(1) CHANGES BY CLAUSE

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
NEW	OLD	NEW		
4			**General requirements**	
4.1			Impartiality	
4.2			Confidentiality	
5			**Structural requirements**	
6			**Resource requirements**	
6.1			General	
6.2			Personnel	Combination of some clauses of the Management System and Personnel clauses of ISO/IEC 17025:2005.
6.3	5.3		Facilities and environmental conditions	
6.4	5.5		Equipment	
6.5	5.6		Metrological traceability	These requirements have been made clearer, with simplified text.
6.6	4.5; 4.6		Externally provided products and services	Subcontracting and Purchasing Services and Supplies from ISO/IEC 17025:2005 have been combined. The principles of ISO 9001:2015 have been adopted. These requirements are now clearer, with simplified text.
7			**Process requirements**	
7.1			Review of requests, tenders and contracts	
7.2	5.4		Selection, verification and validation of methods	In general, there are not many changes in the requirements. This section has been re-organised mainly to differentiate between when the laboratory has to "verify" (7.2.1) that it can properly perform methods versus when the lab has to "validate" (7.2.2) methods.
7.2.1	5.4.2		Selection and verification of methods	

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
NEW	**OLD**	**NEW**		
7.2.2	5.4.5		Validation of methods	
7.3	5.7		Sampling	
7.4	5.8		Handling of test or calibration items	
7.5	4.13		Technical records	
7.6	5.4.6		Evaluation of measurement uncertainty	
7.7	5.9		Assuring the validity of results	Clauses 7.7.1 and 7.7.2 separate the requirements into intralaboratory and external activities respectively.
7.8	5.10		Reporting of results	
7.8.1	5.10.1		General	
7.8.2	5.10.2		Common requirements for reports (test, calibration or sampling)	
7.8.3	5.10.3		Specific requirements for test reports	
7.8.4	5.10.4		Specific requirements for calibration certificates	
7.8.5	5.10.3.2		Reporting sampling - specific requirements	
7.8.6			Reporting statements of conformity	
7.8.7	5.10.5		Reporting opinions and interpretations	
7.8.8	5.10.9		Amendments to reports	
7.9	4.8		Complaints	The requirements have been significantly expanded. Even though this may be the case, many of the revised / new requirements would already be implemented by laboratories. All of the requirements under 7.9 are mandatory ISO/CASCO wording.
7.10	4.9		Nonconforming work	
7.11	4.13		Control of data and information management	

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
NEW	**OLD**	**NEW**		
8			**Management system requirements**	
8.1			Options	
8.1.1			General	
8.1.2			Option A	
8.1.3			Option B	
8.2	4.2		Management system documentation (Option A)	
8.3	4.3		Control of management system documents (Option A)	
8.4	4.13		Control of records (Option A)	
8.5			Actions to address risks and opportunities (Option A)	
8.6	4.10		Improvement (Option A)	4.7, 4.10 and 4.12 in ISO/IEC 17025:2005 have been combined and simplified.
8.7	4.11		Corrective action (Option A)	
8.8	4.14		Internal audits (Option A)	
8.9	4.15		Management reviews (Option A)	

