MOREHOUSE INSTRUMENT COMPANY

CORPORATE QUALITY ASSURANCE PROGRAM MANUAL

FOR

FORCE & TORQUE

CALIBRATION SERVICES

CONTROLLED COPY

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1. MANUAL REVISION STATUS

REVISION LEVEL	DATE	SECTIONS AFFECTED
0	04/15/87	ALL – INITIAL ISSUE
1	09/18/87	1,2,3,4,7,10
2	04/16/90	1,2,4,5,6,7,8,10,13,14
3	01/15/91	1,2,4,5,6,7,8,9,10,12,13,14,15
4	01/15/92	1,2,4,9,10,13,15
5	06/30/94	ALL EXCEPT 11
6	06/17/96	1,2,3,4,5,6,8,9,10,11,14,15
7	12/04/00	ALL
8	03/27/06	1,2,3,4,5,6,7,8,9,11,12,13,15
9	10/19/09	1,2,4,5,7,8,11,12
10	07/15/10	ALL – REVISED TO INCLUDE TORQUE CALIBRATION
11	12/15/11	1,2,6,7,9,10,11,12
12	04/14/14	ALL
12.1	05/02/14	1, 2, 5, 3, 6, 9, 11, 12
13	9/30/15	ALL
14	1/4/16	1, 2, 3, 5, 8, 11, 12, 14, 15
15	11/30/16	1, 2, 3, 11, 13, & 14
16	2/15/18	ALL
17	2/20/19	2, 3, 5, 8, 13, & 14

2. SCOPE OF CALIBRATION & POLICY STATEMENT

Morehouse Instrument Company is committed to maintaining good professional practices and to provide high quality, accurate, and reliable force and torque measurement, calibration, and tests. Services offered include calibration and testing of force to 2,225,000 lbf, torque measuring devices to 2,000 N-m and systems, transducer simulators, and indicating instruments used with force and torque measuring devices and systems. Calibrations and tests shall be within the laboratory's scope of accreditation and be carried out in accordance with stated methods and customer requirements.

The Quality Assurance Program for calibration is documented by written procedures set forth in this Manual and the Force & Torque Calibration Laboratory - Procedure Manual.

The purpose of this Manual and the Force & Torque Calibration Laboratory – Procedure Manual is to establish a management/quality system committed to compliance with current requirements of ISO/IEC 17025 and ANSI Z540.3, to provide for continual improvement of the system relating to quality, to require all personnel contributing to and affected by the quality, administrative, and technical system governing the operation of the Force & Torque Calibration Laboratory be familiar with quality policy and procedures, and insure traceability to SI through a National Metrology Institute (NMI) such as the United States National Institute of Standards & Technology (NIST). These Manuals represent official company policy and shall be used to administer systems for the control of quality and reliability. There shall be no departures from the policies and procedures set forth in this Manual.

This Manual and the Force & Torque Calibration Laboratory – Procedure Manual provide for the most current published requirements of the following:

1. ANSI/NCSL Z540.1 – American National Standard for Calibration – Calibration Laboratories and Measuring and Test Equipment General Requirements
2. ANSI/NCSL Z540.3 – American National Standard for Calibration – Requirements for the Calibration of Measuring and Test Equipment
3. ISO/IEC 17025 – General requirements for the competence of calibration and testing laboratories
4. 10 CFR 50 APPENDIX B – Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
5. 10 CFR PART 21 - United States Nuclear Regulatory Commission – Reporting of Defects and Noncompliance
6. Other Industrial and Government Specifications
7. Customer Specified Requirements

This manual has been reviewed and approved by the Executive QA Committee of Morehouse Instrument Company and found to provide for the requirements of ISO/IEC 17025 and ANSI Z540.3.

February 20, 2019

3. ORGANIZATION & MANAGEMENT

3.1 History & Legal Status:

In 1920 Morehouse Machine Company was founded as a general partnership for the manufacturer of precision parts. The Company earned a reputation for its precision design and manufacturing capabilities. In 1925 Dr. H. L. Whittemore and Dr. S. N. Petrenko of the United States National Bureau of Standards, now named the United States National Institute of Standards and Technology, approached Morehouse about developing a portable device for the calibration of material testing machines. The device was successfully developed and termed a Proving Ring which Morehouse Machine Company began manufacturing and marketing worldwide.

Morehouse Machine Company incorporated under the laws of Pennsylvania on December 12, 1930. As the business evolved and became more involved with the manufacture and calibration of precision force measuring and calibrating instruments and equipment and less involved in general machine work the name was legally changed to Morehouse Instrument Company, Inc. September 6, 1963.

In 2009 Morehouse Instrument Company was approached by the National Physical Laboratory of Great Britain about buying their country's national primary torque standard. Since the United States National Institute of Standards & Technology had decided not to setup a national torque laboratory for the United States Morehouse decided it would purchase this primary torque standard and offer primary torque calibration services.

Today Morehouse Instrument Company manufactures and calibrates some of the most precise force and torque measuring devices and systems in the world. With a commitment to quality and reliability Morehouse has earned a worldwide reputation for the manufacture and calibration of precision force and torque measuring devices and systems.

3.2 Responsibility, Authority, & Job Descriptions:

The President is ultimately responsible for all operations, including the Quality Assurance Program.

The Executive QA Committee reports directly to the President and is responsible for overseeing the quality function at Morehouse Instrument Company, including the establishment, maintenance, implementation, and improvement of the management/quality system for calibration and testing services. The Committee shall include the President, Quality Assurance Manager, Technical Engineering Manager (however named), and Laboratory Manager.

The Quality Assurance Manager reports directly to the Executive QA Committee.

Members of the Executive QA Committee and personnel, including other management and technical personnel, contributing to and affected by the quality, administrative, and technical system governing the operation of the Force and Torque Calibration Laboratory have the responsibility, authority, and freedom to identify quality problems; to initiate, recommend, or provide solutions; to verify the implementation

and effectiveness of the solutions; and recommend improvements to the management/quality system without regard to any commercial, financial, or other pressures that might adversely affect the quality of calibrations and tests performed by Morehouse Instrument Company.

The relationships between the Executive QA Committee, the President, the Quality Assurance Manager, Technical Engineering Manager, the Laboratory Manager, and laboratory personnel are shown in Figure 3.1, Organization Chart.

The Quality Assurance Manager is responsible for the establishment, maintenance, implementation, and improvement of the management/quality system for calibration and testing services, including the preparation and distribution of the Corporate Quality Assurance Program Manual and Force & Torque Calibration Laboratory – Procedure Manual. The position of Quality Assurance Manager may be held by anyone in the organization, including the President. The Quality Assurance Manager shall act without regard to cost, schedule, other duties, and responsibilities within the organization when acting in the capacity of Quality Assurance Manager. In the absence of the Quality Assurance Manager the Technical Engineering Manager shall assume these responsibilities.

The Technical Engineering Manager shall have overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of the Force and Torque Calibration Laboratories. The Technical Engineering Manager has authority to make decisions regarding technical aspects of the Force and Torque Calibration Laboratory operations and is responsible for the maintenance, implementation, and improvement of the management/quality system for calibration and testing services. The Technical Engineering Manager shall act without regard to cost, schedule, other duties, and responsibilities within the organization. In the absence of the Technical Engineering Manager the Quality Assurance Manager shall assume these responsibilities.

The Laboratory Manager is responsible for the daily operation of the Force and Torque Calibration Laboratory and the maintenance, implementation, and improvement of the management/quality system for force and torque calibration and testing services. This includes direct supervision of other qualified force and torque calibration technicians and advising management when extra help is required or overtime should be worked to assure laboratory personnel are insulated from pressures to increase productivity that would compromise the quality of the work. The Laboratory Manager shall act without regard to cost, schedule, other duties, and responsibilities within the organization on items affecting quality.

Force Calibration Technicians are responsible for performing calibrations and tests in accordance with the requirements of this Manual and the Force & Torque Calibration Laboratory – Procedure Manual and the maintenance, implementation and improvement of the management/quality system for Force Calibration Services. They shall review the calibrations and tests to be performed to be sure the proper resources, including appropriate accessories and adaptors, are available before commencing any calibrations. On items affecting quality they shall act without regard to cost, schedule, other duties, and responsibilities within the organization.

Torque Calibration Technicians are responsible for performing calibrations and tests in accordance with the requirements of this Manual and the Force & Torque Calibration Laboratory – Procedure Manual and the maintenance, implementation, and improvement of the management/quality system for Torque

Calibration Services. They shall review the calibrations and tests to be performed to be sure the proper resources, including appropriate accessories and adaptors, are available. On items affecting quality they shall act without regard to cost, schedule, other duties, and responsibilities within the organization.

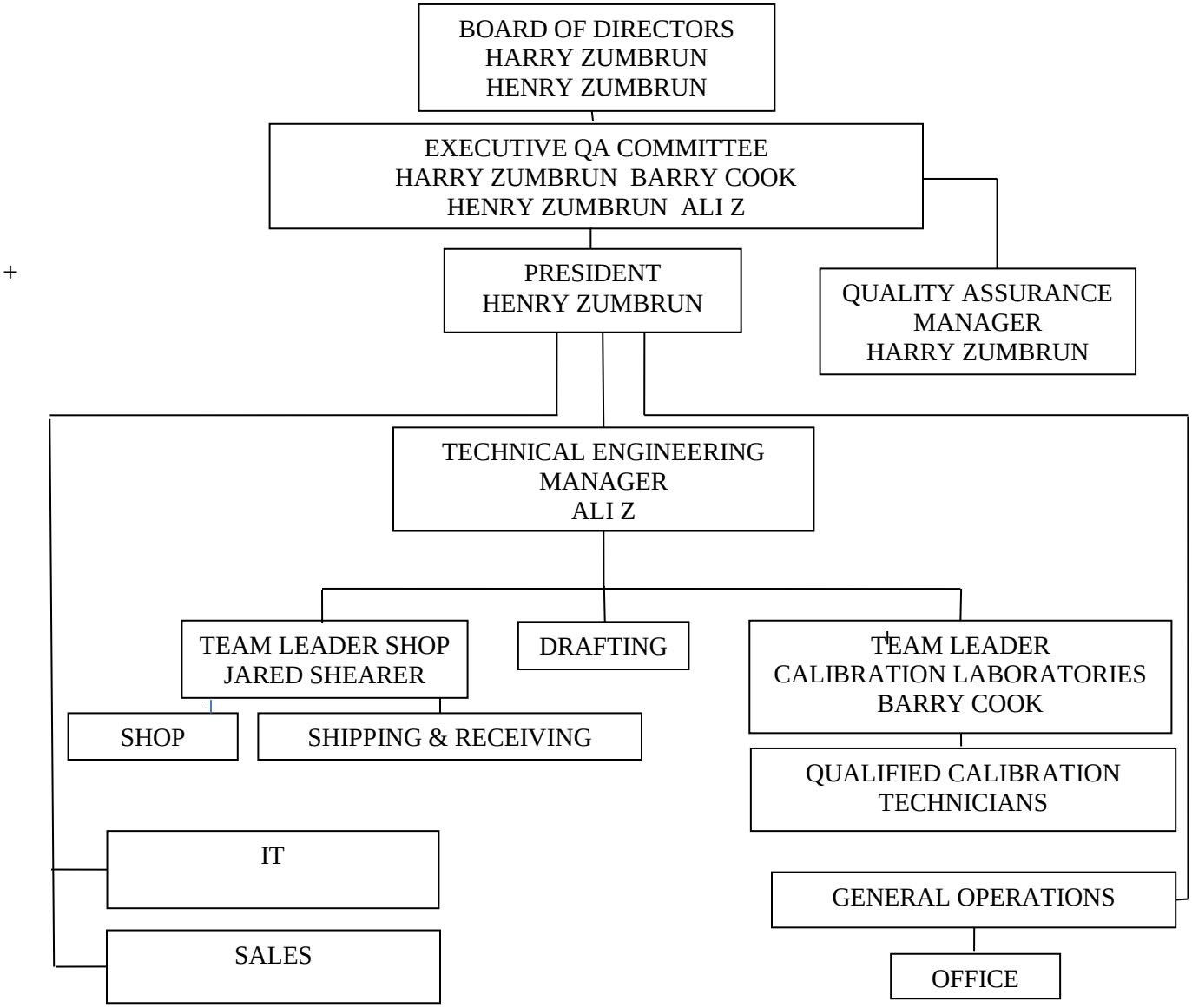
All personnel may communicate with customers as needed. On items affecting quality they shall act without regard to cost, schedule, other duties, and responsibilities within the organization.

