



The American Association for Laboratory Accreditation

C315 – Specific Checklist: TNI Stationary Source Audit Sample (SSAS) Provider Accreditation Program

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This checklist is intended for use in association with A2LA assessments, and is not to be publicly distributed. Use of this document is restricted to A2LA employees, contractors, and applicant and accredited Stationary Source Audit Sample (SSAS) Providers. Any other use of this document is prohibited.

The following pages present the TNI SSAS program requirements for the A2LA Accreditation Program for Providers of Proficiency Testing Programs. These requirements are based on those contained in the TNI SSAS Volume 1, Module 1. These requirements are not intended to be stand alone requirements for this program and shall be used with the ISO/IEC 17043: 2010 Conformity assessment-General requirements for proficiency testing, A2LA Checklist C316. Requirements (clauses) that include the need for a written policy, procedure or arrangement have a thick, black border. Relevant ISO Guide 34 and ISO/IEC 17025 Requirements have been included at the end of this checklist.

PT Provider Instructions: This checklist must be completed and submitted as part of the application for accreditation in order to help both the PT Provider and assessor(s) prepare for the assessment. Correct completion of this checklist may save a significant amount of assessment time and cost. Complete the document reference identifiers in the checklist’s second column (labeled “Reference”) for all requirement clauses within a thick, black border. The appropriate “reference” must identify the document (quality manual, SOPs, etc) and include a “locator” to facilitate identification of the appropriate portion(s) of the relevant document (page number, section number, etc.). The management system documentation and supporting records must be available for the assessor’s review.

A2LA Assessor Instructions: Review the PT Provider’s documented management system to verify compliance with the applicable requirements. Assess to verify that the documented management system is indeed implemented as described. Place a tick mark in the yes (Y), no (N), or not applicable (NA) space for each checklist item. Please note that for all N/A indications, you must document the reason why this requirement is N/A in the comments section. Record comments related to any requirement on the space provided. All deficiencies must be identified and explained in the assessor deficiency report. Assess the PT Provider’s technical competence to provider specific PT schemes. IMPORTANT NOTE: An asterisk (*) in the comments section indicates that the assessor must document the specific traceable objective evidence reviewed in association with that requirement. Objective evidence information is mandatory for those clauses.

PT Provider NAME _____ A2LA Master Code: _____ Asmnt ID: _____

City: _____ State: _____

Technical Manager: _____

Quality Manager: _____

Essential Personnel and Their Unique Capability¹ _____

¹ An Essential Personnel is anyone whose absence or departure would reduce the PT Program’s competence to operate one or more PT programs, and would necessitate removal from the PT Provider’s Scope of Accreditation, any PT program for which that person is contributing unique capabilities.



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Type of Assessment (please indicate):

- Full Assessment
- Surveillance Assessment

To the best of my knowledge, all SSAS provider document references below, as well as actual practices, have been assessed for compliance with the relevant clauses of the TNI SSAS Volume 1, Module 1. I hereby attest that all ‘Yes’ marked compliance clauses, whether initialed or not, meet the aforementioned requirements. Any areas of noncompliance have been fully described in the Assessor Deficiency Report.

Assessor Signature: _____ Date: _____

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
SECTION 5 MANAGEMENT REQUIREMENTS					
5.1 Quality System Requirements					
5.1.1 The provider’s quality management system shall meet the requirements of ISO 9001 for the design, production, testing, and distribution of audit samples, and the evaluation of audit sample analyses results or measurements.					
5.1.2 The provider’s manufacturing system shall meet the requirements of ISO Guide 34. (A2LA Assessor Note: Assess ISO Guide 34 clauses 5.3, 5.4, 5.5, 5.6 and 5.8 which are included at the end of this checklist.)					
5.1.3 The design and operation of the provider’s SSAS Program shall meet the relevant requirements of ILAC G-13 or replaced by ISO 17043, when approved.					



