


		<b>Verify Revision Information Prior to Use</b>		Initials	
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DESCRIPTION OF CHANGES

<b>Justification (required for major revision)</b>
Update with recommendations from Internal Audit.

<b>Page(s)</b>	<b>Description (including summary, reason, initiating document, if applicable)</b>
ALL	Update sections to align directly to ISO/IEC 17025 standard.

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## 1.0 SCOPE

1.1 Energy Northwest Standards Laboratory (ENSL) Quality manual documents the processes for calibration services required by ENSL commercial customers (hereafter referred to as the customer) through contractual or other service agreements with ENSL. General Business Procedures (GBPs) serve as the implementation requirements of the Quality manual. Provide procedural guidance for the accomplishment of accredited calibrations performed at ENSL. The purpose of this program is to demonstrate how ENSL meets and implements the relevant requirements of ANSI/NCSL Z540.1:1994.1, ISO/IEC 17025:2017, Title 10 CFR 50 Appendix B, and ASME NQA-1. The requirements of 10 CFR Part 21 only apply to 10 CFR 50, Appendix B activities and to ASME NQA-1 activities when invoked by contract with the customer. This program also meets the requirements of MIL-STD 45662A, ISO/IEC Guide 25, and Regulatory Guide 1.33 as applicable. By implementing ISO/IEC 17025, the Laboratory satisfies the requirements of QS 9000 for an acceptable subcontractor. ENSL is committed to comply with the requirements of these documents to insure that each customer's requirements are met. Further, ENSL maintains accreditation to ANS/ISO/IEC 17025 and ANSI/NCSL Z540.1 from an International Laboratory Accreditation Council (ILAC) Mutual Recognition Arrangement (MRA) Accreditation Body (AB). Currently, ENSL's accreditation is with the American Association for Laboratory Accreditation (A2LA).

## 2.0 Normative References

- 2.1 The Quality Manual references terms and definitions provided in ISO/IEC Guide 99 International Vocabulary of Metrology – Basic and general concepts and associated terms (VIM) and ISO/IEC 17000 Conformity Assessment-Vocabulary and general principles.
- 2.2 This document describes procedures employed by ENSL Calibration Lab for the calibration of instruments. The paragraph numbering used in this document is consistent with that used in ISO/IEC 17025:2017.
- 2.2.1 Calibration facilities' policies, procedures, and processes established to meet the requirements of ISO/IEC 17025:2017, ANSI/NCSL Z540.1-1994 (R2002) and the needs of customers and/or external registration bodies.

## 3.0 Terms and Definitions

- 3.1 ACCREDITED DISCIPLINE (OR SUB-DISCIPLINE): Areas (or sub-areas) of calibration that are subject to the accreditation requirements of ISO/IEC 17025 as determined by the Calibration Laboratory Manager, Lead Metrologist and Technical Program Manager, and Lab Quality and Business Administration Program Manager.
- 3.2 CALIBRATION: The comparison of a measurement system or instrument of unknown accuracy (Unit Under Test) to a measurement standard with a known accuracy to detect, correlate, report and to eliminate by adjustment if possible any variation in the accuracy of the system or instrument being compared.
- 3.3 CALIBRATION CONDITION CLASSIFICATIONS:

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- 3.3.1 As Found Condition: A set of measurements derived from the initial comparison of values taken for a given calibration standard and a unit under test (UUT) to determine if the values are within customer specified tolerances. The “As Found” condition may be within tolerance, out of tolerance (OOT), or “Actual Value.”
- 3.3.2 If “As Found” values cannot be obtained due to the inoperability of a UUT, the “As Found” condition is annotated as FAIL and the reason explained in the Remarks section of the Calibration Report. This does not include instances where replacement of batteries, fuses, leads and/or power cords, etc. returns the UUT to an operational condition.
- 3.3.3 As Left Condition: A set of measurements denoting the condition of a UUT being returned to a customer. These measurements may be the same as the As-Found values or different as a result of adjustments or other actions performed during the calibration process.
- 3.4 CALIBRATION OR MEASUREMENT STANDARD: A material measure, measuring instrument, reference material or system intended to define, realize, conserve, or reproduce a unit, or one or more known values of a quantity to serve as a reference. Standards include Primary Standards, Reference Standards, Transfer Standards and Working Standards.
- 3.5 CERTIFICATE OF CALIBRATION: Also referred to as Calibration Certificate or Certificate of Conformance.
- 3.6 COMMERCIAL CUSTOMER: For the purposes of this procedure, a commercial customer is any company, organization, group, or individual who requests calibration services or support from the ENSL that is not part of Energy Northwest (EN) or Columbia Generating Station (CGS).
- 3.7 COMMERCIAL CUSTOMER COMPLAINT: For purposes of this procedure, a commercial customer complaint is defined as an expression of dissatisfaction by any person or organization to a laboratory, relating to the activities or results of that laboratory, where a response is expected.
- 3.8 COMMERCIAL SIGNIFICANT CONDITION ADVERSE TO QUALITY (CSCAQ): With respect to the ENSL operations, a significant condition adverse to quality relates to the identification and impact of out-of-tolerance measuring and test equipment (M&TE). A significant condition adverse to quality would be if an out-of-tolerance (OOT) calibration standard was determined to have caused:
  - 3.8.1 A unit under test (UUT) to have been adjusted to an out-of-tolerance (OOT) condition.
  - 3.8.2 A false in tolerance acceptance of an OOT UUT.
- 3.9 COMMERCIAL CONDITION ADVERSE TO QUALITY (CCAQ): ENSL considers a condition adverse to quality any condition that fails to meet the quality requirements as described in the ENSL Quality Manual, QM-1 and that left uncorrected would jeopardize the integrity of the quality program.
- 3.10 DECISION RULE: A rule that describes how measurement uncertainty will be accounted for when stating conformity with a specific requirement.
- 3.11 IMPARTIALITY: Presence of objectivity.

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- 3.11.1 Note 1 to entry: Objectivity is understood to mean that conflicts of interest do not exist, or are resolved so as to not adversely influence the activities of the laboratory.
- 3.11.2 Note 2 to entry: Other terms that are useful in conveying the element of impartiality are freedom from conflicts of interest, freedom from bias, freedom from prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment, and balance.
- 3.12 INTERNATIONAL SYSTEM OF UNITS (SI): The coherent system of units adopted and recommended by the General Conference on Weights and Measures (CGPM).
- 3.13 MEASURAND: The particular quantity subject to measurement.
- 3.14 MEASUREMENT UNCERTAINTY: The parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand.
- 3.15 MEASURING AND TEST EQUIPMENT (M&TE): All of the measuring instruments, measurement standards, reference materials, and auxiliary apparatus that are necessary to perform a measurement. This term includes measuring equipment used in the course of testing and inspection as well as that used in calibration. Moreover, reference material is considered to be a type of measurement standard.
- 3.16 NON-CONDITION ADVERSE TO QUALITY (NON-CAQ): Any deviation, deficiency, failure or non-conformance that adversely affects the expectations of any of a commercial customer, but does not meet the conditions of SCAQ or CAQ. I.e. typographical errors, miscommunication on customer paperwork, or pagination issues, etc.
- 3.17 OPTIMIZE: The process of adjusting a UUT to bring an in-tolerance “As Found” value closer to the desired nominal value.
- 3.18 OUT OF TOLERANCE (OOT): The determination of a condition where an instrument is outside of the allowable error limits on one or more test points. In addition, conditions where conformance to allowable tolerances cannot be determined (lost or suspended standards, catastrophic failure, no “as founds” taken) are to be considered as out of tolerance conditions.
- 3.19 PROFICIENCY TESTING: Determination of laboratory calibration performance by Interlaboratory comparisons or other means.
- 3.20 REFERENCE MATERIAL: A material or substance used as a calibration standard of which one or more properties are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.
- 3.21 TAMPER RESISTANT LABEL: A label, however identified (Calibration Void If Seal Broken, Cal Void If Broken, Certification Seal Void If Broken, etc.) that is placed over screws, cases, access holes, etc. that would break, tear, or otherwise show signs of damage if the label were tampered with, in an attempt to gain access to the interior of the equipment, or access to internal adjustments.
- 3.22 TAMPER RESISTANT SEAL: A seal (wax, glyptol, Loctite, etc.) placed over screws, access ports, etc. where a label is not practical due to the location of where the label would need to be placed, such as adjustment screws on thread ring gauges, adjustment mechanisms on torque

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wrenches, etc., or anywhere the use of a label would not hold up during routine handling through a calibration cycle.

- 3.23 TEST ACCURACY RATIO (TAR): The ratio of the accuracy of the standard relative to the test equipment, usually expressed by dividing the test equipment tolerance by the standard tolerance.
- 3.24 TEST UNCERTAINTY RATIO (TUR): The ratio of the uncertainty of the standard relative to the test equipment, usually expressed by dividing the test equipment tolerance by the standard uncertainty.
- 3.25 TRACEABILITY: The ability to relate individual measurement results to national standards or nationally accepted measurement systems through an unbroken chain of comparisons.
- 3.26 UNIT UNDER TEST (UUT): An instrument that is being calibrated by comparison to a calibration standard.
- 3.27 For this manual, instrument and equipment are used synonymously.

## **4.0 GENERAL REQUIREMENTS**

### **4.1 Impartiality**

- 4.1.1 The Calibration Laboratory Manager, Lead Metrologist and Technical Program Manager, and Lab Quality and Business Administration Program Manager ensures impartiality by focusing on the needs and requirements of customers. This is achieved via management and quality driven reviews and reinforced through all staff mandated training such as Compliance and Ethics annual training.
- 4.1.2 Employees are trained Compliance and Ethics training to utilize specific processes to accomplish their tasks and have a clear understanding of what must be done to realize technically valid results. Those processes have been designed with quality measures in place to ensure conformity of the deliverables.
- 4.1.3 ENSL ensures impartiality through organizational structure and alignment and through strategic, customer, operational, and quality driven objectives and goals. Refer to GBP-LEG-01 Code of Ethics and Form 26908 Code of Ethics.
- 4.1.4 ENSL identifies risks to its impartiality on an on-going basis through documentation of a risk register that documents risks that may arise from its activities, or its relationships, or from the relationships of its personnel.
- 4.1.5 ENSL will demonstrate how it eliminates or minimizes risk, if a risk to impartiality is identified.

### **4.2 Confidentiality**

- 4.2.1 It is the policy of ENSL to assure that customer confidential information, proprietary rights and special requests will be handled appropriately. Records are identified in GBP-REC-01 Records Management Program on records pertaining to customer

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confidential information, proprietary rights, results of calibrations and any special requests regarding customer calibrations are treated as confidential. Refer to GBP-REC-04, CONFIDENTIAL AND PROPRIETARY, INPO LIMITED OR RESTRICTED DISTRIBUTION AND COPYRIGHTED INFORMATION.

- 4.2.2 If ENSL is required by law or authorized by contractual arrangements to release confidential information, follow procedure GBP-REC-03 Public Records Request to inform the associated customer/s of the information provided.
- 4.2.3 Any information obtained from third-parties related to specific customer/s, will be treated as confidential between the customer/s and ENSL. Any third-party information will only be shared with the customer(s) if the source of the information provides agreement to do so.
- 4.2.4 Electronic transfers of data will be made upon agreement with the customer. Information will only be transmitted to the original customer unless permission is granted to transmit to a third party.

## 5.0 **STRUCTURAL REQUIREMENTS**

- 5.1 The Energy Northwest Standards Laboratory (ENSL) was established in 1979 as the organization responsible for verification, testing, and calibration of Measuring and Test Equipment (M&TE) used by the commercial nuclear power station Columbia Generating Station (CGS) and contracted customers.

Energy Northwest is a joint operating agency formed by the Washington state legislature in 1957, representing the convergence of small and big public power.

Our consortium of 27 public utility districts and municipalities across Washington takes advantage of economies of scale and shared services that help utilities run their operations more efficiently and at lower cost, to the benefit of more than 1.5 million customers.

Our agency further improves quality of life throughout the Northwest through the generation of clean, reliable electricity from nuclear, wind, hydro and solar projects.

