Corrosion Testing Laboratories, Inc.

Quality Assurance Manual

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Assigned to:

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POLICY AND AUTHORITY STATEMENT

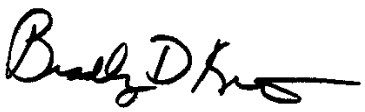
It is the policy of Corrosion Testing Laboratories, Inc. ("CTL") to provide its clients with testing and examination services of the highest quality, consistent with nationally accepted practices and standards. To accomplish this, CTL has developed and implemented the quality assurance program covered by this Manual. This Manual contains the organizational structures and practices required by the documents referred to herein.

This Quality Assurance Manual includes instructions for the preparation and review of written procedures, monitoring of all activities concerned with the control of operations and materials, conducting examinations and tests, calibration of measurement and test equipment, periodic auditing of the overall quality assurance program, required corrective action, retention of essential records, **the protection of customer confidential and proprietary rights**, the preparation of test and examination reports**,** and the purchasing of materials and services to be able to perform all of the above activities.

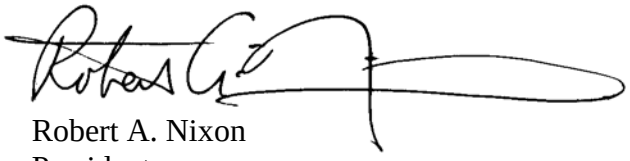
This manual shall apply to all work performed in CTL's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

Corrosion Testing Laboratories, Inc. is a corporation registered in the State of Delaware and is located at 60 Blue Hen Drive, Newark, Delaware 19713.

The authority and organizational freedom is hereby granted to the Quality Assurance Administrator to implement and maintain the quality management systems, including the resources needed to implement and maintain the Quality Systems Program and the responsibilities described in Section 4.6 of this manual. **The signatures below acknowledge the granting of this authority and the acceptance of this responsibility.**



Bradley D. Krantz
Quality Assurance Administrator
Corrosion Testing Laboratories, Inc.



Robert A. Nixon
President
Corrosion Testing Laboratories, Inc.

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SECTION 1

REVISION RECORD

Date	Revision	Sections Revised
03-02-88	0	Original Issue
08-01-88	1	8
11-23-88	2	All
10-03-89	3	All
12-15-89	4	1, 4, 7, 15, 17
12-18-89	5	All
01-08-93	6	All
04-01-96	7	All
04-10-98	8	3, 4
09-27-99	9	1, 9
01-11-05	10	All
03-14-05	11	All
06-23-05	12	2, 4, 6, 9, 12, 14
6-22-09	13	3, 4, 6, 17
	14	All – Updated and reformatted

Deleted items from previous revision are marked with "Δ"
All other changes from previous revision are notated in bold.

SECTION 2

Quality Assurance Program

2.1 SCOPE

2.1.1 **This section describes the documentation systems used at Corrosion Testing Laboratories, Inc. (CTL), including how this quality manual will be controlled.**

2.2 MANUAL CONTROL

2.2.1 This Manual shall apply to all testing and examination performed by CTL to the requirements of the codes, standards, specifications or regulations referenced in Paragraph 2.2. In addition, applicable sections of this Manual shall apply to work subcontracted by CTL to others.

2.2.2 This Manual and associated documents are written so as to comply with the requirements of the following:

ASME Boiler and Pressure Vessel Code, Section III, Subsection NCA 3800/**4200**.

ASME NQA-1

10CFR50, Appendix B.

ANSI/NCSL Z540-1

10CFR21
Δ

2.2.3 This Manual and associated procedures shall be reviewed and revised, as necessary, by the President and/or the Quality Assurance Administrator periodically.

2.2.3.1 The Quality Assurance Administrator is responsible for obtaining all required approvals for this Manual from the President.

2.2.4 Controlled copies of this Manual, distributed to various facilities, shall be assigned a unique control number traceable to a master listing maintained in the Quality Assurance Files. Uncontrolled copies are not recorded.

2..2.5 Controlled Manuals **and revisions** shall be distributed with a letter, to be signed and returned when the Manual is received and the conditions noted in the letter are met.

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2.2.6 If no acknowledgment is received within thirty days, Corrosion Testing Laboratories, Inc. may send notice decontrolling the Manual.

2.3 DOCUMENTATION SYSTEM

2.3.1 Quality Assurance Manual – This Document

2.3.2 Quality Procedures

Quality Procedures are supplemental instructions or procedures to the Quality Assurance Manual.

2.3.3 Laboratory Procedures

Approved laboratory procedures are contained in a separate manual entitled "Corrosion Laboratory Procedure Manual".

