Calibration Services; ISO 17025
Procedure
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1.0 PURPOSE AND SCOPE

1.1 Purpose
1.1.1 The purpose of this procedure is to define the Calibration Services; ISO 17025 at our facility in accordance with ISO 17025 requirements.

1.2 Scope
1.2.1 This procedure is applicable for all Customer orders related to ATS Production Operations Calibration Service activities.

1.2.2 The scope of this work does not include Test Services as defined by ISO 17025:2005.

2.0 APPLICABLE DOCUMENTS

The following documents are applicable as specified herein:

**Industrial/Commercial/Government Documents**
ISO 17025:2005 (E) General requirements for the Competence of Testing and Calibration Laboratories

**ATS Document(s)**
ATS-CGP-1001 Contracts Documentation System
ATS-CGP-1002 Requirements Review, Quote and Bid System
ATS-CGP-1003 Customer Satisfaction
ATS-DCP-1001 Document Control
ATS-DCP-1002 Engineering Change Notice (ECN) Documentation
ATS-DCP-1003 Engineering Release (ER) Documentation
ATS-HRP-1001 Training and Certification
ATS-SOP-1006 Material Handling and Preservation
ATS-SOP-1017 Product Identification and Traceability
ATS-SOP-1020 Packaging and Shipping
ATS-PGP-1001 Purchasing System
ATS-PGP-2001 Supplier Evaluation and Approval/Disapproval
ATS-PGP-2002 Purchase Order Review
ATS-SOP-1003 Service Orders
ATS-QAM-9001 Quality Assurance Manual; ISO 9001
ATS-QAP-1001 Quality Policy
ATS-QAP-1002 Quality Objectives and Planning
ATS-QAP-1003 Continuous Improvement
ATS-QAP-1004 Quality Records
ATS-QAP-1005 Nonconforming Material System
QMS Tier 2
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ATS-QAP-1006 Corrective Action(s) System
ATS-QAP-1008 Internal Audits
ATS-QAP-1009 Management Review
ATS-QAP-1010 Validation of Processes
ATS-QAP-1016 Calibration System
ATS-QAP-1017 Customer Property
ATS-QAP-3001 Control of Customer Confidential and Proprietary Documents/Data
ATS-QAP-3002 Impartiality and Operational Integrity
ATS-QAP-3004 Measurement of Uncertainty; Calibration Lab
ATS-WSM-1001 Workmanship Standards Manual

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3.0 RESPONSIBILITIES

3.1 Responsibilities
3.1.1 Quality Assurance Manager - is responsible for preparing and maintaining this document. In addition, Quality Assurance shall support this procedure as specified herein.

3.1.2 President – shall support this process as defined in this procedure.

3.1.3 Technical Manager/Calibration Services Manager – shall support this process as defined in this procedure.

3.1.4 Operator’s - (Calibration Technician and Engineer personnel) shall support this process as defined in this procedure.

3.1.5 Other Functions - shall support this process as defined in this procedure.

4.0 MANAGEMENT REQUIREMENTS

4.1 ISO 9001 Quality Management System
4.1.1 ATS operates and maintains an ISO 9001 Quality Management System per ATS-QAM-9001, Quality Assurance Manual; ISO 9001.

5.0 TECHNICAL REQUIREMENTS

5.1 General
5.1.1 Many factors determine the correctness and reliability of the calibrations performed by Production Operations. These factors include contributions from:
  • human factors (5.2);
  • accommodation and environmental conditions (5.3);
  • calibration methods and method validation (5.4);
  • equipment (5.5);
  • measurement traceability (5.6);
  • sampling (5.7);
  • the handling of calibration items (5.8).

5.1.2 The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. The Production Operations and Quality Assurance does take account of these factors in developing
5.2 Personnel
5.2.1 The Production Operations and Quality Assurance do ensure the competence of all who operate specific equipment, perform calibrations, evaluate results, and sign calibration certificates. When using other personnel who are undergoing training, appropriate supervision is provided. Personnel performing specific tasks are qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required. See ATS-HRP-1001, Training and Certification for additional information.