DUNS 061666103, WA UBI 034 033 333, Cage Code 1RJ28, NAICS Codes, 811310, 541690

- 5.2 The laboratory is organized under the Energy Services and Development (ESD) Organization and reports to the , Laboratory Services Manager who reports directly to the Vice President Energy Services & Development.
- 5.3 The Calibration facility is accredited to ISO/IEC 17025:2017 and maintains a Scope of Accreditation with an accreditation body. Scope can be obtained by visiting the a2la website.
- 5.4 ENSL Calibration Facility carry out activities in a manner that meet the requirements of ISO/IEC 17025:2017, ANSI/NCSL Z540.1-1994 (R2002), as applicable based on customer and contractual requirements. This applies to activities performed at the main calibration lab, at sites away from the lab, in associated temporary or mobile facilities or at customer facilities. Procedure GBP-ESD-06 covers Field Work.



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5.4.1 ENSL is committed to promoting a climate that encourages a questioning attitude. All laboratory personnel have stop work authority and are obligated to enact those responsibilities if the need arises. The Calibration Laboratory Manager, Lead Metrologist and Technical Program Manager, and Lab Quality and Business Administration Program Manager has the authority to resume work based on appropriate resolution of the cause for any stop work actions. Employees are also made aware of the Energy Northwest General Business Procedures (GBP) and the Industrial Safety Program Manual (ISPM). The GBP and the ISPM contain information concerning "Expectations Regarding Integrity and Ethical Conduct", "Differing Professional Opinions", "Industrial Hygiene" and other topics assuring a quality-oriented safe working environment

5.5 The Laboratory Shall maintain:

- a. Organizational and Management structure of the Laboratory are captured on the ENSL Organizational Chart (Appendix A-1) details the reporting relationship by functional area of personnel in the laboratory. ESD organization is under the department site of the Chief Executive Officer who is accountable for the overall direction and management of Energy Northwest activities. The relationship between management, technical operations and support services work collaboratively as a station to achieve company objectives and goals.

ENSL may request technical support from Columbia Generating Station receives guidance, support and periodic assessments from the Energy Northwest Corporate Quality and Safety organizations. Support services are described in the Energy Northwest General Business Procedures (GBPs). Additional support organizations include Supplier Quality, Contracts, Legal, Supply Chain, Finance, Accounting, Records and Information Management and other organizations required to support laboratory operations.

- b. The responsibilities of the personnel who manage, perform or verify work affecting the results of laboratory activities are documented in the position descriptions maintained on SharePoint.
- c. ENSL will document in its procedures to the extent necessary to ensure consistent application of its laboratories and the validity of the results. The calibration facilities staff understand the objective of calibration and how to assess the validity of the results obtained. Organizational documentation, such as training records, are utilized to satisfy this requirement.
- d. Organizational charts, detailed job descriptions, various process flow charts and written procedures, indicate the responsibility, authority, and connectivity of everyone directly involved in performing calibration activities within the calibration facility.

5.6 ENSL staff provide the technical experience and oversight in calibration methods, processes, instructions, objectives, and assessment of results.

- a. The calibration lab has personnel who are technical subject matter experts in calibration and metrology.

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The calibration Lab is supported by a Lab Quality and Business Administration Program Manager who is responsible for coordinating all quality functions including auditing, vendor assessments, training recommendations, assessment of the effectiveness of the Business Management System and the assistance of employees with the concepts and tools necessary for use within quality improvement projects and initiatives.

- b. All calibration personnel have the authority to identify deviations from the management system or procedures and can initiate actions to prevent such deviations. This is monitored by the quality manager and Calibration Lab manager.
- c. Documentation of actions to prevent or minimize such deviations are captured on the risk register.
- d. The Energy Business Services Manager serves as the final authority for resolving Quality Related disputes. The Business Services Manager also handles responses to new contract requests and for contract renewals.
- e. The Lab Quality and Business Administration Program Manager is responsible for the ENSL quality system and its implementation. The Lab Quality and Business administration Program Manager has direct access to the Calibration Laboratory Manager for all decisions regarding laboratory policy or resources.
- f. The Lead Metrologist and Technical Program Manager is responsible for the technical aspects of the lab and its implementation. The Technical Manager has direct access to the Calibration Laboratory Manager for all decisions regarding laboratory policies and resources.
- g. The Calibration Laboratory Manager is responsible for providing leadership, supervision, and technical direction of bargaining unit staff and the Business Specialists. The Calibration Laboratory Manager has the necessary authority to ensure that planning, resourcing, directing, and controlling of the calibration lab operations are provided to meet customer, quality, and business objectives.
- h. The Business Specialists provides customer quotations, is the primary contact point for customer inquiries of equipment status, generates customer invoices, generates sales orders, supports contract administration and support production schedules that input into the scheduling and customer commitments.
- i. Lead Technicians are assigned a lead role where when the plans for work implementation developed it is their responsibility to carry out the work plan, coordinate efforts of resources, review certifications and act as a direct technical resource to calibration technicians in their respective discipline labs.
- j. Calibration Technicians are responsible for calibration of standards, MT&E for CGS and commercial customers. The technicians are responsible to develop standard laboratory instructions for calibration procedures.
- k. Calibration Laboratory Specialists are responsible for the incoming and outgoing of all MT&E from internal and external customers.

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- i. ENSL's scope of capabilities is delineated in GBP-ESD-07 Calibration Lab Policies or Processes for Commercial Customers Administrative.

#### 5.7 The ENSL Calibration Lab Manager shall:

- a. Provide delegation of authority, as necessary, for matters pertinent to the Laboratory that are not covered in this manual. Others may be delegated signature authority in accordance with the Energy Northwest General Business Procedures GBP-HR-12, "Delegations of Authority".

The ENSL Calibration Lab Manager, Lead Metrologist and Technical Program Manager and Lead Technicians are authorized to act on each other's behalf during routine absences, except for matters of personnel and salary actions. Extended absences of management personnel will be handled in accordance with GBP-HR-12, Delegations of Authority.

The authorized signatories for ENSL calibration certificates and reports, training qualifications, Standards Laboratory Instructions (SLIs) and other forms include the ENSL Calibration Lab Manager, Lead Metrologist and Technical Program Manager and Lead Technician(s).

The authorized signatories for the ENSL Quality Manual, QM-1, follow the required signatures in the Automated Workflow Process (APW).

- b. ENSL ensures the integrity of the management system. When changes are made to the management system they are planned and implemented. ENSL communicates the effectiveness and importance of meeting customer and other requirements through daily standup meetings and incorporates change management briefings on management system modifications.

## 6.0 **RESOURCE REQUIREMENTS**

### 6.1 **General**

- 6.1.1 The Calibration Laboratory Manager, Lead Metrologist and Technical Program Manager, and Lab Quality and Business Administration Program Manager has the responsibility for reviewing all new work to ensure appropriate equipment, resources, and facilities are available to accomplish the proposed work. For additional information, see GBP-ESD-07 Calibration Lab Policies or Processes for Commercial Customers Administrative, discussing Property Management Plan and EN Contracts and Tenders Guidance Documents.

### 6.2 **Personnel**

- 6.2.1 Management Structure:  
ENSL ensures impartiality for all personnel, both internal or external, this is achieved through management and quality driven reviews and reinforced through all staff mandated training such as Compliance and Ethics annual training. The Calibration

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Laboratory Manager, Lead Metrologist and Technical Program Manager, and Lab Quality and Business Administration Program Manager ensures that all personnel be competent and work in accordance with the laboratory's management system. This is achieved by the Laboratory Services Manager who provides Corporate Guidance regarding strategic planning, financial metrics, and serves as the final authority for matters involving Quality disputes. To support the independence of the Laboratory QA and Business Administration Program Manager, report to the Calibration Laboratory Manager.

6.2.2 Competence requirements for each function influencing the results of laboratory activities which may include requirements for education, qualification, training, technical knowledge, skills, and experience are maintained as confidential records. Position descriptions are used to document requirements of training and education for each position. Position Descriptions are located on SharePoint in the following location <http://thecurrent/sites/HR/PositionDescriptions/>

Procedure TPD-23 Standards Laboratory Training Program is used to document training requirements in the laboratory.

- a. The Calibration Lab Manager is responsible for the overall operation and administration of the laboratory including laboratory direction, establishment of goals, organizational long-term planning, staffing, financial oversight and budget, the facility, and ensuring the Laboratory is equipped with the necessary standards and equipment. The Manager is also responsible for the Laboratory's overall quality policy and its contractual agreements with customers. The Manager has the authority and responsibility to make quality and technical decisions affecting the laboratory. The Calibration Lab Manager is committed to the development and implementation of this quality management program and the continual improvement of its effectiveness. Further, the Manager ensures the integrity of the quality management system is maintained when changes to the system are planned and implemented.
- b. The Laboratory QA and Business Administration Program Manager is responsible for the laboratory quality management system program, the ENSL Quality Manual, and assuring that the laboratory operates to the requirements of ANSI/NCSL Z540.1, ANSI/ISO/IEC 17025, 10 CFR 50 Appendix B and ASME NQA-1 as applicable. This includes the review and oversight for the creation, revision and evaluation of procedures, operating methods, traceability of standards, software automation, and database management. In addition, it includes the oversight of the development of written reports, identification and reporting of laboratory deficiencies, input for training needs, management of the commercial customer corrective action program. The Laboratory QA and Business Administration Program Manager has stop work authority for all work performed at ENSL. The role of the Laboratory QA and Business Administration Program Manager involves leading periodic laboratory reviews, audits, and self-assessments, as well as verifying that activities affecting quality have been correctly performed, including review and approval of technical documents. The Laboratory QA and Business Administration Program Manager has the authority, access to areas, and organizational freedom to identify quality problems; initiate, recommend and/or provide solutions to quality problems through proper channels; verify implementation of solutions; and assure work is controlled until proper disposition has been made. The position involves frequent interface in solving problems and

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giving technical direction with various levels of plant management, line personnel and outside customers.

- c. The Lead Metrologist and Technical Program Manager is responsible to support, maintain, and facilitate Standards Laboratory quality program consistent with other external customers' quality and accreditation requirements. Provide technical support for audits, reviews and evaluations of Standards Laboratory quality program, activities, processes, and procedures to ensure compliance with CGS OAQPD and other external customers' quality/accreditation requirements. Assures laboratory processes, procedures and practices comply with the lab's quality program requirements external customer regulatory and accreditation needs. Develops and maintains existing Uncertainty Budgets.
- d. The Business Specialist performs the billing/invoicing and purchasing/accounting functions for the Energy Northwest Standards Laboratory and ensures timely submittal and reporting. Provides administrative guidance and support to calibration specialists, technicians, and laboratory staff. Assists in the identification of present and future customer calibration service needs. Prepares monthly reports, monthly and annual statistics, special financial reports on as needed basis.
- e. Calibration Laboratory Specialist(s) are responsible for the flow of paperwork, shipping and receiving of standards and M&TE, database management, maintenance of calibration reports and instructions, purchasing, monthly reporting, credit card reconciliation, maintain MT&E records for traceability of equipment, maintain training documentation, customer interface, and other administrative support functions necessary for the efficient operation of the lab.
- f. The Calibration Technicians are responsible for the calibration of M&TE and calibration standards. They are also responsible for the quality of their work, including instruction development, review, and revision, assuring the adequacy of standards, utilization of proper techniques and methods, and the proper documentation of results.

### **6.2.3 Competence, Training and Qualification**

- a. Energy Northwest Standards Laboratory personnel who perform, verify, or manage activities affecting quality are qualified for those activities by education, previous experience, and training. See TPD-23 Standards Laboratory Training Program and Standards Laboratory Qualification Directory 2.18.
- b. Personnel are hired to fulfill specific job requirements. Position Descriptions are located on SharePoint in the following location  
<http://thecurrent/sites/HR/PositionDescriptions/>
- c. Formal training may be required as a method of providing employee technical education. On-the-job training (OJT) is utilized when appropriate and gives employees the opportunity to experience new situations or service a broader product range by learning in a controlled environment where assistance is readily available through mentoring. Implementation of OJT is per management discretion and continues until a mentor is satisfied that the required level of competence has

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been attained. Further clarification is provided in TPD-23 Standards Laboratory Training Program and Standards Laboratory Qualification Directory 2.18.

