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| **Details of the certification body** | | | |
| Name: |  | | |
| Address: |  | | |
| File number: |  |  |  |
| Case number | Phase |  |
| Date of assessment: |  | | |
| Accreditation process: |  | | |
| Assessment type[[1]](#endnote-1) : |  | | |
| Certification body with several locations: | | Yes | No |
| Name / Address of assessed locations: | | | |

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| Area: | Within the permanent facilities | | On-site | Mobile facilities |
| Technical management: |  | | | |
| Deputy: |  | | | |
| Quality manager: |  | | | |
| Deputy: |  | | | |
| **Details of the assessor** | | | | |
| Name: |  | | | |
| Status[[2]](#endnote-2) : | LA | SA | TA | O |
| **Assessed area** (technical fields of DAkkS, certification fields, sectorspecific requirements, directives/modules) | | | | |

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**Notes on usage by the certification body (blue colored sectors):**

* On the second page only the name and address of the certification body shall be entered.
* Please enter the following information in the column “Reference documents“:  
  Where is the implementation of the requirement documented?   
  (State the specific reference documents, e.g. specification of the document/chapter/section)   
  Requirements of the standard that are not applicable shall be shall be indicated accordingly.

No further entries shall be made by the certification body.

**Notes on usage by the assessor (orange colored sectors):**

* The column „Responsible“ indicates the assessor responsible to evaluate a section of the standard.
* The column “Appraisal” and “No of NC” shall be entered by the assessor (evaluation key see final marks)
* The appraisal in the first row of a section of the standard (e.g. 5.1 Legal and contractual matters) indicates the overall appraisal after the assessment, including the prior review of documents and records. The appraisal in the first row of a section suffice, if no non-conformity was identified for the relevant section of the standard.

# 5 General requirements

## 5.1 Legal and contractual matters

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| **Result of review of documents and records: [[3]](#endnote-3)** | | |  |  |  |  |

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| Findings / justification of findings / specifics / notes: | | | |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:[[4]](#endnote-4)** | | | |
| No. | OE[[5]](#endnote-5) | Title / Description | Date / Version |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: | | | |
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| **5.1.1** | **Legal responsibility**  The certification body (CB) shall be a legal entity, or a defined part of a legal entity that can be held legally responsible for all its certification activities. A governmental CB is deemed to be a legal entity on the basis of its governmental status. |  |  |  |  |  |
| **5.1.2** | **Certification agreement**  The CB shall have a legally enforceable agreement with each client for the provision of certification activities in accordance with the relevant requirements of this part of ISO/IEC 17021.  In addition, where there are multiple offices of a CB or multiple sites of a client, the CB shall ensure there is a legally enforceable agreement between the CB granting certification and the client that covers all the sites within the scope of the certification.  [🡺NOTE] |  |  |  |  |  |
| **5.1.3** | **Responsibility for certification decisions**  The CB shall be responsible for, and shall retain authority for,  its decisions relating to certification, including the granting, refusing, maintaining of certification, expanding or reducing  the scope of certification, renewing, suspending or restoring following suspension, or withdrawing of certification. |  |  |  |  |  |

## 5.2 Management of impartiality

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| 5.2.1 | Conformity assessment activities shall be undertaken impartially. The CB shall be responsible for the impartiality of its conformity assessment activities and shall not allow commercial, financial or other pressures to compromise impartiality. |  |  |  |  |  |
| 5.2.2 | The CB shall have top management commitment to impartiality in management system (MS) certification activities. The CB shall have a policy that it understands the importance of impartiality in carrying out its MS certification activities, manages conflict of interest and ensures the objectivity of its MS certification activities. |  |  |  |  |  |
| 5.2.3 | The CB shall have a process to identify, analyse, evaluate, treat, monitor, and document the risks related to conflict of interests arising from provision of certification including any conflicts arising from its relationships on an ongoing basis. Where there are any threats to impartiality, the CB shall document and demonstrate how it eliminates or minimizes such threats and document any residual risk.  The demonstration shall cover all potential threats that are identified, whether they arise from within the CB or from the activities of other persons, bodies or organizations. When a relationship poses an unacceptable threat to impartiality (such as a wholly owned subsidiary of the CB requesting certification from its parent), then certification shall not be provided.  Top management shall review any residual risk to determine if it is within the level of acceptable risk.  The risk assessment process shall include identification of and consultation with appropriate interested parties to advise on matters affecting impartiality including openness and public perception. The consultation with appropriate interested parties shall be balanced with no single interest predominating.  [🡺NOTE 1 to 3] |  |  |  |  |  |
| 5.2.4 | A CB shall not certify another CB for its quality MS. |  |  |  |  |  |
| 5.2.5 | The CB and any part of the same legal entity and any entity under the organizational control of the CB [see 9.5.1.2, bullet b)] shall not offer or provide MS consultancy. This also applies to that part of government identified as the CB. [🡺NOTE] |  |  |  |  |  |
| 5.2.6 | The carrying out of internal audits by the CB and any part of the same legal entity to its certified clients is a significant threat to impartiality. Therefore, the CB and any part of the same legal entity and any entity under the organizational control of the CB [see 9.5.1.2, bullet b)] shall not offer or provide internal audits to its certified clients.  A recognized mitigation of this threat is that the CB shall not certify a MS on which it provided internal audits for a minimum of two years following the completion of the internal audits.  [🡺NOTE] |  |  |  |  |  |
| 5.2.7 | Where a client has received MSs consultancy from a body that has a relationship with a CB, this is a significant threat to impartiality. A recognized mitigation of this threat is that the CB shall not certify the MS for a minimum of two years following the end of the consultancy. [🡺NOTE] |  |  |  |  |  |
| 5.2.8 | The CB shall not outsource audits to a MS consultancy organization, as this poses an unacceptable threat to the impartiality of the CB (see 7.5). This does not apply to individuals contracted as auditors covered in 7.3. |  |  |  |  |  |
| 5.2.9 | The CB’s activities shall not be marketed or offered as linked with the activities of an organization that provides MS consultancy. The CB shall take action to correct inappropriate links or statements by any consultancy organization stating or implying that certification would be simpler, easier, faster or less expensive if the CB were used. A CB 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 | In order to ensure that there is no conflict of interests, personnel who have provided MS consultancy, including those acting in a managerial capacity, shall not be used by the CB to take part in an audit or other certification activities if they have been involved in MS consultancy towards the client. A recognized mitigation of this threat is that personnel shall not  be used for a minimum of two years following the end of the consultancy. |  |  |  |  |  |
| 5.2.11 | The CB shall take action to respond to any threats to its impartiality arising from the actions of other persons, bodies or organizations. |  |  |  |  |  |
| 5.2.12 | All CB 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. |  |  |  |  |  |
| 5.2.13 | Certification bodies shall require personnel, internal and external, to reveal any situation known to them that can present them or the CB with a conflict of interests. Certification bodies shall record and 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

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| 5.3.1 | The CB 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. |  |  |  |  |  |
| 5.3.2 | The CB shall evaluate its finances and sources of income and demonstrate 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

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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** | | | |
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| 6.1.1 | The CB shall document its organizational structure, duties, responsibilities and authorities of management and other personnel involved in certification and any committees. When the CB 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 | Certification activities shall be structured and managed so as to safeguard impartiality. |  |  |  |  |  |
| 6.1.3 | The CB shall identify the top management (board, group of persons, or person) having overall authority and responsibility for each of the following:   1. development of policies and establishment of processes  and procedures relating to its operations; 2. supervision of the implementation of the policies,  processes and procedures; 3. ensuring impartiality; 4. supervision of its finances; 5. development of MS certification services and schemes; 6. performance of audits and certification, and responsiveness to complaints; 7. decisions on certification; 8. delegation of authority to committees or individuals, as required, to undertake defined activities on its behalf; 9. contractual arrangements; 10. provision of adequate resources for certification activities. |  |  |  |  |  |
| 6.1.4 | The CB shall have formal rules for the appointment, terms of reference and operation of any committees that are involved in the certification activities. |  |  |  |  |  |

## 6.2 Operational control

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| 6.2.1 | The CB shall have a process for the effective control of certification activities delivered by branch offices, partnerships, agents, franchisees, etc., irrespective of their legal status, relationship or geographical location. The CB shall consider the risk that these activities pose to the competence, consistency and impartiality of the CB. |  |  |  |  |  |
| 6.2.2 | The CB shall consider the appropriate level and method of control of activities undertaken including its processes, technical areas of certification bodies’ operations, competence of personnel, lines of management control, reporting and remote access to operations including records. |  |  |  |  |  |

# 7 Resource requirements

## 7.1 Competence of personnel

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| **Result of review of documents and records:** | | |  |  |  |  |

