

JM Test Systems, Inc.

CALIBRATION LAB. DIVISION

QUALITY MANUAL

Baton Rouge, Louisiana

Alexandria, Louisiana

Odessa, Texas

Clute, Texas

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4 Management requirements

4.1 Organization and management

- 4.1.1 JM test Systems Inc. is privately owned and was incorporated in Louisiana in 1982. All facilities operate under the Quality System. The legal entity of the calibration laboratories:

JM Test Systems, Inc.
Calibration Lab Division
7323 Tom Drive
Baton Rouge, Louisiana 70806

Branch Laboratory
JM Test Systems, Inc.
1600 Watterberg Way
Alexandria, Louisiana 71303

Branch Laboratory
JM Test Systems, Inc.
1020 N. Texas Ave
Odessa, Texas 79761

Branch Laboratory
JM Test Systems, Inc.
738 South Main
Clute, Texas 77531

JM Test Systems has mobile calibration trailers that serve as an extension of the facility they are assigned.

4.1.2 Scope

It is JM Test Systems responsibility and policy to perform calibration and testing activities in accordance with ISO 17025 “General requirements for the competence of testing and calibration laboratories” and ISO 9001:2000 “Quality Management Systems-Requirements”, as well as all customer requirements and regulatory laws. Vocabulary and definitions used will be based on the ISO 9000 standard whenever possible.

JM Test Systems does not design any product. Therefore the Design and Development Section 7.3 of ISO 9001:2000 does not apply to JM Test Systems.

4.1.3 JM Test Systems management system covers all work performed in its permanent facilities, at sites away from its permanent facilities, and ~~both~~ mobile facilities.

4.1.4 JM Test Systems is not part of a parent organization. It is a provider of calibration services only. There are no potential conflicts of interest with any conflicting activity.

4.1.5 JM Test Systems:

- a) Have management and technical personnel with the authority, responsibility, and resources needed to carry out their duties including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the quality system/ procedures for performing calibrations, and to initiate actions to prevent or minimize such departures;
- b) Has arrangements to ensure that management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;
- c) Has policies and procedure QP10 Protecting confidentiality and proprietary rights to ensure the protection of its client's confidential information and proprietary rights including for protecting the electronic storage and transmission of results;
- d) Has procedures and the following policies to avoid employee and company involvement in activities that would diminish confidence in its competence, impartiality, judgement or operational integrity:
 - o Lab Technicians are not compensated based on the number of instruments calibrated,
 - o Lab Technicians do not have a quota of instruments to be calibrated in any specific timeframe.
 - o Lab Technicians are not permitted to process any instruments from their previous place of employment for a period of at least one year.
 - o Lab Technicians are subject to random drug and alcohol testing per Safety Manual requirements.
 - o Lab Technicians are not permitted to compete (race) one another regarding the number of items processed.
 - o Lab Technicians are given Decision Rule training to help eliminate bias and report consistent calibration data.

- Lab Technicians have a management advisory staff (independent of lab management) to ask questions and consult with regarding measurement issues.
 - Lab Technicians calibration work is subject to independent QA inspection to ensure high quality calibrations.
- e) Has defined the organization and management structure Organizational Chart of JM Test Systems and the relationships between quality management, technical operations and support services;
- f) Has specified the responsibility, authority and interrelationships of all personnel who manage, perform or verify the quality of calibrations;
- g) Provides adequate supervision of calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each calibration, and with the assessment of the calibration results;
- h) Has a Technical Manager with the overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;
- i) Has a Quality Manager (ISO 9000 Management Representative) who, irrespective of other duties and responsibilities, has defined responsibility and authority for ensuring that the quality system is implemented and followed at all times; The Quality Manager has direct access to the highest level of management at which decisions are made on laboratory policy or resources; i.e., reports directly to the President of the company. The Quality Manager is responsible for promoting communication of customer requirements.
- j) Appoints deputies for key managerial personnel. The Lab Manager is the deputy Technical Manager and the Technical Manager is the deputy Quality Manager.
- k) Ensures that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.
- 4.1.6 The Quality and Lab Managers are responsible for ensuring that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

4.1.7 Process Identification

Section	Process	Per	Recorded on
Quality Management	Plan quality	QP 25	None
Quality Management	Control documentation and data	QP 12	QF 122
Quality Management	Protection of electronic data	WI-4	None
Quality Management	Control of records	QP 7	Records matrix
Quality Management	Amend reports and certificates	WI-17	QF 104
Quality Management	Control of electronic data	QP 23	None
Management Responsibility	Mgt responsibility and authority	QP 6	None
Management Responsibility	QS Management review	QP 20	QF 101
Resource Management	Training and qualification	QP 8	QF 140
Resource Management	Environmental controls	WI-6	QF 110
Product Realization	Purchasing	QP 13	Purchase Order
Product Realization	Subcontractor controls	QP 3	QF 131-133
Product Realization	Measurement uncertainty	QP 21	None
Product Realization	Contract/Project review	QP 9	QF 100
Product Realization	Inspection and test	QP 26	QF 261
Product Realization	Identification and status	QP 22	Work Order
Product Realization	Handling and storage	QP 1	QF 11
Product Realization	ESD controls	WI-7	Validation label
Product Realization	Packaging	WI-1	None
Product Realization	Customer complaints	QP 18	QF 105
Product Realization	Calibration of equipment	WI-3	Work Order
Product Realization	Processing of standards	QP 17	QF 43/QF 83
Product Realization	Adjustment of intervals	WI-10	QF 553
Product Realization	Reverse traceability	WI-9	QF 43
Measurement/analysis	Proficiency Testing	QP 11	QF 102
Measurement/analysis	Technician fails	WI-16	QF 103
Measurement/analysis	Internal audit	QP 19	QF 108/QF 106
Measurement/analysis	QA of documentation and product	QP 2	QF 103
Measurement/analysis	Corrective/Preventive action	QP 24	QF 105
Measurement/analysis	Departure from procedure/policy	QP 16	QF 105