If any person is or suspects another employee of being involved in an activity that would diminish confidence in the competence, impartiality, judgment, or operational integrity of any measuring device or system being calibrated by Morehouse it should be immediately reported to the Quality Assurance Manager. The Quality Assurance Manager shall determine if the personnel should be removed from any and all involvement in the calibration or test being performed and reassign another person to the task where appropriate. Where another person is assigned any work previously completed shall be verified and/or redone by the new person.

All personnel are encouraged to seek assistance whenever and wherever needed and are authorized to contact customers, manufacturers, or suppliers as needed for clarification of details regarding any calibrations or tests to be performed.

ORGANIZATION CHART

(Figure 3.1)



4. MANAGEMENT/ QUALITY SYSTEM ASSESSMENT, PERSONNEL TRAINING, REPLICATE TESTING, & PROFICIENCY TESTING

4.1 General:

The management/quality system for the Force and Torque Calibration Laboratory at Morehouse Instrument Company is documented and defined by written policies, instructions, operation procedures, and personnel training requirements as detailed in this Manual and the Force & Torque Calibration Laboratory - Procedure Manual. These manuals communicate, provide understanding, and insure implementation of the polices, instructions, operating procedures, and personnel training necessary to maintain good laboratory practice and insure our customers receive consistent high quality. The effectiveness of the management/quality system shall be continually improved by having regular management review of quality policy, audit results, analysis of data, corrective and preventive action, training classes, customer feedback, and other items which contribute to and/or affect the quality objective, as stated in Section 2, of Morehouse Instrument Company.

4.2 Management/Quality System Assessment for Effectiveness, Implementation & Continuous Improvement:

This Manual and the Force & Torque Calibration Laboratory - Procedure Manual are subject to documented approval and periodic review and assessment for effectiveness and implementation by the Executive QA Committee. When warranted changes and revisions in this Manual and/or the Force Calibration Laboratory - Procedure Manual should be made. At no time shall the period between review and assessment exceed one year, except when documented approval is granted by the Quality Assurance Manager.

The initial assessment and approval of any revision level of the manuals shall be documented by having all members of the Executive QA Committee sign each manual in a designated section. The Corporate Quality Assurance Program Manual shall be signed in Section 2, “Policy Statement”, and the Force & Torque Calibration Laboratory - Procedure Manual shall also be signed in Section 2, “Policy Statement”.

The following shall be reviewed by the Executive QA Committee to maintain and assess the effectiveness, implementation of the management/quality system. During the review of these items the Committee shall look for trends or defects that require corrective or preventative action to improve the calibration and testing services and the effectiveness of the management/quality system.

1. Active items left open since last Executive QA Committee meeting
2. Corporate Quality Assurance Program Manual
3. Force & Torque Calibration Laboratory - Procedure Manual
4. Qualifications and approval of those authorized to act as auditors for Morehouse Instrument Company
5. Supplier Audit Summaries
6. Assessments by external bodies

7. Documented defects or out of tolerance conditions
8. Notifications sent to customers advising them of errors or defects
9. Feedback & Complaint Forms
10. Non-Conformance &/or Corrective Action Forms
11. Implementation of corrective action
12. Internal Audit Summary
13. Measurement Assurance Tests
14. Results of Proficiency Tests
15. Assess the effectiveness of training by reviewing records for initial training, refresher training classes, replicate and/or proficiency testing results, and instances of non-conforming work for Qualified Force and Torque Calibration Technician
16. Managerial and supervisory personnel reports
17. Changes in the volume and type work
18. Recommendations for improvement in the calibration and testing service and look for trends or defects in the above that require corrective or preventive action to improve the effectiveness and documentation of the management/quality system.
19. Review of any planned or implemented changes to the management/quality system to ensure they do not run counter to the goal and objectives of the Force Calibration Laboratory and to ensure the changes meet the requirements of ISO/IEC 17025.
20. Preventive Action
21. Other business that is appropriate or necessary

The Quality Assurance Manager shall document the assessment and review by recording minutes detailing the items reviewed and detail any findings or actions that arise at each meeting of the Executive QA Committee. Each member of the Committee shall sign a copy of the minutes as evidence they have participated in the review. The minutes shall be kept on file by Morehouse Instrument Company and are available for review upon request to the Quality Assurance Manager.

Meetings of the Executive QA Committee to review the management/quality system and calibration and testing activities shall be performed at intervals not exceeding one year and are used to continually improve the service and effectiveness of the management/quality system.

4.3 Personnel Training:

Qualified Force and Torque Calibration Technicians must be employees of Morehouse Instrument Company. Upon completion of the required training personnel will be classified as Qualified Force and/or Torque Calibration Technicians and be authorized to work without supervision and sign Certificates of Calibration and Test Reports without further review.

Documented training is required to become a Qualified Force and/or Torque Calibration Technician. The training requirements are outlined in the Force & Torque Calibration Laboratory - Procedure Manual and include reading and becoming familiar with both the Corporate Quality Assurance Program Manual and the Force & Torque Calibration Laboratory – Procedure Manual. Reading these Manuals initially familiarizes the Technicians with the requirements for continual improvement of the services, the

effectiveness of the management/quality system, and ensures they are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management/quality system. The goal of the training requirements is to assure qualified personnel have the skills and knowledge required to perform tasks in accordance with the policies and procedures contained in this Manual and the Force & Torque Laboratory – Procedure Manual. A list of Qualified Force Calibration and Qualified Torque Calibration Technicians, including technicians in training shall be posted in the appropriate Laboratory. This list shall be prepared by and posted by the Quality Assurance Manager.

To ensure changes in procedures and documentation are communicated to personnel there shall be refresher training classes held whenever there is a change in procedures or documentation that affect the effectiveness or implementation of the management/quality system. Examples of when a training class is required include a change in the Corporate Quality Assurance Program Manual, change in the Force Calibration Laboratory – Procedure Manual, change in procedures such as ASTM E74, ASTM 2428, ISO 376 and BS 7882, or changes in other documents included on the Master Documents List which affects the force and/or torque service or the relevance and importance of personnel activities and how they contribute to the achievement of the management/quality system.

The training classes shall be attended by all Qualified Force and Torque Calibration Technicians, and/or other personnel, such as relevant office staff, that contribute to the achievement of the management/quality system. Each training class shall include a review of changes in documentation and procedures and changes in any document included on the Master Documents List which affects the service or the relevance and importance of personnel activities and how they contribute to the achievement of the management/quality system. It shall also provide an opportunity for all attendees to make recommendations for improvements, to voice concerns if any changes run counter to the goals and objectives of the Force and Torque Calibration Laboratory, and ensure the changes meet the requirements of ISO/IEC 17025.

The Quality Assurance Manager shall document training classes by recording minutes detailing the items reviewed and list the names of the personnel in attendance.

All Qualified Force and Torque Calibration Technicians shall participate in replicate and/or proficiency testing programs. The procedure for the replicate and proficiency testing programs are outlined in the Force & Torque Calibration Laboratory - Procedure Manual.

The initial training along with refresher training and annual participation in a replicate and/or proficiency testing program assures Qualified Force and Torque Calibration Technicians receive adequate training, are kept informed of changes in the documentation and implementation of the management/quality system, are familiar with the most current techniques and practices, and assures the quality of calibration and test results.

Training records, including initial, refresher training classes, replicate testing, proficiency testing programs are documented and maintained by the Quality Assurance Manager and reviewed by the Executive QA Committee. They are available for review upon request to the Quality Assurance Manager.

4.4 Proficiency Testing:

Proficiency testing is used as a process for checking the performance of the Force and Torque Calibration Laboratories. There shall be at least one proficiency testing activity per calendar year, every year.

Proficiency testing shall be achieved by participation in a proficiency program operated by an accredited proficiency testing provider or an intra-laboratory organized study. In the case of an intra-laboratory study it shall be carried out in accordance with the Force & Torque Calibration Laboratory - Procedure Manual.

The results and analysis of the proficiency testing shall be documented. Any outlying or unacceptable results shall be documented on a Complaint, Non-Conformance, &/or Corrective Action Form.

Proficiency testing results and subsequent analysis, including outlying or unacceptable results and corrective action responses, shall be submitted in accordance with the accrediting body's policies.

Proficiency testing records, including results and analysis, are documented and maintained by the Quality Assurance Manager and reviewed by the Executive QA Committee. They are available for review upon request to the Quality Assurance Manager.

5. PROCUREMENT DOCUMENT CONTROL

5.1 General:

No purchases shall be made from suppliers or subcontractors for services or supplies that affect the quality of tests or calibrations unless the supplier has been approved in accordance with Section 8, "Control of Purchased Services" of this manual. Services include the calibration or test of any measuring and test equipment used by Morehouse Instrument Company in the performance of calibrations and/or tests or customers' measuring and test equipment sent to Morehouse.

Customers' measuring devices and systems, except for weights, for which Morehouse is entrusted to supply calibrations or tests, are not to be sent to any supplier or subcontractor, except for the United States National Institute of Standards and Technology, without obtaining written permission from the customer. Because Morehouse does not perform any weight calibrations weights may be sent to any approved supplier without first obtaining written permission from the customer.

When calibrations or tests are performed on customers' measuring devices and systems by the United States National Institute of Standards and Technology or other approved supplier the documentation issued by the facility performing the calibration or test shall be passed directly to the customer without change or alteration.

Certificates or Reports issued by approved suppliers, other than National Metrology Institutes (NMI's such as United States National Institute of Standards and Technology (NIST) and National Physical Laboratory UK (NPL), shall include a statement or logo evidencing accreditation to ISO/IEC 17025 by A2LA, NVLAP or other accrediting body recognized through the International Laboratory Cooperation Mutual Recognition Arrangement.

Upon receipt, any measuring devices and systems belonging to a customer or M&TE used by Morehouse that were sent to an approved supplier for calibration and/or testing shall be inspected in accordance with Section 8.7 Receipt Inspections for Measuring Devices & Systems Calibrated &/or Tested by an Approved Supplier of this manual.

