

	ESSCO QUALITY SYSTEM	ECL1
Drafted by: Don Perron	Approved by: <i>David Donnelly</i>	
ISO 9001:2000 – 4.0, 5.1, 5.2, 5.3	ISO 17025:1999 – 4.1, 4.2, 5.0	

0.0 REFERENCES

- A) ISO 9001:2000 Quality management systems - Requirements
- B) ISO 17025:1999 General requirements for the competence of calibration and testing laboratories
- C) MIL-STD-45662A Calibration System Requirements, 1 August 1988 (expired)
- D) ISO 10012-1 Metrological confirmation system for measuring equipment
- E) ANSI/NCSL Z540-1 Calibration Laboratories and Measuring and Test Equipment – General Requirements

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 electronic, electromechanical, physical and dimensional test and measurement equipment, either in our facility or at the customer's location.

2.0 RESPONSIBILITY

All employees are responsible for the contents and compliance to this system.

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.

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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: We will continue to maintain a quality system committed to ISO 9001:2000 and ISO/IEC 17025:1999 and will document, communicate and implement it 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 and reference materials from recognized laboratories and suppliers and consumables and other services 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 within the requirements of the international standards.

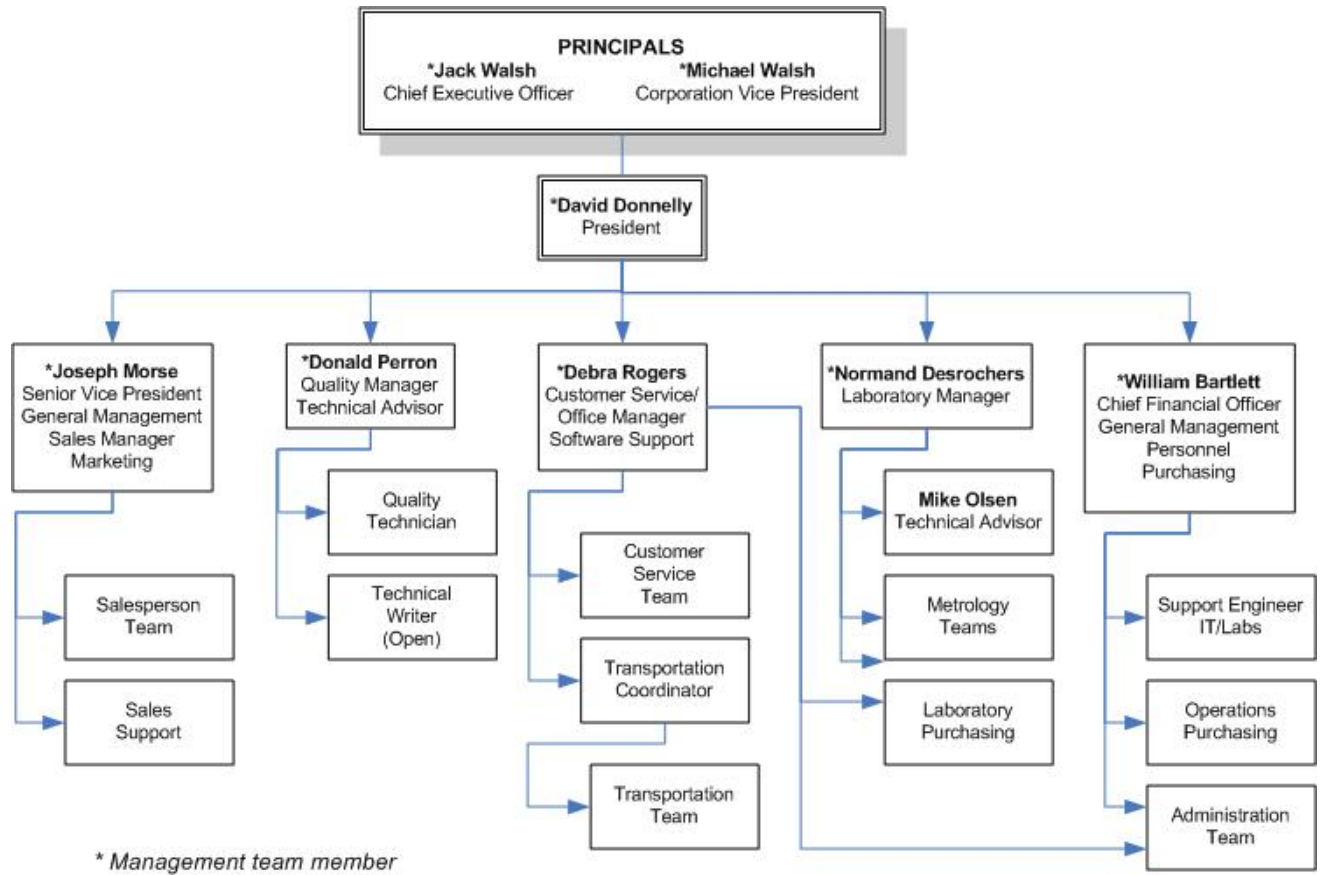
CONTINUOUS IMPROVEMENT: We will continue to advance our skills and capabilities through a partnership of each individual's commitment to improve the company's performance.