(2) MAJOR CHANGES

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
NEW	**OLD**	**NEW**		
4.2 Confidentiality 4.2.1 Borang Integriti & Confidentiality – boleh rujuk borang by PUU (IBS), berdasarkan terms dalam standard [create new form – selaraskan semua, masukkan confidentiality & impartiality]	4.1.5c)	[1]Major	The laboratory is responsible, through legally enforceable commitments, for the management of information obtained or created during its activities. If the laboratory intends to place information in the public domain, it must inform the customer in advance. Unless agreed between the laboratory and customer or the customer makes the information publicly available, all other information is to be regarded proprietary and confidential.	4.2.1 expands on the requirements relating to confidentiality of customer information. Laboratories are now to advice customers of the information they will make publically available. 4.2.1, 4.2.2, 4.2.3 and 4.2.4 significantly expand on the confidentiality requirements concerning customer information cover by 4.1.5c) in ISO/IEC 17025:2005.
6.2 Personnel 6.2.5 [6.2.5a)] Borang Soal Selidik Keperluan Latihan – masukkan kriteria 17025 (intergrate dengan borang Pej Pendaftar) Borang Kriteria Pemilihan dan Pemarkahan Calon - kriteria [6.2.5b)] Kriteria pemilihan personel akan disediakan, CQA akan advise Pej Pendaftar berkaitan pelantikan staf teknikal (bertaraf tetap) yang terlibat dengan makmal 17025 [6.2.5b)] Kriteria pemilihan personal sedia ada, berdasarkan kompetensi latihan & pengalaman kerja	5.2.2; 5.2.3; 5.2.5	[2]Major	Procedures and records need to be maintained for personnel covering: a) determination of competence requirements; b) to e) selection, training, supervision and authorisation; and f) monitoring of competence.	Changed emphasis to include records covering selection, supervision and ongoing monitoring.
6.2.6 [6.2.6a)] Tambahbaik QP validation of method (tambah authorised personnel) [6.2.6b) & c)] Tambahbaik QP issue of test report	5.2.5	[3]Major	Personnel must be authorised to perform specific activities including: a) develop, modify, verify and validate methods; b) analysis of results, statements of conformity and opinions /	Now explicitly includes method validation / verification and analysis of results / statements of conformity.

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NEW	**OLD**	**NEW**		
			interpretations; c) report, review and authorise results.	
6.4 Equipment 6.4.7 Linked dengan new procedure on calibration 9001	5.5.2; 5.6.1	[4]Major	A calibration program shall be established, reviewed and adjusted as necessary, to ensure confidence in the status of calibrations.	Clarity now provided that the calibration program is to be reviewed and adjusted as necessary.
6.6 Externally provided products and services 6.6.2 [6.6.2a)] Current purchasing procedure change into external provided product & services (masukkan sekali spesifikasi) List of external provider (perlu disediakan & disemak jika perlu – perlu details ikut kategori, diluluskan oleh TM Makmal) (create new form) [6.6.2b), c) & d)] Already spell out dalam prosedur Pej. Bendahari	4.5.1; 4.5.4; 4.6.1; 4.6.2; 4.6.3; 4.6.4	[5]Major	A procedure and records are required for: a) defining, reviewing and approving externally provided products and services; b) the criteria for evaluation, selection, monitoring and re-evaluation of external providers; c) ensuring, prior to use or supply to customer, externally provided products and services conform to the laboratory's established requirements or the Standard; d) actions arising from evaluations, monitoring or re-evaluations of external providers.	Emphasis now placed on the laboratory defining its requirements, selecting providers who can meet these and evaluating / monitoring the providers' performance. The previous requirement that the laboratory is responsible to the customer for subcontractor's work has been removed.
7.4 Handling of test or calibration items 7.4.3 QP Review of Request, QP Handling of Test Item/Report & QP Issuance of Test Report – review (tambah disclaimer)	5.8.3	[6]Major	Upon receipt of the item, abnormalities or deviations from specified conditions must be recorded. If there is doubt as to the suitability of the item or when the item does not conform to the description provided, the customer must be consulted before proceeding and record the results of the consultation. Following, if the item is to proceed to testing or calibration, the laboratory must include a disclaimer in the report indicating that results may be compromised.	The requirement to include a disclaimer if a sample deviates from specified conditions is new.

