National Health Systems Resource Centre
New Delhi

Standard Development and Review Process Policy

Division Name: Certification Unit

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National Health Systems Resource Centre
New Delhi

Policy Amendment Sheet

Removed	Inserted/Replace		Amendment Date	Nature of Change	Signature from approval authority
Page No	Page No	Rev No			
NA	3	1	23 March 2022	Revision of roles and responsibilities of QPS and Certification Unit as per Operational Guidelines for Improving Quality in Public Health Facilities 2021	
NA	12	1	23 March 2022	Inclusion of clinical subgroups as part of Standard Development Committee	
NA	13	1	23 March 2022	Inclusion of process for conduct of virtual meeting with SDC members	
NA	3,9,10,21,24,26	1	23 March 2022	Replacing QI division with Quality and Patient Safety (QPS) division as per Office Order vide 2 January 2022	
25			23 March 2022	Amendment to Declaration of Interest form	

Removed	Inserted/Replace		Amendment Date	Nature of Change	Signature from approval authority
Page no	Page No	Rev No			
	6	2	23 March 2024	Inclusion of "Standard Review Committee" in Section 1.4 "For whom this document is intended"	
	7	2	23 March 2024	Schedule for revision of standards is revised to 4 years	
	8	2	23 March 2024	Inclusion of "Ratification by Central Quality Supervisory Committee(CQSC)" in Table 2 : Key Steps for developing new standards , Stage 2.4	
	11	2	23 March 2024	Inclusion of " Preparation of Budget Estimates" in Roles and Responsibility of Project Coordinator	
	11	2	23 March 2024	Deletion of "Certification unit, NHSRC", from member details of project coordinator	
	16	2	23 March 2024	Characteristics of Quality Standards has been updated with inclusion of "Patient Safety"	
	23	2	23rd March 2024	Time Frame to constitute the Standard revision committee for revision of standards is revised from 6 months to 1 year before the scheduled revision	
	24	2	23rd March 2024	Addition of Transition Plan for facilities for revised standards	

Table of Contents

Background

National Health Systems Resource Centre (NHSRC) is a technical support body for the Ministry of Health and Family Welfare (MoHFW) with the mandate to assist in policy and norms development to strengthen public health system and facilitate creative and innovative solutions to continually improve its processes, people and management practices.

Quality and Patient Safety (QPS) Division at NHSRC is focused to improve the health status through supporting in establishment of institutional framework under Quality Assurance and implementation of quality standards in healthcare institutions. While, Certification Unit at NHSRC define standards for service delivery and patient safety and undertake the external assessments with the help of empanelled external assessors.

This policy document defines the principles and processes for development, review and revision of quality standards by NHSRC on behalf of Ministry of Health and Family Welfare.

Scope of this document-

A standards development and review process encompass defined set of activities required to be followed to formulate quality standards and their subsequent revision based on feedback and environmental scanning. This document ensures that process of developing and revising quality standards is a evidence based and multidisciplinary approach, involving input from all stakeholders to minimize the risk of bias.

National Health Systems Resource Centre (NHSRC) has been mandated to develop and maintain the quality standards on for public health facilities and program. Request for developing standards usually come from Ministry of Health and Family Welfare (MoHFW) through one of its Program Divisions. Additionally, request could also be received from state health departments and specialized health agencies. NHSRC may also develop standards Suo moto based on the requirement of Indian public health system. NHSRC develops these products under ambit of National Quality Assurance Standards. National Quality Assurance Standards (NQAS) are utilized to improve and certify quality of health care services in public healthcare facilities as well as public health programs.

NHSRC has a defined framework for standard development and review process through this policy document. This document covers following relevant processes

1. Process for development of new standards
2. Process taking and evaluating feedback from stakeholders
3. Process of environment scanning for new evidence and requirements
4. Process for revision of standards based on inputs.
5. Process for testing and evaluation of draft new and revised standard
6. Process for expert consultation and review of draft standards

7. Process for approval, commissioning and dissemination of new and revised standards

The Standard Development Process policy ensures that the development and publication of quality standards and associated products follows the international benchmarks and best practices as well as meet the requirement of public healthcare facilities in India.

Standard development committee, subcommittees, and working groups conduct their activities by adhering to the policies and following the processes set forth in these *Standards Development and Review process Policy.*

1. Policy Description

1.1 Background

A standard defines specifications and procedures that augment reliability and consistency of product and services being provided. It forms the building block for quality service delivery by establishing requirements those are evidence based the, universally accepted and adopted. Standards are important for continuous improvement of existing systems; met the environmental and implementation challenges and ultimately influence the way it works and improve.

The standard development and review process is a cyclic process which ensures the adherence to a standardized set of activities. It includes need of customers/end users based on environment analysis, involvement of multiple stakeholders and their collective feedback for fair and equitable processes to ascertain that high-quality standards meeting the set benchmarks.

1.2 Policy Statement

The standard development and review process policy envisages its goal of development of quality standards that are credible, current and compliant with national/international benchmarks. This would be achieved through ensuring evidence based, participatory, impartial and iterative approach in its development process. The standards would assimilate effective, relevant, current and evidence-based research, international best practices and experience of knowledge experts. This would ensure that standards are implementable and have positive impact on people' health.

1.3 Principles of Quality Standard Development and review Process

Following are the guiding principles engrained in standard development and review process

(1) Evidence based – Standards development process and its final products are grounded in scientific evidence and global best practices.

(2) Transparency: All the processes and procedures under which standards are developed and reviewed are broadly available & accessible to all interested parties so that participants /stakeholders understand the mechanism of engagement and decision making.

(3) Effectiveness and Relevance: Ensures standards are relevant and effectively respond to current professional and regulatory requirements.

(4) Openness: Ensures steps are taken to provide opportunity to all relevant stakeholders to participate and encourage interested groups (Users, professionals, technical groups etc.) to provide feedback.

(5) Coherence: Encourage coordination with programme divisions, state governments, other ministries and associations interested or involved in standard development

(6) Consensus: Relevant feedback from all participants and stakeholders are considered and addressed during development and finalization of standards and decisions are made based on majority

1.4 For whom is this document intended?

This document is intended for:

- any technical division or staff member involved in formulating quality standards
- members of a standard development committee (SDC)
- members of standard review committee
- members of a standard external review committee; and
- anyone interested in understanding how NHSRC develops quality standards.

