Supporting document for the Testing Laboratory Accreditation Application Form

Name of Laboratory:
Part 1: General Information of organization.
Please tick ✓ in box □
1.1 Type of establishment (Tick in the box of the category under which establishmen
belongs)
☐ Limited Partner Ship
☐ Company limited
☐ Public Company limited
☐ Government Organization
☐ State Enterprises
☐ Educational Institute
Other (please specify)
1.2 Type of the laboratory services.
☐ Within an organization.
☐ Outside an organization.
2. Objective for Applied (Tick in the box)
\square Accreditation of Laboratory according to ISO/IEC 17025: 2005
\square Extension scope of accreditation. Date. Accreditation Number. <u>Testing</u> -
Reassessment. Date. Accreditation Number. <u>Testing</u> -
3. Basic Information of the Applicant Laboratory.
3.1 Management Level Personnel or Deputy.
NamePosition
TelFaxe-mail address
3.2 Name of quality managerPosition
TelFaxe-mail address
3.3 Management system.
Please tick ✓ in box □
3.3.1 Internal audits.
☐ Yes ☐ No ☐ Processing

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3.3.2	Proficiency testing progi	rams.	
	Yes	☐ No	Processing
3.3.3	Interlaboratory comparis	sons.	
	Yes	□ No	Processing

4. Laboratory documents which comply with ISO/IEC 17025:2005

Management requirements

Please define the reference documents/ clause number or page number.

Requirements	Yes	ISO/IEC 17025:2005	referred to Quality Manual	referred to the related document
4.1 Organization		4.1		
4.1.1 The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.		4.1.1		
4.1.2 It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition.		4.1.2		
4.1.3 The management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities.		4.1.3		
4.1.4 If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.		4.1.4		
4.1.5 The laboratory shall		4.1.5		
4.1.5 (a) have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures.		4.1.5(a)		

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Requirements	Yes	ISO/IEC 17025:2005	referred to Quality Manual	referred to the related document
4.1.5 (b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;		4.1.5(b)		
4.1.5(c) have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;		4.1.5(c)		
4.1.5(d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity;		4.1.5(d)		
4.1.5(e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;		4.1.5(e)		
4.1.5(f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;		4.1.5(f)		
4.1.5(g) provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results;		4.1.5(g)		
4.1.5(h) have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;		4.1.5(h)		
4.1.5(i) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;		4.1.5(i)		

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Requirements	Yes	ISO/IEC 17025:2005	referred to Quality Manual	referred to the related document
4.1.5(j) appoint deputies for key managerial personnel (see Note);		4.1.5(j)		
4.1.5(k) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.		4.1.5(k)		
4.1.6 Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.		4.1.6		
4.2 Management system		4.2		
4.2.1 The laboratory shall establish, implement and maintain a management system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programmes, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.		4.2.1		
4.2.2 The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The overall objectives shall be established, and shall be reviewed during management review. The quality policy statement shall be issued under the authority of top management. It shall include at least the following:		4.2.2		
4.2.2(a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers;		4.2.2(a)		
4.2.2(b) the management's statement of the laboratory's standard of service;		4.2.2(b)		
4.2.2(c) the purpose of the management system related to quality;		4.2.2(c)		
4.2.2(d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and		4.2.2(d)		

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Requirements	Yes	ISO/IEC 17025:2005	referred to Quality Manual	referred to the related document
4.2.2(e) the laboratory management's commitment to comply with this International Standard and to continually improve the effectiveness of the management system.		4.2.2(e)		
4.2.3 Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.		4.2.3		
4.2.4 Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.		4.2.4		
4.2.5 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the management system.		4.2.5		
4.2.6 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, shall be defined in the quality manual.		4.2.6		
4.2.7 Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.		4.2.7		
4.3 Document control		4.3		
4.3.1 General		4.3.1		
The laboratory shall establish and maintain procedures to control all documents that form part of its management system.				
4.3.2 Document approval and issue		400		
4.3.2.1 All documents issued to personnel in the laboratory as part of the management system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established.		4.3.2 4.3.2.1		

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Requirements	Yes	ISO/IEC 17025:2005	referred to Quality Manual	referred to the related document
4.3.3 Document changes		4.3.3		
4.3.3.1 Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.		4.3.3.1		
4.4 Review of requests, tenders and contracts		4.4		
4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and calibration.		4.4.1		
4.5 Subcontracting of tests and calibrations		4.5		
4.5.1 When a laboratory subcontracts work, whether because of unforeseen reasons this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this International Standard ISO/IEC 17025 for the work in question.		4.5.1		
4.6 Purchasing services and supplies		4.6		
4.6.1 The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.		4.6.1		
4.6.2 The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of action taken to check compliance shall be maintained.		4.6.2		
4.7 Service to the customer		4.7		
4.7.1 The laboratory shall be willing to cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's		4.7.1		

