

A primary objective of the National Quality Forum (NQF) is to develop consensus among health-care's diverse stakeholders about standardized indicators that can be used to measure and report on healthcare quality. Such indicators or measures may relate to structure, process, or outcome.

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, quality indicators, 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 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,*

¹Public Law 104-113, The National Technology Transfer and Advancement Act

²OMB Circular A-119 (1998)

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.

The NQF is the primary entity to promulgate a comprehensive measurement framework and to endorse specific measures/measure sets that could be used to gauge healthcare performance.

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 or indicator set(s), set(s) of practices, etc., and explanatory text and/or other

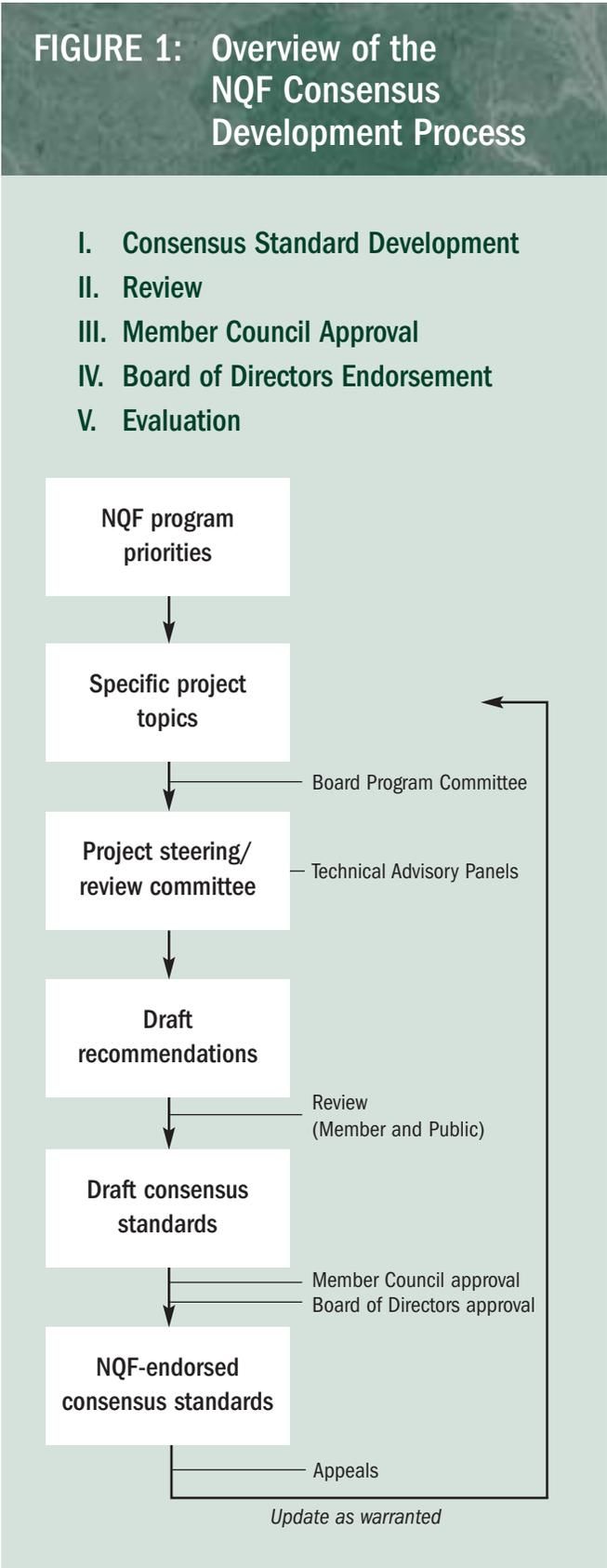
supporting documentation, such as guidelines for reporting the standards.

In addition to endorsing voluntary consensus standards, the 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.

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. Review
- III. Member Council Approval
- IV. Board of Directors Endorsement
- V. Evaluation



A schematic depicting the consensus development process is presented in figure 1.

