

**NOTE:** The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, and other technical data including approval of test results, the quality required, and the management system standard under which they were made.

4.6.4

Requirements	Document Review	Assessment Compliant
Does the laboratory evaluate suppliers of critical consumables, supplies, and services which affect the quality of testing/calibration, and maintain records of these evaluations and list those approved?		*Approved vendor list

4.7 Service to the Customer

4.7.1

Requirements	Document Review	Assessment Compliant
Does the laboratory cooperate with customers/their representatives to clarify customers' requests to monitor the laboratory's performance in relation to work performed, provided the laboratory ensures confidentiality to other customers?		Yes - discussed with management

**NOTE:** Such cooperation may include:

- providing customers/customers' representatives reasonable access to relevant areas of the lab for witnessing of tests/calibrations performed for the customer
- preparation, packaging, and dispatch of test/calibration items needed by the customer for verification purposes

**NOTE:** Customers value the maintenance of good communication, advice/guidance in technical matters, and opinions/interpretations based on results. Communication with the customer, especially in large assignments, should be maintained throughout the work. The lab should inform the customer of any delays/major deviations in performance of tests/calibrations.

4.7.2

Requirements	Document Review	Assessment Compliant
Does the laboratory encourage feedback, both positive and negative, from their customers (e.g. customer surveys)? Is the feedback used to improve the management system, testing/calibration activities, and customer service?		Yes - sent out monthly

**NOTE:** Examples of the types of feedback include customer satisfaction surveys and review of test or calibration reports with customers.

4.8 Complaints

Requirements	Document Review	Assessment Compliant
Does the laboratory have a policy/procedure for resolution of complaints received from customers/other parties?		*MSM, 4.8
Are records maintained of all complaints and of investigations/corrective actions taken by the lab? (see also 4.11)		*Reviewed one complaint from 2007, not deemed necessary to initiate CAR

4.9 Control of Nonconforming Testing/Calibration Work

4.9.1

Requirements	Document Review	Assessment Compliant
Does the laboratory have policies/procedures that are implemented when aspects of its testing/calibration work, or results of this work, do not conform to its own procedures or the agreed requirements of the customer? Do the policies/procedures ensure that:		*MSM 4.9
<ul style="list-style-type: none"> <li>responsibilities/authorities for management of nonconforming work are designated and actions (including halting of work and withholding of test reports/calibration certificates, as necessary) are defined and taken when nonconforming work is discovered?</li> </ul>		Yes
<ul style="list-style-type: none"> <li>an evaluation of the significance of nonconforming work is made?</li> </ul>		Yes
<ul style="list-style-type: none"> <li>corrective actions are taken immediately, together with any decision about the acceptability of nonconforming work?</li> </ul>		Yes
<ul style="list-style-type: none"> <li>where necessary, the customer is notified and work is recalled?</li> </ul>		Yes
<ul style="list-style-type: none"> <li>The responsibility for authorizing resumption of work is defined?</li> </ul>		Yes – MSM 5.2.5

NOTE: Identification of nonconforming work, problems with the management system or with testing/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/calibration certification checking, management reviews, and internal/external audits.

4.9.2

Requirements	Document Review	Assessment Compliant
Where evaluation indicates that nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies/procedures, are corrective action procedures given in 4.11 promptly followed?		*TB-AA08-02

4.10 Improvement

Requirements	Document Review	Assessment Compliant
<p>Does the lab continually improve the effectiveness of its management system through the use of:</p> <ul style="list-style-type: none"> <li>• the quality policy</li> <li>• quality objectives</li> <li>• audit results</li> <li>• analysis of data</li> <li>• corrective/preventive actions</li> <li>• management review</li> </ul>		Yes – see individual sections

4.11 Corrective Action

4.11.1 General

Requirements	Document Review	Assessment Compliant
<p>Has the laboratory established a policy/procedure and designated appropriate authorities for implementing corrective action when nonconforming work or departures from policies/procedures in the management system or technical operations have been identified?</p>		*MSM 4.11

NOTE: A problem with the management system/technical operations of the lab may be identified through a variety of activities, such as control of nonconforming work, internal/external audits, management reviews, and feedback from customers or staff observations.

4.11.2 Cause Analysis

Requirements	Document Review	Assessment Compliant
<p>Does the procedure for corrective action start with an investigation to determine root cause(s) of the problem?</p>		Yes

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/procedures, staff skills/ training, consumables, or equipment and its calibration.

