



IECEE - IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components

IECEX - IEC System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres

IECQ - IEC Quality Assessment System for Electronic Components

IECEE OPERATIONAL DOCUMENT

Checklist for Certification Bodies

ISO/IEC 17065



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This Edition of IECEx OD 107 represents a common ISO/IEC 17065 Checklist for use by all IEC Conformity Assessment Systems and was approved for use by the IECEx during the IECEx Executive Dubai Meeting and notified to CAB during the June 2014 meeting.

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Checklist for Certification Bodies

ISO/IEC 17065

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

PRICE CODE

ZZ

CHECK LIST FOR CERTIFICATION BODIES

This check list is based on INTERNATIONAL STANDARD ISO/IEC 17065: 2012, with equivalent numbering.
The introduction clauses 1, 2 and 3 of this International Standard are left out in this check list.

Edition: 2015-06-03
2.0

Certification body concerned:
(name, address etc.)

Date of completion: _____ Completed by: _____

Please specify the language of the following documents:

Document	Language
Quality Manual	
Quality procedures	
Working Instructions	

Please note: If the language of these documents is not English, at least the Index and Headings must be in English

Legend: Status of compliance: **Y** = YES **N** = NO **N/A** = Not applicable
 Doc. ref.: Document reference of the relevant certification body document

Item	Status	Doc. ref. / Remarks
4 General requirements		
4.1 Legal and contractual matters		
4.1.1	<p>Legal responsibility The certification body shall be a legal entity, or a defined part of a legal entity, such that the legal entity can be held legally responsible for all its certification activities. NOTE A governmental certification body is deemed to be a legal entity on the basis of its governmental status.</p>	
4.1.2 Certification agreement		
4.1.2.1	The certification body shall have a legally enforceable agreement for the provision of certification activities to its clients. Certification agreements shall take into account the responsibilities of the certification body and its clients	
4.1.2.2	<p>The certification body shall ensure its certification agreement requires that the client comply at least, with the following:</p> <p>a) the client always fulfils the certification requirements (see 3.7), including implementing appropriate changes when they are communicated by the certification body (see 7.10);</p> <p>b) if the certification applies to ongoing production, the certified product continues to fulfil the product requirements (see 3.8);</p> <p>c) the client makes all necessary arrangements for 1) the conduct of the evaluation (see 3.3) and surveillance (if required), including provision for examining documentation and records, and access to the relevant equipment, location(s), area(s), personnel, and client's subcontractors; 2) investigation of complaints; 3) the participation of observers, if applicable;</p> <p>d) the client makes claims regarding certification consistent with the scope of certification (see 3.10);</p> <p>e) the client does not use its product certification in such a manner as to bring the certification body into disrepute and does not make any statement regarding its product certification that the certification body may consider misleading or unauthorized;</p> <p>f) upon suspension, withdrawal, or termination of certification, the client discontinues its use of all advertising matter that contains any reference thereto and takes action as required by the certification scheme (e.g. the return of certification documents) and takes any other required measure;</p> <p>g) if the client provides copies of the certification documents to others, the documents shall be reproduced in their entirety or as specified in the certification scheme</p> <p>h) in making reference to its product certification in communication media such as documents, brochures or advertising, the client complies with the requirements of the certification body or as specified by the certification scheme;</p> <p>i) the client complies with any requirements that may be prescribed in the certification scheme relating to the use of marks of conformity, and on information</p>	

Item	Status	Doc. ref. / Remarks
	<p>related to the product;</p> <p>NOTE See also ISO/IEC 17030, ISO/IEC Guide 23 and ISO Guide 27.</p>	
j)	<p>the client keeps a record of all complaints made known to it relating to compliance with certification requirements and makes these records available to the certification body when requested, and</p> <ol style="list-style-type: none"> 1) takes appropriate action with respect to such complaints and any deficiencies found in products that affect compliance with the requirements for certification; 2) documents the actions taken; <p>NOTE Verification of item j) by the certification body can be specified in the certification scheme.</p>	
k)	<p>the client informs the certification body, without delay, of changes that may affect its ability to conform with the certification requirements.</p> <p>NOTE Examples of changes can include the following: -the legal, commercial, organizational status or ownership, -organization and management (e.g. key managerial, decision-making or technical staff), -modifications to the product or the production method, -contact address and production sites, -major changes to the quality management system.</p>	
<p>4.1.3 Use of license, certificates and marks of conformity</p>		
4.1.3.1	<p>The certification body shall exercise the control as specified by the certification scheme over ownership, use and display of licenses, certificates, marks of conformity, and any other mechanisms for indicating a product is certified.</p> <p>NOTE 1 Guidance on the use of certificates and marks permitted by the certification body can be obtained from ISO/IEC Guide 23. NOTE 2 ISO/IEC 17030 provides requirements for the use of third-party marks.</p>	
4.1.3.2	<p>Incorrect references to the certification scheme, or misleading use of licenses, certificates, marks, or any other mechanism for indicating a product is certified, found in documentation or other publicity, shall be dealt with by suitable action.</p> <p>NOTE Such actions are addressed in ISO Guide 27 and can include corrective actions, withdrawal of certificate, publication of the transgression and, if necessary, legal action.</p>	
<p>4.2 Management of impartiality</p>		
4.2.1	<p>Certification activities shall be undertaken impartially.</p>	
4.2.2	<p>The certification body shall be responsible for the impartiality of its certification activities and shall not allow commercial, financial or other pressures to compromise impartiality.</p>	
4.2.3	<p>The certification body shall identify risks to its impartiality on an ongoing basis. This shall include those risks that arise from its activities, from its relationships, or from the relationships of its personnel (see 4.2.12). However, such relationships may not necessarily present a certification body with a risk to impartiality.</p> <p>NOTE 1 A relationship presenting a risk to impartiality of the certification body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new clients, etc. NOTE 2 Identifying risks does not imply risk assessments as stated in ISO 31000.</p>	