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 three levels of review and approval: 1) by a project’s Steering or Review Committee (SC/RC) and its Technical Advisory Panels (TAPs), as applicable; 2) by the NQF Member Councils and the general public; and 3) by the NQF Board of Directors (BoD). Additional review will be sought from the NQF’s Strategic Advisory Council (SAC) and/or other entities, according to the specific issue or project.

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

³OMB 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.

Projects in any of these areas may be suggested by NQF members or Member Councils, NQF staff, the BoD, the NQF's SAC, or external entities. Proposed projects generally should be consistent with NQF priorities and 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). Issues relating primarily to specific diagnostic or therapeutic procedures, rarely-used technology, or specific professional groups will be viewed as having lower priority than those dealing with common conditions or common sites of care. Project topics should explicitly link to the conceptual framework for quality measurement developed by the Strategic Framework Board and endorsed by NQF.

In identifying areas needing measurement and reporting standardization, NQF staff will monitor relevant healthcare trends and other relevant activities. It is anticipated that both the Member Councils and the SAC will also provide important opportunities for discussing potential areas of focus. In addition, the development and discussion of coherent program priorities for standardization will be engaged in at the NQF Annual Meetings, Membership Meetings, and meetings of the BoD. To the extent possible, NQF staff will pursue project

Consensus, defined by the Office of Management and Budget (OMB) as general agreement, but not necessarily unanimity, includes a process for attempting to resolve objections by interested parties.
(OMB Circular No. A-119)

funding opportunities and develop project concepts that are consistent with these priorities.

Project Review. A Program Committee of the Board of Directors exists to provide advice on program initiation issues and to provide prospective review of proposed major projects.

The Program Committee

will also advise on whether a Steering Committee (SC) or a Review Committee (RC) should be appointed to help guide a project. This Committee will consist of the elected representatives to the BoD of each of the four Member Councils, up to two additional Directors, and the President/CEO, who shall chair the Committee.

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. Information in this regard shall be available to Members and the public on request.

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

I. Consensus Standard Development

A. **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.

B. Steering Committees/Review

Committees. The work of most projects will be guided and overseen by a Steering Committee (SC) or a Review Committee (RC). Among other things, the general purpose of the SC/RC will be to work with NQF staff to develop specific project plans, provide advice about the subject, ensure input is obtained from relevant stakeholders, and review draft products. SC/RC members will reflect the diversity of the four major healthcare stakeholder groups (as represented by the Member Councils), as well as specific perspectives of particular importance to the project topic. In general, RCs shall be used to guide and oversee minor projects or updating activities, as determined by the Program Committee and approved by the Board for expedited handling, as described further in section II.D. SC/RC members will be selected in accordance with NQF's "Policy for Establishing Steering Committees for Consensus Development Projects" (attachment 1) and based on their expertise and potential for contribution to the project and the need for input from particular perspectives. SC/RC 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/RCs 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.

C. Technical Advisory Panels. In addition to SCs, projects shall be advised and informed by technical advisory panels (TAPs), as needed. The technical advisors will be selected primarily for their technical expertise and experience. TAPs may be charged with reviewing the evidence supporting potential performance measures, quality indicators, preferred practices, etc., and completing other technical reviews, as required. TAP members also will participate in more general product reviews.

D. Strategic Advisory Council. Input from the SAC will be sought, depending on the issue and clarity of linkage to the NQF's quality measurement framework. When significant SAC input is expected, a SAC liaison to the project may be designated.

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 or indicators, 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/RC before being made available

for public comment or Member Council or Board of Directors review. The SC will be expected to achieve consensus (as defined in OMB Circular A-119) before advancing a document for further NQF action.

Any draft product approved by a SC/RC shall include an appendix or attachment entitled "Commentary." In this Commentary, members of the SC/RC may express dissenting views or other perspectives not covered in the report. Likewise, members of the SC/RC 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 web site once the project is approved. A list of SC/RC members, a schedule of public meetings, a list of TAP members, any draft products for public review, and other relevant materials will also be posted on the web site as they become available. These materials will be available to the public. 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

The NQF was not given the responsibility for implementing measures.

This challenge was envisioned as being the responsibility of others through voluntary market-based approaches, regulatory/ accrediting processes, or combinations thereof.