4.11.3 Selection/Implementation of Corrective Actions

Requirements	Document Review	Assessment Compliant
Where corrective action is needed, does the laboratory identify potential corrective actions? Does it select/implement the action(s) most likely to eliminate the problem and to prevent recurrence?		Yes
Are corrective actions to a degree appropriate to the magnitude and risk of the problem?		Yes
Does laboratory document/implement any required changes resulting from corrective action investigations?		*Yes - CAR file

4.11.4 Monitoring of Corrective Actions

Requirements	Document Review	Assessment Compliant
Does the laboratory monitor the results to ensure that the corrective actions taken have been effective?		Yes - implementation date on form and followed up at management review

4.11.5 Additional Audits

Requirements	Document Review	Assessment Compliant
Where identification of non-conformances or departures casts doubts on the laboratory's compliance with its own policies and procedures or on its compliance with the International Standard, does the lab ensure the appropriate areas of activity are audited in accordance with 4.14 as soon as possible?		MSM, 4.11.4

NOTE: Such additional audits often follow implementation of 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

Requirements	Document Review	Assessment Compliant
Are needed improvements and potential sources of non-conformances, either technical or concerning the management system, identified?		TB-AA08-03
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 opportunities for improvement?		TB-AA08-03

4.12.2

Requirements	Document Review	Assessment Compliant
Do procedures for preventive actions include initiation of such actions and application of controls to ensure that they are effective?		* TB-AA08-03

NOTE: Preventive action is a proactive process to identify opportunities for improvement rather than a reaction to the identification of problems/complaints.

NOTE: Apart from review of operational procedures, preventive action might involve analysis of data, including trend/risk analyses and proficiency-testing results.

4.13 Control of Records

4.13.1 General

4.13.1.1

Requirements	Document Review	Assessment Compliant
Does the laboratory establish/maintain procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposal of quality and technical records?		*MSM 4.13
Do quality records include reports from internal audits and management reviews as well as records of corrective/preventive actions?		*Yes - reviewed internal audits and mgmt reviews

4.13.1.2

Requirements	Document Review	Assessment Compliant
Are all records legible and stored/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?		All electronic
Are retention times of records established?		*Yes - MSM, 4.13.1.2

NOTE: Records may be in any media, such as hard copy or electronic media.

4.13.1.3

Requirements	Document Review	Assessment Compliant
Are all records held secure and in confidence?		Yes - discussed with management

4.13 A.5 ACLASS Requirement - Field (On-Site) Activities

Requirements	Document Review	Assessment Compliant
Are procedures in place for recording and reporting all results obtained in the field (on-site)? These procedures shall ensure confidentiality and integrity of data obtained in the field (on-site).  Note: This only applies to laboratories that perform field (on-site) calibration or testing.		*N/A

4.13 A.6 ACLASS Requirement - Satellite Site Activities

Requirements	Document Review	Assessment Compliant
For satellite sites, are these procedures defined and coordinated with the procedures of the corporate site in order to assure integrity and confidentiality of all data and records?  Note: This only applies to laboratories with satellite sites.		Yes

4.14 Internal Audits

4.14.1

Requirements	Document Review	Assessment Compliant
Does the lab periodically, and in accordance with a predetermined schedule/procedure, conduct internal audits of its activities to verify that its operations continue to comply with requirements of the management system and the International Standard?		*Yes – reviewed plan and progress to date – on FY schedule (due completion 6/30/09)
Does the internal audit program address all elements of the management system, including the testing/calibration activities? It is the responsibility of the quality manager to plan/organize audits as required by the schedule and requested by management.		Yes
Are such audits carried out by trained/qualified personnel who are, wherever resources permit, independent of the activity to be audited?		Yes

NOTE: The cycle for internal auditing should normally be completed in one year.

4.14.2

Requirements	Document Review	Assessment Compliant
If audit findings cast doubt on the effectiveness of operations or on the correctness or validity of the laboratory's test/calibration results, does the laboratory take timely corrective action and notify customers <u>in writing</u> if investigations show that the lab results may have been affected?		*None to date – MSM, 4.14.2

4.13.1.4

Requirements	Document Review	Assessment Compliant
Does the laboratory have procedures to protect/back-up records stored electronically and to prevent unauthorized access to or amendment of these records?		*Yes - labs back up each other daily

4.13.2 Technical Records

4.13.2.1

Requirements	Document Review	Assessment Compliant
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/calibration certificate issued, for a defined period?		*MSM, 4.13
Do records for each test/calibration contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test/calibration to be repeated under conditions as close as possible to the original?		*TB-AA08-05
Do records include the identity of personnel responsible for the performance of each test/calibration and checking of results?		*Yes - test reports

NOTE: In certain fields it may be impossible or impractical to retain records of all original observations.