Item	Status	Doc. ref. / Remarks
4.2.4	If a risk to impartiality is identified, the certification body shall be able to demonstrate how it eliminates or minimizes such risk. This information shall be made available to the mechanism specified in 5.2.	
4.2.5	The certification body shall have top management commitment to impartiality.	
4.2.6	<p>The certification body and any part of the same legal entity and entities under its organizational control (see 7.6.4) shall not:</p> <p>a) be the designer, manufacturer, installer, distributor or maintainer of the certified product;</p> <p>b) be the designer, implementer, operator or maintainer of the certified process;</p> <p>c) be the designer, implementer, provider or maintainer of the certified service;</p> <p>d) offer or provide consultancy (see 3.2) to its clients;</p> <p>e) offer or provide management system consultancy or internal auditing to its clients where the certification scheme requires the evaluation of the client's management system.</p> <p>NOTE 1 This does not preclude the following: the possibility of exchange of information (e.g. explanations of findings or clarifying requirements) between the certification body and its clients; the use, installing and maintaining of certified products which are necessary for the operations of the certification body.</p> <p>NOTE 2 "Management system consultancy" is defined in ISO/IEC 17021:2011, definition 3.3.</p>	
4.2.7	<p>The certification body shall ensure that activities of separate legal entities, with which the certification body or the legal entity of which it forms a part has relationships, do not compromise the impartiality of its certification activities.</p> <p>NOTE See 4.2.3, Note 1.</p>	
4.2.8	<p>When the separate legal entity in 4.2.7 offers or produces the certified product (including products to be certified) or offers or provides consultancy (see 3.2), the certification body's management personnel and personnel in the review and certification decision-making process shall not be involved in the activities of the separate legal entity. The personnel of the separate legal entity shall not be involved in the management of the certification body, the review, or the certification decision.</p> <p>NOTE For the evaluation personnel, impartiality requirements are stipulated in Clause 6 and additional requirements are given in the other relevant International Standards cited in 6.2.1 and 6.2.2.1.</p>	
4.2.9	<p>The certification body's activities shall not be marketed or offered as linked with the activities of an organization that provides consultancy (see 3.2). A certification body shall not state or imply that certification would be simpler, easier, faster or less expensive if a specified consultancy organization were used.</p>	
4.2.10	<p>Within a period specified by the certification body, personnel shall not be used to review or make a certification decision for a product for which they have provided consultancy (see 3.2).</p> <p>NOTE 1 The period can be specified in the certification scheme or, if specified by the certification body, it reflects a period that is long enough to ensure that the review or decision does not compromise impartiality. A specified period of two years is often used.</p> <p>NOTE 2 For the evaluation personnel, impartiality requirements are stipulated in Clause 6 and additional requirements are given in the other relevant International Standards cited in 6.2.1 and 6.2.2.1.</p>	

Item		Status	Doc. ref. / Remarks
4.2.11	The certification body shall take action to respond to any risks to its impartiality, arising from the actions of other persons, bodies or organizations, of which it becomes aware.		
4.2.12	All certification body personnel (either internal or external) or committees who could influence the certification activities shall act impartially.		
4.3 Liability and financing			
4.3.1	The certification body shall have adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations.		
4.3.2	The certification body shall have the financial stability and resources required for its operations.		
4.4 Non-discriminatory conditions			
4.4.1	The policies and procedures under which the certification body operates, and the administration of them, shall be non-discriminatory. Procedures shall not be used to impede or inhibit access by applicants, other than as provided for in this International Standard.		
4.4.2	The certification body shall make its services accessible to all applicants whose activities fall within the scope of its operations.		
4.4.3	Access to the certification process shall not be conditional upon the size of the client or membership of any association or group, nor shall certification be conditional upon the number of certifications already issued. There shall not be undue financial or other conditions. NOTE A certification body can decline to accept an application or maintain a contract for certification from a client when fundamental or demonstrated reasons exist, such as the client participating in illegal activities, having a history of repeated non-compliances with certification/product requirements, or similar client-related issues.		
4.4.4	The certification body shall confine its requirements, evaluation, review, decision and surveillance (if any) to those matters specifically related to the scope of certification.		
4.5 Confidentiality			
4.5.1	The certification body shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of certification activities. Except for information that the client makes publicly available, or when agreed between the certification body and the client (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential. The certification body shall inform the client, in advance, of the information it intends to place in the public domain.		
4.5.2	When the certification body is required by law or authorized by contractual arrangements to release confidential information, the client or person concerned shall, unless prohibited by law, be notified of the information provided.		
4.5.3	Information about the client obtained from sources other than the client (e.g. from the complainant or from regulators) shall be treated as confidential.		

