

# **QMS CB Accreditation Criteria**

2007-09-01

Korea Accreditation Board (KAB)

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## QMS CB Accreditation Criteria

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### Introduction

1. This document set outs criteria for bodies operating assessment and certification of organizations' quality management systems, which was prepared by Korea Accreditation Board (KAB). If such bodies are to be accredited and to maintain their accreditation, they shall meet the requirements of this document and the accreditation procedures specified by KAB.
  2. This document is based on the ISO/IEC Guide 17021:2005 (General requirements for bodies operating assessment and certification of management system), but slightly changed part of definitions for the application to the certification audit in accordance with ISO 9001:2000/KS A 9001. When guidance on the requirements is offered in the IAF Guidance, KAB adopted the relevant guidance of IAF. And if guidance on a clause in the document is not offered by IAF, or if KAB considers that additional guidance is necessary for the operation of accreditation program, KAB provided additional or supplementary guidance of the clause concerned.
  3. IAF Guidance referred in this document will be the basis of mutual accreditation arrangement and need for consistent application of ISO/IEC 17021. IAF MLA signatories will assess each operation of ISO/IEC 17021, which is adopted as general managements principle. And KAB Guidance in this document shall be approved by IAF in accordance with IAF MLA prior to be managed.
  4. The terms "shall" is used through this document to indicate those provisions which, reflecting the requirements of ISO/IEC 17021, are mandatory. The term "should" is used to indicate those provisions which, although they constitute guidance for the application of the requirements, are expected to be adopted by a certification body. Any variation from the guidance by a certification body shall be an exception. Such variations will only be permitted on a case by case basis after the certification body has demonstrated to the KAB that the exception meets the requirements of the relevant clauses of ISO/IEC 17021 and the intent of KAB guidance in some equivalent way.
  5. In this document, the text of ISO/IEC 17021 is classified by clause, and IAF or KAB Guidance where it is offered is identified with the title "KAB Guidance". This document
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may be amended at any time when the relevant ISO Guide and IAF Guidance are revised.

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### 1. Scope

This document specifies general requirements for a third-party body operating quality management system certification to meet if it is to be accredited by KAB as competent and reliable in the operation of quality system certification, in accordance with Article 7 of the Quality Management and Industrial Products Safety Control Act.

### 2 Normative references and Application documents

For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document(including any amendments)applies.

#### 2.1 Normative references

ISO/IEC 17000:2004, Conformity assessment – Vocabulary and general principles  
ISO/IEC 17021:2006 Conformity assessment – Requirements for bodies providing audit and certification of management systems  
IAF annex guideline for application of ISO/IEC Guide  
ISO 9000:2005 Quality management system – Fundamentals and vocabulary  
ISO 9001:2000 /KS A 9001:2001 Quality management system – Requirements  
KS A 19011:2003 Guidelines for quality and/or environmental management systems auditing

#### 2.2 Application documents

KAB Guide I on Application for Accreditation (KAB-G-01))  
KAB Procedure for Complaints and Appeals (KAB-P-20)  
KAB Accreditation Advisory (KAB-A-01~08) Guidelines for quality management systems certification body

### 3. Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000, ISO/IEC 17000 and the following apply.

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### 3.1 Certified client

organization whose management system has been certified.

### 3.2 Impartiality

actual and perceived presence of objectivity

**NOTE 1** Objectivity means that conflicts of interest do not exist or are resolved so as not to adversely influence subsequent activities of the certification body.

**NOTE 2** Other terms that are useful in conveying the elements of impartiality are: objectivity, independence, freedom from conflict of interest, freedom from bias, lack of prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment, balance.

### 3.3 management system consultancy

participation in designing, implementing or maintaining a management system

**EXAMPLES** are

- a) preparing or producing manuals or procedures, and
- b) giving specific advice, instructions, solutions towards the development and implementation of a management system;

**NOTE** Arranging training and participating as a trainer is not considered consultancy, provided that, where the course relates to management systems or auditing, it is confined to the provision of generic information that is freely available in the public domain; i.e. the trainer should not provide company-specific solutions.

## 4. Principles

### 4.1 General

**4.1.1** The principles are the basis for the subsequent specific performance and descriptive requirements in this International Standard. This International Standard does not give specific requirements for all situations that can occur. These principles should be applied as guidance for the decisions that may need to be made for unanticipated situations. Principles are not requirements.

**4.1.2** The overall aim of certification is to give confidence to all parties that a management system fulfils specified requirements. The value of certification is the degree of public confidence and trust that is established by an impartial and competent assessment by a third-party. Parties that have an interest in certification include, but are not limited to:

- a) the clients of the certification bodies;
  - b) the customers of the organizations whose management systems are certified ;
  - c) governmental authorities;
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- d) non-governmental organizations, and
- e) consumers and other members of the public.

### 4.1.3 Principles for inspiring confidence include:

- impartiality
- competence
- responsibility
- openness
- confidentiality
- responsiveness to complaints.

## 4.2 Impartiality

**4.2.1** Being impartial, and being perceived to be impartial, is necessary for a certification body to deliver certification that provides confidence.

**4.2.2** It is recognized that the source of revenue for a certification body is its client paying for certification, and that this is a potential threat to impartiality.

**4.2.3** To obtain and maintain confidence, it is essential that a certification body's decision be based on objective evidence of conformity (or nonconformity) obtained by the certification body, and that its decisions are not influenced by other interests or by other parties.

### 4.2.4 Threats to impartiality include the following:

- a) Self-interest threats: threats that arise from a person or body acting in their own interest. A concern related to certification, as a threat to impartiality, is financial self-interest.
- b) Self-review threats: threats that arise from a person or body reviewing the work done by themselves. Auditing the management systems of a client to whom the certification body provided management systems consultancy would be a self-review threat.
- c) Familiarity (or trust) threats: threats that arise from a person or body being too familiar with or trusting of another person instead of seeking audit evidence.
- d) Intimidation threats: threats that arise from a person or body having a perception of being coerced openly or secretly, such as a threat to be replaced or reported to a supervisor.

## 4.3 Competence

The competence of the personnel supported by the management system of the certification body is necessary to deliver certification that provides confidence. Competence is the demonstrated ability to effectively apply knowledge and skills.

## 4.4 Responsibility

**4.4.1** The client organization, not the certification body, has the responsibility for conformity with the requirements for certification.

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**4.4.2** The certification body has the responsibility to assess sufficient objective evidence upon which to base a certification decision. Based on audit conclusions, it makes a decision to grant certification if there is sufficient evidence of conformity, or not to grant certification if there is not sufficient evidence of conformity.

**NOTE** Any audit is based on sampling within an organization's management system and therefore is not a guarantee of 100 % conformity with requirements.

### 4.5 Openness

**4.5.1** A certification body needs to provide public access to, or disclosure of, appropriate and timely information about its audit process and certification process, and about the certification status (i.e. the granting, extending, maintaining, renewing, suspending, reducing the scope of, or withdrawing of certification) of any organization in order to gain confidence in the integrity and credibility of certification. Openness is a principle of access to, or disclosure of, appropriate information.

**4.5.2** To gain or maintain confidence in certification, a certification body should provide appropriate access to, or disclosure of, non-confidential information about the conclusions of specific audits (e.g. audits in response to complaints), to specific interested parties.

### 4.6 Confidentiality

To gain the privileged access to information that is needed for the certification body to assess conformity to requirements for certification adequately, it is essential that a certification body keep confidential any proprietary information about a client.

### 4.7 Responsiveness to complaints

Parties that rely on certification expect to have complaints investigated and, if these are found to be valid, should have confidence that the complaints will be appropriately addressed and that a reasonable effort will be made to resolve the complaints. Effective responsiveness to complaints is an important means of protection for the certification body, its clients and other users of certification against errors, omissions or unreasonable behavior. Confidence in certification activities is safeguarded when complaints are processed appropriately.

**NOTE** An appropriate balance between the principles of openness and confidentiality, including responsiveness to complaints, is necessary in order to demonstrate integrity and credibility to all users of certification.

## 5. General requirements

### 5.1 Legal and contractual matters

#### 5.1.1 Legal responsibility

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The certification body shall be a legal entity, or a defined part of a legal entity, such that it can be held legally responsible for all its certification activities. A governmental certification body is deemed to be a legal entity on the basis of its governmental status.

### 5.1.2 Certification agreement

The certification body shall have a legally enforceable agreement for the provision of certification activities to its client. In addition, where there are multiple offices of a certification body or multiple sites of a certified client, the certification body shall ensure there is a legally enforceable agreement between the certification body granting certification and issuing a certificate, and all the sites covered by the scope of the certification.

### 5.1.3 Responsibility for certification decisions

The certification body shall be responsible for, and shall retain authority for, its decisions relating to certification, including the granting, maintaining, renewing, extending, reducing, suspending and withdrawing of certification

## 5.2 Management of impartiality

**5.2.1** The certification body shall have top management commitment to impartiality in management system certification activities. The certification body shall have a publicly available statement that it understands the importance of impartiality in carrying out its management system certification activities, manages conflict of interest and ensures the objectivity of its management system certification activities.

**5.2.2** The certification body shall identify, analyse and document the possibilities for conflict of interests arising from provision of certification including any conflicts arising from its relationships. Having relationships does not necessarily present a certification body with a conflict of interest. However, if any relationship creates a threat to impartiality, the certification body shall document and be able to demonstrate how it eliminates or minimizes such threats. This information shall be made available to the committee specified in clause 6.2. The demonstration shall cover all potential sources of conflict of interests that are identified, whether they arise from within the certification body or from the activities of other persons, bodies, or organizations.

**NOTE** A relationship that threatens the impartiality of the certification body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing and payment of a sales commission or other inducement for the referral of new clients, etc.

**5.2.3** When a relationship poses an unacceptable threat to impartiality (such as a wholly owned subsidiary of the certification body requesting certification from its parent), then certification shall not be provided.

**NOTE** See Note to 5.2.2

**5.2.4** A certification body shall not certify another certification body for its management system certification activities.

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**NOTE** See Note to 5.2.2

**5.2.5** The certification body and any part of the same legal entity shall not offer or provide management system consultancy. This also applies to that part of government identified as the certification body.

**5.2.6** The certification body and any part of the same legal entity shall not offer or provide internal audits to its certified clients. The certification body shall not certify a management system on which it provided internal audits within two years following the end of the internal audits. This also applies to that part of government identified as certification body.

**NOTE** See Note to 5.2.2

**5.2.7** The certification body shall not certify a management system on which a client has received management system consultancy or internal audits, where the relationship between the consultancy organization and the certification body poses an unacceptable threat to the impartiality of the certification body.

**NOTE 1** Allowing a minimum period of two years to elapse following the end of the management system consultancy is one way of reducing the threat to impartiality to an acceptable level.

**NOTE 2** See Note to 5.2.2

**5.2.8** The certification body shall not outsource audits to a management system consultancy organization, as this poses an unacceptable threat to the impartiality of the certification body (see 7.5). This does not apply to individual contracted as auditors covered in 7.3.

**5.2.9** The certification body's activities shall not be marketed or offered as linked with the activities of an organization that provides management system consultancy. The certification body shall take action to correct inappropriate claims by any consultancy organization stating or implying that certification would be simpler, easier, faster or less expensive if the certification body were used. A certification body shall not state or imply that certification would be simpler, easier, faster or less expensive if a specified consultancy organization were used.

**5.2.10** To ensure that there is no conflict of interest, personnel who have provided management system consultancy, including those acting in a managerial capacity, shall not be used by the certification body to take part in an audit or other certification activities if they have been involved in management system consultancy toward the client in question within two years following the end of the consultancy.

**5.2.11** The certification body shall take action to respond to any threats to its impartiality arising from the actions of other persons, bodies or organization.

**5.2.12** All certification body personnel, either internal or external, or committees, who could influence the certification activities, shall act impartially and shall not allow commercial, financial or other pressures to compromise impartiality.

