Purpose

This procedure was established to define the controls needed:

a) to approve documents for adequacy prior to issue, in E2 Document Control,
b) to review and update as necessary and re-approve documents, in E2 Document Control,
c) to ensure that changes and the current revision status of documents are identified, in E2 Document Control,
d) to ensure that relevant versions of applicable documents are available at points of use, print from in E2 Document Control only,
e) to ensure that documents remain legible and readily identifiable, all documents are electronic and are identified by a header,
f) to ensure that documents of external origin are identified and their distribution controlled, and, documents are stamped and distributed,
g) to prevent deterioration or loss of documents, all documents are backed up,
h) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose, documents are retired in E2.

In addition, all documents of external origin are controlled as described in *QMSP-1003 Requirements Review/ Contract Review*. At the point of requirements review, which is when the external documents arrive at the company, all appropriate documents are examined per *QMSP-1003 Requirements Review/ Contract Review*. Examples of appropriate documents are drawings, specifications, customer purchase orders and any requested data.

Obsolete documents are retained in the E2 system, within the Quality Module, under Document Control. This is accomplished by changing the document status to “Retired”. This prevents the unintended use of the document as well as applying suitable identification to the document for the purpose of retaining the document. All obsolete documents will be retained for no less then three years from the date of retirement.

Coordination of document changes with customers is handled according to *QMSM-1009 Order Entry*. See *QMSM-1009 Order Entry* for data entry instructions into the E2 system.

General

All controlled documents are written in English, and they are electronic. They are stored in the Controlled Document Repository, on a server which is backed-up daily and tracked through E2 Shop System / Quality / Document Control. The Controlled Document Repository resides on a shared network drive in a directory with the following file system attributes: All employees have READ-only access to all files with the following exceptions: The system administrator grants, READ, WRITE, EDIT and DELETE access to the directory and files to personnel at the direction of the Quality Manager or the person designated to do so by the President of the company. Any employee who wishes to view a controlled document can do so in either hard copy or electronically by requesting it from their supervisor. Documents are named as follows:

QMSX-yyyy [Document Name]

The first 3 letters refer to the function responsible for it, e.g. "**QMS**" = Quality Management System.

The next letter "**X**" refers to the document type. Currently, there are four distinct document types at ROSEWOOD MACHINE AND TOOL CO., they are as follows:

- P = Quality Management System **Procedure**
- F = Quality Management System **Form**
- M = Quality Management System **Map** (as in "Process Map")
- D = Quality Management System **Document** (as in "Quality Manual", etc.)

The next four letters "**yyyy**" refer to a unique number assigned to the file for sorting purposes.

The [**Document Name]** defines the usage of the document. For example, this document is "QMSP-1001 Control of Documents". This name describes a Quality Management System **Procedure**, with a unique number, i.e. "1001" and is utilized to describe the Control of Documents Procedure.

All documents have a revision number, "**Rev. X.Y**", where "**X**" = the major version number and "**Y**" = the minor version number. The major version number is increased by 1 at each major revision, and the minor version number is increased by 1 at each minor revision. When a document is first created it is assigned the revision number "**Rev. 1.0**". After the document has been created and "**Rev. 1.0**" is edited for the first time, the revision number will change to either "**Rev. 1.1**" for a minor revision or "**Rev. 2.0**" for a major revision. An example of a minor revision would be editing out some misspelled

words. An example of a major revision would be adding an entirely new section to a manual.

All documents have an "**Effective date**" of the most recent revision. This is the date that the document was last revised.

All documents have Page x of y, where "x" is the number of the current page and "y" is the total number of pages contained in the document.

The actual procedure below outlines the tasks required to create a new controlled document, Document Creation, store all controlled documents in the Controlled Document Repository, edit an existing controlled document, and how to obtain a list of Controlled Documents that have been printed.

Procedure for Controlled Documents – New documents

Step 1. Document Creation

a) Begin by opening the file *QMSF-1004 Document Header*.doc, which is a Microsoft Word file. Create your document using Microsoft Word as you would normally. In the case of a Microsoft Visio document, open Microsoft Visio and create your document as you would normally. Once you have completed the drawing, open the file *QMSF-1004 Document Header*.doc. Now copy the contents of your Microsoft Visio document and paste it into the file *QMSF-1004 Document Header*.doc.

b) Draft versions are saved on the individual's hard drive until complete, content-wise. Save your file with the appropriate file name in the Controlled Document Repository. The file name adheres to the file naming strategy previously described. For example, if you have just created a new procedure and your QMS documentation currently contains six procedures, name the next one seven, e.g. "QMSP-1009 New Procedure". Be sure to update the file names within the gray bar at the top of the document with the new document number and save the file.

