Writing Procedures: How to Document Your Quality System Effectively

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1 About this Workshop

This workshop is about how to write procedures that will not only be usable but also meet the requirements of the ISO 9000 series. The two things don't necessarily go together. They ought to and can if you use this approach. Most of the workshop is concerned with common sense. It probably describes the day-to-day work of the average technical author. However, it will serve its purpose if it prevents one thing: writing without sufficient preparation. When you come to write procedures, you should have a lot of work already behind you. This workshop takes you through all the stages.

This is a practical workshop with practical exercises. By the end of it you should be able to leave with some relevant, useful, draft procedures.

1.1 The Objectives of this Workshop: A Summary

At the end of this workshop, delegates should be able to:

- State the importance of formal procedures and why they should be documented
- Describe how to approach the identification of procedures
- Put the information into procedures at the right level and in the right place
- Understand and take part in the process of reviewing procedures
- Be able to prepare documented procedures that describe their function in the organisation

2 Standards - Aaaarghh!

Don't worry. Standards are friendly beasts and it's really easy to get to know them. Most people don't realise that standards make life easier! It's true. It's standards that help us to find what we want, when we want it. Have you ever found an index in the middle of a book? A telephone keypad that counts **down** from 9? Standards are not about filing; standards are all about finding things afterwards. Standards are good things by which you can measure the day-to-day work.

Now that we have made friends with standards, let's look at how they help us to write usable procedures. Firstly let's subdivide standards into three categories:

- Structural
- Process
- Cosmetic

Structural standards are the bees knees. They really focus on products and service. Structural standards help us to ensure that rod A really does fit into slot B. We are not going to look at structural standards in this workshop but the information that you will gain will help you to write them if you need to. See "Standards" on page 28.

Process standards are procedures (and we are spending the day looking at these). Think of them as a standard approach to doing things.

Last, but not least, let's look briefly at cosmetic standards. Cosmetic standards describe how documents should look. It's important to single them out like this because people get confused about standards, see them as one generic mass (of trouble) and ignore them rather than get to grips with applying them. Important features of a product or service get lost because they are discarded during discussions about what point size memos should be printed. Strange but true; this sort of thing goes on all the time.

To make sure that all the simple decisions are taken care of so that we can get down to the really interesting bits, we need to set a standard for our procedures. This is useful because it can be applied to so many other documents, giving them a professional finish with no significant added effort. This standard is called a **house style**.

A house style provides a distinctive and consistent appearance for documentation which can be very effective in promoting not only the organisation, its products and services but also **the information that we need to pass between ourselves**. Also, this approach can result in increased productivity as people should be able to work without confusion or wasted effort if they all write to the same conventions.

With the technology available, it is very easy to conform to a housestyle.

3 The Role and Purpose of Procedures

Procedures are all about verbs; they are about doing things. Procedures should tell you what to do, how to do it, when to do it and why you are doing it. Everyone in an organisation is responsible for the quality of his or her work. It is not enough to say to someone 'your software must be of a high quality'. How can they be expected to know what your definition of 'quality' is? How can they find out what they have to do to meet it? And how can they tell whether their work is acceptable?

A documented procedure removes this uncertainty, because:

- It defines the practical things you must do to achieve a quality result
- It provides a definition of acceptability against which the result can be readily assessed
- It provides security and confidence that work carried out according to the procedure will be acceptable

You should have documented procedures because:

- Procedures ensure consistency of results. If everyone follows the same procedure, they will be doing things in the same way. You will be able to depend more on the work of others when it is passed on to you. There will be fewer unpleasant surprises
- Procedures shorten the learning curve for the newcomer
- Procedures are required if you are to achieve BS EN ISO 9000 certification (so there!)