4.1.8 Process Sequence

INCOMING EQUIPMENT

EQUIPMENT TAGGED PER QP 1

EQUIPMENT RECEIVED PER WI-2

EQUIPMENT IDENTIFIED PER QP 22

WORK ORDER GENERATED PER QP 1

PROJECT REVIEW PER QP 9

EQUIPMENT CALIBRATED PER WI-3

EQUIPMENT INSPECTED PER QP 2

EQUIPMENT PACKAGED PER WI-1

STORED RECORDS PER QP 7

4.2 Management System

- 4.2.1 JM Test Systems has established, implemented and maintained a quality system appropriate to the repair, calibration and certification of measuring and test equipment as identified in its Scope of Calibrations.doc. It documents its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of calibration results. JM Test Systems has defined and documented how the requirements for quality are met. JM Test Systems uses a generic Quality Plan contained in a procedure. This quality plan references other documented procedures that form an integral part of the quality system. JM Test Systems Quality System Documentation is communicated to, understood by, available to, and implemented by all appropriate personnel. Quality documentation is reviewed at least every three (3) years and results documented and presented at Quality System Management Reviews.
- 4.2.2 JM Test Systems' management system policies and Quality objectives are defined in this Quality Manual. Management objectives are established and reviewed at formal management review meetings. Laboratory personnel are trained to familiarize themselves with quality documentation and implement the policies and procedures. These overall objectives have been documented in the following quality policy statement issued under the authority of the President:

JM Test Systems, Inc. will return to the customer an instrument that is repaired calibrated and/or certified along with reliable and accurate test data. If necessary, the instrument will be restored to a "like new" appearance. We will continually strive to improve the quality of our services through personnel training, membership in the National Conference of Standards Laboratories, maintaining conformance to ISO 17025 and ISO 9001 requirements along with the use and development of state-of-the-art measurement equipment and techniques.

- 4.2.3 JM Test Systems top management provides evidence of commitment to the development and implementation of its management system and to continually improving its effectiveness.
- 4.2.4 Management communicates to its employees the importance of meeting customer requirements, statutory and regulatory requirements.
- 4.2.5 The quality manual includes supporting procedures including a Documentation matrix & cross reference.doc of applicable procedures. The following is the structure of the quality system documentation:

Level I	Quality Manual (QM)	Policy
Level II	Quality Procedures (QP)	Procedures
Level III	Work Instructions/Calibration Procedures	Work Instructions
Level IV	Quality Forms (QF)	Forms, Tags, Labels

4.2.6 The roles and responsibilities of technical management and the Quality Manager, including their responsibility for ensuring compliance with this International Standard, are defined in the Quality Manual and in QP 6 Management responsibility and authority.doc.

4.2.7 Top management ensures that the integrity of the management system is maintained when changes to the management system are planned and implemented.

4.2.8 Quality planning

JM Test Systems has defined and documented how the requirement for quality is met. A generic quality plan contained in QP 25 “Quality Plan” that references other documented procedures that form an integral part of the quality system.

Quality planning is consistent with other requirements of the quality system and is documented in a format to suit the company’s method of operation. Consideration is made to the following activities;

- A. Preparation of quality plans (See Quality Procedure QP 25)
- B. Identification and acquisition of controls, processes, calibration equipment and standards
- C. Training for the skills required to achieve required quality
- D. Updating inspection, test and quality control techniques
- E. Clarification of standards of acceptability for requirements
- F. The identification and preparation of quality records.

4.3 Document Control

4.3.1 General

JM Test Systems establishes and maintains QP 12 Control and maintenance of documents procedure to control all documents that form its quality system including internally generated or external sources, such as standards, calibration methods, software, drawings, specifications, instructions and manuals. Documents and data can be in the form of any type of media, such as hard copy or electronic media.

4.3.2 Document approval and issue

4.3.2.1 JM Test Systems procedure ensures that:

- a) authorized documents are available on the computer network to all employees where operations essential to the effective functioning of JM Test Systems are performed;
- b) documents are reviewed and revised to ensure continuing adequacy, suitability and compliance with applicable requirements;
- c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;
- d) obsolete documents retained for either legal or knowledge preservation purposes are suitable marked.

4.3.2.2 All quality system documents generated by JM Test Systems are uniquely identified with a revision number, the date of issue and/or revision, title, page number, and the issuing authority.

4.3.2.3 All quality system documents generated by JM Test Systems are reviewed at least every five years. Proof of review is evidenced by updated release date.

4.3.3 Document changes

4.3.3.1 Changes to documents are reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel have access to pertinent background information upon which to base their review and approval.

4.3.3.2 Altered or new text is identified in the document or with appropriate attachments.

4.3.3.3 JM Test System's documentation control system allows for the amendment of documents by hand pending the re-issue of the documents, the procedures and authorities for such amendments are defined. Amendments are clearly marked, initialed and dated. A revised document is formally re-issued as soon as practicable. **These amendments must be approved by the Quality Manager.**

4.3.3.4 QP 12 Control and maintenance of documents procedure is established to describe how changes in documents maintained in computerized systems are made and controlled.

4.4 Review of requests, tenders and contracts

4.4.1 JM Test Systems has established and maintains procedure QP 9 Project/Contract Review for the review of requests, tenders and contracts. The policies and procedure for these reviews leading to a contract for calibration ensures that:

- a) the requirement, including the methods to be used, are adequately defined, documented and understood;
- b) JM Test Systems has the capability and resources to meet the requirements;
- c) the appropriate calibration method is selected and capable of meeting the clients' requirements.

Any differences between the request or tender and the contract are resolved before any work commences. Each contract is acceptable to both JM Test Systems and the client.

4.4.2 Records of reviews, including any significant changes, are maintained. Records are also maintained of pertinent discussions with a client's requirements or the results of the work during the period of execution of the contract.

4.4.3 The review also covers any work that is subcontracted by JM Test Systems.

4.4.4 The client is informed of any deviation from the contract.

4.4.5 If a contract needs to be amended after work has commenced, the same contract review process is repeated and any amendments are communicated to the affected personnel.