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**5.2.13** Certification bodies shall require personnel, internal and external, to reveal any situation known to them that may present them or the certification body with a conflict of interest. Certification bodies shall use this information as input to identifying threats to impartiality raised by the activities of such personnel or by the organizations that employ them, and shall not use such personnel, internal or external, unless they can demonstrate that there is no conflict of interest.

### 5.3 Liability and financing

**5.3.1** The certification body shall be able to demonstrate that it has evaluated the risks arising from its certification activities and that it has adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations in each of its fields of activities and the geographic areas in which it operates.

**[KAB guideline]**

The certification body shall demonstrate that it has adequate arrangements, such as insurance, to cover liabilities arising from its operations and/or activities. In addition, certification body shall document the arrangements for indemnification or compensation and the transfer of certification for a certified organization in case of its accreditation being withdrawn partially or in total for its accredited scopes, make legal preparation for implementing such arrangements, for example, through establishing the contract for the transfer of certification with another certification body, and ensure that it will implement them within the period specified by KAB.

**5.3.2** The certification body shall evaluate its fiancés and sources of income and demonstrate to the committee specified in 6.2 that initially, and on an ongoing basis, commercial, financial or other pressures do not compromise its impartiality.

## 6. Structural requirements

### 6.1 Organizational structure and top management

**6.1.1** The certification body shall document its organizational structure, showing duties, responsibilities and authorities of management and other certification personnel and any committees. When the certification body is a defined part of a legal entity, the structure shall include the line of authority and the relationship to other parts within the same legal entity.

**6.1.2** The certification body shall identify the top management (board, group of persons, or person) having overall authority and responsibility for each of the following:

- a) development of policies relating to the operation of the body;
  - b) supervision of the implementation of the policies and procedures;
  - c) supervision of the finances of the body;
  - d) development of management system certification services and schemes;
  - e) performance of audits and certification, and responsiveness to complaints;
  - f) decisions on certification;
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- g) delegation of authority to committees or individuals, as required, to undertake defined activities on its behalf;
- h) contractual arrangements;
- i) provision of adequate resources for certification activities.

**6.1.3** The certification body shall have formal rules for the appointment, terms of reference and operation of any committees that are involved in the certification activities.

### 6.2 Committee for safeguarding impartiality

**6.2.1** The structure of the certification body shall safeguard the impartiality of the activities of the certification body and shall provide for a committee:

- a) to assist in developing the policies relating to impartiality of its certification activities;
- b) to counteract any tendency on the part of a certification body to allow commercial or other considerations to prevent the consistent objective provision of the certification service;
- c) to advise on matters affecting confidence in certification, including openness and public perception, and
- d) to conduct a review, as least once annually, of the impartiality of the audit, certification and decision-making processes of the certification body.

Other tasks or duties may be assigned to the committee provided that these additional tasks or duties do not compromise its essential role of ensuring impartiality.

**6.2.2** The composition, terms of reference, duties, authorities, competence of members and responsibilities of this committee shall be formally documented and authorized by the top management of the certification body to ensure

- a) representation of a balance of interests such that no single interest predominates (internal or external personnel of the certification body are considered to be a single interest, and shall not predominate),
- b) access to all the information necessary to enable it to fulfil its functions (see also 5.2.2 and 5.3.2), and
- c) that if the top management of the certification body does not respect the advice of this committee, the committee shall have the right to take independent action (e.g. informing authorities, accreditation bodies, stakeholders). In taking independent action, committees shall respect the confidentiality requirements of 8.5 relating to the client and certification body.

**6.2.3** Although this committee cannot represent every interest, a certification body should identify and invite key interests. Such interests may include: clients of the certification body, customers of organizations whose management systems are certified, representatives of industry trade associations, representative of governmental regulatory bodies or other governmental services, or representatives of non-governmental organizations, including customer organizations.

## 7. Resource requirements

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### 7.1 Competence of management and personnel

**7.1.1** The certification body shall have processes to ensure that personnel have appropriate knowledge relevant to the types of management systems and geographic areas in which it operates.

It shall determine the competence required for each technical area (as relevant for the specific certification scheme), and for each function in the certification activity.

It shall determine the means for the demonstration of competence prior to carrying out specific functions.

**7.1.2** In determining the competence requirements for its personnel performing certification, the certification body shall address the functions undertaken by management and administrative personnel in addition to those directly performing audit and certification activities.

**7.1.3** The certification body shall have access to the necessary technical expertise for advice on matters directly relating to certification for technical areas, types of management system and geographic areas in which the certification body operates. Such advice may be provided externally or by certification body personnel.

### 7.2 Personnel involved in the certification activities

**7.2.1** The certification body shall have, as part of its own organization, personnel having sufficient competence for managing the type and range of audit programmes and other certification work performed.

**7.2.2** The certification body shall employ, or have access to, a sufficient number of auditors, including audit team leaders, and technical experts to cover all of its activities and to handle the volume of audit work performed.

**[KAB guideline]**

The certification body shall have at least two auditors including one lead auditor for each of its accredited scopes, and one of the two auditors shall have been qualified for the 3 digit code(s) by the certification body. If the auditor qualified for the 3 digit code(s) is not available, the certification body shall have an additional technical expert qualified for the relevant 3digit code(s) other than two auditors.

**7.2.3** The certification body shall make clear to each person concerned their duties, responsibilities and authorities.

**7.2.4** The certification body shall have defined processes for selecting, training, formally authorising auditors and for selecting technical experts used in the certification activity. The initial competence evaluation of an auditor shall include a demonstration of applicable

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personal attributes and the ability to apply required knowledge and skills during audits, as determined by a competent evaluator observing the auditor conducting an audit.

**7.2.5** The certification body shall have a process to achieve and demonstrate effective auditing, including the use of auditors and audit team leaders possessing generic auditing skills and knowledge, as well as skills and knowledge appropriate for auditing in specific technical areas. This process shall be defined in documented requirements drawn up in accordance with the relevant guidance provided in ISO 19011.

**7.2.6** The certification body shall ensure that auditors (and, where needed, technical experts) are knowledgeable of its audit processes, certification requirements and other relevant requirements. The certification body shall give auditors and technical experts access to an up-to-date set of documented procedures giving audit instructions and all relevant information on certification activities.

**7.2.7** The certification body shall use auditors and technical experts only for those certification activities where they have demonstrated competence.

**NOTE** Assignment of auditors and technical experts to teams for specific audits is addressed in 9.1.3

**7.2.8** The certification body shall identify training needs and shall offer or provide access to specific training to ensure its auditors, technical experts and other personnel involved in certification activities are competent for the functions they perform.

**7.2.9** The group or individual that takes the decision on granting, maintaining, renewing, extending, reducing, suspending or withdrawing certification shall understand the applicable standard and certification requirements, and shall have demonstrated competence to evaluate the audit processes and related recommendations of the audit team.

**7.2.10** The certification body shall ensure the satisfactory performance of all personnel involved in audit and certification activities. There shall be documented procedures and criteria for monitoring and measurement of the performance of all persons involved, based on the frequency of their usage and the level of risk linked to their activities. In particular, the certification body shall review the competence of its personnel in the light of their performance in order to identify training needs.

**7.2.11** The documented monitoring procedures for auditors shall include a combination of on-site observation, review of audit reports and feedback from clients or from the market and shall be defined in documented requirements drawn up in accordance with the relevant guidance provided in ISO 19011. This monitoring shall be designed in such a way as to minimize the disturbance to the normal processes of certification, especially from the client's viewpoint.

**7.2.12** The certification body shall periodically observe the performance of each auditor on-site. The frequency of on-site observations shall be based on need determined from all monitoring information available.

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### 7.3 Use of individual external auditors and external technical experts

The certification body shall require external auditors and external technical experts to have a written agreement by which they commit themselves to comply with applicable policies and procedures as defined by the certification body. The agreement shall address aspects relating to confidentiality and to independence from commercial and other interests, and shall require the external auditors and external technical experts to notify the certification body of any existing or prior association with any organization they may be assigned to audit.

**NOTE** Use of individual auditors and technical experts under such agreement does not constitute outsourcing as described under 7.5.

### 7.4 Personnel records

The certification body shall maintain up-to-date personnel records, including relevant qualifications, training, experience, affiliations, professional status, competence and any relevant consultancy services that may have been provided. This includes management and administrative personnel in addition to those performing certification activities.

### 7.5 Outsourcing

**7.5.1** The certification body shall have a process in which it describes the conditions under which outsourcing (which is subcontracting to another organization to provide part of the certification activities on behalf of the certification body) may take place. The certification body shall have a legally enforceable agreement covering the arrangements, including confidentiality and conflict of interest, with each body that provide outsourced services.

**NOTE1** This can include outsourcing to other certification bodies. Use of auditors and technical experts under contract is addressed in 7.3.

**NOTE 2** For the purpose of this International Standard, the terms “outsourcing” and “subcontracting” are considered to be synonyms.

**7.5.2** Decisions for granting, maintaining, renewing, extending, reducing, suspending or withdrawing certification shall never be outsourced.

#### 7.5.3 The certification body

- a) shall take responsibility for all activities outsourced to another body;
  - b) shall ensure that the body that provides outsourced services, and the individuals that it uses, conform to requirements of the certification body and also to the applicable provisions of this International Standard, including competence, impartiality and confidentiality, and
  - c) shall ensure that the body that provides outsourced services, and the individuals that it uses, is not involved, either directly or through any other employer, with an organization to be audited, in such a way that impartiality could be compromised.
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**7.5.4** The certification body shall have documented procedures for the qualification and monitoring of all bodies that provide outsourced services used for certification activities, and shall ensure that records of the competence of auditors and technical experts are maintained.

### 8. Information requirements

#### 8.1 Publicly accessible information

**8.1.1** The certification body shall maintain and make publicly accessible, or provide upon request, information describing its audit processes and certification processes for granting, maintaining, extending, renewing, reducing, suspending or withdrawing certification, and about the certification activities, types of management systems and geographical areas in which it operates.

**8.1.2** Information provided by the certification body to any client or to the marketplace, including advertising, shall be accurate and not misleading.

**8.1.3** The certification body shall make publicly accessible information about certifications granted, suspended or withdrawn.

**8.1.4** On request from any party, the certification body shall provide means to confirm the validity of a given certification.

**NOTE 1** If the total information is split between several sources (e.g. in printed or electronic form or a combination of both), a system ensuring traceability and absence of ambiguity between the sources can be implemented (e.g. unique numbering system, or hyperlinks on Internet).

**NOTE 2** In exceptional cases, access to a certain information can be limited on the request of the client (e.g. for security reasons).

#### 8.2 Certification documents

**8.2.1** The certification body shall provide certification documents to the certified client by any means it chooses.

**8.2.2** The effective date on a certificate shall not be before the date of the certification decision.

**8.2.3** The certification document(s) shall identify the following:

- a) the name and geographic location of each client whose management system is certified (or the geographic location of the headquarters and any sites within the scope of a multi-site certification);
  - b) the dates of granting, extending, or renewing certification ;
  - c) the expiry date or recertification due date consistent with the recertification cycle;
  - d) a unique identification code;
  - e) the standard and/or normative document, including issue and/or revision, used for
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- audit of the certified client;
- f) the scope of certification with respect to product (including service), process, etc., as applicable at each site;
- g) the name, address and certification mark of the certification body; other marks (e.g. accreditation symbol) may be used provided they are not misleading or ambiguous;
- h) any other information required by the standard and/or other normative document used for certification;
- i) in the event of issuing any revised certification documents, a means to distinguish the revised documents from any prior obsolete documents.

### 8.3 Directory of certified clients

The certification body shall maintain and make publicly accessible, or provide upon request, by any means it chooses, a directory of valid certifications that as a minimum shall show the name, relevant normative document, scope and geographical location (e.g. city and country) for each certified client (or the geographic location of the headquarters and any sites within the scope of a multi-site certification).

