



Support for the National Accreditation Centre MOLDAC
to successfully undergo the EA peer evaluation process
Twinning Project MD14/ENPI/TR/20



ISO/IEC 17021-1: 2015

Key Changes from ISO/IEC 17021:2011

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Purpose

To highlight the key changes of [ISO/IEC 17021-1](#)
“Conformity assessment—Requirements for
bodies providing audit and certification of
management systems – Part 1 Requirements”
Published 15 June 2015
Full conformance of CBs after 24 months ([IAF ID11:2015](#))





Overview – Rationale for the revision

- Several interpretation requests were addressed since the publication of the standard and should be taken into consideration in any revision.
- Experience gained with the implementation of the standard has highlighted the need for clarification of some of the clauses





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The Changes

Classification of nonconformities





Overview – Some Key Changes

- Defines/Classifies nonconformities as major (3.12) and minor (3.13)





Changes – Classification of nonconformities

A Nonconformity is a non-fulfilment of a requirement (3.11)

A Minor Nonconformity does not affect the capability of the management system to achieve the intended results **(3.13)**

A Major Nonconformity affects the capability of the management system to achieve the intended results:

- if there is a **significant doubt** that effective process control is in place, or that products or services will meet specified requirements;
- when a number of minor nonconformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major nonconformity. **(3.12)**





ISO/IEC 17021-1 : 2015

The Changes

Risk based approach





Overview – Some Key Changes

- Adds one new principle for a risk-based approach (4.8)





Changes – 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 (4.8):
 - *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.*





ISO/IEC 17021-1 : 2015

The Changes Impartiality and Organisation





Overview – Some Key Changes

- Adopts a similar approach in ISO/IEC 17065 and not require, but still allow, an impartiality committee (5.2.3)





The changes – Impartiality and Organisation

- 5.2.3 The CBa process to identify, analyse, evaluate, treat, monitor and document risks related to conflicts of interest..... on an ongoing basis.

.....

- Top Management shall review any residual risks to determine if they are within the level of acceptable risk.





The changes – Impartiality and Organisation

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 Sources of threats to impartiality of the certification body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, training, marketing and payment of a sales commission or other inducement for the referral of new clients, etc.

NOTE 2 Interested parties can include personnel and clients of the certification body, customers of organizations whose management systems are certified, representatives of industry trade associations, representatives of governmental regulatory bodies or other governmental services, or representatives of non-governmental organizations, including consumer organizations.

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





The changes – Impartiality and Organisation

5.2.3 - **No mandatory requirement for a committee to safeguard impartiality** BUT the risk assessment process shall include identification of and consultation with appropriate interested parties to advise on matters affecting impartiality – consultation balanced , no single interest predominating.





The changes – Impartiality and Organisation

A committee is still acceptable provided the requirements for terms of reference 6.1.4 establish their input, structure, operation etc., and are confirmed .

Note

Risks must be documented, interested parties identified and consultation shall be balanced





The changes – Impartiality and Organisation

5.2.4

A Management System certification body cannot certify another certification body for its QMS.

now CB can certify other MANAGEMENT SYSTEMS of CBs.(e.g. EMS; OHSAS; ISMS)





The changes – Impartiality and Organisation

Introduces “Organisational Control” i.e. where the CB

- **owns another entity**
- **has major participation on board of directors of entity**
- **has provided documented authority over another entity in a network of legal entities in which CB resides, e.g. a holding company or group with many divisions.**