4.5 Subcontracting of tests and calibrations

- 4.5.1 When JM Test Systems subcontracts work whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting, agency or franchising arrangements), this work is placed with a competent subcontractor as defined in QP 3 “Vendor Evaluation and Qualification”.
- 4.5.2 JM Test Systems advises the client of the arrangement verbally or in writing and, when appropriate, gain the approval of the client, preferably in writing.
- 4.5.3 JM Test Systems is responsible to the client for the subcontractor’ work, except in the case where the client or a regulatory authority specifies which subcontractor is to be used.
- 4.5.4 JM Test Systems maintains an Approved Vendor Listing of all subcontractors that it uses for calibrations or provides critical parts and materials and a record of the evidence of compliance with this International Standard for the work in question.
- 4.5.5 JM Test Systems only subcontracts calibration work to calibration service providers who comply with the requirements of either ISO 17025, ISO 9001, 9002, ISO Guide 25 or ANSI/NCSL Z540-1.

4.6 Purchasing services and supplies

- 4.6.1 JM Test Systems has a policy and procedure QP 13 “Purchasing” for the selection and purchasing of services and supplies it uses that affect the quality of calibrations. Procedures exist for the purchase, reception, inspection and storage of laboratory consumable materials relevant for calibrations.
- 4.6.2 JM Test Systems ensures that purchased supplies and reagents and consumable materials that affect the quality of calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the calibrations concerned. These services and supplies used comply with specified requirements. Records of actions taken to check compliance are maintained.
- 4.6.3 Purchasing documents for items affecting the quality of calibrations contains data clearly describing the services and supplies ordered including but not limited to the type, class, grade, quality system standard to comply to, and other technical requirements. These purchasing documents are reviewed and approved for technical content prior to release.
- 4.6.4 JM Test Systems evaluates suppliers of critical consumables, supplies and services that affect the quality of calibration on the basis of their ability to meet quality system requirements, and maintains records of these evaluations and an Approved Vendors Listing of those that are approved.
- 4.6.5 Outside services (calibration and repairs) and materials (parts) are inspected by the technician before work is certified. The technician ensures parts and consumable equipment is inspected prior to use, to verify conformance with any specification relevant to the item. Upon receipt, critical parts and materials are inspected in accordance with QP 26 “Inspection and Testing Procedure”.

4.7 Service to the customer

JM Test Systems affords clients or their representative's cooperation to clarify the client's request and to monitor JM Test System's performance in relation to the work performed, provided that JM Test Systems ensures confidentiality to other clients.

4.7.1 Verification at subcontractor's premises

Where JM Test Systems proposes to verify purchased product at the subcontractor's premises, JM Test Systems specifies verification arrangements and the method of product release in the purchasing documents.

4.7.2 Customer verification of subcontracted product

When specified in the contract, the Customer or Customers Representative is afforded the right to verify at JM Test Systems premises the conformance of product. Verification by the customer does not absolve JM Test Systems the responsibility to provide acceptable product, nor does it preclude subsequent rejection by the customer.

4.7.3 JM Test Systems seeks customer feedback, both negative and positive. Customer satisfaction survey forms are presented to customers to be filled out. Surveys are used to analysis customer service trends to improve the management system, testing, and calibration activities and customer service.

4.7.3 Servicing

The scope of JM Test Systems quality system does not include servicing.

4.8 Complaints

JM Test Systems has a policy and QP18 Dealing with Customer Complaints procedure for the resolution of complaints received from clients or other parties. Records are maintained of all complaints via Quality Form 105 and of the investigations and corrective actions taken by JM Test Systems. When the investigation of a complaint reveals any deficiency in the quality system or any deficiency that could affect the quality of calibrations, it is corrected as soon as possible.

4.9 Control of nonconforming calibration work

4.9.1 JM Test Systems has a policy and QP 24 Corrective and preventive action.doc procedure that is implemented when any aspect of its calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the client. The policy and procedures ensures that:

- a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of calibration certificates, as necessary) are defined and taken when nonconforming work is identified;
- b) an evaluation of the significance of the nonconforming work is made;
- c) corrective actions are taken immediately, together with any decision about the acceptability of the nonconforming work;
- d) where necessary, the client is notified and work is recalled;
- e) the responsibility for authorizing the resumption of work is defined.

4.9.2 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of JM Test System's operations with its own policies and procedures, the corrective action procedures given in 4.10 are promptly followed.

4.10 Continual Improvement

- 4.10.1 JM Test Systems continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.
- 4.10.2 Improvements to business operations are achieved by using the “ process approach” when reviewing quality system element and operations.

4.11 Corrective action

4.11.1 General

JM Test Systems has established a policy and QP 24 Corrective and preventive action procedure and has designated appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system or technical operations have been identified.

4.11.2 Cause analysis

The procedure for corrective action starts with an investigation to determine the root cause(s) of the problem.

4.11.3 Selection and implementation of corrective actions

Where corrective action is needed, JM Test Systems identifies potential corrective actions. It selects and implements the action(s) most likely to eliminate the problem and to prevent recurrence.

Corrective actions are to a degree appropriate to the magnitude and the risk of the problem.

JM Test System documents and implements any required changes resulting from corrective action investigations.

4.11.4 Monitoring of corrective actions

JM Test Systems monitors the results to ensure that the corrective actions taken have been effective.

4.11.5 Additional audits

Where the identification of nonconformances or departures casts doubts on JM Test System's compliance with its own policies and procedures, or on its compliance with ISO 17025 or 9002, JM Test Systems ensures that the appropriate areas of activity are audited in accordance with 4.13 as soon as possible.

