



EXCERPT From Procedure

1.0 Purpose

1.1 This procedure describes the process for controlling quality system documents.

2.0 Responsibilities

2.1 *Management* is responsible for assigning authors for documents.

2.2 The author is responsible for writing the document, creating related forms, getting a document number and submitting the document to the department manager for review.

2.3 *Department managers* are responsible for approving documents for their area of responsibility.

2.4 The network administrator is responsible for backing up the network daily.

2.5 *Production engineers are responsible for maintaining programs that control equipment. (If you have machine programs, controllers with programs or other software controlling your processes, the programs must be controlled.)*

3.0 Definitions

3.1 Procedure: Document outlining specific work processes and how the requirements of the AS9120 standard are being met.

3.2 Work Instructions: Step by step directions on how a task should be done.

3.3 Templates: Electronic documents used to create quality system documentation.

4.0 Equipment/Software

4.1 Not Applicable.

5.0 Instructions

5.1 Document Creation

5.1.1 When the need for a document is identified, *management* will assign an author for the document. Any employee may be assigned as an author for documents in their area of expertise.

5.1.2 The author writes the document and prepares related forms.

Documents include:

- The Quality Manual
- Procedures



- Work Instructions
- Attachments
- Forms

5.1.3 All documents contain the following information:

Company name

Current Revision and Date

A unique document number

5.2 Document numbering

5.2.1 Procedures, work instructions, forms and attachments are numbered using the following number scheme:

Procedures are numbered with a three-digit number made from the number of the clause of the AS9210 standard and prefixed with a letter to indicate the department responsible for the procedure and a "P" to indicate procedure. For example, Management Responsibility relates to section 5.0 of the standard, and is numbered AP-500, where *A* indicates *Administration*. The Internal Audit procedure relates to section 8.2.2, and is handled by the quality department so it is numbered QP-822.

The following departments prepare, issue and maintain QMS documentation as required:

(E) Engineering: Design Engineering and all related functions

(M) Manufacturing: Production, Service, Warehousing, and Inventory control.

(S) Sales: Marketing, Sales and Customer Service

(A) Administration: Management, Human Resources, Accounting and Purchasing

(Q) Quality Assurance: Quality Assurance and Quality Control, Inspection and Document and Data Control

Work Instructions are numbered WI-XXX-000, where XXX is the related procedure number, and 000 is a number assigned sequentially as work instructions for that procedure are entered. For example: WI-423-001 is the work instruction for maintaining the master list, the first work instruction related to Document Control.

5.3 Documents are reviewed during regular use and during internal audits.

5.3.1 Documents are revised to update or clarify information using the Document Change Request form.



5.3.2 Revisions are made electronically and a revision summary and date of the revision recorded in the revision section of the document.

The document control coordinator uses the document revision checklist (F-423-004) to ensure that all steps are completed.

5.4 Obsolete Document Disposition

5.4.1 One hard copy of the obsolete document is retained and marked "Archive Copy". The document change request is retained with the archived copy.

5.4.2 The archive copy is maintained in a file in the *document control area*.

5.5 Control of data

5.5.1 All programs used for control of production equipment, calculations or analysis are controlled. They are listed on the software spreadsheet with revision date and location of the program.

5.5.2 *Production engineers maintain programs controlling equipment in a protected file. Operators use read only copies of the programs.*

6.0 Forms and Records

6.1 F-423-001 Master Document List

6.2 F-423-002 Software Inventory Spreadsheet

6.3 F-423-003 Document Change Request Form

6.4 F-423-004 Document Revision Checklist

7.0 Attachments

7.1 None

8.0 Related Documents

8.1 *Master Document List Work Instruction (you may want to create this work instruction)*

8.2 T-001 Procedure Template

8.3 T-002 Work Instruction Template

9.0 References

9.1 None