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|  | | | <h2>Risk Management</h2> |
| QMS PQ-6 | Rev B | Date 08-17-17 | Procedure Authority: Quality Assurance Manager |

Purpose: This procedure was created to describe our policy as it relates to risk management.

Scope: The process refers to internal and external risks that impact our processes, and associated equipment, facilities, infrastructure, work force, as well as risks specific to our supply chain.

Responsibility: The Quality Manager is responsible for administering this procedure and Executive Management is responsible for its practice and execution.

Definitions:

ALARA = As low as reasonably achievable.

Reference Documents:

Procedure:

1. Executive management will ensure that internal and external risks to all manufacturing processes and associated equipment, facilities, infrastructure, work force, as well as risks specific to supply chain matters, are identified, evaluated and reconciled with appropriate actions.
2. Our model for risk assessment is expressed in the following matrix, used in a literal or figurative sense, to drive proportionate actions meant to mitigate or eliminate the risk.

| | | | |
|--|------------------------------|---|------------------------------|
| Evaluation & Actions Priority | Low – Acceptable risk | Medium – Reduce risk (ALARA) As low as reasonably achievable | High – Not acceptable |
|--|------------------------------|---|------------------------------|

| Analysis Probability x Severity = Risk Priority | | | Severity | | | |
|--|---|-----------------------|-----------|--------------|-----------------------------|-------------------------|
| | | | 1 | 2 | 3 | 4 |
| | | | No Impact | Minor Impact | Moderate, reversible impact | Major, permanent impact |
| Probability | 1 | Not expected to occur | 1 | 2 | 3 | 4 |
| | 2 | Rarely occurs | 2 | 4 | 6 | 8 |
| | 3 | Sporadically occurs | 3 | 6 | 9 | 12 |
| | 4 | Frequently occurs | 4 | 8 | 12 | 16 |

Procedure contd:

- 3. Upon discovery of a risk potential, the associated department manager, will work within the spirit of the model to approximate probability, severity and determine a resulting risk priority, i.e. Low, Medium, or High
- 4. Depending on the priority level, actions will be taken as follows:

| Priority | Actions |
|-----------------|---|
| Low | Acceptable Risk, no immediate changes are recommended |
| Medium | Notify top management, reduce risk ALARA, with cross functional team as necessary. |
| High | Immediate notification to top management, administer detection and/or containment actions as necessary, assemble cross functional team and reduce risk ALARA. |

- 5. Risks determined to be at a Medium or High priority level will be presented to an Executive management team for proper administrative attention.
- 6. Once an identified risk has been reconciled, the affected process or circumstance will be monitored for effectiveness.

AMENDMENT RECORD

| Revision | Date | Details | Authority |
|-----------------|-------------|--|------------------|
| A | 04-14-03 | Originated | E. Ide |
| B | 08-17-17 | Formerly was Preventive Action; now changed to Risk Management to align with IATF 16949 standard | E. Ide |
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