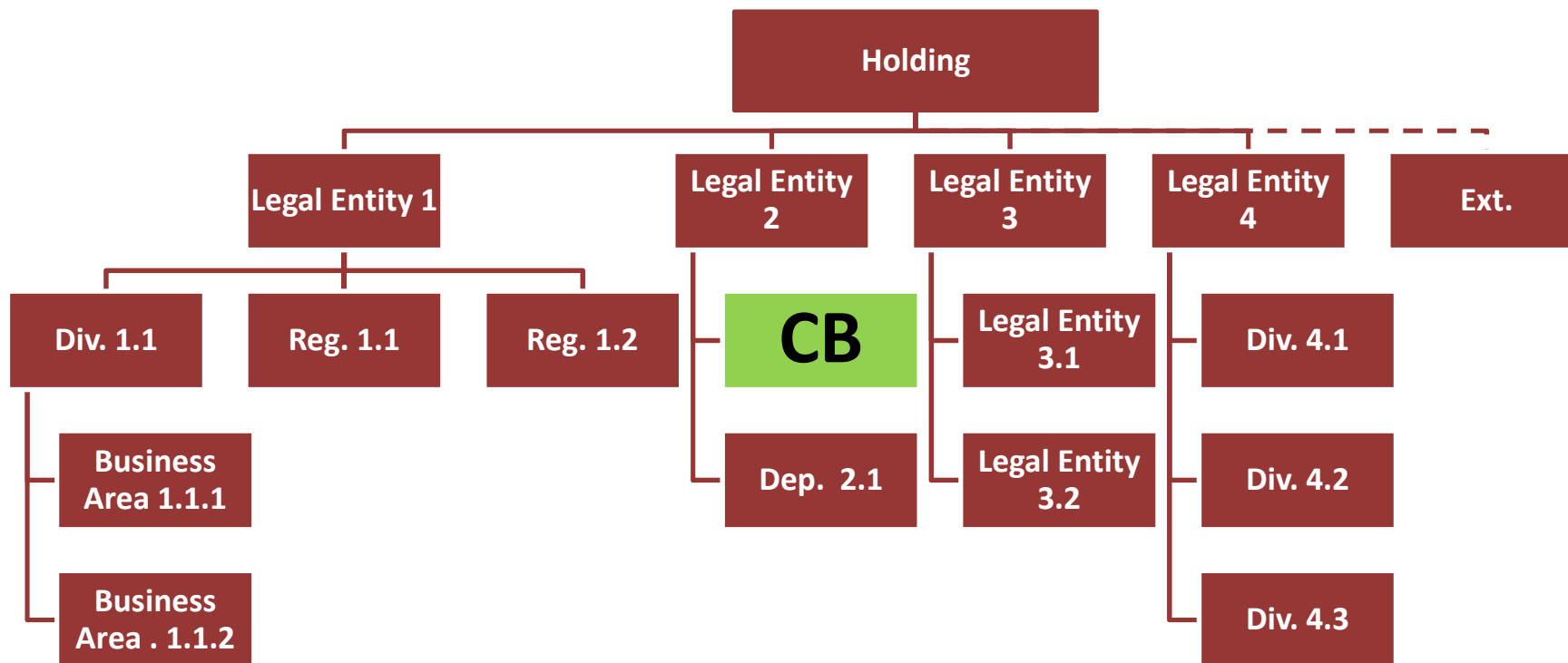
Entities under organisational control cannot offer:

- **Consultancy**
- **Internal audits for certified clients**





How a CB can be positioned in a bigger organisation?





The changes – Impartiality and Organisation

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.





The changes – Impartiality and Organisation

“Organisational Control” could relate to:

- A sister organisation
- A company based overseas owned by the CB
- A joint venture
- A franchise
- An agent.

Organisational Control is not:

