

			<h2>Contingency Plans</h2>
QMS PQ8	Rev B	Date 10-10-17	Procedure Authority: Quality Assurance Manager

Purpose: This procedure was created to describe and to direct actions related to our “Contingency Plans”.

Scope: The process includes contingent planning and intervention related to internal and external risks that impact our processes, and associated equipment, facilities, infrastructure, work force and supply chain.

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

Definitions:

Reference Documents:

Procedure:

1. Executive management will ensure that internal and external risks to all manufacturing processes and associated equipment, facilities, infrastructure, work force and supply chain are identified and evaluated with a focus on meeting requirements.
2. We’ve taken these risks into account and developed contingency plans according to the risk and impact to all interested parties. These risks and contingent responses are conceptualized and illustrated in the following table:

Risk	Contingent Response; (Not necessarily done in this order)			
	1	2	3	4
Equipment Failures	Repair with internal resources	Repair with external resources	Run with alternate equipment	Contract production to contingent supplier
Facility Failures*	Work Overtime	Restore with internal resources	Restore with external resources	Contract production to contingent supplier
IT Failures	Re-establish with internal resources	Re-establish with external services	Initiate manual systems	
Personnel Shortages	Work Overtime	Deploy temp. agency	Run with management and office personnel	Contract production to contingent supplier
Supplier Failures	Contract to alternate sources			

*Note: Facility failures include facility damages and/or utility interruptions

Procedure contd:

3. If at any time, a contingency plan is enacted; all interested parties will be notified to the extent and duration of any situation impacting requirements. Relevant control measures will be performed, consistent with already established methods, and meeting all requirements will be a top priority.
4. Upon completion of an enacted contingency plan, and preceding normal production start-up, the associated product or service will be validated to verify compliance to specifications.
5. Periodically, we will test the contingency plans and the tests will be performed in a manner which provides reasonable satisfaction of effectiveness.
6. Contingency plans will be reviewed by a multidisciplinary team, including top management. These reviews will take place annually and changes will be incorporated as appropriate.
7. Specific changes will be documented and controlled, consistent with the requirements of procedure PQ1 “Control of Documents”.

AMENDMENT RECORD

Revision	Date	Details	Authority
A	08-22-17	Originated	E. Ide
B	10-10-17	Eliminated a duplicated step (#8 was a repeat of step #4)	E. Ide