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| Findings / justification of findings / specifics / notes: | | | |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** | | | |
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| **7.1.1** | **General considerations**  The CB shall have processes to ensure that personnel have appropriate knowledge and skills relevant to the types of MSs (e.g. environmental MSs, quality MSs, information security MSs) and geographic areas in which it operates. |  |  |  |  |  |
| **7.1.2** | **Determination of competence criteria**  The CB shall have a process for determining the competence criteria for personnel involved in the management and performance of audits and other certification activities. Competence criteria shall be determined with regard to the requirements of each type of MS standard or specification, for each technical area, and for each function in the certification process.  The output of the process shall be the documented criteria of required knowledge and skills necessary to effectively perform audit and certification tasks to be fulfilled to achieve the intended results. Annex A specifies the knowledge and skills that a CB shall define for specific functions. Where additional specific competence criteria have been established for a specific standard or certification scheme (e.g. ISO/IEC TS 17021-2, ISO/IEC TS 17021-3 or ISO/TS 22003), these shall be applied.  [🡺NOTE] |  |  |  |  |  |
| **7.1.3** | **Evaluation processes**  The CB shall have documented processes for the initial competence evaluation, and ongoing monitoring of competence and performance of all personnel involved in the management and performance of audits and other certification activities, applying the determined competence criteria.  The CB shall demonstrate that its evaluation methods are effective. The output from these processes shall be to identify personnel who have demonstrated the level of competence required for the different functions of the audit and certification process. Competence shall be demonstrated prior to the individual taking the responsibility for the performance of their activities within the CB. [🡺NOTE 1, 2] |  |  |  |  |  |
| **7.1.4** | **Other considerations**  The CB shall have access to the necessary technical expertise for advice on matters directly relating to certification activities for all technical areas, types of MSs and geographic areas in which the CB operates. Such advice may be provided externally or by CB personnel. |  |  |  |  |  |

## 7.2 Personnel involved in the certification activities

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| 7.2.1 | The CB shall have sufficient, competent personnel for managing and supporting the type and range of audit programmes and other certification work performed. |  |  |  |  |  |
| 7.2.2 | The CB 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. |  |  |  |  |  |
| 7.2.3 | The CB shall make clear to each person concerned their duties, responsibilities and authorities. |  |  |  |  |  |
| 7.2.4 | The CB shall have processes for selecting, training, formally authorizing auditors and for selecting and familiarizing technical experts used in the certification activity. The initial competence evaluation of an auditor shall include the ability to apply required knowledge and skills during audits, as determined by a competent evaluator observing the auditor conducting an audit.  [🡺NOTE] |  |  |  |  |  |
| 7.2.5 | The CB 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. |  |  |  |  |  |
| 7.2.6 | The CB shall ensure that auditors (and, where needed, technical experts) are knowledgeable of its audit processes, certification requirements and other relevant requirements. The CB shall give auditors and technical experts access to an up-to-date set of documented procedures giving audit instructions and all relevant information on the certification activities. |  |  |  |  |  |
| 7.2.7 | The CB 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. |  |  |  |  |  |
| 7.2.8 | The group or individual that takes the decision on granting, refusing, maintaining, renewing, suspending, restoring, or withdrawing certification, or on expanding or reducing the scope of certification, shall understand the applicable standard and certification requirements, and shall have demonstrated competence to evaluate the outcomes of the audit processes including related recommendations of the audit team. |  |  |  |  |  |
| 7.2.9 | The CB shall ensure the satisfactory performance of all personnel involved in the audit and other certification activities. There shall be a documented process for monitoring competence and performance of all persons involved, based on the frequency of their usage and the level of risk linked to their activities. In particular, the CB shall review and record the competence of its personnel in the light of their performance in order to identify training needs. |  |  |  |  |  |
| 7.2.10 | The CB shall monitor each auditor considering each type of MS to which the auditor is deemed competent. The documented monitoring process for auditors shall include a combination of on-site evaluation, review of audit reports and feedback from clients or from the market. This monitoring shall be designed in such a way as to minimize disturbance to the normal processes of certification, especially from the client’s viewpoint. |  |  |  |  |  |
| 7.2.11 | The CB shall periodically evaluate the performance of each auditor on-site. The frequency of on-site evaluations shall be based on need determined from all monitoring information available. |  |  |  |  |  |

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

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| **Result of review of documents and records:** | | |  |  |  | |  |

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| Findings / justification of findings / specifics / notes: | | | |
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|  | The CB shall require external auditors and external technical experts to have a written agreement by which they commit themselves to comply with applicable policies and implement processes as defined by the CB. The agreement shall address aspects relating to confidentiality and impartiality and shall require the external auditors and external technical experts to notify the CB of any existing or prior relationship with any organization they may be assigned to audit. [🡺NOTE] |  |  |  |  |  |

## 7.4 Personnel records

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| **Result of review of documents and records:** | | |  |  |  |  |

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|  | The CB shall maintain up-to-date personnel records, including relevant qualifications, training, experience, affiliations, professional status and competence. This includes management and administrative personnel in addition to those performing certification activities. |  |  |  |  |  |

## 7.5 Outsourcing

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| 7.5.1 | The CB 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 CB) may take place. The CB shall have a legally enforceable agreement covering the arrangements, including confidentiality and conflicts of interests, with each body that provides outsourced services. |  |  |  |  |  |
| 7.5.2 | Decisions for granting, refusing, maintaining of certification, expanding or reducing the scope of certification, renewing, suspending or restoring, or withdrawing of certification shall not be outsourced. |  |  |  |  |  |
| 7.5.3 | The CB shall   1. take responsibility for all activities outsourced to another body, 2. ensure that the body that provides outsourced services, and the individuals that it uses, conform to requirements of the CB and also to the applicable provisions of this part of ISO/IEC 17021, including competence, impartiality and confidentiality; 3. ensure that the body that provides outsourced services, and the individuals that it uses, are not involved, either directly or through any other employer, with an organization to be audited, in such a way that impartiality could be compromised. |  |  |  |  |  |
| 7.5.4 | The CB shall have a process for the approval and monitoring of all bodies that provide outsourced services used for certification activities, and shall ensure that records of the competence of all personnel involved in certification activities are maintained.  [🡺NOTE 1, 2] |  |  |  |  |  |

# 8 Information requirements

## 8.1 Publicly information

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| Findings / justification of findings / specifics / notes: | | | |
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| 8.1.1 | The CB shall maintain (through publications, electronic media or other means), and make public, without request, in all the geographical areas in which it operates, information about   1. audit processes; 2. processes for granting, refusing, maintaining, renewing, suspending, restoring or withdrawing certification or expanding or reducing the scope of certification; 3. types of MSs and certification schemes in which it operates; 4. the use of the CB’s name and certification mark or logo; 5. processes for handling requests for information, complaints and appeals; 6. policy on impartiality. |  |  |  |  |  |
| 8.1.2 | The CB shall provide upon request information about:   1. geographical areas in which it operates; 2. the status of a given certification; 3. the name, related normative document, scope and geographical location (city and country) for a specific certified client.   [🡺NOTE 1, 2] |  |  |  |  |  |
| 8.1.3 | Information provided by the CB to any client or to the marketplace, including advertising, shall be accurate and not misleading. |  |  |  |  |  |

## 8.2 Certification documents

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| 8.2.1 | The CB shall provide by any means it chooses certification documents to the certified client. |  |  |  |  |  |
| 8.2.2 | The certification document(s) shall identify the following:   1. the name and geographical location of each certified client (or the geographical location of the headquarters and any sites within the scope of a multi-site certification); 2. the effective date of granting, expanding or reducing the scope of certification, or renewing certification which shall not be before the date of the relevant certification decision;   [🡺NOTE]   1. the expiry date or recertification due date consistent  with the recertification cycle; 2. a unique identification code; 3. the MS standard and/or other normative document,  including indication of issue status (e.g. revision date  or number) used for audit of the certified client; 4. the scope of certification with respect to the type of activities, products and services as applicable at each site without being misleading or ambiguous; 5. the name, address and certification mark of the CB;  other marks (e.g. accreditation symbol, client’s logo) may  be used provided they are not misleading or ambiguous; 6. any other information required by the standard and/or  other normative document used for certification; 7. in the event of issuing any revised certification documents,  a means to distinguish the revised documents from any  prior obsolete documents. |  |  |  |  |  |

## 8.3 Reference to certification and use of marks

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| 8.3.1 | A CB shall have rules governing any MS certification mark that it authorizes certified clients to use. These rules shall ensure, among other things, traceability back to the CB. There shall be no ambiguity, in the mark or accompanying text, as to what has been certified and which CB has granted the certification. This mark shall not be used on a product nor product packaging nor in any other way that may be interpreted as denoting product conformity. [🡺NOTE] |  |  |  |  |  |
| 8.3.2 | A CB shall not permit its marks to be applied by certified clients to laboratory test, calibration or inspection reports or certificates. |  |  |  |  |  |
| 8.3.3 | A CB shall have rules governing the use of any statement on product packaging or in accompanying information that the certified client has a certified MS. Product packaging is considered as that which can be removed without the product disintegrating or being damaged. Accompanying information is considered as separately available or easily detachable. Type labels or identification plates are considered as part of the product. The statement shall in no way imply that the product, process or service is certified by this means. The statement shall include reference to:  — identification (e.g. brand or name) of the certified client;  — the type of MS (e.g. quality, environment) and the applicable standard;  — the CB issuing the certificate. |  |  |  |  |  |
| 8.3.4 | The CB shall through legally enforceable arrangements require that the certified client:   1. conforms to the requirements of the CB when making reference to its certification status in communication media such as the internet, brochures or advertising, or other documents; 2. does not make or permit any misleading statement regarding its certification; 3. does not use or permit the use of a certification document or any part thereof in a misleading manner; 4. upon withdrawal of its certification, discontinues its use of all advertising matter that contains a reference to certification, as directed by the CB (see 9.6.5); 5. amends all advertising matter when the scope of certification has been reduced; 6. does not allow reference to its MS certification to be used in such a way as to imply that the CB certifies a product (including service) or process; 7. does not imply that the certification applies to activities and sites that are outside the scope of certification; 8. does not use its certification in such a manner that would bring the CB and/or certification system into disrepute and lose public trust. |  |  |  |  |  |
| 8.3.5 | The CB 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] |  |  |  |  |  |