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/RC 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/RC recommends further consideration, at which time all information available to the SC/RC 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/RC does not recommend the item(s) advance.

II. Review

A. **Pre-Voting Member Review.** Draft products containing recommendations that have been approved by the project SC/RC will be provided to each member organization for review and comment. Comments by members must be submitted directly to NQF. Comments that do not indicate a copy to the Member Council Chair will be forwarded by NQF staff to the Member Council Chair and/ or the Chair will be advised of its availability. All comments received by NQF in writing within stated deadlines will be

posted on the NQF web site and formally considered before voting commences.

Each Member Council is responsible for establishing its own procedures for communicating the Council's aggregate comments and position on the candidate standard. Member Council leadership will be primarily responsible for representing the views of each Council to the Board of Directors. 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.

An advance copy of the draft product may also be provided to the SAC and BoD, if deemed appropriate by NQF management.

In general, NQF member organizations and the Member Councils 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 Member Councils, 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/RC or BoD. NQF staff will review and summarize the comments from these sources and forward the comments (or summaries, as appropriate) to the Member Councils for consideration in their deliberations. All public comments received by the deadline for such comments will be available to the Member Councils before voting on the document commences.

C. Consideration of Member and Other Comments. A summary or verbatim copies of comments will be subsequently made available to the public on the NQF web site. Following the review period, staff may revise the draft standard based on comments received. The revised draft will be recirculated to members and the Member Councils and SC/RC for additional review or for voting. Other input – e.g., from TAPs – 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 – a review period of 30 calendar days shall be assumed, but may be reduced to 14 calendar days if recommended by the Program Committee and approved by the BoD. Similarly, 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.⁴ Board approval of expedited consideration should be obtained prior to commencing such a review.

A RC shall oversee work conducted under an expedited process. RC appointments shall be governed by NQF's "Policy for Establishing Steering Committees for Consensus Development Projects," except the nominations process for RCs shall be 14 calendar days.

The following criteria shall be considered by the BoD in approving an expedited process:⁵

1. a recommendation from the Program Committee of the BoD to use the expedited process.

NQF members should take ownership of the products and, working individually and collectively, identify a full range of strategies for implementation.

2. the extent to which the measure set has been sufficiently tested, is already in wide use, and/or whether the set has been formally vetted by, at minimum, member organization(s) from at least two Member Councils.
3. whether the scope of the project/measure set is relatively narrow.

III. Member Council Approval

- 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, and staff will confirm that ballots have been delivered. 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 and manner in which the ballot should be returned to NQF. Prior to the close of the voting period, NQF will contact non-respondents at least once. The minimum period for voting in the first round shall be 30 calendar days.

Only ballots cast in the affirmative or negative shall be tallied to determine the outcome of a vote within a Member Council. The affirmative or negative

⁴This provision may be deployed only after the BoD establishes criteria and/or evaluation thresholds for what constitutes a significant revision to a previously NQF-endorsed voluntary consensus standard.

⁵Approved by the BoD on April 23, 2002.

action receiving the highest number of votes shall prevail. For purposes of balloting on consensus products, a quorum of fifty percent shall not be required. As illustrative examples, consider the following: Council X is composed of 50 member organizations. Five ballots are returned yay, 3 ballots are returned nay, 10 ballots abstain, and 32 members do not vote. The Council shall be recorded as voting yay. Alternatively, Council Y is composed of 60 members. Five ballots are returned yay, 6 ballots are returned nay, 30 ballots abstain, and 19 members do not vote. The Council shall be recorded as nay.

- B. Votes with Proposed Modifications and/or Conditions.** Suggested modifications to draft standards that are proposed during the voting process must be sent in writing to the NQF offices. All such comments received at least seven calendar days before the voting deadline will be posted on the members' only portion of the web site prior to the close of the voting period; comments received less than seven days will be posted as soon as possible, but might not be available until after the voting deadline.

If a member organization wishes to change its vote based on comments received within the voting period, it may direct a written request to the Corporation Secretary. The requested change must be forwarded by the same signatory as the initial ballot and must be filed prior to the voting deadline or

within five calendar days of being notified by the NQF of the results of a vote, whichever is later.