- Outsourcing
- Individuals working directly for the CB





The changes – Impartiality and Organisation

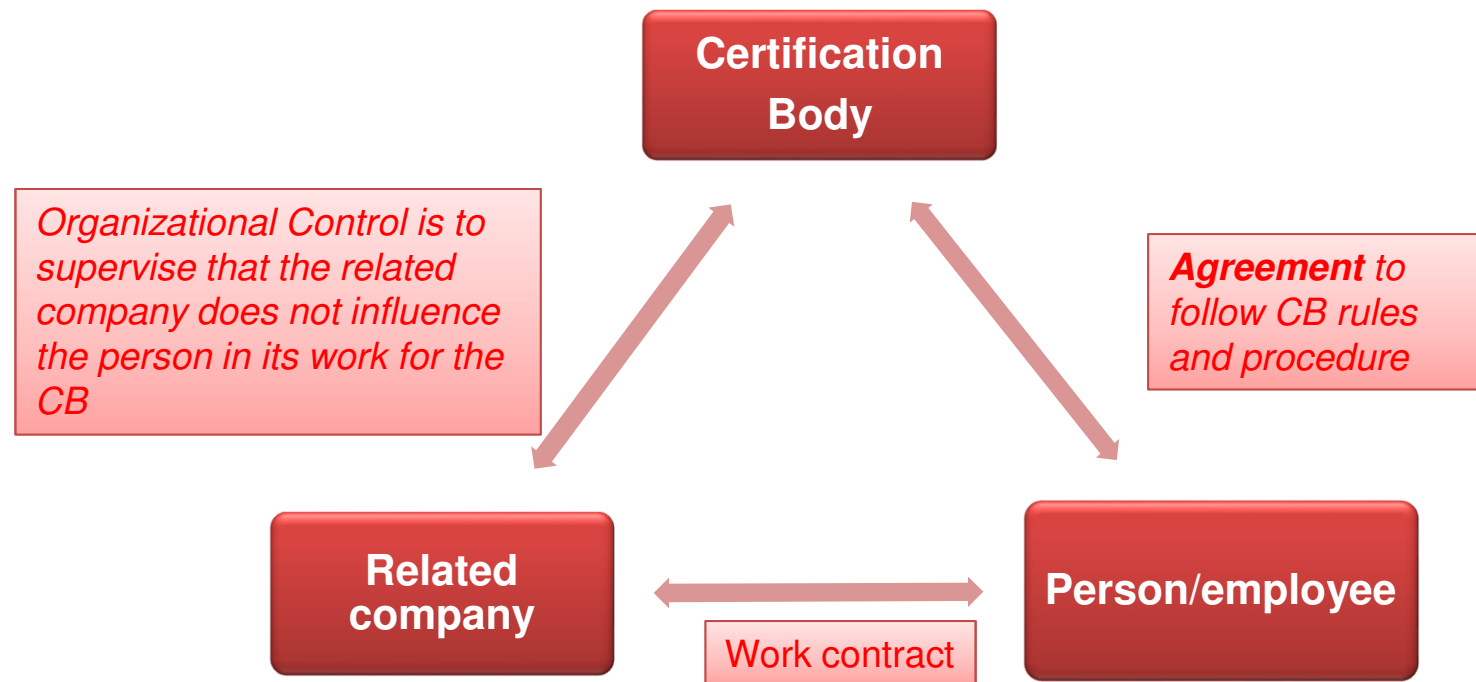
Improving control by CBs

- Requirement for a CB to demonstrate effective operational control of its remote offices and personnel regardless of their organizational structure (6.2)
 - *branch offices, partnerships, agents, franchisees, etc., irrespective of their legal status, relationship or geographical location.*
- Requirement for a CB to demonstrate effective organizational control for persons making certification decisions (DM) (9.5)
 - *The DM employed by, or under contract with, entities under organizational control shall fulfil the same requirements as persons employed by, or under contract with, the certification body. "... → shall have appropriate competence"*





This is one possibility for organizational control among many



This relates to Clauses 5.2.5 of ISO 17021-1 and 7.6.4 of ISO 17065.





Comparison with clause 7.6.4 of ISO/IEC 17065

7.6.4 A certification body's organizational control shall be one of the following:

- 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.

NOTE For governmental certification bodies, other parts of the same government can be considered to be "linked by ownership" to the certification body.