4 The Place of Procedures in a Quality System

The ISO 9000 series sets out a framework for the components of a quality system. Figure 1, on the next page, shows a model for the documents required to support, effectively, such a system. This workshop explains how to build up the components to fit into this framework. Figure 1 also shows a recommended split between a quality manual and a manual of procedures. Many consider the term 'quality manual' to suffice and include all documents under one cover. However, in terms of the day-to-day need to reference the documentation, the 'operating instructions' will be in use far more than the descriptive documents.
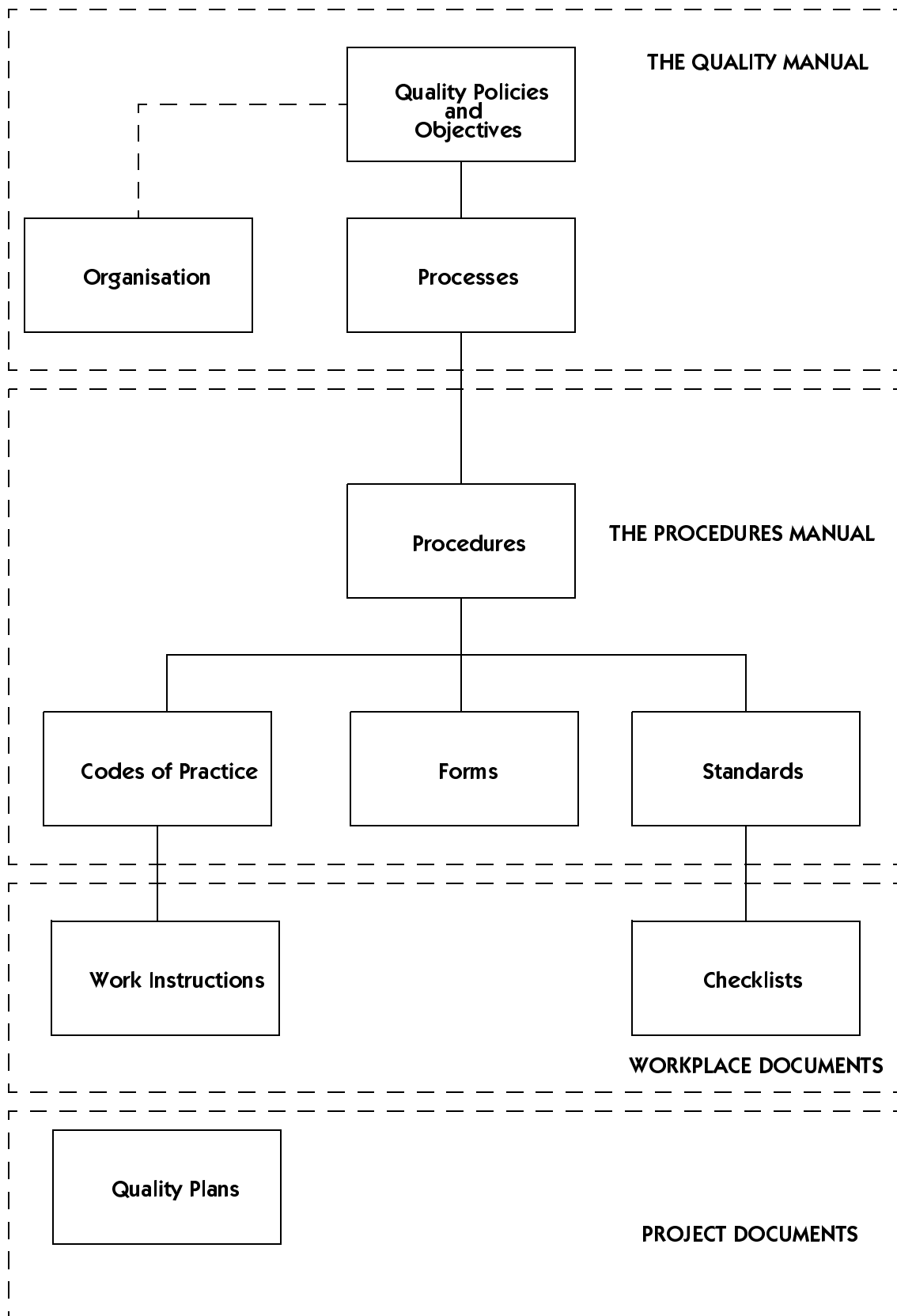
Figure 1: The documentary components of a quality system

5 The Quality System's Place in an Organisation

Quality systems are usually presented as systems in their own right; they are not. A quality system is an integral part of a company's workings. A quality system is a reflection of how a company works. Now I will describe the way a company controls its operations as:

- Its management structure
- Its company processes and procedures (please don't read too much into the term procedure)
- The use of its resources - such as its equipment
- Its staff (and that includes the chief executive, the directors and the managers)

These are the components of a quality system. The quality system sets out what a company does, how the company is organised and how it goes about doing it. The quality system must be designed to ensure that the organisation provides products and services that meet its customers' requirements.

Sometimes the quality system can be organised in two or more levels. For example:

- A top corporate level
- A local operational level
- A departmental level

Although the day-to-day operation of a unit of the organisation may have its own quality system, it may lie within the framework of a much larger quality system that comes down from a corporate level. The important thing is to focus on the issue at hand at any one time. Local procedures may take some overall guidance from the corporate level. However, do not let corporate policies distract you from local need for detail.

6 Identifying How Your Organisation Works: Processes

What you are doing at this stage is nothing less than systems analysis. You are going to define a model of your organisation. There is only one right answer: the model with which everyone is most comfortable. You are going to define a list of objectives and document the procedures that must be carried out to fulfil those objectives.

This is a task that has to be done when you start to organise your quality system. Your organisation will change so the 'finished' model will only be snapshot that must be regularly updated. Don't let the thought of change put you off starting. Like regular exercise, the hardest part is getting off the couch and out of the front door.

6.1 Forming a Review Team

It is at this stage, if you have not already done so, you must identify a review team to review the process model that you are building. No one can really have an independent, unbiased view of the working of your organisation. So, while you are going to do the bulk of the work at this stage, it is important that you identify key roles in the organisation. These people will review your model (of which I shall say more below) and verify it against their personal knowledge or any wider audience with whom they feel the need to consult. This is essential groundwork that must be done so that when you come to write the procedures, you are actually writing the procedures that need to be written.

6.2 Defining Objectives

When you define your model, start from the top. What are the objectives of your organisation? Once these are clear you can start setting out what your organisation does to meet these objectives. You will probably use this information in your quality manual but that is another topic that I shall not cover here. See "The Quality Manual" on page 12.

The type of objectives that you may define could be to supply effective training or consultancy services. The organisation may have 'developing software that is fit for its purpose' as an objective. You may need to quantify these statements later but at this stage keep the level high. Under no circumstances try to define how the organisation delivers its products and services. That is for procedures to define.

Throughout this and the procedure modelling stage (see below), use any tools that you have available. Data flow diagrams, for example, are an excellent way of breaking up a complex organisation into a manageable model.

6.3 Identifying Processes

When the objectives are set down on paper, continue the modelling process and pick out the processes used by your organisation to meet those objectives. Examples of the level of process that should come out of this stage are:

- The quality system
- Product and service development
- Product and service delivery and operations
- Business planning
- Financial management
- Human resource management

- Administration

I have included the quality system at the process level because it forms banner for several 'subsystems' such as a system of management review and the internal quality audit system. These run across all the other processes.

Note that we have limited this top level to seven items. This is a sound psychological principal known as the Miller limit. People have difficulty remembering more than seven (7 ± 2 to be precise) items at a time. Although we don't expect everyone to learn all these processes by heart, this restriction helps us to limit how much we subdivide what we do into manageable chunks. We can get too carried away by breaking everything down into small and smaller tasks. We then need more and more documentation to manage our processes and procedures. As Sellars and Yateman (of '1066 and All That' fame) would say, this is a bad thing.