Jack R Walsh

Chief Executive Officer
ESSCO Calibration Laboratory

Figure 1. Quality Policy

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Walsh Engineering Services, Inc. Corporate Organization Chart
10/6/2005

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 CEO, cross functional inputs on technical and business matters and provides for some redundancy in some functions. The Management Team is responsible for identifying and providing the resource requirements for all lab and business functions. The Management Team will monitor and measure the company performance against the stated objectives. *The Management Team 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.*

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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 9001:2000, ISO 10012-1 and ISO 17025:1999; the national standards of MIL-STD-45662A (expired) and ANSI/NCSL Z540-1-1994 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.

The hierarchy of the documented system is depicted in Figure 3 below.

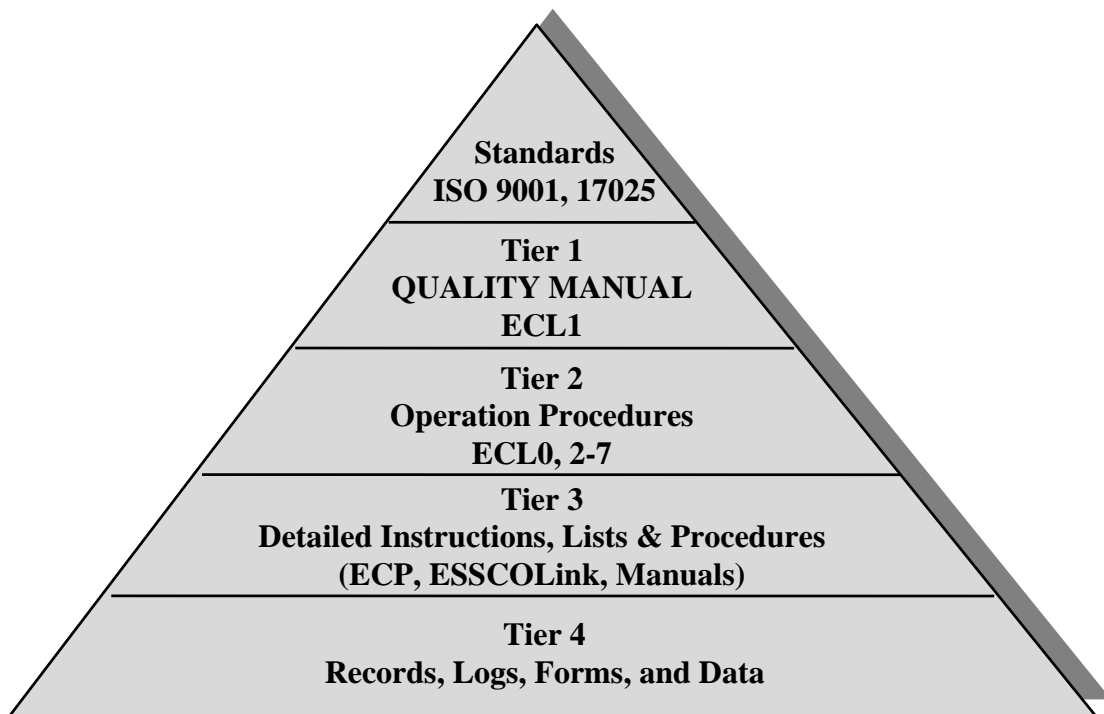


Figure 3. ESSCO Quality System Document Hierarchy

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Figure 4. Quality System Cross Reference

Essco Procedure	ISO 9001	ISO 17025
ECL 0: Scope of work	N/A	4.4 Review of requests
ECL 1: Essco Quality System 3.1 Policy/ 3.2 Organization/ 3.3 Quality System Structure / 3.4 Customer Focus / 3.5 Work Scope	4 General requirements 5.1 Management commitment 5.2 Customer focus 5.3 Quality policy	4.1 Organization 4.2 Quality System 5.0 Technical requirements
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	5.5 Administration (personnel) 6.2 Human Resources	5.2 Personnel
ECL 3: Equipment, Procedures and Environmental Management 3.1 Adequacy & Traceability / 3.2 Primary & Reference Standards / 3.3 Intervals & Cycles / 3.4 Equipment Identification / 3.5 Calibration & Maintenance Records / 3.6 Care of Standards / 3.7 Reference Materials & Consumables / 3.8 Use of Vendors / 3.9 OOT Standards / 3.10 New & Retired Standards / 3.11 ILC & Checks / 3.12 Calibration Procedures / 3.13 Environmental Management / 3.14 ESD Controls / 3.15 Outsourcing Service	6.3 Facilities 6.4 Work environment 7.4 Purchasing 7.6 Control of IM&TE	4.6 Purchasing 5.3 Environment 5.5 Equipment 5.6 Traceability 5.9 Assuring quality