## 8.4 Confidentiality

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| 8.4.1 | The CB shall be responsible, through legally enforceable agreements, for the management of all 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. |  |  |  |  |  |
| 8.4.2 | The CB 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 accessible by the client, shall be considered confidential. |  |  |  |  |  |
| 8.4.3 | Except as required in this part of ISO/IEC 17021, information about a particular certified client or individual shall not be disclosed to a third party without the written consent of the certified client or individual concerned. |  |  |  |  |  |
| 8.4.4 | When the CB is required by law or authorized by contractual arrangements (such as with the accreditation body) to release confidential information, the client or individual concerned  shall, unless prohibited by law, be notified of the information provided. |  |  |  |  |  |
| 8.4.5 | Information about the client from sources other than the client (e.g. complainant, regulators) shall be treated as confidential, consistent with the CB’s policy. |  |  |  |  |  |
| 8.4.6 | Personnel, including any committee members, contractors, personnel of external bodies or individuals acting on the CB’s behalf, shall keep confidential all information obtained or created during the performance of the CB’s activities except as required by law. |  |  |  |  |  |
| 8.4.7 | The CB shall have processes and where applicable equipment and facilities that ensure the secure handling of confidential information. |  |  |  |  |  |

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

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| **Objective evidence / Reviewed documents (OE/RD) on-site:** | | | |
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| **8.5.1** | **Information on the certification activity and requirements**  The CB shall provide information and update clients on the following:   1. a detailed description of the initial and continuing certification activity, including the application, initial audits, surveillance audits, and the process for granting, refusing, maintaining of certification, expanding or reducing the scope of certification, renewing, suspending or restoring, or withdrawing of certification; 2. the normative requirements for certification; 3. information about the fees for application, initial certification and continuing certification; 4. the CB’s requirements for clients to:   1) comply with certification requirements;  2) 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;  3) make provisions, where applicable, to accommodate the presence of observers (e.g. accreditation assessors or trainee auditor);   1. 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 8.3; 2. information on processes for handling complaints and appeals. |  |  |  |  |  |
| **8.5.2** | **Notice of changes by a certification body**  The CB shall give its certified clients due notice of any changes to its requirements for certification. The CB shall verify that each certified client complies with the new requirements. |  |  |  |  |  |
| **8.5.3** | **Notice of changes by a certified client**  The CB shall have legally enforceable arrangements to ensure that the certified client informs the CB, without delay, of matters that may affect the capability of the MS to continue to fulfil the requirements of the standard used for certification. These include, for example, changes relating to:   1. the legal, commercial, organizational status or ownership; 2. organization and management (e.g. key managerial, decision-making or technical staff); 3. contact address and sites; 4. scope of operations under the certified MS; 5. major changes to the MS and processes.   The CB shall take action as appropriate. |  |  |  |  |  |

# 9 Process requirements

## 9.1 Pre-certification activities

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| **9.1.1** | **Application**  The CB shall require an authorized representative of the applicant organization to provide the necessary information to enable it to establish the following:   1. the desired scope of the certification; 2. relevant details of the applicant organization as required by the specific certification scheme, including its name and the address(es) of its site(s), its processes and operations, human and technical resources, functions, relationships and any relevant legal obligations; 3. identification of outsourced processes used by the organization that will affect conformity to requirements; 4. the standards or other requirements for which the applicant organization is seeking certification; 5. whether consultancy relating to the MS to be certified has been provided and, if so, by whom. |  |  |  |  |  | |
| **9.1.2** | **Application review** |  |  |  |  |  | |
| 9.1.2.1 | The CB shall conduct a review of the application and supplementary information for certification to ensure that:   1. the information about the applicant organization and its MS is sufficient to develop an audit programme (see 9.1.3); 2. any known difference in understanding between the CB and the applicant organization is resolved; 3. the CB has the competence and ability to perform  the certification activity; 4. the scope of certification sought, the site(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.). |  |  |  |  |  | |
| 9.1.2.2 | Following the review of the application, the CB shall either accept or decline an application for certification. When the CB declines an application for certification as a result of the review of application, the reasons for declining an application shall be documented and made clear to the client. |  |  |  |  | |  |
| 9.1.2.3 | Based on this review, the CB shall determine the competences it needs to include in its audit team and for the certification decision. |  |  |  |  | |  |
| **9.1.3** | **Audit programme** |  |  |  |  | |  |
| 9.1.3.1 | An audit programme for the full certification cycle shall be developed to clearly identify the audit activity/activities required to demonstrate that the client’s MS fulfils the requirements for certification to the selected standard(s) or other normative document(s). The audit programme for the certification cycle shall cover the complete MS requirements. |  |  |  |  | |  |
| 9.1.3.2 | The audit programme for the initial certification shall include a two-stage initial audit, surveillance audits in the first and second years following the certification decision, and a recertification audit in the third year prior to expiration of certification. The first three-year certification cycle begins with the certification decision. Subsequent cycles begin with the recertification decision (see 9.6.3.2.3).  The determination of the audit programme and any subsequent adjustments shall consider the size of the client, the scope and complexity of its MS, products and processes as well as demonstrated level of MS effectiveness and the results of any previous audits. [🡺NOTE1 to 3] |  |  |  |  | |  |
| 9.1.3.3 | Surveillance audits shall be conducted at least once a calendar year, except in recertification years. The date of the first surveillance audit following initial certification shall not be more than 12 months from the certification decision date. [🡺NOTE] |  |  |  |  | |  |
| 9.1.3.4 | Where the CB is taking account of certification already granted to the client and to audits performed by another CB, it shall obtain and retain sufficient evidence, such as reports and documentation on corrective actions, to any nonconformity. The documentation shall support the fulfilling of the requirements in this part of ISO/IEC 17021. The CB shall, based on the information obtained, justify and record any adjustments to the existing audit programme and follow up the implementation of corrective actions concerning previous nonconformities. |  |  |  |  | |  |
| 9.1.3.5 | Where the client operates shifts, the activities that take place during shift working shall beconsidered when developing the audit programme and audit plans. |  |  |  |  | |  |
| **9.1.4** | **Determining audit time** |  |  |  |  | |  |
| 9.1.4.1 | The CB shall have documented procedures for determining audit time. For each client the CB shall determine the time needed to plan and accomplish a complete and effective audit of the client’s MS. |  |  |  |  | |  |
| 9.1.4.2 | In determining the audit time, the CB shall consider, among other things, the following aspects:   1. the requirements of the relevant MS standard; 2. complexity of the client and its MS; 3. technological and regulatory context; 4. any outsourcing of any activities included in the scope  of the MS; 5. the results of any prior audits; 6. size and number of sites, their geographical locations  and multi-site considerations; 7. the risks associated with the products, processes  or activities of the organization; 8. whether audits are combined, joint or integrated.   [🡺NOTE 1 and 2]  Where specific criteria have been established for a specific certification scheme, e.g. ISO/TS 22003 or ISO/IEC 27006, these shall be applied. |  |  |  |  | |  |
| 9.1.4.3 | The duration of the MS audit and its justification shall be recorded. |  |  |  |  | |  |
| 9.1.4.4 | The time spent by any team member that is not assigned as an auditor (i.e. technical experts, translators, interpreters, observers and auditors-in-training) shall not count in the above established duration of the MS audit. [🡺NOTE] |  |  |  |  | |  |
| **9.1.5** | **Multi-site sampling**  Where multi-site sampling is used for the audit of a client’s MS covering the same activity in various geographical locations,  the CB shall develop a sampling programme to ensure proper audit of the MS. The rationale for the sampling plan shall be documented for each client. Sampling is not allowed for some specific certification schemes, and where specific criteria have been established for a specific certification scheme, e.g.  ISO/TS 22003, these shall be applied. [🡺NOTE] |  |  |  |  | |  |
| **9.1.6** | **Multiple management systems standards**  When certification to multiple MS standards is being provided  by the CB, the planning for the audit shall ensure adequate  on-site auditing to provide confidence in the certification. |  |  |  |  | |  |

## 9.2 Planning audits

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| **Result of review of documents and records:** | | |  |  |  |  |