7 Dividing Processes into Procedures

When you have set out the list of processes, ensure that this list is thoroughly reviewed (several iterations may be needed). Consider suggestions and amend the list with any new information that becomes available during the review. When the list is as complete as possible, you can begin to identify the procedures that are involved in each process. These procedures describe the things to do to effect the results of each process. For example, take the list of processes above. The following procedures may be identified for each process:

- The quality system
    - Document control
    - Project management
    - Monitoring policy changes
    - Internal quality audits
    - Change control
- Product and service development
    - Development lifecycle
- Product and service delivery and operations
    - Service level agreements
    - Support
    - Operations
    - Administration
- Business planning
    - Research
    - Planning
    - Review
    - Report
    - Marketing
- Financial management
    - Budgeting
    - Purchasing
    - Proposals for expenditure
    - Petty cash
    - Income management
    - Travelling
- Human resource management
    - Human resource planning
    - Recruitment and selection
    - Induction
    - Performance support
    - Training and development
    - Retirement, redundancy and resignation

- Administration
    - Communications
    - Meetings and presentations
    - Time management
    - Risk management

The procedures listed above are not meant to be a comprehensive set of procedures that will meet the requirements of ISO 9000. The list is only an illustration of the path to defining procedures. From such a list, common procedures should become apparent. For example, review procedures occur at many points and so it may be worthwhile adopting a common approach to review whether it is for business planning or product development.

Note how the Miller limit has been applied to the next level down.

If you find two processes or parts of processes being done by different parts of the organisation then your ultimate aim should be for synthesis into a single set of procedures. However this may not be possible in the short term for reasons as diverse as practicality (learning new procedures) or company politics (apparently unavoidable).

The short term solution may be to document (and work with) two procedures. Trying to achieve the ideal solution may mean that procedures are never issued or worse: the published procedure may be an unachievable wish-list.

Another option may be to take on one of the procedures. However, one side will have to be very flexible. In the long term you should aim to take the best bits of both approaches. You may want to adopt a completely new approach. Some of the organisations who have reported benefits from implementing formal quality systems found quick cost benefits from adopting better procedures during this phase of rationalisation. The change in working practices here, as at all stages, must be carefully managed; otherwise areas of the organisation can cease to function.

8 The Ownership of Procedures

A word of warning! If the ownership of a process is at too high a level (for an extreme example, take the Managing Director) there is a risk that it will not be changed or not reflect the real 'shop floor' practice. Operational staff will be reluctant to challenge or follow it.   Don't let the definition of processes get too high. Managing Directors should set policy not process. Select the appropriate level of ownership for each process and procedure. A local manager may be required for approval, but make sure that those who actually carry out the task have a say in the formulation of the procedure (the written definition of that task).

9 Documenting The Quality System: The First Step

The first step to make is that of recognition. You must recognise that the quality system needs to be flexible. If you align the documentation of the quality system according to the structure of the organisation, the quality system may breakdown if you reorganise. At the very least, you will be faced with the possibility of considerable work to bring your documentation into line with the changes.

So the first task in planning your procedures is to separate the structure of the organisation from what the organisation does.   The key word is function. The organisation of the company, however complex or fluid, can be contained in one short document. What your organisation does in terms of manufacturing materials, developing hardware or software or supplying services will need far more words and but will be less changeable than you think.

Refer to roles rather than job titles. Your organisation is probably far less hierarchical when it comes down to getting the job done. Procedures must be operational within this flatter structure to take account of the various roles that an individual may take on during the course of a process.

9.1 The Quality Manual

THE QUALITY MANUAL

Quality Policies and Objectives

Organisation

Processes
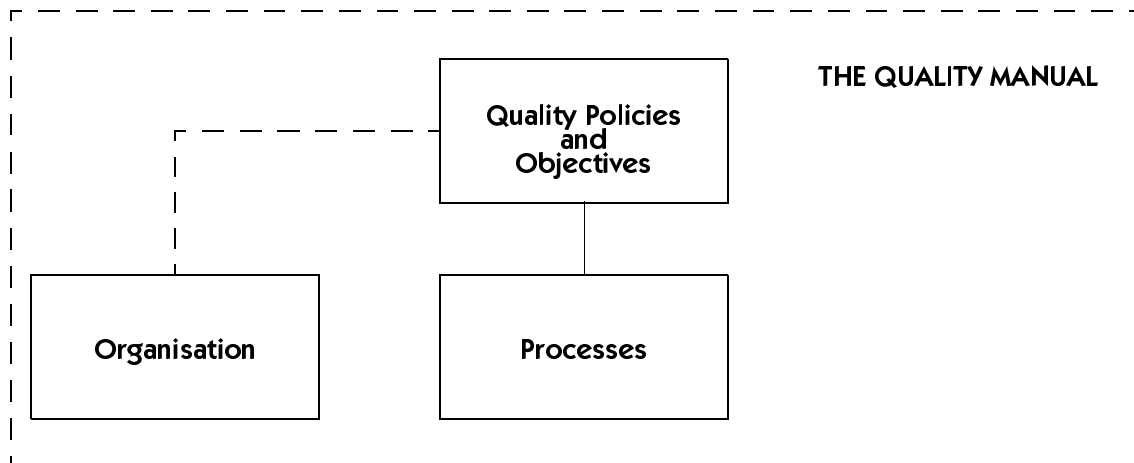
This is where you start to capture all the overview information that you need to form a framework for writing procedures. The quality manual may be on two or more levels such as:

- corporate information
- departmental information

The quality manual is where the structure and objectives of the organisation (the 'what') meets the activities of the organisation (the 'how').

