Risks and Opportunities Guidelines

- The risks and opportunities are determined and addressed in order to ensure that the QMS can achieve its intended result(s), prevent, or reduce, undesired effects, and achieve continual improvement.
- Options to address risks and opportunities can include: avoiding risk, taking risk in order to pursue an
 opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or
 retaining risk by informed decision.
- Actions to address the risks and opportunities are planned in order to integrate and implement them into the processes and to evaluate the effectiveness of these actions.
- Actions taken to address risks and opportunities are proportionate to the potential impact on the conformity of products and services.
- With inputs from the Quality team / ISO steering committee, this risk and opportunity worksheet is prepared by the Quality team leader / ISO management representative.
- The Quality team / ISO steering committee is responsible to set priorities for projects where risks and opportunities need to be addressed and to assign risk or opportunity project responsibilities.

The following instructions are used to assess the risks associated with the planning of the QMS processes and to assign priorities for the actions needed to address the risks and opportunities.

To determine the risks and opportunities that need to be addressed:

- In table below identify the activities/processes that are risk and opportunity candidates.
- Assign a value for each assessment category.
- R-values of 1 and 2 represent Risks/Threats, and O-values of 3 and 4 represent Opportunities.
- The project planning worksheet F-810-002 is used to plan high priority projects.

Customer Impact: How much does the customer care?

- 1 = Low customer priority
- 4 = Very important to the customer

Changeability Index: Can you fix it?

- 1 = Very Difficult / Expensive to fix
- 4 = Relatively easy / cheap to fix

Performance Status: How broken is it?

- 1 = Only a few problems in the past
- 4 = Always seems to be causing problems

Business Impact: How important is it to the business?

- 1 = Has little impact on the business
- 4 = Is very important to the business

Work Impact: What resources are available?

- 1 = People who have capability to work on this activity are scarce
- 4 = People who have capability to work on this activity can be available

INSERT YOUR COMPANY LOGO/NAME HERE

F-610-001 Risk and Opportunity Worksheet

Risk Analysis - Risk Management Worksheet - Optional Method

The first 6 columns of this form are used to list the Potential Risks and Assess the Significance of the Risks.

The last 2 columns of this form are used to indicate whether or not the Process Step / Activity are at risk and require attention.

- * Refer to process steps / activities where the process details can be identified, describe in process flow diagrams.
- ** Where both the Severity and the Likelihood are high, the risk is significant and the Process Step requires corrective action.

* Step	What is present or could be introduced as a risk?	Description of Risk	Significance ** 1 = Severity 2 = Likelihood 3 = Significance		Does a next step in process eliminate the risk?	What controls exist to address the risk?	Is the Process Step at risk? Yes / No	** If YES, Issue the Corrective Action Request	
			1 2 3		Justifications			CAR#	

Compiled by management representative:	, Date:
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