

Differences between ISO/IEC 17021:2011 and ISO/IEC 17021-1:2015

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Clause No	ISO/IEC 17021-1:2015 Clause	ISO/IEC 17021:2011 Clause No	Notes on changes
	Foreword	Foreword	
	Introduction	Introduction	
1	Scope	1	
2	Normative references	2	
3	Terms and definitions	3	Added definitions for: 3.11 Nonconformity 3.12 Major nonconformity 3.13 Minor nonconformity 3.14 Technical expert 3.15 Certification scheme 3.16 Audit time 3.17 Duration of management system certification audits
4	Principles	4	
4.1	General	4.1	
4.2	Impartiality	4.2	
4.3	Competence	4.3	
4.4	Responsibility	4.4	

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4.5	Openness	4.5	
4.6	Confidentiality	4.6	
4.7	Responsiveness to complaints	4.7	
4.8	Risk-based approach	NA	New principle added
5	General requirements	5	
5.1	Legal and contractual matters	5.1	
5.1.1	Legal responsibility	5.1.1	
5.1.2	Certification agreement	5.1.2	Additional note regarding linked agreements
5.1.3	Responsibility for certification decisions	5.1.3	Addition of refusing, renewing and restoring following suspension of certification
5.2	Management of impartiality	5.2	
5.2.1		NA	New requirement. Not a new concept, but now a shift away from having a committee to stating the CAB is responsible for impartiality. Some duplication with 5.2.12
5.2.2		5.2.1	Second sentence: 'publicly accessible statement' is replaced by 'policy', but 8.1.1 (f) requires it to be made public.
5.2.3		5.2.2, 5.2.3 and 6.2.3	First sentence amended to require 'a process to identify, analyse, evaluate, treat, monitor and document the risks related to Col'. Second sentence talks about documenting residual risk. Third sentence covers internal and external threats to impartiality. Additional sentence re the need to review any residual risk to determine if it is within the level of acceptable risk. New note 3 allows committee approach to be retained

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5.2.4		5.2.4	Replaced 'management system certification activities' with 'quality management system'.
5.2.5		5.2.5	Included 'and any entity under the organisational control of the certification body (see 9.5.1.2 b))'. Also added a note re exchange of information.
5.2.6		5.2.6	Includes recognised mitigation as two years separation Also expanded to include bodies under organisational control
5.2.7		5.2.7	Includes recognised mitigation as two years separation
5.2.8		5.2.8	
5.2.9		5.2.9	
5.2.10		5.2.10	Reworded to include recognised mitigation as two years separation in line with 5.2.6 and 5.2.7.
5.2.11		5.2.11	
5.2.12		5.2.12	
5.2.13		5.2.13	Amended to include requirement for recording of conflicts of interest
5.3	Liability and financing		
5.3.1		5.3.1	
5.3.2		5.3.2	Removed the need for the Impartiality Committee to review income analysis
6	Structural requirements	6	
6.1	Organizational structure and top management	6.1	
6.1.1		6.1.1	

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6.1.2		NA	New requirement. Requires certification activities to be structured so as to ensure impartiality.
6.1.3		6.1.2	a) add 'and establishment of processes and procedures relating to its operations' b) include 'processes' c) new requirement – ensuring impartiality.
6.1.4		6.1.3	
6.2	Operational control	NA	
6.2.1		NA	New requirement. Emphasis on the control of sites, agencies and franchisees
6.2.2		NA	New requirement. Requirements CAB to establish appropriate level and method of control activities.
7	Resource requirements	7	
7.1	Competence of personnel	7.1	Heading was 'Competence of management and personnel'
7.1.1	General considerations	7.1.1	First para expanded to include skills Second para removed as duplication of requirements in 7.1.2 3 rd para moved to 7.1.3
7.1.2	Determination of competence criteria	7.1.2	Examples taken out of the NOTE and generic statement included.
7.1.3	Evaluation processes	7.1.3	Third para of old 7.1.1 inserted requiring competence to be demonstrated prior to performing activities. Note 2 added. Makes reference to Annex C
7.1.4	Other considerations	7.1.4.2	Old 7.1.4.1 deleted
7.2	Personnel involved in the certification activities		