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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** | | | |
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| **9.2.1** | **Determining audit objectives, scope and criteria** |  |  |  |  |  |
| 9.2.1.1 | The audit objectives shall be determined by the CB. The audit scope and criteria, including any changes, shall be established  by the CB after discussion with the client. |  |  |  |  |  |
| 9.2.1.2 | The audit objectives shall describe what is to be accomplished  by the audit and shall include the following:   1. determination of the conformity of the client’s MS, or parts  of it, with audit criteria; 2. determination of the ability of the MS to ensure the client meets applicable statutory, regulatory and contractual requirements;   [🡺NOTE]   1. determination of the effectiveness of the MS to ensure  the client can reasonably expect to achieving its specified objectives; 2. as applicable, identification of areas for potential improvement of the MS. |  |  |  |  |  |
| 9.2.1.3 | The audit scope shall describe the extent and boundaries of the audit, such as sites, organizational units, activities and processes to be audited. Where the initial or re-certification process consists of more than one audit (e.g. covering different sites), the scope of an individual audit may not cover the full certification scope, but the totality of audits shall be consistent with the scope in the certification document. |  |  |  |  |  |
| 9.2.1.4 | The audit criteria shall be used as a reference against which  conformity is determined, and shall include:   * the requirements of a defined normative document on MSs; * the defined processes and documentation of the MS developed by the client. |  |  |  |  |  |
| **9.2.2** | **Audit team selection and assignments** |  |  |  |  |  |
| 9.2.2.1 | General |  |  |  |  |  |
| 9.2.2.1.1 | The CB shall have a process for selecting and appointing the audit team, including the audit team leader and technical experts as necessary, taking into account the competence needed to achieve the objectives of the audit and requirements for impartiality. If there is only one auditor, the auditor shall have the competence to perform the duties of an audit team leader applicable for that audit. The audit team shall have the totality of the competences identified by the CB as set out in 9.1.2.3 for the audit. |  |  |  |  |  |
| 9.2.2.1.2 | In deciding the size and composition of the audit team, consideration shall be given to the following:   1. audit objectives, scope, criteria and estimated audit time; 2. whether the audit is a combined, joint or integrated; 3. the overall competence of the audit team needed to achieve the objectives of the audit (see Table A.1); 4. certification requirements (including any applicable statutory, regulatory or contractual requirements); 5. language and culture.   [🡺NOTE] |  |  |  |  |  |
| 9.2.2.1.3 | The necessary knowledge and skills of the audit team leader and auditors may be supplemented by technical experts, translators and interpreters who shall operate under the direction of an auditor. Where translators or interpreters are used, they shall be selected such that they do not unduly influence the audit.  [🡺NOTE] |  |  |  |  |  |
| 9.2.2.1.4 | Auditors-in-training may participate in the audit, provided an auditor is appointed as an evaluator. The evaluator shall be competent to take over the duties and have final responsibility for the activities and findings of the auditor-in-training. |  |  |  |  |  |
| 9.2.2.1.5 | The audit team leader, in consultation with the audit team, shall assign to each team member responsibility for auditing specific processes, functions, sites, areas or activities. Such assignments shall take into account the need for competence, and the effective and efficient use of the audit team, as well as different roles and responsibilities of auditors, auditors-in-training and technical experts. Changes to the work assignments may be made as the audit progresses to ensure achievement of the audit objectives. |  |  |  |  |  |
| 9.2.2.2 | Observers, technical experts and guides |  |  |  |  |  |
| 9.2.2.2.1 | Observers  The presence and justification of observers during an audit activity shall be agreed to by the CB and client prior to the conduct of the audit. The audit team shall ensure that observers do not unduly influence or interfere in the audit process or outcome of the audit. [🡺NOTE] |  |  |  |  |  |
| 9.2.2.2.2 | Technical experts  The role of technical experts during an audit activity shall be agreed to by the CB and client prior to the conduct of the audit. A technical expert shall not act as an auditor in the audit team. The technical experts shall be accompanied by an auditor.  [🡺NOTE] |  |  |  |  |  |
| 9.2.2.2.3 | Guides  Each auditor shall be accompanied by a guide, unless otherwise agreed to by the audit team leader and the client. Guide(s) are assigned to the audit team to facilitate the audit. The audit team shall ensure that guides do not influence or interfere in the audit process or outcome of the audit. [🡺NOTE 1]   1. establishing contacts and timing for interviews; 2. arranging visits to specific parts of the site or organization; 3. ensuring t hat rules concerning site safety and security procedures are known and respected by t he audit team members; 4. witnessing the audit on behalf of the client; 5. providing clarification or information as requested  by an auditor.   [🡺NOTE 2] |  |  |  |  |  |
| **9.2.3** | **Audit plan** |  |  |  |  |  |
| 9.2.3.1 | General  The CB shall ensure that an audit plan is established prior to each audit identified in the audit programme to provide the basis for agreement regarding the conduct and scheduling of the audit activities. [🡺NOTE] |  |  |  |  |  |
| 9.2.3.2 | Preparing the audit plan  The audit plan shall be appropriate to the objectives and the scope of the audit. The audit plan shall at least include or refer to the following:   1. the audit objectives; 2. the audit criteria; 3. the audit scope, including identification of the organizational and functional units or processes to be audited; 4. the dates and sites where the on-site audit activities will be conducted, including visits to temporary sites and remote auditing activities, where appropriate; 5. the expected duration of on-site audit activities; 6. the roles and responsibilities of the audit team members and accompanying persons, such as observers or interpreters.   [🡺NOTE] |  |  |  |  |  |
| 9.2.3.3 | Communication of audit team tasks  The tasks given to the audit team shall be defined, and require the audit team to:   1. examine and verify the structure, policies, processes, procedures, records and related documents of the client relevant to the MS standard; 2. determine that these meet all the requirements relevant  to the intended scope of certification; 3. determine that the processes and procedures are established, implemented and maintained effectively, to provide a basis for confidence in the client’s MS; 4. communicate to the client, for its action, any inconsistencies between the client’s policy, objectives and targets. |  |  |  |  |  |
| 9.2.3.4 | Communication of audit plan  The audit plan shall be communicated and the dates of the audit shall be agreed upon, in advance, with the client. |  |  |  |  |  |
| 9.2.3.5 | Communication concerning audit team members  The CB 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 to object to the appointment of any particular audit team member and for the CB to reconstitute the team in response to any valid objection. |  |  |  |  |  |

## 9.3 Initial certification

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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** | | | |
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| **9.3.1** | **Initial certification audit** |  |  |  |  |  |
| 9.3.1.1 | General  The initial certification audit of a MS shall be conducted in two stages: stage 1 and stage 2. |  |  |  |  |  |
| 9.3.1.2 | **Stage 1** |  |  |  |  |  |
| 9.3.1.2.1 | Planning shall ensure that the objectives of stage 1 can be met and the client shall be informed of any “on site” activities during stage 1. [🡺NOTE] |  |  |  |  |  |
| 9.3.1.2.2 | The objectives of stage 1 are to:   1. review the client’s MS documented information; 2. evaluate the client’s site-specific conditions and to undertake discussions with the client’s personnel to determine the preparedness for stage 2; 3. 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 MS; 4. obtain necessary information regarding the scope of the MS, including:    * the client’s site(s);    * processes and equipment used;    * levels of controls established (particularly in case  of multisite clients);    * applicable statutory and regulatory requirements; 5. review the allocation of resources for stage 2 and agree  the details of stage 2 with the client; 6. provide a focus for planning stage 2 by gaining a sufficient understanding of the client’s MS and site operations in the context of the MS standard or other normative document; 7. evaluate if the internal audits and management reviews are being planned and performed, and that the level of implementation of the MS substantiates that the client is ready for stage 2.   [🡺NOTE] |  |  |  |  |  |
| 9.3.1.2.3 | Documented conclusions with regard to fulfilment of the stage 1 objectives and the readiness for stage 2 shall be communicated to the client, including identification of any areas of concern that could be classified as a nonconformity during stage 2. [🡺NOTE] |  |  |  |  |  |
| 9.3.1.2.4 | In determining the interval between stage 1 and stage 2, consideration shall be given to the needs of the client to resolve areas of concern identified during stage 1. The CB may also need to revise its arrangements for stage 2. If any significant changes which would impact the MS occur, the CB shall consider the need to repeat all or part of stage 1. The client shall be informed that the results of stage 1 may lead to postponement or cancellation of stage 2. |  |  |  |  |  |
| 9.3.1.3 | **Stage 2**  The purpose of stage 2 is to evaluate the implementation, including effectiveness, of the client’s MS. The stage 2 shall take place at the site(s) of the client. It shall include the auditing of at least the following:   1. information and evidence about conformity to all requirements of the applicable MS standard or other normative documents; 2. performance monitoring, measuring, reporting and reviewing against key performance objectives and targets (consistent with the expectations in the applicable MS standard or other normative document); 3. the client’s MS ability and its performance regarding meeting of applicable statutory, regulatory and contractual requirements; 4. operational control of the client’s processes; 5. internal auditing and management review; 6. management responsibility for the client’s policies. |  |  |  |  |  |
| 9.3.1.4 | Initial certification audit conclusions  The audit team shall analyse all information and audit evidence gathered during stage 1 and stage 2 to review the audit findings and agree on the audit conclusions. |  |  |  |  |  |

