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0	97/08/01	First issue	A. Babaei	A. Babaei	F. Kashani
01	07/09/1400	Totally review based on ISO 17021-1	M.Gholami	A. Babaei	F. Kashani
02	19/02/1401	Totally review based on ISO 17021-1	M. Gholami	A. Babaei	F. Kashani
03	1402/09/01	Requirement of MD09	Narges Hoseininasab	F.Kashani	F. Kashani
04	1402/09/30	The form PR01-FR04 was deleted in the context because the audit plan PR01-Fr02 is used as audit activity	Narges Hoseininasab	F.Kashani	F. Kashani
05	1403/10/15		Narges Hoseininasab	F.Kashani	F. Kashani
06	1404/03/04	Addition of OH&SMS specific parts and and make change suspending procedure	M. Gholami	Mr.Babaei	F. Kashani
07	1404-11-08	Requirement of ISO22003-1:2022	Narges Hoseininasab	F.Kashani	F. Kashani
08	1405-2	Standard Transition	M. Gholami	Mr.Babaei	F. Kashani

1. Planning audits

A. Determining audit objectives, scope and criteria

The audit objectives will be determined by the AGAH AFARIN ARIA. The audit scope and criteria, including any changes, will be established by the AGAH AFARIN ARIA after discussion with the client.

The audit objectives shall describe what is to be accomplished by the audit and shall include the following:

a) determination of the conformity of the client's management system, or parts of it, with audit criteria;

b) determination of the ability of the management system to ensure the client meets applicable statutory, regulatory and contractual requirements;

c) determination of the effectiveness of the management system to ensure the client can reasonably expect to achieving its specified objectives;

d) as applicable, identification of areas for potential improvement of the management system.

B. Audit team selection and assignments

The AGAH AFARIN ARIA have a **process for selecting and appointing the audit team as per PR06 and PR 23**,PR24 including the audit team leader and technical experts as necessary, taking into account the competence needed to achieve the objectives of the audit and requirements for impartiality. If there is only one auditor, the auditor shall have the competence to perform the duties of an audit team leader applicable for that audit.

In deciding the size and composition of the audit team, consideration shall be given to the following:

a) audit objectives, scope, criteria and estimated audit time;

b) whether the audit is a combined, joint or integrated;

c) the overall competence of the audit team needed to achieve the objectives of the audit

d) certification requirements (including any applicable statutory, regulatory or contractual requirements);

e) language and culture.

The necessary knowledge and skills of the audit team leader and auditors may be supplemented by **technical experts, translators and interpreters** who shall operate under the direction of an auditor, Where translators or interpreters are used, they shall be selected such that they do not unduly influence the audit.

Auditors-in-training may participate in the audit, provided an auditor is appointed as an evaluator. The evaluator shall be competent to take over the duties and have final responsibility for the activities and findings of the auditor-in-training.

The audit team leader, in consultation with the audit team, shall assign to each team member

responsibility for auditing specific processes, functions, sites, areas or activities. Such assignments shall take into account the need for competence, and the effective and efficient use of the audit team, as well as different roles and responsibilities of auditors, auditors-in-training and technical experts.

Observers

The presence and justification of observers during an audit activity shall be agreed to by the AGAH AFARIN ARIA and client prior to the conduct of the audit. The audit team shall ensure that observers do not unduly influence or interfere in the audit process or outcome of the audit.

NOTE Observers can be members of the client's organization, consultants, witnessing accreditation body personnel, regulators or other justified persons.

Technical experts

The role of technical experts during an audit activity shall be agreed to by the AGAH AFARIN ARIA and client prior to the conduct of the audit. A technical expert shall not act as an auditor in the audit team. The technical experts shall be accompanied by an auditor.

Guides

Each auditor shall be accompanied by a guide, unless otherwise agreed to by the audit team leader and the client. Guide(s) are assigned to the audit team to facilitate the audit. The audit team shall ensure that guides do not influence or interfere in the audit process or outcome of the audit.

The responsibilities of a guide can include:

a) establishing contacts and timing for interviews;

b) arranging visits to specific parts of the site or organization;

c) ensuring that rules concerning site safety and security procedures are known and respected by the audit team members;

d) witnessing the audit on behalf of the client;

C. Audit plan

The AGAH AFARIN ARIA ensures that an audit plan is established prior to each audit identified in the audit programme to provide the basis for agreement regarding the conduct and scheduling of the audit activities as per **PR01-FR02(Audit plan).**

The audit plan shall be appropriate to the objectives and the scope of the audit. The audit plan shall at least include or refer to the following:

a) the audit objectives;

b) the audit criteria;

c) the audit scope, including identification of the organizational and functional units or processes to be audited;

d) the dates and sites where the on-site audit activities will be conducted, including visits to temporary sites and remote auditing activities, where appropriate;

e) the expected duration of on-site audit activities;

f) the roles and responsibilities of the audit team members and accompanying persons, such as observers or interpreters.

Audit plan will provide by auditor, then will send to customer.

Planning coordinator will make communication with customer and auditor to specified audit time.

2. Initial certification

The initial certification audit of a management system shall be conducted in two stages: stage 1 and stage 2.

Before conducting of any audits, for ensuring of impartiality, auditor names and audit plan will send to customer about 10 days before audit day.

When Agah Afarin Aria has audited a client against a regulatory scheme that includes or goes beyond the requirements of ISO 13485, it does not need to repeat the audit for conformity with the elements of ISO 13485 previously covered, provided Agah Afarin Aria can demonstrate that all the requirements of this document have been complied with.

Note: Some examples of regulatory schemes that include or go beyond the requirements of ISO 13485 are European Medical Device Regulations.

