ASF-GOV-001

Standards Development Methodology

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Applies to	All ASF standards development, revision, and withdrawal activities
Related documents	ASF-GOV-002 Standards Committee Terms of Reference ASF-GOV-003 Impartiality Policy ASF-EV-001 Standards Evidence Bibliography ASF-EV-002 Stakeholder Consultation Summary ASF-EV-003 Pilot and Field Validation Summary ASF-EV-004 ISQua EEA Crosswalk
Supersedes	ASF-GOV-001 V2.0 (2026-09-30)
Next review	September 2031, or earlier on trigger (see Section 11)

Version History

Version	Date	Nature of change	Approved by
V0.1	2024-11-10	Initial outline — internal working draft	—
V1.0	2025-01-20	First full draft published for Standards Committee review	Standards Development Committee
V2.0	2025-06-15	Revised following pilot survey feedback; 9-stage lifecycle added; criterion classification table expanded	Prof. G. Pkhakadze, ASF President
V3.0	2026-03-08	Full evidence annotation added; ISQua EEA alignment section; references expanded to 20	Standards Development Committee
V4.0	2026-09-30	Final pre-submission revision; approved for ISQua EEA application package	Prof. G. Pkhakadze, ASF President

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1. Purpose

1.1 This document establishes the methodology by which Accréditation Sans Frontières (ASF) develops, consults upon, approves, publishes, monitors, revises, and, where necessary, withdraws healthcare accreditation standards. The methodology is designed to ensure that all ASF standards are evidence-informed, stakeholder-tested, independently reviewed, transparently governed, and subject to continuous improvement.

1.2 The methodology described herein applies to:

- **(a)** development of new accreditation standards for any healthcare facility type;
- **(b)** major revision of existing standards (defined in Section 9);
- **(c)** minor revision and editorial maintenance;
- **(d)** suspension or withdrawal of standards no longer in use.

1.3 This document is reviewed at planned intervals not exceeding five years (see Section 11) and updated whenever a material change to ASF's standards development practice is adopted.

1.4 This methodology is aligned with the requirements of the ISQua International Accreditation Programme (IAP) — External Evaluation Association (EEA) Principles for Standards, 6th Edition, and in particular with Principles 1 (Evidence), 2 (Stakeholder Engagement), 3 (Transparency), and 5 (Review). It should be read alongside the ASF ISQua EEA Crosswalk (ASF-EV-004), which maps each clause of this document to the applicable EEA criterion.

2. Scope

2.1 This methodology governs all ASF healthcare accreditation standards currently in development or active use, including:

- **(a)** ASF Hospital Accreditation Standard (all editions and facility-size variants);
- **(b)** ASF Ambulatory Clinic Accreditation Standard (base and specialty endorsements);
- **(c)** ASF Long-Term Care Accreditation Standard;
- **(d)** ASF Primary Health Clinic Accreditation Standard;
- **(e)** ASF Fitness and Wellness Facility Accreditation Standard;
- **(f)** any further healthcare facility standards developed by ASF in the future.

2.2 The methodology does not cover the development of assessment tools (survey forms, decision worksheets) or surveyor training materials, which are governed by ASF-OPS-002 (Surveyor Competency Policy) and ASF-OPS-009 (Surveyor Training Programme) respectively.

3. Governance and Responsibilities

3.1 Overall accountability for ASF standards development rests with the ASF Standards Development Committee (SDC). The SDC operates under formally approved Terms of Reference (ASF-GOV-002) defining membership criteria, quorum requirements, conflict-of-interest management procedures, and decision-making rules.

3.2 The responsibilities assigned within the standards development process are as follows:

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Role	Responsibilities in standards development
ASF President	Ultimate approval authority for all ASF standards; appoints SDC members; approves this methodology and any substantive revisions to it.
Standards Development Committee (SDC)	Strategic oversight of the standards portfolio; review and approval of all draft and final standards; governance of the consultation process; conflict-of-interest oversight; approval of the evidence bibliography; annual review of the forward review schedule.
Technical Drafting Lead	Leads evidence review and initial drafting; manages technical revision; coordinates expert and stakeholder input; maintains the evidence bibliography (ASF-EV-001); prepares the draft consultation documents.
Stakeholder Coordination	Identifies and engages stakeholder groups; facilitates the formal consultation process; maintains the comment matrix; prepares the Stakeholder Consultation Summary (ASF-EV-002).
Independent Expert Reviewers	External experts engaged on an ad hoc basis to review draft standards for clinical accuracy, measurability, and implementation feasibility. Reviewers are not members of the SDC and declare all conflicts of interest.
Document Control	Version control of all controlled documents; archiving of superseded versions; publication on france-asf.fr; maintenance of the master document register.

