How to Set Up a Quality Assurance System
A Step by Step Guide to Quality Control Management System

By BizMove Management Training Institute

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1. Basic Quality Elements

This guide presents a sample quality control system closely prepared from one developed by a fortune 500 company. It may be used as a guide in initiating your own quality assurance system, whether you sell to consumers, industrial users, or government.

All quality and inspection systems have simple, basic elements in common:

Organization - setting and assigning specific authority and responsibility for each phase of the system;

Quality Planning - writing work instructions with realistic "defect prevention" rules, looking at manufacturing processes for possible quality trouble spots, setting acceptance/rejection standards, controlling accepted/rejected products, and setting up a means of using suppliers' and customers' failure information to improve product quality;

Product Specification Control - making sure everyone always has the latest technical data for properly producing, inspecting, and shipping the product;

Supplier Product Quality Control - watching purchases to make sure that the people you buy from know and observe your quality requirements as well as technical specifications;

Measurement and Test Equipment Control - setting up a system to insure that such equipment is properly and regularly calibrated to established standards;

Nonconforming Material Control - spotting defects as early in production as possible and keeping faulty items from reaching customers; and

Records and Reports - setting up a system that tracks all steps of the production, inspection, and shipping cycle to identity existing and potential problem areas.

The following sample manual incorporates these basics. It may be adapted to fit your needs. It is recommended that each section of a manual you work up be on a loose-leaf sheet for easy reference and revision. Remember, the best manual in the world won't do any good unless every employee - not just those in Quality Assurance - is convinced that producing quality products is of prime importance.

2. A Sample Manual

Introduction

This manual describes for our employees and customers our quality control system. The system applies both to the items we produce and to the items we buy from our suppliers.

As dictated by the complexity of product design, manufacturing techniques used, and customer requirements, more specific written procedures may be required to implement the policies set in this manual.

No changes may be made to this manual or any supplementary quality control procedures unless approved by the plant manager or an authorized representative.

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1.0 Scope

1.1 The quality control system includes: receiving, identifying, stocking and issuing parts and material; all manufacturing processes; packing, storing; and shipping.

1.2 The system is designed to ensure customer satisfaction through quality control management of supplies made and services performed here, and by our suppliers at their facilities. It is designed to spot processing problems early so we can correct them before we've produced a lot of faulty items.

1.3 Written inspection and test procedures will be prepared to supplement drawings and other specifications, as necessary.

2.0 Responsibilities

2.1 The supervisor of quality assurance reports directly to the plant manager.

2.2 The quality assurance supervisor's responsibilities include:

2.2.1 Planning how to meet customer's quality requirements

2.2.2 Reviewing customer drawings and specifications.

2.2.3 Determining inspection points.

2.2.4 Writing inspection and test instructions.

2.2.5 Establishing (and making sure employees follow) the most effective and efficient quality assurance procedures possible.

2.2.6 Keeping adequate quality assurance records.

2.2.7 Reviewing quality assurance records and overseeing follow-up for correction and prevention of defects.

2.2.8 Assuring that our suppliers' quality control and follow-up are adequate.

2.2.9 Inspecting all special and standard gages, test equipment, and tooling used to manufacture products when we acquire them and calibrating them on a regularly scheduled basis.

2.2.10 Coordinating in-plant correction of items rejected by customers, explaining to customers what action will be taken, and evaluating the actions for effectiveness.

2.2.11 Making sure inspectors make unbiased decisions to accept or reject items.

3.0 Purchase Order Control

3.1 All of our purchase orders to suppliers must be approved by the plant manager or an authorized representative.

3.2 When the purchase order is released, our buyer will send our supplier all required drawings, specifications, and other customer requirements (such as material or process certifications, physical or chemical analysis, source inspections) with the purchase order.

3.3 If there is a drawing or specification change after our order is placed with the supplier, our buyer will send the supplier a purchase order change, including our latest Engineering change and the latest drawings or other specifications.

3.4 Copies of all purchase orders will be kept on file for our customers to review.

4.0 Drawing and Specification Change Control

4.1 We manufacture to customer drawings and specifications. Sets of these are filed in job number folders in Production Control files.

4.2 Production Control is responsible for charging out and keeping track of drawings and specifications.

4.3 The Sales Department receives Engineering changes from our customers and is responsible for sending these changes to Production Control immediately.

