sCONTRACTOR/PARTNER TEST LAB ASSESSMENT FORM

Report Number: 09971171.017

☐ Initial Accreditation ☒ Surveillance of Accreditation

☐ Re-Accreditation ☐ Extension of Accreditation (Addition of Standards)

Application for: ☐ Contractor ☒ Partner Test Lab ☐ NRTL / TUV-US Subcontractor

☐ Factory Inspection Subcontractor (Also see Appendix 1 for additional requirements)

Scope of Accreditation (Standards): IEC/EN/UL/CAN/CSA 60950-1, 61010-1, 60065 and 60601-1, IEC/EN/UL/CAN/CSA 60601-1-1, 60601-1-2, 60601-1-4, 60601-1-6, 60601-1-8, 60601-1-11, 60601-2-10

NRTL Subcontractors: N/A

☐ The independent lab is capable of doing the tests (facilities, personnel, equipment)
☐ The independent lab does not compromise independence of TRNA as a NRTL
☐ The laboratory is independent according to ISO 17025 and OSHA Guidelines

Address of the assessed location:

Name:	**Washington Laboratories Ltd**
Street:	**4840 Winchester Blvd, Suite 4**
City/State/Zip:	**Frederick, MD 21703**
Contact Person:	**Elmer I. Rodriguez**
Phone/Fax	**301-216-1500 / 301-216-1590**

Name:	**Washington Laboratories Ltd**
Street:	**7560 Lindbergh Drive**
City/State/Zip:	**Gaithersburg, MD 20879**
Contact Person:	**Steven D. Koster**
Phone/Fax	**301-216-1500 / 301-216-1590**

Details of the auditor:

Name:	**Jan Komarzynski**
Institution:	**TUV Rheinland of North America, Inc.**
Telephone/Fax:	**203-426-0888 Ext. 4126 / 203-426-4009**

sCONTRACTOR/PARTNER TEST LAB ASSESSMENT FORM

☒ Lead Auditor ☒ Technical Expert

Auditor:

Jan Komarzynski		11/16/16
Typed	signature	date

Reviewer:

kkamer@amer.tuv.com

Digitally signed by kkamer@amer.tuv.com
DN: cn=kkamer@amer.tuv.com
Date: 2016.11.22 07:56:57 -05'00'

Kenneth Kamer		11/21/16
Typed	signature	date

Reference to **ISO/IEC 17025:2005** is required for formal interpretation to subclauses of the following sections.

Legend: Status: **Y** = YES **N** = NO **N/A** = Not applicable

Doc. ref.: Document reference of the relevant laboratory: ***Management System Manual (MSM).***

There are no changes in the MSM referenced in this Report. The MSN was attached to previously issued audit reports.

Remarks:

1) Organization chart has been revised to reflect latest personal and organizational changes in Washington Laboratories Ltd.

2) The above mentioned document is provided as separate Attachment 1 to this Report.

Item		Status	Doc. ref. / Remarks
4	**Management requirements**		
4.1	**Organization and management**		
4.1.1	Is the laboratory or the organization of which it is a part an entity that can be held legally responsible ?	Y	Management System Manual (MSM) 4.1.1
4.1.2	Does the laboratory feel responsibility 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 authori-ties or organisations providing recognition ?	Y	MSM 4.1.2 WLL conducts tests and calibration to compliance with established procedures and standards.
4.1.3	Does the laboratory management system cover work carried out in the laboratory's		
	• permanent facilities ?	Y	MSM 4.1.3 The Management System is applicable to the main Gaithersburg Facility.
	• at sites away from its permanent facilities ?	Y	MSM 4.1.3 The Management System is applicable to the Frederick Facility.
	• or in associated temporary or mobile facilities ?	Y	MSM 4.1.3 The Management System is applicable to the mobile test stations located on customer sites for on-site testing.
4.1.4	If the laboratory is a part of an organization performing activities other than testing and/or calibration, are the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory defined in order to identify potential conflicts of interest ?	Y	MSM 4.1.4 WLL is an independent laboratory, by definition there is no conflict of interest. Where potential does exist in EMC areas different personnel review the work that was tested by others.
	Note 1 Where a laboratory is part of a larger organization, the organisational arrangements should be such that departments having conflicting interests, such as production, commercial marketing or financing do not adversely influence the laboratory's compliance with the requirements of this International Standard.		
	Note 2 If the laboratory wishes to be recognised as a third-party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgement. The third-party testing or calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgement and integrity in relation to its testing or calibration activities.		
4.1.5	Does the laboratory		
	a) have managerial and technical personnel with the authority and resources needed to carry out their duties and to identify the occurrence of depar-tures from the quality system or the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimise such departures (see also 5.2) ?	Y	MSM 4.1.5 WLL staff has sufficient knowledge, training, and authority to accomplish tasks and to initiate CARs when deviations to the system are noted.
	b) have arrangements to ensure that its manage-ment and personnel are free from any undue internal or external commercial, financial and other pressures and influences that may adversely affect the quality of their work ?	Y	MSM 4.1.5.2 WLL personnel are forbidden from accepting compensation or direct employment from clients. Personnel are empowered to alert management to issues of internal or external influences.
	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 ?	Y	MSM 4.1.5.3 Non-disclosure agreements are negotiated and created between WLL and its clients. All employees are bound to maintain the confidentiality and proprietary rights of clients. All employees must sign a non-disclosure agreement.
	d) have policies and procedures to avoid involve-	Y	MSM 4.1.5.4

Item			Status	Doc. ref. / Remarks
		ment in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity ?		Employees are mandated from activities which could impair their abilities, impartiality, or competence.
	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 ?	Y	MSM 4.1.5.5, Org Chart Org chart defines position and inter-relation.

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4.1	**Organization and management** (contd.)			
4.1.5 (contd.)	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 ?	Y	MSM 4.1.5.6, Org Chart Individual job descriptions define responsibility, org chart defines inter-relation.
	g)	provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, and with the assessment of the test or calibration results ?	Y	MSM 4.1.5.7, Org Chart Org chart defines supervision.
	h)	have the technical management which has overall responsibility for the technical operations and the provisions of the resources needed to ensure the required quality of laboratory operations ?	Y	MSM 4.1.5.8 VP of Operations responsible for technical aspects of organization and ensuring adequacy of QA system.
	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 is implemented and followed at all times ?	Y	MSM 4.1.5.9 QA Manager is the Management representative responsible for overseeing and implementing the QA system.
		does the quality manager have direct assess to the highest level of management at which decisions are made on laboratory policy or resources ?	Y	MSM 4.1.5.9
	j)	appoint deputies for key managerial personnel such as the quality manager (see note) ?	Y	MSM 4.1.5.10 Appropriate deputies defined.
	Note	Individuals may have more than one function and it may be impractical to appoint deputies for every function.		
	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?	Y	MSM 4.1.5.11
4.1.6		Does the Top management ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system?	Y	MSM 4.1.6
4.2	**Management system**			
4.2.1		Has the laboratory established, implemented and maintained a management system appropriate to the scope of its activities ?	Y	MSM 4.2.1
		Has the laboratory documented its policies, systems programs, procedures and instructions to the extent necessary to enable the laboratory to ensure the quality of the test and/or calibration results ?	Y	MSM 4.2.1
		Is documentation used in this system communicated to, understood by, available to, and implemented by the appropriate personnel ?	Y	MSM 4.2.1 New employees are trained in the QA system, procedures and meetings supplement training and records of such are

