Quality Manual

Warneke Paper Box Company

4500 Joliet Street

Denver, Colorado 80239

www.warnekepaperbox.com

Table of Contents

1 Introduction

Warneke Paper Box Company (Warneke) is a 4th generation family owned, woman owned, small business founded in 1907. Our mission is to be the preferred provider of quality, custom printed paper boxes, set-up boxes, transparent boxes, pop-up displays, pocket folders and related products. We manufacture products for medical devices, pharmaceuticals, food, cosmetics, advertising, consumer products, and many other applications at our Denver, Colorado facility. Our commitment to excellence is displayed through continual improvements of our products and processes through training, management involvement, and technical improvements. We continually analyze and set quality objectives to improve our products and processes. Warneke's goal is to satisfy our customers and we employ formal procedures using methods and techniques that encourage continuous improvement, good business practices, and good manufacturing practices. At Warneke our Business Management System is synonymous with our Quality Management System, as our business is quality.

2 Purpose

The purpose of this Manual is to serve as a link between Warneke's Quality Management System (QMS) and the current version of the ISO 9001 Standard on which our QMS is based. Our system also ensure compliance to Forest Stewardship Council (FSC) or Sustainable Forestry Initiative (SFI), when required by customers.

3 Quality Management System Scope

The scope of Warneke's QMS applies to activities conducted at their facility at 4500 Joliet Street, in Denver, CO 80239. This QMS is designed to meet the requirements of the current versions of the ISO 9001, Forestry Stewardship Council FSC-STD-40-004 Chain of Custody Certification (FSC), and Sustainable Forestry Initiative Chain of Custody (SFI) Standards with no exclusions or sections identified as being not applicable.

For ISO 9001, the scope of Warneke's QMS is:

THE DESIGN, MANUFACTURE, AND SALES OF CUSTOM PRINTED FOLDING CARTONS, SET-UP BOXES, POP DISPLAYS, POCKET FOLDERS, VINYL BOXES, AND RELATED PRODUCTS AND SERVICES.

For FSC and SFI, the scope of Warneke's QMS is:

MANUFACTURE OF FOLDING CARTONS, SET-UP BOXES, POP DISPLAYS, POCKET FOLDERS, AND RELATED PRODUCTS.

Warneke's FSC Chain of Custody process uses the TRANSFER SYSTEM. For our SFI Chain of Custody processes we use the PHYSICAL SEPARATION METHOD.

FSC & SFI Input Materials	Output Product Groups (per FSC-STD-40-004a)
FSC Mix	P5.1-Packaging and wrappings of Paper - Cardboard packaging
FSC 100%	P5.7-Packaging and wrappings of Paper - Optical disc packaging and Covers
FSC Recycled	P7.3-Stationary of paper (printed & unprinted) – File Folders
SFI Certified Forest	P8.4-Printed Materials - Advertising materials
SFI Chain of Custody	P8.7-Printed materials - Toys and games made with paper
SFI Certified Sources	P10-Other pulp & paper products n.e.c.
SFI Post-Consumer Recycled	

4 Leadership

4.1 Leadership & Commitment

Warneke management leads by example, demonstrating leadership and commitment to our QMS by:

- being accountable for the effectiveness of the QMS,
- ensuring that our quality policy and quality objectives are established, and are compatible with our context and strategic direction,
- ensuring the QMS requirements are integrated into our regular business processes,
- promoting the use of the process approach and risk-based thinking,
- ensuring needed resources are available to ensure conformity of product and services, to improve the QMS, its processes, and resulting product and service, to promote customer satisfaction,
- communicating the importance of effective quality management and of conforming to our QMS requirements, the benefits of improved performance, and the implications of not conforming with our QMS requirements,
- ensuring the QMS achieves its intended results,
- engaging, directing, and supporting personnel to contribute to the effectiveness of the QMS,
- promoting improvement,
- supporting other management roles to demonstrate their leadership as it applies to their area of responsibility,
- ensuring that customer and applicable statutory and regulatory requirements are determined, understood, and consistently met,
- ensuring the risks and opportunities that can affect conformity of our products and services, and the ability to enhance our customer satisfaction are determined and addressed, when appropriate,
- ensuring the focus on enhancing customer satisfaction is maintained,
- by leading and/or participating in our QMS planning, management reviews, and internal audits,
- developing and managing mutually beneficial relationships with our external providers (suppliers, contractors, and service providers) to enhance the ability of both to create value,
- encouraging and utilizing evidence-based decision making,

