FLW QUALITY MANUAL
APPROVAL SIGNATURES

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DOCUMENT CHANGE RECORD

Revision	Section	DCF ID Number	Description of Change
5.0	ALL	N/A	Manual rewritten to meet the requirements in ISO 9002
5.1	Various	00001	Renumbered level two documents, changed references
6.0	Various	00011	Upgrade to ISO 9002:1994 revisions
7.0	Various	00028	Changes made to correct or clarify in compliance with NQA audit number 96/92626/M01 - 1)added 'suitability & effectiveness to 2nd para. In 4.1.1; 2)added management rep. To fig 1; 3) added supplier quality statement to 4.2.2; 4) revised 4.2.3 to reinforce planning; 5) added 4.5.2-external documents; 6) removed para. Citing 'customer data' from 4.1.b; 7) added policy statement on accuracy to 4.11.2; 8) removed reference to customer-owned material from 4.13; 9) removed 'if at all possible' from 4.17;10) changed 4.0 to reflect quality reviewing for 'suitability and effectiveness; 11) rewrote 4.19 to reflect intent of standard.
7.1	4.1.1	00053	Change quality policy to clarify.
8.0	Various	00058	Add changes to comply with ARD 9000. Clarify certain paragraphs. Simplify organizational chart in 4.1.2.1 and refer to organizational charts P205-03 and P370-05.1. Made changes to bring QA100 in closer compliance with the ISO-9002 Standard.
9.0	Various	00096	Modify Organizational Chart and move from fig. 1 to Appendix D. Change references from ARD9000 to AS9000. Make corrections as required for clarity.
9.1	Appendix D	00113	Change Office Manager name
10.0		00115	Correct typo in 4.6, added to 4.20
11.0	ALL	00167	To bring QMS into conformance with ISO 9001:2000
11.1	Various	00183	Correct typographical errors & formatting; update management
12.0	All	00186	Bring QMS into conformance with ISO 9001:2008; correct formatting.
12.1	Appendix C, 4.2.1	00188	Addition of Appendix C – Interaction of Processes; clarify section 4.2.1 regarding outsourced processes.
13.0	Various	00196	Bring QMS into conformance with ISO/IEC 17025:2005. Updated Appendix B – Org. Chart Revised 4.1.2.1.6 to include Quality & Technical Managers.
13.1	4.2.2	00202	Clarification needed - revised section 4.2.2 to state the organization quality objectives will be outlined in management review meetings.

TABLE OF CONTENTS

1.0 SCOPE

The FLW **Q**uality **M**anagement **S**ystem is applicable to the sales, service, repair and calibration of products and systems for measurement, test and control. This QMS complies fully with all requirements of ISO 9001:2008 with the sole exception of clauses 7.3 and 7.5.2; Design and Development, and Validation of processes for production and service provision. The organization does not maintain responsibility for, or realize, perform, or outsource the design or development of any process or product, or any service as defined in paragraph 7.5.2, within the scope of the organization's certification.

2.0 REFERENCES

2.1 International Standard ISO 8402:1994 - Quality Management and Quality Assurance - Vocabulary.

2.2 International Standard ISO 9001:2008 - Quality Management Requirements

2.3 International Standard ISO/IEC 17025:2005 – General Requirements For The Competence of Testing and Calibration Laboratories

2.4 ISO 10012:2003 - Quality Assurance Requirements for Measuring Equipment - Part 1.

2.5 ANSI/NCSL Z540-1-1994 (R2002) - Calibration Laboratories and Measuring and Test Equipment - General Requirements.

2.6 ANSI/NCSL Z540.3-2006 - Calibration Laboratories and Measuring and Test Equipment

2.7 MIL-STD-45662A:1988 - Calibration Systems Requirements.

2.8 ISO 9000:2000(E) - Fundamentals and Vocabulary

2.9 ISO 9004:2000(E) - Guidelines for Performance Improvement

2.10 ISO/TC 176/SC 2/N 524R3, 525R, 544R and 526R

3.0 DEFINITIONS

3.1 For the purposes of this document, the definitions given in International Standard IS0 8402, Quality Management and Quality Assurance – Vocabulary, and the following definitions apply:

3.1.1 Customer-owned property - Any type of instrumentation, accessories, manuals, or shipping containers that belong to a customer.

3.1.2 Customer-supplied product - Any type of material provided to FLW to be incorporated in the supplies for related activities.

3.1.3 Distribution Material - Distribution material is product which is FLW (company) owned and is used for resale.

3.1.4 Local Service Procedures - These are procedures written by FLW for calibration and repair on instrumentation which does not have written manufacturer's procedures or for clarification on existing written procedures.

3.1.5 Service Material - Service material is product (parts, components, assemblies, etc.) that is used to repair or modify distribution material or customer-owned property.

3.1.6 Material supplied by companies for whom FLW acts as Representative - Material that is delivered directly to the customer from the original manufacturer and is not stocked, handled, stored, or processed by FLW and which is considered to be outside the FLW Quality System.

3.1.7 Special Process Procedures - Procedures written by the customer for calibration, modification or repair of their instrumentation that FLW is asked to service.

3.1.8 Key Characteristics – The features of a material or part whose variation has a significant influence on product fit, performance, service life, or manufacturability.

3.1.9 Re-grade – A disposition of a nonconformity that (1) determines that the product is not acceptable for its original intended design, and (2) directs the product to be re-designated or modified for an alternate use.

3.1.10 Customer – recipient of a product provided by the organization

3.1.11 Organization – provides a product to the customer. For the purposes of this Quality Manual, the organization is FLW, Inc.

3.1.12 Supplier – the company that provides a product to the organization

3.1.13 Product – The result of a process. There are four generic product categories: services (transport), software (computer program, dictionary), hardware (mechanical part), processed materials (lubricant). Service is usually the result of at least one activity necessarily performed at the interface between customer and the supplier and is generally intangible.

3.2 In addition to the definitions in 3.1 above the definitions in ISO 9000:2000(E), Fundamentals and Vocabulary, and ISO/TC 176/SC2 **526R ,** Guidance on the Terminology used in ISO 9001:2008 and ISO 9004:2000 also apply to this QMS and are made part of this document. Some of these definitions are listed below.

3.2.1 Continual Improvement - recurring activity to increase the ability to fulfill requirements.

NOTE: The process of establishing objectives and finding opportunities for improvement is a continual process through the use of audit findings

and audit conclusions, analysis of data, management reviews or other means and generally leads to corrective or preventive action.

3.2.2 Customer Satisfaction: customer's perception of the degree to which the customer's requirements have been fulfilled.

NOTE 1: Customer complaints are a common indicator of low customer satisfaction but their absence does not necessarily imply high customer satisfaction.

NOTE 2: Even when customer requirements have been agreed with the customer and fulfilled, this does not necessarily ensure the achievement of customer satisfaction.

3.2.3 Quality Improvement: part of quality management, focused on increasing the ability to fulfill quality requirements.

NOTE: The requirements can be related to any aspect such as effectiveness, efficiency or traceability.

3.2.4 Requirement: A need or expectation that is stated, generally implied or obligatory.

NOTE 1: "Generally implied" means that it is custom or common practice for the organization, its customers and other interested parties that the expectation under consideration is implied.

NOTE 2: A qualifier can be used to denote a specific type of requirement, e.g. product requirement, quality management requirement, customer requirement.

NOTE 3: A specified requirement is one which is stated, for example, in a document.

NOTE 4: Requirements can be generated by different interested parties.

