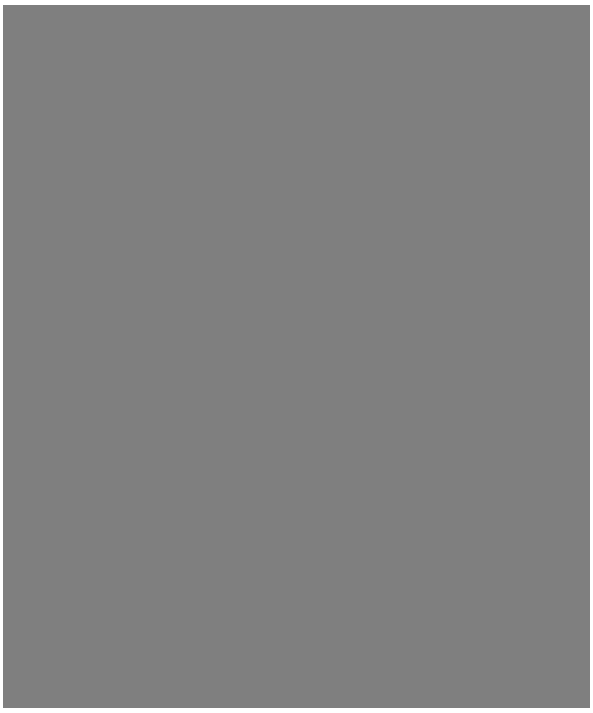


EQMS Procedure

Data Analyis

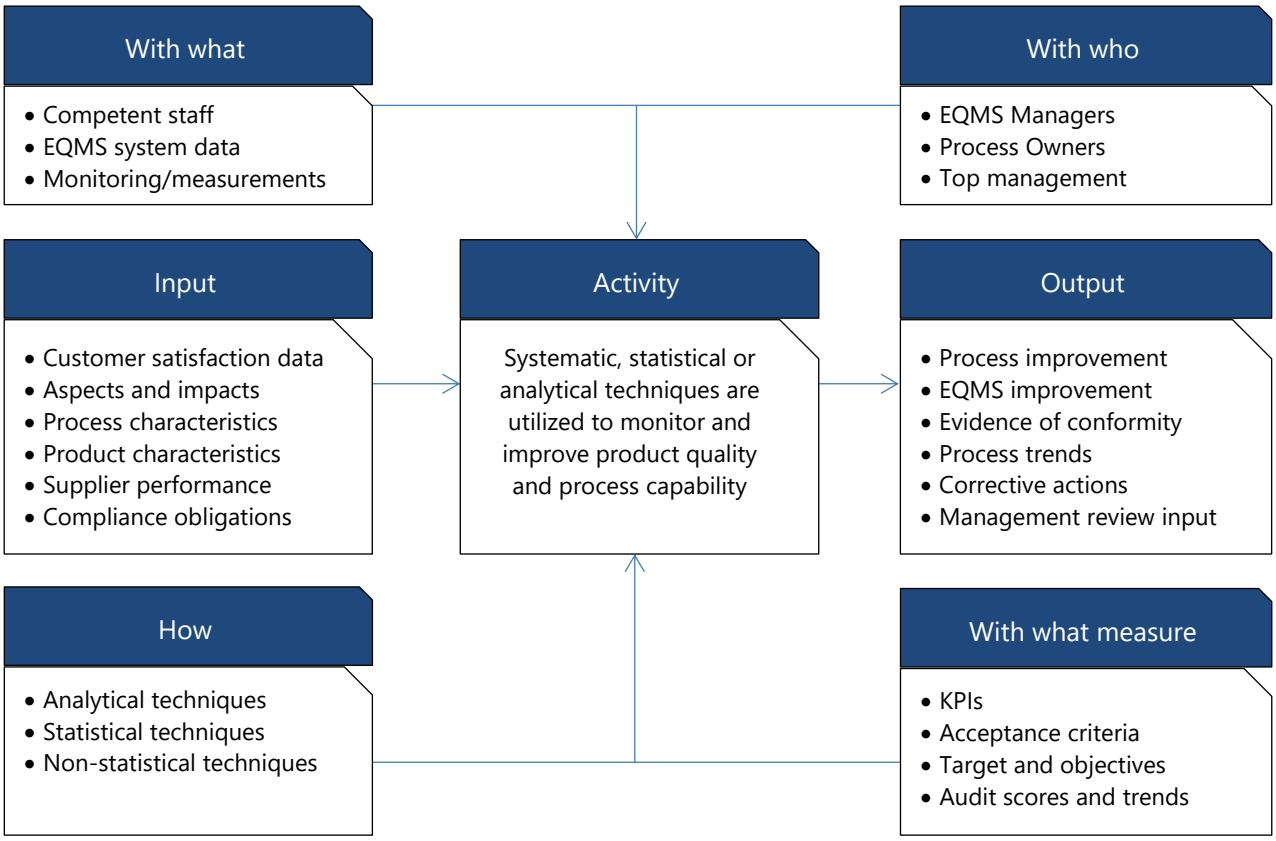
Table of Contents

1 Data Analysis

1.1 Introduction & Purpose

The purpose of this procedure is to establish and define the roles and responsibilities for analyzing and reporting EQMS data in order to drive continual improvement and to facilitate a factual approach to decision making.

1.1.1 Process Activity Map



1.1.2 References

Standard	Title	Description
BS EN ISO 9000:2015	Quality management systems	Fundamentals and vocabulary
BS EN ISO 9001:2015	Quality management systems	Requirements
BS EN ISO 14001:2015	Environmental management systems	Requirements
BS EN ISO 9004:2000	Quality management systems	Guidelines for performance improvements
BS EN ISO 19011:2011	Auditing management systems	Guidelines for auditing

1.1.3 Terms & Definitions

Term	Definition
Continual improvement	A recurring activity to increase the ability to fulfill requirements
Statistical Technique	Mathematical concepts, formulas, models used in the statistical analysis of data
Non-Statistical Technique	Sampling that relies on judgment to determine sample size, selection and evaluation

6. Adverse Event Reporting;
7. Process Controls;
8. Finished Product;
9. Internal and External Audits;
10. Product Recall;
11. Spare Parts Usage;
12. Service Reports;
13. Returned Product;
14. Market/Customer Surveys;
15. Scientific Literature;
16. Media Sources;
17. Design, Purchasing, Production, and Service and Customer Information;
18. Risk Management.

1.4.5 Measurement & Analysis using Data Sources

Once the data sources, data elements and acceptance criteria are specified, as part of the planning process, Your Organization performs measurement, monitoring and analyzes processes to determine levels conformity or non-conformity.

1.4.6 Measure

