SHAMKRIS®

Audit and certification process

1. Purpose

This document covers the activities within the audit and certification process. This document would be used to train the auditors on how the requirements of the accreditations standards have been addressed within our system.

2. Scope

This procedure applies to all the management system audit and certification processes. Activities specific to a scheme has been addressed in separate annexes to this procedure.

3. Responsibility

The Management Representative (MR) shall be responsible for upkeep and control of this document. Scheme managers are responsible for ensuring that the procedure is effectively implemented and followed within their schemes. Changes to the documentation may be initiated by the scheme managers (without affecting the accreditation arrangements) and implemented through the MR within the system after due approvals.

4. Reference documents

a. ISO/IEC 17021 – 1: 2015 Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements
b. ISO/IEC TS 17021 – 2:2016 Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 2: Competence requirements for auditing and certification of environmental management systems
c. ISO/IEC TS 17021 – 3: 2013 Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 3: Competence requirements for auditing and certification of quality management systems
d. ISO/IEC TS 17021-10:2018 Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 10: Competence requirements for auditing and certification of occupational health and safety management systems
e. ISO/TS 22003-1:2022: Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems
f. IAF ID1: 2014 IAF Informative Document for QMS and EMS Scopes of Accreditation
g. IAF MD19 2016_multisite without sampling
h. IAF MD1 2007 Certification of Multiple Sites Based on Sampling
i. IAF MD5 2013 QHSE _ Audit Duration
j. IAS MD9 2022 Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems
k. Other normative documents applicable to the respective schemes

5. Procedure

This procedure is divided into the following sections:

Scheme specific audit conduct is further guided by the respective documents established by governance:

For example:

- ISO 17021-2 for ISO 14001 2015
- ISO 17021-2 for ISO 9001 2015
- ISO 17021-10 for ISO 45001 2018
- ISO TS 22003 for ISO 22000 2018
- ISO TS 22002 (applicable parts) specific to application of PRP in ISO 22000
- ISO 27006 2024 for ISO 27001 2013
- IAF MD9 2022 for ISO 13485
- Other associated mandatory documents developed and applied by the governance entities like Accreditation bodies

5.1 Pre-certification activities

5.1.1 Pre-certification activities include Application, application contract review, auditor appointment and audit programme and Audit time determination

5.1.2 All conflicts, gaps of understanding and missing information are cleared during this set of activities, so that planning for audits can take place.

5.2 Planning for the audit

5.2.1 Objectives, scope and criteria of the audits are reviewed from the pre-certification process.

5.2.2 Competent audit team is selected and appointed (including TE when required).

5.2.3 Audit plan is prepared by the team leader and sent to the auditee reasonably in advance to enable the auditee to request any changes in the audit plan. Changes in audit plan shall not affect audit objective, scope and audit time frame.

5.3 Pre-certification (Pre-assessment) audit

5.3.1 The auditee may request to conduct a precertification audit on site. Precertification audit is NOT considered as part of the initial certification audit process. Pre-certification audit is a value addition process that may be opted by the auditee.

5.3.2 This is an option the auditee (client) has chosen at their expense, normally, to achieve a set of objectives the client wants to achieve something of value, without compromising the initial certification audit process.

5.3.3 Typical set of activities that happen during the pre-certification audit, are

- explanation of the audit and certification process,
- answering queries and addressing any areas of concern, from the auditee personnel, related to the initial certification audit process,
- performing sample audit to demonstrate the audit process,
- identifying any areas that may hinder the audit and certification process,
- ensure the facilities and arrangement required for the initial certification audit are in place,
- review the scope of certification being requested,
- meeting with the top management and key personnel to address their concerns and answer queries,
- Identifying needs for training and other competency issues.

5.3.4 The agenda for the pre-certification audit may be agreed suitably between the audit team leader and the auditee.

5.3.5 Findings including non-conformities are not formally reported during pre-certification visits. They are identified as ‘observations’ and presented.

