

ISO/IEC 17021:2011 AUDIT PROCESS

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Audit Process

2 Normative references

- **ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary***
- ~~ISO 19011:2002, *Guidelines for quality and/or environmental management systems auditing*~~²⁾
- **ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles***
- ~~2) References in this document to the relevant guidance in ISO 19011 apply to the auditing of all other types of management systems.~~

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Audit Process

3 Terms and definitions

3.4 third-party certification audit

audit carried out by an auditing organization independent of the client and the user, for the purpose of certifying the client's management system

NOTE 4 A joint audit is when two or more auditing organizations cooperate to audit a single client.

NOTE 5 A combined audit is when a client is being audited against the requirements of two or more management systems standards together.

NOTE 6 An integrated audit is when a client has integrated the application of requirements of two or more management systems standards into a single management system and is being audited against more than one standard.

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3 Terms and definitions

3.5 client

organization whose management system is being audited for certification purposes

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3 *Terms and definitions*

3.6 *auditor*

person who conducts an audit

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3 Terms and definitions

3.8 guide

person appointed by the client to assist the audit team

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3 Terms and definitions

3.9 observer

person who accompanies the audit team but does not audit

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Audit Process

9 Process requirements

9.1 General requirements

9.1.1 Audit programme

9.1.1.1 An audit programme for the full certification cycle shall be developed to clearly identify the audit activity(ies) required to demonstrate that the client's management system fulfils the requirements for certification to the selected standard(s) or other normative document(s).

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Audit Process

9 Process requirements

9.1 General requirements

9.1.1 Audit programme

9.1.1.2 The audit programme shall include a two-stage initial audit, surveillance audits in the first and second years, and a recertification audit in the third year prior to expiration of certification. The three-year certification cycle begins with the certification or recertification decision. The determination of the audit programme and any subsequent adjustments shall consider the size of the client organization, the scope and complexity of its management system, products and processes as well as demonstrated level of management system effectiveness and the results of any previous audits.

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Audit Process

9 Process requirements

9.1 General requirements

9.1.1 Audit programme

9.1.1.2

NOTE 1 Annex E is a flowchart of a typical third-party audit and certification process.

NOTE 2 Annex F lists additional items that can be considered when developing or revising an audit programme.

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Audit Process

9 Process requirements

9.1 General requirements

9.1.1 Audit programme

9.1.1.3 Where a certification body is taking account of certification or other audits already granted to the client, it shall collect sufficient, verifiable information to justify and record any adjustments to the audit programme.

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Audit Process

9 Process requirements

9.1.2 Audit plan

9.1.2.1 General

The certification body shall ensure that an audit plan is established for each audit identified in the audit programme to provide the basis for agreement regarding the conduct and scheduling of the audit activities. This audit plan shall be based on documented requirements of the certification body. ~~drawn up in accordance with the relevant guidance provided in ISO 19011.~~

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Audit Process

9 Process requirements

9.1.2.2 Determining audit objectives, scope and criteria

9.1.2.2.1 The audit objectives shall be determined by the certification body. The audit scope and criteria, including any changes, shall be established by the certification body after discussion with the client.

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Audit Process

9 Process requirements

9.1.2.2 Determining audit objectives, scope and criteria

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

- a) ...determination of conformity...with audit criteria;**
- b) ...ability of the management system to ensure the client organization meets applicable statutory, regulatory and contractual requirements;**

NOTE A management system certification audit is not a legal compliance audit.

- c) ...effectiveness of the management system to ensure the client organization is continually meeting its specified objectives;**
- d) ...areas for potential improvement of the management system.**

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Audit Process

9 Process requirements

9.1.2.2 Determining audit objectives, scope and criteria

9.1.2.2.3 The audit scope shall describe the extent and boundaries of the audit, such as physical locations, organizational units, activities and processes to be audited. Where the initial or re-certification process consists of more than one audit (e.g. covering different locations), the scope of an individual audit may not cover the full certification scope, but the totality of audits shall be consistent with the scope in the certification document.

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Audit Process

9 Process requirements

9.1.2.2 Determining audit objectives, scope and criteria

9.1.2.2.4 The audit criteria shall be used as a reference against which conformity is determined, and shall include:

- the requirements of a defined normative document on management systems;**
- the defined processes and documentation of the management system developed by the client.**

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Audit Process

9 Process requirements

9.1.2.3 Preparing the 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 are to be conducted, including visits to temporary sites, as appropriate;**
- e) the expected time and duration of on-site audit activities;**
- f) the roles and responsibilities of the audit team members and accompanying persons.**

NOTE 1 The audit plan information can be contained in more than one document.

NOTE 2 Annex F lists additional items that can be considered when preparing or revising the audit plan.

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Audit Process

9 Process requirements

9.1.3 Audit team selection and assignments

9.1.3.1 The certification body shall have a process for selecting and appointing the audit team, including the audit team leader, taking into account the competence needed to achieve the objectives of the audit. ~~This process shall be based on documented requirements, drawn up in accordance with the relevant guidance provided in ISO 19011.~~ 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.