4.2 Quality Policy

Warneke's commitment to meeting requirements, satisfy customers, and continuously improve our QMS and our resulting products and services resulted in the following quality policy:

Dedicated to exceeding customer expectations.

This is achieved through our integrated QMS. This policy is the foundation for establishing our quality objectives that our organization's performance can be measured.

Warneke reviews this quality policy as part of our management review process to ensure it:

- is appropriate to the purpose and context of our organization and supports our strategic direction,
- provides a framework for setting our quality objectives,
- includes a commitment to satisfy applicable requirements, and
- includes a commitment to continual improvement of our QMS,

Warneke's quality policy is made available to relevant interested parties, when determined appropriate by Management. We communicate our quality policy through prominent postings of this policy and training to ensure it is understood and applied throughout the organization.

4.3 Quality Objectives

Warneke management has developed quality objectives at relevant functions, levels, and processes needed for our QMS. These objectives support our Quality Policy, take into account applicable requirements, are relevant to conformity of our products and services, and help us boost customer satisfaction.

These objectives are recorded and tracked in the Objectives tab of our QMS Planning Workbook. This data is evaluated as part of our management review process, and objectives are updated as needed. Where management determines appropriate these objectives are communicated within our organization and to our interested parties.

5 QMS Overview

5.1 General Overview

Our QMS is designed to around the processes affecting the quality of products and services offered. The QMS has been developed and implemented to promote quality and improvement, and is managed to meet the requirements of ISO 9001, FSC and SFI standards, customer requirements, and all applicable regulatory and statutory requirements.

The QMS is a system of interacting processes that are categorized as primary processes or secondary processes. Primary processes involve product and service realization activities intended for customers. Secondary processes support the overall QMS and don't directly provide products or services to our customers. These processes and the resulting products include:

Primary Processes

Production Processes

- Production
- Prepress (multiple)
- Cutting & Sheeting
- Printing
- Die Making
- Die-Cutting
- Scrapping
- Finishing (Gluing)
- Setup
- Quality Inspection
- Shipping
- Receiving & Warehousing

Customer Services Processes

- CAD based structural design
- Complete graphic design
- Computer art preparation

Other Processes

- Purchasing
- Customer Order Fulfillment

Secondary Processes

- Document Information
- Internal Audits
- Training
- Calibration
- Corrective Action

Products or Services

- Paperboard folding boxes
- Set-up boxes
- Transparent boxes
- Pop Displays
- Pocket folders
- Related products
- Structural design
- Graphic artwork

All Production Processes have their own Standard Operating Procedures (SOPs) or Operating Instructions (OIs). Customer Services Processes do not have separate SOPs or OIs, but described as part of our Customer Order Fulfillment SOP, which is its own primary process and includes the sales function. The Customer Order Fulfillment SOP also provides an outline of the general sequence and interactions of all primary processes.

Secondary processes support the overall QMS and operate in conjunction with the primary processes. An overview of all QMS processes can be found in section 6 & 7 of this manual.

When production or services are outsourced, (e.g., bindery work, large item printing or large item die-cutting) requirements are controlled per the Purchasing & SOP. Outsourcing results are verified through the Production SOP and Receiving & Warehousing OI. If internal audits are outsourced, they are controlled, and the results verified per the Internal Audits SOP and Purchasing SOP.