5.2 Content of Purchasing Documents:

Quality assurance criteria, applicable regulatory requirements, and special instructions must be passed to subcontractors for the calibration of measuring and test equipment used by Morehouse and for customer's measuring devices and systems. This includes, but is not limited to the following:

1. The service must be provided in accordance with their accredited ISO/IEC 17025 program and scope of accreditation.
2. A statement of the scope of work
3. Technical requirements by reference to specifications or procedures
4. Requirement for no subcontracting

5. Requirement evidence of accreditation and accreditation certificate number by an accrediting body recognized by the ILAC MRA that encompasses the latest revision of ISO/IEC-17025, "General Requirements for the Competence of Testing and Calibration Laboratories".

and

1. Requirement for right of access to plant facilities and records for source inspections/audits
2. Requirement a Calibration Certificate/Report shall be issued and include identification of the laboratory standards used
3. Provide "As Found" and "As Left" data where applicable
4. Statement requiring any non-conformances be reported to Morehouse Instrument Company within five working days of discovery for approval or other disposition
5. Any special instructions and requirements

Additionally, all purchase orders and change orders shall require the calibration provide for the most recent published editions of the following:

1. ANSI/NCSL Z540.1 – American National Standard for Calibration – Calibration Laboratories and Measuring and Test Equipment General Requirements
2. ANSI/NCSL Z540.3 - American National Standard for Calibration – Requirements for the Calibration of Measuring and Test Equipment

Purchase orders and change orders that are for, or to be used for nuclear safety related calibrations and issued to a supplier approved under Morehouse's commercial grade dedication program shall not impose the requirements of the most recent published editions of the following:

1. 10 CFR 50 APPENDIX B – Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
2. 10 CFR PART 21 - United States Nuclear Regulatory Commission – Reporting of Defects and Noncompliance

It is the responsibility of Morehouse to provide for these requirements under its commercial grade dedication program.

5.3 Review & Approval of Purchasing Documents:

Purchase orders and change orders issued to procure service, either for customer's measuring devices and systems or measuring and test equipment used by the Morehouse Force or Torque Calibration Laboratory, shall be reviewed for technical content and signed by the Quality Assurance Manager prior to release.

6. CALIBRATION, TEST, & VERIFICATION PROCEDURES & INSTRUCTIONS

6.1 General:

All calibrations, tests, and verifications, including those performed on new measuring devices or systems manufactured by Morehouse, shall be performed in accordance with approved procedures and instructions. These procedures and instructions are derived from, or in direct accordance with, technical manuals and publications such as ASTM E74, ASTM 2824, ISO 376, BS 7882 and other publications published by authorities such as the United States National Institute of Standards & Technology (NIST) and the National Physical Laboratory UK (NPL).

6.2 Inspection Prior to Calibration &/or Test:

Prior to calibration and/or test all measuring and test equipment to be calibrated by Morehouse shall be inspected by a Qualified Force Calibration Technician or Qualified Torque Calibration Technician to assure it is suitable for calibration and/or test. Force Calibration Technicians and Torque Calibration Technicians are responsible for reviewing all services to be performed to be sure the customer's requirements can be met and the proper resources, including appropriate accessories and adaptors, are available before commencing any service.

Upon inspection if it is determined the calibration and/or test cannot be performed because the item is unsuitable, it does not conform with the description provided by the customer, or the calibration and/or test cannot be performed in accordance with the customer's technical requirements the Laboratory Manager shall be notified, and the customer contacted. To show evidence the customer was notified the purchase order or other permanent record shall be marked with the name of the person contacted, the date contacted, what was discussed, and the name or initials of the person who contacted the customer. The calibration &/or test shall not be performed until all questions are answered and all problems and deficiencies are resolved.

6.3 Calibration Procedures & Instructions:

The procedures and instructions used by the Force and Torque Calibration Laboratory of Morehouse Instrument Company are documented in this Manual and the Force & Torque Calibration Laboratory - Procedure Manual. Both manuals are controlled in accordance with Section 7, "Document Control", of this Manual and are reviewed and approved by the Executive QA Committee as required in Section 4, "Management/Quality System Assessment, Personnel Training, & Proficiency Testing", of this Manual. The review and approval by the Executive QA Committee shall constitute confirmation, validation, fitness for use, and Morehouse Instrument Company's capability to perform any calibration, test, or verification procedure.

Calibration, test, and verification procedures used by Morehouse Instrument Company shall be documented in the Force & Torque Calibration Laboratory – Procedure Manual and include the following information:

1. Identification of procedure
2. Scope of calibration, test, or verification
3. Type of measuring device or system to be calibrated, tested, or verified using the procedure
4. Description of calibration, test, or verification procedure
5. Recording of calibration, test, or verification data including measured value or values
6. Customer's specified accuracy, including units of measure, where appropriate
7. Where the calibration, test, or verification procedure determines errors or other contributors used to calculate a standard and/or expanded uncertainty these values should be included on the Certificate of Calibration and/or Test Report along with the method used to determine the values
8. Disposition of non-conforming measuring devices or systems
9. Measuring & test equipment used to perform the calibration, test, or verification procedures with a description of any limitations of use.

Unless specified otherwise by a customer all calibrations, tests, and verifications are to be performed in accordance with the procedures and instructions in the current revisions of this Manual and the Force & Torque Calibration Laboratory - Procedure Manual.

Where it is necessary to employ methods that are not established, these shall be subject to agreement with the customer, be fully validated and documented in the Force & Torque – Calibration Procedure Manual, validated, and be available to the customer and other recipients of the relevant reports. To show evidence of the customer agreement the purchase order or other permanent record shall be marked with the name of the person contacted, the date contacted, what was discussed, and the name or initials of the person who contacted the customer. The calibration &/or test shall not be performed until all questions are answered and all problems and deficiencies are resolved.

6.4 Laboratory Developed Methods:

Calibration, test, and verification procedures developed for use in-house can be developed by anyone. Before they are authorized for use they must be documented in the Force & Torque Calibration Laboratory – Procedure Manual and reviewed and approved by the Executive QA Committee. The review and approval by the Executive QA Committee shall constitute confirmation, validation, fitness for intended use, and Morehouse Instrument Company's capability to perform these procedures.

7. DOCUMENT CONTROL

7.1 General:

The Quality Assurance Manager is responsible for maintaining a Master Document List of all documents and publications, including the Corporate Quality Assurance Program Manual and Force & Torque Calibration Laboratory - Procedure Manual, that form part of the management/quality system, whether internally generated or from external sources and ensure they are available for use by Force Calibration Laboratory and Torque Calibration Laboratory personnel as needed.

7.2 Master Document List for Control of Documents and Publications used by the Force & Torque Calibration Laboratory:

A Master Document List shall be maintained by the Quality Assurance Manager. The list shall include current editions of the documents and publications that form part of the management/quality system, whether internally generated or from external sources. This list may be in print and/or digital format.

All documents and publications included on the Master Document List will be maintained by the Quality Assurance Manager. Documents and publications may be in print and/or digital format.

During the internal audit it shall be verified the Master Document List is up to date and includes the most recent editions of all documents and publications listed. When it is found any of the documents and publications on the Master Document List are not the most current edition the current edition shall be procured and the Master Document List revised and updated as needed.

Print versions of the Master Document List and print versions of documents and publications included on the list are available upon request to the Quality Assurance Manager.

Where digital versions of the Master Document List and digital versions of documents and publications included on the list may also be available on the Company's computer network.

7.3 Procedures for Distribution, Control, and Maintenance of the Corporate Quality Assurance Program Manual and Force & Torque Calibration Laboratory - Procedure Manual:

The Corporate Quality Assurance Program Manual and Force & Torque Calibration Laboratory - Procedure Manual are internally generated documents. The Quality Assurance Manager is responsible for the preparation, distribution, and control of amendments and revisions to these manuals. Manuals may be maintained and distributed in print and/or digital form.

To uniquely and clearly identify these manuals all pages of both manuals shall include the following in their heading:

1. Title of manual

2. Page number and total number of pages
3. Date of issue
4. Current revision level

Controlled copies of the Corporate Quality Assurance Program Manual shall be made available to all customers who have requested them. Copies not controlled may be provided to customers or prospective customers as needed. All requests for controlled or uncontrolled copies should be made to the Quality Assurance Manager.

The Force & Torque Calibration Laboratory - Procedure Manual is a controlled document and contains proprietary information. It is for internal use by Morehouse Instrument Company. Controlled copies of this Manual will not be distributed outside the Company. Uncontrolled copies of this manual or parts of it may be sent out upon request at the discretion of the Quality Assurance Manager.

A log of controlled copies of the Corporate Quality Assurance Program Manual and Force & Torque Calibration Laboratory - Procedure Manual will be maintained by the Quality Assurance Manager so updating can be controlled. No distribution record is maintained for the uncontrolled manuals and no updating of uncontrolled manuals is provided.

Amendments and revisions for both the Corporate Quality Assurance Program Manual and Force & Torque Calibration Laboratory - Procedure Manual will be incorporated by replacing the entire manual. The number of any sections changed will be noted on the revision sheet of the appropriate manual and the date and revision number of the complete manual will be updated and changed. After any amendments or revisions are made complete manuals shall be distributed to all holders of controlled copies.

Where practicable, the altered or new text shall be identified in the Corporate Quality Assurance Program Manual and Force & Torque Calibration Laboratory - Procedure Manual being revised. This marked up copy shall be maintained by the Quality Assurance Manager.

7.4 Obsolete Documents and Publications:

Print versions of obsolete documents and/or publications included on the Master Document List kept for either legal or knowledge preservation purposes shall be maintained by the Quality Assurance Manager. To prevent accidental use of obsolete print versions of documents and publications maintained on file by the Quality Assurance Manager shall be marked with the word “OBSOLETE” on their cover page.

Digital versions of obsolete documents and/or publications included on the Master Document List kept for either legal or knowledge preservation purposes shall be deleted from the Company’s computer network or moved to a file clearly identified the file contains obsolete documents.

8. CONTROL OF PURCHASED SERVICES

8.1 General:

No suppliers or subcontractors shall be used to calibrate any measuring and test equipment used by Morehouse Instrument Company or customers' measuring devices and systems sent to Morehouse unless the supplier is included on the Approved Supplier List.

Customers' measuring devices and systems for which Morehouse is entrusted to supply calibrations, will not be sent to any supplier or subcontractor, except for the United States National Institute of Standards and Technology, without obtaining written authorization from the customer.

8.2 Approved Supplier List (ASL):

A list of suppliers approved to supply calibration services and other services necessary to manage and perform laboratory activities (i.e. determination of material density, proficiency testing providers and laboratory accreditation services) shall be maintained. The list shall include the name of the supplier, what they are approved for, and any restrictions or limitations. The Approved Supplier List is available for review upon request to the Quality Assurance Manager.

8.3 Requirements for Proficiency Testing Providers to be Placed on ASL:

To be placed on the Approved Supplier List proficiency testing providers shall be accredited to ISO/IEC 17043 by an accrediting body having an ILAC signatory.

8.4 Requirements for ISO/IEC 17025 Accreditation Services to be Placed on ASL:

To be placed on the Approved Supplier List ISO/IEC 17025 accreditation services shall be an ILAC signatory.

8.5 Requirements for Calibration & Material Density Suppliers to be Placed on ASL:

To insure an unbroken chain of measurement traceability exists and the laboratories have the competence and measurement capability to be included on the Approved Supplier List the supplier of calibration services and material density determinations must be a National Metrology Institute (NMI) such as the United States National Institute of Standards and Technology (NIST) or National Physical Laboratory, Teddington, England (NPL) or approved under Morehouse's commercial grade dedication plan. Where traceability is through an NMI other than NIST a mutual recognition agreement, such as the Comité International des Poids et Mesures (CIPM) Mutual Recognition Arrangement (MRA), must be in effect with the National Institute of Standards and Technology.