Additionally, other countries are adopting or considering adopting ISO 13485 into their Medical Device Regulations.

nonconformity

non-fulfilment of a requirement

major nonconformity

nonconformity that affects the capability of the management system to achieve the intended results

Note 1 to entry: Nonconformities could be classified as major in the following circumstances:

— if there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements;

— a number of minor nonconformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major nonconformity.

minor nonconformity

nonconformity that does not affect the capability of the management system to achieve the intended results

A. Stage 1

Planning ensures that the objectives of stage 1 can be met and the client shall be informed of any "on site" activities during stage 1. Stage 1 does not require a formal audit plan.

The stage 1 audit time shall be 20-30% of the whole audit time.

Note: For higher risk medical devices (C and D) are concerned, the stage 1 should be performed on-site.

The **objectives of stage 1** are to:

a) review the client's management system documented information;

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.

All of records of Stage 1 audit will be registered in PR01-FR03/01 (Stage 1 Audit report).

In determining the interval between stage 1 and stage 2, consideration shall be given to the needs of the client to resolve areas of concern identified during stage 1 and it is not more than **6 months**. The AGAH AFARIN ARIA may also need to revise its arrangements for stage 2. If any significant changes which would impact the management system occur, the AGAH AFARIN ARIA considers the need to repeat all or part of stage 1. The client shall be informed that the results of stage 1 may lead to postponement or cancellation of stage 2.

For auditing of food safety management system:

Stage 1 shall include review of the client's PRPs, food safety hazards, HACCP plan, and categorization into food chain categories.

The objectives of stage 1 are to provide a focus for the planning of stage 2 of the initial audit by gaining an understanding of the organization's FSMS and the organization's state of preparedness for stage 2 by reviewing the extent to which:

a) the organization has identified PRPs that are appropriate to the business (e.g. regulatory, statutory, customer and certification scheme requirements);

b) the FSMS includes adequate processes and methods for the identification and assessment of the organization's food safety hazards, and subsequent selection and categorization of control measures (combinations);

c) the FSMS includes adequate processes and methods for the identification and implementation of relevant food safety legislation;

d) the FSMS is designed to achieve the organization's food safety policy;

e) the FSMS implementation programme justifies proceeding to stage 2;

f) the validation of control measures, verification of activities and improvement programmes conform to the requirements of the FSMS standard;

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

h) there is any additional documentation which needs to be reviewed and/or information which needs to be obtained in advance.

Where an organization has implemented externally developed elements of a FSMS, stage 1 shall review the documentation included in the FSMS to determine if the combination of control measures:

— is suitable for the organization;

— was developed in conformity to the requirements of ISO 22000 or other sets of specified FSMS requirements;

— is kept up to date.

The availability of relevant authorizations shall be checked when collecting the information regarding the compliance to regulatory aspects.

For FSMS, stage 1 shall be carried out at the client's premises in order to achieve the objectives stated above. In exceptional circumstances or events, all or part of stage 1 can take place off-site or remotely through the use of ICT and shall be fully justified. The evidence demonstrating that stage 1 objectives are fully achieved shall be provided.

NOTE: Exceptional circumstances or events can include a very remote location, a natural disaster, a pandemic, a short seasonal production and other special situations.

NOTE: Any part of the FSMS that is audited during the stage 1 audit, and determined to be fully implemented, effective and in conformity with requirements, does not necessarily need to be re-audited during stage 2. In this case, the audit report includes these findings and clearly states that conformity has been established during the stage 1 of the audit.

The interval between stage 1 and stage 2 shall not be longer than six months. Stage 1 shall be repeated if a longer interval is needed.

So, in brief FSMS audits (ISO 22000), Stage 1 shall additionally include:

- Review of the client's Prerequisite Programs (PRPs) for adequacy relevant to the food chain category
- Review of the hazard analysis and HACCP plan
- Confirmation of the client's food chain category classification using PR03-FR10
- Evaluation of the client's understanding of applicable statutory and regulatory requirements (Iran FDA, Ministry of Health, INSO)
- Verification that the client has identified and addressed any specific seasonality or cultural factors relevant to the category

A. Stage 2

The purpose of stage 2 is to evaluate the implementation, including effectiveness, of the client's management system. The stage 2 shall take place at the site(s) of the client. It 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.

Stage 2 including, PR01-FR06(Checklist of ISO 9001:2015), PR01-FR010(Checklist ISO 14001:2015), PR01-FR015(Check List of ISO45001:2018), PR01-FR12(Checklist of ISO 13485:2016), PR01-FR09(Stage 2 Audit report).Checklist ISO 22000:2018 PR01-FR14.

All of NCs, type of NC, description of NC, specification of customer, will register in PR01-FR07(NC) and will give to the customer, after closing of NC, customer must fill the root cause, correction and corrective action related to NC.

Examples of major nonconformities which require the acceptance and the verification of the effectiveness of correction and corrective actions are as follows:

a) failure to fully address applicable requirements and implement an entire process for quality management systems (e.g., failure to have a complaint handling or training system)

b) failure to implement applicable requirements for quality management systems

c) failure to implement appropriate corrective and preventative action when an investigation of post market data indicates a pattern of product defects

d) products which are put onto the market and cause undue risk to patient and/or users when the device is used according to the product labelling

e) the existence of products which clearly do not comply with the client's specifications and/or the regulatory requirements

f) repeated nonconformities from previous audits

The audit team analyses all information and audit evidence gathered during stage 1 and stage 2 to review the audit findings and agree on the audit conclusions.

The Organization is required to carry out an analysis of non-conformity root causes and is committed to communicate to Agah afarin Aria the correction and/or the corrective actions taken against the non-conformities, in accordance with modalities and timings mentioned in the relevant Certification Regulations applicable to this audit. This time **is 30 days for Major(correction and corrective actions) and Minor(client's plan for correction and corrective action)**non- conformities

to close the nonconformities in the certification audit, the required time could not be more than **3 months** for

Document review for FSMS audits (ISO 22000):

Prior to the Stage 2 audit, Agah Afarin Aria shall conduct a documented review of the client's FSMS documentation in accordance with ISO 22003-1:2022, Clause 9.2.2.2. This review shall include:

- Obtaining and reviewing the client's FSMS programme documentation;
- Reviewing documentation against ISO 22000 requirements;
- Verifying the adequacy of the client's documented management system;
- Determining whether the client's documents meet requirements or identifying nonconformities;
- Establishing investigative lines for the Stage 2 audit;
- Confirming the client's readiness for the Stage 2 audit.