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
NEW	**OLD**	**NEW**		
7.7 Assuring the validity of results 7.7.2 Procedure Quality Control – review	5.9.1b)	[7]Major	The laboratory must monitor its performance by comparison with results of other laboratories, where possible and appropriate. This monitoring shall be planned and reviewed and include, but not limited to: a) participation in proficiency testing; b) participation in interlaboratory comparisons.	Even though participation in PT was not mandatory in ISO/IEC 17025:2005, it was included as a requirement in NATA's ISO/IEC 17025 Standard Application Document. Therefore, the requirement is not new for NATA accredited laboratories.
7.8 Reporting of results 7.8.6.2 Masukkan statement of conformity, meet the requirement or not, decision rule (MU @ std limit @ range) dalam test report	5.10.3.1b); 4.10.4.2	[8]Major	The laboratory must report on the statement of conformity: a) the results to which the statement of conformity applies; b) which specifications, standards or parts thereof that are met or not met; c) the decision rule applied (unless inherent in the requested specification or standard).	Reports which include statements of conformity are now also required to include the decision rule applied. Refer to 7.1.3 and 7.8.6.1.
8.1 Options 8.1.2 Masukkan risk assessment untuk setiap makmal Decision – Option A (integrate dengan QMS)		[9]Major	**Option A** The management system is to address, as a minimum; • management system documentation (8.2); • control of management system documents (8.3); • control of records (8.4); • actions to address risks and opportunities (see 8.5); • improvement (8.6) • corrective actions (8.7); • internal audits (8.8); • management reviews (8.9).	The management system now includes requirements for actions to address risks and opportunities.

(3) NEW CLAUSE ADDED TO THE STANDARD

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
NEW	**OLD**	**NEW**		
4.1 Impartiality 4.1.4 Spell out impartiality dalam risk assessment		[1]New	On an ongoing basis, the laboratory must identify risks to impartiality, including those arising from its activities or relationships or the relationships of its personnel.	
4.1.5 Spell out impartiality dalam risk assessment		[2]New	The laboratory must be able to demonstrate how it minimises or eliminates the risks it identifies.	
4.2 Confidentiality 4.2.2 1. Akujanji baru (staf) 2. Request form (customer)		[3]New	When the laboratory is required by law or authorised by contractual arrangements to release otherwise confidential information, the customer or individual is to be notified (unless the notification is prohibited by law).	4.2.1, 4.2.2, 4.2.3 and 4.2.4 significantly expand on the confidentiality requirements concerning customer information cover by 4.1.5c) in ISO/IEC 17025:2005.
4.2.3 Procedure impartiality, confidentiality & integrity		[4]New	Information about the customer, obtained from other sources, is to be regarded as confidential. The source is to remain confidential to the customer unless otherwise agreed to by the source.	4.2.1, 4.2.2, 4.2.3 and 4.2.4 significantly expand on the confidentiality requirements concerning customer information cover by 4.1.5c) in ISO/IEC 17025:2005.
4.2.4 Procedure impartiality, confidentiality & integrity		[5]New	Personnel must keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.	4.2.1, 4.2.2, 4.2.3 and 4.2.4 significantly expand on the confidentiality requirements concerning customer information cover by 4.1.5c) in ISO/IEC 17025:2005.
5 Structural requirements 5.3 LQM		[6]New	The laboratory needs to define and document the range of activities which it claims conformity to the Standard. The range of activities cannot include externally provided laboratory activities on an ongoing.	

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NEW	**OLD**	**NEW**		
6.6 Externally provided products and services 6.6.3 Procurement		[7]New	Communication to external providers is required for: a) the products and services to be provided; b) acceptance criteria; c) competence of personnel; d) activities to be performed by the laboratory or laboratory customers at the external provider's premises.	Emphasis now placed on the laboratory communicating its needs to external providers.
7.1 Review of requests, tenders and contracts 7.1.3 Statement of conformity such as meet the requirement or not, decision rule (MU @ std limit @ range) – stated in sample submission & request form		[8]New	The standard or specification and the decision rule must be clearly defined when the customer requests a statement of conformity to a specification or standard for a test or calibration. The decision rule must be communicated to and agreed with the customer, unless inherent in the requested specification of standard.	Clause 5.10.3.1b) and 5.10.4.2 in ISO/IEC 17025:2005 covered statements of compliance. Hence, statements of conformity are not a new concept. However, the laboratory is now required to consider such at the request / contract review stage and to include the decision rule in the report on results. Also refer to clause 7.8.6.
7.8.2 Common requirements for reports (test, calibration or sampling) 7.8.2.2 Sedia ada (note pada belakang test report)/ disclaimer Amendment pada request form – laboratory is not responsible for sampling State in the report that the results apply to the sample as received		[9]New	The laboratory is responsible for all the information in the report, except that provided by the customer. Data provided by the customer is to be clearly identified. Additionally, a disclaimer must be included when information is supplied by the customer which can affect the validity of the results. When the laboratory is not responsible for sampling, e.g. the sample has been supplied by the customer, it must state in the report that the results apply to the sample as received.	

