0.0 REFERENCES

A)	ISO 9001:2015	Quality management systems - Requirements
B)	ISO/IEC 17025:2017	General requirements for the competence of testing and calibration laboratories
C)	ANSI/NCSL Z540-1-1994 (R2002)	Calibration Laboratories and Measuring and Test Equipment –General Requirements
D)	NIST HB 150:2020	NVLAP Procedures and General Requirements
E)	NIST HB 150-2:2024	NVLAP Calibration Laboratories

1.0 PURPOSE and SCOPE

This procedure is the Tier 1 document of the Essco Quality System and provides an overview of the system used at Essco Calibration Laboratory to calibrate and repair inspection, measuring and test equipment; either in our facility or at the customer's location.

2.0 RESPONSIBILITIES

All employees are responsible for reviewing and understanding the contents of this manual, and to maintain compliance to the Quality Management System described within.

The Vice President of Operations fills the role of Technical Leader(s) whose responsibilities in addition to those listed in ECL 2 Table I include:

- Ensuring compliance to ISO/IEC 17025:2017, NIST HB 150:2020, ANSI/NCSL Z540-1-1994, NIST HB 150-2:2024 & ISO 9001:2015.
- Reviewing and evaluating the work of laboratory technicians as required.

The Lab Manager and Lab Supervisor fill the role of Technical Leader(s) whose responsibilities in addition to those listed in ECL 2 Table I include:

- Reviewing and evaluating the work of laboratory technicians as required.

The Quality Manager's roles and responsibilities in addition to those established in ECL 2 Table I include:

- Ensuring compliance to ISO/IEC 17025:2017, NIST HB 150:2020, ANSI/NCSL Z540-1-1994, NIST HB 150-2:2024 & ISO 9001:2015.
- Acts as the primary contact for accreditation bodies.

3.0 PROCEDURES

3.1 Quality Policy

The company's quality policy is defined in Figure 1. Our quality system evolves from these goals and the national and international standards that guide our industry.

3.2 Organization

The organizational structure of ESSCO is depicted in Figure 2 of this procedure. The exact responsibilities, authority and interrelation of personnel who manage, perform, and verify the work affecting quality is defined in ECL2, Personnel Management.

Figure 1. Quality Policy

ESSCO QUALITY POLICY

Mission Statement

Our mission is to provide customer satisfaction by maintaining an environment dedicated to quality, capability and timeliness.

Policies & Values

QUALITY SYSTEM: Essco's Quality Management system is committed to ensuring ongoing compliance to ISO/IEC 17025:2017, NIST HB 150:2020, NIST HB 150-2:2024, ANSI/NCSL Z540-1-1994 (R2002) & ISO 9001:2015. This will be documented, communicated and implemented throughout the organization. Our quality system is the framework around which we operate the laboratory and it guides all facets of our business in order to meet our mission.

CAPABILITY: We will use a team-focused approach to effectively operate our business. Our team members are committed to our quality system, good professional laboratory practices, standardized methods, and our customers' requirements.