The results of the document review shall be recorded in PR01-FR03 (Stage 1 Audit Report).

A. Conducting the opening meeting

A formal opening meeting, shall be held with the client's management and, where appropriate, those responsible for the functions or processes to be audited. The purpose of the opening meeting, usually conducted by the audit team leader, is to provide a short explanation of how the audit activities will be undertaken as **PR01-FR06/01 (Checklist of ISO 9001:2015), PR01-FR010/0 (Checklist ISO 14001:2015), PR01-FR015/0 (Check List of ISO45001:2018), PR01-FR12/01 (Checklist of ISO 13485:2016), PR01-FR09/0 (Stage 2 Audit report),Checklist ISO 22000:2018 PR01-FR14.**

The degree of detail will be consistent with the familiarity of the client with the audit process and shall consider the following:

a) Introduction of the participants, including an outline of their roles;

b) Confirmation of the scope of certification;

c) Confirmation of the audit plan (including type and scope of audit, objectives, criteria, and methodology, including that auditing is based on sampling), any changes, and other relevant arrangements with the client, such as the date and time for the closing meeting, interim meetings between the audit team and the client's management;

d) Confirmation of formal communication channels between the audit team and the client;

e) Confirmation that the resources and facilities needed by the audit team are available;

f) Confirmation of matters relating to confidentiality;

g) Confirmation of relevant work safety, emergency, security, and food safety procedures for the audit team;

h) Confirmation of the availability, roles, and identities of any guides, observers, or escorts;

i) The method of reporting, including any grading of audit findings;

j) Information about the conditions under which the audit may be prematurely terminated;

k) Confirmation that the audit team leader and audit team representing the certification body are responsible for the audit and shall be in control of executing the audit plan, including audit activities and audit trails;

l) Confirmation of the status of findings from the previous review or audit, if applicable;

m) Confirmation of the language to be used during the audit;

n) Confirmation that, during the audit, the client will be kept informed of audit progress and any concerns;

o) Opportunity for the client to ask questions;

p) Completion of meeting records.

Communication during the audit

-During the audit, the audit team shall periodically assess audit progress and exchange information. The audit team leader shall reassign work as needed between the audit team members and periodically communicate the progress of the audit and any concerns to the client.

- Where the available audit evidence indicates that the audit objectives are unattainable or suggests the presence of an immediate and significant risk (e.g. safety), the audit team leader shall report this to the client and, if possible, to the certification body to determine appropriate action. Such action may include reconfirmation or modification of the audit plan, changes to the audit objectives or audit scope, or termination of the audit. The audit team leader shall report the outcome of the action taken to the certification body.

- The audit team leader shall review with the client any need for changes to the audit scope which becomes apparent as on-site auditing activities progress and report this to the certification body.

- Obtaining and verifying information

During the audit, information relevant to the audit objectives, scope and criteria including :

- information relating to interfaces between functions, activities and processes

-Verify the process flow chart.

- Assess the effectiveness of the implementation of control measures and processes.

- Verify the effectiveness of corrective actions of previous nonconformities/deficiencies.

- Perform the process approach audit.

shall be obtained by

appropriate sampling and verified to become audit evidence.

- Methods to obtain information shall include, but are not limited to:

a) interviews;

b) observation of processes and activities;

c) review of documentation and records.

Conducting Audits (MD 22)

The audit team shall interview the following personnel:

i) the management with legal responsibility for Occupational Health and Safety,

ii) employees' representative(s) with responsibility for Occupational Health and Safety,

iii) personnel responsible for monitoring employees' health, for example, doctors and nurses. Justifications in case of interviews conducted remotely shall be recorded,

iv) managers and permanent and temporary employees.

Other personnel that should be considered for interview are:

i) managers and employees performing activities related to the prevention of

Occupational Health and Safety risks, and

ii) contractors' management and employees.

In case of ISO45001 ,Based on MD22:

The Agah Afarin have procedures detailing the actions to be taken in the event that it discovers a non-compliance with relevant regulatory requirements. These procedures include a requirement that any such non compliances are immediately communicated to the organization being audited.

These items are highlighted in training courses related to 45001 auditors and are included in checklists.

B. <u>Identifying and recording audit findings</u>

Audit findings summarizing conformity and detailing nonconformity will be identified, classified and recorded to enable an informed certification decision to be made or the certification to be maintained as per, **<u>PR01-FR06 (Checklist of ISO 9001:2015), PR01-FR010 (Checklist ISO 14001:2015), PR01-FR015 (Check List of ISO45001:2018), PR01-FR12 (Checklist of ISO 13485:2016), PR01-FR09 (Stage 2 Audit report).Checklist ISO 22000:2018 PR01-FR14</u>**.

Opportunities for improvement may be identified and recorded, unless prohibited by the requirements of a management system certification scheme. Audit findings, however, which are nonconformities, shall not be recorded as opportunities for improvement.

A finding of nonconformity shall be recorded against a specific requirement, and shall contain a clear statement of the nonconformity, identifying in detail the objective evidence on which the nonconformity is based. Nonconformities shall be discussed with the client to ensure that the evidence is accurate and that the nonconformities are understood. The auditor however shall refrain from suggesting the cause of nonconformities or their solution.

The audit team leader shall attempt to resolve any diverging opinions between the audit team and the client concerning audit evidence or findings, and unresolved points shall be recorded and reported to Agah Afarin Aria .

During the Audit , Where the available audit evidence indicates that the audit objectives are unattainable or suggests the presence of an immediate and significant risk ,the audit team leader has reported this to the client and, if possible, to the Agah Afarin Aria to determine appropriate action.

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any such noncompliance with relevant regulatory requirements, are immediately communicated to the organization being audited.