4.12 Preventive action

- 4.12.1 Needed improvements and potential sources of nonconformances, either technical or concerning the quality system, are identified. If preventive action is required, action plans are developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformances and to take advantage of the opportunities for improvement.
- 4.12.2 Procedure QP 24 Corrective and preventive action for preventive actions include the initiation of such actions and application of controls to ensure that they are effective.
- 4.12.3 JM Test Systems monitors certain performance trends. Opportunities for preventive actions are identified by analyzing selected data. A decision is made what degree of preventive action effort is required to prevent occurrence.

4.13 Control of records

4.13.1 General

- 4.13.1.1 JM Test Systems has established and maintain QP 7 Control and maintenance of quality records procedure for the identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions. Hard paper files are JM Test Systems official records.
- 4.13.1.2 All records are legible and are stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment that prevents damaged or deterioration and prevents loss. Retention times of records have been established. Where agreed to by contract, records are available for evaluation by the customer or the customer representative.
- 4.13.1.3 All records are held secure and in confidence.
- 4.13.1.4 JM Test Systems protects and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.

4.13.2 Technical records

- 4.13.2.1 JM Test Systems retains records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each calibration certificate issued, for a defined period. The records for each calibration contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the calibration to be repeated under conditions as close as possible to the original. The records include the identity of personnel responsible for the sampling, performance of each calibration and checking of results.
- 4.13.2.2 Observations, data and calculations are recorded at the time they are made and are identifiable to the specific task.
- 4.13.2.3 When mistakes occur in records, each mistake is crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records are signed or initialed by the person making the correction. In the case of records stored electronically, equivalent measures are taken to avoid loss or change of original data.

4.14 Internal audits

- 4.14.1 JM Test Systems periodically, and in accordance with a predetermined Quality system audit schedule and procedure, QP 19 Quality system audit conducts internal audits of its activities to verify that its operations continue to comply with the requirements of JM Test Systems quality system and both ISO 17025 and ISO 9001. The internal audit program addresses all elements of the quality system including calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits are carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.
- 4.14.2 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of JM Test System's calibration results, JM Test Systems takes timely corrective action, and notifies clients in writing if investigations show that JM Test Systems results may have been affected.
- 4.14.3 The area of activity audited, the audit findings and corrective actions that arise from them are recorded.
- 4.14.4 Follow-up audit activities verify and record implementation and effectiveness of the corrective action taken.

4.15 Management reviews

4.15.1 In accordance with a predetermined schedule and procedure, QP 20 Quality system management review, JM Test Systems executive management biannually conducts a review of JM Test System's quality system and calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review takes account of:

- q the suitability of policies and procedures;
- q reports from managerial and supervisory personnel;
- q the outcome of recent internal audits;
- q corrective and preventive actions;
- q assessments by external bodies;
- q the results of interlaboratory comparisons or proficiency tests;
- q changes in the volume and type of work;
- q client feedback;
- q complaints;
- q other relevant factors, such as quality control activities, resources and staff training.

4.15.2 Findings from management reviews and the actions that arise from them are recorded as meeting minutes. Management ensures that those actions are carried out within an appropriate and agreed timescale.

4.16 Customer-supplied product

- 4.16.1 JM Test Systems considers a limited definition of customer-supplied product. When taken into consideration the nature of calibration activities at JM Test Systems, customer-supplied product is considered as accessories to calibration activities. Examples are; Operating manuals, technical materials, software, cables, power supplies, fluids, carrying cases, consumables, supplied parts for repair, and reference materials.
- 4.16.2 JM Test Systems, Inc. has established and maintains QP 1 “Receiving, and handling of measuring and test equipment” for the control of verification, storage and maintenance of any customer-supplied product provided for incorporation into the calibration or repair process.
- 4.16.3 When equipment arrives it is processed per QP 1 and QP 26. A Work Order number tag is placed on it along with any accessories for tracking it.
- 4.16.4 Any instances where equipment or accessories provided by customers does not meet with requirements, is lost or damaged, it is recorded and reported to the customer.
- 4.16.5 The equipment is tagged and segregated pending resolution and the situation is recorded on the Work Order.

4.17 Product identification and traceability

- 4.17.1 JM Test Systems, Inc. has established and maintains Quality Procedure QP 1 “Receiving, and handling of measuring and test equipment” for the control of product identification and traceability. It provides for unique identification and traceability of customer and company owned product by suitable, traceable and recorded means from pick-up or receipt through all stages of calibration/repair to delivery.

4.18 Inspection and testing

JM Test Systems has procedures for the inspection and testing activities in order to ensure that the calibration and repair services it provides meet specified requirements. Required inspection and testing is established in Quality Procedure QP 25 “Quality Plan” and QP 26 “Inspection and test”.

4.18.1 Receiving inspection and test

- 4.18.1.1 Incoming product is not used or processed until it is inspected or verified as conforming to specified requirements. Verification of the requirements are described in Quality Procedure QP 1 “Receiving, and handling of measuring and test equipment” and QP 26 “Inspection and test”.
- 4.18.1.2 Consideration is given to the amount of control enforced at the supplier’s facility or any recorded historical evidence of provided conformance when determining the amount and nature of receiving inspections.
- 4.18.1.3 In the event that equipment is released for urgent purposes, prior to verification, it is positively identified and recorded in order to permit immediate recall and replacement.

4.18.2 In-process inspection and test

- 4.18.2.1 Inspection and testing of equipment is accomplished via applicable calibration procedure and the Technicians Guide Work Instruction WI-3.
- 4.18.2.2 Employees are not allowed to use parts and materials until required inspection and tests are complete.

4.18.3 Final inspection and test

- 4.18.3.1 Final inspection and test is accomplished per QP 25 “Quality Plan” and QP 2 “QA of documentation” requirements.
- 4.18.3.2 The Quality Plan and inspection procedures require all specified inspections and tests are completed and the results meet specified requirements.
- 4.18.3.3 Measuring and test equipment is not released until all activities specified in the quality plan and documented procedures have been satisfactorily completed.

