Helpful information you can provide to manufacturers when they need assistance with a quality manual

Two concepts should be kept in mind while developing a quality system:

1) Do not write the quality system for the certification program. Write it to solve your practical business problems. Make it a usable, useful living document that is a vital information source for your business operation. Then ensure the certification program requirements are covered.

2) Broadly stated, the philosophy for meeting quality system requirements for a certification program should be: "Say what you do, do what you say, and be able to prove it".

The following are some basic topics or concepts which should be covered by a quality system:

3) Quality Manual – there should be a single book or location that organizes and includes all material and information regarding your quality system.

4) Operating Procedure – As a minimum, the major or vital processes of manufacture and operation should be documented or written.

5) Scope/Purpose – What does the manual cover? What doesn't it cover? What is its intended purpose?

6) Organizational Structure – An organizational chart. Who is responsible for what, and what is the chain of command. Specifically, someone needs to have specific responsibility for the quality system and quality manual.

7) Purchasing – What are your requirements or specifications for the raw materials you purchase and use in your products.

8) Incoming material inspection/test – How do you know what you purchased is what was delivered? If it isn't, what do you do about corrective action?

9) Final Product lnspection of Test - How do you know what you manufactured met your internal requirements? Was it acceptable to ship? What if it wasn't, what do you do?

10) Calibration – How do you know the equipment or instruments you use to check the acceptability of incoming material and outgoing product is accurate?

11) Internal Audits – How do you know your quality system is being followed? Is adherence to your own requirements reviewed on a regular basis?

12) Customer complaints – How do you handle customer complaints? How do you feedback information from these complaints to better the manufacturing process?

Additional sections that may be considered:

Quality Policy Statement Definitions
Corporate Structure and Legal Status
Personnel requirements, training, reviews
Purchasing and Contract Review
Record Keeping
Subcontracting
Quality Manual control and update procedure
Product information
Storage, Shipping and Handling
Product engineering and design

Calibration (Definition, FAQs, examples)

What is calibration?

Calibration and Calibration Checks may be used to verify the accuracy of devices or equipment used to provide critical measurements that affect the quality and performance of the end product.

Calibration can be thought of as a comparison. The comparison is made by taking a device of known accuracy and correctness and comparing it to the measuring device you are verifying for accuracy. Calibration may include the act of performing adjustments to the tested device while calibration checks are performed periodically to verify the device has retained its accuracy.

What do you check calibration against?

Devices of known accuracy can be purchased or verified from multiple sources. When establishing your devices of known accuracy you should consider if they have been verified accurate to an established and trusted national standard (example - NIST). If you do not purchase a device of known accuracy then you should document sound logic to justify the use of the device.

Devices of known accuracy may include:

Weights

Gauge blocks

Length comparator

Digital torque tester

Mechanical torque loader

Angle Blocks

What should be calibrated?

Your organization should determine measuring instruments that should be calibrated. You can evaluate the needs of your business to calibrate by considering measuring instruments that are critical to providing and end product that meets customer requirements, specifications, and performance requirements. In general these may include (not all inclusive):

Torque Wrenches

Machine Stops

Tape Measures

Rulers

Cutting blade angles

Thermometers

Load gauges or scales

Pressure gauges

Frequently asked questions:

My CNC machine does an electronic calibration when we turn it on. Does that satisfy the calibration requirements?

Equipment that performs self- tests or self- adjustments may be serviced at intervals determined by manufacturer recommendations, national standards, and or requirements established by your organization. An operator calibration log may be useful to document the calibration check was performed at machine startup.

Why do I have to calibrate a tape measure?

All measuring devices can change in accuracy due to wear and accidental bending.

How often do I need to do a calibration check?

Your organization should establish a requirement for calibration of each device. Considerations may include number of uses, time since last checked, accidental handling (dropped), number of cycles (torque wrench), manufacturer recommendations, national standards, and other sound logic.

How do I document calibration?

Documentation of calibration may include - certificates of calibration from outside testing agencies, calibration check logs, daily machine operator logs, blade replacement logs, equipment readiness logs or documentation.

How do I track devices to be calibrated?

You may establish a numbering system, organizational method of serialization, or use of manufacturer unique serial numbers to identify devices your organization deems best for traceability.

