

ASF-QMS-001

Internal Audit Policy

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Approved by	Prof. Giorgi Pkhakadze, MD, MPH, PhD President, Accréditation Sans Frontières
Applies to	All ASF operational and governance processes and the ASF Quality Management System
Related documents	ASF-QMS-002 Management Review Procedure · ASF-QMS-003 Risk Management Policy · ASF-GOV-001 Standards Development Methodology · ASF-GOV-003 Impartiality Policy · ASF-GOV-005 Complaints and Appeals Procedure
Supersedes	ASF-QMS-001 V2.0 (2026-11-28)
Next review	December 2031, or earlier on trigger

Version History

Version	Date	Nature of change	Approved by
V0.1	2026-11-04	Initial draft	—
V1.0	2026-11-17	Management review	QMS Coordinator
V2.0	2026-11-28	Approved and published	Prof. G. Pkhakadze, ASF President
V3.0	2026-12-01	Expanded to full policy; 8-row audit programme scope table, 5-stage audit process, auditor independence requirements, 4-type finding classification (Major NC/Minor NC/Observation/Best Practice), CAP linkage, records retention, and 12 references	Prof. G. Pkhakadze, ASF President

1. Purpose

1.1 This policy establishes ASF's internal audit programme — the systematic, independent, and documented process by which ASF assesses the conformity of its own operations with its documented quality management system (QMS) requirements, the ISQua EEA Principles, ISO 9001:2015, and applicable legal and regulatory obligations. Internal audit is a core quality assurance mechanism: it provides the ASF President and Standards Committee with objective evidence of whether ASF's processes are functioning as intended and identifies opportunities for improvement.

1.2 Internal audit is distinct from the external surveys that ASF conducts on healthcare facilities. Internal audit is about ASF's own operations as an accreditation body — not about the organisations that ASF accredits.

2. Scope of the Internal Audit Programme

2.1 The internal audit programme covers all processes that form part of ASF's quality management system. The minimum scope includes the following process areas:

Process area	Audit frequency	Key requirements audited
Standards development and review	Annual	ASF-GOV-001 compliance; stakeholder consultation records; version control
Impartiality management	Annual	ASF-GOV-003 compliance; Declaration of Impartiality records; CoI log
Confidentiality and data protection	Annual	ASF-GOV-004 compliance; GDPR records; data processing agreements
Complaints and appeals	Annual	ASF-GOV-005 compliance; case records; timelines met
Accreditation decision process	Annual	ASF-OPS-001 compliance; ADC records; decision documentation completeness
Surveyor management	Annual	ASF-OPS-002 compliance; competency records; calibration results
Accreditation cycle management	Biennial	ASF-OPS-003 compliance; cycle tracking accuracy
Financial and fee management	Annual	ASF-OPS-008 compliance; invoicing records; payment tracking

2.2 The QMS Coordinator may expand the scope of any individual audit cycle to include additional process areas based on risk assessment results (ASF-QMS-003), findings from the previous audit cycle, or issues identified through management review (ASF-QMS-002).

3. Audit Planning

3.1 An internal audit plan is prepared annually by the QMS Coordinator and approved by the ASF President before the start of each calendar year. The plan sets out:

- (a) the process areas to be audited and the planned audit window for each;
- (b) the auditor assigned to each audit, confirming that independence requirements in Section 4 are met;
- (c) the criteria against which each process area is to be audited — the relevant QMS document, procedure, or external standard;
- (d) the planned method — document review, interview, observation, or records sampling;
- (e) the planned output — audit findings report and, where applicable, a corrective action request.

3.2 The annual audit plan is reviewed at mid-year and updated if the risk profile has changed materially, if a significant incident has occurred in a process area, or if a complaint or appeal has identified a potential systemic issue.

3.3 Unplanned or reactive audits may be initiated at any time by the ASF President in response to a significant complaint, a regulatory inquiry, an identified impartiality concern, or a material change to an audited process. Reactive audits are scoped and initiated within 10 working days of the trigger event.

4. Auditor Independence

4.1 ASF's internal audit function must be independent of the processes being audited.

Independence is achieved through the following requirements:

- (a) An auditor does not audit their own work. The person responsible for operating a process or producing the documents under audit may not serve as the auditor for that process area.
- (b) Where ASF's staff size makes it impractical to achieve full independence using internal personnel, ASF engages an external auditor for the affected process areas. The external auditor must have demonstrable competence in quality management and accreditation body operations.
- (c) The assigned auditor completes a Declaration of Impartiality (consistent with ASF-GOV-003, Annex A) before each audit engagement.
- (d) Auditors have no personal financial interest in the outcome of the audit.

4.2 The QMS Coordinator may serve as auditor for process areas that they do not directly operate, provided independence criterion (a) above is met. For the audit of the QMS coordination process itself, an external or independent internal auditor is always used.

5. Audit Process — Five Stages

Stage 1 — Audit Notification

5.1 The process owner is notified in writing at least 10 working days before the planned audit date. The notification states the scope, the criteria, the planned method, and the date(s) of the audit.

