

Revised by: C. Mikin	<b>NSL Analytical Services, Inc.</b>	<b>NSL 1</b>
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# QUALITY MANUAL

**Revision March 11, 2010**

Approved: *Craig Mikin*  
Quality Assurance Manager

Approved: *L. Somrack*  
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Control: \_\_\_\_\_

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### Quality Manual Revisions

<u>Date</u>	<u>Revision</u>
06/22/09	Included organizational chart, clarified levels of quality system documentation, clarified process for non-standard test methods, editorial
10/25/06	Revised to comply with the changes and additions in the Second edition of the ISO/IEC standard, ISO/IEC 17025:2005(E).
05/01/05	Update letter of intent, figure 1 removed, change all references from Lab Manager to Technical Managers, editorial updates, update logo, and remove section 5.10.3.6.
07/01/01	Completely revised to comply with ISO/IEC 17025 requirements and removed procedural items.
08/31/00	1.0 added ISO/IEC Guide 25, ISO 10012, ANSI Z540-1; 2.0 updated President' letter; 5.0 updated organizational chart; 18.3 removed "Vendor Self Audit"; 18.4 and 18.5 updated to meet ISO/IEC Guide 25.
06/30/99	Completely updated
06/20/96	Revised
05/31/96	Revised
10/27/95	6.0 Designated Customer listing extended to 131; 11.0 revised and added 11.13, 11.14, Figure 11-2, deleted Revision Page
09/25/95	7.0 changed to "Vendor Self-Audit Survey Form"; 15.6.5 revised, added Figure 15-1; 17 renamed to "Nonconformance/ Discrepancy Report"; 18 changed to "Vendor Self-Audit Report"; 21.3.1 revised, added Figure 21.1
08/12/95	12 entire section revised; 13.3.1, 13.3.2 revised, added 13.3.3, Figures 13-1, 13-2; 16 added Figure 16-1
06/15/95	4.3.9 revised; 5.0 revised QA Manager title and Job Description; 8.7, 8.8, Figures 8-1, 8-2 revised, 9.0 updated Documentation Form, Figure 9A; 10.3 updated Lab. Mgr. title; 14 updated QA Mgr. & Lab. Mgr. titles; 19 revised; 22.3.2 revised; 23.3.1, 23.3.4, 23.3.5 revised
11/01/94	1.0 updated customer requirements; 2.0 revised header; 3.0 revised header; 20.0 revised header; added Appendix D
09/10/93	Added Appendix B, Appendix C
06/30/92	completely updated, added Appendix A
09/20/91	Revised
04/15/90	Revised
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## **INTRODUCTION**

This Quality Manual defines the quality system at NSL Analytical Services, Inc. in compliance with the intent of the quality system requirements of the following quality assurance or quality control programs where applicable: ISO/IEC 17025:2005(E), SAE AS 7101, ISO 10012-1, ANSI/NCSL Z540-1, 10CFR21, 10CFR50 Appendix B, 21CFR820, MIL-Q-9858A and MIL-STD-45662A.

This Quality Manual provides personnel and clients of NSL Analytical Services, Inc. with a description of company policy for maintaining an effective and economical quality assurance system planned and developed in conjunction with other management functions.

### **1. SCOPE**

- 1.1. The policy of NSL Analytical Services, Inc. is to apply the quality system to all testing and analytical activities undertaken on behalf of the client or an accrediting organization.
- 1.2. Written procedures for implementing the policies described herein are further detailed by the several sections that comprise this Quality Manual. These procedures are binding on all personnel of NSL Analytical Services, Inc. and shall be adhered to implicitly.

### **2. RELATED DOCUMENTATION**

- 2.1. ISO/IEC 17025:2005(E), General requirements for the competence of testing and calibration laboratories.
- 2.2. SAE AS 7101, National Aerospace and Defense Contractors Accreditation Program (Nadcap) General Requirements for Materials Testing Laboratory Accreditation Program.
- 2.3. ISO 10012-1, Quality assurance requirements for measuring equipment - Part 1: Metrological confirmation system for measuring equipment.
- 2.4. ANSI/NCSL Z540-1, Calibration Laboratories and Measuring and Test Equipment - General Requirements.
- 2.5. 10 CFR Part 21, Reporting of Defects and Noncompliance.
- 2.6. 10 CFR Part 50 Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.
- 2.7. 21 CFR Part 820, Food and Drug Administration (FDA), Department of Health and Human Services (DHHS), Quality System Regulation.
- 2.8. MIL-Q-9858A, Quality Program Requirements.
- 2.9. MIL-STD-45662A, Calibration System Requirements.