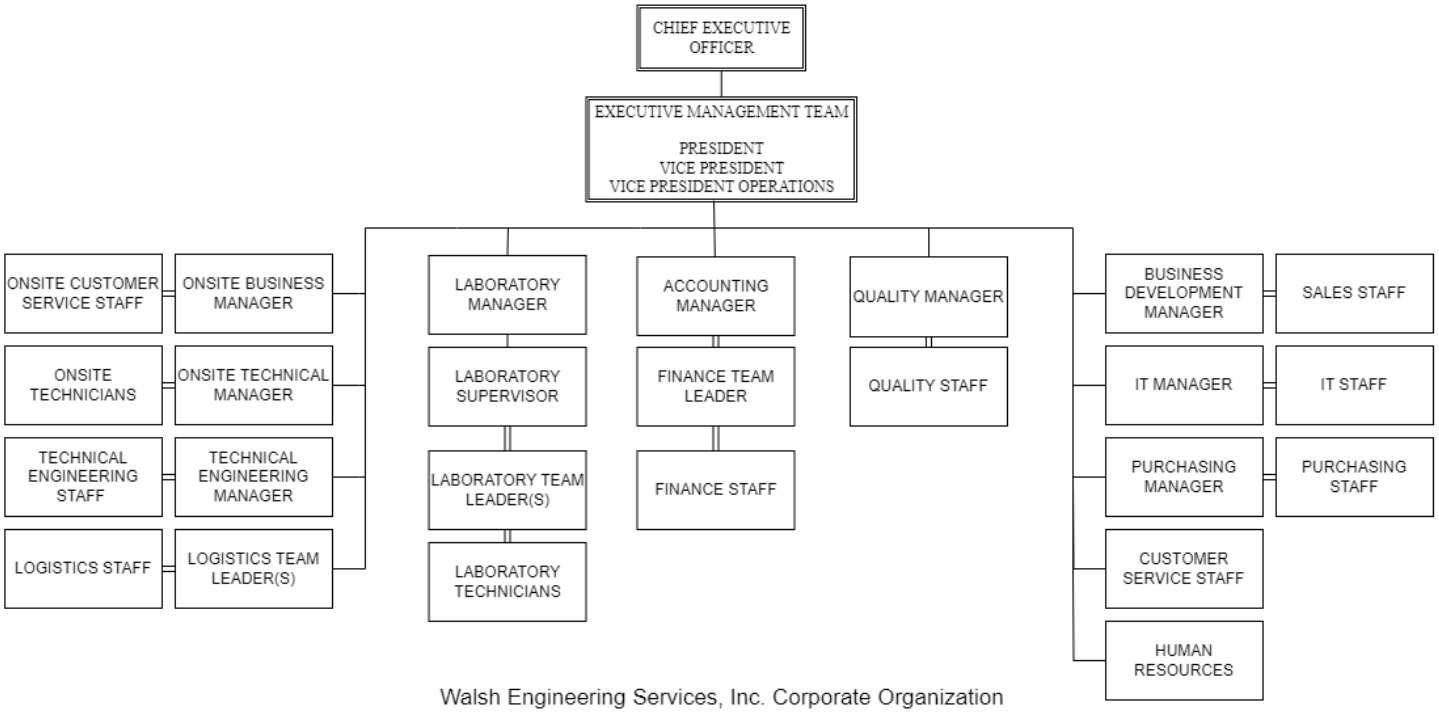
Our training policy is to provide the necessary technical and management training and certifications so that our team members can meet our laboratory goals. We will procure accredited and/or competent calibrations, reference materials, consumables and other services from recognized laboratories and suppliers to support the level of calibrations we provide.

We will protect our client's confidential information and proprietary rights. We pledge to avoid activities that would diminish confidence in our competence, impartiality, judgment or operational integrity. We will strive to resolve all customer concerns or non-conformances in a timely and competent manner.

TIMELINESS: We will endeavor to meet our customers' goals for timeliness while concurrently maintaining the requirements of the international standards.

CONTINUOUS IMPROVEMENT: We will continue to advance our skills and capabilities through a partnership of each individual's commitment to improve the company's performance.

Figure 2.
Essco Organization Chart



The team structure depicted in Figure 2 allows for the full function of the organization in the absence of the president, cross-functional inputs on technical and business matters, and provides for redundancy for business operations. The Executive Management Team is responsible for identifying and providing the resource

requirements for all lab and business functions. The Executive Management Team is committed to impartiality ensuring there are no conflicts of interest in reporting structure. The reporting structure shall undergo review as needed and at least annually during the management review to ensure impartiality on an ongoing basis. The Executive Management Team will monitor and measure the company performance against the stated objectives. Essco Management is committed to the operation and continual improvement of our management system. Management shall report in the Management review, during Management Team meetings, and at other appropriate times on the efforts of the Management Team towards the management system.

ESSCO is legally identifiable as Walsh Engineering Services, Inc. d/b/a ESSCO Calibration Laboratory, a private corporation established in Massachusetts. Essco is assigned a Federal Tax Identification number and is listed with Dun and Bradstreet.

3.3 Quality System Structure

Our quality system is designed to include the requirements of the international standards, ISO/IEC 17025:2017 and ISO 9001:2015, NIST Handbooks 150:2020 & 150-2:2024, the National Standards of ANSI/NCSL Z540-1-1994(R2002) and the pertinent regulatory requirements of 21 CFR Part 211 (GMP), and 21 CFR Part 820 (QSR). We have applied the applicable portions of industry-specific standards to our quality system and operations; we do not operate nor fully comply with these standards in their entirety, as they are not applicable to the operation of a calibration laboratory. Figure 3 below depicts the hierarchy of the documented system.

