Transparency** The PINS and supporting documentation from developers are published in Standards Action. Developers may charge a fee for supporting documentation.

	NQF	ANSI
	Process The steering committee reviews all submitted comments and may also seek out technical advice or other specific input from external sources as needed. After review of the submitted comments, the steering committee may choose to revise its recommendations within the draft report in response to a specific comment or series of comments. Any revisions will be reflected in the revised draft report. Should the steering committee gauge its revisions to be substantial in nature, a revised version of the draft report may be re-circulated either for additional review in advance of the voting period or for review as part of the voting process. If a revised version of the draft report is re-circulated for a second review and comment period, the review will follow the same process as the initial review and comment period. Link	Submitted comments are reviewed and responded to by the developer. The commenter receives written notification of the response. If the commenter does not provide a response indicating disagreement with the developer response after 15 days, the issue is considered resolved. **Process** At the consensus body level.
6. Voting on Proposed Standards	**Timing** When the steering committee completes review of the comments submitted revisions to the draft report, recommended candidate standards may be voted on during a 15 day period. **Eligibility** Only NQF member organizations may vote on the candidate standards recommended by the committee. **Transparency** When a voting period opens, email notification is sent to NQF member organizations and voting information is made available on the NQF website. Voting is conducted electronically via the email notification or the NQF website. **Process** Each NQF member organization may cast one vote in favor of or against approval of a steering committee's recommendations. A member organization may also abstain from voting on a particular consensus development project.	Consensus is demonstrated, in part, **by a vote of the consensus body**. **Transparency** Voting membership on 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. **Process** Voting must meet numerical requirements for consensus as described in a developer's accredited procedures. An example of the criteria for consensus includes a requirement that a majority of the consensus body cast a vote (counting abstentions) and at least two-thirds of those voting approve (not counting abstentions). **The developer may submit for approval an alternative methodology for determining consensus.** Votes for the approval of a candidate standard may be obtained by letter, fax, recorded votes at a meeting, or electronic means. All members of the consensus body must have the opportunity to vote. Votes are in the following form: a) Affirmative; b) Affirmative, with

	NQF	ANSI
	All candidate consensus standards that are recommended as a result of voting by the membership will proceed to the next step: decision by the CSAC. Link	comment; c) Negative, **with reasons** (the reasons for a negative vote must be given and if possible should include specific wording or actions that would resolve the objection); d) Abstain.
7. Review of Consensus Body Recommendations a. Review of Consensus Recommendations b. Review of Voting	**Timing** The CSAC reviews the recommendations of steering committees and the results of NQF Member voting periods. **Transparency** At each CSAC meeting, audience members have the opportunity to comment on the candidate standards under consideration. Information about each CSAC meeting is available on the NQF website, including the meeting's agenda and materials and the physical location or dial-in information. CSAC decisions are posted on the NQF website. **Process** After detailed review of a candidate standard, the CSAC determines if consensus has been reached across the various NQF Member Councils. They seek further input from Council Leaders if there is a lack of consensus. The CSAC may request a second round of member voting. In such cases, NQF follows the same procedure to notify membership and conduct the voting as outlined above. The CSAC may grant full endorsement, time-limited endorsement, or deny endorsement of a candidate standard. Decisions by the CSAC are forwarded to the NQF Board of Directors for ratification. Link	Appears this would occur if there is **an appeal to ANSI, in the following order:** • Board of Standards Review (BSR) • ANSI Appeals Board (AB)[xi]
8. Ratification	All consensus standards that are recommended must be ratified by the Board for endorsement. **Transparency** After ratification by the NQF Board, the endorsement status of a consensus standard or set of standards is published on the NQF website. In addition, a searchable list of all NQF-endorsed® national voluntary consensus standards is available through the NQF website.	

