

EMPHN Quality Management System Framework

Unique identifier	QMS-001F
Version	1.4
Prepared by	Manager Business Services, ISO Quality Group, Lead Continuous Improvement
Approved by	Executive Management Committee (minuted meeting 13 Feb 18)
Approval Date	13 February 2018
Review Date	Feb 2019
Responsible person	Executive Director Corporate Services

EMPHN Quality Management System Framework

Contents

1.	Quality Framework Purpose	3
2.	ISO 9001:2015 Quality Management System requirements	3
3.	Scope of the Quality Management System (QMS).....	5
4.	Quality Policy Statement	7
5.	QMS Objectives	7
6.	Roles and Responsibilities.....	8
7.	Internal Quality Audits.....	10
8.	Glossary of Terms	11
9.	Amendment History	12
10.	References	12
11.	Appendix.....	12

1. Quality Framework Purpose

Eastern Melbourne PHN (EMPHN) is committed to maintaining and enhancing our reputation for delivering quality services that meet the needs of its members, stakeholders and the community. As EMPHN's purpose is to achieve better health outcomes for individuals and the community and better experiences of healthcare for both health service consumers and practitioners, our Quality Management System will be an integral way to ensure the requirements of all our stakeholders are met. In providing quality services, we will demonstrate leadership at all levels, take a risk based thinking approach, embrace new ideas, technology and innovation, ensure a customer centred approach to external and internal customers, and strive for continual improvement to maintain our reputation as a high performing organisation.

This document outlines EMPHN's Quality Management System operations.

2. ISO 9001:2015 Quality Management System requirements

EMPHN has adopted the internationally recognised ISO 9001:2015 Quality Management System (the Standard). The Standard aligns with the Commonwealth expectations of EMPHN's service delivery and our funding deed obligations and the expectations of health consumers within our catchment

The Standard is based on the following principles:

- customer focus
- leadership
- engagement of people
- process approach
- improvement
- evidence-based decision making
- relationship management.

The Standard specifies requirements for a quality management system when an organisation:

- needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
- aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

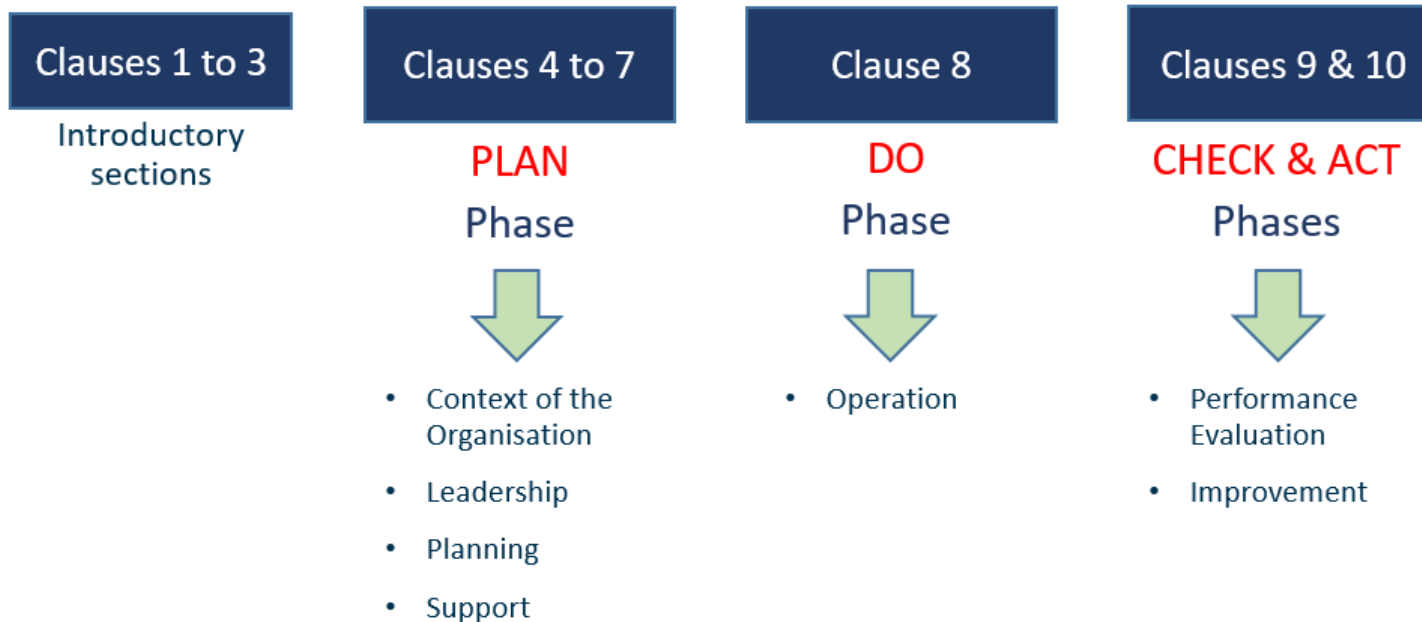
ISO 9001 is our Continuous Improvement methodology. It is the Plan Do Check Act Cycle (PDCA) in action to facilitate Continuous Improvement, as described in the following diagram.