- 4.18.4 Inspection and test records
 - 4.18.4.1 JM Test System has an established record system to provide evidence that specified products have been inspected and tested. Quality Procedure QP 7 “Quality Records” addresses the control of quality records. The records show clearly whether the product passed or failed the inspections and tests.
 - 4.18.4.2 Inspection records identify the Inspector who passed or failed the product.
 - 4.18.4.3 Nonconforming product is controlled per the nonconforming product procedure.

4.19 Inspection and test status

- 4.19.1 Inspection and test status of Measuring and test equipment is identified in Quality Procedure QP 22 “Identification and test status of Measuring and test equipment”.
- 4.19.2 The identification of the inspection and test status is maintained throughout the calibration process to ensure that only items that has passed the specified inspections and tests pass to the next operation.

4.20 Servicing

- 4.20.1 The scope of JM Test Systems’ Business and Quality System include servicing. JM Test provides servicing to our customers at multiple levels- from equipment pick-up to equipment return and subsequent onsite service to customers after sales or rental of equipment.

4.21 Statistical Techniques

4.21.1 Some activities and processes performed by JM Test Systems, Inc., include the use of statistical techniques. JM Test Systems management determined that statistical techniques is required for establishing, controlling and verifying process capability and calibration characteristics. JM Test Systems has established and released a quality procedure to implement the policy.

JM Test Systems applies statistical techniques for establishing, controlling and verifying some process capability and calibration characteristics. In addition, this allows the company to better target improvement opportunities determine customer satisfaction and improve ways to identify and prevent potential problems. Some activities and processes that include the use of analysis of data;

Statistical techniques using Uncertainty toolbox ® software to determine Uncertainties

Statistical control charts using Excel spreadsheet software to monitor and control standards accuracy

Statistical techniques using Excel software to determine Quality Objectives

5 Technical requirements

5.1 General

5.1.1 Many factors determine the correctness and reliability of calibrations performed by JM Test Systems. These factors include contributions from:

- q human factors;
- q accommodation and environmental conditions;
- q calibration methods and method validation;
- q equipment
- q measurement traceability;
- q sampling;
- q handling of calibration items.

5.1.2 The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) calibrations. JM Test Systems takes account of these factors in developing calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.

5.2 Personnel

- 5.2.1 JM Test Systems management ensures the competence of all who operate specific equipment, perform calibrations, evaluate results, and sign reports and calibration certificates. When using staff 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.
- 5.2.2 The management of JM Test Systems formulates the goals with respect to the education, training and skills of JM Test Systems personnel. JM Test Systems has a policy and QP 8 Training procedure for identifying training needs and providing training of personnel. The effectiveness of training is assessed. The training program is relevant to the present and anticipated tasks. The effectiveness of the training is evaluated by completion of tests and/or feedback from students.
- 5.2.3 JM Test Systems uses personnel who are employed by JM Test Systems. Where contracted and additional technical and key support personnel are used, JM Test Systems ensures that such personnel are supervised and competent and that they work in accordance with JM Test System's quality system.
- 5.2.4 JM Test Systems maintains current job descriptions for managerial, technical and key support personnel involved in calibrations. Job qualifications are categorized using a letter system that segregates work into letter coded areas. Technicians performing calibrations in an area must have been qualified for the area or be obtaining "OJT" in the area while under direct supervision of a qualified technician. Technicians assigned to new areas will receive training in the area until qualified in the area. Training and qualifications are recorded in the technician personal training record. A technician qualifications list is posted on the work assignment board listing each technicians name, stamp number, initials, and qualified areas.
- 5.2.5 The management authorizes specific personnel to perform particular types of calibrations, to issue calibration reports/certificates, to give opinions and interpretations and to operate particular types of equipment. JM Test Systems maintains records of the relevant authorizations, competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information is readily available and includes the date on which authorization and/or competence is confirmed.

5.3 Accommodation and environmental conditions

- 5.3.1 JM Tests Systems facilities for calibration, including but not limited to energy sources, lighting and environmental conditions, are such as to facilitate correct performance of calibrations.

JM Test Systems ensures that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care is taken when calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of calibrations are controlled. *Environmental controls are addressed and governed by Work Instruction WI-6.*

- 5.3.2 JM Test Systems monitors, controls and records environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention is paid, for example, to biological sterility, ventilation, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Calibration activities are stopped when the environmental conditions jeopardize the results of calibrations. The Laboratory Manager makes the decision when to proceed with calibration operations based on equipment type and adjustments.
- 5.3.3 There is effective separation between neighboring areas in which there are incompatible activities. Measures are taken to prevent cross-contamination.
- 5.3.4 Access to and the use of areas affecting the quality of calibrations are controlled. JM Test Systems determines the extent of control based on its particular circumstances.
- 5.3.5 Measures are taken to ensure good housekeeping in JM Test Systems facilities. A weekly scheduled cleanup is maintained at all facilities.

5.4 Calibration methods and method validation

5.4.1 General

JM Test Systems uses appropriate calibration methods (calibration procedures) for all calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of calibration data.

JM Test Systems has instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for calibration where the absence of such instructions could jeopardize the results of calibrations. All instructions, standards, manuals and reference data relevant to the work of JM Test Systems is kept up to date and is made readily available to personnel in the technical library. Deviation from calibration methods occur only if the deviation has been documented, technically justified, and authorized per QP16 Departure from documented policy and procedures.

5.4.2 Selection of methods

JM Test Systems uses calibration methods, including methods for sampling, which meet the needs of the client and which are appropriate for the calibrations it undertakes. JM Test Systems uses Calibration Procedures (CP) for all calibrations performed. Documented calibration procedures are essential to ensure consistency and to reduce reliance on the technician's memory. Calibration procedures will provide instructions to enable technicians to adequately calibrate each test characteristic or measurement parameter of interest. Calibration procedures are available from four sources:

- A. Equipment manufacturer technical/operation manuals
- B. JM Test Systems developed Calibration Procedures (CP)
- C. Government Industry Data Exchange Program (GIDEP)
- D. U.S. Military and Government procedures and standards

When the client does not specify the method to be used, JM Test Systems selects appropriate methods from the above four sources. JM Test Systems-developed calibration procedures may also be used if they are appropriate for the intended use. The client is informed if any different calibration method other than the above four sources is chosen. JM Test Systems informs the client when the method proposed by the client is considered to be inappropriate or out of date.