ISO/IEC 17021-1 : 2015

The Changes

Information Requirements





The changes – Information Requirements

8.1 Public Information

Adopted same approach as ISO/IEC 17024 regarding public information with, or without, request (8.1)

- **Public without request** in all geographical areas:
 - *Audit process, certification grant, withdrawal, suspension process, complaints appeals, impartiality, policy, use of name/marks etc.*
- **Information on request:** -
 - *Geographical areas, status of a given certificate, details re certification of a specified client*

No longer requiring a “public” directory of certifications granted





The changes – Information Requirements

8.2 Certification Document

New “note” included regarding dates when certificate expires and where there is a gap before re-certification decision /date.

“NOTE: The certification body can keep the original certification date on the certificate when a certificate lapses for a period of time provided that:

- The current certification cycle start and expiry date are clearly indicated;
- The last certification cycle expiry date be indicated along with the date of recertification audit.”





The changes – Information Requirements

Marks on Products

Now allows a statement, but no mark, on product packaging (not on product) and accompanying literature that a company has a certified management system (8.3.3)

- cannot imply the product is certified.
- to include the name of the CB.





ISO/IEC 17021-1 : 2015

The Changes

Competence criteria





Determination of competence criteria 7.1.2 – No changes

- 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.





The changes - Determination of competence criteria (7.1.2)

- 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.





The changes - Competence criteria (Annex A)

- Normative Annex A revised to include expanded statements explaining competence requirements
- Eliminates the X and X+ (*felt to have created some confusion for the users*)
- Now 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.**





Annex A - Technical specifications Specific competence requirements

- [ISO/IEC 17021-1](#): generic competence requirements for any MS
- [ISO/IEC TS 17021-2](#): competence for EMS
- [ISO/IEC TS 17021-3](#): competence for QMS
- ISO/IEC TS 17021-4: competence for event sustainability MS
- ISO/IEC TS 17021-5: competence for asset MS
- ISO/IEC TS 17021-6: competence for business continuity MS
- [ISO/IEC TS 17021-7](#): competence for road traffic safety MS
- ISO TS 22003: includes competence for food safety MS
- ISO 28003: includes competence for supply chain security MS
- ISO 50003: includes competence for energy MS
- ISO/IEC 27006: includes competence for information security MS





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The Changes

Process Requirements





The changes – Process Requirements

Section 9

Requirements now re-ordered to reflect how certification audits and services are provided by a CB





Process Requirements – Determining audit time

Defined **audit time** from planning to reporting

- 3.16 - Time needed to plan and accomplish a complete and effective audit of the client organization's

Defined **audit duration** from opening to closing meeting (3.17)

- 3.17 Part of audit time (3.16) spent conducting audit activities from the opening meeting to the closing

Refocused requirements for justification on audit duration

- 9.1.4.3 - The duration of the management system audit and its justification shall be recorded.

Consistent with ISO/IEC TS 17023 guidelines & revision of IAF MD5 defining audit time

This clarification is important as it reinforced the existing requirement that the CB shall “determine the time needed to plan and accomplish a complete and effective audit” (9.1.4.1)





Process Requirements – Audit programme

- New requirement on transfers requiring a CB to obtain and retain sufficient evidence such as reports and documentation on corrective actions for prior nonconformities (9.1.3.4) - (see also [MD2:2007](#))
- New requirement for consideration of shifts in the audit program (9.1.3.5) - (see also [MD5:2015](#))
- New requirement to plan for adequate auditing when certifying to multiple management systems standards (9.1.6) - (see also [MD11:2013](#))





Process Requirements – Granting Certification

- If a CB is unable to verify effective correction and corrective action 6 months after an **initial** audit, another Stage 2 shall be conducted (9.5.3.2)
 - Based on the change above the requirement for the first surveillance audit after initial certification is now 12 months after the initial certification decision date (9.1.3.3) (No longer 12 months after stage 2)
- When a transfer of certification is envisaged from one certification body to another, the accepting certification shall have a process for obtaining sufficient information in order to take a decision on certification (9.5.3.3) – (see [MD-02:2007](#))