Do I have to calibrate everything?

Your organization should evaluate and establish guidelines that support your business and the ability to deliver an end product that meets customer requirements, specifications, and performance requirements.

Calibration Log:

Device Name	**Serial Number**	**Calibration Check Date**	**Results of check**	**Calibration Frequency Requirement (Daily, Monthly, Prior to use, Annual)**	**Next Calibration due date**

Blade Replacement Log:

Date	**Calibration Performed**	**Result**	**Operator Initial**

Daily Startup Log (CNC, Tiger stop, or other electronically controlled measurement):

Date **(indicate "not operated" if machine not used that day)**	**Startup calibration performed (y/n)**	**Results**	**Operator Initials**

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ABC Company
DC01- Quality Manual

= NFRC/Hallmark Procedural Guide Requirement = Referenced Document

By signing below I authorize and agree to uphold the policies defined in this Quality Manual:

President Date

Quality Manager Date

Revision Log				
Rev #	**Date**	**Author**	**Approver**	**Description of changes**
0	**3-5-18**	**John Doe**	**Jane Doe**	**Initial Publication**

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Table of Contents

Reference Documents
The below documents are used in the implementation of the Quality Management System.

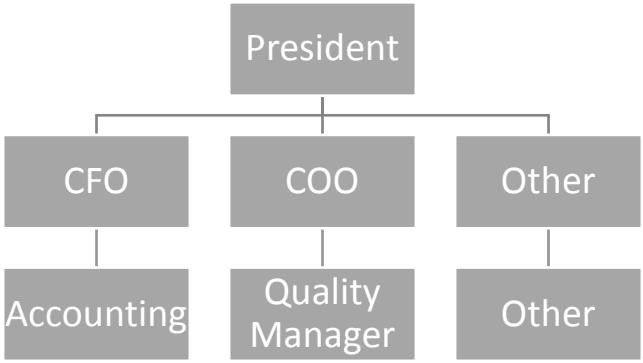
DocCtrl #	Rev	Title
DC01	**0**	**Quality Manual**
DC02	**0**	**Quality Policy and Objectives**
DC03	**0**	**Document Control Procedure**
DC04	**0**	**Internal Audit Schedule**
DC05	**0**	**Internal Audit Form**
DC06	**0**	**Corrective and Preventive Action Procedure**
DC07	**0**	**Customer Feedback Log**
DC08	**0**	**Lumber Receiving Log**
DC09	**0**	**Shipping Inspection Log**
DC10	**0**	**Product Inspection Log**
DC11	**0**	**Calibration Record Log**

1. **Scope**

   The scope of this document outlines policies and procedures regarding the design phase, production phase and the delivery of products to the end consumer.

2. **Organizational Chart**

   This can be written out or shown in chart format.



3. Quality Policy and Objectives

It is the quality policy of Organization to deliver products that meet customer expectations consistently through management of our processes. The voice of the customer is at the forefront of our decisions and we are always looking to improve our product.

Organization has implemented a Quality Management System (QMS) to measure and evaluate our processes, identifying quality issues and correcting any problems found. Our QMS also works to prevent issues before they occur, saving both the company and the customer time and money.

4. Terms and Definitions

Throughout this Quality Manual, the term "organization" refers to ABC Company.

Policy – overall stance on intent or direction of the organization, usually comes from management
Quality Manual – document specifying quality management system, typically includes quality policies and objectives
Process – set of interrelated activities, transform inputs into outputs
Procedure – Specific way to carry out activity or process
Work instruction – detailed step-by-step directions on how to complete a task
Document – form of communicating information (i.e. safety manual, this presentation, SoPs)
Record – when a document becomes historic (unique). i.e. when a worksheet is filled out it becomes a record. Records should never be changed, they are evidence of what happened.
Internal Audit - first-party check of quality management system (i.e. ABC glass check their own QMS)

5. Quality Management System

5.1 General

We have established, documented, implemented and currently maintain a Quality Management System (QMS). We continually manage and improve its effectiveness in accordance with the requirements of our customers.