Figure 3. ESSCO Quality System Document Hierarchy

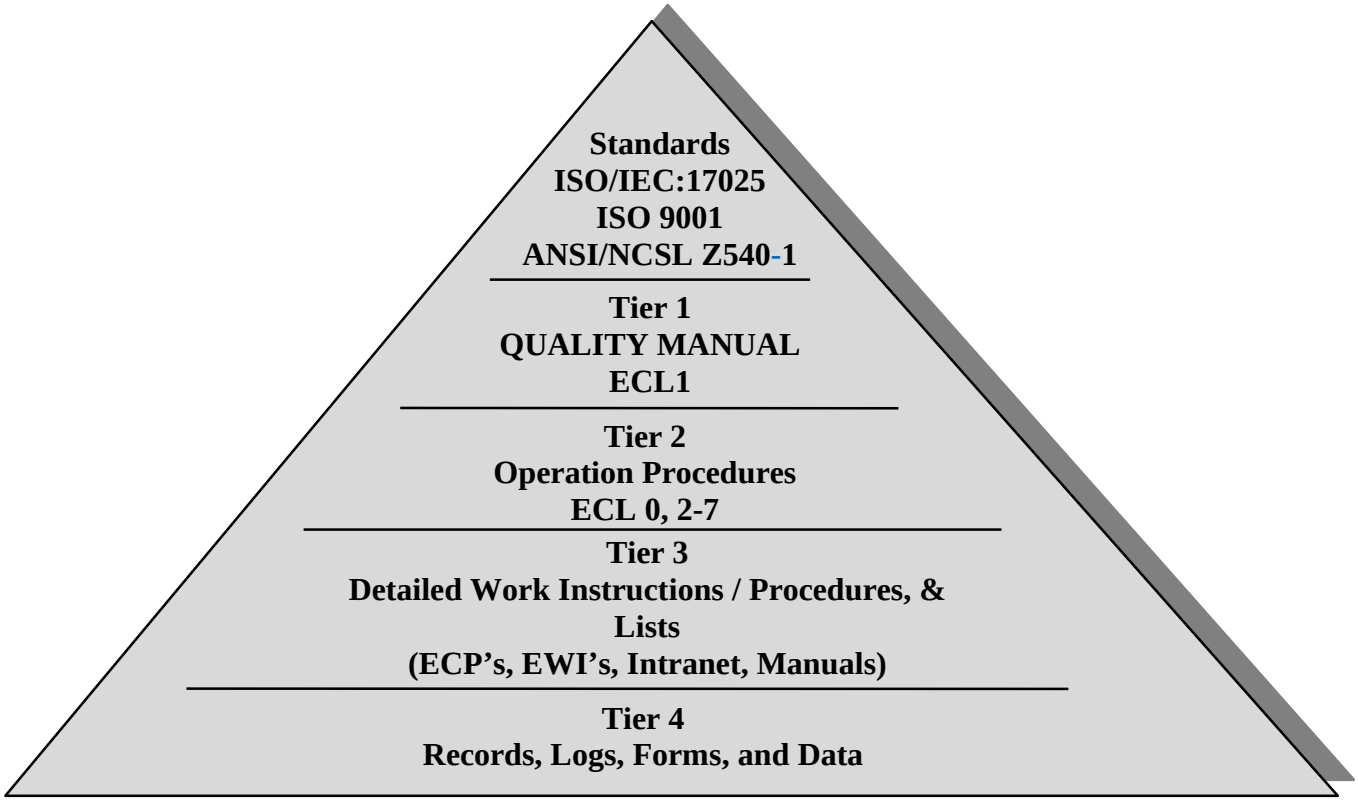


Figure 4. Quality System Cross Reference

Essco Procedure	ISO 9001: 2015	ISO/IEC 17025: 2017
ECL 0: Scope of work All sections.	8.2 Requirements for products or services.	7.1 Review of requests, tenders and contracts.
ECL 1: Essco Quality System 3.1 Quality Policy/ 3.2 Organization/ 3.3 Quality System Structure / 3.4 Customer Focus / 3.5 Work Scope	5.1.1 General 5.1.2 Customer focus 5.2 Quality policy 7.1 Resources 7.3 Awareness of Quality Policy 7.4 Communication	4.1 Impartiality/Risks 5.1, 5.2, 5.4 Structural Requirements: a/ Identification of status b/ Organization c/ Responsibilities d/ Customer Focus
ECL 2: Personnel Management 3.1 Organization / 3.2 Responsibilities & Authorities / 3.3 Employee Indoctrination / 3.4 Metrologist Qualifications / 3.5 Employee Training / 3.6 Employee Evaluation	7.1 Resources 7.1.6 Organization Knowledge (aka resources)	5.5 Structural Requirements 5.6 Structural Requirements 6.1 General 6.2 Personnel
ECL 3: Equipment, Procedures and Environmental Management 3.1 Adequacy & Traceability / 3.2 Primary & Reference Measurement Standards / 3.3 Intervals & Cycles / 3.4 Equipment Identification / 3.5 Calibration & Maintenance Records / 3.6 Care of Measurement Standards / 3.7 Reference Materials, Certified Reference Materials & Consumables/ 3.8 Use of Suppliers / 3.9 OOT Calibration Measurement Standards/3.10 New & Retired Measurement Standards / 3.11 Proficiency Tests, Interlaboratory Comparisons/ In-Service Performance Checks/ 3.12 Calibration Procedures / 3.13 Environmental Management / 3.14 Laboratory Housekeeping/Pest Control/Security / 3.15 ESD Controls / 3.16 Outsourcing Service / 3.17 Sampling	7.1.3 Infrastructure 7.1.4 Work Environment 8.4 control of externally provided Processes, products or services. 7.1.5.2 Measurement traceability	6.3 Facilities/Environmental 6.4 Equipment 6.5 Metrological Traceability 6.6 External Services (Subs) 5.3 Lab Activities 7.2 Selection, verification and validation of methods (ECPs) 7.5 Technical Records
ECL 4: Lab Management Processes 3.1 New Customer Establishment / 3.2 Receiving / 3.3 Handling & Storage / 3.4 Work Review & Priorities / 3.5 Calibration / 3.6 Subcontracting & Repairs / 3.7 Second Look Process / 3.8 Reporting the Calibration/ 3.9 Inspection, Packaging & Delivery / 3.10 Onsite Calibration	8.4 Externally provided services (Subs) 8.5.4 Preservation (handling) 8.5 Control of Production & service operations	6.4 Equipment 6.6 External Services (Subs) 7.1 Review of requests, tenders and contracts. 7.4 Handling of test or calibration items 7.3 Sampling N/A 7.8 Reporting of results