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7.2.1		7.2.1	Deleted 'as part of its own organisation'. Different words same intent
7.2.2		7.2.2	
7.2.3		7.2.3	
7.2.4		7.2.4	
7.2.5		7.2.5	
7.2.6		7.2.6	
		7.2.7	Old clause has been deleted
7.2.7		7.2.8	
7.2.8		7.2.9	Added refusing, restoring, expanding or reducing the scope of certification.
7.2.9		7.2.10	" Add 'record' competence
7.2.10		7.2.11	Add requirement for monitoring each auditor 'considering each type of management system to which the auditor is deemed competent'.
7.2.11		7.2.12	Replace 'observation' with 'evaluation'.
7.3	Use of individual external auditors and external technical experts	7.3	Independence from commercial and other interests replaced with impartiality. NOTE reworded
7.4	Personnel records	7.4	Deleted the need for personnel records to include 'and any relevant consultancy services that they may have been provided'.
7.5	Outsourcing	7.5	
7.5.1		7.5.1	Two NOTES removed to end of clause.

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			Note 1 different words same intent
7.5.2		7.5.2	Added refusing, restoring, expanding or reducing the scope of certification.
7.5.3		7.5.3	
7.5.4		7.5.4	'Procedures' replaced by 'process' and 'qualification' replaced by 'approval'.
8	Information requirements		
8.1	Public information	8.1	Heading changed from 'Publicly accessible information'
8.1.1		8.1.1, 8.1.3, 8.1.4	Reworked 8.1.1, 8.1.3 and 8.1.4 into a list. Without request is important, as it replaces 'publicly accessible'. 8.1.1 (c) introduces types of management systems and certification schemes in which it operates 8.1.1 (f) old 5.2.1 publicly accessible statement now reads policy on impartiality
8.1.2		8.1.1, 8.1.3, 8.1.4	c) is a new requirement. New NOTE 1 is old NOTE 2. Added a new NOTE 2.
8.1.3		8.1.2	
8.2	Certification documents		
8.2.1		8.2.1	Reworded
8.2.2		8.2.2 & 8.2.3	b) amended to reflect the 'effective' date of granting 'expanding or reducing the scope of certification, or renewing' certification. NOTE added under b) e) reworded f) changes to 'activities, products and services' and words added to the end 'without being misleading or ambiguous'.

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		8.3	Old clause deleted
8.3	Reference to certification and use of marks	8.4	
8.3.1		8.4.1	'Policy' for use of marks replaced with 'rules'. 'Mark' expanded to 'management systems' third party mark'. Deleted 'seen by the consumer'.
8.3.2		8.4.2	Added: not permits marks be applied "by certified clients" on reports and "certificates"
8.3.3		NA	New requirement. Now allows use of statements on packaging.
8.3.4		8.4.3	Added 'through legally enforceable arrangements'.
8.3.5		8.4.4	
8.4	Confidentiality	8.5	
8.4.1		8.5.1	Reworded
8.4.2		8.5.2	
8.4.3		8.5.3	
8.4.4		8.5.3	Added 'or authorised by contractual arrangements (such as with the accreditation body)'.
8.4.5		8.5.4	
8.4.6		8.5.5	Added 'except as required by law'.
8.4.7		8.5.6	Added requirement for 'processes' that ensure secure handling of confidential information.
8.5	Information exchange between a certification body and its clients	8.6	
8.5.1	Information on the certification activity and requirements	8.6.1	a) Added refusing, expanding or reducing the scope of certification, renewing and restoring certification.

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			d) Deleted 'prospective'
8.5.2	Notice of changes by a certification body	8.6.2	NOTE removed
8.5.3	Notice of changes by a certified client.	8.6.3	Added 'The certification body shall take action as appropriate'. NOTE re Guide 28 removed
9	Process requirements		
9.1	Pre-certification activities		
9.1.1	Application	9.2.1	added 'specific certification schemes & sites, its processes, human and technical resources, functions, relationships'. e) added 'if so, by whom'.
9.1.2	Application review	9.2.2	
9.1.2.1		9.2.2.1	a) added 'to develop an audit programme (see 9.1.3). b) deleted from old clause
9.1.2.2		9.2.2.2	NOTE deleted
9.1.2.3		9.2.2.3	
9.1.3	Audit programme	9.1.1	
9.1.3.1		9.1.1.1	Added further sentence 'the audit programme for the certification cycle shall cover the complete management system requirements'.
9.1.3.2		9.1.1.2 Annex F	Now differentiates between the audit programme for the initial certification cycle and subsequent certification cycles. Informative annex F reduced to a set of dot points in a NOTE. Note 3 added
9.1.3.3		9.3.2.2	Clarifies that surveillances need to be undertaken once in a 'calendar' year, except in recertification years