NOTE: Technical records are accumulations of data (see 5.4.7) and information which result from carrying out tests/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

Requirements	Document Review	Assessment Compliant
Are observations, data, and calculations recorded at the time they are made and identifiable to the specific task?		Yes - discussed with management

4.13.2.3

Requirements	Document Review	Assessment Compliant
When mistakes occur in records, is each mistake crossed out (not erased, made illegible, or deleted) and the correct value entered alongside?		MSM 4.13.2 - none seen
Are all such alterations to records signed or initialed by the person making the correction? In the case of records stored electronically, are equivalent measures taken to avoid loss or change of original data?		None seen

4.14.3

Requirements	Document Review	Assessment Compliant
Are the areas of activity audited, the audit findings, and corrective actions that arise from them recorded?		*Yes - reviewed spreadsheet

4.14.4

Requirements	Document Review	Assessment Compliant
Do follow-up audit activities verify and record the implementation/effectiveness of the corrective action(s) taken?		*MSM, 4.14.4

4.14 A.7 ACLASS Requirement - Satellite Site Activities

Requirements	Document Review	Assessment Compliant
Does the corporate site include the satellite site in its internal audit? This internal audit shall be carried out according to the procedures of the corporate site including visiting the satellite site(s) by the designated internal auditor.  Note: This only applies to laboratories with satellite sites.		Yes - in spreadsheet

4.15 Management reviews

4.15.1

Requirements	Document Review	Assessment Compliant
In accordance with a predetermined schedule and procedure, does the laboratory's executive management periodically conduct a review of the laboratory's management system and testing/calibration activities to ensure their continuing suitability/effectiveness, and to introduce necessary changes/improvements? Does the review take account of: <ul style="list-style-type: none"> <li>• the suitability of policies/procedures?</li> <li>• reports from managerial/supervisory personnel?</li> <li>• the outcome of recent internal audits?</li> <li>• corrective/preventive actions?</li> <li>• assessments by external bodies?</li> <li>• the results of inter-laboratory comparisons/ proficiency tests?</li> <li>• changes in volume/type of work?</li> <li>• customer feedback?</li> <li>• complaints?</li> <li>• recommendations for improvement?</li> <li>• other relevant factors, such as quality control activities, resources, and staff training?</li> </ul>		*Yes - annual - minutes from 11/29/07  Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes - in new template Yes

NOTE: A typical period for conducting a management review is once every 12 months.

NOTE: Results should feed into the lab planning system and should include the goals, objectives, and action plans for the coming year.

NOTE: A management review includes consideration of related subjects at regular management meetings.

4.15.2

Requirements	Document Review	Assessment Compliant
Are findings from management reviews and actions that arise from them recorded?		*Yes - minutes from 11/07
Does management ensure that those actions are carried out within an appropriate/agreed timescale?		Yes

4.15 A.8 ACLASS Requirement - Satellite Site Activities

Requirements	Document Review	Assessment Compliant
Do records indicate management reviews have taken into account the satellite site activities?		*Yes - minutes from 11/07
Note: This only applies to laboratories with satellite sites		

5. Technical requirements

5.1 General

5.1.1

Requirements	Document Review	Assessment Compliant
<p>Many factors contribute to the correctness and reliability of the tests/calibrations performed by a lab. These factors include:</p> <ul style="list-style-type: none"> <li>• human factors (5.2)</li> <li>• accommodation and environmental conditions (5.3)</li> <li>• test/calibration methods and method validation (5.4)</li> <li>• equipment (5.5)</li> <li>• measurement traceability (5.6)</li> <li>• sampling (5.7)</li> <li>• the handling of test/calibration items (5.8)</li> </ul>		See Below

5.1.2

Requirements	Document Review	Assessment Compliant
The extent to which factors contribute to the total uncertainty of measurement differs considerably between (types of) tests/calibrations. Does the laboratory take into account these factors in developing test/calibration methods and procedures, in training and qualification of personnel, and in selection/calibration of the equipment it uses?		Yes

5.2 Personnel

5.2.1

Requirements	Document Review	Assessment Compliant
Does management ensure the competence of all who operate specific equipment, perform tests/calibrations, evaluate results, and sign test reports/calibration certificates?		Yes - training matrix and discussed with management
When using staff that are undergoing training, is appropriate supervision provided?		Yes - discussed with management
Are personnel performing specific tasks qualified on the basis of appropriate education, training, experience/demonstrated skills, as required?		*Yes - training matrix

NOTE: In some technical areas (e.g. nondestructive testing), it may be required that personnel performing certain tasks hold personnel certification. The lab 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: Personnel responsible for the opinions/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, material, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service
- knowledge of the general requirements expressed in the legislation and standards
- an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned

5.2.2

Requirements	Document Review	Assessment Compliant
Does management formulate goals with respect to the education, training, and skills of laboratory personnel?		Yes
Does the laboratory have policies/procedures for identifying training needs and providing training of personnel?		*MSM, 5.2.2
Are training programs relevant to the present and anticipated tasks of the lab?		Yes
Is the effectiveness of the training actions taken evaluated?		Yes

5.2.3

Requirements	Document Review	Assessment Compliant
Does the laboratory use personnel who are employed by, or under contract to, the lab?		All employees

Where contracted and additional technical/key support personnel are used, does the laboratory ensure such personnel are supervised and competent and that they work in accordance with the laboratory's management system?		N/A
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5.2.4

Requirements	Document Review	Assessment Compliant
Does the laboratory maintain current job descriptions for managerial, technical, and key support personnel involved in tests/calibrations?		*Yes – reviewed job description

NOTE: Job descriptions can be defined in many ways. As a minimum, the following should be defined:

- the responsibilities with respect to performing tests/calibrations
- the responsibilities with respect to the planning of tests/calibrations and evaluation of results
- the responsibilities for reporting opinions and interpretations
- the responsibilities with respect to method modification and development and validation of new methods
- expertise and experience required
- qualifications and training programs
- managerial duties

5.2.5

Requirements	Document Review	Assessment Compliant
Does management authorize specific personnel to perform particular types of tests/calibrations, to issue test reports/calibration certificates, to give opinions and interpretations, and to operate particular types of equipment?		*Training matrix
Does the laboratory maintain records of relevant authorizations, competence, educational and professional qualifications, training, skills, and experience of all technical personnel, including contracted personnel?		*Training matrix
Is this information readily available and does it include the date on which authorization and/or competence is confirmed?		Yes

5.2 A.9 ACLASS Requirement - Field (On-Site) and Satellite Site Activities

Requirements	Document Review	Assessment Compliant
Does the laboratory ensure personnel indirectly affiliated or subcontracted with the laboratory seeking accreditation do not perform field (on-site) or satellite site tests and/or calibrations unless they meet all training requirements and are supervised by staff of the accreditation-seeking laboratory?		*N/A
Note: This only applies to laboratories that perform field (on-site) calibration or testing and laboratories with satellite sites.		

**5.2 A.10 ACLASS Requirement - Satellite Site Activities**

Requirements	Document Review	Assessment Compliant
Do procedures exist at the corporate site to ensure staff at the satellite site(s) are technically competent and trained? Training records shall be available for the satellite personnel.		*Yes - MSM and training matrix
Note: This only applies to laboratories with satellite sites.		

**5.3 Accommodation/Environmental Conditions**

**5.3.1**

Requirements	Document Review	Assessment Compliant
Do laboratory facilities for testing/calibration (including but not limited to energy sources, lighting, and environmental conditions), facilitate correct performance of tests/calibrations?		Yes - verified during witnessing
Does the laboratory ensure environmental conditions do not invalidate results or adversely affect the required quality of any measurement?		Yes
Is particular care taken when tests/calibrations are undertaken at sites other than a permanent lab facility? Are the technical requirements for accommodation/environmental conditions that can affect the results of tests/calibrations documented?		N/A

**5.3.2**

Requirements	Document Review	Assessment Compliant
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?		*Yes - verified during witnessing and on test reports
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?		Yes
Are tests/calibrations stopped when the environmental conditions jeopardize the results of the tests/calibrations?		Yes

**5.3.3**

Requirements	Document Review	Assessment Compliant
Is there effective separation between neighboring areas in which there are incompatible activities?		Yes
Are measures taken to prevent cross-contamination?		Yes

5.3.4

Requirements	Document Review	Assessment Compliant
Is access to/use of areas affecting the quality of the tests/calibrations controlled?		Yes
Does the lab determine the extent of control based on its particular circumstances?		Yes

5.3.5

Requirements	Document Review	Assessment Compliant
Are measures taken to ensure good housekeeping in the lab?		Yes
Are special procedures prepared where necessary?		*N/A

5.3 A.11 ACLASS Requirement - Field (On-Site) and Satellite Site Activities

Requirements	Document Review	Assessment Compliant
Procedures shall be in place for each site to monitor environmental conditions which may affect instrumentation and test and/or calibration results. Monitoring records shall be maintained.  Note: This only applies to laboratories that perform field (on-site) calibration or testing and laboratories with satellite sites.		*Compliant