3.3 All persons involved in standards development — including SDC members, technical drafters, expert reviewers, and stakeholder consultees who are also surveyors or applicants — are required to declare any conflict of interest in accordance with ASF-GOV-003 (Impartiality Policy). Declarations are retained as controlled records. Any person with a declared conflict is excluded from decisions on the relevant standards or clauses.

4. Standards Development Lifecycle

4.1 ASF applies a defined nine-stage lifecycle to all standards development activities. Each stage is documented and retained as controlled information to ensure a full audit trail from initial concept to published standard. The nine stages are:

1. **Stage 1 — Needs Identification and Scoping**
2. **Stage 2 — Evidence and Benchmark Review**
3. **Stage 3 — Draft Development**
4. **Stage 4 — Stakeholder Consultation**
5. **Stage 5 — Technical and Independent Expert Review**
6. **Stage 6 — Pilot Testing or Field Validation**
7. **Stage 7 — Formal Approval and Publication**
8. **Stage 8 — Post-Implementation Monitoring**
9. **Stage 9 — Scheduled Periodic Review**

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4.2 The nine stages are described in full in Sections 5 through 9 below.

4.3 For new standards, all nine stages are completed before publication. For major revisions, Stages 1–7 are repeated in full, unless the SDC formally determines in Stage 1 that certain stages are not applicable (for example, where evidence and pilot findings from the prior edition remain current). The rationale for any stage exemption is documented.

5. Evidence-Informed Approach (Stages 1 and 2)

5.1 Needs Identification and Scoping

5.1.1 The first stage of every standards development activity is a formal needs assessment, leading to a documented Scoping Brief approved by the SDC. The Scoping Brief defines:

- **(a)** the healthcare facility type and population to which the proposed standard applies;
- **(b)** the regulatory and policy context in ASF's principal operating jurisdictions;
- **(c)** the patient safety and quality improvement rationale for the standard;
- **(d)** an assessment of existing international standards addressing the same scope;
- **(e)** the intended relationship to existing ASF standards (complementary, superseding, or standalone);
- **(f)** the proposed timeline and resource requirements for the development cycle.

5.1.2 The Scoping Brief is approved by the SDC before evidence review or drafting commences. Approval constitutes formal initiation of the development programme for the standard in question.

5.2 Evidence and Benchmark Review

5.2.1 ASF applies an evidence-informed approach to standards development, drawing on the following source categories:

- **(a)** international healthcare accreditation standards — in particular the standards of ISQua member accreditation bodies, Accreditation Canada, the Joint Commission International (JCI), the Australian Council on Healthcare Standards (ACHS), and KFSH&RC (Saudi Arabia);
- **(b)** peer-reviewed scientific and clinical literature — systematic reviews, clinical guidelines, patient safety studies, and health systems research, sourced from PubMed/MEDLINE, Cochrane Library, WHO institutional repository, and comparable databases;
- **(c)** WHO normative guidance — including WHO patient safety guidelines, WHO surgical safety checklist, WHO hand hygiene guidelines, and WHO standards for improving quality of maternal and newborn care in health facilities;
- **(d)** ISQua guidance documents — including the ISQua EEA Principles for Standards, 6th Edition, and related ISQua publications on good practice in accreditation;
- **(e)** applicable regulatory requirements in ASF's principal operating jurisdictions — including EU healthcare regulation, Georgian healthcare legislation (Law of Georgia on Health Care), and relevant French regulatory standards;
- **(f)** patient safety surveillance data and adverse event analysis from national and international registries;
- **(g)** expert consensus — documented through structured consensus processes where peer-reviewed evidence is limited or emerging. Consensus-based requirements are identified as

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such in the evidence bibliography (ASF-EV-001) and flagged for prioritised review at the next standards revision cycle.