2. Overview of Standard development and review process

The standard development and review process could be triggered by on of following three ways

I. Request for developing new standards
II. Scheduled periodic revision of standards
III. Focused revision of standards because new evidence or major programmatic update

Table 1: Characteristics of the streams of standards developed by NHSRC

Type of Stream	Purpose	Scope	Trigger	Turnaround time
New standards	To develop new standards for a health care facility, services or disease condition	Comprehensive	Request from Government, Governing board of NHSRC or any other institutional Stakeholders	6 to 18 Months based on scope
Scheduled revision of standards	To review and revise the existing standards according at planned schedule based on feedback and environmental screening	Comprehensive	As per the standards revision plan. After every four years	6 months
Focused revision of standards	To revise specific sections of standards due to new evidence or recommendations	Focused	Request from program divisions of Ministry due to change in national guidelines/policies/programs New evidence or recommendation from reputed agencies / experts	3 to 6 months

2.2 Developing new standards: NHSRC primarily develops standards for Ministry of Health and Family Welfare on request. Additionally, request could also be received from state health departments and specialized health agencies. NHSRC may also develop standards Suo moto based on the requirement of Indian public health system.

Standards development process usually take between 6 and 18 months to complete, depending on their scope, and are be prepared after a wide consultation on their needs, context, existing norms, scope and rationale. These be supported by the technical inputs from experts and finalized after meetings of the Standard Development Committee (SDC). A draft set of standards must be reviewed externally (via feedback) within a specified time limit. Following table illustrates the key steps to be followed for developing new quality standards.

Table 2: Key steps for developing new standards

Stage	Steps
PLANNING (2.1)	Request received from MoHFW/Program divisions/ State health department /Governing body of NHSRC/ others institutional stakeholders to develop programme specific quality standards
	Need Assessment and feasibility evaluation
	Develop of interim critical pathway and project timelines
	Constitution of Standard Development Committee (SDC)
	Organize first meeting of standard development committee.
	Finalize of the scope of the standards and project timelines
DEVELOPMENT (2.2)	Environment scan of defined scope
	Search and review recommendations against defined scope
	Define the overarching structure and layout of standards
	Review and updating of draft standards
FIELD TESTING (2.3)	Developing pilot design and decide who will conduct field testing
	Selection of testing sites
	Defining field testing design
	Collection of data
	Data analysis of field tested data
REVIEW AND APPROVAL (2.4)	Review final version of standards & submit for approval to Standard development committee The standard are further submitted for ratification by Central Quality Supervisory Committee(CQSC)
PUBLISHING & COMMISSIONING (2.5)	Writing editing & proof reading
	Layout & Printing
	Dissemination of standards

2.1 Planning Stage

The more planning and thought that goes into standard development at the beginning, the more efficient the entire process will be and the better final product. The principles of good project management and participatory approach apply to standard development as well. NHSRC's role

as technical secretariat is to ensure adequate resource planning, neutrality of development process and engaging best experts for the task.

2.1.1 Receipt of request

The planning process triggers with receipt of request for developing new standards at NHSRC. Usually these requests originate from the Ministry of Health and Family Welfare (MoHFW) through one of its Programme divisions. Though request may be received from other Ministries, state health departments or any other institutional stakeholders. All such request is channeled through Executive Director, NHSRC and sent to Advisor, Quality and Patient Safety for appraisal and need assessment.

2.1.2 Need assessment and feasibility evaluation

Standards development is time-consuming and expensive projects. Before venturing into development NHSRC conducts quick assessment of need of such standards. A quick evaluation is also done for feasibility of developing such standards in terms of availability resources and experts for requested task. Decision is taken based on cost/benefit principle. If need of developing such standards is urgent NHSRC may reallocate resources and initiate the work. Alternatively, such request could be deferred for next work plan of NHSRC.
Following is a list of criteria which can be used to decide the need before framing the quality standards:

1. Policy Significance:
• Not relevant to any specified government health policy • Relevant to specified government health policies
2. Coverage of standards
• Covering all geographical areas or population • Covering majority of population • Covering limited cohort or geographical area
3. Leading to significant morbidity or disability (for Clinical standards)
• Causes low or no mortality or disability • Causes intermediate mortality or disability • Causes high mortality or disability
4. Availability of standards/resource material
• Updated standards/resource material exist • Some standards/resource material (not up to date) available • No standards/resource material exists
5. Estimated resource impact
• Expected to have significant resource/cost implications • Expected to be cost neutral/low cost • Expected to be cost saving
6. Timelines or urgency
• No time issues/urgency

- Need to be timely
- Is urgent/pressing need

Based on the outcome of need assessment a proposal is submitted to ED NHSRC for approval of project and resource allocation.

2.1.3 **Interim critical pathway and project timelines –** Once internal approval is received; Advisor Quality and Patient Safety appoints one of the team members as project coordinator. Project coordinator prepares a roadmap for standards development process, key milestones and timelines. Project coordinator also prepare budget estimates and ad-hoc list of experts, those will be contacted for being expert members of standard development committee. If required external consultant may be hired to provide technical and/or managerial support for the standard development process.

2.1.4 **Constitution of Standard Development Committee**

The entire process of standard development lies with the various stakeholders ranging from healthcare professionals, government officials, domain and knowledge experts, programme officers, methodology experts and end-users who with their mutual coordination, discussions, support in various capacities, deliver evidence-based quality standards. NHSRC maintains and regularly updates a list of experts for various clinical, programs and health systems domains. Project coordinator in consultation with Advisor, QPS prepares a list expert to be contacted for being member of Standards Development Committee. Project coordinator also consults the respective program/ technical division in Ministry of Health and Family Welfare for potential experts.

Invitation letters is sent by the NHSRC to all potential experts. Upon acceptance from invitees their names are included in final list of members, subject to declaration of interest by the member.

2.1.4.1 Composition of Standard Development Committee

The Standard Development Committee comprised of technical experts whose central task is to develop evidence-based quality standards under consideration. The SDC members are multidisciplinary and composed of subject matter experts, and other professionals, experts from a nursing background, knowledge partners, public health specialists, representatives from NGOs & professional bodies and health economists. The aim is to have a diverse group. The strength of the group is usually 10-15 members though may vary based on the scope and stakeholders involved.