Data collected from the measurement of products, process and the EQMS are acquired throughout the life-cycle of the product. Your Organization defines the frequency of the measurement, precision and the accuracy of the data. Your Organization also ensures that the data collected is current and relevant.

Measurement data is retained as a quality record in a format that is retrievable, suitable for analysis and meets both EQMS and regulatory requirements.

Monitoring is the systematic and regular collection of a measurement. Your Organization defines, during the planning phase what, when and how data is monitored. The data is defined such that it can be analyzed for further action. The monitoring of data may be continuous or periodic, depending on the type of data source and elements within. The monitoring processes are periodically reviewed for continued suitability.

1.4.7 Analyze

Analysis is performed to identify non-conformity or potential non-conformity or to identify areas where further investigation should be initiated. In addition, analysis is used to demonstrate the suitability and effectiveness of the product, processes and the EQMS. Analysis is performed utilizing analytical tools, a team of experts, process owners or independent reviewers as required. The results of the analysis are documented.

After it is determined what will be measured, statistical techniques are identified to help understand variability and thereby help Your Organization to maintain or improve effectiveness and efficiency. These techniques also facilitate better use of available data to assist in decision making. Statistical techniques assist in identifying, measuring, analyzing, interpreting and modeling variability.

For the analysis of non-conformity, appropriate statistical and non-statistical techniques are applied, examples of statistical techniques which may be used are:

1.7 EQMS Data Points Process Map