FAR WEST TECHNOLOGY, INC.

Quality Manual

Revision [2.2]

27 November 2024

0.0 Revision History and Approval

Rev.	Nature of changes	Approval	Date
0	Original release.	John Rickey	1997 Aug 27
1	Minor revisions reflecting change in personnel	John Rickey	2005 Dec 31
1.1	Editorial revisions for clarification	John Rickey	2022 Oct 20
2	Revision to new format	Scot Larson	2023 Oct 31
2.1	Remove/revise items in Appendix B due to changes as we update procedures	John Rickey	2024 Oct 28
2.2	Update reflecting retirement of QPs	John Rickey	2027 Nov 27

1.0 Welcome to FAR WEST TECHNOLOGY, INC.

Far West Technology, Inc. (FWT) designs, manufactures, services and distributes radiation measuring devices. The RACM division manufactures radiochromic dosimeters that measure high levels of radiation. They are used in radiation processing, including medical product sterilization and multiple other processes. The detector division manufactures detectors used in medical and industrial applications where precision measurements are important. The Health Physics Division manufactures instruments and detectors to detect ionizing radiation. The instruments are used in national laboratories, universities, industry and hospitals. The calibration division provides calibration service for instruments that detect ionizing radiation.

2.0 Quality Policy

FWT Quality team has developed the following Quality Policy which governs day-to-day operations to ensure quality. The Quality Policy is communicated and implemented throughout the organization. FWT prides itself on producing high quality products.

The Quality Policy of FWT is as follows:

FWT's success is based on employee involvement and continuous improvement to produce high quality products that satisfy our customers.

3.0 Context of the FWT Organization

FWT has reviewed and analyzed key aspects of the organization and its stakeholders to determine the strategic direction of the company. This requires understanding internal and external issues that are of concern to FWT and its interested parties*.*

The issues determined above are identified through an analysis of risks facing FWT and its interested parties. “Interested parties” are those stakeholders who receive our Products or Services, or who may be impacted by them, or those parties who may otherwise have a significant interest in our company.

Such issues are monitored and updated as appropriate, and discussed as part of management reviews. This information is then used by senior management to determine the company’s strategic direction. This is defined in records of management review, and periodically updated as conditions and situations change.

4.0 Scope of the FWT Quality Management System

Based on an analysis of the issues of concern, interests of stakeholders, and in consideration of its products and services, FWT has determined the scope of the quality management system (QMS) as follows:

The QMS is structured to meet the requirements for contracts between FWT (including the Health Physics Instruments division) and its customers, and demonstrates FWT’s capability to design, manufacture, supply products and provide services that meet requirements and prevent nonconformities.

This manual provides a description of the quality management system requirements and serves as a reference for implementing and maintaining FWT’s quality management system. The quality system applies to all processes, activities, and employees of the following locations within the company.

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5.0 QMS Processes

FWT has adopted a process approach for its management system. By identifying the top-level processes within the company, and then managing each of these discretely, this reduces the potential for nonconforming Products or Services discovered during final processes or after delivery. Instead, nonconformities and risks are identified in real time, by actions taken within each of the top-level processes.

Note: not all activities are considered “processes” – the term “process” in this context indicates the activity has been elevated to a higher level of control and management oversight. The controls indicated herein are applicable only to the top-level processes identified.

The following top-level processes have been identified for Far West Technology, Inc.:

- Control of Documents
- Control of Records

- Internal Audits
- Corrective and Preventive Actions
- Control of Non-conforming Products
- Continuous Improvement
- Production and Calibration Services

Each process may be supported by other activities, such as tasks or sub-processes. Monitoring and control of top-level processes ensures effective implementation and control of all subordinate tasks or sub-processes.

The sequence of interaction of these processes is illustrated in Appendix A.

Note: Appendix A represents the typical sequence of processes, and may be altered depending on customer or regulatory requirements at the job or contract level, as needed.

Additional QMS documented procedures have been developed to support the QMS and its processes; these are listed in Appendix B. This list only provides some top-level procedures, and may not reflect the entirety of all QMS documentation.

Each process has at least one objective established for it; this is a statement of the intent of the process. Each objective is then supported by at least one “metric” or key performance indicator (KPI) which is then measured to determine the process’ ability to meet the quality objective.