5.4 Test/Calibration Methods and Method Validation

5.4.1

Requirements	Document Review	Assessment Compliant
Does the laboratory use appropriate methods/procedures for all tests/calibrations within its scope? Do these include handling, transport, storage, and preparation of items to be tested/calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test/calibration data?		Yes – verified during witnessing
Does the laboratory have instructions on use/operation of all relevant equipment, and on handling/preparation of items for test/calibration, or both, where the absence of such instructions could jeopardize the results of tests/calibrations?		*Yes – verified during witnessing
Are all instructions, standards, manuals, and reference data relevant to the work of the lab kept up to date and made readily available to personnel? (see 4.3)		Yes
Do deviations from test/calibration methods occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer?		Yes – discussed with management – new section on report template

NOTE: International, regional, or national standards, or other recognized specifications that contain sufficient and concise information on how to perform the tests/calibrations do not need to be supplemented or rewritten as internal

procedures if these standards are written in a way that they can be used as published by the operating staff in a lab. It may be necessary to provide additional documentation for optional steps in the method or additional details.

**5.4.2 Selection of Methods**

Requirements	Document Review	Assessment Compliant
Does the laboratory use test/calibration methods which meet the needs of the customer and which are appropriate for the tests/calibrations it undertakes?		Yes - verified during witnessing
Are the preferred methods published in international, regional, or national standards used?		Yes
Does the laboratory ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so?		Yes
When necessary, is the standard supplemented with additional details to ensure consistent application?		Yes
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 organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment? Lab-developed methods or methods adopted by the lab may also be used if they are appropriate for the intended use and if they are validated.		Yes
Is the customer informed as to the method chosen?		Yes
Does the laboratory confirm it can properly operate standard methods before introducing the tests/calibrations?		Yes
If the standard method changes, is the confirmation repeated?		Yes
Does the laboratory inform the customer when the method proposed by the customer is considered to be inappropriate or out of date?		Yes

**5.4.3 Lab-Developed Methods**

Requirements	Document Review	Assessment Compliant
Is introduction of test/calibration methods developed by lab for its own use a planned activity and assigned to qualified personnel equipped with adequate resources?		Yes - discussed with management
Are plans updated as development proceeds and is effective communication among all personnel involved ensured?		Yes

5.4.4 Non-Standard Methods

Requirements	Document Review	Assessment Compliant
When it is necessary to use methods not covered by standard methods, are these subject to agreement with the customer and do they include a clear specification of the customer's requirements and the purpose of the test/calibration?		Yes
Is the method developed validated appropriately before use?		Yes

NOTE: For new test/calibration methods, procedures should be developed prior to the tests/calibrations being performed and should contain at least the following information:

- appropriate identification
- scope
- description of the type of item to be tested/calibrated
- parameters or quantities and ranges to be determined
- apparatus and equipment, including technical performance requirements
- reference standards and reference materials required
- environmental conditions required and any stabilization period needed
- description of the procedure
- 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
- calibration and adjustment of the equipment before each use
- method of recording the observations and results
- any safety measures to be observed
- criteria and/or requirements for approval/rejection
- data to be recorded and method of analysis and presentation
- uncertainty of the procedure for estimating uncertainty

5.4.5 Validation of Methods

5.4.5.1

Requirements	Document Review	Assessment Compliant
Validation is confirmation by examination and the provision of objective evidence that particular requirements for a specific intended use are fulfilled.		See Below

5.4.5.2

Requirements	Document Review	Assessment Compliant
Does the laboratory validate non-standard methods, lab-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?		Yes
Is validation as extensive as is necessary to meet the needs of the given application or field of application?		Yes
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?		*Yes

NOTE: Validation may include procedures for sampling, handling and transportation.

NOTE: 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
- inter-laboratory 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: 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.

5.4.5.3

Requirements	Document Review	Assessment Compliant
Are 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-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, relevant to the customers' needs?		Yes
Do the procedures contain the required range and tolerance or uncertainty of each item or unit parameter being calibrated or verified? Do they contain the generic description of the measurement standards and equipment needed with the required parameter, range, tolerances, or uncertainties, and specifications for performing the measurement of the calibration or verification, and/or representative types (manufacturer, model, option) that are capable of meeting the generic description for the measurement standards? Are they consistent with the accuracy required and with any standard specifications relevant? (Z-540)		N/A

NOTE: Validation includes 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: As method-development proceeds, regular review should be carried out to verify the needs of customer are still being fulfilled. Any change in requirements requiring modifications to the development plan should be approved/authorized.