**NOTE** The directory remains the sole property of the certification body.

### 8.4 Reference to certification and use of marks

**8.4.1** A certification body shall have a policy governing any mark that it authorises certified clients to use. This shall assure, among other things, traceability back to the certification body. There shall be no ambiguity, in the mark or accompanying text, as to what has been certified and which certification body has granted the certification. This mark shall not be used on a product or product packaging seen by the consumer or in any other way that may be interpreted as denoting product conformity.

**NOTE** ISO/IEC 17030 provides requirements for use of third-party marks.

**8.4.2** A certification body shall not permit its marks to be applied to laboratory test, calibration or inspection reports, as such reports are deemed to be products in this context.

**8.4.3** The certification body shall require that the client organization

- a) conforms to the requirements of the certification body when making reference to its certification status in communication media such as the internet, brochures or advertising, or other documents,
  - b) does not make or permit any misleading statement regarding its certification,
  - c) does not use or permit the use of a certification document or any part thereof in a misleading manner,
  - d) upon suspension or withdrawal of its certification, discontinues its use of all advertising matter that contains a reference to certification, as directed by the certification body (see 9.6.3 and 9.6.6),
  - e) amends all advertising matter when the scope of certification has been reduced,
  - f) does not allow reference to its management system certification to be used in such a way to imply that the certification body certifies a product (including service) or process,
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- g) does not imply that the certification applies to activities that are outside the scope of certification, and
- h) does not use its certification in such a manner that would bring the certification body and/or certification system into disrepute and lose public trust.

**8.4.4** The certification body shall exercise proper control of ownership and shall take action to deal with incorrect references to certification status or misleading use of certification documents, marks or audit reports.

**NOTE** Such action could include request for correction and corrective action, suspension, withdrawal of certification, publication of the transgression and, if necessary, legal action.

### 8.5 Confidentiality

**8.5.1** The certification body shall, through legally enforceable agreements, have a policy and arrangements to safeguard the confidentiality of the information obtained or created during the performance of certification activities at all levels of its structure, including committees and external bodies or individuals acting on its behalf.

**8.5.2** The certification body shall inform the client, in advance, of the information it intends to place in the public domain. All other information, except for information that is made publicly available by the client, shall be considered confidential.

**8.5.3** Except as required in this standard, information about a particular client or individual shall not be disclosed to a third party without the written consent of the client or individual concerned. Where the certification body is required by law to release confidential information to a third party, the client or individual concerned shall, unless prohibited by law, be notified in advance of the information provided.

**8.5.4** Information about the client from sources other than the client (e.g. complainant, regulators), shall be treated as confidential, consistent with the certification body's policy.

**8.5.5** Personnel, including any committee members, contractors, personnel of external bodies or individuals acting on the certification body's behalf, shall keep confidential all information obtained or created during the performance of the certification body's activities.

**8.5.6** The certification body shall have available and use equipment and facilities that ensure the secure handling of confidential information (e.g. documents, records).

**8.5.7** When confidential information is made available to other bodies (e.g. accreditation body, agreement group of a peer assessment scheme), the certification body shall inform its client of this action.

### 8.6 Information exchange between a certification body and its clients

#### 8.6.1 Information on the certification activity and requirements

The certification body shall provide and update clients on the following:

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- a) a detailed description of the initial and continuing certification activity, including the application, initial audits, surveillance audits, and the process for granting, maintaining, reducing, extending, suspending, withdrawing certification and recertification;
- b) the normative requirements for certification;
- c) information about the fees for application, initial certification and continuing certification;
- d) the certification body's requirements for prospective client
  - 1) to comply with certification requirements;
  - 2) to make all necessary arrangements for the conduct of the audits, including provision for examining documentation and the access to all processes and areas, records and personnel for the purposes of initial certification, surveillance, recertification and resolution of complaints, and
  - 3) to make provisions, where applicable, to accommodate the presence of observers (e.g. accreditation auditors or trainee auditors);
- e) documents describing the rights and duties of certified clients, including requirements, when making reference to its certification in communication of any kind in line with the requirements in 8.4;
- f) information on procedures for handling complaints and appeals.

### 8.6.2 Notice of changes by a certification body

The certification body shall give its certified clients due notice of any changes to its requirements for certification. The certification body shall verify that each certified client complies with the new requirements.

**NOTE** Contractual arrangements with certified clients could be necessary to ensure implementation of these requirements. A model of a license agreement for the use of certification, including the aspects related to a notice of changes, as far as applicable, is found in Annex E of ISO/IEC Guide 28:2004.

### 8.6.3 Notice of changes by a client

The certification body shall have legally enforceable arrangements to ensure that the certified client informs the certification body, 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. 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, and
- e) major changes to the management system and processes.

**NOTE** A model of license agreement for the use of certification, including the aspects related to a notice of changes, as far as applicable, is found in Annex E of ISO/IEC Guide 28:2004.

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### 9. Process requirements

#### 9.1 General requirements

**9.1.1** 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. 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.

**9.1.2** The certification body shall ensure that an audit plan is established for each audit 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.

**9.1.3** 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.

**[KAB guideline]**

The audit team shall include at least an auditor qualified for the relevant scope of accreditation of this document and an auditor or technical expert qualified for 4 digit code(s) per the relevant criteria and procedure defined by the certification body based on the Korea Standard Industry Classifications (KSIC).

**9.1.4** The certification body shall have documented procedures for determining audit time, and for each client the certification body shall determine the time needed to plan and accomplish a complete and effective audit of the client's management system. The audit time determined by the certification body, and the justification for the determination, shall be recorded. In determining the audit time, the certification body shall consider, among other things, the following aspects:

- a) the requirements of the relevant management system standard;
- b) size and complexity;
- c) technological and regulatory context;
- d) any outsourcing of any activities included in the scope of the management system;
- e) the results of any prior audits;
- f) number of sites and multi-site considerations.

**9.1.5** Where multi-site sampling is utilized for the audit of a client's management system covering the same activity in various locations, the certification body shall develop a

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sampling programme to ensure proper audit of the management system. The rationale for the sampling plan shall be documented for each client.

**9.1.6** The tasks given to the audit team shall be defined and shall be made known to the client organization, and shall require the audit team

- a) to examine and verify the structure, policies, processes and procedures, records and related documents of the client organization relevant to the management system,
- b) to determine that these meet all the requirements relevant to the intended scope of certification,
- c) to determine that the processes and procedures are established, implemented and maintained effectively, to provide a basis for confidence in the client's management system , and
- d) to communicate to the client, for its action, any inconsistencies between the client's policy, objectives and targets (consistent with the expectations in the relevant management system standard or other normative document) and the results.

**9.1.7** The certification body shall provide the name of and, when requested, make available background information on each member of the audit team, with sufficient time for the client organization to object to the appointment of any particular auditor or technical expert and for the certification body to reconstitute the team in response to any valid objection.

**9.1.8** The audit plan shall be communicated and the dates of audit shall be agreed upon, in advance, with the client organization.

**9.1.9** 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.

**NOTE1** 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.

**NOTE2** The term "auditee" as used in ISO 19011 means that the organization being audited.

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

**9.1.11** The certification body shall require the client to analyse the cause and describe the specific correction and corrective actions taken, or planned to be taken, to eliminate detected nonconformities, within a defined time.

**9.1.12** The certification body shall review the corrections and corrective actions submitted by the client to determine if these are acceptable.

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**9.1.13** The audited organization shall be informed if an additional full audit, an additional limited audit, or documented evidence (to be confirmed during future surveillance audits) will be needed to verify effective correction and corrective actions.

**9.1.14** The certification body shall ensure that the persons or committees that make the certification or recertification decisions are different from those who carried out the audits.

**9.1.15** The certification body shall confirm, prior to making a decision, that

- a) the information provided by the audit team is sufficient with respect to the certification requirements and the scope for certification;
- b) it has reviewed, accepted and verified the effectiveness of correction and corrective actions, for all nonconformities that represent
  - 1) failure to fulfil one or more requirements of the management system standard, or
  - 2) a situation that raises significant doubt about the ability of the client's management system to achieve its intended outputs;
- c) it has reviewed and accepted the client's planned correction and corrective action for any other nonconformities.

## 9.2 Initial audit and certification

### 9.2.1 Application

The certification body shall require an authorized representative of the applicant organization to provide the necessary information to enable it to establish the following

- a) the desired scope of the certification;
- b) the general features of the applicant organization, including its name and the address(es) of its physical location(s), significant aspects of its process and operations, and any relevant legal obligations;
- c) general information, relevant for the field of certification applied for, concerning the applicant organization, such as its activities, human and technical resources, functions and relationship in a larger corporation, if any;
- d) information concerning all outsourced processes used by the organization that will affect conformity to requirements;
- e) the standards or other requirements for which the applicant organization is seeking certification;
- f) information concerning the use of consultancy relating to the management system.

### 9.2.2 Application review

**9.2.2.1** Before proceeding with the audit, the certification body shall conduct a review of the application and supplementary information for certification to ensure that

- a) the information about the applicant organization and its management system is sufficient for the conduct of the audit;
  - b) the requirements for certification are clearly defined and documented, and have been provided to the applicant organization;
  - c) any known difference in understanding between the certification body and the applicant organization is resolved;
  - d) the certification body has the competence and ability to perform the certification activity;
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- e) the scope of certification sought, the location(s) of the applicant organization's operations, time required to complete audits and any other points influencing the certification activity are taken into account(language, safety conditions, threats to impartiality, etc);
- f) records of the justification for the decisions to undertake the audit shall be maintained.

**9.2.2.2** Based on this review, the certification body shall determine the competence it needs to include in its audit team and for the certification decision.

**9.2.2.3** The audit team shall be appointed and composed of auditors (and technical experts, as necessary) who, between them, have the totality of the competences identified by the certification body as set out in 9.2.2.2 for the certification of the applicant organization. The selection of the team shall be performed with reference to the designations of competence of auditors and technical experts made under 7.2.5, and may include the use of both internal and external human resources.

**9.2.2.4** The individual(s) who will be conducting the certification decision shall be appointed to ensure appropriate competence is available (see 7.2.9 and 9.2.2.2).

### **9.2.3 Initial certification audit**

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

#### **9.2.3.1 Stage 1 audit**

**9.2.3.1.1** The stage 1 audit shall be performed

- a) to audit the client's management system documentation;
  - b) to evaluate the client's location and site-specific conditions and to undertake discussions with the client's personnel to determine the preparedness for the stage 2 audit;
  - c) to 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) to collect necessary information regarding the scope of the management system, processes and location(s) of the client, and related statutory and regulatory aspects and compliance, (e.g. quality, environmental, legal aspects of the client's operation, associated risk etc);
  - e) to review the allocation of resources for stage 2 and agree with the client on the details of the stage 2 audit;
  - f) to provide a focus for planning the stage 2 audit by gaining a sufficient understanding of the client's management system and site operations in the context of possible significant aspects;
  - g) to evaluate if the internal audits and management review are being planned and performed, and that the level of implementation of the management system substantiates that the client organization is ready for the stage 2 audit.
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For most management systems, it is recommended that at least part of the stage 1 audit be carried out at the client's premises in order to achieve the objectives stated above.

**9.2.3.1.2** Stage 1 audit findings shall be documented and communicated to the client, including identification of any areas of concern that could be classified as nonconformity during the stage 2 audit.

**9.2.3.1.3** In determining the interval between stage 1 and stage 2 audits, consideration shall be given to the needs of the client to resolve areas of concern identified during the stage 1 audit. The certification body may also need to revise its arrangements for stage 2.

### **9.2.3.2 Stage 2 audit**

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

- a) information and evidence about conformity to all requirements of the applicable management system standard or other normative document;
- b) performance monitoring, measuring, reporting and reviewing against key performance objectives and targets (consistent with the expectation in the applicable management system standard or other normative document);
- c) the client's management system and performance as regards legal compliance;
- d) operational control of the client's processes;
- e) internal auditing and management review;
- f) management responsibility for the client's policies;
- g) links between the normative requirements, policy, performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document), any applicable legal requirements, responsibilities, competence of personnel, operations, procedures, performance data and internal audit findings and conclusions.

