QUALITY MANUAL

Revision March, 2015

Approved: _____

President

Approved: _____ Approved: _____

Technical Director – NSL Analytical

Site Leader – NSL Metallurgical

Approved: _____

Quality Assurance Manager

Quality Manual Revisions

Date	Revision
3/15/15	Removed references to "Central Testing" and previous Transportation Blvd. location. Additional minor changes from 9/11/13 and 11/10/14 document reviews. Added applicable quotations from ASME NQA--1:2008 with 2009 Addenda, and NSL responses. Changed content and references to comply with new revision of Nadcap MTL audit checklist, AC7101/1 Rev. F.
09/14/12	Per ACLASS audit non-conformance, added NSL site addresses to QSM.
08/15/12	Complete re-write of document, based on combined requirements of ISO 17025, Nadcap AC7101/1, and 10 CFR Part 50 Appendix B. New System Manual also serves as basis for complete re-write of procedures. (Revision not released externally.)
03/11/10	Various revisions not documented by then-current quality manager.
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

04/15/89 Revised

04/15/88 Revised

04/08/87 Revised

09/30/86 Revised

03/31/86 Revised

09/15/85 Revised

03/15/85 Revised

09/15/82 Revised

This Quality System Manual pertains to all NSL Analytical Services, Inc. sites. These sites are located:

NSL Analytical
4450 Cranwood Parkway
Cleveland, OH 44128

NSL Metallurgical
4535 Renaissance Parkway
Cleveland, OH 44128

Throughout this document, the actual text of ISO 17025:2005 is reproduced in Arial font, Nadcap AC7101/1 Rev. F (intellectual property *and copyright* of PRI / SAE; *used with permission*) is reproduced in Rockwell font, 10 CFR Part 50 Appendix B (Aug. 28, 2007) is reproduced in Californian font, and ASME NQA-1-2008 with 2009 Addendum is reproduced in Calibri font. NSL Analytical responses to these requirements, and references to related procedures, are made in the Times New Roman font, (in blue for easy distinction).

Customers are always welcomed and encouraged to tour NSL. During regular business hours, NSL is always open to visits from customers or regulatory representatives (FDA, NRC, etc.) to tour, observe testing, or review records related to testing. All tours have an NSL host and customer confidentiality will be maintained during visits. Advanced notice of visits is always preferred, but not required.

Through a mass email, NSL Analytical will inform active customers of revisions to the Quality Assurance System Manual (available on request through the NSL external web site: http://www.nslanalytical.com/), changes in facility location, changes in key management staff, and changes in accreditation status (renewed certificate, etc.). Please note that distributed copies of this manual will not contain the actual text of ISO 17025 or ASME NQA-1 (for copyright reasons), but only the section headers. The text of AC7101/1 *Rev. F* is reproduced under kind permission of Scott Klavon, Director of Nadcap Program and Aerospace Operations, received *January 28, 2014*. All sections of the CFR are public documents and therefore reproducible when appropriately referenced.

NSL does not provide any calibration services. Therefore, references and requirements regarding calibration service providers in ISO 17025 do not apply to NSL.

The NSL Quality Management System does not explicitly address the nuclear-facility-specific Part II or "non-mandatory guidance in Part III" of ASME NQA-1: 2008 / 2009. Any requirements invoked by an NSL customer from these "Parts" will be considered customer-specific requirements.

Regarding customers in the pharmaceutical or nutraceutical industries who must comply with FDA requirements: NSL is not a captive QC lab. As such, requirements of 21 CFR Parts 111, 210, 211, and related do not directly apply. Any requirements in these documents that pertain to general lab practices (competence of personnel, validation of methods, calibration of equipment, preservation of records, etc.) are met or exceeded by the general QMS requirements defined or referenced in this document.

Regarding specifications referenced in previous editions of NSL-1:

Z540-1 applies only to calibration service providers and not to testing labs. Therefore, it is not appropriate for NSL Analytical (per NCSLI comparison of Z540-1 to ISO 17025).

Per research, MIL-STD-45662A (Calibration Systems Requirements) was cancelled in 1995, directing parties to Z540-1 and 10012-1. Z540-1 is applicable to calibration service providers only, not to testing labs. 10012-1 was superseded in 2003 by 10012. Per Dilip Shah (industry consultant and ASQ Fellow), any applicable content in 10012:2003 is addressed in 17025, so we do not need to list / apply these requirements in addition to 17025. MIL-Q-9858A (Quality Program Requirements) was cancelled without replacement (or direction to another document, except general direction to ISO/ANSI QMS requirements) in 1996.

4 Management requirements

4.1 Organization

NSL Analytical Services, Inc. (known throughout this document as "NSL") is a legally responsible entity (not a "captive lab"). Please see SOP 4.1 for details.

4.1.2

AC 7101/1 2.1 The laboratory demonstrates compliance to an acceptable quality system as defined in NOP-002. Nadcap Materials Testing Laboratories recognizes existing quality systems approvals in the form of ISO/IEC 17025 certifications by an ILAC Approved source (www.ilac.org).

As documented in this manual, NSL will meet the requirements of ISO 17025, and maintain accreditation through a ILAC approved accrediting body.

Nadcap Notification Requirements

AC 7101/1 2.3 Procedure(s) are used to ensure Nadcap notification in accordance with NIP 7-04: Nadcap will be notified of any changes to the content on form number t-frm-11 "Notification of change/request for revised certification".

As documented in this manual, NSL will meet the requirements of ISO 17025, applicable Nadcap checklists, and applicable sections of 10 CFR. As they are flowed down by NSL customers, additional accreditation or regulatory requirements are addressed through customer or market-specific Work Instructions. Please see SOP 4.1 for details.

The Quality Assurance Manager is responsible for advising PRI of significant changes to QMS documentation or key personnel. Please see SOP 4.1 for details.

ASME NQA-1, Part I ; 200

NSL Analytical Services, Inc. does not generate nuclear power, manage a reactor, or process nuclear fuel. As such, NQA-1 only applies to NSL as flowed down by customers in the nuclear industry, and much of NQA-1 is not applicable to NSL. NQA-1 specifically requires that "applications of this Part, or portions thereof, shall be invoked by written contracts, policies, procedures, specifications, or other appropriate documents." NSL expects customers to invoke those sections of NQA-1 that customers determine applicable. NSL, through this QMS, will describe what we have determined to be applicable through our own estimation. Not applicable sections of NQA-1 have been omitted from this document. Please see NQA-1, Part I Introduction, Section 400 for official NQA-1 terms and definitions.

4.1.3.

This manual addresses the work carried out at NSL permanent facilities. At the time of issue of this document, NSL only conducts off-site services on a very limited basis. Please see SOP 4.1 for details.

4.1.4

NSL is an independent, impartial, testing lab (third-party). It is the responsibility of NSL to provide objective results to customers that are accurate to the limits of our processes. Managers and decision makers are restricted in any business relationship that could potentially contribute to a conflict of interest. Technicians and analysts do not regularly communicate directly with customers to ensure their independence. Instead, customer communication is provided through Customer Support and, on technical issues, the Technical Specialists. Please see SOP 4.1 for details.

4.1.5 a)
NSL personnel across the organization take responsibility for the quality and accuracy of analyses and tests, and for the constant improvement of the quality management system. Analysts, team leaders, and Technical Specialists review each test to ensure that applicable instructions were followed and that results are reasonable. All non-conformances are documented through the Laboratory Information Management System (LIMS) and reviewed. Where appropriate, actions are taken to reduce the potential for a reoccurrence. Please see SOP 4.1 for details.

4.1.5 b)
See 4.1.4, above.

4.1.5 c)
NSL recognizes its responsibility to protect customer information. When requested, management representatives sign non-disclosure agreements to protect NSL and customer intellectual property. Electronic data systems are secured with limited access to protect information, and information is distributed only to contacts and addresses provided to NSL by the customer. Please see SOP 4.1 for details.
All hard copies that contain customer-sensitive data are shredded either immediately after use (special secure bins available throughout NSL) or after their defined retention period. Please see SOP 4.7 for details.

4.1.5 d)
See 4.1.4, above.

4.1.5 e)
The NSL organizational structure is defined in the current organizational chart. The chart includes relationships between sites and departments, including quality, technical, and support functions.

4.1.5 f)
All functional roles in NSL are represented on the organizational chart and described in corresponding job descriptions.

4.1.5 g)
All technicians and analysts work under the supervision of an experienced, competent Technical Specialist or Manager. Until competence has been demonstrated, all trainees work under the direct supervision of an experienced technician or analyst.

4.1.5 h)
At each site, a Technical Manager (or similar) is invested with the responsibility for ensuring that instruments, equipment, environment, and personnel are appropriate, capable, and competent for all tests offered.

4.1.5 i)
NSL has a management-level Quality Assurance Manager, as indicated on the organizational chart. The Quality Assurance Manager is responsible for the implementation, maintenance, accreditation, compliance, and improvement of the quality management system. The Quality Assurance Manager has direct access to the President of NSL, should this be necessary to address a quality or resource related issue.

4.1.5 j)
The defined duties of any person listed on the organizational chart may be carried out by the person that they report to, including approvals and other quality management system duties. More specific deputies / substitutions are defined in SOP 4.1. Use of electronic signatures is also addressed in SOP 4.1.

4.1.5 k)
All persons at NSL are made aware of the Quality Policy Statement, and how the statement relates to their responsibilities. Responsibilities, including duties that affect quality, are mentioned in job descriptions and detailed in SOPs, Work Instructions, and Methods applicable to that position.

4.1.6
The management team holds regular "all-hands" meetings where performance to key business metrics is reviewed. The Quality Assurance Manager will report on issues essential to the QMS, as these issues arise. In addition, the Quality Assurance Manager regularly communicates with NSL staff regarding internal and external audits, management reviews, etc. Please see SOP 4.1 for details.

AC 7101/1 5.1 ‡The Q.A. function in the laboratory has stop-work/stop-ship authority.

AC 7101/1 5.5 The Q.A. function has authority to require the implementation, extension or modification of internal technical documents.

NSL has a management-level Quality Assurance Manager, as indicated on the organizational chart. While the "QA function" at NSL is distributed through the company, the Quality Assurance Manager is ultimately responsible for compliance to the QMS. As described in section 4.14, the Quality Assurance Manager is responsible for the internal audit system. As a manager with access to the President, the Quality Assurance Manager may stop progress of testing or the issue of a test report. This authority is also delegated to the Technical Manager (or site-similar) and Technical Specialists performing tech review of test data. See also 4.1.5 i., above regarding responsibility for the QMS. The Quality Assurance Manager reviews all documents prior to issue or revision, including technical documents, and may request changes. See section 4.3.

10 CFR Part 50 Appendix B; I. Organization, The applicant[1] shall be responsible for the establishment and execution of the quality assurance program.... The authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components shall be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance functions are those of (1) assuring that an appropriate quality assurance program is established and effectively executed; and (2) verifying, such as by checking, auditing, and inspecting, that activities affecting the safety-related functions have been correctly performed. The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. These persons and organizations performing quality assurance functions shall report to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program at any location where activities subject to this appendix are being performed, shall have direct access to the levels of management necessary to perform this function.

[1] While the term "applicant" is used in these criteria, the requirements are, of course, applicable after such a person has received a license to construct and operate a nuclear power plant or a fuel reprocessing plant or has received an early site permit, design approval, design certification, or manufacturing license, as applicable. **These criteria will also be used for guidance in evaluating the adequacy of quality assurance programs in use by holders of** construction permits, operating licenses, early site permits, design approvals, combined licenses, and **manufacturing licenses**.

As indicated elsewhere in this section, the President is ultimately responsible for meeting customer expectations, communicated through the organization as appropriate. Responsibility for the function of the QMS has been delegated to the Quality Assurance Manager (see 4.1.2 and 4.1.5 i.). Reporting relationships are indicated in the organizational chart and specific duties and responsibilities are mentioned in job descriptions and detailed in SOPs, Work Instructions, and Methods applicable to that position. Other requirements in this paragraph are addressed in sections 4.1.2, 4.1.4, and 4.1.5, above.

10 CFR Part 50 Appendix B; II. Quality Assurance Program, The applicant shall establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a quality assurance program which complies with the requirements of this appendix. This program shall be documented by written policies, procedures, or instructions and shall be carried out throughout plant life in accordance with those policies, procedures, or instructions.... Activities affecting quality shall be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanness; and assurance that all prerequisites for the given activity have been satisfied. The program shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by

inspection and test. The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. The applicant shall regularly review the status and adequacy of the quality assurance program.