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4.6 Publicly available information		
	The certification body shall maintain (through publications, electronic media or other means), and make available upon request, the following:	
	a) information about (or reference to) the certification scheme(s), including evaluation procedures, rules and procedures for granting, for maintaining, for extending or reducing the scope of, for suspending, for withdrawing or for refusing certification;	
	b) a description of the means by which the certification body obtains financial support and general information on the fees charged to applicants and to clients;	
	c) a description of the rights and duties of applicants and clients, including requirements, restrictions or limitations on the use of the certification body's name and certification mark and on the ways of referring to the certification granted;	
	d) information about procedures for handling complaints and appeals.	
5 Structural requirements		
5.1 Organizational structure and top management		
5.1.1	Certification activities shall be structured and managed so as to safeguard impartiality.	
5.1.2	The certification body shall document its organizational structure, showing duties, responsibilities and authorities of management and other certification personnel and any committees. When the certification body is a defined part of a legal entity, the structure shall include the line of authority and the relationship to other parts within the same legal entity.	
5.1.3.	<p>The management of the certification body shall identify the board, group of persons, or person having overall authority and responsibility for each of the following:</p> <p>a) development of policies relating to the operation of the certification body;</p> <p>b) supervision of the implementation of the policies and procedures;</p> <p>c) supervision of the finances of the certification body;</p> <p>d) development of certification activities;</p> <p>e) development of certification requirements;</p> <p>f) evaluation (see 7.4);</p> <p>g) review (see 7.5);</p> <p>h) decisions on certification (see 7.6);</p> <p>l) delegation of authority to committees or personnel, as required, to undertake defined activities on its behalf;</p>	

Item	Status	Doc. ref. / Remarks
j)		
k)		
l)		
m)		
n)		
5.1.4.		
5.2 Mechanism for safeguarding impartiality		
5.2.1		
a)		
b)		
c)		
5.2.2		
a)		
b)		
5.2.3		

Item		Status	Doc. ref. / Remarks
	should document the reasoning behind the decision to not follow the input and maintain the document for review by appropriate personnel.		
5.2.4	<p>Although every interest cannot be represented in the mechanism, a certification body shall identify and invite significantly interested parties.</p> <p>NOTE 1 Such interested parties can include clients of the certification body, customers of clients, manufacturers, suppliers, users, conformity assessment experts, representatives of industry trade associations, representatives of governmental regulatory bodies or other governmental services, and representatives of non-governmental organizations, including consumer organizations. It can be sufficient to have one representative of each interested party in the mechanism.</p> <p>NOTE 2 These interests can be limited, depending on the nature of the certification scheme.</p>		
6 Resource requirements			
6.1 Certification body personnel			
6.1.1 General			
6.1.1.1	<p>The certification body shall employ, or have access to, a sufficient number of personnel to cover its operations related to the certification schemes and to the applicable standards and other normative documents.</p> <p>NOTE The personnel include those normally working for the certification body, as well as persons working under an individual contract or a formal agreement that places them within the management control and systems/procedures of the certification body (see 6.1.3).</p>		
6.1.1.2	The personnel shall be competent for the functions they perform, including making required technical judgments, defining policies and implementing them.		
6.1.1.3	Personnel, including any committee members, personnel of external bodies, or personnel acting on the certification body's behalf, shall keep confidential all information obtained or created during the performance of the certification activities, except as required by law or by the certification scheme.		
6.1.2 Management of competence for personnel involved in the certification process			
6.1.2.1	The certification body shall establish, implement and maintain a procedure for management of competencies of personnel involved in the certification process (see Clause 7). The procedure shall require the certification body to:		
	a) determine the criteria for the competence of personnel for each function in the certification process, taking into account the requirements of the schemes;		
	b) identify training needs and provide, as necessary, training programmes on certification processes, requirements, methodologies, activities and other relevant certification scheme requirements;		
	c) demonstrate that the personnel have the required competencies for the duties and responsibilities they undertake;		
	d) formally authorize personnel for functions in the certification process;		