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
NEW	**OLD**	**NEW**		
7.8.4 Specific requirements for calibration certificates 7.8.4.1 Include dalam calibration cert	5.10.4.1; 5.10.4.2; 5.10.4.3; 5.10.5	[10]New c)	In addition to 7.8.2, calibration certificates must include: a) the MU presented in the same unit as the measurand or in a term relative to them; b) the conditions under which the calibrations were made that have an influence on the measurement results; c) a statement to indicate how the measurements are metrologically traceable; d) results before and after any adjustments or repair; e) where relevant, a statement of conformity with requirements or specifications; f) where appropriate, opinions and interpretations.	f) is a new point, however, ISO/IEC 17025:2005 did not preclude the inclusion of opinions and interpretations in calibration reports as covered in that standard by 5.10.5. Accordingly, 7.8.4.1 in the new standard is considered to only cover editorial changes.
7.8.4.2 Laboratory is not responsible for sampling		[11]New See 7.8.5	When the laboratory is responsible for sampling, calibration certificates must meet the requirements in 7.8.5, where necessary for the measurement results.	ISO/IEC 17025:2005, clause 5.10.3.2 only related sampling as applicable to test reports and not calibration certificates.
7.8.5 Reporting sampling - specific requirements Laboratory is not responsible for sampling	5.10.3.2	Editorial [12]New f)	When the laboratory is responsible for sampling, in addition to 7.8.2 reports must include the following where necessary for the interpretation of results: a) date of sampling; b) unique identification of the item or material sampled; c) the location of sampling, including any diagrams, sketches or photographs; d) a reference to the sampling plan and sampling method; e) details of any environmental conditions that affect the interpretation of the test results; f) information required to evaluate MU for subsequent testing or calibration.	The standard now also requires information to evaluate MU for subsequent testing or calibration to be included.

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
NEW	**OLD**	**NEW**		
7.8.6 Reporting statements of conformity 7.8.6.1 Masukkan statement of conformity, meet the requirement or not, decision rule (MU @ std limit @ range) dalam test report/risk		[13]New	When a statement of conformity to a specification or standard is provided, the laboratory must document the decision rule it employs, taking into account the level of risk associated with the decision rule, and apply the decision rule.	Clause 5.10.3.1b) and 5.10.4.2 in ISO/IEC 17025:2005 covered statements of compliance. Hence, statements of conformity are not a new concept. However, the laboratory is now required to record the decision rule adopted taking into account the risk such a rule will have on reporting false positive or negative results. Refer also to clause 7.1.3.
7.8.8 Amendments to reports 7.8.8.1 Spell out dalam procedure issuance of test report & control of record		[14]New	When an issued report requires changing, amendment, or reissuing, any change of information must be clearly identified. Where appropriate, the reason for the change is to be included in the report.	
7.9 Complaints 7.9.2 Procedure resolution of complaint		[15]New	A description of the complaint handling process must be available to any interested party on request. Upon receiving a complaint, the laboratory must determine if it relates to the laboratory activities it is responsible for and if so, needs to deal with the complaint. The laboratory is responsible for all decisions in handling the complaint.	
7.9.3 Procedure resolution of complaint		[16]New	The complaints handling process must include: a) a description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it; b) tracking and recording complaints, including actions taken to resolve them; c) ensuring that any appropriate action is taken.	