8.6 Commercial Grade Dedication Plan for Suppliers:

ISO/IEC 17025 accredited laboratories may be placed on the Approved Supplier List based on a commercial grade dedication of the service to be performed. Approved suppliers must be accreditation to ISO/IEC 17025 by an ILAC MRA signatory in accordance with the latest revision of NEI 14-05A, Guidelines for the use of Accreditation in lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services.

Performing a commercial grade dedication for suppliers requires the following:

1. Identify the service to be provided and perform a technical evaluation to identify and document the service.
   a. The type service required by Morehouse is calibration or material density determination. The technical evaluation shall consist of reviewing the scope of accreditation of the supplier being considered as an approved supplier to ascertain they can provide the service required.
   b. This review shall be documented on the receipt inspection report.
2. Identify and document the credible failure modes for the service. There are no credible failure modes.
3. Identify and document safety functions of the service.
   a. The safety functions are the supplier's ability to provide the service required (i.e. temperature, electrical, force, mass, etc.) The supplier's ISO/IEC 17025 scope of accreditation includes the safety functions of the service to be provided. The safety functions are the same as the critical characteristics and include the following:
      i. Method or procedure, where appropriate
      ii. Range
      iii. Accuracy
4. Identify and document the critical characteristics of the service.
   a. The supplier's ISO/IEC 17025 scope of accreditation includes the critical characteristics of the service to be provided. The critical characteristics are the same as the safety functions.
   b. A current scope of accreditation of an approved supplier shall be checked to ascertain the service performed, including method, range, and accuracy, is within their accredited scope. This review shall be documented on the receipt inspection report.
5. Select acceptance method.
   a. The method used to accept a supplier and place them on the ASL is to use their accreditation to ISO/IEC 17025 by an ILAC MRA signatory in accordance with the latest revision of NEI 14-05A, Guidelines for the use of Accreditation in lieu of Commercial Grade Dedication Surveys for Procurement of Laboratory Calibration and Test Services.
   b. It shall be verified and documented on the receipt inspection report for each piece of equipment received from an approved supplier this requirement in is met.

The "Certificates of Accreditation" and "Scopes of Accreditation" shall be viewed and/or downloaded directly from the accreditation body's web site. Downloaded copies shall be maintained by the Quality Assurance Manager and are available for review upon request to the same.

8.7 Receipt Inspections for Measuring Devices & Systems Calibrated &/or Tested by an Approved Calibration Supplier:

There shall be a documented receipt inspection for all measuring devices and systems, both customer's and Morehouse's, sent to a supplier for calibration that includes the following:

1. Verify the calibration and/or test was performed by a National Metrology Institute (NMI) or an approved supplier.
2. Where the calibration and/or test was performed by an approved supplier verify the supplier is accredited to the latest revision of ISO/IEC 17025 by an ILAC MRA Signatory accreditation body.
3. When using an ISO/IEC 17025 accredited supplier verify the published scope of accreditation for the supplier covers the needed calibration service, method of calibration (where appropriate), ranges, and accuracy.
4. When using an ISO/IEC 17025 accredited supplier verify the Certificate of Calibration and/or Test Report issued by the supplier certifies the contracted calibration and/or test has been performed in accordance with their ISO/IEC 17025 program and the calibration performed is within their scope of accreditation,
5. The purchase order's requirements are met.
6. That any software used with the measuring and test equipment has been updated

The receipt inspection shall also include reviewing the Certificate of Calibration and/or Test Report issued by the approved supplier for the following:

1. The accuracy and/or uncertainty is as required
2. The calibration and/or test was performed in accordance with the prescribed method
3. Customer specified requirements and instructions are met
4. Traceability to SI through a National Metrology Institute (NMI) such as the United States National Institute of Standards & Technology (NIST)

Any damages or discrepancies shall be immediately brought to the attention of the Quality Assurance Manager. The Quality Assurance Manager is responsible for preparing a written report documenting the discrepancy and for determining what corrective action, if any, is required. The report may be issued as a Non-Conformance and/or Corrective Action Form or any other format deemed appropriate by the Quality Assurance Manager.

Where it is determined there is damage that has an adverse impact on the proper functioning of the measuring and test equipment it shall be repaired and recalibrated and/or tested prior to being put into service in the Force Calibration Laboratory.

The Inspection and Review Report shall be stored with the Certificate of Calibration and/or Test Report of the measuring and test equipment that was inspected and is available for review from the Quality Assurance Manager.

9. CONTRACT REVIEW & IDENTIFICATION OF CUSTOMER'S MEASURING DEVICES & SYSTEMS

9.1 General:

There shall be a documented review of all contracts for measuring devices and systems to be calibrated and/or tested by Morehouse Instrument Company. This contract review shall be performed before order entry and applies to measuring devices and systems sent to Morehouse as well as new measuring devices or systems supplied or manufactured by Morehouse.

9.2 Contract Review & Identification of Measuring Devices and Systems:

It is not practical to have a formal review of requests and tenders for calibration and/or testing services due to the financial impact this would have. Therefore, Morehouse Instrument Company will only require formal contract review for contracts when measuring devices or systems are received for calibration and/or testing or when Morehouse receives an order to manufacture or supply measuring devices or systems.

The person responding to a request or tender shall determine at the time of their response if we can meet the customer's requirement. If they are not sure if we can meet the customer's requirements, they shall seek advice and guidance from others.

A contract may be any written or oral agreement to provide a customer with calibration and/or testing services.

A documented contract review shall be performed for measuring devices or systems received for calibration and/or testing and for contracts for the manufacture or supply of measuring devices or systems. Personnel performing contract reviews shall be familiar with this manual and the Force & Torque Calibration Procedure. Any personnel contributing to the achievement of the management/quality system, including those that perform contract review, system shall attend appropriate training classes. On items affecting quality they shall act without regard to cost, schedule, other duties, and responsibilities within the organization.

If it is determined a calibration or test cannot be performed because the item is unsuitable, it does not conform with the description provided by the customer, or the calibration or test cannot be performed in accordance with the customer's technical requirements, such as inappropriate or out of date methods being requested, the customer shall be contacted. To show evidence the customer was notified the purchase order, digital record, or other permanent record shall be marked with the name of the person contacted, the date contacted, what was discussed, and the name or initials of the person who contacted the customer.

Upon completion of the contract review, including reconciliation of any problems or deficiencies a calibration order will be issued by the office. The order may be in any form. It may be issued as an Inspection, Repair, & Calibration Order; Repair & Calibration Order; a copy of the customer's order or

contract, or simply a handwritten note from the office. Orders can be issued both manually and/or electronically. All orders issued by the office that include calibration and/or test shall clearly identify the measuring device or system to be calibrated and/or tested, either by serial number or other appropriate means, and contain any special instructions, such as the requirement for "As Received" required by the contract.

If a customer revises or changes any of their instructions or requirements the changes affecting orders already issued these changes shall be communicated. It is the responsibility of the person receiving the notification of change or revision to notify the affected department and if the customer has not provided a written record to make a permanent record of any pertinent discussions with the customer relating to their requirements. The communication to the affected department shall be accomplished by providing a copy of the customer's revised purchase order or other written instruction and attaching it to the existing calibration order, by making notes of any changes on the existing order and forwarding a copy of such to the affected department. In the case where the customer has not provided the instruction in writing the record of any discussion with the customer shall be made by noting on the purchase order or other permanent record the date, what was discussed, the name of the customer's personnel with whom the discussion took place, and the identity of the Morehouse personnel with whom the discussion took place.

Digital orders shall be available on the Company's computer network as needed throughout the process. Written orders will travel with the measuring and test equipment as it moves through the process.

Prior to calibration and/or test all measuring and test equipment to be calibrated by Morehouse shall be inspected by a Qualified Force Calibration Technician or Qualified Torque Calibration Technician to assure it is suitable for calibration and/or test. Force Calibration Technicians and Torque Calibration Technicians are responsible for reviewing all services to be performed to be sure the customer's requirements can be met and the proper resources, including appropriate accessories and adaptors, are available before commencing any service.

Upon inspection if it is determined the calibration and/or test cannot be performed because the item is unsuitable, it does not conform with the description provided by the customer, or the calibration and/or test cannot be performed in accordance with the customer's technical requirements the Laboratory Manager shall be notified, and the customer contacted. To show evidence the customer was notified the purchase order or other permanent record shall be marked with the name of the person contacted, the date contacted, what was discussed, and the name or initials of the person who contacted the customer. The calibration &/or test shall not be performed until all questions are answered and all problems and deficiencies are resolved.

After all processes have been completed and the measuring device or system is ready for shipping written and/or digital documents shall be forwarded to the office. These documents will be kept on file as required by Section 14, "Quality Assurance Records, Record Retention, & Limitation to Record Access to Protect Customer's Rights to Confidentiality & Proprietary Rights", of this Manual.

Prior to shipping there shall be a review of the customer's requirements, including any revisions or changes, to insure all requirements are met. If any of the customer's requirements have not been or cannot be met the customer shall be contacted. To show evidence the customer was notified the purchase order

or other permanent record shall be marked with the name of the person contacted, the date contacted, what was discussed, and the name or initials of the person who contacted the customer. If all requirements are met the individual performing the review shall initial and date the purchase order or other permanent record.

10. RECEIVING, HANDLING, STORAGE, & SHIPPING OF CUSTOMER'S MEASURING DEVICES & SYSTEMS

10.1 General:

Morehouse Instrument Company has established the following controls to insure all measuring devices and systems received for calibration, testing, and/or repair are handled in a way to maintain proper control and protect them from damage that may have an adverse effect on their capability.

10.2 Receiving & Handling:

This section applies to unpacking and checking contents against packing lists.

The person who unpacks any measuring device or system received will check the contents against the packing list and note any discrepancies on the packing list or other receiving document. If no packing list or other document was included with the shipment, the person unpacking the measuring device or system will complete a receiving report noting as much detail as necessary to properly identify the measuring device or system. Additionally, the person performing the unpacking will note on the packing list or other receiving document the date unpacked, his initials, and if known the method of transportation.

If there is obvious damage noticed by the person unpacking the measuring device or system or if inspection by a qualified person in either laboratory indicates any damage was suffered in transit the packing slip, or other receiving document(s), shall be noted accordingly and taken immediately to the office and the customer contacted. To show evidence the customer was notified the purchase order or other permanent record shall be marked with the name of the person contacted, the date contacted, what was discussed, and the name or initials of the person who contacted the customer. The receiving container will should be kept with the measuring device or system for possible inspection by the transportation company personnel.

If the measuring device or system is otherwise satisfactory on receipt they will be taken to the appropriate Calibration Laboratory or staging area outside the Laboratory. The shipping container will be marked with the serial number, or other identification, so that if it is reusable it can be used to return the measuring device or system to the owner. When a device or system has been stored in a non-temperature controlled area it shall be moved to a temperature controlled area for a minimum of 24 hours before it is calibrated.

10.3 Storage:

Measuring devices or systems not requiring repair will be stored in the appropriate Force or Torque Calibration Laboratory or staging area outside the Laboratory while in the possession of Morehouse until they are ready to ship.