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	e) monitor the performance of the personnel.	
6.1.2.2	The certification body shall maintain the following records on the personnel involved in the certification process (see Clause 7):	
	a) name and address;	
	b) employer(s) and position held;	
	c) educational qualification and professional status;	
	d) experience and training;	
	e) the assessment of competence;	
	f) performance monitoring;	
	g) authorizations held within the certification body;	
	h) date of most recent updating of each record.	
6.1.3 Contract with the personnel		
	The certification body shall require personnel involved in the certification process to sign a contract or other document by which they commit themselves to the following:	
	a) to comply with the rules defined by the certification body, including those relating to confidentiality (see 4.5) and independence from commercial and other interests;	
	b) to declare any prior and/or present association on their own part, or on the part of their employer, with: <ul style="list-style-type: none"> 1) a supplier or designer of products, or 2) a provider or developer of services, or 3) an operator or developer of processes to the evaluation or certification of which they are to be assigned;	
	c) to reveal any situation known to them that may present them or the certification body with a conflict of interest (see 4.2).	
	Certification bodies shall use this information as input into identifying risks to impartiality raised by the activities of such personnel, or by the organizations that employ them (see 4.2.3).	

Item	Status	Doc. ref. / Remarks
6.2 Resources for evaluation		
6.2.1 Internal resources		
	<p>When a certification body performs evaluation activities, either with its internal resources or with other resources under its direct control, it shall meet the applicable requirements of the relevant International Standards and, as specified by the certification scheme, of other documents. For testing, it shall meet the applicable requirements of ISO/IEC 17025; for inspection, it shall meet the applicable requirements of ISO/IEC 17020; and for management system auditing, it shall meet the applicable requirements of ISO/IEC 17021. The impartiality requirements of the evaluation personnel stipulated in the relevant standard shall always be applicable.</p> <p>NOTE Examples of reasons as to why some requirements are not applicable include the following:</p> <ul style="list-style-type: none"> - expertise is available within the certification body when using the results of the evaluation activity; - the extent of control the certification body has over testing (including witnessing the testing), inspection (e.g. specifying inspection methods or parameters) or management system assessment (e.g. requiring specific details of a management system); - a particular requirement is covered in an equivalent way by this International Standard, or is not needed to give confidence in the certification decision. 	
6.2.2 External resources (outsourcing)		
6.2.2.1	<p>The certification body shall outsource evaluation activities only to bodies that meet the applicable requirements of the relevant International Standards and, as specified by the certification scheme, of other documents. For testing, it shall meet the applicable requirements of ISO/IEC 17025; for inspection, it shall meet the applicable requirements of ISO/IEC 17020; and for management system auditing, it shall meet the applicable requirements of ISO/IEC 17021. The impartiality requirements of the evaluation personnel stipulated in the relevant standard shall always be applicable. Customer: Jim Munro - No. of User(s): 1 - Company: Jim Munro International Compliance Pty Ltd.</p> <p>NOTE 1 Examples of reasons as to why some requirements are not applicable include the following:</p> <ul style="list-style-type: none"> - expertise is available within the certification body when using the results of the evaluation activity; - the extent of control the certification body has over testing (including witnessing the testing), inspection (e.g. specifying inspection methods or parameters) or management system assessment (e.g. requiring specific details of a management system); - a particular requirement is covered in an equivalent way by this International Standard, or is not needed to give confidence in the certification decision. <p>NOTE 2 This can include outsourcing to other certification bodies. Use of external personnel under contract is not outsourcing.</p> <p>NOTE 3 For the purposes of this International Standard, the terms "outsourcing" and "subcontracting" are considered to be synonyms.</p>	
6.2.2.2	<p>Where evaluation activities are outsourced to non-independent bodies (e.g. client laboratories), the certification body shall ensure that the evaluation activities are managed in a manner which provides confidence in the results, and that records are available to justify the confidence.</p>	
6.2.2.3	<p>The certification body shall have a legally binding contract with the body that provides the outsourced service, including provisions for confidentiality and conflict of interest as specified in 6.1.3, item c).</p>	

Item	Status	Doc. ref. / Remarks
6.2.2.4		
<p>The certification body shall:</p> <p>a) take responsibility for all activities outsourced to another body;</p> <p>b) ensure that the body that provides outsourced services, and the personnel that it uses, are not involved, either directly or through any other employer, in such a way that the credibility of the results could be compromised;</p> <p>c) have documented policies, procedures and records for the qualification, assessing and monitoring of all bodies that provide outsourced services used for certification activities;</p> <p>d) maintain a list of approved providers of outsourced services;</p> <p>e) implement corrective actions for any breaches of the contract in 6.2.2.3 or other requirements in 6.2.2 of which it becomes aware;</p> <p>f) inform the client in advance of outsourcing activities, in order to provide the client with an opportunity to object.</p> <p>NOTE If the qualification, assessing and monitoring of the bodies that provide outsourced services are performed by other organizations (e.g. by accreditation bodies, peer assessment bodies or governmental authorities), the certification body can take this qualification and monitoring into account provided that: - it is provided for within the scheme requirements; - the scope is applicable to the work being undertaken; = the validity of the qualification, assessing and monitoring arrangements is verified at a periodicity determined by the certification body.</p>		
7 Process requirements		
7.1 General		
7.1.1		
7.1.2		
7.1.3		