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Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5.1.4 The testing facilities used to support the verification, homogeneity, and stability testing required in this Standard (Volume 1, Module 1) shall meet the requirements of ISO 17025.					
5.1.6 Providers shall maintain all records related to each audit sample manufacturing lot for a minimum of five (5) years.					
5.2 Provider Conflict of Interest and Confidentiality Providers seeking to obtain or maintain accreditation shall:					
5.2 a) Document and certify to the satisfaction of the provider accreditor that they do not have any conflict of interest with any participant in their SSAS Program;					
5.2 b) Inform all internal and contract personnel who perform work on the SSAS Program of the provider's obligation to report personal and organizational conflicts of interest to the provider accreditor;					
5.2 c) Have a continuing obligation to identify and report any actual or potential conflicts of interest arising during the performance of work in support of the SSAS Program;					



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Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5.2 d) Immediately make a full disclosure to the provider accreditor of any identified actual or potential organizational conflict of interest. The disclosure shall include a description of any action that the provider has taken or proposes to take after consultation with the provider accreditor to avoid, mitigate, or neutralize the actual or potential conflict of interest;					
5.2 e) Have written procedures to ensure that the confidentiality of data associated with audit samples and the SSAS Program is not compromised;					
5.2 f) Not release the assigned values or acceptance limits of any audit sample prior to the reporting of the audit sample analyses results; and					
5.2 g) Not disclose specific facility, laboratory, or stationary source tester results or evaluations to any parties other than as specified in Section 11.1.2 without written release from the facility, laboratory, or stationary source tester.					



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5.3 Provider Facilities and Personnel					
5.3.1 Providers shall have appropriate facilities, equipment, and analytical instrumentation in place to produce, analytically verify, distribute, and provide data evaluation and reporting functions for every audit sample for which they wish to obtain or maintain accreditation.					
5.3.2 Providers shall employ sufficient technical and support staff to design, produce, analyze, distribute, and provide data evaluation and reporting functions for every audit sample for which they wish to achieve or maintain accreditation.					
5.3.3 No portion of the design, production, testing, distribution, data collection, data evaluation, or data reporting functions may be outside the direct control of the provider for any particular manufacturing lot. For the purposes of this Standard (Volume 1, Module 1), “direct control” means that these functions are performed in the provider’s facilities by the provider’s staff or are subcontracted by means of a written agreement with defined provider supervision to ensure that all requirements of this Standard are met.					
5.3.4 Any subcontracted function related to the design, production, testing, distribution, data collection, data evaluation, or data reporting shall be assessed by the provider accreditor and shall meet the applicable requirements of this Standard.					



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<p>5.4 Complaints Handling</p>					
<p>5.4.1 Providers shall have written procedures for handling both written and verbal complaints from participants who receive audit sample reports.</p>					
<p>5.4.2 Providers shall record all complaints received concerning their SSAS Program, including any remedial or corrective actions taken. This record shall be provided to the provider accreditor upon request.</p>				<p>*</p>	
<p>5.4.3 Any complaint received by a provider that remains unresolved after ninety (90) days shall be submitted to the provider accreditor.</p>					
<p>5.5 Notification of Sample Integrity If any audit sample or analyte used in the SSAS Program is found to not meet any of the requirements of this Standard (Volume 1, Module 1), the provider shall notify all affected participants and the provider's provider accreditor within seven (7) calendar days of the discovery of the nonconformance.</p>					
<p>SECTION 6 AUDIT SAMPLE DESIGN AND MANUFACTURE</p>					
<p>6.1 Design Review Providers shall demonstrate to the satisfaction of the provider accreditor that their audit sample design and manufacturing processes:</p>					



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6.1 a) Permit participants, conforming to the calibration and quality control requirements of the analytical method(s) for which the audit sample was designed, to generate results that fall within the acceptance limits defined in the SSAS Table;					
6.1 b) Provide equivalent challenge to all participants; and					
6.1 c) Result in participant acceptable/not acceptable rates that are consistent with historical norms.					
6.2 Audit Sample Matrices The matrices of all audit samples shall, to the extent possible, resemble the matrices which participants routinely analyze.					
6.3 Audit Sample Analytes					
6.3.1 Providers shall prepare audit samples that are compliant with the criteria defined by the SSAS Expert Committee and published in the SSAS Table on the TNI website. If requested by the regulatory agency and/or the facility, analytes or ranges that are not listed in the SSAS Table may be included in an audit sample if the purpose and technical justification are documented, and if, where appropriate, the regulatory agency and/or facility are notified in advance.					
6.3.2 When the SSAS Expert Committee makes changes to the audit sample design criteria, providers shall comply with the revised requirements per the SSAS Expert Committee's implementation schedule.					
6.3.3 The provider shall spike the analytes of interest into the audit sample according to the SSAS Table.					