NOTE: 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-sensitivity) 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

Requirements	Document Review	Assessment Compliant
Does the calibration/testing laboratory, performing its own calibrations, have and apply a procedure to estimate the uncertainty of measurement for all calibrations/types of calibrations?		*Yes

5.4.6.2

Requirements	Document Review	Assessment Compliant
Do the testing labs have and apply procedures for estimating uncertainty of measurement? In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement.		Yes
In these cases, does the lab at least attempt to identify all the components of uncertainty and make a reasonable estimation, and ensure that the form of reporting of the result does not give a wrong impression of the uncertainty?		TB-AA08-06
Is the reasonable estimation based on knowledge of the performance of the method and on the measurement scope and does it make use of, for example, previous experience and validation data?		Yes

NOTE: 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: In those cases where a well-recognized 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 lab is considered to have satisfied this clause by following the test method and reporting instructions (see 5.10)

5.4.6.3

Requirements	Document Review	Assessment Compliant
When estimating the uncertainty of measurement, are all uncertainty components which are of importance in the given situation taken into account using appropriate methods of analysis?		Yes
Does the laboratory ensure that the calibrations uncertainties are sufficiently small so that the adequacy of the measurement is not affected? NOTE: Well defined and documented measurement assurance techniques or uncertainty analyses may be used to verify the adequacy of a measurement process. If such techniques or analyses are not used, then the collective uncertainty of the measurement standards shall not exceed 25% of the acceptable tolerance (e.g., manufacturer's specification) for each characteristic of the measuring and test equipment being calibrated or verified. This is often expressed as a TUR of less than 4:1 (Z-540)		N/A

NOTE: Sources contributing to the uncertainty include, but are not 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: The predicted long-term behavior of the tested/calibrated item is not normally taken into account when estimating the measurement uncertainty.

NOTE: For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement.  
5.4.7 Control of Data

4.7.1

Requirements	Document Review	Assessment Compliant
Are calculations and data transfers subject to appropriate checks in a systematic manner?		Yes

5.4.7.2

Requirements	Document Review	Assessment Compliant
When computers or automated equipment are used for acquisition, processing, recording, reporting, storage, or retrieval of test/calibration data, does the lab ensure that:		See below
<ul style="list-style-type: none"> <li>computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use?</li> </ul>		Yes
<ul style="list-style-type: none"> <li>procedures are established and implemented for protecting the data?</li> <li>such procedures include, but are not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission, and data processing?</li> </ul>		Yes
<ul style="list-style-type: none"> <li>computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test/calibration data?</li> </ul>		Yes
<ul style="list-style-type: none"> <li>all the requirements of ANSI Z-540 - 1 are complied with? (Z-540)</li> </ul>		N/A

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, lab software configuration/modifications should be validated as in 5.4.7.2a

5.4 A.12 ACLASS Requirement - Field (On-Site) and Satellite Site Activities

Requirements	Document Review	Assessment Compliant
Are all relevant procedures available at the location where field (on-site) or satellite site testing or calibration occurs?.		Yes
Note: This only applies to laboratories that perform field (on-site) calibration or testing and laboratories with satellite sites		

5.4 A.13 ACLASS Requirement - Field (On-Site) and Satellite Site Activities

Requirements	Document Review	Assessment Compliant
Does the corporate site have procedures to ensure up-to-date test and/or calibration procedures are available and supplied to the field (on-site) and/or satellite site personnel? They shall use only corporate-provided and approved methods.		*Yes - same procedures available
Note: This only applies to laboratories that perform field (on-site) calibration or testing and laboratories with satellite sites.		

5.4 A.14 ACLASS Requirement - Field (On-Site) and Satellite Site Activities

Requirements	Document Review	Assessment Compliant
Does the laboratory ensure that field (on-site) and satellite site environmental conditions, when relevant, are taken into consideration when calculating measurement uncertainty?  Note: This only applies to laboratories that perform field (on-site) calibration or testing and laboratories with satellite sites.		Yes

5.5 Equipment

5.5.1

Requirements	Document Review	Assessment Compliant
Is the lab furnished with all items of measurement and test equipment required for the correct performance of the tests/calibrations (including preparation of test/calibration items and processing and analysis of test/calibration data)? In those cases where the lab needs to use equipment outside its permanent control, does it ensure that the requirements of the International Standard are met?		Yes

5.5.2

Requirements	Document Review	Assessment Compliant
Is equipment/software used for testing and calibration capable of achieving the accuracy required and does it comply with the specifications relevant to tests/calibrations concerned?		Yes
Are calibration programs established for key quantities or values of the instruments where these properties have a significant effect on the results?		Yes
Before being placed into service, is equipment (including that used for sampling) calibrated/checked to establish that it meets the lab's specification requirements and complies with the relevant standard specifications? Is it checked/calibrated before use?(see 5.6)		Yes