### **3. TERMS AND DEFINITIONS**

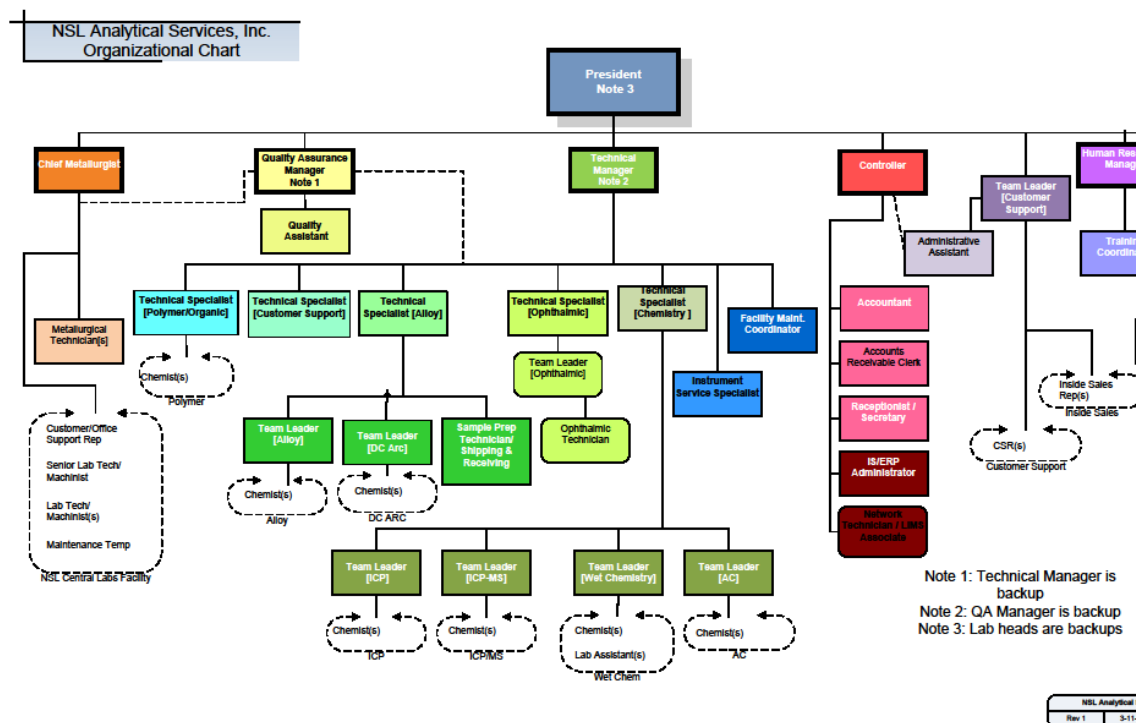
- 3.1. The document will reflect the relevant terms and definitions in the ISO/IEC 17000 and 17025:2005 Standards. For the purpose of this document, the terms "Quality System"

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and “Management System” may be used interchangeably. Quality Assurance Manager will be used in lieu of quality manager and the term “Client” will be used to describe any individuals or organizations that contract NSL Analytical Services, Inc. for use of our laboratory services.

#### 4. MANAGEMENT REQUIREMENTS

##### 4.1. Organization / Organizational Chart



4.1.1. NSL Analytical Services, Inc. is an incorporated in the State of Ohio organization and is owned the majority ownership is primarily by the senior management and technical personnel of NSL Analytical Services, Inc.

4.1.2. It is the responsibility of NSL Analytical Services, Inc. to carry out its testing and calibration activities in such a way as to meet the requirements of ISO/IEC 17025, and Nadcap the applicable portions of the documents listed in the Related Documents section of this Quality Manual, and to satisfy the needs of the client, regulatory authorities, and organizations providing recognition.

4.1.3. The quality system and this Quality Manual covers work carried out in NSL Analytical Services, Inc. permanent facilities, at sites away from permanent facilities, and in associated temporary or mobile facilities.

4.1.4. NSL Analytical Services, Inc. is an independent commercial testing laboratory and is not a part of any other manufacturing or service organization. NSL

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Analytical Services, Inc. personnel are free from any undue commercial, financial and other pressures which might influence their technical judgment. NSL Analytical Services, Inc. does not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its testing or calibration activities.

#### 4.1.5. Laboratory personnel, policies, procedures, and arrangements

- 4.1.5.1. Managerial and technical personnel, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures.
- 4.1.5.2. Procedure NSL 5046, Management and Personnel Arrangements defines the arrangements to ensure that management and personnel are free from any undue pressures or influences that may adversely affect the quality of their work.
- 4.1.5.3. Procedure NSL 5032, Client Confidentiality, and procedure NSL 5033, Report Protection, specifies methods used for protection of test reports to clients, specifies the methods used to ensure the protection of clients' confidential information and proprietary rights including methods for protecting the electronic storage and transmission of results. Procedure NSL 5036, Access to Laboratory, provides for control of personnel to laboratory facilities
- 4.1.5.4. Procedure NSL 5047, Competence, Impartiality, Judgment and Operational Integrity defines the techniques to avoid involvement in any activities that would diminish confidence in services provided by NSL Analytical Services, Inc.
- 4.1.5.5. The NSL Analytical Services, Inc. Organizational Chart depicts the relationships between quality management, technical operations, and support services. Quality has authority over all functions to assure compliance to the Quality Systems NSL is approved.
- 4.1.5.6. The President is responsible for directing, administering, and coordinating all duties in relation to the organization as well as all testing services of NSL Analytical Services, Inc. The President formulates, implements, and monitors overall corporate management systems, policies, and procedures and is responsible for ensuring creation and implementation of the strategic

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plan. The President has overall responsibility for the technical operations and the resources to ensure the required quality of laboratory operations.

- 4.1.5.7. The Quality Assurance Manager reports to the president and has the responsibility and authority for ensuring that the quality system is implemented and followed at all times. The Quality Assurance Manager is responsible for control of the Quality Manual and related procedures refer to NSL 5051, Quality Documentation and Records Control. The Quality Assurance Manager, in conjunction with the appropriate technical personnel and department managers, resolves quality problems, performs and coordinates quality audits, directs quality training, continuous improvement, lean principles, administers quality activities which contribute to achieving quality goals and objectives, maintains positive employee relations, standards of ethics and confidentiality and other assigned duties.
- 4.1.5.8. Duties, authority, and responsibilities of other management and personnel, such as the supervision of testing and calibration staff and the assessment of the test or calibration results, are defined in the respective Job Descriptions for each position.
- 4.1.5.9. Duties for key managerial personnel are defined in procedure NSL 5034, Deputies and Approved Signatories.
- 4.1.5.10. The management of the Quality System as described in this Quality Manual is the responsibility of the "Quality Team." The Quality Assurance Manager chairs the team. Additional members of the team are the Organizational Managers and the President, ensuring that the Quality Assurance Manager has direct access to the highest levels of management that defines NSL's policies, procedures and the allocation of company resources.
- 4.1.5.11. The Organizational Managers and the Section Supervisors assist in monitoring, record-keeping, statistical techniques, calibration, and other functions required by the Quality System. These people are the "designates." or "deputies" (Referred to as "deputies in the ISO/IEC 17025:2005 Standard.)
- 4.1.5.12. The Quality Team ensures that all NSL personnel are aware of the relevance and importance of each individual's activities and how they contribute to the achievement of the management system, its ultimate goal being superior customer satisfaction for NSL clients.
- 4.1.5.13. Top Management ensures that appropriate communication takes place within NSL, using such techniques as daily meetings. These meetings are attended by all department heads and are used to identify and address any

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issues that would deter from the effectiveness of the management system.