### **9.2.4 Initial certification audit conclusions**

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

### **9.2.5 Information for granting initial certification**

**9.2.5.1** The information provided by the audit team to the certification body 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 (see 9.2.2).
  - d) a recommendation whether or not to grant certification, together with any conditions or observations.
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**9.2.5.2** The certification body shall make the certification decision on the basis of an evaluation of the audit findings and conclusions and any other relevant information (e.g. public information, comments on the audit report from the client).

### 9.3 Surveillance activities

#### 9.3.1 General

**9.3.1.1** The certification body shall 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.

**9.3.1.2.** Surveillance activities shall include on-site audits assessing the certified client's management system's fulfilment of specified requirements with respect to the standard to which the certification is granted. Other surveillance activities may include

- a) enquiries from the certification body to the client on aspects of certification,
- b) reviewing any client's statements with respect to its operations(e.g. promotional material, website),
- c) requests to the client to provide documents and records (on paper or electronic media), and
- d) other means of monitoring the certified client's performance.

#### 9.3.2 Surveillance audit

**9.3.2.1** 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 certified management system continues to fulfil requirements between recertification audits. The surveillance audit programme shall include, at least:

- a) internal audits and management review,
- b) a review of actions taken on nonconformities identified during the previous audit,
- c) treatment of complaints,
- d) effectiveness of the management system with regard to achieving the certified client's objectives,
- e) progress of planned activities aimed at continual improvement,
- f) continuing operational control,
- g) review of any changes, and
- h) use of mark and/or any other reference to certification

**9.3.2.2** Surveillance audits shall be conducted at least once a year. The date of the first surveillance audit following initial certification shall not be more than 12 months from the last day of the stage 2 audit.

#### 9.3.3 Maintaining certification

The certification body shall maintain the 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, provided that

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- a) for any 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 appropriately competent personnel(see 7.2.9), different from those who carried out the audit, to determine whether certification can be maintained, and
- b) competent personnel of the certification body monitor its surveillance activities, including monitoring the reporting by its auditors, to confirm that the certification activity is operating effectively.

### 9.4 Recertification

#### 9.4.1 Recertification audit planning

**9.4.1.1** A recertification audit shall be planned and conducted to evaluate the continued fulfillment of all of the requirements of the relevant management system standard or other normative document. 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.

**9.4.1.2** The recertification audit shall consider the performance of the management system over the period of certification, and include the review of previous surveillance audit reports.

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

**9.4.1.4** In the case of multiple sites or certification to multiple management system standard being provided by the certification body, the planning for the audit shall ensure adequate on-site audit coverage to provide confidence in the certification.

#### 9.4.2 Recertification audit

**9.4.2.1** The recertification audit shall include 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) whether the operation of the certified management system contributes to the achievement of the organization's policy and objectives.

**9.4.2.2** When, during a recertification audit, instances of nonconformity or lack of evidence of conformity is identified, the certification body shall define time limits for correction and corrective actions to be implemented prior to the expiration of certification.

#### 9.4.3 Information for granting recertification

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The certification body shall make decisions on renewing certification based on the results of recertification audits as well as the results of the review of the system over the period certification and the complaints received from users of certification.

### 9.5 Special audits

#### 9.5.1 Extensions to scope

The certification body shall, in response to an application for extension to 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.

#### 9.5.2 Short-notice audits

It may be necessary for the certification body to conduct audits of certified clients at short notice to investigate complaints (see 9.8), or in response to changes (see 8.6.3), or as follow up on suspended clients (see 9.6). In such cases

- a) the certification body shall describe and make known in advance to the certified clients (e.g. in documents as described in 8.6.1) the conditions under which these short notice visits are to be conducted, and
- b) the certification body shall 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.

### 9.6 Suspending, withdrawing or reducing scope of certification

**9.6.1** The certification body shall have a policy and documented procedure(s) for suspension, withdrawal or reduction of the scope of certification, and shall specify the subsequent actions by the certification body.

**9.6.2** The certification body shall 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, or
- the certified client has voluntarily requested a suspension.

**9.6.3** Under suspension, the client's management system certification is temporarily invalid. The certification body shall have enforceable arrangements with its clients to ensure that in case of suspension the client refrains from further promotion of its certification. The certification body shall make the suspended status of the certification publicly available (see 8.1.3) and shall take any other measures it deems appropriate.

**9.6.4** Failure to resolve the issues that have resulted in the suspension in a time established by the certification body shall result in withdrawal or reduction of the scope of certification.

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**NOTE** In most cases the suspension would not exceed six months.

**9.6.5** The certification body shall reduce the client's scope of certification to exclude the parts not meeting the requirements, when the 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 standard used for certification.

**9.6.6** The certification body shall have enforceable arrangements with the certified client concerning conditions of withdrawal [(see 8.4.3 d)] ensuring upon notice of withdrawal of certification that the client discontinues its use of all advertising matter that contains any reference to a certified status.

**9.6.7** Upon request by any party, the certification body shall correctly state the status of certification of a client's management system as being suspended, withdrawn or reduced.

### 9.7 Appeals

**9.7.1** The certification body shall have a documented procedure to receive, evaluate and make decisions on appeals.

**9.7.2** A description of the appeals-handling process shall be publicly available.

**9.7.3** The certification body shall be responsible for all decisions at all levels of the appeals-handling process. The certification body shall ensure that the persons engaged in the appeals-handling process are different from those who carried out the audits and made the certification decisions.

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

**9.7.5** The appeal-handling process shall include at least the following elements and methods:

- a) an outline of the process for receiving, validating and investigating the appeal, and deciding what action are 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 and corrective action are taken.

**9.7.6** The certification body shall acknowledge receipt of the appeal and shall provide the appellant with progress reports and the outcome.

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

**9.7.8** The certification body shall give formal notice of the end of the appeals- handling process.

### 9.8 Complaints

**9.8.1** A description of the complaints-handling process shall be publicly available.

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**9.8.2** Upon receipt of a complaint, the certification body shall confirm whether the complaint relates to certification activities that it is responsible for and, if so, shall deal with it. If the complaint relates to a certified client, then examination of the complaint shall consider the effectiveness of the certified management system.

**9.8.3** Any complaint about a certified client shall also be referred by the certification body to the certified client in question at an appropriate time.

**9.8.4** The certification body shall have a documented process to receive, evaluate and make decisions on complaints. This process shall be subject to requirements for confidentiality, as it relates to the complainant and to the subject of the complaint.

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

- a) an outline of the process of receiving, validating, investigating the complaint, and for deciding what action are to be taken in response to it;
- b) tracking and recording complaint, including actions undertaken in response to them;
- c) ensuring that any appropriate and corrective action are taken.

**NOTE** ISO 10002 provides guidance for complaint handling.

**9.8.6** The certification body receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.

**9.8.7** Whenever possible, the certification body shall acknowledge receipt of the complaint, and shall provide the complainant with progress reports and the outcome.

**9.8.8** 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.

**9.8.9** Whenever possible, the certification body shall give formal notice of the end of the complaints- handling process to the complainant.

**9.8.10** The certification body shall determine, together with the client and the complaint, whether and, if so to what extent, the subject of the complaint and its resolution, and all be made public.

### 9.9 Records of applicants and clients

**9.9.1** The certification body shall maintain 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.

**9.9.2** Records on certified clients shall include the following:

- a) application information and initial, surveillance and recertification audit reports;
  - b) certification agreement;
  - c) justification of the methodology used for sampling;
  - d) justification for auditor time determination (see 9.1.4);
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- 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.

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

**9.9.3** The certification body shall keep the records on applicants and clients secure to ensure that the information is kept confidential. Records shall be transported, transmitted or transferred in a way that ensures that confidentiality is maintained.

**9.9.4** The certification body shall have a documented policy and documented procedures on retention of records. Records shall be retained for the duration of the current cycle plus one full certification cycle.

**NOTE** In some jurisdictions, the law stipulates that records need to be maintained for a longer time period.

## 10. Management system requirements for certification bodies

### 10.1 Options

The certification body shall establish and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this International Standard. In addition to meeting the requirements of Clauses 5 to 9, the certification body shall implement a management system in accordance with either

- a) management system requirements in accordance with ISO 9001 (see 10.2), or
- b) general management system requirements (see 10.3).

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

#### 10.2.1 General

The certification body shall establish and maintain a management system, in accordance with the requirements of ISO 9001, that is capable of supporting and demonstrating the consistent achievement of the requirements of this international standard, amplified by 10.2.2 to 10.2.5

#### 10.2.2 Scope

For application of the requirements of ISO 9001, the scope of the management system shall include the design and development requirements for its certification services.

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### 10.2.3 Customer focus

For application of the requirements of ISO 9001, when developing its management system, the certification body shall consider the credibility of certification and address the needs of all parties (as set out in 4.1.2) that rely upon its audit and certification services, not just its clients.

### 10.2.4 Management review

For application of the requirements of ISO 9001, the certification body shall include as input for management review, information on relevant appeals and complaints from users of certification activities.

### 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.

## 10.3 Option 2: General management system requirements

### 10.3.1 General

The certification body shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this International Standard.

The certification body's top management shall establish and document policies and objectives for its activities. The top management shall provide evidence of its commitment to the development and implementation of the management system in accordance with the requirements of this International Standard. The top management shall ensure that the policies are understood, implemented and maintained at all levels of the certification body's organization.

The certification body's top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that include

- a) ensuring that processes and procedures needed for the management system are established, implemented and maintained, and
- b) reporting to top management on the performance of the management system and any need for improvement.

### 10.3.2 Management system manual

All applicable requirements of this International Standard shall be addressed either in a manual or in associated documents. The certification body shall ensure that the manual and relevant associated documents are accessible to all relevant personnel.

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### 10.3.3 Control of documents

The certification body shall establish procedures to control the documents (internal and external) that relate to the fulfilment of this International Standard. The procedures shall define the controls needed

- a) to approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approval documents,
- c) to ensure that changes and the current revision status of documents are identified
- d) to ensure that relevant versions of applicable documents are available at points of use,
- e) to ensure that documents remain legible and readily identifiable,
- f) to ensure that documents of external origin are identified and their distribution controlled, and
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

**NOTE** Documentation can be in any form or type of medium.

### 10.3.4 Control of records

The certification body shall establish procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records related to the fulfilment of this International Standard.

The certification body shall establish procedures for retaining records for a period consistent with its contractual and legal obligations. Access to these records shall be consistent with the confidentiality arrangements.

**NOTE** For requirements for records on certified clients, see also 9.9

### 10.3.5 Management review

#### 10.3.5.1 General

The certification body's top management shall establish procedures to review its management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this International Standard. These reviews shall be conducted at least once a year.

#### 10.3.5.2 Review inputs

The input to the management review shall include information related to

- a) results of internal and external audits,
  - b) feedback from clients and interested parties related to the fulfilment of this International Standard,
  - c) feedback from the committee for safeguarding impartiality
  - d) the status of preventive and corrective actions,
  - e) follow-up actions from previous management reviews,
  - f) the fulfilment of objectives
  - g) changes that could affect the management system, and
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h) appeals and complaints.

### 10.3.5.3 Review outputs

The outputs from the management review shall include decisions and actions related to

- a) improvement of the effectiveness of the management system and its processes,
- b) improvement of the certification services related to the fulfilment of this International Standard, and
- c) resource needs.

### 10.3.6 Internal audits

10.3.6.1 The certification body shall establish procedures for internal audits to verify that it fulfils the requirements of this International Standard and that the management system is effectively implemented and maintained.

**NOTE** ISO 19011 provides guidelines for conducting internal audits.

**10.3.6.2** An audit programme shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits.

**10.3.6.3** Internal audits shall be performed at least once every 12 months. The frequency of internal audits may be reduced if the certification body can demonstrate that its management system continues to be effectively implemented according to this International Standard and has proven stability.

**10.3.6.4** The certification body shall ensure that

- a) internal audits are conducted by qualified personnel knowledgeable in certification auditing and the requirements of this International Standard,
- b) auditors do not audit their own work,
- c) personnel responsible for the area audited are informed of the outcome of the audit,
- d) any actions resulting from internal audits are taken in a timely and appropriate manner, and
- e) any opportunities for improvement are identified.

