



Quality Manual

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Table of Contents

Introduction	4
1. Scope	4
2. Normative References	4
3. Terms and Definitions	5
4. Context of the Organisation	5
4.1 Understanding the Organization and its Context	5
4.2 Understanding the Needs and Expectations of Interested Parties	8
4.3 Determining the Scope of the Quality Management System (QMS)	9
4.4 Quality Management System and its Processes	10
5. Leadership	11
5.1 Leadership and commitment	11
5.1.1 General	11
5.1.2 Customer focus	11
5.2 Policy	12
5.3 Organisational Roles, Responsibilities and Authorities	12
6. Planning	14
6.1 Actions to Address Risks and Opportunities	14
6.2 Quality Objectives and Planning to Achieve Them	14
6.3 Planning Changes	14
7. Support	15
7.1 Resources	15
7.2 Competence	15
7.3 Awareness	16
7.4 Communication	16
7.5 Documented information	16
8. Operation	17
8.1 Operational Planning and Control	17
8.2 Requirements for Products and Services	17

8.3 Design and Development of Products and Services.....	17
8.4 Control of Externally Provided Processes, Products and Services	17
8.5 Production and Service Provision	18
8.6 Release of Products and Services	18
8.7 Control of Nonconforming Outputs	18
9. Performance Evaluation.....	19
9.1 Monitoring, Measurement, Analysis and Evaluation.....	19
9.1.1 <i>General</i>	19
9.1.2 <i>Customer Satisfaction</i>	19
9.1.3 <i>Analysis and Evaluation</i>	19
9.2 Internal Audit.....	20
9.3 Management Review	20
10. Improvement	21
10.1 General	21
10.2 Nonconformity and Corrective Action	21
10.3 Continual Improvement	21

Appendices

Appendix 1: MLN Stakeholders

Appendix 2: Organisation Chart

Appendix 3: Main Processes and Key Activities

Introduction

The Malta Laboratories Network has developed and implemented a quality management system (QMS) using ISO 9001:2015 as a framework, which allows the organisation to document and improve its practices in order to better satisfy the needs and expectations of the customers, stakeholders and interested parties.

The Quality Manual describes the QMS, whilst also delineating authorities, inter relationships and responsibilities of personnel operating within the management system. The Quality Manual also provides references to procedures and activities that also comprise the QMS.

1. Scope

The quality management system of the Malta Laboratories Network meets the requirements of ISO9001:2015 and uses the Plan, Do, Check and Act approach to process planning.

The Quality Manual demonstrates the capability of the Malta Laboratories Network to continuously provide support and sustain laboratory services in Malta, through the application of a unique model of co-operation based on fostering innovation, exchange of resources and empowerment of stakeholders.

2. Normative References

ISO9000:2015 Quality Management Systems- Fundamentals and vocabulary

ISO9001:2015 Quality Management Systems-Requirements

ISO9004:2018 Quality Management-Quality of an Organisation-Guideline to achieve sustained success

3. Terms and Definitions

For the purpose of this Quality Manual, the Malta Laboratories Network references the terms and definitions listed in the current ISO 9000:2015 “Quality Management Systems Fundamentals and Vocabulary” document.

4. Context of the Organisation

4.1 Understanding the Organization and its Context

The Malta Laboratories Network is organised in the following directorates and unit:

Scientific Research, Development and Implementation Directorate

The Scientific Research, Development and Implementation Directorate’s primary responsibility is to promote Malta as a centre of excellence in a number of science and technology related areas. This is achieved by establishing mechanisms and approaches for showcasing Malta’s potential in scientific innovation and research. It is also responsible for leading a global strategy in attracting new partnerships and investments in the scientific field on an international basis, as well as to identify opportunities for potential investments with key stakeholders in the scientific community and the private sector. Another essential role of the Directorate includes leading a strategy to enhance the link between the scientific industry and academic institutions, hence, creating an attractive environment which provides opportunities for both undergraduate and postgraduate students. This Directorate also endeavours to establish and promote standards of practice

and quality across the scientific community by providing scientific advice and acting as a liaison between scientists and non-scientists.

Strategic Operations, Administration and Communication Directorate

The Strategic Operations, Administration and Communication Directorate is responsible for the development and implementation of the Network's strategy, work plan, programs and activities. This directorate monitors and oversees the day-to-day operations and is involved in the setting up and management of the financial objectives and budget. The engagement and management of staff and health and safety issues are overseen by this directorate. This directorate is also the focal point of communication with stakeholders.