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6.3.4 The provider shall produce audit samples that conform to the method being tested.					
6.3.5 The provider shall be allowed to add interferences (not to be analyzed), normally present in the matrix being tested, to the audit sample.					
6.4 Audit Sample Concentration Ranges					
6.4.1 Providers shall supply audit samples that reflect the concentration ranges in the SSAS Table.					
6.4.2 Assigned values for audit sample analytes that are measured (chemical concentrations, isotope activities, etc.) shall:					
6.4.2 a) Be equal to the made-to values of the analytes based on gravimetric and volumetric measurements of a starting material of known concentration if possible, and if not possible, shall be set to the mean of the determined measured value; and					
6.4.2 b) Be presented in three (3) significant figures.					
SECTION 7 AUDIT SAMPLE TESTING					
7.1 Verification of Assigned Value					
7.1.1 Providers shall analytically verify the assigned value of all analytes in all manufacturing lots of audit samples prior to use.					



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<p>7.1.2 Providers shall verify the assigned value by direct analysis against a calibration standard made from, or traceable to, a primary reference material (e.g., National Institute of Standards and Technology), if available.</p>					
<p>7.1.3 If a primary reference material is not available, then verification shall be performed against an independently prepared calibration material.</p>					
<p>7.1.4 The assigned value verification analytical event shall also include the analysis of a second source reference material from a source independent of the calibration standard and the audit sample being verified.</p>					
<p>7.1.5 The provider shall have documented criteria for the acceptance of the results of the second source reference material.</p>					
<p>7.1.6 The analytical method used by the provider for assigned value verification shall have a repeatability relative standard deviation of not more than one-sixth of the acceptance limits for the participant laboratories.</p>					
<p>7.1.7 For test methods listed in the SSAS Table, where the method performance precludes the use of the one-sixth limit defined in Section 7.1.6, the provider shall document the technical justification that the method used to verify the audit sample assigned value is adequate to ensure that it meets data user requirements. This shall be reviewed and approved by the provider accreditor.</p>					



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7.1.8 The relative standard deviation of the provider's verification method shall be established by a method validation study for each method and instrument.					*
7.1.9 For analytes in aqueous media, the assigned value of an analyte is verified if the mean of the provider's verification analyses is within one-third of the laboratory acceptance limits, to a maximum of 10%, as calculated per Section 10.2, of either:					
7.1.9 a) The assigned value, if an unbiased verification method is used; or					
7.1.9 b) The expected mean value for the analyte, if a biased method is used.					
7.1.10 For analytes contained on or in sampling media, the assigned value of an analyte is verified if the mean of the provider's verification analyses is within one-half of the laboratory acceptance limits, as calculated per Section 10.2, of either:					
7.1.10 a) The assigned value, if an unbiased verification method is used; or					
7.1.10 b) The expected mean value for the analyte, if a biased method is used.					
7.1.11 The standard deviation of the verification analyses shall be less than one standard deviation, as calculated for the participant laboratories.					



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7.1.12 Any manufacturing lot that fails to meet the requirements of this Section shall not be used as an audit sample.					
7.2 Homogeneity Testing					
7.2.1 Providers shall analytically verify that all analytes in all manufacturing lots of audit samples within a packaging event are sufficiently homogeneous prior to their use as an audit sample.					
7.2.2 Homogeneity shall be verified using the procedure described in TNI Standards Volume 1 Module 1, Appendix A or a procedure with an equivalent ability, as determined by the provider accreditor, to verify that differences between audit samples will not impact the evaluation of the stationary source test.					
7.2.3 Homogeneity testing shall be performed on a representative selection of audit samples randomly selected from each final packaged audit sample batch prior to shipment to participant laboratories.				*	
7.2.4 Any manufacturing lot that fails to meet the requirements of this Section shall not be used as an audit sample.					
7.3 Stability Testing					
7.3.1 Providers shall verify the expiration date of the audit sample manufacturing lot and shall verify that all analytes in all audit samples remained stable.				*	