Other than this, representatives from states, hospital administration, technical coordinator from Quality and Patient Safety division of NHSRC, may also be included in the SDC. Gender representations should also be considered avoiding biases in gender-related issues. Standard Development Committee is supported by a technical secretariat comprised of selected team

members from Certification Unit at NHSRC. This secretariat support SDC in organizing meetings, literature search and preparing zero draft of standards.

Table 3: Roles and Responsibilities of the SDC:

Member	Key tasks
Chairperson	• Selection of chairperson resides with members of the committee • Convene and organizes meetings • Finalize the scope of standards in consultation with members of SDC • Delegate review the current available research, evidence and internationally recognized guidelines • If the available requirements do not cover the Indian context, define the contextualized requirements • Facilitate expert consensus on recommendations/ requirements are not available in Indian context • Make consensus with members to finalize the standards • Submit the draft to Government for consultation in public domain/other interested parties • Submit the final document for approval
Project Coordinator (Certification Unit, NHSRC)	• Oversees and facilitates the whole process and organizes SDC meeting as and when required • Prepares the critical pathway with defined milestones and timelines and responsible person for various activities • Provides administrative, technical and liaising support to the SDC members • Collect and assess disclosures of interest and mange conflicts • Oversee publication and dissemination of the quality standards • If required, more than one technical coordinator can be taken from NHSRC • Preparation of the Budget Estimates
Healthcare Professional Members/domain and knowledge experts/technical expert/Health System Specialist	• Review the current available research, evidence and internationally recognized guidelines and discuss with team members whether they can be adopted entirely, individual recommendations from one or more selected guidelines could be adapted/adopted. Suggest new wording in case adaption is required • Review standards which are developed whether they are according to the defined criteria or not • Review whether all the key issues in the scope are addressed in the standards • Review the standards from a public health perspective and provide insights on the feasibility of the standards

	• Guide the team in revision of standards if new guidelines or changes made in existing health policy and programmes • Guide in predicting the implementation issue with the standards by end-users • Contribute constructively to meetings and have good communication and team-working skills; this should include a commitment to the needs of patients and their families • Need-based clinical sub-groups (like Medicine, Surgery, Obstetrics & Gynaecology, Pathology, Microbiology, Anaesthesia, Paediatricians, Ophthalmology, ENT, Psychiatrist, etc.) could be constituted for standard revision
Representatives from NGOs/ Professional bodies	• Professional bodies like Indian Medical Association (IMA) and representatives from NGOs may also be involved as they work in close association with community
End-users	• All committees must have at least 2 end-users' members with experience or knowledge of issues • It could be a service users or frontline services providers

2.1.4.2 Conflict of Interest

A conflict of interest is an important potential source of bias and results in diminished credibility in the development of the standards. "A conflict of interest is any interest that may **affect** or reasonably be **perceived to affect** the expert's **objectivity & independence** in providing advice".

All committee members and anyone who gives direct input into the standard development process must declare any potential conflicts of interest. The format used for obtaining declaration of interest from the committee members is attached as ***Annexure 1***.

2.1.5 Convening the first meeting of SDC -

The committee is multidisciplinary, and its members bring with them different beliefs, values, and experience, also they come from different boundaries. Getting them together for a face-to-face meeting, therefore entails a lot of resources in terms of time and money. So, it is essential to plan the meeting beforehand so that all members are present in the first meeting for a vis-à-vis interaction and it is fruitful in all aspects. Each member should have an equal opportunity to contribute in the development of quality standards. In the meeting, finalize the scope, prepare the work plan and define timelines & responsible person for various activities. All the proceedings of the meeting should be duly recorded and shared with all the members of the group within a set time limit. Afterwards, other meetings can be convened by inviting experts via online platform (if required). Efforts should be made to minimise the number of meetings through matriculas planning and shifting some the meeting on digital platforms.

Virtual Meetings

COVID-19 crisis has challenged the traditional mode of convening SDC member's meeting and open avenues to an online/virtual mode of meetings. This platform could be used not only in such pandemic crisis but also could be used in other exceptional circumstances. Logistic arrangements will be ensured by the project coordinator as per below mentioned requirements:

- The coordinator will arrange a web meeting link and share it with all the committee members at least one week prior to schedule
- Arrangement of Audio-Visual system for the members to attend the training
- Pre-installation of requisite IT platform like Cisco WebEx, Zoom, Google meet, Microsoft, etc.
- Check the AV system for its appropriateness 30 mins before the start of the meeting
- Initiate meeting 15 mins before the actual time-schedule and the same may be communicated to the members too
- Share the meeting agenda, resource material, draft standards in advance (soft and hard copy, if feasible) with the members, at least one week prior the meeting
- Share the Declaration of Interest form (soft copy-Annexure A) with the members and collection of scanned & signed copy from the members by the project coordinator before the meeting
- Keep a record of the attendance and attach as an annexure in the Minutes of Meeting
- Recording of the meeting after due permission of Chairperson and SDC members

2.1.6 Define scope

Scoping is the process of defining what the standards will and will not cover. To establish the scope, you need to determine:

- the area of practice, service delivery or policy to which the standards applies.
- the level of achievement to requirements – basic, moderate, advance
- the level of healthcare facility for implementation for example primary, secondary, or tertiary care.
- the interventions approach or exposures of interest (i.e. the priority topics).
- the individuals and/or populations (including subpopulations) that the standards are intended to affect; and
- the important outcomes − both benefits and harms—that may result.

The process of scoping will establish the focus for the defined range of services, as well as the key questions that will govern the search for evidence to cover the range of services. This process should ensure that the standards are designed as per the level of facility to which they will be implemented, adequately focused, and capable of being executed by the whole healthcare facility or a specific service within the allocated time frame and with the available resources.

Steps for Scoping of the standards

Below mentioned the steps in developing the scope:

Draft the potential scope– Draft a potential scope for the proposed programme specific standard. The scope is drafted by the Chairperson of the standard development committee in consultation with other members of the committee.