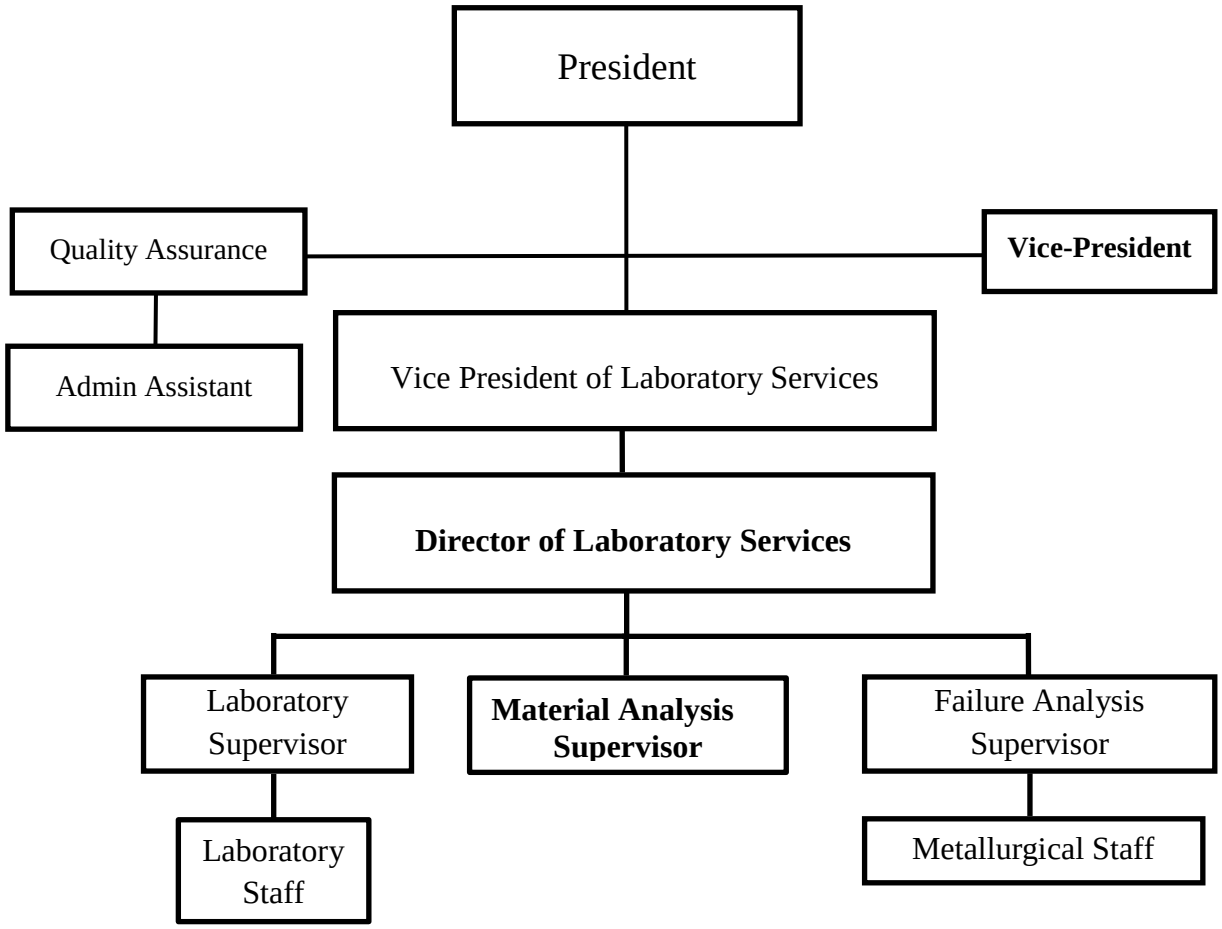
Approved calibration procedures are contained in a separate manual identified as "Calibration Procedures".

Job specific approved procedures are maintained with the specific job documentation.

SECTION 3

ORGANIZATIONAL CHART

CORROSION TESTING LABORATORIES, Inc.



Modifications may be made to the organizational structure. However, the Quality Assurance Administrator and the Quality Department shall always report to the President so that required authority and organizational freedom are maintained.

SECTION 4

PERSONNEL: RESPONSIBILITIES, QUALIFICATIONS, CERTIFICATIONS

4.1 It shall be the ultimate responsibility of the President, and/or the Quality Assurance Administrator to assure that all personnel performing functions within the scope of this Manual are qualified and/or certified for the work they perform. Personnel shall be trained to the implementing document for which they are responsible for implementing prior to the start of work. Periodic evaluations shall be performed to determine the need for additional training.

4.2 Independence - Personnel responsible for defining and measuring the overall effectiveness of the quality assurance program shall:

4.2.1 Be designated;

4.2.2 Be sufficiently independent from the pressures of production;

4.2.3 Have direct access to responsible management at a level where appropriate action can be initiated.

4.3 Responsibilities - All Personnel

4.3.1 Proper handling of materials to preclude damage or contact with detrimental materials.

4.3.2 Maintenance of material traceability while in the possession of CTL.

4.3.3 Proper Disposition of received materials after testing has been completed, e.g., return to client, storage, etc.

4.3.3 Notification to the President, and/or the Quality Assurance Administrator of the following:

a) Suspected loss of traceability.
b) Equipment malfunctions.
c) Procedural discrepancies.
d) Contaminated materials.
e) Suspected fraud or malpractice.