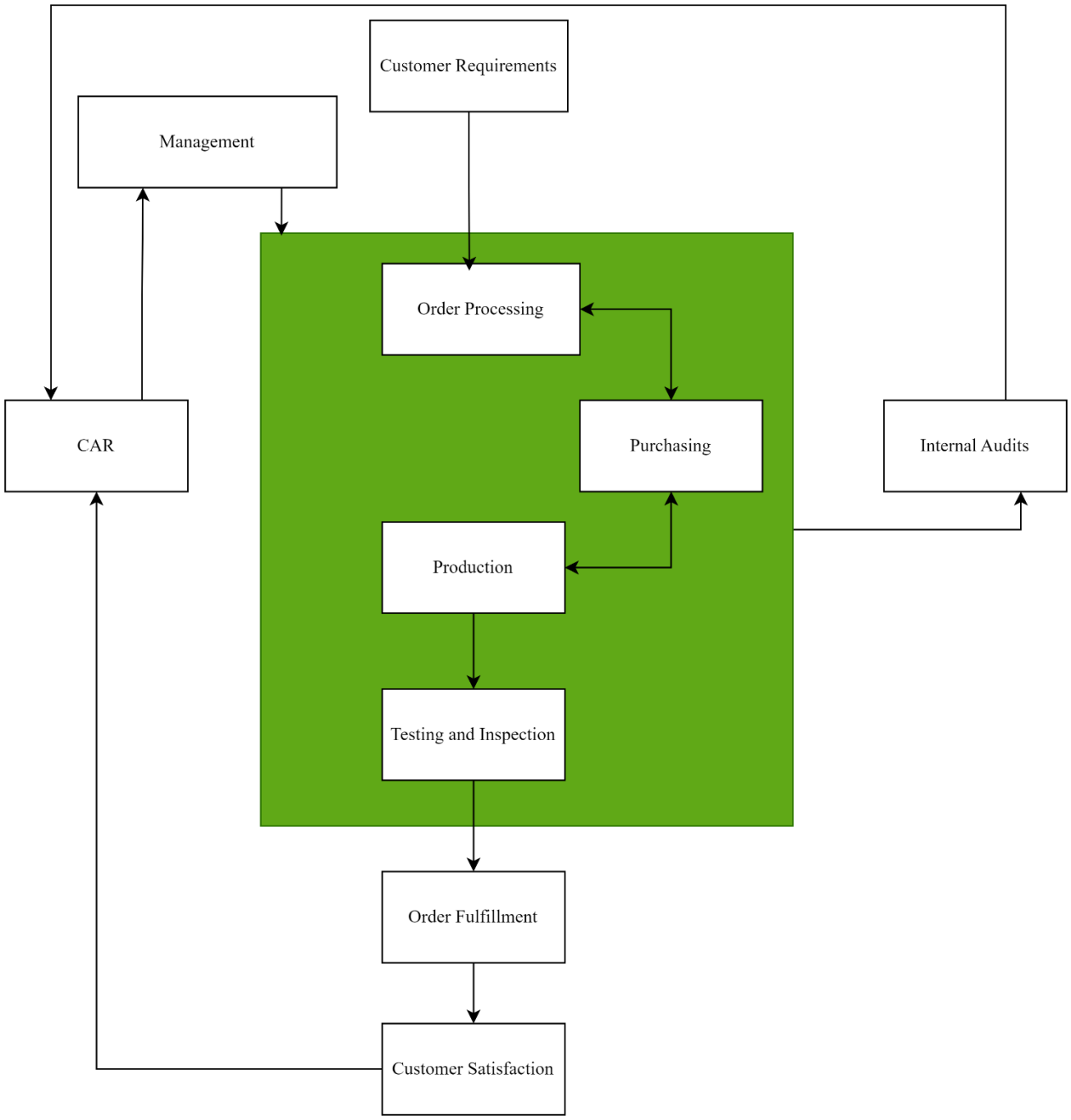
Throughout the year, metrics data is measured and gathered by process owners or other assigned managers, in order to present the data to the Quality Manager. The data is then analyzed by Quality Team in order that the Quality Team may set goals and make adjustments for the purposes of long-term continual improvement.

Metrics, along with current standings and goals for each objective, are also recorded in records of management review.

When a process does not meet a goal, or an unexpected problem is encountered with a process, the corrective and preventive action process is implemented to research and resolve the issue. In addition, opportunities for improvement are sought and implemented for the identified processes.

Any process performed by a third party is considered an “outsourced process” and must be controlled, as well. The company’s outsourced processes, and the control methods implemented for each, are defined in FWT-001 Subcontractor Assessment procedure.

Appendix A: Overall Process Sequence & Interaction



Appendix B: Subordinate QMS Procedures

- Calibration – MET-001; GRM-002; HPI-004 to HPI-009
- Change Mgmt – FWT-004; FWT-014
- Control of Documents – FWT-004
- Control of NCP and NC Service – FWT-007; GRM-004; HPI-001
- Control of Records – FWT-004
- Corrective Preventive Action – FWT-007
- Customer Complaints – FWT-015
- Customer Property – GRM-006
- Equipment Validation – FWT-014
- IInternal Auditing – FWT-008
- Management Review – FWT-005
- Outsourced Processes – FWT-001
- Preventive Maintenance – PEM-001
- Purchasing Proc. – FWT-003
- Quoting and Orders – FWT-001; FWT-002
- Receiving Proc. – FWT-003
- Risk Management Proc. – FWT-007, FWT-013
- Training Proc. – FWT-009; GRM-001; HPI-010; HPI-013