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Audit Process

9 Process requirements

9.1.3 Audit team selection and assignments

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

- a) audit objectives, scope, criteria and estimated time of the audit;**
- b) whether the audit is a combined, integrated or joint audit;**
- 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;**
- f) whether the members of the audit team have previously audited the client's management system.**

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Audit Process

9 Process requirements

9.1.3 Audit team selection and assignments

9.1.3.3 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 are to be selected such that they do not unduly influence the audit.

- **NOTE The criteria for the selection of technical experts are determined on a case-by-case basis by the needs of the audit team and the scope of the audit.**

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Audit Process

9 Process requirements

9.1.3 Audit team selection and assignments

9.1.3.4 Auditors-in-training may be included in the audit team as participants, 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.

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Audit Process

9 Process requirements

9.1.3 Audit team selection and assignments

9.1.3.5 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. Changes to the work assignments may be made as the audit progresses to ensure achievement of the audit objectives.

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9 Process requirements

9.1.4 Determining audit time

9.1.4.1 ...documented procedures for determining audit time, and ...audit time determined by the CB, and the justification for the determination, shall be recorded. In determining the audit time, the CB shall consider, among other things, the following aspects:

- a) the requirements of the...standard;**
- b) size and complexity;**
- c) technological and regulatory context;**
- d) any outsourcing...;**
- e) the results of any prior audits;**
- f) number of sites and multi-site considerations;**
- g) the risks...the products, processes or activities ...;**
- h) when audits are combined, joint or integrated.**

Where specific criteria have been established for a specific certification scheme, e.g. ISO/TS 22003 or ISO/IEC 27006, these shall be applied.

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Audit Process

9 Process requirements

9.1.4 Determining audit time

9.1.4.2 The time spent by any team member that is not assigned as an auditor (i.e. technical experts, translators, interpreters, observers and auditors-in-training) shall not count in the above established audit time.

NOTE The use of translators, interpreters can necessitate additional audit time.

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9 *Process requirements*

9.1.5 *Multi-site sampling*

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Audit Process

9 *Process requirements*

9.1.6 *Communication of audit team tasks*

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Audit Process

9 *Process requirements*

9.1.7 *Communication concerning audit team members*

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Audit Process

9 *Process requirements*

9.1.8 *Communication of audit plan*

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Audit Process

9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.1 General

The certification body shall have a process for conducting on-site audits. defined in documented requirements drawn up in accordance with the relevant guidance provided in ISO 19011. This process shall include an opening meeting at the start of the audit and a closing meeting at the conclusion of the audit.

NOTE In addition to visiting physical location(s) (e.g. factory), “on-site” can include remote access to electronic site(s) that contain(s) information that is relevant to the audit of the management system.

NOTE 2 The term “auditee” as used in ISO 19011 means the organization being audited.

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Audit Process

9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.2 Conducting the opening meeting

A formal opening meeting, where attendance shall be recorded, 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, which shall usually be conducted by the audit team leader, is to provide a short explanation of how the audit activities will be undertaken and shall include the following elements. The degree of detail shall be consistent with the familiarity of the client with the audit process:

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9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.2 Conducting the opening meeting

- 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 and criteria), 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;***

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Audit Process

9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.2 Conducting the opening meeting

- 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 and security procedures for the audit team;***
- h) confirmation of the availability, roles and identities of any guides and observers;***

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9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.2 Conducting the opening meeting

- ▣ ***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 is responsible for the audit and shall be in control of executing the audit plan including audit activities and audit trails;***

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Audit Process

9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.2 Conducting the opening meeting

- l) confirmation of the status of findings of the previous review or audit, if applicable;***
- m) methods and procedures to be used to conduct the audit based on sampling;***
- n) confirmation of the language to be used during the audit;***
- o) confirmation that, during the audit, the client will be kept informed of audit progress and any concerns;***
- p) opportunity for the client to ask questions.***

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Audit Process

9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.3 Communication during the audit

9.1.9.3.1 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.

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Audit Process

9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.3 Communication during the audit

9.1.9.3.2 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.

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9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.4 Observers and guides

9.1.9.4.1 Observers

The presence and justification of observers during an audit activity shall be agreed to by the certification body and client prior to the conduct of the audit. The audit team shall ensure that observers do not 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.

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9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.4 Observers and guides

9.1.9.4.2 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.

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Audit Process

9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.4 Observers and guides

9.1.9.4.2 Guides

NOTE 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;

e) providing clarification or information as requested by an auditor.

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Audit Process

9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.5 Collecting and verifying information

9.1.9.5.1 During the audit, information relevant to the audit objectives, scope and criteria (including information relating to interfaces between functions, activities and processes) shall be collected by appropriate sampling and verified to become audit evidence.

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Audit Process

9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.5 Collecting and verifying information

9.1.9.5.2 Methods to collect information shall include, but are not limited to:

- a) interviews;**
- b) observation of processes and activities;**
- c) review of documentation and records.**

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Audit Process

9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.6 Identifying and recording audit findings

9.1.9.6.1 Audit findings summarizing conformity and detailing nonconformity and its supporting audit evidence shall be recorded and reported to enable an informed certification decision to be made or the certification to be maintained.