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<p>7.3.1.1 Providers shall conduct stability testing of each lot of audit sample material or have data showing, to the satisfaction of the provider accreditor, that the sample was stable during the time period of use in the SSAS Program</p>					<p>*</p>
<p>7.3.2 Where appropriate, providers shall retain samples of audit samples of the original audit sample manufacturing lot for use in confirmation of the lot assigned values and subsequent analytical verification.</p>					
<p>7.3.3 The provider shall use a stability verification procedure approved by the provider accreditor.</p>					
<p>7.3.4 Audit samples or analytes that fail to meet the criteria of this Section shall be invalidated, and all sample recipients notified with a detailed discussion report.</p>					
<p>7.4 Verification, Homogeneity, and Stability Testing Reporting</p>					
<p>7.4.1 Upon request, and only after the provider has released their evaluation of the audit sample analyses results, the provider shall release, to a designated participant, the results of the provider’s assigned value verification, homogeneity, and stability testing for any audit sample/analyte for which the participant has reported or received data.</p>					
<p>7.4.2 Upon request, and only after the provider has released their evaluation of the audit sample analyses results, the provider shall release to the PT Board the results of the provider’s assigned value verification, homogeneity, and stability testing for any audit sample/analyte.</p>					



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<p>7.4.3 To protect the blind nature of the audit sample, the provider shall ensure the manufacturing lot number does not appear on any labels or documentation they provide to participants and the PT Board, for assigned value verification, homogeneity, or stability testing.</p>					
<p>7.5 Providers shall label each audit sample with a unique identifier.</p>					
<p>SECTION 8 ORDERING AND REPORTING INSTRUCTIONS</p>					
<p>8.1 The provider shall receive an audit sample order from a facility. The provider shall contact the appropriate regulatory agency to request any specific requirements (e.g., changes to the audit sample concentration and/or shipment address) prior to shipment of the audit sample. The provider may ship the audit sample if response is not received from the regulatory agency within fifteen (15) calendar days of the email of such request.</p>					
<p>8.1 a) The provider shall ensure that the audit sample is sealed such that opening or tampering will be apparent.</p>					
<p>8.1 b) The provider shall ship the audit sample to the facility, unless the regulatory agency requests that it be shipped, instead, to the regulatory agency.</p>					
<p>8.1 c) If the facility cancels or modifies an audit sample order at any time, the provider shall notify the regulatory agency of such cancellation or modification, within two (2) business days of the receipt of such notice.</p>					



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8.2 The provider shall provide instructions with each audit sample shipment, describing:					*
8.2 a) How to handle, store, dilute or otherwise prepare the audit sample;					
8.2 b) How to report the data. The following attestation statement must be signed and submitted with the data; <i>“By affixing your signature below, you attest that the audit sample analyses results have met the following criteria:</i>					
8.2 b) 1) <i>You have no prior knowledge of the concentration of target analyte(s) in the audit sample. No additional information was solicited or received concerning the assigned values or acceptance ranges for the audit sample.</i>					
8.2 b) 2) <i>The audit sample(s) you are reporting was/were analyzed in the same laboratory under the same calibration, utilizing the same quality control standards, by the same analysts following audit sample instructions as the stationary source test samples.”</i>					
8.2 b) 3) <i>The stationary source test results and the audit sample analyses results have been reported to the appropriate regulatory agency.”</i>					
8.2 c) The expiration date or valid time frame of the audit sample being provided;					
8.2 d) A warning that the TNI Standard requires audit samples to be analyzed at the same time as the stationary source test samples utilizing the same analysts, methods, and quality control procedures; and					



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8.2 e) A warning that the TNI Standard requires audit samples that test the field stack sampling process (e.g., for EPA Methods 18 and 25), to be collected before, during, or after the collection of the field samples, or as directed by the Regulatory Agency, utilizing the same methods and quality control procedures.					
8.3 The Provider shall not:					
8.3 a) Provide inappropriate assistance to the participants, nor encourage the non-routine analysis of audit samples;					
8.3 b) Suggest or direct that laboratories use additional quality control samples or quality control samples designed specifically for a given audit sample, in conjunction with any audit sample;					
8.3 c) Provide excessive volume of any audit sample that may encourage non-routine analyses;					
8.3 d) Provide actual concentration ranges of audit sample to the facility; and					
8.3 e) Ship an audit sample past its established expiration date.					
SECTION 9 SYSTEM FOR REPORTING BY FACILITIES					
9.0 The Provider shall:					
9.0 a) Have procedures and systems in place to ensure the accurate, timely, and secure transmission of audit sample data from facilities to the provider;					



