The National Quality Forum's Consensus Development Process

Purpose

This document describes the NQF's consensus development process. This is the formal process that NQF will use when endorsing voluntary consensus standards, including performance measures, measurement frameworks, preferred practices, or reporting guidelines.

In considering the process detailed here, it should be recognized that this is a "living process"—i.e., NQF will continually look for ways to improve the process and will periodically review and revise the consensus development process as experience is gained in promulgating healthcare voluntary consensus standards.

Background and Context

The National Quality Forum (NQF) is a voluntary consensus standards-setting organization as defined by the National Technology Transfer and Advancement Act of 1995 and Office of Management and Budget (OMB) Circular A-119.[1,2] As such, the NQF has a formal process by which it achieves consensus on standards that it endorses.

OMB Circular A-119 (1998) defines the term "standards" as:

> *1) common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods, and related management systems practices; and 2) the definition of terms; classification of components; delineation of procedures; specification of dimensions, materials, performance, designs, or operations; measurement of quality and quantity in describing materials, processes, products, systems, services, or practices; test methods and sampling procedures; or descriptions of fit and measurements of size or strength. The term "standard" does not include the following: 1) professional standards of personal conduct; and 2) institutional codes of ethics. 'Performance standard' is a standard as defined above that states requirements in terms of required results with criteria for verifying compliance but without stating the methods for achieving required results. A performance standard may define the functional requirements for the item, operational requirements, and/or interface and interchangeability characteristics. A performance standard may be viewed in juxtaposition to a prescriptive standard which may specify design requirements, such as materials to be used, how a requirement is to be achieved, or how an item is to be fabricated or constructed. 'Voluntary consensus standards' are standards developed or adopted by voluntary consensus standards bodies, both domestic and international. These standards include provisions requiring that owners of relevant intellectual property have agreed to make that intellectual property available on a non-discriminatory, royalty-free or reasonable royalty basis to all interested parties. For purposes of this Circular, 'technical standards' that are developed or adopted by voluntary consensus standard bodies" is an equivalent term.*

NQF endorsement of voluntary consensus standards will follow the process and pathway described in this document. The expected product(s) of these standard-setting activities will include the actual measures, frameworks, set(s) of practices, etc., and explanatory text and/or other supporting documentation, such as guidelines for reporting the standards.

In addition to endorsing voluntary consensus standards, NQF will engage in other activities aimed at promoting the use of such standards, linking quality measurement to strategies for quality improvement, providing leadership, disseminating information, and exchanging knowledge and ideas. Many of those activities will not require the development of formal consensus and will not follow the process detailed here.

[1] Public Law 104-113, The National Technology Transfer and Advancement Act
[2] OMB Circular A-119 (1998)

The NQF Consensus Development Process

The NQF's general consensus development process consists of five principal steps. These steps follow a project's conceptualization, prioritization, and planning. The five steps are:

I. Consensus Standard Development

II. Widespread Review

III. Member Voting

IV. Consensus Standards Approval Committee Action and Board of Directors Endorsement

V. Evaluation

This process addresses the five key elements of a voluntary consensus process for standards development that are specified by the National Technology Transfer and Advancement Act of 1995: openness, balance, due process, consensus,[3] and a mechanism for appeals. The process emphasizes NQF member involvement, a necessary component of a membership organization. Finally, the process assumes that most decision products resulting from NQF projects will undergo at least four levels of review and approval: 1) by a project's Steering Committee (SC) and its Technical Advisory Panels (TAPs), as applicable; 2) by the NQF Member Councils and general public; 3) by the Consensus Standards Approval Committee (CSAC); and 4) by the NQF Board of Directors (BoD). Additional review will be sought from the general public and/or other entities, according to the specific issue or project.

Conceptualization, Prioritization, and Planning of Consensus Projects. At the present time, NQF's core activities fall into three broad categories: 1) consensus development projects; 2) priority setting and other convening functions; and 3) conducting leadership, educational, and award activities. This portfolio of activities may well change over time with changing quality improvement needs and circumstances.

Projects in any of these areas may be suggested by NQF Members or Member Councils, NQF staff, the CSAC, NQF's BoD, or external entities. Proposed projects generally should be consistent with NQF priorities and national goals, as defined by the National Priorities Agenda, and may relate to a particular population (e.g., the vulnerable elderly), a service line or mode of care (e.g., intensive care, acute hospital care), a condition or disease (e.g., pregnancy, diabetes, or asthma), or a cross-cutting care issue (e.g., pain management or patient safety).