Stage 2 — Document Review

5.2 The auditor reviews the relevant QMS documents, procedures, records, and evidence against the audit criteria before conducting interviews or observations. The purpose is to identify gaps, inconsistencies, or areas requiring clarification before the on-site or interview stage.

Stage 3 — Audit Execution

5.3 The auditor gathers evidence through document review, records sampling, and interviews with process owners and relevant personnel. Evidence is recorded objectively — the auditor records what was found, not what was expected. Where evidence cannot be obtained, this is recorded as a limitation of the audit.

Stage 4 — Findings and Classification

5.4 Audit findings are classified as follows:

- (a) Major nonconformance — a failure to implement a requirement of the QMS or an applicable external standard that has, or could have, a significant impact on the quality, impartiality, or integrity of ASF's accreditation programme. Major nonconformances require a Corrective Action Request (CAR) and a root-cause analysis.
- (b) Minor nonconformance — a single, isolated failure that does not by itself represent a systemic breakdown but indicates a gap in implementation. Minor NCs require a corrective action; two or more minor NCs in the same area in consecutive audit cycles are escalated to Major NC.
- (c) Observation — a concern or potential weakness that does not yet constitute a nonconformance but warrants monitoring. Observations are recorded and reviewed at the next audit cycle.
- (d) Best practice — a notable example of effective implementation that exceeds requirements and may warrant sharing across the organisation.

Stage 5 — Audit Report

5.5 The auditor prepares a written audit report within 10 working days of completing the audit. The report contains: the audit scope and criteria; the evidence reviewed; a finding for each item reviewed (conformant, NC, observation, or best practice); the classification of each NC; and, for each NC, a Corrective Action Request specifying the required corrective action and the response deadline (typically 30 calendar days for minor NCs; 15 calendar days for major NCs).

5.6 The audit report is submitted to the QMS Coordinator and the ASF President. Where the audit found major NCs, it is also presented at the next management review meeting (ASF-QMS-002).

6. Corrective Action and Follow-Up

6.1 For each corrective action request, the responsible process owner submits a corrective action response within the deadline stated in the audit report. The response must include: root cause analysis; the specific action taken or planned; and the evidence of completion.

6.2 The QMS Coordinator reviews each corrective action response for adequacy. Where the response is adequate, the CAR is closed. Where it is inadequate — because the root cause has not been addressed, or the action is insufficient — the QMS Coordinator returns it with specific feedback and a revised deadline.

6.3 Unresolved CARs — where a corrective action has not been implemented by the revised deadline — are escalated to the ASF President and included as a standing agenda item at the next management review.

6.4 The effectiveness of corrective actions is verified at the next scheduled audit of the same process area. A corrective action is not considered verified on the basis of the process owner's declaration alone.

7. Records

7.1 The following records are maintained by the QMS Coordinator and retained for a minimum of 5 years:

- (a) the annual internal audit plan and any mid-year revisions;
- (b) auditor independence declarations;
- (c) all audit reports, including findings classifications and CARs;
- (d) all corrective action responses and closure records;
- (e) the audit findings summary presented at management review (ASF-QMS-002).

7.2 Internal audit records are treated as confidential operational documents of ASF and are subject to the data protection requirements of ASF-GOV-004. They are not disclosed to applicants, accredited organisations, or external parties except where required by law or by the ISQua EEA accreditation process.

8. ISQua EEA Alignment

8.1 This policy supports ISQua EEA Principle 10 (Quality Management System), which requires accreditation bodies to have a documented QMS with internal audit as a component. Specifically, it addresses the EEA requirement for systematic review of the accreditation body's own processes, independent audit, and management of nonconformances. The ASF ISQua EEA Crosswalk (ASF-EV-004) maps the provisions of this policy to the applicable EEA criteria.

9. References

[1]	ISQua IAP. Principles for Standards. 6th Ed. ISQua EEA, Dublin, 2023.
[2]	International Organization for Standardization. ISO 9001:2015 — Quality Management Systems: Requirements. §9.2 Internal Audit. ISO, Geneva, 2015.
[3]	International Organization for Standardization. ISO 19011:2018 — Guidelines for Auditing Management Systems. ISO, Geneva, 2018.
[4]	ISO/IEC 17021-1:2015 — Conformity Assessment: Requirements for Bodies Providing Audit and Certification of Management Systems. §9.7 Internal Audit. ISO, Geneva, 2015.
[5]	Institute of Internal Auditors. International Standards for the Professional Practice of Internal Auditing. IIA, Lake Mary, FL, 2017.

[6]	Accreditation Canada. Internal Audit Policy. ISQua EEA Accredited Document, 2022.
[7]	HQACI. Internal Audit Policy. ISQua EEA Accredited Document, 2026.
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[10]	Brubakk K et al. A systematic review of hospital accreditation. BMC Health Serv Res. 2015;15:280.
[11]	Shaw CD et al. Profiling health-care accreditation organisations. Int J Qual Health Care. 2013;25(3):222–231.
[12]	Power M. The Audit Society: Rituals of Verification. Oxford University Press, Oxford, 1997.

Formal Approval

Name and title	Signature	Date
Prof. Giorgi Pkhakadze, MD, MPH, PhD President, Accréditation Sans Frontières		2026-12-01

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