Item	Status	Doc. ref. / Remarks
7.2 Application		
	<p>For application, the certification body shall obtain all the necessary information to complete the certification process in accordance with the relevant certification scheme.</p> <p>NOTE 1 The following are examples of necessary information:</p> <ul style="list-style-type: none"> - the product(s) to be certified; -- the standards and/or other normative documents for which the client is seeking certification (see 7.1.2); - the general features of the client, including its name and the address(es) of its physical location(s), significant aspects of its process and operations (if required by the relevant certification scheme), and any relevant legal obligations; - general information concerning the client, relevant to the field of certification for which the application is made, such as the client's activities, its human and technical resources, including laboratories and/or inspection facilities, and its functions and relationship in a larger corporation, if any; - information concerning all outsourced processes used by the client that will affect conformity to requirements; if the client has identified a legal entity/entities for producing the certified product(s) that is different from the client, then the certification body can establish appropriate contractual controls over the legal entity/entities concerned, if necessary for effective surveillance; if such contractual controls are needed, they can be established prior to providing formal certification documentation (see 7.7); - all other information needed in accordance with the relevant certification requirements, such as information for initial evaluation and surveillance activities, e.g. the locations where the certified product(s) are produced and contact personnel at these locations. <p>NOTE 2 A variety of media and mechanisms can be used to collect this information at various times, including an application form. Such information gathering can be in conjunction with, or separate from, the completion of the legally binding agreement (the certification agreement) specified in 4.1.2.</p> <p>NOTE 3 Application for an extension of the certification scope could involve similar products, different locations, etc.</p>	
7.3 Application review		
7.3.1	<p>The certification body shall conduct a review of the information obtained (see 7.2) to ensure that:</p> <ul style="list-style-type: none"> a) the information about the client and the product is sufficient for the conduct of the certification process; b) any known difference in understanding between the certification body and the client is resolved, including agreement regarding standards or other normative documents; c) the scope of certification (see 3.10) sought is defined; d) the means are available to perform all evaluation activities; e) the certification body has the competence and capability to perform the certification activity. 	
7.3.2	<p>The certification body shall have a process to identify when the client's request for certification includes</p> <ul style="list-style-type: none"> -a type of product, or -a normative document, or -a certification scheme <p>with which the certification body has no prior experience,</p>	

Item	Status	Doc. ref. / Remarks
7.3.3		
7.3.4		
7.3.5		
7.4 Evaluation		
7.4.1		
7.4.2		
7.4.3		
7.4.4		
7.4.5		
7.4.6		

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7.4.7	If one or more nonconformities have arisen, and if the client expresses interest in continuing the certification process, the certification body shall provide information regarding the additional evaluation tasks needed to verify that nonconformities have been corrected.	
7.4.8	If the client agrees to completion of the additional evaluation tasks, the process specified in 7.4 shall be repeated to complete the additional evaluation tasks.	
7.4.9	<p>The results of all evaluation activities shall be documented prior to review (see 7.5).</p> <p>NOTE 1 This documentation can provide an opinion as to whether product requirements (including requirements such as those for the quality management system under which the product is produced, if required by the certification scheme) have been fulfilled.</p> <p>NOTE 2 The certification scheme can indicate whether the evaluation is performed by the certification body, under its responsibility, or is performed prior to the application (see 7.2) for the certification process. In the latter case, the requirements of 7.4 are not applicable</p>	
7.5 Review		
7.5.1	The certification body shall assign at least one person to review all information and results related to the evaluation. The review shall be carried out by person(s) who have not been involved in the evaluation process.	
7.5.2	Recommendations for a certification decision based on the review shall be documented, unless the review and the certification decision are completed concurrently by the same person.	
7.6 Certification decision		
7.6.1	The certification body shall be responsible for, and shall retain authority for, its decisions relating to certification.	
7.6.2	<p>The certification body shall assign at least one person to make the certification decision based on all information related to the evaluation, its review, and any other relevant information. The certification decision shall be carried out by a person or group of persons [e.g. a committee (see 5.1.4)] that has not been involved in the process for evaluation (see 7.4).</p> <p>NOTE The review and the certification decision can be completed concurrently by the same person or group of persons.</p>	
7.6.3	<p>The person(s) [excluding members of committees (see 5.1.4)] assigned by the certification body to make a certification decision shall be employed by, or shall be under contract with, one of the following:</p> <ul style="list-style-type: none"> - the certification body (see 6.1); - an entity under the organizational control of the certification body (see 7.6.4). 	
7.6.4	<p>A certification body's organizational control shall be one of the following:</p> <ul style="list-style-type: none"> - whole or majority ownership of another entity by the certification body; - majority participation by the certification body on the board of directors of another entity; - a documented authority by the certification body over another entity in a network of legal entities (in which the certification body resides), linked by ownership or board of director control. <p>NOTE For governmental certification bodies, other parts of the same government can be considered to be "linked by</p>	