4.0 QUALITY-SYSTEM REQUIREMENTS

4.1 Management Responsibility

4.1.1 Quality Policy

QUALITY IS EVERYONE'S RESPONSIBILITY. FLW, INC. IS COMMITTED TO PROVIDING ITS CUSTOMERS WITH THE HIGHEST QUALITY SALES AND SERVICE. IT IS OUR OBLIGATION TO DETERMINE AND UNDERSTAND OUR CUSTOMERS' REQUIREMENTS AND THEN MEET OR EXCEED THEIR EXPECTATIONS ON EVERY JOB. THIS INVOLVES CONTINUOUSLY IMPROVING OUR PROCESSES AND MANAGEMENT SYSTEM IN ORDER TO EFFECTIVELY AND EFFICIENTLY DELIVER A QUALITY PRODUCT.

_____

Andrew Peek, President

This policy is relevant to FLW's organizational goals and the expectations and needs of its customers. It has been defined and documented by FLW management with executive responsibility. This policy will be evaluated at least once a year by management to confirm that its suitability and effectiveness is being met. It is management's responsibility to ensure this policy is appropriate to the purpose of the organization, meets customer as well as statutory and regulatory

requirements, provides a framework for establishing and reviewing quality objectives, is reviewed for continuing suitability, includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, is understood, implemented, distributed to and maintained at all levels of the organization, and to ensure that quality objectives are established.

4.1.2 Organization

4.1.2.1 Responsibility and Authority

Top management shall ensure that the responsibilities and authorities are defined and communicated within the organization.

Personnel listed below and in related documents have the responsibility and authority to define, manage and verify the work affecting quality and communicate these responsibilities and authorities within the organization.

4.1.2.1.1 They have the freedom and authority to initiate action to prevent the occurrence of any nonconformity relating to the product, process or quality system;

4.1.2.1.2 They have the responsibility to identify and record any problems relating to the quality process;

4.1.2.1.3 Initiate, recommend or provide solutions; and

4.1.2.1.4 Verify the implementation of these solutions;

4.1.2.1.5 Control further processing or delivery of nonconforming product until any deficiency has been corrected and

4.1.2.1.6 Communicate to the organization the importance of meeting customer as well as statutory and regulatory requirements.

Detailed Sales and Service and Quality department organizational charts as well as responsibilities, authority and the interrelation of personnel are contained in documents FQD 101, FPD 205 and FPD 370.

Top management shall provide evidence of its commitment to the development and implementation of the quality management system. The President is responsible for the organizational structure, the allocation of resources and information, the development of policies, monitoring, measurement (where applicable) and analysis of company processes, implementing actions necessary to achieve planned results, continual improvement of processes, establishing the quality policy and ensuring that quality objectives are established, ensuring the availability of resources, conducting management reviews, and communicating the importance of meeting customer as well as statutory and regulatory requirements.

The President must also ensure that customer requirements are determined and met with the aim of enhancing customer satisfaction.

The Quality Assurance Manager is responsible for developing, directing and monitoring the quality system's goals, procedures

and policies. The QA Manager is responsible for the coordination of all quality activities of the FLW organization. The QA Manager reports directly to the president.

The Sales Department Office Manager is responsible for directing and monitoring the quality system goals, procedures and policies for Distribution and Representative sales and their associated purchasing, shipping, and receiving functions. The Sales Department Office Manager reports directly to the president.

The Service Manager is responsible for directing and monitoring the quality system goals, procedures and policies for calibration/verification and repair, purchasing of required materials, and shipping and receiving in the Laboratory and Service areas. The Service Manager, Technical Manager and Quality Manager are responsible for maintaining the Laboratory's compliance with MIL-STD-45662A, ANSI/NCSL Z540-1-1994 (R2002), ANSI/NCSL Z540.3-2006, ISO/IEC 17025:2005 and ISO 9001:2008.

4.1.2.2 Resources

The personnel listed in Appendix B above shall identify resource requirements adequate resources to implement and maintain the quality management system and continually improve its effectiveness and to enhance customer satisfaction by meeting customer requirements.

The assignment of personnel performing work affecting product quality shall be determined on the basis of appropriate education, training, skills and experience.

4.1.2.3 ISO Management Representative

FLW management with executive responsibility will designate a member of the organization's management as ISO Management Representative with defined authority and responsibility for:

4.1.2.3.1 Ensuring that the processes needed for an effective quality system are established, implemented and maintained in accordance with ISO 9001:2008, MIL-STD-45662A, ANSI/NCSL Z540-1 (R2002), ANSI/NCSL Z540.3:2006, and ISO/IEC 17025:2005;

4.1.2.3.2 Reporting on the performance of the quality system to FLW top management for review and as a basis for any need for improvement of the quality system.

4.1.2.3.3 Ensuring the promotion of awareness of customer requirements throughout the organization are implemented, maintained and are effective

4.1.2.3.4 The ISO Management Representative reports directly to the President.

NOTE: The responsibility of the ISO Management Representative also includes liaison with external parties on matters relating to the supplier's quality system. Also, more than one ISO Management Representative in the organization will be permitted.

4.1.2.4 Suppliers Responsibilities

Suppliers having a quality assurance activity that effect the FLW quality system shall have procedures that define the specific tasks and responsibilities that are authorized and the corresponding requirements and training necessary to perform those tasks.

4.1.2.5 Internal Communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

Examples of methods for communicating requirements, objectives and accomplishments may include: team briefings and other meetings, notice boards and in-house newsletters/magazines, audio/visual and electronic media.

4.1.3 Management Review

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

4.1.3.1 Top management will review the organization's quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality

policy and quality objectives. Records from management reviews shall be maintained.

4.1.3.2 Review input

The input to management review shall include information on:

- the results of audits,
- customer feedback,
- process performance and product conformity,
- status of preventive and corrective actions,
- follow-up actions from previous management reviews,
- changes that could affect the quality management system, and
- recommendations for improvement.

4.1.3.3 Review output

The output from the management review shall include any decisions and actions related to:

- improvement of the effectiveness of the quality system and its processes,
- improvement of product related to customer requirements, and
- resource needs.

4.1.3.4 Continual improvement

Continual Improvement, according to ISO 9000:2008 is: recurring activity to increase the ability to fulfill requirements. Further, continual improvement is the process of establishing objectives and finding opportunities for improvement, a

continual process through the use of audit findings and audit conclusions, analysis of data, management reviews or other means and generally leads to corrective action or preventive action

Continual improvement efforts are clearly linked to the management review process and the achievement of quality processes. Continual improvement must be a part of this organization's overall strategy. That is, management should be linking the goals, strategies and objectives of the organization to its continual improvement efforts.

Continual improvement of ISO 9001:2008 8.5.1, is linked to clauses 8.4, Analysis of Data, 8.1, Measurement, Analysis and Improvement, and 5.6, Management Review, as well as the result of audits, corrective action, preventive action, and the quality policy and quality objectives.

This organization's management review minutes should reflect decisions and actions relating to the continual improvement of the effectiveness of the Quality Management System performance. Actions should be taken to correct negative trends as they present themselves through CARs and audits to correct the situation and to ensure they are being carried out according to plan.

4.1.4 Processes in the Management System

The company has identified and determined the sequence and interaction for the processes needed for the quality management system and their application throughout the organization for all processes that affect quality. Processes include written work instructions, requirements for

the conformance to standards and codes that apply to industry. Control of processes includes continuous monitoring of the process, customer feedback, and regular re-approval of all processes or whatever criteria and methods may be needed to ensure effective control and operations of processes. Refer to ISO/TC 176/SC 2N 554R**,** Guidance on the Process Approach to quality management systems, for operational suggestions and guidance on understanding the process approach, and to identify, implement, manage and continually improve the effectiveness of these processes that are necessary for this quality management system. Section 5 of FQD-101 covers implementation of the process approach in relation to ISO 9001:2008 requirements.