In identifying areas needing measurement and reporting standardization, NQF staff will monitor relevant healthcare trends and other relevant activities. It is anticipated that the Member Councils and the CSAC also will provide important opportunities for discussing potential areas of focus. In addition, the development and discussion of coherent program priorities and national goals will be engaged in at the NQF Annual Meetings, Membership Meetings, CSAC meetings, and meetings of the BoD and its advisory committees. To the extent possible, NQF staff will pursue project funding opportunities and develop project concepts that are consistent with these priorities.

Notification of Consensus Projects. The BoD will be regularly apprised of all projects being worked on and the reasons for accepting or declining any proposed consensus project. NQF will post on its website descriptions of all current projects and measures under consideration.

Project funding. Work on a project generally will not commence until adequate funding to complete the project has been identified.

I. Consensus Standard Development

A. **Measure Steward.** It is expected that each measure or measure set will have a measure steward (developer) who will assume responsibility for the submission of the measure and subsequent updates as needed.

B. **Program Officer.** Each project will be assigned to an NQF staff person who shall serve as the program officer. This program officer shall be the project's primary point of contact within NQF.

C. **Steering Committees.** The work of most projects will be guided and overseen by a Steering Committee (SC). Among other things, the general purpose of the SC will be to work with NQF staff to advise on project scope, develop specific project plans, provide advice about the subject, ensure input is obtained from relevant stakeholders, and review draft products. SC members will reflect the diversity of the NQF membership, as well as specific perspectives of particular importance to the project topic. SC members

[3] OMB Circular A-119, which provides instruction to federal agencies regarding the interpretation of the National Technology Transfer and Advancement Act, defines "consensus" as "general agreement, but not necessarily unanimity." According to this interpretation, a voluntary consensus process must include a process for attempting to resolve objections, and the opportunity for consensus body members to change their votes after reviewing comments.

will be selected in accordance with NQF's *Policy for Establishing Steering Committees for Consensus Development Projects* and *Conflict of Interest Guidelines* and based on their expertise and potential for contribution to the project and the need for input from particular perspectives. SC members generally will be individuals affiliated with NQF member organizations unless the needed perspective or expertise is not available among NQF's membership. The SCs are generally analogous to the expert advisory committees that federal agencies typically convene to provide advice and input when developing draft regulations, position statements, or other such products.

D. **Technical Advice.** Projects shall be advised and informed by technical advisors. The technical advisors may be constituted as a technical advisory panel (TAP) or utilized on an ad hoc basis for expert input. The technical advisors will be selected primarily for their content expertise and experience. Technical advisors may be charged with reviewing the evidence supporting potential performance measures, preferred practices, etc., and completing other technical reviews, as required.

E. **Evidence Basis.** All NQF consensus reports, as well as other products, shall be explicit about the scientific evidence and experience underlying the recommended measures, the criteria for selecting them, and the rationale for recommending the particular item or approach.

F. **Draft Recommendations.** Products that include draft recommendations for action (e.g., a recommended measure set or areas for research) shall be approved by the SC before being made available for public, Member, CSAC, and/or Board of Directors review. The SC will be expected to achieve consensus (as defined in OMB Circular A-199), before advancing a document for further NQF action.

All proposed consensus standards must comport with NQF's *Intellectual Property Policy*.

Any draft product approved by a SC shall include an appendix or attachment entitled "Commentary." In this Commentary, members of the SC may express dissenting views or other perspectives not covered in the report. Likewise, members of the SC may write in support of the majority view to emphasize certain points or to stress the importance of particular aspects of the recommended action.

G. **Availability of Project Information.** Information on each new NQF project will be posted on the NQF public web site. A list of SC members, a schedule of public meetings, a list of technical advisors, any draft products for public review, and other relevant materials will also be posted on the web site as they become available. Some materials (e.g., SC meeting agendas and minutes, background materials, draft recommendations) may be limited in distribution to NQF Members or may be made available only to NQF Members for an interval before they are made available to the general public. Interim project information of a proprietary nature—e.g., confidential business information (CBI) related to a potential voluntary consensus standard—may be limited in its availability to the SC and NQF staff, only, at the request of the party owning the information. All information held as CBI shall be fully disclosed to NQF Members and the public only if the SC recommends further consideration, at which time all information available to the SC and NQF staff shall be fully disclosed to NQF Members and the public. No information held as CBI shall be disclosed to NQF Members and the public if the SC does not recommend the item(s) advance.