As indicated in 4.1.2, the QMS defined in this document meets applicable requirements of 10 CFR Part 50 Appendix B, as they would apply to an independent testing lab performing testing services for customers who are in the nuclear power plant supply chain. Controlled conditions, including training and inspection, are addressed in sections 5.1 – 5.5. The "status" and "adequacy" of the QMS are regularly reviewed through audits (section 4.14) and management review (4.15).

ASME NQA-1, REQUIREMENT 1

See 4.1.5a., e., f., h., and i.,above.
The Quality Assurance Manager meets these responsibilities. See 4.1.5,above.
(1) Usually identified by Account Managers or Technicians, and documented with Client Concern Reports or Non-conformance Reports. See section 4.9.
(2) Once problems are identified and documented, they are resolved through the with Client Concern or Non-conformance systems. See section 4.9.
(3) Representatives of the Quality Department are responsible for reviewing and approving verification of solutions. See section 4.9.
(4) Holding of test reports until non-conformances are resolved is addressed in section 4.9.

ASME NQA-1, REQUIREMENT 1, 202

See 4.1.5.j.,above.

4.2 Management system

4.2.1

The NSL QMS is documented through this System Manual, related Standard Operating Procedures (SOPs), Work Instructions (WIs) and specific preparation and analysis Methods. As indicated elsewhere in this document, these documents are approved, controlled, and made accessible to the people who need to use them. Use of these documents assures the quality of test results.

ASME NQA-1, REQUIREMENT 5, 100

NSL maintains SOPs, WIs, and Methods with sufficient detail and, where applicable, criteria for acceptance, to ensure accurate and repeatable sample preparation and testing performance. See SOP 4.3 Document Control for descriptions of NSL's QMS documents.

4.2.2 a) – e)

This document is the NSL Quality System Manual. As indicated in the Quality Statement, business and quality objectives are maintained through the key performance indicators.

NSL QUALITY STATEMENT (Approved by Lawrence A. Somrack, President, January 17, 2012)
NSL's goal is to provide quality material testing evaluations which consistently meet or exceed our customers' expectations. The NSL Quality Management System is the foundation for delivering the highest customer satisfaction in our industry. We are committed to the following principles:

- Trust
  - Consistently provide accurate and repeatable results as measured by our customers' satisfaction
- Technology
  - Continuous investment in people, processes, instrumentation, and equipment that ensures industry-leading effectiveness
- Turnaround
  - On-time delivery in all phases of our business as measured against our customers' requirements

Our very professional, highly skilled workforce is trained to the highest standards and follows the processes defined in our Quality Management System. We utilize all available resources to continuously improve our quality, health, and safety management systems in support of all of our certifications, accreditations (e.g. ISO 17025 and Nadcap) and customer requirements. We measure our success (objectives) on our ability to meet or exceed our key performance indicators (KPI) that are aligned to our corporate strategic goals on a continuous basis.

Everyone at NSL is familiar with the essentials of the quality policy statement (three principles / aims) and their contribution to quality of results and satisfaction of the customer.

4.2.3
The President and management team demonstrate commitment to the NSL QMS by supporting third-party accreditation of the quality management system. Commitment to continuous improvement is demonstrated through regular management review meetings (section 4.15) and awareness of corrective actions, and internal, customer, and accreditation audits.

4.2.4
The President and management team have ensured that pertinent customer and regulatory requirements are communicated through the documents of the QMS. The LIMS and, where appropriate, customer or industry-specific work instructions communicate customer and industry specific requirements clearly and effectively through the organization.

4.2.5
Where appropriate, this manual makes reference to specific procedures (SOPs). The structure of the documentation, including technical Work Instructions or Methods, is addressed in 4.2.1.

4.2.6
Roles and responsibilities of the Technical Manager, Quality Assurance Manager, and all staff at NSL, including responsibilities for quality and the QMS, are defined in job descriptions.

4.2.7
As noted below in section 4.3, the Quality Assurance Manager reviews and approves any new document or revised document do not have any negative effect on the effectiveness of the system, or on compliance with the requirements that NSL is required to comply with.

ASME NQA-1, REQUIREMENT 2
See 4.1.5., 4.2.1.above, and 4.9, 4.15, 5.1, and 5.2 below.

4.3 Document control
AC 7101/1 8.11 ‡ Procedures are used to ensure technical revisions of standards publications (e.g. ASTM, EN, ISO and any other revision controlled documents used within test method procedures) in the laboratory's scope of accreditation are implemented/incorporated within six months from the date the standard/document is issued. A record of revision review is maintained which includes date of reference document revision, date of laboratory incorporation, brief summary of actions taken to demonstrate the revision review was completed.

10 CFR Part 50 Appendix B; V. Instructions, Procedures, and Drawings; Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

NSL has procedures that define control for the documents in the QMS, including documents of internal and external origin. The instructions in these documents are followed to ensure the quality of test results. As applicable, documents include criteria for acceptance or rejection of a sample preparation or analysis. Industry standards are considered a specific category of documents of external origin. They are reviewed quarterly to ensure that NSL is working to current versions, and any revisions are reviewed by Tech Specialists for their impact on NSL Methods. *Records of these reviews and their outcomes are maintained.* Please see SOP 4.3 and related Work Instructions for details.

4.3.2 Document approval and issue
4.3.2.1
NSL has procedures for definition of review, approval, control, and distribution of the documents of the QMS issued by NSL, or obtained from outside sources. Logs are maintained so that current revision status is ensured. "Document Owner" and approval parties are noted in the header of each SOP, WI, or Method. Please see SOP 4.3 and related Work Instructions for details.

AC 7101/1 8.1 Procedures are approved by the customer, when required.

Other than customer-supplied Methods, which are handled separately by NSL, no customers currently request to approve NSL test Methods. Customers are always welcome to visit NSL and review our written Methods on-site.

4.3.2.2 a) – d)

AC 7101/1 4.4 Current revisions of test procedures are used

4.3.2.3
Current documentation is made readily available to the people who need the documents. NSL has procedures that define how documents are authorized and distributed or made available for use, how they are reviewed, and how obsolete documents are recalled or identified. Each SOP, WI, and Method has a header at the top with a unique identifying number, an indication of the release version (revision letter or issue date), the "Document Owner," and reviewing / approving parties. Please see SOP 4.3 and related Work Instructions for details.

ASME NQA-1, REQUIREMENT 6, (a) – (e)
Identification, distribution, responsibilities, review, and assurance of correct document revision are all addressed in SOP 4.3. Also see 4.3.1 and 4.3.2 above.

4.3.3 Document changes
4.3.3.1 - 4.3.3.4

AC 7101/1 2.2 The following summaries are complete (format not cause for NCR, only content) – Personnel Summary, Procedure Summary, IRR / PT Summary

10 CFR Part 50 Appendix B; VI. Document Control, Measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality. These measures shall assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization.

All SOPs, WIs, and Methods are assigned a "Document owner." The "Owner" may or may not be the person who wrote the document, but it is the person most directly responsible for the performance of the content of the document. The "Owner" must approve the document initially, supervises regular reviews of the document, and approves any revisions. Changed text in revised documents is identified. Temporary, hand-written changes are allowed when authorized, and when a formal document change order is also in place. QMS documents are made available and controlled through the Electronic Document Management System. Maintenance of Nadcap *summaries (was Tables and Figures)* is provided by the Document Coordinator. Please see SOP 4.3 and related Work Instructions for details.

ASME NQA-1, REQUIREMENT 6, 300 - 302
NSL does not distinguish between minor and major changes. See 4.3.3, above.

4.4 Review of requests, tenders and contracts

4.4.1 a) – c)

NSL maintains procedures for review of customer quotation requests, and review of paperwork provided with samples (submission documents). When requests are received, they are carefully reviewed to ensure customer requirements and expectations are clearly defined. Once defined, NSL ensures that we have the proper method and capacity to meet the customer's need. Any tests that need to be subcontracted are clearly communicated to the customer (see 4.5). If there is any question about NSL's ability to perform a test that meets the customer's expectations, this is addressed with the customer before the quote is issued or sample accepted. Please see SOP 4.4 and related Work Instructions for details.

AC 7101/1 8.3 A procedure is used to review the requirements presented to the laboratory, however defined. The procedure addresses:

- how the requirements are assessed
- how the requirements are effectively communicated to the laboratory
- how the laboratory determines if the requirements can be met

As noted above, NSL has a written procedure to review requirements, determine if requirements can be met, and communicate the requirements to the laboratory via the LIMS. Please see SOPs 4.4 and 5.8.1.

4.4.2

Review of customer requirements is documented by Account Managers (for a quote) or Customer Support (for submission). Records of conversations with customers are captured in the CRM database and where appropriate noted in the LIMS. Please see SOP 4.4 and related Work Instructions for details.

4.4.3

As noted in 4.4.1, any tests that need to be subcontracted are clearly communicated to the customer (see 4.5). Please see SOP 4.4 and related Work Instructions for details.

4.4.4 - 4.4.5

The customer is informed and approval is received before any changes are implemented to a quotation or acknowledged sample submission. This includes subcontracting a test due to capacity constraints or instrument availability.
If the customer wishes a change when a quotation has been issued, the request is reviewed and, if acceptable to NSL, the quotation is revised. If the customer wishes a change after a sample submission has been acknowledged, the Account Manager and perhaps a technical representative discuss the proposed change with the customer. If the change is something that NSL can accommodate, the change is entered in the LIMS to be communicated with all affected technicians and staff. Please see SOP 4.4 and related Work Instructions for details.

4.5 Subcontracting of tests and calibrations

4.5.1

NSL maintains a list of approved testing subcontractors. The list is maintained by the quality department and all subcontractors added or removed are approved by the Quality Assurance Manager. Criteria for initial approval and periodic review of subcontractors is defined. All subcontracted testing is arranged with a source on the approved subcontractor list. Please see SOP 4.5 for details.

No tests are subcontracted for customers who indicate "nuclear safety" or "10 CFR Part 21 compliance" on their purchasing documents, unless explicit approval has been received from the customer and the subcontractor has been subject to additional flow-down requirements. Please see Work Instruction NUCLEAR for details.

AC 7101/1 7.1 ‡Subcontractor evaluation is based on Nadcap accreditation, customer qualification list or at least 3 of the following:

- Documentation and initial survey
- 100% inspection of product/service
- Sampling inspection of product/service
- Periodic on-site survey by the Q.A. function

When subcontractors are selected for Nadcap-approved testing, only subcontractors who are themselves Nadcap approved, and who have the specific test in their scope, are selected for the test. Where Nadcap approval is not a customer requirement, subcontractors are selected based on ISO 17025 accreditation or other approval criteria. Please see SOP 4.5 for details.

4.5.2
When NSL intends to subcontract a test and this is known at the quoting stage, the intent to subcontract one or more tests is clearly indicated on the quote. Reference to the quote in the customer's purchasing documents is seen as acceptance of the subcontracted testing arrangement. When a test is to be subcontracted after sample acceptance, usually for a capacity constraint, a representative of NSL Customer Support will contact the customer and seek approval prior to subcontracting the test. Please see SOP 4.5 for details.

4.5.3
NSL assumes responsibility for the accuracy and on-time delivery of all subcontracted tests. If NSL does not approve of a subcontractor required by a customer, NSL will not take the job.

4.5.4
NSL maintains a list of approved testing subcontractors. When subcontractors have ISO 17025 accreditation, current certificates and scopes are maintained and reviewed to ensure a specific test is within the range of their scope. If a subcontractor does not have ISO 17025 accreditation, additional approval criteria is defined, and the subcontractor is subject to a higher level of surveillance. Please see SOP 4.5 for details.

AC 7101/1 5.7 ‡The Q.A. function participates in the organization or planning of subcontractor selection and survey.

See 4.5.1, above.

AC 7101/1 7.2 Access to subcontractor facilities is provided to the laboratory for quality audits if requested.

NSL flows down the requirement to all subcontractors that the subcontractor will be open to audits when requested. Please see SOP 4.5 for details.

AC 7101/1 7.3 Applicable quality assurance requirements specified in the contract are transmitted to subcontractors.

NSL flows down applicable customer requirements to subcontractors through the purchasing documents. Please see SOP 4.5 for details.

AC 7101/1 10.2 Transfer of work outside the laboratory for sub-contracted processes is performed in accordance with procedures which ensure (1) traceability of documents/records with test articles is maintained and (2) verification that work performed was in accordance with purchase order requirements.

NSL provides sufficient documentation with the submission to the subcontractor to maintain traceability to the unique NSL submission and sample identification numbers. Documentation is reviewed prior to release of the sample to the subcontractor. *Results from subcontractors are reviewed prior to release to customer.* Please see SOP 4.5 for details.