For example, a quality manual may contain:

- Title page
- Distribution list

- Record of amendments

- List of contents

- Introducing this manual - why you should read it.

- The company - quality and marketing go together; say how the organisation originated and state its mission

- Products and services- include an overview of what the organisation does

- Distribution of this manual - how you get access to a copy of this manual regularly

- Document control and change control - who gets the updated versions but more importantly, who is allowed to change it!

- Quality policy - what is the attitude of the organisation to what the customers want

- Quality objectives - how does the organisation aim to fulfil the quality policy

- Organisation of the organisation - its structure

- How does it organise its activities so that objectives are met; for example:

  - The quality system
    The quality system and its documentation
    Internal quality audits
    Document control
    Control of nonconformity product and corrective action
    Quality records

  - Product and service development
    Customer-supplied product
    Inspection, testing and review of products and services

  - Product and service delivery and operations
    Contract review
    Process control
    Product identification and traceability
    Handling, storage, packaging and delivery
    Maintenance and support

  - Business planning

  - Financial management
    Purchasing
    Inspection and testing of purchased products and services

  - Human resource management
    Project management
    Training

  - Administration

- Procedures index or guide

- Glossary of terms

10 How to Write the Procedures

10.1 Preparation

Now you have a list of procedures to be written. Put that pen down! The first step is to think. Yes. This means planning as well - for each document. Does this task really need a procedure or a set of work instructions (see below)? Does it have to be done in a certain way, or does it just have to be done? If the latter is the case, a one-line reference to it in a higher level procedure will do.

10.2 A Procedure for Procedures

Yes! You really need one. Don't be confused between the birth of your quality system and its maintenance. The procedure for procedures will mainly apply to the latter but use it as a framework for keeping control of the initial drafting.

Such a procedure will follow these lines.

10.2.1 A Procedure for Procedures: Purpose

To describe the format, preparation, numbering, revision, distribution and administration of all procedures, work instructions and standards applicable to the quality system.

This procedure also serves as an example of how a procedure is to be prepared, written and set out.

10.2.2 A Procedure for Procedures: Scope

This procedure applies to the creation and modification of all procedures which form part of the quality system.

10.2.3 A Procedure for Procedures: References

Guidelines for Text Layout apply to the presentation of procedure documentation.

10.2.4 A Procedure for Procedures: Responsibilities

The Quality Manager is responsible for ensuring that this procedure is up-to-date and relevant.

The Quality Manager is responsible for ensuring that all activities involved in the preparation and administration of procedures are carried out in accordance with this procedure.

10.2.5 A Procedure for Procedures: Definitions

Procedure   A written statement that details the purpose and scope of an activity and specifies how and by whom it is to be carried out.

10.2.6 A Procedure for Procedures: Procedure

Authorisation to Initiate a Procedure

Any member of staff who identifies the need for a procedure shall report the need in writing to the Quality Manager using a Procedure Request Form (PRF).

PRFs shall be reviewed by the Quality Manager. If necessary, the relevant departmental manager shall be consulted to decide on the action to be taken.

If the request is approved, an author and a technical approver shall be appointed. If rejected, the reason shall be documented on the form.

In either case the PRF shall be filed in the Procedure Request File and a copy sent to the originator.

If the requirement is for a new procedure the Quality Manager shall allocate a unique procedure number following the Procedure Numbering guidelines and enter it into the Document Control Register.

If the procedure requires forms or standards, the Quality Manager shall allocate reference numbers and enter the numbers in the appropriate register.

If any subsequent decision is made not to issue the procedure, the Quality Manager shall annotate the registers accordingly. To avoid confusion, the number should not be used again.

The author shall follow this procedure as the model for producing a procedure.

Procedure Components

All procedures shall be written to the same headings. See "Contents" on page 18.

The component headings shall always be used, even if they are not relevant to a particular procedure. In that case, 'None' should be inserted under the heading.

Procedure Format/Layout

Guidelines for Text Layout shall be applied to procedures using the standard documentation/ wordprocessing facility.

Issue for Comment

When a procedure has been drafted, it shall be identified as *Issue 0.1, For Comment.* After checking it, the Quality Manager shall copy it to all those involved in the activity and their managers for review and comment, stating a timescale for response.

When all comments have been received, or the deadline for their receipt has passed, the Author shall amend the procedure document as necessary, consulting the relevant managers and the Quality Manager to resolve any differences.

If it is necessary to circulate the updated document again for further comment, raise the Issue number by 0.1 (that is, to 0.2) to denote the revised working document.

Checking and Approval

The appropriate manager shall check the procedure and, once any necessary changes have been made, sign the cover page in the Technical Approval space.

After Technical Approval the Quality Manager shall check and signify compliance with Quality systems requirements by signing the cover page in the Quality Approval space.

The amended procedure, when accepted, shall be identified as *Issue 1.0.*

Revision

Requests for revisions to procedures shall be submitted in writing, using the PRF. These shall be processed in the same way as new procedure requests described above.

Action will usually result in the allocation of an author and the preparation of a draft copy of the revised procedure. This shall be issued for comment as described above, except that the issue number shall be of format A.B where A is the current issue number and B is the working document version (that is, 1.1, 2.1, 2.2 and so on).

Checking and approval shall be carried out as described above, except that the revised procedure document shall be identified as the next issue number (that is, A + 1).

Procedures shall be replaced by updated issues, and obsolete editions destroyed by holders of copies. The Distribution List identifies each copy holder, who has the responsibility to ensure that new issues are inserted and old copies shall be destroyed.

Document Control

The Quality Manager shall establish and maintain a file for each procedure containing:

- The master procedure
- The record of revisions

Previous versions of procedures shall be retained for a period of eighteen months after the procedure has been reissued.