Identify the range of services- This determines the breadth and depth of the work. As it is not feasible to include everything. Concentrate on the areas which need interventions, critical to quality and feasible. Focus on areas where inequity, controversy or uncertainty exist. For example, policies required to strengthen the management of Bio-medical waste, any legal requirements, adherence with clinical guidelines and protocols, etc.

Search the literature– At this stage, a preliminary search of the literature should be undertaken to identify relevant information, including existing guidelines and systematic reviews, economic evaluations, etc.

Review and Finalize– Once the scope is finalized, a summary of the scope should be circulated to the SDC for comments. If any changes are suggested by the members, they should be discussed and applied. Once there is consensus among the members, the scope is finalized.

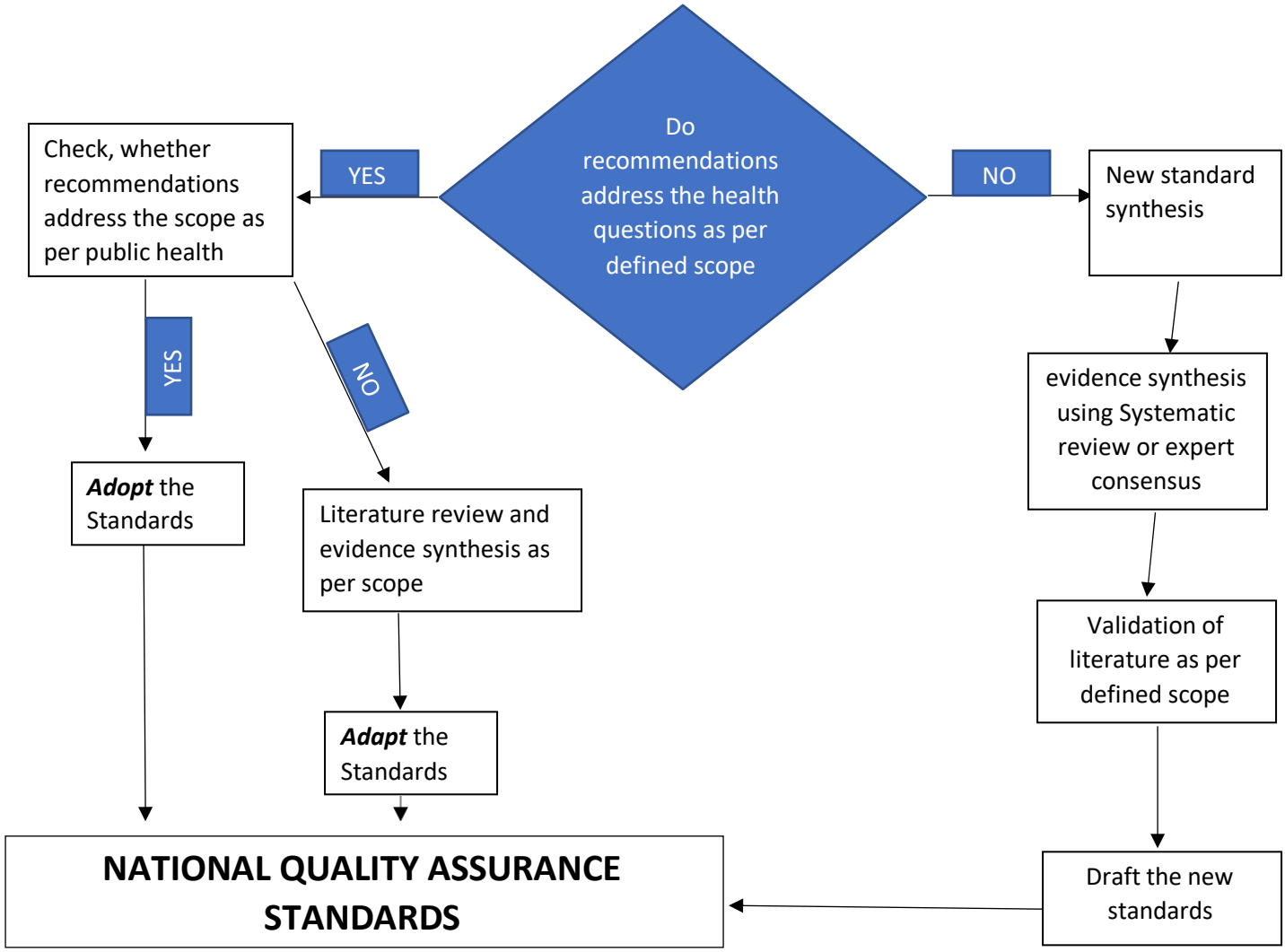
2.2 DEVELOPMENT STAGE

2.2.1 Environmental scan for defined scope

Based on the defined scope, a search strategy is developed and followed. Inclusion and exclusion criteria, the year of development and language should be determined beforehand. Afterwards, a preliminary assessment of key domains covered by standards the identified review literature should be carried out to eliminate those that are clearly not relevant to the Indian public health system.

2.2.2 Search and review recommendations against defined scope

After the searched literature/guidelines are validated, the next step is to examine the recommendations in the guideline with respect to the domain of the scope. This is a decision-making stage, where it is needed to choose one of the below mentioned choices:



Flow Chart :1 Selection Process for development of National Quality Assurance Standards

Decision making occurs around the following three options:

I. Adopt: If the available literature contains a recommendation which have our specified scope as per the Indian context; in such a case take the recommendations/standards as verbatim, without any changes from the available literature

II. Adapt: This entails making some changes to the recommendations, it could be a minor edit to ensure compatibility with the country setting or adding precision to the verbatim to clarify the recommendation.

III. New standard synthesis - When the existing available standards do not cover the range of services which are specified in the scope and are not appropriate in Indian Context because of specific demographic factors or resource constraints. And when specialty specific standards are not available, in such scenarios new standards will be formulated by fresh evidence synthesis and/or expert consensus.