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			maintained in employee's file.
4.2.2	Are the laboratory's management system policies related to quality, including a quality policy statement, defined in a quality manual (however named)?	Y	MSM 4.2.2 WLL policy defined.
	Are the overall objectives established and reviewed during management review?	Y	MSM 4.2.2 .
	Are the overall objectives documented in a quality policy statement ?	Y	MSM 4.2.2 Objectives documented.
	Is the quality policy statement issued under the authority of the top management ?	Y	MSM 4.2.2 Issued by the President.
	Does the manual at least include the following:		
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 ?	Y	MSM 4.2.2 Stated.
	b) the management's statement of the laboratory's standard of service ?	Y	MSM 4.2.2 Stated.
	c) the purpose of the management system related to quality;?	Y	MSM 4.2.2 Stated.
	d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarise themselves with the quality documentation and implement the policies and procedures in their work ?	Y	MSM 4.2.2 Personnel are trained and work activities reviewed.
	e) the laboratory management's commitment to continually improve the effectiveness of the management ?	Y	MSM 4.2.2
	Note The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and customers' requirements. When the test and/or calibration laboratory is part of a larger organization, some quality policy elements may be in other documents.		
4.2.3	Does the Top management provide evidence of commitment to the development and implementation of the management system and continually improving its effectiveness?	Y	MSM 4.2.3
4.2.4	Does the Top management communicate to the organization the importance of meeting customer as well as statutory and regulatory requirements?	Y	MSM 4.2.4
4.2.5	Does the quality manual include or make reference to the supporting procedures including technical procedures. Does the quality manual outline the structure of the documentation used in the management system?	Y	MSM 4.2.5
4.2.6	Are 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.	Y	MSM 4.2.6

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4.2.7	Does the Top management ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented?	Y	MSM 4.2.7
4.3	**Document control**		
4.3.1	**General** Has the laboratory established and maintained procedures to control all documents that form part of its management system (internally generated and from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals ?	Y	MSM 4.3.1 Procedures defined.
	Note 1 In his context "document" could be policy statements, procedures, specifications calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analogue, photographic or written. Note 2 The control of data related to testing and calibration is covered in 5.4.7. The control of records is covered in 4.12		

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4.3.2	**Document approval and issue**		
4.3.2.1	Are all documents issued to personnel in the laboratory as part of the management system reviewed and approved for use by authorised personnel prior to issue ?	Y	MSM 4.3.2 Signatories defined. Documents are reviewed during internal audits for suitability.
	Is a master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system established and readily available to preclude the use of invalid and/or obsolete documents ?	Y	MSM 4.3.2
4.3.2.2	Do the procedures adapted ensure that:		
	a) authorised editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed ?	Y	MSM 4.3.2 All standards have copy numbers according to manual.
	b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements ?	Y	MSM 4.3.2
	c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use ?	Y	MSM 4.3.2 Obsolete documents are removed from use and placed in archive location for reference.
	d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked ?	Y	MSM 4.3.2 Hard copies are physically placed in archive location or marked "OLD". Electronic copies moved into archive location.

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4.3.2.3	Are management system documents generated by the laboratory uniquely identified ?	Y	MSM 4.3.2 Identified.
	Does such identification include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies) ?	Y	MSM 4.3.2 Identified.
4.3.3	**Document changes**		
4.3.3.1	Are changes to documents reviewed and approved by the same function that performed the original review unless specifically designated otherwise ?	Y	MSM 4.3.3 Approval verified by QA manager who approves changed. Electronics signatures are used on electronic datasheets.
	Do the designated personnel have access to pertinent background information upon which to base their review and approval ?	Y	MSM 4.3.3
4.3.3.2	Where practicable, is the altered or new text identified in the document or its appropriate attachments ?	Y	MSM 4.3.3 Track changes are software enabled with change bars and strike through.
4.3.3.3	If the laboratory's documentation control system allows for the amendment of documents by hand pending the re-issue of documents, are the procedures and authorities for such amendments defined ?	Y	MSM 4.3.3 Ink changes defined.
4.3.3.3	Are amendments clearly marked, initialled and dated ?	Y	MSM 4.3.3
	Is a revised document formally re-issued as soon as practicable ?	Y	MSM 4.3.3
4.3.3.4	Are procedures established to describe how changes in documents maintained in computerised systems are made and controlled ?	Y	MSM 4.3.4 Electronic document procedures defined.
4.4			
4.4.1	Has the laboratory established and maintained procedures for the review of requests, tenders or contracts ?	Y	MSM 4.4.1 President defines service offerings and pricing, personnel process requests.
	Do the policies and procedures for these reviews leading to a contract for testing and/or calibration ensure that:	Y	MSM 4.4.1
	a) the requirements, including the methods to be used are adequately defined, documented and understood ? (see 5.4.2)	Y	MSM 4.4.1 Defined.
	b) the laboratory has the capability and resources to meet the requirements ?	Y	MSM 4.4.1 Review of request triggers quote based upon services listed in services brochure.
	c) the appropriate test and/or calibration method is selected and capable of meeting the customer's requirements ? (see 5.4.2)	Y	MSM 4.4.1
	Are any differences between the request or tender and the contract resolved before any work commences ?	Y	MSM 4.4.1
	Is each contract acceptable both to the laboratory and the customer ?	Y	MSM 4.4.1
	Note 1 The request, tender and contract review should be conducted in a practical and efficient manner, and the effect of financial, legal and time schedule aspects should be taken into account. For internal customers, reviews and requests, tenders and contracts can be performed in a simplified way.		
	Note 2 The review of capability should establish that the laboratory possesses the necessary physical, personnel and		

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	information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests and/or calibrations in question. The review may also encompass results of earlier participation in interlaboratory comparisons or proficiency testing and/or the running of trial test or calibration programs using samples of items of known value in order to determine uncertainties of measurements, limits of detection, confidence limits, etc. Note 3 A contract may be any written or oral agreement to provide a customer with testing and/or calibration services.		
4.4.2	Are records of such reviews, including any significant changes, maintained ? Are records maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract ?	Y Y	MSM 4.4.2 MSM 4.4.2
	Note For reviews of routine and other simple tasks, the date and the identification (e.g. the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial inquiry stage or on granting of the contract for on-going routine work performed under a general agreement with the customer, provided that the customer's requirements remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more comprehensive record should be maintained.		
4.4.3	Does the review also cover any work that is subcontracted by the laboratory ?	Y	MSM 4.4.3 Client involved in subcontractor selection.
4.4.4	Is the customer informed about any deviation from the contract ?	Y	MSM 4.4.4 Client acknowledges deviation, record kept in database.
4.4.5	If a contract needs to be amended after the work has commenced, is the same contract review repeated and any amendments communicated to all affected personnel ?	Y	MSM 4.4.5 If contract amendment is required after job opens, review process is repeated.