- d. Training and education goals for the calibration facilities personnel are reviewed each year as part of the employee job performance. Available training may include formal training classes, attendance of metrology conferences, etc. Training records are maintained for each member of the calibration lab. Under the direction of the calibration lab manager, the technicians can develop technical areas of specialization. The calibration technicians are responsible for creating and continuously improving processes, procedures, and software in the assigned area(s) of responsibility. These activities form much of the basis for technician technical training. The technician with primary responsibility for an area also oversees any day-to-day cross training of other technicians in that technical area. See TPD-23 Standards Laboratory Training Program and Standards Laboratory Qualification Directory 2.18.
- e. Technicians in Training undergo a training program in accordance with a training program known as Workplace Training an A2LA company. The laboratory's training documents and On the Job Training (OJT) with Experienced Technicians, Computer Based Training (CBT) as assigned by management. Trainees perform calibrations when training and competency has been demonstrated. The Trainer will review and sign as Trainor on all calibration reports that the Trainee performs. The demonstration of competence is an exercise that the trainee performs independent of supervision that is documented as part of their qualification for their discipline qualification they are in process of obtaining. The trainee is considered competent after the specified criteria has been successfully met and demonstrated.

#### **6.2.4 Communication of Duties, Responsibilities and Authorities**

- a. Laboratory management ensures that laboratory personnel have the competence to perform their duties and to evaluate the significance of deviations.
- b. ENSL maintains job descriptions for the various positions within the Laboratory through Human Resources Department and can be found on SharePoint.
- c. The laboratory maintains active job descriptions for managerial, technical, and key administrative support personnel involved in laboratory activities. Job descriptions are established based on current duties and technologies utilized.
- d. The laboratory employees involved in laboratory activities have access to standards, instrument manufacturers' manuals, and laboratory procedures for reference.
- e. Effective communication from the company and management occurs through, but not limited to, memos, newsletters, electronic presentations ie: power points, emails, or verbally to laboratory personnel regarding all company information including but not limited to the effectiveness of the management system.

6.2.5 The laboratory shall have procedure(s) and shall retain records for the following:

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- a. Determining the competence requirements – Refer to TPD-23 Standards Laboratory Training Program
- b. Selection of personnel – Interview Candidate ranking form is used refer to GBP-HR-09 Applicant Selection Process
- c. Training of personnel – Refer to TPD-23 Standards Laboratory Training Program
- d. Supervision of personnel - Refer to GBP-HR-09 Applicant Selection Process
- e. Authorization of personnel – Hiring Panel Request Form 12121 Refer to GBP-HR-09 Applicant Selection Process
- f. Monitoring competence of personnel – Refer to TDI-05 Qualification Management Procedure and Task Observation form 26799, PQD, Nantel and A2LA Workplace training

6.2.6 The laboratory shall authorize personnel to perform specific laboratory activities, including, but not limited to, the following:

- a. Development, modification, verification, and validation of methods.
- b. Analysis of results, including statement of conformity or opinions and interpretations.
- c. Report, review, and authorization of results.

### **6.3 Facilities and environmental Conditions**

6.3.1 The Energy Northwest Standards Laboratory is climate controlled and has provisions for cleanliness, temperature, and humidity. Individual environments within ENSL are controlled to the extent required for the most sensitive measurement performed.

6.3.2 In determining the calibration environment, consideration is given to the operating specifications of the required standards or M&TE as well as the operating specifications of the Unit Under Test (UUT). The operating temperature specification for most electronic instruments is 32°F to 130°F. Typical laboratory specifications are 64°F to 82°F, or 73°F ± 9°F, or will be characterized with temperature corrections. Relative humidity is typically specified to 10% to 80%, non-condensing. Environmental conditions for Dimensional Standards areas are specified at 68°F ± 2°F. When specific temperature and/or humidity requirements are required to meet calibration control limits, those requirements are specified in the respective Standards Laboratory Instructions. A 24 hour acclimation time is required in the dimensional lab prior to performing any calibration.

6.3.3 Ambient temperature and relative humidity (%) are continuously monitored and recorded in all calibration areas. In remote or mobile calibrations, the ambient temperature and humidity is monitored with a portable temperature/humidity analyzer, as required

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6.3.4 If any one of the environmental factors affecting a given calibration are violated, calibration activities are stopped until environmental control is restored in the affected discipline lab(s). Measures to control facilities shall be implemented, monitored, and periodically reviewed and shall include but not be limited to the following:

- a. Access to and use of areas affecting laboratory activities.
- b. Prevention of contamination, interference of adverse influences on laboratory activities. ENSL was designed to effectively separate all areas of calibration activity where those activities are incompatible. Areas for handling potentially radioactive contaminated equipment are designed and operated in accordance with Plant Procedure Manual (PPM) 1.11.15, Control of Radioactive Material and are physically segregated from commercial customers received equipment. Handling of any radioactive material is under the auspices of the nuclear station radiological procedures. The various areas of ENSL are environmentally controlled for specific applications, access to those areas is limited. Where particularly sensitive measurements are being made, areas may be placarded or roped off to prevent inadvertent entry. Additional controls are outlined in GBP-SEC-05, Access Controls to Energy Northwest Non-Nuclear.
- c. Effective separation between areas with incompatible laboratory activities. ENSL personnel are responsible for housekeeping within their work or personal area. General areas and systems are maintained by the facilities group and/or contract personnel who are aware of access and security requirements.

6.3.5 When calibrations are performed at a customer's site, ENSL monitors and records the environmental conditions. ENSL requires a typical set of conditions in which to perform the calibrations.

## 6.4 Equipment

6.4.1 The Energy Northwest Standards Laboratory is supported by a system of calibration standards with an accuracy, resolution, stability, and calibration range that satisfy the requirements imposed by measuring and test equipment specifications. Calibration standards are selected to assure proper type, range, accuracy, uncertainty, and tolerance for a given calibration. GBP-ESD-07, Calibration Lab Policies or Processes for Commercial Customers Administrative contains an attachment with a listing of the major components of the calibration system identified on the A2LA Scope of Accreditation.

- a. For calibration gas standards and solutions, ISO 17034 contains additional information on reference material producers (RMPs) that meet the requirements of ISO 17034 which demonstrates manufacturing competency. ISO 17034 are provided with a product information sheet and certificate that is accredited amongst other characteristics for certificated reference materials.

6.4.2 ENSL staff are responsible for the review and acceptance of new work based upon laboratory capabilities including calibration standards required. When the calibrations require capabilities beyond the current scope of ENSL, calibration services external to ENSL may be required. When the laboratory uses equipment outside its permanent control for offsite services, it shall ensure that the requirements for equipment of this Quality Manual and ISO 17025 are met.



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- a. Should it be necessary to borrow equipment, the ENSL calibration lab ensure that equipment on loan from other organizations or suppliers (ie: rented, customer supplied, etc.), are calibrated (if required) traceable to national or international standards and free from viruses refer to SWP-CSW-15 Portable Media and Digital Device Use. Arrangements must be made to ensure the calibration integrity of equipment while on loan. Since out-of-tolerance conditions require further investigation, loaned equipment must be uniquely identified in the entity's calibration tracking system. Equipment loaned to another facility will be subject to functional and physical checks prior to being returned to service. Should the verification check indicate a potential problem, a full calibration shall be performed. Equipment loaned to organizations outside of ENSL shall be re-calibrated upon return.

- 6.4.3 Handling, transport, storage, use, and planned maintenance of ENSL owned equipment is performed with the same care as customer equipment. Procedure SWP-MMP-03 Packaging and Shipping of Material or Equipment provides requirement for packaging and shipping of Energy Northwest material or equipment and this process is followed for packaging and shipping of all commercial customer materials or equipment.
- 6.4.4 Routine maintenance of calibration standards is accomplished in accordance with the manufacturer's maintenance manual and is performed at the time of calibration. Maintenance of ENSL M&TE and calibration standards may be limited to cleaning, lubrication (if required) and/or filter checks and are performed at the time of calibration. Any instrument that is known or suspected to be broken, out of tolerance, unstable or have intermittent problems, or is otherwise deficient is removed from use or labeled with an appropriate label to prevent its use for calibration purposes until appropriate corrective action can be completed. Routine maintenance for equipment is accomplished in accordance with GBP-ESD-07, Calibration Lab Policies or Processes for Commercial Customers Administrative
- 6.4.5 Reference standards are identified, controlled, and calibrated in accordance with the program detailed in this section. For those standards whose calibration is beyond ENSL capabilities, refer to GBP-ESD-07 Calibration Lab Policies or Processes for Commercial Customers (Admin). This process assures that all calibrations are traceable through an unbroken chain of calibrations to national, international, or intrinsic standards. Reference Standards are used for internal standards lab calibrations only. Any reference standard that is known or suspected to be broken, out of tolerance, unstable, have intermittent problems, or is otherwise deficient is removed from use or labeled with an appropriate label to prevent its use for calibration purposes until appropriate corrective action can be completed. Documentation which substantiates and identifies the means of achieving traceable measurements of Transfer/Working or Reference standards to national, international, or intrinsic standards are maintained in the metrology files of the laboratory. Forward traceability can be demonstrated for calibration standards to document chain of traceability.
- 6.4.6 Each ENSL metrology discipline shall have a documented procedure known as Standards Laboratory Instruction (SLI) for the calibration of equipment used for testing. These are used for all equipment that have a significant effect on the accuracy or validity of the test result. The measurement accuracy or measurement uncertainty affects the validity of the reported results and/or the calibration of the equipment is

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required to establish the metrological traceability of the reported results. Types of equipment influencing the validity of the reported results can include those used for direct measurement of the measurand, those used to make correctios to the measured value, and those used to obtain a measurement result calculated from multiple quantities. All equipment described above shall be calibrated prior to being put into service.

- 6.4.7 ENSL laboratory shall establish a calibration program, which shall be reviewed and adjusted as necessary to maintain confidence in the status of calibration.
- 6.4.8 Each piece of equipment including reference materials, is labeled, or coded to indicate its calibration, preventative maintenance, inspection, test and/or operating status. Labels or coding are affixed to the unit without obscuring other information. To ensure calibration integrity, tamper-resistant seals are used to prevent access to calibration controls or adjustments that may, if adjusted, affect calibration. If the equipment is of a size that precludes application of a calibration label, the label may be applied to its container or an attached tag. These requirements also apply to calibrations performed by EN Evaluated Suppliers (ESL) subcontractors.
- a. As a minimum, calibration labels used by ENSL contain the following attributes:
    - 1) The ENSL logo, name, or both.
    - 2) A unique ID number for each instrument.
    - 3) Date Calibrated.
    - 4) Due Date for recalibration - Unless exception requested by customer.
    - 5) Identification of the person responsible for the calibration.
  - b. If the extent of the calibration or performance of the M&TE is limited, or has other special conditions, a label with the limitation shall be applied. A "LIMITED CALIBRATION" label may be used to denote calibration status if an item is not calibrated over its entire range and/or functions, or to indicate other anomalies. Labeling requirements may vary for equipment calibrated by ENSL per customer requirements and/or specifications.
- 6.4.9 M&TE that is known or suspected to be malfunctioning, out of tolerance, unstable or have intermittent problems shall be removed from use or flagged with an appropriate label, tie on tag, or other suitable means, to guard against unintended use until appropriate corrective action has been taken. When non-conforming work is reported, an evaluation is performed. Non-conforming work can be the discovery of an improper calibration method, a mistake in a calibration procedure, an out of limit condition of the environment, or an out of tolerance condition of a standard. Out of Tolerance (OOT) conditions are the most common form of non-conforming work. If the out of tolerance or undetermined condition will significantly affect the calibration of other devices, the calibration facilities will identify all suspect calibrations. All customer non-conforming work is documented as a "Customer Complaint" or a Condition report if the asset is a lab standard and logged into a computer based tracking system.

