

# EN ISO/IEC 17021:2015

---

---



# ISO CASCO WG 21





NORME TECNICHE: LE NOSTRE AMICHE INVISIBILI

**UNI** ENTE ITALIANO  
DI NORMAZIONE





## Where we are NOW

Published on 15-06-2015

**2 year of transition** (decision taken on October 2014 by IAF in Vancouver).

ISO/IEC TS 17022:2012 (audit report) will be deleted, the main points are already included into ISO 17021-1

**All the ABs have to define a transition plan to agree with their CABS**

The CABS have to prepare a plan (see here the example into the circular letter of ACCREDIA)



Accredia Circular on transition ISO 17021.pdf - Adobe Acrobat Reader DC

File Modifica Vista Finestra ?

Home Strumenti Accredia Circular o... x

3 / 4 146%

**Example of a transition plan to ISO- IEC 17021-1:2015**

All CBs shall complete this module (or prepare an equivalent document) and make it available to the ACCREDIA assessment team either before or during the transition assessment.

The documentation shall also be attached giving the required evidence to answer the questions in the questionnaire.

N°	Question	Space reserved for ACCREDIA
1.	How will communication with clients regarding the handling of the transition be managed? Attach evidence.	Closure C <input type="checkbox"/> O <input type="checkbox"/> If "Open", clarification is necessary:
2.	With what modalities and timeframe will the training of staff with responsibilities for the contract review and the audit program be carried out and evaluated?	Closure C <input type="checkbox"/> O <input type="checkbox"/> If "Open", clarification is necessary:



### 3.3 management system consultancy

*Participation in establishing, implementing or maintaining a management system*

EXAMPLE 1 Preparing or producing manuals or procedures.

EXAMPLE 2 Giving specific advice, instructions or solutions towards the development and **implementation** of a management system.

NOTE 1 to entry: Arranging training and participating as a trainer is not considered consultancy, provided that, where the course relates to management systems or auditing, it is confined to the provision of generic information; i.e. the trainer should not provide client-specific solutions.

NOTE 2 to entry: The provision of generic information, but not client specific solutions for the improvement of processes or systems, is not considered to be consultancy. Such information may include:

- explaining the meaning and intention of certification criteria;
- identifying improvement opportunities;
- explaining associated theories, methodologies, techniques or tools;
- sharing non-confidential information on related best practices;
- other management aspects that are not covered by the management system being audited.

**Training is NOT consulting, but now it is present in the threats to impartiality (5.2.3 note 1)**

**Implementing includes also the developing of risk analysis**





### 3.11 Nonconformity

*non-fulfilment of a requirement*

### 3.12 major nonconformity

nonconformity (3.11) that affects the capability of the management system to achieve the intended results

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

- if there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements;
- a number of minor nonconformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major nonconformity.

### 3.13 minor nonconformity

nonconformity (3.11) that does not affect the capability of the management system to achieve the intended results

#### **Distinction between minor and major NCs**

**Effectiveness of the Corrective actions of Major NCs has to be evaluated BEFORE granting certification. For the Minors is enough the Plan (§ 9.5.2)**

Paradox: is it possible to grant a certificate with a Minor NC?



**New principle, not verifiable.**

**It is not mandatory that the risk analysis takes into considerations all these risks. The analysis of impartiality risk is the minimum.**

#### **4.8 Risk-based approach**

Certification bodies need to take into account the risks associated with providing competent, consistent and impartial certification. Risks may include, but are not limited to, those associated with:

- the objectives of the audit;
- the sampling used in the audit process;
- real and perceived impartiality;
- legal, regulatory and liability issues;
- the client organization being audited and its operating environment;
- impact of the audit on the client and its activities;
- health and safety of the audit teams;
- perception of interested parties;
- misleading statements by the certified client;
- use of marks.



## 5.2 Management of impartiality

**5.2.3** 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.

NOTA 3 One way of fulfilling the consultation requirement of this clause is by the use of a committee of these interested parties.

