SYGNETICS

Success Through Synergy

Instructions for Developing Quality System Documentation

Based on
ISO 9001:2015 Quality Management System

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1 Instructions for Developing Procedures

Procedures should be developed to identify how various tasks will be performed during the production of a product or providing the services. The following sections describe the necessary steps to develop procedures.

2 Steps in Developing Quality System Procedures (QSPs)

2.1 Identify Key Aspects of the Activity

Review the specific requirement. Determine how many procedures are needed to cover the ISO 9001 requirement.

2.2. Document Current Practices

2.2.1 Flow chart or outline the necessary practices and required steps to execute the process.

Each activity or task (rectangle) should address the following issues:

- Who: Who should do the task? Who is responsible?
- What: What needs to be done? What is the task that needs to be accomplished?
- Where: Where should this task be done? (Include if this is important)
- When: When should this task occur? What is the sequence, frequency, etc.? (Include if this is important)
- How: How should one do this task? This is not a detailed explanation, but rather a reference to the work instructions, forms, etc. required to perform a specific step.

2.2.2 Always examine the flow chart to identify opportunities for improvement (i.e. look to eliminate or simplify any steps that do not add value, or that cause scrap, rework, or other waste.)

2.2.3 The written draft should explain each task or activity (rectangle) in the flow chart by using a directive statement specifying who does what, when, where, and how the outcome is verified, or how the task should be done according to a referenced work instruction. Be as brief as possible, using simple language. One to two short sentences per step are ideal.

2.3 Put the Procedure in a Standardized Format

2.3.1 All quality system procedures (QSPs) are to be formatted using the following format (Programs/projects may divert slightly from this format when the following does not work).

Software Application - Microsoft Word, Arial, 12pt Font Size

Revision box - The revision box of the procedure should include the company name, procedure number and title, page number, revision number, and issue date.

The procedures should include the following sections:

1 **Purpose (Bold)**
A clear statement addressing the procedure's intent, focus, and importance.

2 **Scope (Bold)**
A description of the functional areas, personnel, and other organizational aspects covered and affected by the procedure. The scope also states the specific ISO 9001clause addressed by the procedure, and the section of the quality management system manual from which the procedure is referenced.

3 **Responsibilities (Bold)**
This section defines positional responsibilities of all personnel as defined in the procedure.

4 **Procedure (Bold)**
This section defines the actual requirements of the procedure so that action can be taken to accomplish the purpose.

5 **Related Documentation (Bold)**
This section lists all required documentation (procedure, work instructions, or forms) involved in or resulting from the procedure.

2.4 Numbering

Indented numbers should be used to ensure that the steps are adequately understood. An example of this is:

5.1
5.1.1
5.1.1.1

2.5 Document Review and Modification

2.5.1 Once the quality management system specific procedures have been completed in this format, it should be given to the ISO coordinator for review and to be processed into a formal document. Project specific documents should be given to the appropriate manager for approval. All document discrepancies should be addressed and resolved before proceeding further.

2.6 Approval

2.6.1 The document is not considered to be in effect until the required signature has been obtained and incorporated into the document system. Once the required signature has been obtained, the original document should be returned to the ISO coordinator and filed and maintained in a secure file. Verifiable copies shall be distributed to the affected areas and controlled manuals.

2.6.2 Division or contract specific procedures should be approved and maintained by the appropriate program/project manager.

2.7 Revisions

2.7.1 When changes are made to a procedure a solid vertical line in the right hand margin will identify the nature of the changes.

3 Quality System Work Instructions (QSWIs)

3.1 Document the step-by-step instructions and information necessary to do a particular task. Always look for improvement opportunities. (i.e. greater ease, simplicity, clarity, etc.) Follow Section 2.2.1 of the work instruction replacing procedure for work instructions.

3.1.1 When changes are made to a procedure a solid vertical line in the right hand margin will signify that portion of the document has been changed in the latest revision. The revision will include lists of documents, equipment, tools, and materials necessary to properly perform the task. Quality System Revision Form QSF 4.2.3-1 will be used to synopsize the nature of the change.

3.1.2 Write instructions to be as brief as possible, using simple language. One to two short sentences per step are ideal.

3.1.3 Assign each step in the instruction a "step number" for easy reference.

3.1.4 Reference any product-related work instructions consist of part-specific written instructions, flow charts, drawings and/or sketches, bills of material, routings, specification sheets, checklists, photographs, etc.

3.2 Quality System Work Instructions (QSWIs) Format

3.2.1 The revision box of the QSWI should include: the company name, procedure number and title, page number, revision number, and issue date.

3.2.2 No specific format is required to document work instructions. Flow charts may be used for work instructions.

3.2.3 Follow section 2.5 through 2.7 of this document to review and approve the work instructions.