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- 6.4.10 Test Equipment Vendor Manuals and/or equipment performance history shall outline any performance checks required on equipment. Procedures shall establish the time frame for checking based on the specifics of the testing performed with the equipment. Calibration checks shall not be less stringent than the manufacturer's recommendations. Each metrology discipline shall have procedures to perform checks on reference, primary or working standards and reference materials to maintain confidence in their performance. Each metrology discipline will have documented procedures for routinely checking the reliability of their reagents as required.
- 6.4.11 Should correction factors be required to improve measurement accuracy, any standard's factors shall be updated in the associated correction factor management system. In such cases, the process for updating these data files must ensure the accuracy of correction factor data. In cases where data is entered manually, some means of validating the data entry are used, and a record of the validation maintained.
- 6.4.12 The laboratory shall take practicable measures to prevent unintended adjustments of equipment invalidating results. All M&TE and calibration standards shall be sealed with tamper resistant seals to preclude any tampering with user accessible calibration controls or adjustments that may affect calibration. Refer to GBP-ESD-07 section 4.16 on tamper seals. Examples of controls and adjustments requiring seals include gain adjustment potentiometers accessible from a front panel hole in pressure gauges (but not necessarily the zero adjust), software calibration enable switches on digital equipment and any calibration controls or adjustments which are not specified as part of an operators normal operating procedure for the unit. Units with broken tamper-resistant seals, when discovered on calibration facility standards or measuring and test equipment shall immediately be corrected in accordance with the organization's calibration processes and procedures and reported through Columbia Generating Station SWP-CAP-01 Correct Action Program.
- 6.4.13 Records for ENSL M&TE, and calibration standards are maintained in accordance with Energy Northwest General Business Procedure GBP-REC-01, Records Management Program. Calibration Records for customer equipment are handled per contract requirements, in accordance with Energy Northwest General Business Procedure GBP-REC-01, Records Management Program and requirements outlined in the CORE-01 Local Government Common Records Retention Schedule and UTILITY-01 Utility Services Records Retention Schedule. Disposition of records are identified and managed by submitting a Records Disposal/Destruction Notice (RDN) through the APW process. Guidance can be found in GBP-REC-06 Scan and Toss Program for maintaining records digitally.

The records for M&TE or standards contain the following information:

- a) Instrument identification (including trace number, and software and firmware version),
- b) Manufacturer's name, model number, serial number, and a description of the item
- c) Most recent calibration record,
- d) Current physical location,

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- e) Current calibration interval, date of last calibration, and calibration history,
- f) Period of validity for reference material (if applicable, such as a shelf life),
- g) Maintenance plans and history as applicable, Refer to GBP-ESD-05 Calibration Lab Policies or Procedures for Commercial (Technical) section 2.1 Routine Maintenance.
- h) Repair history as applicable, such as indications of erratic behavior or operational failures.

## 6.5 Traceability

- 6.5.1 ENSL maintains metrological traceability of all its measurement results through an unbroken chain of calibration, each contributing to the measurement uncertainty (NIST Traceable).
- 6.5.2 ENSL uses standards traceable to the SI via national, international, or intrinsic standards of measurement. Traceability is stated on calibration documentation. NIST Traceable standards are procured by Vendors from the ENSL Evaluated Suppliers List. Certain standards may be inter-compared to assure equipment stability, accuracy, and repeatability.
  - a. In all cases, traceability is stated on respective calibration documentation. Reference and working standards used in the system are calibrated against higher-level standards.
  - b. ENSL employs several types of reference materials in its calibration operations. Photographic Step Tablets and other standard reference materials (SRMs) are purchased directly from the National Institute of Standards and Technology (NIST). Hardness standards, calibration gases, chemical liquid standards, etc., are procured from Energy Northwest Evaluated Suppliers List approved vendors, who in turn provide NIST traceability for each type of material ordered/used.
  - c. Direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.
- 6.5.3 When traceability to SI units is not technically possible, traceability to appropriate reference such as:
  - a. Certified values of certified reference materials provided by a vendor from the ESL
  - b. Results of reference measurement procedures specified methods or measurement standards that shall be clearly described and accepted as providing measurements results for their intended use and validated by suitable comparison and documented in the associated uncertainty analysis.

## 6.6 External Products and Services

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- 6.6.1 When the calibration of standards or M&TE requires capabilities beyond the current scope of ENSL, external calibration sources may be required.
- a. External suppliers of calibration services are intended for incorporation into the laboratory's own activities.
  - b. Services are provided in part, or in full directly to the customer by the laboratory, as received from the external provider.
  - c. The services are used to support the operation of the laboratory.
    - 1) These external suppliers are evaluated by one of the following methods:
      - a) On site audit, Commercial Grade Survey, Source surveillance, ANSI/ISO/IEC 17025 Accreditation, Other means as applicable with customer concurrence.
- 6.6.2 The laboratory shall have a procedure and retain records for:
- a. Defining, reviewing, and approving the laboratory's requirements for externally provided products and services; Refer to procedure SWP-ASU-01 Evaluation of Programs, Processes, and Suppliers.
  - b. Defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers; Refer to procedure SWP-ASU-01 Evaluation of Programs, Processes, and Suppliers and SQI-7-2 Evaluation of Suppliers and Form 290 Request for Supplier Evaluation.
  - c. Ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this quality manual, before they are used or directly provided to the customer; Refer to Supplemental Purchasing Clauses SPC-400 clauses 494, 495 and 496 and GBP-ESD-07 section 4.29.2.
  - d. Taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers. Refer SQI-18-3 Supplier Audits.
- 6.6.3 The laboratory shall communicate its requirements to external providers for the following:
- a. The products and services to be provided; ENSL requires that calibration services providers are required to have a quality program that either meets the requirements of ANSI/NCSL Z540.1 and / or ISO/IEC 17025 or, when coupled with ENSL's quality program, meet the requirements. In addition, for certain calibration activities related to CGS and other commercial customers, 10 CFR 50, Appendix B including 10 CFR Part 21, ASME NQA-1 may also be invoked. The purchase and receipt of consumable materials is controlled by Energy Northwest Site Wide Procedure SWP-PUR-04, "Material, Equipment, Parts and Supplies Procurement." Storage of consumable materials is in accordance with manufacturer's instructions, where available.
  - b. The acceptance criteria; applicable technical requirements are imposed on lower tier calibration service providers through the procurement documents. The

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applicable QA requirements are passed down to lower tier suppliers via Purchase Orders, Sales Orders, or Contract. Documentation of incoming receipt inspections are accomplished by stamping incoming records as either 'Sat' or 'Unsat' based on compliance to inspection or test criteria. The stamped documents are included in the ENSL Calibration Certifications and Reports, which are quality records

- c. Competence, including any required qualification of personnel; Refer to procedure SQI-7-2 Evaluation of Suppliers. Records of suppliers on the EN Evaluated Suppliers List (ESL) are available on the Energy Northwest intranet and are retained by EN as a Quality record. Source surveillance/inspection would typically require witnessing of a calibration by a sub-tier contractor. This process may be utilized to ensure the work activities performed by a provider not currently on the ESL meets the specified quality requirements.
- d. Activities that the laboratory, or its customer, intends to perform at the external provider's premises. ENSL will obtain concurrence from customers when subcontractor calibration services will be used, and the use of subcontractor calibration services is annotated in the respective calibration reports. ENSL is responsible to the customer for all subcontractor work. Subcontractors are responsible to comply with procurement documents issued to them by ENSL.

## **7.0 Process Requirements**

### **7.1 Review of Requests, Tenders and Contracts**

- 7.1.1 EN has a procedure for the Review of Requests, Tenders and Contracts see GBP-ESD-07. This procedure shall ensure that:
  - a. The requirements are adequately defined, documented, and understood
  - b. The laboratory has the capability and resources to meet the requirements.
  - c. Where external providers are used, the requirements of section 6.6 are applied, and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer approval
  - d. The appropriate methods or procedures are selected and shall meet the customers' requirements.
- 7.1.2 Contractual arrangements between the customer and the Standards Laboratory which specify requirements in addition to or more restrictive than those specified by regulatory requirements, Codes or Standards may be applied provided the requirements do not negate any rules of the governing code or degrade the quality level specified. This program may be adapted in part or in whole to jobs not subject to regulatory or code requirements provided it does not compromise the quality of our service.
- 7.1.3 When the customer requests a statement of conformity to a specification or standard for the test or calibration ie: pass/fail, in tolerance/out of tolerance, the specification or standard and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated

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to and agreed with the customer. The National Institute of Standards and Technology (NIST) along with State Laboratories such as Bureaus of Weights and Measures may be utilized without being added to the ESL, provided they have a program approved by NIST. In addition, ENSL through Energy Northwest Supplier Quality may also solicit and add to the ESL calibration services providers who have received accreditation to ISO/IEC 17025 by an International Laboratory Accreditation Council (ILAC) Mutual Recognition Arrangement (MRA) Accreditation Body (AB) (e.g., National Voluntary Laboratory Accreditation Program (NVLAP), or American Association for Laboratory Accreditation (A2LA)). When these calibration services providers are utilized, the requested calibration shall be within the respective laboratory's Scope of Accreditation, measurement uncertainties shall be reported, and the calibration report shall contain the logo and/or certificate number of the accreditation body for that laboratory. Exceptions are allowed under A2LA policies where accredited calibration services are not currently readily available (e.g., calibration gases) in which case alternate sources may be used.

a. **Compliance with Specification Statement of Conformity**

The uncertainty of measurement has been considered when determining compliance with specification, as per ILAC-G8:09/2019. If the expanded measurement uncertainty intervals centered about one or more measured values were both in as well as out of specification (upper or lower), it is not possible to state compliance or non-compliance based on a 95% coverage probability for the expanded measurement uncertainty. An overall statement of compliance for all tests performed as received, and as completed (if any adjustments / repairs were performed) is included in the calibration report. Statements of compliance apply only to warranted specifications. When functional verification tests are performed, results are reported in the "Functional Test" section, and do not affect these statements of compliance. The status summaries relate to the tested item only. A final decision about whether the item's performance satisfies requirements of the user can only be made by the user.

b. **Uncertainty of Measurement Statement**

The uncertainty evaluation has been performed in accordance with ISO/IEC Guide 98-3:2008 (GUM). The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor  $k$  such that the coverage probability corresponds to approximately 95%. This probability corresponds to a coverage factor of  $k=2$  for a normal distribution.

c. **Functional Test Statement of Conformity**

Functional test results are not part of an accredited calibration service, even if they are part of an otherwise accredited calibration report. The following tests document the functional verification of the instruments' non-warranted performance. Neither a statement of conformance or decision rule is used for a Functional Test, measurement uncertainties are only provided by exception. For a "Functional Test" the test results are reported as "Pass" when showing expected performance and "Fail" otherwise. For qualitative or quantitative "Functional Tests" the test results are not warranted, and no judgment is made. The "actual" measured results are helpful to users for some applications.

d. ENSL obtains agreement from the customer before employing calibration methods that have not been well defined. The basis for the calibration method employed is documented. The decision rules utilized by ENSL are defined in the ENSL

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Instrument Calibration Report. This is clearly communicated to the customer when ENSL confirms a calibration service.

- 7.1.4 All differences between the customer request and service order are resolved with the customer prior to performing any work. This is documented in the sales order or purchase order and acceptance of the customer's purchase order.

<p><b>NOTE:</b> If, during a calibration process, it becomes evident the work will deviate from what was requested by the customer, the customer will be notified, and concurrence obtained.</p>
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- 7.1.5 The customer is informed of any deviations to the previously agreed-upon contract, and this is documented in the order management process.

- 7.1.6 Amendments to the contract, purchase order or sales order may require additional review including revision to the calibration service being requested, re-assignment of personnel or resources, and distribution of the revised documents and information to all parties necessary.

- 7.1.7 ENW will have cooperation with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed.
- a. Cooperation can include providing reasonable access to relevant areas of the laboratory to witness customer specific laboratory activities. Customers are permitted to visit calibration facilities, provided ENSL is given adequate notice. These visits may be in the form of a formal audit of our calibration processes or to observe calibration procedures. Appropriate measures are taken to ensure the confidentiality of all client equipment, materials, and information present in the calibration laboratory.
  - b. Such cooperation may also include preparation, packaging, and dispatch of items needed by the customer for verification purposes.

- 7.1.8 Records pertaining to requests, tenders and contracts shall be maintained per the policy GBP-REC-01 Records Management Program. Records may include but not be limited to records of reviews, pertinent discussions with a customer relating to the customer's requirements of the results of the laboratory activities.