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NEW	**OLD**	**NEW**		
7.9.4 Procedure resolution of complaint		[17]New	The laboratory receiving the complaint is responsible for gathering and verifying all information to validate the complaint.	
7.9.5 Procedure resolution of complaint		[18]New	Whenever possible, the laboratory must acknowledge receipt of the complaint and provide the complainant progress reports and the outcome.	
7.9.6 Procedure resolution of complaint		[19]New	The outcomes are to be communicated to the complaint by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.	This implies that a single person laboratory will need to engage an external resource.
7.9.7 Procedure resolution of complaint		[20]New	Whenever possible, the laboratory is to give formal notice of the end of the complaint handling to the complainant.	
7.10 Nonconforming work 7.10.2 Review - Procedure Control of NC Work		[21]New	Records must be retained of nonconforming work and actions as specified in 7.10.1 b) to f).	ISO/IEC 17025:2005 did not explicitly state that records must be retained.
7.11 Control of data and information management 7.11.1 Review – Procedure Control of Record		[22]New	The laboratory must have access to the data and information needed to perform its activities.	
7.11.4 Tidak berkenaan		[23]New	If the LIMS is maintained off-site or by an external provider, the laboratory must ensure that the provider complies with all applicable requirements of the Standard.	
8 Management systems requirements 8.1 Options 8.1.1 General Option A		[24]New	The laboratory must establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of the Standard and assuring the quality of laboratory results. In addition to meeting the requirements of clauses 4 to 7, the management system implemented must comply with	The laboratory may now choose either Option A or B to fulfil the management system requirements provided the option taken supports fulfilment of the General, Structural, Resource and Process requirements. In ISO/IEC 17025:2005 there was only one way to meet the management system

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NEW	**OLD**	**NEW**		
			Option A or B.	requirements i.e. what is basically covered by Option A in the new standard. Option B in the new standard allows a laboratory to implement a system compliant with ISO 9001. The requirements of ISO 9001 that are relevant to laboratory activities have been included into Option A. Laboratories that implement Option A will operate generally in accordance with the principles of ISO 9001. Annex B (Informative) - provides some background and text.
8.1.3 Tidak berkenaan		[25]New	**Option B** A laboratory that maintains a management system, in accordance with the requirements of ISO 9001 which supports and demonstrates the consistent fulfilment of clauses 4 to 7, fulfils the intent of the management system requirements of 8.2 to 8.9.	The NATA General Accreditation Criteria ISO/IEC 17025 Standard Application Document (SAD) describes how NATA will assess facilities who have adopted ISO 9001 in accordance with Option B.
8.5 Actions to address risks and opportunities (Option A) 8.5.1 Identify risk assessment Bengkel pemurniaan risiko		[26]New	Risks and opportunities associated with the laboratory activities must be considered in order to: • give assurance the management system achieve its intended results; • enhance opportunities to achieve the purpose and objectives of the laboratory; • prevent or reduce impacts and potential failures in the laboratory activities; • achieve improvement.	Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects. The laboratory is responsible for deciding which risks and opportunities need to be addressed. There is no requirement for a formal process or documented procedure for risk management.

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NEW	**OLD**	**NEW**		
8.5.2 Risk assessment – cth dr INTROP		[27]New	The laboratory must plan; a) actions to address risks and opportunities; b) how to integrate and implement the actions into its management system in addition to evaluating the effectiveness of the actions.	
8.5.3 Bengkel pemurniaan risiko		[28]New	Actions taken to address risks and opportunities need to be proportional to the potential impact on the validity of the laboratory results.	
8.9 Management reviews (Option A) 8.9.2 Review – Procedure MRM	4.15.1	Editorial [29]New a), b), d), k) and m)	Inputs to the management review are to be recorded and include information related to: a) changes in relevant internal and external issues; b) fulfilment of objectives; c) suitability of policies and procedures; d) status of actions from previous management reviews; e) outcomes of recent internal audits; f) corrective actions; g) assessments by external bodies; h) changes in the volume or in the range of laboratory activities; i) customer and personal feedback; j) complaints; k) effectiveness of any implemented improvements; l) adequacy of resources; m) results of risk identification; n) outcomes of the assurance of the validity of results; o) other relevant factors, such as monitoring activities and training.	The management review requirements are essentially the same, however, the elements to review have been expanded, notably points a), b), d), k) and m).
Makmal Kalibrasi FK		[30]New	Annex A (informative) – Metrological traceability	Refer to the Standard for details.
Semua (info)		[31]New	Annex B (informative) – Management system	Refer to the Standard for details.