We have:

a) identified the processes needed for the quality management system and their application throughout the organization
b) determined the sequence and interaction of these processes
c) determined criteria and methods needed to ensure that both the operation and control of these processes are effective
d) established the availability of resources and information necessary to support the operation and monitoring of these processes
e) established means to monitor, measure and analyze these processes, and
f) Implement actions necessary to achieve planned results and continual improvement of these processes.

Where ABC Company chooses to outsource any process that affects product conformity with requirements, the organization ensures control over such processes. Controls of such outsourced processes are identified within the quality management system.

5.2 Documentation

Our Quality Management System documentation includes:

a) Quality plan and objectives
b) a quality manual
c) operational procedures or work instructions,
d) records

5.3 Quality Manual

ABC Company has established and currently maintains a Quality Manual that includes:

a) the documented procedures established for the quality management system, or reference to them, and
b) a description of the interaction between the processes of the quality management system.

5.3.1 Document Control

To assure consistent Quality, ABC Company utilizes written, approved procedures for our operations. The quality manager is responsible for controlling the issue, distribution, revision, and archiving of these procedures. Records are a special type of document and are controlled according to the requirements outlined in the Record Retention Policy.

ABC Company has established Document Control Procedure (DC03) to define the controls needed:

a) to review/approve documents for adequacy prior to issue,
b) to review/update as necessary and re-approve documents,
c) to ensure that changes and the current revision status of documents are identified,
d) to ensure that relevant versions of applicable documents are available at points of use,
e) to ensure that documents remain legible and readily identifiable,

f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

5.3.2 Record Retention

Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records are retained for XX years and include traceability to materials used in products. WDMA Hallmark 10 years, NFRC 5 years.

Types of records maintained:
Financial – XX years
Product Testing – XX years (or term of certification or warranty)
Employee - Permanent

Records are legible, readily identifiable and retrievable.

5.3.3 Resource Management

Key Person competent in Quality Management Systems

ABC Company has appointed a key person who, irrespective of other responsibilities, has the responsibility and authority that includes implementing, maintaining, and ensuring the Quality Management System is in place and working.

Competence, Awareness and Training
ABC Company:

a) maintains documents providing evidence of trained skills and work experience for personnel used in its Quality processes. Evidence includes diplomas, certificates, licenses, and/or documented on-the job training.
b) assesses and evaluates personnel to determine competence in job classification; these assessments are performed as a minimum upon hire, annually, and when job duties significantly change.
c) Continuing education requirement are established based on job classification and duties. Records of completed continuing education are retained on file.

Work Environment
ABC Company determines and manages the work environment needed to achieve conformity to product requirements.

5.3.4 Customer Feedback/Complaints

Customer feedback (including complaints) is captured and recorded on the Customer Feedback Log (DC07). Any actions taken to resolve customer complaints are recorded and are checked for effectiveness during our Internal Audit.

5.3.5 Incoming Material/Product Inspection and Testing

The organization show adequate control of materials receiving and evaluate such materials for compliance with required specifications.
Controls include:

a) inspection of received materials See Lumber Receiving Log (DC08)
b) receiving log
c) controlled material holding or storage area
d) labeling or other identification for shipping See Shipping Inspection Log (DC09)
e) internal frequency of product inspections/testing logged See Product Inspection Log (DC10)

5.3.6 Calibration/Maintenance

The organization has established a Calibration policy below for verifying the accuracy of instruments used to make critical measurements. See Calibration Log (DC11) for a complete list of all calibrated or verified equipment. Also reference document (Calibration - definition, FAQs, example logs)

Where necessary to ensure valid results, measuring equipment is:

a) calibrated at specified intervals, or prior to use,
b) Uniquely identified in order to determine its calibration status;
c) safeguarded from adjustments that would invalidate the measurement result;
d) protected from damage and deterioration during handling, maintenance and storage.

Records of the results of calibration and verification are maintained.

5.3.7 Internal Audit

The ABC Company conducts internal audits at least annually to determine whether the quality management system and processes used to manage operational areas of the organization:

a) are effectively implemented and maintained.

An audit schedule has been planned (Internal Audit Schedule DC04), 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 are defined. Selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process. Auditors do not audit their own work.