## **7.2 Selection, Verification and Validation of Methods**

### **7.2.1 Selection and Verification of Methods**

- 1) Method(s) and procedures for all laboratory activities will be utilized and where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.
- 2) To assure the ability to maintain repeatability of measurements and correct operation of its equipment, ENSL, as applicable and necessary, maintains



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documented instructions in the form of manufacturer's/vendor's manuals and/or other documentation for the proper operation, maintenance and use of its M&TE, calibration standards, and ancillary equipment. ENSL maintains manufacturer and vendor manuals as needed for customer M&TE. When an OEM procedure is not available or deemed inappropriate or inadequate, appropriate methods are developed by the Lead Metrologist and Technical Program Manager using industry standard calibration methods.

NOTE: International, regional, or national standards or other recognized specifications that contain sufficient and concise information on how to perform laboratory activities do not need to be supplemented or rewritten as internal procedures. If these standards are written in a way that they can be used by the operating personnel in a laboratory. It may be necessary to provide additional documentation for optional steps in the method or additional details.

- 3) The laboratory will ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary the laboratory will supplement the application of the method with additional details to ensure that there is consistent application.
- 4) When customers do not specify methods to be used on their requests, tenders, and contracts, then ENSL approved calibration procedures are used. The method used will be documented. For ISO 17025 calibrations, uncertainties are calculated using the expanded uncertainty of the measurement, and the coverage factor and confidence level must be stated. See GBP-ESD-05 Calibration Lab Policies or Processes for Commercial Customers (Technical).
- 5) Verification and validation by laboratory staff shall be done to verify that the lab can properly perform methods before introducing them by ensuring that the lab can achieve the required performance. If a method is revised by the issuing body, then verification will need to be repeated to the extent necessary. When ENSL develops new calibration procedures they are fully verified to ensure the required performance can be achieved.
- 6) When method development is required, procedures available from manufacturers, government, military, industrial, customer, etc. (i.e., ANSI, ASME, ASTM, GIDEP, GGG, etc.), as well as published standard practices or commercially available programs or procedures are acceptable and need not be rewritten, provided they meet the above requirements. Procedures / Standards Laboratory Instructions, at a minimum, specify the standards to be used or minimum accuracies of the required standards and equipment, test points of the unit under test and tolerances and/or uncertainties, any special environmental controls to the extent necessary, and use of compensating factors for abnormal use conditions. The laboratory performs calibrations using standards of the best reasonably achievable accuracy. For Z540.1 customer, standards adequacy is determined by computing the ratio of test instrument tolerance to standard tolerance (Test Accuracy Ratio, or TAR – see Section 3, Definitions). A TAR of 4:1 or greater is considered acceptable. TARs of less than 4:1 are handled on a case-by-case basis, either by

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mathematically reducing the test instrument tolerance to provide the same level of confidence as a 4:1 ratio (also known as guard banding) or documentation of the actual uncertainty ratio (with concurrence or direction from customer). The preparation, review, approval, issuance and change of documents affecting quality are controlled to assure that correct documents are being employed. Such documents, including changes thereto, are reviewed for adequacy and approved for release by ENSL staff prior to use. Approval authority for the laboratory implementing instructions and calibration instructions is vested with the Calibration Laboratory Manager, Lead Metrologist and Technical Program Manager, and Lab Quality and Business Administration Program Manager. See Standards Laboratory Instruction GBP-ESD-07, for the section on Standards Laboratory Instruction Development and Control.

- 7) Deviations from methods for all laboratory activities may be used if the deviation has been documented, technically justified, authorized, and accepted by the customer. Other methodologies may be employed with the concurrence of the customer, including a statement of uncertainty analysis, widening the test instrument tolerance, or outsourcing the calibration to a laboratory capable of providing the required accuracy (if possible).

### **7.2.2 Validation of Methods**

- 1) Where calibration methods are not specified, ENSL shall, , select methods that have been published in international or national standards, or those published by reputable technical organizations. Non-Standard calibration methods are documented when used and with customer concurrence.
- 2) Changes to calibration procedures are documented and re-validated if necessary.
- 3) The validation process includes steps to validate the range and accuracy of the calibration procedure as compared to the associated calibration test source. The validation methods shall be relevant to the customers' needs and consistent with specified requirements.
- 4) The following is maintained as evidence of calibration procedure validation:
  - a) Validation plan or procedure used.
  - b) Reference to specifications/ test source of the requirements.
  - c) Validation that the procedure includes the necessary test parameters per the test source and the determination of the performance characteristics of the method.
  - d) Any applicable validation results obtained
  - e) Verification that the test method is metrologically sound, including traceability to SI, and level of calibration which indicates its validity of use

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### 7.3 **Sampling**

- 7.3.1 Sampling methodologies, should they need to be used, will be based on standard statistical methods with Lab Manager's approval.

### 7.4 **Handling of Test Items**

- 7.4.1 ENSL instruments, reference standards, and customer equipment shall be handled, stored, and transported in a manner which shall not adversely affect the calibration or physical condition of the equipment or its measurement integrity. The shipping and receiving departments use Energy Northwest's documented shipping and handling procedures in conjunction with ENSL procedures. M&TE and calibration standards are handled, stored, and transported in a manner which will not adversely affect the calibration or physical condition of the equipment. This includes, but is not limited to, such conditions as excessively rough movement, dropping, water or other liquid entry, etc. Any M&TE or calibration standard subjected to mishandling or suspected to be mishandled is recalibrated to restore the calibration integrity before further internal usage or customer shipments occur. Such incidents are reported to the Calibration Laboratory Manager, Lead Metrologist and Technical Program Manager, and Lab Quality and Business Administration Program Manager to be processed as required by the quality program. Any incidents involving completed customer serviced equipment is reported to the Calibration Laboratory Manager, Lead Metrologist and Technical Program Manager, and Lab Quality and Business Administration Program Manager and the item is retested prior to shipment. Storage and handling of M&TE and standards is further delineated in GBP-ESD-07 Property Management Plan section. Storage will be provided when a calibration item is to be held secure per contractual requirements.
- 7.4.2 Upon initial receipt of M&TE or standards for calibration, the laboratory shall assign a unique identification number to the item. A unique tag is placed on the unit and is to be retained while the item is under the responsibility of the laboratory at a minimum. This number is used to track the equipment in the LIMS database. The LIMS system shall ensure that items will not be confused when referred to in records or other documents. All equipment received for calibration are verified or matched to appropriate paperwork such as model number, serial number, etc. In the event of any discrepancy, the appropriate interested parties are notified, and the discrepancy resolved and updated in the order management system.
- 7.4.3 When items are received for calibration, ENSL staff note any abnormalities or departures from standard conditions. When there is doubt as to the suitability of the equipment for calibration, the customer shall be consulted with before proceeding. If an instrument experiences an operational failure during the calibration process, the customer is notified prior to proceeding. For subcontracted equipment, receipt inspection is accomplished in accordance with GBP-ESD-07 Property Management section. These activities are completed by ENSL personnel thus providing inspection by persons other than those who performed or supervised the work as well as providing assurance that applicable quality clauses and specifications set forth in the procurement documents were met.
- 7.4.4 Environmental conditions for how items need to be stored are covered in GBP-ESD-07.

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## **7.5 Technical Records**

- 7.5.1 Calibration records, specifically derived data (where applicable), original observations, and certificates of calibration, are generated for each calibration performed. Original observations are interpreted to mean measured values or pass/fail results, correctional data, as appropriate. The personnel involved in the process of performing the calibration are identified on records by appropriate means. Copies of records are retained by ENSL in either paper format or electronic form. This allows replication of the calibration for the customer if needed. Records of each calibration and associated data are recorded at the time of the calibration event. This information is identifiable to each calibrated device by a unique equipment identification number or service order number.
- 7.5.2 When an amendment is necessary to a previously approved report, the laboratory shall ensure that the corrected certificate can be tracked to previous versions or to original observations. Both the original and the corrected data and files shall be retained.

## **7.6 Evaluation of Measurement Uncertainty**

- 7.6.1 A statement that the total uncertainties or tolerances of the standards used are no greater than 25% of the tolerance of the unit tested unless otherwise noted and/or a statement of the estimated uncertainty of the calibration result (where relevant) (If a calibration certificate or test report contains a statement of the measurement result and the associated uncertainty, then the uncertainty statement is accompanied by an explanation of the meaning of the uncertainty statement. For example: "This uncertainty represents an expanded uncertainty expressed at approximately the 95% confidence level using a factor of  $k=2$ .");
- 7.6.2 ENSL uses the same measurement uncertainty processes for both internal and customer calibrations.
- 7.6.3 The methodology used for deriving the expanded measurement uncertainty is in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement" (ISO/IEC Guide 98-3) or its supplements. Other methods may have been used for earlier analysis and have been deemed to be acceptable.

## **7.7 Ensuring the Validity of Results**

- 7.7.1 ENSL monitors the operations of the calibration laboratory using one or more of the following techniques. Where applicable statistical techniques are applied to review the results. Reference GBP-ESD-05, Routine Maintenance Section.
- a) Use of reference materials (in physical/dimensional discipline)
  - b) Use of alternative instrumentation that has been calibrated to provide traceable results
  - c) Functional checks of measuring and test equipment

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- d) Use of check standards with control charts where applicable
- e) Periodic intermediate checks on measuring equipment
- f) Replicate tests or calibrations using the same or different methods
- g) Retesting or recalibration of retained items
- h) Correlation of results for different characteristics of an item
- i) When calibration results are found to be potentially suspect, reviews are completed by competent personnel of reported results
- j) Intra laboratory comparisons
- k) Other activities may be performed on a facility-by-facility basis. Ie: testing of blind sample(s)

7.7.2 ENSL calibration laboratory participate in a program of inter-laboratory comparisons and proficiency testing as necessary to maintain confidence in their measurements. ENSL participates in inter-laboratory comparisons (ILC), proficiency testing (PT), and Round Robin programs. (See GBP-ESD-07, Proficiency Testing and Inter-Laboratory Comparisons Section.) Proficiency programs might include:

- a) Participation in industry sponsored ILCs, PTs or Round Robins
- b) Submission of a previously calibrated item to an Energy Northwest approved vendor or Accredited Lab for inter-laboratory data comparison
- c) Recalibration of a previously calibrated item using the same calibration standard(s) by the same or different technician and inter-compare data.

7.7.3 Data from monitoring activities, such as from 7.7.1 and 7.7.2, are analyzed and used to improve the calibration laboratory activities. If the results are found to be outside of pre-defined criteria or show suspect results appropriate corrective action is taken. For Calibration Standards SWP-CAP-01 is used for guidance for corrective action. For commercial customer equipment GBP-ESD-07 is used for guidance for the appropriate customer complaints.

- a. Certifications, expiration dates and condition of any reference material is verified prior to each use.
- b. Replication of results using other techniques is often used in confirming failure of standards calibration or verification. Documentation is not required.
- c. Correlation of results is conducted in association with inter-laboratory comparisons and proficiency testing programs.

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- d. Acceptance of repair work, whether performed by the original equipment manufacturer (OEM), by outside calibration services provider, or by ENSL, is based on a satisfactory functional check and post-repair calibration of the subject item. The functional check and post-repair calibration shall be performed either by ENSL or a calibration services provider listed on the EN Evaluated Supplier List. Final inspection of customer equipment to verify conformance to established specifications is provided via as found data annotated on the calibration report or as left data if different than the as found data.

## **7.8 Reporting of Results**

### **7.8.1 General**

- 1) Results shall be reviewed and authorized prior to release.
- 2) The results shall be provided accurately, clearly, unambiguously, and objectively, usually in a report and shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as technical records. Refer to GBP-ESD-01 for additional guidance on records management.
- 3) A Calibration report includes both a certificate and data report. Each calibration includes specific information based on the type of calibration service rendered and customer specific requirements, if any.
  - a) A review of all calibration procedures and certificates is conducted and validates that the data generated is accurate and complete.
  - b) This review may be conducted by another technician prior to review by management.
  - c) Approvals are conducted in the Automated Process Workflow (APW) and final approval is required by management.
  - d) The results of tests or calibrations may be reported to the client in a simplified manner. This package shall contain sufficient information to comply with the customers' requirements. Regardless of customer requirements for a calibration certificate or data report, all information concerning the calibration shall be recorded and maintained except under special circumstances initiated by the customer and explicitly stated as a custom calibration deliverable in a written agreement. This includes all "As Found" and "As Left" data.