Measuring devices or systems requiring repair that cannot be accomplished in the Calibration Laboratory may be moved to the shop area of sent to a third party for repair. After repair the measuring device or system shall be returned to the appropriate Calibration laboratory.

Measuring devices or systems which cannot be repaired will be removed from the Force or Torque Calibration Laboratory and prepared for return to the customer.

10.4 Shipping:

When a measuring device or system is ready for shipment the office will provide the necessary documents.

When the measuring device or system is ready to be packed the person doing the packing should check the serial number or other identification against the packing list and other documents provided and take all items listed on the packing slip to the shipping area.

If the container in which the measuring device or system was received is in usable condition for the return shipment the packer will retrieve it from the storage area.

If the container is not reusable, the packer will provide a container from Morehouse stock being certain that a minimum of "proper cushioning material" is provided on all sides.

The proper level of packing and cushioning should preclude the measuring device or system from suffering any adverse effects on its capability during handling and transportation. The level of packing and cushioning is left to the discretion of the individual performing the packing.

When measuring devices or systems for shipping are packed, the person doing the packing will notify the office so the shipping label can be prepared and placed on the shipment.

11. CERTIFICATES OF CALIBRATION, TEST REPORTS, CALIBRATION LABELS, & TAMPER RESISTANT SEALS FOR CUSTOMER'S MEASURING & TEST EQUIPMENT

11.1 General:

Morehouse Instrument Company will issue a Certificate of Calibration or Test Report for all measuring devices or systems calibrated and/or tested. Certificates of Calibration or Test Reports shall not contain any opinions or interpretations. The Certificate or Test Report will contain information required by the customer in addition to the following:

1. Title i.e. Certificate of Calibration or Test Report
2. Description and/or unique identification, such as by serial number, of measuring device or system calibrated
3. Identification of the method or procedure used to perform the calibration and/or test, including deviations from, additions to, or exclusions from the method or procedure
4. Condition of the instrument calibrated and/or tested, where appropriate, and inclusion of "As Received" and "As Returned" data
5. Name and address of the customer, where appropriate
6. Statement that Certificate of Calibration is issued in accordance with Morehouse QAM (specify revision), ISO/IEC 17025 (specify revision), and/or ANSI/NCSL Z540 (specify revision), where appropriate.
7. Customer's specified tolerance (accuracy or error) including units of measure with a statement of compliance (conformance to a specification) relating to the metrological aspects of specifications, where appropriate
8. Where the calibration and/or test method determines errors or other contributors used to calculate a standard and/or expanded uncertainty of a measuring device or system these values should be included on the Certificate of Calibration and/or Test Report along with the method used for their determination
9. Values for the measuring device or system's resolution expressed in units of measure, where appropriate
10. Where a measuring device or system's output is expressed in mV/V and a separate power supply is used to supply the excitation voltage the nominal excitation voltage used during the performance of the calibration and/or test shall be listed of the certificate and/or test report.
11. Expanded uncertainty which is the aggregate uncertainty of the Morehouse measurement process and the resolution of the unit under test. It is stated with a coverage factor such that the coverage probability corresponds to approximately 95%.
12. Environmental considerations
13. Traceability statement like, "Traceable to SI through a National Metrology Institute (NMI) such as the United States National Institute of Standards & Technology"
14. Identification of measuring and test equipment used to perform the calibration and/or test (including, where appropriate, any multimeter maintained by the Force or Torque Calibration Laboratory), and their serial number.
15. Statement of CMC (Calibration and Measurement Capability) for measuring and test equipment used to perform the calibration and/or test

16. Signature, manual or digital. and name of Qualified Technician person who performed calibration and/or test or is accepting responsibility for the content of the certificate or report
17. Date calibration and/or test performed
18. Unique report number assigned in accordance with instructions in Force Calibration Laboratory - Procedure Manual
19. Page number and total number of pages when Certificate or Test Report exceeds one page.
20. Name & address where calibration and/or test was performed as follows:

    Morehouse Instrument Company, Inc.
    Force Calibration Laboratory/Torque Calibration Laboratory
    1742 Sixth Avenue
    York, Pennsylvania 17403
21. A statement to the effect the Certificate or Test Report shall not be reproduced except in full, without written approval from Morehouse Instrument Company
22. Statement to the effect the measurement results only apply to the measuring device or system identified on this document.

The Certificate of Calibration or Test Report is designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse. The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.

Further explanation for the above items that are not self-explanatory follows in Section 11.2 through 11.11.

11.2 Identification of the Method or Procedure used to Perform Calibration and/or Test:

The test method or calibration procedure used should be stated on the Certificate of Calibration and/or Test Report. The test method or calibration procedure can reference a national or international standard, such as ASTM E74, ISO 376, ASTM E2428, or BS 7882, or can simply be a statement the calibration and/or test was performed in accordance with the latest revision of the Morehouse Corporate Quality Assurance Program Manual. When the Morehouse Corporate Quality Assurance Program is referenced the revision number and date of the revision in effect at the time the measuring device or system was calibrated shall be referenced. Other methods and procedures such as, ANSI/NCSL Z540, ISO/IEC 17025, 10 CFR 50 APPENDIX B, and 10 CFR PART 21 can also be referenced.

11.3 Condition of Measuring Device or System Calibrated and/or Tested and Inclusion of As Received and As Returned Data when the Measuring device or system Requires Repair and/or Adjustment:

Measuring devices or systems received for calibration and/or test shall be inspected in accordance with Section 6.2 of this manual.

Unless the customer has advised the measuring device or system does not require "As Received" data, or similar words to that effect, measuring devices or systems shall be treated as requiring "As Received" and shall be provided with "As Received" and "As Returned" data where appropriate.

Following are various scenarios under which calibrations and/or tests can be performed with explanations of how and when to include "As Received" and/or "As Returned" data.

11.3.1 Where the Customer has not Specified an Accuracy or Error Tolerance:

11.3.1.1 "As Received" not Required:

11.3.1.1.1 Where no repairs or adjustments were the report shall include a statement "no repairs or adjustments were made" or similar wording.

11.3.1.1.2 Where repairs and/or adjustments were made the report shall include a statement "repairs and or adjustments were made" or similar wording.

11.3.1.2 "As Received" Required:

11.3.1.2.1 Where only as received data is on the report the report shall include statements "no repairs or adjustments were made" and "As Received/As Returned" or similar wording.

11.3.1.2.2 Where both as received and as returned data are on the same report the report shall include statements "repairs and/or adjustments were made" and "As Received and As Returned" or similar wording.

11.3.1.2.3 Where the as received and as returned data are on separate reports each report shall include statements "repairs and/or adjustments were made" and "As Received" or "As Returned" or similar wording on the appropriate report.

11.3.1.2.4 On inspection of the measuring device or system if it is determined it is inoperable or unsafe to calibrate before repairs and/or adjustments the report shall include statements "repairs and/or adjustments were made before the measuring device or system was calibrated" and "As Returned".

11.3.2 Where the Customer Specified an Accuracy or Error Tolerance:

11.3.2.1. "As Received" not Required:

11.3.2.1.1 Where no repairs or adjustments were made and the measuring device or system is within the specified requirement the report shall include statements "no repairs or adjustments were made" and "This measuring device or system is within the specified tolerance of (insert value with units of measure)", or similar wording.

11.3.2.1.2 Where no repairs or adjustments were made and the measuring device or system is not within the specified requirement the report shall include statements "no repairs or adjustments were made" and "This measuring device or system is not within the specified tolerance of (insert value and units of measure)", or similar wording

11.3.2.1.3 Where repairs and/or adjustments are made and the measuring device or system is within the specified requirement the report shall include statements “repairs or adjustments were made” and “This measuring device or system is within the specified tolerance of (insert value and units of measure)”, or similar wording.

11.3.2.1.4 Where repairs and/or adjustments are made and the measuring device or system is not within the specified requirement the report shall include statements “repairs or adjustments were made” and “This measuring device or system could not be repaired and/or adjusted to meet the specified tolerance (insert value and units of measure)”, or similar wording.

11.3.2.2 “As Received” Required:

11.3.2.2.1 Where only as received data is included on the report and the data is within the specified requirement the report shall include statements “no repairs or adjustments were made”, “The measuring device or system is within the required tolerance of (insert value and units of measure)” and “As Received/As Returned” or similar wording.

11.3.2.2.2 Where only as received data is included on the report and the data is not within the specified requirement the report shall include statements “no repairs or adjustments were made”, “The measuring device or system does not meet the required tolerance of (insert value and units of measure)” and “As Received/As Returned” or similar wording.

11.3.2.2.3 Where both as received and as returned data are on the same report, both are within the required tolerance, and repairs and/or adjustments were made to improve the calibration and/or test results the report shall include statements “repairs and/or adjustments were made”, “Both the as received and as returned data are within the specified tolerance of (insert value and units of measure)”, and “As Received and As Returned” or similar wording.

11.3.2.2.4 Where both as received and as returned data are on the same report, the as received data is not within the required tolerance, and the as returned data is within the required tolerance the report shall include statements “repairs and/or adjustments were made”, “The as returned data is within the specified tolerance of (insert value and units of measure)”, and “As Received and As Returned” or similar wording.

11.3.2.2.5 Where both as received and as returned data are on the same report and nether are within the required tolerance the report shall include statements “repairs and/or adjustments were made”, “This measuring device or system could not be repaired and/or adjusted to meet the specified tolerance of (insert value and units of measure)”, and “As Received and As Returned” or similar wording.

11.3.2.2.6 Where the as received and as returned data are on separate reports, both are within the required tolerance, and repairs and/or adjustments were made to improve

calibration and/or test results the reports shall include statements "repairs and/or adjustments were made", "Both the as received and as returned data are within the specified tolerance of (insert value and units of measure)", and "As Received and As Returned" or similar wording.

11.3.2.2.7 Where the as received and as returned data are on separate reports, the as received is not within the required tolerance and the as returned data is within the required tolerance the reports shall include statements "repairs and/or adjustments were made", "The as returned data is within the specified tolerance of (insert value and units of measure)", and "As Received" or "As Returned" or similar wording on the appropriate report.

11.3.2.2.8 When as received and as returned data are on separate reports and both are not within the required tolerance the reports shall include statements "repairs and/or adjustments were made", "This measuring device or system could not be repaired and/or adjusted to meet the specified tolerance of (insert value and units of measure)", "and "As Received" or "As Returned" or similar wording on the appropriate report.

11.3.2.2.9 On inspection of the measuring device or system it is determined the measuring device or system may not meet the required tolerance before repairs and/or adjustments the customer shall be contacted and so advised. The customer shall advise if a full calibration or test shall be attempted, a partial calibration or special test shall be performed, or no as received data is required. Where the customer requests a partial calibration or special test using non-standard methods that are not included in this Manual or the Force & Torque Calibration Laboratory - Procedure Manual they shall provide complete details of the method to be used.

11.4 Name & Address of Customer:

When the name and address of the customer is included on the Certificate of Calibration and/or Test Reports the name listed will be as shown on the customer's order and the address will be the shipping address, unless specified otherwise by the customer. Where the calibration is for a third party the customer may specify the name and address to be listed. Where the customer has specified only the name to be included no address will be listed.1

11.5 Statement that Certificate of Calibration is issued in accordance with Morehouse QAM, ISO/IEC 17025, and/or ANSI/NCSL Z540:

Certificates of Calibration and/or Test Reports for measurement devises or systems shall include a statement indicating the standards and specifications, including revision level, to which they are issued. These standards and specifications include Morehouse Quality Assurance Program Manual (Morehouse QAM) ISO/IEC 17025, and ANSI/NCSLI Z540.