### 10.3.7 Corrective actions

The certification body shall establish procedures for identification and management of nonconformities in its operations. The certification body shall also, where necessary, take actions to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the impact of the problems encountered. The procedures shall define requirements for

- a) identifying nonconformities (e.g. from complaints and internal audits),
  - b) determining the causes of nonconformity
  - c) correcting nonconformities,
  - d) evaluating the need for actions to ensure that nonconformities do not recur,
  - e) determining and implementing in a timely manner, the action needed,
  - f) recording the results of action taken, and
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- g) reviewing the effectiveness of the corrective actions.

### 10.3.8 Preventive actions

The certification body shall establish procedure for taking preventive actions to eliminate the causes of potential nonconformities. Preventive actions taken shall be appropriate to the probable impact of the potential problems. The procedures for preventive actions shall define requirements for

- a) identifying potential nonconformities and their causes,
- b) evaluating the need for action to prevent the occurrence of nonconformities,
- c) determining and implementing the action needed,
- d) recording the results of actions taken, and
- e) reviewing the effectiveness of the preventive actions taken.

NOTE The procedures for corrective and preventive actions do not necessarily have to be separate.

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[Annex 1]

### Scope of Accreditation

Scope of Accreditation		Detailed scope of accreditation		KSIC (2000 edition)
01	Agriculture, fishing	011	Agriculture	0111, 0112, 0113, 0114, 0115, 0121, 0122, 0123, 0129, 0130, 0141, 0142, 0143, 0150
		012	Forestry	0201, 0202, 0203
		013	Fishing	0511, 0512, 0521, 0522
02	Mining and Quarrying	021	Mining of coal, uranium, thorium, metal and non-metallic minerals	1011, 1012, 1030, 1110, 1120, 1211, 1212, 1221, 1222, 1229
		022	Extraction of crude petroleum and natural gas, and the related services	1021, 1022
03	Food products, beverages and tobacco	031	Manufacture of food products	1511, 1512, 1513, 1514, 1520, 1531, 1532, 1533, 1541, 1542, 1543, 1544, 1545, 1549, 1551, 1552, 1553, 1554
		032	Manufacture of tobacco products	1600
04	Textiles and textile products	041	Manufacture of textile products (excluding textile dyeing & processing)	1710, 1720, 1731, 1732, 1791, 1792, 1793, 1799
		042	Textile dyeing & processing	1740
		043	Manufacture of sewn wearing apparel and fur products	1811, 1812, 1813, 1814, 1815, 1820
05	Leather and leather products	051	Manufacture of leather	1910
		052	Manufacture of luggage, handbags and other leather products	1921, 1929
		053	Manufacture of footwear	1930
06	Wood and wood products	061	Manufacture of wood & wood products (excluding furniture)	2010, 2021, 2022, 2023, 2024, 2029

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07	Pulp, paper and paper products	071	Manufacture of pulp, paper & paper products	2111, 2112, 2121, 2129
08	Publishing companies	081	Publishing	2211, 2212, 2213, 2219
09	Printing companies	091	Printing and reproduction of recorded media	2221, 2222, 2230
10	Manufacture of coke and refined petroleum products	101	Manufacture of coke, refined petroleum products and related products	2310, 2321, 2322
11	Nuclear fuel	111	Nuclear fuel processing	2330
12	Chemicals, chemical products and fibres	121	Manufacture of chemicals and chemical products	2411, 2412, 2413, 2414, 2415, 2431, 2432, 2433, 2434, 2439, 2440
13	Pharmaceuticals	131	Manufacture of Pharmaceuticals	2421, 2422, 2423
14	Rubber and plastic products	141	Manufacture of rubber and plastic products	2511, 2519, 2521, 2522, 2523, 2524, 2529
15	Non-metallic mineral products	151	Manufacture of glass and glass products, ceramic ware, and other non-metallic mineral products	2611, 2612, 2619, 2621, 2622, 2623, 2691, 2692, 2699
16	Concrete, cement, lime, plaster etc	161	Manufacture of cement, lime and plaster and its products	2631, 2632
17	Basic metals and fabricated metal products	171	Manufacture of basic metals	2711, 2712, 2713, 2719, 2721, 2722, 2729, 2731, 2732
		172	Manufacture of fabricated metal products (except machinery and furniture)	2811, 2812, 2813, 2891, 2892, 2893, 2894, 2899
18	Machinery and equipment	181	Manufacture of general purpose machinery	2911, 2912, 2913, 2914, 2915, 2916, 2917, 2919, 9211
		182	Manufacture of special purpose machinery, weapons and ammunition	2921, 2929, 2931, 2932, 2933, 2934, 2935, 2936, 2939, 2940, 9211
		183	Manufacture of other domestic appliances	2951, 2952
19	Electrical and optical equipment	191	Manufacture of computers, office machinery, other electrical machinery and apparatuses	3001, 3002, 3110, 3120, 3130, 3140, 3151, 3152, 3191, 3199
		192	Manufacture of electronic components, radio, television and communication equipment and apparatuses	3211, 3219, 3220, 3230
		193	Manufacture of medical appliances and instruments	3311, 3319

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		194	Manufacture of precision and optical instruments, watches and clocks	3321, 3322, 3331, 3332, 3340
20	Shipbuilding	201	Building of ships and boats	3511, 3512
21	Aerospace	211	Manufacture of aircraft, spacecraft and its parts	3531, 3532
22	Other transport equipment	221	Manufacture of motor vehicles and trailers	3411, 3412, 3420
		222	Manufacture of railway equipment	3520
		223	Manufacture of other transport equipment	3591, 3592, 3599
		224	Manufacture of parts and accessories for motor vehicles	3430
23	Manufacturing not elsewhere classified	231	Manufacture of furniture	3611, 3612, 3619
		232	Manufacture of musical instruments	3692
		233	Manufacture of sports goods	3693
		234	Other manufacturing (toys, decorations)	3691, 3694, 3695, 3696, 3697, 3699
24	Recycling	241	Recycling	3710, 3720
25	Electricity supply	251	Production, collection and distribution of electricity	4011, 4012
26	Gas supply	261	Manufacture of gas, distribution of gaseous fuel through mains	4020
27	Water supply	271	Steam and hot water supply	4030
		272	Collection, purification and distribution of water	4101, 4102
28	Construction	281	Building of constructions	4521, 4522
		282	Heavy construction, special trade construction for civil engineering	4511, 4512, 4611
		283	Building construction, electrical and communication works, building completion	4612, 4631, 4632, 4641, 4642, 4649
		284	Building installation	4620
		285	Renting of construction equipment	4650

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29	Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods	291	Wholesale and retail trade	5011, 5012, 5020, 5030, 5040, 5110, 5120, 5131, 5132, 5133, 5141, 5142, 5143, 5144, 5145, 5146, 5147, 5149, 5151, 5152, 5159, 5160, 5171, 5172, 5173, 5181, 5189, 5191, 5199, 5211, 5212, 5219, 5221, 5222, 5231, 5232, 5241, 5242, 5243, 5251, 5252, 5253, 5261, 5262, 5263, 5264, 5265, 5266, 5267, 5269, 5270, 5281, 5282, 5289
		292	Repair of motor vehicles, and personal and household goods	9221, 9222, 9231, 9239
30	Hotels and restaurants	301	Accommodation	5511, 5519
		302	Restaurants	5521, 5522, 5523, 5524
31	Transport, storage and communication	311	Land, water, air and pipeline transport	6010, 6021, 6022, 6023, 6031, 6032, 6040, 6111, 6112, 6113, 6120, 6210, 6220
		312	Activities of travel agencies, warehousing and transport related services	6310, 6320, 6331, 6339, 6391, 6392, 6393, 6399
		313	Communication	6411, 6412, 6421, 6422, 6429
32	Financial intermediation; real estate; renting	321	Financing and insurance	6511, 6512, 6591, 6592, 6593, 6599, 6601, 6602, 6603, 6604, 6605, 6711, 6712, 6719, 6720
		322	Real estate	7011, 7012, 7021, 7022
		323	Renting of machinery and consumption products	7111, 7112, 7121, 7122, 7129, 7130
33	Information technology	331	Computer system design and consultancy, repair services of machinery for office accounting, electric, electronic, communication and precision	7210, 7290, 9212
		332	Software consultancy and supply, data processing and computer facilities management services, database activities and on-line information provision services	7220, 7231, 7232, 7240
34	Engineering services	341	Research and development on natural sciences and engineering	7310
		342	Research and development on social sciences and humanities	7320
		343	Architectural, engineering services	7431, 7432
35	Other services	351	Legal and accounting, market research and management consulting services	7411, 7412, 7421, 7422, 7423, 7511
		352	Scientific and technical services	7441, 7449

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		353	Advertising	7451, 7459
		354	Services related to business not elsewhere classified	7491, 7512, 7591, 7592, 7593, 7594, 7599, 7460, 7499
36	Public administration	361	Public administration	7611, 7612, 7621, 7622, 7631, 7632, 7640, 7650
37	Education	371	Education	8011, 8012, 8021, 8022, 8030, 8041, 8042, 8091, 8092, 8093, 8099
38	Health and social Work	381	Human health activities	8511, 8512, 8513, 8519
		382	Veterinary activities	8520
		383	Social work activities	8611, 8612, 8613, 8621, 8629
39	Other social services	391	Recreational, cultural and sporting activities	8711, 8712, 8713, 8714, 8721, 8722, 8731, 8732, 8733, 8734, 8810, 8821, 8822, 8823, 8831, 8832, 8833, 8839, 8891, 8892, 8899
		392	Other community and personal service activities	9011, 9012, 9021, 9022, 9023, 9030, 9111, 9112, 9120, 9191, 9192, 9193, 9199, 9311, 9312, 9391, 9392, 9399
		393	Private households with employed persons and extra-territorial organizations	9500, 9900

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[ANNEX 2]

### Auditor Time

This annex provides guidance on clause 9.1.4 of this document. It should also be read in conjunction with the KAB Guidance on Clauses 9.2 and 9.3 and 9.4.

This annex provides guidance for a certification body on the development of its own procedures for determining the amount of time required for the assessment of organizations of differing sizes and complexity over a broad spectrum of activities.

Certification bodies need to identify the amount of auditor time to be spent on initial assessment, surveillance and reassessment for each applicant and certified organization.

The Guidance in this annex does not stipulate minimum / maximum times but provides a framework to be used by certification bodies to determine appropriate auditor time, taking into account the specifics of the organization to be audited. Use of procedures in line with this framework at the audit planning phase should lead to a consistent approach to the determination of appropriate auditor time.

The Auditor Time Chart provided below sets out an average number of initial audit days which experience has shown to be appropriate for organizations with a given number of employees. Therefore, the number of employees serves as an appropriate starting point to establish auditor time required.

Experience has also demonstrated that for organizations of a similar size, some will need more time and some less. The variation of time spent on each assessment depends on a number of factors including the size, scope of the audit, logistics, complexity of the organization and its state of preparedness for audit. These and other factors need to be examined during the certification body's contract review process for their potential impact on the amount of auditor time to be allocated. Therefore the Auditor Time Chart cannot be used in isolation.

The Auditor Time Chart below provides the framework for a process that could be used for Audit planning by identifying a starting point based on the number of Employees, then adjusting for the significant factors applying to the organization to be audited, and attributing to each factor an additive or subtractive weighting to modify the base figure.

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Guide for Process to Determine Auditor Time for Initial Audit  
 (Auditor Time Chart)

Number of Employees Note 1	Auditor Time for Initial Audit (auditor days) Notes 2+3	Additive and Subtractive Factors	Total Auditor Time
1-10	2		
11-25	3		
26-45	4		
46-65	5		
66-85	6		
86-125	7		
126-175	8		
176-275	9		
276-425	10		
426-625	11		
626-875	12		
876-1175	13		
1176-1550	14		
1551-2025	15		
2026-2675	16		
2676-3450	17		
3451-4350	18		
4351-5450	19		
5451-6800	20		
6801 -8500	21		
8501-10700	22		
> 10700	Follow progression above		

1. “Employees” as referenced in the table refers to all individuals whose work activities support the scope of the certification as described by the quality management system. The total number of employees for all shifts is the starting point for determination of audit time.