4.3.4 Maintenance of controlled procedures issued to themselves, including revisions.

4.3.5 Preparation, maintenance and completion of a Job File for all work performed.

4.4 Responsibilities – President, except where job conflicts exist

4.4.1 Approval of any revision and control of this Manual.

4.4.2 Approval of purchase orders, including those with special quality requirements.

4.4.3 Assuring that the Quality Assurance Administrator has the authority and organizational freedom to perform the duties listed on Page **2** of this Manual, **Policy and Authority Statement**.

4.4.4 Performance of a management audit of the Quality Assurance Manual once each year, except where job conflicts exists.

4.4.5 Storage of quality records.

4.4.6 Assuring that facilities, equipment and personnel are adequate to perform the required work, and those personnel are trained and qualified to perform their assigned jobs.

4.4.7 Reporting of applicable deficiencies in accordance with the requirements of 10CFR21.

4.4.8 May perform initial and final review of jobfiles.

4.4.9 Review and approval of final reports.

4.5 Responsibilities – Vice-President – Reports to the President

4.5.1 Reports to the President.

4.5.2 In the absence of the President, performs responsibilities as stated in Paragraphs 4.4.4 and 4.4.6.

4.6 Responsibilities – Quality Assurance Administrator, except where job conflicts exist.

4.6.1 Reports to the President.

4.6.2 Review and control of all quality assurance and test procedures, including customer submittals.

4.6.3 Control of non-conforming materials, equipment and services.

4.6.4 Performance of vendor quality evaluations, and if necessary audits, and preparation and control of approved vendor lists.

4.6.5 Control and documentation of calibration procedures.

4.6.6 Performance of internal audits, except where job conflicts exist.

4.6.7 Preparation and control of corrective action requests, as applicable.

4.6.8 Monitoring of the quality assurance program, and reporting regularly to management on its effectiveness.

4.6.9 Assuring that the policies in this Manual are followed for all work performed under the scope of this Manual.

4.6.10 **Delegates others to perform these responsibilities, provided they are independent of the activity or process but retains the overall responsibility for ensuring compliance with the requirements of the QA Program.**

4.6.10 Review of all purchase orders referencing ASME Section III requirements. This review may also be performed by the President, **Vice President of Laboratory Services,** and/or the **Director of Laboratory Services.**

4.7 Responsibilities – Vice President of Laboratory Services

4.7.1 The Vice President of Laboratory Services reports to the President.

4.7.2 The Vice President of laboratory Services is responsible for formulating policies, managing daily operations and planning the use of materials and human resources.

4.7.4 May perform initial and final review of jobfiles, and is designated by the President to do so.

4.7.4 May approve reports, and is designated by the President to do so.

4.7.5 May approve purchase orders, including those with special quality requirements, and is designated by the President to do so.

4.8 Responsibilities – Director of Laboratory Services

4.8.1 The Director of Laboratory Services reports to the Vice President of Laboratory Services and provides assistance to the Vice President of Laboratory Services in carrying out his responsibilities.

4.8.2 May perform initial and final review of jobfiles, and is designated by the President to do so.

4.8.3 May approve reports, and is designated by the President to do so.

4.8.4 In the absence of the Vice President of Laboratory Services, performs additional responsibilities as stated in Section 4.7

4.9 Responsibilities - Lab Supervisor, **Materials Analysis Supervisor**, and Failure Analysis **Supervisor**

4.9.1 Assuring that all work performed under their supervision is in accordance with the quality assurance requirements stated in this Manual.

4.9.2 Assuring that all personnel under their supervision are trained, qualified and certified, as applicable, for the work they perform.

4.9.3 May perform initial and final review of jobfiles, and is designated by the President to do so.

4.9.4 May approve reports, and is designated by the President to do so.

4.9.5 Assuring that all equipment under their control is properly maintained and calibrated.

4.10 Responsibilities - Metallurgical Staff

4.10.1 The Metallurgical Staff, which may include Engineers, Scientists, Technologists and Technicians, shall be trained and qualified for the work they perform.

4.10.2 Be responsible for overseeing the quality of work they perform.

4.10.3 Stay abreast of current technological advances in their area of technical responsibility.

4.10.4 Interface with the Laboratory Staff to insure quality of work performed.

4.10.5 Maintain the laboratory facilities and equipment in a neat, clean and orderly manner.

4.10.6 Accurately maintain and record data in the laboratory Job File

4.11 Responsibilities - Laboratory Technical Staff

4.11.1 The Laboratory Staff, which may include Scientists, Technologists and Technicians, shall be trained and qualified for the work they perform.