11.6 Customer Specified Tolerance, (Accuracy or Error) Including Units of Measure:

Accuracy is the qualitative term for the extent of the approximation of the measurement result to a "true value". Measurement error is the difference between a measurement and the quantity being measured.

Where the customer has specified a tolerance, either by reference to a manufacturer's specification or by advising a tolerance directly to Morehouse, this value, including the units of measure, shall be included on the Certificate of Calibration and/or Test Report.

Where statements as to whether the measuring devices or system is within the customer's specified tolerance or statements relating to the metrological aspects of specifications are included on the Certificate of Calibration and/or Test Report the laboratory shall ensure the specification is a national or international standard or one that has been agreed to or defined by the customer. In these cases, a TUR and PFA shall be calculated and reported in accordance with the Force & Torque – Calibration Laboratory Procedure Manual

See 11.3.2 for examples of statements. The measurement error shall be determined as the difference between the measurement and the measured value. It shall not take into account the CMC of the measuring and test equipment used to perform the calibration.

Measuring devices or systems; such as load cells connected to indicators programmed for direct reading, crane scales, and direct reading force gauges; are generally calibrated to show evidence they are operating within an accuracy or error band specified by the customer. When the calibration and/or tests are to verify an accuracy or error band specified by the customer the accuracy shall be listed on the Certificate or Test Report. The following or similar wording should appear on the report, "Customer Specified Accuracy = +/- 0.5 % of Full Scale."

Certificates of Calibration and/or Test Reports issued for measuring devices and systems calibrated by Morehouse may include an accuracy specification, where appropriate.

11.7 Expanded Uncertainty for the Measuring Device or System being Calibrated and/or Tested:

Where an expanded uncertainty for the measuring device or system under test is required it shall be determined in accordance with the latest revision of ILAC P-14, ILAC Policy for Uncertainty in Calibration.

The numeric value for the expanded uncertainty of the measuring device and/or system expressed to not more than two significant figures along with the following statement, or one with similar wording and meaning, shall be included on the certificate and/or test report:

"The reported expanded uncertainty of measurement for (identify by serial number) is stated as the standard uncertainty of measurement multiplied by the coverage factor k = (insert number here) such that the coverage factor probability corresponds to approximately 95 %."

11.8 Environmental Considerations:

Temperature is the only environmental condition that requires monitoring. Temperature shall be monitored and reported in accordance with the Force & Torque Calibration Laboratory - Procedure Manual.

11.9 Statement of CMC for M&TE Used to Perform the Calibration and/or Test:

The CMC for the measuring and test equipment used to calibrate and/or test a device along with the units of measure and the value of "k" associated with the uncertainty shall be included on the certificate and/or report issued for that measuring device or system.

11.10 Signature of Qualified Technician Taking Responsibility for the Certificate or Report:

The Qualified Technician signing or reviewing the Certificate or report shall insure compliance with A2LA and ISO/IEC: 17025, including the following, before it is issued to the customer:

1. Review of items required by the contract
2. Inclusion of before and after data, where applicable
3. The measurement uncertainty is not smaller than the CMC claim on Morehouse's Scope of Accreditation
4. A label in accordance with 11.12 is provided

11.11 Assignment of Interval or Due Date for Customer's Measuring Device or System:

It should not be the responsibility of the laboratory performing the calibration and/or test to determine and assign a due date or interval for a customer's measuring and test equipment. A due date or interval will not be listed on a Certificate, Test Report, or calibration label unless requested by the customer. The customer must advise what interval is desired or in the case where a measuring device or system is calibrated in accordance with ASTM E74 or ISO 376 they may request the due date be assigned in accordance with this specification or other legal published specification. When the customer specifies the due date, it shall be listed on the Certificate and/or Test Report and the label.

11.12 Label:

A label will be supplied for each measuring device or system calibrated by Morehouse Instrument Company. The label will include the following:

1. Address where service performed:
   Morehouse Instrument Company, Inc.
   Force Calibration Laboratory/Torque Calibration Laboratory

1742 Sixth Avenue
York, PA 17403

2. Description and/or unique identification, such as by serial number of the measuring device or system
3. Suggested due date – when specified by the customer
4. Identity of person who performed calibration and/or test or is accepting responsibility
5. Date calibration and/or test performed

The label shall not be attached to any element that is subject to deflection. It is preferable to attach the label to the measuring device or system case or an area that will not affect the deflection or reading of the measuring device or system. If there is no suitable place to attach a label it should be sent with the measuring device or system.

11.13 Amendments to Certificates and Test Reports:

When it is necessary to make a correction to data reported to a customer on a Certificate of Calibration and/or Test Report the correction shall be made by replacing the entire Certificate and/or Test Report. The amended Certificate and/or Test Report shall be labeled "Amendment", include an amendment number, the date of amendment, a description of the amendment, and a reference to document it replaces.

11.14 Electronic Transmission of Calibration and Test Reports:

Certificates of Calibration and/or Test Reports shall not be sent by fax or other electronic means unless requested by the customer. When the customer requests information be sent by fax or other electronic means it shall be sent in accordance with the customers instructions. Once the data has been sent it is the customer's responsibility to safeguard the information.

Customers can access their Certificates of Calibration and/or Test Reports through our web site. To safeguard acquisition of data over the internet the customer is issued a QR code which gives them access to their data only.

11.15 Fitness for Use:

It is the responsibility of the user to determine fitness for use of the measuring device or system based on the calibration and/or test report data supplied for that measuring device or system by Morehouse Instrument Company.

11.16 Tamper-Resistant Seals:

If a customer desires Morehouse to affix tamper-resistant seals to any measuring and test equipment sent to Morehouse, the request must be made in writing. The customer must supply the seal along with

instructions as to where and how the seal is to be affixed. It is the responsibility of the customer to develop and enforce the use of tamper-resistant seals and the disposition of items whose seals are broken for their own equipment.

11.17 Non-Accredited Data:

Data which is not within Morehouse's Scope of Accreditation shall not be included on any report with the term A2LA and/or A2LA logo.

12. CONTROL OF MEASURING & TEST EQUIPMENT & SOFTWARE USED BY MOREHOUSE TO VERIFY, CALIBRATE, &/OR TEST

12.1 General:

All measuring and test equipment, including equipment for subsidiary measurements (e.g. for environmental conditions), and computer software used in the performance of calibration and/or testing services by Morehouse Instrument Company shall be properly calibrated and/or verified, controlled, and uniquely identified. In no case shall any measuring and test equipment or software be used unless the validity of its status has been established. Software is defined as any instructions that are processed by a computer or other automated equipment to capture, process, manipulate, record, report, store, or retrieve data.

Morehouse Instrument Company's Force and Torque Calibration Laboratories are provided with all measuring and test equipment and software required. A list of the measuring and test equipment used by the Force and Torque Calibration Laboratory is maintained in the Force & Torque Calibration Laboratory - Procedure Manual. This list shall identify the measuring & test equipment by the following:

1. Nomenclature
2. Capacity (where appropriate)
3. Serial number
4. By whom it is to be calibrated or requirements for calibration supplier
5. Assigned interval (where appropriate)
6. Maximum tolerance (where appropriate).

Instructions for the use and maintenance of measuring and test equipment, including manuals provided by the manufacturer, shall be kept in a digital file and/or the appropriate Force or Torque Calibration Laboratory so they are available for use by laboratory personnel.

All measuring and test equipment and other equipment used by Morehouse Instrument Company shall be used for calibration and related services only. They shall be calibrated and maintained in accordance with the manufacturer's instructions and/or the procedures set forth in this Manual and the Force & Torque Calibration Laboratory - Procedure Manual.

Computers and automated equipment shall be maintained to ensure proper functioning and provided with an environmental and operating conditions necessary to maintain the integrity of test and calibration data.

12.2 Measuring & Test Equipment/Calibrated Standards:

All measuring and test equipment, including equipment for subsidiary measurements (e.g. for environmental conditions), subject to calibration and/or verification used in the performance of calibrations and/or tests shall be calibrated traceable to SI through a National Metrology Institute (NMI) such as the United States National Institute of Standards & Technology (NIST). Where traceability is through an NMI other than NIST a mutual recognition agreement, such as the Comité International des Poids et Mesures

(CIPM) Mutual Recognition Arrangement (MRA), must be in effect with the National Institute of Standards and Technology. Where measuring and test equipment is to be calibrated by other than in house by Morehouse Instrument Company the supplier performing the service must be on the "Approved Supplier List".

A schedule listing all measuring and test equipment subject to calibration and /or verification used in the performance of calibrations shall be maintained. The schedule may be in print and/or digital format. The schedule shall include, as a minimum, the following:

1. Nomenclature
2. Capacity, where appropriate
3. Serial number
4. Date of last calibration and/or verification
5. Date next due for calibration and/or verification
6. NIST or other number for traceability
7. Any limitations of use including the capacity to which it is calibrated when not calibrated to full capacity

This schedule serves as a status labeling system, identification system to determine current status, and lists any limitations on the use of measuring test equipment used by the Force and Torque Calibration Laboratory. Additional labeling and/or marking of measuring and test equipment to aid the Technicians in identification may be used but is not required.

When the schedule is in print copies are to be kept in the Force Calibration Laboratory and Torque Calibration Laboratory. When the schedule is maintained in digital format it will be available on the Company's computer network. The schedule serves as a notice to prevent the use of any measuring and test equipment that is overdue for calibration and/or verification. Because the schedule includes the calibration and/or verification due date for all measuring and test equipment it also serves as a mandatory recall system to assure timely calibration and/or verification and as an overdue notice for any measuring and test equipment not submitted for calibration and/or verification on time. The schedule is available for review upon request from the Quality Assurance Manager.

Certificates of Calibration and/or Test Reports shall be maintained for all measuring and test equipment, including equipment for subsidiary measurements (e.g. for environmental conditions), and those calibrated and/or tested in house. These certificates and/or reports shall include identification of the measuring device or system, the source of calibration or test, if not calibrated directly by a NMI such as NIST a statement of traceability to SI through a National Metrology Institute (NMI) such as the United States National Institute of Standards & Technology, evidence of accreditation and accreditation certificate number by an accrediting body recognized by the ILAC MRA that encompasses the latest revision of ISO/IEC-17025, a report number, date the calibration or test performed, conditions under which the calibration or test was performed, any corrections which must be applied, the measured value or values determined by calibration or test including "As Found" and where appropriate "As Left" data, errors or other contributors determined by the calibration and/or test that are needed to calculate standard and/or expanded uncertainties along with the method by which they were determined that meets the requirements of ILAC P14:01/2013 ILAC Policy for Uncertainty in Calibration. For measuring and test equipment calibrated by an ISO/IEC 17025 accredited

laboratory the certificate and/or reports shall include a statement of accreditation or the logo of the accrediting body accompanied by the certificate number and an indication of the type organization.

The Certificates of Calibration and/or Test Reports along with any records of damage, malfunction, modification, or repair shall be kept in the appropriate serial number file for measuring and test equipment used by Morehouse.

These records shall be maintained in accordance with Section 14, "Quality Assurance Records, Record Retention, & Limitation to Record Access to Protect Customer's Rights to Confidentiality & Proprietary Interests", of this manual.