ECL 5: Document and Records Management 3.1 Documents & Records / 3.2 Essco Intranet/ 3.3 LIMS / 3.4 MIS / 3.5 Calibration and/or Data Acquisition Software / 3.6 EsscoNET/ 3.7 Calibration Procedure Documentation/ 3.8 Data Templates/ 3.9 Certificates & Reports/ 3.10 Revisions to Calibration Certificates / 3.11 Confidentiality	7.5 Documented information. 7.5.1 General 7.5.2 Creating/Updating 7.5.3 Control	8.4 Control of Documents/Records /Confidentiality 7.11 Control of data/information management.
ECL 6: Quality System Maintenance 3.1 Quality Planning / 3.2 Management Reviews & Planning/ 3.3 Internal Audits / 3.4 Nonconforming Work / 3.5 Corrective Actions / 3.6 Preventive Actions / 3.7 Complaints / 3.8 Continual Improvement / 3.9 Customer Satisfaction Measurement / 3.10 New Process Adoption, Development and Change/ 3.11 Monitoring, Metrics and Analysis/ 3.12 Risk Management & Opportunities	9.3 Management review 9.1.2 Customer satisfaction 8.3.6.2 Design & development 8.1 Operational Planning 8.2 Customer Communication 10.0 Nonconformity and corrective actions, Continual Improvement, Analysis	7.9 Complaints 7.10 Nonconforming work 8.5 Actions for risks/opportunities 8.6 Improvement 8.7 Corrective Action 8.3, 8.4 Control of records 8.8 Internal Audits 8.9 Management reviews
ECL 7: Accredited Calibration Process 3.1 Scope of Work / 3.2 Offering Accredited Calibration Service / 3.3 Promotion & Advertising / 3.4 Customer Setup & Contract Review / 3.5 Preparation for Calibration / 3.6 Reporting / 3.7 Review and Release / 3.8 Onsite / 3.9 Revisions to Certificates	ISO 9001 not applicable to this procedure.	7.1 Review of requests, tenders and contracts. 7.6 Evaluation of measurement uncertainty 6.6 External Services (Subs) 6.5 Metrological Traceability

Our system meets the requirements of ISO 9001:2015 as this system is most understood by our customers. The more stringent quality requirements of ISO/IEC 17025:2017 are the primary guidance for calibration labs and this quality system. Figure 4 is a cross-reference matrix for these two standards and our system. This matrix also outlines the content of our quality system.

