



ROSEWOOD MACHINE AND TOOL CO.	QMSP-1008 Risk Management		
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Purpose

The purpose of this procedure is to specify a risk management process for the company to identify the hazards associated with manufacturing products and to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. This procedure/process is intended to establish and document a risk management plan in accordance with the risk management process. This procedure along with the resultant documented information of the risk assessment comprises the risk management file.

General

This procedure establishes, documents, and maintains, throughout the life-cycle, an ongoing process for identifying hazards associated with manufacturing the company's products. The procedure also defines the process for estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the controls.

It is the responsibility of the Quality Manager at the company or his/her designated appointee to execute the risk management plan and maintain the required documented information.

Procedure for Risk Management

This procedure has two component parts. The component parts utilized together in harmony comprise the risk management process at the company. There are three documents used or referred to or both by this procedure as part of the risk management process. They are this document *QMSP-1008 Risk Management*, *QMSF-1015 PFMEA* and *QMSD-1006 PFMEA Directions*. These documents also represent the risk management file (i.e., set of documented information and other documents that are produced by risk management).

To perform the procedure, read the *QMSD-1006 PFMEA Directions*, obtain the document *QMSF-1015 PFMEA*, and perform the failure mode and effect analysis on the part in question. Document the results on the form.

Risk Management Report

Documenting the results of the analysis and evaluation on *QMSF-1015 PFMEA* serves as the risk management report.

Production and Post-Production information



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Any information discovered during in-house testing that could have an adverse affect on risk management is entered into the Corrective Actions portion of the E2 Quality Module, see *QMSP-1006 Corrective Actions*.

Any post-production information obtained from clients in the field is entered into the Feedback portion of the E2 Quality Module. This assures the review of risk management as all feedback reports are reviewed by management at management review meetings on a regularly scheduled basis.