Process Requirements – Maintaining certification

- When **recertification** is completed prior to expiration, the expiration date can be based on the existing certification so certification may be longer than 3 years) (9.6.3.2.3)
 - ***The issue date on a new certificate shall be on or after the recertification decision.***
- If the recertification audit is not completed, or any major nonconformity not verified, by the expiration date, then recertification cannot be recommended and the validity of the certification cannot be extended (9.6.3.2.4)
- Six months allowed for recertification following expiration of certification; otherwise, a Stage 2 shall be conducted (9.6.3.2.5)





Process Requirements – Audit report

9.4.8.3 (a) - New requirement (from consideration of ISO/IEC TS 17022:2012)

The report shall also contain:

- a) statement on the conformity and the effectiveness of the management system **together with a summary of the evidence relating to:**
 - *the capability of the management system to meet applicable requirements and expected outcomes;*
 - *the internal audit and management review process;*
- b) **a conclusion on the appropriateness of the certification scope;**
- c) confirmation that the audit objectives have been fulfilled.





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Workshop Exercises



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Workshop Exercise 1

THE FOLLOWING IS / IS NOT CONSIDERED CONSULTANCY?	YES	NO
1 - Preparing or producing manuals or procedures		
2 - Giving solutions towards the development and implementation of a management system.		
3 - Arranging training and participating as a trainer in a course related to management systems or auditing, which provides client-specific solutions.		
4 - Explaining the meaning and intention of certification criteria;		
5 - Arranging training and participating as a trainer in a course related to management systems or auditing, which provides generic information		
6 - Explaining associated theories, methodologies, techniques or tools;		
7 - Sharing non-confidential information on related best practices;		
8 - Explaining management aspects that are not covered by the management system being audited.		
9 - Giving specific advice, instructions towards the development and implementation of a management system.		
10 - Identifying generic improvement opportunities;		
11 - Is any kind of training a threat to impartiality of the CB that need that shal subject to risk analys of conflict of interest?		
12 – Is the preparation of a risk analysis to be considered an implementation of a management system?		





Workshop Exercise 2

Based on the presentation, please consider the following question:

According to 5.2.5 an entity under the organizational control of the CB cannot offer or provide consultancy.

But what if the CB is under the organisational control of the consultancy organisation, for example if the consultancy organisation has a major participation in the board of directors of the CB?





Workshop Exercise 3

Based on the presentation, please consider the following question:

What are the implications of the changes to impartiality requirements, especially with regard to the removal of the specific requirement for an impartiality committee;

- *what changes and alternatives might be implemented by Certification Bodies?*
- *what do NABs need to do differently to assess them?*





Workshop Exercise 4

Based on the presentation, please consider the following question:

Consider clauses 9.6.3.2.4 and 9.6.3.2.5. Please offer a practical interpretation of these clauses in terms of decision dates and information on certificates.

Can a CB take a recertification decision after the expiry date of the certification ?





Workshop Exercise 5

Based on the presentation, please choose the only acceptable combination of requirements to be fulfilled prior to making a decision to grant a certification:

A - the information provided by the audit team is sufficient with respect to the certification requirements and the scope for certification;

B - for any nonconformities, it has reviewed, accepted and verified the correction and corrective actions;

C - for any minor nonconformities it has reviewed and accepted the client's plan for correction and corrective action.