Item	Status	Doc. ref. / Remarks
		ownership" to the certification body.
7.6.5		The persons employed by, or under contract with, entities under organizational control shall fulfil the same requirements of this International Standard as persons employed by, or under contract with, the certification body.
7.6.6		The certification body shall notify the client of a decision not to grant certification, and shall identify the reasons for the decision. NOTE If the client expresses interest in continuing the certification process, the certification body can resume the process for evaluation from 7.4.
7.7 Certification documentation		
7.7.1		<p>The certification body shall provide the client with formal certification documentation that clearly conveys, or permits identification of the following:</p> <ul style="list-style-type: none"> a) the name and address of the certification body; b) the date certification is granted (the date shall not precede the date on which the certification decision was completed); c) the name and address of the client; d) the scope of certification (see 3.10); NOTE Where the standard(s) or other normative document(s) (see 7.1.2) to which conformity is being certified include reference to other standards or normative documents, these do not need to be included in the formal certification documentation. e) the term or expiry date of certification, if certification expires after an established period; f) any other information required by the certification scheme.
7.7.2		<p>The formal certification documentation shall include the signature or other defined authorization of the person(s) of the certification body assigned such responsibility.</p> <p>NOTE The name and title of an individual whose agreement to be responsible for certification documentation is on record at the certification body is an example of a "defined authorization" other than a signature.</p>
7.7.3		<p>Formal certification documentation (see 7.7) shall only be issued after, or concurrent with, the following:</p> <ul style="list-style-type: none"> a) the decision to grant or extend the scope of certification (see 7.6.1) has been made; b) certification requirements have been fulfilled; c) the certification agreement (see 4.1.2) has been completed/signed.
7.8 Directory of certified products		
		<p>The certification body shall maintain information on certified products which contains at least the following:</p> <ul style="list-style-type: none"> a) identification of the product;

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b)		
the standard(s) and other normative document(s) to which conformity has been certified;		
c)		
identification of the client.		
The parts of this information that need to be published or made available upon request in a directory (through publications, electronic media or other means) are stipulated by the relevant scheme(s). As a minimum, the certification body shall provide information, upon request, about the validity of a given certification. NOTE Where the certification body provides the information to a scheme, the scheme directory would satisfy this requirement.		
7.9 Surveillance		
7.9.1	If surveillance is required by the certification scheme, or as specified in 7.9.3 or 7.9.4, the certification body shall initiate surveillance of the product(s) covered by the certification decision in accordance with the certification scheme. NOTE 1 ISO/IEC 17067 provides examples of surveillance activities in certification schemes. NOTE 2 The criteria and process for surveillance activities are defined by each certification scheme.	
7.9.2	When surveillance utilizes evaluation, review or a certification decision, the requirements in 7.4, 7.5 or 7.6, respectively, shall be fulfilled.	
7.9.3	When continuing use of a certification mark is authorized for placement on a product (or its packaging, or information accompanying it) (for process or service, see 7.9.4) of a type which has been certified, surveillance shall be established and shall include periodic surveillance of marked products to ensure ongoing validity of the demonstration of fulfilment of product requirements.	
7.9.4	When continuing use of a certification mark is authorized for a process or service, surveillance shall be established and shall include periodic surveillance activities to ensure ongoing validity of the demonstration of fulfilment of process or service requirements.	
7.10 Changes affecting certification		
7.10.1	When the certification scheme introduces new or revised requirements that affect the client, the certification body shall ensure these changes are communicated to all clients. The certification body shall verify the implementation of the changes by its clients and shall take actions required by the scheme. NOTE Contractual arrangements with clients can be necessary to ensure implementation of these requirements. A model of a license agreement for the use of certification, including the aspects related to a notice of changes, as far as applicable, is given in ISO/IEC Guide 28:2004, Annex E.	
7.10.2	The certification body shall consider other changes affecting certification, including changes initiated by the client, and shall decide upon the appropriate action. NOTE Changes affecting certification can include new information related to the fulfilment of certification requirements obtained by the certification body after certification has been established.	

