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**ISO 9001:2015**

**Control of Analysis & Evaluation**

Approval

The signatures below certify that this management system procedure has been reviewed and accepted, and demonstrates that the signatories are aware of all the requirements contained herein and are committed to ensuring their provision.

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Amendment Record

This procedure is reviewed to ensure its continuing relevance to the systems and process that it describes. A record of contextual additions or omissions is given below:

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The electronic version of this procedure is the latest revision. It is the responsibility of the individual to ensure that any paper material is the current revision. The printed version of this manual is uncontrolled, except when provided with a document reference number and revision in the field below:

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1. Control of Data Analysis
   1. Introduction & Purpose

The purpose of this procedure is to establish and define the roles and responsibilities for collecting and analyzing data using appropriate statistical and non-statistical techniques to determine the suitability and effectiveness of key quality management system processes using data in order to drive continual improvement and to facilitate a factual approach to decision making.

* + 1. Process Activity Map

Output

* Process improvement
* QMS improvement
* Evidence of conformity
* Process trends
* Corrective actions
* Management review input

How

* Analytical techniques
* Statistical techniques
* Non-statistical techniques

With what measure

* KPIs
* Acceptance criteria
* Target and objectives
* Audit scores and trends

With what

* Competent staff
* QMS system data
* Monitoring/measurements

With who

* QMS Manager
* Process Owners
* Top management
* Design Team

Activity

Systematic, statistical or analytical techniques are utilized to monitor and improve product quality and process capability

Input

* Customer satisfaction data
* Process characteristics
* Product characteristics
* Supplier performance
* Data sources
* Data elements
  + 1. 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 9004:2018 | Quality management systems | Guidelines for performance improvements |
| BS EN ISO 19011:2018 | Auditing management systems | Guidelines for auditing |

* + 1. 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 |
| Product | Product for Manufacturing Made Easy Ltd is Product Design and maybe the prototype of the product (i.e. 3D model, 2D model). |

* 1. Application & Scope

Data analysis is a key part of our QMS. Manufacturing Made Easy Ltd uses appropriate techniques to support continuous improvement of products and processes. We monitor trends in:

1. Customer satisfaction and dissatisfaction data;
2. Conformity to product requirements;
3. Characteristics of processes, products and their trends;
4. Suppliers and their performance;
5. Quality management system data.

If issues are identified, we follow a standard process: investigate, find root causes, take action, verify results, and check effectiveness.

* 1. Responsibilities

The Quality Manager is required to:

1. Direct the use of statistical techniques;
2. Determine the need for the use of statistical, or non-statistical techniques;
3. Ensure that staff involved in the application of statistical techniques are provided with the necessary tools and knowledge;
4. Ensure that all staff involved in the application of statistical techniques are suitably trained.
   1. Analysis of Data
      1. Planning

As part of planning, top management reviews key processes to ensure they meet quality, and regulatory requirements. Relevant data sources are selected to support performance monitoring and improvement.

During planning, we consider:

1. Identification of relevant internal and external data sources that are indicators of process and product performance;
2. Provision for adequate resources and establish responsibilities and authorities to enable the necessary actions.
3. Resources may include technical experts, testing laboratories, data management, infrastructure, training, etc.;
4. Definition of requirements for each identified data source, including limits, acceptance criteria, escalation criteria and mechanisms for reporting of non-conformities or potential non-conformities;
5. Analysis of data elements within data sources;
6. Coordination and analysis of data across data sources.

Criteria are defined for each data element—quantitative where possible, and clear even when qualitative—to support consistent analysis. Acceptance criteria are based on system, product, and process requirements, usually identified during design and development process.

* + 1. Data Sources

The processes within our integrated management system that provide sources of information are analyzed to identify non-conformities, or potential non-conformities. Where we encounter situations that have not actually caused a non-conformity, but may do so in the future, such situations may require corrective action. For example, product design or acceptance testing trend data indicates that control limits are being approached, and a revision of product design (process, equipment or facilities) requirements may be necessary.

* + 1. Planning for Measurement, Analysis & Improvement

During planning, Manufacturing Made Easy Ltd considers product type, target markets, user needs, and regulatory and stakeholder requirements—aligned with business objectives.

Management reviews key processes and selects data sources for monitoring, analysis, and improvement.

We define data elements, how often they are measured, and how they are analyzed. Each element has specific measurement requirements and is monitored regularly to ensure effective QMS performance.

Data sources are classified as reactive (corrective) or proactive (preventive), depending on their purpose.

* + 1. Establish Data Sources & Criteria

The Manufacturing Made Easy Ltd should identify and document relevant data sources and their data elements, both internal and external to the organization. Data elements provide information regarding non-conformities, potential nonconformities and the effectiveness of the established processes within the data sources. Examples of data sources can be, but are not restricted to:

1. Regulatory and Obligation Commitments;
2. Management Review;
3. Supplier (performance/controls);
4. Complaint Handling;
5. Adverse Event Reporting;
6. Process Controls;
7. Internal and External Audits;
8. Service Reports;
9. Market/Customer Surveys;
10. Scientific Literature;
11. Media Sources;
12. Design, Purchasing, and Service and Customer Information;
13. Risk Management.
    * 1. Measurement & Analysis using Data Sources

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

* + 1. Measure

Data collected from the measurement of products, process and the QMS are acquired throughout the life-cycle of the product design and development. Manufacturing Made Easy Ltd defines the frequency of the measurement, precision and the accuracy of the data. Manufacturing Made Easy Ltd 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 QMS and regulatory requirements.