	NQF	ANSI
	Process CSAC decisions regarding consensus standards are submitted to the Board of Directors. The Board can affirm or deny a CSAC decision. Link	
9. Appeals	**Appeal of endorsement decision to NQF Board of Directors:** • CSAC review and recommendation • Board of Directors disposition The CSAC reviews appeals and evaluates the scientific evidence available that is germane to the endorsed standard. After discussions, the CSAC will make a recommendation to the NQF Board of Directors regarding the appeal. The Board of Directors will take action on an appeal within seven calendar days of its consultation with the CSAC.	**Appeals to ANSI:** • Board of Standards Review (BSR) • ANSI Appeals Board (AB)[xii] The BSR considers whether due process was afforded; it does not evaluate the content of standards and does not hear appeals of purely technical issues.[xiii] The BSR follows the Operating Procedures for the ANSI Board of Standards Review. If the BSR finds that the criteria for due process have not been met or that the **evidence of consensus is inadequate** in connection with a standard that it has reviewed, it will not approve that standard as an American National Standard (ANS). ANSI operation procedures advise that inadequate consensus or lack of due process indicates that there was opposition to the voluntary adoption and use of the standard, and it should not be designated as an ANS. The final decision of the BSR may be appealed to the ANSI Appeals Board.
	Eligibility For an appeal to be considered by NQF, the appeal must include written evidence that the appellant's interests are directly and materially affected by the consensus standard or sets of standards recently endorsed by NQF, and that NQF's endorsement of this standard has had, or will have, an adverse effect on those interests. An appeal may only be filed in response to NQF endorsement of a candidate standard or set of standards; that is, an interested party may not file an appeal regarding the decision to not endorse a candidate standard. An interested party may file a concern about any measure (whether endorsed or not endorsed) in the NQF consensus development process and this concern will be reviewed by the CSAC.	**Eligibility** Directly and materially affected persons (organizations, companies, government agencies, individuals, etc.) who have concluded appeals at the standards developer level are eligible to appeal the approval or disapproval of a candidate standard by the BSR.
	Timing After a consensus standard has been formally endorsed by NQF, any	**Timing** Those who have concluded appeals at the standards developer level are

	NQF	ANSI
	interested party may file an appeal of the endorsement decision with the NQF Board of Directors. Appeal of an endorsed standard must be filed in writing within 30 days of the endorsement decision.	eligible to appeal the approval or disapproval of a candidate standard by the BSR. An appeal must be filed in writing within 15 working days of an action by the BSR. An appellant may receive an extension of 15 additional working days, however if materials are not filed within the extended period the right to further appeal is forfeited.
	Filing Fee N/A	**Filing Fee** There is a filing fee for appeals, but it may be waived or reduced upon sufficient evidence of hardship.
	Form of Appeal For an appeal to be considered by NQF, the appeal must include written evidence that the appellant's interests are directly and materially affected by the consensus standard or sets of standards recently endorsed by NQF, and that NQF's endorsement of this standard has had, or will have, an adverse effect on those interests.	**Form of Appeal** An appeal must include a statement with evidence as to why the action of the BSR should be modified.
	Response to Appeal [N/A]	**Response to Appeal** Respondents are notified of an appeal and are given 15 working days after notification to oppose the appeal. A respondent may receive an extension of 15 additional working days to respond, however if no response is filed within the additional time, the respondent forfeits the right to respond.
	Pendency of Appeal Endorsement decision stands until appeal is completed. There is no prohibition on communication while the matter is pending.	**Pendency of Appeal** The original action of the BSR shall stand until all levels of appeal at ANSI have been completed unless the BSR determines otherwise. No party to an appeal may communicate with any member of the BSR while the matter is pending.
	Appeals Hearing Appeals are compiled and the Consensus Standards Approval Committee (CSAC) reviews them and evaluates the scientific evidence available that is germane to the endorsed standard. At each CSAC meeting, audience members have the opportunity to comment. Information about each CSAC meeting is available on the NQF website, including the meeting's agenda and materials and the physical location or dial-in information.	**Appeals Hearing** A panel consisting of at least five BSR members may conduct the appeals hearing at the next regularly scheduled meeting, or on a date mutually agreeable to all parties concerned. Appellant and respondents must be notified of date and time at least 15 working days in advance and invited to be represented at the hearing.
	Appeals Decision	**Appeals Decision**

