1.0 Purpose/Scope

1.1 This procedure describes the process for controlling the design and development of product or services to ensure the subsequent provision of products and services at Your Company.

1.2 The procedure applies to the design and development projects that are initiated and planned for new products or services.

2.0 Responsibilities and Authorities

2.1 The Research & Development / Technical manager has the prime responsibility and approval authority for this procedure.

2.2 In support of the Research & Development / Technical manager, the Project manager / design engineer are responsible for initiating the design plan, getting appropriate approvals and holding design reviews.

2.3 Additional responsibilities for project manager / design engineer / design team / sales and marketing personnel are detailed in relevant paragraphs of section 5.0.

3.0 References and Definitions

3.1 Reference

3.1.1 This document relates to clause 8.3 of the AS 9100 D standard covering, Design and development of products and services.

3.2 Definitions

3.2.1 Design Verification: Determination that the product meets requirements.

3.2.2 Design Validation: Determination of the product's ability to meet user needs.

3.2.3 Design Changes: Changes made to the inputs or plan during design and development activities.

4.0 Resources

4.1 None

5.0 Instructions

5.1 In support of the planning procedures P-810 for Operational planning and control, and P-910 for Monitoring, measurement, analysis and evaluation, design and development projects are initiated and planned for new products or services, or processes.

5.1.1 The need for a new product, service or process is based on customer requests, market conditions, new product, service or process ideas, new equipment or other situation when the detailed requirements are not already established or not defined by the customer or by other interested parties.

5.1.2 Design projects detail the requirements for products and services so that

1.0 Purpose/Scope

1.1 The purpose of this procedure is to provide a method to assist assigned individuals in performing consistent, complete, satisfactory root cause analysis.

2.0 Responsibilities and Authorities

2.1 The Management Representative is responsible for determining whether or not a Root Cause Analysis is appropriate for the situation.

2.2 The Management Representative is responsible for ensuring that all completed Root Cause Analysis documentation is filed and stored appropriately.

2.3 The Management Representative is responsible for the overall coordination of the Root Cause Analysis process including closure after satisfactory results have been obtained.

2.4 The Management Representative is responsible for the coordination of root cause analysis training with procedure P-720 for Competence and awareness.

3.0 References and Definitions

3.1 References

3.1.1 This document relates to clause 9.1.3, Analysis and evaluation and clause 10.2, Nonconformity and corrective action, of AS 9100 D standard.

3.2 Definitions

3.2.1 Cause: An event or condition that results in an effect. Anything that shapes or influences the outcome.

3.2.2 Event: A real-time occurrence describing one action, typically an error, failure, or malfunction or unwanted condition.

3.2.3 Condition: Any found state, whether or not resulting from an event, that may have safety, health, quality, security, operational, or environmental implications.

3.2.4 Barrier: A physical device or an administrative control used to reduce risk of the undesired outcome to an acceptable level. Barriers can provide physical intervention or procedural separation in time and space.

3.2.5 Contributing Factor: An event or condition that may have contributed to the occurrence of an undesired outcome but, if eliminated or modified, would not by itself have prevented the occurrence.

3.2.6 Organizational Factors: Any operational or management structural entity that exerts control over the system at any stage in its life cycle, including but not limited to the system's concept, development, design, fabrication, test, maintenance, operation, and disposal.

3.2.7 Root Cause Analysis (RCA) a structured evaluation method that identifies the root causes for an undesired outcome and the actions adequate to prevent recurrence. Root cause analysis should continue until organizational factors have been identified, or until data has been exhausted.

3.2.8 Root Cause(s): One or more factors that contributed to or created the proximate cause and subsequent undesired outcome and, if eliminated,

INSERT YOUR COMPANY LOGO/NAME HERE

P-1020-A

Nonconformity and Corrective Action

1.0 Purpose/Scope

1.1 This procedure describes the process at Your Company for dealing with nonconformity through the use of a system for corrective action.

1.2 The procedure applies to the process of dealing with non-conformances and determining effective corrective action.

1.3 This procedure provides and maintains the documented information that defines the nonconformity and corrective action management processes.

2.0 Responsibilities and Authorities

2.1 The Quality assurance manager has the prime responsibility and approval authority for this procedure.

2.2 In support of the Quality assurance manager, the Quality team / AS steering committee is responsible for dealing with the consequences of non-conformances and to determine effective corrective action.

2.3 Additional responsibilities for the Employees, the Supervision, the Corrective action coordinator / management rep are detailed in relevant paragraphs of section 5.0 below.

3.0 References and Definitions

3.1 Reference

3.1.1 This document relates to clause 10.2 of the AS 9100 D standard, Nonconformity and corrective action.

3.2 Definitions

3.2.1 Corrective Action: Action taken to eliminate the cause of a non-conformance that has occurred, and prevent reoccurrence of the nonconformance.

3.2.2 Preventive Action: Action taken to eliminate the cause of a potential non-conformance and prevent the nonconformance from occurring.

3.2.3 The concept of preventive action is expressed through a risk-based approach in dealing with remedial action.

4.0 Resources

4.1 None

5.0 Instructions

5.1 In support of the procedure P-1010 for Improvement, this procedure addresses nonconformity and corrective action.

5.1.1 The Quality assurance manager / Quality team / AS steering committee ensures that non-conformances are dealt with as they occur and that corrective action is taken to control and correct it.

5.2 Nonconformity and corrective action request (CAR) is used to evaluate the need