*****_As relevant, mix of all three approach can be used in standard development process as per scope_

2.2.3 **Define the overarching structure and layout of standards** –

- Standard Development Committee need to dwell on how the standards need to be grouped, arranged, and presented in the documents. It's also critical to define the subcomponents of standards that will be helpful in explaining and measuring the performance against standards in objective way. For the purpose of consistency and scalability all efforts should be made to keep terminology and layout coherent with existing NQAS standards. This pertains to arrangement of requirements in Area of concern, Standards and Measurable Elements. The number and content of each component will vary based on scope of standards being developed. The structure and layout of standards should be evolved using structured tools such as affinity diagram.
- After scoping and defining the overarching structure , the next step in standard development is to do an extensive literature review and web-based search to formulate quality standards which includes evidence-based recommendations on quality, research literature from established journals, international quality standards for accreditation, technical and operational guidelines by the Ministry of Health, various professional bodies, etc.
- Technical secretariat from NHSRC assists in review of all the information from the extensive literature review and present to Standard Development Committee for drafting of quality standards.

Characteristics of the Quality Standards

- Standards statement need to be clear and unambiguous
- Should be measurable, specific, concise, and patient centered.
- Standards need to be comprehensive and capture aspects of quality assurance and Patient Safety
- Standards need to be contextual to fulfill needs of public health facilities or local context

- Standards need to be evidence based and operational & technical aspect of subject need to be factored in
- Standards need to be user friendly and avoid using abbreviations or jargons in the statement
- Standards need to be contemporary and require incorporating relevant best practices
- Each standard should typically cover one concept. Minimise the overlaps. Though wherever applicable linkages are shown.

Language Considerations- Statements of standard requirements are written in declarative format avoiding use of words such as should or will. Standard are written in patient centric language though in some cases statements may be with perspective of care providers. Wherever possible jargon should be avoided.

2.2.4 Review and updating draft standards

2.2.4.1 Internal Review

After the draft standards are in place, the next step will be the internal consensus for harmonization of scope, recommendations and characteristics of quality standards through a wider consultation meeting involving all members from SDC and a technical team of NHSRC.

Comments received from the internal reviewers should be considered and discussed by the Standard Development Committee, followed by responding to the comments. Changes must be made with the agreement of the development committee unanimously by convening another meeting (if required, for which date should be agreed in advance to ensure that all group members can attend).

2.2.4.2 External Review

Post the internal review, the final draft is put up for public consultation/online review. Similarly, it is shared with potential users (health facility), professional, service provider and service users, government and other stakeholders for their technical feedback/comments. The comments received in a stipulated time frame are analysed by the Standard Development Committee.

2.3 FIELD TESTING

Before finalization of the standards, it is important to evaluate the effectiveness of individual quality standards to ensure that each standard is relevant, understandable, measurable, beneficial, and achievable (RUMBA) to its end users. This exercise focuses on whether end-users believe the quality standard is “fit for purpose”; whether target audiences are aware of quality standards that are relevant to their health context; and whether quality standards are embedded in current local settings. If not, SDC plans, prioritizes, and works toward closing this gap.

2.3.1 Who will conduct: An external research organization in the given field or NHSRC itself can perform the pilot testing of the toolkit, based on the resource availability and recommendation of SDC. If, pilot testing is conducted by NHSRC itself; an expert appraisal from external research

organization of developed questionnaires using is performed for identifying the validity of field-testing tools. The team of field-testing team should comprise of certified external assessors and research methodologists.

2.3.2 Field testing sites:

Field testing sites are selected in consultation with standard development committee and external research organization to draw representative sample as per the scope and reach of the standards. Following are normative considerations for selecting the field testing sites –

1. Geographic perspective – Select sites to ensure proportional representation of regions, division, districts of country or state where standards are applicable. Also consider representation of rural and urban areas.
2. Health care facility perspective - If standards are applicable on a range of health care facilities based on size and scope of services, ensure field testing sites have representative samples of these cohorts
3. Health system perspective- Select field testing sites to ensure equal representative samples from categories of states based on their health system development level. Eg. EAG (Empowered Action Group) and Non EAG states.
4. Continuum of care perspective- If standards are applicable to the services spreading beyond healthcare facilities, include peripheral sites too for field testing. eg. Outreach sessions (immunization) or Ambulances (Emergency Medical Services)
5. Ownership Perspective – If standards are supposed to be applicable on not for profit or private healthcare facilities, include their representation in field testing sites.

The total number of sites for field testing should be judiciously balanced taking the above-mentioned criteria and resources and time available for the project.

2.3.3 Field testing design: Field testing design is primarily focus in testing standards on following five parameters

Relevant- Standards are relevant and context specific
for healthcare services / programs as per defined scope. This could ascertain through measuring face validity of standards though feedback from experts and end user on quantitative scale as well as qualitative feedback.

Understandable – Standards and assessment tools are comprehendible, clear, and easy to use specially for end users such as assessors and implementors at health care facilities. This include comparing feedback from multiple users for consistency interpretation of standards and ease of using assessment tools in field testing.

Measurable – Standards and its measurable elements are objective, precise, and verifiable with assessment methods such as staff interview and record review. Assessment tools have a consistent scoring system and outcome of assessment is truly

representative of quality of care of services being measured. This could be assessed though statistical tools for testing the reliability of the standards as well as feedback from assessors on their hand on experience on collecting information to compare with requirements of standards