The following FLW processes have been identified as needed for this quality management system and have been documented in the quality manual:

- Management Review
- Handling ESD devices
- Control of non-conforming products
- Corrective and preventive actions
- Training
- Customer complaints, feedback and opinions
- Document, record and data control
- Internal and external audits
- Purchasing and contracts
- Product identification, traceability, handling, storage, packaging, inspection and test
- Product and service

Additional guidance on process control as it relates to customers and other interested parties may be found in ISO 9004:2000 (7.2). Much of

this material is already documented in FLW QA-100 (FQD-160), (FQD-130), (FPD-370) and other parts of this quality manual. Future revisions of this quality manual may expand on the identification and interaction of process as FLW becomes more mature in the use and understanding of the ISO 9001:2008 QMS.

4.2 Quality System

4.2.1 General requirement

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with ISO 9001:2008. It shall identify the processes needed for quality management and their application throughout the organization, determine the sequence and interaction of processes (see FQD-160, 101-5.0, FPD-370), determine criteria and methods needed to ensure that both the operation and control of these processes are effective(see FQD-100), ensure the availability of resources and information necessary to support the operation and monitoring of these processes (see FQD 4.1.2.1) and implement actions necessary to achieve planned results and continual improvement of these processes which will be managed by the organization in accordance with the requirements of the standard (see FQD 101-5.7).

Where FLW chooses to outsource any process that affects product conformity with requirements, FLW shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system, which should include processes for management activities, provision of resources, product realization and measurement. FLW only outsources its calibration process if it is determined that it cannot meet a customer's requirement or is unable to calibrate a customer's item in FLW's calibration laboratory. This

process is described in FPD 370 – Calibration System, sections 14 and 15. The approval of suppliers that can provide calibration to FLW (and subsequently its customers) is described in FPD 322 – Supplier Audits, Calibration. FLW's approved calibration vendors are detailed on form Q160-04.

The quality management system documentation shall include: a) documented statements of a quality policy and quality objectives (see 4.1.1 and 4.2.4), b) a quality manual (see QA-100), c) documented procedures required by this international standard, d) documents needed to ensure the effective planning, operation and control of process (see QA100-4.2.3) and records required by the international standard (see FQD101-5.6 and FQD-112). Note: Where the term "documented procedure" appears within this document, this means that the procedure is established, documented, implemented and maintained.

The sequence and interactions of the QMS must be defined down to the appropriate level of detail within the organization to ensure effective operation and control of processes (see FQD 160, FQD 101, and Appendix C).

A quality manual must be established and maintained that includes the scope of the quality management system, including details of and justification for any exclusions (see QA100-1.0), the documented procedures established for the quality management system, or reference to them, and a description of the interaction between the processes of the quality management system (see FQD 160, FQD 101). Also reference the guidance in IS) 544R (4) and (6).

4.2.2 Quality Objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. All quality objectives will be noted in the minutes of the Management Review meetings.

4.2.3 Quality management system planning

Top management shall ensure that:

4.2.3.1 the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and

4.2.3.2 the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

FLW has:

- prepared documented procedures consistent with the requirements of ISO 9001:2008 and FLW's stated Quality Policy;
- effectively implemented the quality system and its documented procedures;
- ensured that quality system procedures are readily available to personnel who are responsible for compliance to requirements, and to customers and/or regulatory agency representatives.

NOTE: Documented procedures may refer to work instructions that define how an activity is performed. For the purposes of this document, the range and detail of the procedures that form part of the quality system

shall be dependent upon the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying out the activity.

Quality System Procedures are documented to establish and maintain continuity of each activity or function affecting quality. Quality procedures are readily available to personnel for reference and implementation. The quality document structure is illustrated in Figure 1.

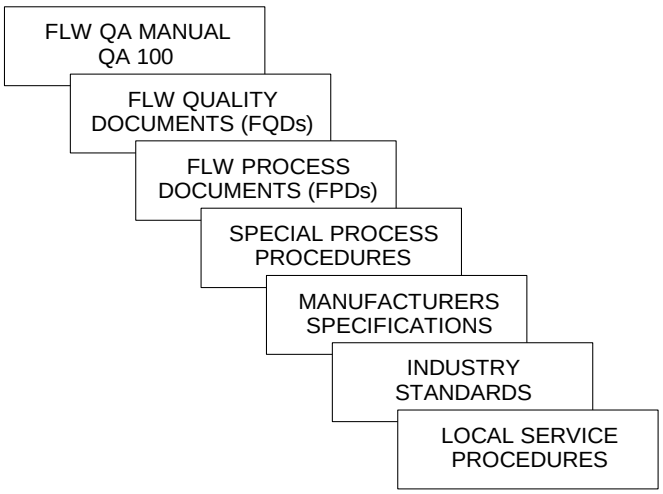


Figure 1

4.2.4 Quality Planning

The requirements for quality will be met by setting and documenting specific quality objectives and specifying necessary operational processes including meeting contractual requirements, understanding and meeting customer needs and with emphasis on problem prevention. Considerations will be given for updating the quality system in relation to changes brought about by new technologies, quality concepts, market

strategies and social or environmental conditions. Written quality and audit plans will be prepared for these changes which will be consistent with all other requirements of the company's quality management system. Top management will ensure that the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Quality and audit plans should include:

4.2.4.1 the preparation of the quality and audit plan. (This plan may be in the form of a reference to the appropriate documented procedures that form an integral part of this quality system.)

4.2.4.2 acquiring appropriate Measurement and Test Equipment, processes, fixtures, resources and skills that may be needed to achieve the required quality results;

4.2.4.3 the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics;

4.2.4.4 making sure that the process, servicing, installation, inspection and test procedures and documentation are appropriate and compatible;

4.2.4.5 Updating quality control and inspection and test procedures as required, including the development of new instrumentation &/or procedures;

4.2.4.6 identification of necessary measurement requirements involving capability that exceed known state of the art, in sufficient time for the needed capability to be developed;

4.2.4.7 identification of in-process and final inspections &/or verification at appropriate stages in the realization of product;

4.2.4.8 the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization;

4.2.4.9 the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element;

4.2.4.10 the identification and preparation of quality records and test procedures.

4.2.4.11 the identification and selection of suppliers capable of meeting quality requirements and the appropriate flow down of requirements – (see QA100, 4.6.5)

4.2.4.12 the establishment of appropriate process controls and development of control plans if key characteristics have been identified by the customer

References: FQD 180 - Servicing; FPD 370 – Calibration; FQD 101 – Quality System.

4.2.5 Customer satisfaction & communications

The organization shall determine and implement effective arrangements for communication with customers in relation to a) product information,

b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints.

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

References: FQD 106 - Customer complaints; FQD 115 - Customer reply card program; FQD 160 - Purchasing; FQD 100 - Management review; QA 100 (4.2.4) Customer satisfaction.