### **7.8.2 Common Requirements for Reports**

- 1) Each calibration report shall, at a minimum, include the following information:
  - a) A title, e.g., "Calibration Report" or Calibration Certificate.

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- b) Name and address of laboratory
- c) Location where the calibration was carried out if different from the address of the laboratory.
- d) Unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages.
- e) Name and address of customer, where appropriate.
- f) Identification of the calibration procedure used; A statement regarding the origin of the specifications employed by the calibration method (e.g., manufacturer, government, military, industrial, customer).
- g) Description and unambiguous identification of the item; Characterization and condition of the calibrated item.
- h) Date of receipt of the test or calibration item(s)
- i) Date(s) of performance of calibration, where appropriate; Calibration due date, as applicable.
- j) Date of issue of the Report.
- k) Reference to sampling procedure, where relevant.
- l) A statement to the effect that the results relate only to the items calibrated.
- m) A statement with, where appropriate the units of measurement
- n) Any deviation from, additions to, or exclusions from the calibration method, and any other information relevant to a specific calibration, such as environmental conditions.
- o) A signature and title or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced)
- p) Clear identification when results are from external providers
- q) Measurements, examinations, and derived results, supported by tables, graphs, sketches, and photographs, as appropriate, and any failures identified (This includes recording as-found data and, as applicable due to adjustments, changes, repairs, optimization, etc., as-left data if different than the as-found data.
- r) A statement that the total uncertainties or tolerances of the standards used are no greater the 25% of the tolerance of the unit tested unless otherwise noted and/or a statement of the estimated uncertainty of the calibration result (where relevant) (If a calibration certificate or test report contains a statement of the measurement result and the associated

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uncertainty, then the uncertainty statement is accompanied by an explanation of the meaning of the uncertainty statement. For example, "This uncertainty represents an expanded uncertainty expressed at approximately the 95% confidence level using a factor of  $k=2$ ."

- s) A statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory.
  - t) Special limitations of use, as applicable.
  - u) Traceability statement.
- 2) ENSL maintains responsibility for the information provided in the calibration report. Should measurements be provided by the customer those are clearly identified and ENSL are not to be responsible for the data provided by the customer. A disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results. Should testing be performed the requirements of ISO 17025:2017 are adhered to.

### **7.8.3 Specific Requirements for test reports**

- 1) In addition to the requirements listed in 7.8.2, test reports shall as applicable, for the interpretation of the test results, include the following:
  - a) Information on specific test conditions, such as environmental conditions. The conditions under which the calibrations were made that have an influence on the measurement results. Environmental monitoring equipment does not provide traceable parameters for calibrations and so the associated equipment does not need to be listed on the calibration certificate. The environmental conditions provided by this equipment are typically accounted for in the uncertainty analysis.
  - b) Where relevant a statement of conformity with specifications.
  - c) The measurement uncertainty of the measurement results presented in the same units as that of the measurand or in a term relative to the measurand when it is relevant to the validity or application of the test results, a customer's instruction required or the measurement uncertainty affects conformity to a specific limit.
  - d) Where appropriate, opinions and interpretations.
  - e) Additional information that may be required by specific methods, authorities, customers, or groups of customers.
- 2) Should sampling activities occur, the certificate will meet the requirements of ISO 17025:2017 and the requirements listed in 7.8.5 where necessary for the interpretation of the test results.



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#### **7.8.4 Specific Requirements for calibration certificates**

- 1) In addition to the requirements listed in 7.8.2, calibration certificates shall include the following:
  - a) The measurement uncertainty of the measurement results presented in the same units as that of the measurand or in a term relative to the measurand when it is relevant to the validity or application of the test results, a customer's instruction required or the measurement uncertainty affects conformity to a specific limit.
  - b) Information on specific test conditions, such as environmental conditions. The conditions under which the calibrations were made that have an influence on the measurement results. Environmental monitoring equipment does not provide traceable parameters for calibrations and so the associated equipment does not need to be listed on the calibration certificate. The environmental conditions provided by this equipment are typically accounted for in the uncertainty analysis.
  - c) A statement identifying how the measurements are metrological traceable
  - d) The result before and after any adjustment or repair, if available
  - e) Where relevant a statement of conformity with specifications.
  - f) Where appropriate, opinions and interpretations.
- 2) Should sampling activities occur the certificate will meet the requirements of ISO 17025:2017 and the requirements listed in 7.8.5 where necessary for the interpretation of the test results.
- 3) Calibration certificates or labels shall not contain any recommendation on the calibration interval except where this has been agreed with the customer. Such agreements are documented. The minimum requirements for a calibration label are:
  - a) Date of calibration
  - b) Identification of the calibration event (service order number or equivalent)
  - c) Unique identification of item being calibrated (asset number or serial number)
  - d) Calibration due date when there is a prior agreement with customer for accredited calibrations. If the calibration is for an internal calibration standard a due date is always applied.

#### **7.8.5 Reporting sampling – Specific Requirements**

Should sampling activity be necessary then the requirements of 17025:2017 requirements will be followed.

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### **7.8.6 Reporting Statements of Conformity**

- 1) For calibrations that include an accrediting body symbol when a statement of to a specification is provided a decision rule is employed accounting for the associated level of risk associated.
- 2) When a statement of conformity is reported the statement clearly identifies conformity.
  - a) Results the statement of conformity applies.
  - b) Which specifications are met or not met.
  - c) The decision rule applied

### **7.8.7 Reporting Opinions and Interpretations**

- 1) ENSL, in general, does not provide opinions and interpretations on calibration services. Should an opinion or interpretation be performed the requirements of ISO 17025:2017 are adhered to.
- 2) The opinions and interpretations expressed in reports shall be based on the results obtained from the tested or calibrated item and shall be clearly identified as such.
- 3) When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained.

### **7.8.8 Amendments to Calibration Reports**

- 1) When an issued report needs to be changed, amended, or re-issued any change of information is clearly identified including the reason for the change.
- 2) Amendments to calibration reports will be issued as a separate document informing the customer of the amendment/supplement. This document will include the statement "Corrected Copy" (or equivalent) referencing the original that it replaces.
  - a) Test Reports and Calibration Certificates are available for reprint/reissue. These documents will be reprint/reissues of the originals that they replace. Such amendments shall meet all requirements of this document.
- 3) When it is necessary to issue a complete new report, this is uniquely identified and references the original that it replaces.

## **7.9 Complaints**

- 7.9.1 ENSL employs a Customer Complaint Program as the basis for its Corrective Action process. Use of the Customer Complaint Program is the first stage of reporting

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circumstances that deviate from predetermined established standards that are above and beyond the reporting of OOTs, repairs and other out-of-calibration instances.

- a. Customer Complaints form 20019 Commercial Customer Complaint Form may be originated from any ENSL customer or by any ENSL personnel. Use of the Customer Compliant process described in GBP-ESD-07, Customer Relations section and includes the identification of the issue, evaluation, resolution and management review and approval.

7.9.2 A customer requesting description of the complaint, shall be available to any interested party on request. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints.

7.9.3 The Customer Complaint process includes the following elements:

- a. Description of the process for receiving, validating, investigating the complaint(s), and deciding what actions are to be taken in response to the complaint.
- b. Tracking and recording the complaint(s).
- c. Ensure that the appropriate action(s) are taken.
- d. Complaints are logged and tracked in the ENSL SharePoint Customer Complaint Library.
- e. Records are maintained of all complaints, investigations and corrective actions taken by the laboratory. They are maintained in the ENSL SharePoint Customer Complaint Library

7.9.4 ENSL takes responsibility to gather and verify all necessary information to validate the complaint.

7.9.5 The Customer Information Reporting (CIR) process requires ENSL to keep the customer informed during the progression of the complaint process. (Reference GBP-ESD-07 Customer Complaint Section)

7.9.6 The Customer Complaint process has oversight at the Energy Business Services corporate quality level which maintains independence from the individual calibration facilities.

7.9.7 Customer complaints are reviewed for completion and trending as recurrence control during the ENSL Management Quality Review as documented in QM-1. Complaints and corrective actions are evaluated to determine if a negative trend has developed. Corrective actions, to include follow up audits and surveillances as necessary, are taken to eliminate negative trends. Whenever possible ENSL provides a formal notice of the final complaint resolution

- a. Customer complaints are reviewed for completion and trending as recurrence control during the review process. Complaints and corrective actions are evaluated to determine if a negative trend has developed. Corrective actions, to include follow up audits and surveillances as necessary, are taken to eliminate negative trends.

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- b. Findings or issues requiring corrective action which are identified via audits, surveillances, internal assessments, customer feedback, customer complaints, or during normal operations are documented in the Customer Complaint Library.

## 7.10 Non-conforming Work

- 7.10.1 Upon identification of a laboratory activity that does not conform to our procedures or agreed requirements of the customer including an out-of-tolerance condition of a calibration standard, the lab will have a procedure to ensure that:
  - a. The responsibilities and authorities for the management of nonconforming work are defined.
  - b. Actions are based on the risk levels established by the laboratory.
  - c. An evaluation is made of the significance of the nonconforming work, including impact analysis on previous results.
  - d. A decision is taken on the acceptability of the nonconforming work.
  - e. Where necessary, the customer is notified, and work is recalled;
  - f. The responsibility for authorizing the resumption of work is defined.
  - g. Upon the identification of an M&TE out-of-tolerance condition, the customer is notified as to the nature and extent of the condition. Should the non-conforming work be identified to impact customer calibrations previously performed, all affected customers shall be notified, advised of the nature and extent of the incident, and given the opportunity to decide the course of action as they evaluate the impact of the non-conforming work on their products, processes, or services. In cases where customers consider the non-conforming work condition to be significant, the liability of the calibration facility will be limited to a re-calibration of the affected equipment at no charge.
  - h. ENSL Calibration Lab Manager, Lead Metrologist and Technical Program Manager, Lab Quality and Business Program Manager or Lead Technician have the responsibility to halt work, or withhold calibration certificates or reports when nonconforming work is identified. The
- 7.10.2 Records shall be retained of nonconforming work and actions as specified in 7.10.1 a-h.
- 7.10.3 When the evaluation of nonconforming work indicates that the nonconformance can reoccur, or if it indicates that there is doubt about the conformity of the laboratory operations with its own management system, the lab shall implement corrective actions.
  - a. When an item is received for calibration and it is found to be damaged, inoperative or out-of-tolerance written documentation of the nonconformance is

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provided to the customer. If the nonconforming item cannot be satisfactorily corrected, the item is tagged with a calibration "Rejected" label to identify the item as not being in calibration to prevent inadvertent use and the information is included in the calibration documentation. After the calibration process, the item is returned to the equipment custodian for any further actions as may be necessary.

- b. A calibration standard that is found to be out-of-tolerance or otherwise out-of-calibration during the calibration process will have the non-conformance documented through a Columbia Generating Station Condition Report as per SWP-CAP-01. Additionally, a customer complaint will be created, and the affected customer(s) notified.

## **7.11 Control of Data and Information Management**

- 7.11.1 All ENSL calibration facilities are connected to the Energy Northwest Corporate network and have access to all the information necessary to facilitate calibration activities.
- 7.11.2 The ENSL information management system is managed by the Energy Northwest Information Technology (IT) department. The information management system includes all aspects of networking and software. ENSL will follow the SQA Software Quality Assurance process to manage software which includes software configuration, modification to off the shelf software, authorization, documentation, and validation of the software before implementation. Major software components of ENSL (i.e., Laboratory Information Management System (LIMS), BarCode Magician, etc.) are controlled through Energy Northwest Site Wide Procedure, SWP-CSW-01, "Software Quality Assurance Program" and GBP-ESD-07, Standards Laboratory Instruction Development and Control section.
- 7.11.3 The Energy Northwest IT department manages the process to authorize network access for all employees. The laboratory information management system shall:
  - a. Be protected from unauthorized access.
  - b. Be safeguarded against tampering and loss.
  - c. Be operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription.
  - d. Be maintained in a manner that ensures the integrity of the data.
  - e. Include recording system failures and the appropriate immediate and corrective actions.
- 7.11.4 Most information is maintained by the Energy Northwest Information Technologies IT department. When external providers are used appropriate Confidential Disclosure Agreements and Cyber Security controls are in place and follow the IT Security and Energy Northwest SWP-CSW procedure compliance requirements.