5.4.3 JM Test Systems-developed calibration methods

The introduction of Calibration Procedures developed by JM Test Systems for its own use is a planned activity and is assigned to Metrology Engineers who are qualified and who are equipped with adequate resources.

Calibration procedures are updated as development proceeds and effective communication amongst all personnel involved is ensured.

5.4.4 Non-standard methods

When it is necessary to use methods not covered by the above four sources, these are subject to agreement with the client and include a clear specification of the client's requirements and the purpose of the calibration. The method developed is validated appropriately before use.

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 JM Test Systems validates non-standard methods, internally-developed methods, standards 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 is as extensive as is necessary to meet the needs of the given application or field of application. JM Test Systems records the results obtained, the procedure used for the validation, and a statement as to whether method is fit for the intended use.

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, is relevant to the clients' needs.

5.4.6 Estimation of uncertainty of measurement

5.4.6.1 JM Test Systems has and applies QP 21 Procedure for determining measurement uncertainty, calibration adequacy, and analysis of calibration data for all calibrations and types of calibrations.

5.4.6.2 JM Test Systems applies a procedure 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, JM Test Systems attempts to identify all the components of uncertainty and make a reasonable estimation, and ensures 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 makes use of, for example, previous experience and validation data.

5.4.6.3 When estimating the uncertainty of measurement, all uncertainty components that are 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 quality assurance checks in a systematic manner as specified in QP 23 QA of Documentation.

5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of calibration data, JM Test Systems ensures that:

- a) Computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;
- b) Procedure QP 22 “Procedure To Ensure the Integrity Of Electronic Calibration Data” are established and implemented for protecting the data; such procedures includes, but is not 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 calibration data.

5.5 Equipment

- 5.5.1 JM Test Systems is furnished with all items of sampling, measurement and test equipment required for the correct performance of the calibrations (including sampling, preparation of calibration item, processing and analysis of calibration data). In those cases where JM Test Systems needs to use equipment outside its permanent control, it ensures that the requirements of ISO 17025 are met.
- 5.5.2 Equipment and its software used for calibration and sampling is capable of achieving the accuracy required and complies 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) is calibrated or checked to establish that it meets JM Test System's specification requirements and complies with the relevant standard specifications. It is checked and/or calibrated before use.
- 5.5.3 Equipment is operated by authorized personnel. 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 laboratory personnel.
- 5.5.4 Each item of equipment and its software used for calibration and significant to the result is, uniquely identified.
- 5.5.5 Records are maintained of each item of equipment and its software significant to the calibrations performed. The records 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;
 - 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 JM Test Systems has 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, is taken out of service. It is isolated to prevent its use or clearly labeled “Do not use” until it has been repaired and calibrated and is performing correctly. Management may institute QP 24 Corrective and Preventive action procedure to document any nonconforming work. JM Test Systems examines the effect of the defect or departure from specified limits on previous calibrations using Work Instruction WI-9 “Reverse traceability searches”.
- 5.5.8 All equipment under the control of JM Test Systems and requiring calibration is labeled and identified to indicate the status of calibration, including the date when last calibrated and the date recalibration is due.
- 5.5.9 When, for whatever reason, equipment goes outside the direct control of JM Test Systems, JM Test Systems ensures that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.
- 5.5.10 When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks are carried out according to the manufacturer’s manual or procedure.
- 5.5.11 Where calibrations give rise to a set of correction factors, JM Test Systems will provide a procedure to ensure that copies (e.g. in computer software) are correctly updated.
- 5.5.12 Test and calibration equipment, including both hardware and software, are safeguarded from adjustments that would invalidate the calibration results. Tamper-resistant seals are affixed to operator accessible controls or adjustments on calibration items which, if moved, will invalidate the calibration. If JM Test Systems equipment is found with a broken seal the equipment is removed from service and the Lab Manager investigates the condition of the equipment before returning it to service.

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 calibration or sampling are calibrated before being put into service. JM Test Systems has established programs and QP 17 “Procedure for Calibration Standards” for the calibration of its equipment.

5.6.2 JM Test Systems measurement traceability policy and specific requirements

JM Test System policy requires that:

5.6.2.1 All calibrations and verifications of measuring and test equipment and reference standard's must be conducted by:

- A calibration laboratory accredited to ISO/IEC 17025 by a mutually recognized Accreditation Body; or a recognized National Metrology Institute (NMI).
- A mechanical testing laboratory accredited by A2LA to ISO/IEC 17025 and found to meet the A2LA Calibration Program Requirements as indicated on their Mechanical Scope of Accreditation.
- A Lab that produces an accredited test report containing appropriate statements of measurement results, measurement uncertainty, and traceability can be considered to satisfy traceability requirements; or
- A laboratory accredited by A2LA to ISO/IEC 17025 and found to meet the T9 requirements of the A2LA Traceability requirement document for their in-house calibrations

5.6.2.2 When possible, all reference materials shall be obtained from:

- A reference material producer accredited to ISO Guide 34 in combination with ISO/IEC17025 by a recognized Asia Pacific Laboratory Accreditation Cooperation (APLAC) signatory recognized for accrediting reference material producers; or
- A recognized National Metrology Institute (NMI).