II. <u>Widespread Review</u>

A. **Pre-Voting Member Review.** Draft products containing recommendations that have been approved by the project SC will be provided to each member organization for review and comment either electronically or in hard copy, at NQF's discretion. Comments by Members must be submitted directly to NQF. All comments received by NQF in writing within stated deadlines will be posted on the NQF web site for NQF Members and the CSAC and formally considered before voting commences.

Each Member Council is responsible for establishing its own procedures for communicating the Council's aggregate position, if one exists, on the candidate consensus standard. The Member Council synthesis shall append the list of organizations providing comments and any relevant votes or other documentation. The Corporation Secretary may request copies of comments not directly provided to the NQF, notwithstanding the provision above, so that the NQF's records are complete.

In general, NQF member organizations and the Members will be expected to complete their review within 30 calendar days. In rare circumstances, the Board of Directors may vote to expedite the review process, but in no case shall it be fewer than 14 calendar days. Section II.D further describes the expedited consideration process.

B. **General Public Review.** Once a draft product has been provided to the Members, it also will be made available for general public review via the NQF web site and other usual and customary information dissemination venues. Additional targeted dissemination of draft products for review by non-member stakeholders may be done based upon the advice of the SC, CSAC, or BoD. NQF staff will review and summarize the comments from these sources. All public comments received by the deadline for such comments also will be available to Members when voting on the document commences.

C. **Consideration of Member and Other Comments.** Following the review period, staff may revise the draft report based on comments received. The revised draft will be re-circulated to Members, the SC, and CSAC for additional review or for voting. Other input, including technical advice, may be solicited as well. Revised drafts will be accompanied by a summary of significant comments (identified by source) and the action taken in response.

Revised drafts submitted for further review (i.e., a second review cycle) will generally adhere to the process in II.A, except that NQF management may provide for a review period of, at minimum, 14 calendar days.

D. **Expedited Consideration.** In recognition that some measure sets are very well-established and widely used, application of the CDP may proceed via an expedited process. CSAC approval of expedited consideration should be obtained prior to commencing such a review. For expedited reviews, the nominating process for SC members shall be no less than 10 business days; the call for measures shall be no less than 10 business days; and the review and comment period for draft documents shall be no less than 10 business days. Previously endorsed NQF voluntary consensus standards that are updated or adjusted to a degree such that re-consideration is necessary, may proceed under an expedited process.

The following criteria shall be considered by the CSAC in approving an expedited process for other projects:[4]

1. the extent to which the measure set has been sufficiently tested and/or is already in wide use, and
2. whether the scope of the project/measure set is relatively narrow.

III. Member Voting

A. **Member Voting.** All Members in good standing (i.e., current on dues, other invoices, etc.) shall be provided the opportunity to vote on any consensus project. Ballots shall be sent to the Member's designated primary liaison or the primary liaison shall be notified of the availability of a web-based ballot. Ballots will specify the components of the document or other product for which vote(s) are being sought and will also provide an option to abstain. Ballots shall also identify the specific deadline. Prior to the close of the voting period, NQF will contact non-respondents at least once. The minimum period for voting shall be 30 calendar days.

B. **Votes with Proposed Modifications and/or Conditions.** Suggested modifications to draft standards that are proposed during the voting process will be posted on the members' only portion of the web site; all comments received will be posted within 7 days after the voting deadline.

C. **Voting Results.** For each candidate standard/set of standards or other draft product a report of the results of Member voting by Council and other relevant stakeholder group shall be prepared. For example, results for hospital-level consensus standards will be provided for both the Provider Council, generally, as well as specifically for hospitals (i.e., votes for long-term care providers would be encompassed by the Provider Council display, but not the hospital-specific tally). The results of voting shall be advanced to the CSAC. All results shall be forwarded to the CSAC for consideration for approval after the first ballot

D. **Second Round of Member Voting.** A second round of voting shall be undertaken only if directed so by the CSAC.

IV. Consensus Standards Approval Committee Action and Board of Directors Endorsement

A. **Consensus Standard Approval Committee Approval of Voluntary Consensus Standards.** All products approved by the NQF membership under the CDP will be submitted to the CSAC for review and action—i.e., approval or second round of voting. NQF endorsement of voluntary consensus standards will not be considered to have been achieved until the candidate standards/draft products have been approved by CSAC, and endorsed by the BoD. To the extent possible, an opportunity will be provided for Members to comment during the CSAC's deliberations prior to the CSAC taking action.

