1.0 Purpose of Procedure

This document is intended to describe the The Risk Management Process as part of the Design and Development Process for Product Resources commitment under our Quality System.It provides for a procedure and assigns responsibilities.

2.0 Scope of Process

The scope of this procedure is to describe the Risk Management Process as it pertains to the Overall Design and Devlopment Process

3.0 Process Owner(s)

3.1 Engineering Manager

4.0 Procedure

4.1 Responsibilities

4.1.1 Operational Responsibility

The Project Manager has the responsibility to oversee the Risk Management Process and ensure that all required activities and documentation are performed and recorded.

4.1.2 Approval Responsibility

The Project Manager has the responsibility and authority to approve Risk Management output documents, if any, for less complex projects, Class 1-4, non-Medical and non-explosive atmosphere.
On complex projects (Class 5) or projects for Medical Devices or explosive atmosphere compliant products, the Quality Manager, or designee, has oversight of the Risk Management Process and must approve the Risk Management output documentation.

4.2 Process Description

4.2.1 Planning

The Project Manager shall refer to the Project Checklist to determine which Risk Management items need be completed, if any. The Checklist and Project Classification will indicate the recommended Risk Management documents to be completed. If the Project Manager decides not to complete certain documents, the reason must be stated on the Checklist.
If additional documents or activities are to be completed and tracked, they must be added to the Checklist.
For all documents described here, existing risk management documents for this or related products shall be used as the starting point for new risk management activities.
The Project Manager or designee shall generate a Risk Management Plan, and get approval if required by the process or the contract.

- **Risk Management Plan**

  The Risk Management Plan shall identify all Risk related design and development activities. It may be, at a minimum, the Project Checklist which calls for certain activities to be performed and documentation to be completed. If necessary by the complexity of the project or contract requirements, the Plan may be a separate document suitable for the project. If Risk Management activities are required, they shall be indicated in the Plan and indicated on the Checklist.

If required for the project, the Plan shall be filed in the sub-directory indicated on the Checklist.

- **Other Risk Management Activities**

  If required by the Plan, and as indicated on the Checklist, documents shall be completed and filed.

4.2.2 Design Engineering

Based upon the Checklist requirements, complete the following:

- **Hazard analysis**

  The Hazard Analysis shall be completed if required by the Risk Management Plan as indicated on the Checklist. Use the Hazard Analysis Template or the customer's requested format.
  If required for the project, the Hazard Analysis shall be filed in the sub-directory indicated on the Checklist.

- **Application FMEA**

  The Application FMEA shall be completed if required by the Risk Management Plan as indicated on the Checklist. Use the Application FMEA Template, or the customer's requested format.
  If required for the project, the Application FMEA shall be filed in the sub-directory indicated on the Checklist.

- **Design FMEA**

  The Design FMEA shall be completed if required by the Risk Management Plan as indicated on the Checklist. Use the Design FMEA Template or the customer's requested format.
  If required for the project, the Design FMEA shall be filed in the sub-directory indicated on the Checklist.

- **Other Design Engineering Risk Management Activities**

  If required by the Plan, and as indicated on the Checklist, documents shall be completed and filed as designated on the Checklist.

- **Updates to Risk Analysis Documents**

  All Risk Analysis documents generated during the Design Engineering phase shall be reviewed and updated at the end of this phase.

4.2.3 Manufacturing Engineering

Based upon the Checklist requirements, Complete the following:

- **Process FMEA**

  The Process FMEA shall be completed if required by the Risk Management Plan as indicated on the Checklist. Use the Process FMEA form 80-3000 or the customer's requested format. Refer to 91-7006, Product Process Analysis and Validation for more information on Process FMEA.

- **Other Manufacturing Engineering Risk Management Activities**

If required by the Plan, and as indicated on the Checklist, documents shall be completed and filed as designated on the Checklist.

- **Updates to Risk Analysis Documents**

  All Risk Analysis documents generated during the Manufacturing Engineering phase shall be reviewed and updated at the end of this phase.

5.0 Control of Documents

The storage location and retention period for records referenced above are given in 91-6002, Control of Records.