5.6.2.3 Measurement Traceability

To maintain conformance to A2LA Traceability (T) requirements, JM Test Systems requires:

- External calibrations and verifications, must be recorded in a calibration certificate or report endorsed by the recognized Accreditation Body's symbol (or otherwise makes reference to accredited status by a specific, recognized accreditation body) with an indication of the type of entity that is accredited (e.g., via an accreditation certificate number, inclusion of "calibration laboratory" with the symbol, etc.) or endorsed by the National Metrology Institute (NMI). (T2)
- Internal calibrations and verifications, those requirements outlined in requirement T9 of A2LA Measurement Traceability policy document apply. For reference materials, these must be recorded in a certificate meeting the requirements of ISO Guide 31 endorsed by the recognized Accreditation Body's symbol (or otherwise makes reference to accredited status by a specific, recognized accreditation body) with an indication of the type of entity that is accredited or endorsed by the recognized NMI.
- Its policy for achieving measurement traceability is placed in this section of the Quality Manual and also for achieving traceability for reference materials, if applicable. (T3)
- Its calculations of measurement uncertainty be in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement." These uncertainties, when reported, shall be reported as the expanded uncertainty with a defined coverage factor, k (typically $k = 2$) and the confidence interval (typically to approximate the 95% confidence level). (T4)
- That if a calibration certificate or test report contains a statement of the measurement result and the associated uncertainty, then the uncertainty statement shall be accompanied by an explanation of the meaning of the uncertainty statement. (For example, "This uncertainty represents an expanded uncertainty expressed at approximately the 95% confidence level using a coverage factor of $k=2$.) (T5)
- Its TURs shall be calculated using the expanded uncertainty of the measurement, not the "collective uncertainty of the measurement standards". (T6)

- Implicit uncertainty statements be accompanied by words to the effect that the uncertainty ratio was calculated using the expanded measurement uncertainty. In addition the coverage factor and confidence level must be stated. (T7)

- Calibration reports and certificates issued by A2LA-accredited calibration laboratories contain a traceability statement. (T8)

- All in-house calibrations shall be supported by the following minimal set of elements (T9):
 - a) The in-house laboratory shall maintain documented procedures for the in-house calibrations and the in-house calibrations shall be evidenced by a calibration report, certificate, or sticker, or other suitable method, and calibration records shall be retained for an appropriate, prescribed time;

 - b) The in-house laboratory shall maintain training records for calibration personnel and these records shall demonstrate the technical competence of the personnel performing the calibrations;

 - c) The in-house laboratory shall be able to demonstrate traceability to national or international standards of measurement by procuring calibration services from appropriately accredited calibration labs or an NMI and/or purchasing reference materials from appropriately accredited reference material producers or an NMI;

 - d) The in-house laboratory shall have and apply procedures for evaluating measurement uncertainty. Measurement uncertainty shall be calculated for each type of calibration and records of these calculations shall be maintained. (Note: Records of these calculations must be maintained for calibrations done as of 8/1/06.) Measurement uncertainty shall be taken into account when statements of compliance with specifications are made;

 - e) Reference standards shall be recalibrated at appropriate intervals to ensure that the reference value is reliable. Policy and procedures for establishing and changing calibration intervals shall be based on the historical behavior of the reference standard.

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:

- 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 interlaboratory comparisons.

5.6.2.1 Calibration

- 5.6.2.1.1 The program for calibration of equipment is designed and operated so as to ensure that calibrations and measurements made by JM Test Systems are traceable to the International System of Units (SI).

JM Test Systems has established traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to 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 which are standards calibrated by another national metrology institute. When using external calibration services, traceability of measurement is assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

5.6.3 Reference standards and reference materials

5.6.3.1 Reference standards

JM Test Systems has a program and procedure QP 17 Procedure for calibration standards for the calibration of its reference standards. Reference standards are calibrated by a body that can provide traceability to NIST. Such reference standards of measurement held by JM Test Systems are used for calibration only and for no other purpose. Reference standards are calibrated before and after any adjustment.

5.6.3.2 Reference materials

Reference materials are, where possible, traceable to SI units of measurement, or to certified reference materials. Internal reference materials are checked as far as is technically and economically practicable.

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.

5.6.3.4 Transport and storage

JM Test Systems has a procedure QP 1 “Receiving and handling of measuring and test equipment” for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

5.7 Sampling

5.7.1 JM Test Systems does not perform sampling activities.

5.8 Handling of calibration items

- 5.8.1 JM Test Systems has QP 1 Procedure for the receiving and handling of measuring and test equipment for the transportation, receipt, handling, protection, storage, retention and/or disposal of calibration items, including all Customer-supplied product and provisions necessary to protect the integrity of the calibration item, and to protect the interests of JM Test Systems and the client.
- 5.8.2 JM Test Systems has a Work Order (WO) computer system for identifying calibration items. The identification is retained throughout the life of the item at JM Test Systems laboratories. The system is designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents.
- 5.8.3 Upon receipt of the test or 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, JM Test Systems consults the client for further instructions before proceeding and records the discussion on the Work Order document.
- 5.8.4 JM Test Systems has QP 1 Procedure for the receiving and handling of measuring and test equipment procedure and appropriate facilities for avoiding deterioration, loss or damage to calibration items 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 test or calibration item or a portion of an item is to be held secure, JM Test Systems has arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned. JM Test Systems controls the packaging, packing, and marking process (including materials used) to the extent necessary to ensure conformity to specified requirements.
- 5.8.5 The inspection and test status of measuring and test equipment is delineated in QP 22 Identification and test status of measuring and test equipment. The identification of the measuring and test equipment status is maintained throughout the calibration process to ensure that only product that has passed the specified inspections and tests is released.
- 5.8.6 JM Test Systems has arrangements to protect the quality of its products after final inspection and test. Where specified by contract, this protection is extended to include delivery to destination.

5.9 Assuring the quality of calibration results

5.9.1 JM Test Systems has quality control procedures for monitoring the validity of calibrations undertaken. The resulting data is recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to the reviewing of the results. This monitoring is 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 as delineated in QP 11 Interlaboratory comparisons and proficiency testing programs.
- c) replicate calibrations using the same or different methods;
- d) recalibration of retained items;
- e) correlation of results for different characteristics of an item.

5.9.2 Quality control data is analyzed and if found to be outside the pre-defined criteria, planned action is taken to correct the problem and to prevent incorrect results from being reported.