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9.0 b) Have a reporting mechanism that ensures that the results received by the provider are consistent with those submitted by the facilities;					
9.0 c) Ensure that results reported by facilities are not delayed or lost due to the provider’s reporting mechanism;					
9.0 d) Ensure that facility data are kept secure and that they are not subject to unauthorized dissemination either during or after data reporting to the provider; and					
9.0 e) Evaluate only the analytes of interest for each audit sample, as reported by the facility.					
SECTION 10 AUDIT SAMPLE DATA ANALYSIS					
10.1 Data Review On a periodic basis to be determined by the provider accreditor, the provider shall review the data reported by the facilities for the following conditions:					
10.1.1 Providers shall review all audit sample data for bimodal or multi-modal distributions and/or situations where results from a given method have disproportionately large failure rates or reporting anomalies.					
10.1.2 If a multi-modal distribution is found related to an analytical method, this data shall be reported to the SSAS Expert Committee.					
10.1.3 Providers shall review all audit sample data for disproportionately high or low failure rates compared to historical norms.					



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10.2 Acceptance Limit Determination					
10.2.1 Providers shall calculate acceptance limits as defined in the SSAS Table.					
10.2.1 The provider shall evaluate a result as “Acceptable” if it falls within the SSAS Table-defined acceptance limits.					
10.2.2 The provider shall evaluate a result as “Not Acceptable” if it falls outside the acceptance limits.					
10.2.3 The provider shall evaluate a result as “Not Acceptable” if it cannot be evaluated (e.g., alpha characters for a quantitative test or reported as a less than or greater than value).					
10.2.4 If the provider invalidates an analyte in the audit sample, all evaluations for data reported for that analyte shall be “No Evaluation” and a discussion of the situation leading to the invalidation shall be included in the final report to participants.					
SECTION 11 GENERATION OF REPORTS					
11.1 Schedule					
11.1.1 The provider shall submit the evaluation reports defined in Section 11.2 to the required parties no later than three business days after the reporting of the audit sample data.					
11.1.2 The provider shall submit evaluation reports to facilities, facility-requested regulatory agencies, other parties requested by the facility, and to the SSAS Central Database within the same twenty-four (24) hour period.					



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11.2 Evaluation Report					*
11.2.1 The Provider shall include the following information in the evaluation report:					
11.2.1 a) Provider name;					
11.2.1 b) Provider accreditation number;					
11.2.1 c) Participant Facility name;					
11.2.1 d) Participant Facility physical address;					
11.2.1 e) Name, title, and telephone number of Facility point of contact, as provided;					
11.2.1 f) Laboratory's or Stationary Source Tester's name, address, and other contact information (e.g., telephone, email, and fax);					
11.2.1 g) Date evaluation report was prepared;					
11.2.1 h) Date evaluation report was amended, if applicable; and					
11.2.1 i) Discussion including any pertinent information which addresses unusual details of the audit sample (e.g., need to change an assigned value or delete an analyte from evaluation).					
11.2.2 The Provider shall include the following information for each audit sample/analyte in the final evaluation report:					*
11.2.2 a) SSAS Number;					
11.2.2 b) Analyte name;					



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11.2.2 c) Analyte code defined in the SSAS Table;					
11.2.2 d) Identification of any analytes not included in the Provider's accreditation;					
11.2.2 e) Assigned value;					
11.2.2 f) Acceptance limits;					
11.2.2 g) Laboratory value, as reported;					
11.2.2 h) Method name or description, as reported;					
11.2.2 i) Matrix description					
11.2.2 j) Analysis dates, as reported by the participating Laboratory; and					
11.2.2 k) Evaluation, per Section 10.3 above;					
11.2.3 Each page of the final evaluation report shall include an indication of the length of the report, presented by either "Page X of Y" or the total number of pages with each page consecutively numbered.					
RELEVANT CLAUSES OF ISO GUIDE 34 as per TNI SSAS C315 clause 5.1.2					
5.3 Production Planning					
5.3.1 The reference material producer shall identify and plan those processes which directly affect the quality of reference material production and shall ensure that they are carried out in accordance with specified procedures.					