The Quality Manager, or any member of the Executive Management Team in the absence of the Quality Manager, may grant written departures from established procedures within this quality system or from standards as technical prudence and conditions dictate. These deviations will be limited in application, scope, and time period and are not intended for permanent application.

The operation and interrelations within our quality system and our lab can be seen in Figure 5.

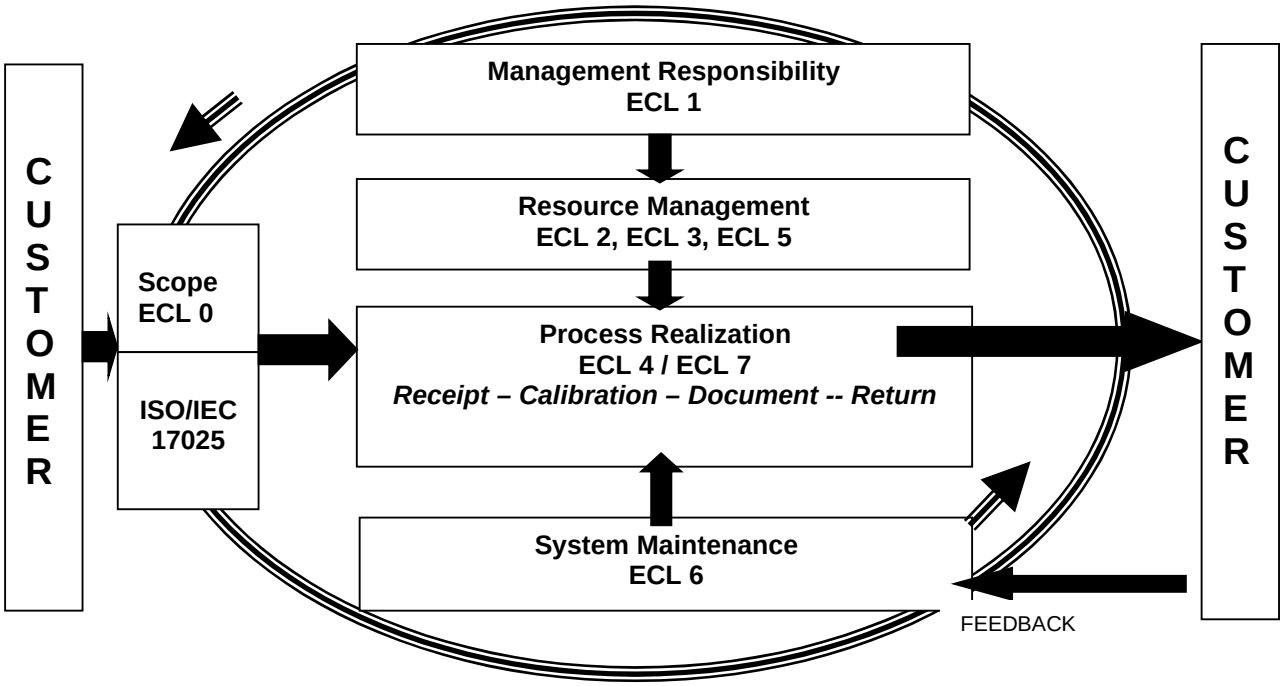


Figure 5. Quality System Model

3.4 Customer Focus

We acknowledge that no business can continue to thrive without including the customer's wishes and needs in their system. While we strive to maintain this customer focus, many facets of our system are determined by the prescriptive nature of the international standard ISO/IEC 17025:2017 and we must meet these requirements first and foremost. We will always continue to listen and provide efficient and secure methods (mail, phone, fax, e-mail & Internet) to communicate with our customers and within our own organization. Where no conflict arises, we will endeavor to use our quality and lab management systems to meet the customer's wishes. Essco, upon Sales or Executive Management approval, will afford the customers the opportunity to access our facility and records to audit our performance and witnessing of tests or calibrations. Visits for the purpose of witnessing tests or calibrations must be prearranged with the Lab Manager, Lab Supervisor, and/or affected Team Leads to ensure the equipment, technician(s),standards and/or bench time is available.

3.5 Work Scope

Essco's complete scope of the work performed by Essco Calibration Laboratory (which includes both commercial and accredited calibrations) is defined by ECL0. Our Scope of Accreditation issued by the Accreditation Body defines the details of our accredited scope portion of our work.