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4.5	**Subcontracting of tests and calibrations**		
4.5.1	Where a laboratory subcontracts work whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting, agency or franchising arrangements), is this work placed with a competent ? A competent subcontractor is one that, for example, complies with this International Standard for the work in question.	Y	MSM 4.5.1 Subcontractors/vendors are assessed by QA manager to ensure quality competency.
4.5.2	Does the laboratory advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing ?	Y	MSM 4.5.2 WLL personnel assigned to job works with client to obtain approval of subcontractor.
4.5.3	Is the laboratory responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used ?	Y	MSM 4.5.3 WLL assumes responsibility.
4.5.4	Does the laboratory maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this International Standard for the work in question ?	Y	MSM 4.5.4 Approved vendor/subcontractor list maintained.
4.6	**Purchasing services and supplies**		
4.6.1	Does the laboratory have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that may affect the quality of the tests and/or calibrations? Do procedures exist for the purchase, reception and storage of reagent and laboratory consumable materials	Y Y	MSM 4.6.1 MSM 4.6.1

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	relevant for the tests and calibrations ?		
4.6.2	Does the laboratory ensure that purchased supplies and reagents and consumable materials that may effect 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 ?	Y	MSM 4.6.2 Purchased parts are for convenience of client or construction of test fixture which is verified against test standard. Purchasing reference sheet provided for list of approved safety department supplies.
	Do the services and supplies used comply with specified requirements ?	Y	MSM 4.6.2
	Are records of actions taken to check compliance maintained ?	Y	MSM 4.6.2
4.6.3	Do purchasing documents, for items affecting the quality of laboratory output, contain data describing the services and products ordered ? Are these purchasing documents reviewed and approved for technical content prior to release ?		
	Note The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the management system standard under which they were made.		
4.6.4	Does the laboratory evaluate suppliers of critical consumables, supplies and services which may affect the quality of testing and calibration ?	Y	MSM 4.6.4
	Does the laboratory maintain records of these evaluations and list thosesupplier approved?	Y	MSM 4.6.4

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4.7	**Service to the customer**		
4.7.1	Is the laboratory willing to cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers?	Y	MSM 4.7 Co-operation encouraged, policy defines process.
	Note 1 Such cooperation may include: a) providing the customer or the customer's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the customer; b) preparation, packaging, and dispatch of test and/or calibration items needed by the customer for verification purposes. Note 2 Customers value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the customer, especially in large assignments, should be maintained throughout the work. The laboratory should inform the customer of any delays or major deviations in the performance of the tests and/or calibrations.		
4.7.2	Does the laboratory seek, both positive and negative feedback from its customers? Is the feedback used and analysed to improve the management system, testing and calibration activities and customer service?	Y	MSM 4.7 After completion of a project, the business development office contacts the customer to ensure satisfaction and solicits suggestions.
	Note Examples of the types of feedback include customer satisfaction surveys and review of test or calibration reports with customers.		

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4.8	**Complaints**		
	Has the laboratory a policy and procedure for the resolution of complaints received from customers or other parties ?	Y	MSM 4.8.1 Employees encouraged to bring complaints to management, if required, may generate a CAR for formal resolution.
	Are records maintained of all complaints and of the investigations and corrective actions taken by the laboratory ? (see also 4.10)	Y	MSM 4.8.2 Records maintained.
4.9	**Control of nonconforming testing and/or calibration work**		
4.9.1	Has the laboratory a policy and procedures to be implemented when any aspect of its testing and/or calibration work, or the result of this work, do not conform to its own procedures or the agreed requirements of the customer ?	Y	MSM 4.9.1 Appropriate technical authority reviews to find root cause of nonconforming work.
	Do the policy and procedures ensure that:		
	a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified ?	Y	MSM 4.9.1 Technical authority performs review.
	b) an evaluation of the significance of the nonconforming work is made ?	Y	MSM 4.9.1 Extent of non-conformance determined.
	c) remedial actions are taken immediately, together with any decision about the acceptability of the nonconforming work ?	Y	MSM 4.9.1 Required actions determined by reviewing technical authority are taken.
	d) where necessary, the customer is notified and work is recalled ?	Y	MSM 4.9.1 Client is notified and required resolution determined.
	e) the responsibility for authorising the resumption of work is defined ?	Y	MSM 4.9.1 Client is apprised and authorization sought by reviewing technical authority.
	Note Identification of nonconforming work or problems with the management system or with testing and/or calibration activities can occur at various places within the management system and technical operations. Examples are customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate checking, management reviews and internal or external audits.		
4.9.2	Where the evaluation indicates that the non-conforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, are the corrective action procedures given in 4.10 promptly followed ?	Y	MSM 4.9.2 In situations where non c0confiming work may lead to recurrence, a CAR is generated and reviewed to identify root cause.
4.10	**Improvement**		
	Does the laboratory 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?	Y	MSM 4.10 Input is continually requested.
4.11	**Corrective action**		
4.11.1	**General** Has the laboratory established a policy and procedures and designated appropriate authorities for implementing corrective action when non-conforming work or departures from the policies and procedures in the management system or technical operations have been identified?	Y	MSM 4.11.1 MSM documents the procedures for corrective action.
	Note A problem with the management system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of non-conforming work, internal or external audits, management reviews,		

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	feedback from customers or staff observations.		
4.11.2	**Cause analysis** Does the procedure for corrective action start with an investigation to determine the root cause(s) of the problem ?	Y	MSM 4.11.2
	Note Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.		
4.11.3	**Selection and implementation of corrective actions** Where corrective action is needed, has the laboratory identified potential corrective actions?	Y	MSM 4.11.3
	Does the laboratory select and implement the action(s) most likely to eliminate the problem and to prevent recurrence ?	Y	MSM 4.11.3
	Are corrective actions to a degree appropriate to the magnitude of the risk of the problem ?	Y	MSM 4.11.3
	Does the laboratory document and implement any required changes resulting from corrective action investigations ?	Y	MSM 4.11.3
4.11.4	**Monitoring of corrective actions** Does the laboratory monitor the results to ensure that the actions they have been taken are effective ?	Y	MSM 4.11.4
4.11.5	**Additional audits** Where the identification of non-conformances or departures casts doubt on the laboratory's compliance with its own policies and procedures, or on its compliance with this International Standard, does the laboratory ensure that the appropriate areas of activity are audited in accordance with 4.13 as soon as possible ?	Y	MSM 4.11.5
	Note Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified.		
4.12	**Preventive action**		
4.12.1	Are needed improvements and potential sources of non-conformances, either technical or concerning the management system, identified ?	Y	MSM 4.12 MSM documents to the methods for preventive action.
	If preventive action is required, are action plans developed, implemented and monitored, to reduce the likelihood of occurrence of such non-conformances and to take advantage of the opportunities for improvement ?	Y	MSM 4.12
4.12.2	Do procedures for preventive actions include the initiation of such actions and application of controls to ensure that they are effective ?	Y	MSM 4.12
	Note 1 Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints. Note 2 Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analysis and proficiency testing results.		
4.13	**Control of records**		
4.13.1	**General**		
4.13.1.1	Has the laboratory established and maintained proce-	Y	MSM 4.13.1

Item		Status	Doc. ref. / Remarks
	dures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records ?		Listing of controlled records maintained by QA manager.
	Do quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions ?	Y	MSM 4.13.1 Included.
4.13.1.2	Are all records legible and stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss ?	Y	MSM 4.13.1 Soft and hard copies of records stored in appropriate locations relevant to content.
	Are retention times of records established ?	Y	MSM 4.13.2
	Note Records may be in any media, such as hard copy or electronic media.		
4.13.1.3	Are all records held secure and in confidence ?	Y	MSM 4.13.3
4.13.1.4	Does the laboratory have procedures to protect and back-up data records stored electronically and to prevent unauthorised access to or amendment of these records ?	Y	MSM 4.13.4 Backup system is in place.
4.13.2	**Technical records**		
4.13.2.1	Does the laboratory retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period ?	Y	MSM 4.13.5
	Do the records for each test or calibration contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original ?	Y	MSM 4.13.5
	Do the records include the identity of personnel responsible for the sampling, performance of each test and/ or calibration and checking of results ?	Y	MSM 4.13.5
	Note 1 In certain fields it may be impossible or impracticable to retain records of all original observations. Note 2 Technical records are accumulations of data (see 5.4.7) and information which result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, check sheets, work notes, control graphs, external and internal test reports and calibration certificates, customers' notes, papers and feedback.		
4.13.2.2	Are observations, data and calculations recorded at the time they are made and identifiable to the specific task ?	Y	MSM 4.13.5
4.13.2.3	When mistakes occur in the records, is each mistake crossed out, not erased, made illegible or deleted, and the correct value entered alongside ?	Y	MSM 4.13.5
	Are all such alterations to records signed or initialled by the person making the correction ?	Y	MSM 4.13.5
	In case of records stored electronically, are equivalent measures taken to avoid loss or change of original data ?	Y	MSM 4.13.5
4.14	**Internal audits**		
4.14.1	Does the laboratory 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 ?	Y	MSM 4.14.1 QA manager initiates and implements audits, calendar maintained to ensure all areas are covered.