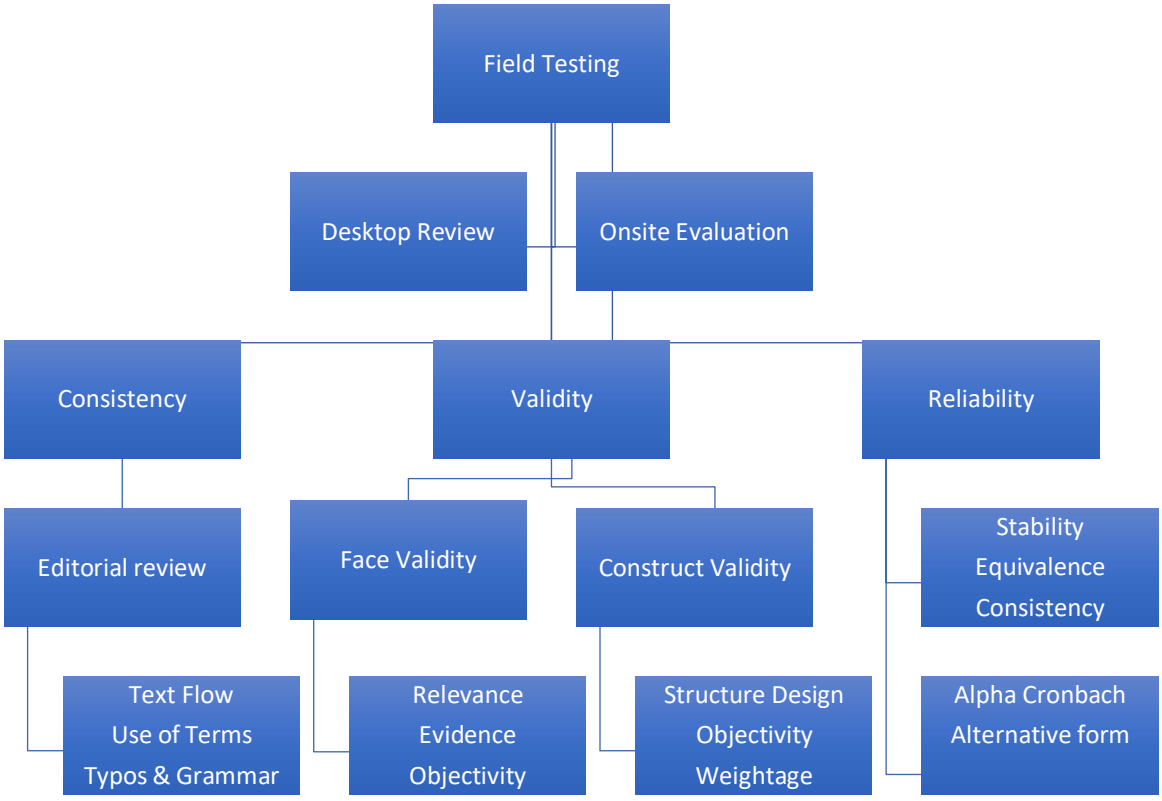
Beneficial – The requirements in standards are critical to quality and trigger improvement in services being measured. Different component is adequately represented in measurement system so to incentivise compliance and proportionally reflected in obtained scores. This attribute is ensured through rigorous evidence tracing of the requirements of the standards as well as obtaining feedback from end users.

Achievable – Standards should be optimally aspirational, though requirements need to be moderated based on ground reality, resource availability and overall goals and objectives of quality certification of program. Achievability of standards could be assessed though comparing the obtained scores in field testing internally as well as comparing their equivalence with other established quality standards

2.3.4 Collecting data: A standard research methodology should be developed to facilitate accurate and reliable data collection, and it should be done via validated sampling technique and statistical tool. Data can be collected using any of the following validated technique:

- Interviews (Open-ended or close-ended questionnaire)
- Focus group discussions
- Obtaining scores in assessment at field testing sites

2.3.5 Data Analysis: Once the raw data has been collected with any of the collecting tool, data can be entered in a statistical software for data cleaning, data mining and data analysis to test the accuracy and reliability of data e.g. by using **Cronbach's alpha reliability coefficient.** In addition, qualitative analysis of feedback received from field testing analyzed. Result of the pilot and field testing can be interpreted/summarized and informed to modify the draft standards. Following diagram illustrate filed testing approaches for quality standards



This exercise focuses on whether end-users believe the quality standard is "fit for purpose"; whether target audiences are aware of quality standards that are relevant to their health context; and whether quality standards are embedded in current local settings. If not, SDC plans, prioritizes, and works toward closing this gap.

2.4 REVIEW AND APPROVAL

Afterwards, the development committee will take the final call for inclusion and exclusion of received comments and findings received from field testing evaluation report. As per the decision taken by the SDC, all the inputs are deployed to update the standard document. The final document is approved by Standard Development Committee in after reaching the consensus. The proceedings of consensus and approval is recorded in the minutes and kept by NHRSC secretariat for further reference.

Standard Development Committee is the technical body to approve the standards. The standards are further submitted for ratification of Central Quality Supervisory Committee (CQSC) appointed by Ministry of Health and Family Welfare, in its next possible meeting.

2.5. PUBLISHING & COMMISIONING

The final standards, post approval from the SDC prepared for publication. This phase of quality standard development is critical. To reach the target audience timely, the standard guidebook publication requires careful planning.

2.5.1 Writing, Editing and Proofreading

To avoid multiple authors, identify a editor early in the process to guarantee quality, consistency and timely completion of the task. This should be followed by the final editing and proofreading of the final document.

2.5.2 Layout and Printing

Once an edited and carefully checked document that has received full clearance from the standard development committee and NHSRC, send the document for layout. Layout could include cover design, publication number, Copywrite and a barcode (if required).

2.5.3 Disseminating the standards

Dissemination involves making standards accessible, advertising their availability, and distributing them widely through various platforms:

Online publication: Quality Standards can appear on the Internet in a variety of formats. At a mini-mum, a web ready portable document format (PDF)–a smaller file size than the PDFs produced for print—that is easier to download and navigate. Depending on the length of the standard document and its intended audience, additional materials, both electronic and printed, can be shared with the potential users.

Archiving: At the time of publication, the division would ensure that archiving requirements are met. Division would send the final electronic file of their document to the NHSRC website for inclusion in the Web Repository for further reference. If printed copies are produced, one should also be sent for inclusion in the print collection of the respective division. In case of revision made in the existing standards/guidelines, documents which are no longer valid would be archived/saved in the NHSRC server cloud.

Other forms of dissemination: A variety of approaches should be considered. These can include an official launch, a workshop and/or conference, an announcement on the NHSRC website, and endorsement by stakeholders and interest groups. A dissemination letter issued by MoHFW/ Head of Quality and Patient Safety Division addressing to state program officers, end-users, and other stakeholders about release/revision of standards and stating to develop an implementation plan for health facilities.

3. Updating quality standards

The quality standards are revised and updated in two ways

- Scheduled review and update of the standards
- Focused review and update of standards

3.1 Scheduled review and update-

The scheduled review of quality standards is defined during its commissioning and usually four years. A team member of the Certification Unit is assigned as the 'focal point' for managing feedback and updating standards. The responsibility of this person is to –

I. Conduct the periodic environmental scans for change in evidence, guidelines, terminology or programmatic components within scope of the quality standards.
II. Collate and analyse the proactive and reactive feedback from end users and experts
III. Hand hold the process of expert consultation and updating of standards.