Advanced Inter-collaborative Educational Leadership Directorate

The Advanced Inter-collaborative Educational Leadership Directorate promotes innovation, excellence and collaboration in scientific initiatives. It is responsible to identify educational and training needs within the dynamic scientific field according to stakeholder needs. It aims to enhance knowledge sharing by organising interactive and advanced educational training and development courses in the field of science and technology. These courses are designed according to the MQF/EQF levels and relevant accreditation. This unit is also involved in the entire process of drafting and negotiation of Memorandum of Understanding agreements with various entities and stakeholders.

Quality Assurance, Standards and Requirements Unit

The Quality Assurance, Standards and Requirements Unit is responsible for ensuring that the processes needed for the quality management system are

established, implemented and maintained. This unit reports on the performance of the quality management system to management and the need for continuous improvement whilst ensuring that there is a concept of customer focus throughout the organisation. This unit ensures that the integrity of the QMS is maintained during changes and that the responsibilities and authorities related to the QMS are communicated and understood by all. This unit assists the Advanced Inter-collaborative Educational Leadership Directorate in managing applications for programme accreditation, reviews, validations, recognitions and other initiatives of the National Commission for Further and Higher Education, validating partners and other external bodies.

Management is committed to identify external and internal issues that are relevant to the context. The organisation shall monitor and review information about these external and internal issues periodically.

Internal issues	External Lab issues
Employee competency	Certified/Accredited Labs
Qualified Trainers	Lab/Customers Satisfaction
Certified trainers	Highly Quality Training
Overall Capacity	Duplication of resources
Health, Safety and Environmental Requirements	Memorandum of understanding
Internal Policies and Contracts/ Agreements	Accreditation and Certification Support
Workforce Wellness	EN ISO/IEC 17025 Awareness EN ISO/IEC 17020 EN ISO 9001

Work-life balance	Central information Website
Quality	
Continual Improvement	Good Manufacturing Practice (GMP)
Communication	Supplier Performance/ Qualified Suppliers
Research and Innovation	Regulatory Issues

4.2 Understanding the Needs and Expectations of Interested Parties

Management shall determine:

- the interested parties that are relevant to the quality management system;
- the requirements of these interested parties that are relevant to the quality management system.

Management shall monitor and review information about these interested parties and their relevant requirements periodically.

The main stakeholders of the Malta Laboratories Network are:

- Line Ministry
- Government entities
- Public and Private Sector Laboratories
- Academia and Media
- Health Care Professionals

- Industrial and Scientific Sectors
- MLN employees
- MLN suppliers

A comprehensive stakeholder map is presented in Appendix 1.

As part of this commitment to the interested parties, the Malta Laboratories Network has implemented a system to manage quality in its operations and in its service to customers and stakeholders.

International standards for quality in manufacturing and service organisations are set out in a series of standards produced by the International Organisation for Standardisation (ISO). ISO 9001 provides the basis for the development, implementation and maintenance of a comprehensive quality management system. The Malta Laboratories Network Quality Manual is devised in the format of ISO9001 and the section and paragraph numbers reflect those of the standard.

4.3 Determining the Scope of the Quality Management System (QMS)

The scope of the quality management system is to provide:

- training services;
- accreditation support;
- accreditation/certification of laboratories and processes;
- act as a network.

MLN falls within the portfolio of the Ministry as assigned by the Prime Minister.

MLN is a network focused on the development and sustainability of laboratory services in Malta, through the application of a unique model of co-operation based on fostering innovation, exchange of resources and empowerment of stakeholders.

4.4 Quality Management System and its Processes

MLN ensures the QMS includes the documented information according to the requirements of the ISO 9001:2015 standard and additionally any documented information identified by the organisation that demonstrates the effective operation of the QMS. These will be maintained and continually improved according to ISO 9001:2015.

The MLN has chosen to maintain documented information in the format of a Quality Manual and Quality Policy that encompasses a high-level description of the quality management system.

The quality management system is also supported by standard operating procedures, policies and forms which are subject to control and are not included in the quality policy or manual. During the annual management review, the QMS and its processes are evaluated for continual improvement.

5. Leadership

5.1 Leadership and commitment

5.1.1 General

Management of the Malta Laboratories Network are accountable for the effectiveness of the QMS and providing resources to ensure that the Quality Policy is compatible with the strategic direction and the context of the organisation.

Management and the officers/fellows reporting at the MLN are committed to the development, implementation and continuous improvement of the quality management system (QMS).

The importance of an effective QMS is emphasized to personnel by management through formal communication channels. The QMS is focused on the customer and structured on a process approach whereby decisions are taken based on risk. This approach supports management to demonstrate leadership in their areas of responsibility.

Management ensures that the QMS requirements are integrated into the business processes of the MLN and that the QMS is achieving the intended results.

5.1.2 Customer focus

MLN is focused on maintaining and enhancing customer satisfaction.