Procedure: Handling Non-Compliance with Regulatory Requirements

1. Identification of Non-Compliance

- **During an audit**, if an auditor identifies a deviation from regulatory requirements, they must:
  - Document the non-compliance (e.g., in the audit report).
  - Classify the severity (Major/Minor).
  - Gather objective evidence (e.g., records, observations, interviews).

2. Immediate Communication to the Audited Organization

- **Verbal Notification** (if critical):
  - Inform the organization's management **immediately** if the non-compliance poses a significant risk (e.g., safety, legal, or regulatory violation).
- **Written Notification** (formal):
  - Issue a **Non-Conformance Report (NCR)** or **Corrective Action Request (CAR)** within **24-48 hours**.
  - Include:
    - Description of the non-compliance.
    - Reference to the violated regulation/standard (e.g., ISO 9001, FDA, EU MDR).
    - Evidence supporting the finding.
    - Deadline for corrective action.

3. Evaluation of Impact

- The **certification body's technical/regulatory team** assesses:
    - Whether the non-compliance affects the validity of the certification.
    - If immediate suspension/withdrawal is required (for severe cases).

4. Corrective Action Plan (CAP) from the Organization

- The audited organization must:
    - Submit a **root cause analysis (RCA)**.
    - Propose corrective and preventive actions (CAPA).
    - Provide evidence of implementation (e.g., updated procedures, training records).

5. Verification & Closure

- The certification body reviews the CAPA for adequacy.
- If acceptable:
    - Close the NCR.
    - Schedule a follow-up audit (if needed).
- If unacceptable:
    - Escalate (e.g., suspend certification until compliance is confirmed).

6. Record Keeping & Reporting

- Maintain records of:
    - Non-compliances identified.
    - Communications with the organization.
    - Corrective actions taken.
- Report to regulatory authorities (if mandated by law).

Preparing audit conclusions

Under the responsibility of the audit team leader and prior to the closing meeting, the audit team shall:

a) review the audit findings, and any other appropriate information obtained during the audit, against the audit objectives and audit criteria and classify the nonconformities;

b) agree upon the audit conclusions, taking into account the uncertainty inherent in the audit process;

c) agree any necessary follow-up actions;

d) confirm the appropriateness of the audit programme or identify any modification required for future audits (e.g. scope of certification, audit time or dates, surveillance frequency, audit team competence).

C. <u>Conducting the closing meeting</u>

A formal closing meeting, where attendance shall be recorded, shall be held with the client's management and, where appropriate, those responsible for the functions or processes audited. The purpose of the closing meeting, usually conducted by the audit team leader, is to present the audit conclusions, including the recommendation regarding certification. Any nonconformities shall be presented in such a manner that they are understood, and the timeframe for responding shall be agreed.

Prior to the closing meeting, the audit team shall:

- Hold an audit team preparatory meeting (if required);
- Analyse audit findings and compare them with requirements;
- Confirm the completion of the audit plan;
- Categorize, review and finalize any nonconformities and opportunities for improvement, and relate them to the process and the system;
- Prepare the preliminary audit report.

During the closing meeting, the following elements shall be included, where the degree of detail shall be consistent with the familiarity of the client with the audit process:

a) Advising the client that the audit evidence obtained was based on a sample of the information, thereby introducing an element of uncertainty;

b) The method and timeframe of reporting, including any grading of audit findings;

c) The certification body's process for handling nonconformities including any consequences relating to the status of the client's certification;

d) The timeframe for the client to present a plan for correction and corrective action for any nonconformities identified during the audit;

e) The certification body's post-audit activities;

f) Information about the complaint and appeal handling processes;

g) Presentation and review of audit findings (nonconformities and/or opportunities for improvement);

h) Confirmation that the objectives of the audit have been met;

i) Provision of positive feedback;

j) Explanation of the next steps (e.g., appeals, post-audit processes, certification decision-making timeline);

k) Obtaining written acknowledgement of nonconformities;

l) Completion of meeting records.

In case of ISO45001 ,Based on MD22:

The organization representative shall be requested to invite the management legally responsible for occupational health and safety, personnel responsible for monitoring employees' health and the employees' representative(s) with responsibility for occupational health and safety to attend the closing meeting. Justification in case of absence shall be recorded.

D. Audit report

AGAH AFARIN ARIA provides a written report for each audit to the client. The audit team may identify opportunities for improvement but shall not recommend specific solutions. Ownership of the audit report shall be maintained by AGAH AFARIN ARIA. The audit report provides an accurate, concise and clear record of the audit to enable an informed certification decision to be made and shall include or refer to the following:

a) identification of the certification body;

b) the name and address of the client and the client's representative;

c) the type of audit (e.g. initial, surveillance or recertification audit or special audits);

d) the audit criteria;

e) the audit objectives;

f) the audit scope, particularly identification of the organizational or functional units or processes audited and the time of the audit;

g) any deviation from the audit plan and their reasons;

h) any significant issues impacting on the audit programme;

i) identification of the audit team leader, audit team members and any accompanying persons;

j) the dates and places where the audit activities (on site or offsite, permanent or temporary sites) were conducted;

k) audit findings, reference to evidence and conclusions, consistent with the requirements of the type of audit, including a description of findings against the certification standard's requirements (e.g., nonconformities, opportunities for improvement);

l) significant changes, if any, that affect the management system of the client since the last audit took place;

m) any unresolved issues, if identified;

n) where applicable, whether the audit is combined, joint or integrated;

o) a disclaimer statement indicating that auditing is based on a sampling process of the available information;

p) recommendation from the audit team;

q) the audited client is effectively controlling the use of the certification documents and marks, if applicable;

r) verification of effectiveness of taken corrective actions regarding previously identified nonconformities, if applicable;

s) comments on the competence and conformity of the client's management system;

t) the final audit conclusions;

u) any unusual circumstances that occurred during the audit.