5.2.2 The evidence review produces an updated Standards Evidence Bibliography (ASF-EV-001) that records, for each standards chapter or domain: the principal evidence sources; the quality of evidence assessed against a structured framework; and any evidence gaps or areas of expert consensus.

5.2.3 Where significant evidence gaps are identified, this is noted in the Scoping Brief and the affected criteria are marked in the standard itself as requiring enhanced post-implementation monitoring (Stage 8).

> *ASF-EV-001 currently documents evidence supporting 30 key reference sources across all active ASF healthcare standards. The bibliography is updated at each major revision and is publicly available on france-asf.fr.*

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6. Draft Development (Stage 3)

6.1 Based on the approved Scoping Brief and the evidence review, the Technical Drafting Lead develops an initial draft standard following ASF's standard document architecture:

- **(a)** numbered chapters corresponding to the principal quality domains (e.g. governance, patient safety, clinical care, environment and facilities);
- **(b)** numbered criteria within each chapter, each stating a measurable requirement using the verb 'shall';
- **(c)** criteria classified according to the ASF four-tier system: Critical, Essential, Significant, and Developmental (see clause 6.2);
- **(e)** guidance notes providing implementation guidance and examples, presented separately from the normative requirements;
- **(f)** a cross-reference table mapping each criterion to its principal evidence source(s) in ASF-EV-001.

6.2 All ASF accreditation criteria are classified into four tiers, which determine their weighting in the accreditation scoring system:

Tier	Classification	Definition
Critical	*ASF Criterion Class 1 — CRITICAL*	Life-safety requirements whose absence creates an immediate risk to patient or staff life. Non-compliance is a barrier to accreditation.
Essential	*ASF Criterion Class 2 — ESSENTIAL*	Core quality requirements directly linked to patient safety or clinical effectiveness. Majority compliance is required for accreditation.
Significant	*ASF Criterion Class 3 — SIGNIFICANT*	Important quality improvement requirements. Performance is scored and contributes to the accreditation decision.
Developmental	*ASF Criterion Class 4 — DEVELOPMENTAL*	Good practice requirements reflecting the highest performance tier. Distinguished facilities may achieve these as evidence of organisational excellence.

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6.3 Draft standards are version-controlled from the first draft (V0.1) and stored in the ASF controlled document register. All drafts are clearly watermarked 'DRAFT — NOT FOR EXTERNAL USE' until approved for consultation under clause 7.1.

6.4 The initial draft is reviewed by the SDC at a scheduled meeting before proceeding to stakeholder consultation. The SDC may require revision before releasing the draft for consultation. The SDC's review comments and decisions are documented in the meeting minutes.

7. Stakeholder Consultation (Stage 4)

7.1 Stakeholder consultation is a mandatory stage in every new standards development cycle and every major revision. It ensures that ASF standards reflect the perspectives of those who will implement them, those who assess against them, and those whose care or outcomes they are intended to improve.

7.2 ASF's stakeholder consultation process engages the following principal stakeholder categories:

- **(a)** Healthcare facility managers and quality officers — those responsible for implementing the standards;
- **(b)** Clinical professionals — physicians, nurses, and allied health professionals whose practice areas are covered by the standard;
- **(c)** Patient and family representatives — reflecting patient-centred care principles embedded in the standards;
- **(d)** Healthcare regulatory bodies — to ensure alignment with mandatory legal requirements in relevant jurisdictions;
- **(e)** Academic and research experts — to validate the evidence base and assess clinical and scientific rigour;
- **(f)** ASF surveyors — to ensure practical assessability of each criterion;
- **(g)** Peer accreditation bodies — where collaboration or alignment agreements are in place.

7.3 The formal consultation period is open for a minimum of 28 calendar days. A longer period may be adopted where the scope of the standard is broad or where diverse international stakeholder groups are engaged.

7.4 ASF publishes the consultation draft on france-asf.fr and distributes it directly to identified stakeholders with a structured feedback form. The form requests stakeholders to indicate, for each section of the standard: whether the requirements are clear and measurable; whether they are evidence-based and appropriate; whether they are implementable in the relevant facility type; and any proposed amendments with supporting rationale.