These meeting are documented on NSL's intranet.

## **4.2. Quality System**

- 4.2.1. NSL's quality system ensures that all policies, systems, programs, procedures and instructions are documented to assure the quality of our testing and/or calibration results. In addition, the quality system has established goals, objectives, and policies developed under the authority of the President of NSL Analytical Services, Inc. that applies directly to the scope of our activities with Nadcap, ISO/IEC17025 and others.
- 4.2.2. NSL Analytical Services, Inc. quality policy is reflected in our quality goals and objectives. These goals and objectives are evaluated during the management review. The quality goals and objectives of NSL Analytical Services, Inc. are:
- 4.2.2.1. To assure the accuracy and precision, as well as the reliability of the laboratory results produced for our clients, or at the request of regulatory or accrediting bodies. Administrative, management, investigative, preventative and corrective techniques will be employed to maximize reliability of the data.
  - 4.2.2.2. To put into service good professional methods, lean techniques and practices capable of meeting the user's needs for precision, accuracy and sensitivity.
  - 4.2.2.3. To ensure that all staff members and technical personnel receive training in quality technology, the provisions of this Quality Manual, and the workings of the quality system to assure continuous improvement in the areas of quality and customer satisfaction.
  - 4.2.2.4. To establish quality levels of the laboratory's routine performance as a baseline against which to measure the effectiveness of quality efforts.
  - 4.2.2.5. To make any changes in routine methodology found necessary to make it compatible with established performance needs.
  - 4.2.2.6. To monitor the routine operations performance of the laboratory through participation in inter-laboratory testing programs, when appropriate, and to provide for corrective actions as necessary.
  - 4.2.2.7. To comply with the requirements of the ISO/IEC 17025:2005 standard, our accrediting bodies, regulatory agencies and clients and to continually improve the quality system.
- 4.2.3. The top management of NSL Analytical Services, Inc. is committed to the development and implementation of the quality system and its continuous improvement. To ensure this, the following practices have been developed:

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- 4.2.3.1. Management of NSL Analytical Services, Inc. is committed to good professional laboratory practice and to the quality of testing services to clients.
- 4.2.3.2. Quality activities shall emphasize the prevention rather than detection of quality problems and the correction of problems after they occur.
- 4.2.3.3. All Employees engaged in making decisions affecting the quality of the laboratory output shall undergo training programs commensurate with their positions, duties, and responsibilities.
- 4.2.3.4. The laboratory shall use published analytical and test methods wherever available.
- 4.2.3.5. The laboratory shall retain copies of all test and analytical reports in a manner and for a period specified by our clients, regulatory or accrediting bodies.
- 4.2.3.6. The laboratory shall have a calibration program involving all instrumentation used for making determinations, the results of which are recorded.
- 4.2.3.7. The laboratory shall use appropriate, fresh reagents and chemicals, certified when necessary, and appropriate calibrated glass-ware.
- 4.2.3.8. The laboratory shall establish and maintain an inter-laboratory quality control system, as appropriate, to assure precision and accuracy of laboratory results.
- 4.2.3.9. The laboratory shall participate in an inter-laboratory testing program as appropriate, or as prescribed by an accrediting organization.
- 4.2.3.10. Any changes in key personnel or conformance to requirements specified by our clients, regulatory or accrediting bodies will require notification and approval of those clients and organizations that are affected by these changes.
- 4.2.3.11. All laboratory personnel concerned with testing and calibration activities are required to be familiar with the quality system and documentation and implement the policies and procedures in their work.
- 4.2.3.12. Management of NSL Analytical Services, Inc. is committed to compliance with the requirements of the applicable portions of the following standards: ISO/IEC 17025:2005(E), SAE AS 7101, ISO 10012-1, ANSI/NCSL Z540-1, 10 CFR 21, 10 CFR 50 Appendix B, 21CFR820, MIL-Q-9858A and MIL-STD-45662A.
- 4.2.4. Management of NSL Analytical Services, Inc. is committed to meeting customer requirements and communicates this daily during the documented planning meeting.

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4.2.4.1. Management of NSL Analytical Services, Inc. is committed to meeting safety, statutory and regulatory requirements and communicates this during daily documented planning meetings, management review and safety meetings.

4.2.4.2. This Quality Manual is supported by Procedures and Work Instructions, which are also part of the quality system.

4.2.4.3. The roles and responsibilities of management and the Quality Assurance Manager are defined in Section 4.1.5.

4.2.4.4. Changes to the management system shall be reviewed during management review to ensure the integrity of the management system is maintained.

#### **4.3. Document control**

4.3.1. Management of NSL Analytical Services, Inc (NSL) has developed a comprehensive document control plan as part of our quality system. It addresses, through the following procedures, document approval, issue, changes, and revisions of all regulations, standards, test and calibration methods, specifications, instructions and manuals. NSL maintains a quality system based on four levels of documentation. These are as follows:

Level 1: Quality Manual

Level 2: SOPs

Level 3: Work Instructions

Level 4: Forms and Records (Paper and electronic)

#### **4.3.2. Document approval and issue**

4.3.2.1. Procedure NSL 5045, Management of the Quality Manual, defines the tasks and responsibilities relating to the preparation, distribution, review and maintenance of the Quality Manual.

4.3.2.2. Procedure NSL 5051, Quality Documentation Forms and Records Control describes how the laboratory will:

- Control the issuance and retrieval of all documents relating to the analytical and testing activities of the laboratory;
- Control the quality of these activities; and
- Control the storage and security of technical documentation generated by these activities.

#### **4.3.3. Document Changes**

4.3.3.1. Procedure NSL 5011, Technical Document Change Notice describes the methods used to control changes to documents. Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise.