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Audit Process

9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.6 Identifying and recording audit findings

9.1.9.6.2 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 in accordance with 9.1.15 b) and c) shall not be recorded as opportunities for improvement.

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Audit Process

9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.6 Identifying and recording audit findings

9.1.9.6.3 A finding of nonconformity shall be recorded against a specific requirement of the audit criteria, contain a clear statement of the nonconformity and identify 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.

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Audit Process

9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.6 Identifying and recording audit findings

9.1.9.6.3

NOTE Nonconformities, consistent with the requirements of 9.1.15 b), can be classified as major, whereas other nonconformities [9.1.15 c)] can be classified as minor nonconformities.

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Audit Process

9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.6 Identifying and recording audit findings

9.1.9.6.4 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.

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Audit Process

9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.7 Preparing audit conclusions

Prior to the closing meeting, the audit team shall:

- a) review the audit findings, and any other appropriate information collected during the audit, against the audit objectives;***
- b) agree upon the audit conclusions, taking into account the uncertainty inherent in the audit process;***
- c) identify any necessary follow-up actions;***
- d) confirm the appropriateness of the audit programme or identify any modification required (e.g. scope, audit time or dates, surveillance frequency, competence).***

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Audit Process

9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.8 Conducting the closing meeting

9.1.9.8.1 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, which shall normally be 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.

NOTE "Understood" does not necessarily mean that the nonconformities have been accepted by the client.

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Audit Process

9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.8 Conducting the closing meeting

9.1.9.8.2 The closing meeting shall also include the following elements. 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 collected 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;**

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Audit Process

9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.8 Conducting the closing meeting

9.1.9.8.2

- 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 handling and appeal processes.**

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Audit Process

9 Process requirements

9.1.9 Conducting on-site audits

9.1.9.8 Conducting the closing meeting

9.1.9.8.3 The client shall be given opportunity for questions. Any diverging opinions regarding the audit findings or conclusions between the audit team and the client shall be discussed and resolved where possible. Any diverging opinions that are not resolved shall be recorded and referred to the certification body.

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Audit Process

9 Process requirements

9.1.10 Audit report

9.1.10.1 The certification body shall provide a written report for each audit. The report shall be based on relevant guidance provided in ISO 19011. The audit team may identify opportunities for improvement but shall not recommend specific solutions. Ownership of the audit report shall be maintained by the certification body.

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Audit Process

9 Process requirements

9.1.10 Audit report

9.1.10.2 The audit team leader shall ensure that the audit report is prepared and shall be responsible for its content. The audit report shall provide an accurate, concise and clear record of the audit to enable an informed certification decision to be made...

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Audit Process

9 Process requirements

9.1.10 Audit report

9.1.10.2

...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 management representative;***
- c) the type of audit (e.g. initial, surveillance or recertification audit);***
- d) the audit criteria;***
- e) the audit objectives;***

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Audit Process

9 Process requirements

9.1.10 Audit report

9.1.10.2

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

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

h) the dates and places where the audit activities (on site or offsite) were conducted;

i) audit findings, evidence and conclusions, consistent with the requirements of the type of audit;

j) any unresolved issues, if identified.

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Audit Process

9 Process requirements

9.1.12 Effectiveness of corrections and corrective actions

The certification body shall review the corrections, identified causes and corrective actions submitted by the client to determine if these are acceptable. The certification body shall verify the effectiveness of any correction and corrective actions taken. The evidence obtained to support the resolution of nonconformities shall be recorded. The client shall be informed of the result of the review and verification.

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Audit Process

9 Process requirements

9.1.12 Effectiveness of corrections and corrective actions

NOTE Verification of effectiveness of correction and corrective action can be carried out based on a review of documentation provided by the client, or where necessary, through verification on-site.

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Audit Process

9 *Process requirements*

9.1.13 *Additional audits*

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Audit Process

9 *Process requirements*

9.1.14 *Certification decision*

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Audit Process

9 *Process requirements*

9.1.15 *Actions prior to making a decision*

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Audit Process

9 Process requirements

9.2 Initial audit and certification

9.2.1 Application

9.2.2 Application review

9.2.2.2 Following the review of the application, the certification body shall either accept or decline an application for certification. When the certification body declines an application for certification as a result of the review of application, the reasons for declining an application shall be documented and made clear to the client.

NOTE When declining an application for certification, the certification body should be careful not to act in conflict with the principles set out in Clause 4.

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Audit Process

10 Management system requirements for certification bodies

10.2 Option 1: Management system requirements in accordance with ISO 9001

~~10.2.5 Design and development~~

- ~~— For application of the requirements of ISO 9001, when developing a new management system certification scheme, or adapting an existing one to special circumstances, the certification body shall ensure that the guidance given in ISO 19011, and which is appropriate to third-party situations, is included as a design input.~~**