5.2.2 The Production Operations management and Quality Assurance formulate the goals with respect to the education, training and skills of the ATS Production Operations Operators (Test & Inspection personnel). ATS Production Operations does have a procedure for identifying training needs and providing training of personnel. The training program is relevant to the present and anticipated tasks of the ATS Production Operations. The effectiveness of the training actions taken is evaluated. See ATS-HRP-1001, Training and Certification for additional information.

5.2.3 Production Operations management only uses personnel who are employed by, or under contract to, the ATS laboratory. Where contracted and additional technical and key support personnel are used, Production Operations management ensures that such personnel are supervised and competent and that they work in accordance with the ATS management system.

5.2.4 The Production Operations management and Quality Assurance maintains current job descriptions for managerial, technical and key support personnel involved in calibrations. These job descriptions are defined in our documented and approved ISO 9001 Quality Assurance Manual (ATS-QAM-9001) and department procedures.

5.2.5 The Production Operations management/Quality Assurance authorize specific personnel to perform particular types of sampling, calibration, to issue calibration certificates, to give opinions and interpretations and to operate particular types of equipment via document training records per ATS-HRP-1001, Training and Certification. The Quality Assurance does maintains records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information is readily available and does include the date on which authorization and/or competence is confirmed. See ATS-HRP-1001, Training and Certification for additional information.
5.3 Accommodation and environmental conditions

5.3.1 ATS laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, are such as to facilitate correct performance of the calibrations. Laboratory operations management ensures that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care is taken when sampling and calibrations are undertaken at sites other than a permanent ATS facility. We maintain our Laboratory environment at 75 degrees F +/- 10 degrees, Relative Humidity: 30 to 90%. When required by Customer order or when more precision measurements are needed, Production Operations management and QA will define the conditions in a documented procedure/instruction and include this information on the product's Service Order issued per ATS-SOP-1003, Service Orders.

5.3.2 The Production Operations/Quality Assurance personnel do 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 are 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. Calibrations are stopped when the environmental conditions jeopardize the results of the calibrations.

5.3.3 There are effective separations between neighboring areas in which there are incompatible activities. Measures are taken to prevent cross-contamination via written test procedures or the Service Order per ATS-SOP-1003, Service Orders.

5.3.4 Access to and use of areas affecting the quality of the calibrations is controlled. Production Operations/Quality Assurance does determine the extent of control based on its particular circumstances. When such areas exist, Production Operations/Quality Assurance clearly identifies the area(s) with posted signs or written memos.

5.3.5 Measures are taken to ensure good housekeeping in the ATS laboratory. Special procedures are prepared where necessary. See ATS-SOP-1006, Material Handling and Preservation for additional information.

5.4 Calibration methods and method validation

5.4.1 General

Production Operations does use appropriate methods and procedures for all 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 calibration data. Production Operations does 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 calibrations. All instructions, standards, manuals and reference data relevant to the work of the ATS laboratory are kept up to date and are made readily available to personnel (see 4.3). Deviation from calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer. See ATS-DCP-1001, Document Control and ATS-SOP-1003, Service Orders for additional information.
5.4.2 **Selection of methods**
Production Operations uses calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used. Production Operations does 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 is supplemented with additional details to ensure consistent application. When the customer does not specify the method to be used, the ATS laboratory does 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. ATS laboratory developed methods or methods adopted by the ATS laboratory may also be used if they are appropriate for the intended use and if they are validated. The Customer is informed as to the method chosen. Production Operations does confirm that it can properly operate standard methods before introducing the calibrations. If the standard method changes, the confirmation is repeated. Production Operations does inform the customer when the method proposed by the customer is considered to be inappropriate or out of date. See ATS-DCP-1001, Document Control, and ATS-SOP-1003, Service Orders for additional information.