ECL 4: Lab Management Processes 3.1 New Customers / 3.2 Receiving / 3.3 Handling & Storage / 3.4 Work Review & Priorities / 3.5 Calibration / 3.6 Subcontracting & Repairs / 3.7 Reporting / 3.8 Inspection, Packaging & Delivery / Onsite Calibration	7.5 Production & service operations	4.4 Review of requests 4.5 Subcontracting 4.7 Service to the client 5.7 Sampling 5.8 Handling 5.10 Reporting
ECL 5: Document and Records Management 3.1 Documents & records / 3.2 EsscoLINK / 3.3 LabMate / 3.4 MIS / 3.5 Software / 3.6 EsscoNET / 3.7 Procedures	5.5 Administration (documents)	4.3 Document Control 4.12 Control of records
ECL 6: Quality System Maintenance 3.1 Quality Planning / 3.2 Management Reviews / 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 Processes	5.4 Quality planning 5.6 Management review 7.1 Planning of realization processes 7.2 Customer-related processes 7.3 Design & development 8.1 Planning 8.2 Measuring & monitoring 8.3 Control of nonconformity 8.4 Analysis of data 8.5 Improvement	4.8 Complaints 4.9 Nonconformance 4.10 Corrective actions 4.11 Preventive actions 4.13 Internal audits 4.14 Management reviews 5.4 Methods
ECL 7: Accredited Calibration Process 3.1 Scope of Work / 3.2 Offering Service / 3.3 Promotion / 3.4 Setup & Review / 3.5 Preparation for Calibration / 3.6 Reporting / 3.7 Review and Release / 3.8 Onsite / 3.9 Revisions to Certificates	N/A	4.4 Review of requests 4.5 Subcontracting 5.6 Traceability 5.9 Assuring quality 5.10 Reporting

Our system meets the requirements of ISO 9001:2000; this system is most understood by our customers. The more stringent quality requirements of ISO 17025 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 the President in his absence) 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.