The Chairperson and the staff of the MLN are committed to providing an efficient and effective service in order to meet the requirements of their customers and stakeholders in line with the relevant statutory and regulatory requirements.

By addressing risks and opportunities in the services provided, MLN strives to enhance customer satisfaction and address their needs.

5.2 Policy

Management at the Malta Laboratories Network has established a Quality Policy P-Q01 which clearly outlines the mission and objectives of the organisation and represents the framework for continually improving the QMS. The mission and objectives are reviewed by management on a regular basis and updated as necessary, in line with feedback received from the relevant stakeholders.

5.3 Organisational Roles, Responsibilities and Authorities

Management is responsible to ensure quality in their daily activities and in the services offered by the MLN to stakeholders. This is accomplished by providing the necessary resources needed to implement and improve the QMS. Management is authorised for business planning and development, for the communication and establishment of the QMS, policies and quality objectives. Management is to attend a Management Review Meeting at least annually.

As part of their role, management are to assign and communicate the relevant responsibilities and authorities to all employees at the MLN to ascertain that:

- the QMS conforms to ISO9001:2015;
- continuous improvement is an ongoing process;

- customer focus is endorsed throughout the organisation;
- the integrity of the QMS is sustained during changes;
- the responsibilities and authorities related to the QMS are understood.

Management supports the development and improvement of the QMS by contributing to the internal audit processes and fostering the concept of continuous improvement within the organisation and placing special emphasis on the effectiveness and efficiency of key system processes.

Management is authorised and responsible for the execution and implementation of the QMS by planning and controlling the processes within their remit and ensuring the set-up of operational level objectives that are necessary to implement and improve these processes.

All staff is responsible to ensure quality in their work and in the implementation of policies, procedures and processes that they work on. Staff is to identify and report any known or potential problems that they encounter while in their line of duty and to assist in the maintenance of the QMS, by recommending quality improvements and corrective actions. In order to attain the quality required, staff is to undergo training relevant to their job description and to focus on customer satisfaction in their daily activities.

The Head of Quality is to ensure that the processes required for the management of the QMS are maintained and the performance and required improvements are reported to management. The promotion of customer focus throughout the organisation is an essential role for the Head of Quality. The Head of Quality is also responsible to perform an annual review of the QMS in collaboration with all management.

6. Planning

6.1 Actions to Address Risks and Opportunities

During the planning process, MLN considers the context of the organisation, needs and expectations of interested parties and the scope of the QMS. MLN determines the risks and opportunities in order to ensure that the QMS can achieve the intended results, enhance desirable results or reduce undesired effects. These need to be compatible with the context of the organisation and conducive to an environment of continuous improvement.

6.2 Quality Objectives and Planning to Achieve Them

Management has established the mission, vision and objectives of the Malta Laboratories Network as outlined in P-Q01, the Quality Policy, which are appropriate to the purpose of the organisation.

Management is committed to comply with the requirements for continuous improvement in relation to the effectiveness of the quality management system. Both external and internal environmental factors, customer and employee feedback are taken into consideration to ascertain that the objectives are suitable to the changing environment. Objectives are reviewed by management at least annually during management review meetings, in order to monitor their realisation and to include any new or modified objectives.

6.3 Planning Changes

Changes to the QMS are planned by management. The purpose of the changes, potential consequences, integrity of the QMS, availability of resources and

allocation or relocation of responsibilities and authorities are all taken into consideration.

7. Support

7.1 Resources

Management is responsible for identifying the resources necessary to maintain the quality management system and to ensure efficiency in the provision of services. This will ensure that the processes and activities carried out are of the required standards with the resources that are available.

7.2 Competence

MLN provides staff with the necessary knowledge and skills, organisational structure and financial resources for the establishment, implementation, maintenance and improvement of the QMS.

In cases where it is deemed necessary or justified, MLN will subcontract external experts or organisations from relevant fields to realise activities for which the organisation does not have the required resources.

Management is responsible for identifying the training needs and conducting training for relevant staff who carry out activities which have a significant impact on the service provided by the organisation and on customer satisfaction.

Management is responsible for the competency of staff, on the basis of education, training and/ or work experience, in accordance with the exigencies of their work.

The effectiveness of their work is evaluated through work output and performance appraisals. The appropriate documented information is maintained as evidence of competence.

7.3 Awareness

MLN ensures that all employees are aware of the Quality Policy and Quality Manual, relevant quality objectives, the importance of their contribution to the effectiveness of the QMS and the implications of nonconformance with the QMS requirements.

7.4 Communication

Management and staff are responsible for ensuring effective external communication with stakeholders and communication within the MLN.