5.5.3

Requirements	Document Review	Assessment Compliant
Is equipment operated by authorized personnel? Are up-to-date instructions on the use/maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) readily available for use by the appropriate lab personnel?		Yes

5.5.4

Requirements	Document Review	Assessment Compliant
Is each item of equipment and its software used for testing/calibration and significant to the result, when practicable, uniquely identified?		Yes

5.5.5

Requirements	Document Review	Assessment Compliant
Are records maintained of each item of equipment and its software significant to the tests/calibrations performed? Do the records include at least the:		*Yes – equipment records
<ul style="list-style-type: none"> <li>identity of the item of equipment and its software?</li> </ul>		Yes
<ul style="list-style-type: none"> <li>manufacturer's name, type identification, and serial number or other unique identification?</li> </ul>		Yes
<ul style="list-style-type: none"> <li>checks that equipment complies with the specification? (see 5.5.2)</li> </ul>		Yes
<ul style="list-style-type: none"> <li>current location, where appropriate?</li> </ul>		Yes
<ul style="list-style-type: none"> <li>manufacturer's instructions, if available, or reference to their location?</li> </ul>		Yes
<ul style="list-style-type: none"> <li>dates, results, and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration?</li> </ul>		Yes
<ul style="list-style-type: none"> <li>maintenance plan, where appropriate, and maintenance carried out to date?</li> </ul>		Yes
<ul style="list-style-type: none"> <li>damage, malfunction, modification, or repair to the equipment?</li> </ul>		Yes
<ul style="list-style-type: none"> <li>measured value observed for each parameter found to be out of tolerance during calibration /verification? (Z-540)</li> </ul>		N/A

5.5.6

Requirements	Document Review	Assessment Compliant
Does the lab have procedures for safe handling, transport, storage, use, and planned maintenance of measuring equipment to ensure proper functioning and to prevent contamination or deterioration?		*TB-AA08-04

NOTE: Additional procedures may be necessary when measuring equipment is used outside the permanent lab for tests, calibrations, or sampling.

5.5.7

Requirements	Document Review	Assessment Compliant
Is equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, taken out of service?		Yes

Is it isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration/test to perform correctly?		Yes
Does the laboratory examine the effect of the defect or departure from specified limits on previous tests/calibrations and institute the "Control of nonconforming work" procedure? (see 4.9).		Yes

5.5.8

Requirements	Document Review	Assessment Compliant
Whenever practicable, is all equipment under the control of the lab and requiring calibration labeled, coded, or otherwise identified to indicate the status of calibration, including the date of the last calibration and the date or expiration criteria when re-calibration is due?		Yes - labels
Does the laboratory have a procedure stating the its policy for establishing and changing calibration intervals for equipment that it controls? (Z-540)		*N/A

5.5.9

Requirements	Document Review	Assessment Compliant
When, for whatever reason, equipment goes outside the direct control of the laboratory, does the laboratory ensure that the function/calibration status of the equipment is checked and shown to be satisfactory before the equipment is returned to service?		Yes

5.5.10

Requirements	Document Review	Assessment Compliant
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?		*None done

5.5.11

Requirements	Document Review	Assessment Compliant
Where calibrations give rise to a set of correction factors, does the laboratory have procedures to ensure that copies (e.g. in computer software) are correctly updated?		*N/A

5.5.12

Requirements	Document Review	Assessment Compliant
Is test/calibration equipment, including both hardware and software, safeguarded from adjustments which would invalidate the test/calibration results?		Yes

<p>Are tamper-resistant seals affixed to operator-accessible controls or adjustments on measurement standards or measuring and test equipment which, if moved, would invalidate the calibration? Does the laboratory's calibration system provide instructions for the use of such seals and for the disposition of equipment with damaged or broken seals? (Z-540)</p>		<p>*N/A</p>
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5.5 A.15 ACLASS Requirement - Field (On-Site) Activities

Requirements	Document Review	Assessment Compliant
<p>Does the laboratory maintain procedures for transporting, storing, operating, and calibrating equipment used in field (on-site) testing or calibrations?                       Note: This only applies to laboratories that perform field (on-site) calibration or testing.</p>		<p>N/A</p>

5.5 A.16 ACLASS Requirement - Field (On-Site) and Satellite Site Activities

Requirements	Document Review	Assessment Compliant
<p>If field (on-site) or satellite personnel use equipment not owned by the corporate site, does the provider of such equipment meet the requirements of sections 5.5 and 5.6 of ISO/IEC 17025?                       Note: This only applies to laboratories that perform on-site calibration and testing and satellite sites</p>		<p>N/A</p>

5.6 Measurement Traceability

5.6.1

Requirements	Document Review	Assessment Compliant
<p>Is all equipment used for test/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?</p>		<p>Yes</p>
<p>Does the laboratory have an established program and procedure for the calibration of its equipment?</p>		<p>* Management System Manual, paragraph 5.6.1</p>
<p>Does the laboratory document any and all exemptions from periodic calibration or verification of its equipment? (Z-540)</p>		<p>N/A</p>

NOTE: Such a program should include a system for selecting, using, calibrating, checking, controlling, and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform tests/calibrations.

