

# **DOCUMENT CONTROL**

## PROCEDURE

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## 1. PURPOSE

Documents required by the quality management system must be controlled. The purpose of this procedure is to define the controls required,

- a) to approve documents for adequacy prior to issue
- b) to review and update as necessary and re-approve documents
- c) to ensure that changes and the current revision status of documents are identified
- d) to ensure that relevant versions of applicable documents are available at points of use
- e) to ensure that documents remain legible and readily identifiable
- f) to ensure that documents of external origin are identified and their distribution controlled, and
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

## 2. SCOPE

This procedure related to all documents associated with providing evidence of conformity to requirements. Records are a special type of document and shall be controlled according to the procedure for Control of Records TK-QP-102.

## 3. **DEFINITIONS.**

#### 3.1 QUALITY MANUAL

The governing working document within the company that describes how each element of the quality programme shall be met. It also serves as a guide to the outside reviewer.

#### 3.2 PROCEDURE

A procedure is a specified way of carry out an activity or process. It also provides a description of the responsibilities pertaining to the process.

#### 3.3 RECORD

A record is a special type of document established to provide evidence of conformity to requirements. It is controlled according to the procedure for Control of Records TK-QP-102.

## 4. **REFERENCES**

4.1 Planning, review and improvement of the Quality Management System TK-QP-010

## 5. ASSOCIATED DOCUMENTS

- 5.1 Quality Manual
- 5.2 All procedures
- 5.3 All forms

## 6. PROCEDURE

#### 6.1 PROCEDURE WRITING FORMAT

A procedure shall contain the following sections:

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#### 6.1.1 PURPOSE

This should answer the question "Why does the procedure exist?" It should be short and to the point.

#### 6.1.2 SCOPE

This should set the boundaries of the procedure being described. The purpose and scope may be combined.

#### 6.1.3 DEFINITIONS

Those words and terms used in the procedure that might cause confusion and thus require clarification should be defined here. If there are none then state 'nil'.

#### 6.1.4 REFERENCES

Only references that give background information or from which direct quotations are taken should be listed. If there are none then state 'nil'.

#### 6.1.5 ASSOCIATED DOCUMENTS

List all documents (instructions, forms, etc.) that are used in the procedure.

#### 6.1.6 PROCEDURES

All responsibilities and actions except those described in referenced documents should be given. Responsibilities should be indicated by title or rank. Actions shall be described in sufficient detail so that the purpose of the procedure can be easily understood.

The description of actions should also include :

- a) information to be processed or distributed
- b) methods to be used
- c) equipment use , or reference to operating instructions
- d) records to be completed, the details and distribution
- e) timing and locality of actions
- f) reasons for actions, where this may be beneficial.

#### 6.2 NEW PROCEDURES

The need for a new procedure shall be reported to or identified by the Quality Review Committee who shall ask one of their members to draft the new procedure. Comments shall then be obtained from each person with a defined responsibility, and these reviewed by the Quality Review Committee, and incorporated as necessary. Upon agreement of the Committee, the Procedure shall be approved by the Quality Manager and issued in accordance with section 6.5 of this procedure.

#### 6.3 APPROVALS

The Quality Manager will approve all new and revised procedures. This approval will be signified by the placement of the new or revised procedure of the document onto the computer network in accordance with 6.6

#### 6.4 **REVISIONS**

The Quality Review Committee shall be responsible for all revisions to the Quality Manual, Procedures and all forms and documents used within the procedures. The frequency of review and

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incorporation of changes shall be decided by the Committee that shall agree all such changes. All queries or suggestions for changes shall be submitted to the Quality Assurance Manager.

The first revision of a document shall be Revision 1, the second Revision 2 etc, which shall be included into the document number (see 6.6).

For changes and issues of drawings used in manufacture see TK-QP-002 Design Control Procedure.

With each document revision, and before its issue, the Quality Manager shall ensure that all sections of the revision block on the front page of the procedure and the revision sheet of the Quality Manual are completed.

The Quality Manager shall maintain a record sheet showing a brief description of each change made to a procedure.

#### 6.5 DOCUMENTATION NUMBERING AND FILE NAMING

#### 6.5.1 NUMBERING

Numbering shall indicate the company, document type and number, i.e. TK for Thomas Keating and QM for Quality Manual, QP for Quality Procedure followed by the allocated number, 001,002 etc. Forms shall utilize the numbering series QF etc with A, B, C, etc rising in alphabetical order, to denote issue level.