B. **Notification of CSAC Decisions.** Notice of all CSAC decisions for consensus products will be disseminated to the BoD, NQF Members, as well as made available to the public on the NQF web site and by other vehicles (e.g., press releases and other public announcements). Information in this regard also will be routinely promulgated in other NQF information dissemination instruments (e.g., newsletters).

C. **Final Board Endorsement.** The BoD shall affirm or overturn the actions of the CSAC within seven calendar days, which shall run concurrently with the initial seven days of the appeals period. Products endorsed by the BoD shall be designated as NQF-endorsed™ consensus standards.

[4] Approved by the BoD on April 23, 2002.

D. **Time Limited Endorsement.** The CSAC may recommend to the BoD that a proposed consensus standard be endorsed for a limited period of time provided that the proposed consensus standard meets the NQF-endorsed evaluation criteria with the exception of not having been adequately field tested. Such time limited endorsement shall be in effect for a period of 12 to 24 months, during which time the consensus standard "owner" shall provide evidence and results from the testing to the CSAC. Upon completion of adequate testing and provision of the results, the CSAC may remove the time limitation on the endorsement. If no such evidence is provided by the end of the designated period or if the evidence provided indicates that the measure does not meet NQF criteria, NQF endorsement will expire and NQF shall issue a public notification that the consensus standard is no longer endorsed by using the same dissemination mechanisms described in Section IV.B. Measures for which evidence of adequate field testing is provided will be provided NQF endorsement without further time limitation.

E. **Appeal of Board Endorsement.** Anyone may register a request for reconsideration of an endorsed voluntary consensus standard by notifying the NQF in writing within 30 days of public notification that the voluntary consensus standard had been approved by the CSAC. For an appeal to be considered, the notification letter to the NQF must include information clearly demonstrating that the appellant has interests that are directly and materially affected by the NQF-endorsed voluntary consensus standard(s), and that the NQF decision has had (or will have) an adverse effect on those interests.

Appeals will be reviewed by NQF staff and management, who may consult with the project's technical advisors, Steering Committee, and/or other sources, as appropriate, before a recommendation is provided to the CSAC and BoD. Following consultation with the CSAC, the BoD shall act on an appeal within seven calendar days of the CSAC's recommendation to BoD regarding the appeal. The result of this BoD action shall be promulgated in the same manner as the original decision.

NQF will maintain a record of all appeals, as well as post them on the web site.

V. Evaluation

A. **Operationalization of NQF-endorsed Voluntary Consensus Standards.** Regardless of the degree to which NQF-endorsed voluntary consensus standards may have been previously utilized and/or refined, it is anticipated that implementation of some standards may identify data collection, analysis, and/or reporting issues that are identified only after widespread use. NQF will deploy a web-based mechanism that any party may use to report standard-specific implementation issues arising from use of NQF-endorsed voluntary consensus standards. Reference to this feedback site shall be included in all NQF publications and public notifications of endorsed voluntary consensus standards. By standard-specific issues, NQF generally means technical matters relating to measure specifications or the need for specification refinement, data elements, definitions, or risk adjustment algorithm and not issues of lack of funding, accessible infrastructure, etc.

Information received through the web-based mechanism shall be promptly forwarded to the developer/owner of the voluntary consensus standard for that entity's consideration. Comments shall be accompanied by a request for a response from the developer/owner of the voluntary consensus standard.

B. **Evaluation Mechanisms.** Once endorsed, voluntary consensus standards shall be continuously evaluated and updated, as appropriate. The measure steward has the responsibility to maintain the currency and relevance of the measure. NQF is responsible for maintenance of the NQF endorsement. Ad hoc reviews will be conducted when measure review is needed due to a change in evidence or associated safety concerns. The timing of the review will be determined by the urgency of the request and the relation of the measure change to safety or unintended consequences. Further recommendations for measure maintenance will be reviewed by the CSAC.