	NQF	ANSI
	Recommendations regarding appeals require a majority vote of the CSAC [check]. The CSAC provides initial consultation and recommendations to the Board on appeals of endorsement decisions. The Board acts on appeals within seven calendar days of its notification of the CSAC's recommendation.	Appeals decisions require an affirmative vote of at least two-thirds of the BSR members voting or present is required, after excluding abstentions (and votes deemed to be abstentions). The appellant and respondents may reach an informal settlement at any time. If settlement leads to material changes to the standard, the standard must be reviewed within the consensus process.
	Transparency All appeals for endorsement and decisions are published on the NQF website. Each of the NQF Board of Directors' actions regarding an appeal of endorsement is published on the NQF website, where they are available to all site visitors.	**Transparency** Individual notification is sent by ANSI staff to eligible participants based on the evidence submitted by the accredited standards developer.
	Further appeal N/A	**Further appeal** The final decision of the BSR may be appealed to the ANSI Appeals Board. The Appeals Board is the final level of appeal within ANSI. **Timing** *[unclear]* **Eligibility** The ANSI Appeals Board only considers appeals by directly and materially affected persons (organizations, companies, government agencies, individuals) who believe they have been, or will be, adversely affected by a decision of ANSI, whether in the form of action or inaction or in the implementation of ANSI procedures.
Approval Transparency	After ratification by the NQF Board, the endorsement status of a consensus standard or set of standards is published on the NQF website. In addition, a searchable list of all NQF-endorsed® national voluntary consensus standards is available through the NQF website.	The standard must be published and made available as soon as possible, but no later than six months after approval. The developer must publish the standard or shall grant the right of publication to ANSI. The developer may request an extension of time. The ExSC or its designee must publish a notice in Standards Action of intent to withdraw approval if the developer a) fails to publish the standard or fails to grant ANSI the right to publish within six months after its approval as an ANS and does not request an extension of the deadline despite follow-up or fails to meet the extended deadline. Notice of the BSR's final action on all standards shall be published in Standards Action (www.ansi.org/standardsaction).

[i] http://www.qualityforum.org/Measuring_Performance/Consensus_Development_Process.aspx

[ii] *Assessment of NQF's Consensus Development Process*, Mathematical Policy Research, Table IV.5. Summary of NQF and Selected other Consensus Processes on Selected Dimensions, December 2010. Although ANSI itself does not develop American National Standards (ANSs), it provides all interested U.S. parties with a neutral venue to come together and work towards common agreements. The process to create these voluntary standards is guided by the Institute's cardinal principles of consensus, due process and openness and depends heavily upon data gathering and compromises among a diverse range of stakeholders. The Institute ensures that access to the standards process, including an appeals mechanism, is made available to anyone directly or materially affected by a standard that is under development.

[iii] *IBID*.

[iv] *IBID*.

[v] Voluntary consensus standards-setting organizations as defined by the National Technology Transfer and Advancement Act of 1995 and Office of Management and Budget Circular A-119 (Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities).

[vi] The White House, U.S. Office of Management and Budget, Circular No. A-119, February 10, 1998, Washington, DC: Office of Management and Budget; 1998. Available at http://www.whitehouse.gov/omb/circulars_a119/. Last accessed August 2012.

[vii] *ANSI Essential Requirements: Due process requirements for American National Standards*, http://www.ansi.org/essentialrequirements. Last accessed August 2012.

[viii] Indicated via the BSR9 form, attached.

[ix] The purpose of the deliberation is to provide the relevant stakeholders with an opportunity to discuss whether there is a compelling need for the proposed standards project.

[x] *ANSI PINS Process: An Informative Summary*, October 13, 2009, available at http://www.ansi.org/. Last accessed August 2012.

[xi] Omitted appeals to Executive Standards Council (ExSC); relates to accreditation of entities.

[xii] Omitted appeals to Executive Standards Council (ExSC); relates to accreditation of entities.