D - for any major nonconformities, it has reviewed, accepted and verified the correction and corrective actions;

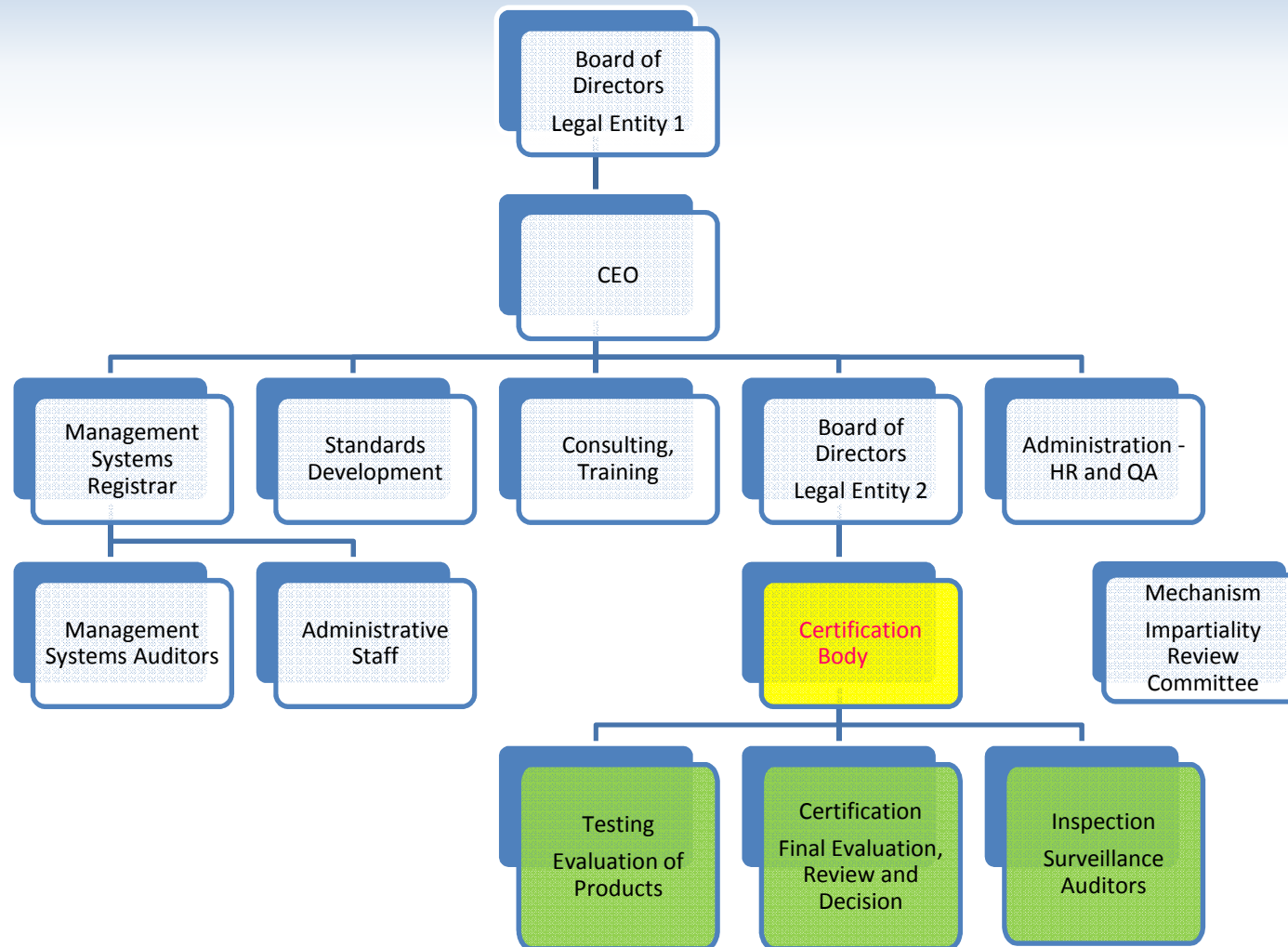
E - for any nonconformities it has reviewed and accepted the client's plan for correction and corrective action.