**6.2? GONE!! Now the CSI is no more requires, it is only an option.**

**Interests partes has to be identified, but it is not necessary to have a meeting. The CB can make individual consultations (one by one), however a balanced involvement has to be considered.**

**Be aware that in the document review (10.2.5.2 ) there is this requirement  
"Gli input del riesame di direzione devono comprendere informazioni relative ...  
alle informazioni di ritorno da parte di clienti e parti interessate»**



**5.2.5** The certification body and any part of the same legal entity and any entity under the organizational control of the certification body [see 9.5.1.2, bullet b)] shall not offer or provide management system consultancy. This also applies to that part of government identified as the certification body.

NOTA This does not preclude the possibility of exchange of information (e.g. explanation of findings or clarification of requirements) between the certification body and its clients.

**It is in line with ISO 17065.**

**The CB has to be verified wholly.**

**This requirement is more stringent than in the past.**

Ask to the CBs to prepare the list of the organizations linked or controlled by the audited CB, to demonstrate their impartiality.



# The same concepts of ISO 17065 regarding “organization”

## 9.5 Certification decision

### 9.5.1 General

**9.5.1.2** The person(s) [excluding members of committees (see 6.1.4)] assigned by the certification body to make a certification decision shall be employed by, or shall be under legally enforceable arrangement with either the certification body or an entity under the organizational control of the certification body. A certification body’s organizational control shall be one of the following:

- a) whole or majority ownership of another entity by the certification body;
- b) majority participation by the certification body on the board of directors of another entity;
- c) una 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.



**The requirement to not certify for 2 years, in case of a conflict of interest, is no more a note, it is in the text (so, it is more strong than before).**

**5.2.6** The carrying out of internal audits by the certification body and any part of the same legal entity to its certified clients is a significant threat to impartiality. Therefore, the certification body and any part of the same legal entity and any entity under the organizational control of the certification body [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 certification body shall not certify a management system on which it provided internal audits for a minimum of two years following the completion of the internal audits.

**5.2.7** Where a client has received management systems consultancy from a body that has a relationship with a certification body, this is a significant threat to impartiality. A recognized mitigation of this threat is that the certification body shall not certify the management system for a minimum of two years following the end of the consultancy.



## 7.1.2 Determination of competence criteria

The certification body 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 management system 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 certification body 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.

**Automatically are mandatory all the standards of the “family” ISO 17021-xxxx**



## 7.1.2 Determination of competence criteria

Note The term “technical area” is applied differently depending on the management system standard being considered. For any management system, the term is related to products, processes and services in the context of the scope of the management system standard. The technical area can be defined by a specific certification scheme (e.g. ISO/TS 22003) or can be determined by the certification body. It is used to cover a number of other terms such as “scopes”, “categories”, “sectors”, etc., which are traditionally used in different management system disciplines.

**Now it is more clear the concept of technical area (that in the most of the times can be the same as ID01 codes)**





**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.

**Competence has to be consistent with the role.**

**Competence of decision maker is not the same of auditors: see also IAF MD10 and annex A of ISO 17021-1**



**7.2.10** The certification body shall monitor each auditor considering each type of management system 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 certification body 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.

**It has been changed observe with evaluate.**

**It is not necessary that the monitoring person is external of the team (observers)**

**Monitoring for EACH scheme (QMS, EMS, OHSAS..).**



## 7.5 Outsourcing

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

NOTE 1 For 7.5.1 to 7.5.4, where the certification body engages individuals or employees of other organizations to provide additional resources or expertise, these individuals do not constitute outsourcing provided they are individually contracted to operate under the certification body's management system (see 7.3).

**External people can take a decision (it is not outsourcing of a decision).**

**Also organizations under the control of the CAB can do it...like ISO 17065**



**8.1.2** The certification body shall provide upon request information about:

- a) geographical areas in which it operates;
- b) the status of a given certification;
- c) the name, related normative document, scope and geographical location (city and country) for a specific certified client.

