

ASF-GOV-001

Standards Development and Revision Methodology

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Approved by	Prof. Giorgi Pkhakadze, MD, MPH, PhD — President, Accréditation Sans Frontières
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Applies to	All ASF standards development and revision activities
Replaces	N/A — first edition

Version History

Version	Date	Description	Approved by
V0.1	2026-10-20	Initial draft	—
V1.0	2026-11-03	Standards Committee review	Standards Development Committee
V2.0	2026-11-17	Final approved and published	Prof. G. Pkhakadze, ASF President

1. Purpose and Scope

1.1 This document establishes the structured, transparent, and evidence-informed methodology used by Accréditation Sans Frontières (ASF) 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 ASF maintains a structured and transparent methodology for the development, review, and revision of all healthcare accreditation standards. This methodology is consistently applied across all standards development activities.

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 This 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 ASF Standards Development Committee.

2.2 The Committee:

- a) oversees the full standards development lifecycle
- b) ensures methodological rigour and scientific credibility
- c) approves draft and final versions of all standards
- d) monitors post-implementation feedback
- e) recommends updates based on emerging evidence, regulatory changes, or operational experience

2.3 The Committee operates under formally approved Terms of Reference (ASF-GOV-002) defining membership criteria, quorum requirements, conflict-of-interest management procedures, and decision-making rules.

2.4 ASF ensures that clear responsibility is assigned for all standards development activities. Responsibilities are distributed as follows:

Function	Responsibility
Standards Development Committee	Strategic oversight and formal final approval
Technical drafting	Preparation of draft standards and evidence review
Methodological oversight	Ensuring consistency of approach across all standards
Stakeholder coordination	Organisation of consultation and feedback activities
Document control	Version control, records traceability, archive management

2.5 Multidisciplinary expertise is ensured through the participation of clinical, quality improvement, health management, and patient safety experts, as appropriate to the standards domain being developed.

3. Standards Development Lifecycle

3.1 ASF 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 independent 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, ensuring a full audit trail from initial concept to published standard.

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

- a) international accreditation frameworks and globally recognised good practice
- b) peer-reviewed scientific and clinical literature
- c) WHO, ISQua EEA, and other international guidance documents
- d) applicable regulatory requirements across jurisdictions in which ASF operates
- e) patient safety data, adverse event data, and quality improvement evidence
- f) expert consensus where evidence is limited or emerging

4.2 Evidence sources are reviewed at each revision cycle to ensure continued relevance and scientific credibility.

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

5. Stakeholder Engagement and Consultation

5.1 ASF incorporates structured stakeholder input during standards development and at each major revision.

5.2 Stakeholders engaged in consultation may include, as applicable:

- a) healthcare professionals (clinical and non-clinical)
- b) healthcare managers and quality officers
- c) patient or service user representatives
- d) quality and patient safety experts
- e) regulatory or policy representatives
- f) academic and research experts
- g) international accreditation bodies and peer organisations

5.3 All feedback received during consultation is analysed, documented in a formal comment matrix, and considered in the finalisation of standards. Decisions to accept, modify, or reject comments are recorded with rationale.

5.4 For major standards development or revision, ASF conducts structured consultation for a defined period, with all comments logged, analysed, and dispositioned. Summary feedback reports are produced where appropriate.

5.5 ASF maintains records of consultation methods used (written submissions, focus groups, pilot participant feedback) and retains these as controlled documents.

6. Expert and Technical Review

6.1 Draft standards undergo independent technical and expert review prior to submission to the Standards Development Committee for approval.

6.2 The review process evaluates:

- a) clarity and measurability of each standard element
- b) alignment with quality and patient safety principles
- c) feasibility of implementation across the range of facility types and settings
- d) consistency with other standards in the ASF portfolio
- e) potential unintended consequences or risks

6.3 Identified issues are addressed, documented, and resolved before the standard proceeds to formal approval.

6.4 All reviewers are required to declare any conflicts of interest prior to participation. Such declarations are retained as controlled records under the ASF Impartiality Policy (ASF-GOV-003).

7. Pilot Testing and Field Validation

7.1 Where feasible, ASF conducts pilot testing or limited field validation of new or substantially revised standards prior to full release. Pilot testing assesses:

- a) usability and practical application of standards in real facility settings
- b) clarity of measurable elements and scoring criteria

- c) implementation burden on assessed organisations
- d) interpretability and consistency of application by assessors

7.2 Findings from pilot activities are documented in a Pilot and Field Validation Summary (ASF-EV-003) and inform refinement of the standards prior to full release.

7.3 Any decision to waive pilot testing is formally justified and approved by the Standards Development Committee, with the rationale documented and retained.

ASF conducted pilot accreditation activities in 2021–2022 (four facilities under the Basic Standard) and launched a second cohort in February 2025 (seven facilities across multiple facility types). Findings from both cohorts informed subsequent standards refinements. A formal Pilot and Field Validation Summary is maintained as ASF-EV-003.

8. Version Control and Change Management

8.1 ASF maintains formal version control for all standards and governance documents. Every published version includes:

- a) version number in the format V[major].[minor]
- b) effective date
- c) summary of key changes from the previous version
- d) rationale for major revisions

8.2 Revisions are classified as follows:

- a) Major revision: changes affecting intent, scope, measurable elements, scoring logic, or introducing new requirements. Requires full lifecycle review and Standards Development Committee approval.
- b) Minor revision: editorial or clarifying updates that do not change intent. Managed through the document control process without full lifecycle review.

8.3 Superseded versions of all standards are archived but remain retrievable to ensure a full audit trail and historical traceability. The archive is maintained under ASF document control procedures.

8.4 ASF maintains a version history register listing all standards, their current version, effective date, and the nature of changes made at each revision.

9. Post-Implementation Monitoring and Review Cycle

9.1 Standards are reviewed at planned intervals not exceeding five (5) years from the effective date of the current version, or earlier when triggered by:

- a) significant regulatory change in any jurisdiction in which ASF operates
- b) emerging patient safety risks or adverse event evidence
- c) major updates to international evidence or guidance
- d) stakeholder feedback indicating a standard is unclear, unworkable, or insufficient
- e) system performance data from accreditation surveys

9.2 The review process follows the same structured methodology described in Section 3 above.

9.3 ASF maintains a forward review schedule identifying upcoming review dates for all standards. This schedule is reviewed annually by the Standards Development Committee and monitored by the designated document control function.

10. Transparency and Accessibility

10.1 The current version of all ASF accreditation standards and associated guidance documents is made publicly available through france-asf.fr. Access to the full standards documentation is provided to all organisations participating in the ASF accreditation programme.

10.2 ASF ensures that users of the standards have access to:

- a) the current published version of each standard
- b) effective dates and version numbering
- c) guidance for interpretation, where provided

10.3 Where a major revision has been made, ASF publishes a high-level summary of the key changes to support user awareness and implementation readiness.

10.4 ASF accreditation standards are developed for use within the ASF accreditation programme and are the intellectual property of Accréditation Sans Frontières. Use of ASF standards by external assessment organisations for independent external evaluation purposes is not authorised without a formal written agreement with ASF specifying the scope of use, governance arrangements, intellectual property protection, and mechanisms for feedback and review.

11. Methodology Review and Continuous Improvement

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

11.2 The next scheduled review of this document is November 2031, or earlier if triggered by the conditions described in Section 9.1.

Approved by

Name and title	Signature	Date
Prof. Giorgi Pkhakadze, MD, MPH, PhD President, Accréditation Sans Frontières		2026-11-17

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