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			NOTE added re adjustment of frequency to accommodate factors.
9.1.3.4		9.1.1.3	Now also includes types of evidence to be obtained and retained.
9.1.3.5		NA	Specific requirement for auditing of shifts.
9.1.4	Determining audit time	9.1.4	
9.1.4.1		9.1.4.1	
9.1.4.2		9.1.4.1	Two NOTES added "size" from old 9.1.4.1 b) moved to 9.1.4.2 f) Old 9.1.4.1 b has added management system to form 9.1.4.2 b)
9.1.4.3		9.1.4.1	
9.1.4.4		9.1.4.2	'Audit time' changed to 'duration of the management system audit'
9.1.5	Multi-site sampling	9.1.5	Introduces sampling around scheme Note added
9.1.6	Multiple management systems	NA	New requirements regarding auditing of systems against multiple management system standards.
9.2	Planning audits	9.1.2	Audit plan
		9.1.2.1	Old clause deleted
9.2.1	Determining audit objectives, scope and criteria	9.1.2.2	
9.2.1.1		9.1.2.2.1	
9.2.1.2		9.1.2.2.2	b) and c) evaluation has been replaced by determination c) "organization is continually meeting" replaced by "can reasonably expect to achieving" Note deleted

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9.2.1.3		9.1.2.2.3	Changes 'locations' to 'sites'.
9.2.1.4		9.1.2.2.4	
9.2.2	Audit team selection and assignments	9.1.3	
9.2.2.1	General	NA	
9.2.2.1.1		9.1.3.1	Added 'and technical experts'. Also added that the audit team shall have the totality of the competencies identified for the audit.
9.2.2.1.2		9.1.3.2	f) removed, but mention of impartiality in 9.2.2.1.1 NOTE added re the knowledge of the team leader of an integrated management system audit.
9.2.2.1.3		9.1.3.3	
9.2.2.1.4		9.1.3.4	
9.2.2.1.5		9.1.3.5	
9.2.2.2	Observers, technical experts and guides	9.1.9.4	Technical experts added
9.2.2.2.1	Observers	9.1.9.4.1	
9.2.2.2.2	Technical experts	NA	New Requirements. Added requirements around the role of the Technical Expert.
9.2.2.2.3	Guides	9.1.9.4.2	Note 2 added
9.2.3	Audit plan	9.1.2	
9.2.3.1	General	9.1.2.1	Deleted second sentence NOTE added
9.2.3.2	Preparing the audit plan	9.1.2.3	Added 'and remote auditing activities' to d) Note 2 deleted e) time removed

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			f) examples of accompanying persons added e.g. observers and interpreters
9.2.3.3	Communication of audit team tasks	9.1.6	Deleted 'and shall be made known to the client organisation' d) old words in brackets and "and the results" deleted
9.2.3.4	Communication of audit plan	9.1.8	
9.2.3.5	Communication concerning audit team members	9.1.7	
9.3	Initial certification	NA	
9.3.1	Initial certification audit	9.2.3	
9.3.1.1	General	9.2.3	
9.3.1.2	Stage 1	9.2.3.1	
9.3.1.2.1		NA	New requirement – planning shall ensure objectives of stage 1 can be met Note added – Stage 1 does not require formal audit report
9.3.1.2.2		9.2.3.1.1	Sets objectives for the Stage 1 audit rather than requirements. d) levels of control included f) "possible significant aspects" changed to "management systems standards or other normative documents" the recommendation at end of list put into a new Note
9.3.1.2.3		9.2.3.1.2	
9.3.1.2.4		9.2.3.1.3	'Significant changes...' added
9.3.1.3	Stage 2	9.2.3.2	c) " legal compliance" replaced by "meeting of applicable statutory, regulatory and contractual requirements" Old g) deleted