**It is no more required to the CBs to have a database**

**Note: see the new IAF project on database (principles, case studies, 60.000 \$ for the consultant)**



## 8.2 The certification document(s) shall identify the following:

- a) 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);
- b) 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;
- c) the expiry date or recertification due date consistent with the recertification cycle;
- f) the scope of certification with respect to the type of activities, products and services as applicable at each site **without being misleading or ambiguous;**

**Effective date can be after the decision (never before)... also 10 days later to have the full payment from the Client (in this case, the certificates will last 3 years less 10 days)**

**Deadline consistent with certification cycle**

**Avoid that MS certificate is considered a product certification!**



**It is possible to keep the expiry date every 3 years (like credit cards!).**

**It has been include the relevamt IAF decision o this topic.**

**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.



### 9.1.3 Audit programme

**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 management system, products and processes as well as demonstrated level of management system effectiveness and the results of any previous audits.

**Certification cycle starts AFTER decisions.**

**So, 2 surveillances and 1 renewal.**

**This could have an influence on ISO 17011**

**VERY IMPORTANT for the coverage of the scope in the cycle**

**9.1.3.2 some exceptions are allowed (see ISO 20121)**

NOTA 3 If specified by the industry specific certification scheme, the certification cycle can be different from three years.



## 9.1.3 Audit programme

### 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.

NOTA It can be necessary to adjust the frequency of surveillance audits to accommodate factors such as seasons or management systems certification of a limited duration (e.g. temporary construction site).

**9.1.3.5** Where the client operates shifts, the activities that take place during shift working shall be considered when developing the audit programme and audit plans.





**ISO 17023 is included into this standard.**

**Definition of “duration of a MS audit” is in line with ISO 17023 and MD05**

#### **9.1.4 Determining audit time**

**9.1.4.2** In determining the audit time, the certification body shall consider, among other things, the following aspects:

- the requirements of the relevant management system standard;
- complexity of the client and its management system;
- technological and regulatory context;
- any outsourcing of any activities included in the scope of the management system;
- the results of any prior audits;
- size and number of sites, their geographical locations and multi-site considerations;
- the risks associated with the products, processes or activities of the organization;
- whether audits are combined, joint or integrated.



NOTE 1 Time spent travelling to and from audited sites is not included in the calculation of the duration of the management system audit days.

NOTE 2 The certification body can use the guidelines established in ISO/IEC TS 17023 for determining the duration of management system audit when documenting these procedures. 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 management system 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 management system audit.



## It is more clear now the competence required in the Team for integrated MS

### 9.2.2.1.2

NOTE The team leader of a combined or integrated audit is expected to have in-depth knowledge of at least one of the standards and an awareness of the other standards used for that particular audit.



**This requirement is still HERE!  
In one draft it was disappeared.**

**ISO /TS 17022 will be deleted.  
All the requirements with “shall” has been incorporated.**

### **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.



#### 9.4.10 Effectiveness of corrections and corrective actions

The certification body shall review the corrections, identified causes and corrective actions submitted by the client to determine if these are acceptable. The certification body shall verify the effectiveness of any correction and corrective actions taken. The evidence obtained to support the resolution of nonconformities shall be recorded. The client shall be informed of the result of the review and verification. 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 Verification of effectiveness of correction and corrective action can be carried out based on a review of documented information provided by the client, or where necessary, through verification on-site. Usually this activity is done by a member of the audit team.

**At least now there is an indication on who has to evaluate the Corrective actions**



## 8.3 Reference to certification and use of marks

**8.3.1** ...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.

**8.3.3** A certification body shall have rules governing the use of any statement on product packaging or in accompanying information that the certified client has a certified management system. 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 management system (e.g. quality, environment) and the applicable standard;
- the certification body issuing the certificate.



The initial certification audit of a management system 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 Stage 1 does not require a formal audit plan (see 9.2.3).

**Is it now clear that it is not necessary the audit plan for STAGE 1**



### 9.5.3 Information for granting initial certification

**9.5.3.2** If the certification body 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 certification body shall conduct another stage 2 prior to recommending certification.

**9.5.3.3** When a transfer of certification is envisaged from one certification body to another, the accepting certification body shall have a process for obtaining sufficient information in order to take a decision on certification.

**Transfer is now present in the standard.**

**Now it is clear what to do if stage 2 goes wrong (do again stage 2 if it takes more than 6 months to close Major NCs)**





## 9.6.3 Recertification

### 9.6.3.1 Recertification audit planning

**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 certification body has not completed the recertification audit or the certification body 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 certification body 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.