7.5 Documented information

Documented information of the Quality Management System is carried out through the following documents:

- Quality Policy, Quality Objectives
- Quality Manual
- Procedures for Document and Record Control
- Documented information determined by the organisation as being necessary for the effectiveness of the quality management system

8. Operation

8.1 Operational Planning and Control

Management is responsible for planning and developing the work of the Malta Laboratories Network and the processes needed.

8.2 Requirements for Products and Services

Management defines the communication with customers, the process of determining and reviewing the requirements related to the product and services and changes to the requirements.

8.3 Design and Development of Products and Services

The Malta Laboratories Network identifies, reviews and controls changes made during, or subsequent to, the design and development of products and services. This is completed to the extent necessary to ensure that there is no adverse impact on conformity to requirements. All relevant documentation on design and development changes, the results of reviews, the authorisation of changes and the actions taken to prevent adverse impacts is retained.

8.4 Control of Externally Provided Processes, Products and Services

The Malta Laboratories Network ensures that externally provided processes, products and services conform to requirements. All documented information of these activities and any necessary evaluations are retained and controlled in line with documented standard operating procedures and/ or policies.

8.5 Production and Service Provision

The Malta Laboratories Network defines activities and executes product realisation under controlled conditions as described and in accordance with standard operation procedures, in order to ensure full capability of the process and to prevent nonconformities.

All documented information describing the results of the review of changes, the persons authorising the change and any necessary actions arising from the review are retained and controlled in line with the relevant standard operating procedures and/or policies.

8.6 Release of Products and Services

It is the responsibility of management and their designated staff to implement planned arrangements, at appropriate stages, to verify that the products and service requirements have been met.

All documented information on the release of products or services is retained and controlled in line with the relevant standard operating procedures and/or policies. The documented information shall include evidence of conformity with the acceptance criteria; traceability to the person(s) authorising the release.

8.7 Control of Nonconforming Outputs

The Malta Laboratories Network ensures that nonconforming outputs are identified and controlled to prevent their unintended use or delivery.

A documented procedure is in place for dealing with findings and a database of findings and any subsequent actions taken, is maintained by Head of Quality.

A procedure is in place to allow for exceptional deviations from policies/procedures. Deviations require the authorisation of Top Management and/or Heads in the absence of a Line Director. A database is maintained by the Head of Quality for deviation requests and their authorisation or otherwise and any subsequent action where applicable.

9. Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

Management will evaluate the performance of the QMS during management meetings and management review. Management determines what will be monitored and measured, as well as the methods and timing for this to occur.

9.1.2 Customer Satisfaction

MLN monitors customers' perceptions and feedback in order to assess if their needs and expectations have been achieved.

9.1.3 Analysis and Evaluation

MLN analyses and evaluates appropriate data and information resulting from the monitoring and measurement exercises. This data is used to analyse:

- the conformity of products and services;
- the degree of customer satisfaction;
- the performance and effectiveness of the Quality Management System;
- if planning was implemented effectively;
- the effectiveness of the actions taken to address risks and opportunities;
- the performance of external providers;
- the need for improvements to the Quality Management System.

9.2 Internal Audit

MLN conducts internal audits at planned intervals to demonstrate conformance and effectiveness of the Quality Management System.

9.3 Management Review

Management conduct reviews of the QMS, at least on an annual basis.

Periodic reviews of the quality management system are necessary in order to assess the suitability and effectiveness of the Quality Policy and the objectives of the MLN. There are also *ad hoc* operational meetings to cover the interim period.

The data from the management review assists in the annual planning. The information obtained from this meeting assists in the decision-making processes in relation to the resources necessary for the upkeep of the QMS, such as the allocation or recruitment of staff and financial resources.

10. Improvement

10.1 General

All staff of the MLN have the responsibility to determine and propose opportunities for improvement. Management and employees implement the necessary actions to meet customer requirements and enhance customer satisfaction. This is achieved by:

- improving the products and services provided to meet both the current requirements as well as to address future needs and expectations;
- correcting, preventing or reducing undesired effects;
- improving the performance and effectiveness of the Quality Management System.

10.2 Nonconformity and Corrective Action

MLN manages the nonconformities in order to assess the impact, control and implement corrective actions. MLN has a system in place to investigate and document the root cause and actions to correct non-conformities.

10.3 Continual Improvement

MLN continually improves the suitability, adequacy and effectiveness of the Quality Management System. Continuous improvement is achieved by preventing or reducing undesired effects and improving the performance and effectiveness of the QMS by analysing the data obtained from management review, internal audits and operations meetings or customer feedback. This

determines if there are needs or opportunities to be addressed as part of continual improvement.

Approved by

Signed

Date

Chairperson - Malta Laboratories Network

Director - Scientific Research, Development &
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Director - Strategic Operations, Administration and
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