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<p>5.3.2 Organizational and technical input of the different collaborators involved shall be identified and the necessary information documented and regularly reviewed. A mechanism (e.g. a management/technical advisory group) shall be established to make recommendations on how to plan the production processes.</p>					
<p>5.3.3 In planning the production processes, the reference material producer shall have procedures and service facilities, where appropriate, for:</p>					
<p>a) Material selection (including, where appropriate, sampling);</p>					
<p>b) Maintaining suitable environments for all aspects of production;</p>					
<p>c) Material preparation;</p>					
<p>d) Measuring/testing;</p>					
<p>e) Calibration/validation of equipment/measurement methods;</p>					
<p>f) Assessing material homogeneity;</p>					
<p>g) Assessing material stability;</p>					
<p>h) Organizing interlaboratory studies with its collaborators;</p>					
<p>i) Assigning property values based on the results of measurements;</p>					



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j) Producing uncertainty budgets and uncertainty intervals to the assigned property values;					
k) Ensuring adequate storage facilities and conditions;					
l) Ensuring adequate packaging facilities;					
m) Ensuring appropriate transport arrangements;					
n) Ensuring an adequate post-distribution service.					
5.4 Production control					
The reference material producer shall identify the verification procedures necessary to ensure the quality of each stage of reference material production, and shall assign adequate resources and personnel for such activities. These activities should include inspection, testing and monitoring of all stages of production.					
5.5 Environment					
5.5.1 The reference material producer shall ensure that all laboratory accommodation, calibration and measurement areas, material preparation and packaging areas, energy sources, lighting, temperature, pressure and ventilation are such as to facilitate proper material preparation and packaging, as well as proper performance of calibration and measurements.					



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<p>It is imperative that all possible precautions are taken against possible contamination of the reference material during its production and certification. All reference material production and testing areas, in addition to satisfying requirements for humidity and temperature, should be protected from vibration, airborne dust and microbiological contamination, magnetic fields and electromagnetic radiation (as appropriate). For example, the packaging of a cement material requires conditions of low humidity, while the preparation and characterization of a material in which the content of traces of lead is to be measured requires cleanroom conditions to prevent contamination from airborne lead particulates due to car emissions. Cleanroom conditions may also be required for other types of trace analysis.</p>					
<p>5.5.2 The reference material producer shall also ensure that all environmental requirements are also met by any collaborator involved in any production process.</p>					
<p>5.5.3 Where appropriate to do so, the environment in which these activities are undertaken shall be monitored with appropriately calibrated equipment, controlled and recorded, such that results and processes are not adversely affected.</p>					
<p>5.5.4 Appropriate health, safety and environmental protection precautions shall also be implemented where necessary (e.g. when handling pesticides or serum).</p>					
<p>5.6 Material handling and storage</p>					
<p>5.6.1 In order to avoid any contamination, the reference material producer shall identify, preserve and segregate (i.e. from other chemicals and samples) all candidate materials and reference materials from the time of preparation through to their distribution to users.</p>					



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<p>5.6.2 The reference material producer shall ensure adequate packaging of all reference materials (e.g. where appropriate, use air-free, moisture-free or inert gas packaging) and provide secure storage areas/stock rooms which prevent damage or deterioration of any item or material between characterization and distribution. Appropriate methods for authorizing dispatch to, and receipt from, such areas should be stipulated.</p>					
<p>5.6.3 The condition of all stored/stocked items and materials shall be assessed at appropriate intervals throughout their storage life, in order to detect possible deterioration.</p>					
<p>5.6.4 The reference material producer shall control packing and marking processes to the extent necessary to ensure conformity with the safety and transport requirements.</p>					
<p>The reference material producer should ensure that the integrity of the reference material is maintained until the seal has been broken, or up to the point when presented for analysis. The producer cannot be held responsible for the material once its seal has been broken. This may require, in some cases, that the reference material be packaged in unit quantities sufficient for a single use.</p>					
<p>5.6.5 The reference material label shall be securely attached to the product packaging of an individual reference material unit, and shall be designed to remain legible and intact within the period of validity of the material. The label shall identify the material, the producer, its batch and catalogue numbers, and any other information necessary to enable the material to be uniquely distinguished and referenced, where appropriate, to its statement or certificate.</p>					