The Quality Manager shall update and distribute the Procedure Index in the Quality Manual as necessary.

The Quality Manager shall maintain and update the Document Control Register which details the status of all procedures issued, in preparation, or withdrawn.

Preliminary pages in procedures manuals shall be controlled by date.

Distribution

The Quality Manager shall maintain a set of Distribution Lists that are used to identify the holders of procedures.

The Quality Manager shall ensure that approved procedures and subsequent revisions are distributed according to Distribution Lists.

If the review of the quality system identifies obsolete procedures, the Quality Manager shall circulate notification of intent to withdraw giving one calendar month notice instructing the removal and destruction of copies of the redundant procedures. This shall be circulated to all copy holders on the Distribution List.

Appendices

- Guidelines for Text Layout
- Procedure Numbering
- Document Control Register
- Procedure Request Form

10.3 Structure

Every procedure should have the same type of information in it as every other procedure.

Each procedure should have a title page that bears the copy number and the following type of document control information:

Document: A unique identifier.

Title: What is the document called?

Issue: What is the status of the document?

Date: When was this issue written?

Author: Who wrote it?

Distribution lis:t   Who needs a copy?

Number of pages: How many pages? Any appendices?

Technical approval: Signed off for technical accuracy.

Quality approval: Signed off as suitable for issue.

Document numbers can be in the format **A-XX-BB-CC** where **A** identifies the process area such as:

Q   Quality

B   Business planning

F   Financial management

D   Product and service development

O   Product and service delivery and operations

H   Human resource management

A   Administration

XX is a two-letter identifier for use at the discretion of the process owners. If not used, OO is the default.

BB is a two-letter identifier that shows the reader what type of document it is (and therefore how it fits into the quality system):

PR   Procedure

WI   Work Instruction

FM   Form

ST   Standard

CL   Checklist

QM   Quality Manual

For example:

Document:	Q-OO-PR-001
Title:	How to Prepare and Administer Procedures
Issue:	0.1
Date:	1 July 1995
Author:	Martin Smith
Distribution list:	Corporate
Number of pages:	4 + appendices
Technical approval:	*Elijah Baley*
Quality approval:	*Arch Stanton*

The procedure (or the manual in which it is housed) should contain an amendment record with the following type of information:

Revision:	Which issue?
Date:	When was it written?
Revision Description:	Why was it written?

For example:

Revision	Date	Revision Description
0.1	22 May 1994	Initial draft for comment
1.0	13 December 1994	For issue
1.1	4 April 1995	Information lost between departments; mailing system revised. See para. 6.3
2.0	5 May 1995	New mailing system approved; procedure for issue

10.4 Contents

After the preliminary page, will come the body of the procedure. Procedures will have the following contents probably, but not necessarily, divided into these sections:

- Purpose
- Scope
- References
- Responsibilities
- Definitions
- Procedure

- Appendices

10.4.1 Purpose

The purpose section of a procedure should contain an overview of what the procedure is for and a description of the reason you have the procedure.

10.4.2 Scope

The scope section of a procedure should describe when the procedure should be used, and to which roles the procedure applies. It should, wherever possible state any exceptions and the conditions when these exceptions may arise.

10.4.3 References

The references section of a procedure should list any associated procedures or helpful documentation that should be considered with the procedure itself.

10.4.4 Responsibilities

The responsibilities section of a procedure describes to whom this procedure applies. It may suffice to state simply who is responsible for carrying out the procedure. Also, it should state who is not permitted to carry out the task or function (again, as appropriate).

It is also worthwhile using this section to state who is responsible for keeping the procedure up-to-date and who is authorised to sign off the procedure when it is ready for use (that is, the **owner of the procedure**); this information is helpful when maintaining the quality system.

10.4.5 Definitions

The definitions section describes the meaning of any terms, used in the procedure, that everyone cannot be assumed to understand.

10.4.6 Procedure

The procedure definition section of a procedure will contain a step by step description of the task or function to be carried out.

10.4.7 Appendices

These are supporting documents that help people to carry out the details of the procedure. These may be:

- Guidelines for information only but enhancing the basic details of the main procedure
- Standards - mandatory measures or descriptions that apply to the work described in the procedure
- Forms - mandatory proformas to ease the flow of information called for by the procedure

10.5 Nitty Gritty Procedure Writing

Ask yourself questions and answer them on paper. How is the task carried out now? Is this adequate? If not, how can it be improved? Can things be made simpler? For example, one form instead of three.

What are the inputs to the task and the outputs from it? From whom should the input be taken, and to whom should the output be distributed? (This also applies to information - if your procedure involves generating a project plan, who needs a copy of it?)

What records need to be generated for you to be able to prove that the task has been completed? Who needs to know?

Now break the task down into component steps. What order should they come in?

For each step, should there be a detailed description or a simple instruction? (If you say 'Insert a low density floppy disk into drive A, format it, then copy the database file to the disk', you are failing to comply if you use a high density disk or format it in drive B - and the auditor will get you. Apply the KISS principle (Keep It Simple, Stupid). Perhaps all you really needed to say was 'copy the file to a blank floppy disk'.)

For each step, does there need to be proof that it has been carried out? Do any results need to be recorded? Who needs to know?

Remember, procedures are meant to be our servants rather than our masters. Eliminate all that is unnecessary. Write a procedure that minimises the work involved in complying with it. Design the procedure as if YOU were going to have to follow it every working day for the rest of your life!