4.3 Contract Review

4.3.1 General

Procedures have been established and are maintained for contract review. The Sales Department Office Manager and the Service Department Manager are responsible for coordinating and supervising contract review to make sure that the needs of the customer are well understood and documented, that differences with the original contract, if any, are resolved, and that all requirements can be met. While responsibility rests with the departmental managers, trained Product Specialists implement the customer/company interface. (see FQD 160 5.0)

4.3.2 Review; Determination of requirements related to the product

Before submission of a tender, or the acceptance of a contract or order (statement of requirement), the tender, contract or order shall be reviewed by the organization to ensure that:

4.3.2.1 The requirements specified by the customer, including the requirements for delivery and post-delivery activities are adequately defined and documented. Where requirements are not stated by the customer but necessary for specified use or and intended use, where known, the organization shall ensure that the order requirements are agreed on before their acceptance;

4.3.2.2 Also any differences between the contract or order requirements and those in the tender are resolved, statutory and regulatory requirements related to the product are defined and any additional requirements determined by the organization

4.3.2.3 The organization has the capability to meet the contract or order requirements.

4.3.2.4 Records of the results of the review and actions arising from the review shall be maintained.

NOTE: In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

4.3.3 Amendments to a Contract

Amendments to any order or contract by the customer may be submitted in writing or negotiated by telephone, FAX or E-mail. If negotiated by telephone, a written record will be made and placed with the original purchase order or contract. These records may be eliminated after the order is placed on the electronic file. It is the Product Specialists responsibility to adjust all records to reflect contract amendments, notify relevant personnel and correct any work in progress changes. All changes must be reviewed and approved by appropriate personal before

implementation. Ultimate responsibility in each department is the department manager.

4.3.4 Records

Customer contracts, contract review, purchase orders, parts orders, and job orders will be maintained while active and archived as stated in section 4.16. Appropriate and effective contract review is assumed when the order or contract is entered into the FLW electronic data file.

References: FQD 130 - Contract Review

4.4 Design Control

The FLW quality management system does not maintain responsibility for, or realize, perform, or outsource the design or development of any process or product within the scope of the companies' certification. This QMS complies fully with all requirements of ISO 9001:2008 with the exception of clause 7.3, Design and Development.

4.5 Document and Data Controls

4.5.1 Control of Documents

Documents required by the quality management system shall be controlled. Quality records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed:

- to approve documents for adequacy prior to issue,
- to review and update as necessary and re-approve documents,

- to ensure that changes and the current revision status of documents are identified,
- to ensure that relevant versions of applicable documents are available at points of use,
- to ensure that documents remain legible and readily identifiable,
- to ensure that documents of external origin are identified and their distribution controlled, and
- to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.5.2 Document and Data Approval and Issue

All new or updated internal documents shall be reviewed and approved or re-approved for adequacy by authorized personnel prior to issue. Internal documents are controlled with current revisions identified in the Master Document Index (Form Q110-06) which is the first section of this Quality Manual. The QA Manager maintains this index. Authorized personnel will track the status, revision number, and location of all documentation under their control.

They will ensure that:

4.5.2.1 the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;

4.5.2.2 that invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

4.5.2.3 any obsolete documents retained for legal and/or knowledge-preservation purposes are suitable identified.

NOTE: The authorized authority for each type of document is as follows:

a. Quality manual and quality procedures - QA Manager;
b. Engineering drawings, documents related to testing and inspection, work instructions, inspection instructions, laws, regulations, standards documents, customer specifications, and similar documents - Service Manager;
c. Purchase orders, customer contact forms, and similar documents - Product Specialists;
d. Sales related documents - Sales Office Manager;
e. Other documents – Sales Office Manager

4.5.3 Document and data changes

Changes to documents and data shall be reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise. The designated functions/organizations shall have access to pertinent background information upon which to base their review and approval. Where practicable, the nature of the change shall be identified in the document of the appropriate attachments.

Master lists of document locations and revisions have been created, maintained, and are audited at least once a year for effectiveness (Forms Q110-07 and –08).

An internal audit of the document control procedures will be made at least once each year or whenever there is any question of the system's proper operation.

4.5.3.1 Document Change Incorporation

A process has been established to ensure the timely review, distribution, implementation and maintenance of all authorized and released drawings, standards, specifications, planning, and changes. A record of change effectively is maintained and, when required, these effectivities will be coordinated with the customer. (AS9000)

4.5.4 External documents

4.5.4.1 Sales Department

Documents of External Origin are not controlled.

4.5.4.2 Service Department

Documents of External Origin that apply to calibration, test, modification, upgrade, service and repair of all Measurement and Test Equipment are indexed and placed in the Service Department library. Changes to these documents supplied by the Original Equipment Manufacturer are incorporated. Changes made to these documents will be noted on the document in an appropriate location. The Service Manager has responsibility for control, issue, and approval of external documents in the department.

Documents that do not pertain to the calibration and/or service process (sales literature, technical information of general purpose, sketches and notes made to assist in departmental work, technical magazines, and literature and manuals of uncontrolled equipment such as computers and other 'tools' are uncontrolled.

4.5.5 Forms and Records

In this document a record is information contained on a Form. This document will contain only Forms. Records will be kept in the master file or distributed as required.

4.6 Purchasing

4.6.1 General

Established and documented procedures for purchasing are found in this section and in FQD 160. FLW Product Specialists are responsible for assuring that products purchased by FLW comply with stated requirements. Qualified suppliers are utilized for the purchase of replacement parts, distribution products, repair and calibration services. Suppliers are monitored for maintaining required quality standards. Suppliers not meeting requirements will be "deselected".

4.6.2 Evaluation of Suppliers

4.6.2.1 Suppliers will be evaluated and selected on their ability to meet contract requirements, including their quality system and any specific quality assurance requirements. The QA Manager is responsible for the approved Suppliers list, performing Supplier audits, and maintaining audit records.

4.6.2.2 The Supplier approval process is handled with documented procedures (FQD 160, FPD 322, FPD 370-14.0 & 15.0). Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained. This system

allows for qualifying Suppliers to different levels of relationships depending on the type of product, or the impact of subcontracted product on the final product. Where applicable, Supplier approval may be based on the quality audit reports and/or quality records showing the previously demonstrated capability and performance of supplier. Extra surveillance, normal control, or reduced control designations (i.e. the type and extent of control applied) for the supplier and the purchased product may be dependent upon the effect of the purchased product on subsequent product realization or the final product and may be noted on the approved Supplier list. Records will be maintained in accordance with section 4.16.

NOTE: Definition of the extent of control includes a system for disapproval, if necessary (See FQD160 – 5.2.2).

4.6.2.3 A list of acceptable suppliers is located on Form Q160-02.

4.6.2.4 The organization and all suppliers must use customer-approved special process sources when required by contract.

4.6.3 Purchasing Data

Purchasing documents shall contain data clearly describing the product or service being ordered, including where applicable:

4.6.3.1 the type, class, grade or other precise identification;

4.6.3.2 the title or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data, including

requirements for approval or qualification of product, procedures, process equipment and personnel

4.6.3.3 the title, number and issue of the quality system standard to be applied.

4.6.3.4 requirements for approval of product, procedures, processes and equipment

4.6.3.5 requirements for qualification of personnel

4.6.3.6 quality management system requirements.
4.6.1.1

Product Specialists will review and approve purchasing documents for adequacy of the specified requirements before release and their communication to the supplier.

4.6.4 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

NOTE: Verification methods for purchased product may include receiving / source verification, delegation of verification to the supplier, or supplier certification.

4.6.4.1 Organization verification at supplier's premises

Where the organization or its customer intends to perform verification at the supplier's premises, the Organization shall

specify verification arrangements and the method of product release in the purchasing documents.

4.6.4.2 Customer verification of subcontracted product

Where specified in the contract, the organization's customer or the customer's representative shall be afforded the right to verify at the organization's premises and the supplier's premises that subcontracted product conforms to specified requirements. Such verification shall not be used by the organization as evidence of effective control of quality by the supplier. Verification by the customer shall not absolve the organization of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

4.6.4.3 Right of Entry

The organization shall include provisions in subcontracts to allow the organization, the customer, and regulatory agencies right of entry to any place necessary to determine and verify the quality of contracted work, records and material.

4.6.4.4 Delegation of Supplier Verification to Suppliers.

Where the organization proposes to delegate product verification to a supplier, the organization shall define the requirements for the delegation and maintain a list of the delegations.