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	Does the internal audit program address all elements of the management system, including the testing and/or calibration activities ?	Y	MSM 4.14.1
	Is the quality manager responsible to plan and organise audits as required by the schedule and requested by management ?	Y	MSM 4.14.1
	Are such audits carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited ?	Y	MSM 4.14.1
	Note The cycle for internal auditing should normally be completed in one year.		
4.14.2	When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, does the laboratory take timely corrective action and notify customers in writing if investigations show that the laboratory results may have been affected ?	Y	MSM 4.14.2 If audit reveals ineffective operations, then corrective action is taken and customer is notified.
4.14.3	Are the area of activity, the audit findings and corrective actions that arise from them recorded ?	Y	MSM 4.14.3 Audit findings part of audit plan.
4.14.4	Do follow-up audit activities verify and record the implementation and effectiveness of the corrective action taken ?	Y	MSM 4.14.4 If CAR generated, audit used to verify if implemented measures were effective.
4.15	**Management reviews**		
4.15.1	In accordance with a predetermined schedule and procedure, does the laboratory's management 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 ?	Y	MSM 4.15.1 Minutes from management review meeting act as records of review.
	Does the review take account of:		
	• the suitability of policies and procedures ?	Y	MSM 4.15.1
	• reports from managerial and supervisory personnel ?	Y	MSM 4.15.1
	• the outcome of recent internal audits ?	Y	MSM 4.15.1
	• corrective and preventive actions ?	Y	MSM 4.15.1
	• assessment by external bodies ?	Y	MSM 4.15.1
	• the result of interlaboratory comparisons or proficiency tests ?	Y	MSM 4.15.1
	• the suitability of policies and procedures ?	Y	MSM 4.15.1
	• customer feedback ?	Y	MSM 4.15.1
	• complaints ? • recommendations for improvement?	Y Y	MSM 4.15.1 MSM 4.15.1
	• other relevant factors such as quality control activities, resources and staff training ?	Y	MSM 4.15.1
	Note 1 A typical period for conducting management reviews is once every 12 months.		
	Note 2 Results should feed into the laboratory planning system and should include the goals, objectives and action plans for the coming year.		
	Note 3 A management review includes consideration of related subjects at regular management meetings.		
4.15.2	Are findings from management reviews and the action arising from them recorded ?	Y	MSM 4.15.2 Findings are reported as part of audit report.
	Does the management ensure that those actions are discharged within an appropriate and agreed time scale ?	Y	MSM 4.15.2 Corrective actions shall be taken on the agreed timescale for those corrections.
5	**Technical requirements**		
5.1	**General**		

Item		Status	Doc. ref. / Remarks
5.1.1	Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from: • human factors (5.2), • accommodation and environmental conditions (5.3), • test and calibration methods and method validation (5.4), • equipment (5.5), • measurement traceability (5.6), • sampling (5.7), • the handling of test and calibration items (5.8).		
5.1.2	The extent to which these factors contribute to the total measurement uncertainty differs considerably between (types of) tests and between (types of) calibrations. Does the laboratory take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses ?	Y	MSM 5.1.2 MSM documents how WLL has addressed uncertainty of measurement.
5.2	**Personnel**		
5.2.1	Does the laboratory management ensure the competency of all personnel who operate specific equipment, perform tests and/ or calibrations, evaluate results, and sign test reports and calibration certificates ?	Y	MSM 5.2.1 Personnel performing tests and calibrations properly trained, educated, and experienced.
	When using staff who are undergoing training, is appropriate supervision provided ?	Y	MSM 5.2.1 Technical manager provides oversight.
	Are personnel performing specific tasks qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required ?	Y	MSM 5.2.1 Personnel performing tests and calibrations properly trained, educated, and experienced.
	Note 1 In some technical areas (e.g. non-destructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might be regulatory, included in the standards for the specific technical field, or required by the customer. Note 2 The personnel responsible for the opinions and interpretations included in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out, also have: • relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and the defects or degradations which may occur during or in service; • knowledge of the general requirements expressed in the legislation and standards; and • an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned.		
5.2.2	Has the management of the laboratory formulated the goals with respect to the education, training and skills of the laboratory personnel ?	Y	MSM 5.2.2 VP of Operations ultimately responsible. Training accomplished through various methods.
	Does the laboratory have a policy and procedures for identifying training needs and providing training of personnel ?	Y	MSM 5.2.2
	Is the training program relevant to the present and anticipated tasks of the laboratory ? Is the effectiveness of the training actions taken (of the laboratory personnel) evaluated by the management of the laboratory	Y	MSM 5.2.2
5.2.3	Does the laboratory use personnel who are employed by, or under contract to, the laboratory ?	Y	MSM 5.2.3 Employees or contract personnel used.
5.2.3	Where contracted and additional technical and key support personnel are used, does the laboratory ensure that such personnel are supervised and that they work in accordance with the laboratory's management system ?	Y	MSM 5.2.3 Employees and contract personnel evaluated to assure they have the required qualifications for assigned duties.
5.2.4	Does the laboratory maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations ?	Y	MSM 5.2.4 Job descriptions on filed for each position.
	Note Job descriptions can be defined in many ways. As a minimum, the following should be defined: • the responsibilities with respect to performing tests and calibrations;		

Item		Status	Doc. ref. / Remarks
	• the responsibilities with respect to the planning of tests and/or calibrations and evaluation of results; • the responsibilities for reporting opinions and interpretations; • expertise and experience required; • qualifications and training programs; • managerial duties.		
5.2.5	Does the management authorise 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 ?	Y	MSM 5.2.5 Org chart identifies responsible personnel.
	Does the laboratory maintain records of the relevant authorisation(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel ?	Y	MSM 5.2.5 Records maintained.
	Is this information readily available and include the date the authorisation and/or competence is confirmed ?	Y	MSM 5.2.5
5.3	**Accommodation and environmental conditions**		
5.3.1	Are the laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, such as to facilitate correct performance of tests and/or calibrations ?	Y	MSM 5.3.1 Proper facilities exist.
	Does the laboratory ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement ?	Y	MSM 5.3.1
	Is particular care taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility ?	Y	MSM 5.3.1
	Are the technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations documented ?	Y	MSM 5.3.1
5.3.2	Does the laboratory monitor, control and record environmental conditions as required by relevant specifications, methods and procedures or where they influence the quality of the results ?	Y	MSM 5.3.2
	Is due attention paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned ?	Y	MSM 5.3.2
	Are tests and calibrations stopped when the environmental conditions jeopardise the results of the tests and/or calibrations ?	Y	MSM 5.3.2
5.3.3	Are there effective separation between neighbouring areas in which there are incompatible activities ?	Y	MSM 5.3.3 Personnel are trained on requirements for identification of conditions that may affect test results.
	Are measures taken to prevent cross-contamination ?	Y	MSM 5.3.3
5.3.4	Is access to and use of areas affecting the quality of tests and/ or calibrations controlled ?	Y	MSM 5.3.4 Lab test stations are access controlled, in other areas, traffic is limited.
5.3.4	Has the laboratory decided the extent of control based on its particular circumstances ?	Y	MSM 5.3.4
5.3.5	Are measures taken to ensure good housekeeping in the laboratory ?	Y	MSM 5.3.5 All personnel are to maintain work areas. Storage areas are provided for test equipment and customer supplied product.
	Are special procedures prepared where necessary ?	Y	MSM 5.3.5