EMPHN Quality Methodology

ISO 9001 is our Continuous Improvement methodology. It is the PDCA cycle in action to assure Continuous Improvement

- ISO 9001 is not prescriptive. It specifies what must be done (the requirement) but not *how*.
- This means knowing what the requirements are, what they mean, and understanding how to apply them to our organisation.

ISO 9001:2015 – Quality management system – Requirements:



3. Scope of the Quality Management System (QMS)

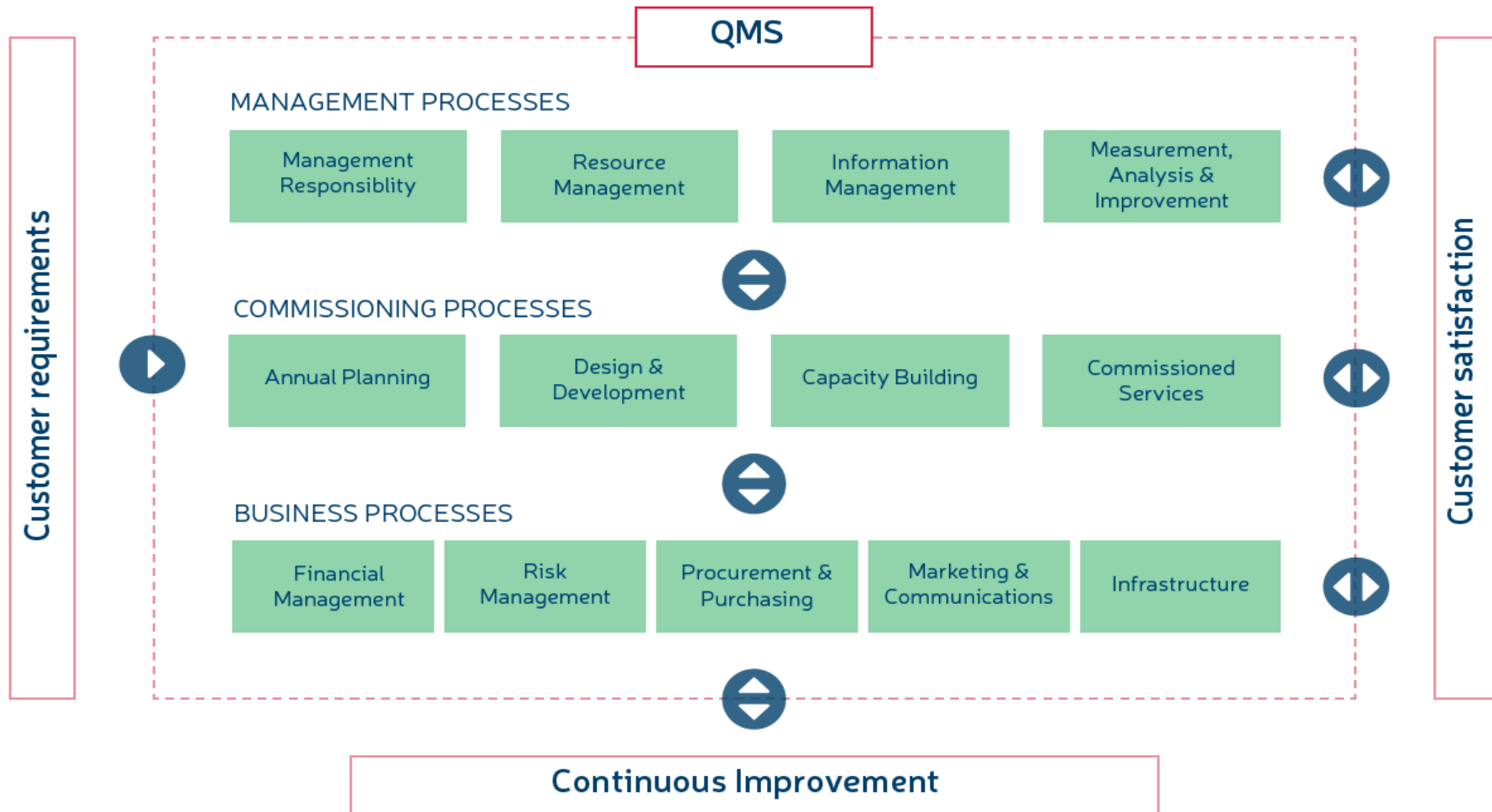
The Scope defines the physical and organisational boundaries to which EMPHN's QMS applies. In determining the Scope, the context of the organisation, needs and expectations of interested parties and the extent of control and influence that the Quality Management System exerts over activities and services has been considered, including regulatory, statutory and funding compliance. To ensure the conformity of its services and the enhancement of customer satisfaction, the QMS scope is defined as follows:

- **Processes and activities:** All process and activities used in the provision of services by EMPHN
- **Services:** All commissioned services delivered to external parties
- **Organisational units and functions:** All directorates and functions
- **Locations:** The scope of EMPHN's QMS applies to both facilities:
 - 18 – 20 Prospect Street, Box Hill, VIC, 3128 (approximately 80 employees)
- **Exclusions from the scope:** Nil
- **Exclusions of ISO 9001:2015 requirements:** Nil

The following schematic illustrates the scope of the QMS at EMPHN:

EMPHN Quality Management System Scope

Supports all our activities with the outcome of Continuous Improvement.
This is where the methodology is applied:



4. Quality Policy Statement

EMPHN will:

- Provide solutions and services that comply with applicable statutory, funding, contractual, standards and other code obligations
- Strive for quality in the services we commission and deliver added value to our clients by identifying, monitoring and responding to their needs, expectations and level of satisfaction
- Continually review and improve the effectiveness of the Quality Management System (QMS) to maintain its relevance
- Ensure the QMS meets ISO 9001 requirements and aligns with our business processes and ensure all EMPHN employees and stakeholders are aware of their responsibility for quality and service standards

The CEO is responsible for approving the Quality Policy Statement and ensuring it is appropriately communicated to all persons working for or on behalf of EMPHN and available to other relevant stakeholders.

Robin Whyte

CEO Eastern Melbourne PHN

April 2018

5. QMS Objectives

EMPHN's initial Quality Objectives are always evolving and are reviewed and adjusted to align with changes in our Commonwealth Funding and Statutory obligations and the identified needs of our stakeholders. Our inaugural QMS objectives are:

1. To achieve and maintain ISO 9001:2015 certification
2. To maintain an effective Quality Management System (QMS)
3. To ensure effective customer feedback processes and quality responses
4. To maintain an effective document and records management system
5. To ensure a focus on continuous improvement through a system of planning, internal audits, analysis, measurement and evaluation

6. Roles and Responsibilities

EMPHN has established the following Management Review structure to comply with the Standard.

Who	Responsibilities	When
Quality, Risk & Safety Committee	<ul style="list-style-type: none"> Confirm the Scope of the QMS Approve the annual quality action plan and audit schedule including the Objectives (A) Quality Action Plan quarterly status report 	Annually
		Annually
		Quarterly
Executive Management Committee	<ul style="list-style-type: none"> Review and endorse the Scope of the QMS Review and endorse the Quality Action Plan and Audit Schedule Determine allocation of resources to ensure the Quality Action Plan can be achieved Review and endorse the progress report including audit reports 	Annually
		Annually
		Quarterly
Senior Leadership Team	<ul style="list-style-type: none"> Promote understanding of the QMS and its relationship within their portfolios Provide input into developing the annual quality plan and audit schedule Provide feedback on the implementation of Quality objectives and performance outcomes Ensure agreed resources are available as required to action the Quality Action Plan and audit Schedule Review and accept audit report recommendations and implement agreed actions for audits within their portfolios 	Ongoing
		Annually
		Monthly
		Ongoing
		Ongoing

EMPHN Quality Management System Framework

Who	Responsibilities	When
Quality Portfolio Manager	<ul style="list-style-type: none"> Ensure QMS processes are established & maintained (e.g. Audits being performed, monthly reporting, etc.) and compliance to ISO 9001 Promote understanding of the QMS and support its adoption through mentoring and coaching Coordinate the development and approval of the Annual QMS Action Plan and Audit Schedule Coordinate the completion of the audits as per the schedule Monitor delivery to the QMS Action Plan and Audit Schedule and ensure outcomes of audits are prioritised and actioned Prepare all quality reports in line with the Standard Ensure effective feedback and evaluation of the QMS at least annually Maintain relevant Quality management records 	Ongoing
		Ongoing
		Annually
		Ongoing
		Ongoing
		Monthly
		Annually
		Ongoing
Quality Representatives	<ul style="list-style-type: none"> Undertake internal auditor training Actively participate in the development and implementation of the Quality Action Plan and Audit Schedule Complete allocated audits Promote understanding of the QMS within their portfolios 	As required
		Ongoing
		Ongoing
		Ongoing
All employees	<ul style="list-style-type: none"> Comply with all policies and procedures Proactively identify and record areas where EMPHN processes may fall short of meeting our obligations (nonconformances) and opportunities for improvement Ensure an understanding of our QMS and how the work they do contributes to achieving the QMS objectives Participate in continuous improvement project 	Ongoing

7. Internal Quality Audits

EMPHN will conduct internal audits as an integral part of our Quality Management System to ensure our operations are conforming to the Standard and EMPHN's internal requirements. We will ensure audits are conducted in an objective and impartial way. Audit results can include praise, recommendations for improvements, and nonconformities (major and minor).