5.3.6 Corrective action process does not apply to the observations present from a pre-certification audit,

5.3.7 Consultancy advice is not permitted. Auditor/audit team shall be careful and not provide a perception that consultancy is being provided,

5.3.8 A formal opening/closing meeting shall be conducted to inform the objective of the audit and clearly explain, among other routines, that:

- The pre-certification audit is NOT part of the initial certification audit process,
- No advice or consultancy shall be provided,
- No formal non-conformance report shall be provided and thus no formal corrective action process is expected,
- Audit time shall be agreed with the client based on the extent of value addition required from the pre-certification audit, by the auditee
- A formal report may be provided with clear indication that it does not form part of initial certification audit.

5.4 Initial certification

5.4.1 The onsite audit process starts here, after having completed the pre-certification activities (including pre-certification visit)

5.4.2 At this point the audit team is clear about the objective, scope and criteria of the audit to prepare for the audit process. Requisite communication and arrangement between the certification body, the client and audit team should have been completed now.

5.4.3 Different audit schemes may have their audit requirements in addition to the generic audit requirement. These requirements may relate to sampling and other areas. This procedure addresses the generic areas common to all schemes and the respective annexes clarify the scheme specific requirements.

5.4.4 Initial certification shall be conducted in two stages:

Stage 1 audit (detailed below 5.5)

Stage 2 audit (detailed below 5.6)

5.4.5 Conduct of the audits on site is presented in procedure P17.

5.4.6 The gap between the stage 1 and stage 2 audit shall be sufficient to provide opportunity to the auditee to address issues and concerns raised during the stage 1 audit. Normally, this is expected to be about a week minimum and not more than 6 months.

5.4.7 If the gap between stage 1 and stage audits exceed 6 months, a stage 1 audit shall be repeated unless a valid reason is provided, the audit team leader recommends and the scheme manager approves.

5.4.8 A back-to-back stage 1/stage 2 audit can be conducted subject to:

- the organization is very small (typically below 10 personnel) or classified as low risk
- Situations like takeover or transfer of certification can be done remote (off-site) or virtual. ,
- the stage 1 audit may be done remote or off-site due to logistics or other issues which prevent on-site visits (stage 1),
- the audit team is ready to conduct the stage 2 audit,
- the auditee is ready for the stage 2 audit,
- the scheme specific standards/accreditation documents do not prevent,
- the scheme manage approves the back-to-back audit,
- the client made aware of the risk of identification major non-conformances resulting in the certification not being recommended and hence a re-audit, and
- Justification for conduct of the back-to-back audit indicated in the certification recommendation documentation.

5.4.9 Audit report is submitted to the certification body the certification decision process is managed by procedure for Certification decisions

5.4.10 Suspending, withdrawing, reduction or extension of scope is managed by procedure established.

5.4.11 Certification cycle is normally valid for a period of 3 years. Shorter period may be considered and approved by the scheme manager.

5.4.12 Maintenance of certification is by a process of surveillances and recertification at the end of 3 years. Recertification may happen before when the certification maintenance procedure is not adhered to.

5.5 Conduct of Stage 1 audit (Onsite audit procedure)

5.5.1 Stage 1 is normally conducted on-site. Virtual, remote or off-site audit may be permitted if circumstances (logistics, travel, pandemic, etc.) do not permit on-site audits and:

- when the risk of identifying a major nonconformity is very low,
- when the scheme specific requirements do not mandate on-site audit,
- The scheme manager approves an off-site process based on review of the pre-audit documentation and communication,
- the audit objectives of a stage 1 audit, as indicated below, can be achieved, and
- The client shall be informed of the risk of major non-conformance under such instances.