10.6 Format

Keep your format simple. Follow a standard set of guidelines for text layout. For example:

- Use a main heading and three levels of heading (and no more) below it
- Use bold text rather than underlining
- If paragraph numbering is used, limit it to three levels (for example 4.2.3)
- Use rectos (right-hand pages) for odd-numbered pages
- Versos (left-hand pages) for even numbered pages
- Prefer double-sided (rectos and versos) document to single sided
- If a document is single-sided, use only rectos; treat blank rectos as a blank pages
- Make use of white space to help text and illustrations stand out
- Avoid point sizes less than 12 point; use 12 point for standard body text
- Use a consistent pattern for bullets and punctuation

10.7 Writing Style

There is probably enough material about the writing style that should be used in procedures to fill a medium-sized text book. All right. Several medium-sized text books. However there is not that much that you really need to know to get started; the rest will come with practice.

Their are two approaches, which I shall call:

- Formal Approach
- Informal Approach

10.7.1 Formal Approach

The formal apporach is a bit of a paradox. No one likes to read it but most people find it easier to write. You can tell when a procedure uses the formal approach because the author uses 'shall' a lot. You have to decide whether you prefer:

(1)   The Productions Services Manager shall sign the form

or, addressing the procedure to the Production Services Manager:

(2)   Sign the form

but never (please):

(3)   A tick shall be placed in the box by the Production Services Manager

Formal procedure writing should also be **active**, **instructional** and **concise**. These are described below.

10.7.2 Informal Approach

Your writing should have four attributes. It should be:

- **Active.** A procedure is there to be carried out. People make quality systems - paper manuals don't
- **Direct.** Talk directly to the readers (the people who will use the procedures). Use 'you' in the instructions. Only use the third person singular as a last resort. Don't be too conscious of using he and she. Non-sexist writing can be confusing and often ungrammatical - it should be unnecessary
- **Instructional.** Tell people exactly what they should do. If you don't, then the worth of your procedure is immediately brought into question
- **Concise.** Make a point once. Don't repeat it

These ideas can be used as quality criteria, against which your procedures can be reviewed. Reviewing procedures is discussed in detail below.

10.8 Sentence and Paragraph Length

Write simple, short sentences. Try to avoid using several clauses in one sentence; break such a sentence into shorter ones. Write one instruction only per sentence.

Keep to a single topic in each paragraph.

10.9 Vocabulary

Do not try to impress anyone with your vocabulary. Use short, common words (even if it doesn't sound very interesting). As Einstein said, 'If you are out to describe the truth, leave elegance to the tailor'.

10.10 Active and Passive Voice

Use the active voice in preference to the passive. Tell someone to 'Pass the specification to the moderator' and not 'The specification is passed to the moderator'. Note the strength in the first version. It makes it clear that the reader has to do something rather than the vain hope that an event will take place.

10.11 Positive Statements

Positive statements are easier to understand than negative ones. Write 'Complete the approval form and return the specification to the author' and not 'Do not return the specification to the author until you have completed the approval form'.

10.12 Keeping the Order Logical

Describe the steps of a procedure in the order in which they occur.

10.13 Tense

Keep to the present tense wherever possible.

11 A Short Exercise in Writing a Procedure

The purpose of this exercise is to get you used to using the standard contents of a procedure without having to worry about a real process. So, relax a bit and have bit of fun. At the same time, remember this is a serious exercise so please include everything; make some decisions!

(1)   Take the standard headings for a procedure:

- Purpose
- Scope
- References
- Responsibilities
- Definitions
- Procedure
- Appendices

(2)   Fill them with the appropriate information to successfully carry out one of the following tasks:

- Organising a trip to the theatre
- Preparing a three course meal (you may skip the recipe details!)
- Doing the laundry
- Giving a foreign tourist directions to a place of historic interest
- Using a coffee vending machine

Note: Remember to ask questions such as:

Why is this procedure needed?
What will be a satisfactory result of the procedure?
What preparations are needed?
Who does what?
How should each task be done?
When should each task be carried out?
Where should information be passed?
How do you know that you have finished?

12 How to Review Procedures

12.1 Introduction

No matter how good your procedure is, there will be someone somewhere who will not accept it until they have had the opportunity to comment on it. The review of a procedure is essential (and this also applies to modifications to existing procedures). Of course we must keep this in perspective. Do not call a review meeting if you have just altered the wording to make something clearer or correct a spelling mistake.

12.2 Review Your Own Work

Before getting help from others to review your procedures, check each one yourself by applying the ETVX principle. (Yes, I know this is not an acronym that flows off the tongue but at least the principle is sound.)

ETVX stands for:

- Entry criteria
- Task
- Verification step
- Exit criteria

Check your procedure to make sure the that it has the minimum contents to be effective. Before a procedure (for example, planning, design, support) is carried out, some criteria are met (for example, requirements are defined, people are available, a request is received). The procedure should be carried out in such a way that its successful completion can be checked before the procedure can be deemed complete.

12.3 Validating Procedures

There are several different ways of validating procedures. These range from Fagan inspection to 'suck it and see'.

The 'suck it and see' is the least satisfactory method and is usually coupled with the misuse of internal quality audits. The internal quality audit is not meant to provide guidance about the correctness of a procedure. The purpose of the internal quality audit system is one of verification. They should be run to monitor conformance to both the documented quality system in operation and to the requirements of the ISO 9000 standard. The System provides the mechanism for discovering nonconformances within the operating quality management system, ensuring that appropriate corrective action is planned, implemented and effective. Day-to-day carrying out of procedures should be helped by training (once a procedure is in place).   Don't rely on the internal quality audit system to 'test' procedures; that is like waiting for system testing to identify fundamental design flaws in the software.

This said, do not wait for perfection. Issue usable procedures and improve them with time. Withhold them until every last detail is sorted out and you can issue them to find that the goal posts have moved and the procedures does not meet their objectives.