7.5 All consultation responses are recorded in a Comment Matrix, which captures for each comment: the stakeholder category; the standard chapter and criterion number; the comment text; ASF's decision (accepted, accepted with modification, or rejected); and the rationale for the decision. The Comment Matrix is retained as a controlled record and summarised in the Stakeholder Consultation Summary (ASF-EV-002), which is published on france-asf.fr.

7.6 No material changes to ASF standards may be made between the close of consultation and publication without either a further consultation round or a documented decision by the SDC with recorded rationale.

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ASF has completed three formal stakeholder consultation rounds (2020–2021, 2021–2022, and 2024–2025) across its hospital and ambulatory standards portfolio. Round 3 (2024–2025) generated 47 substantive comments from 23 respondents across eight countries. All comments are documented in ASF-EV-002.

8. Expert Review and Pilot Testing (Stages 5 and 6)

8.1 Independent Expert Review

8.1.1 Following stakeholder consultation and revision, the revised draft is submitted for independent technical and expert review by at least one expert who was not involved in the drafting process and who has no conflict of interest with ASF (declared in accordance with ASF-GOV-003).

8.1.2 Expert review evaluates the draft standard against the following criteria:

- **(a)** Clinical and scientific accuracy — are the requirements consistent with current evidence and clinical practice?
- **(b)** Clarity and measurability — can each requirement be assessed consistently by a trained surveyor?
- **(c)** Feasibility — are the requirements implementable in the intended facility type at a proportionate cost and effort?
- **(d)** Completeness — are there significant quality or safety domains not addressed?
- **(e)** Consistency — are requirements internally consistent and non-contradictory across chapters?
- **(f)** Alignment — are the requirements aligned with international standards and with ASF's existing standards portfolio?

8.1.3 Expert review findings are provided in writing and documented in the SDC record. The SDC considers each finding at its next scheduled meeting and records its response.

8.2 Pilot Testing and Field Validation

8.2.1 Where practicable, ASF conducts a structured pilot or field validation exercise before full release of a new or substantially revised standard. The purpose of pilot testing is to validate that the standard can be applied consistently in practice, that criteria are assessable with the evidence types typically available in the target facility type, and that the survey process based on the standard is proportionate in duration and resource requirement.

8.2.2 Pilot testing involves a minimum of three participating facilities selected to represent the range of types, sizes, and resource settings for which the standard is intended. Participation is voluntary and findings are anonymised in the published Pilot and Field Validation Summary (ASF-EV-003).

8.2.3 Where operational constraints preclude full pilot testing before publication (for example, in the case of a new facility type with limited participating facilities available), ASF may proceed to publication subject to a formal post-implementation evaluation within 12 months of first use, the findings of which are documented and considered at the first scheduled review of the standard.

ASF conducted pilot accreditation activities across two cohorts: Cohort 1 (2021–2022, four facilities) validated the initial Hospital Standard; Cohort 2 (February 2025, seven facilities across Hospital, Ambulatory Clinic, and Long-Term Care types) generated findings incorporated into current editions. Full findings are documented in ASF-EV-003.

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9. Approval, Version Control, and Publication (Stage 7)

9.1 Following satisfactory completion of Stages 1–6 (or such stages as are applicable for the revision type), the Technical Drafting Lead submits a final draft to the SDC for formal approval. The submission package includes:

- **(a)** the final draft standard;
- **(b)** a summary of changes from the previous version (for revisions) or a full development history (for new standards);
- **(c)** the updated ASF-EV-001 (evidence bibliography);
- **(d)** the completed Comment Matrix and ASF-EV-002 (stakeholder consultation summary);
- **(e)** expert review findings and ASF responses;
- **(f)** pilot testing outcomes and ASF-EV-003 (pilot summary), where applicable;
- **(g)** a statement of alignment with ISQua EEA Principles, cross-referenced to ASF-EV-004.

9.2 Formal approval requires a quorum as defined in ASF-GOV-002 (SDC Terms of Reference). Approval is by majority decision of SDC members present; where a vote is tied, the SDC Chair casts a deciding vote. The outcome is recorded in SDC minutes retained as a controlled record.

9.3 Following SDC approval, the standard is submitted to the ASF President for final sign-off. The President's approval is documented on the cover page of the published standard and in the version history table.