(4) MINOR CHANGES

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
NEW	**OLD**	**NEW**		
6.2 Personnel 6.2.3 Monitoring via worksheet	4.1.5 a) & k); 5.2.1	[1]Minor 5.2.2; 5.2.3; 5.2.5	It must be ensured that personnel are competent to perform the activities for which they are responsible and to evaluate the significance of deviations.	Emphasis is now on staff's ability to not only identify departures from procedures, but also to evaluate the significance of these.
6.2.4 Establish JD & org chart, mesy pengurusan lab/PTJ	4.2.1; 4.2.4	[2]Minor	Duties, responsibilities and authorities shall be communicated to personnel.	
6.3 Facilities and environmental conditions 6.3.4 Review - Procedure of Housekeeping (FPV & IBS masih belum ada) a) log book – std kan b) notice to prevent c) awareness to technical staff	5.3.2; 5.3.3; 5.3.4	[3]Minor	Measures to control facilities are to be implemented, monitored and periodically reviewed and include: a) access; b) prevention of contamination; c) effective separation of incompatible activities.	Emphasis now also placed on periodic review.
6.4 Equipment 6.4.5 Lab y buat measurement, kena ada MU	5.5.2	[4]Minor	Equipment shall be capable of achieving the measurement accuracy or measurement uncertainty (MU) required to provide a valid result.	Clarity provided that the equipment's capability is also to consider the MU contribution to the results of the laboratory activity, even if accuracy is not in question. ISO/IEC 17025:2005 stated that equipment shall comply with specifications, which implied that the MU had to be considered.
6.4.11 Jika ada new correction factor, kena update & gunakan dalam pengiraan data seterusnya	5.5.11	[5]Minor	When calibration or reference material data includes reference values or correction factors, it must be ensured the reference values or correction factors are updated and implemented as appropriate to meet specified requirements.	Equipment includes reference data, hence clarity provided that correction factors are to include such data sets.
6.4.13 Already covered dalam worksheet/ manual alat/ std ref material	5.5.5	[6]Minor	Records need to be retained for equipment which can influence laboratory activities, including: a) identity; b) manufacturer's name, type and serial number; c) evidence of verification; d) location; e) calibration dates, results,	Equipment now includes reference materials.

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NEW	**OLD**	**NEW**		
			adjustments, acceptance criteria, next calibration due date or interval; f) reference material documentation, results, acceptance criteria, relevant dates and period of validity g) maintenance plan and maintenance performed; h) details of damage, malfunction, modifications or repair.	
6.6 Externally provided products and services 6.6.1 Declare – no outsource (mentioned tiada outsource dalam Review of Request)	4.5.1; 4.6.1	[7]Minor	Only suitable externally provided products and services that affect laboratory activities are to be used when such products or services are: a) incorporated into the laboratory's own activities; b) provided directly to the customer by the laboratory as received from the external provider; c) used to support the operation of the laboratory.	
7.1 Review of requests, tenders and contracts 7.1.4 Kena masukkan statement 'deviations not to impact the integrity of the laboratory or validity of results' dalam test report	4.4.1	[8]Minor	Before laboratory activities commence, any differences between the request or tender and the contract must to be resolved. Deviations requested by the customer shall not impact the integrity of the laboratory or validity of results.	Emphasis now placed on deviations not to impact the integrity of the laboratory or validity of results.
7.2.2 Validation of methods 7.2.2.2 1. History of changes 2. Validation report (tak perlu setiap tahun)	5.4.5.2 Note 3	[9]Minor	When changes are made to validated methods, the influence of such changes must be determined and validation performed again, if appropriate.	This was included as a Note in ISO/IEC 17025:2005. Whilst it has now been made an explicit requirement of the Standard, the intent of method validation remains unchanged.