- The effective number of employees includes non-permanent (seasonal, temporary, and sub-contracted) staff who will be present at the time of the audit. A certification body should agree with the organization to be audited the timing of the audit which will best demonstrate the full scope of the organization. The consideration could include season, month, day/date and shift as appropriate.

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- Part-time employees should be treated as full-time-equivalent employees. This determination will depend upon the number of hours worked as compared with a full-time employee.
2. "Auditor time" includes the time spent by an Auditor or Audit Team in planning (including off-site document review, if appropriate); interfacing with organization, personnel, records, documentation and processes; and report writing. It is expected that the Auditor time involved in such planning and report writing combined should not typically reduce the total on-site Auditor time to less than 90% of the time shown in the Auditor Time Chart. Where additional time is required for planning and/or report writing, this will not be justification for reducing on-site Auditor time. Auditor travel time is not included in this calculation, and is additional to the Auditor time referenced in the chart.
  3. If remote auditing technique such as interactive web-based collaboration, web meetings, teleconference and/or electronic verification of the organization, these activities should be identified in the assessment plan (see 9.1.2), and may be considered as partially contributing to the total "on-site auditor time". If the certification/registration body plans an audit plan for which the remote auditing activities represent more than 30% of the planned on-site auditor time, the certification/registration body shall justify the audit plan and obtain specific approval from the accreditation body prior to its implementation.

**NOTE** : On-site auditor time refers to the on-site auditor time allocated for individual sites. Electronic audits of remote sites are considered to be remote audits, even if the electronic audits is physically carried out on the organization's premises.

Regardless of the remote auditing techniques used, the organization shall be physically visited at least annually

4. "Auditor time" as referenced in the chart is stated in terms of "Auditor Days" spent on the assessment. An "Auditor Day" is typically a full normal working day of 8 hours. The number of Auditor days employed may not be reduced at the initial planning stages by programming longer hours per work day.
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5. For the initial Assessment cycle, Surveillance time for a given organization should be proportional to the time spent at Initial Audit with the total amount of time spent annually on surveillance being about 1/3 of the time spent on the Initial Audit. The planned surveillance time should be reviewed from time-to-time to account for changes in the organization, system maturity, etc., and at least at the time of re-assessment. For the second and subsequent assessment cycles, the certification/registration body may choose to design an individualized surveillance and reassessment program in accordance with Annex 5.
  
6. The total amount of time spent performing the re-assessment will depend upon the findings of the review as defined in paragraphs 9.3.2.1 and 9.4.2. The amount of time spent at re-assessment should be proportional to the time that would be spent at initial assessment of the same organization and should be about 2/3 of the time that would be required for initial assessment of the same organization at the time that it is to be re-assessed. Re-assessment is time spent above and beyond the routine Surveillance time, but, when re-assessment is carried out at the same time as a planned routine Surveillance visit, the re-assessment will suffice to meet the requirement for Surveillance as well. Regardless of what conclusion is made, the guidance in 9.1.4 applies.

Once the general starting point for determining the required Auditor Time has been made for the typical organization with the number of employees indicated, some adjustments need to be considered to account for the differences that could affect the actual Auditor Time required to perform an effective audit for the specific organization to be audited.

Some factors requiring additional auditor time could be, as examples:

- Complicated logistics involving more than one building or location where work is carried out. e.g., a separate Design Center must be audited.
  - Staff speaking in more than one language (requiring interpreter(s) or preventing individual auditors from working independently)
  - Very large site for number of employees (e.g., a timberland)
  - High degree of regulation (food and drugs, aerospace, nuclear power, etc.)
  - System covers highly complex processes or relatively high number of unique activities
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- Processes involve a combination of hardware, software, process, and service

Some factors permitting less auditor time could be, as examples:

- Organization is not “Design Responsible” and/or other Standard elements not covered in scope.
- No/low risk product/processes
- Prior knowledge of organization system (e.g., already registered to another Standard by the same Registrar)
- Very small site for number of employees (e.g., Office complex only)
- Client preparedness for registration (e.g., already registered or recognized by another 3rd party scheme)
- Processes involve a single general activity (e.g., Service only)
- Maturity of management system
- High percentage of employees doing the same, simple tasks

All attributes of the organization’s system, processes, and products/services should be considered and a fair adjustment made for those factors that could justify more or less auditor time for an effective audit. Additive factors may be off-set by subtractive factors. In all cases where adjustments are made to the time provided in the Auditor Time table, sufficient evidence and records shall be maintained to justify the variation.

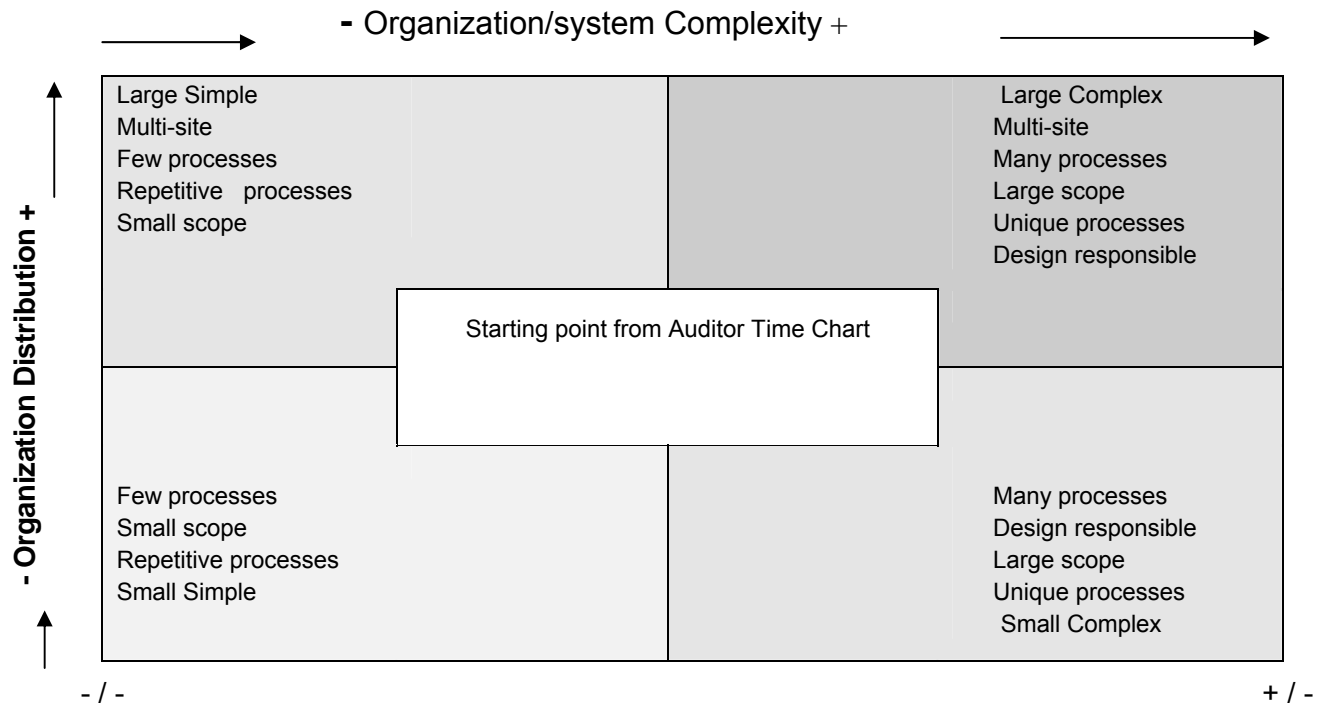
It would be unlikely that the sum total of all adjustments made for a given organization, considering all factors would reduce the required Auditor Time for the initial audit by more than 30% from the time found in the Auditor Time table.

The following graphic illustrates the potential interaction of additive and subtractive factors on the Auditor Time found in the chart above.

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[ANNEX 3]

## Mutisite Certification

This document provides normative criteria for the consistent application of Clause 9.1.5. All clauses of ISO/IEC 17021:2006 continue to apply and this document does not supersede any of the requirements in that standard.

### **0. INTRODUCTION**

- 0.1. The aim of this document is to establish criteria for the audit and, if appropriate, the certification of management systems in organizations with a network of sites to ensure that the audit provides adequate confidence in the conformity of the management system to the relevant standard across all sites listed and that the audit is both practical and feasible in economic and operative terms.
  - 0.2. Normally initial audits for certification and subsequent surveillance and recertification audits should take place at every site of the organization that is to be covered by the certification. However, where an organization's activity subject to certification is carried out in a similar manner at different sites, all under the organization's authority and control, a certification body may put into operation appropriate procedures for sampling the sites at the initial audit and subsequent surveillance and recertification audits. This document addresses the conditions under which this is acceptable for accredited certification bodies and provides criteria on calculation of sample size and audit duration.
  - 0.3. The criteria in this document do not apply to the audits of organizations that have multi-sites where fundamentally dissimilar processes or activities are used at the different sites, or a combination of sites, even though they may be under the same management system. The conditions under which certification bodies can make any reduction in the normal full audit of every site in these circumstances have to be justified at each site where a reduction is proposed.
  - 0.4. This document is applicable to accredited certification bodies that employ sampling in their audit and certification of multi-site organizations. Nevertheless an accredited certification body may exceptionally deviate from these criteria under condition it is able to produce relevant justifications. These justifications shall, under evaluation by the accreditation body, demonstrate that the same level of confidence in the conformity of the management system across all the sites listed can be obtained.
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When an organization is considered a candidate for certification based on sampling, the certification body shall have arrangements to explain the applicable criteria within this document to the organization prior to the commencement of the audit,

### 1. DEFINITIONS

#### 1.1. Organization

The term organization is used to designate any company or other organization owning a management system subject to audit and certification.

#### 1.2. Site

A site is a permanent location where an organization carries out work or a service.

#### 1.3. Temporary Site

A temporary site is one set up by an organization in order to perform specific work or a service for a finite period of time and which will not become permanent site.

#### 1.4. Additional Sites

A new site or group of sites that will be added to an existing certified multi-site network.

#### 1.5. Multi-site Organization

A multi-site organization is defined as an organization having an identified central function (hereafter referred to as a central office – but not necessarily the headquarters of the organization) at which certain activities are planned, controlled or managed and a network of local offices or branches (sites) at which such activities are fully or partially carried out.

### 2. EXPLANATORY REQUIREMENTS

#### 2.1. Site

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- 2.1.1. A site could include all land on which activities under the control of an organization at a given location are carried out including any connected or associated storage of raw materials, by-products, intermediate products, end products and waste material, and any equipment or infrastructure involved in the activities, whether or not fixed. Alternatively, where required by law, definitions laid down in national or local licensing regimes shall apply.
- 2.1.2. Where it is not practicable to define a location (e.g. for services), the coverage of the certification should take into account the organization's headquarters activities as well as delivery of its services. Where relevant, the certification body may decide that the certification audit will be carried out only where the organization delivers its services. In such cases all the interfaces with its central office shall be identified and audited.

### 2.2. Temporary Site

- 2.2.1. Temporary sites that are covered by the organization's management system may be subject to audit on a sample basis to provide evidence of the operation and effectiveness of the management system. They may, however be included within the scope of a multi-site certification subject to agreement between the certification body and the client organization. Where included in the scope, such sites shall be identified as temporary.

### 2.3. Multi-site Organization

- 2.3.1. A multi-site organization need not be a unique legal entity, but all sites shall have a legal or contractual link with the central office of the organization and be subject to a common management system, which is laid down, established and subject to continuous surveillance and internal audits by the central office. This means that the central office has rights to require that the sites implement corrective actions when needed in any site. Where applicable this should be set out in the formal agreement between the central office and the sites.