5.5.2 The objectives of stage 1 audit are to:

a) Review the client's management system documented information for adequacy and confirm that all process controls are included. e.g. for FSMS, confirm that following specific requirements are addressed;

i) Organisation has identified PRPs that are appropriate to the business.

ii) FSMS includes adequate processes and methods for the identification and assessment of the organisation's food safety hazards and subsequent selection and categorisation of control measures (combinations).

iii) FSMS includes adequate processes and methods for the identification and implementation of relevant food safety regulations

iv) FSMS is designed to achieve the organisations food safety policy

v) FSMS implementation programme justify proceeding to stage 2 audit.

vi) Validation of control measures, verification of activities and improvement programme conform to the requirements of FSMS standard

vii) FSMS documents and arrangements are in place to communicate internally and with relevant suppliers, customers and interested parties

viii) Any additional documentation which needs to be reviewed and /or information which needs to be obtained in advance.

b) Evaluate the client's site-specific conditions and to undertake discussions with the client's personnel to determine the preparedness for stage 2.

c) Review the client's status and understanding regarding requirements of the standard, in particular with respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system;

d) Obtain necessary information regarding the scope of the management system, including:

— The client's site(s);

— processes and equipment used;

— Levels of controls established (particularly in case of multisite clients);

— Applicable statutory and regulatory requirements;

e) Review the allocation of resources for stage 2 and agree the details of stage 2 with the client;

f) provide a focus for planning stage 2 by gaining a sufficient understanding of the client's management system and site operations in the context of the management system standard or other normative document;

g) Evaluate if the internal audits and management reviews are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for stage 2.

5.5.3 Finding from the stage 1 audit, areas of concern which would otherwise be raised as non-conformance in a stage 2 audit and any areas of concern shall be communicated to the client. Formal non-conformance report need not be raised during a stage 1 audit.

5.5.4 It is not necessary that a stage 1 meet all the requirement for a complete audit report.

5.5.5 Determining the interval between stage 1 and stage 2 (also refer 5.4.6 above) shall be with consideration to:

- needs and time frames required by the client to resolve areas of concern identified during stage 1,
- ability of the certification body to revise its arrangements for stage 2, and
- Review of any significant changes which would require a repeat of the stage 1 audit and thus cancellation of the stage 2 audit arrangements.

The client shall be informed that the results of stage 1 may lead to postponement or cancellation of stage 2.

5.6 Conduct of Stage 2 audit (Onsite audit procedure)

5.6.1 The purpose of stage 2 is to evaluate the implementation, including effectiveness, of the client's management system.

5.6.2 The stage 2 shall take place at the site(s) of the client and shall include the auditing of at least the following:

a) Information and evidence about conformity to all requirements of the applicable management system standard or other normative documents;

b) Performance monitoring, measuring, reporting and reviewing against key performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document);

c) The client's management system ability and its performance regarding meeting of applicable statutory, regulatory and contractual requirements;

d) Operational control of the client's processes;

e) Internal auditing and management review;

f) Management responsibility for the client's policies.

5.6.3 Stage 2 audit shall also review the links between the normative requirements, policy and performance objectives consistent with the respective management system standards.

5.6.4 Stage 2 audit shall also be used to reconfirm the surveillance programme for maintenance of certification.

5.7 Surveillance audit (Onsite audit procedure)

5.7.1 The certification has to be maintained by demonstrating that the client continues to satisfy the requirements of the management system standard.

5.7.2 Surveillance audits are independent reviews and are used to ensure that the client continues to satisfy the requirements of certification and the management standard.

5.7.3 Any major non-conformance to other situation identified during surveillance audits may lead to suspension or withdrawal of certification.

5.7.4 Surveillance activities are developed by the certification body so that representative areas and functions covered by the scope of the management system are monitored on a regular basis, and take into account changes to its certified client and its management system.

5.7.5 Surveillance audits are on-site audits, but are not necessarily full system audits, and shall be planned together with the other surveillance activities so that the certification body can maintain confidence that the client's certified management system continues to fulfil requirements between recertification audits. Each surveillance for the relevant management system standard shall include:

a) Internal audits and management review;

b) A review of actions taken on nonconformities identified during the previous audit;

c) Complaints handling;

d) Effectiveness of the management system with regard to achieving the certified client's objectives

And the intended results of the respective management system (s);

e) Progress of planned activities aimed at continual improvement;

f) Continuing operational control;

g) Review of any changes;

h) Use of marks and/or any other reference to certification;

i) Reviewing any certified client's statements with respect to its operations (e.g. promotional material, website); and

j) Any other methods of verification to ensure the certified management system meets requirements.