4.6.5 Requirements Flow down

The Organization shall flow down quality system requirements to suppliers to the extent necessary to ensure that characteristics not

verifiable upon receipt are adequately controlled by the supplier. Key characteristics requirements shall be flowed down if the supplier subcontracts the key characteristics process.

Material that is ordered by a customer directly from a manufacturer (or ordered through FLW) where the material is not received, handled, stored, modified or shipped by FLW is considered to be outside the FLW Quality System.

References:
FQD 160 - Purchasing; FPD 370 Calibration System

4.7 Control of Customer-Supplied Product

The Organization has established and maintains documented procedures for the control of, verification, identification, storage and maintenance of, any non-organization owned property including customer-supplied product, which may be provided for any purposes including its incorporation into the supplies or for related activities. Customer-supplied product may also include intellectual property. Any such product that is lost, damaged or is otherwise unsuitable for use shall be recorded and reported to the customer.

Verification by the Organization does not absolve the customer of the responsibility to provide acceptable product.

Reference:
FQD 150 – Product Control; FQD 140 – Product Identification and Traceability.

4.8 Product Identification and Traceability

The Organization has established and maintains documented procedures for identifying the product by suitable means from receipt and during all stages of

production, delivery and installation and also with respect to monitoring and measurement requirements. Where and to the extent that traceability is a specified requirement, the organization has established and maintains documented procedures for unique identification of individual product or batches. This identification shall be recorded.

Product Specialists are responsible for product identification and traceability of product at all stages of production and delivery. All distribution material and customer owned material is recorded at receipt on electronic data bases. All material is then stored in unique locations for protection, identification and traceability.

Distribution material is recorded only by part number and quantity. Customer owned Measurement and Test Equipment is recorded by manufacturer, by manufacturer's serial number, by a unique FLW tracking number, customers' name and, if possible, by customer's purchase order or other customer tracking number. References: FQD 140 – Product Identification and Traceability; FQD 150 – Product Control; FQD 160 – Purchasing

4.9 Process Control, Infrastructure and Work Environment

The organization will identify, validate and plan controls and methods for monitoring and, where applicable, measurement of the quality management system processes that directly affect quality. These methods shall demonstrate the ability of the processes to achieve planned results. Such controls shall include written work instructions as necessary describing the characteristics of the product with examples of workmanship standards, where possible, conformance to standards and codes that apply to industry, continuous monitoring of the process, and approval of all processes and new machinery. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product. Special processes will be continuously monitored to assure conformance to requirements.

Processes should be carried out under controlled conditions. Controlled conditions include the following:

4.9.1 documented procedures defining the manner of production, installation and servicing, where the absence of such procedures could adversely affect quality;

4.9.2 use of specific methods and procedures, suitable production, installation and servicing equipment, and a suitable working environment. The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable;

4.9.3 buildings, workspace and associated utilities,

4.9.4 process equipment (both hardware and software), and

4.9.5 supporting services (such as transport or communication)

The organization shall determine and manage the work environment needed to achieve:

4.9.6 conformity to product requirements.

4.9.7 compliance with reference standards/codes, quality plans, and/or documented procedures;

4.9.8 monitoring and control of suitable process parameters and product characteristics;

4.9.9 the approval of processes and equipment, and qualification of personnel as appropriate;

4.9.10 criteria for review and approval of the process and workmanship stipulated in the clearest practical manner;

4.9.11 use of suitable equipment and maintenance of the equipment to ensure continuing process capability;

4.9.12 accountability for all product during manufacture;

4.9.13 recorded evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized;

4.9.14 provisions for the prevention, detection, and removal of foreign objects;

Where the results of processes cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, the processes shall be validated by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure that the specified requirements are met.

This validation shall demonstrate the ability of these processes to achieve planned results. Arrangements for these processes including, as applicable

4.9.15 defined criteria for review and approval of the processes,

4.9.16 approval of equipment and qualification of personnel,

4.9.17 use of specific methods and procedures,

4.9.18 requirements for records, and

4.9.19 revalidation shall be established.

The requirements for any validation and revalidation of process operations, including the availability and implementation of monitoring and measuring devices and associated equipment and personnel (see FQD 105) shall be specified. Controlled conditions also include the implementation of release, delivery and post-delivery activities.

Records shall be maintained for qualified processes, equipment and personnel, as appropriate (see FQD 112).

NOTE: Such processes requiring pre-qualification of their process capability are frequently referred to as special processes.

4.10 Inspection and Testing

4.10.1 General

Documented procedures are established and maintained for inspection and testing activities in order to verify that the specified requirements for the product are met. Required records and procedures for inspection and testing will be detailed in the quality plan or in documented procedures.

4.10.1.1Subcontracting Inspection Activities

When the supplier proposes to subcontract inspection activities, the supplier shall control the subcontracted activity consistent with the requirements of Section 4.6.

4.10.2 Receiving Inspection and Testing

4.10.2.1 Incoming product will not be used or processed (except in the circumstances described in 4.10.2.3) until it has been inspected or otherwise verified as conforming to specified requirements. Verification of conformance to the specified requirements shall be in accordance with the quality plan and/or documented procedures. FLW Product Specialists are responsible for receiving inspection and verification as required for all products under their control. (see FQD 160)

Incoming service material will be inspected for the correct part number and quantity received. Service materials used in repairs and calibrations are tested when they are installed in the instrument, the instrument is then tested to insure it meets specifications.

Customer-owned property is inspected to insure all items received match those listed on the customer's paperwork and that there is no evidence of shipping damage. The Service Manager has overall responsibility for all test and inspection in the Laboratory and holding areas.

4.10.2.2 FLW will determine the amount and nature of receiving inspection, with consideration to the amount of control exercised at the suppliers' premises and the recorded evidence of conformance provided.

4.10.2.3 Where incoming product is released for urgent production purposes prior to verification it shall be positively identified and recorded in order to permit immediate recall and replacement in the event of nonconformity to specified requirements.

4.10.2.4 When certification test reports are used as a means of product acceptance, procedures shall document the types and frequencies of analyses to validate certifications.

Reference: FQD 141 – Inspection and Test

4.10.3 In-Process Inspection

4.10.3.1 the product will be inspected and tested as required by the quality plan and/or documented procedures;

4.10.3.2 the product will be held until the required inspection and tests have been completed or necessary reports have been received and verified, except when product is released under positive-recall procedures (see 4.10.2.3).

4.10.4 Final Inspection and Testing

All final inspection and testing shall be made in accordance with the quality plan and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.

The quality plan and/or documented procedures for final inspection and testing shall require that all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and the results meet specified requirements.

No product shall be dispatched until all the activities specified in the quality plan and/or documented procedures have been satisfactorily completed and the associated data and documentation are available and authorized.

4.10.5 Inspection and Test Records

Records have been established and are maintained which provide evidence that the product has been inspected and/or tested. These records show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming product shall apply (see 4.13).

Records identify the inspection authority responsible for the release of product (see FQD 141).

References: FQD 141 - Inspection & Test; FPD 370 - Calibration System

4.11 Control of Inspection, Measuring and Test Equipment

4.11.1 General

Documented procedures are established and maintained for the control, calibration and maintenance of inspection & measuring and test equipment (including test software) used to demonstrate the conformance of product to the specified requirements. Inspection, measuring and test equipment shall be used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability (see FPD 370). Records of these inspections will be maintained for audit purposes. This process is the responsibility of the Service Manager.

Where necessary to ensure valid results, measuring equipment shall:

4.11.1.1be calibrated or verified at specified intervals. or prior to use, against measurement standards traceable to international or

national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;

4.11.1.2be adjusted or re-adjusted as necessary;

4.11.1.3be identified to enable the calibration status to be determined;

4.11.1.4be safeguarded from adjustments that would invalidate the measurement result;

4.11.1.5be protected from damage and deterioration during handling, maintenance and storage

The organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained.