Step 2. Attach the document in E2

a) Log onto the E2 Application.
b) Select **Quality** from the E2 menu and then **Document Control**.
c) In the top left corner of the **Document Control** window, select **New**. This will bring you to the **Add Document** window. You will notice that the Document Number field is highlighted and filled in. Type in the new procedure name (first nine characters only in the Document Number field. For example, if we were attaching the document created in step1 above, we would type in "QMSP-1009".

Step 3.

a) Return to the open **Add Document** window in E2. Place the cursor in the Description box, left click the mouse to activate the field and fill in the document description.
b) Next, from the **Document Type** pull down menu, select the appropriate document type, in this case "**Procedure**".
c) The **Document Status** field will be filled in automatically for a new document and should display "**Proposed**".
d) Place the cursor in the **Revision Level** box, left click the mouse to activate the field, and type in the revision level of the document. (See the General section above for assigning a revision number to a document).
e) Place the cursor in the **Revision Date** box, left click the mouse to activate the field, and the current date will be filled into the box.
f) Go to the **File Attachment** section in the lower right corner of the Add Document window and select **Attach**.
g) This will open a Browse for Document window. Locate the document in the Controlled Document Repository, which you just renamed. Highlight the document and click **Open**. The document will be selected and will now appear in the Path/Filename field of the **Add Document** window.
h) Click on the **OK** button in the upper right of the Add Document window to complete Step 4.

Procedure for Controlled Documents – Editing an Existing Document

a) Log onto the E2 Application.
b) Select Quality from the E2 menu and then **Document Control**.
c) Use the **Search** button at the bottom to find the document you wish to edit. Next, click on the document in the list and the document will become highlighted.
d) Click on the **Edit** button. This will bring up the Update Document Window. The information for the document you selected previously will now be displayed in the Update Document Window.
e) In the Update Document Window, select the Revision History tab.
f) Click on the New Revision button, this will bring up the Create New Revision Window. Fill in the New Revision Level and briefly describe the changes you are about to make to the document in the comments section.
g) In the Create New Revision Window, select the File Attachment tab.
h) Click on the Edit button.
i) Make the changes to the document.

j) Update the Rev. number within the gray bar at the top of the document, following the guidelines from the "General" section above regarding document revision changes, and update the date. **Save** the document and exit the application.
k) In the Create New Revision window, click the **OK** button.
l) This will bring up the Confirm Revision Change Window, click on the Yes button.
m) In the Update Document Window, click the **OK** button.
n) The E2 database is now updated.

Procedure for Controlled Documents – Approval Guidelines

Anyone can propose a new document in the E2 System. Generally, this is done by the owner of that process. All documents must be approved and released by the Management Representative or Quality Manager once the document is completed and proposed or has been brought to a new revision.

a) Log onto the E2 Application.
b) Select Quality from the E2 menu and then **Document Control**.
c) Use the **Search** window at the bottom to find the document. Next, click on the document in the list and the document will become highlighted.
d) Click on the **Edit** button. This will bring up the Update Document window. The information for the document you selected previously will now be displayed in the Update Document window.
e) Next, in the Update Document Window click on the **Email** button. This will bring up the New Message window.
f) In the New Message window select **Address** from the menu, then **E2 Address Book**. This will bring up the Address Book window. The window will contain a list of Contacts, go to the contact list, under E2 users, and click on the name of the person you are sending this to. Their name should be highlighted.
g) Now go to the bottom of the Recipient Section and click on **Add to List**. This will display the name in the Recipient Section. Repeat this process to add additional names. Click on **OK**.
h) This will take you back to the New Message Window. Type in the appropriate message and click on the **Send** Button (the **Send** Button looks like and envelope with a stamp on it). This will take you back to the Update Document Window. Click on the **OK** button. This will initiate the

Management approval phase. Once the authorized person has approved the proposed change, they will change the document status to Released.

Procedure for Controlled Documents - Obtaining a List of Controlled Documents that have been printed

By definition, a printed document is no longer a controlled document because a document revision could occur at anytime, and at that point the printed document is out of rev. In order to avoid this situation, we need a method to track printed documents and destroy them when a revision occurs. This process is detailed below.

The Document Control Summary report in E2 is utilized to control hardcopies of controlled documents. Any hardcopy of any controlled document is logged in E2 under Quality, Document Control in the description field of the Update Document and using the word “copy”. The following format is recommended “copy – 5 copies to <Employee Name Here>”. This report can be run to find out how many copies are outstanding at any given time. When the copies are returned or destroyed, follow the above steps and remove the comment “copy – 5 copies to <Employee Name Here>”.

a) Log onto the E2 Application.
b) Select **Quality** from the E2 menu and then **Document Control Summary** at the bottom.
c) Make sure none of the boxes are checked in the main section if you want a complete list of all documents. Otherwise, check the boxes to apply the filters to obtain the document list you’re looking for. To obtain a report showing which documents have printed copies outstanding, filter for “description like” and type “copy” into that field.
d) In the bottom right, choose the **Report Destination** (screen, printer, etc.) and then hit **Generate Report.**