Any samples sent to a subcontractor for subcontract preparation or testing are uniquely identified and packaged so as to reasonably protect against damage or contamination. Please see SOPs 5.8 and 4.5 for details.

Returned samples are packaged so as to reasonably protect against damage or contamination. Please see SOP 5.8 for details.

In all cases, any shipped sample is shipped in accordance with applicable hazardous material packaging and identification requirements. Remnants of hazardous material samples are disposed of through licensed, qualified disposal sources. Please see SOP 5.8 for details.

4.6 Purchasing services and supplies

4.6.1

NSL has written procedures for the purchase of any materials or services that have a direct effect on the quality of test results. Please see SOP 4.6 for details.

4.6.2

All purchased supplies and reagents are confirmed prior to use. Any supply that does not meet requirements is documented in a non-conformance report. Please see SOP 4.6 for details.
Certified Reference Materials are inspected and confirmed as well. Please see SOP 5.1 for details.

4.6.3

Standard, general requirements for suppliers are documented in an NSL supplier requirements document. This includes any applicable flow-down requirements from major customers or regulatory / accreditation requirements that pertain to NSL. This document is referenced in NSL purchase orders placed for products or services that affect test quality. Specific requirements, like grade, purity, etc. are listed directly on the purchase order. Purchase orders are reviewed for completeness and accuracy prior to release to the supplier. Please see SOP 4.6 for details.

4.6.4

NSL has defined criteria to select and approve suppliers of products and services that affect test quality. All approved product and service providers are listed on the Approved Supplier List, maintained under the authority of the Quality Assurance Manager. Please see SOP 4.6 for details.

ASME NQA-1, REQUIREMENT 7, 200 (a) – (c)

For products or services that have a direct influence on test quality, NSL only purchases from suppliers on the Approved Supplier List. These suppliers are approved for a specific scope, in a way that is appropriate for the product or service that is to be received. See 4.6.4, above.

ASME NQA-1, REQUIREMENT 7, 300

For products or services that have a direct influence on test quality, NSL only solicits quotations or purchases from suppliers on the Approved Supplier List.

10 CFR Part 50 Appendix B; IV. Procurement Document Control; Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this appendix.

NSL purchase orders and the supplier requirements document adequately communicate applicable requirements to NSL suppliers. Please see 4.6.3, above.

10 CFR Part 50 Appendix B; VII. Control of Purchased Material, Equipment, and Services, Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. Documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear power plant or fuel reprocessing plant site prior to installation or use of such material and equipment. This documentary evidence shall be retained at the nuclear power plant or fuel reprocessing plant site and shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services

This requirement is largely not applicable to NSL, as NSL does not provide any products that will be shipped to a nuclear power plant or fuel reprocessing plant. However, NSL does qualify suppliers initially according to defined criteria and regularly evaluates suppliers. Please see 4.6.4, above. NSL also reviews purchased product prior to use. Please see 4.6.2, above.

ASME NQA-1, REQUIREMENT 4, 100
NSL provides sufficient detail in purchasing documents to ensure that proper requirements are defined. Since NSL does not subcontract testing for safety related applications, flow-down of NQA-1 (or 10 CFR Part 21 or 10 CFR 50 Appendix B) does not apply. See 4.6.2 and 4.6.3, above.

ASME NQA-1, REQUIREMENT 4, 200 - 201
Statement of work is only applicable when NSL is purchasing calibration services. See WI Dedication of Commercial Grade Items or Services for details.

ASME NQA-1, REQUIREMENT 4, 202
NSL Purchase Orders describe materials or services to be purchased in sufficient detail to ensure that NSL is provided with materials or services that meet our needs for testing. Since NSL provides testing services and does not ship parts or products, drawings and elaborate specifications are not necessary to accurately communicate NSL's needs to their suppliers. See SOP 4.6 for details.

ASME NQA-1, REQUIREMENT 4, 203
When NSL approves a supplier, a significant part of that approval process is evaluating the supplier's quality management system, and perhaps third party approval or accreditation, as it pertains to the intended product or service to be purchased. When NSL requires specific quality system requirements or accreditations, like ISO 17025 accreditations for providers of calibration services for instance, these requirements are communicated on the NSL purchase order. See SOP 4.6 Purchasing and 4.6wi 1Dedication of Commercial Grade Items or Services for details.

ASME NQA-1, REQUIREMENT 4, 204
NSL defines its "right of access" expectations in the Supplier Requirements Document, which must be reviewed and accepted by the supplier before NSL will add them to the Approved Supplier List (for any products or services that directly affect the quality of testing).

ASME NQA-1, REQUIREMENT 4, 205
When specific documentation is required, this is addressed in the NSL purchase order (usually provided at the time of delivery of product or service). When NSL has specific requirements for supplier record retention, these are addressed in the Supplier Requirements Document.

ASME NQA-1, REQUIREMENT 4, 206
Reporting of non-conformances is addressed in the Supplier Requirements Document.

ASME NQA-1, REQUIREMENT 4, 207
Since NSL does not ship parts or products, identification of spares is largely N/A to NSL. When NSL requires spare or replacement parts for instrument maintenance, this are identified and stored in a way to ensure that they are used for their intended purpose.

ASME NQA-1, REQUIREMENT 4, 300
NSL purchase orders are reviewed for accuracy and adequacy prior to issue. See 4.6.3, above.

ASME NQA-1, REQUIREMENT 4, 400
NSL purchase orders, if changed, are reviewed similarly to initial issue, prior to re-issue. See SOP 4.6 for details.

ASME NQA-1, REQUIREMENT 7, 100
NSL does not perform source inspection. Otherwise, see 4.6, above.

ASME NQA-1, REQUIREMENT 7, 400
After review and approval, NSL retains documents from suppliers in a way appropriate to the product or service obtained. See SOP 4.6 and SOP 4.3 for details.

ASME NQA-1, REQUIREMENT 7, 500 -501
All items purchased for use in preparing or testing samples are approved prior to use. See 4.6.2, above. Certificates for calibration services are reviewed and approved before the calibration is accepted. See SOP 4.6 and SOP 5.5 for details. Any items or services that do not meet expectations are documented in a non-conformance report.

ASME NQA-1, REQUIREMENT 7, 502
As appropriate, NSL performs verification of materials or services prior to use. See 4.6.2, above. Since NSL is not a nuclear facility site, Certificate of Conformance, source verification, and post installation test are not performed by NSL.

ASME NQA-1, REQUIREMENT 7, 503 (a) - (f)
NSL does not request certificates of conformance.

ASME NQA-1, REQUIREMENT 7, 504
NSL does not perform source verification.

ASME NQA-1, REQUIREMENT 7, 505 (a) – (e)
NSL verifies purchased materials prior to use. See 4.6.2, above.

ASME NQA-1, REQUIREMENT 7, 506
NSL does not rely on post installation verification of purchased materials. See 4.6.2, above.

ASME NQA-1, REQUIREMENT 7, 507 (a) – (c)
are adequately reviewed and approved. See SOP 4.6 for details.

ASME NQA-1, REQUIREMENT 7, 600, (a) – (b), (b) (1) –(4) and (c) – (e)
Since NSL provides testing services and does not ship parts or products, NSL addresses supplier non-conformances in a way appropriate to the materials purchased for testing purposes. Requirements are communicated to NSL suppliers through the Supplier Requirements Document.

ASME NQA-1, REQUIREMENT 7, 700
Purchase of commercial grade items and services is addressed in 4.6wi 1, WI Dedication of Commercial Grade Items or Services.

ASME NQA-1, REQUIREMENT 7, 800 (a) – (d)
Appropriate records of purchasing processes are maintained. See SOP 4.6, 4.6wi 1, and SOP 4.3, section 13.

4.7 Service to the customer

4.7.1

NSL recognizes that its sole purpose is to accurately determine, effectively communicate, and reliably meet the expectations of its customers. As addressed in section 4.4, Requirement Review, NSL personnel carefully review all quotation requests and sample submissions to ensure that we clearly understand the customer's expectation. If there are any questions (request differs from previous requests, customer references an obsolete version of an industry specification, etc.), NSL personnel will contact the customer and clarify the issue before processing the quotation or sample. NSL monitors its own performance through internal reporting systems (see SOP 4.15, Management Review), and through communication received from the customer, to ensure that customer expectations are met. Customer feedback, including surveys, is reviewed formally through the management review system (see 4.15 and SOP 4.15), and assessed through a number of means.
NSL maintains the confidentiality of customer information, as addressed in SOP 4.1. With appropriate notice, customers are welcome to visit NSL for tours, auditing, or process observation purposes. Where appropriate, competent members of the NSL staff provide professional opinion and advice to customers. When it becomes apparent that NSL will not meet the acknowledged date for test results, an NSL representative will contact the customer with a response plan. See SOP 4.7 for details.

4.7.2
Customer feedback is gathered by formal and informal exchanges with customers and communicated through the sales and customer support teams to upper management. Surveys are conducted among customers and the results reviewed for ways to improve (see SOP 4.15). All customer concerns are logged in the Concern system in the LIMS and processed through the Review Group, chaired by the Quality Assurance Manager. Where appropriate, client concerns can been rolled into formal corrective actions. See SOP 4.7 for details.

4.8 Complaints
As noted in 4.7.2, above, all customer concerns are logged in the Concern system in the LIMS and processed through the Review Group, chaired by the Quality Assurance Manager. Where appropriate, client concerns can been rolled into formal corrective actions. See SOP 4.7 for details.

4.9 Control of nonconforming testing and/or calibration work
4.9.1 a) – e)
NSL has a number of systems to address non-conformances. Non-conformances in testing method or suspect results are documented through the Non-Conformance system in the LIMS. These may be initiated at any point in a lab process, and must be reviewed and closed by a Technical Specialist. Results are not reported to the customer until the report is closed. Where appropriate, the Quality Assurance Manager is contacted to assist with resolution of the issue. Please see SOP 4.9 for details.

The non-conformance reports are reviewed in summary by top management at least quarterly to identify trends and look for proactive ways to improve lab processes. Please see SOP 4.15 for details.
Customer complaints are captured and responded to through the Client Concern system. Please see SOP 4.7 for details.
Non-conformances from internal audits are managed through the internal audit system. Please see SOP 4.14 for details.
Non-conformances from external audits, and any issue that is considered to have appropriate significance is escalated to a formal corrective action, and is managed through the Improvement Report System. Please see SOP 4.10 for details.

4.9.2
As indicated in 4.9.1, above, where appropriate, the Quality Assurance Manager is contacted to assist with resolution of a non-conformance, and these may be escalated to the Improvement Report system. Please see SOP 4.9 for details.

AC 7101/1 6.5 Operators are trained to recognize a properly executed analysis or test, to distinguish between valid and invalid test data, and to justify invalidating data.

Operators are trained to recognize properly executed analyses and tests, and to recognize valid from invalid data, as defined in the lab Work Instructions and Methods. Training is documented in individual Competency Lists. Justifying invalid data is addressed in SOP 4.9.

AC 7101/1 11.1 ‡ Procedures are used to ensure RETESTS allowed by material or customer specification, are performed in accordance with the material or customer specification.

Please see SOP 4.9 for details.

AC 7101/1 11.1.1 ‡ Unless otherwise specified, procedures are used to ensure a minimum of three RETESTS per NON-CONFORMING TEST-RESULT are performed and reported.

For NSL Materials, any out-of-tolerance result is confirmed with three re-tests via the same method, including re-prepping of samples in each case. The reported result is the average of the initial and repeated tests. For NSL Metallurgical, since most tests are destructive of the sample, *additional specimens are prepared to conduct three additional tests (where material is available).* Please see SOP 4.9 for details.

AC 7101/1 11.2 ‡ Procedures are used to ensure replaced tests are recorded and cross-referenced with the original tests, including explanations where applicable.

All non-conforming or repeated tests (including legitimate out-of-tolerance results) are documented and associated with the original tests *in the LIMS*. All tests are reviewed and approved. Please see SOP 4.9 for details.

AC 7101/1 11.3 ‡ Procedures are used to ensure records of replaced tests are reviewed periodically for trends which could indicate test process deterioration. Procedure(s) are used to respond to defined criteria for test process deterioration which requires corrective action.

All non-conformance reports generated by the lab are reviewed. Instances of corrective action are addressed, and where trends are identified, improvement projects are implemented. Please see SOP 4.9 for details.

AC 7101/1 12.1 ‡ Procedures are used to ensure errors in testing are assessed. The laboratory reports errors in testing in accordance with the time period that is required by the customer.

Any error in testing identified by NSL after the test report has been released will result in a revised test report being sent to the customer, with a technical explanation provided. Additional provisions may apply if the testing was safety related. Please see SOP 4.9 for details.