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<p>5.6.6 The reference material producer shall make arrangements to ensure the integrity of each reference material throughout the entire production process. Where contractually specified, this protection shall be extended to include delivery to destination.</p>					
<p>5.8 Material preparation</p>					
<p>5.8.1 The reference material producer shall establish whether the item or material has received adequate preparation for its intended use. Procedures for material preparation should include, where appropriate:</p>					
<p>a) Qualitative analysis for verification of material type;</p>					
<p>b) Machining, grinding, blending, sieving and riffing (i.e. dividing into representative samples);</p>					
<p>c) Determination of particle size distribution;</p>					
<p>d) Cleaning of sample containers;</p>					
<p>e) Drying (including lyophilization) and sterilization;</p>					
<p>f) Packaging (e.g. bottling, etc.) representative samples from the batch;</p>					
<p>g) Homogeneity testing;</p>					
<p>h) Stability testing over a range of conditions which may affect the property values and/or matrix composition of the reference materials being produced (e.g. different levels of humidity, temperature, light, magnetic fields, etc.).</p>					



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<p>5.8.2 The reference material producer shall be able to demonstrate that the candidate reference material is sufficiently homogeneous; i.e. the difference, if any, between units shall be smaller than the uncertainty limits stated in the certificate.</p>					
<p>RELEVANT CLAUSES OF ISO/IEC 17025:2005 as per TNI SSAS C315 clause 5.1.4</p>					
<p>ISO/IEC 17025:2005 REQUIREMENTS</p>					
<p>5 Technical requirements</p>					
<p>5.2 Personnel</p>					
<p>5.2.1 The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates.</p>					
<p>When using staff who are undergoing training, appropriate supervision shall be provided.</p>					
<p>Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.</p>					
<p>5.2.2 The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel.</p>					
<p>The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory.</p>					



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<p><i>The effectiveness of the training actions taken shall be evaluated.</i></p>					
<p>5.2.3 The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's <i>management</i> system.</p>					
<p>5.2.4 The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.</p>					
<p>5.2.5 The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment.</p>					
<p>The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.</p>					
<p>5.3 Accommodation and environmental conditions</p>					
<p>5.3.1 Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.</p>					



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<p>The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility.</p>					
<p>The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.</p>					
<p>5.3.2 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be 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.</p>					
<p>Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.</p>					
<p>5.3.3 There shall be effective separation between neighboring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.</p>					
<p>5.3.4 Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances.</p>					
<p>5.4 Test and calibration methods and method validation</p>					



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<p>5.4.1 General</p> <p>The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.</p>					
<p>The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations.</p>					
<p>All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel (see 4.3).</p>					
<p>Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the <i>customer</i>.</p>					
<p>5.4.2 Selection of methods</p> <p>The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the <i>customer</i> and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used.</p>					



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<p>The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.</p>					
<p>When the <i>customer</i> does not specify the method to be used, the laboratory shall 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. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated.</p>					
<p>The <i>customer</i> shall be informed as to the method chosen.</p>					
<p>The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated.</p>					
<p>The laboratory shall inform the <i>customer</i> when the method proposed by the <i>customer</i> is considered to be inappropriate or out of date.</p>					
<p>5.4.3 Laboratory-developed methods The introduction of test and calibration methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources.</p>					



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<p>Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.</p>					
<p>5.4.4 Non-standard methods When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the <i>customer</i> and shall include a clear specification of the <i>customer's</i> requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use.</p>					
<p>5.4.5 Validation of methods</p>					
<p>5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.</p>					
<p>5.4.5.2 The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.</p>					



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<p>5.4.5.3 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, shall be relevant to the <i>customer's</i> needs.</p>					
<p>5.4.6 Estimation of uncertainty of measurement</p>					
<p>5.4.6.1 A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.</p>					
<p>5.4.6.2 Testing laboratories shall have and shall 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. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.</p>					
<p>5.4.6.3 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.</p>					



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5.4.7 Control of data					
5.4.7.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.					
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, the laboratory shall ensure that:					
a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;					
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;					
c) 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 and calibration data.					
5.5 Equipment					
5.5.1 The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data).					