A simple but effective approach involves three stages:

(1)   Preparing to review the procedure

(2)   Reviewing the procedure

(3)   Completing or reworking the procedure

12.4 Preparing to Review the Procedure

Select a team of reviewers. Ask them to review a procedure from a particular point of view. Three possible aspects are described here:

- A technical review
- A usability review
- A business review

A technical review should determine whether the procedure specifies the correct activities in the correct sequence and that responsibilities are correctly assigned and consistent with the authority necessary to carry out the task.

A usability reviewer should decide whether the procedure is explicit enough that it can be used and is useful. It should also consider whether the activities specified can actually be performed.

Procedures may implicitly require resources to be available at certain times. The business review should consider whether both the implicit and explicit resources are likely to be available and the overhead this could add in terms of time and cost to the performance of the task.

To make the aspect to be reviewed clear to each reviewer, use checklists.   Supply each reviewer with a copy of the procedure and a predefined checklist. Here are some examples of the type of questions that may be appropriate to each aspect.

A technical review checklist:

- Is the scope, as specified, appropriate?
- Does the procedure all the possible situations that can occur within the specified scope?
- Are the 'mechanics' of the procedure correct?
- Are any timescales mentioned feasible?

A usability review checklist:

- Is the level of detail appropriate to the task bearing in mind who is responsible for performing the task?
- Is it possible to perform the activities as specified?
- When strung together, do the activities form a coherent process?
- Are the roles described to an appropriate level of detail?
- Will this procedure be useful?
- Is it practical to implement for the prescribed scope?

A business review checklist

- Is the approach taken in the document sufficient to minimise any business risks involved in this task?
- Is the procedure practical to implement from a resource, time taken and timescale point of view?

12.5 Reviewing the Procedure

Essentially, there are three methods that you can use to review procedures:

- Peer review or desk checking by one or more reviewers
- Review by informal meeting
- Formal documentation inspection or Fagan Inspection

In each type of review, reviewers should have a clear picture of their role and the time constraints of the review. Reviewers are also responsible for ensuring that they clearly communicate the results of their reviews.

These three methods represent three levels of review that vary from simple to formal. The level of review depends on:

- How important is the procedure?
- How capable and experienced is the author of the procedure?
- Does the procedure describe the interconnections between different functions?

The questions must be answered honestly. They must not be used to try to dilute the quality assurance process.

## 12.6 Reworking or Completing the Procedure

The results of each review must be carefully considered and appropriate changes made. Where copious change results from a review, the procedure may have to be reviewed again. If a formal review technique was used for the initial review, a less formal method may suffice for the second or subsequent reviews. Give reviewers the opportunity to see changes wherever practical.

When the procedure is sound, make sure that it receives a review for language, typing and so on. A fact, strange but true, is that faith can be lost in an excellent procedure because of a few careless typographical errors. Typical questions for a proofreader are:

- Does the document conform to accepted housestyle?
- Is the document free from spelling mistakes?
- Is the document free from grammatical mistakes?
- Is the document free from any other typographical mistakes?

Note: Review checklists are not afterthoughts. Use them when writing the first draft of the procedure.