4.4 Production Control is responsible for issuing the latest Engineering changes, drawings, and specifications of departments that need them and for voiding outdated Engineering changes, drawings, and specifications.

4.5 A standard procedure will be set up to control changes by effective date or serial/lot number.

5.0 Receiving Inspection

5.1 All parts and materials will be received and logged in by the Receiving Department.

5.2 All parts and materials will be sent to Receiving Inspection after logging in.

5.3 Receiving Inspection will assure that proper certification, physical and chemical test data, special process certifications, or source inspection certifications are with the items to be inspected.

5.4 The receiving inspector must document the complete results of all inspection and tests.

5.5 Inspection will identify accepted lots and send them to stock.

5.6 Rejected lots will be identified and set aside in Receiving Inspection until the buyer and Production Control decide on disposition.

5.7 The Receiving Department will send a copy of each rejection report to the Purchasing Department and the supplier.

5.8 The Purchasing Department has the responsibility of assuring that a pattern of continually receiving faulty items from any supplier doesn't develop and assuring supplier corrective action.

5.9 The Quality Department will follow-up to see that a supplier who has sent us items we reject has effectively corrected what it has been doing wrong.

5.10 Receiving Inspection instructions will be written with consideration given to the complexity of the parts, material received, and customer requirements. Follow customer instructions (if any) for inspection.

5.11 Sample according to customer requirements (if any).

5.12 The Quality Department will review Receiving Inspection records periodically to see if any suppliers are consistently failing to meet standards.

5.13 All inspection records will show the number inspected, the number rejected, and the name of the inspector.

5.14 Inspection records will also show the disposition of supplier-provided records and data.

6.0 Raw Material Control

6.I Raw materials, bar stock, sheet stock, and castings will be marked so they can be traced to their certification, and stored in an area apart from the normal flow of in-process material.

6.2 Copies of all certifications will be filed in the job order number folder by job order number and available for customer review.

6.3 Only raw material accepted by Receiving Inspection will be released for production.

6.4 Certified stock will be issued from its storage area only for job order requirements.

6.5 Verification of suppliers' certifications will be ordered from independent testing laboratories when deemed necessary by the Quality Department or to meet our customers' requirements.

6.6 All certifications will be traceable to purchase order, date of receipt of the material, and the inspector of the material.

In Process Inspection

7.1 The Quality Department will make first piece inspection after set up is completed and approved by Production.

7.2 No production runs will be made until first piece inspection is accepted.

7.3 After first piece inspection acceptance, in-process inspections will be made by the Quality Department at intervals adequate for early detection of processes producing material that doesn't meet standards.

7.4 The Quality Department will keep records of all first piece and in-process inspections.

7.5 The inspection records will be stored in the job number folder and will be available for customer review.

7.6 Tag or otherwise identify rejected items and move them to an area apart from the normal flow of in-process materials.

7.7 The Quality Department will follow-up to prevent recurrence of faulty material.

7.8 Inspection records will list: the number of pieces accepted, the number rejected, kind of defects and basic causes of rejection, date of inspection, and the inspector's name.

7.9 Attachment shows the locations of fabrication and inspection stations. For each station, it lists the types of items subject to inspection, the kind of inspection done, and the applicable drawings and specifications.

7.10 Special processes will require appropriate inspections and controls, including qualification and certification of personnel and equipment.

8.0 Assembly Inspection and Functional Testing

8.1 Production personnel will make assembly inspections and do functional testing, as required.

8.2 The Quality Department will check functional test under an established sampling plan.

8.3 The Quality Department will keep the inspection records.

8.4 The inspection records will be kept in the job number folder and will be available for customer review.

8.5 All faulty (discrepant) assemblies will be marked and set apart so they won't be accidentally used.

8.6 The Quality Department will initiate corrective and follow-up action to prevent recurrence of faulty material.

8.7 Inspection records will list: the number accepted, the number rejected, the date of the inspection, and the inspector's name.

9.0 Final inspection and Testing

9.1 Final inspection and tests will be performed either on 100 percent or on a sample of the items. The number of items sampled will depend on the complexity of the items and customer requirements. Inspection will follow either customer-supplied procedures when available or MIL-STD-105D.