Item		Status	Doc. ref. / Remarks
5.4	**Test and calibration methods and method validation**		
5.4.1	**General**		
	Does the laboratory use appropriate methods and procedures for all tests and/or calibrations within its scope ?	Y	MSM 5.4.1 WLL uses standard test methods and calibration methods.
	Do these include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated ?	Y	MSM 5.4.1
	Do these, when appropriate, include an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data ?	Y	MSM 5.4.1
	Does the laboratory have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardise the results of tests and/or calibrations ?	Y	MSM 5.4.1
	Are all instructions, standards, manuals and reference data relevant to the work of the laboratory kept up to date and made readily available to personnel ? (see 4.3)	Y	MSM 5.4.1
5.4	**Test and calibration methods and method validation** (contd.)		
5.4.1 (contd.)	Do deviations from test and calibration methods only occur if the deviations have been documented, technically justified, authorised and accepted by the customer ?	Y	MSM 5.4.1
	Note International, regional or national standards or other recognised specifications that contain sufficient and concise information on how to perform the tests and/or calibrations do not need to be supplemented or rewritten as internal procedure if these standards are written in a way that they can be used as published by the operating staff in a laboratory. It may be necessary to provide additional documentation for optional steps in the method or additional details.		
5.4.2	**Selection of methods**		
	Does the laboratory 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 ?	Y	MSM 5.4.2 Technical personnel confirm the applicability of test standards to evaluate products. Selection is made with client involvement.
	Are the methods published in international, regional or national standards preferably used ?	Y	MSM 5.4.2 Tests performed to the appropriate standard for the project.
	Does the laboratory ensure that it uses the latest valid edition of the standards unless it is not appropriate or possible to do so ?	Y	MSM 5.4.2
	When necessary, is the standard supplemented with additional details to ensure consistent application ?	Y	MSM 5.4.2
	When the customer does not specify the method to be used, does the laboratory select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organisations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment ?	Y	MSM 5.4.2
	If laboratory-developed methods or methods adopted by the laboratory are used, are these appropriate for the intended use and validated ?	Y	MSM 5.4.2
	Is the customer informed as to the method chosen ?	Y	MSM 5.4.2
	Does the laboratory confirm that it can properly operate standard methods before introducing the tests or calibrations ?	Y	MSM 5.4.2
	If the standard method changes, is the confirmation repeated ?	Y	MSM 5.4.2
	Does the laboratory inform the customer when the method proposed by the customer is considered to be	Y	MSM 5.4.2

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	inappropriate or out of date ?		
5.4.3	**Laboratory-developed methods**		
	Is the introduction of test and calibration methods developed by the laboratory for its own use a planned activity and assigned to qualified personnel equipped with adequate resources ?	Y	MSM 5.4.3 WLL methods are based upon applicable standards.
	Are plans updated as development proceeds and does it ensure effective communication amongst all personnel involved ?	Y	MSM 5.4.3
5.4.4	**Non-standardised methods**		
	When it is necessary to employ methods not covered by standard methods, are these subject to agreement with the customer and include a clear specification of the customer's requirements and the purpose of the test and/or calibration?	Y	MSM 5.4.4 Client is involved in developing requirements in these cases.
	Has the method developed been validated appropriately before use ?	Y	MSM 5.4.4
	Note For new test and/or calibration methods, procedures should be developed prior to the tests and/or calibrations being performed and should contain at least the following information: a) appropriate identification; b) scope; c) description of the type of item to be tested or calibrated; d) parameters or quantities and ranges to be determined; e) apparatus and equipment, including technical performance requirements; f) reference standards and reference materials required; g) environmental conditions required and any stabilisation period needed; h) description of the procedure, including • affixing of identification marks, handling, transporting, storing and preparation of items, • checks to be made before the work is started, • checks that the equipment is working properly and, when required, calibration and adjustment of the equipment before each use, • the method of recording the observations and results, • any safety measures to be observed; i) criteria and/or requirements for approval/rejection; j) data to be recorded and method of analysis and presentation; k) the uncertainty or procedure for estimating uncertainty.		
5.4.5	**Validation of methods**		
5.4.5.1	Validation is the confirmation by examination and the provision of effective evidence that the particular requirements for a specific intended use are fulfilled.	Y	MSM 5.4.5
5.4.5.2	Does the laboratory validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplification and modifications of standard methods to confirm that the methods are fit for the intended use ?	Y	MSM 5.4.5
	Is the validation as extensive as is necessary to meet the needs of the given application or field of application?	Y	MSM 5.4.5
	Does the laboratory record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use ?	Y	MSM 5.4.5
	Note 1 Validation may include procedures for sampling, handling and transportation; Note 2 The techniques used for the determination of the performance of a method should be one of, or a combination of, the following: • calibration using reference standards or reference materials; • comparison of results achieved with other methods; • interlaboratory comparisons; • systematic assessment of the factors influencing the result; • assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience. Note 3 When some changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out.		

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5.4.5.3	Is the range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensivity against interference from the matrix of the sample/test object), as assessed for the intended use relevant to the customers' needs ?	Y	MSM 5.4.5
	Note 1 Validation includes the specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity. Note 2 As method-development proceeds, regular reviews should be carried out to verify that the needs of the customer are still fulfilled. Any changes in requirements requiring modifications to the development plan should be approved and authorised. Note 3 Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g. accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensivity) can only be given in a simplified way due to lack of information.		
5.4.6	**Estimation of uncertainty of measurement**		
5.4.6.1	Does a calibration laboratory, or a testing laboratory performing its own calibration, have procedures and apply these to estimate the uncertainty of measurement for all calibrations and types of calibrations ?	Y	MSM 5.4.6
5.4.6.2	Do testing laboratories have and also apply procedures for estimating uncertainties of measurements ?	Y	MSM 5.4.6
	In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid calculations of uncertainty of measurement. In these cases, does the laboratory at least attempt to identify all the components of uncertainty and make a reasonable estimation and ensure that the form of reporting of the results does not give a wrong impression ?	Y	MSM 5.4.6
	Is the reasonable estimation based on knowledge of the performance of the method and on the measurement scope by use of, for example, previous experience and validation data ?	Y	MSM 5.4.6
	Note 1 The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as: • the requirements of the test method; • the requirements of the customer; • the existence of narrow limits on which decisions on conformance to a specification are based. Note 2 In those cases where a well-recognised test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.10).		
5.4.6.3	When estimating the uncertainty of measurement, are all uncertainty components which are of importance in the given situation taken into account by using appropriate methods of analysis ?	Y	MSM 5.4.6
	Note 1 Sources contributing to the uncertainty include, but are necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator. Note 2 The predicted long-term behaviour of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty. Note 3 For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement (see bibliography).		
5.4.7	**Control of data**		
5.4.7.1	Are calculations and data transfers subject to appropriate checks in a systematic manner ?	Y	MSM 5.4.7