4.11.2 Perform assigned tests according to approved standards and practices.

4.11.3 Interface with the Metallurgical Staff to insure quality of work performed in the lab.

4.11.4 Maintain the laboratory facilities and equipment in a neat, clean and orderly manner.

4.11.5 Accurately maintain and record data in the laboratory Job File.

4.11.6 Stay abreast of current technological advances in their area of technical responsibility.

4.12 Personnel Training

4.12.1 CTL employees shall have the education, experience, and training to provide laboratory testing services to meet all customer requirements.

4.12.2 Training procedures are maintained in CTL procedure "Personnel Training".

4.12.3 The QA Administrator shall ensure employees whose function affects quality receive the training and/or indoctrination they need for their position.

4.12.4 Personnel performing and managing specific assigned tasks are qualified on the basis of appropriate education, training, and/or experience.

4.12.5 When contract employees are used, CTL shall ensure that such personnel are competent and that they work in accordance with the CTL Quality System.

4.13 Changes to Responsibilities

4.13.1 The President, upon written notification to the QA Administrator, may revise or append the responsibilities and authority stated in this manual.

SECTION 5

ORDER ENTRY / QUALITY REVIEW

5.1 Scope

This Section details the requirements for order entry and quality review of orders for materials and services within the scope of this Manual.

5.2 Procedure

5.2.1 When an order is received, applicable information shall be entered in the **Job Login section of the CTL Database. This includes client contact information, Department and person responsible for the job, and job requirements. Any materials received shall also be logged in per CTL Procedure "Material Log-in Procedure".**

5.2.2 **A work request form shall be generated and submitted to the appropriate supervisor for review. The reviewer shall ensure that:**

- **Orders include the appropriate technical requirements and/or methods are referenced and understood.**
- **The requirements are within the scope of CTL's technical capability and resources.**
- **The appropriate test methods are selected and capable of meeting the customer's needs.**
- **Any services to be sub-contracted are identified and appropriate.**

5.2.3 **Additional instructions concerning order entry and execution are contained in CTL procedure "Job Instructions".**

5.3 Changes to Orders

5.3.1 The appropriate area supervisor shall be notified, in writing, of any changes to orders affecting processing. Upon approval of the change order, the notified individual is responsible for up-dating the Job File to reflect the changes. **Changes for pricing or delivery do not require documentation of the review.**

5.3.2 Additional instructions concerning Change Orders and customer notification are contained in CTL Procedure "Change Orders".

SECTION 6

PROCUREMENT

6.1 Scope

6.1.1 This Section details the requirements for approval of vendors supplying materials and services, including calibration and testing.

6.2 Requirements

6.2.1 All vendors to be used for subcontract services shall meet CTL's standards for insuring the quality of work they perform. These vendors will submit to either an audit by CTL personnel or representative, or provide evidence that they have an on-going QA program [Subcontractor/Vendor Quality Evaluation Survey Questionnaire] that fulfills the basic requirements of a nationally and/or internationally recognized organization, such as ANSI/ASME/**ISO**.

6.2.1.1 Vendors that will provide materials or services under the auspices of ASME Section III shall be audited by CTL as having and implementing a quality assurance program that meets or exceeds the requirements of Corrosion Testing Laboratories.

6.2.1.2 **As an alternative to survey and audit of suppliers of subcontracted services, a Certificate Holder, Material Organization, or approved supplier may accept accreditation by accrediting bodies recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). A document review of the vendor's accreditation status and scope of accreditation is required along with any previous service provided by the vendor.**

6.2.1.2.1 The calibration laboratory's scope of accreditation must be current and include the needed measurement parameters, ranges, and uncertainties needed for the required calibration.

6.2.1.2.2 The testing laboratory's scope of accreditation must be current and include the needed testing services including test methodology and tolerances/uncertainties.

6.2.1.2.3 Procurement documents submitted to vendors approved in this manner shall contain additional technical, quality, and administrative requirements, as necessary, to satisfy CTL's Quality Assurance requirements. These additional requirements are described in CTL Procedure "Purchasing Instructions".

6.2.1.3 Vendors supplying materials and services that do not fall under the auspices of ASME Section III testing may be subjected to a quality review performed by CTL. At CTL's discretion, an independent registration or third-party accreditation, such as NAVLAP/ ISO, etc., may be substituted for all or part of this review.

6.2.1.5 The President and/or the Quality Assurance Administrator of Corrosion Testing Laboratories, shall approve or reject the vendor **based on an audit or quality review.**

6.2.1.6 For ASME Section III work, the qualified vendor will be placed on an Approved ASME Vendors List. Approved vendors shall remain on this list for a period of three (3) years or until performance is unsatisfactory, whichever is earlier.