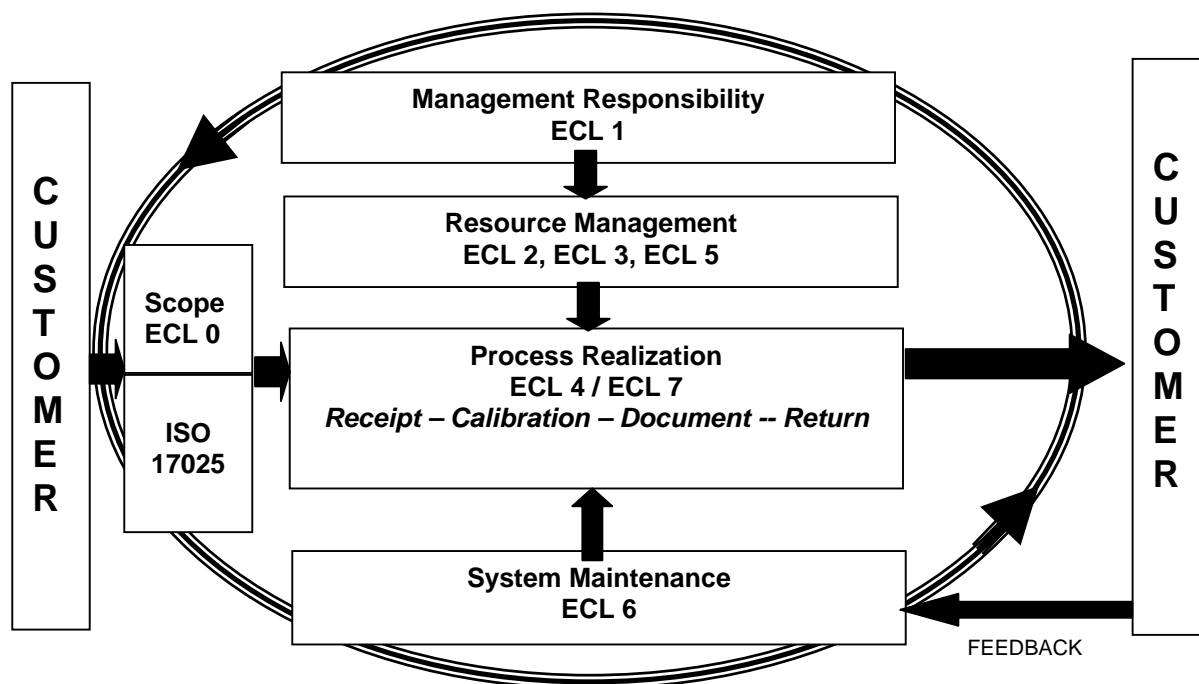


Figure 5. Quality System Model

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 17025 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 will afford the customers the opportunity to access our facility and records to audit our performance.

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3.5 Work Scope

The scope of the work performed by Essco Calibration Laboratory is defined by ECL0. Our “Scope of Accreditation” issued by the A2LA defines the accredited scope of our work.

4.0 REVISION HISTORY

<u>Revision</u>	<u>Date</u>	<u>Reason for Change</u>
13	8 Jan 2001	Revised for ISO 9001:2000 and ISO 17025 (formerly EQC000.0)
14	12 July 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	9 Sept 2002	Clarified compliance to other standards, added more detailed index of QA system
18	16 Jan 2004	Updated organization chart, Figure 2
19	1 Sept 2004	Updated organization chart, Figure 2
20	26 Jan 2005	Changed title from VP Quality to Quality Manager
21	6 June 2005	Deleted references to 10CFR 21
22	21 Feb 2006	<i>Added references per ISO 17025:2005, New Organization Chart</i>

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