## 9.4 Conducting audits

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| **9.4.1** | **General**  The CB shall have a process for conducting on-site audits.  This process shall include an opening meeting at the start of  the audit and a closing meeting at the conclusion of the audit.  Where any part of the audit is made by electronic means or where the site to be audited is virtual, the CB shall ensure that such activities are conducted by personnel with appropriate competence. The evidence obtained during such an audit shall  be sufficient to enable the auditor to take an informed decision on the conformity of the requirement in question. [🡺NOTE] |  |  |  |  |  |
| **9.4.2** | **Conducting the opening meeting**  A formal opening meeting, shall be held with the client’s management and, where appropriate, those responsible for the functions or processes to be audited. The purpose of the opening meeting, usually conducted by the audit team leader, is to provide a short explanation of how the audit activities will be undertaken. The degree of detail shall be consistent with the familiarity of the client with the audit process and shall consider the following:   1. introduction of the participants, including an outline  of their roles; 2. confirmation of the scope of certification; 3. confirmation of the audit plan (including type and scope of audit, objectives and criteria), any changes, and other relevant arrangements with the client, such as the date and time for the closing meeting, interim meetings between the audit team and the client’s management; 4. confirmation of formal communication channels between  the audit team and the client; 5. confirmation that the resources and facilities needed  by the audit team are available; 6. confirmation of matters relating to confidentiality; 7. confirmation of relevant work safety, emergency and security procedures for the audit team; 8. confirmation of the availability, roles and identities  of any guides and observers; 9. the method of reporting, including any grading of audit findings; 10. information about the conditions under which the audit  may be prematurely terminated; 11. confirmation that the audit team leader and audit team representing the CB is responsible for the audit and shall  be in control of executing the audit plan including audit activities and audit trails; 12. confirmation of the status of findings of the previous review or audit, if applicable; 13. methods and procedures to be used to conduct the audit based on sampling; 14. confirmation of the language to be used during the audit; 15. confirmation that, during the audit, the client will be kept informed of audit progress and any concerns; 16. opportunity for the client to ask questions. |  |  |  |  |  |
| **9.4.3** | **Communication during the audit** |  |  |  |  |  |
| 9.4.3.1 | During the audit, the audit team shall periodically assess audit progress and exchange information. The audit team leader shall reassign work as needed between the audit team members and periodically communicate the progress of the audit and any concerns to the client. |  |  |  |  |  |
| 9.4.3.2 | Where the available audit evidence indicates that the audit objectives are unattainable or suggests the presence of an immediate and significant risk (e.g. safety), the audit team leader shall report this to the client and, if possible, to the CB to determine appropriate action. Such action may include reconfirmation or modification of the audit plan, changes to the audit objectives or audit scope, or termination of the audit. The audit team leader shall report the outcome of the action taken to the CB. |  |  |  |  |  |
| 9.4.3.3 | The audit team leader shall review with the client any need for changes to the audit scope which becomes apparent as on-site auditing activities progress and report this to the CB |  |  |  |  |  |
| **9.4.4** | **Obtaining and verifying information** |  |  |  |  |  |
| 9.4.4.1 | During the audit, information relevant to the audit objectives, scope and criteria (including information relating to interfaces between functions, activities and processes) shall be obtained by appropriate sampling and verified to become audit evidence. |  |  |  |  |  |
| 9.4.4.2 | Methods to obtain information shall include, but are not limited to:   1. interviews; 2. observation of processes and activities; 3. review of documentation and records. |  |  |  |  |  |
| **9.4.5** | **Identifying and recording audit findings** |  |  |  |  |  |
| 9.4.5.1 | Audit findings summarizing conformity and detailing nonconformity shall be identified, classified and recorded to enable an informed certification decision to be made or the certification to be maintained. |  |  |  |  |  |
| 9.4.5.2 | Opportunities for improvement may be identified and recorded, unless prohibited by the requirements of a MS certification scheme. Audit findings, however, which are nonconformities, shall not be recorded as opportunities for improvement. |  |  |  |  |  |
| 9.4.5.3 | A finding of nonconformity shall be recorded against a specific requirement, and shall contain a clear statement of the nonconformity, identifying in detail the objective evidence on which the nonconformity is based. Nonconformities shall be discussed with the client to ensure that the evidence is accurate and that the nonconformities are understood. The auditor however shall refrain from suggesting the cause of nonconformities or their solution. |  |  |  |  |  |
| 9.4.5.4 | The audit team leader shall attempt to resolve any diverging opinions between the audit team and the client concerning audit evidence or findings, and unresolved points shall be recorded. |  |  |  |  |  |
| **9.4.6** | **Preparing audit conclusions**  Under the responsibility of the audit team leader and prior  to the closing meeting, the audit team shall:   1. review the audit findings, and any other appropriate information obtained during the audit, against the audit objectives and audit criteria and classify the nonconformities; 2. agree upon the audit conclusions, taking into account  the uncertainty inherent in the audit process; 3. agree any necessary follow-up actions; 4. confirm the appropriateness of the audit programme  or identify any modification required for future audits  (e.g. scope of certification, audit time or dates, surveillance frequency, audit team competence). |  |  |  |  |  |
| **9.4.7** | **Conducting the closing meeting** |  |  |  |  |  |
| 9.4.7.1 | A formal closing meeting, where attendance shall be recorded, shall be held with the client’s management and, where appropriate, those responsible for the functions or processes audited. The purpose of the closing meeting, usually conducted by the audit team leader, is to present the audit conclusions, including the recommendation regarding certification. Any nonconformities shall be presented in such a manner that they are understood, and the timeframe for responding shall be agreed. [🡺NOTE] |  |  |  |  |  |
| 9.4.7.2 | The closing meeting shall also include the following elements where the degree of detail shall be consistent with the familiarity of the client with the audit process:   1. advising the client that the audit evidence obtained was based on a sample of the information; thereby introducing  an element of uncertainty; 2. the method and timeframe of reporting, including any grading of audit findings; 3. the CB’s process for handling nonconformities including  any consequences relating to the status of the client’s  certification; 4. the timeframe for the client to present a plan for correction and corrective action for any nonconformities identified  during the audit; 5. the CB’s post audit activities; 6. information about the complaint and appeal handling  processes. |  |  |  |  |  |
| 9.4.7.3 | The client shall be given opportunity for questions. Any diverging opinions regarding the audit findings or conclusions between the audit team and the client shall be discussed and resolved where possible. Any diverging opinions that are not resolved shall be recorded and referred to the CB. |  |  |  |  |  |
| **9.4.8** | **Audit report** |  |  |  |  |  |
| 9.4.8.1 | The CB shall provide a written report for each audit to the client. The audit team may identify opportunities for improvement but shall not recommend specific solutions. Ownership of the audit report shall be maintained by the CB. |  |  |  |  |  |
| 9.4.8.2 | The audit team leader shall ensure that the audit report is prepared and shall be responsible for its content. The audit report shall provide an accurate, concise and clear record of the audit to enable an informed certification decision to be made and shall include or refer to the following:   1. identification of the CB; 2. the name and address of the client and the client’s representative; 3. the type of audit (e.g. initial, surveillance or recertification audit or special audits); 4. the audit criteria; 5. the audit objectives; 6. the audit scope, particularly identification of the organizational or functional units or processes audited and the time of the audit; 7. any deviation from the audit plan and their reasons; 8. any significant issues impacting on the audit programme; 9. identification of the audit team leader, audit team members and any accompanying persons; 10. the dates and places where the audit activities (on site or offsite, permanent or temporary sites) were conducted; 11. audit findings (see 9.4.5), reference to evidence and conclusions, consistent with the requirements of the type of audit; 12. significant changes, if any, that affect the MS of the client since the last audit took place; 13. any unresolved issues, if identified; 14. where applicable, whether the audit is combined, joint  or integrated; 15. a disclaimer statement indicating that auditing is based  on a sampling process of the available information; 16. recommendation from the audit team 17. the audited client is effectively controlling the use  of the certification documents and marks, if applicable; 18. verification of effectiveness of taken corrective actions regarding previously identified nonconformities, if applicable. |  |  |  |  |  |
| 9.4.8.3 | The report shall also contain:   1. a statement on the conformity and the effectiveness of the MS together with a summary of the evidence relating to:  * the capability of the MS to meet applicable requirements and expected outcomes; * the internal audit and management review process;  1. a conclusion on the appropriateness of the certification scope; 2. confirmation that the audit objectives have been fulfilled. |  |  |  |  |  |
| **9.4.9** | **Cause analysis of nonconformities**  The CB 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. |  |  |  |  |  |
| **9.4.10** | **Effectiveness of corrections and corrective actions**  The CB shall review the corrections, identified causes and corrective actions submitted by the client to determine if these are acceptable. The CB shall verify the effectiveness of any correction and corrective actions taken. The evidence obtained to support the resolution of nonconformities shall be recorded. The client shall be informed of the result of the review and verification. The client shall be informed if an additional full audit, an additional limited audit, or documented evidence (to be confirmed during future audits) will be needed to verify effective correction and corrective actions. [🡺NOTE] |  |  |  |  |  |