Examples of possible multi-site organizations are:

- 1) Organizations operating with franchises
- 2) Manufacturing companies with a network of sales offices (this document would apply to the sales network)
- 3) Service companies with multiple sites offering a similar service
- 4) Companies with multiple branches

## 3. ELIGIBILITY CRITERIA OF AN ORGANIZATION FOR SAMPLING

- 3.1.1. Certification documents can be issued covering multiple sites provided that each site included in the scope of registration has either been individually audited by the certification body or audited using the sample approach outlined in this guidance.
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- 3.1.2. The processes at all the sites have to be substantially of the same kind and have to be operated to similar methods and procedures. Where some of the sites under consideration conduct similar, but fewer processes than others, they may be eligible for inclusion under multi-site certification providing that the site(s) which conduct the most processes, or critical processes are subject to full audit.
- 3.1.3. The organization's management system shall be under a centrally controlled and administered plan and be subject to central management review. All the relevant sites (including the central administration function) shall be subject to the organization's internal audit program and all shall have been audited in accordance with that program prior to the certification body starting its audit.
- 3.1.4. It shall be demonstrated that the central office of the organization has established a management system in accordance with the relevant management system standard under audit and that the whole organization meets the requirements of the standard. This shall include consideration of relevant regulations.
- 3.1.5. The organization should demonstrate its ability to collect and analyse data (including but not limited to the its authority and ability to initiate organizational change if required):
- System documentation and system changes;
  - Management review;
  - Complaints;
  - Evaluation of corrective actions;
  - Internal audit planning and evaluation of the result;
  - Changes to aspects and associated impacts for environmental management systems (EMS) and
  - Different legal requirements.
- 3.1.6. Not all organizations fulfilling the definition of "multi-site organization" will be eligible for sampling.
- 3.1.7. Not all management systems standards are suitable for consideration for multi-site certification. For example, multi-site sampling would be unsuitable where the audit of variable local factors is a requirement of the standard. Specific rules apply also for some schemes, for example those including automotive (TS 16949) and aerospace (AS 9100 series) and the requirements of such schemes shall take precedence.
- 3.1.8. Certification bodies should have documented procedures to restrict such sampling where site sampling is inappropriate to gain sufficient confidence in the effectiveness of the management system under audit. Such restrictions should be defined by the certification body with respect to:
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- Scope sectors or activities (i.e. based on the assessment of risks or complexity associated with that sector or activity);
- Size of sites eligible for multi-site audit;
- Variations in the local implementation of the management system such as the need for frequent recourse to the use of plans within the management system to address different activities or different contractual or regulatory systems;
- Use of temporary sites that operate under the management system of the organization and which are not to be included within the scope of certification.

### 4. ELIGIBILITY CRITERIA FOR THE CERTIFICATION BODY

4.0.1. The certification body shall provide information to the organization about the criteria set out in this document and the relevant management system standards before starting the audit process, and should not proceed if any of the criteria are not met. Before starting the audit process, the certification body should inform the organization that the certificate will not be issued if during an initial audit nonconformities in relation to these criteria are found.

#### 4.1. Contract Review

4.1.1. The certification body's procedures should ensure that the initial contract review identifies the complexity and scale of the activities covered by the management system subject to certification and any differences between sites as the basis for determining the level of sampling.

4.1.2. The certification body shall identify the central function of the organization with which it has a legally enforceable agreement for the provision of certification activities.

4.1.3. The certification body should check, in each individual case, to what extent sites of an organization operate substantially the same kind of processes according to the same procedures and methods. See clause for sites which conduct fewer, but similar processes than other sites Only after a positive examination by the certification body that all the sites proposed for inclusion in the multi-site exercise meet the criteria may the sampling procedure be applied to the individual sites.

4.1.4. If all the sites of a service organization where the activity subject to certification is performed are not ready to be submitted for certification at the same time, the organization shall be required to inform the certification body in advance of the sites that it wants to be included in the certification and those which are to be excluded.

#### 4.2. Audit

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- 4.2.1. The certification body shall have documented procedures to deal with audits under its multi-site procedure. Such procedures shall establish the way the certification body satisfies itself that the same management system governs the activities at all the sites, is actually applied to all the sites and that all the eligibility criteria for the organization in clause 3 above are met. This requirement also applies to a management system where electronic documents and/or process control, and/or other electronic processes are used. The certification body shall justify and record the rationale for proceeding with a multi-site approach.
- 4.2.2. If more than one audit team is involved in the audit/surveillance of the network, the certification body should designate a unique audit leader whose responsibility is to consolidate the findings from all the audit teams and to produce a synthesis report.

### 4.3. Nonconformities

- 4.3.1. When nonconformities are found at any individual site, either through the organization's internal auditing or from auditing by the certification body, investigation should take place to determine whether the other sites may be affected. Therefore, the certification body should require the organization to review the nonconformities to determine whether they indicate an overall system deficiency applicable to other sites or not. If they are found to do so, corrective action should be performed and verified both at the central office and at the individual affected sites. If they are found not to do so, the organization should be able to demonstrate to the certification body the justification for limiting its follow-up action.
- 4.3.2. The certification body shall require evidence of these actions and increase its sampling frequency and/or the size of sample until it is satisfied that control is re-established.
- 4.3.3. At the time of the decision making process, if any site has a nonconformity, certification shall be denied to the whole network of listed sites pending satisfactory corrective action.

It shall not be admissible that, in order to overcome the obstacle raised by the existence of a nonconformity at a single site, the organization seeks to exclude from the scope the "problematic" site during the certification process. Such exclusion can only be agreed in advance (See clause .1.4).

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### 4.4 Certification Document

- 4.4.1 . Certification documents can be issued covering multiple sites provided that each site included in the scope of certification has either been individually audited by the certification body or audited using the sample approach outlined in this document. The certification body shall provide certification documents to the certified client by any means it chooses. Such certification documents shall comply in all respects with ISO/IEC 17021:2006.
- 4.4.2 . The documents These documents shall contain the name and address of the central office of the organization and a list of all the sites to which the certification documents relate. The scope or other reference on these documents shall make clear that the certified activities are performed by the network of sites inon the list. If the certification scope of the sites is only issued as part of the general scope of the organization, its applicability to all the sites shall be clearly stated. . Where temporary sites are included in the scope, such sites shall be identified as temporary in the certification documents.
- 4.4.3 . Sub-Certification documents may be issued to the organization for each site covered by the certification under condition that they contain the same scope, or a sub-scope of that scope, and include a clear reference to the main certification documentation..
- 4.4.4 . The certification documentation will be withdrawn in its entirety, if the central office or any of the sites does not/do not fulfill he necessary criteria for the maintenance of the certification.
- 4.4.5 . The list of sites shall be kept updated by the certification body. To this effect, the certification body shall request the organization to inform it about the closure of any of the sites covered by the certification. Failure to provide such information will be considered by the certification body as a misuse of the certification, and it should act consequently according to its procedures.
- 4.4.6 . Additional sites can be added to an existing certification as the result of surveillance/ recertification activities or enhancement of scope. The certification body shall have documented a procedures for the addition of new sites.

## 5. CRITERIA FOR SAMPLING

### 5.1. Methodology

- 5.1.1. The sample should be partly selective based on the factors set out below and partly non-selective, and should result in a representative range of different sites being selected, without excluding the random element of sampling.
  - 5.1.2. At least 25% of the sample should be selected at random.
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5.1.3. Taking into account the criteria mentioned below, the remainder should be selected so that the differences among the sites selected over the period of validity of the certificate is as large as possible.

**5.1.4. The site selection criteria may include among others the following aspects:**

- Results of internal site audits and management reviews or previous certification audits
- Records of complaints and other relevant aspects of corrective and preventive action
- Significant variations in the size of the sites
- Variations in shift patterns and work procedures
- Complexity of the management system and processes conducted at the sites
- Modifications since the last certification audit
- Maturity of the management system and knowledge of the organization
- Significance of environmental issues if appropriate and extent of aspects and associated impacts for environmental (EMS) management systems
- Environmental issues if appropriate (eg. potential interaction with sensitive environment)
- Geographical dispersion

5.1.5. This selection does not have to be done at the start of the audit process. It can also be done once the audit at the central office has been completed. In any case, the central office shall be informed of the sites to be included in the sample. This can be on relatively short notice, but should allow adequate time for preparation for the audit.

5.1.6. The central office shall be audited during every initial certification and recertification audit and at least annually as part of surveillance.

### **5.2. Size Of Sample**

5.2.1. The certification body shall have a documented procedure for determining the sample to be taken when auditing sites as part of the audits and certification of a multi-site organization. This should take into account all the factors described in this document.

5.2.2. The certification body shall have records on each application of multi-site sampling justifying it is operating in accordance with this document.

5.2.3. The following calculation is an example based on the example of a low to medium risk activity with less than 50 employees at each site. The minimum number of sites to be visited per audit is:

- **Initial audit:** the size of the sample should be the square root of the number of remote sites:  $(y=\sqrt{x})$ , rounded to the upper whole number.
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- **Surveillance audit:** the size of the annual sample should be the square root of the number of remote sites with 0.6 as a coefficient ( $y=0.6 \sqrt{x}$ ), rounded to the upper whole number.
- **Re-certification audit:** the size of the sample should be the same as for an initial audit. Nevertheless, where the management system has proved to be effective over a period of three years, the size of the sample could be reduced by a factor 0.8, i.e.: ( $y=0.8 \sqrt{x}$ ), rounded to the upper whole number.

5.2.4. Additionally, the central office shall be visited at each initial, surveillance and recertification audit.

5.2.5. The size or frequency of the sample should be increased where the certification body's risk analysis of the activity covered by the management system subject to certification indicates special circumstances in respect of factors such as:

- The size of the sites and number of employees (eg. more than 50 employees on a site)
- The complexity or risk level of the activity and of the management system,
- Variations in working practices
- Variations in activities undertaken
- Records of complaints and other relevant aspects of corrective and preventive action
- Any multinational aspects
- Results of internal audits and management review.

5.2.6. When the organization has a hierarchical system of branches (e.g. head (central) office / national offices / regional offices / local branches), the sampling model for initial audit as defined above applies to each level.

### Example:

1 head office: visited at each audit cycle (initial/surveillance/recertification)

4 National offices: sample = 2: minimum 1 at random

27 regional offices: sample = 6: minimum 2 at random

1700 local branches: sample = 42: minimum 11 at random.

## 5.3. Audit Times

5.3.1. The audit time to spend for each individual site is another important element to consider, and the certification body shall be prepared to justify the time spent on multi-site audits in terms of its overall policy for allocation of audit time.

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- 5.3.2. , he number of man-days per site, including the central office, should be calculated for each site using the chart in Annex 2 in [QMS CB Accreditation Criteria](KAB-R-01) and for TL 9000, the chart in Annex 2 in [TL 9000 CB Accreditation Criteria]
- 5.3.3. Reductions can be applied to take into account the clauses that are not relevant to the central office and/or the local sites. . Reasons for the justification of such reductions shall be recorded by the certification body.
- 5.4. Additional Sites**
- 5.4.1. On the application of a new group of sites to join an already certified multi-site network, each new group of sites should be considered as an independent set for the determination of the sample size. After inclusion of the new group in the certificate, the new sites should be cumulated to the previous ones for determining the sample size for future surveillance or recertification audits.

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### Transfer of Accredited Certification

This document provides normative criteria for the consistent application of Clause 9.1.1.

#### 0. Introduction

- 0.1 This annex provides guidance on the transfer of ISO 9001 quality management system certificates between certification/registration bodies.
- 0.2 The objective of this guidance is to assure the maintenance of the integrity of accredited quality management system certificates issued by one certification body if subsequently transferred to another such body.
- 0.3 The guidance states minimum requirements for the transfer of certification. Certification bodies may implement procedures or actions which are more stringent than those contained herein provided that an organization's freedom to choose a certification body is not unduly or unfairly constrained.