10 CFR Part 50 Appendix B; XV. Nonconforming Materials, Parts, or Components, Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations....

It is NSL's responsibility to clearly indicate on a customer's test report when a sample meets or does not meet specification requirements, when specification compliance is communicated to NSL. It is the responsibility of NSL's customer to act on information received. (i.e. Identify, segregate, and disposition "non-conforming" materials represented by NSL test results.)

ASME NQA-1, REQUIREMENT 15, 100

It is NSL's responsibility to clearly indicate on a customer's test report when a sample meets or does not meet specification requirements, when specification compliance is communicated to NSL. It is the responsibility of NSL's customer to act on information received. (i.e. Identify, segregate, and disposition "non-conforming" materials represented by NSL test results.)
Management of non-conforming test results is addressed in 4.9, above.
Any materials or services received by NSL that are determined to be non-conforming are identified and not used. See section 4.6, above.

4.10 Improvement

NSL utilizes the tools identified in 4.10 to improve the QMS. The quality policy and its use is addressed in section 4.2.2. Quality objectives, audit results, analysis of data, and review of corrective and preventative actions are addressed in Management Review, section 4.15.
Corrective Action Reports, Preventative Action Reports, and Continuous Improvement Initiatives are all maintained through the Improvement Report system. See SOP 4.10 for details.

4.11 Corrective action

4.11.1 General

4.11.2 - 4.11.5

10 CFR Part 50 Appendix B; XVI. Corrective Action, Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

The Quality Assurance Manager reviews client concerns, lab non-conformances, internal and external audits, management team input, and formal customer corrective action requests to determine when to open a corrective action report. All corrective actions are assigned a unique number and their status is tracked through the Improvement Report Log. The corrective action form, by design, leads the responsible party through containment, determination of applicability of Part 21, identification of root cause, determination of corrective action, determination of a plan to determine effectiveness, and verification of effectiveness by a member of the Quality department. Where appropriate, the corrective action and plan to determine effectiveness may include a limited-scope internal audit. Top management regularly reviews all Improvement Reports. See SOP 4.10 for details.

ASME NQA-1, REQUIREMENT 16, 100
NSL maintains a robust corrective action system to identify and correct conditions adverse to quality, and determine if Part 21 applies. See section 4.11, above.

4.12 Preventive action
4.12.1 - 4.12.2
The management team and quality assurance manager review lab non-conformance and client concern data to determine opportunities for preventative action. See SOP 4.15 for details.
Review of customer requirements (SOP 4.4) often leads to preventative measures that are documented and communicated through the LIMS.
Assessment of measurement uncertainty often presents opportunities for process improvement or preventative action. See Work Instruction 5.4.6.
The Quality Assurance Manager determines when to open a formal preventative action report. These reports reflect the format of the corrective action report (described in 4.11) and are maintained in the Improvement Report Log to ensure that improvements are identified and implemented. All Improvement Reports include a "preventative action" section to encourage application of "lessons learned" in a pro-active, preventative fashion. See SOP 4.10 for details.

4.13 Control of records
4.13.1 General
4.13.1.1 - 4.13.1.2
NSL maintains QMS records, including records of internal audits, management reviews, and improvement reports. Records are retained for defined minimum retention periods, according to SOP 4.3, section 13.

AC 7101/1 4.1 Records are available to the customer upon request within three working days.

AC 7101/1 4.2 A procedure is used to control records (technical data and test reports) generated by the laboratory in compliance with customer requirements including record retention policy.

Requested records can be provided upon customer request within three business days. Test reports are maintained in the LIMS indefinitely and can be reproduced on request. *Technical data supporting tests is maintained either in the LIMS or in some other permanent storage location.* See SOP 4.3, section 13 for additional record retention instructions.

4.13.1.3 - 4.13.1.4
All records at NSL that are specific to a customer, either in hardcopy or electronic copy, are secured within NSL and disclosed only to the identified customer. Network storage locations are restricted by log-in password. Electronic records in the LIMS and on the network are password protected to restrict access. Please see SOP 4.1 (confidentiality) for details. All electronic records and the LIMS are regularly backed up. Please see SOP 5.4.7 for details.

10 CFR Part 50 Appendix B; XVII. Quality Assurance Records, Sufficient records shall be maintained to furnish evidence of activities affecting quality. The records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Records shall be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.

NSL's record retention exceeds the requirements of 10 CFR Part 50, Appendix B, Section XVII, as defined in SOP 4.3, section 13. Record identity and retention are also addressed in SOP 4.3, section 13.

ASME NQA-1, REQUIREMENT 17, 100
NSL maintains records to document its activities, and to provide evidence that the processes of the business and quality system are functioning properly. See section 4.13.1, above.

ASME NQA-1, REQUIREMENT 17, 200 (a) – (c)
See section 4.13.1, above.

ASME NQA-1, REQUIREMENT 17, 300 (a) – (b), (b) (1) – (2)
NSL test reports are authenticated by the inclusion of the signature of a technical representative of NSL. See section 5.10, below. All other records are "authenticated" by process of issue. NSL does not maintain a system of stamps or formal initials for common QMS records. When it is important to know who generated or approved a record, this is captured in the record itself.

4.13.2 Technical records
4.13.2.1

AC 7101/1 4.3 Records (technical data) are maintained, traceable to each certification, such that the laboratory could reproduce the test method or identify incorrectly tested material..

4.13.2.2 - 4.13.2.3
NSL retains records of all significant operators and data related to preparation and analysis. Records are created as processes are completed. Most of these records are retained by submission and sample number in the LIMS. The remaining data is preserved in log books or on backed-up instrument hard drives. All "technical data" is retained indefinitely, along with digital copies of test reports. Data verifications are captured in the LIMS by password log-in. Corrections to records are made by line-out and initial / date in ink, or by password-protected operator identification and time stamp. Please see SOP 4.3, section 13 for details.

ASME NQA-1, REQUIREMENT 17, 400 (a) – (d), 401.1 (a) – (d), and 401.2
NSL has no way of knowing what the end use is of any material tested by NSL. Since this is the case, NSL retains all technical data indefinitely (section 4.13.2, above.).

ASME NQA-1, REQUIREMENT 17, 402, and 700 (a) – (b)
Records of QMS processes, and other records defined in the NSL SOPs are retained according to the retention times and locations defined in the Record Retention Log.

ASME NQA-1, REQUIREMENT 17, 500
NSL does not receive records so much as generate records. Any significant data or paperwork received from the customer that describes the material to be tested or other customer expectation is scanned and saved in the secure LIMS. This data is retained indefinitely. NSL has defined processes for storing records off-site. See SOP 4.3 for details.

ASME NQA-1, REQUIREMENT 17, 601 (a), (1)-4), (b) – (d)
Records are organized and retained in a way that minimizes loss or destruction. Records are kept in restricted-access buildings with suitable environmental control. When records are stored off-site, services are selected that maintain appropriate safety and protection of the records. See section 4.13.1.

ASME NQA-1, REQUIREMENT 17, 602 - 602.1
Records considered essential to NSL's technical data or evidence of the function of NSL's Quality Management System that are maintained only in hard copy are retained when not in use in facilities with a certified minimum two-hour fire rating.

ASME NQA-1, REQUIREMENT 17, 602.2
NSL scans QMS and technical data records and stores these files on a server that is daily backed up to the sister NSL facility, thus retaining these records in "dual facilities."

ASME NQA-1, REQUIREMENT 17, 603
NSL does not make use of "temporary storage of records." At the end of each day, any hard-copy-only record is stored in a cabinet with a minimum two-hour fire rating.

ASME NQA-1, REQUIREMENT 17, 800 (a) – (f), (f) (1) – (2)
Preservation and maintenance of records is addressed in 4.13, above, and SOP 4.3.

4.14 Internal audits

4.14.1
The Quality Assurance Manager maintains an internal audit procedure and schedule. Internal audits will be performed to all significant accreditation or regulatory requirements as defined in the system manual (currently ISO 17025, Nadcap, 10 CFR Part 50 Appendix B, and ASME NQA-1) and the applicable NSL QMS documentation. The internal audit scope includes all labs and sites within NSL, and all audit criteria is audited at least once per year. This includes all applicable Nadcap "commodity" checklists. The Quality Assurance Manager plans and conducts audits with the assistance of a trained internal audit team, diverse enough to ensure that auditors are independent of the process audited. Please see SOP 4.14 for details.

AC 7101/1 2.4 Self-Audit was completed with references which will satisfy all audit criteria in all applicable checklists in the current audit scope.

NSL will complete internal audits to all applicable Nadcap checklists as part of the annual internal audit cycle. Audit records will clearly show relationship between Nadcap audit criteria and NSL documents.

ASME NQA-1, REQUIREMENT 18, 100
NSL has an effective internal audit program and NQA-1 requirements, as applicable to NSL, are included in the annual internal audit cycle. See 4.14.1, above, regarding the program and 4.14.3, below, regarding follow-up action.

ASME NQA-1, REQUIREMENT 18, 200
An annual schedule for internal audits is maintained. See 4.14.1, above.

4.14.2
If an audit determines that previously issued test results are suspect, an investigation is initiated and documented. If it is determined that test results should be revised, the revised reports are sent to all affected customers, along with an explanation for the revision. Please see SOP 4.14 for details.

4.14.3
All internal audits, any substantiated non-conformances, and follow-up actions are documented. Non-conformances that cannot be resolved in a reasonable period of time will be rolled into corrective actions for tracking. Please see SOP 4.14 for details.

4.14.4
All non-conformances will be reviewed in a future internal audit to verify implementation and effectiveness of corrective action taken. Review will be documented in a future internal audit report, and / or a corrective action report if one has been assigned. If appropriate, the Quality Assurance Manager may call for a special re-audit of the process or related processes. Please see SOP 4.14 for details.

AC 7101/1 6.2 Qualification of laboratory personnel includes documented periodic "observations of test" to assess the employee's compliance to procedures used for Nadcap test codes.

As noted in section 4.14.1 above, the internal audit system includes all applicable Nadcap "commodity" checklists. Internal audits include audits of preparation and testing processes, and the technicians performing these processes. Please see SOP 4.14 for details.

AC 7101/1 2.6 A minimum of three job audits were performed by the PRI auditor. Within the job audits, all methods were reviewed.

As noted in section 4.14.1 above, the internal audit system includes auditing to all applicable Nadcap requirements. This includes "job audits" that trace the process from the receipt of the customer's requirements to delivery of a test report. Please see SOP 4.14 for details.

10 CFR Part 50 Appendix B; XVIII. Audits, A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Follow-up action, including re-audit of deficient areas, shall be taken where indicated.

As noted in sections 4.14.1 – 4.14.4 above, NSL conducts comprehensive internal audits, according to written procedures, using trained, independent lead auditors. All audit reports are reviewed by the management team and top management (see also 4.15). Corrective actions are documented and verified, and all aspects of the quality system are re-audited at least annually.

ASME NQA-1, REQUIREMENT 18, 301
The Lead Auditor writes the audit plan and scope and schedules the Audit Team prior to the audit. See SOP 4.14 for details.

ASME NQA-1, REQUIREMENT 18, 302
While in the role of internal auditor, all NSL staff function under the direct authority of the Quality Assurance Manager. The Quality Assurance Manager has the authority and organizational freedom to ensure an objective (meaningful and effective) internal audit process. Only qualified lead auditors will audit NSL to NQA-1 criteria.

ASME NQA-1, REQUIREMENT 18, 303
The Lead Auditor is assigned prior to each audit and names the Audit Team in the audit plan (for NQA-1 audits, the lead auditor functions as the audit team). Auditors are trained to be effective in their capacity and records of training and competency reviews are maintained. See SOP 4.14 for details.

ASME NQA-1, REQUIREMENT 18, 400
The NSL internal audit program observes good audit practice, using trained and effective auditors. See SOP 4.14 for details. See section 4.14.3, above, regarding corrective actions.

ASME NQA-1, REQUIREMENT 18, 500 (a) – (d)
NSL audit reports are written by the audit team, with the documented review and approval of the Lead Auditor. NSL audit reports meet all the requirements of this section. See SOP 4.14 for details.

ASME NQA-1, REQUIREMENT 18, 600
All observations and non-conformances identified in the audit report are reviewed in the closing meeting (held with the supervisor of the function audited). Action items are identified and effective implementation is reviewed by a member of the Quality Department prior to audit report closure. See SOP 4.14 for details.

ASME NQA-1, REQUIREMENT 18, 700.
See "600 AUDIT RESPONSE," above.

ASME NQA-1, REQUIREMENT 18, 800
Appropriate records of the internal audit process are maintained. See SOP 4.14 and SOP 4.3 for details.