6.2.3 Purchase orders for materials and services shall include, as a minimum, appropriate technical and quality requirements. These requirements may take the form of a reference to an industry accepted standard or specific detailed requirements.

6.2.4 The President, **his designee**, or the Quality Assurance Administrator, prior to transmittal to the vendor, shall approve all Purchase Orders for materials and services.

6.2.5 Upon receipt of materials or services affecting quality, the materials or services will be evaluated to determine if the requirements of the purchase order have been met. This acceptance will be documented prior to reliance on the purchased materials or services for further work.

6.2.6 Vendors providing general supplies will not fall under this quality assurance manual.

6.2.7 Additional requirements concerning the approval of vendors and purchasing procedures are contained in CTL Procedure "Purchasing Instructions."

6.2.8 On occasion it may be necessary to use a vendor who has not been previously qualified as a CTL Approved Vendor. In this instance a designated CTL employee shall witness the vendors work to ensure traceability and quality standards are met. See CTL procedure "Source Verification Procedure".

SECTION 7

MARKING AND TRACEABILITY

7.1 **SCOPE:**

7.1.1 This section shall outline the requirements for marking or identification of material and to maintain traceability from the time CTL receives the material, through completion of testing or examination, and ships the material back to the customer or scraps the material at CTL.

7.2 Markings on materials shall be verified against the purchase order at the time of receipt. Discrepancies shall be reported to the President or Quality Assurance Administrator.

7.2.1 **Material shall be tagged, marked or otherwise identified with the CTL Sample Number as described in CTL Procedure "Material Log-in Procedure". Customer markings are included in the CTL Job folder.**

7.2.1.2 Markings on the material shall be maintained from the receipt of the material through final disposition. Markings on material shall not be removed unless required by the test or examination procedure. **When removed,** marking shall be re-applied **as soon as possible. The assigned CTL Sample number may be used in place of the customer's markings**.

7.3 **Material submitted for examination and testing that are suspected of having lost traceability in the CTL facility, shall be reported immediately to the Quality Assurance Administrator and segregated in a holding area designated by Quality Assurance.**

SECTION 8

EXAMINATION AND TESTING

8.1 Corrosion Testing and Examination

8.1.1 All corrosion testing and examinations shall be performed by personnel qualified as specified in Section 4. Current personnel qualification records shall be kept on file for each person performing corrosion testing and examination.

8.1.2 All contractually required corrosion testing and examination shall be performed in accordance with written procedures, industry specifications, and/or ultimate customer instructions, and approved or reviewed by the President or Quality Assurance Administrator. **CTL Test Procedures are maintained in the Laboratory Procedure Manual.**

8.1.3 All corrosion testing and examination procedures shall be noted in the **Job** File.

8.1.4 When a corrosion test or examination is completed, a report shall be prepared showing the results, date, signature and level of personnel performing the work**.**

8.1.5 When corrosion tests and examinations are performed by an outside source, the President, **QA Administrator, or the supervisor of the respective area involved** shall review the results of the testing and/or examination for discrepancies.

8.2 Chemical and Metallurgical Tests

8.2.1 All chemical and metallurgical testing shall be performed by personnel qualified as specified in Section 4. Current personnel records shall be kept on file for each person performing the testing.

8.2.2 Chemical and metallurgical testing that is performed by CTL or an approved outside source shall be performed in accordance with written procedures, industry specifications, and/or equipment manufacturers' instructions.

8.3 Records and Reports

8.3.1 Testing and examination results shall be recorded in the Job File and reviewed by the applicable supervisors **Additional instructions concerning review of the job are contained in CTL Procedure "Job Instructions".**

8.3.2 T**est reports shall meet the minimum requirements of CTL Procedure "Examination of Test Specimens and Reporting of Results"**. Data included in

reports shall be identified in a manner that facilitates traceability to the materials tested and any procedures used to provide the results of analysis.

8.4 Procedure Availability

8.4.1 Specific examination and testing procedures are available for customer review when contractually required.

8.5 Customer "Hold" Points

8.5.1 Orders requiring customer witnessing of tests shall have the words "Hold Points" printed across the face of the associated Job File folder and **on the Work Request.**

8.5.2 **When work is ready for testing, the appropriate area supervisor is responsible for notifying the customer or their designated representative to coordinate a suitable time for witnessing of the test.**

8.5.3 Work shall not proceed until appropriate instructions are received from **the customer or their designated representative.**

8.5.4 CTL shall ensure the confidentiality of work being performed for other customers during such monitoring,

8.6 Sampling

8.6.1 Material received for testing and examination is assumed to be homogenous such that test specimens or test samples may be randomly selected, unless otherwise stipulated.

8.7 Software

8.7.1 When software is used to perform analysis that produces results that are not later verified, the software shall be identified, including version, and tested to a known benchmark to verify that the software is performing its intended function. The results of the software verification shall be documented.