#### **4.4. Review of requests, tenders and contracts**

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4.4.1. Procedures NSL 5003, Sample Login and Procedure NSL 5024, Receiving Samples, define the methods used for the review of client requests, tenders, contracts, and purchase orders. The review ensures that:

4.4.1.1. The requirements and methods are adequately defined, documented and understood.

4.4.1.2. NSL Analytical Services, Inc. has the capability and resources to meet the requirements.

4.4.1.3. The appropriate test and/or calibration method is selected and capable of meeting the clients' requirements.

4.4.1.4. Any differences between the request and the contract shall be resolved before any work commences and that each contract shall be acceptable to both the laboratory and the client.

4.4.2. Records are maintained of the reviews, including any significant changes or pertinent discussions with the customer, and of modifications to the client requirements.

4.4.3. The review also includes any subcontracted work.

4.4.4. The client shall be notified of any deviation from the contract.

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

#### **4.5. Subcontracting of tests and calibrations**

4.5.1. Subcontracted tests and calibrations shall be placed with competent suppliers that are compliant with the requirements of the applicable quality system standard such as ISO/IEC 17025:2005(E), SAE AS 7101, or other similar standard. Refer to procedure NSL 5006, Standard Procedure for Subcontracting Samples.

4.5.2. NSL Analytical Services, Inc. will advise the client in writing, when their tests are subcontracted. When appropriate, client approval, preferably in writing, will be obtained for subcontracting of services. Procedure NSL 5006, Standard Procedure for Subcontracting Samples, defines the process for subcontracting samples.

4.5.3. NSL Analytical Services, Inc. is responsible to the client for the subcontractor's work, except in the case where the client or a regulatory authority specifies which subcontractor is to be used.

4.5.4. A record of the evidence of compliance with the applicable quality system standard is maintained for each approved supplier.

#### **4.6. Purchasing services and supplies**

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- 4.6.1. NSL maintains a procedure describing the requirements for the control of the quality of purchased services and supplies that affect the quality of tests and/or calibrations. It also includes the listing of approved services and supplies sources.
- 4.6.2. Purchased supplies, reagents, and consumable materials that affect the quality of tests and/or calibrations are not used until they have been verified as complying with specifications or requirements. Records of the verifications are maintained.
- 4.6.3. Procedure NSL 5009, Purchasing, defines the process for ordering services and supplies and the review and approval prior to release.
- 4.6.4. Procedure NSL 5055, Services and Supplies Procurement, Suppliers of critical consumables, supplies and services that affect the quality of testing and calibration are evaluated. Records of these evaluations are maintained.

#### **4.7. Service to the client**

- 4.7.1. NSL Analytical Services, Inc. is cooperative with clients, or their representatives, in clarifying the customer's request and in monitoring our performance in relation to the work performed. This includes informing the client of any delays or major deviations in the performance of tests or calibrations. Procedure NSL 5035, Client Notification - Potential Nonconforming Results, is used when client material potentially may not meet requirements, and procedure NSL 5028, Data Reporting-Nonconforming and Non Representative Tests is used when samples are suspected of being non-representative. These requests are complied with in a manner that ensures complete confidentiality in relationship to other clients.
  - 4.7.1.1. This cooperation may include the client or their representative reasonable access to relevant areas of our facility for the purpose of witnessing tests or calibrations performed for the client. Client access to relevant areas of the laboratory is provided as long as the provisions of procedure NSL 5036, Access to Laboratory and procedure NSL 5032, Client Confidentiality, are followed.
  - 4.7.1.2. This cooperation may include the preparation, packaging, and dispatch of test or calibration items needed by the client for verification purposes.
  - 4.7.1.3. Test records are be available to the client within 3 working days upon request of such request. Electronic test records are also available through our secure Customer Access Internet Portal.
- 4.7.2. NSL Analytical Services, Inc. encourages feedback from our clients, both positive and negative, through customer surveys. This feedback is used in conjunction with the corrective action process and management review to improve the overall management system, testing and calibration activities, and customer service

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#### **4.8. Complaints**

- 4.8.1. Resolution of complaints received from clients or other parties is performed per procedure NSL 5031, Client Concerns.
- 4.8.2. All complaints are investigated, corrective action taken when necessary, and records of the activities are maintained. (see also 4.11 of this document)

#### **4.9. Control of nonconforming testing and/or calibration work**

- 4.9.1. When testing and/or calibration work does not conform to NSL Analytical Services, Inc. procedures, standard test methods, or the agreed client requirements, it will be documented following procedure NSL 5005, Documentation of Nonconformance. This procedure does the following:
  - 4.9.1.1. Defines responsibilities for the management of nonconforming material and for the authorization for the resumption of work.
  - 4.9.1.2. Ensures evaluation of the nonconforming material.
  - 4.9.1.3. Ensures evaluation of the acceptability of the nonconforming material and makes sure correction is taken immediately.
  - 4.9.1.4. Ensures Quality is informed for determination if client notification is warranted.
- 4.9.2. Where the evaluation indicates nonconforming work or problems with the quality system, then the corrective action process given in 4.11 will be followed.

#### **4.10.Improvement**

- 4.10.1. The staff of NSL Analytical Services, Inc. continually improves the effectiveness of its quality system through continued use of our quality policy, quality objectives, audit results, data analysis, corrective and preventative actions, and lean methodologies verified through management review.

#### **4.11.Corrective action**

##### **4.11.1. General**

- 4.11.1.1. When nonconforming work or departures from the policies and procedures in the quality system or technical operations have been identified, corrective action is performed per procedure NSL 5049, Corrective Action.

##### **4.11.2. Cause analysis**

- 4.11.2.1. The corrective action process begins with a root cause analysis to determine the basis for the system discrepancy.

##### **4.11.3. Selection and implementation of corrective actions**

- 4.11.3.1. The next step in the corrective action process is the selection and implementation of corrective actions appropriate to the magnitude and risk of the problem.
- 4.11.3.2. The corrective actions are documented per NSL 5049 and any changes resulting from the corrective action are implemented.