ASME NQA-1, REQUIREMENT 2, 303
The requirements for NQA-1 qualified lead auditors are defined and addressed in SOP 4.14.

ASME NQA-1, REQUIREMENT 2, 400 (a)
See comments in blue (for anyone performing testing or inspection of test data). Lead Auditor qualification and records is addressed in SOP 4.14.

(1) Addressed in NSL Competency Lists or in training records
(2) Addressed in NSL Competency Lists or in training records
(3) Addressed in NSL Competency Lists, or in the training matrix
(4) Addressed in NSL Competency Lists
(a) Addressed in NSL Competency Lists or in training records
(b) Addressed in NSL Competency Lists (participation in blind sample or IRR testing)
(c) Addressed in NSL Competency Lists
(5) Addressed in NSL Test Quality Plans (for PT and IRR requirements), and records of PT and IRR participation
(6) N/A to NSL
(7) Addressed in NSL Competency Lists or in training records
(8) Addressed in NSL Competency Lists or in training records. Recertification is not required when Technicians remain active in a specific lab.
(b) N/A to NSL

ASME NQA-1, REQUIREMENT 2, 500 (a) – (c)
NSL maintains records of training per section 4.13.1, above. Lead Auditor qualification and records is addressed in SOP 4.14.

4.15 Management reviews
4.15.1 - 4.15.2
The NSL Management Team, led by Top Management, conducts regular reviews of the performance of the company and the QMS. These scheduled reviews include evaluation of the suitability and effectiveness of our processes, and recommendations for improvement. The Management Review process addresses all items identified in 4.15.1 and *review of records as required by AC7101/1*. Records of meetings are captured, and action items are tracked and addressed. Please see SOP 4.15 for details.

5 Technical requirements
5.1 General
5.1.1

AC 7101/1 8.4 Procedures are used to ensure use of ASTM E 29 for rounding unless the method is otherwise stated in the certificate of test/test report.

AC 7101/1 8.5 Procedures define methods and test specifications used to perform data unit conversions.

Practices for conversion of units and rounding are addressed in the lab general practices, or if there is something unique, in specific Methods. Please see SOPs 5.1 and 5.1.1 for details.

5.1.2
The requirements listed in 5.1.1 are addressed below. Assessment and control of sources of variation, contributors to measurement uncertainty, are addressed in 5.4.6.

General practices observed across the labs are addressed in SOP 5.1. (Analytical) and SOP 5.1.1 (Metallurgical)

5.2 Personnel
5.2.1
Each role at NSL, including testing and approval roles, has a defined competency list. The competency list consists of necessary competencies, typical responsibilities, and required qualifications. When a new employee is hired, or if someone changes roles, that person works under direct supervision until fully approved by their supervisor. Supervisors document how each competence is met, either through education, experience, training, demonstrated skills, or some combination of

these. Once completed, competence records are maintained by the Training Coordinator. Along with general competency lists, each technician / analyst is also qualified and trained for each instrument / method / process. Performance must be reviewed and accepted by a supervisor (in the form of a training record) before a technician can work without direct supervision and sign off results in the LIMS. Please see SOP 5.2 for details.

NSL does not perform any NDT, and no regulatory or certification requirements pertain to roles at NSL. All competencies are defined and assessed by NSL.

Only personnel at NSL with significant knowledge or experience in their field have the background to offer interpretations or opinions.

AC 7101/1 5.6 ‡The Q.A. function oversees training and qualification of personnel.

The "quality function" is distributed to the management team, so that persons most familiar with requirements are responsible for verification of competencies. The quality department does perform audits of training during regular internal audits (see 4.14).

AC 7101/1 6.1 Qualification and training of laboratory personnel complies with laboratory quality manual and/or procedures, applicable customer requirements and is documented.

Qualification and training of laboratory personnel is addressed in SOP 5.2. As noted in that SOP, records of training are maintained.

AC 7101/1 6.4 Operators are trained to recognize proper operation of the equipment.

Operators are trained to recognize proper operation of the equipment, as defined in the lab Work Instructions and Methods. Training is documented in individual Competency Lists.

5.2.2
Working with the Human Resources Manager, managers and supervisors define plans for education and training based on the need to develop specific competencies in individuals. Needs may develop because NSL is planning to utilize new instruments / methods / applications, or to broaden the competence of a specific individual. Training is reviewed and approved for effectiveness by the supervisor / manager after training has been conducted. Please see SOP 5.2 for details.

AC 7101/1 6.6 If degreed personnel "or equivalent" are required, definition of "equivalent" is documented.

In job descriptions, when an equivalent is acceptable for specific training or education, the means of equivalence is defined. Please see SOP 5.2 for details.

AC 7101/1 6.3 Individual training records and supporting procedures indicate participation in inter-operator comparison as defined by the laboratory.

Qualifying a Technician for a new instrument / process / method includes participation in an internal round robin. Performance must be reviewed and approved by the Technician's supervisor, and records are maintained. *Participation in IRR is repeated over time per the NSL IRR schedule.* Please see SOP 5.2 *(initial) and SOP 5.9 (over time)* for details.

5.2.3
Contract or other personnel are treated as employees in the sense that they work under direct supervision until competence is approved and documented. See also section 5.2.1.

5.2.4
NSL competency lists generally fulfill the role of job descriptions, as described in section 5.2.1.

NSL keeps Nadcap-*compliant employee tables* up to date for persons performing tests or approval of data or test reports. As indicated in 5.2.1, above, training records are maintained by the Training Coordinator. Please see SOP 5.2 for details.

5.2.5
As indicated in section 5.2.1, all roles at NSL are defined with a competency list. Records of qualification and evaluation of competence are maintained by the Training Coordinator. Please see SOP 5.2 for details.

ASME NQA-1, REQUIREMENT 2, 200
See 5.2.1.,above.

ASME NQA-1, REQUIREMENT 2, 201
As with any department, members of the Quality Department are evaluated upon hire and effectively trained to meet the requirements of their responsibilities, as defined in Competency Lists. Technical Specialists who review and approve technical data are similarly trained and demonstrate proficiency. All NSL employees are instructed regarding their responsibilities regarding 10 CFR Part 21as defined in WI Nuclear. Please see SOP 5.2 for details.

ASME NQA-1, REQUIREMENT 2, 202
See 5.2.2.,above.

ASME NQA-1, REQUIREMENT 2, 300
See 5.2.1.,above. Nondestructive examination or testing (NDT) is not applicable to the services offered by NSL.

ASME NQA-1, REQUIREMENT 2, 302
See 5.2.1., and 5.2.2., above. Technical Specialists perform review and acceptance of test data, which is the primary "inspection" role at NSL. All technicians who perform sample preparation or testing are effectively evaluated and trained, or re-trained if their duties change.

5.3 Accommodation and environmental conditions
5.3.1
Lighting, and other infrastructure requirements are provided in a way suitable for testing. Temperature, humidity, and air quality are appropriately controlled and recorded. No testing is performed by NSL off-site. Please see SOP 5.3 for details.

5.3.2

AC 7101/1 3.1 Environmental conditions in the laboratory are in accordance with test technical requirements such as to facilitate correct performance of the tests and/or calibrations.

AC 7101/1 3.2 Environmental conditions are monitored, controlled and recorded as required. Test environment conditions are considered in creating test method procedures.

Environmental conditions are suitably controlled so as to not adversely affect testing, *and are in compliance with technical requirements.* When specific temperature *or humidity* controls are required by a testing specification or method, the temperature *and humidity* of the lab is recorded at the time of the test. Each lab has an approved temperature range. When these ranges are exceeded, or use of the instruments indicates that results are being affected, testing is halted until the temperature is returned to the proper range. *Lab environment is considered and addressed as appropriate in Work Instructions and Methods.* Please see SOP 5.3 for details.

5.3.3 - 5.3.5

AC 7101/1 3.3 Cleanliness of test area minimizes contamination.

Cleanliness of labs is maintained so as to not introduce contamination. Please see SOPs 5.1 and 5.1.1 for details.

AC 7101/1 3.4 Employees demonstrate compliance to applicable safety program.

All NSL facilities are arranged and constructed so as to physically separate incompatible processes. At NSL Metallurgical, sample preparation is separated from metallography. At NSL Materials, labs are separated by walls, doors, ventilation systems, and pressure gradients, and the physical sample preparation area is separated from the labs. Access to all NSL buildings, and therefore lab areas, is controlled by a fob-driven security system that controls access. Appropriate cleanliness and organization are practiced in each lab and enforced by the area Tech Specialist. NSL has a Safety Officer, Safety Committee, and a documented safety program. Please see SOP 5.3 for details.

AC 7101/1 3.5 ‡ Facility operations affecting specific testing – Procedures ensure notification of customers in the event of interruption due to power outage or equipment failure that has an effect on the test results.

If a power interruption or other environmental condition adversely affects testing, NSL will document the adverse condition in the test report. Please see SOP 5.3 for details.

5.4 Test and calibration methods and method validation

5.4.1

Handling and protection of samples is addressed in 5.8, below. Method measurement uncertainty is addressed in 5.4.6, below. Where specific instructions are required for the handling, preparation, or testing of samples, NSL has written, accessible, controlled Methods. Changes to Methods are reviewed by appropriate parties through the Technical Document Change Process. Deviations to written Methods are only allowed if approved by a Technical Specialist (see 4.3.3 regarding document changes). Please see SOP 5.4 for details.

AC 7101/1 9.1.7 Controlled, written procedure(s) exist for detailed testing methods.

Specific, detailed Methods are documented, available, and used in the lab for testing. Please see SOP 5.4 for details.

AC 7101/1 8.7 Procedures are used to ensure all software programs and equipment automation are revision controlled and that the correct revision is used for testing and data analysis/compilation/reporting.

Software programs and changes to them are verified and controlled through the Instrument Validation process. Please see 5.5.2.

AC 7101/1 8.8 Procedures that are used for each test method reference the source of the requirement. For example: specific industry standard(test specification) or customer specification.

AC 7101/1 8.9 Procedures are sufficiently detailed so that the test can be consistently repeated.

Where applicable, Methods draw from the guidance available in industry standards. Methods are sufficiently detailed to ensure that trained Technicians and Analysts can perform the sample preparation or test repeatably. Please see SOP 5.4 for details.

5.4.2

When a customer makes a request for quotation, NSL technical personnel create a routing sheet to determine how the sample will be analyzed. This routing determines the lab(s) and type of instrument(s) that will be utilized. Once the sample is received, the routing sheet is reviewed to ensure that it is appropriate, and the sample is routed to the lab. Once in the lab, a trained Analyst determines which written Method to follow for sample preparation or testing. Please see SOP 4.4 regarding quoting and SOP 5.8.1 regarding sample receipt and processing.

NSL Methods draw applicable guidance from industry testing specifications, where these are available. These specifications are referenced in the individual methods. NSL Methods are written by technical personnel and are specific to the instruments, equipment, and circumstances at NSL. Please see SOP 5.4 for details.

Testing process (instrument type) is identified on the customer quote and the test report. Use of the unique sample number allows NSL to trace an analysis back to a specific Method or Methods, should a customer wish to review these during an on-site visit. Confirmation / verification of Methods is addressed in 5.4.5, below. If a customer is requesting reference to an

industry standard that is obsolete or out of date, Customer Support staff will verify with the customer the customer's intention prior to accepting the sample. Please see SOP 5.8.1.

For management of industry specifications, including how NSL keeps them current, please see SOP 4.3.

AC 7101/1 5.4 ‡The Q.A. function participates in the management (creation, revision, implementation, etc.) of test procedures.

As an aspect of the document control and revision process, all new or changed Methods are reviewed and approved by the Quality Assurance Manager. Please see SOP 4.3 for details.

ASME NQA-1, REQUIREMENT 11, 100
NSL performs testing services in response to customer requirements (and so does not determine what tests should be conducted). Testing is based on industry specifications and guidance, when this is available. See 5.4.2, above. Validation of NSL test methods is addressed in 5.4.5, below.

5.4.3
In some instances where there is sufficient detail, NSL will use an industry testing specification as written. Otherwise, NSL technical staff develop method documents and make use of industry specifications for testing when these are available. Method creation is a planned activity. Please see SOP 5.4 for details.

5.4.4 Non-standard methods, a) – k)

AC 7101/1 8.10 Details required to reproduce non-standard tests are documented and traceable to the test report/results.

NSL does not use "non-standard methods" unless we are developing a method in direct partnership with a customer. In those instances, there is clear communication at all times with the customer as to the status of the method development and the test results presented. Otherwise, NSL is using industry test specifications or lab-developed methods that address all of the items in this section. Please see SOP 5.4 for details.