After the audit report is delivered, AGAH AFARIN ARIA shall conduct the following post-audit activities:

- Deliver the audit report to the client;
- Communicate any information regarding nonconformity resolution timing;
- Review corrective actions for appropriateness;
- Determine requirements for the verification of corrective actions;
- Verify the effectiveness of implementation of corrective actions;
- Report any necessary adjustment of the audit programme, as appropriate.

Cause analysis of nonconformities

All of NCs, type of NC, description of NC, specification of customer, will register in PR01-FR07 (NC) and will give to the customer, after closing of NC, customer must fill the root cause, correction and corrective action related to NC then, effectiveness on NC will review by auditor.

E. Effectiveness of corrections and corrective actions

AGAH AFARIN ARIA reviews the corrections, identified causes and corrective actions submitted by the client to determine if these are acceptable. AGAH AFARIN ARIA verifies the effectiveness of any correction and corrective

actions taken. The evidence obtained to support the resolution of nonconformities will be recorded. The client shall be informed of the result of the review and verification by **reviewing of NC by Auditor** and send it to customer. The client shall be informed if an additional full audit, an additional limited audit, or documented evidence (to be confirmed during future audits) will be needed to verify effective correction and corrective actions by letter that sent to customer by AGAH AFARIN ARIA. **All of report reviews will conduct by head of certification or Quality Coordinator/Specialist and GD.**

for any major nonconformities, it has reviewed, accepted and verified the correction and corrective actions;
for any minor nonconformities it has reviewed and accepted the client's plan for correction and corrective action. For Major NC, follow up audit maybe conduct considering of lead auditor opinion.

3. Certification decision

AGAH AFARIN ARIA ensures that the persons or committees that make the decisions for granting or refusing certification, expanding or reducing the scope of certification, suspending or restoring certification, withdrawing certification or renewing certification are **different from those who carried out the audits**. The individual(s) appointed to conduct the certification decision shall have appropriate competence. **As per PR10(Certification Decision Competence Appraisal).**

4. Information for granting initial certification

The information provided by the audit team to AGAH AFARIN ARIA for the certification

decision shall include, as a minimum:

a) the audit report;

b) comments on the nonconformities and, where applicable, the correction and corrective actions

taken by the client;

c) confirmation of the information provided to the certification body used in the application review

d) confirmation that the audit objectives have been achieved;

e) a recommendation whether or not to grant certification, together with any conditions or observations.

If AGAH AFARIN ARIA is not able to verify the implementation of corrections and corrective actions of any major nonconformity within 6 months after the last day of stage 2, AGAH AFARIN ARIA conduct another stage 2 prior to recommending certification.

When a **transfer of certification** is envisaged from one certification body to another, the accepting

AGAH AFARIN ARIA gather sufficient information in order to take a decision on Certification that including **(last certificate, last audit report, NC and CAPA of NC related to last audit)**

5. Information for granting recertification

AGAH AFARIN ARIA makes decisions on renewing certification based on the results of the recertification audit, as well as the results of the review of the system over the period of certification and complaints received from users of certification.

6. Maintaining certification

AGAH AFARIN ARIA maintains certification based on demonstration that the client continues to satisfy the requirements of the management system standard. It may maintain a client's certification based on a positive conclusion by the audit team leader without further independent review and decision, provided that:

a) for any major nonconformity or other situation that may lead to suspension or withdrawal of certification, the certification body has a system that requires the audit team leader to report to the certification body the need to initiate a review by competent personnel, different from those who carried out the audit, to determine whether certification can be maintained;

b) competent personnel of the AGAH AFARIN ARIA monitor its surveillance activities, including monitoring the reporting by its auditors, to confirm that the certification activity is operating effectively.

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Independently from the involvement of the competent regulatory authority, a special audit may be necessary in the event that the Certification Body becomes aware that there has been a serious incident related to occupational health and safety, for example, a serious accident, or a serious breach of regulation, in order to investigate if the management system has not been compromised and did function effectively. The Certification Body shall document the outcome of its investigation. Information on incidents such as a serious accident, or a serious breach of regulation necessitating the involvement of the competent regulatory authority, provided by the certified client (see G 8.5.3) or directly gathered by the audit team during the special audit, (G 9.6.4.2) shall provide grounds for the Certification Body to decide on the actions to be taken, including a suspension or withdrawal of the certification, in cases where it can be demonstrated that the system seriously failed to meet the OH&S certification requirements. Such requirements shall be part of the contractual agreements between the CAB and the organization.

If the facilities and work areas are subject to closure, the OH&S risks change, as there may no longer be the same risks to employees, but there may be new risks applicable to members of the public (e.g. in case of lack of suitable maintenance and surveillance activities). The Certification Body shall verify that the management system continues to meet the OH&SMS standard and to be effectively implemented in respect of the closed facilities and work areas, and, if not, suspend the certificate.

Where the organization may not be in legal compliance, it shall be able to demonstrate it has activated an implementation plan to achieve full compliance within a declared date, supported by a documented agreement with the regulator, wherever possible for the different national conditions. The successful implementation of this plan shall be considered as a priority within the OH&SMS.

IAF MD 4:2023, IAF MANDATORY DOCUMENT FOR THE USE OF INFORMATION AND COMMUNICATION TECHNOLOGY (ICT) FOR AUDITING/ASSESSMENT PURPOSES

Security and Confidentiality

The security and confidentiality of electronic or electronically-transmitted information is particularly important when using ICT for audit/assessment purposes.

The use of ICT for audit/assessment purposes shall be mutually agreed upon by the body being audited/assessed and the body performing the audit/assessment in accordance with information security and data protection measures and regulations before ICT is used for audit/assessment purposes.

In the case of non-fulfilment of these measures or non-agreement of information security and data protection measures, the body performing the audit/assessment activities shall use other methods to conduct the audit/assessment.

When no agreement is reached for the use of ICT for audit/assessment, other methods shall be used to fulfil audit/assessment objectives.