5.4.3 **ATS laboratory-developed methods**
The introduction of calibration methods developed by the ATS laboratory for its own use are a planned activity and are assigned to qualified personnel equipped with adequate resources. Plans are updated as development proceeds and effective communication amongst all personnel involved is ensured. See ATS-DCP-1001, Document Control, ATS-SOP-1003, Service Orders and ATS-HRP-1001, Train and Certification for additional information.
5.4.4 **Non-standard methods**
When it is necessary to use methods not covered by standard methods, these methods are subject to agreement with the customer and do include a clear specification of the customer's requirements and the purpose of the calibration. The method developed shall have been validated appropriately before use by Quality Assurance/Production Operations.

5.4.5 **Validation of methods**
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.

5.4.5.2 Production Operations does validate non-standard methods, ATS 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 are as extensive as is necessary to meet the needs of the given application or field of application. Production Operations records the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use. See ATS-DCP-1001, Document Control and ATS-SOP-1003, Service Orders for additional information.

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, are relevant to the customers' needs.
5.4.6 Estimation of uncertainty of measurement

5.4.6.1 A calibration ATS laboratory, or a testing ATS 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. ATS Quality Assurance uses subcontractors to perform equipment calibrations in accordance with ATS-QAP-1016, Calibration System Requirements. For internal calibrations, see ATS-QAP-3004, Measurement of Uncertainty; Calibration Lab.

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 ATS laboratory does at least attempt to identify all the components of uncertainty and make a reasonable estimation, and do ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation is 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. ATS Quality Assurance uses ATS-QAP-3004, Measurement of Uncertainty; Calibration Lab

5.4.6.3 When estimating the uncertainty of measurement, all uncertainty components which is of importance in the given situation are taken into account using appropriate methods of analysis.

5.4.7 Control of data

5.4.7.1 Calculations and data transfers are subject to appropriate checks in a systematic manner by Production Operations personnel.

5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of calibration data, Production Operations does 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 does 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 maintains the integrity of calibration data.
5.5 Equipment

5.5.1 Production Operations are furnished with all items of sampling, measurement and test equipment required for the correct performance of the calibrations (including sampling, preparation of calibration items, processing and analysis of calibration data). In those cases where the ATS laboratory needs to use equipment outside its permanent control, Production Operations/Quality Assurance ensures that the requirements of this International Standard are met per ATS-QAP-1016, Calibration System Requirements.

5.5.2 Equipment and its software used for testing, calibration and sampling are capable of achieving the accuracy required and shall comply with specifications relevant to the calibrations concerned. Calibration programs are established for key quantities or values of the instruments where these properties have a significant effect on the results. Before being placed into service, equipment (including that used for sampling) are calibrated or checked to establish that it meets the ATS specification requirements and complies with the relevant standard specifications. It is checked and/or calibrated before use (see 5.6). Production Operations/Quality Assurance ensures that the requirements are met per ATS-QAP-1016, Calibration System Requirements.

5.5.3 Production Operations equipment is operated by trained personnel per ATS-HRP-1001, Training and Certification. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) are readily available for use by the appropriate ATS Production Operations personnel. See ATS-SOP-1003, Service Orders and ATS-DCP-1001, Document Control for additional information.

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. See ATS-SOP-1003, Service Orders, ATS-QAP-1016, Calibration System Requirements and ATS-DCP-1001, Document Control for additional information.

5.5.5 Records are maintained of each item of equipment and its software significant to the calibrations performed. The records does include at least the following:
   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.

See ATS-QAP-1016, Calibration System Requirements for additional information.

5.5.6 Production Operations does 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. See ATS-QAP-1016, Calibration System Requirements and ATS-SOP-1006, Materials Handling and Storage for additional information.