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#### **4.11.4. Monitoring of corrective actions**

4.11.4.1. The implemented corrective actions are monitored for their effectiveness through the use of internal audits.

#### **4.11.5. Additional Audits**

4.11.5.1. NSL Analytical Services, Inc. conducts additional audits when a non conformity casts doubts regarding compliance with procedures.

#### **4.12. Preventive Action**

4.12.1. Preventive action is performed per procedure NSL 5050, Preventive Action. Needed improvements and potential sources of nonconformance are identified. When improvement opportunities are identified or preventive action is required, action plans are developed, implemented, and monitored to reduce the likelihood of the nonconformance and to take advantages of opportunities for improvement.

4.12.2. The preventive action procedure includes the initiation of such actions and application of controls to ensure that they are effective. Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

#### **4.13. Control of records**

4.13.1. Procedure NSL 5051, Quality Documentation and Records Control describes how the laboratory will:

4.13.1.1. Control the issuance and retrieval of all documents relating to the analytical and testing activities of the laboratory, and all documents relating to the quality system. These include internal audit reports, corrective and preventive actions and management reviews.

4.13.1.2. Control the storage and retrievability of the documents.

4.13.1.2.1. Establish retention times for the documents.

4.13.2. Control the storage and security of technical documentation generated by these activities.

4.13.2.1. NSL Analytical Services, Inc. uses follows Procedure NSL 5070 for backups of all information stored electronically. All information is protected by a restricted access password system and information is available within 3 working days.

#### **4.13.3. Technical Records**

4.13.3.1. In the case of electronic records, measures are taken to preserve the original data and prevent unauthorized access to or amendment of these records.

4.13.3.2. Written Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

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4.13.3.3. In case of an error in written records, the erroneous entry will be crossed out, but be left legible, the correct data entered along side of the original. The originator of the correction will sign or initial and date the record. Similar measures will be taken through electronic tracking to avoid the loss or change or original data stored in an electronic medium.

#### **4.14. Internal audits**

- 4.14.1. Procedure NSL 5044, Quality System Audits describes the conduct of internal audits and includes the audit check list. These audits verify that our operations comply with the requirements of the quality system and the international standards to which NSL Analytical Services, Inc. is certified to. It is the responsibility of the Quality Assurance Manager to plan and organize audits as required by the schedule and as requested by management. These audits will be carried out by trained and qualified personnel who are independent of the activity to be audited. Internal quality system audits are normally completed on one year cycles and address all elements of the quality system.
- 4.14.2. When audit findings cast doubt on the effectiveness of the operations or validity of results, corrective action shall be taken and documented, and clients shall be notified if laboratory results may have been affected.
- 4.14.3. The area of activity audited, the audit findings and corrective actions that arise from the audits shall be documented in accordance with procedure NSL 5044.
- 4.14.4. Follow-up audits will be conducted as a result of the corrective action process to verify and record the implementation and effectiveness of the corrective action taken.

#### **4.15. Management reviews**

- 4.15.1. The top management staff of NSL Analytical Services, Inc. has the responsibility for the annual review of the adequacy and the status of the quality system, and to introduce necessary changes or improvements. The management review takes account of:
  - 4.15.2. The suitability of policies and procedures;
  - 4.15.3. Reports from managerial and supervisory personnel;
  - 4.15.4. The outcome of internal audits;
  - 4.15.5. Corrective and preventive actions;
  - 4.15.6. Assessments by external organizations;
  - 4.15.7. Results of inter-laboratory comparisons and proficiency tests;
  - 4.15.8. Changes in volume and type of work
  - 4.15.9. Client feedback and complaints
  - 4.15.10. Recommendations for improvement
  - 4.15.11. Quality activities, resources, and staff training.

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4.15.12. Results of the management review and planned actions are documented. Management ensures that planned activities are carried out within the scheduled timescale.

## **5. TECHNICAL REQUIREMENTS**

### **5.1. General**

5.1.1. Many factors determine the correctness and reliability of the tests and/or calibrations performed by NSL Analytical Services, Inc. These factors include contributions from:

- 5.1.1.1. Personnel (human factors), see paragraph 5.2
- 5.1.1.2. Accommodation and environmental conditions see paragraph 5.3
- 5.1.1.3. Test and calibration methods and method validation, see paragraph 5.4
- 5.1.1.4. Equipment, see paragraph 5.5
- 5.1.1.5. Measurement traceability, see paragraph 5.6
- 5.1.1.6. Sampling, see paragraph 5.7
- 5.1.1.7. Handling of test and calibration items, see paragraph 5.8

5.1.2. The extent to which the factors contribute to the total uncertainty of measurement differs considerably between types of tests and between types of calibrations. NSL Analytical Services, Inc. takes into account these factors when developing test and calibration methods, in the training and qualification of personnel, and the selection and calibration of the equipment it uses.

### **5.2. Personnel**

5.2.1. NSL Analytical Services, Inc. ensures the competence of all personnel who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates.

5.2.1.1. Procedure NSL 5056, Personnel Training and Qualification describes the training and qualification methods.

5.2.1.2. Personnel responsible for the opinions and interpretations included in test reports also have appropriate experience and satisfactory knowledge of the testing carried out, relevant knowledge of the technology of the items being tested, general requirements of applicable legislation and standards, and an understanding of significance of deviations with regard to normal use of the items.

5.2.2. Training needs are identified for new personnel and as part of the performance review. Training needs include goals with respect to the education, training and skills of the laboratory personnel. The procedure for identifying training needs and providing training of personnel is included in procedure NSL 5056, Personnel Training and Qualification. The effectiveness of the training is evaluated through testing or supervised instrument operation.