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<p>In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this International Standard are met.</p>					
<p>5.5.2 Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned.</p>					
<p>Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results.</p>					
<p>Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use (see 5.6).</p>					
<p>5.5.3 Equipment shall be operated by authorized personnel.</p>					
<p>Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.</p>					
<p>5.5.4 Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.</p>					
<p>5.5.5 Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following:</p>					



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a) the identity of the item of equipment and its software;					
b) the manufacturer's name, type identification, and serial number or other unique identification;					
c) checks that equipment complies with the specification (see 5.5.2);					
d) the current location, where appropriate;					
e) the manufacturer's instructions, if available, or reference to their location;					
f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;					
g) the maintenance plan, where appropriate, and maintenance carried out to date;					
h) any damage, malfunction, modification or repair to the equipment.					
5.5.6 The laboratory shall 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.					
5.5.7 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly.					



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<p>The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the “Control of nonconforming work” procedure (see 4.9).</p>					
<p>5.5.8 Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.</p>					
<p>5.5.9 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.</p>					
<p>5.5.10 When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure.</p>					
<p>5.5.11 Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g. in computer software) are correctly updated.</p>					
<p>5.5.12 Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.</p>					
<p>5.6 Measurement traceability</p>					



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<p>5.6.1 General</p> <p>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 shall be calibrated before being put into service.</p>					
<p>The laboratory shall have an established program and procedure for the calibration of its equipment.</p>					
<p>5.6.2 Specific requirements</p>					
<p>5.6.2.1 Calibration</p>					
<p>5.6.2.1.2 There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:</p>					
<p>- the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;</p>					
<p>- the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.</p>					
<p>Participation in a suitable program of interlaboratory comparisons is required where possible.</p>					
<p>5.6.2.2 Testing</p>					



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<p>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 contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.</p>					
<p>5.6.2.2.2 Where 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 laboratories (see 5.6.2.1.2).</p>					
<p>5.6.3 Reference standards and reference materials</p>					
<p>5.6.3.1 Reference standards The laboratory shall have a program and procedure for the calibration of its reference standards.</p>					
<p>Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1.</p>					
<p>Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated.</p>					
<p>Reference standards shall be calibrated before and after any adjustment.</p>					



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<p>5.6.3.2 Reference materials</p> <p>Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.</p>					
<p>5.6.3.3 Intermediate checks</p> <p>Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules.</p>					
<p>5.6.3.4 Transport and storage</p> <p>The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.</p>					
<p>5.8 Handling of test and calibration items</p>					
<p>5.8.1 The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the <i>customer</i>.</p>					



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<p>5.8.2 The laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained throughout the life of the item in the laboratory. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory.</p>					
<p>5.8.3 Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded.</p>					
<p>When there is 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, the laboratory shall consult the <i>customer</i> for further instructions before proceeding and shall record the discussion.</p>					
<p>5.8.4 The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation. Handling instructions provided with the item shall be followed.</p>					
<p>When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.</p>					
<p>Where a test or calibration item or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.</p>					



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5.9 Assuring the quality of test and calibration results

5.9.1 The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken.

The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results.

This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

- a) regular use of certified reference materials and/or internal quality control using secondary reference materials;
- b) participation in interlaboratory comparison or proficiency-testing programs;
- c) replicate tests or calibrations using the same or different methods;
- d) retesting or recalibration of retained items;
- e) correlation of results for different characteristics of an item.

5.9.2 *Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned actions shall be taken to correct the problem and to prevent incorrect results from being reported.*

5.10 Reporting the results



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<p>5.10.1 General</p> <p>The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.</p>					
<p>The results shall be reported, usually in a test report or a calibration certificate (see note 1), and shall 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. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4.</p>					
<p>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.</p>					
<p>5.10.6 Testing and calibration results obtained from subcontractors</p> <p>When the test report contains results of tests performed by subcontractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically.</p>					
<p>5.10.7 Electronic transmission of results</p> <p>In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this International Standard shall be met (see also 5.4.7).</p>					



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<p>5.10.8 Format of reports and certificates</p> <p>The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.</p>					
<p>5.10.9 Amendments to test reports and calibration certificates</p> <p>Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement:</p> <p style="padding-left: 40px;">“Supplement to Test Report [or Calibration Certificate], serial number ... [or as otherwise identified]”,</p> <p>or an equivalent form of wording. Such amendments shall meet all the requirements of this International Standard.</p>					
<p>When it is necessary to issue a complete new test report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.</p>					