5.6.2 Specific Requirements

5.6.2.1 Calibration

5.6.2.1.1

Requirements	Document Review	Assessment Compliant
For calibration laboratories, is the program for calibration of equipment designed and operated so as to ensure that calibrations and measurements made by the lab are traceable to the International System of Units (SI) (Système international d'unités)?		N/A
A calibration lab establishes traceability of its own measurement standards and measuring instruments to SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI standards which are standards calibrated by another national metrology institute.		See Below
When using external calibration services, is traceability of measurement assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability, and traceability?		*N/A
Do the calibration certificates issued by these laboratories 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).		*N/A

NOTE: Calibration labs fulfilling requirements of the International Standard are considered to be competent. A calibration certificate bearing an accreditation body logo from a calibration lab accredited to the International Standard, for the calibration concerned, is sufficient evidence of traceability of the calibration data reported.

NOTE: 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 national 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: Calibration labs 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 the national metrology institute.

NOTE: 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: When the terms "international standard" or "national standard" are used in connection with traceability, it is assumed that these standards fulfill the properties of primary standards of the realization of SI units

NOTE: 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: If a calibration lab wishes or needs to obtain traceability from a national metrology institute other than in its own country, this lab should select a national metrology institute that actively participates in the activities of BIPM either directly or through regional groups.

NOTE: The unbroken chain of calibrations or comparisons may be achieved in several steps carried out by different labs that can demonstrate traceability

5.6.2.1.2

Requirements	Document Review	Assessment Compliant
<p>There are certain calibrations that currently cannot be strictly made in SI units. In these cases does the laboratory provide confidence in measurements by establishing traceability to appropriate measurement standards such as:</p> <ul style="list-style-type: none"> <li>• the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of material?</li> <li>• the use of specified methods and/or consensus standards that are clearly described and agreed to by all parties concerned?</li> <li>• participation in a suitable program of inter-laboratory comparisons where possible?</li> </ul>		N/A

5.6.2.2 Testing

5.6.2.2.1

Requirements	Document Review	Assessment Compliant
For testing laboratories, requirements given in 5.6.2.1 apply for measuring/test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result.		TB-AA08-07
When this situation arises, does the laboratory ensure that the equipment used can provide the uncertainty of measurement needed?		TB-AA08-07

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 requirements should be strictly followed.

5.6.2.2.2

Requirements	Document Review	Assessment Compliant
When traceability of measurements to SI units 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 labs (see 5.6.2.1.2).		N/A

5.6.3 Reference Standards and Reference Materials

5.6.3.1 Reference Standards

Requirements	Document Review	Assessment Compliant
Does the laboratory have a program and procedure for the calibration of its reference standards?		*Yes
Are reference standards calibrated by a body that can provide traceability as described in 5.6.2.1?		* TB-AA08-07
Are such reference standards of measurement held by the lab used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated?		Yes
Are reference standards calibrated before and after any adjustment?		Yes

5.6.3.2 Reference materials

Requirements	Document Review	Assessment Compliant
Are reference materials, where possible, traceable to SI units of measurement, or to certified reference materials?		N/A
Are internal reference materials checked as far as is technically and economically practicable?		N/A

5.6.3.3 Intermediate Checks

Requirements	Document Review	Assessment Compliant
Are checks needed to maintain confidence in the calibration status of reference, primary, transfer, or working standards and reference materials carried out according to defined procedures and schedules?		*None done

5.6.3.4 Transport and Storage

Requirements	Document Review	Assessment Compliant
Does the laboratory 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?		* TB-AA08-04

NOTE: Additional procedures may be necessary when reference standards and reference materials are used outside the permanent lab for tests, calibrations or sampling.

5.6 A.17 ACLASS Requirement - Field (On-Site) and Satellite Site Activities

Requirements	Document Review	Assessment Compliant
Does the corporate site ensure the traceability of all reference standards and equipment used by field (on-site) and satellite site personnel?		TB-AA08-07
Note: This only applies to laboratories that perform field (on-site) calibration or testing and laboratories with satellite sites.		