

Quality Control Manuals



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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?


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- ◆ **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?

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- ◆ **A planned and systematic pattern of all actions necessary to provide adequate confidence that a product fulfills customer's expectations; ie, 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**

Design



- ◆ **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**

Drawing and Document Control



- ◆ **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**

Drawing and Document Control



- ◆ **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!**

Measurement and Test Equipment



- ◆ **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

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- ◆ **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?

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- ◆ **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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