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Requirements	Yes	ISO/IEC 17025:2005	referred to Quality Manual	referred to the related document
4.7 Service to the customer (cont.)				
Performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers.				
4.7.2 The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyzed to improve the management system, testing and calibration activities and customer service.		4.7.2		
4.8 Complaints		4.8		
The laboratory shall have a policy and procedure for the resolution of complaints received from customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory.				
4.9 Control of nonconforming testing and/or calibration work		4.9		
4.9.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. The policy and procedures		4.9.1		
4.9.2 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.11 shall be promptly followed.		4.9.2		
4.10 Improvement		4.10		
The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.				
4.11 Corrective action		4.11		
4.11.1 The laboratory shall establish a policy and a				
procedure and shall designate appropriate authorities for implementing corrective action when				

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Requirements	Yes	ISO/IEC 17025:2005	referred to Quality Manual	referred to the related document
4.11 Corrective action		4.11		
nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.				
4.12 Preventive action		4.12		
4.12.1 Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.		4.12.1		
4.12.2 Procedures for preventive actions shall include the initiation of such actions and the application of controls to ensure that they are effective.		4.12.2		
4.13 Control of records		4.13		
4.13.1 The laboratory shall establish and maintain		4.13.1.1		
procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.				
4.13.2 The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.		4.13.1.4		
4.14 Internal audits		4.14		
The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this International Standard.				

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Requirements	Yes	ISO/IEC 17025:2005	Referred to Quality Manual	Referred to the related document
4.15 Management reviews 4.15.1 In accordance with a predetermined schedule and procedure, the laboratory's top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements.		4.15		

5. Laboratory documents which comply with ISO/IEC 17025:2005

Technical requirements

Requirements	Yes	ISO/IEC 17025:2005	referred to Quality Manual	referred to the related document
5.1 General 5.2 Personnel		5.1		
5.2.1 The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.		5.2 5.2.1		
5.2.2 The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training programme shall be relevant to the present and anticipated tasks of the laboratory. The effectiveness of the training actions taken shall be evaluated.		5.2.2		
5.2.3 The laboratory shall use personnel who are employed by, or under contract to, the laboratory.		5.2.3		
5.2.4 The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.		5.2.4		

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Requirements	Yes	ISO/IEC 17025:2005	referred to Quality Manual	referred to the related document
5.2.5 The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment.		5.2.5		
5.3 Accommodation and environmental conditions		5.3		
5.3.1 Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.		5.3.1		
5.3.2 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results.		5.3.2		
5.4 Test and calibration methods and method validation		5.4		
5.4.1 The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.		5.4.1		
The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibrations, or both				
5.4.2 The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes.		5.4.2		
5.4.3 The introduction of test and calibration methods developed by the laboratory for its own use shall be a planned activity.		5.4.3		
5.4.4 When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer.		5.4.4		

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Requirements	Yes	ISO/IEC 17025:2005	referred to Quality Manual	referred to the related document
5.4.5 The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use.		5.4.5.2		
5.4.6 A testing laboratory performing its own calibrations shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.		5.4.6.1		
Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement.		5.4.6.2		
5.4.7 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.		5.4.7.1		
When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use; procedures are established and implemented for protecting the data.		5.4.7.2		
5.5 Equipment		5.5		
5.5.1 The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this International Standard are met.		5.5.1		
5.5.2 Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibration concerned.		5.5.2		
5.5.3 Equipment shall be operated by authorized personnel.		5.5.3		
5.5.4 Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.		5.5.4		

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Requirements	Yes	ISO/IEC 17025:2005	referred to Quality Manual	referred to the related document
5.5.5 Records shall be maintained of each item of		5.5.5		
equipment and its software significant to the tests				
and/or calibrations performed.				
5.5.6 The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment.		5.5.6		
5.5.7 Equipment that has been subjected to		5.5.7		
overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service.				
5.6 Measurement traceability		5.6		
5.6.1 All equipment used for tests and/or calibrations, including equipment for subsidiary measurements having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established programme and procedure for the calibration of its equipment.		5.6.1		
5.6.2 The laboratory shall have a programme and procedure for the calibration of its reference standards.		5.6.3.1		
5.6.3 Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.		5.6.3.2		
5.6.4 The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.		5.6.3.4		
5.7 Sampling		5.7		
5.7.1 The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration.		5.7.1		

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Requirements	Yes	ISO/IEC 17025:2005	referred to Quality Manual	referred to the related document
5.8 Handling of test and calibration items		5.8		
5.8.1 The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items.		5.8.1		
5.8.2 The laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained throughout the life of the item in the laboratory. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents.		5.8.2		
5.8.3 The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation.		5.8.4		
5.9 Assuring the quality of test and calibration results		5.9		
5.9.1 The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken.		5.9.1		
5.9.2 Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported.		5.9.2		
5.10 Reporting the results		5.10		
5.10.1 The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.		5.10.1		
5.10.2 When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.		5.10.5		
5.10.3 When the test report contains results of tests performed by subcontractors, these results shall be clearly identified.		5.10.6		

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Requirements	Yes	ISO/IEC 17025:2005	referred to Quality Manual	referred to the related document
5.10.4 Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer.		5.10.9		
When it is necessary to issue a complete new test report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.				