Where test software or comparative references such as test hardware are used as suitable forms of inspection, they shall be checked to prove that they are capable of verifying the acceptability of product prior to release for use during production, installation or servicing, and shall be rechecked at prescribed intervals. FLW has established the extent and frequency of such checks and shall maintain records as evidence of control (see FPD 370 9.0)

Where the availability of technical data pertaining to the inspection, measuring and test equipment is a specified requirement, such data shall be made available, when required by the customer or customer's representative, for verification that the inspection, measuring and test equipment is functionally adequate.

NOTE: For the purposes of this document, the term "measuring equipment" includes measurement devices.

4.11.1.6 Definition: Inspection, measuring and test equipment includes all types of devices used by any supplier or supplier personnel to verify materials, products, processes, or other inspection, measuring and test equipment. This includes tooling used as media of inspection, test hardware, test software, automated test equipment (ATE), and plotters used to produce inspection media. Also included is personally owned equipment used for product or process acceptance.

4.11.2 Control Procedure

Documented procedures shall:

4.11.2.1 determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring and test equipment that is capable of the necessary accuracy and precision.

4.11.2.2 identify all inspection, measuring and test equipment that affect product quality and calibrate and adjust them at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to internationally or nationally recognized standards. Where no such standards exist, the basis used for calibration shall be documented;

4.11.2.3 define the process used for the calibration of inspection, measuring and test equipment, including details of equipment type, unique identification, location, frequency of checks, check

method, acceptance criteria and the action to be taken when the results are unsatisfactory. The process shall consider the recall of inspection equipment, as appropriate.

4.11.2.4 identify inspection, measuring and test equipment with a suitable indicator or approved identification record to show the calibration status;

4.11.2.5 maintain calibration records for inspection, measuring and test equipment;

4.11.2.6 assess and document the validity of previous inspection and test results when, inspection, measuring and test equipment is found to be out of calibration;

4.11.2.7 ensure that the environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out;

4.11.2.8 ensure that the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for the use are maintained;

4.11.2.9 safeguard inspection, measuring and test facilities, including both hardware and test software, from adjustments which would invalidate the calibration setting.

NOTE: The metrological confirmation system for measuring equipment given in ISO 10012 may be used for guidance.

References: FPD 370 - Calibration System

4.12 Inspection and Test Status

The inspection and test status of product shall be identified by suitable means, which indicate the conformance or nonconformance of product with regard to inspection and tests performed. The identification of inspection and test status shall be maintained, as defined in the quality plan and/or documented procedures, throughout production, installation and servicing of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized concession (see 4.13.2) is dispatched, used or installed.

4.12.1 Acceptance Authority Media

When acceptance authority media are used (e.g., stamps, electronic passwords), the supplier's system shall establish and document controls for the media. (AS 9000)

References: FQD 142 - Test Status; FQD 140 – Product Inspection and Traceability; FQD150 – Product Control; FQD-370, 8.0, 9.0 – Calibration System

4.13 Control of Non-Conforming Material

4.13.1 General

Documented procedures have been established and maintained to ensure that product which does not conform to specified requirements is prevented from unintended use or installation. This control provides for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product, and for notification to the functions concerned.

NOTE 1: Parties requiring notification of nonconforming product may include internal organization, customers, distributors and government agencies.

NOTE 2: The term "nonconforming product" includes nonconforming product returned from a customer.

FLW measurement standards, inspection, measuring and test equipment found to be in non-conformance relative to their intended use, are labeled and removed from the work areas to prevent usage.

4.13.2 Review and Disposition of Non-Conforming Product

The responsibility for review and authority for the disposition of nonconforming product is defined in FQD103 3.0.

Non-conforming product shall be reviewed in accordance with documented procedures. It may be:

4.13.2.1reworked to meet the specified requirements,

4.13.2.2accepted with or without repair by concession,

4.13.2.3re-graded for alternative applications, or

4.13.2.4rejected or scrapped.

Where required by the contract, the proposed use of repair of product (see 4.13.2b) which does not conform to specified requirements shall be reported for concession to the customer or customer's representative. The description of the nonconformity that has been accepted, and of repairs, shall be recorded to denote the actual condition.

Repaired and/or reworked product shall be re-inspected in accordance with the quality plan and/or documented procedures.

4.13.2.5Material Review Authority

Notwithstanding the requirements of 4.13.2, the supplier shall not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if (1) the product is produced to customer design, or (2) the nonconformity results in a departure from the contract requirements.

4.13.2.6Re-grading Material

Product dispositioned for re-grade requires a change in product identification to preclude the product's original use. Adequate test reports and certifications shall reflect the re-grading.

4.13.2.7Scrap Material

Product dispositioned for scrap shall be conspicuously and permanently marked until physically rendered unsuitable for use in completed products. (AS 9000)

4.13.2.8Notification

The organization's system shall provide for timely reporting of nonconformance that may affect product already delivered. When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

References: FQD 103 - Control of Non-Conforming Material

4.14 Corrective and Preventive Action

4.14.1 General

Documented procedures are established and maintained for implementing corrective and preventive action. Corrective or preventive actions taken to eliminate causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered

Changes to documented procedures resulting from corrective and preventive action will be implemented and recorded.

4.14.2 Corrective Action and Analysis of Data

The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

4.14.2.1customer satisfaction;

4.14.2.2conformity to product requirements,

4.14.2.3characteristics and trends of processes and products including opportunities for preventive (and corrective) action, and

4.14.2.4suppliers.

Comment: Organizations must identify appropriate data sources, analyze this data and then use it for improvement. Analysis of data should include evaluation against quality objectives.

Procedures for corrective action will include:

4.14.2.5effective handling of customer complaints and reports of product nonconformities;

4.14.2.6investigation of the causes of nonconformities relating to product, process and quality system, and recording the results of the investigation;

4.14.2.7determination of the corrective action needed to eliminate the causes of nonconformities;

4.14.2.8application of controls to ensure that corrective action is taken and that it is effective.

4.14.2.9reviewing corrective action taken.

4.14.2.10 records of results of action taken

4.14.2.11 reviewing the effectiveness of corrective action taken.

4.14.3 Preventive Action

Preventive actions shall be taken to eliminate the causes of potential nonconformities in order to prevent their occurrence. Both corrective

actions and preventive actions shall be appropriate to the effects of the potential problems.

Procedures for preventive action will include:

4.14.3.1 the use of appropriate sources of information such as, processes and work operations which affect product quality, concessions, audit results, quality records, service reports and customer complaints to detect, analyze and eliminate potential causes of nonconformities;

4.14.3.2 determination of the steps needed to deal with any problems requiring preventive action;

4.14.3.3 initiation of preventive action and application of controls to ensure that it is effective;

4.14.3.4 ensuring that relevant information on actions taken is submitted to management for review.

4.14.3.5 records of results of action taken

4.14.3.6 reviewing the effectiveness of preventive action taken.

References: FQD 104 - QA Corrective Action Procedure, FQD 106 Customer Complaints; FQD 115 – Customer Reply Card Program.

4.15 Preservation of Product - Handling, Storage, Packaging, Preservation and Delivery

4.15.1 General

The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

4.15.2 Handling

Methods of handling product have been established that prevent damage or deterioration. (see FQD 150)

4.15.3 Storage

Areas have been designated for the storage of product to prevent damage or deterioration pending use of delivery. Methods for authorizing receipt to and dispatch from such areas have been stipulated. To prevent deterioration, the condition of product in stock is regularly assessed (see FQD102 and FQD150).