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7.10.3		
<p>The actions to implement changes affecting certification shall include, if required, the following:</p> <ul style="list-style-type: none"> - evaluation (see 7.4); - review (see 7.5); - decision (see 7.6); - issuance of revised formal certification documentation (see 7.7) to extend or reduce the scope of certification; - issuance of certification documentation of revised surveillance activities (if surveillance is part of the certification scheme). 		
<p>These actions shall be completed in accordance with applicable parts of 7.4, 7.5, 7.6, 7.7 and 7.8. Records (see 7.12) shall include the rationale for excluding any of the above activities (e.g. when a certification requirement that is not a product requirement changes, and no evaluation, review or decision activities are necessary).</p>		
<p>7.11 Termination, reduction, suspension or withdrawal of certification</p>		
7.11.1		
<p>When a nonconformity with certification requirements is substantiated, either as a result of surveillance or otherwise, the certification body shall consider and decide upon the appropriate action.</p> <p>NOTE Appropriate action can include the following:</p> <ul style="list-style-type: none"> a) continuation of certification under conditions specified by the certification body (e.g. increased surveillance); b) reduction in the scope of certification to remove nonconforming product variants; c) suspension of the certification pending remedial action by the client; d) withdrawal of the certification. 		
7.11.2		
<p>When the appropriate action includes evaluation, review or a certification decision, the requirements in 7.4, 7.5 or 7.6, respectively, shall be fulfilled.</p>		
7.11.3		
<p>If certification is terminated (by request of the client), suspended or withdrawn, the certification body shall take actions specified by the certification scheme and shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure it provides no indication that the product continues to be certified. If a scope of certification is reduced, the certification body shall take actions specified by the certification scheme and shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the client and clearly specified in certification documentation and public information.</p>		
7.11.4		
<p>If certification is suspended, the certification body shall assign one or more persons to formulate and communicate the following to the client:</p> <ul style="list-style-type: none"> - actions needed to end suspension and restore certification for the product(s) in accordance with the certification scheme; - any other actions required by the certification scheme. <p>These persons shall be competent in their knowledge and understanding of all aspects of the handling of suspended certifications (see 6.1).</p>		
7.11.5		
<p>Any evaluations, reviews or decisions needed to resolve the suspension, or that are required by the certification scheme, shall be completed in</p>		

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	accordance with the applicable parts of 7.4, 7.5, 7.6, 7.7.3, 7.9 and 7.11.3.		
7.11.6	If certification is reinstated after suspension, the certification body shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure all appropriate indications exist that the product continues to be certified. If a decision to reduce the scope of certification is made as a condition of reinstatement, the certification body shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the client and clearly specified in certification documentation and public information.		
7.12 Records			
7.12.1	The certification body shall retain records to demonstrate that all certification process requirements (those in this International Standard and those of the certification scheme) have been effectively fulfilled (see also 8.4).		
7.12.2	The certification body shall keep records confidential. Records shall be transported, transmitted and transferred in a way that ensures confidentiality is maintained (see also 4.5).		
7.12.3	If the certification scheme involves complete re-evaluation of the product(s) within a determined cycle, records shall be retained at least for the current and the previous cycle. Otherwise, records shall be retained for a period defined by the certification body. NOTE In defining retention times, legal circumstances and recognition arrangements can be considered		
7.13 Complaints and appeals			
7.13.1	The certification body shall have a documented process to receive, evaluate and make decisions on complaints and appeals. The certification body shall record and track complaints and appeals, as well as actions undertaken to resolve them.		
7.13.2	Upon receipt of a complaint or appeal, the certification body shall confirm whether the complaint or appeal relates to certification activities for which it is responsible and, if so, shall address it.		
7.13.3	The certification body shall acknowledge receipt of a formal complaint or appeal.		
7.13.4	The certification body shall be responsible for gathering and verifying all necessary information (as far as possible) to progress the complaint or appeal to a decision.		
7.13.5	The decision resolving the complaint or appeal shall be made by, or reviewed and approved by, person(s) not involved in the certification activities related to the complaint or appeal.		
7.13.6	To ensure that there is no conflict of interest, personnel (including those acting in a managerial capacity) who have provided consultancy (see 3.2) for a client, or been employed by a client, shall not be used by the certification body to review or approve the resolution of a complaint or appeal for that client within two years following the end of the consultancy or employment.		

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7.13.7		
Whenever possible, the certification body shall give formal notice of the outcome and the end of the complaint process to the complainant.		
7.13.8		
The certification body shall give formal notice of the outcome and the end of the appeal process to the appellent.		
7.13.9		
The certification body shall take any subsequent action needed to resolve the complaint or appeal.		
8 Management system requirements		
8.1 Options		
8.1.1 General		
	The certification body shall establish and maintain a management system that is capable of achieving the consistent fulfilment of the requirements of this International Standard in accordance with either Option A or Option B.	
8.1.2 Option A		
	The management system of the certification body shall address the following: -general management system documentation (e.g. manual, policies, definition of responsibilities, see 8.2); -control of documents (see 8.3); -control of records (see 8.4); -management review (see 8.5); -internal audit (see 8.6); -corrective actions (see 8.7); -preventive actions (see 8.8).	
8.1.3 Option B		
	A certification body that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of this International Standard, fulfils the management system clause requirements (see 8.2 to 8.8). NOTE Option B is included to enable a certification body which operates a management system in accordance with ISO 9001 to use that system to demonstrate fulfilment of the management system requirements in 8.2 to 8.8 of this International Standard. Option B does not require that the certification body's management system is certified to ISO 9001.	
8.2 General management system documentation (Option A)		
8.2.1	The certification body's top management shall establish, document, and maintain policies and objectives for fulfilment of this International Standard and the certification scheme and shall ensure the policies and objectives are acknowledged and implemented at all levels of the certification body's organization.	
8.2.2	The certification body's top management shall provide evidence of its commitment to the development and implementation of the management system and its effectiveness in achieving consistent fulfilment of this International Standard.	
8.2.3	The certification body's top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that include the following:	