5.8 Recertification audit (Onsite audit procedure)

5.8.1 Recertification audit is carried out to confirm the continued conformity and effectiveness of the management system as a whole, and its continued relevance and applicability for the scope of certification.

5.8.2 Recertification audit shall be planned and conducted to evaluate the continued fulfilment of all of the requirements of the relevant management system standard or other normative document.

5.8.3 Recertification audit shall be planned and conducted in due time to enable for timely renewal before the certificate expiry date.

5.8.4 The recertification activity shall include the review of previous surveillance audit reports and consider the performance of the management system over the most recent certification cycle.

5.8.5 Recertification audit activities may need to have a stage 1 in situations where there have been significant changes to the management system, the organization, or the context in which the management system is operating (e.g. significant changes to legislation).

5.8.6 Recertification audit shall be an on-site audit and shall address:

a) The effectiveness of the management system in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of certification;

b) Demonstrated commitment to maintain the effectiveness and improvement of the management system in order to enhance overall performance;

c) The effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system (s).

5.8.7 For any major non-conformity, the time limits for correction and corrective actions shall be indicated. These actions shall be implemented and verified prior to the expiration of certification.

5.8.8 When recertification activities are successfully completed prior to the expiry date of the existing certification, the expiry date of the new certification can be based on the expiry date of the existing certification. The issue date on a new certificate shall be on or after the recertification decision.

5.8.9 Recertification shall not be recommenced if the recertification audit has not been completed or unable to verify the implementation of corrections and corrective actions for any major nonconformity prior to the expiry date of the certification and the validity of the certification shall not be extended. The client shall be informed and the consequences shall be explained.

5.8.10 following expiration of certification, the certification can be restored within 6 months provided that the outstanding recertification activities are completed, otherwise at least a stage 2 shall be conducted. The effective date on the certificate shall be on or after the recertification decision and the expiry date shall be based on prior certification cycle.

5.9 Special audits (Onsite audit procedure)

5.9.1 Special audits happen when:

a) Extension / reduction of scope of certification due to changes in the certified management system,

b) Short notice audit happen in response to complaints, appeals or any such events. Short notice audits may be announced or unannounced depending upon the objective of the special audit.

c) As part of the special requirement of the certification scheme,

d) As part of reinstatement of a suspended certification, and

e) As part of an agreed certification arrangement with the client.

5.9.2 Choice of audit team for special audits shall take care that the audit team shall be in scope,

5.9.3 In an unannounced audit, the audit team shall be chosen in such a way that the team is acceptable to the auditee and prevent opportunity to the auditee to object to the team or its members. One method is to use the audit team/members who did the previous audits.

5.9.4 Certification documents describe and make known in advance to the certified clients, the conditions under which such audits will be conducted;

5.10 Remote Auditing

5.10.1 Remote auditing is the method of auditing an auditee (client) by the auditor without being physically present in the client's premises, but virtually through the help of many online tools

5.10.2 For more details on Remote Auditing, please refer to Procedure No. ----------

5.11 Audit report

5.11.1 Audit report shall be prepared in different documents.

- Summary Audit report to client
- Detailed on-site audit report
- Non-conformance Report (NCR) also referred to, as Corrective Action Request (CAR)

5.11.2 Audit report shall normally be submitted at the end of audit or within reasonable time period after the audit. This shall be indicated during the closing meeting.

5.11.3 Audit report shall be made available to the client using suitable media and method.

5.12 Certification status change: The policy for suspending, withdrawing or reduction the scope of certification.

5.12.1 Action/s shall be taken on clients' certification status when they do not continue to meet the certification requirements. The situations can be the following, but not limited to:

- The management system of the client is not able to, persistently and seriously, meet the requirement of the standard and that of certification;
- Results of a special audit based on reports of serious deficiencies including legal non-compliance, indicate serious lack of conformance (refusal to present themselves for such a special audit shall be construed to indicated serious lack of conformance);
- The certified clients do not allow or present themselves for surveillance activities as part of the agreed audit programme;
- The certified clients do not allow or present themselves for recertification activities as part of the agreed audit programme;
- The certified client has voluntarily requested for a suspension or withdrawal of certification.