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- 7.11.5 The lab shall ensure that instructions, manuals, and reference data relevant to the laboratory information management system(s) are made readily available to personnel.
- a. ENSL complies with the requirements of ANSI/NCSL Z540.1 , ISO/IEC 17025, 10CFR50, Appendix B, and NQA-1 regarding software and computer automation.
  - b. Virus checking software is run on all networked computers on a routine basis. The Energy Northwest Information Systems group maintains ENSL computers.
  - c. ENSL's LIMS and calibration software COTS products have multiple levels of password protected security to provide for data integrity.
  - d. Equipment that contains software or programmable hardware is calibrated, adjusted, and maintained as a unit. Changes to software contained in M&TE that affect calibration, require recalibration of the equipment prior to use.
  - e. ENSL's laboratory management database and calibration software are commercial, off the shelf (COTS) products designed and developed for calibration automation. Documentation for the software applications are provided by the manufacturer.
- 7.11.6 Data transfers, such as calibration factors, are subject to appropriate checks when completed manually. Majority of data transfers are automatic through calibration software.

## **8.0 Management System Requirements**

### **8.1 Options**

- 8.1.1 This document is intended to define and communicate the Energy Northwest Standards Laboratory's (ENSL) commitment to quality and good laboratory practices. The various elements of the quality management system are described in the following paragraphs. The ENSL Lab Quality and Business Administration Program Manager has the responsibility to review and amend the Quality Manual as necessary to assure continuing applicability in the changing laboratory environment, and to ensure that the changes are effectively communicated. ENSL fully understands and maintains compliance with the A2LA Advertising Policy. See GBP-ESD-07 A2LA Advertising Policy section for instructions.
- a. In addition to meeting the requirements of clauses 4-7, the laboratory shall implement a management system in accordance with option A or option B.
- 8.1.2 Option A has been selected by ENSL to be implemented into the management system. Which includes the following to be addressed in the Management Quality Review:
- a. management system documentation (see 8.2);

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- b. control of management system documents (see 8.3);
- c. control of records (see 8.4);
- d. actions to address risks and opportunities (see 8.5);
- e. improvement (see 8.6);
- f. corrective actions (see 8.7);
- g. internal audits (see 8.8);
- h. management reviews (see 8.9).

8.1.3 Option B has not been selected to be implemented into the management system.

## **8.2 Management System Documentation (Option A)**

- 8.2.1 ENSL is committed to continuous improvement of the management quality system and its effectiveness. ENSL has established, documents, and maintains policies and objectives to fulfill the purposes of this document and shall ensure that the policies are acknowledged and implemented at all levels of the laboratory organization.
- 8.2.2 ENSL policies and objectives shall address the competence, impartiality, and consistent operation of the laboratory.
- 8.2.3 Evidence of this commitment is contained in the annual Management Quality Review and monthly staff / safety meetings. The monthly staff meetings are also used to convey to the organization the importance of meeting customer requirements as well as regulatory requirement while continually improving its effectiveness.
- 8.2.4 All documentation, processes, systems, records, and anything related to the fulfillment of the requirements of this document shall be included, referenced or linked to the management system.
- 8.2.5 All personnel involved in laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities. The Quality Policy Statement from the Calibration Laboratory Manager is included in the preface to the Quality Manual.

## **8.3 Control of Management System Documents (Option A)**

- 8.3.1 ENSL shall control the documents that relate to the fulfillment of this document. Refer to the SWP-PRO Series for document control processes require in section 8.3.
- 8.3.2 The laboratory shall ensure that:

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- a. The preparation, review, approval, issuance and change of documents affecting quality are controlled to assure that correct documents are being employed. Such documents, including changes thereto, are reviewed for adequacy and approved for release by the Calibration Lab Manager, Lead Metrologist and Technical Program Manager, and Lab Quality and Business Administration Program Manager prior to use.
- b. Documents are periodically reviewed and updated as necessary; Approval authority for the laboratory implementing instructions and calibration instructions is vested with the Calibration Laboratory Manager, Lead Metrologist and Technical Program Manager, and Lab Quality and Business Administration Program Manager. See GBP-ESD-07, Standards Laboratory Instruction Development and Control section.
- c. Changes and the current revision status of documents are identified.
- d. Relevant versions of applicable documents are available at points of use and where necessary and their distribution is controlled.
- e. Documents are uniquely identified.
- f. The unintended use of obsolete documents is prevented and suitable identification is applied to them if they are retained for any purpose.
- g. Procedures / Standards Laboratory Instructions, at a minimum, specify the standards to be used or minimum accuracies of the required standards and equipment, test points of the unit under test and tolerances and/or uncertainties, any special environmental controls to the extent necessary, and use of compensating factors for abnormal use conditions.
- h. Procedures available from manufacturers, government, military, industrial, customer, etc. (i.e., ANSI, ASME, ASTM, GIDEP, GGG, etc.), as well as published standard practices or commercially available programs or procedures are acceptable and need not be rewritten, provided they meet the above requirements. Approved SLI's will be approved through the APW approval process.

#### **8.4 Control of Records (Option A)**

- 8.4.1 Individual records are maintained in the laboratory for each piece of M&TE or standard. These records are paper (hardcopy) or electronic media or a combination of both. The records for M&TE or standards contain the following information:
  - a. Instrument Identification (Asset Number);
  - b. Description of Equipment.
  - c. Equipment location, if appropriate.
  - d. Current Calibration Interval.
  - e. Documentation for Interval Adjustment, as applicable.



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- f. Date of Last Calibration.
- g. Identification of standards used.
- h. Calibration Procedure used.
- i. Results of Previous Calibrations, if applicable.
- j. Corrective Action Taken, if required.
- k. Indications of Erratic Behavior or Operational Failures.
- l. Identification of individual/vendor performing the calibration.

8.4.2 Energy Northwest records are archived in accordance with Energy Northwest GBP-REC-01, "Records Management Program" and SWP-REC-01, "Quality Assurance Records Program." Energy Northwest can accommodate other (customer) requirements through mutual agreement. ENSL maintains copies of calibration records performed for any piece of M&TE or calibration standard in accordance with the requirements of the EN records retention schedule (RIDS). Details of Energy Northwest policy on protecting customers' proprietary interests can be found in GBP-ESD-07, Customer Relations section.

## 8.5 **Actions to Address Risks and Opportunities (Option A)**

- 8.5.1 The Calibration Laboratory Manager, Lead Metrologist and Technical Program Manager, and Lab Quality and Business Administration Program Manager meet regularly to assess risks and opportunities associated with all laboratory activities to:
- a. Assure the management system achieves its intended results.
  - b. Enhance opportunities to achieve the purpose and objectives of the laboratory.
  - c. Prevent, or reduce negative impacts and potential failures in laboratory activities.
  - d. Achieve improvement

Examples of areas evaluated consist of the following, although the list is not all inclusive:

- 1) Turnaround times for data reporting.
- 2) Training and competency.
- 3) Structure to ensure impartiality of personnel.
- 4) Equipment issues.
- 5) Program requirements.
- 6) Facilities/Environment.

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- 7) Effectiveness of corrective and preventive actions.
- 8) Outcomes of internal audits.
- 9) Complaints.
- 10) Processes to ensure confidentiality.

8.5.2 ENSL Plans, final evaluation, actions and implementation of actions, improvement, and assurance of intended actions are outlined in section 8.9 Management Reviews.

- a. Actions taken to address risks and opportunities are proportional to the potential impact on the validity of laboratory results.
- b. ENSL also plans how to integrate and implement these actions into the management system and how to evaluate the effectiveness of these actions.

8.5.3 ENSL will ensure that actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results. Options may include eliminating the risk source, sharing the risk, retaining risk by informed decision to name a few. Opportunities may include expanding the scope, addressing new customers with new technology or meeting customer needs.

## 8.6 Improvement (Option A)

8.6.1 The Laboratory shall identify and select opportunities for improvement and implement any necessary actions. It is the policy of the Energy Northwest Standards Laboratory and all personnel assigned to consistently provide the customer with quality calibration services in a cost-effective manner, consistent with the applicable standards and regulations. The guidelines contained in this manual reflect our quality standards for the performance of calibration services and the conduct of business. It is required that all ENSL personnel familiarize themselves with the quality documentation and implement these policies in their work.

8.6.2 The laboratory shall seek feedback, both positive and negative from its customers. The feedback shall be analyzed and used to improve the management system, laboratory activities and customer service. ENSL uses Survey Monkey to conduct such feedback from its customers through a survey of questions which are both positive and negative in nature.

8.6.3 The achievement of those objectives will be manifested by application of the Energy Northwest's Core Values:

- a. **Safety first**, A strong safety culture permeates the organization – every employee takes personal responsibility and demonstrates commitment to nuclear, industrial, radiological, and environmental safety.
- b. **Integrity in all we do**, We earn trust by doing what we say we will do, ensuring our actions and words are consistent, honest, and ethical. We will help each other succeed through collaboration, mutual respect, and trust.

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- c. **Accountability for our actions**, We take ownership and personal responsibility for both individual and team actions and results.
- d. **Excellence in performance**, Relentless pursuit of the highest performance expectations through continuous improvement and zero tolerance for deviation from standards, and dedication to fostering an environment of teamwork.

8.6.4 Personnel employed at the Energy Northwest Standards Laboratory are expected to use Error Prevention Tools - to assure they have the right tools for the job, that the job is appropriate, that the job is performed as intended, and yields the expected results. Self-Checking aids laboratory personnel in getting it right the first time and every time. These attributes are also included in the Energy Northwest Excellence Model.

8.6.5 Calibration Laboratory Manager is committed to providing the technical support, training, resources, and environment necessary to deliver the highest quality calibration services our customers expect and deserve.

## 8.7 **Corrective Actions (Option A)**

8.7.1 When a non-conformance is identified, the corrective action chosen addresses the magnitude of the non-conformance and the risk attributed to the non-conformance.

- a. Immediate action is implemented to correct a nonconformity and address the consequences.
- b. An evaluation is performed to determine the cause(s), a history of similar issue(s), potential for recurrence, and the need for action to eliminate the problem to prevent recurrence.
- c. Corrective actions are determined and implemented based upon this evaluation.
- d. A review of the effectiveness of corrective actions is performed.
- e. If necessary, updates for risks and opportunities are determined during planning.
- f. Essential changes discovered during the corrective action investigation are implemented within the management system, where necessary.

8.7.2 Corrective actions are appropriate to the effects of the nonconformities encountered.

8.7.3 Corrective actions are recorded, to include the

- a. nature of the nonconformities, cause(s) and subsequent actions taken
- b. including the results of any corrective action.

## 8.8 **Internal Audits (Option A)**

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8.8.1 Planned and scheduled internal audits are performed.

- a. These audits verify compliance and determine the effectiveness of the ENSL Quality Management Program to include training and qualification, calibration system, contract requirements, measurement standards, calibration instructions, environmental controls, calibration intervals, calibration status, storage, and handling, out-of-tolerances, records and software. The audits are performed by trained and qualified personnel who are, wherever resources permit, independent of the activity being audited.
- b. These audits are performed in accordance with written procedures or checklists. The results of these audits are documented, reported to and reviewed by The Calibration Laboratory Manager, Lead Metrologist and Technical Program Manager, and Lab Quality and Business Administration Program Manager to ensure it is effectively implemented and maintained.

8.8.2 The Lab Quality and Business Administration Program Manager coordinates internal audits of the laboratory. These audits may be conducted internally by ENSL itself, in coordination with Energy Northwest Corporate Quality organization, or by qualified contracted agencies. Internal Audits are scheduled, documented, and planned, to provide coverage and coordination with ongoing activities and to assure compliance and effectiveness with all aspects of the Quality Program. See Section 6.6 for subcontracting of calibration services and evaluation of external suppliers. The Calibration Laboratory Manager, Lead Metrologist and Technical Program Manager, and Lab Quality and Business Administration Program Manager will review and modify the system as necessary, based on audit and assessment results, customer feedback and other relevant factors. The laboratory shall

- a. Plan, establish, implement, and maintain an audit program which includes the frequency, methods, responsibilities, requirements, and reporting. Consideration will be taken of the changes affecting the laboratory and the results of the previous audit.
- b. Audit criteria will be defined and a scope will be provided for each audit;
- c. The results will be reported to relevant management.
- d. Appropriate corrective actions will be taken without delay.
- e. Records will be retained as evidence of the implementation of the audit program and the audit results.