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- 5.2.3. NSL Analytical Services, Inc. uses personnel who are employed by, or under contract to, the laboratory. If contracted and additional technical and key personnel are used, NSL Analytical Services, Inc. ensures that such personnel are supervised and competent and that they work in accordance with the quality system.
- 5.2.4. Current job descriptions are maintained for managerial, technical and key support personnel involved in tests and/or calibrations. The job descriptions include the following:
- 5.2.4.1. Responsibilities with respect to performing tests and/or calibrations.
  - 5.2.4.2. Responsibilities with respect to the planning of tests and/or calibrations and evaluation of results.
  - 5.2.4.3. Responsibilities for reporting opinions and interpretations.
  - 5.2.4.4. Responsibilities with respect to method modification and development and validation of new methods.
  - 5.2.4.5. Expertise and experience required.
  - 5.2.4.6. Qualifications and training programs.
  - 5.2.4.7. Managerial duties.
- 5.2.5. Management of NSL Analytical Services, Inc. authorizes specific personnel to perform particular activities including sampling, testing and/or calibration, issuing of test reports and calibration certificates, giving opinions and interpretations, and operating specific equipment.
- 5.2.5.1. For all technical personnel, including contracted personnel, records of the authorizations include competence, educational and professional qualifications, training, skills and experience, and the date on which the authorizations and/or competence is confirmed.

### **5.3. Accommodation and environmental conditions**

- 5.3.1. Technical requirements for accommodation and environmental conditions are documented in the applicable external standards or internal procedures and work instructions. Conditions include, but are not limited to, energy sources, lighting and environmental factors.
- 5.3.2. Environmental conditions which influence the quality of the results are monitored, controlled and recorded as required by the relevant specifications, methods and procedures. Tests and/or calibrations shall be stopped when the environmental conditions jeopardize the results.
- 5.3.3. For incompatible activities, there is effective separation to prevent cross-contamination.
- 5.3.4. Access to and use of areas affecting the quality of the tests and/or calibrations is controlled per procedure NSL 5036, Access to Laboratory.

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5.3.5. Measures are taken to ensure good housekeeping in the laboratory and are communicated by management to the employees.

#### **5.4. Test and calibration methods and method validation**

##### **5.4.1. General**

- 5.4.1.1. NSL Analytical Services, Inc. (NSL) uses appropriate methods and procedures for all tests and/or calibrations within its scope of services. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated. Where appropriate, statistical techniques are used to aid in the estimation or measurement uncertainty as well as aiding in the analysis of test and/or calibration data.
- 5.4.1.2. The quality system includes procedures and work instructions on the use and operation of all relevant equipment, handling and preparation of items for test and/or calibration, where the absence of such instructions could jeopardize the results.
- 5.4.1.3. NSL uses industry standard testing methods and does not develop testing methods except under the direction of the customer.

##### **5.4.2. Selection of methods**

- 5.4.2.1. Test and/or calibration methods are selected based upon the client requirements and are based upon consensus standards or client agreed methods. In each case, the current revision is used, unless the client specifies otherwise or unless it is not appropriate to do so.
- 5.4.2.2. When the client does not specify the method to be used, NSL Analytical Services, Inc. selects appropriate methods from laboratory generated procedures or from consensus standards and informs the client of the methodology used.
- 5.4.2.3. When the client proposes a method that is considered to be inappropriate or out of date, the client is notified.

##### **5.4.3. Laboratory-developed methods**

- 5.4.3.1. Development of laboratory methods are performed by qualified personnel, equipped with adequate resources, and the procedures are available to all personnel involved with the specific methods. A procedure documents the planned activity of developing internal test methods, including the means for updating the testing plans and communication amongst personnel involved in the plan development.

##### **5.4.4. Non-standard methods**

- 5.4.4.1. When it is necessary to use non-standard methods, these shall be subject to agreement with the client and will include clear specifications of the client's requirements and the purpose of the test and/or calibration.

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5.4.4.2. Non-standard methods shall have been validated before use.

5.4.4.3. New test and/or calibration methods are documented using a procedure or work instruction which includes: identification, scope, type of test item, equipment, reference standards, environmental conditions or other criteria or requirements for acceptance/rejection, the data to be recorded, and the uncertainty or procedure for estimating uncertainty.

#### **5.4.5. Validation of methods**

5.4.5.1. Test methods are validated by examination to provide evidence that they are suitable for the specific intended uses. Where standard methods are used, this confirmation is done by means of testing reference materials or following manufacturer's instructions.

5.4.5.2. Non-standard methods, laboratory developed methods, and standard methods used outside their intended scope are validated to confirm that they are fit for the intended use. Non-standard methods also must comply with the requirements of 5.4.4.2. NSL Analytical Services, Inc. uses one or a combination of the following techniques for the determination of the performance of a method:

5.4.5.2.1. calibration using reference standards or reference materials;

5.4.5.2.2. comparison of results achieved with other methods;

5.4.5.2.3. inter-laboratory comparisons;

5.4.5.2.4. Systematic assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

5.4.5.3. The extent to which methods are validated is based upon the client's needs, the range and accuracy required, and a balance of costs and risks.

#### **5.4.6. Estimation of uncertainty of measurement**

5.4.6.1. Procedure NSL 5065, Estimation of Uncertainty of Measurement, describes the methods for estimation of uncertainty of measurement for calibrations performed by NSL Analytical Services, Inc.

5.4.6.2. Procedure NSL 5065, also describes the methods for estimation of uncertainty of measurement for tests performed by NSL Analytical Services, Inc. In cases where well recognized or consensus test methods or standards are used, and the method specifies limits to the values of major sources of uncertainty of measurement, those values are deemed acceptable as long as the test method is followed and it meets the requirements of the client.

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5.4.6.3. When estimating the uncertainty of measurement, all uncertainty components which are of importance, and relevant to the specific method, are taken into account.

#### **5.4.7. Control of data**

5.4.7.1. Documentation and NSL 5063, Data Validation for additional information.

5.4.7.2. Where computers or automated equipment is used for acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, procedures NSL 5027, Computer Software - Storage, Handling and Access and NSL 5059, Software Quality Assurance define the methods used to protect the data, and to maintain the integrity and confidentiality of the data.

### **5.5. Equipment**

5.5.1. For the scope of services provided, NSL Analytical Services, Inc. is furnished with all items of sampling, measurement and test equipment required for the correct performance of tests and/or calibrations.

5.5.1.1. Refer to the NSL 3000 Series, NSL Calibration Procedures and NSL 4000 Series, Instrument Parameters for additional information on specific instruments.