5.10 Reporting calibration results

5.10.1 General

The results of each calibration or series of calibrations carried out by JM Test Systems is reported accurately, clearly, unambiguously and objectively, and in accordance with specific instructions in the calibration procedures.

The results are reported in a calibration certificate and data sheet that includes all the information requested by the client and necessary for the interpretation of the calibration results and all information required by the calibration procedure used.

5.10.2 Calibration certificates

Each Calibration Certificate and associated data sheet includes at least the following information:

- a) a title “Certificate of Calibrations”;
- b) the name and address of JM Test Systems, and the location where the calibrations were carried out;
- c) Certificate/traceability number of the calibration certificate 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 client;
- e) identification of the calibration procedure used;
- f) a description of the item and the condition of the item calibrated;
- g) the date of receipt of calibration item and the date of performance of the calibration;
- h) reference to the sampling plan and procedure used by JM Test Systems or other bodies where these are relevant to the validity or application of the results;
- i) the calibration results with the units of measurement;
- j) the name, function and signature identification of person authorizing the calibration certificate;
- k) A statement to the effect that the results relate only to the items calibrated.

- l) A statement that the certificate and data sheet will not be reproduced except in full, without the written approval of JM Test Systems.

5.10.3 Test Reports

5.10.3.1 In addition to the requirements listed in 5.10.2, test reports, where necessary for the interpretation of the test results, include the following:

- a) deviations from, additions to, or exclusions from the calibration procedure, and information on specific test conditions, such as environmental conditions;
- b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications;
- c) A statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a client's instruction so requires, or when the uncertainty affects compliance to a specification limit;
- d) where appropriate and needed, opinions and interpretation;
- e) additional information which may be required by specific methods, clients or groups of clients.

5.10.3.2 Test reports containing the results of sampling are included in the following, where necessary for the interpretation of test results:

- a) the date of sampling;
- b) unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate);
- c) the location of sampling, including any diagrams, sketches or photographs;
- d) a reference to the sampling plan and procedures used;
- e) details of any environmental conditions during sampling that may affect the interpretation of the test results;
- f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.

5.10.4 Calibration certificate

5.10.4.1 Calibration certificates include the following, where necessary for the interpretation of calibration results:

- a) the environmental conditions 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 metrological specification or clauses thereof;
- c) measurements are traceable to National Institute of Standards and Technology (NIST).

5.10.4.2 The calibration certificate relates only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this identifies 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, JM Test Systems records those results and maintains them for possible future reference.

When statements of compliance are made, the uncertainty of measurement is taken into account.

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.

5.10.4.4 A calibration certificate or calibration label does not contain any recommendation on the calibration interval except where this has been agreed with the client.

5.10.5 Opinions and interpretations

When opinions and interpretations are included, JM Test Systems documents the basis upon which the opinions and interpretations have been made. Opinions and interpretations are clearly marked as such.

5.10.6 Calibration results obtained from subcontractors

When calibration reports contain results of tests performed by subcontractors, these results are clearly identified.

When a calibration has been subcontracted, the subcontracted laboratory performing the work issues the calibration certificate to the contracting laboratory.

5.10.7 Electronic transmission of results

In the case of transmission of calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this International Standard are met.

5.10.8 Format of reports and certificates

The format is designed to accommodate each type of calibration carried out and to minimize the possibility of misunderstanding or misuse.

5.10.9 Amendments to calibration certificates and data sheets

Material amendments to a calibration certificate or data sheet after issue is made only in the form of a further document, or data transfer, which includes the statement:

“Supplement to Calibration Certificate, number”, or an equivalent form of wording.

Such amendments meet all the requirements of ISO 17025.

When it is necessary to issue a complete calibration certificate, it is uniquely identified and contains a reference to the original that it replaces.

5.11 Customer Satisfaction

JM Test Systems monitors information relating to its customer perception to determine if customer requirements were met. Methods used to measure customer satisfaction include the monitoring of;

- 5.11.1 Customer complaints
- 5.11.2 Questionnaire Surveys
- 5.11.3 Warranty returns
- 5.11.4 Point-of-contact feedback with Sales personal

Change history

Revision	Date	Change Description
1.9	10/1/01	Complete Revision to Quality Manual to conform to ISO 17025 Quality System requirements.
1.10	2/15/02	Revisions : Revised ¶ 4.5.1, 4.5.4, 4.5.5 Added Sections 4.2.5, 4.15, 4.16, 4.17, 4.18, 4.19 and 4.20 Revised the Quality Policy in paragraph 4.2.2
1.11	8/1/02	Revisions: Revised ¶ 4.1.5j Revised ¶ 4.2.1 Revised ¶ 4.12.1.1 Revised ¶ 5.10.3 Revised ¶ 5.3.1 Revised ¶ 5.5.7 Revised ¶ 5.7.1
1.12	9/25/03	Revised to include new ISO 9001:2000 requirements Added sections 5.11 and 5.12 Revised paragraphs 4.11.3, 4.13.1, 4.1.5, 4.1.2 Created Index
1.13	11/25/03	Added section 4.1.6 and 4.1.7

1.14	6/25/06	<p>Updated to ISO 17025:2005 revision.</p> <p>Revised paragraphs;</p> <p>4.1.5 a) 4.2.2 5.2.2</p> <p>Added new paragraphs;</p> <p>4.1.5 k) 4.1.6 4.2.3 4.2.4 4.2.7 4.7.3 4.10 5.9.2</p> <p>Added Odessa Facility</p>
1.15	10/10/06	<p>Revised and expanded paragraph 4.1.5 d.</p> <p>Corrected Index page and paragraph numbering</p>
1.16	6/15/09	<p>Revised;</p> <p>Paragraph 4.1.1 added Clute Laboratory</p> <p>Paragraph 4.1.2 "Scope"</p> <p>Section 5.6-Complete revision</p>

		Removed; Paragraph 4.2.2 Quality Objectives Added; Paragraph 4.3.2.3 “Document review policy” Paragraph 4.21 “Statistical Techniques”
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Approved by:

S. Morrison
President

Date