5.2 Organizational Roles, Responsibilities, and Authorities

Warneke management ensures that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the organization. These are defined in our Organizational Chart, job titles, SOPs and OIs.

Ultimately, all authorities and responsibilities reside with Executive Management, but can be delegated to functions and/or individual members of staff within their control, as determined appropriate. All personnel who manage, perform and/or verify work are responsible for the quality of products produced by Warneke. All such personnel are authorized to identify and record problems relating to products or services, processes, and the overall QMS. All staff and personnel have the responsibility to comply with documented procedures and the direction of management. All personnel have the responsibility to assure that process(s) in which they are working is in a state of control and that tasks are completed in a safe and responsible manner.

All personnel are also responsible for identifying nonconforming product, identifying such product as being nonconforming, notifying management, and controlling further processing until the problem has been corrected. To prevent nonconformities, they may also initiate, recommend, or provide solutions through designated channels.

The President is responsible for formulating the Quality Policy, initiating, and supervising the quality system, providing the necessary resources to maintain the system, as well as chairing the Management Review meetings.

Major functions with their responsibilities, authorities, means of communication, and quality planning methods, required for the product realization system are described in the Customer Order Fulfillment SOP.

The Vice President is appointed as our QMS Management Representative, and FSC and SFI Chain of Custody (CoC) Manager. They serve as the primary liaison to external parties on matters concerning the QMS and CoC programs. In the absence of, or when delegated by the Management Representative, the President, Quality System Manager, the Quality Administrator, or other designee may be assigned these duties. Regardless of other duties, their main responsibility and authority is to lead the organization in:

- Establishing, implementing, and maintaining our QMS and CoC programs,
- Ensuring our QMS continues to be compliant with the ISO 9001 requirements,
- Ensuring our CoC program continues to be compliant with the FSC and SFI requirements,
- Reporting on and evaluating the effectiveness of the QMS and CoC program with attendees at scheduled Management Review Meetings, and for making suggestions to improve the system.

5.3 QMS Planning

Warneke's QMS is developed, implemented, and all improvements and modifications are reviewed to ensure they meet our requirements, our customer's requirements, other stakeholder requirements, our Quality Objectives, and the requirements of the ISO 9001, FSC and SFI Standards.

We monitor customer feedback, perform internal audits, conduct management reviews, perform corrective and preventive actions, and have integrated a risk-based approach into our primary and secondary processes to help ensure we meet our requirements, reduce risks, prevent nonconformance, can take advantage of on opportunities, and continuously improve our systems.

5.4 Resource Management

Warneke management ensures that resource requirements are determined, and that adequate resources, and trained personnel are provided, to:

- establish, implement, maintain and continual improve the QMS,
- achieve quality objectives,
- implement change in a controlled manner,
- provide conforming products and services.

Resources may include people (including their qualification or training needs), subcontractors, buildings and associated utilities, equipment (including maintenance, hardware, and software), transportation resources, information technologies, other infrastructure, and work environment related resources, etc.

Resource needs can be determined during routine daily activities, management reviews, audits, corrective or preventive actions, etc. Resource acquisition can be made through the Purchasing process, direct hires, or other means as determined appropriate.

Management has issued procedures defining the requirements, including resources, for specific tasks and the corresponding responsibilities for quality assurance activities performed by Warneke personnel, including those built into processes as well as any resulting inspections/verifications; see the Production SOP.

5.5 Monitoring, Measurement, Analysis and Evaluation

To ensure they achieve requirements all processes are monitored and measured at least through Internal Audits, objectives set at Management Reviews (see QMS Planning Workbook), routine process reviews, etc. Warneke will define what information is needed to determine the suitability and effectiveness of these processes and the QMS. Data such as customer satisfaction, product conformance to requirements, product and process characteristics and their trends, supplier information, is collected, analyzed, and evaluated for continuous improvement. When desired results are not achieved appropriate action, including corrective action, is taken. (see Production SOP; Purchasing SOP; Internal Audits SOP; Management Review Form; QMS Planning Workbook; Corrective Action SOP).