12.3 Handling, Transport, & Storage of Measuring and Test Equipment:

To protect measuring and test equipment used in the performance of calibrations and/or tests from damage or deterioration it shall only be handled by inspection and repair personnel, Qualified Force Calibration Technicians, Qualified Torque Calibration Technicians, the Technical Engineering Manager, or the Quality Assurance Manager, except when being prepared for transport or during transport.

Whenever possible measuring and test equipment used in the performance of calibrations and/or tests should be transported by company personnel in private vehicles. When being transported in this manner no packing is required.

When transportation is by common carrier the level of packing and cushioning should preclude the measuring and test equipment from suffering any adverse effects on its capability during handling and transportation. The level of packing and cushioning is left to the discretion of the individual performing the packing.

On receipt of measuring and test equipment used by Morehouse to perform calibrations and/or tests sent to any approved supplier it shall be inspected in accordance with Section 8.7 Procedure for Supplier Audits of this manual.

To prevent deterioration and contamination, all measuring and test equipment used to perform calibrations and/or tests shall be stored and maintained in the Force or Torque Calibration Laboratory. If any measuring and test equipment is removed from the Force or Torque Calibration Laboratory, upon its return it will not be used until adequate time has been allowed for its temperature to return to the ambient temperature of the Laboratory.

If measuring and test equipment is outside the control of Morehouse for any reason and the calibration is suspect an intermediate check or verification shall be performed and documented in accordance with instructions contained in the Force & Torque Calibration Laboratory – Procedure Manual to restore confidence in that piece of measuring and test equipment.

12.4 Calibration Intervals & Intermediate Checks for Measuring & Test Equipment:

The frequency or interval between calibration, verification, or tests of measuring and test equipment is controlled by calendar time. The time interval is set to prevent the use of out of tolerance measuring and test equipment. Intervals will be adjusted in accordance with the Force & Torque Calibration Laboratory - Procedure Manual, when necessary, to maintain 100% reliability of measuring and test equipment.

The intervals and criteria for adjusting the intervals for the measuring and test equipment used by the Force Calibration Laboratory or Torque Calibration Laboratory shall be in accordance with the instructions contained in the Force & Torque Calibration Laboratory – Procedure Manual.

When establishing the calibration interval, the following criteria are considered:

1. Industry recognized and published standards
2. Usage and past performance of the measuring device or system

The interval of all measuring and test equipment shall be in accordance with the requirements of ILAC-G24 and A2LA R20, Specific Requirements: Calibration Laboratory Accreditation Program. The next calibration, test, or verification date shall be included on the schedule listing all measuring and test equipment maintained by the Quality Assurance Manager.

It may be necessary from time to time to grant temporary extensions to the interval of measuring and test equipment because of scheduling or other requirements. Temporary extensions may be approved by the Quality Assurance Manager or Technical Engineering Manager. In evaluating temporary extensions 100% reliability must be maintained. Temporary extensions shall be considered a non-conformance and must be documented in accordance with Section 13, "Complaints, Non-Conformance, & Corrective Action", of this Manual.

Intermediate checks and verifications made to maintain confidence in the status of measuring and testing equipment used to perform shall be performed and documented in accordance with instructions contained in the Force & Torque Calibration Laboratory – Procedure Manual.

12.5 Determination and Reporting the CMC of Measuring & Test Equipment:

A CMC for all measuring and test equipment used by Morehouse Instrument Company shall be determined in accordance with the instructions contained in the Force & Torque Calibration Laboratory - Procedure Manual. The statistical analysis shall be in accordance with the "Guide to the Expression of Uncertainty in Measurement*"* (GUM) and shall include all contributors to the CMC including, but not limited to, resolution, reproducibility, reference standard uncertainty, stability, and environmental factors. The CMC shall be expressed as the expanded uncertainty and have a specific coverage probability of approximately 95% level of confidence using the appropriate coverage factor.

The calculation of the CMC shall not exclude a contributor from the best existing device.

The numerical value of the CMC shall be given to no more than two significant figures.

On the scope of accreditation the CMC shall be expressed in terms of percent of applied force or torque, a single value valid through a measurement range, or a mathematical function of the measurand.

Calculation of the CMC, including any assumptions made in the calculation, shall be documented. CMC's are available for review upon request to the Quality Assurance Manager.

12.6 Evaluation and Verification of Measuring & Test Equipment (Measurement Assurance Program):

Where possible, measuring and test equipment shall be calibrated before and after any repairs or adjustments.

Any measuring and test equipment is to be considered significantly out of tolerance if at its test, verification, or calibration the uncertainty or accuracy exceeds its maximum allowable tolerance. The maximum uncertainty tolerance of all measuring and test equipment used by Morehouse is listed in the Force & Torque Calibration Laboratory – Procedure Manual.

Any measuring and test equipment that is not properly handled, stored, or transported shall be considered defective and not used until it is verified there has been no adverse impact on its proper functioning.

Additionally, a secondary force or torque standard is suspected of being damaged by overload, mishandling, accident, or through use when it has a permanent zero load change of 1% or more of the capacity deflection during the performance of a calibration and/or test.

Any measuring and test equipment used in the performance of calibrations and/or tests believed to be damaged, out of tolerance, or otherwise defective shall be immediately verified in accordance with the instructions contained in the Force & Torque Calibration Laboratory - Procedure Manual.

Any measuring and test equipment that is found to have an accuracy or uncertainty greater than its maximum allowable tolerance or is due for test, verification, or calibration will be considered significantly out of tolerance and be immediately removed from the Calibration Laboratory or tagged and marked **DO NOT USE - OUT OF CALIBRATION.** Such measuring and test equipment will be repaired and tested, verified, or recalibrated to be within acceptable limits before it is returned to use.

Any measuring and test equipment that is found to be consistently out of tolerance and cannot be repaired will be removed from service. Consistently out of tolerance shall be defined as exhibiting a condition that caused the accuracy or uncertainty to be greater than the maximum tolerance of that measuring device or system for three successive calibrations and/or tests.

It is the intent of this evaluation system to act as a measurement assurance program and prevent the use of defective or out of tolerance measuring and test equipment. The reliability goal is 100%.

12.7 Reporting & Evaluation of Defective & Out of Tolerance Conditions of Measuring & Test Equipment:

In the event any measuring and test equipment is found to be defective or out of tolerance, the individual detecting the condition should immediately notify the Quality Assurance Manager. Any measuring and test equipment overdue for test, verification, or calibration for which an extension has not been granted is to be considered defective.

The Quality Assurance Manager shall be responsible for preparing a written report describing the defect or out of tolerance condition.

The Quality Assurance Manager and Technical Engineering Manager, Qualified Force Calibration Technician, or Qualified Torque Calibration Technician will review the defect or out of tolerance condition. They will be responsible for determining if the error is such that any data previously established by its use may be suspect. If any data supplied to a customer is suspect, the customer will be notified in accordance with Section 13, "Complaints, Non-Conformance, & Corrective Action", of this Manual.

The Quality Assurance Manager is responsible for documenting the review and analysis of the defect or out of tolerance condition. Any documented reviews and analyses should be reported to and reviewed by the Executive QA Committee at their next meeting.

12.8 Tamper-Resistant Seals for Measuring & Test Equipment:

The use of tamper-resistant seals is not appropriate for the measuring and test equipment used by Morehouse Instrument Company.

12.9 Environmental Conditions:

There are no unusual environmental or special procedures needed that require control other than temperature.

Measuring and test equipment used by Morehouse Instrument Company shall be stored and maintained in the appropriate Force Calibration Laboratory or Torque Calibration Laboratory. The Force Calibration Laboratory and Torque Calibration are separated from the plant area and have their own heating and cooling systems.

The temperature shall be maintained, and correction factors applied, when appropriate, in accordance with the procedures contained in the Force & Torque Calibration Laboratory - Procedure Manual.

There are no other environmental conditions which could jeopardize the results of calibrations performed by Morehouse.

Both the Force and Torque Calibration Laboratories at Morehouse are separated from the shop and have their own dedicated HVAC system.

12.10 Access Control:

Access to Calibration Laboratories shall be restricted to employees of Morehouse Instrument Company. Visitors entering a Laboratory must be accompanied by a Morehouse employee. To help control access to the Force Calibration Laboratory and the Torque Calibration Laboratory each shall have only one main entry.

12.11 Housekeeping:

Housekeeping shall be such as to maintain a clean and comfortable work environment.

12.12 Software Verification and Control:

All software shall have a unique name and must be documented and verified in accordance with the procedures contained in the Force & Torque Calibration Laboratory - Procedure Manual. All software calculations must be verified anytime a change is made that could affect the calculated results of the software. Upon verification of the software it shall be evaluated for adequacy of use and approved by the Quality Assurance Manager.

The Quality Assurance Manager shall be responsible for maintaining documentation consisting of a list of all approved software and their verifications. At no time shall any software not included on this list be used.

During the performance of internal audits, the Quality Assurance Manager shall verify all approved software. The verifications shall be performed in accordance with procedures contained in the Force & Torque Calibration Laboratory - Procedure Manual. The purpose of verification is to document and insure the integrity of the software.

The documented software verifications are available for review upon request from the Quality Assurance Manager.

13. FEEDBACK (POSITIVE & NEGATIVE), EVENT REPORTING, NON-CONFORMANCE, & CORRECTIVE ACTION

13.1 General:

Morehouse Instrument Company shall actively seek written and/or oral feedback, both positive and negative, from its customers and from within the Company. Feedback from customers shall be solicited during sales calls and/or other interaction with customers. Positive feedback shall be recorded in the customers digital file. Negative feedback shall be reported to the Quality Assurance Manager.

13.2 Reporting Negative Feedback to the Quality Assurance Manager:

Negative feedback, whether written or oral, received from a customer or from within the Company, regarding force and/or torque calibration and/or testing, shall be brought to the attention of the Quality Assurance Manager by completing an Event Form.

Additionally, any condition, complaint, or event which causes lost time or material, is not in conformance with or which adversely affects the Quality Assurance Program for force and torque calibrations, including departures from the policies and procedures in the management/quality system, technical operations, and deviations from customer's requirements, shall be reported using an Event Form.

Any employee may complete and submit an Event Form to the Quality Assurance Manager.

The employee reporting the event shall complete an Event Form for legitimate and substantiated events and submit the form to the Quality Assurance Manager

The Event Form shall include the following:

1. Date
2. Event reported
3. Action taken to resolve event, where applicable.
4. Is follow-up required?
5. Is Non-Conformance &/or Corrective Action Form required?

Completed forms shall be maintained by the Quality Assurance Manager and are available for review upon request to the same.

The Quality Assurance Manager shall record the Event Form in a log. The log shall be maintained by the Quality Assurance Manager. This log will include

1. Date
2. Brief description of event
3. Department affected by event

4. If a Non-Conformance Form is required

The log can be used to look for trends which require corrective action not apparent from reviewing a single event. This log is available for review upon request from the Quality Assurance Manager.

13.3 Non-Conformance &/or Corrective Action Form:

Any event found not to be in conformance with, or which adversely affects the Quality Assurance Program, including departures from the policies and procedures in the management/quality system, technical operations, and/or deviations from customer's requirements, shall be immediately brought to the attention of the Quality Assurance Manager by submitting an Event Form. The Quality Manager shall review the event form and determine if it should be considered a non-conformance and a Non-Conformance &/or Corrective Action be initiated. The Quality Assurance Manager may complete a Non-Conformance &/or Corrective Action without first completing an Event Form.