Combination	YES	NO
B + C		
C + D		
A + C + D		
A + E		
A + B + D		



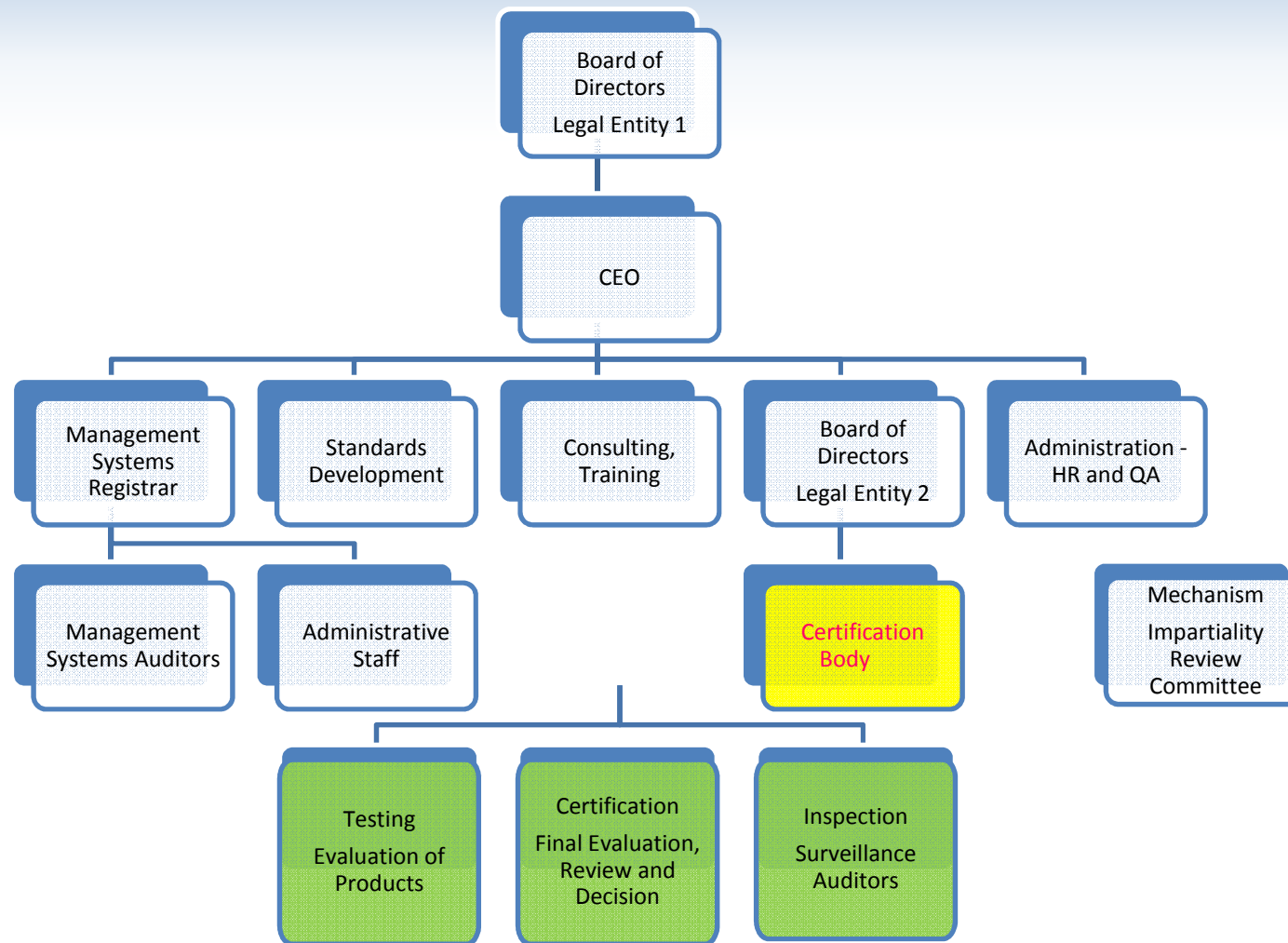


Workshop Exercise 6 - **Acceptable?**





Workshop Exercise 7 - **Acceptable?**





Workshop Exercise 8 - **Acceptable?**