5.6 Continual Improvement

Warneke is committed to continual improve the suitability, adequacy, and effectiveness of our QMS. Improvement is facilitated through:

- Our Quality Policy,
- Quality objectives,
- Internal audits,
- The analysis of data collected within our QMS,
- Corrective and preventive actions, and
- Our Management Reviews.

6 QMS Primary Processes

6.1 Customer Order Fulfillment SOP

This all-encompassing procedure describes the steps Warneke performs to process and deliver customer orders. Main process heading covered are: Quote, Artwork Design, Order Review & Prep, Prepress, Tool Design, Production, Delivery, and Order Close Out. This SOP describes key information in how to set up and properly identify FSC and SFI product. See the Customer Order Fulfillment SOP for more details.

6.2 Production SOP (and related Operating Instructions)

This procedure describes the processes associated with production, including manufacturing, assembly, dealing with nonconforming product, inspection activities equipment maintenance, and set-up of new equipment. It also describes how to identify and process FSC and SFI product through production.

All production work is monitored and inspected by experienced and qualified personnel, per the Training SOP and Production SOP. All personnel involved with inspections and testing ensure that product does not progress to subsequent process stages—including final release—until inspected or otherwise verified as required or is appropriately identified to prevent their unintentional use or shipment to a customer. Warneke personnel are responsible for carrying out checks of their own workmanship during processing, and when appropriate the results recorded. No product is dispatched from Warneke until all inspections have been completed and final authorization to ship is available, unless under a waiver or concession. Inspection activities that are subcontracted are done so according to the Purchasing SOP.

All items purchased for incorporation into a customer order are subject to inspection to ensure that the correct item, quantity, and standard of product have been supplied. In determining the appropriate receiving inspection, consideration is given to the controls exerted over the supplier and to the evidence of conformance provided with the shipment. If items are to be released for urgent production purposes without being verified, Warneke will define appropriate positive recall procedure.

In all cases, Quality has the authority for approval, or to withdraw approval, of any product at any stage of processing, including final release. Where identified, Quality approval may be required for release of product to the next processing step, including final release of product before shipping.

See the Production SOP for more details.

6.3 Purchasing SOP

This procedure describes how materials are purchased to ensure that they meet their intended requirements and that purchasing documents describe the product or service being ordered in adequate detail. It describes the processes for Supplier Review & Qualification, Outsourcing, Creating & Processing Purchase Orders, and Dealing with Property Belonging to Customers or External Providers. This SOP also describes how FSC and SFI raw materials are purchased from qualified sources. See the Purchasing SOP for more details.

7 QMS Secondary Processes

7.1 Calibration SOP

This procedure describes the control system for the calibration and maintenance of all inspection, measuring and test equipment used to demonstrate conformance to specifications. It also ensures that the uncertainty of equipment measurement is understood and is consistent with the required measurement capability. Since records of calibration and verification are generated and maintained, Warneke may provide the data when requested by customers.

Where customers specify that technical data relating to measuring equipment be made available, the requirement is identified by Sales personnel during contract review and is communicated to Quality. Quality will provide the data as required.

See the Calibration SOP for more details.

7.2 Corrective Action SOP

This procedure documents the method for processing complaints from both external (customers, third-party auditors or any party regarding and FSC claim) and internal customers (within Warneke), to ensure the complaints and problems are effectively addressed, and that appropriate corrective and preventive actions are initiated, implemented, and verified. This procedure also covers the customer return process that may or may not be associated with a complaint, to ensure that the material is properly tracked and processed through the system. Finally, the process for managing recalls is also described.

Corrective Action - While other means may be used, Warneke's Corrective Action SOP is the main vehicles for recording and processing nonconformities; especially those of significant scope or impact. This SOP describes processes for reviewing problems, determining root cause, determining implementing appropriate measures to prevent recurrence, and reviewing the corrective action for effectiveness.