5.5.7 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has shown to be defective or outside specified limits, are taken out of service. It are 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. Production Operations does examine the effect of the defect or departure from specified limits on previous calibrations and shall institute the “Control of nonconforming work” procedure (see 4.9). See ATS-QAP-1016, Calibration System Requirements for additional information.

5.5.8 Whenever practicable, all equipment under the control of the ATS laboratory and requiring calibration are labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when reccalibration is due. See ATS-QAP-1016, Calibration System Requirements for additional information.

5.5.9 When, for whatever reason, equipment goes outside the direct control of the ATS laboratory, the ATS laboratory does ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service. See ATS-QAP-1016, Calibration System Requirements for additional information.

5.5.10 When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks are carried out per ATS-QAP-1016, Calibration System Requirements for additional information.

5.5.11 Where calibrations give rise to a set of correction factors, Production Operations/Quality Assurance has a procedure to ensure that copies (e.g. in computer software) are correctly updated. See ATS-QAP-1016, Calibration System Requirements for additional information.
5.5.12 Calibration equipment, including both hardware and software, are safeguarded from adjustments that would invalidate the calibration results. See ATS-QAP-1016, Calibration System Requirements for additional information.

5.6 Measurement traceability

5.6.1 General

All equipment used for 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 are calibrated before being put into service. Production Operations/Quality Assurance has established a procedure for the calibration of its equipment. See ATS-QAP-1016, Calibration System Requirements for additional information.

5.6.2 Specific requirements

5.6.2.1 Calibration

5.6.2.1.1 As a calibration laboratory, our program for calibration of equipment is designed and operated so as to ensure that calibrations and measurements made by the ATS laboratory are traceable to the International System of Units (SI). The calibration subcontractor establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to 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 units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards that are standards calibrated by another national metrology institute. When using external calibration services, traceability of measurement are assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by subcontract laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified method/procedure specification (see also 5.10.4.2).

5.6.2.1.2 There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration does provide confidence in measurements by establishing traceability to appropriate measurement standards such as:

- the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;
- the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned. Participation in a suitable program of internal laboratory comparisons is required where possible.
5.6.2.2 Testing

5.6.2.2.1 ATS is not a Test laboratory, so this section is applicable.

5.6.3 Reference standards and reference materials
5.6.3.1 Reference standards
Production Operations has a procedure for the calibration of its reference standards. Reference standards are calibrated by a body that can provide traceability as described in 5.6.2.1. Such reference standards of measurement held by the ATS laboratory are used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards are calibrated before and after any adjustment. Reference standards or reference materials are calibrated by approved subcontractors/suppliers per ATS-QAP-1016, Calibration System Requirements and ATS-PGP-1001, Purchasing System.

5.6.3.2 Reference materials
Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials are checked as far as is technically and economically practicable. See ATS-QAP-1016, Calibration System Requirements for additional information.

5.6.3.3 Intermediate checks
Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials are carried out according to defined procedures and schedules. See ATS-QAP-1016, Calibration System Requirements and ATS-SOP-1003, Service Orders for additional information.

5.6.3.4 Transport and storage
Production Operations has a procedure 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. See ATS-SOP-1006, Materials Handling and Storage and ATS-QAP-1016, Calibration System Requirements for additional information.

5.7 Sampling
5.7.1 Production Operations has a sampling procedure for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling plan, as well as the sampling procedure are available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the calibration results. See ATS-QAP-1901, Statistical Sampling, MIL-STD-105, Level II, AQL 1.0 for additional information.
5.7.2 Where the customer requires deviations, additions or exclusions from the documented sampling procedure, these are recorded in detail with the appropriate sampling data and are included in all documents containing calibration results, and are communicated to the appropriate personnel. See ATS-SOP-1003, Service Orders for additional information.

5.7.3 Production Operations has a procedure for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records does include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon. See ATS-SOP-1003, Service Orders for additional information.