Example: Consider a procedure new procedure to be given the reference 110. This will be Issue A, Revision 0. The document number will therefore be,

TK-QP-110-A0	QP	=	Quality Procedure
	110	=	Reference number
	А	=	Issue
	0	=	Revision

#### 6.5.2 FILENAMES

When a Word Processor file is used to construct the document, the filename will be constructed from the document number, revision and issue. This filename will be included (automatically, using the **[Insert]-[Field]-[Document Information]-[Filename]** function) in the footer of every page of the document thus giving a clear indication of the document status.

Example: Consider the example above, TK-QP-110-A0 .The filename for this document would be **TK-QP-100-A0** if a new revision were produced (Revision: 1) then a revised document would be produced and given the name **TK-QP-110-A1** 

In this way not only will the most recent version be easily identifiable, any hardcopy produced from the network version will include the correct revision/issue information.

#### 6.5.3 DOCUMENT RELEASE/ 'SIGNING'

Following approval by the Quality Assurance Manager the revised Document is approved by appropriate filenaming (as above) and by placing a password protected/Read only version onto the network. This process is approved by the Quality Assurance Manager and is effectively a "signing" process.

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#### 6.6 DOCUMENTATION ISSUE AND DISTRIBUTION

The following ensures that relevant versions of applicable documents are available at points of use.

#### 6.6.1 QUALITY MANUAL

#### 6.6.1.1 Control of Quality Manual

Manuals shall be issued either as controlled (C) or uncontrolled (UC):

#### a) Controlled Copies

Controlled manuals shall be identified as controlled, individually numbered and issued to registered holders and kept up-to-date with any revisions.

#### b) Uncontrolled Copies

Uncontrolled Manuals shall be clearly marked 'uncontrolled' and issued for information purposes only and will not be updated with any revisions.

#### 6.6.1.2. Manual Issue

The Quality Assurance Manager shall be responsible for the issue of all Manuals. All copies will be issued to members of the Company or other authorized individuals according to the distribution list. It will be the responsibility of the Quality Assurance Manager to ensure that all amendments are incorporated and that the Manuals are maintained up-to-date and are available to all relevant staff. A list of uncontrolled Manual holders will be retained by the Quality Assurance Manager. Serialization and accountability of Manuals are the responsibility of the Quality Assurance Manager, who will retain a complete register of Quality Manual holders.

#### 6.6.1.3 Reissue

Amendments to the Manual shall be carried out as required in section 5.5 to reflect the current Quality Assurance Programme. Each amended procedure is identified by the revision number on page one of the procedure and dated on the amendments list. Amendments are numbered consecutively until such time as an issue of the new Manual incorporates all amendments. Issues of Manuals are identified in alphabetical order.

Each issue cancels and supersedes all previous issues and amendments. The amendment list indicates all the amendments to the latest issue of the Manual. Amendments will not be implemented until the relevant section has been rewritten, approved by the Quality Assurance Manager and issued. The Quality Assurance Manager distributes amendments and reissues of the Manual to all registered holders.

#### 6.6.1.4 Internal Distribution

The Quality Manual is available through the computer network to the following personnel. There are also additional numbered hard copies.

- # Quality Assurance Manager/Production Manager. (Plus Hard copy No.1)
- # Managing Director.
- # Sales Manager/Estimator.# Sales Director.

Sales Director. Designer. Technical Manager. Office Manager. Toolroom Supervisor. Works Copy. (Hard copy only – copy No. 2)

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S.G.S. Yarsley. (Hard copy only – copy No. 3)

# Indicates a member of the Quality Review Committee

#### 6.6.2 PROCEDURES AND OTHER DOCUMENTS

All written procedures and other controlled documents are issued by the Quality Assurance Manager to all people who require a copy for the effective operation of the quality programme. The Quality Assurance Manager will ensure that the issued procedures are fully maintained.

#### 6.6.3 DRAWINGS

For issue of drawings used in manufacture seeTK-QP-002 Design Control Procedure.

#### 6.7 DOCUMENT CHECKING

It is the responsibility of the users of the documents to ensure that they remain legible and readily identifiable. If a problem is found with a document, the Quality Assurance Manager should be informed immediately.

#### 6.8 OBSOLETE DOCUMENTS

To prevent the unintended use of obsolete documents any such documents will either be disposed of or will be suitably marked to identify them as obsolete if they are to be retained for any purpose.

#### 6.9 DOCUMENTS OF EXTERNAL ORIGIN

Any documents that originate from sources external to Thomas Keating Limited and which are used in processes that might affect the effectiveness of the Quality Management System will be identified and controlled.

The Sales Director or Sales Manager shall acknowledge acceptance of customer specifications, drawings and standards that shall be subject to the same document controls.

## 7. REVIEW PROCEDURE

Any suggested improvements or modifications to this procedure are to be passed on to the Quality Assurance Manager for discussion at the next Quality Review Committee meeting.

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