Process Requirements

3A identifies and document the risks and opportunities that may impact audit/assessment effectiveness for each use of ICT under the same conditions, including the selection of the technologies, and how they are managed.

When ICT is proposed for the audit/assessment activities, the application review shall include a check that the client and the audit/assessment body have the necessary infrastructure to support the use of the ICT proposed.

Considering the risks and opportunities identified, the audit/assessment plan shall identify how ICT will be utilized and the extent to which ICT will be used for audit/assessment purposes to optimize audit/assessment effectiveness and efficiency while maintaining the integrity of the audit/assessment process.

When using ICT, auditors/assessors and other involved persons (e.g. drone pilots, technical experts) shall have the competency and ability to understand and utilize the information and communication technologies employed to achieve the desired results of audit(s)/assessment(s). The auditor/assessor shall also be aware of the risks and opportunities of the information and communication technologies used and the impacts that they may have on the validity and objectivity of the information gathered.

If ICT is used for audit/assessment purposes, it contributes to the total audit/assessment time as additional planning may be necessary which may impact audit/assessment duration.

Note: When determining audit/assessment time and duration, please refer to the Normative References for additional requirements which may impact the application of ICT. The impact upon audit/assessment duration using ICT is not limited by this MD.

Audit/assessment reports and related records shall indicate the extent to which ICT has been used in carrying out audit/assessment and the effectiveness of ICT in achieving the audit/assessment objectives.

If virtual sites are included within the scope, the certification/accreditation documentation shall note that virtual sites are included and the activities performed at the virtual sites shall be identified.

A. Surveillance activities

AGAH AFARIN ARIA develop its surveillance activities 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.

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 AGAH AFARIN ARIA 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) review of actions taken for notification of adverse events, advisory notices, and recalls

At least 9-12 month before certificate expiry, customer must audit and NC must close(Periode of Surveilance Audit)

If the non-conformities are not closed within the stipulated time, the organization will review the matter with the relevant team and if not justified, the certificate will be suspended.

B. Recertification

The purpose of the recertification audit is 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. A recertification audit will be planned and conducted to evaluate the continued fulfilment of all of the requirements of the relevant management system standard or other normative document. This will be planned and conducted in due time to enable for timely renewal before the certificate expiry date.

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.

The recertification audit includes an on-site audit that addresses the following:

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).

For any major nonconformity, AGAH AFARIN ARIA define time limits for correction and corrective actions. These actions shall be implemented and verified prior to the expiration of certification.

If the AGAH AFARIN ARIA has not completed the recertification audit or is unable to verify the implementation of corrections and corrective actions for any major nonconformity prior to the expiry date of the certification, then recertification won't be recommended and the validity of the certification shall not be extended. The client will be informed and the consequences will be explained.

Following **expiration of certification**, AGAH AFARIN ARIA **can restore** certification within **6 months** provided that the outstanding recertification activities are completed, otherwise at least a stage 2 will be conducted. The effective date on the certificate will be on or after the recertification decision and the expiry date shall be based on prior certification cycle.

C. Special audits

I. Expanding scope

AGAH AFARIN ARIA will, in response to an application for expanding the scope of a certification already granted, undertake a review of the application and determine any audit activities necessary to decide whether or not the extension may be granted. This may be conducted in conjunction with a surveillance audit.

II. Short-notice audits

It may be necessary for AGAH AFARIN ARIA to conduct audits of certified clients at short notice or unannounced to investigate complaints, or in response to changes, or as follow up on suspended clients and may be required when:

a) external factors apply such as:

a. devices in scope of certification indicate a possible significant deficiency in the quality management system

b. significant safety and performance related information becoming known to the CAB

b) significant changes occur which have been submitted as required by the regulations or become known to Agah Afarin Aria, and which could affect the decision on the client's state of compliance with the regulatory requirements

c) when required by legal requirements under public law or by the relevant Regulatory Authority

In such cases:

a) AGAH AFARIN ARIA describe and make known in advance to the certified clients, the conditions under which such audits will be conducted;

b) AGAH AFARIN ARIA exercise additional care in the assignment of the audit team because of the lack of opportunity for the client to object to audit team members.

The following are examples of such changes which could be significant and relevant to the CAB when considering that a short notice or unannounced audit is required, although none of these changes should automatically trigger a short term or unannounced audit:

a) QMS – impact and changes:

i) new ownership

ii) extension to manufacturing and/or design control

iii) new facility, site change

a. modification of the site operation involved in the manufacturing activity (e.g., relocation of the manufacturing operation to a new site or centralizing the design and/or development functions for several manufacturing sites)

iv) new processes, process changes

a. significant modifications to special processes (e.g., change in production from sterilization through a supplier to an on-site facility or a change in the method of sterilization)

v) QM management, personnel

a. modifications to the defined authority of the management representative that impact:

i. quality management system effectiveness or regulatory compliance

ii. the capability and authority to assure that only safe and effective medical devices are released

b) product related changes:

i) new products, categories

ii) addition of a new device category to the manufacturing scope within the quality management system (e.g., addition of sterile single use dialysis sets to an existing scope limited to haemodialysis equipment, or the addition of magnetic resonance imaging to an existing scope limited to ultrasound equipment)

c) QMS & Product related changes:

i) changes in standards, regulations

ii) post market surveillance, vigilance

An unannounced or short-notice audit may also be necessary if the CAB has justifiable concerns about implementation of corrective actions or compliance with standard and regulatory requirements.

In case of ISO45001,Based on MD22;

Independently from the involvement of the competent regulatory authority, **a special** audit may be necessary in the event that the Certification Body becomes aware that there has been a **serious incident** related to occupational health and safety, for example, a serious accident, or a serious breach of regulation, in order to investigate if the management system has not been compromised and did function effectively. The Certification Body shall document the outcome of its investigation.

III. Suspending, withdrawing or reducing the scope of certification

AGAH AFARIN ARIA have a policy and documented procedure(s) for suspension, withdrawal or reduction of the scope of certification, and specify the subsequent actions by AGAH AFARIN ARIA.