3.1.1 Environmental Scan-

A systemic environmental scan is conducted by the nodal officer every six to twelve months. The literature review includes –

I. New technical guidance issued by Ministry of Health and Family Welfare or any other national technical agencies such as Indian Council of Medical Research (ICMR) and National Centre for Disease Control (NCDC)
II. Newly introduced programs, service modalities and operational guidelines for delivery public health programs
III. New or updated guidance by reputed international organizations such as WHO and ISQUA
IV. New or updated requirements from standard setting agencies such and Bureau of Indian Standards (BIS),
V. New or updated research evidence that may alter the recommendation/ requirements within the scope of the standards under review
VI. Change in the requirements by licencing and regulatory agencies such as Clinical Establishment Council, National Health Authority (NHA), Central Pollution Control Board (CPCB) and Insurance Regulatory and Development Authority of India
VII. Change in the definitions and terminology of programs, concepts, diseases conditions and practices
VIII. Redundant, decommissioned or contraindicated practice recommendations
IX. Any other new development that may require re-scoping or repositioning of standards

3.1.2 Feedback from users-

Following mechanism has been placed to obtain continues feedback from users –

I. Following assessment, feedback on standards and assessment tool is requested from assessors on prescribed format. This a continuous process, where feedback is taken from all external assessors after completion of external assessor. This feedback is managed is by certification manager at NHSRC. Data is collated and shared with 'Focal point for standards on quarterly basis.
II. End user feedback is obtained though periodic survey (annually) from healthcare facilities, state and district quality assurance officers, Patient groups, Quality improvement consultants and officials in National and state Ministry of Health
The format for feedback is provided in **Annexure 2**
III. Feedback on user satisfaction on rating scale is taken annually from internal and external assessors. While feedback from external assessors is collected by certification manager, the feedback from internal assessors and facility level users is collected through state quality assurance unit.
The format for feedback on rating scale is provided in **Annexure 3**

3.1.3 Revision process The feedback is analysed by 'focal point' for specific standards to identify performance gap and suggest informed recommendations.

A Standard Revision Committee (SRC)is constituted for scheduled revision of standards at least one year in advance before the revision due date. The members of SRC could be pooled from Standard Development Committee (SDC) originally developed the standards if available. Additional members could be invited considering revised scope of standards or expertise need because of change in evidence or program modalities. The structure, task delegation and process of interactions remain same as earlier illustrated for Standard Development Committee (SDC) The Certification Unit ' focal point' share the outcome of periodic environmental scans as well as user feedback, illustrating gaps and action required. The expert committee deliberate on the revision areas and recommendations in a face to face meetings. The minutes of meeting are recorded, and decision taken for revisions are deployed in the standards. The approval, publishing and dissemination process of revised standards remains same as illustrated earlier for new standards in this document.

3.2 Focused revision of standards -

In certain situations, there may be immediate requirement of updating the standards, that could not be postponed till scheduled revision. Some of these scenarios may be-

I. Substantial modification in program or technical guidance that may impose risk of obsolesce to current standards
II. Major shift in the recommendation of a current practice, that may have serious consequence on safety or patient outcome.

3.2.1 Who can raise the request: Request raised by Quality and Patient Safety division or Program division of Ministry of health and family welfare.

3.2.2 How to address the request: All request communicated to Advisor/Head of Quality and Patient Safety Division NHSRC.

3.2.3 Process to be followed: After reviewing, Advisor QPS initiate the process of according to the laid down principles for quality standard development and revision. Subsequently if request needs to be addressed, Advisor (QPS) will decide whether an expert consultation with technical members required or not considering the fact that development of new recommendations may have emerged to complement or supersede previous recommendations.

3.2.4 Action taken: Here following actions can be taken-

If new evidence in terms of new recommendations, revised policies, health programmes and regulatory requirements are published. This new evidence should always be seen in the context of the existing quality standards supporting the previous recommendations and thus should be aid in updating quality standards. Any updated recommendation that necessitates revision of quality standards will be reviewed by the NHSRC. Updates that add new evidence without changing the standard neither require external review or review from technical experts nor requires approval from the Ministry of Health and Family Welfare. However, in case if the topic or new evidence requisites addition/deletion of existing quality standards than under such circumstances, due consultation with technical experts followed by review, may be advisable.

3.2.5 Transition of Standards: Current Edition to Revised Edition

Following the revision of quality standards, it is imperative to implement these new standards in all facilities. The transition from current to revised new standards must be smooth and uninterrupted. Ensure that already existing activities are not affected. The duration of this transition period shall be limited to a maximum of one year. Over the course of this one-year transition, state assessors & other stakeholders will be sensitized, informed and trained on the new standards through various modes like

- Capacity Building through Internal Assessors cum Service Provider Training,
- Orientation and Refresher Trainings
- Workshops
- Guiding Documents and Guidelines

This structured approach ensures compliance with updated standards, minimizes disruptions, and enhances health outcomes.

A transition plan in form of notification will be uploaded on the NHSRC website and advisory will be issued to all the states in this regard

Below is the implementation and migration plan for Revised National Quality Assurance Standards.

S.No.	National Certification Stages	Applicable Edition		Transition time
		Fresh Application	**Recertification Application**	
1.	New Applications for which state assessment was conducted on previous edition	On previous edition	On previous edition	3 years from launch of revised edition
2.	New Applications which already have uploaded the documents on portal	On previous edition	On previous edition	
3.	New Applications after 6 months of launch of new edition	On new edition	On new edition	
4.	Recertification Application	On new edition	On new edition	

Annexure

FORM FOR DECLARATION OF INTEREST

I, (please print your name)_____, do not have an actual, potential, or perceived, conflict of interest in respect of the work of the Standard Development Committee.