## 9.5 Certification decision

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| **9.5.1** | **General** |  |  |  |  |  |
| 9.5.1.1 | The CB shall ensure that the persons or committees that make the decisions for granting or refusing certification, expanding or reducing the scope of certification, suspending or restoring certification, withdrawing certification or renewing certification are different from those who carried out the audits. The individual(s) appointed to conduct the certification decision shall have appropriate competence. |  |  |  |  |  |
| 9.5.1.2 | The person(s) [excluding members of committees (see 6.1.4)] assigned by the CB to make a certification decision shall be employed by, or shall be under legally enforceable arrangement with either the CB or an entity under the organizational control of the CB. A CB’s organizational control shall be one of the following:   1. whole or majority ownership of another entity by the CB; 2. majority participation by the CB on the board of directors of another entity; 3. a documented authority by the CB over another entity in a network of legal entities (in which the CB resides), linked by ownership or board of director control.   [🡺NOTE] |  |  |  |  |  |
| 9.5.1.3 | The persons employed by, or under contract with, entities under organizational control shall fulfil the same requirements of this part of ISO/IEC 17021 as persons employed by, or under contract with, the CB. |  |  |  |  |  |
| 9.5.1.4 | The CB shall record each certification decision including any additional information or clarification sought from the audit team or other sources. |  |  |  |  |  |
| **9.5.2** | **Actions prior to making a decision**  The CB shall have a process to conduct an effective review prior to making a decision for granting certification, expanding or reducing the scope of certification, renewing, suspending or restoring, or withdrawing of certification, including, that   1. the information provided by the audit team is sufficient with respect to the certification requirements and the scope for certification; 2. for any major nonconformities, it has reviewed, accepted and verified the correction and corrective actions; 3. for any minor nonconformities it has reviewed and accepted the client’s plan for correction and corrective action. |  |  |  |  |  |
| **9.5.3** | **Information for granting initial certification** |  |  |  |  |  |
| 9.5.3.1 | The information provided by the audit team to the CB  for the certification decision shall include, as a minimum:   1. the audit report; 2. comments on the nonconformities and, where applicable, the correction and corrective actions taken by the client; 3. confirmation of the information provided to the CB used in the application review (see 9.1.2); 4. confirmation that the audit objectives have been achieved; 5. a recommendation whether or not to grant certification, together with any conditions or observations. |  |  |  |  |  |
| 9.5.3.2 | If the CB is not able to verify the implementation of corrections and corrective actions of any major nonconformity within  6 months after the last day of stage 2, the CB shall conduct another stage 2 prior to recommending certification. |  |  |  |  |  |
| 9.5.3.3 | When a transfer of certification is envisaged from one CB to another, the accepting CB shall have a process for obtaining sufficient information in order to take a decision on certification.  [🡺NOTE] |  |  |  |  |  |
| **9.5.4** | **Information for granting recertification**  The certification body shall make decisions on re-newing certification based on the results of the recertification audit, as well as the results of the review of the system over the period of certification and complaints received from users of certification. |  |  |  |  |  |

## 9.6 Maintaining certification

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| **9.6.1** | **General**  The CB shall maintain certification based on demonstration that the client continues to satisfy the requirements of the MS standard. It may maintain a client’s certification based on a positive conclusion by the audit team leader without further independent review and decision, provided that:   1. for any major nonconformity or other situation that may lead to suspension or withdrawal of certification, the CB has a system that requires the audit team leader to report to the CB the need to initiate a review by competent personnel (see 7.2.8), different from those who carried out the audit, to determine whether certification can be maintained; 2. competent personnel of the CB monitor its surveillance activities, including monitoring the reporting by its auditors, to confirm that the certification activity is operating effectively. |  |  |  |  |  |
| **9.6.2** | **Surveillance activities** |  |  |  |  |  |
| 9.6.2.1 | General |  |  |  |  |  |
| 9.6.2.1.1 | The CB shall develop its surveillance activities so that representative areas and functions covered by the scope of the MS are monitored on a regular basis, and take into account changes to its certified client and its MS. |  |  |  |  |  |
| 9.6.2.1.2 | Surveillance activities shall include on-site auditing of the certified client’s MS’s fulfilment of specified requirements with respect to the standard to which the certification is granted. Other surveillance activities may include:   1. enquiries from the CB to the certified client on aspects of certification; 2. reviewing any certified client’s statements with respect to its operations (e.g. promotional material, website); 3. requests to the certified client to provide documented information (on paper or electronic media); 4. other means of monitoring the certified client’s performance. |  |  |  |  |  |
| 9.6.2.2 | Surveillance audit  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 CB can maintain confidence that the client’s certified MS continues to fulfil requirements between recertification audits. Each surveillance for the relevant MS standard shall include:   1. internal audits and management review; 2. a review of actions taken on nonconformities identified during the previous audit; 3. complaints handling; 4. effectiveness of the MS with regard to achieving the certified client’s objectives and the intended results of the respective MS (s); 5. progress of planned activities aimed at continual improvement; 6. continuing operational control; 7. review of any changes; 8. use of marks and/or any other reference to certification. |  |  |  |  |  |
| **9.6.3** | **Recertification** |  |  |  |  |  |
| 9.6.3.1 | Recertification audit planning |  |  |  |  |  |
| 9.6.3.1.1 | The purpose of the recertification audit is to confirm the continued conformity and effectiveness of the MS as a whole, and its continued relevance and applicability for the scope of certification. A recertification audit shall be planned and conducted to evaluate the continued fulfilment of all of the requirements of the relevant MS standard or other normative document. This shall be planned and conducted in due time to enable for timely renewal before the certificate expiry date. |  |  |  |  |  |
| 9.6.3.1.2 | The recertification activity shall include the review of previous surveillance audit reports and consider the performance of the MS over the most recent certification cycle. |  |  |  |  |  |
| 9.6.3.1.3 | Recertification audit activities may need to have a stage 1 in situations where there have been significant changes to the MS, the organization, or the context in which the MS is operating (e.g. changes to legislation). [🡺NOTE] |  |  |  |  |  |
| 9.6.3.2 | Recertification audit |  |  |  |  |  |
| 9.6.3.2.1 | The recertification audit shall include an on-site audit that addresses the following:   1. the effectiveness of the MS in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of certification; 2. demonstrated commitment to maintain the effectiveness and improvement of the MS in order to enhance overall performance; 3. the effectiveness of the MS with regard to achieving the certified client’s objectives and the intended results of the respective MS (s). |  |  |  |  |  |
| 9.6.3.2.2 | For any major nonconformity, the CB shall define time limits for correction and corrective actions. These actions shall be implemented and verified prior to the expiration of certification. |  |  |  |  |  |
| 9.6.3.2.3 | When recertification activities are successfully completed prior to the expiry date of the existing certification, the expiry date of the new certification can be based on the expiry date of the existing certification. The issue date on a new certificate shall be on or after the recertification decision. |  |  |  |  |  |
| 9.6.3.2.4 | If the CB has not completed the recertification audit or the CB is unable to verify the implementation of corrections and corrective actions for any major nonconformity (see 9.5.2.1) prior to the expiry date of the certification, then recertification shall not be recommended and the validity of the certification shall not be extended. The client shall be informed and the consequences shall be explained. |  |  |  |  |  |
| 9.6.3.2.5 | Following expiration of certification, the CB can restore certification within 6 months provided that the outstanding recertification activities are completed, otherwise at least a stage 2 shall be conducted. The effective date on the certificate shall be on or after the recertification decision and the expiry date shall be based on prior certification cycle. |  |  |  |  |  |
| **9.6.4** | **Special audits** |  |  |  |  |  |
| 9.6.4.1 | Expanding scope  The CB shall, in response to an application for expanding the scope of a certification already granted, undertake a review of the application and determine any audit activities necessary to decide whether or not the extension may be granted. This may be conducted in conjunction with a surveillance audit. |  |  |  |  |  |
| 9.6.4.2 | Short-notice audits  It may be necessary for the CB to conduct audits of certified clients at short notice or unannounced to investigate complaints, or in response to changes, or as follow up on suspended clients. In such cases:   1. the CB shall describe and make known in advance to the certified clients (e.g. in documents as described in 8.5.1) the conditions under which such audits will be conducted; 2. the CB 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. |  |  |  |  |  |
| **9.6.5** | **Suspending, withdrawing or reducing the scope of certification** |  |  |  |  |  |
| 9.6.5.1 | The CB 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 CB. |  |  |  |  |  |
| 9.6.5.2 | The CB shall suspend certification in cases when, for example:   * the client’s certified MS has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the MS; * the certified client does not allow surveillance or recertification audits to be conducted at the required frequencies; * the certified client has voluntarily requested a suspension. |  |  |  |  |  |
| 9.6.5.3 | Under suspension, the client’s MS certification is temporarily invalid. |  |  |  |  |  |
| 9.6.5.4 | The CB shall restore the suspended certification if the issue that has resulted in the suspension has been resolved. Failure to resolve the issues that have resulted in the suspension in a time established by the CB shall result in withdrawal or reduction of the scope of certification. [🡺NOTE] |  |  |  |  |  |
| 9.6.5.5 | The CB shall reduce the scope of certification to exclude the parts not meeting the requirements, when the certified client has persistently or seriously failed to meet the certification requirements for those parts of the scope of certification. Any such reduction shall be in line with the requirements of the standard used for certification. |  |  |  |  |  |