8.7.1.2 **Successful calibration of an instrument that uses software for data collection and calculation is considered adequate software validation. The software revision shall be included in the documentation of the calibration.**

SECTION 9

NON-CONFORMING TESTING or MATERIAL

9.1 Rejected Material

9.1.1 Material that has been ordered or purchased for use and subsequently rejected as a result of examination or test shall be painted, tagged, or stickered as "REJECTED" by the person performing the test.

9.1.2 Material that is suspected of having lost tractability at CTL shall be reported immediately, in writing, to the appropriate supervisor and quarantined until proper disposition is determined.

9.2 Discrepant Equipment or Processing

9.2.1 Any CTL employee can initiate a Non-Conformance Report or QA Discrepancy Report. The work in question shall be stopped, including the withholding of test reports until the nonconformance or discrepancy has been dispositioned.

9.2.2 Any deficiency in equipment shall be reported to the President or QA Administrator in writing on a **Non-Conformance Report** form. Orders involved shall not be moved until corrective action has been determined and taken, and a **QA Corrective Action Report** issued. Such equipment will be tagged as "*Non-Conforming*" and shall not be used for work without the explicit written authorization from the President or the QA Administrator. The President and/or the Quality Assurance Administrator shall review all previous jobs using the non-conforming piece of equipment to determine the impact on quality and what corrective action is to be implemented including possible 10CFR21 reporting

9.2.2 Any deficiency in processing or personnel, such that it potentially disqualifies the test results, changes the results, requires a repeat of the work, or affects QA records or reports, shall be reported to the President and/or Quality Assurance Administrator in writing on a **QA Discrepancy Report** form. The report shall address the deficiency, corrective action, and follow-up.

9.2.4 CTL shall notify customers promptly of any identification of defective measuring and test equipment that casts a doubt on the validity of results given in any Test Report.

9.3 10CFR21 Compliance

9.3.1 For discrepant conditions reportable under the provisions of 10CFR21, the President shall be notified in writing **by the QA Administrator. The President is responsible for all notifications outside the company in accordance with established procedures.**

9.3.2 The Procedure "Reporting Defects in Accordance with 10CFR Part 21" along with required documents shall be posted in an area accessible and conspicuous to all employees.

SECTION 10

TEST REPORT APPROVAL

10.1 **Scope**

10.1.1 This section describes the requirements for Test Reports completed by CTL.

10.2 Test Reports

10.2.1 Test reports shall be prepared by the person performing the test work. Upon completion, the report and associated Job File shall be reviewed, approved and signed or equivalent identification of responsible management as designated in Section 4.

10.2.2 The test report shall meet the requirements of CTL Procedure "Examination of Test Specimens and Reporting of Results" and include the customer's required information.

SECTION 11

HANDLING, STORAGE, PRESERVATION AND SHIPMENT

11.1 **Scope**

11.1.1 This section describes the way that CTL shall handle, store, preserve and ship material or items that come to CTL for testing.

11.2 Method of Handling, Storage, Preservation and Shipment.

11.2.1 All material shall be stored and moved in containers that are not detrimental to the material. In general, materials will be stored and moved in the container in which they were received, and shall not come in contact with detrimental materials while in CTL's possession.

11.2.2 Material **that is to be returned to the customer** shall be returned in accordance with best commercial practice and Interstate Commerce rules.

11.2.3 Specific instructions about handling or storage of certain materials shall be put into working procedures, or the work order when specified by contract.

SECTION 12

EQUIPMENT, TOOL AND INSTRUMENT CONTROL

12.1 Scope

12.1.1 To cover the calibration of all equipment, tools and instruments used for inspection and examination.

12.2 Equipment, tool and instrument control is maintained in accordance with ANSI/NCSL Z540-94, which includes the following requirements:

a) Serialization of all equipment, tools and instruments, except general hand tools.

b) Calibrated equipment found out-of-calibration, the validity of previous results using that equipment since its last calibration shall be evaluated and the results documented.

c) Positive identification and disposition of out-of-service equipment, tools and instruments.

d) Acceptable standards for instrument calibration.

e) Calibration intervals and adjustments.

f) Record maintenance.

g) Calibration standards traceable to national standards, where such standards exist, and have accuracy greater than required of the item under calibration.

h) Control of material tested with equipment, tools or instruments discovered to be out of calibration.

i) Calibrated equipment shall be labeled, tagged, or otherwise suitably marked to indicate the calibration status. (i.e., Date of Calibration, Calibration Due Date)

j) The use of calibrated equipment shall be documented.

k) Calibrated equipment shall be properly handled and stored to maintain accuracy.

12.3 Calibration and control measures are not required for commercial equipment, such as rulers, tape measurers, etc., if such equipment provides the required accuracy.