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NEW	**OLD**	**NEW**		
7.3 Sampling 7.3.3 Declare – no sampling	5.7.3	[10]Minor	The sampling method must include: a) the selection of samples or sites; b) sampling plan; c) preparation and treatment of a sample(s) from a substance, material or product.	Items b), c), e) and h) are new record requirements.
7.4 Handling of test or calibration items 7.4.1 Sedia ada (kena ambil kira Lab Kalibrasi @ FK)	5.8.1; 5.8.4	[11]Minor	The laboratory must have a procedure for the transportation, receipt, handling, protection, storage, retention and disposal or return of test or calibration items. This includes provisions to protect the item, the interests of the laboratory and the customer.	The requirements have been expanded to include protection of items during transport.
7.5 Technical records 7.5.2 Sedia ada	4.13.2.3	[12]Minor	Amendments to technical records must be traceable to previous versions or to original observations. Original and amended data or files are to be kept, including date of alteration, an indication of the altered aspects and the identity of the personnel responsible.	The requirement has been enhanced compared to ISO/IEC 17025:2005.
7.6 Evaluation of measurement uncertainty 7.6.1 Sedia ada	5.4.6.3	[13]Minor	The contributions to measurement uncertainty (MU) must be identified. All contributions which are of significance, including those arising from sampling, are to be taken into account using appropriate methods of analysis.	Expanded to include the contributions from sampling.
7.7 Assuring the validity of results 7.7.1 Sedia ada (dalam QC plan)	5.9.1	[14]Minor	The laboratory shall have a procedure for monitoring the validity of results. The data is to be recorded in such a way as to allow trend analysis and where practical, statistical techniques are to be applied to review the results. Monitoring is to be a planned activity and must include, where appropriate: a) use of reference materials or quality control materials;	The standard now includes, for clarity, several additional quality control tools covered by b), c), i), j) and k). These would already be adopted by laboratories.

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
NEW	**OLD**		**NEW**	
			b) use of alternative calibrated instrumentation providing traceable results; c) functional checks of measuring and testing equipment; d) use of check or working standards with control charts; e) intermediate checks on measuring equipment; f) replicate tests or calibrations; g) retesting or recalibration of retained items; h) correlation of results for different characteristics of an item; i) review of reported results; j) intralaboratory comparisons; k) testing of blind sample(s).	
7.7.3 Sedia ada	5.9.2	[15]Minor	Data from monitoring activities must be analysed, used to control and if applicable, improve the improve laboratory activities. Where the results of data analysis are outside pre-defined criteria, appropriate action is to be taken to prevent incorrect results being reported.	Additional emphasis now placed on monitoring processes to control and improve laboratory activities. This emphasis, however, is not a new concept for NATA accredited laboratories.
7.8 Reporting of results 7.8.1.1 Sedia ada	5.10.2 j)	[16]Minor	Results must be reviewed and authorised prior to release.	Review of results has now been included and together with authorisation articulated as a separate subclause.
7.8.1.3 Raw data @ full report shj – dibolehkan (full results mesti disimpan & traceable)	5.10.1	[17]Minor	The results can be reported in simplified manner when agreed with the customer. Any information in 7.8.2 to 7.8.7 not reported to the customer must be available.	ISO/IEC 17025:2005 specifically required written agreement with the customer.
7.8.2 Common requirements for reports (test, calibration or sampling) 7.8.2.1 Sedia ada	5.10.2; 5.10.3.1 a); 5.10.6	[18]Minor	Unless there is a valid reason for not doing so, each report must include at least: a) title; b) name and address of the laboratory; c) location of the performed activities;	ISO/IEC 17025:2005 required the name and address of customer rather than contact information. The new standard now additionally requires points j), n) and p). Point l) has also had