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5.4.7.2	When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, does the laboratory ensure that:	Y	MSM 5.4.7
	a) computer software developed by the user is documented in sufficient detail and is suitable validated as being adequate for use ?	Y	MSM 5.4.7
	b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing ?	Y	MSM 5.4.7
	c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental conditions necessary to maintain the integrity of test and calibration data ?	Y	MSM 5.4.7
	Note Commercial off-the-shelf software (e.g. word-processing, database and statistical programs) in general use within their designed application range may be considered to be sufficiently validated. However, laboratory software configuration/modifications should be validated as in 5.4.7.2a).		
5.5	**Equipment**		
5.5.1	Is the laboratory 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) ?	Y	MSM 5.5.1
	In those cases where the laboratory needs to use equipment outside its permanent control, does the laboratory ensure that the requirements of this International Standard are met ?	Y	MSM 5.5.1
5.5.2	Is the equipment and its software used for testing, calibration and sampling capable of achieving the accuracy required and does it comply with specifications relevant to the tests and/or calibrations concerned ?	Y	MSM 5.5.2
	Are calibration programs established for key quantities or values of the instruments where these properties have a significant effect on the results ?	Y	MSM 5.5.2
	When received, is equipment (including that used for sampling) calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications ?	Y	MSM 5.5.2
	Is it checked and/or calibrated before use ? (see 5.6)	Y	MSM 5.5.2
5.5.3	Is equipment operated by authorised personnel ?	Y	MSM 5.5.3
	Are up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) readily available for use by the appropriate laboratory personnel ?	Y	MSM 5.5.3
5.5.4	Is each item of equipment and its software used for testing and calibration and significant to the test result, when practicable, uniquely identified ?	Y	MSM 5.5.4
5.5.5	Are records maintained for each item of equipment and its software significant to the tests and/or calibrations performed ?	Y	MSM 5.5.5
	Do these records include at least the following:		

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	a) the identity of the item of equipment and its software ?	Y	MSM 5.5.5
	b) the manufacturer's name, type identification and serial number or other unique identification ?	Y	MSM 5.5.5
	c) checks that equipment complies with the specification ? (see 5.5.2)	Y	MSM 5.5.5
	d) the current location, where appropriate ?	Y	MSM 5.5.5
	e) the manufacturer's instructions, if available, or reference to their location ?	Y	MSM 5.5.5
	f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and due date of next calibration ?	Y	MSM 5.5.5
	g) the maintenance plan, where appropriate, and maintenance carried out to date ?	Y	MSM 5.5.5
	h) any damage, malfunction, modification or repair to the equipment ?	Y	MSM 5.5.5
5.5.6	Does the laboratory have procedures for safe handling, transport, storage, use and, planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration ?	Y	MSM 5.5.6
	Note Additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations or sampling.		
5.5.7	Is equipment that has either been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, taken out of service ?	Y	MSM 5.5.7
	Is such equipment isolated to prevent its use or clearly labelled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly ?	Y	MSM 5.5.7
	Does the laboratory examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and institute the "Control of non-conforming work" procedure ? (see 4.9)	Y	MSM 5.5.7
5.5.8	Whenever practicable, is all equipment under the control of the laboratory and requiring calibration labelled, coded or otherwise identified to indicate the status of calibration and the date or expiring criteria when recalibration is due ?	Y	MSM 5.5.8
5.5.9	When, for whatever reason, equipment goes outside the direct control of the laboratory, does the laboratory ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service ?	Y	MSM 5.5.9
5.5.10	When intermediate checks are needed to maintain confidence in the calibration status of the equipment, are these checks carried out according to a defined procedure ?	Y	MSM 5.5.10
5.5.11	Where calibrations give rise to a set of correction factors, does the laboratory have procedures to ensure that copies (e.g. computer software) are correctly updated ?	Y	MSM 5.5.11
5.5.12	Is test and calibration equipment, including both hardware and software, safeguarded from adjustments which	Y	MSM 5.5.12

Item		Status	Doc. ref. / Remarks
	would invalidate the test and/or calibration results ?		
5.6	**Measurement traceability**		
5.6.1	**General**		
	Is all equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling, calibrated before being put into service ?	Y	MSM 5.6.1 Test instruments that produce measurements without outside means for verify the measurement are subjected to a calibration program that verifies measurements traceable to a national reference standard before being placed into service.
	Does the laboratory have an established program and procedure for the calibration of its equipment ?	Y	MSM 5.6.1
	Note Such a program should include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference standards used as measurement standards, and measuring and test equipment used to perform tests and calibrations.		
5.6.2	**Specific requirements**		
5.6.2.1	**Calibration**		
5.6.2.1.1	For calibration laboratories, is the program for calibration of equipment designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units SI ?	Y	MSM 5.6.2.1
	Has the calibration laboratory established traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to the relevant primary standards of the SI units of measurement ?	Y	MSM 5.6.2.1
	Is the link to SI units achieved by reference to national measurement standards ?	Y	MSM 5.6.2.1
	Are national measurement standards primary standards which are primary realisations of the SI units or agreed representations of SI units based on fundamental physical constants or secondary standards which are standards calibrated by another national metrology institute ?	Y	MSM 5.6.2.1
	When using external calibration services, is traceability of measurement assured by the use of calibration services for laboratories that can demonstrate competence, measurement capability and traceability ?	Y	MSM 5.6.2.1
	Do the calibration certificates issued by these laboratories contain the measurement result, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification ? (see also 5.10.4.2).	Y	MSM 5.6.2.1
	Is the traceability of measurement assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability ?	Y	MSM 5.6.2.1
	Do the calibration certificates issued by these laboratories show that there is a link to a primary standard or to a natural constant realising the SI unit by an unbroken chain of calibrations ?	Y	MSM 5.6.2.1
	Do the calibration certificates contain the measurement results including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.10.4.2) ?	Y	MSM 5.6.2.1
	Note 1 Calibration laboratories fulfilling the requirements of this International Standard are considered to be competent. A calibration certificate bearing an accreditation body logo from a calibration laboratory accredited to this International Standard for the calibration concerned, is sufficient evidence of traceability of the calibration data report.		

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	Note 2 Traceability to SI units of measurement may be achieved by reference to an appropriate primary standard (see VIM:1993, 6.4) or by reference to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weights and Measures (CGPM) and the International Committee for Weights and Measures (CIPM). Note 3 Calibration laboratories that maintain their own primary standard or representation of SI units based on fundamental physical constants can claim traceability to the SI system only after these standards have been compared , directly or indirectly, with other similar standards of a national metrology institute. Note 4 The term "identified metrological specification" means that it must be clear from the calibration certificate which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification.		
	Note 5 When the terms "international standard" or "national standard" are used in connection with traceability, it is assumed that these standards fulfil the properties of primary standards for realisation of SI units. Note 6 Traceability to national measurement standards does not necessarily require the use of the national metrology institute of the country in which the laboratory is located. Note 7 If the calibration laboratory wishes or needs to obtain traceability from a national metrology institute other than in its own country, this laboratory should select a national metrology institute that actively participates in the activities of BIPM either directly or through regional groups.		
	Note 8 The unbroken chain of calibrations or comparisons may be achieved in several steps carried out by different laboratories that can demonstrate traceability.		
5.6	**Measurement traceability**		
5.6.2.2	**Testing**		
5.6.2.2.1	For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated calibration uncertainty contributes little to the total uncertainty of the test result.	Y	MSM 5.6.2.2
	When this situation arises, does the laboratory ensure that equipment used can provide the accuracy of measurement needed ?	Y	MSM 5.6.2.2
	Note The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of the calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirement should be strictly followed.		
5.6.2.2.2	Where traceability to the SI units of measurement is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration laboratories (see 5.6.2.1.2).	Y	MSM 5.6.2.2
5.6.3	**Reference standards and reference materials**		
5.6.3.1	**Reference standards**		
	Has the laboratory a program and procedure for the calibration of its reference standards ?	Y	MSM 5.6.3
	Are reference standards calibrated by a body that can provide traceability as described in 5.6.2.1 ?	Y	MSM 5.6.3
	Are such reference standards of measurement held by the laboratory used for calibration only and for no other purposes, unless it can be shown that their performance as reference standards would not be invalidated ?	Y	MSM 5.6.3
	Are reference standards of measurement calibrated before and after any adjustment ?	Y	MSM 5.6.3
5.6.3.2	**Reference materials**		
	Are reference materials, where possible, traceable to SI units of measurement, or to certified reference materials ?	Y	MSM 5.6.3
	Are internal reference materials checked as far as is technically and economically practicable ?	Y	MSM 5.6.3
5.6.3.3	**Intermediate checks**		
	If checks are needed to maintain confidence in the calibration status of reference, primary, transfer or working	Y	MSM 5.6.3