If you have declared an actual, potential, or perceived conflict of interest above, please describe the nature and extent of that conflict of interest in the following space provided. Please attach one or more additional pages if required.
Description (if you have no interests in this category, state 'None')
Other than disclosed above, do you have any relationships or interests that could compromise, or be perceived to compromise, your ability to exercise your judgment or decision-making objectively, independently and without bias as a member of the Collaborative Committee.
Description (if you have no interests in this category, state 'None')

Signature: ……

Name: …… **Date:** ……

Annexure 2

Users/Assessors/Stakeholders Feedback on National Quality Assurance Standards (NQAS)

Dear Sir/Ma'am,

Being an eminent assessor and implementer of quality standards within the health facility, your feedback will be valuable to make standards more relevant, understandable, measurable and achievable.

Non-disclosure of information

Respecting the privacy of our Users/Assessors/Stakeholders, all information will be kept confidential and not be disclosed or discussed with anyone. The provided information will be utilized in strengthening of quality standards to improve health outcomes.

1. Type of workplace organization

☐Government organization

☐Non-government organization

☐Development Partners

☐Academic Institutions

☐Research organization

☐Any other

2. There is need to revise National Quality Assurance Standards to meet compliance with current programme guidelines and advancements in health system. Please state your level of agreement with this statement:

☐Strongly disagree

☐Disagree

☐Neither disagree nor agree

☐Agree

☐Strongly agree

If you have selected "Disagree" or "Strongly disagree", please provide details:

3. The wording of the Standards is clear and unambiguous. Please state your level of agreement with this statement:

☐Strongly disagree

☐Disagree

☐Neither disagree nor agree

☐Agree

☐Strongly agree

Please provide details of any standard which you consider to be unclear or ambiguous

4. There is clear measurable elements and checkpoints for these standards that makes them easy to use. Please state your level of agreement with this statement:

☐Strongly disagree

☐Disagree

☐Neither disagree nor agree

☐Agree

☐Strongly agree

If you have selected "Disagree" or "Strongly disagree", please provide details:

5. There is clear means of verification for these measurable elements and checkpoints that makes them easy to understand. Please state your level of agreement with this statement:

☐Strongly disagree

☐Disagree

☐Neither disagree nor agree

☐Agree

☐Strongly agree

If you have selected "Disagree" or "Strongly disagree", please provide details:

6. Rate objectivity of current assessment tool (Mark one box)

Very Subjective	**1**	**2**	**3**	**4**	**5**	**Very Objective**
	☐	☐	☐	☐	☐	

7. Upon review of the Standards, should any measurable elements be included or excluded

8. Mention factual error, outdated checkpoints, grammatical errors, if any:

9. Do you want to add any new program, guidelines, protocols in the existing NQAS assessment toolkit

10. Please provide any further feedback about the standards which you feel is relevant:

11. What changes can you suggest for improvising the standards/assessment toolkit:

***Optional:**

Name: **Place:** **Date:**

Email address:

Annexure 3

Feedback on Assessment Tool (Checklists) for NQAS

Dear Sir/Madam,

Please Provide your valuable feedback to make tools more user friendly, relevant and objective.

*Required

1. Email address *

_____

2. Rate objectivity of current assessment tool
   Mark any one oval

	1	2	3	4	5	
Very Subjective	◯	◯	◯	◯	◯	Very Objective

3. Rate the ease of using the current Assessment Tool s (checklist)
   Mark any one oval

	1	2	3	4	5	
Very easy	◯	◯	◯	◯	◯	Too Complex

4. What is your overall impression about the length of Checklists?
   Mark any one oval

- ◯ *Too lengthy to Manage*
- ◯ *Lengthy but Manageable*
- ◯ *Optimal, Just Perfect*
- ◯ *Short*
- ◯ *Other: Specify* _____

5. What should be the optimal number of checkpoints in a Departmental Checklist
   Mark any one oval

   ◯ *Less than 100*
   ◯ *100-150*
   ◯ *151-200*
   ◯ *201-250*
   ◯ *251-300*
   ◯ *More than 300*
   ◯ *Other: Specify* _____

6. What weight age you would like to give to Area of Concern A (Service Provision)?
   Mark any one oval

   1 2 3 4 5 6 7 8 9 10
   Less Important ◯◯◯◯◯◯◯◯◯◯ Most Important

7. What weight age you would like to give to Area of Concern B (Patient Rights)?
   Mark any one oval

   1 2 3 4 5 6 7 8 9 10
   Less Important ◯◯◯◯◯◯◯◯◯◯ Most Important

8. What weight age you would like to give to Area of Concern C (Input)?
   Mark any one oval

   1 2 3 4 5 6 7 8 9 10
   Less Important ◯◯◯◯◯◯◯◯◯◯ Most Important

9. What weight age you would like to give to Area of Concern D (Support Services)?
   Mark any one oval

1 2 3 4 5 6 7 8 9 10

Less Important ⬭⬭⬭⬭⬭⬭⬭⬭⬭⬭ Most Important

10. What weight age you would like to give to Area of Concern E (Clinical Services)?
Mark any one oval

1 2 3 4 5 6 7 8 9 10

Less Important ⬭⬭⬭⬭⬭⬭⬭⬭⬭⬭ Most Important

11. What weight age you would like to give to Area of Concern F (Infection Control)?
Mark any one oval

1 2 3 4 5 6 7 8 9 10

Less Important ⬭⬭⬭⬭⬭⬭⬭⬭⬭⬭ Most Important

12. What weight age you would like to give to Area of Concern G (Quality Management)?
Mark any one oval

1 2 3 4 5 6 7 8 9 10

Less Important ⬭⬭⬭⬭⬭⬭⬭⬭⬭⬭ Most Important

13. What weight age you would like to give to Area of Concern H (Outcome)?
Mark any one oval

1 2 3 4 5 6 7 8 9 10

Less Important ⬭⬭⬭⬭⬭⬭⬭⬭⬭⬭ Most Important

14. Which one would be the most user friendly medium for using checklists?
Mark any one oval

⬭ *Paper Checklist*
⬭ *Mobile application*
⬭ *Tablet application*

◯ *Other: Specify*

15. Do you want to delete any standards or measurable or Departmental Checklists from existing system?

_____

16. Mention Factual Error, Outdated information, grammatical error if any

_____

17. Do you want to add any new program, guidelines, protocols, Quality issues in the existing standards?

_____

18. Any other suggestion for improvement of Quality Measurement System.

_____