5.8 Handling of calibration items
5.8.1 Production Operations has a procedure for the transportation, receipt, handling, protection, storage, retention and/or disposal of calibration items, including all provisions necessary to protect the integrity of the calibration item, and to protect the interests of the ATS laboratory and the customer. See ATS-SOP-1006, Materials Handling and Storage and ATS-SOP-1020, Packaging and Shipping for additional information.

5.8.2 Production Operations has a system for identifying calibration items. The identification is retained throughout the life of the item in the ATS laboratory. The system are 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 subdivision of groups of items and the transfer of items within and from the ATS laboratory. See ATS-SOP-1003, Service Orders for additional information.

5.8.3 Upon receipt of the calibration item, abnormalities or departures from normal or specified conditions, as described in the calibration method, are recorded. When there is doubt as to the suitability of an item for calibration, or when an item does not conform to the description provided, or the calibration required is not specified in sufficient detail, the ATS laboratory does consult the customer for further instructions before proceeding and shall record the discussion. See ATS-SOP-1003, Service Orders for additional information and ATS-QAP-1016, Calibration Requirements System for additional information.

5.8.4 Production Operations has a procedure and appropriate facilities for avoiding deterioration, loss or damage to the calibration item during storage, handling and preparation. Handling instructions provided with the item are followed. When items have to be stored or conditioned under specified environmental conditions, these conditions are maintained, monitored and recorded. Where a calibration item or a portion of an item is
to be held secure, the ATS Production Operations does have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned. See ATS-SOP-1003, Service Orders for additional information and ATS-QAP-1016, Calibration Requirements System for additional information.

5.9 Assuring the quality of calibration results

5.9.1 Production Operations does have Calibration Technician and Engineer procedures for monitoring the validity of calibrations undertaken. The resulting data are recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to the reviewing of the results. This monitoring are planned and reviewed and may include, but not be limited to, the following:
   a) regular use of certified reference materials and/or internal Calibration Technician and Engineer using secondary reference materials;
   b) participation in internal laboratory comparison or proficiency-testing programs;
   c) replicate calibrations using the same or different methods;
   d) recalibrations of retained items;
   e) correlation of results for different characteristics of an item.

See ATS-SOP-1003, Service Orders for calibrations performed by ATS approved personnel.

5.9.2 Calibration Technician and Engineer data are analyzed and, where they are found to be outside pre-defined criteria, planned action is taken to correct the problem and to prevent incorrect results from being reported. See ATS-SOP-1003, Service Orders for calibrations performed by ATS approved personnel.
### 5.10 Reporting the results

#### 5.10.1 General

The results of each test, calibration, or series of calibrations carried out by the ATS laboratory are reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the calibration methods. The results are reported, usually in a test report or a calibration certificate (see Note 1), and does include all the information requested by the customer and necessary for the interpretation of the calibration results and all information required by the method used. This information is normally required per paragraphs 5.10.2, and 5.10.3 or 5.10.4. In the case of 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. Any information listed in 5.10.2 to 5.10.4 that is not reported to the Customer is readily available in the ATS laboratory that carried out the calibrations. See ATS-SOP-1003, Service Orders for calibrations performed by ATS approved subcontractors.

#### 5.10.2 Calibration Reports and Certificates

Each calibration certificate does include at least the following information, unless the ATS Production Operations has valid reasons for not doing so:

- a) a title (e.g. “Calibration Certificate”);
- b) the name and address of the ATS laboratory, and the location where the calibrations were carried out, if different from the address of the ATS laboratory;
- c) unique identification of the calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the calibration certificate, and a clear identification of the end of the calibration certificate;
- d) the name and address of the customer;
- e) identification of the method used;
- f) a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;
- g) the date of receipt of the calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the calibration;
- h) reference to the sampling plan and procedures used by the ATS laboratory or other bodies where these are relevant to the validity or application of the results;
- i) the calibration results with, where appropriate, the units of measurement;
- j) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the calibration certificate;
- k) where relevant, a statement to the effect that the results relate only to the items tested or calibrated.