## 9.7 Appeals

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| 9.7.1 | The CB shall have a documented process to receive, evaluate and make decisions on appeals. |  |  |  |  |  |
| 9.7.2 | The CB shall be responsible for all decisions at all levels of the appeals-handling process. The CB 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. |  |  |  |  |  |
| 9.7.3 | Submission, investigation and decision on appeals shall not result in any discriminatory actions against the appellant. |  |  |  |  |  |
| 9.7.4 | The appeals-handling process shall include at least the following elements and methods:   1. an outline of the process for receiving, validating and investigating the appeal, and for deciding what actions need to be taken in response to it, taking into account the results of previous similar appeals; 2. tracking and recording appeals, including actions undertaken to resolve them; 3. ensuring that any appropriate correction and corrective action are taken. |  |  |  |  |  |
| 9.7.5 | The CB receiving the appeal shall be responsible for gathering and verifying all necessary information to validate the appeal. |  |  |  |  |  |
| 9.7.6 | The CB shall acknowledge receipt of the appeal and shall provide the appellant with progress reports and the result of the appeal. |  |  |  |  |  |
| 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 CB shall give formal notice to the appellant of the end of the appealshandling process. |  |  |  |  |  |

## 9.8 Complaints

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| 9.8.1 | The CB shall be responsible for all decisions at all levels of the complaints handling process. |  |  |  |  |  |
| 9.8.2 | Submission, investigation and decision on complaints shall not result in any discriminatory actions against the complainant. |  |  |  |  |  |
| 9.8.3 | Upon receipt of a complaint, the CB 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 MS. |  |  |  |  |  |
| 9.8.4 | Any valid complaint about a certified client shall also be referred by the CB to the certified client in question at an appropriate time. |  |  |  |  |  |
| 9.8.5 | The CB 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. |  |  |  |  |  |
| 9.8.6 | The complaints-handling process shall include at least the following elements and methods:   1. an outline of the process for receiving, validating, investigating the complaint, and for deciding what actions need to be taken in response to it; 2. tracking and recording complaints, including actions undertaken in response to them; 3. ensuring that any appropriate correction and corrective action are taken.   [🡺NOTE] |  |  |  |  |  |
| 9.8.7 | The CB receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint. |  |  |  |  |  |
| 9.8.8 | Whenever possible, the CB shall acknowledge receipt of the complaint, and shall provide the complainant with progress reports and the result of the complaint. |  |  |  |  |  |
| 9.8.9 | 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. |  |  |  |  |  |
| 9.8.10 | Whenever possible, the CB shall give formal notice of the end of the complaints-handling process to the complainant. |  |  |  |  |  |
| 9.8.11 | The CB shall determine, together with the certified client and the complainant, whether and, if so to what extent, the subject of the complaint and its resolution shall be made public. |  |  |  |  |  |

## 9.9 Client records

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|  | **SA + TA** |  |  |  |  | |  |
| **Result of review of documents and records:** | | |  |  |  |  | |

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| --- | --- | --- | --- |
| Findings / justification of findings / specifics / notes: | | | |
|  | | | |
| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** | | | |
| No. | OE | Title / Description | Date / Version |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: | | | |
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| 9.9.1 | The CB 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:   1. application information and initial, surveillance and recertification audit reports; 2. certification agreement; 3. justification of the methodology used for sampling of sites, as appropriate;   [🡺NOTE]   1. justification for auditor time determination (see 9.1.4); 2. verification of correction and corrective actions; 3. records of complaints and appeals, and any subsequent correction or corrective actions; 4. committee deliberations and decisions, if applicable; 5. documentation of the certification decisions; 6. certification documents, including the scope of certification with respect to product, process or service, as applicable; 7. related records necessary to establish the credibility of the certification, such as evidence of the competence of auditors and technical experts; 8. audit programmes. |  |  |  |  |  |
| 9.9.3 | The CB 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 CB shall have a documented policy and documented procedures on the retention of records. Records of certified clients and previously certified clients shall be retained for the duration of the current cycle plus one full certification cycle.  [🡺NOTE] |  |  |  |  |  |

# 10 Management system requirements for certification bodies

## 10.1 Options

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|  | | | **SA** |  |  |  |  | |  |
|  |  | Option A | General management system requirements (according to 10.2) | | | | | | |
|  |  | Option B | Management system requirements in accordance with ISO 9001 (according to 10.3)  ***Note:*** *In the case* *that option B was chosen, the assessors have to assess and to review the implementation of the requirements according to clause 10.2. Remarks to clause 10.3 are generally not necessary.* | | | | | | |
| **Result of review of documents and records:** | | | | |  |  |  |  | |

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| --- | --- | --- | --- |
| Findings / justification of findings / specifics / notes: | | | |
|  | | | |
| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** | | | |
| No. | OE | Title / Description | Date / Version |
|  |  |  |  |
|  |  |  |  |
| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: | | | |
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|  | The CB shall establish, document, implement and maintain a MS that is capable of supporting and demonstrating the consistent achievement of the requirements of this part of ISO/IEC 17021. In addition to meeting the requirements of Clauses 5 to 9, the CB shall implement a MS in accordance with either:   1. general MS requirements (see 10.2); or 2. MS requirements in accordance with ISO 9001 (see 10.3). |  |  |  |  |  |

## 10.2 Option A: General management system requirements

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|  | * **SA** (If no SA used: LA for 10.2.5 and 10.2.6) * **SA + TA:** For 10.2.4 and 10.2.7 |  |  |  |  | |  |
| **Result of review of documents and records:** | | |  |  |  |  | |

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| Findings / justification of findings / specifics / notes: | | | |
|  | | | |
| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** | | | |
| No. | OE | Title / Description | Date / Version |
|  |  |  |  |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: | | | |
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| **10.2.1** | **General**  The CB shall establish, document, implement and maintain a MS that is capable of supporting and demonstrating the consistent achievement of the requirements of this part of ISO/IEC 17021.  The CB’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 MS in accordance with the requirements of this part of ISO/IEC 17021. The top management shall ensure that the policies are understood, implemented and maintained  at all levels of the CB’s organization.  The CB’s top management shall assign responsibility and authority for:   1. ensuring that processes and procedures needed for the MS are established, implemented and maintained; 2. reporting to top management on the performance of the MS and any need for improvement. |  |  |  |  |  |
| **10.2.2** | **Management system manual**  All applicable requirements of this part of ISO/IEC 17021 shall be addressed either in a manual or in associated documents. The CB shall ensure that the manual and relevant associated documents are accessible to all relevant personnel. |  |  |  |  |  |
| **10.2.3** | **Control of documents**  The CB shall establish procedures to control the documents (internal and external) that relate to the fulfilment of this part of ISO/IEC 17021. The procedures shall define the controls needed to:   1. approve documents for adequacy prior to issue; 2. review and update where necessary and re-approve documents; 3. ensure that changes and the current revision status  of documents are identified; 4. ensure that relevant versions of applicable documents  are available at points of use; 5. ensure that documents remain legible and readily identifiable; 6. ensure that documents of external origin are identified and their distribution controlled; 7. prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.   [🡺NOTE] |  |  |  |  |  |
| **10.2.4** | **Control of records**  The CB 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 part of ISO/IEC 17021.  The CB 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] |  |  |  |  |  |
| **10.2.5** | **Management review** |  |  |  |  |  |
| 10.2.5.1 | General  The CB’s top management shall establish procedures to review its MS at planned intervals to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this part of ISO/IEC 17021. These reviews shall be conducted at least once a year. |  |  |  |  |  |
| 10.2.5.2 | Review inputs  The input to the management review shall include information related to:   1. results of internal and external audits; 2. feedback from clients and interested parties; 3. safeguarding impartiality; 4. the status of corrective actions; 5. the status of actions to address risks; 6. follow-up actions from previous management reviews; 7. the fulfilment of objectives; 8. changes that could affect the MS; 9. appeals and complaints. |  |  |  |  |  |
| 10.2.5.3 | Review outputs  The outputs from the management review shall include decisions and actions related to   1. improvement of the effectiveness of the MS and its processes; 2. improvement of the certification services related to the fulfilment of this part of ISO/IEC 17021; 3. resource needs; 4. revisions of the organization’s policy and objectives. |  |  |  |  |  |
| **10.2.6** | **Internal audits** |  |  |  |  |  |
| 10.2.6.1 | The CB shall establish procedures for internal audits to verify that it fulfils the requirements of this part of ISO/IEC 17021 and that the MS is effectively implemented and maintained. [🡺NOTE] |  |  |  |  |  |
| 10.2.6.2 | 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. |  |  |  |  |  |
| 10.2.6.3 | Internal audits shall be performed at least once every 12 months. The frequency of internal audits may be reduced if the CB can demonstrate that its MS continues to be effectively implemented according to this part of ISO/IEC 17021 and has proven stability. |  |  |  |  |  |
| 10.2.6.4 | The CB shall ensure that:   1. internal audits are conducted by competent personnel knowledgeable in certification, auditing and the requirements of this part of ISO/IEC 17021; 2. auditors do not audit their own work; 3. personnel responsible for the area audited are informed of the outcome of the audit; 4. any actions resulting from internal audits are taken in a timely and appropriate manner; 5. any opportunities for improvement are identified. |  |  |  |  |  |
| **10.2.7** | **Corrective actions**  The CB shall establish procedures for identification and management of nonconformities in its operations. The CB shall also, where necessary, take actions to eliminate the causes 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:   1. identifying nonconformities (e.g. from valid complaints and internal audits); 2. determining the causes of nonconformity; 3. correcting nonconformities; 4. evaluating the need for actions to ensure  that nonconformities do not recur; 5. determining and implementing in a timely manner,  the actions needed; 6. recording the results of actions taken; 7. reviewing the effectiveness of corrective actions. |  |  |  |  |  |

