Introduction

◆ How to Write a Quality Control Manual
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Topics of Discussion

◆ What are Quality Control (QC) and Quality Assurance (QA)?
◆ What items need to be addressed?
◆ Why are these items necessary?
What is Quality?

- I’m not sure but I know when something doesn’t have it!
- Quality is a degree of excellence; an inherent or distinguishing characteristic or property
What is Quality Control?

- It's a system for verifying and maintaining a desired level of quality in a product or process by careful planning, inspection and corrective action.
- Basically – it’s doing!
What is Quality Assurance?

- A planned and systematic pattern of all actions necessary to provide adequate confidence that a product fulfills customer’s expectations; i.e., it’s problem free and able to perform the task it was designed for.

- Basically - it’s planning!
Topics We’ll Discuss

- Management Organization
- Receiving Inspection
- Material Storage
- In-Process Controls
- Final Assembly and Test
Topics We’ll Discuss

- Non Conforming Materials
- Procurement and Supplier Control
- Design Selection
- Drawing and Document Control
- Corrective Action
Topics We’ll Discuss

- Measurement and Test Equipment
- Personnel Training and Certification
- Recordkeeping
- Miscellaneous
Management Organization

- **Basic Concept**
- Management must establish and document the policy.
- Form the basic guidelines
- Set internal authorizations and responsibilities
Management Organization

- **Common Deficiency**
- **Scope and responsibility can’t be determined**
Management Organization

- **Cause**
  - Top management has not prepared a policy statement defining responsibilities and authority
Receiving Inspection

- **Basic Concept**
- Verification of physical and operational characteristics
- Should include inspection instructions
- Useful life of products
Receiving Inspection

- Common Deficiency
- Inspections performed without written instructions
Receiving Inspection

♦ Cause
♦ No written procedures available, lack of enforcement by supervisors and inadequate training of personnel
Material Storage

- **Basic Concept**
- **Temporary holding of raw materials**
- **Not to change the material in any way**
- **Adequate identification – prevents damage, deterioration, loss and theft**
Material Storage

- **Common Deficiencies**
- No inspection status marked on stored items
- Over age material in storage
- Material not physically protected against freezing and moisture
Material Storage

◆ **Cause**

◆ No written procedures available, lack of enforcement by supervisors and inadequate training of personnel
In-Process Controls

- **Basic Concept**
  - Program must be maintained to ensure that contracts, drawings and specifications are met
  - If ignored, unacceptable end product may result which introduces costly delays, repairs and rework
In-Process Controls

- Common Deficiency
- Obsolete drawings or documents are in use
In-Process Controls

- **Cause**
- No system for recall of outdated drawings or documents
Final Assembly and Test

Basic Concept

Similar to in-process inspection except that this is your last opportunity to verify many characteristics
Final Assembly and Test

- Common Deficiency
- Unauthorized changes made to procedures or inadequate instructions
Final Assembly and Test

- **Cause**
  - No written procedures available, lack of enforcement by supervisors and inadequate training of personnel
Non-conforming Materials

Basic Concept

Whenever material is found which departs from the requirements, it is necessary to identify, segregate and remove the non-conforming material to a controlled area.
Non-conforming Materials

- **Common Deficiency**
- Material review area is not adequately segregated from acceptable material
Non-conforming Materials

- **Cause**
- **Lack of effort and training**
Design

- **Basic Concept**
- To mark, document, describe or plan an image of accomplishment
Common Deficiency

Design verification – intended to provide a detailed review or analysis – is sometimes just “signed off”
Design

- **Cause**
- **Extent of review effort and expertise needed are not adequately defined**
Basic Concept

A system must be maintained for the control of all documents affecting the quality program and the incorporation of subsequent changes.
Drawing and Document Control

- **Common Deficiency**
- Change control system does not provide for the orderly disposition and removal of obsolete drawings and documents
Cause

Companies are often not concerned with removing obsolete drawings and documents
Corrective Action

Basic Concept

A program for reporting and follow-up on deficiencies discovered during any phase of the contract performance is essential to maintaining an effective quality program.
Corrective Action

- **Common Deficiency**
- **Corrective action due dates are ignored**
Corrective Action

♦ Cause
♦ Unresolved items do not get reported
♦ Note: the higher up in management these actions travel, the more likely they will not occur in the 1st place!
Basic Concept

To ensure accuracy, equipment must be calibrated at scheduled intervals against approved standards traceable to national standards.
Measurement and Test Equipment

- **Common Deficiency**
- **Expired calibration dates found on equipment in use**
Measurement and Test Equipment

- **Cause**
- **Lack of a system identifying equipment and due dates**
Personnel Training and Certification

Basic Concept

A positive training program should be maintained for personnel who have an effect on or are responsible for determining product quality
Personnel Training and Certification

◆ Common Deficiency
◆ Training programs do not provide a quantitative means of determining the proficiency of the trainee.
Personnel Training and Certification

◆ **Cause**
◆ **Lack of emphasis on the evaluation of training**
◆ **Note:** Someone may be an excellent installer but a poor trainer!
Recordkeeping

- **Basic Concept**
- Provides a means for what has (or hasn’t) occurred
Recordkeeping

- **Common Deficiency**
- **Date when items can be discarded are not shown**
Recordkeeping

◆ **Cause**

◆ No written procedures available, lack of enforcement by supervisors and inadequate training of personnel
Miscellaneous Items to Address

- Assign a unique document name
- Assign a date of issue
- Show revision levels
- Number all pages and appendices
- Include a Table of Contents
Miscellaneous Items to Address

- Make it available to all personnel
- Require all personnel to annually review the manual (and sign a statement acknowledging they have reviewed it and understand it)
- Conduct your own internal review – don’t count solely on outside organizations
What makes for good Quality?

- Support and commitment by upper management
- Written instructions addressing foreseeable events and situations
- Knowing that an ounce of prevention is worth a pound of cure
Thank You!

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