5.5.1.2. When equipment outside of the permanent control is used, NSL Analytical Services, Inc. ensures that the requirements of the applicable standards are met.

5.5.2. Equipment and software used for testing, calibration, and sampling is capable of achieving the accuracy required and conforms to the requirements of the relevant specifications.

5.5.2.1. Before being placed in service, equipment and software is calibrated or checked to establish that it meets applicable requirements.

5.5.2.2. Refer to the NSL 3000 Series, NSL Calibration Procedures for additional information on specific instruments and procedure NSL 5027, Computer Software - Storage, Handling and Access for information on software control.

5.5.3. Equipment is operated by authorized personnel and tests and calibrations are performed in accordance with internal procedures, work instructions, and standard test methods that are readily available for use by the appropriate personnel.

5.5.4. Each item of equipment and its software used for testing and calibration that is significant to the results is uniquely identified, when practicable.

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- 5.5.5. Records are maintained for each item of equipment and its software used for testing and calibration that is significant to the results. The records include at least the following information:
- 5.5.5.1. The identity of the item and its software.
  - 5.5.5.2. The manufacturer's name, model, serial number or other unique identification.
  - 5.5.5.3. Verification that the item complies with applicable specifications.
  - 5.5.5.4. The current location, where appropriate.
  - 5.5.5.5. Manufacturer's instructions, if available or reference to their location.
  - 5.5.5.6. Dates, results and copies of certificates of all calibrations, adjustments, acceptance criteria, and the due date of the next calibration.
  - 5.5.5.7. The maintenance plan, if maintenance is required and maintenance history. Procedure NSL 5061, Preventive Maintenance, describes the process for planned maintenance.
  - 5.5.5.8. Any damage, malfunction, modification or repair to the equipment.
- 5.5.6. The majority of instruments used at NSL Analytical Services, Inc. are normally stationary. For instruments which are portable, methods for safe handling, transport, storage and use are described in the applicable instrument procedure(s) and work instruction(s).
- 5.5.7. Equipment that has been subjected to overloading or mishandling, gives suspect results, has been shown to be defective, or is outside specified limits, is taken out of service and clearly labeled.
- 5.5.7.1. Prior to returning the equipment to service, it is repaired and/or calibrated as described in 5.5.2.1.
  - 5.5.7.2. The effects of the equipment on test and calibration results is examined and if results were adversely affected, procedures NSL 5035, Client Notification – Potential Nonconforming Results and NSL 5049, Corrective Action are followed.
- 5.5.8. Whenever practicable, all equipment under the control of NSL Analytical Services, Inc. is labeled or otherwise identified to indicate the calibration status of the equipment.
- 5.5.9. When equipment goes outside the direct control of NSL Analytical Services, Inc., the function and calibration status is checked and found to be satisfactory before the equipment is returned to service.
- 5.5.10. When intermediate checks are required to maintain confidence in the calibration status of equipment, these checks are carried out in accordance with the procedures and work instructions for the specific equipment.

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5.5.11. Where calibrations give rise to a set of correction factors, the procedures and work instructions for the specific method and equipment ensure that the factors are updated and applied, for example in computer software.

5.5.12. Test and calibration equipment, including both hardware and software is safeguarded from adjustments which would invalidate the results.

## **5.6. Measurement traceability**

### **5.6.1. General**

5.6.1.1. All equipment used for tests and/or calibrations which has a significant effect on the accuracy or validity of test results is calibrated before being placed in service. These calibrations are carried out in accordance with the procedures and work instructions for the specific equipment.

### **5.6.2. Specific requirements**

#### **5.6.2.1. Calibration**

5.6.2.1.1. Where possible, all measuring, test, and calibration equipment is traceable through an unbroken chain of calibrations or comparisons to the International System of Units (SI) (Système international d'unités) or by reference to a natural constant, the value of which is known.

5.6.2.1.2. Where traceability of measurements to SI units is not possible and/or not relevant, traceability is to certified reference materials, agreed methods, and/or consensus standards

5.6.2.1.3. NSL Analytical Services, Inc. participates in a suitable program of inter-laboratory comparisons where possible

### **5.6.3. Reference standards and reference materials**

#### **5.6.3.1. Reference standards**

5.6.3.1.1. Reference standards are calibrated by a body that can provide traceability as described in 5.6.2.

5.6.3.1.2. Reference standards are used for calibration only, unless it can be shown that their performance as reference standards would not be invalidated. They are calibrated before and after any adjustment.

#### **5.6.3.2. Reference materials**

5.6.3.2.1. Reference materials, where possible, are traceable to SI units of measurement or to certified reference materials.

#### **5.6.3.3. Intermediate checks**

5.6.3.3.1. When intermediate checks are needed, they are performed in accordance with defined procedures and schedules.

#### **5.6.3.4. Transport and storage**

5.6.3.4.1. Additional procedures for reference standards and reference materials are given in NSL 5062, Reference Standards, which also includes

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procedures for safe handling, transport, storage, and use of reference standards and reference materials.

## **5.7. Sampling**

- 5.7.1. "Where sampling is required for subsequent testing, NSL shall maintain a sampling plan and procedures defining the process for selecting a representative sample. The sampling plan, whenever reasonable, shall be based upon proper statistical methods, and shall describe factors to be controlled to ensure the validity of test results."When the client requires deviations from the documented sampling procedures, these are documented and included in all documents containing test and/or calibration results, and are communicated to the appropriate personnel.
- 5.7.2. NSL shall record relevant data from sampling operations. These records include the sampling procedure used, identification of the person performing the sampling, and other relevant information including environmental conditions.

## **5.8. Handling of test and calibration items**

- 5.8.1. Procedure NSL 5024, Receiving Samples, describes the methods used when receiving samples.
- 5.8.2. Procedure NSL 5052, Sample Handling, Storage, and Shipping includes provisions for sample integrity, shipments of samples that are returned to the client, sample identification, and sample storage.
- 5.8.3. Procedure NSL 5052 also defines methods to be used when samples are received for testing. This includes checking sample integrity, and in the event of damage, notification of the client.
- 5.8.4. Procedure NSL 5052 includes the methods for avoiding deterioration, loss or damage during sample handling, storage, and shipping.