See ATS-SOP-1003, Service Orders for calibrations performed by ATS approved subcontractors.
5.10.3 **Test reports**
5.10.3.1 Test laboratory reports are not included in the scope of our QMS.

5.10.4 **Calibration certificates**
5.10.4.1 In addition to the requirements listed in 5.10.2, calibration certificates does include the following, where necessary for the interpretation of calibration results:
   a) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;
   b) the uncertainty of measurement and/or a statement of compliance with an identified method/procedure specification or clauses thereof;
   c) evidence that the measurements are traceable (see Note 2 in 5.6.2.1.1).

See ATS-SOP-1003, Service Orders for calibrations performed by ATS approved personnel

5.10.4.2 The calibration certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met. When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the ATS Production Operations does record those results and maintains them for possible future reference. When statements of compliance are made, the uncertainty of measurement are taken into account. See ATS-SOP-1003, Service Orders for product testing and ATS-QAP-1016, Calibration System Requirements for calibrations performed by ATS approved subcontractors.

5.10.4.3 When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, are reported. See ATS-SOP-1003, Service Orders for calibrations performed by ATS approved personnel

5.10.4.4 A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the customer. This requirement may be superceded by legal regulations. See ATS-SOP-1003, Service Orders for calibrations performed by ATS approved personnel
5.10.5 **Opinions and interpretations**
When opinions and interpretations are included, the ATS Production Operations does document the basis upon which the opinions and interpretations have been made. Opinions and interpretations are clearly marked as such in a test report. See ATS-SOP-1003, Service Orders for calibrations performed by ATS approved personnel.

5.10.6 **Calibration results obtained from subcontractors**
5.10.6.1 Calibration results obtained from subcontractors are reviewed upon and receipt for correctness and completeness, and retained by Quality Assurance in accordance with ATS-QAP-1016, Calibration System Requirements.

5.10.7 **Electronic transmission of results**
5.10.7.1 Electronic transmission of results are sent in a manner to ensure privacy and are sent when authorized by the Customer as defined in the Customer order or other written means.

5.10.8 **Format of reports and certificates**
5.10.8.1 Format of reports and certificates are documented in a manner that meets Customer order requirements and/or as specified in ATS-QAP-1402, Final Inspection.

5.10.9 **Amendments to calibration certificates**
5.10.9.1 Amendments to calibration certificates are performed by the originator or Production Operations management/Quality Assurance in accordance with ATS-QAP-1004, Quality Records. The change is documented and approved as defined in ATS-QAP-1004, Quality Records.
Figure 1 – Electronic Laboratories, Inc. Quality System Organizational Chart

See the Organizational Chart defined in ATS-QAM-9001, Quality Assurance Manual, ISO 9001
Figure 2 - Responsibility, Authority and Interrelationships

In general, each manual, procedure and instruction issued within our company define who is responsible for assigned activities. See Figure 1 for interrelationship information. In addition, the below information shall be used as a global interpretation of assigned Responsibility and Authority.

**President** – The President has overall management responsibility for the business including sales, financial, resource staffing, and laboratory effectiveness and compliance. The President ensures that laboratory test and inspection activities are conducted in a manner that meets the requirements of 4.1.5 in this manual.

**QA Manager** – The QA Manager has the responsibility overseeing the laboratories compliance and conducting internal audits and reporting conflicts of interest to the President.

**Technical Manager/Calibration Services Manager** – The Technical Manager/Calibration Services Manager has the responsibility for scheduling work, planning job activities and ensuring laboratory test and inspection activities are performed in an effective and complete manner as defined in this manual.

**Calibration Technician and Engineer Personnel** – The Calibration Technician and Engineer personnel are responsible for ensuring laboratory test and inspection activities are performed in an effective and complete manner as defined in this manual.
Figure 3 – Laboratory QMS Documentation Structure