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9.3.1.4	Initial certification audit conclusions	9.2.4	
9.4	Conducting audits	9.1.9	Replaced heading 'Conducting on-site audits'
9.4.1	General	9.1.9.1	2 nd Para added, introduces electronic means and virtual audits
9.4.2	Conducting the opening meeting	9.1.9.2	No need to record attendance
9.4.3	Communication during the audit	9.1.9.3	
9.4.3.1		9.1.9.3.1	
9.4.3.2		9.1.9.3.2	
9.4.3.3		9.1.9.3.3	
9.4.4	Obtaining and verifying information	9.1.9.5	'Collecting' replaced by 'Obtaining' throughout clause
9.4.4.1		9.1.9.5.1	
9.4.4.2		9.1.9.5.2	
9.4.5	Identifying and recording audit findings	9.1.9.6	
9.4.5.1		9.1.9.6.1	Deleted 'and its supporting audit evidence'. "recorded and reported" changed to "identified, classified and recorded"
9.4.5.2		9.1.9.6.2	Removed reference to definition of nonconformity as this has been removed and included in definitions.
9.4.5.3		9.1.9.6.3	NOTE deleted
9.4.5.4		9.1.9.6.4	
9.4.6	Preparing audit conclusions	9.1.9.7	Includes that this is the responsibility of the audit team leader. a) Audit criteria and classify nonconformities added d) 'for future audits' added
9.4.7	Conducting the closing meeting	9.1.9.8	

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9.4.7.1		9.1.9.8.1	
9.4.7.2		9.1.9.8.2	
9.4.7.3		9.1.9.8.3	
9.4.8	Audit report	9.1.10	
9.4.8.1		9.1.10.1	
9.4.8.2		9.1.10.2	Sub-clauses g), h), l), n), o), p), q) and r) added 'Permanent or temporary sites' added to j).
9.4.8.3		NA	New requirement
9.4.9	Cause analysis of nonconformities	9.1.11	
9.4.10	Effectiveness of corrections and corrective actions	9.1.12 and 9.1.13	Note enhanced to give additional ways for verification Added to inform client in case of need for additional audit or evidence to verify them
9.5	Certification decision	9.1.14	
9.5.1	General	9.1.14	
9.5.1.1		9.1.14 and 9.2.2.5	Clarified by the types of decisions by adding 'for granting certification, expanding or reducing the scope of certification, suspending or restoring certification, withdrawing certification or renewing certification'.
9.5.1.2		NA	New requirement. Clarifies how personnel and be under 'organisational control of the certification body'.
9.5.1.3		NA	New requirement. Clarifies that those employed and those under organisational control will also need to meet the same requirements.

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9.5.1.4		NA	New requirement. Requires recording of the certification decision and information taken into consideration in making the decision.
9.5.2	Actions prior to making a decision	9.1.15	Added requirement for a process for review prior to the decision being made. Reworded slightly. b) Changed to align with Major nonconformity
9.5.3	Information for granting initial certification	9.2.5	
9.5.3.1		9.2.5.1	d) added
9.5.3.2		NA	New requirement, including timeframes associated with closure of a Major
9.5.3.3		NA	New requirement. Regarding transfer of certification
9.5.4	Information for granting recertification	9.4.3	
9.6	Maintaining certification	9.3.3	
9.6.1	General	9.3.3	Amended to refer to Major Nonconformity.
9.6.2	Surveillance activities	9.3	
9.6.2.1	General	9.3.1	
9.6.2.1.1		9.3.1.1	
9.6.2.1.2		9.3.1.2	
9.6.2.2	Surveillance audit	9.3.2 and 9.3.2.1	c) reworded d) added 'and the intended results of the respective management system(s)'.
9.6.3	Recertification	9.4	
9.6.3.1	Recertification audit planning	9.4.1	