Item		Status	Doc. ref. / Remarks
	standards and reference materials, are such checks carried out according to defined procedures and schedules ?		
5.6.3.4	**Transport and storage** Has the laboratory 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 ?	Y	MSM 5.6.3
	Note Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations or sampling.		
5.7	**Sampling**		
5.7.1	Does the laboratory have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration ?	Y	MSM 5.7.1 Sampling during product testing is used to qualify product compliance based on testing a limited quantity of like features.
	Is the sampling plan as well as the sampling procedure available at the location where sampling is undertaken ?	Y	MSM 5.7.1
	Are sampling plans, wherever reasonable, based on appropriate statistical methods ?	Y	MSM 5.7.1
	Does the sampling process address the factors to be controlled to ensure the validity of the test and calibration results ?	Y	MSM 5.7.1
	Note 1 Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration a representative sample of the whole. Sampling may also be required by the appropriate specification for which the substance, material or product is to be tested or calibrated. In certain cases (e.g. forensic analysis), the sample may not be representative but determined by availability. Note 2 Sampling procedures should describe the selection, sampling plan, withdrawal and preparation of a sample or samples from a substance, material or product to yield the required information.		
5.7.2	Where the customer requires deviations, additions or exclusions from the documented sampling procedure, are these recorded in detail with the appropriate sampling data and included in all documents containing test and/or calibration results, and communicated to the appropriate personnel ?	Y	MSM 5.7.2
5.7.3	Does the laboratory have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is under-taken ?	Y	MSM 5.7.3
	Do these records include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling proce-dures are based upon ?	Y	MSM 5.7.3
5.8	**Handling of test and calibration items**		
5.8.1	Does the laboratory have procedures for the trans-portation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer ?	Y	MSM 5.8.1 Client products scheduled for testing or calibration are received by admin or test personnel and a customer product list is generated and filed at WLL reception.
5.8.2	Does the laboratory have a system for identifying test and/or calibration items ?	Y	MSM 5.8.2
	Is the identification retained throughout the life of the item in the laboratory ?	Y	MSM 5.8.2
	Is the system designed and operated so as to ensure that items cannot be confused physically, or when	Y	MSM 5.8.2

Item		Status	Doc. ref. / Remarks
	referred to in records or other documents ?		
	Does the system, if appropriate, accommodate a subdivision of groups of items and the transfer of items within and from the laboratory ?	Y	MSM 5.8.2
5.8.3	Upon receipt of the test or calibration item, are abnormalities or departures from normal or specified conditions, as described in the relevant test or calibration method recorded ?	Y	MSM 5.8.3
	When there is any doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, does the laboratory consult the customer for further instruction before proceeding and records the discussion ?	Y	MSM 5.8.3
5.8.4	Does the laboratory have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation ?	Y	MSM 5.8.4
	Are handling instructions provided with the item followed ?	Y	MSM 5.8.4
	When items have to be stored or conditioned under specified environmental conditions, are these conditions maintained, monitored and recorded ?	Y	MSM 5.8.4
	Where a test or calibration item or portion of an item is to be held secure, does the laboratory have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned ?	Y	MSM 5.8.4
	Note 1 Where test items are to be returned into service after testing, special care is required to ensure that they are not damaged or injured during the handling, testing or storing/waiting process. Note 2 A sampling procedure and information on storage and transport of samples, including information on sampling factors influencing the test or calibration result, should be provided to those responsible for taking and transporting the samples. Note 3 Reasons for keeping a test or calibration item secure can be for reasons of record, safety of value, or to enable complementary tests and/or calibrations to be performed later.		
5.9	**Assuring the quality of test and calibration results**		
	Does the laboratory have quality control procedures for monitoring the validity of tests and calibrations undertaken ?	Y	MSM 5.8.4 Test and calibration data are subjected to review by a subject matter technical authority upon completion of the data collection process. The review checks for completeness of the data collection, including identification info, test equipment listing, and environmental conditions. In addition, the reviewer verifies that the data are consistent with standard requirements and with the technical expectations for that type of data.
5.9.1	Is the resulting data recorded in such a way that trends are detectable and, where practicable, statistical techniques applied to the reviewing of results ?	Y	MSM 5.9.1
	Is this monitoring planned and reviewed and include, but not limited to, the following:	Y	MSM 5.9.1
	a) regular use of certified reference materials and/or internal quality control using reference materials ?	Y	MSM 5.9.1
	b) participation in interlaboratory comparison or proficiency testing programs ?	Y	MSM 5.9.1
	c) replicate tests or calibrations using the same or different methods ?	Y	MSM 5.9.1
	d) re-testing or re-calibration of retained items ?	Y	MSM 5.9.1
	e) correlation of results for different characteristics of an item ?	Y	MSM 5.9.1

Item		Status	Doc. ref. / Remarks
	Note The selected methods should be appropriate for the type and volume of the work undertaken.		
5.9.2	Does the laboratory analyse the quality control data where they are found to be outside predefined criteria, and does the laboratory take planned action to correct the problem and to prevent incorrect results from being reported?	Y	MSM 5.9.2
5.10	**Reporting the results**		
5.10.1	**General**		
	Are the results of each test, calibration, or series of tests or calibrations (see note 1) carried out by the laboratory reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods ?	Y	MSM 5.10.1 Test and calibration results are reported using a formal test report, letter report, or distribution of data sheets as requested by the client. Each of the reporting methods provides the results in a manner that is not subject to interpretation by the client or agency receiving the report.
	Are the results usually reported in a test report or a calibration certificate (see note 1) and include all the information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the method used ?	Y	MSM 5.10.1
	Is this information normally that required by 5.10.2, 5.10.3 and 5.10.4 ?	Y	MSM 5.10.1
	In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way. Is the information listed in 5.10.2 to 5.10.4 which is not reported to the customer readily available in the laboratory which carried out the tests and/or calibrations ?	Y	MSM 5.10.1
	Note 1 Test reports and calibration certificates are sometimes called test certificates and calibration reports, respectively.		
	Note 2 The test reports or calibration certificates may be issued as hard copy or by electronic data transfer provided that the requirements of this International Standard are met.		
5.10.2	**Test reports and calibration certificates**		
	Unless the laboratory has exceptional reasons for not doing so, does each test report or calibration certificate include at least the following information:	Y	MSM 5.10.2
	a) a title, e.g. “Test Report”/”Calibration Certificate” ?	Y	MSM 5.10.2
	b) the name and address of laboratory, and location where the tests and/or calibrations were carried out, if different from the address of the laboratory ?	Y	MSM 5.10.2
	c) unique identification of the report or certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognised as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate ?	Y	MSM 5.10.2
	d) the name and address of the customer ?	Y	MSM 5.10.2
	e) identification of the method used ?	Y	MSM 5.10.2
	f) a description of, the conditions of, and unambiguous identification of the item(s) tested or calibrated ?	Y	MSM 5.10.2
	g) date of receipt of test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration ?	Y	MSM 5.10.2