## 10.3 Option B: General management system requirements in accordance with ISO 9001

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|  | **SA** |  |  |  |  | |  |
| ***Note:***  *In the case* *that option B was chosen, the assessors have to assess and to review the implementation of the requirements according to clause 10.2. Remarks to clause 10.3 are generally not necessary.* | | | | | | | |
| **Result of review of documents and records:** | | |  |  |  |  | |

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| Findings / justification of findings / specifics / notes: | | | |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** | | | |
| No. | OE | Title / Description | Date / Version |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: | | | |
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| **10.3.1** | **General**  The CB shall establish and maintain a MS, in accordance with the requirements of ISO 9001, which is capable of supporting and demonstrating the consistent achievement of the requirements of this part of ISO/IEC 17021, amplified by 10.3.2 to 10.3.4. |  |  |  |  |  |
| **10.3.2** | **Scope**  For application of the requirements of ISO 9001, the scope of the MS shall include the design and development requirements for its certification services. |  |  |  |  |  |
| **10.3.3** | **Customer focus**  For application of the requirements of ISO 9001, when developing its MS, the CB shall consider the credibility of certification and shall 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. |  |  |  |  |  |
| **10.3.4** | **Management review**  For application of the requirements of ISO 9001, the CB shall include as input for management review, information on relevant appeals and complaints from users of certification activities and a review of impartiality. |  |  |  |  |  |

# Further issues of the assessment

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| **Additional requirements** | | **Responsible** | **Reference documents** | **Appraisal** | | | **No. of** |
|  | |  | **for the implementation** | **1** | **2** | **3** | **NC** |
| * **Use of the accreditation symbol / References to the accreditation** | **SA** (If no SA used: LA) | |  |  |  |  |  |
| Compliance with the rule 71 SD 0 011 on the use of the accreditation symbol in certificates, business letters, offers, letterhead, website, other documents and advertising media as well as on other cross references to the accreditation **Not applicable for the assessment for initial accreditation)** | | |
| **Result of review of documents and records:** | | | |  |  |  |  |

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| Findings / justification of findings / specifics / notes: | | | |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** | | | |
| No. | OE | Title / Description | Date / Version |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: | | | |
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| **Compliance of relevant IAF- and EA-Rules** | | | | | | | | | | |
|  | **IAF-Rule** | | **Responsible** | **Reference documents** | **Appraisal** | | | | | **No. of** |
|  |  | |  | **for the implementation** | **1** | | **2** | **3** | | **NC** |
| **IAF MD 1** | IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization | | **SA + TA** |  |  |  | | |  |  |
| Applicable: | Yes | No |  | | | | | | | |

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| Remarks: |  |

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| **IAF MD 2** | IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems | | **SA + TA** |  |  |  |  |  |
| Applicable: | Yes | No |  | | | | | |

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| Remarks: |  |

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| **IAF MD 4** | IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes | | **SA + TA** |  |  |  |  |  |
| Applicable: | Yes | No |  | | | | | |

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| **IAF MD 5** | Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems | | **SA + TA** |  |  |  |  |  |
| Applicable: | Yes | No |  | | | | | |

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| **IAF MD 9** | Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485) | | **SA + TA** |  |  |  |  |  |
| Applicable: | Yes | No |  | | | | | |

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| **IAF MD 11** | IAF Mandatory Document for Application of ISO/IEC 17021-1 for Audits of Integrated Management Systems | | **SA + TA** |  |  |  |  |  |
| Applicable: | Yes | No |  | | | | | |

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| Remarks: |  |

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| **IAF MD 22** | Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH & SMS) | | **SA + TA** |  |  |  |  |  |
| Applicable: | Yes | No |  | | | | | |

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| Remarks: |  |

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| **IAF MD 23** | Control of Entities Operating on Behalf  of Accredited Management Systems Certification Bodies | | **SA + TA** |  |  |  |  |  |
| Applicable: | Yes | No |  | | | | | |

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| Remarks: |  |

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|  | **EA-Rule** | | | | | | | |
| **EA-6/02** | EA Guidelines on the Use of  ISO/IEC 17065 and ISO/IEC 17021-1 for Certification to EN ISO 3834 | | **SA + TA** |  |  |  |  |  |
| Applicable: | Yes | No |  | | | | | |

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| Remarks: |  |

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| **EA-7/04** | Legal Compliance as a part of Accredited  ISO 14001:2015 Certification | | **SA + TA** |  |  |  |  |  |
| Applicable: | Yes | No |  | | | | | |

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| Remarks: |  |

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| Is the certification body notified for the assessed scope in the frame of **EU directives/modules or is the notification requested**? | | | SA + TA |  |  | | | |
| Yes | No | | | | | | | |
| Implementation of additional requirements according  to relevant **directives/modules** (taking into account  EA 2/17, Decision No. 768/2008/EC) | | | SA + TA |  |  |  |  |  |
| Yes | No | Not applicable | **If the answer is „Yes” or “No”, please note the next line!** | | | | | |

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| Remarks: | *If the previous question was answered in the affirmative, this field must explicitly address the implementation of the essential directive-specific requirements by the certification body with reference to the applicable articles of the directive (corresponding to article R 17 of decision 768/2008/EC) (e.g. independence, subcontracting, participation in the coordination group, notification obligations to the notifying authority).* |

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| * Fulfilment of imposed conditions and implementation  of the corrective actions from the previous assessment | **SA + TA** | |  | |
| Yes | | No | | Not applicable |

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| Remarks: |  |

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| **Preliminary assessment of documents and records completed on:** |  |

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| **No. of non-conformities:** | Non critical: |  | Critical: |  |

|  |
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| **Reductions of the scope of accreditation (indication of certification methods):** |

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| **Summary, remarks and improvement potential** |
| Appropriateness of personnel and other resources • fulfilment of additional requirements • overall impression with respect to the certification body’s particularities, strengths and areas requiring improvement, appraisal of the appropriateness and effectiveness of the quality system including potential for improvement • final evaluation • key aspects/considerations for the following assessment, if applicable |

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| **Recommendation on accreditation:**[[6]](#endnote-6)), [[7]](#endnote-7)) | | | **Yes** | **No** | |
| Place: |  | Date: |  | Signed *Assessor Name:* | [[8]](#endnote-8) |

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| **Report reviewed by the case manager:** | | |  | | |
| Place: |  | Date: |  | Signed *Case manager:* |  |

Note: The assessor does not confirm the complete correctness of the reference documents of the conformity assessment body.

\* Grading of fulfilment the requirements of a section of the standard to be entered by the assessor:

1 N**o** non-conformity

2 N**on critical** non-conformity

3 **Critical** non-conformity

\*\* NC = Non-conformity

1. Under assessment type, the assessment technique is to be indicated, whereby several assessment types can be used in the context of an assessment. Please select the applicable element or combination of elements from the following options to indicate the type of assessment:

   On-site assessment / Remote assessment / Witness audit (on-site) / Witness audit (remote) / Witness examination / Document review / Other assessment activity (please specify if necessary) [↑](#endnote-ref-1)
2. Status in the assessment team: LA=Lead Assessor; SA=System Assessor; TA=Technical Assessor; O=Observer [↑](#endnote-ref-2)
3. Only if the review of documents and records reveals that an assessment cannot be performed, the assessor prepares   
   a separate partial assessment report/checklist for the review of documents and records according to this form. [↑](#endnote-ref-3)
4. As an alternative to entering the OE/RD here, the separate form provided for this purpose can be used. [↑](#endnote-ref-4)
5. “Objective evidence” are to be distinguished from „Reviewed documents“ by marking with a cross „x“. [↑](#endnote-ref-5)
6. In the closing meeting the laboratory was informed about the preliminary result of the assessment, non-conformity reports   
   were handed over, if applicable. [↑](#endnote-ref-6)
7. Subject to a sufficient correction of non-conformities [↑](#endnote-ref-7)
8. This report was prepared personally by on . [↑](#endnote-ref-8)