In the event a change of vote is requested within the voting period, the record shall duly note both the original and the change, and the changed vote shall be incorporated into the final tally. Requests to change a vote after the voting deadline shall be limited only to the specific ballot option(s) – i.e., no additional comments shall be considered. Post-deadline changes will be duly noted in the record of the vote, but will not be used for purposes of the decision to forward the document to the BoD.

- C. Approval by Member Councils.** If a candidate standard/set of standards or other draft product is approved by all four Member Councils without revision after the first round of voting, then it shall be advanced to the BoD for consideration. If, after the first round of voting, one or more Member Councils has been unable to obtain agreement by a majority of members of that Council casting affirmative or negative votes, NQF staff will attempt to resolve the matter and submit a revised draft to all Councils for further consideration and a second vote – i.e., an effort will be made to obtain majority approval on all Member Councils.
- D. Second Round of Member Voting.** If majority agreement, as specified in III.A., across all Councils is not achieved after two rounds of voting, but has been achieved by at least two Councils, then

the document will be forwarded to the BoD accompanied by a summary of the major issues and points of disagreement among the Member Councils. In the event of a second round of voting, the time allowed for the second round will be at least 14 calendar days, but shall not exceed 21 calendar days.

IV. Board of Directors Endorsement

A. Board of Directors Endorsement of Voluntary Consensus Standards. All products approved by the NQF membership under the CDP will be submitted to the BoD for review and action – i.e., endorsement or re-consideration. NQF endorsement of voluntary consensus standards will not be considered to have been achieved until the candidate standards/draft products have been approved by consensus of the NQF membership and endorsed by the BoD. To the extent possible, an opportunity will be provided for members to comment during the BoD’s deliberations prior to the BoD taking action.

B. Notification of Board Decisions.

Notice of all BoD decisions for consensus products will be disseminated to members and also will be made available to the public on the NQF web site and by other vehicles (e.g., press releases and other public announcements), as appropriate, within 30 days of BoD action. Information in this regard also will be routinely promulgated in other NQF

information dissemination instruments (e.g., newsletters).

C. 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 Board. 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 Steering Committee, TAPs, and/or other sources, as appropriate, before a recommendation is provided to the BoD. The BoD shall be notified of all appeals and act on them within 60 days of receiving the appeals package and staff recommendation 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 refreshed, as

appropriate. Recommendations for updating measures and other standards may be accomplished by several mechanisms, including the following:

1. **Standing Working Groups.** To accommodate technical changes to NQF-endorsed voluntary consensus standards that occur as a result of a developer/owner's continuous refinement process and/or that occur (or should occur) in response to significant scientific developments, NQF shall establish standing Working Groups, as appropriate, for the purpose of recommending standard(s) changes to the BoD regarding whether:
 - a. a change adopted by the developer/owner is technically called for and of a nature so as to *not* require re-consideration of the standard through the CDP but only notification of interested parties;
 - b. a change adopted by the developer/owner is technically called for, but makes the voluntary consensus standard sufficiently different so as to require re-consideration of the standard through the CDP; or
 - c. scientific developments warrant a change to the specifications that the developer/owner declines to incorporate, thereby making the voluntary consensus standard a candidate for BoD withdrawal of NQF endorsement.

The periodicity of Working Group reviews shall be on an as-needed basis.

2. **NQF Staff.** NQF staff shall compile standard-specific implementation issues received through the web-based form and other means, including but not limited to implementation outcomes and/or pilot testing by NQF members or non-members, and shall regularly summarize these matters in a report to the BoD, which shall also be posted on the web site once reviewed by the BoD. Comments originating from a developer/owner and/or arising as a result of NQF forwarding external comment shall also be included.
3. **Routine Review.** Regardless of whether feedback is received through the web-based tool, NQF staff will undertake a formal review of voluntary consensus standard-specific implementation issues for NQF endorsed products within 12 to 24 months of endorsement. Such a review may be incorporated with the work of the BoD's Advisory Committee on Implementation Strategy and Priorities, if appropriate.

NQF

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