Preventive Action - Whenever corrective actions are implemented, Warneke always considers if similar situations may occur elsewhere and if action is appropriate to prevent potential nonconformities. Preventive actions may also be initiated without a corrective action. Preventive actions can be recorded, evaluated, processed, and reviewed just like corrective actions, using the Corrective Action SOP. Preventive Action may also be managed through Management Review Action Item List or the Risk Matrix in the QMS Planning Workbook.

See the Corrective Action SOP for more details.

7.3 Documented Information SOP

This procedure documents the control systems applying to Quality system documentation and data. The scope of these controls will include the issue, use and revision of such documentation to ensure that accurate and approved copies are available to personnel and to ensure that obsolete documents are removed from use. This procedure also describes the process for retaining Quality Records.

Control of Documents (Maintained Documented Information) - The approval, issue and control of this Quality Manual, SOP's, relevant documents from external sources (customer drawings or specifications, industry, and quality standards, etc.), and all other Warneke QMS documentation are detailed in the Documentation and Change Control SOP. This SOP ensures that:

- All documents and changes to documents are reviewed and approved prior to use,
- Ensures that outdated or inaccurate information is not accidentally used,
- Documents are available where they are needed,
- We ensure that our documents are usable and legible.

Control of Quality Records (Retained Documented Information) - Quality Records are maintained by Warneke to prove we continue to meet requirements and for the effective operation of our QMS. Quality Records are retained and filed in a manner that ensures that they are readily available and protected from loss, damage, and deterioration. Our Document Information SOP describe our record retention processes.

See the Documented Information SOP for more details.

7.4 Internal Audits SOP

This procedure is to documents the process for planning and implementing internal audits to determine if working practices match procedures, determine if practices and procedures comply with the requirements of the ISO 9001, Forest Stewardship Council (FSC) and Sustainable Forestry Initiative (SFI) Standards, uncover process problems and initiate corrective actions, as appropriate. This procedure also describes the process for reporting audit results to executive management.

Quality is responsible for ensuring that the quality system defined in this manual meets the requirements of the ISO 9001, FSC, and SFI standards, by scheduling and managing regular internal quality audits per our Internal Audit SOP. Each Level 1 and Level 2 written procedure, and relevant Level 3 procedures when appropriate, is subject to audits according to the Audit Schedule. Audits are performed by trained Internal Auditors who are objective, impartial, and independent of the area being audited. Quality, or designated representatives, verify the effective implementation of corrective and preventive actions during subsequent audits or special follow-up audits. Audit findings are addressed in a timely manner and results are reviewed at Management Review Meetings and recorded on our Management Review records.

See the Internal Audit SOP for more details.

7.5 Training (Training SOP)

This procedure describes the system for identifying training needs, providing training, and retaining training records. Warneke management ensures that adequate competent personnel are available, and that appropriate records are retained per the Training SOP. For quality assurance activities performed by Warneke personnel, including those built into processes as well as any resulting inspections/verifications, there are procedures defining the requirements for the specific tasks and the corresponding responsibilities for which people are trained.

See the Training SOP for more details.

7.6 Management & Management Review

While this is not documented as a procedure, there is a documented Management Review Form and QMS Planning Workbook used to provide instructions for this process. Management Review Meetings are held to assess, evaluate, and improve the quality system to ensure its continued effectiveness and suitability in satisfying the requirements of the ISO 9001, FSC and SFI standards, and our stated quality policy and measurable objectives. Reviews are carried out as frequently as necessary, but at least once per year. We review the results of internal audits (Internal Audit SOP), all irregularities and comments (Corrective Action SOP), external influences on our business, and the effectiveness of the whole quality system to ensure that our business and quality objectives are maintained. The review includes quality system planning to ensure that changes in our processes are evaluated and that quality system requirements are addressed prior to their implementation. Additionally, in our Management Review Meetings we may evaluate potential non-conformances and take actions to prevent their occurrences, identify resource needs, and potential improvements, risk or opportunities to our products, services, and processes. Topics discussed and resulting action plans are recorded on our Management Review Form, in Management Review Action Item List or on the QMS Planning Workbook, which are retained as quality records in accordance with the Record Retention Form.