Records of the audits and their results maintained on the Internal Audit Form (DC05)

5.3.8 Corrective and Preventive Action

ABC Company takes action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

ABC Company has established Corrective and Preventive Action Procedure (DC06) that defines requirements for:

a) identifying nonconformities (including customer complaints).
b) determining the causes
c) evaluating to prevent recurrence
d) determining and implementing action
e) recording of the results and review effectiveness of actions taken of action taken

DC04 - INTERNAL AUDIT SCHEDULE 2018-2019

PROJECT/EVENT	INTERNAL AUDIT SCHEDULE
ORGANIZER	COMPANY NAME

Internal audits allow an opportunity for a second set of eyes to review processes and procedures in place. It is an opportunity for our company to identify areas of improvement in the areas of efficiency, quality, and profitability.

AUDIT AREAS	WEEK	RESPONSIBLILITY	FOCUS AREAS TO REVIEW
MATERIALS RECEIVING AND INVENTORY	8.3.2018	COO	**RECEIVING LOGS, INSPECTION, LABELING, CONTROLS, PROTECTION OF MATERIALS**
PRODUCT INSPECTIONS	9.7.2018	President	**BRIEF OVERVIEW OF ITEMS TO BE REVIEWED**
SHOP OPERATIONS	10.5.2018	Quality Manager	**MAYBE YOU HAVE BEEN HAVING A GASKET LEAKAGE PROBLEM – YOU COULD NOTE TO AUDIT THAT PROCESS**
TESTING AND CERTIFICATION	11.16.2018	Quality Manager	
ESTIMATING AND PM	1.11.2018	CFO	
ADMINISTRATIVE PROCESSES	2.15.2018	President	
QUALITY MANAGEMENT SYS.	3.7.2018	Various	
EXTERNAL REQUIREMENTS (EX. NFRC/WDMA HALLMARK)	4.4.2018	Quality Manager	

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JUNE 2015						
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DECEMBER						
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JANUARY 2016						
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31						

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APRIL						
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MAY						
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29	30	31				

Revision Log				
Rev #	**Date**	**Author**	**Approver**	**Description of changes**
0	6-10-15	John Doe	Jane Doe	Initial Publication

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# DC05 – Internal Audit Form	PROCESS OR AREA AUDITED (From DC04 Internal Audit Schedule):
AUDITED BY:	AUDIT DATE:
AUDIT CRITERIA (WORK INSTRUCTIONS, COMPANY POLICIES, DIRECTIVES, MANUFACTURERS CRITERIA OR INSTRUCTIONS)	
OBSERVATIONS	
AUDIT FINDINGS (EXAMPLES: Opportunities for Improvement, TRAINING NEEDED, MISSING/BROKEN EQUIPMENT, LACK OF PROCEDURES)	
AUDITOR SIGNATURE/DATE	
QUALITY MANAGER / DATE	

Revision Log				
Rev#	**Date**	**Author**	**Approver**	**Description of changes**
0	**6-10-15**	**John Doe**	**Jane Doe**	**Initial Publication**

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DC06- Corrective and Preventive Action Procedure

Revision Log				
Rev #	**Date**	**Author**	**Approver**	**Description of changes**
0	**6-10-15**	**John Doe**	**Jane Doe**	**Initial Publication**

When a Corrective or Preventive Action is necessary, fill out the table below. (steps 1-8)

1. Date: 2. Documented By:
3. Details of Issue:
4. Root Cause Analysis (as necessary):
5. Action(s) Taken:
6. Notice given to involved parties: ☐ Yes ☐ No
7. Closing (ensure correction is effective and recurrence has been prevented) 8. Effectiveness Verified By: Date:

DC08 Lumber Receiving Log

Company Name: **Updated:**

Date	Vendor	Type	Moisture under 12%	PO#	Quantity

DC09 Shipping Inspection Log

Company Name: **Updated:**

Job Name	Tag#	PO#	Hardware	Glass Order #	Glass Vendor	Permanent Label	Temporary Label	Jamb	Initial	Shipper	Date

DC10 Product Inspection Log

Company Name: **Updated:**

Job Name	Plan #	Tag #	Type	Glass	WS Color	Hinge Type	Hinge Color	Jamb Type	Jmab Size	Sill Type	Swing

DC11 Calibration Log

Company Name: **Updated:**

Equipment #	Description	Dept/Area	Last Calibrated	Days until Next Calibration	Next Calibration