8.8.3 ENSL may also be audited by Columbia Generating Station Quality Organization or by outside organizations as part of contractual and/or quality requirements. These audits permit ENSL to be placed on the auditing organization's Evaluated/Approved Suppliers Lists as a calibration services provider. Additionally, to maintain its ISO 17025 accredited status, ENSL is audited by an ILAC MRA Accreditation Body (AB). Findings and/or recommendations from these audits are also reviewed and incorporated as necessary into the ENSL quality program.

## 8.9 Management Review

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- 8.9.1 The Calibration Laboratory Manager, Lead Metrologist and Technical Program Manager, and Lab Quality and Business Administration Program Manager is responsible for conducting an annual internal management quality review (MQR) at planned intervals to ensure its continuing suitability, adequacy, and effectiveness including the stated policies and objectiveness related to the fulfillment of this document.
- 8.9.2 The elements in the management review shall be recorded in the MQR and shall include information related to the following:
- a. Changes in internal and external issues that are relevant to the laboratory
  - b. Fulfillment of objectives
  - c. Suitability of policies and procedures
  - d. Status of actions from previous management reviews
  - e. Outcome of recent internal audits
  - f. Corrective actions
  - g. Assessments by external bodies
  - h. Changes in the volume and type of the work or in the range of laboratory activities
  - i. Customer and personnel feedback
  - j. Complaints
  - k. Effectiveness of any implemented improvements
  - l. Adequacy of resources
  - m. Results of risk identification
  - n. Outcomes of the assurance of the validity of results
  - o. Other relevant factors such as monitoring activities and training
  - p. Other topics determined to be germane to the respective management review
- 8.9.3 The outputs from the management review shall record all decisions and actions related to at least the following:
- a. The effectiveness of the management system and its processes
  - b. Improvement of the laboratory activities related to the fulfillment of the requirements of this document
  - c. Provision of required resources

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d. Any need for change

- 8.9.4 General Business Procedure GBP-ASU-03, Self-Assessment and Benchmark Process, may be used as a guide during the Management Quality Review process. ENSL maintains documentation of the review and results of the review.

## 9.0 References

- 9.1.1 ANSI/NC SL Z540-1 - American National Standard for Calibration – Calibration Laboratories and Measuring and Test Equipment – General Requirements
- 9.1.2 ANSI/NC SL Z540.1-1994, Calibration Laboratories and Measuring and Test Equipment- General Requirements
- 9.1.3 ASME NQA-1-1989, 2000, 2008, 2009 Quality Assurance Program Requirements for Nuclear Facility Application
- 9.1.4 Handbook for the Interpretation and Application of ANSI/NC SL Z540.1-1994
- 9.1.5 ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories
- 9.1.6 ISO/IEC 17034, General requirements for the competence of reference material producers
- 9.1.7 ISO/IEC Guide 98.3.2008, Uncertainty of Measurement
- 9.1.8 Title 10 CFR 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Processing plants
- 9.1.9 CORE-01, Local Government Common Records Retention Schedule
- 9.1.10 UTILITY-01, Utility Services Records Retention Schedule
- 9.1.11 Form 20019, Energy Northwest Standards Laboratory Commercial Customer Complaint Form
- 9.1.12 Form 25800, M&TE Suspension/Rejection Report
- 9.1.13 Form 290, Request for Supplier Evaluation
- 9.1.14 Form 26799, Task Performance Evaluator Evaluation Observation
- 9.1.15 Form 12121, Applicant Action Form
- 9.1.16 EN General Business Procedure GBP-ASU-03, Self-Assessment and Benchmark Process
- 9.1.17 EN General Business Procedure GBP-ECP-03, Differing Professional Opinions
- 9.1.18 EN General Business Procedure GBP-ESD-06, Field Calibrations

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- 9.1.19 EN General Business Procedure GBP-ESD-05, Calibration Lab Policies or Processes for Commercial Customers Technical
- 9.1.20 EN General Business Procedure GBP-ESD-07, Calibration Lab Policies or Processes for Commercial Customers Administrative
- 9.1.21 EN General Business Procedure GBP-HR-12, Delegations of Authority
- 9.1.22 EN General Business Procedure GBP-HR-09, Applicant Selection Process
- 9.1.23 EN General Business Procedure GBP-CAP-01, Non-Regulatory Action Program
- 9.1.24 EN General Business Procedure GBP-REC-01, Records Management Program
- 9.1.25 EN General Business Procedure GBP-REC-04, Confidential and Proprietary, INPO Limited or Restricted Distribution and Copyrighted Information
- 9.1.26 EN General Business Procedure GBP-REC-06, Scan and Toss Program
- 9.1.27 EN General Business Procedure GBP-SEC-05, Access Controls to Energy Northwest Non-Nuclear Facilities
- 9.1.28 EN Industrial Safety Manual ISPM-11, Hazard Communication Program
- 9.1.29 EN Plant Procedure Manual PPM 1.5.4, Control of Measuring and Test Equipment/Transfer Standards/Portable Tools
- 9.1.30 EN Plant Procedure Manual PPM 1.10.1, Notifications and Reportable Events (Part 21)
- 9.1.31 EN Plant Procedure Manual PPM 1.11.15, Control of Radioactive Materials
- 9.1.32 EN Site Wide Procedure SWP-ASU-01, Evaluations of Programs, Processes and Suppliers
- 9.1.33 EN Site Wide Procedure SWP-CAP-01, Corrective Action Program Description
- 9.1.34 EN Site Wide Procedure SWP-CHE-05, Chemical Management Program
- 9.1.35 EN Site Wide Procedure SWP-CSW-01, Software Quality Assurance Program
- 9.1.36 EN Site Wide Procedure SWP-CSW-15, Portable Media and Digital Device Use
- 9.1.37 EN Site Wide Procedure SWP-MMP-03, Packaging and Shipping of Material and Equipment
- 9.1.38 EN Site Wide Procedure SWP-PUR-01, Procurement of Services
- 9.1.39 EN Site Wide Procedure SWP-PUR-04, Material, Equipment, Parts and Supplies Procurement
- 9.1.40 EN Site Wide Procedure SWP-REC-01, Quality Assurance Records Program

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- 9.1.41 EN Site Wide Procedure SWP-PRO-01, Procedure Work Instruction Use and Adherence
- 9.1.42 EN Site Wide Procedure SWP-PRO-02, Preparation, Review, Approval and Distribution of Procedures
- 9.1.43 EN Site Wide Procedure SWP-PRO-03, Writers Manual
- 9.1.44 EN Site Wide Procedure SWP-PRO-04, Procedure Program- Including Procedures, Instructions, Forms and Manuals
- 9.1.45 EN Training Program Description, TPD-23 Standards Laboratory Training Program
- 9.1.46 EN Operational QA Program Description (EN-QA-004) (OQAPD)
- 9.1.47 EN Supplemental Purchasing Clauses, EN-0040, Section 400
- 9.1.48 EN Plant Procedure Instruction QA, SQI-7-2, Evaluation of Suppliers
- 9.1.49 EN Plant Procedure Instruction QA, SQI-18-3, Supplier Audits
- 9.1.50 EN Qualification Directory, Standards Laboratory Qualification Directory Section No. 2.18
- 9.1.51 DOE/RW-0333P, Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements Document (QARD)
- 9.1.52 Vocabulaire International des Termes Fondamentaux et Generaux de Metrologie (VIM) (International Vocabulary of Basic and General Terms in Metrology)

## **10.0 Change Control**

- 10.1.1 Revision 0: April 9, 1999 New
- 10.1.2 Revision 1: April 27, 1999 complete revision, formatted to ANSI/NSCL Z540.1:1994 1994
- 10.1.3 Revision 2: June 15, 1999 Replaced all references to "Washington Public Power Supply System" with "Energy Northwest"; other minor editorial changes
- 10.1.4 Revision 3: October 11, 1999 Added Office of Civilian Radioactive Waste Management (OCRWM) software/hardware requirement
- 10.1.5 Revision 4: April 20, 2000 General revision and editorial changes
- 10.1.6 Revision 5: March 15, 2001 General revision
- 10.1.7 Revision 6: June 24, 2002 General revision
- 10.1.8 Revision 7: August 22, 2002 Minor changes including Battelle and Bechtel Audit inputs and clarifications



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- 10.1.9 Revision 8: May 1, 2006 Major revision to better reflect ISO 17025, 10 CFR 50 Appendix B and NQA 1 1989 compliance plus editorial changes
- 10.1.10 Revision 9: October 1, 2010 Major revision to bring QM 1 into better compliance with ISO 17025. This revision also corrects typos, references and other items identified in past audits and assessments.
- 10.1.11 Revision 10: November 13, 2014 Major revision to include changes in corporate documents and to more closely align with the Excellence Model. Removed references to obsolete programs and incorporated Appendix 2 into the main body of the Quality Manual. Organizational changes also updated. Minor revision editorial only.  
11/25/2014
- 10.1.12 Revision 11: January 8, 2019 Major revision to address changes in corporate reorganization and ISO/IEC 17025:2017 requirements.
- 10.1.13 Revision 12: October 6, 2020 Major Revision to address new ISO 17025 2017 requirements
- 10.1.14 Revision 12: Minor Rev 1: October 21, 2020 Minor Revision to add Template with effective date.
- 10.1.15 Revision 13: Major Revision to address Internal Audit findings.

## 11.0 **Attachments**

- 11.1 Appendix A-1 Organizational Chart



Governing Procedure: GBP-PRO-03

**ENERGY NORTHWEST  
MAJOR REVISION  
REVIEWS AND APPROVALS**

**General Information**

Procedure Number QM-1

Cancellation/Supersede: None Superseded by: N/A

Justification for Cancellation/Supersede: N/A

EC Number (for incorporation purposes). \_\_\_\_\_

Originator Train, Amanda M.

Identify other procedure, instruction, manual, or form revisions to be issued in parallel (attach additional sheet if more space is needed).

Document Number	Revision	Document Number	Revision	Document Number	Revision

**Impact Considerations**

Consider the following Impacts when revising the procedure and contact appropriate departments

- Change Management Required?
- Other Documents impacted – notify sponsors?
- Emergency Preparedness Impacts?
- Safety Impacts?
- Environmental Impacts?
- Commitment Changes?

Governing Procedure: GBP-PRO-03

**ENERGY NORTHWEST  
MAJOR REVISION  
REVIEWS AND APPROVALS**

**General Information**

Procedure Number QM-1

**Cross Discipline Reviews**

**If any manual approvals (hard copy signatures) are obtained then included printed name, signature, and date.**

Reviewer(s)

28/04/22 4:44:59 -07:00

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Prasad, Sanjesh , Lead Metrologist/T...  
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CDReview3

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CDReview5

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CDReview7

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CDReview9

Reviewer(s)

X

CDReview2

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CDReview4

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CDReview6

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CDReview8

X

CDReview10

Cross Discipline Reviews

X

CDReview11

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CDReview12

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CDReview13

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CDReview14

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CDReview15

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CDReview16

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CDReview17

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CDReview18

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CDReview19

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CDReview20

**ENERGY NORTHWEST  
MAJOR REVISION  
REVIEWS AND APPROVALS**

**General Information**

Procedure Number QM-1

**Final Review and Approvals**

**If any manual approvals (hard copy signatures) are obtained then include printed name, signature, and date.**

Fire Protection for Fire Protection Element Related Changes {R-\*BTP APCS B 9.5-1, Appendix B.03}

X

Fire Protection

Sponsor (As Identified in Asset Suite)

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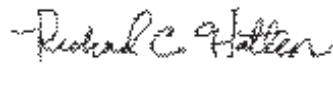


Train, Amanda M. , Program Manag...  
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Responsible Approving Manager/Supervisor (Approving Authority)

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Hatten, Richard C. , Calibration Lab...  
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Chief Executive Officer (for PSMs and ISPMs)

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CEO