## See decision of IAF and Accredia circular letter

DC2016SSV311.pdf - Adobe Acrobat Reader DC

File Modifica Vista Finestra ?

Home Strumenti DC2016SSV311.pdf x Accedi

1 / 3 146%

**Subject.: ACCREDIA Department of Certification and Inspection – Circular n. 28/2016**  
**Clarifications regarding recent interpretations published by the Maintenance Group of ISO CASCO concerning the topics:**

- **Renewal of certification**
- **Certification of a CB in accordance with ISO 9001**
- **Temporary Site on certificates**
- **Periodicity of internal audits**

The ISO/CASCO Maintenance Group recently published four interpretations of ISO/IEC 17021-1:2015, attached herewith. The documents can be found, in their updated version, in the ISO website [http://www.iso.org/iso/conformity-assessment\\_resources](http://www.iso.org/iso/conformity-assessment_resources)

Some clarifications are given below:

**1. ISO/IEC 17021-1:2015, 9.6.3.2.4 and 9.6.3.2.5 – Renewal of certification**

If renewal activities are not successfully completed within the expiry date of the certificate it is necessary to proceed – depending on applicability – as follows:

a) *Renewal activity (verification and decision) begins before or after the date of expiry of the certification and*

210 x 297 mm



### 9.6.3.2.5

Write the effective date of the certificate, and the expire has to be consistent with the previous cycle.

### 8.2.2

**If you want to write ALSO the first issue date, so you have to specify the interval**

#### **Example:**

- First issue: 01/01/2010
- First expiry date: 01/01/2013
- Renewal (in late.. After 3 monthes): 31/03/2013
- Decision on renewal: 01/04/2013

#### **So, you have 2 options:**

- Or only 01/04/2013 (Decision on renewal) and expiry 01/01/2016 (consistent with the previous cycle)
- If you want to write also the First issue, than you have to write also 01/01/2010 (First issue) and the expiry of the first cycle: 01/01/2013. this is importat to make clear that for 3 monthes the certificates was not valid at all

**Very important for tenders!!**

### 9.6.4.1 Expanding scope

The certification body 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.

**Extention of scope can be made during surveillance**



### 9.6.4.2 Short-notice audits

It may be necessary for the certification body 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:

- the certification body 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;
- the certification body shall exercise additional care in the assignment of the audit team because of the lack of opportunity for the client to object to audit team members.

**It is possible for the CB to do audit without notice!**

**It could be possible to do also unannounced audit (mystery audit).**



## 5.1.2 Certification agreement

The certification body 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 certification body or multiple sites of a client, the certification body shall ensure there is a legally enforceable agreement between the certification body granting certification and the client that covers all the sites within the scope of the certification.

NOTE An agreement can be achieved through multiple agreements that reference or otherwise link to one another.

l'organismo di certificazione deve garantire l'esistenza di un contratto legalmente valido fra l'organismo di certificazione che rilascia la certificazione ed il cliente, stipulato direttamente o tramite un intermediario formalmente autorizzato da parte dell'OdC

**So, a contract can be signed by an Agency, if there is an agreements between the CB and the agency, and if the contract has effects to the CB.**



## Annex A (normative)

### Tabella A.1 – Required knowledge and skills

Knowledge and skills	Conducting the application review to determine audit team competence required, to select the audit team members, and to determine the audit time	Reviewing audit reports and making certification decisions	Auditing and leading the audit team
Knowledge of business management practices			X (A.2.1)
Knowledge of audit principles, practices and techniques		X (A.3.1)	X (A.2.2)
Knowledge of specific management system standards/normative documents	X (A.4.1)	X (A.3.2)	X (A.2.3)
Knowledge of certification body's processes	X (A.4.2)	X (A.3.3)	X (A.2.4)
Knowledge of client's business sector	X (A.4.3)	X(A.3.4)	X (A.2.5)
Knowledge of client products, processes and organization	X (A.4.4)		X (A.2.6)
Language skills appropriate to all levels within the client organization			X (A.2.7)
Note-taking and report-writing skills			X (A.2.8)
Presentation skills			X (A.2.9)
Interviewing skills			X (A.2.10)
Audit-management skills			X (A.2.11)

**Annex A ha been explained for each point**

The x has not the same meaning!