9.4 Revision types are classified as follows:

- **(a)** Major revision — any change that affects the intent, scope, number, or measurable content of one or more criteria; any change that adds or removes an entire chapter; or any change to the criteria tier classification. Major revisions require completion of all stages of the lifecycle (subject to clause 4.3) and increment the version from V1.x to V2.0.
- **(b)** Minor revision — editorial corrections, clarification of intent without change to the requirement, correction of typographical or cross-referencing errors, or updates to referenced external documents without change to the criterion. Minor revisions may be approved by the SDC Chair without a full lifecycle review and increment the version as V1.1, V1.2, etc.

9.5 On publication, the full text of the current version is made available on france-asf.fr. Prior versions are archived and remain accessible to accredited organisations that were surveyed against an earlier edition.

10. Post-Implementation Monitoring (Stage 8)

10.1 Following publication, ASF actively monitors performance against each standard to identify criteria that are proving difficult to assess consistently, criteria where compliance rates indicate either unexpected difficulty or insufficient challenge, and emerging safety or quality evidence that may necessitate unplanned revision.

10.2 Post-implementation monitoring draws on:

- **(a)** survey findings data — distribution of scores and compliance rates by criterion, chapter, and facility type, compiled from each completed accreditation survey;

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(b) surveyor feedback — structured debrief from surveyors following each survey, including observations on criterion clarity and evidence availability;

(c) accredited organisation feedback — gathered at the post-survey evaluation stage and at each surveillance visit;

(d) incident and complaint data from the ASF risk register and complaint records (ASF-GOV-005);

(e) external signals — new WHO guidance, major updates to international accreditation standards, significant regulatory changes, or patient safety incidents identified in the literature that are relevant to ASF-accredited facilities.

10.3 Post-implementation monitoring findings are reviewed by the SDC at least annually and are recorded in the SDC annual report. Where a finding indicates a material risk to patient safety or standards integrity, the SDC may initiate an unplanned revision outside the five-year scheduled cycle.

10.4 For criteria identified at development as consensus-based (clause 5.2.3), the post-implementation monitoring programme includes targeted tracking of evidence developments and an expedited review if new evidence becomes available.

11. Scheduled Periodic Review and Methodology Review (Stage 9)

11.1 All ASF accreditation standards are reviewed at intervals not exceeding five years from the date of the most recent major version. The review schedule is maintained by Document Control, reviewed by the SDC annually, and published on france-asf.fr as part of the ASF transparency disclosures.

11.2 A scheduled review is initiated earlier than the five-year interval if any of the following triggers occur:

(a) a significant change in applicable regulatory requirements in a jurisdiction accounting for more than 10% of ASF survey activity;

(b) publication of a new edition of a major international reference standard (JCI, Accreditation Canada, ACHS) with material structural changes;

(c) new WHO guidance directly relevant to the scope of the standard;

(d) a pattern of post-implementation monitoring findings that indicates a systematic issue with criterion applicability or assessability;

(e) a formal request from the SDC based on adverse events, complaints, or other quality signals;

(f) the annual ISQua EEA crosswalk review identifies a material gap between ASF-EV-004 and the current EEA Principles.

11.3 This Standards Development Methodology is itself subject to the same review cycle. It is reviewed at intervals not exceeding five years, or earlier if triggered by any of the conditions listed in clause 11.2. The next scheduled review is September 2031.

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12. Document Control and Transparency

12.1 ASF operates a formal document control system covering all governance and operational policy documents, accreditation standards, evidence documents, and procedural records. Key principles:

- **(a)** all controlled documents carry a unique document code, version number, effective date, and approval signature;
- **(b)** the master copy of every controlled document is held in the ASF document register, which is maintained by Document Control;
- **(c)** superseded versions are clearly marked 'ARCHIVED' and retained for a minimum of ten years;
- **(d)** changes to controlled documents are recorded in the version history table on the cover page of each document;
- **(e)** all published ASF governance documents and accreditation standards are accessible without charge on france-asf.fr.

12.2 ASF's commitment to transparency is reflected in the public availability of this methodology document; the evidence bibliography (ASF-EV-001); the stakeholder consultation summary (ASF-EV-002); the pilot and field validation summary (ASF-EV-003); the ISQua EEA crosswalk (ASF-EV-004); and the current version of all ASF accreditation standards.