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a)		
ensuring that processes and procedures needed for the management system are established, implemented and maintained;		
b)		
reporting to top management on the performance of the management system and any need for improvement.		
8.2.4		
All documentation, processes, systems, records, etc. related to the fulfilment of the requirements of this International Standard shall be included, referenced, or linked to documentation of the management system.		
8.2.5		
All personnel involved in certification activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.		
8.3 Control of documents (Option A)		
8.3.1		
The certification body shall establish procedures to control the documents (internal and external) that relate to the fulfilment of this International Standard.		
8.3.2		
The procedures shall define the controls needed to:		
a)		
approve documents for adequacy prior to issue;		
b)		
review and update (as necessary) and re-approve documents;		
c)		
ensure that changes and the current revision status of documents are identified;		
d)		
ensure that relevant versions of applicable documents are available at points of use;		
e)		
ensure that documents remain legible and readily identifiable;		
f)		
ensure that documents of external origin are identified and their distribution controlled;		
g)		
prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.		
NOTE Documentation can be in any form or type of medium.		
8.4 Control of records (Option A)		
8.4.1		
The certification body shall establish procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records related to the fulfilment of this International Standard.		
8.4.2		
The certification body shall establish procedures for retaining records (see 7.12) for a period consistent with its contractual and legal obligations. Access to these records shall be consistent with the confidentiality arrangements.		
8.5 Management review (Option A)		
8.5.1 General		
8.5.1.1		
The certification body's top management shall establish procedures to review its management system at planned intervals, in order to ensure its		

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	continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this International Standard.	
8.5.1.2	These reviews shall be conducted at least once a year. Alternatively, a complete review broken up into segments shall be completed within a 12-month time frame. Records of reviews shall be maintained.	
8.5.2 Review inputs		
	The input to the management review shall include information related to the following:	
	a) results of internal and external audits;	
	b) feedback from clients and interested parties related to the fulfilment of this International Standard; NOTE Interested parties can include scheme owners.	
	c) feedback from the mechanism for safeguarding impartiality;	
	d) the status of preventive and corrective actions;	
	e) follow-up actions from previous management reviews;	
	f) the fulfilment of objectives;	
	g) changes that could affect the management system;	
	h) appeals and complaints.	
8.5.3 Review outputs		
	The outputs from the management review shall include decisions and actions related to the following:	
	a) improvement of the effectiveness of the management system and its processes;	
	b) improvement of the certification body related to the fulfilment of this International Standard;	
	c) resource needs.	
8.6 Internal audits (Option A)		
8.6.1	The certification body shall establish procedures for internal audits to verify that it fulfils the requirements of this International Standard and that the management system is effectively implemented and maintained. NOTE ISO 19011 provides guidelines for conducting internal audits.	
8.6.2	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.	
8.6.3	Internal audits shall normally be performed at least once every 12 months, or completed within a 12-month time frame for segmented (or rolling) internal audits. A documented decision-making process shall be followed to change (reduce or restore) the frequency of internal audits or the time frame in	

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	which internal audits shall be completed. Such changes shall be based on the relative stability and ongoing effectiveness of the management system. Records of decisions to change the frequency of internal audits, or the time frame in which they will be completed, including the rationale for the change, shall be maintained.	
8.6.4	The certification body shall ensure that:	
	a) internal audits are conducted by personnel knowledgeable in certification, auditing and the requirements of this International Standard;	
	b) auditors do not audit their own work;	
	c) personnel responsible for the area audited are informed of the outcome of the audit;	
	d) any actions resulting from internal audits are taken in a timely and appropriate manner;	
	e) any opportunities for improvement are identified.	
8.7 Corrective actions (Option A)		
8.7.1	The certification body shall establish procedures for identification and management of nonconformities in its operations.	
8.7.2	The certification body shall also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence.	
8.7.3	Corrective actions shall be appropriate to the impact of the problems encountered.	
8.7.4	The procedures for corrective actions shall define requirements for the following:	
	a) identifying nonconformities (e.g. from complaints and internal audits);	
	b) determining the causes of nonconformity;	
	c) correcting nonconformities;	
	d) evaluating the need for actions to ensure that nonconformities do not recur;	
	e) determining and implementing the actions needed in a timely manner;	
	f) recording the results of actions taken;	
	g) reviewing the effectiveness of corrective actions.	
8.8 Preventive actions (Option A)		
8.8.1	The certification body shall establish procedures for taking preventive actions to eliminate the causes of potential nonconformities.	
8.8.2	Preventive actions taken shall be appropriate to the probable impact of the potential problems.	

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8.8.3	The procedures for preventive actions shall define requirements for the following:	
	a) identifying potential nonconformities and their causes;	
	b) evaluating the need for action to prevent the occurrence of nonconformities;	
	c) determining and implementing the action needed;	
	d) recording the results of actions taken;	
	e) reviewing the effectiveness of the preventive actions taken.	
	NOTE The procedures for corrective and preventive actions do not necessarily have to be separate.	

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