5.4.5 Validation of methods

5.4.5.1 - 5.4.5.2
When NSL is using industry specifications for testing, the methods are considered sufficiently validated. This is further supported by regular participation in test quality assurance (please see 5.9, below). When NSL is using lab-developed methods, these are validated using the approaches indicated in this section, or other well-supported, industry recognized approaches. Please see SOP 5.4 for details.

5.4.5.3
NSL lab-developed methods are validated prior to use. This includes clear, objective evaluation of the capabilities and limits of the process, including determination of measurement uncertainty (see 5.4.6, below). Technical personnel review the customer requirements and ensure that the selected NSL Method meets these requirements prior to testing. Please see SOP 5.4 for details.

5.4.6 Estimation of uncertainty of measurement
5.4.6.1
NSL does not provide calibration services, nor does it verify calibration of its own instruments. Calibration verification intervals are addressed by qualified service providers. Please see SOP 5.5 for details.

5.4.6.2
For all quantitative methods in the NSL ISO 17025 scope of approval, NSL has identified systematically all contributors to variation, and therefore, measurement uncertainty. In each case, using an approach that is appropriate to the method, existing data has been reviewed and measurement uncertainty has been estimated / determined. Please see SOP 5.4.6 for details.

5.4.6.3
As indicated in 5.4.6.2, above, NSL has identified systematically all contributors to variation, and therefore, measurement uncertainty. Please see SOP 5.4.6 for details.

5.4.7 Control of data
5.4.7.1
All manual data entries or calculations are "peer reviewed" by at least one other competent party to guard against transposed numbers or inaccuracies. All "peer reviews" are documented. Calculations performed automatically by computer programs are verified for accuracy before their first use. Please see SOP 5.1 for details.

5.4.7.2 a) - c)
NSL Analytical makes use of commercially available LIMS software to manage data exchange between the sample submission function and instruments. This software has been validated for accuracy by the manufacturer prior to installation at NSL. In addition, all instrument installations, including any software necessary to link the instrument to the LIMS, is validated as part of the new instrument validation process. Please see SOP 5.5.2 for details.
NSL has specific instructions regarding the collection, back-up, and safeguarding of customer and test data. Please see SOP 5.4.7 for details.
All computers are provided with an environment appropriate to their proper use. See SOP 5.3 for details.

5.5 Equipment
5.5.1

AC 7101/1 5.2 ‡ The Q.A. function participates in the organization or planning of equipment definition and selection.

Tools, equipment, and instruments have been selected to ensure that NSL Analytical can provide accurate and effective testing to customers for all methods offered. Equipment and instrument needs are determined by the Technical Manager or Site Leader and provided to the President for funding. The Quality Assurance Manager reviews significant instrument acquisitions. NSL does not make use of any equipment or instruments outside of its immediate control, unless enlisting the services of a subcontractor. Please see SOP 5.5 for details.

ASME NQA-1, REQUIREMENT 12, 200
Tools, equipment, and instruments have been selected to ensure that NSL Analytical can provide accurate and effective testing to customers for all methods offered. See 5.5.1, above.

5.5.2
All instruments and related software are thoroughly calibrated, tested, and verified for accuracy prior to testing customer samples. Please see SOP 5.5.2 for details.
Instruments are regularly calibrated / checked for accuracy according to defined plans. Please see SOP 5.5 for details.

AC 7101/1 8.6 Procedures are used to ensure all software programs and equipment automation are validated prior to use.

As noted above, all instruments and related software are thoroughly calibrated, tested, and verified for accuracy prior to testing customer samples. Please see SOP 5.5.2 for details.

ASME NQA-1, REQUIREMENT 12, 100
All instruments are thoroughly calibrated, tested, verified for accuracy prior to testing customer samples, and maintained. See 5.5.2, above.

ASME NQA-1, REQUIREMENT 12, 301
All instruments are calibrated or verified at defined intervals, or when their accuracy is called into question. Instruments are calibrated using traceable standards. See 5.5.7, below and SOP 5.5 for details.

5.5.3
Technicians and analysts are qualified on specific methods and equipment / instruments, as documented in training matrices. Where necessary, manufacturers' manuals are available for use. Please see SOPs 5.5 and 5.5.2 for details.

5.5.4
All instruments are uniquely identified, either through a uniquely assigned number or a unique name. These names or numbers are captured in analytical data for traceability.

ASME NQA-1, REQUIREMENT 12, 303.1
Records of instrument selection use for testing are maintained in the LIMS. When it is impractical to maintain traceability of instruments used for sample preparation, these instruments are verified regularly prior to use to limit exposure to an out-of-tolerance condition. See SOP 5.5 for details.

ASME NQA-1, REQUIREMENT 12, 303.6
All instruments are appropriately identified, including, where appropriate, calibration status. See 5.5.4, above, and 5.5.8, below.

5.5.5 a) – h)
Records are maintained for each significant instrument or piece of equipment used for sample preparation or testing. The records include the identity, and where necessary serial number for the equipment or instrument. If applicable, manufacturers' instructions are referenced for calibration or repair. Records are maintained separately for NSL locations, so equipment or instrument location is self-evident. Regular service maintenance is performed and documented for equipment and instruments. Failures, repairs, service visits, and preventative maintenance visits are documented. Please see SOP 5.5 for details.
Calibration and testing records include checks against traceable standards and pass / fail criteria. All calibration records are maintained and suitably identify the instrument, pass / fail criteria and status, any adjustments performed, and the date the next calibration verification is due. Please see 5.5 wi 1 for details.

AC 7101/1 5.3 ‡The Q.A. function participates in the organization or planning of maintenance and calibration of test facilities and equipment.

AC 7101/1 8.2 Procedure(s) are used for calibration of all Measuring and Test Equipment (M&TE) used for testing or producing results.

The Quality Department maintains a list of all instruments with a defined calibration interval, and arranges for calibration services from approved service providers. Please see SOP 5.5 for details.

AC 7101/1 9.1.1 Calibration cycle extension: When calibration cycles are extended, procedures are used in accordance with NCSL (National Conference of Standard Laboratories), recommended Practice 1, or other recognized statistical review process to support the extended time interval. Any calibration cycle extensions are in accordance with standard methods or customer requirements.

Calibration intervals, where defined by Nadcap, customer, or industry specification, are followed. Any deviation from standard calibration intervals are substantiated by historical calibration data. Please see SOP 5.5 for details.

AC 7101/1 9.1.2 ‡Calibration: The laboratory uses a calibration schedule with frequencies in accordance with manufacturers' recommendations, Appendix E, or the individual checklist requirements for all internal and external calibrations performed on testing equipment. This schedule documents duration between calibrations (frequency) and responsibility for calibration (source).

The Quality Department maintains a list of all instruments with a defined calibration interval, and arranges for calibration services from approved service providers. Please see SOP 5.5 for details.

AC 7101/1 9.1.3 Calibration: Procedures are used during calibration certificate review to ensure the following:

- calibration certificates document the name and address of the agency performing the calibration.
- approved calibration suppliers are used.
- ‡ description(s) of equipment and operating range, including the precision of the instrument, are documented on the calibration certificate.
- primary standards or equipment are documented on the calibration certificate and are traceable to a national standard.
- the calibration method is documented on the calibration certificate.
- the date of calibration is documented on the calibration certificate.
- the "as found" and "as left" conditions are documented on the calibration certificate when the instrument was adjusted or repaired during the course of calibration.
- the calibration personnel are documented on the calibration certificate.
- the environmental conditions are documented on the calibration certificate where required by standard/spec/customer.

The Quality Assurance Manager, or a trained designate, reviews all calibration certificates for appropriateness and completeness of information. Please see 5.5 wi 1 for details.

AC 7101/1 9.1.5 Calibration: Procedures are used to address the calibration and use of "employee-owned" Measuring and Test Equipment (M&TE).

NSL does not allow the use of equipment or instruments for testing or acceptance that are not owned and maintained by NSL. Please see SOP 5.5 for details.

AC 7101/1 9.1.6 Calibrations not performed by the laboratory are performed by an ISO17025 accredited source or documented evaluation.

All calibration service providers are reviewed and approved by the Quality Assurance Manager, and must have ISO 17025 accreditation *or a defined basis for approval* (as evidenced by the calibration service providers on the Approved Supplier List). The Quality Assurance Manager, or a trained designate, reviews all calibration certificates for appropriateness and completeness of information. Please see 5.5 wi 1 for details.

AC 7101/1 9.2.1 Maintenance: Procedures are used to ensure planned maintenance of measuring equipment is performed to ensure proper functioning and in order to prevent contamination or deterioration.

See 5.5.5, above.

AC 7101/1 9.2.2 Maintenance: Procedures are used to ensure maintenance records identify the maintenance plan, maintenance activities to date, any damage, malfunction, modification, adjustment or repair to the equipment.

See 5.5.5, above (calibration) and 5.5.6, below (maintenance).

ASME NQA-1, REQUIREMENT 12, 401

See 5.5.5, above.

ASME NQA-1, REQUIREMENT 12, 402

Calibration certificates are reviewed and approved prior to acceptance. See 5.5wi 1 for details.

5.5.6

Equipment and instruments are not regularly moved after they have been installed. Any significant move is planned for, documented, and the equipment or instrument is verified prior to use. Instruments are maintained and stored to preserve their accuracy. NSL does not have any mobile or remote locations, or perform off-site testing services. Please see SOP 5.5 for details.

ASME NQA-1, REQUIREMENT 12, 303.3
See 5.5.6, above.

5.5.7

AC 7101/1 9.2.3 Maintenance: Procedures are used to identify equipment which is out of service.

Any instrument that is dropped or otherwise used outside of its standard use parameters (excessive heat or cold in the lab, etc.) will be considered suspect. Any suspect or out-of-service equipment or instruments are either removed from production / lab areas or positively identified to prevent unintentional use and not used until verified as accurate. An "Instrument Out of Tolerance" report will be completed and, if appropriate, samples will be treated as suspect as well. Please see SOP 5.5 for details.

AC 7101/1 9.2.4 Maintenance: When maintenance is performed to address a malfunction of calibrated equipment, procedures are used to assess the possible effect on test values.

After any instrument is repaired, the effect on calibration is assessed and if necessary addressed prior to return to service. Please see SOP 5.5 for details.

ASME NQA-1, REQUIREMENT 12, 303
All instruments that are not defined as "reference only" have defined calibration processes, either through regular use of CRMs, or through a defined calibration verification interval. Instruments that are overdue for calibration or that are suspect are visually identified and are not used. Through review of Out of Tolerance Reports, instruments that become unreliable are replaced. See SOP 5.5 for details.

ASME NQA-1, REQUIREMENT 12, 303.2
See 5.5.7, above.

5.5.8

AC 7101/1 9.1.4 Calibration: Calibration status is identified for each test machine or associated laboratory equipment requiring calibration.

All instruments with a defined calibration verification interval are identified with the most recent and next due calibration. Please see SOP 5.5 for details.

5.5.9
Since NSL does not perform any off-site testing or loan out instruments, this would only apply to instruments sent out for calibration verification or repair. Instruments are always packaged appropriately to protect against damage in-transit, and inspected upon receipt. Any instrument too sensitive to transport is repaired or calibrated on-site. Please see SOP 5.5 for details.

5.5.10
Instruments with a defined calibration interval that see sufficient use to possibly diminish their accuracy between calibration verifications are also subject to regular checks by NSL personnel. Standards or other consistent samples are used. Criteria for acceptance is documented and records of checks are maintained. Please see SOP 5.5 for details.

5.5.11
Once reviewed and accepted by a qualified technician / analyst, correction factors ("type standardization," etc.) are automatically transferred in the instrument software and captured in the analytical data.

5.5.12
All instrument software is password protected to limit to authorized persons the ability to adjust parameters or calibration. Technicians and analysts are trained to recognize what adjustments they are allowed to make, and to distinguish from those that require third-party assistance and calibration verification. In many cases, instruments would require disassembly in order for adjustments to be performed. Please see SOP 5.5 for details.

10 CFR Part 50 Appendix B; XII. Control of Measuring and Test Equipment, Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

See 5.5.2, 5.5.3, and 5.5.5, above.

ASME NQA-1, REQUIREMENT 12, 303.4
All instruments are used in environments that are controlled to the extent necessary to ensure accuracy. See section 5.3, above. Proper environmental conditions are assessed, controlled, and recorded during calibration. Please see 5.5wi 1 for details.

ASME NQA-1, REQUIREMENT 12, 303.5
When instruments are calibrated or verified by a service provider, "as received" data is requested prior to any repair or adjustment. Please see 5.5wi 1 for details.