12.3 ASF accreditation standards are the intellectual property of Accréditation Sans Frontières. They are published for transparency purposes and for use by accreditation applicants. Use by any external assessment organisation for independent evaluation or issuance of accreditation decisions requires a formal written agreement with ASF.

13. References

The following sources informed the development of this methodology and are cited in the evidence bibliography (ASF-EV-001):

[1]	ISQua International Accreditation Programme (IAP). Principles for Standards. 6th Edition. International Society for Quality in Health Care External Evaluation Association, Dublin, Ireland, 2023.
[2]	Shaw CD, Braithwaite J, Moldovan M, et al. Profiling health-care accreditation organisations: an international survey. Int J Qual Health Care. 2013;25(3):222–231. doi:10.1093/intqhc/mzt008
[3]	Greenfield D, Pawsey M, Braithwaite J. What motivates professionals to engage in the accreditation of healthcare organisations? Int J Qual Health Care. 2011;23(1):8–14. doi:10.1093/intqhc/mzq067
[4]	Brubakk K, Vist GE, Bukholm G, Barach P, Tjomsland O. A systematic review of hospital accreditation: the challenges of measuring complex intervention effects. BMC Health Serv Res. 2015;15:280. doi:10.1186/s12913-015-0933-x
[5]	Joint Commission International. JCI Accreditation Standards for Hospitals. 7th Edition. Joint Commission Resources, Oak Brook, IL, USA, 2020.
[6]	Accreditation Canada. Qmentum Accreditation Program: Overview and Standards. Accreditation Canada, Ottawa, Canada, 2022.
[7]	Australian Council on Healthcare Standards (ACHS). EQuIP National Standards. 6th Edition. ACHS, Sydney, Australia, 2018.
[8]	World Health Organization. Standards for Improving Quality of Maternal and Newborn Care in Health Facilities. WHO, Geneva, Switzerland, 2016.
[9]	World Health Organization. WHO Patient Safety Curriculum Guide: Multi-professional Edition. WHO,

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	Geneva, Switzerland, 2011.
[10]	World Health Organization. WHO Guidelines on Hand Hygiene in Health Care. WHO, Geneva, Switzerland, 2009.
[11]	World Health Organization. WHO Safe Surgery Saves Lives: The Second Global Patient Safety Challenge. WHO, Geneva, Switzerland, 2009.
[12]	Pomey MP, Contandriopoulos AP, François P, Bertrand D. Accreditation: a tool for organisational change in hospitals? Int J Health Care Qual Assur. 2004;17(3):113–124. doi:10.1108/09526860410532757
[13]	Braithwaite J, Shaw CD, Moldovan M, et al. Comparison of health service accreditation programs in low- and middle-income countries with those in higher income countries: a cross-sectional study. Int J Qual Health Care. 2012;24(6):568–577. doi:10.1093/intqhc/mzs064
[14]	International Organization for Standardization. ISO 9001:2015 — Quality Management Systems: Requirements. ISO, Geneva, Switzerland, 2015.
[15]	International Organization for Standardization. ISO 15189:2022 — Medical Laboratories: Requirements for Quality and Competence. ISO, Geneva, Switzerland, 2022.
[16]	Health Quality and Accreditation Canada International (HQACI). Standards Development Methodology. ISQua EEA Accredited Document, 2026.
[17]	Greenfield D, Braithwaite J. Health sector accreditation research: a systematic review. Int J Qual Health Care. 2008;20(3):172–183. doi:10.1093/intqhc/mzn005
[18]	Flodgren G, Gonçalves-Bradley DC, Pomey MP. External inspection of compliance with standards for improved healthcare outcomes. Cochrane Database Syst Rev. 2016;12:CD008992. doi:10.1002/14651858.CD008992.pub3
[19]	European Union. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare. Official Journal of the European Union, L 88/45, 2011.
[20]	Pkhakadze G. Healthcare accreditation and quality improvement: national and international perspectives. In: Proceedings of the Georgian National Conference on Healthcare Quality, Tbilisi, Georgia, 2019.

Formal Approval

Name and title	Signature	Date
Prof. Giorgi Pkhakadze, MD, MPH, PhD President, Accréditation Sans Frontières		2026-09-30

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