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9.6.3.1.1		9.4.1.1	Reworded but same requirements, except now clearly requires renewal before expiry date
9.6.3.1.2		9.4.1.2	
9.6.3.1.3		9.4.1.3	Note added
9.6.3.2	Recertification audit	9.4.2	
9.6.3.2.1		9.4.2.1	c) reworked
9.6.3.2.2		9.4.2.2	Changed to include Major nonconformity
9.6.3.2.3		NA	New requirement. Requirement re the new certification date.
9.6.3.2.4		NA	New requirement. Extension of term of validity where the CAB has not completed recertification activities prior to expiry.
9.6.3.2.5		NA	New requirement. Restoring certification post expiry date.
9.6.4	Special audits	9.5	
9.6.4.1	Expanding scope	9.5.1	Heading changed from 'Extensions to scope'
9.6.4.2	Short-notice audits	9.5.2	Introduces unannounced audits
9.6.5	Suspending, withdrawing or reducing the scope of certification	9.6	
9.6.5.1		9.6.1	
9.6.5.2		9.6.2	
9.6.5.3		9.6.3	Last two sentences from old requirement deleted.
9.6.5.4		9.6.4	Added requirement regarding restoration of certification post suspension.
9.6.5.5		9.6.5	
		9.6.7	Old 9.6.7 moved to 8.1.2b)

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9.7	Appeals	9.7	
9.7.1		9.7.1	
		9.7.2	Old 9.7.2 moved to 8.1.1e)
9.7.2		9.7.3	
9.7.3		9.7.4	
9.7.4		9.7.5	
9.7.5		NA	New requirement. CAB responsible for gathering and verifying all information to validate the appeal.
9.7.6		9.7.6	
9.7.7		9.7.7	
9.7.8		9.7.8	
9.8	Complaints	9.8	
9.8.1		NA	New requirement. CAB to be responsible for all decisions at all levels of complaints handling process. Description to be publicly accessible now at 8.1.1e)
9.8.2		NA	New requirement. Not to be discriminatory.
9.8.3		9.8.2	
9.8.4		9.8.3	Valid added i.e. now reads 'Any <u>valid</u> complaint'
9.8.5		9.8.4	
9.8.6		9.8.5	
9.8.7		9.8.6	
9.8.8		9.8.7	

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9.8.9		9.8.8	
9.8.10		9.8.9	
9.8.11		9.8.10	
9.9	Client records	9.9	Changed heading from 'Records of applicants and clients'
9.9.1		9.9.1	
9.9.2		9.9.2	c) clarified that sampling is of sites. NOTEs repositioned k) added – to include audit programmes.
9.9.3		9.9.3	
9.9.4		9.9.4	Clarified the records are 'of certified clients and previously certified clients'.
10	Management system requirements for certification bodies	10	
10.1	Options	10.1	Options A and B transposed
10.2	Option A: General management system requirements	10.3	
10.2.1	General	10.3.1	Doesn't require a member of management to be responsible for the functioning and reporting on the management system
10.2.2	Management system manual	10.3.2	
10.2.3	Control of documents	10.3.3	
10.2.4	Control of records	10.3.4	
10.2.5	Management review	10.3.5	
10.2.5.1		10.3.5.1	
10.2.5.2		10.3.5.2	c) committee safeguarding impartiality removed

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			e) added
10.2.5.3		10.3.5.3	d) added
10.2.6	Internal audits	10.3.6	
10.2.6.1		10.3.6.1	
10.2.6.2		10.3.6.2	
10.2.6.3		10.3.6.3	
10.2.6.4		10.3.6.4	
10.2.7	Corrective actions	10.3.7	
		10.3.8	Old clause has been deleted
10.3	Option B: Management system requirements in accordance with ISO 9001	10.2	
10.3.1	General	10.2.1	
10.3.2	Scope	10.2.2	
10.3.3	Customer focus	10.2.3	
10.3.4	Management review	10.2.4	Amended to include the need for a review of impartiality
Annex A (normative)	Required knowledge and skills	Annex A	<p>The number of columns in this table have been reduced to three following the merging of 'Auditing' and 'Leading the audit team'. Table at Annex A has been amended to remove X+ entries. There has also been additional text included against each of the entries in the table. Additional clauses A.2 to A.4.4. under the following headings:</p> <p>A.2 Competence requirements for management systems auditors A.3 Competence requirements for personnel reviewing audit reports and making certification decisions</p>

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			A.4 Competence requirements for personnel conduction the application review to determine audit team competence required, to select the audit team members and to determine the audit time.
Annex B (informative)	Possible evaluation methods	Annex B	
Annex C (informative)	Example of a process flow for determining and maintaining competence	Annex C	
Annex D (informative)	Desired personal behaviour	Annex D	
Annex E (informative)	Audit and certification process	Annex E	Small rearrangement of the flowchart.

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