ASME NQA-1, REQUIREMENT 12, 304
When commercial equipment is appropriate for use (usually for early preparation stages at Metallurgical), they are placed into service without additional formal calibration verification. Such instruments are not used for critical measurements.

5.6 Measurement traceability
5.6.1
All instruments and equipment that NSL uses for the preparation or testing of samples that could have a significant effect on the accuracy of testing, or produces results that are not verified later with a calibrated instrument, are calibrated prior to use. Calibration on these instruments and equipment is maintained. Please see SOP 5.5 for details.

All standards and Certified Reference Materials (CRMs) used to perform or verify calibration are controlled and traceable. See sections below.

ASME NQA-1, REQUIREMENT 12, 302
All standards used for calibration are left to the selection of the calibration service contracted to conduct the calibration, using knowledge of the instrument in question and the specifications cited for calibration. Accuracy and resolution of the standards used are captured in the measurement uncertainty of the calibration, which is required by NSL. See SOP 5.5

5.6.2 Specific requirements
5.6.2.1 Calibration
5.6.2.1.1
Since NSL Analytical does not provide any calibration services, this section is only applicable as it applies to calibration service providers utilized by NSL. Applicable requirements are defined and flowed down to calibration service providers through the requirements defined in SOP 5.5.

5.6.2.1.2
Again, since NSL does not provide any calibration services, this section is not applicable.

5.6.2.2 Testing
5.6.2.2.1
NSL determines process measurement uncertainly, not just instrument measurement uncertainty, so all possible contributors to variation through the preparation and testing process are evaluated and their contribution to total process uncertainty captured. Please see SOP 5.4.6 for details.

5.6.2.2.2
NSL uses, where available, Certified Reference Materials (CRMs) that provide certificates that include traceability to international standards. Where these are not commercially available, NSL uses the best industry-recognized reference

materials available. Traceability to international standards, or alternative means for determining accuracy are clearly defined on reference material certificates. NSL prefers, but does not require, ISO Guide 34 accreditation for providers of CRMs.

5.6.3 Reference standards and reference materials

5.6.3.1

As indicated above, NSL uses Certified Reference Materials (CRMs) with certificates that include traceability to international standards or, when not commercially available, the best industry-recognized reference materials available. When these reference materials are subject to change (like weights used for mass verification or loading), they are verified at regular, defined intervals. All standards and CRMs are clearly identified and used only for calibration and calibration verification purposes. Please see SOP 5.5 for details. Regular use of standards and CRMs is addressed in SOP 5.1.

5.6.3.2 Reference materials

Please see section 5.6.2.2.2.

5.6.3.3 Intermediate checks

As indicated in section 5.6.3.1, any reference materials subject to change are verified at regular, defined intervals.

5.6.3.4 Transport and storage

NSL does not perform any testing off-site, so no standards or CRMs are taken off-site. All standards and CRMs are clearly identified and suitably protected against deterioration or contamination. Please see SOP 5.1 for details.

5.7

The primary responsibility for lot-representative sampling lies with the NSL customer. It is the customer that provides a sample to NSL and who holds full responsibility for determining how NSL test results of that submitted sample are representative of any larger lot. When a customer provides a sample and has specific intentions for sampling, those intentions are clarified (often with the use of an engineering drawing, or written instructions) and considered part of the NSL knowledge-base for that customer. When the customer does not have specific intentions for the selection of the test specimen from the sample, NSL uses general written principles to ensure homogeneity of the provided sample prior to selecting the specimen(s). Please see SOP 5.1 for details.

5.7.2

Any customer-required deviation from a standard NSL sampling plan will be documented and communicated either through the LIMS or a controlled hard-copy. Please see SOP 5.1 for details.
Where significant sampling was conducted and customer guidance has been received (specific sampling plan), this is referenced on the NSL test report. See 5.10.3.2 f).

5.7.3

Data related to sampling (quantity, location, etc.) and the identification of the person performing the sampling are documented either through the LIMS or the hard-copy test data page (often called the “Daily Sheet” at NSL Metallurgical). If appropriate, a procedure, conditions, diagrams, or pictures are captured and communicated. If specific sampling instructions are based on statistical selection, the basis for the selection is referenced as well. Please see SOP 5.1 for details.

5.8 Handling of test and calibration items

5.8.1

NSL has procedures that cover receipt of customer samples, their identification and preservation through the lab, and eventual return to the customer or disposal. Please see SOP 5.8 for details.

ASME NQA-1, REQUIREMENT 13, 100

See 5.8.1, above. Handling and storage of CRMs, consumables, reagents, or other materials used in the testing process are addressed in SOPs. 5.1 and 5.1.1.

5.8.2
Upon receipt, all submissions to NSL receive a unique submission number, assigned by the LIMS. In addition, each sample received in the submission receives a unique sample ID number assigned by the LIMS. All containers are identified with these submission and sample numbers, even as samples are subdivided or their form is changed (ex. powder dissolved to liquid), through the entire life of the sample at NSL. At any point in time, the preparation and test status of any sample can be identified either in the LIMS, or in accompanying hard copy paperwork. Please see SOP 5.8 for details.

ASME NQA-1, REQUIREMENT 8, 100
NSL only provides services and does not manufacture, assembly, or ship materials or parts. Therefore, identification and control primarily applies to customer provided samples for test, which is addressed in 5.8.2, above. NSL also carefully identifies and maintains identification on any CRMs, consumables, reagents, or other materials used in the testing process. See SOPs 5.1 and 5.1.1

5.8.3
If a received sample appears damaged or otherwise does not meet the description either in the NSL quote or the customer's submission documents, the customer is contacted and the situation resolved before testing begins. When additional quantities of a sample are required to perform requested tests, the customer is contacted. Records of these exchanges are maintained in Customer Service email accounts. Please see SOP 5.8 for details.

5.8.4
NSL does not recommend that any sample provided to NSL for testing and subsequently returned to the customer be entered into service. Samples are returned to customers for additional inspection and analytical purposes (use as reference standard, etc.) if requested.

NSL maintains appropriate containers to preserve each sample received, in both its initial state and as the specimen is prepared for testing. Handling processes ensure that samples are protected from deterioration and contamination. If the customer provides special sample handling instructions, these are entered in the LIMS for communication and followed. At the time of the writing of this document, no customer requires NSL to maintain or record specific environmental conditions or secure conditions for their samples. If this changes, the Quality System Manual and related SOP will be revised. Please see SOP 5.8 for details.

After testing is completed, NSL retains all remaining sample fragments (in their original form) for 90 days. During this time, identification of the sample by unique sample number is maintained and the sample is protected from damage, contamination, or deterioration. The sample may be returned to the customer upon request. Returned samples are packaged so as to reasonably protect against damage or contamination. Otherwise the sample is destroyed / disposed of / recycled. Please see SOP 5.8 for details.

Any samples sent to a subcontractor for subcontract preparation or testing are uniquely identified and packaged so as to reasonably protect against damage or contamination. Please see SOPs 5.8 and 4.5 for details.

AC 7101/1 10.1 Unique identification is assigned to each test specimen in accordance with a procedure. The identification is retained throughout the life of the test specimen and is traceable to the final documentation.

See section 5.8 above regarding receipt and handling of samples. The unique submission and sample numbers, assigned and maintained by the LIMS, allow direct traceability to customer request, material tested, preparation methods used, testing methods used, results, and test certificate issued. Please see SOP 5.8 and related SOPs for details.

Specimen fracture surfaces are protected from damage.

At NSL Metallurgical, all fracture samples are taped together and stored in such a way to preserve the integrity of the fractured surface until the sample is disposed of or returned to the customer. Please see SOP 5.8 for details.

10 CFR Part 50 Appendix B; VIII. Identification and Control of Materials, Parts, and Components, Measures shall be established for the identification and control of materials, parts, and components.... These measures shall assure that

identification of the item is maintained by… appropriate means, either on the item or on records traceable to the item, as required throughout… use of the item. These identification and control measures shall be designed to prevent the use of incorrect or defective material, parts, and components.

10 CFR Part 50 Appendix B; XIII. Handling, Storage and Shipping, Measures shall be established to control the handling, storage, shipping, cleaning and preservation of material… to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, shall be specified and provided.

10 CFR Part 50 Appendix B; XIV. Inspection, Test, and Operating Status, Measures shall be established to indicate, by… suitable means, the status of inspections and tests performed upon individual items….

NSL does not manufacture or ship parts or materials, but rather offers testing services. All samples received for testing are appropriately identified and protected from receipt until disposal. See 5.8, above.

ASME NQA-1, REQUIREMENT 8, 302
NSL maintains adequate systems to identify limited shelf-life items (typically aqueous standards or reagents) and remove them from use prior to expiration. See SOPs 5.1 and 5.1.1 for details.

ASME NQA-1, REQUIREMENT 14, 100
Items provided to NSL for testing are usually destroyed, or at least significantly modified during testing. Infrequently, sample remnants are returned to the customer after test, only when requested. The status of any sample or subdivision of the sample can be determined by entering its unique sample number in the LIMS and determining what preparations or tests have been conducted. Test reports are not issued until all tests are complete.

5.9 Assuring the quality of test and calibration results

5.9.1 a) – e)
NSL has a number of analytical methods that fall under both ISO 17025 and Nadcap scopes. Due to the requirements of Nadcap, all of these methods have a schedule for regular Internal Round Robin and External Round Robin / Proficiency Testing (option "b," above). For the remaining methods in the NSL ISO 17025 scope, NSL has a written Test Quality Plan that defines the approach ("a-e," above) and the interval. Please see SOP 5.9 for details.

5.9.2
All Internal Round Robin, External Round Robin, Proficiency, and Test Quality Plan testing is evaluated both by the Quality Assurance Manager and the Technical Director / Site Leader. Any results that do not meet expectations or acceptance criteria are investigated and, where appropriate, formal corrective or preventative actions are opened (see also sections 4.11 & 4.12). Please see SOP 5.9 for details.

NADCAP PROFICIENCY TESTING AND INTERNAL ROUND ROBIN REQUIREMENTS

AC 7101/1 14.0 Participation in proficiency testing (PT) and internal round robins (IRR) is required. Frequency requirements are given in Appendix B. Selection of proficiency test providers is described in Appendix C. Testing protocol for PT and IRR is described in Appendix D.

For all methods in the Nadcap scope, NSL performs Internal Round Robin and Proficiency Testing compliant with Nadcap requirements. Please see SOP 5.9 for details.

The Document Coordinator shall ensure that *a Nadcap-compliant table summarizing PT and IRR participation and plans* is maintained and current for each NSL site. All methods on the Nadcap scope for each site shall appear in this Figure. Please see SOP 5.9 for details.

AC 7101/1 14.1.1 The internal round robin program meets the established requirements as described in Appendix D.

For each lab, the Technical Specialist is the coordinator of the IRR program. The Document Coordinator is responsible for archiving all results and maintaining related Nadcap Figures and Tables. The Technical Specialist defines the list of participants – usually all technicians or analysts considered competent by NSL to perform testing to the method, *or the number of validated and active instruments*. The Technical Specialist defines the nature of the test, the number of replicates, *and how often it must be performed*. Tests are designed and conducted in compliance with AC7101/1 Appendix D. Please see SOP 5.9 for details.

AC 7101/1 14.1.2 Internal round robin programs are in place to compare testing equipment used for the same test/method, if required. (see Appendix B for frequency and requirements)

AC 7101/1 14.1.3 Internal round robin programs are in place to compare testing personnel performing the same test/method, if required. (see Appendix B for frequency and requirements)

AC 7101/1 14.1.4 ‡Participation in the internal round robin program meets the frequency requirements for all test codes held by the laboratory as described in AC7101/1 Appendix B.

See AC7101/1 *14.1.1*, above.

AC 7101/1 14.1.5 Procedures are used to ensure participation in Internal Round Robin Programs and analyze the results of internal round robins against defined acceptance criteria.

Analysis of results and definition of acceptance criteria is addressed in SOP 5.9.

AC 7101/1 14.2.1 Procedures ensure participation in Proficiency Testing Program(s)

AC 7101/1 14.2.2 The laboratory used a Proficiency Testing provider in accordance with Appendix C.

AC 7101/1 14.2.3 The participation of the laboratory in Proficiency Testing Program(s) is documented.

AC 7101/1 14.2.4 ‡Participation in the Proficiency Testing meets the frequency requirements for all test codes held by the laboratory (see Table 1 of Appendix B).

AC 7101/1 14.2.5 The requirements in Appendix D were followed.