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that have an involvement or influence on the testing and/or calibration activities of the laboratory. 6.1 List of names, education, experience and responsibility of personnel 6.1.1 Top management. Full Name Position Education_____ Experience_____ Responsibility 6.1.2 The deputy of Top management. Full Name Position Education_____ Experience_____ Responsibility 6.1.3 **Quality Manager** Full Name _____Position _____ Education Experience_____ Responsibility 6.1.4 Deputy of Quality Manager Full Name Position Education_____ Experience_____

6. List of names, education, experience and responsibilities of key personnel in the organization

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Responsibility

6.1.5	Technic	cal Managements	
	6.1.5.1	Full Name	Position
		Education	
		Experience	
		Responsibility	
	6.1.5.2	Full Name	Position
		Education	
		Experience	
		Responsibility	
	6.1.5.3		Position
		Education	
		Experience	
		Responsibility	
0.4.0	5		
6.1.6	-	es of Technical Managements	
	6.1.6.1		Position
		Experience	
	6160		Desition
	0.1.0.2		Position
	6163		Position
	0.1.0.0		

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6.1.7	•	sors	•	
	6.1.7.1			Position
		Experience		
		Responsibility		
	6170			Pacition
	0.1.7.2			Position
	6173			Position
	0.1.7.0			
	6.1.7.4			Position
	6.1.7.5	Full Name		Position
		Education		
		Responsibility		

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.8	Lechr	nical staffspersons	
	6.1.8.1	Full Name	Position
		Education	
		Responsibility	
	6.1.8.2	Full Name	Position
		Education	
		Responsibility	
	6.1.8.3	Full Name	Position
		Education	
	6.1.8.4	Full Name	Position
		Education	
		Responsibility	
	6.1.8.5	Full Name	Position
		Education	
		. , , , , , , , , , , , , , , , , , , ,	

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7. The requested scope of testing laboratory accreditation

Item	Test Material / Product	Test Item / Range of Testing	Test Method /
number			Technique Used
<u></u>			

(If space in this Form is inadequate, please print out and continue in additional sheets.)

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	Main equipments Page/											
Name o	Name of laboratory :											
Accred	Accreditation No./Applicant NoDate of record :											
No.	Name of equipment (test items)	Identification number	Manufacturer	Type / Model	Capacity (an acceptance Tolerance)*	Resolution*	Laboratory (calibration/ verification / performance check)	Uncertainty of measurement * (95%)	Frequency of calibration / verification / performance check* (last check date)			

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^{*} Specify SI unit

	Reference standards Page/											
Name o	Name of laboratory :											
Accred	Accreditation No./Applicant NoDate of record :											
No.	Name of reference standards	Identification number	Producer	Serial No./ Batch No.	Capacity (an acceptance tolerance)*	Resolution*	Calibration laboratories	Uncertainty of measurement* (95%)	Frequency of calibration (last calibration date)			

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^{*} Specify SI unit

	Certified reference materials / Reference materials											
Name of laboratory :												
Accreditation No./Applicant No												
No.	Name of certified reference materials/reference materials (Test items)	RM (✔)	CRM (✔)		dard) solution	Serial No./ Batch No.	Producer	Assigned value*	Uncertainty of measurement* (95%)	Expired date		

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^{*} Specify SI unit

		Valid	dation and verificat	ion of methods	Page/
Name o	of laboratory :				
Accred	itation No./Applicant No.			Date of record :	
No.	Test items	Range of validation methods*	Range of verification of standard methods*	Characteristics of validation methods and verification of standard n	nethods

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^{*} Specify SI unit

		Internal quality control of test results	Page/		
Name of laboratory :					
Accred	litation No./Applicant No.	Date of record :	Date of record :		
No.	Test items	Parameters of internal quality control and an acceptance criteria *	Frequency of check		

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^{*} Specify SI unit

Uncertainty of measurement					
Name of laboratory :					
Accred	Accreditation No./Applicant NoDate of record :				
No.	Test items	Results*	Uncertainty of measurement* (95%)	% Relative of measurement uncertainty	

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^{*} Specify SI unit

Proficiency testing activity of accredited and applicant laboratories				page /				
Name	Name of laboratory :							
Accreditation No. / Applicant No.				Date of re	ecord :			
PT Re	PT Results							
No.	Proficiency testing scheme /	Scheme/	PT Provider	Date of	Date of final	Result of PT	Details of	Date of closed
	Test item	Code No.		participation	report	participation,	corrective	out corrective
						Z-score or	actions	action
						others		

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	Proficiency testing activity of a	accredited and applicant laboratories	page /		
Name of laboratory :					
Accreditation No. / Applicant No.		Date of record :			
PT P	PT Plan				
No.	Proficiency testing scheme /	PT Provider	Month/Year of participation		
	Test item				

Note Proficiency testing activity includes international or national inter-laboratory comparisons or measurement audits

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