12.4 Computerized Equipment

12.4.1 When computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage, or retrieval of test data, CTL shall assure that:

- **All applicable requirements are complied with;**
- **Computer software is documented and adequate for use;**
- **Computer and automated equipment is maintained to ensure proper functioning and provided with the environment and operating conditions necessary to maintain the integrity of the test data;**
- **The collected data files are adequately stored for security and retrieval. See CTL Procedure "Record Storage"**

SECTION 13

DOCUMENT CONTROL

13.1 Scope

13.1.1 This Section provides instructions for the preparation, review, issuance and maintenance of **customer, commercial, military and internal procedures, specifications, and standards covering** systems, traceability, testing and examination.

13.2 Preparation

13.2.1 Procedures shall be prepared and include or reference quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished, where appropriate.

13.2.2 Technical procedures shall be prepared by someone technically competent in the subject area. Prepared procedures shall be submitted to the QA Administrator for review.

13.3 Review, Approval, and Revision

13.3.1 All CTL procedures and revisions shall be reviewed for applicability, correctness, adequacy, completeness, accuracy, and compliance with established requirements. The person performing the review shall be independent of the preparer. The reviewed procedure shall be submitted to the President for approval.

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13.4 Distribution

13.4.1 **All standard internal lab procedures are available in the CTL Laboratory Manual located in the Laboratory Bookshelf and available in electronic form on the CTL Server. Additional hardcopies are issued to the President, Vice President of Laboratory Services and the Director of Laboratory Services. The Master copy is maintained by the QA Administrator.**

13.4.2 **Affected personnel will be notified of new and revised procedures by the QA Administrator.**

13.4.3 It is the responsibility of the QA Administrator to assure that invalid or obsolete procedures are removed from the CTL Lab Manual, all hard copies and electronic copies. Superseded online procedures are segregated into a non-public folder. Original hardcopies of superseded procedures are identified and maintained in Quality Assurance.

13.5 Published Industry and Customer Documents

13.5.1 Published documents (either hardcopy or in electronic format) such as ASTM, NACE, ASME, SAE, and ISO shall be obtained as required. CTL shall keep up to date with new releases, revisions or addenda of required standards/specifications. Hardcopies are stored in the CTL library. Electronic copies are stored on the CTL Server in an appropriate subfolder in the Reference Directory.

13.4.2 Customer procedures, standards, specifications and drawings shall be maintained in either hardcopy or electronic and available on an as needed basis.

SECTION 14

INTERNAL AUDIT

14.1 Scope

14.1.1 To furnish procedures for auditing all phases of CTL activities affecting quality.

14.2 Procedure

14.2.1 Personnel conducting internal quality assurance audits shall be qualified according to CTL procedure "**Auditor Qualifications"**, and have no direct line responsibility for the area or activity being audited.

14.2.2 Internal quality assurance audits shall be scheduled for each area contained within the scope of this Manual and shall be conducted at least once per year.

14.2.3 Follow-up audits of deficient areas shall be conducted within a reasonable time after the initial audit to confirm that corrective action has been taken. Sufficient time will be allowed for corrective action and shall be determined by CTL management based on seriousness and impact on product/service quality.

14.2.4 Areas showing repeated deficiencies shall be audited more frequently until the deficiencies are corrected.

14.2.5 Audits shall be conducted using an internal audit report form, checklists, or procedures by qualified personnel.

14.3 **Management Review**

14.3.1 The President is responsible for performance of an annual review of the Quality Assurance Program to determine its adequacy, effectiveness and implementation. The review shall take account of:

- **the suitability of policies and procedures;**
- **reports from managerial and supervisory personnel;**
- **the outcome of recent internal audits;**
- **corrective and preventative actions;**
- **assessments by external bodies;**
- **the results of interlaboratory comparisons or proficiency tests;**
- **changes in the volume and type of work;**
- **customer feedback;**
- **complaints;**
- **recommendations for improvement;**

- **other relevant factors, such as staff training and lab resources.**

14.3.2 Findings from the management review and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.

14.3.3 The Management Review report shall be kept in the Quality Assurance files. Copies shall be routed to the Management Review Committee.

SECTION 15

CORRECTIVE ACTION, PREVENTATIVE ACTION, and CONTINUOUS IMPROVEMENT

15.1 Scope

15.1.1 This section describes the requirements for corrective action for conditions that have an adverse effect on quality, preventative action, and continuous improvement.

15.2 Corrective Action

15.2.1 The need for corrective action and prevention of reoccurrence shall be determined by discrepancy reposts, non-conformance reports, formal or informal audit results, customer complaints, management reviews, or other avenues that identify conditions adverse to quality. Preparation of corrective action requests is the responsibility of the QA Administrator.

15.2.2 Evaluation of the corrective action and follow-up to corrective action shall be performed by personnel independent of the activity within the time noted on the corrective action request and documented on the follow-up report.