For each lab, the Technical Specialist is the coordinator of the Proficiency Testing program. The Document Coordinator is responsible for archiving all results and maintaining related Nadcap Figures and Tables. The Technical Specialist selects the provider and defines the list of participants. Statistical analysis and correlation are provided by the testing provider and NSL is evaluated against its peer group. Testing is evaluated both by the Quality Assurance Manager and the Technical Director / Site Leader. Any results that do not meet expectations or acceptance criteria are investigated and, where appropriate, formal corrective or preventative actions are opened (see also sections 4.11 & 4.12). Tests are conducted at proper intervals and in compliance with AC7101/1 Appendix D. Please see SOP 5.9 for details.

AC 7101/1 14.3.1 Statistical analysis and correlation of the data are performed and documented for both internal round robin testing and proficiency testing, if applicable. It is the host facility's duty to provide a statistical evaluation of the data in the final report, if applicable.

See AC7101/1 *14.2, above*.

AC 7101/1 14.3.2 Procedure(s) are used for investigation of outliers.

See 5.9.2 *above*.

5.10 Reporting the results

10 CFR Part 50 Appendix B; X. Inspection, A program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. Such inspection shall be performed by individuals other than those who performed the activity being inspected….

All test data is reviewed and approved by a technical person, other than the person performing the test, prior to release of the test report. See SOP 5.10 for details.

ASME NQA-1, REQUIREMENT 10, 100
All test data is reviewed and approved by a technical person, other than the person performing the test, prior to release of the test report. These reviews are documented in the LIMS. "Characteristics subject to inspection" would be any characteristic or feature being measured by NSL to report to a customer. See SOP 5.10 for details. Inspection performed upon receipt of purchased items or services is addressed in section 4.6, above.

ASME NQA-1, REQUIREMENT 10, 200 and 604
NSL tech specialists review test data to ensure that it is consistent and reasonable. When the customer has provided a material acceptance specification, NSL indicates clearly on the test report if the characteristics tested meet the specification or not. See also 5.10.3 b), below.

ASME NQA-1, REQUIREMENT 10, 600 - 601
All non-conformances related to a specific test are addressed, resolved, and closed prior to approval of the test data and the release of the test report. See SOPs 4.9 and 5.10 for details.

5.10.1
NSL provides clear, written test reports to customers for each submission received. If several samples are provided to NSL at once, all appear on the same test report, but each is clearly identified with any information that the customer has provided, as well as NSL's unique submission (report) and sample numbers. Preliminary reports, provided on a very limited basis, are the only test reports not provided in NSL's standard, formal format. Please see SOP 5.10 for details.

AC 7101/1 13.1 The certificate of test/test report meets the requirements of the applicable specification.

Where special requirements for reporting exist, these requirements are document in the NSL Method specific to the test. Please see specific NSL Methods for examples.

5.10.2 a) – b)

AC 7101/1 13.2 The certificate of test/test report includes the name and address of the laboratory, and the location where the tests and/or calibrations were executed, if different from the address of the laboratory.

NSL test reports clearly indicate a title, "NSL Analytical," and the street address of the NSL site where testing was conducted. *If any of the testing was subcontracted, this is clearly indicated in the test report.* Please see SOP 5.10 for details.

5.10.2 c)

AC 7101/1 13.13 ‡The certificate of test/test report includes each page numbered "page __ of__ ".

AC 7101/1 13.14 The certificate of test/test report includes unique identification traceable to the laboratory identification system.

NSL test reports list the unique submission (report) and sample identification number, and clearly indicate the number of pages in the test report. Please see SOP 5.10 for details.

5.10.2 d)

AC 7101/1 13.3 The certificate of test/test report includes the name and address of the customer.

NSL test reports list the name and address of the customer as provided by the customer. Please see SOP 5.10 for details.

5.10.2 e)

AC 7101/1 13.5 The certificate of test/test report identifies the testing specification or procedure used, if not called out by the material specification. Any non-standard practices must be documented.

NSL test reports list the general analytical method used for each reported test result. Upon request, these general methods can be cross referenced to NSL internal method documents, and these in turn draw from and reference relevant industry specifications. Please see SOP 5.10 for details.

5.10.2 f)

AC 7101/1 13.4 The certificate of test/test report includes identification of the test article and identification and issue(s)/revision(s) of the material specification(s) used for conformance disposition. (Example: Inco 718, AMS5662 Rev H).

AC 7101/1 13.11 ‡ The certificate of test/test report includes appropriate description of test specimens (quantity, form, and condition, etc), when applicable, and all identification necessary to assure traceability of laboratory report to the material supplier/customer records (e.g., sample number, heat number, lot number, P.O. number).

NSL test reports list the identification of the samples as provided by the customer in the submission documents. When provided, material type, lot, heat, physical description, customer purchase order number, and applicable specifications with revision are listed. Please see SOP 5.10 for details.

5.10.2 g) - i)
AC 7101/1 13.6 The certificate of test/test report includes the numerical results of all tests and inspections performed for which the material specification establishes numerical requirements.

All test results are provided where appropriate with numerical values and units of measurement. Please see SOP 5.10 for details.

AC 7101/1 13.7 ‡Test values on the certificate of test/test report are recorded, at a minimum, to the number of digits as defined by the controlling specification(s).

Test values are recorded with at least the number of significant figures called out in the customer requested specification. Please see SOP 5.10 for details.

5.10.2 j)

AC 7101/1 4.5 Laboratory management assigns responsibility for the review and approval of test results, training and qualification of personnel, and procedures.

As noted below, the Technical Specialist reviews and approves test results. See SOP 5.10. The Human resources and Quality functions review and approve training and qualification of personnel. See SOP 5.2. All procedures are reviewed and approved. See SOP 4.3.

AC 7101/1 13.21 Computer generated certificates of test/test reports require either (a) an actual or facsimile signature, or (b) a letter accompanying the certificate, signed by the laboratory's representative attesting that the laboratory is using a computerized system, the typed name on the document is an authorized employee, and the laboratory is responsible for the information it contains. If a laboratory uses computer-generated certificates with an actual or facsimile signature, or typed name, the system has security (password or other identity control) to ensure the name on the document represents the individual who performed the indicated function.

NSL test reports list the name, title, and electronic signature of the Technical Specialist who has reviewed and approved the test data. The NSL LIMS maintains security such that a signature will only be applied to the test report when a Technical Specialist with a password-protected account has approved the test data. Please see SOP 5.10 for details.

5.10.2 k)
See 5.10.2 c).

AC 7101/1 13.12 ‡ The certificate of test/test report includes a statement that it shall not be reproduced except in full without the written approval of the laboratory.

NSL test reports include statements that the results provided pertain only to the samples tested, and that the test report may not be reproduced except in full. Please see SOP 5.10 for details.

5.10.3 Test reports
5.10.3.1 a) – b)

AC 7101/1 13.8 ‡The certificate of test/test report includes descriptions of the results (e.g., conform/non-conform) of all tests for which the material specification does not establish numerical requirements.

AC 7101/1 13.9 ‡ Any unusual observations are noted on the certificate of test/test report (and identified as such, e.g. as "Observation"). Applicable at laboratory discretion.

AC 7101/1 13.10 ‡ Test results for all specimens in the same set are included on the same certificate of test/test report; that is, separate certificates of test/test reports are not issued for conforming versus nonconforming material.

AC 7101/1 13.16 ‡The certificate of test/test report includes re-test values, and values known to be nonconforming (i.e., when compared against mandatory specification values), and they shall be clearly identified as such.

AC 7101/1 13.22 The certificate of test/test report documents a statement of conformance when testing is performed for conformance to material specifications.

If applicable or relevant, NSL test reports state any deviations from selected or required analytical method, environmental conditions at the time of test, *and any unusual observations.* When a standard for compliance is provided by the customer, the test report clearly states either that the tests comply with the requirements or they do not comply. If they do not comply, the specific element or test out of tolerance is identified. The standard and its revision are clearly stated. When re-test results are provided, these are clearly indicated on the test report. *NSL does not intentionally separate conforming from non-conforming results on test reports.* Please see SOP 5.10 for details.

AC 7101/1 13.23 ‡ Procedures are used to ensure correct transcription of data from the original source to the certificate of test/test report. Procedure(s) are used to respond to transcription errors.

All test data is either transferred electronically from the instrument to the LIMS to the test report (validated during instrument validation) or reviewed by a second person (peer review) to preclude transcription errors. Please see SOP 5.10 for details.

5.10.3.1 c) - e)
Where applicable or when requested, NSL provides a clear statement of measurement uncertainty on test reports. Opinions, interpretations, and any other requested information is clearly identified on the test report when requested. Please see SOP 5.10 for details.

AC 7101/1 13.17 The certificate of test/test report includes documentation of all test articles provided to the laboratory for testing. Example of test without results: "Specimen 4A253: No Test - broke in grips". Test values from replaced specimens need not be reported.

AC 7101/1 13.18 ‡ The certificate of test/test report is traceable to the request to perform work.

AC 7101/1 13.19 ‡The certificate of test/test report includes a statement of work with conformance requirements stated. If the conformance requirements are written in the statement of work (rather than a specification or similar document) and revised after submission to the laboratory, revision to those requirements is documented in the certificate.

NSL test reports indicate how many samples were provided. A customer's purchase order, sample, and submission documents are considered sufficient authorization to test. *When provided, NSL reproduces the customer's purchase order number on the test report*. The test report indicates methods followed and specifications that define tolerances, as required by the customer. *Changes to conformance requirements are indicated as a change on the test report.* Please see SOP 5.10 for details.

AC 7101/1 13.20 ‡The certificate of test/test reports includes description(s) of any applicable thermal treatments performed by the laboratory.

Any heat treat or other thermal treatment provided by NSL prior to test is indicated on the test report. Please see SOP 5.10 for details.

5.10.3.2 a) – f)
Most of the responsibility for sampling lies with the customer. It is up to the customer to provide a homogeneous, representative sample of material when the customer wished to use the results to form their decisions on a lot of material. Where sampling is conducted at NSL to obtain a specimen, processes are followed to provide as representative a specimen as possible. When sampling is conducted and customer guidance has been received, the sampling plan, date sampled, identification of the substance, appropriate identification of the specimen location, applicable environmental conditions, and any deviations from the method or specification are referenced in the test report. Please see SOP 5.10 for details.

5.10.4 Calibration certificates
5.10.4.1 a) – c)
5.10.4.2 - 5.10.4.4
Since NSL does not provide any calibration services or reports, section 5.10.4 does not pertain to NSL. NSL flows these requirements down to organizations that provide calibration services to NSL. Please see SOP 5.5 for details.

5.10.5 Opinions and interpretations
When NSL provides opinions or interpretations, these and their basis are clearly indicated on the test report. When opinions or interpretations are communicated verbally, these are documented. Please see SOP 5.10 and SOP 4.7 for details.

5.10.6
When any aspect of testing is subcontracted, all subcontractors provide their test results either in writing or electronically. NSL then merges this information with NSL test data and the NSL test report format. Subcontracted aspects of testing are clearly identified on the NSL test report. Please see SOP 5.10 and SOP 4.5 for details.

5.10.7
NSL does not disclose test results verbally. All test information is only communicated to the fax, email, or post address provided to NSL by the customer, or subsequently approved by the customer. See also 5.4.7.

5.10.8 Format of reports and certificates

NSL uses a standard, clear format for test reports. Please see SOP 5.10 for details.

5.10.9 Amendments to test reports and calibration certificates

AC 7101/1 13.15 ‡The certificate of test/test report includes, when applicable, appropriate error corrections and revision indication. Manual corrections are prohibited. Digital documents must have a means for recording corrections such that the original and corrected data can be observed during an audit.

AC 7101/1 13.24 Procedures are used to address revision of certificates of test/test reports and notification of customers when errors are found. Customers are notified within the time period that is required by the customer.

When NSL issues a revised or supplemental test report, these are clearly identified as such, along with the actual additional data. Any request for a reproduction of a test report is met by retrieval from the LIMS. Test reports are not altered once issued, and may only be re-issued as revised or supplemental. Please see SOP 5.10 for details.

It would be very unusual for NSL to determine that results are questionable after a test report has been issued to a customer. However, if a subsequent internal audit, review of calibration records, etc. places suspicion on issued results, the NSL Technical and Quality Assurance Manager will create a plan to determine if results should be revised. If it is determined that results should be revised, customers will receive a revised test report and an explanation of the change. If the revised test report is not available after discovery *within the time period identified by the customer*, any potentially affected customer will be informed that an investigation is underway, and they will be informed of the outcome of the investigation. Please see SOP 4.9 for details. If results reported to a customer in the nuclear power plant supply chain are later revised from "conforming" to "non-conforming," special provisions apply. See NSL WI Nuclear for details.