Monitoring is the systematic and regular collection of a measurement. Manufacturing Made Easy Ltd 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. 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 QMS. 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 Manufacturing Made Easy Ltd 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. Statistical Process Control (SPC) charts;
2. Pareto analysis;
3. Data trending;
4. Linear and non-linear regression analysis;
5. Experimental design (DOE – Design of Experiments) and analysis of variance;
6. Graphical methods (histograms, scatter plots, etc.).

Non-statistical techniques are for example:

1. Management reviews;
2. Results from quality meetings;
3. Safety committees (internal/external);
4. Failure Mode and Effect Analysis (FMEA);
5. Fault Tree Analysis (FTA).

In addition to the analysis within the data sources there is also analysis across the data sources to determine the extent and significance of the non-conformity or potential non-conformity. The linkage of data from different data sources is referred to as horizontal analyses.

* + 1. Review

Manufacturing Made Easy Ltd defines what meaningful data is reported for Management Review. Such data is specific to the quality and environmental objectives and is reported regularly. The results of data analysis are depicted within appropriate trend charts whenever possible and distributed to members of top management.

* 1. Data Sources & Data Elements

Examples of data sources and their data elements that are considered, but are not restricted to:

| **Data Source** | **Data Element** |
| --- | --- |
| Legal & Regulatory Compliance Requirements | Results of legal or regulatory inspections |
| New or revised legal or regulatory requirements |
| Management Review | Management review output |
| Supplier Performance & Controls | Number of batches received |
| Batch and/or shipment |
| Inspection and test records |
| Quantity of rejects or deviations |
| Reason for rejection |
| By supplier, if more than one supplier |
| Supplier problems |
| Complaint Handling | Quantity |
| By product family |
| By customer |
| Reason for complaint |
| Complaint codes |
| Severity |
| Component involved |
| Adverse Event Reporting | Event |
| Quantity |
| By product family |
| By customer |
| Component involved |
| Categories of environmental incidents |
| Process Controls | By product |
| Personnel |
| Work shift |
| Equipment and/or instruments used |
| Inspection and test records |
| In-process control results |
| Process control parameters |
| Inspection process |
| Final acceptance |
| Rejects |
| Special process |
| Validation study results |
| Process monitoring observations |
| Finished Product | Inspection and test records |
| Internal & External Audits | Observations (number, category, regulatory requirements, significance, etc.) |
| Repeat observations (indicative of effectiveness) |
| Overall acceptability of contractor or supplier |
| Compliance to audit programme |
| Audit personnel |
| Spare Parts Usage | Frequency of replacement |
| Batch number of spare part |
| By supplier of spare part, if more than one supplier |
| By customer |
| By location or area of customer |
| Service Reports | Installation |
| First use of equipment |
| Frequency of maintenance visits |
| Types of repairs |
| Frequency of repairs |
| Usage frequency |
| Parts replaced |
| Service personnel |
| Market & Customer Feedback | Customer preferences |
| Customer service response time |
| Solicited information on new or modified products |
| Industry Literature | Research papers |
| Media Sources | Articles in trade journals |
| Operational control including Design, Purchasing, Production and Servicing and Customer information | Design and development review results |
| Design and development verification results |
| Design and development validation results |
| Design and development changes (reason for change, effectiveness of change, etc.) |
| Controls on purchased products or services (See Supplier Performance/Controls) |
| Verification results of purchased product |
| Inspection and testing data of purchased product |
| Production and Service processes |
| Installation results |
| Servicing and Maintenance if required (See also: Service Reports) |
| Verification and validation results of processes and products |
| Traceability Data |
| Controls of monitoring and measuring devices |
| Calibration and maintenance of equipment |
| Customer Information- New or repeat customer |
| Customer feedback maybe in other forms than complaints or returned |
| Product (Customer Service call data, repeat sales, delivery/distribution data) |
| Risk and Impact Management | Published reports/literature of failures of similar products |
| Stakeholder concerns |
| Risk acceptability criteria |

* 1. Forms & Records

All documentation and records generated by the analysis of data process are retained and managed in accordance with the *Documented Information Procedure*.

* 1. QMS Data Points Process Map

Valid complaint?

**YES**

**NO**

Purchased Part N/C

Product N/C

**YES**

**NO**

Internal, External & Supplier Audits

QMS Data Points

Data Analysis & Trending

**YES**

**NO**

Action required?

Known Problem?

Complaint entered onto complaint handling system

Data Analysis & Trending

**NO**

Continue to monitor

**YES**

Initiate Corrective Action

Risk & Opportunity Process

Action required?

* Product changes
* Process changes
* Supplier changes
* Field upgrades
* Input for new products
* Input to Management Review

|  |  |  |
| --- | --- | --- |
| **Service & Product** | **Product Design and Development** | **Management System** |
|  |  |  |
| Reports and complaints | Non-conformities and defects | Non-conformities and defects |