Appendix A
Process Map to ISO 9001:2015 Standard

Warneke Procedures/Processes ➔ / ISO 9001:2015 ➔	QMS, Quality Manual & Management	Customer Order Fulfillment	Production	Purchasing	Management Review	Corrective Action	Internal Audits	Documented Information	Training	Calibration
4. Context of the organization										
4.1 Understanding the organization & its context					X					
4.2 Understanding the needs & expectations of interested parties					X					
4.3 Determining the scope of the quality management system	X									
4.4 Quality management system & its processes	X									
5. Leadership										
5.1 Leadership & commitment										
5.1.1 General	X									
5.1.2 Customer focus	X									
5.2 Policy										
5.2.1 Establishing the quality policy	X									
5.2.2 Communicating the quality policy	X									
5.3 Organizational roles, responsibilities & authorities	X									
6. Planning										
6.1 Actions to address risks & opportunities					X	X				
6.2 Quality objectives & planning to achieve them					X					
6.3 Planning of changes					X					
7. Support										
7.1 Resources										
7.1.1 General	X									
7.1.2 People	X									
7.1.3 Infrastructure	X									
7.1.4 Environment for the operation of processes	X									
7.1.5 Monitoring & measuring resources										
7.5.1 General										X
7.5.2 Measurement Traceability										X
7.1.6 Organizational knowledge									X	
7.2 Competence									X	
7.3 Awareness									X	
7.4 Communication	X									
7.5 Documented information										
7.5.1 General								X		
7.5.2 Creating & updating								X		
7.5.3 Control of documented information								X		
8. Operation										
8.1 Operational planning & control	X	X								

Quality Manual

WARNEKE PAPER BOX COMPANY

Warneke Procedures/Processes ➔ / ISO 9001:2015 ➓	QMS, Quality Manual & Management	Customer Order Fulfillment	Production	Purchasing	Management Review	Corrective Action	Internal Audits	Documented Information	Training	Calibration
8.2 Requirements for products & services										
8.2.1 Customer communication		X								
8.2.2 Determining the requirements for products & services		X								
8.2.3 Review of the requirements for products & services		X								
8.2.4 Changes to requirements for products & services		X								
8.3 Design & development of products & services										
8.3.1 General		X								
8.3.2 Design & development planning		X								
8.3.3 Design & development inputs		X								
8.3.4 Design & development controls		X								
8.3.5 Design & development outputs		X								
8.3.6 Design & development changes		X								
8.4 Control of externally provided processes, products & services										
8.4.1 General				X						
8.4.2 Type & extent of control				X						
8.4.3 Information for external providers				X						
8.5 Production & service provision										
8.5.1 Control of production & service provision			X							
8.5.2 Identification & traceability			X							
8.5.3 Property belonging to customers or external providers			X	X				X		
8.5.4 Preservation			X							
8.5.5 Post-delivery activities			X							
8.5.6 Control of changes			X							
8.6 Release of products & services			X							
8.7 Control of nonconforming outputs			X							
9. Performance evaluation										
9.1 Monitoring, measurement, analysis & evaluation										
9.1.1 General	X									
9.1.2 Customer satisfaction					X					
9.1.3 Analysis & evaluation					X					
9.2 Internal audit							X			
9.3 Management review										
9.3.1 General					X					
9.3.2 Management review inputs					X					
9.3.3 Management review outputs					X					
10. Improvement										
10.1 General					X					
10.2 Nonconformity & corrective action						X				
10.3 Continual improvement					X					