AS 9100 D

Quality Management Systems

Quality Manual / Documented Information

Document No. QM-9100-D

Street Address

City, State, Zip

Tel,

Cell Phone:

Email:

Web Site:

Introduction

Your Company developed and implemented a Quality Management System in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

To fully understand the organization and its context, Your Company determined the external and internal issues that are relevant and that affect its ability to achieve the intended results of the quality management system.

The Quality Management System of Your Company meets the requirements of the international standard AS 9100 D. The system addresses the design, development, production, installation, and servicing of the company's products. It incorporates the process approach where consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes.

This process approach provides for the management of the quality system and its processes through the application of a "Plan-Do-Check-Act" methodology and a focus on "Risk-Based-Thinking" leading to the prevention of undesirable outcomes.

The manual is divided into sections that correlate to the Quality Management System sections of AS 9100 D. The manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides the documented information with procedures or references for all activities comprising the Quality Management System that ensures the compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the AS standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or interested parties. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

The manual is approved by a top management representative.

President: _____ Date: _____

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 NAME/LOGO HERE

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Key Characteristic – Critical Item Identification

Instructions: Use the following table to record the identification and justification for the designation of a characteristic as a key characteristic.
Delete the blue, italicized type as you start to complete the form.

Key Characteristic Identification				
Document Number:		Description:		
Engineer:		Date:		
Characteristic Selected	Relevancy	Analysis Performed	Summary of Analysis Results	Justification for Designation as a key characteristic
Enter selected key characteristic.	• *Product fit* • *Form* • *Function* • *Performance* • *Service life* • *Producibility*	*Describe the various types of analysis performed.*	*Enter the summary of all analysis performed.*	*Enter the justification / need for designating this particular characteristic as a key characteristic.*

Attach all data, reports and summaries referenced in the above table that support the key characteristics selected above.