4.15.4 Packaging

Appropriate methods for packing, packaging and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements are in place and monitored for effectiveness (see FQD102 and FQD150).

4.15.5 Preservation

Appropriate methods for preservation and segregation of product when the product is under supplier's control have been implemented (see FQD102 and FQD150).

4.15.6 Delivery

Arrangements have been made for the protection of the quality of product after final inspection and test. Where contractually specified, protection shall be extended to include delivery to destination (see FQD150).

Deliveries are accomplished by one of the following methods:

4.15.6.1an approved common carrier;

4.15.6.2method stipulated by the customer;

4.15.6.3FLW van;

4.15.6.4customer pick up.

4.16 Control of Quality Records

FLW has established and maintains documented procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records. The Quality Manager has the responsibility for maintaining these records.

Quality records are maintained to show evidence of conformity to specified requirements and the effective operation of the quality management system. Pertinent quality records from suppliers are maintained as an element of these data.

All quality records must be legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of quality records. Records will be stored and retained so they are readily available. They will be stored to prevent damage, deterioration and/or loss. Retention times of quality records have been established and recorded (see FQD 112). Where agreed to

contractually, quality records are made available for evaluation by the customer or the customer's representative for an agreed period.

Records may be in the form of any type of media, such as hard copy or electronic media.

4.16.1 Record Availability

Records shall be readily available for review by the customer or regulatory agencies (AS9000).

Reference: FQD 112 - Record Control

4.17 Internal Quality Audits

Documented procedures have been established and are maintained for planning and implementing internal quality audits. Quality audits will be used to verify whether quality activities and related results comply with planned expectations to determine the effectiveness of the quality system. The QA Manager has the responsibility for implementing internal quality audits. Reports of all internal quality audits will be recorded and copies routed to the Service Manager and the President. Records will be preserved in accordance with FQD 112 - Record Control.

Internal quality audits will be scheduled on the basis of the status and importance of the activity to be audited and shall be carried out by personnel independent of those having direct responsibility for the activity being audited. Special attention will be given to the Service Department (Laboratory), the Quality System, the Audit System and the Document System. Audits will be made in accordance with the requirements found in ISO 9001:2008(E), ISO/IEC 17025:2005, ANSI/NCSL Z540.3-2006 and/or ANSI/NCSL Z540-1-1994 (R2002). Audits will be in accordance with guidelines set forth in ISO 19011. Audit results will be brought to the attention of the person responsible for the area. The management personnel responsible for the area shall

take timely corrective action on deficiencies found during the audit. Deficiencies found during the audit will require a corrective action report as per section 4.14.

Internal audits will determine if the QMS conforms to the planned arrangement, to the requirements of ISO 9001:2008, and to the organizations' requirements to determine if the QMS is effectively implemented and maintained. Audit programs shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartially of the audit process. Auditors shall not audit their own work

Follow-up audit actives will be used to verify and record the implementation and effectiveness of the corrective action taken. Audit results and any resulting corrective action required will be reviewed in the regular Management Review meeting.

References: FQD 120 - Quality Audits; FPD121- Internal Audits; FQD100 – Management Review.

4.18 Competence, Awareness and Training

FLW has established and maintains documented procedures to determine the necessary competence for personnel performing work affecting product quality and to provide for the training of all personnel performing these activities. Personnel performing specific assigned tasks will be qualified on the basis of appropriate education, training and/or experience, as required. Effectiveness of this training or any other actions to satisfy these needs will be evaluated. Personnel will be made aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives of the company. The importance of training at FLW is reflected in paragraph 4.1.1 of this document - Quality Policy. The QA Manager is responsible for training and related documentation. Records of

training, education, skills and experience will be controlled and maintained as quality records in accordance with section 4.5.

References: FQD 105 - Training Requirements

4.19 Servicing

Where servicing is a specified requirement, the supplier shall establish and maintain documented procedures for performing, verifying and reporting that the servicing meets the specified requirements.

Servicing activities are normally contractual and the following should be considered:

4.19.1 service responsibilities among supplier, distributor and user should be clarified;

4.19.2 service activities should be planned;

4.19.3 special tools, jigs, parts and measurement and test equipment should be acquired as appropriate;

4.19.4 Quality and Audit plans should be made;

4.19.5 provisions should be made for whatever special labor, equipment, parts, documentation, quality procedures, etc., may be required,

4.19.6 provision should be made for adequate back-up, to include technical advice and support, customer personnel training and Laboratory personnel training;

4.19.7 plans should be made for corrective and preventative action as required.

When appropriate, the supplier shall maintain a system for receiving and acting on service information consistent with contractual and/or regulatory requirement. (AS9000)

References: FQD 180 - Servicing; FPD 370 - Calibration System

4.20 Statistical Techniques

4.20.1 Identification of Need

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to a) demonstrate conformity of the product, b) ensure conformity of the quality management system, and c) continually improve the effectiveness of the quality management system. This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

NOTE: Standards, such as MIL-STD 45662A and IEEE-498(1985) encourage the use of arbitrary test accuracy ratios (TARs) as a means for controlling the penalties associated with inaccurate measurements. In these standards, a TAR of 4:1 is declared to be satisfactory for the purposes of those invoking the standard.

(A TAR of 4:1 means that the specification limits of the parameter tested must be at least four times greater than the uncertainty of the instrument or system used to measure it.)

As standards change; or if a requirement arises, FLW will establish a system for statistical techniques, especially in the area of statistical methods for instrument calibration. It will be the responsibility of both

the QA Manager and the Service Manager to implement and document this process.

FLW realizes that the documentation resulting from the application of statistical methods can be an effective means of demonstrating conformance to requirements for quality, and can be used as a form of quality records.

4.20.2 Procedures

The organization shall establish and maintain documented procedures to implement and control the application of the statistical techniques and/or uncertainties. Various methods and processes are available in the Guide to Uncertainty Measurements (GUM), ANSI-NCSL Z40-2, NCSL RP-12, NIST Technical Note 1297, NAMAS NIS 3003, ISO 10012 and ISO 5725-1. The use of the Uncertainty Calculator form the Compaq Company is authorized.

4.20.3 Sampling Inspection

When the organization uses sampling inspection as a means of product acceptance, the plan shall be statistically valid and appropriate for use. The plan shall preclude the acceptance of known defectives in the lot.

Appendix A – Correspondence Between ISO 9001:2008 and QA-100

ISO 9001:2008	FLW QA-100
4.0	Quality Management System
4.1	General requirement QA-100 4.2.1
4.1.a	QA-100 4.1.4
4.1.b	FQD 101 5.0, FQD 160, FPD 370
4.1.c	FQD 100
4.1.d	QA 100 4.1.2.1, 4.1.2.2
4.1.e	QA 100 4.14.2, 4.20, 4.1.3
4.1.f	FQD 101 5.7
4.1 Outsourced processes	QA 100 4.2.2, FPD 370 14.0
4.2	Documentation requirements
4.2.1	General
4.2.1.a	QA-100 4.1.1, 4.2.2, 4.2.1
4.2.1.b	QA-100
4.2.1.c	FQD 110, FQD 112, FPD 121, FQD 103, FQD 104
4.2.1.d	FQD 114 4.1
4.2.2	Quality manual QA-100 4.2.1
4.2.2.a	QA-100 1.0
4.2.2.b	QA-100 4.2.1
4.2.2.c	FQD 160, FPD 370
4.2.3	Control of documents QA-100 4.5.1
4.2.3.a	FQD 110 6.5
4.2.3.b	FQD 110 6.1
4.2.3.c	FQD 110 6.9, 6.3
4.2.3.d	FQD 110 6.11
4.2.3.e	FQD 110 6.2, 6.3.1.2
4.2.3.f	FQD 110 6.14, 6.15
4.2.3.g	FQD 110 6.7
4.2.4	Control of quality records QA-100 4.16, FQD112
5.0	Management Responsibility
5.1	Management commitment QA-100 4.1.2.1
5.2	Customer focus QA-100 4.1.2.1

