HEALTHCARE QUALITY
ACCREDITATION
COUNCIL INTERNATIONAL

HQACI Standards Development and Revision Methodology

MAN-002-V1

Approved by the General Director

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29/05/2025

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HQACI

Version History

Version	Date	Description	Approved by
1.0	29/05/2025	First official version	General Director, ORD-003/2025, 29/05/2025

1. Purpose and Scope

1.1. This document establishes the structured, transparent, and evidence-informed methodology used by HQACI for the development, review, revision, and maintenance of healthcare accreditation standards. It integrates both policy direction and procedural requirements to ensure methodological consistency, scientific credibility, and audit readiness.

1.2. HQACI maintains a structured and transparent methodology for the development, review, and revision of healthcare accreditation standards.

1.3. The methodology ensures that standards are evidence-informed, relevant to the healthcare context, and suitable for external evaluation of quality and patient safety.

1.4. The methodology applies to:

a) development of new standards.

b) periodic review of existing standards.

c) major and minor revisions.

d) withdrawal or consolidation of standards where applicable.

2. Governance and Responsibilities

2.1. Overall accountability for standards development rests with the designated HQACI Standards Development Committee (or equivalent authority).

2.2. The committee:

a) oversees the development lifecycle

b) ensures methodological rigor

c) approves draft and final versions

d) monitors implementation feedback

e) recommends updates based on emerging risks and evidence

2.3. The committee operates under formally approved Terms of Reference, including defined membership criteria, quorum requirements, conflict-of-interest management, and decision-making procedures.

2.4. HQACI ensures that clear responsibility is assigned for standards development activities. Functions may be performed by one or more designated persons or groups, as appropriate. Typical responsibilities include:

- **Standards Development Committe**e - strategic oversight and final approval
- **Technical drafting** - preparation of draft standards and evidence review
- Methodological oversight - ensuring consistency of approach
- Stakeholder coordination - organization of consultation activities
- Document control - version control and record traceability

2.5. Multidisciplinary expertise is ensured through participation of clinical, quality, and health system experts as appropriate.

3. Standards Development Lifecycle

3.1. HQACI applies a defined lifecycle approach consisting of the following stages:

a) Needs identification and scoping

b) Evidence and benchmark review

c) Draft development

d) Stakeholder consultation

e) Technical and expert review

f) Pilot testing or field validation (where feasible)

g) Formal approval and publication

h) Post-implementation monitoring

i) Scheduled periodic review

3.2. Each stage is documented and retained as controlled information.

3.3. For each development or major revision cycle, HQACI maintains a documented project plan specifying timelines, responsible persons, and key deliverables. Minimum stage outputs typically include:

a) scoping note or concept paper

b) evidence review summary

c) draft standards with measurable elements

d) stakeholder comment matrix

e) expert review report

f) pilot summary (where applicable)

g) formal approval record

4. Evidence-Informed Approach

4.1. Standards are developed using an evidence-informed methodology that may include:

a) international accreditation frameworks

b) peer-reviewed literature

c) ISQua, WHO, and other global guidance

d) regulatory requirements

e) patient safety data and trends

f) expert consensus

4.2. Evidence sources are periodically reviewed to ensure continued relevance and scientific credibility.

4.3. Where evidence is limited or emerging, HQACI documents the rationale for expert-consensus-based requirements and flags such standards for prioritized future review.

5. Stakeholder Engagement and Consultation

5.1. HQACI incorporates structured stakeholder input during standards development and major revisions.

5.2. Stakeholders may include, as applicable:

a) healthcare professionals

b) healthcare managers

c) patient or service user representatives

d) quality and safety experts

e) regulatory or policy representatives

f) academic experts

5.3. Feedback is analyzed, documented, and considered in the finalization of standards.

5.4. For major standards development or revision, HQACI conducts structured consultation for a defined period. All comments are logged, analyzed, and dispositioned using a formal comment matrix.

5.5. HQACI maintains records of consultation methods (surveys, focus groups, public comment) and produces summary feedback reports where appropriate.

6. Expert and Technical Review

6.1. Draft standards undergo independent technical and expert review prior to approval.

6.2. The review process evaluates:

a) clarity and measurability

b) alignment with quality and patient safety principles

c) feasibility of implementation

d) consistency across the standards set

e) potential unintended risks

6.3. Identified issues are addressed and documented before final approval.

6.4. Reviewers are required to declare conflicts of interest prior to participation, and such declarations are retained as controlled records.

7. Pilot Testing and Field Validation

7.1. Where feasible, HQACI conducts pilot testing or limited field validation to assess:

a) usability

b) clarity of measurable elements

c) implementation burden

d) interpretability by surveyors and organizations

7.2. Findings from pilot activities inform refinement prior to full release.

7.3. Any decision to waive pilot testing is formally justified and approved by the Standards Development Committee.

8. Version Control and Change Management

8.1. HQACI maintains formal version control for all standards.

8.2. Each edition includes:

a) version number

b) publication date

c) summary of key changes

d) rationale for major revisions

8.3. Minor updates are tracked through controlled document management processes.

8.4. HQACI classifies revisions using defined criteria:

a) **Major revision** - changes affecting intent, scope, measurable elements, scoring logic, or introducing new requirements; requires full lifecycle review and committee approval.

b) **Minor revision** - editorial or clarifying updates that do not change intent; managed through document control processes.

8.5. Superseded versions are archived but remain retrievable to ensure full audit trail and historical traceability.

9. Post-Implementation Monitoring and Review Cycle

9.1. Standards are reviewed at planned intervals not exceeding 5 (five) years, or earlier when triggered by:

a) significant regulatory change

b) emerging patient safety risks

c) major evidence updates

d) stakeholder feedback

e) system performance data

9.2. The review process follows the same structured methodology described above.

9.3. HQACI maintains a forward review schedule and monitoring dashboard to track upcoming reviews and trigger-based revisions.

10. Transparency and Accessibility

10.1. Information about the current standards and relevant guidance is made publicly available through appropriate HQACI communication channels. Access to the full standards documentation is provided to organisations participating in the HQACI accreditation program.

10.2. HQACI ensures that users of the standards have access to:

a) current version

b) effective dates

c) guidance for interpretation (where applicable)

10.3. Where appropriate, HQACI publishes a high-level summary of major revisions to support user awareness and implementation readiness.

10.4. HQACI accreditation standards are developed for use within the HQACI accreditation program and are not authorised for use by independent external assessment organisations unless formally licensed by HQACI through a specific written agreement.

10.5. Any authorised external use of the standards requires a formal written agreement specifying the scope of use, governance arrangements, intellectual property protection, and mechanisms for feedback and review.

11. Methodology Review and Continuous Improvement

11.1. HQACI periodically reviews this Standards Development and Revision Methodology at intervals not exceeding five (5) years, or earlier if significant changes in international accreditation practice, regulatory expectations, or organizational strategy occur. Improvement actions are documented and implemented through the document control process.