#### 1. DEFINITION

##### 1.1 Transfer of Certification/registration.

The transfer of certification/registration is defined as the recognition of an existing and valid, [but see clause 2.3.1 of this Annex], quality management system certificate, granted by one accredited certification/registration body, [hereinafter referred to as the “issuing certification/registration body”], by another accredited certification/registration body, [hereinafter referred to as the “accepting certification/registration body”] for the purpose of issuing its own certification/registration.

**Note:** Multiple certification/registration does not fall under the definition above, and is not encouraged by IAF.

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### 2. MINIMUM REQUIREMENTS

#### 2.1 Accreditation

Only certificates which are covered by an accreditation of an EA, PAC, IAAC or IAF MLA signatory should be eligible for transfer. If the existing certification is accredited by a body that belongs to a regional MLA only, the transfer shall be limited to other accreditations valid within that regional agreement. Organizations holding certificates that are not covered by such accreditations shall be treated as new clients.

#### 2.2 Pre-Transfer Review

2.2. A competent person from the accepting certification body shall carry out a review of the certification of the prospective client. This review shall be conducted by means of both a documentation review and should, normally, include a visit to the prospective client. Reasons for not conducting a visit shall be fully justified and documented and a visit shall be conducted if no contact can be made with the issuing certification body. The review should cover the following aspects: and its findings shall be fully documented:

- 2.2.1. Confirmation that the client's certified activities fall within the accredited scope of the accepting certification body.
  - 2.2.2. The reasons for seeking a transfer.
  - 2.2.3. That the site or sites wishing to transfer certification hold an accredited certification that is valid in terms of authenticity, duration, and scope of activities covered by the management system certification. If practical, the validity of certification and the status of outstanding nonconformities should be verified with the issuing certification body unless it has ceased trading. Where it has not been possible to communicate with the issuing certification body, the accepting certification body shall record the reasons.
  - 2.2.4. A consideration of the last certification/recertification audit reports, subsequent surveillance reports and any outstanding nonconformities arising therefrom. This consideration shall also include any other available, relevant documentation regarding the certification process i.e. handwritten notes, checklists. If the last certification/recertification/subsequent surveillance audit
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reports are not made available or if the surveillance audit is overdue then the organization shall be treated as a new client.

2.2.5. Complaints received and action taken.

2.2.6. The stage in the current certification cycle. See paragraph 2.3.4 of this document.

### 2.3. Certification

2.3.1 Normally, only valid accredited certification should be transferred. In cases where certification has been granted by a certification body which has ceased trading or whose accreditation has expired, been suspended or withdrawn, the accepting certification body may consider such a certification for transfer at its discretion. In such cases, before it proceeds with the transfer, the accepting certification body shall obtain agreement from the accreditation body, whose mark it intends to place on the certificate. In the case of acquisitions the acquiring certification body should, where practical, fulfil the contractual obligations of the acquired certification body.

2.3.2 Certificates which are known to have been suspended or to be under threat of suspension should not be accepted for transfer.

2.3.3 Outstanding nonconformities should be closed out, if practical, with the issuing certification body, before transfer. Otherwise they should be closed out by the accepting certification body.

2.3.4 If no further outstanding or potential problems are identified by the pre-transfer review a certificate, dated from the date of completion of the review, may be issued following the normal decision making process. The pattern of the previous regime should be utilised to determine the programme of on-going surveillance and re-assessment unless, as a result of the review, the accepting certification body has performed an initial or re-assessment audit.

2.3.5 Where doubt continues to exist, after the pre-transfer review, as to the adequacy of a current or previously held certification, the accepting certification / registration body should, depending upon the extent of doubt, either:

- Treat the applicant as a new client or
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- Conduct an assessment concentrating on identified problem areas  
The decision as to the action required will depend upon the nature and extent of any problems found and should be explained to the organization and the justification for the decision shall be documented and the records maintained by the certification body.
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[Annex 5]

### Advanced Surveillance and Reassessment Procedures

This document provides normative criteria for advanced surveillance and recertification procedures (ASRP) for consistent application of clause 9.3 and 9.4

#### 0. INTRODUCTION

- 0.1. For a client organization that has established confidence in its quality management system by consistently demonstrating effectiveness over a period of time, the certification body, in consultation with the organization, may choose to apply the Advanced Surveillance and Recertification Procedures (ASRP) provided for in this document. Such an advanced surveillance and recertification program may place greater (but not total) reliance on the organization's internal audit and management review processes, include targeted surveillance topics, take into account specific design input from the organization and/or use other methods as appropriate, to demonstrate conformity of the management system.
- 0.2. The objective of this document is to assure the provision of more effective and efficient audits to organizations that have a proven performance record while at the same time maintaining the integrity of the accredited quality management system certificates they hold.
- 0.3. This document states minimum requirements for the application of the ASRP. Certification bodies may implement procedures or actions which are more stringent than those contained herein provided that an organization's justifiable request for the ASRP is not unduly or unfairly constrained.

#### 1. MINIMUM REQUIREMENTS

##### 1.1 Prerequisite

In order to utilize the ASRP, the certification body shall first demonstrate to an IAF MLA signatory accreditation body of QMS:

- 1) That it has been operating an accredited certification scheme for the quality management system for a minimum of one complete accreditation cycle.
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- 2) That it is competent to design an ASRP program for each individual organization in quality management system, in accordance with the requirements of ISO 9001:2000/KS A 9001:2001 clause 7.3 and using the design input criteria mentioned in clause 1.3.2 below.

### 1.2 Accreditation Scope

The competence of the certification body to meet 1.1 (2) above shall be assessed by the accreditation body after which, if successful, specific reference to the approval for ASRP for QMS, as appropriate, shall be included in the certification body's accreditation scope.

### 1.3 Eligibility and Design Input Criteria

The certification body shall inform the accreditation body prior to every new utilization of ASRP for each specific organization, and shall be able to demonstrate that the following criteria in 1.3.1 and 1.3.2 have been satisfied:

#### 1.3.1 Eligibility Criteria

- a) The certification body shall confirm that the organization's management system has been in demonstrated conformity with the requirements of the applicable standard(s) for a period of at least one complete certification cycle including initial, surveillance and recertification audits.

**NOTE:** The certification body may base this confirmation of demonstrated conformity on the outcome of the first recertification audit (non-ASRP) of the organization conducted at the end of a three-year certification cycle.

- b) All nonconformities raised during the certification cycle immediately prior to the utilization of ASRP shall have been successfully resolved.
- c) For an EMS, the certification body shall confirm that the organization has established compliance with applicable legal requirements and has not had any sanctions imposed by the relevant regulatory authority(ies) for the period of a) above.
- d) The certification body shall have agreed suitable performance indicators with the organization, on which to judge the ongoing effectiveness of the management system, and shall ensure that the organization is consistently meeting agreed performance targets. these performance indicators shall address, as a minimum, the organization's demonstrated ability to consistently provide product that meets customer and applicable regulatory requirements
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(see ISO 9001:2000/KS A 9001:2001 clause 1.1), and shall incorporate requirements for the continual improvement of the effectiveness of the QMS

**NOTE:** For a QMS, “indicator” means the characteristic to be measured and “target” means the quantitative/qualitative requirements to be met.

- e) The certification body shall have enforceable arrangements with the organization to provide for access to relevant information. For a QMS, this information is all customer satisfaction data collected or otherwise available, and in particular the relevant regulatory authority(ies). When it becomes necessary for the certification body to communicate directly with the source of such information in order to validate the information, mutually agreed confidentiality policies and procedures shall be applied.
- f) The certification body shall verify that the organization’s internal audit process is being managed in accordance with the guidance of KS A ISO 19011, with particular reference to auditor competence defined in clause 7. The internal audit process shall be sufficiently coordinated and integrated so as to provide an evaluation of the quality management system as a whole, not only the performance of individual components.
- g) The certification body shall have contractually enforceable arrangements to enable it to increase the scope, frequency and duration of its audits in the event of a deterioration of the organization’s ability to meet agreed performance targets.

### 1.3.2 Design Input Criteria

In addition to organization-specific input criteria, the design of each individual ASRP shall address the following:

- a) The frequency and duration of the certification body audits shall be sufficient to allow the certification body to conform with this criteria document including the following b) and c), among others.

For each proposed utilization of ASRP, the certification body shall determine the base level (non-ASRP) auditor time using relevant IAF Guidance or Normative Criteria Documents, and, if applicable, IAF NCD Z for sampling of multi-sites. If the certification body plans an individual ASRP program that reduces the auditor time to less than 70% of this base-level, the certification body shall justify such reductions and seek specific approval from the accreditation body prior to its implementation.

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- b) In addition to auditing a statistically significant number of samples of the organization's management system processes to confirm the adequacy and effectiveness of the internal audit process, the certification body itself shall continue to carry out the following activities at each on-site surveillance and recertification audit, **as a minimum** (with other activities defined by the ASRP; see clause 1.4 below):
- interview top management and the management representative;
  - evaluate management review inputs and outputs, including a verification of the organization's ability to meet the agreed performance targets;
  - review the internal audit process, including the procedures and records of internal audits, and the competence of internal auditors; and
  - review corrective and preventive actions plans, and verify their effective implementation.
- c) The certification body shall ensure that all the requirements for accredited certification (including the requirements of ISO/IEC 17021:2006 and any applicable sector scheme) continue to be met.

### 1.4 Design Output

The design output for each application of the certification body's ASRP program shall include the following a) – f):

- a) The extent to which the certification body will utilize the organization's internal audit and management review processes to complement the certification body's activities;
- b) Criteria for witnessing the organization's internal audits, including sampling of both auditors and processes to be audited;
- c) Criteria for accepting and monitoring the competence of the organization's internal auditors and the method of reporting internal audit results;
- d) Criteria for ongoing adjustments to the audit program, taking into account the organization's demonstrated ability over time to meet the agreed performance targets;
- e) The components of the management system that will necessarily be audited by the certification body at each surveillance and recertification audit (see 1.3.2 b); and
- f) Specific certification body auditor competence criteria.

### 1.5 Certificates

The certification body shall not differentiate between ASRP and non-ASRP

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### additional clause

1. This criteria can be applied on 1 September 2007, on 15 September 2008, all accredited Certification Bodies are expected to be in full compliance with this criteria. The implementation should be verified during normal scheduled surveillance activities. However, additional assessments may be necessary for a Certification Body not prepared transition plan before 15 September 2008 and requesting accreditation within an accelerated time frame.
2. A certification body that applies for accreditation following the publication of this criteria shall be applied by this criteria.
3. Transition plan
  - 3.1. Transition to this criteria for Certification Bodies accredited by KAB may require translations, changes to procedures, contracts, committees and other arrangements which will take time. therefore, Certification Bodies should commence identification of differences immediately. The Certification Bodies are advised to make a transition plan to determine both the changes to their QMS and the time frame required to execute them. Certification Bodies are further advised to agree their transition plan with their Accreditation Body.
  - 3.2. In recognition of the need to limit the disruption to a Certification Body's clients, certain changes may be more appropriately carried out at the time of contract renewal or certificate re-issue and may not have been completed fully by the end of the two year transition period. Where such an occasion exists, it should have been identified in the Certification Body's transition plan and agreed with the relevant Accreditation Body. Any additional time to implement outstanding issues should be consistent with the normal business cycle but under no circumstance should this exceed 12 months beyond the 24 month transition period (i.e. beyond 15 September 2008).
4. Nonconformities

Accreditation Bodies should make it clear to Certification Bodies that where this criteria is not yet fully applicable(before 15 September 2008), that issues against this criteria may be

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raised during the transition period and that these will be redefined as nonconformities after the transition deadline. Where specific exceptions have been agreed in advance, related nonconformities will not adversely affect accreditation and will not preclude the issue of an accreditation certificate to this criteria.

### 5. End of transition and Accreditation Certificate Issue

On 15 September 2008, twelve months after publication of the this new criteria, all accredited Certification Bodies are expected to be in full compliance with ISO/IEC 17021 and a new accreditation certificate issued.