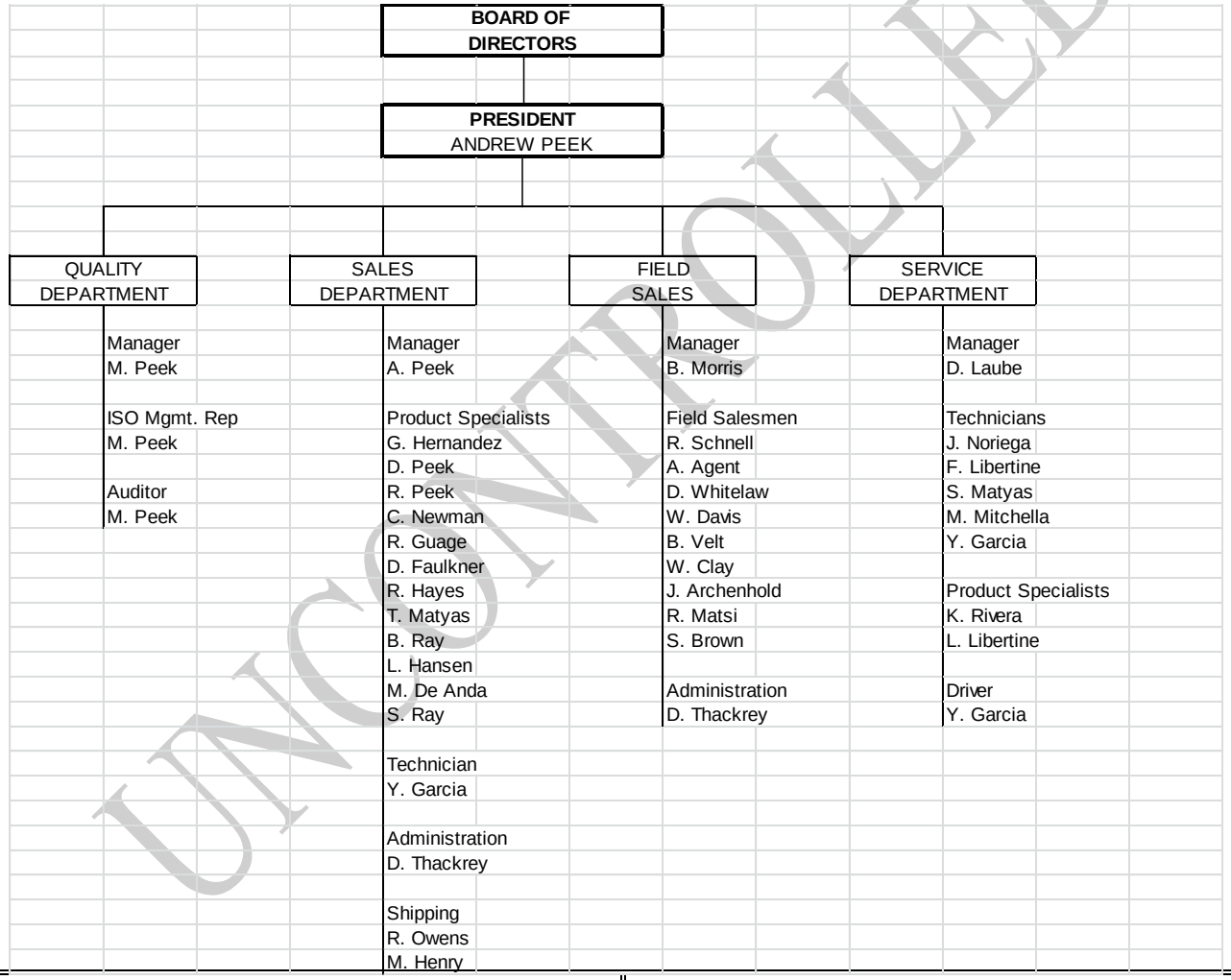
5.3	Quality policy QA-100 4.1.1
5.4	Planning
5.4.1	Quality objectives QA-100 4.2.2
5.4.2	Quality management planning QA-100 4.2.3
5.5	Responsibility, authority and communication
5.5.1	Responsibility and authority QA-100 4.1.2.1
5.5.2	Management representative QA-100 1.2.3
5.5.3	Internal communication QA-100 4.1.2.5
5.6	Management review
5.6.1	General QA-100 4.1.3, FQD-100
5.6.2	Review input QA-100 4.1.3.2
5.6.3	Review output QA-100 4.1.3.3
6.0	Resource Management
6.1	Provision of resource QA-100 4.1.2.2
6.2	Human resources
6.2.1	General QA-100 4.1.2.2
6.2.2	Competence, awareness and training QA-100 4.18, FQD-105
6.3	Infrastructure QA-100 4.9.2
6.4	Work environment QA-100 4.9.2

7.0	Product Realization
7.1	Planning of product realization QA-100 4.2.2, 4.2.3, 4.2.4, 4.3.2, 4.9, 4.10.1 FQD 101 5.6, FQD 180 5.2, FQD 160 FQD 170
7.2	Customer-related processes
7.2.1	Determination of requirements QA-100 4.3.2, FQD 130
7.2.2	Review of requirements related to the product QA-100, 4.3.2, 4.3.3, 4.3.4
7.2.3	Customer communication QA-100 4.2.5, FQD 106, FQD 130, FQD 160
7.3	Design and development QA-100 4.4, QA-100 1.0 (Scope)
7.4	Purchasing
7.4.1	Purchasing process QA-100 4.6.2, FQD-160
7.4.2	Purchasing information QA-100 4.6.3, FQD 160
7.4.3	Verification of purchased product QA-100 4.6.4, QA-100 4.10.2, 4.10.3, 4.10.4 FQD 160 5.4
7.5	Production and service provision
7.5.1	Control of production and service provision QA-100 4.9, 4.10.3, 4.15.6 FQD 170, FQD 180, FPD-370
7.5.2	Validation of processes for production and service QA-100 4.9, FQD 170
7.5.3	Identification and traceability QA-100 4.8, 4.10.5, 4.12 FQD 140, FPD 370
7.5.4	Customer property QA-100 4.7, FQD-150
7.5.5	Preservation of product QA-100 4.15, FQD 102, 105

8.0	Measurement, Analysis and Improvement
8.1	General QA-100 4.10, 4.17, 4.20.1
8.2	Monitoring and measurement
8.2.1	Customer satisfaction QA-100 4.2.5, FQD 106, FQD 115, FQD 160, FQD 100
8.2.2	Internal audit QA-100 4.17, FPD 121
8.2.3	Monitoring and measurement of processes QA-100 4.9, 4.17, 4.20.1
8.2.4	Monitoring and measurement of product QA-100 4.10.2, .3, .4, .5, QA-100 4.20.1
8.3	Control of nonconforming product QA-100 4.13.1, 4.13.2 FQD 103
8.4	Analysis of data QA-100 4.14.2
8.5	Improvement
8.5.1	Continual improvement QA-100 4.1.3.4
8.5.2	Corrective action QA-100 4.14, FQD 104.6.2, 6.3
8.5.2	Preventive action QA-100 4.14, FQD 104.6.3, 6.3

APPENDIX B – FLW ORGANIZATIONAL CHART

Note: This record was last modified on May 2013



APPENDIX C – INTERACTION OF PROCESSES