[xiii] Responsibilities of the BSR include approval and withdrawal of American National Standards. Functions include: implementing procedures for the approval and withdrawal of standards as American National Standards and adjudicating questions or conflicts that develop in the standards approval procedure; and determining whether standards submitted to the Institute for approval or withdrawal as American National Standards (ANS) meet the requirements of the Institute and acting on all requests for approval, reaffirmation, revision and withdrawal of American National Standards.

General Timelines for Several ANSI Accredited Standards Organizations

	NQF	SAE	The NECLAC Institute	International Safety Equipment Association	International Committee for Information Technology Standards
Project Initiation	90 days (call for measures, implementation comments, and call for nominations)		Approximately 6 months before meeting; 2 meetings per year (summer and winter)	Project initiation (time NA) then 30 days for comment on initiation announcement; concurrent with seeking consensus reviewers	N/A
Public Comment	30 days	Two periods of at least 28 days; comments must be submitted through a committee member	Minimum of 45 days; report must be published 30 days before meeting it's discussed at; comments are accepted at the meeting and written comments are accepted with 15 days of the meeting.	45 days on draft standard (while consensus review is happening)	Yes, time NA
Member Voting	15 days		30 days, plus 15 days prior for review of draft. Requires 2/3 approval	30 days or as soon as all ballots returned	30 days
Appeals	A written appeal must be submitted within 30 days after publication of endorsement.		30 days after publication	30 days after notification	30 days after notification
Total time to approve standards	7-9 months for a set of measures reviewed in a project	6 months to 1-2 years, depending on complexity, level of interest, how much research needs to be done (they develop the standards)	At least 495 days http://www.nelac-institute.org/docs/TNI_SOP_2-100_2.pdf Appendix 1	More info but not dates: http://safetyequipment.org/c/ISEAStandardizationProgram.cfm	NA

General Timelines for Several ANSI Accredited Standards Organizations

	NQF	HL-7[i]	AAMI[ii]	ISA[iii]
Project Initiation	90 days (call for measures, implementation comments, and call for nominations)	90 days (New Work Item Proposal)	A decision as to whether a New Work Item Proposal submission is approved occurs within 6 months of receipt of the new work item.	New Standards Project Proposal form must be submitted and reviewed.
Public Comment	30 days	5 months (comments are reviewed by the working groups)	Minimum of 30, 45, or 60 days dependent upon ease of availability of the standards review	Minimum of 30, 45, or 60 days dependent upon ease of availability of the standards review
Member Voting	15 days	60 days (Final Draft International Standard Ballot)	The ballot period for a full ballot is generally 6 weeks. The ballot period for a continuation ballot is generally 4 weeks. No ballot shall be less than 3 weeks.	The voting period for Committee ballots on draft standards, recommended practices, and technical reports shall be at least four (4) weeks from the date of issue. Voting requirements vary depending on the action occurring; some actions require approval by a majority of voting members, some actions require approval by a majority of the total eligible voting members, and some actions require approval by 2/3rds of the total eligible voting members.
Appeals	A written appeal must be submitted within 30 days after publication of endorsement.	A written appeal must be submitted within 15 days of Board of Standards Review.	An appeal must be filed in writing to the AAMI office within fifteen working days after notification by AAMI of an action of the Standards Board, committee, or committee (co)chairs.	A written appeal must be submitted within 30 days of notification of the action taken.
Total time to approve standards	7-9 months for a set of measures reviewed in a project		Time from approval of new work to date of completion shall not exceed 5 years for standards, 4 years for recommended practices, or 18 months for technical information reports, unless authorized by the Standards Board.	

General Timelines for Several ANSI Accredited Standards Organizations

[i] http://www.hl7.org/documentcenter/public_temp_399C8B3E-1C23-BA17-0C8390662FCF369C/membership/HL7_Governance_and_Operations_Manual.pdf
[ii] http://www.aami.org/standards/downloadables/aamiproc.doc
[iii] http://www.isa.org/filestore/standards/ISA_Standards_Procedures-2011_revision-final.pdf