13 Other Quality System Documents
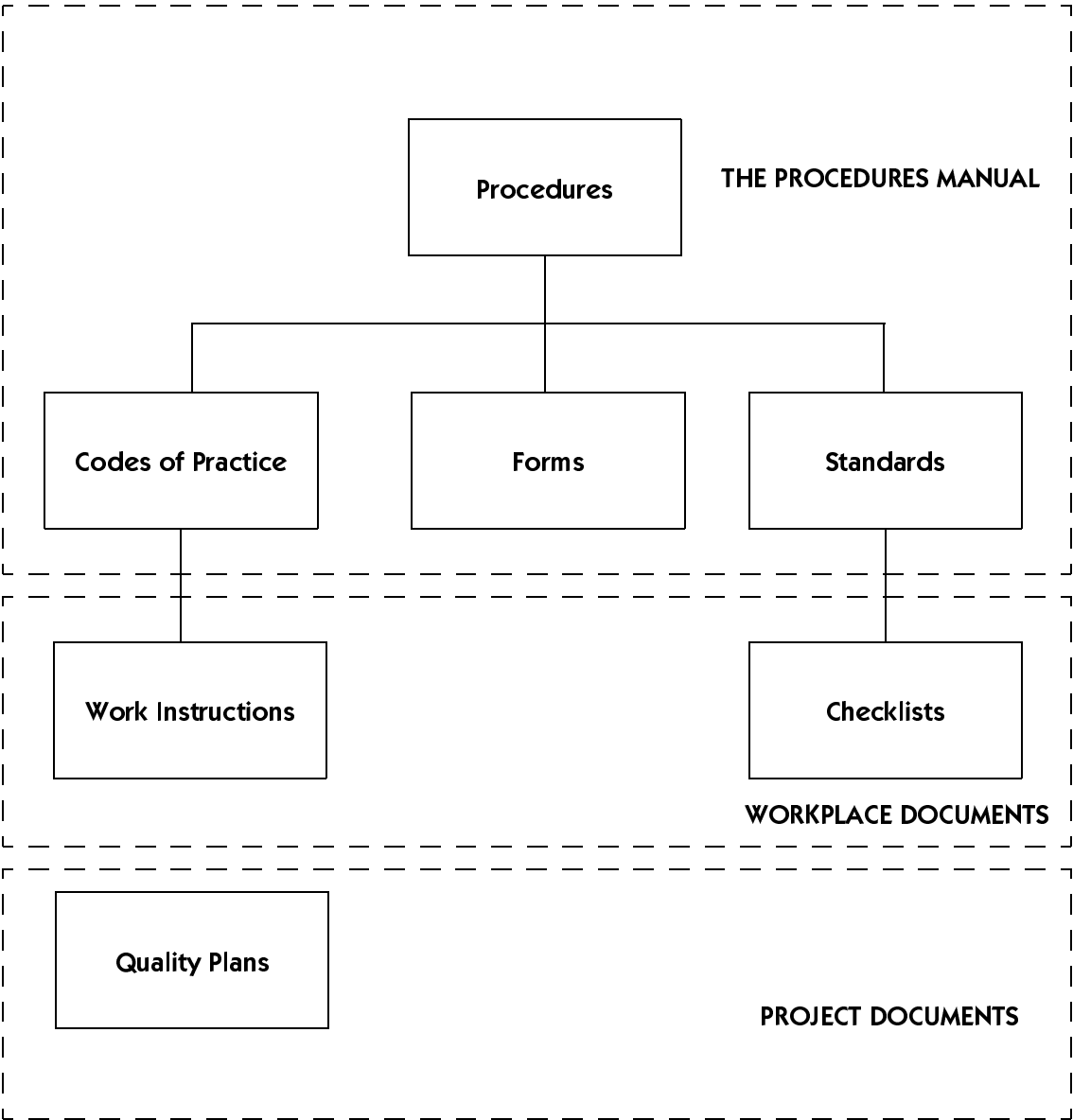
13.1 Codes of Practice

Procedures are mandatory parts of the quality system; we must follow their instructions. However there are often many hints and tips that we want to pass on to people but that we don't want to put into a procedure (because it would make it too long or too complicated to follow). Codes of practice collect the best practices and communicate them to people using the procedures. They are valuable training aids.

13.2 Work Instructions

Work Instructions are procedures that detail day-to-day working practices such as how to initiate a production process or how to file a set of documents.

13.3 Standards

We've already looked at standards and how we should differentiate standards from procedures. Standards are those yardsticks against which we can measure the quality of our work. They describe such things as:

- The content of a document
- The structure of a program
- The format of computer data
- The size of a printed circuit board

A standard is an established or accepted model. Standards provide us with references against which we can measure the work we do. For example, a standard shall tell us the contents of a technical specification. Such a standard enables the author of the specification to concentrate on the creative part of writing and not the administrative part of deciding what information is required. Similarly, readers of the specification shall be familiar with the format and shall be able to find the information they seek in a familiar place.

A quality system will include:

- Corporate standards
- Industry standards
- Pertinent British, European and International standards

13.4 Forms and Checklists

For those who fear that a quality system is a constraint, forms are often the most off-putting element of the documentation. Forms should be the most useful element.

An organisation cannot adopt all the practices of a formal quality system overnight. People need time to get used to using new tools; especially the tools of a quality system. Remember, the foundations of the quality system lie in good communication. Communication means the effective transfer of useful information.

People like to receive information in a familiar arrangement. Mother-tongue English speakers feel comfortable receiving (and sending) information in English. Unfortunately, whatever language we speak, we surround important information with chaff or, in electrical terms, noise; additional words which detract from the important message. Apart from the noise, we also have the problems of deciding the order in which we convey various pieces of information or we forget key issues. There are two options:

- Carefully arrange the information in a suitable order
- Churn it out as we think about it, or more accurately, as we remember about it

This is where tools come in. These tools are forms. Well designed forms are checklists of what information is required. They relieve the worry of the order into which information should be arranged. Forms are a tool to select and transmit information in (what will soon become) a readily familiar format.

Form design is an art. Briefly, I advise the following:

- Give each form a title (avoiding the word 'form')
- Think carefully about the space for each item and don't use too much or leave too little

- Explain each item on the form (on the reverse if necessary) with general instructions, hints and tips about using the form

- Include instructions about what to do with the completed form on the form

Now, I have said that forms can be used as checklists, and we can use this idea to a further advantage. We can present standards and procedures as, or with, forms. We can make the job of carrying out a procedure or meeting a standard easier by presenting the required stages as checklists on ready-to-use forms.

Forms are no different from any other documentary component of a quality system. They must have clear reference numbers and, even more importantly, clear issue numbers. The quality system documentation must clearly show which are the current forms, possibly by attaching forms to a particular standard or procedure.

Supplies of forms should be limited to controlled places so that out-of-date forms are not proliferated.

Forms and templates must be useful. If they are not, then they will not be used. A review should check that redundant information does not appear on forms, that those responsible for using them are not expected to provide information which is not easily available to them, and that different forms do not require the same information.

Ask:

- Will the forms be useful to the people using the procedure or those who require information from the process?

- Will sufficient information be recorded on the forms to be useful?

- Are the forms sensibly formatted?

- Is there sufficient information on the forms and in the procedure to complete the forms?

14 Writing and Reviewing Procedures: A Practical Exercise

14.1 Writing a Procedure (90 minutes)

(1)   Take the standard procedure format and the procedure for procedures.

(2)   Select a procedure that needs writing.

(3)   Work by yourself or with one other person, to write the first draft of the procedure.

14.2 Reviewing a Procedure (105 minutes)

(1)   Divide yourselves into groups of three or four.

(2)   Select one of the procedures that you have just written.

(3)   Assign roles to each in your group (for example: review leader, author, technical reviewer, business reviewer).

(4)   Carry out a review of the selected procedure; use the checklists in these notes and add to them as necessary:

   • Prepare (30 minutes)
   • Review meeting (up to 1 hour)

(5)   Report/Discussion/Feedback (15 minutes).

15 Document Management

The process of developing quality system documentation that is described in this document will deliver individual documents commensurate with requirements. However, it is essential to have document control mechanisms in place so that the information in the procedures and their supporting documents is readily available.

The management of the documentation used by most organisations is paper-based. Do not belittle this technique. Looking for an on-line solution may delay the your implementation so never be afraid of paper manuals; on-line manuals, hypertext or otherwise is something that you can work towards.