Item		Status	Doc. ref. / Remarks
	h) reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results ?	Y	MSM 5.10.2
	i) the test and calibration results with, where appropriate, the units of measurement ?	Y	MSM 5.10.2
	j) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorising the test report or calibration certificate ?	Y	MSM 5.10.2
	k) where relevant, a statement to the effect that the results relate only to the items tested or calibrated?	Y	MSM 5.10.2
	Note 1 Hard copies of test reports and calibration certificates should also include the page number and total number of pages.		
	Note 2 It is recommended that laboratories include a statement specifying that the test report or calibration certificate shall not be reproduced except in full, without written approval of the laboratory.		
5.10.3	**Test reports**		
5.10.3.1	In addition to the requirements listed in 5.10.2, do test reports, where necessary for the interpretation of the test results include:	Y	MSM 5.10.3.1
	a) deviations from, additions to or exclusions from the test method, and information on specific test conditions, such as environmental conditions ?	Y	MSM 5.10.3.1
	b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications?	Y	MSM 5.10.3.1
	c) where applicable, a statement on the estimated uncertainty of measurement ? Information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when uncertainty affects compliance to a specification limit	Y	MSM 5.10.3.1
	d) where appropriate and needed opinions and interpretations ? (see 5.10.5)	Y	MSM 5.10.3.1
	e) additional information which may be required by specific methods, customers or groups of customers ?	Y	MSM 5.10.3.1
5.10.3.2	In addition to the requirements listed in 5.10.2 and 5.10.3.1, do test reports containing the results of sampling include the following, where necessary for the interpretation of the test results:		
	a) the date of sampling ?	Y	MSM 5.10.3.2
	b) unambiguous identification of substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate) ?	Y	MSM 5.10.3.2
	c) the location of sampling, including any diagrams, sketches or photographs ?	Y	MSM 5.10.3.2
	d) a reference to the sampling plan and procedure used ?	Y	MSM 5.10.3.2
	e) details of any environmental condition during sampling that may affect the interpretation of the test results ?	Y	MSM 5.10.3.2
	f) any standard or other specification for the sampling method or procedure, and deviations,	Y	MSM 5.10.3.2

Item		Status	Doc. ref. / Remarks
	additions to or exclusions from the specification concerned ?		
5.10.4	**Calibration certificates**		
5.10.4.1	In addition to the requirements listed in 5.10.2, do calibration certificates include the following, where necessary for the interpretation of calibration results:	Y	MSM 5.10.4.1
	a) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results ?	Y	MSM 5.10.4.1
	b) the uncertainty of measurement and/or a state - ment of compliance with an identified metrological specification or clauses thereof ?	Y	MSM 5.10.4.1
	c) evidence that the measurements are traceable ? (see note in 5.6.2.1.1)	Y	MSM 5.10.4.1
5.10.4.2	Does the calibration certificate relate only to quantities and the results of functional tests ?	Y	MSM 5.10.4.2
	If a statement of compliance with a specification is made, does this identify which clauses of the specifi- cation are met or not met ?	Y	MSM 5.10.4.2
	When a statement of compliance with a specification is made, omitting the measurement results and associated uncertainty, does the laboratory record those results and maintain them for possible future reference ?	Y	MSM 5.10.4.2
	When statements of compliance are made, is the uncertainty of measurement taken into account ?	Y	MSM 5.10.4.2
5.10.4.3	When an instrument for calibration has been adjusted or repaired, are the calibration results before and after adjustment or repair, if available, reported ?	Y	MSM 5.10.4.3
5.10.4.4	Does a calibration certificate (or calibration label) contain any recommendation on the recalibration interval except where this has been agreed with the customer ?	Y	MSM 5.10.4.4
	This requirement may be superseded by legal regu- lations.	Y	MSM 5.10.4.4
5.10.5	**Opinions and interpretations**		
	When opinions and interpretations are included, does the laboratory document the basis upon which the opinions and interpretations have been made ?	Y	MSM 5.10.5
	Are opinions ad interpretations clearly marked as such in a test report ?	Y	MSM 5.10.5
	Note 1 Opinions and interpretations should not be confused with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC Guide 65.		
	Note 2 Opinions and interpretations included in a test report may comprise, but not be limited, to the following: • an opinion on the statement of compliance/non-compliance of the results with requirements; • fulfilment • of contractual requirements; • recommendations on how to use the results; • guidance to be used for improvements.		
	Note 3 In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the customer. Such dialogue should be written down.		
5.10.6	**Testing and calibration results obtained from Subcontractors**		
	When the test report contains results of tests performed by subcontractors, are these results clearly identified ?	Y	MSM 5.10.6
	Does the subcontractor report the results in writing or electronically ?	Y	MSM 5.10.6
	When a calibration has been subcontracted, has the laboratory performing the work issued the calibration	Y	MSM 5.10.6

Item		Status	Doc. ref. / Remarks
	certificate to the contracting laboratory ?		
5.10.7	**Electronic transmission of results** In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, are the requirements of this International Standard met ? (see also 5.4.7)	Y	MSM 5.10.7
5.10.8	**Format of reports and certificates** Is the format designed to accommodate each type of test or calibration carried out and to minimise the possibility of misunderstanding or misuse ?	Y	MSM 5.10.8
	Note 1 Attention should be given to the lay-out of the test report or calibration certificate, especially with regard to the presentation of the test or calibration data and ease of assimilation by the reader. Note 2 The headings should be standardised as far as possible.		
5.10.9	**Amendments to test reports and calibration Certificates** Are material amendments to a test report or calibration certificate after issue made only in form of a further document, or data transfer, which includes the statement “Supplement to Test Report [or Calibration Certificate], serial number …. [or as otherwise identified]“, or an equivalent form of wording ?	Y	MSM 5.10.9
	Do such amendments meet all the requirements of this International Standard ?	Y	MSM 5.10.9
	When it is necessary to issue a complete new test report or calibration certificate, is this uniquely identified and contains a reference to the original that it replaces ?	Y	MSM 5.10.9

Appendix 1
Factory Inspection Requirements

Item		Status	Doc. ref. / Remarks
App. 1	**Factory Inspections**	N/A	
	Does the subcontractor use all relevant TUVRNA procedures for conducting factory inspections for TUVRNA.	N/A	
	Does the subcontractor use all relevant TUVRNA procedures in place for the completion of the TUVRNA factory inspection audit report.	N/A	
	Does the subcontractor have procedures in place for submitting factory inspector nominees to TUVRNA.	N/A	
	Does the subcontractor have procedures in place to ensure that only TUVRNA qualified factory inspectors are used.		
	Does the subcontractor maintain records of all trained factory inspectors and their qualifications.		
	Does the subcontractor use all relevant TUVRNA procedures in place for collecting of production samples when required for routine testing at TUVRNA.		
	Does the subcontractor use all relevant TUVRNA procedures in place for addressing nonconformities found during a factory inspection.	N/A	
	Does the subcontractor have procedures in place for submitting completed factory inspection audit reports to TUVRNA for review and storage.	N/A	
	Do any potential conflicts of interest exist between the subcontractor and the applicant and/or the factories it will be inspecting that might affect the independence of TUVRNA.	N/A	

APPENDIX 2

Audit Summary

Nonconformities (NCR's)

NCR #	Requirement	Minor or Major*	Comments / Deviation from Requirement	NCR Closed (Y/N)	Describe How NCR Was Closed / Re-Audit Necessary?
	No NCR's found				

*Note: PTL Program Manager must be informed of any major nonconformities issued in order to assess the nonconformity and determine the course of action for the Subcontractor/PTL.

End of Test Report