AGAH AFARIN ARIA suspend certification in cases when, for example:

— the client's certified management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the management system;

— the certified client does not allow surveillance or recertification audits to be conducted at the required frequencies(surveillance audit should be perform at least 9-11 month after issue date or maximum time which could be extended for 12 month if the audit has not been performed so the certificate will be suspended) ;
— the certified client has voluntarily requested a suspension.
Under suspension, the client's management system certification is temporarily invalid.

AGAH AFARIN ARIA restore the suspended certification if the issue that has resulted in the suspension has been resolved. Failure to resolve the issues that have resulted in the suspension in a time established by AGAH AFARIN ARIA result in **withdrawal or reduction of the scope of certification.**
In Case of withdrawal the customer must return the Certificate.
In most cases, the suspension would not **exceed six months**.
In case of suspension, the company will be informed by official letter from AGAH AFARIN ARIA and the company should try to correct any issues resulted certificate suspension before the defined deadline. And certificate situation will be published as "Suspended " in web site .
AGAH AFARIN ARIA reduce the scope of certification to exclude the parts not meeting the requirements, when the certified client has persistently or seriously failed to meet the certification requirements for those parts of the scope of certification. Any such reduction shall be in line with the requirements of the standard used for certification.
Also for ISO13485 audit, Agah Afarin Aria is responsible for determining that the client organization has evaluated statutory and regulatory compliance and can show that appropriate action has been taken in cases of non-compliance with relevant legislation and regulations, including the notification to the Regulatory Authority of any incidences that require reporting.

In case of ISO45001,Based on MD22;
Information on incidents such as a serious accident, or a serious breach of regulation necessitating the involvement of the competent regulatory authority, provided by the certified client or directly gathered by the audit team during the special audit, shall provide grounds for the Certification Body to decide on the actions to be taken, including a suspension or withdrawal of the certification, in cases where it can be demonstrated that the system seriously **failed to meet the OH&S** certification requirements. Such requirements shall be part of the contractual agreements between the CAB and the organization.

7. Appeals

AGAH AFARIN ARIA has a documented process to receive, evaluate and make decisions on appeals as per PR11/0.

AGAH AFARIN ARIA is responsible for all decisions at all levels of the appeals-handling process. AGAH AFARIN ARIA ensures **that the persons engaged in the appeals-handling process are different from those who carried out the audits and made the certification decisions.**

Submission, investigation and decision on appeals will not result in any discriminatory actions against the appellant.

The appeals-handling process includes at least the following elements and methods:

a) an outline of the process for receiving, validating and investigating the appeal, and for deciding what actions need to be taken in response to it, taking into account the results of previous similar appeals;

b) tracking and recording appeals, including actions undertaken to resolve them;

c) ensuring that any appropriate correction and corrective action are taken.

AGAH AFARIN ARIA receiving the appeal is responsible for gathering and verifying all necessary information to validate the appeal.

AGAH AFARIN ARIA will acknowledge receipt of the appeal and provide the appellant with progress reports and the result of the appeal.

The decision to be communicated to the appellant will be made by, or reviewed and approved by, individual(s) not previously involved in the subject of the appeal.

AGAH AFARIN ARIA gives formal notice to the appellant of the end of the appeals-handling process.

8. Complaints

AGAH AFARIN ARIA is responsible for all decisions at all levels of the complaints handling process.

Submission, investigation and decision on complaints won't result in any discriminatory actions against the complainant.

Upon receipt of a complaint, AGAH AFARIN ARIA **confirms whether the complaint relates to certification activities** that it is responsible for and, if so, will deal with it. If the complaint relates to a certified client, then examination of the complaint will consider the effectiveness of the certified management system.

Any valid complaint about a certified client shall also be referred by AGAH AFARIN ARIA to the certified client in question at an appropriate time.

AGAH AFARIN ARIA has a documented process to receive, evaluate and make decisions on complaints. This process is subject to requirements for confidentiality, as it relates to the complainant and to the subject of the complaint.

The complaints-handling process include at least the following elements and methods:

a) an outline of the process for receiving, validating, investigating the complaint, and for deciding what actions need to be taken in response to it;

b) tracking and recording complaints, including actions undertaken in response to them;

c) ensuring that any appropriate correction and corrective action are taken.

AGAH AFARIN ARIA receiving the complaint is responsible for gathering and verifying all necessary information to validate the complaint.

Whenever possible, AGAH AFARIN ARIA will acknowledge receipt of the complaint, and shall provide the complainant with progress reports and the result of the complaint.

The decision to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not **previously involved in the subject of the complaint**.

Whenever possible, AGAH AFARIN ARIA give formal notice of the end of the complaints-handling process to the complainant.

AGAH AFARIN ARIA determines, together with **the certified client** and the **complainant,** whether and, if so to what extent, the subject of the complaint and its resolution shall be made public.

9. Client records

AGAH AFARIN ARIA maintains records on the audit and other certification activities for all clients, including all organizations that submitted applications, and all organizations audited, certified, or with certification suspended or withdrawn.

Records on certified clients includes the following:

a) application information and initial, surveillance and recertification audit reports;

b) certification agreement;

c) justification of the methodology used for sampling of sites, as appropriate;

NOTE Methodology of sampling includes the sampling employed to audit the specific management system and/or to select sites in the context of multi-site audit.

d) justification for auditor time determination

e) verification of correction and corrective actions;

f) records of complaints and appeals, and any subsequent correction or corrective actions;

g) committee deliberations and decisions, if applicable;

h) documentation of the certification decisions;

i) certification documents, including the scope of certification with respect to product, process or service, as applicable;

j) related records necessary to establish the credibility of the certification, such as evidence of the competence of auditors and technical experts;

k) audit programmes.

AGAH AFARIN ARIA keeps the records on applicants and clients secure to ensure that the information is kept confidential. Records are transported, transmitted or transferred in a way that ensures that confidentiality is maintained.