9.2 Each end item will be inspected/tested 100 percent, unless the customer asks otherwise.

9.3 The Quality Department will keep all final inspection and test records.

9.4 Inspection and test records will be filed in the job number folder and will be available for customer review,

9.5 The Quality Department will follow-up to see that processes producing faulty materials are corrected and to prevent recurrence of faulty material from those processes.

9.6 All faulty material will be marked and set apart from the normal flow of finished material.

9.7 Faulty material will not be shipped to the customer without specific customer instructions to submit such Nonconforming material.

9.8 Rejected material which has been repaired, reworked, or sorted must be resubmitted to final inspection to make sure it meets requirements.

9.9 Inspection records will list: the number of pieces accepted, the number rejected, the date of inspection; and the inspector's name.

10.0 Faulty (Discrepant) Material Control

10.1 All faulty (Nonconforming) material, supplies, or parts will be placed in a "DO NOT USE" area. The items will be clearly marked with job number, part number, revision letter, lot size, defect, inspector's name, and any other information necessary.

10.2 The specific reason an item has been rejected will be clearly written on a rejection tag attached to each part or container.

10.3 No one may remove items from the "DO NOT USE" area until disposition is determined by a Material Review Board made up of the plant manager, and representatives of the Production and Quality Departments.

10.4 Nonconforming material will not be shipped unless the customer's buyer approves it. The shipping documents will be marked with what's wrong with the items.

10.5 The Quality Department will control all lots submitted for acceptance inspection. Each lot will be kept as a unit, apart from other lots, and out of the normal flow of material.

10.6 During the processing of material all production and inspection operations must be kept in proper order. Each step must be completed before the next step is begun.

10.7 The Quality Department will set up a system so that the stage of inspection each item is in, can easily be identified.

10.8 Unidentified material will be taken out of the normal flow of production until it is inspected to insure that it meets all specifications.

10.9 Reworked material will be segregated from other material until the Quality Department determines its status.

11.0 Tool and Gage Control

11.1 All special tools, jigs, fixtures, gages, and measuring equipment must be properly identified,

11.2 Each new or reworked tool, jig, fixture, gage, and item of measuring equipment will be inspected before issue for use.

11.3 All gages, measuring and test equipment will be calibrated to standards.

11.4 A written schedule for calibrating gages, measuring and test equipment will be set and strictly followed. Frequency of calibration will be based on type and purpose of the equipment and severity of usage.

11.5 A restricted area for storing and calibrating gages, measuring, and test equipment will be set up.

11.5.1 A strict system of issue, control, and return will be set and followed.

11.6 If the customer supplies special gages, they will be checked at the intervals the customer sets. If the customer supplies no inspection schedule, the equipment will be checked according to a schedule that takes into account type, purpose, and severity of use.

11.7 Calibration will follow the written procedures kept in the calibration area.

11.8 Obsolete or out-of service tools and gages will be tagged.

11.9 Decals or stickers will be put on tools and gages or their containers to show the last date of calibration and the due date of the next calibration.

11.10 Personal, as well as company-0wned production and inspection tools, must be properly and regularly calibrated.

12.0 Overrun Stock Control

12.1 The Quality Department will oversee overrun stock.

12.2 The Quality Department will insure that any overrun parts sent to stock are properly marked "accepted." The part number, latest drawing number and specification revision, date of inspection, job number, and quantity of parts will be shown. The Quality Department will periodically check to see that the parts are properly packed to prevent deterioration and damage.

12.3 No overrun parts will be shipped to a customer until they are reinspected and found in acceptable condition and to meet the latest drawing and specification revisions.

13.0 Packing and Shipping

13.1 No order will be shipped to a customer until all shipping papers are stamped or signed and dated by the final inspector.

13.2 No order will be shipped until all required certifications, test reports, special samples, etc., have been packed with the material in accordance with the customer's requirements and accepted by the final inspector.

13.3 All material will be packed to prevent damage deterioration, and substitution.

13.4 The customer will be identified on the packaging, parts, and as otherwise necessary to prevent lost and misdirected shipments.

13.5 The order will be packed as directed by the customer, if applicable.

14.0 Identification

14.1 All materials and articles will be identified by a basic part number and revision letter.

14.2 Critical materials and articles will also carry a serial or lot number. If required, a list of materials and articles by identification numbers will be attached.

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