15.2.3 The corrective action report shall include:

- **investigation to determine the root cause(s) of the nonconformance;**
- **determination of the appropriate corrective action;**
- **document any required changes resulting from the corrective action investigation;**
- **controls to ensure that the corrective action is taken and that it is effective.**

15.2.4 The results of the Corrective Action shall be reported to the President, Vice President of Laboratory Services and all other affected personnel.

15.3 Preventative Action and Continuous Improvement

15.3.1 Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

15.3.2 Any CTL employee may initiate a preventative action request.

15.3.3 The preventative action request shall be submitted to the QA Administrator for evaluation and disposition.

15.4 Customer Complaints

15.4.1 Customer complaints shall be processed in accordance with CTL Procedure "Customer Complaints". Customer complaints are generated based on the customer's verbal or written notification.

15.4.2 Customer complaints may result in the generation of Discrepancy Reports or Non-Conformance Reports depending on the extent of the complaint.

15.5 Vendor Corrective Action and Prevention of Recurrence.

15.5.1 CTL may require corrective action from its vendors whenever material or services are received which are non-conforming or upon deficiencies identified during an audit of the vendors quality system. Failure of the vendor to take and document positive corrective action may result in their removal from the qualified vendors list.

15.6 Records.

15.6.1 All Corrective Action Reports shall be kept on file by the Quality Assurance Department.

15.7 Monitoring of Corrective Actions

15.7.1 CTL will monitor the results of corrective actions and prevention of recurrence actions to ensure that the actions taken have been effective.

SECTION 16

RECORD STORAGE AND RETENTION

16.1 **This section describes the requirements for the control of Quality Records which may be in any media, such as hardcopy or electronic media.**

16.2 Quality Records

16.2.1 Definition – Quality records are those completed records that furnish documentary evidence of activities affecting quality.

16.2.1.1 Quality records include, but are not limited to; calibration records, personnel qualifications and certifications, examination procedures, internal audits, corrective action, non-conformance reports, discrepancy reports, **internal audits**, management **reviews and** reports, vendor audits, c**ustomer complaints, completed test reports and any records or original observations derived from data and sufficient information to establish an audit trail.**

16.2 All quality records shall be stored in a manner to protect them from damage, deterioration, or loss, so as to promote retrievability and traceability. **Storage of electronic records shall comply with CTL procedure "Record Storage".**

16.3 All quality records, in the absence of contractual requirements, shall be stored for a minimum of ten years.

16.4 Materials tested and remnants shall be retained as described in CTL Procedure "Material Log-in Procedure"

16.5 The President shall be responsible for adequate storage and retrieval of all records.

16.6 **Corrections made to Quality Records shall be in accordance with CTL Procedure "Hand Corrections". Errors shall be crossed out with a single line, not erased or whited out, made illegible or deleted, and the corrected value entered alongside. All such alterations to records shall be signed or initialed and dated by the person making the correction. The use of correction fluid on any Quality Record is strictly prohibite**d.

SECTION 17

ACCOMMODATION and ENVIRONMENT

17.1 Scope

17.1.1 This section describes the general requirements for accommodation and environment for the Laboratory.

17.2 General Requirements

17.2.1 Each area where testing is conducted shall have appropriate energy sources, lighting, heating, ventilation and environmental conditions to facilitate correct performance of tests.

17.2.2 Testing that requires documentation of specific lighting, heating, ventilation, or other environmental conditions shall have specific requirements described in working procedures for the particular test or test area.

17.2.3 The environment in which testing is performed shall be undertaken so as not to invalidate the results or adversely affect the required accuracy of measurement or the test.

17.2.4 Tests shall be stopped when the environmental conditions jeopardize the results of the tests or calibrations.

17.2.5 It is the responsibility of all employees to maintain acceptable housekeeping within their respective area.

17.2.5.1 Acceptable housekeeping shall be defined as floors and equipment clean of litter, trash, grease, oil, dust and anything else that will prohibit personnel from performing their respective jobs.

17.2.6 Access and use of areas affecting the quality of the tests or calibrations is limited to authorized personnel.

SECTION 18

Quality Procedures Referenced in this Manual

Procedure Number	Manual Section	Procedure Title	Reference Location
	4	Personnel Training	4.11.2
	5,7,16	Material Log-in Procedure	5.2.1 7.2.1 16.3
	5,8	Job Instructions	5.2.3 8.3.1
	5	Change Orders	5.3.2
	6	Purchasing Instructions	6.2.7
	6	Source Verification	6.2.8
	8, 10	Examination of Test Specimens and Reporting of Results	8.3.2 10.2.2
	9	Reporting Defects in Accordance with 10CFR Part 21	9.3.2
	12 16	Record Storage	12.4.1 16.2
	14	Auditor Qualifications	14.2.1
	15	Customer Complaints	15.4.1
	16	Hand Corrections	16.6