Records of certified clients and previously certified clients are retained for the duration of **the current cycle + <u>one full certification cycle</u>**.

10. <u>Notice of changes by a certified client</u>

AGAH AFARIN ARIA has legally enforceable arrangements to ensure that the certified client informs AGAH AFARIN ARIA, without delay, of matters that may affect the capability of the management system to continue to fulfil the requirements of the standard used for certification in contract as per PR03-FR03/01. These include, for example, changes relating to:

a) the legal, commercial, organizational status or ownership;

b) organization and management (e.g. key managerial, decision-making or technical staff);

c) contact address and sites;

d) scope of operations under the certified management system;

e) major changes to the management system and processes.

All of changes will be registered in PR01-FR11, changes will be discus by quality coordinator, head of certification and general director. Final result will inform to the customer within 7 days.

Based on MD22:2023

The legally enforceable arrangements shall also require that the certified client informs the Certification Body, without delay, of the occurrence of a serious incident or breach of regulation necessitating the involvement of the competent regulatory authority

Standard Transition:

In the event of a standard update, (taking into account the approval of the Agah Afarin from the Accreditation Body) the certificates **issued are valid for 3 years** after the date of issuance of the new standard, but during this period, customers are informed about the new version of the standard through the website , Announcements including official letter, certification rules, etc., and also during surveillance audits for The new required documents that should be completed over time, and during this 3-year period, if an old customer(certified Before) requests an audit based on the new standard version, there will be no prohibition on it.

Regarding the certification of new customers after 18 months from the issuance of the new version of the standard, audits will be conducted based on the new version.

For example for new version of ISO14001 :2026

For FSMS certified clients, the legally enforceable arrangements shall additionally require the client to inform Agah Afarin Aria without delay of:

- Any food safety incident or product recall;
- Any regulatory enforcement action related to food safety (e.g., from Iran FDA or Ministry of Health).

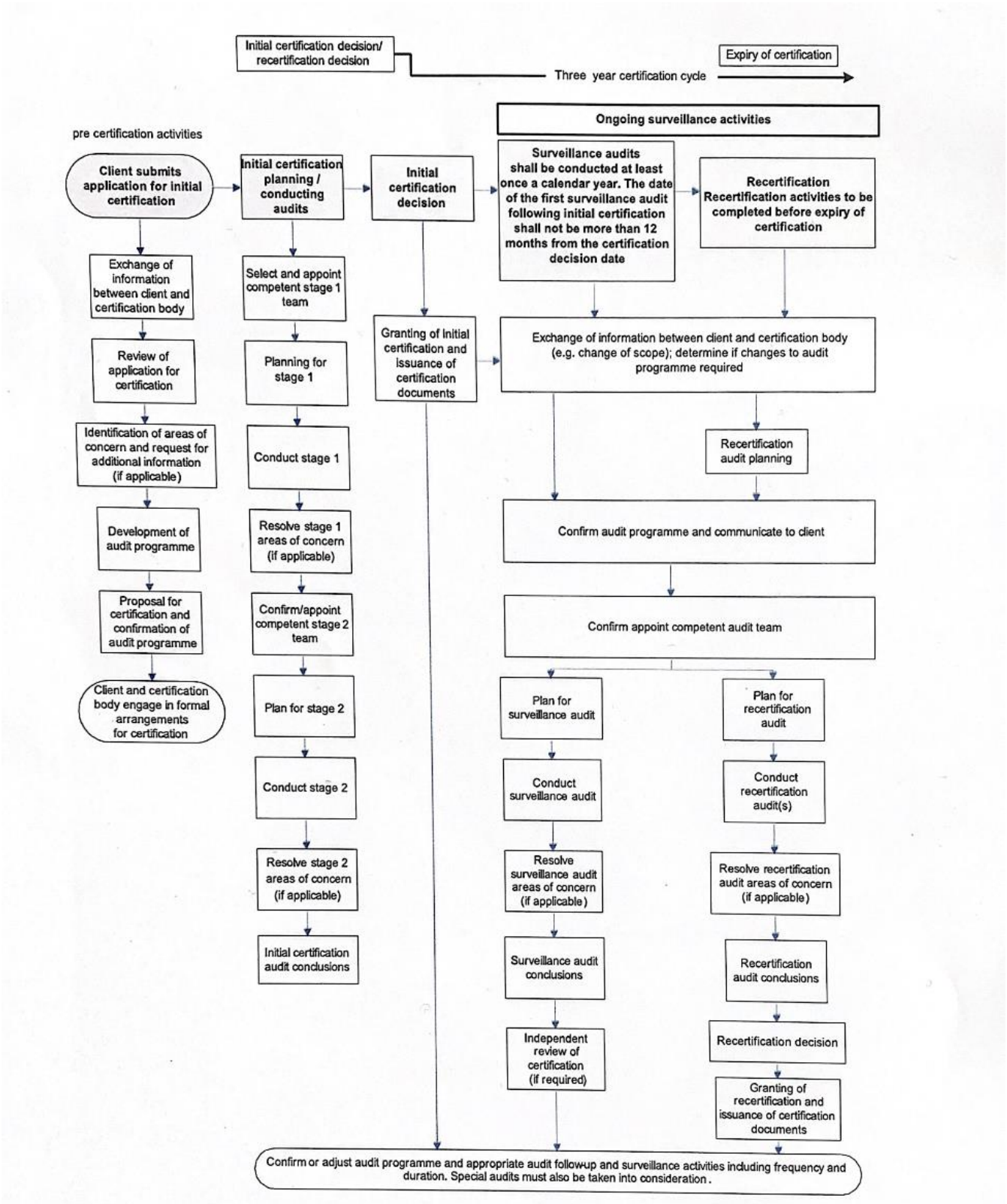

Figure E.1 — Typical process flow for audit and certification process

index:

References :

ISO17021-1:2015

ISO17021-2:2016

ISO17021-3:2017

ISO17021-10:2018

IAF MD 22:2023

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