

1.0 Purpose/Scope

- 1.1 The purpose of this procedure is to establish the process for the monitoring, measurement, analysis and evaluation of product realization processes and the QMS processes at ACCES I/O.
- 1.2 The procedure applies to product realization processes and QMS processes where performance is evaluated.

2.0 Responsibilities and Authorities

- 2.1 The Production Manager has the prime responsibility and approval authority for this procedure.
- 2.2 In support of the Production Manager, the Quality team is responsible for identifying the appropriate monitoring, measurement, analysis and evaluation processes.
- 2.3 Additional responsibilities 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 9.1 of the ISO 9001:2015 standard, Monitoring, measurement, analysis and evaluation.

3.2 Definitions

- 3.2.1 Product Realization: Processes from customer input through delivery and service) that lead to the creation of the final product or service.

4.0 Resources

- 4.1 None

5.0 Instructions

- 5.1 In support of the procedure P 810-001 for Operational planning and control, this procedure addresses the monitoring, measuring, analysis and evaluation of both the product realization processes and the QMS processes.
 - 5.1.1 For the products and services, the VP of Operations and/or the Quality Team determines what needs to be monitored and measured, the methods for monitoring, measurement, analysis and

evaluation, when the monitoring and measuring is to be performed, and when the results from monitoring and measurement are to be analyzed and evaluated.

- 5.1.2 The Quality Team makes use of the results of analysis are used to evaluate:
- Conformity of products and services,
 - Degree of customer satisfaction,
 - Performance and effectiveness of the QMS,
 - Effectiveness of actions taken to address risks and opportunities,
 - Performance of external providers,
 - Need for improvements to the QMS.
- 5.2 As new products and services are developed, the procedure, P 830-001 for Design and development, provides monitoring, measurement, analysis and evaluation inputs.
- 5.3 Monitoring and measuring requirements for the QMS processes are documented on the Management Review Output, F 930-002.
- The process requiring measurement (Process Point)
 - The planned measurement
 - Measurement frequency
 - Function responsible for measurement (Performed by)
 - Function responsible for analysis (Analyzed by)
 - Analyses methodology
 - Quality Objective to measure against (Documentation)
 - Improvement goals (Quality Objective)
- 5.3.1 The responsible functions perform the required inspection or monitoring.
- 5.3.2 The responsible functions prepare summaries of performance. The Quality Team analyzes the data prior to review as defined in the procedure P 930-001 for management review.
- 5.4 Review and evaluation of processes

- 5.4.1 The Quality Team identifies what summaries are required from data generated by measuring and monitoring of product and product realization processes.
- 5.4.2 The Quality Team identifies customer feedback projects as identified from the customer satisfaction procedure P 912-001 and assigns responsibility for improvement projects.
- 5.4.3 The Quality team evaluates the performance of external providers with the procedure P 840-001 for control of external providers.
- 5.4.4 The Quality team identifies continual improvement opportunities through the analysis and evaluation of data generated by the QMS with the procedure P 1010-001 for Improvement.
- 5.4.5 Records associated with the monitoring, measuring, analysis and evaluation are retained as evidence of the results with the procedure P 750-001 for Control of documented information.
- 5.4.6 The review and evaluation of processes may also be conducted with the use of a turtle diagram.

6.0 Forms and Documented Information

- 6.1 Documented information / Related processes
 - 6.1.1 P 600-001 Planning for the Quality management system
 - 6.1.2 P 715-001 Control of monitoring and measuring equipment
 - 6.1.3 P 750-001 Control of documented information
 - 6.1.4 P 810-001 Operational planning and control
 - 6.1.5 P 830-001 Design and development
 - 6.1.6 P 840-001 Control of external providers
 - 6.1.7 P 912-001 Customer satisfaction
 - 6.1.8 P 930-001 Management review.
 - 6.1.9 P 1010-001 Improvement

7.0 Opportunities and Risks

- 7.1 The planning procedure P 600-001 for Planning for the Quality management system addresses opportunities and risks (risk-based thinking).

7.2 ACCES I/O has identified the following risks and mitigation to those risks:

Potential Risks:

- 1) Objective information is not measured

Risk Mitigation

- 1) Ensure all KPI's are measurable.

8.0 Revision History

| Rev | Date | Section | Paragraph | Summary of change | Authorized by |
|-----|----------|---------|-----------|-------------------|---|
| A | 03/03/17 | | | Initial issue |  |
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