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NEW	**OLD**		**NEW**	
			d) unique identification that all its components are recognised as a portion of a complete report and a clear identification of the end; e) name and contact information of the customer; f) method used; g) a description, unambiguous identification, and if necessary, the condition of the item; h) date of receipt or date of sampling of the item where this is critical to the validity and application of the results; i) date(s) of the performance of the laboratory activity; j) date of issue of the report; k) reference to the sampling plan and sampling method used if relevant to the validity and application of the results; l) statement to the effect that the results only relate to the item tested, calibrated or sampled; m) the results with the units of measurement, where appropriate; n) additions, deviations or exclusions from the method; o) identification of the person authorising the report; p) clear identification when the results are from external providers.	"where relevant" deleted compared to the previous standard.
7.8.7 Reporting opinions and interpretations 7.8.7.2 Kena nyatakan opinion & interpretations	5.10.4.2; 5.10.5	[19]Minor	Opinions and interpretations included in reports are to be based on the results obtained from the tested or calibrated item and be clearly identified as such.	Clarity provided that opinions and interpretations are to be based on the results.
7.8.7.3 Kena catat details tarikh, masa, penerima, sampel, catatan perkara yang komunikasi *Sediakan skrip	5.10.5 Note 3	[20]Minor	When opinions and interpretations are verbally communicated to the customer, a record of the dialogue must to be kept.	ISO/IEC 17025:2005 included this requirement only as an informative Note.

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NEW	**OLD**	**NEW**		
7.11 Control of data and information management 7.11.2 Tidak berkenaan	5.4.7.2 a)	[21]Minor	The laboratory information management system(s) (LIMS) used for the collection, processing, recording, reporting, storage or retrieval of data must be validated for functionality. This includes the proper functioning of interfaces within the LIMS by the laboratory before introduction. Whenever there are changes, including modifications to commercial off-the shelf software or laboratory software configuration, they need to be authorised, documented and validated before implementation.	The standard now clarifies that changes / modifications to LIMS are to be validated. This was still implied in ISO/IEC 17025:2005.
7.11.5 Tidak berkenaan	4.13.1.1	[22]Minor	Instructions, manuals and reference data relevant to the LIMS must be readily available to personnel.	The standard now explicitly states this information to be available for LIMS.
8.7 Corrective action (Option A) 8.7.1 Sedia ada	4.9.1; 4.11.2; 4.11.3; 4.11.4	[23]Minor	When a nonconformity occurs, the laboratory must: a) react and take appropriate actions to control and correct the nonconformity and address the consequences; b) evaluate the need for action to eliminate the cause(s) of nonconformity in order that it does not recur or occur elsewhere; c) implement any action needed; d) review the effectiveness of any corrective action taken; e) update risks and opportunities determined during planning; f) make changes to the management system, if required.	The principles of corrective action remain the same in the standard, however, the prescriptive nature of the requirements in ISO/IEC 17025:2005 have been simplified. A key change is that the impact of any nonconformity in relation to risks and opportunities must be determined.
8.7.3 Sedia ada	4.11.3; 4.13.1.1	[24]Minor	Records are to be retained as evidence of: a) the nature of the nonconformities, cause(s) and any actions taken; b) the results of corrective action.	

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8.8 Internal audits (Option A) 8.8.1 Authorised Personnel (QM)	4.14.1; 4.14.2	[25]Minor	Internal audits must be conducted at planned intervals to provide information on whether the management system: a) conforms to the laboratory's own requirements for the management system (including the laboratory activities) and the requirements of the Standard; b) is effectively implemented and maintained.	ISO/IEC 17025:2005 specified that internal audits were the responsibility of the quality manager. The new standard now requires personnel to be authorised (refer to 6.2).