5.12.2 This procedure shall be applied to any client which undergo such conditions where suspension of certification is a strong possibility.

5.12.3 Reduction of scope, when requested by the client, shall be subjected to regular off-site or on-site review as determined after a review of the request.

5.12.4 Reduction of scope may be determined as a result of the complaint/feedback mechanism involving an interested party.

5.12.5 Under suspension, the client's certificate is temporarily invalid. This shall be informed to the client by suitable means.

5.12.6 Suspension, in most cases, would not exceed 6 months. If the suspension exceeds more than 6 months, the scheme manager shall review to decide if an on-site audit required to revoke the suspension.

5.12.7 There would be no change in the overall validity end date, nor a proportional extension, of the certificate period even when part of the period has been lost in suspension.

5.12.8 The scope of certification shall be reduced to exclude the parts not meeting the certification requirements, when a certified client has persistently or seriously failed to meet the certification requirements for those parts of the scope of certification. Such reduction shall meet the requirements specific to the scheme.

5.12.9 Status change approval shall be given by the Scheme Manager.

5.12.10 Certification status changes shall be registered indicating the reasons and action taken.

5.12.11 Status change registrations shall be reviewed to consider follow-up actions

5.13 Transfer of certification

5.13.1 Transfer of certification is a process by which the recognition of an existing and valid management system certification, granted by one accredited certification body by another accredited certification body.

5.13.2 The individual or committee taking decisions on certification that lead to granting or refusing, expanding or reducing, suspending or restoring, withdrawing or renewing shall be responsible to take decisions on transfer of certification.

5.13.3 Certifications issued by multiple certification bodies to a single client is not covered by this procedure. The procedure for transfer of such certification shall be determined by the team respective scheme managers after assessing the status of certification and the risk.

5.13.4 Persons or committee taking decisions on transfer of certification shall be different from those who carried out or were part of the audits.

5.13.5 Once a certification is transferred all policies and procedures applied would be the same as for those issued by the certification body.

Actions prior to transfer

5.13.6 A review of the certification documentation shall be conducted before making decisions on transfer certification. This, normally, includes a visit to the site of the prospective client. If a visit is not done, reasons shall be indicated.

5.13.7 The reviewer considers the information available. The missing information shall be gathered by suitable means.

5.13.8 A virtual / remote / off-site audit shall be recorded to ensure that information sufficient for a site visit is available.

5.13.9 If a site visit is required, the same is done and the pre-transfer site visit report is completed.

5.13.10 SGIS shall collect the previous audit report and verify the validity of the certificate shall be verified. Additionally, SGIS shall validate the recency of the certificate, audit report and the content of it as well as collect the audit program from the certification body. In absence of the same SGIS shall contact the accreditation board for the support or shall term the client as fresh certification and not a transfer case.

Transfer of certification

5.13.11 the pre-transfer review should have been completed and the relevant information provided.

5.13.12 when it is known that the prospective certification is suspended or under the threat of certification, transfer of certification shall not be proceeded. The reason such suspension or suspension notice shall be reviewed. A transfer of certification shall not be initiated until these reasons have been resolved.

5.13.13 outstanding non-conformities shall be closed out, if practical, before transfer of certification. However, after review of the non-conformities, the decision maker may accept a closure action after transfer of certification.

5.13.14 The Audit programme and the surveillances shall be based on the existing certification regime, unless the pre-transfer site visit report has recommended the need for a change.

5.13.15 should there be any doubts after the pre-transfer review, on the adequacy of the current certification, the transfer applicant may be treated as:

- a new applicant, or
- Carry out an audit of areas where problems have been identified.

6. Issue/Revision history

Issue/rev #	Date	Brief details
1	9/10/24	ISO/TS 22003-1:2022 reference revised
2	7/12/24	FSMS specific stage 1 objectives added to cl. 5.5.2
3	01/02/2026	Remote Auditing Process added
4	01/04/2026	Incorporated guidelines for verification and validation of transfer cases.