4.0 REVISION HISTORY

Revision	Date	Reason for Change
13	08 Jan 2001	Revised for ISO 9001:2000 and ISO 17025 (formerly EQC000.0)
14	12 Jul 2001	Revised after A2LA Surveillance
15	14 Jan 2002	Revised for altered lab organization
16	31 May 2002	Revised policies per ISO 17025; new org chart; added ECL 7
17	09 Sep 2002	Clarified compliance to other standards, added more detailed index of QA system
18	16 Jan 2004	Updated organization chart, Figure 2
19	01 Sep 2004	Updated organization chart, Figure 2
20	26 Jan 2005	Changed title from VP Quality to Quality Manager
21	06 Jun 2005	Deleted references to 10CFR 21
22	21 Feb 2006	Added references per ISO 17025:2005, New Organization Chart
23	16 Feb 2007	Updated Organization Chart, Update to ISO 17025:2005
24	16 May 2008	Updated organizational chart
25	08 Oct 2008	Updated Organizational Chart
26	29 Sep 2009	Updated Organizational Chart
27	15 Dec 2009	Revise sections 0.0 references, 3.2 Quality policy, 3.3 Structure to reflect quality system certification to ISO 9001:2008. Revise references of ISO 10012-1 to ISO 10012:2003.
28	25 Feb 2010	Updated Org Chart.
29	17 Sep 2010	Updated Org Chart.
30	24 Jun 2011	Updated Org Chart.
31	23 Aug 2011	Revised figure 4 and section 3.4 to include Customer Witnessing of tests and calibrations.
32	03/30/2012	Revised section 2 Responsibilities to include the roles and responsibilities of the technical manager and quality manager and include commitment to maintain compliance to NIST HB 150. Revised section 3.5 to remove specific reference to A2LA.
33	03/11/2013	Updated Org Chart, add reference (F) to NIST HandBook 150.
34	04/24/2013	Updated Org Chart, replaced Lab Manager with President.
35	03/20/2015	Updated Org Chart.
36	12/10/2015	Revised section 3.2 figure 1, Quality Policy to document Essco's commitment to maintain compliance to ISO 17025 and NIST HB 150 (current revision). Updated Org chart

37	04/24/2017	Updated Org Chart.
38	06/09/2017	Updated references section 0.0, 2.0 and figure 1 to include NIST HB 150-2:2016
39	02/06/2018	Updated Org Chart.
40	08/09/2018	Updated Org Chart.
41	03/29/2019	Updated Org Chart. General updates to Updated references to ISO/IEC 17025, ISO 9001, figure 4 Quality System Cross reference chart and section 2 responsibilities.
42	07/01/2019	Updated section 3.2 to address impartiality – 17025:2017. Redefined role in section 3.3
43	11/08/2019	Updated section 2.0 & 3.2 to update reporting structure. Section 3.3 added NIST Handbooks 150 & 150-2 references. Updated figure 4 with current information.
44	05/27/2020	Updated Figure 2 (Organization Chart).
45	09/21/2020	Updated Figure 2 (Organization Chart). Updated revision year of NIST handbooks 150 & 150-2. Added revision year of ANSI Z540.1 & MIL-STD-45662. Updated References/clarified responsibilities in sections 0.0, 3.2, 3.3 and Figure 3. Figure 3 added EWI work instructions. Clarified Essco's scope of work in section 3.5.
46	02/15/2022	Edited "Responsibilities section to current reflect current reporting structure. Clarified compliance references in "Quality System" section. Updated Figure 2 (Organization Chart).
47	05/18/2023	Updated section 2 to replace reference to the Senior Operations Managers roles and responsibilities to that of the Executive Management Team. Section 3.3 removed reference to Senior Operations Manager and replaced with Executive Management Team. Updated Org Chart to reference Business Development Manager, remove Facilities Staff, and change two references of "Quality Assurance" to "Quality".
48	10/03/2023	Updated references. Section 1.0 purpose and scope; updated to refer to inspection, measurement, and test equipment. Updated Org Chart. Updated Figure 4 to reflect current ECL sections. Section 3.4 customer focus; additional roles added for customer visit approval. General format updates for clarity and consistency.
49	03/19/2024	Updated Org Chart. Updated references to the role of Laboratory Supervisor.
50	06/27/2024	Updated Org Chart. Included references to Metrology Manager. In Section 2.0 references updated and "Executive management team" replaced with "Vice President of Operations." General format updates for clarity and consistency.
51	03/11/2025	Updated Org Chart (Removed Sr.Metrology Operations Engineer and Metrology Manager). Removed references to Metrology Manager. Updated references. Updated references to NIST HB 150-2 to current revision. Updated references in Figure 4.