## **5.9. Assuring the quality of test and calibration results**

- 5.9.1. The monitoring of the validity of tests and calibrations is documented, and where practicable, statistical techniques are used for analysis of the data and identification of trends. This monitoring may include, but is not limited to the following:
- 5.9.1.1. Regular use of standard reference materials (SRM), certified reference materials (CRM), and secondary reference materials.
  - 5.9.1.2. Participation in inter-laboratory comparison and proficiency testing programs, refer to procedure NSL 5013, Round Robins/ QA Samples.
  - 5.9.1.3. Replicate tests using the same or different methods.
  - 5.9.1.4. Retesting or recalibration of retained items.
  - 5.9.1.5. Correlation of results for different characteristics of an item.

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5.9.2. Quality control data is analyzed and, when found to be outside of predefined criteria, corrective action is taken to correct the problem and to prevent incorrect results from being reported.

## **5.10. Reporting the results**

### **5.10.1. General**

- 5.10.1.1. The results of each test or calibration carried out by NSL Analytical Services, Inc. is reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the method and as required by the client.
- 5.10.1.2. The results are reported, usually in a test report or a calibration certificate and include all information requested by the client and necessary for the interpretation of the results and information required by the method used.

### **5.10.2. Test reports and calibration certificates**

- 5.10.2.1. Test reports and calibration certificates include a title, unique identification, the name of the client; description of the item(s) tested or calibrated results and identification of the person authorizing the report.
- 5.10.2.2. Refer to procedures NSL 5004, Lab Reports, and NSL 5028, Data Reporting-Nonconforming and Non Representative Tests for additional requirements.

### **5.10.3. Test reports**

- 5.10.3.1. In addition to the requirements listed in 5.10.2, test reports shall, where necessary for the interpretation of the test results, include the following:
  - 5.10.3.1.1. Deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions.
  - 5.10.3.1.2. Where relevant, a statement of compliance or non-compliance with requirements and/or specifications.
  - 5.10.3.1.3. Where applicable, a statement on the estimated uncertainty of measurement.
  - 5.10.3.1.4. Where appropriate, opinions and interpretations.
  - 5.10.3.1.5. Additional information as required by the specific method, standard or client.
- 5.10.3.2. In addition to the requirements listed in 5.10.2, calibration certificates shall, where necessary for the interpretation of calibration results, include the following:
  - 5.10.3.3. The date of the sampling

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- 5.10.3.4. Unambiguous identification of the substance, material or product sampled, including the name of the manufacturer and types of designation or serial numbers as appropriate.
- 5.10.3.5. The location of the sampling, including any diagrams, sketches or photographs.
- 5.10.3.6. References to the sampling plans and procedures used.
- 5.10.3.7. Details of any environmental conditions during sampling that may affect the interpretation of the test results.
- 5.10.3.8. Any standard or other specifications for the sampling method or procedure, deviations, and additions to or exclusions from the specification concerned.

**5.10.4. Calibration certificates**

- 5.10.4.1. In addition to the requirement listed 5.10.2, calibration certificates include the following for the interpretation of calibration results when necessary.
  - 5.10.4.1.1. The conditions under which the calibrations were made that have an influence on the measurement results.
  - 5.10.4.1.2. The uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clause.
  - 5.10.4.1.3. Evidence that the measurements are traceable.
- 5.10.4.2. The calibration certificate relates to only to quantities and the results of the functional tests.
  - 5.10.4.2.1. When a statement of compliance is made omitting the measurement results and associated uncertainties, NSL Analytical Services, Inc. records the results and maintains them for possible future reference.
  - 5.10.4.2.2. If an NSL Client is unfamiliar with the analysis method, a customer service representative explains the analysis process to the client during the initial quote. This information includes the degree of uncertainty of the instrument analysis. When statements of compliance are made, the uncertainty of measurement is taken into account by the client.
- 5.10.4.3. When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment, if available, shall be reported.
- 5.10.4.4. NSL Analytical Services, Inc. calibration certificates do not contain any recommendation on calibration intervals except when agreed upon with the client or superseded by legal regulations.

**5.10.5. Opinions and interpretations**

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5.10.5.1. When opinions and interpretations are included NSL Analytical Services, Inc. documents the basis on which the opinions and interpretations have been made. These are clearly marked as such on the test report.

5.10.5.2. Interpretations and opinions may compromise, but not be limited to, the following:

5.10.5.2.1. Opinions on the statement of compliance/noncompliance of the results with the requirements.

5.10.5.2.2. Fulfillment of contractual requirements

5.10.5.2.3. Recommendations on how to use the results.

5.10.5.2.4. Guidance to be used for improvements

#### **5.10.6. Testing and calibration results obtained from subcontractors**

5.10.6.1. When the test report contains testing and calibration results obtained from subcontractors, these results are clearly identified.

5.10.6.2. When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the NSL Analytical Services, Inc.

#### **5.10.7. Electronic transmission of results**

5.10.7.1. Electronic transmission of results by telephone, facsimile or other electronic means is done in accordance with procedure 5644, Client Reporting and procedure NSL 5032, Client Confidentiality, which include methods for protecting the transmission of results.

#### **5.10.8. Format of reports and certificates**

5.10.8.1. The format of reports and certificates are designed to accommodate each type of test and are standardized as far as possible.

#### **5.10.9. Amendments to test reports and calibration certificates.**

5.10.9.1. Material amendments to test reports and calibration certificates after issue are made only in the form of a further document or data transfer, which includes a statement such as "Supplement to ..." When the test report is revised, a new report is issued that is uniquely identified and contains a reference to the original that it replaces.

## **6. REFERENCED DOCUMENTS**

6.1. Consult NSL's Controlled Document Master List for a current and complete listing of all controlled documents [procedures, work instructions, forms] referenced in this Quality Manual.