Non-Conformance &/or Corrective Action Form must include the following:

1. Date
2. Deficiency reported
3. Requirements that lead to the deficiency.
4. Root cause of deficiency.
5. Corrective action to correct deficiency or non-conformance and prevent recurrence
6. Evaluation to determine if customer or NRC notification required
7. If 10 CFR Part 21 reporting is required.
8. Follow up to verify corrective action has been implemented and is effective

Completed forms shall be approved by the Quality Assurance Manager and reviewed by a member of the Executive QA Committee. Non-Conformance &/or Corrective Action Forms are available for review upon request from the Quality Assurance Manager.

A log shall be maintained by the Quality Assurance Manager to show the current status of Non-Conformance &/or Corrective Action Forms. This log will include the number, date initiated, date completed, and any comments pertaining to that form. The log will serve as a quick reference to determine the current status of non-conformances and corrective actions and is available for review upon request from the Quality Assurance Manager.

13.4 Corrective Action:

The Quality Assurance Manager shall review the feedback, complaint, or deficiency and determine the corrective action required to prevent its recurrence and effect its implementation.

Upon review of the feedback, complaint, or non-conformance the Quality Assurance Manager shall, if necessary, halt work and withhold Certificate of Calibrations until corrective action has been implemented

and the root cause of the non-conformance has been eliminated. If work has been halted or Certificates of Calibration withheld work shall only be resumed and Certificates released upon order of the Quality Assurance Manager. These orders may be issued verbally. Any work stoppage or withholding of Certificates of Calibration shall be documented on a Non-Conformance &/or Corrective Action Form.

It is the responsibility of the Quality Assurance Manager to perform a follow-up for the effectiveness of the corrective action. This follow-up shall be documented on the appropriate Non-Conformance &/or Corrective Action Form.

13.5 Customer Notification:

Where a deficiency causes the results of any data supplied to a customer to be in error or contain incorrect information Morehouse Instrument Company is obligated to provide notification to those customers. Notification must be made within five working days of the date of discovery of the defect.

Notification shall be made in writing to all involved customers under the signature of the President or Vice President. The customer shall be advised of the suspected error or defect, the possible impact on the accuracy of the calibration, and either an appropriate correction factor or instructions for returning the measuring device or system.

Notification letters will be mailed to customers via certified mail, return receipt requested or sent via email. They will be mailed or emailed to the holder of Morehouse Instrument's Company's controlled Corporate Quality Assurance Program Manual. If the customer does not have a controlled copy of Morehouse's Corporate Quality Assurance Program Manual the notification will be sent to the best contact we have for that customer.

A "Calibration Log" will be maintained in the Force Calibration Laboratory for each standard. This log will be maintained in accordance with the procedures in the Force Calibration Laboratory - Procedure Manual and can be used to determine what calibrations and/or tests were performed using an out of tolerance standard.

13.6 Reporting of Defects and Non-compliance to the Nuclear Regulatory Commission:

It is the responsibility of every employee of Morehouse Instrument Company to report any defect or noncompliance to their supervisor. For orders on which 10CFR21 is referenced if the employee feels the supervisor or the Company has ignored their concerns regarding any defects and/or non-compliances they have the right to contact the Nuclear Regulatory Commission and report the defect.

A copy of 10CFR21, "Reporting of Defects and Non-compliance" will be kept posted on the company bulletin board.

Since we are not familiar with how the customer uses the data supplied we are not able to determine if NRC notification is required. Therefore, it is the responsibility of the customer to determine if NRC notification is required and submit notification to the NRC as required by 10CFR21. In accordance with 10CFR21 the

customer shall then have 60 days to evaluate the finding and determine if NRC notification is required. Where NRC notification is required the customer shall notify the person in charge of notifying the NRC of the defect within five working days of completion of the evaluation. The person in charge is then required to make initial notification to the NRC within two days and written notification within 30 days.

13.7 Notice to customer of Defects and Non-compliance:

Notice to the customer of any defect or non-conformance which results in data being in error or containing incorrect information shall be within five working days of the date of discovery of the defect.

13.8 Additional Audits:

Where non-conformances cast serious doubts on compliance with the policies and procedures of this Manual or the Force & Torque Calibration Laboratory – Procedure Manual the areas for which corrective action was implemented shall be audited in accordance with Section 15, "Internal Audits", within one month to confirm the corrective action is effective.

13.9 Management Review & Preventive Action:

It is the intent of Morehouse's management/quality system to continually improve the quality/management system and to minimize negative feedback, complaints, and non-conformances while providing customers with reliable calibration data to meet their requirements. To attain this goal the Executive QA Committee shall review internal audit reports, proficiency testing results, replicate testing results, measurements assurance test results, Feedback & Complaint Forms, and Non-Conformance &/or Corrective Action Forms to look for trends which require preventive Action.

14. QUALITY ASSURANCE RECORDS, MAKING CHANGES TO CONTROLLED DATA, RECORD RETENTION, & LIMITATION OF RECORD ACCESS TO PROTECT CUSTOMER'S RIGHTS TO CONFIDENTIALITY & PROPRIETARY INTERESTS

14.1 General:

Morehouse Instrument Company will maintain records on all activities, including individual records for all measuring and test equipment, relating to and/or affecting the quality of force and torque calibration services.

Records for measuring and test equipment used by Morehouse shall include measuring device or system identification; date of last calibration, verification, or test; calibration interval; calibration source; calibration procedure; results of previous calibrations and/or tests; any corrective action taken, indications of erratic behavior or operational failures; record of repairs, and a Certificate of Calibration or test report traceable to SI through a National Metrology Institute (NMI) such as the United States National Institute of Standards & Technology.

Records for measuring devices or systems calibrated by Morehouse for its customers shall include identification; calibration procedure; record of repairs, original observations, derived data and a Certificate of Calibration or test report traceable to SI through a National Metrology Institute (NMI) such as the United States National Institute of Standards & Technology.

14.2 Making Changes to Controlled Data:

The record of original observations may include data that has been transferred from one media to another (e.g., written on paper, then entered into a computer). The form of original recording need not be maintained in the record system after transfer (e.g., the original paper may be destroyed). In cases where data is recorded on a form which contains some information which is part of the permanent record any data which has been transferred to another media, such as instrument readings observed, shall not be considered part of the controlled permanent record. Data shall not be considered controlled until the Certificate of Calibration and/or Test Report has been issued and sent to the customer. Up till that time it is permissible to make changes to the data without keeping record of such changes. For example: If it is determined a calibration was performed incorrectly there is no reason to keep any record of the incorrect calibration provided the customer did not receive the incorrect data. Another example would be an error in data entry. It would not be necessary to keep track of this error provided the incorrect data had not been provided to the customer.

Where changes to controlled data is recorded it shall be done in such a manner as to retain record of the original data and the date, reason for the change, and person making the change. For example: The data being changed could have a single line drawn through it with the correct data written near it and dated and initialed by the person making the change.

14.3 Record Retention and Access:

Records will be maintained for a minimum of ten years and are indexed so they are readily retrievable. All records may be stored as paper or digitally. All digital records shall be PDF files and stored on the server so they are automatically backed up off site.

Records associated with a specific measuring device or system are filed in accordance with the measuring device or system's serial number or with the original purchase order. Purchase Orders are filed alphabetically according to year.

Paper records maintained by the Quality Assurance Manager, such as personnel qualifications, proficiency testing records, audit reports, and records associated with measuring and test equipment used by Morehouse shall be stored in the office at the northeast corner of the building located at 1742 Sixth Ave. This area has been selected because it has limited access and is deemed to have a low risk of hazards, such as fire and water.

Records are maintained to prevent loss, damage, deterioration, and protect customer's rights to confidentiality and proprietary rights. In order to protect our customer's right to confidentiality and proprietary rights access to records is limited to Morehouse personnel. Customer access shall be accomplished through requests made to the Quality Assurance Manager. Requests for access to any records shall be denied where, in the opinion of the Quality Assurance Manager, such access reveals customers' proprietary rights or violates their rights to confidentiality.

15. INTERNAL AUDITS, AUDITS PERFORMED BY THIRD PARTIES, & CUSTOMER AUDITS

15.1 General:

Internal audits of the management/quality and technical system shall be performed to verify Morehouse's operations comply with its requirements and to assess the effectiveness of its implementation. The internal audit of the management/quality system and technical system shall be combined into a single audit and shall include verification of compliance with the requirements of ISO/IEC Guide 17025.

Third party audits, such as those performed by A2LA and NVLAP, will be performed at intervals determined by the accrediting body. During the audit, the accessor will be granted full access to all areas and records pertaining to the operation of the force and torque calibration laboratories.

Customers and potential customers will be granted full access to all areas and records pertaining to the quality system of the force and torque calibration laboratories for the purpose of auditing the quality program. While it is preferred these audits be scheduled, existing customers are granted full access to all areas and records pertaining to the quality system of the force and torque calibration laboratories at unscheduled intervals.

15.2 Internal Audit Schedule:

Internal audits are scheduled by the Quality Assurance Manager so the time between audits does not exceed one year, except for just cause, and when the Quality Assurance Manager grants documented approval.

15.3 Internal Auditor Training:

Internal audits shall be led by a person approved as an auditor by the Executive QA Committee. The approval shall be based on their understanding and knowledge of the Corporate Quality Assurance Program Manual, the Force & Torque Calibration Laboratory - Procedure Manual, ASTM E74, ASTM E2428, ISO 376, BS 7882, and the requirements for the verification, testing, and calibration of the measuring and test equipment used by and calibrated in Morehouse Instrument Company's Force and Torque Calibration Laboratory. The approved individual shall also have participated in audits performed by customers of Morehouse Instrument Company.

Any person acting as a lead auditor for Morehouse Instrument Company must be approved or re-qualified by the Executive QA Committee within one year of the date the audit is performed. Re-qualification shall be determined by the Executive QA Committee based on the person participating in a least one audit (either internal audit, supplier audit, supplier audit, or third party accreditation audit).

In cases where the lead auditor has direct responsibility for any areas being audited the lead auditor shall appoint an audit team member to audit those areas. The appointed audit team member shall not have any

direct responsibilities for the area they will be auditing. The audit team member shall document objective evidence for those areas being audited. Any findings of the audit team member shall be reported in the Audit Summary.

15.4 Internal Audit Procedure:

Internal audits shall be performed and documented using checklists that address all elements of the management/quality system. During the performance of an internal audit it shall be verified findings from the previous audit have been addressed, adequate corrective action implemented, and the root cause has not recurred.

When conducting internal audits the individual or individuals doing so shall act independently without regard to other responsibilities within the organization and without regard to cost or schedule.

Internal audit findings shall be documented on a Non-Conformance &/or Corrective Action Form. The form shall be completed and reviewed in accordance with Section 13, "Non-Conformances & Corrective Action" of this manual.

If the internal audit is not lead by the Quality Assurance Manager, he shall be responsible for reviewing the audit.

15.5 Internal Audit Reporting:

To assure company management is aware of internal audit results they shall be reviewed at the first meeting of the Executive QA Committee following the completion of the internal audit. The review shall include the audit summary, any findings, concerns, and observations, any Non-Conformance &/or Corrective Action Forms necessitated by the audit, and, if requested by the Executive QA Committee, the complete Internal Audit Report. This review shall be documented in accordance with Section 4, "Quality Assurance Program", of this manual.