EMPHN bases its audit programme on considerations of the importance of internal processes to our service delivery, risk factors, changes affecting the organisation, and the results of previous audits. Our audit schedule is developed as part of the annual Quality Action Plan (QAP) in consultation with Directorates (internal customers), which is submitted for Management Review and approval as part of EMPHN's annual planning cycle. The schedule includes scope, area of focus (QMS element), resourcing and timing of the audits.

EMPHN is committed to ensuring that audit results are reported to relevant management and agreed actions are taken without unreasonable delay. An audit register will be maintained.

8. Glossary of Terms

Term	Definition
Commissioned Services	Contractual service providers who are responsible for maintaining their own quality and clinical governance systems and processes, as part of meeting their contractual obligations
Correction	removal of the consequences/effects of the nonconformity
Corrective Action	removal of the cause of the nonconformity
Customers	GPs and allied health professionals, third-party health consumers, Commonwealth Government, Department of Health, Government of Victoria,
Document & Record	<u>Document</u> : information and the medium on which it is contained <u>Record</u> : document stating results achieved or providing evidence of activities performed <u>Documented information</u> : information required to be controlled and maintained by an organisation and the medium on which it is contained
Interested Parties	Interchangeable with “stakeholders”. Refer to Stakeholder Engagement Framework for list of EMPHN’s stakeholders
Nonconformity	Non-fulfilment of a requirement
Major nonconformance	occurs when there is an absence or total breakdown in the system to meet the ISO 9000 requirement
Management Review	Top management review of the organisation’s quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organisation.
Minor nonconformance	a deficiency that does not seriously impact the quality management system and is not likely to result in reducing the system in its ability to assure controlled processes or products
PDCA Cycle	Plan-Do-Check-Act cycle. See Appendix for further explanation
QMS	Quality Management System: collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction; it is aligned with an organisation's purpose and strategic direction
QPM	Quality Portfolio Manager (Business Services Manager)
Quality Representatives	Previously the ISO Working Group/ISO Quality Committee personnel
Risk-based thinking	Preventive action is built-in when a management system is risk-based. See Appendix for further explanation
Standard	Refers to ISO 9001:2015 Quality management systems - Requirements
Top management	Term used in the Standard “person or group of people who directs and controls an organisation at the highest level”. At EMPHN this means the Board, CEO, Executive Management Committee and the Senior Leadership Team.

9. Amendment History

Version	Details of change	Amended by	Date
d0.1	First draft	Jane Clarke and Gabby DiRamio	25/01/2018
d0.2	Inclusion of diagrams and update of section 8	Jane Clarke and Gabby DiRamio	01/02/2018
d0.3	Inclusion of Quality Plan and amendments to diagrams	Jane Clarke and Gabby DiRamio	05/02/2018
d0.4	Style and editorial review	Ellie Cope	08/02/2018
1.0	EMC review	Gabby DiRamio	09/02/2018
1.1	Expanded Glossary and added appendices 1 & 2	Gabby DiRamio	16/02/2018
1.2	Changed Quality Lead to Quality Representative per Quality Meeting 6 March 2018	Gabby DiRamio	14/03/2018
1.3	Addition of “Strive for quality in the services we commission” to Quality Policy statement; addition of “and quality responses” to Objective 3, as per QRS Board Committee April 2018 request.	Gabby DiRamio	30/05/2018
1.4	At item 3. Scope of the Quality Management System: <ul style="list-style-type: none"> • Deleted reference to the Bundoora office • Changed section for “Exclusions of ISO 9001:2015 requirements” to read as no exclusions 	Gabby DiRamio	10/01/2019

10. References

ISO 9001:2015 Quality management system – Requirements

EMPHN Quality Action Plan 2017/2018

Tracy, RB (2017) *EtQ Quality, EHS & Compliance Management Blog*. Available at [Risk based thinking mean in the context of new iso standards](#) (Accessed 16 February 2018)

11. Appendix

1. Plan-Do-Check-Act cycle
2. Risk-based thinking explained

Appendix 1

1 Plan-Do-Check-Act Cycle

Explained briefly, Plan-Do-Check-Act cycle (PDCA) is a model for carrying out change. It is an essential part of the lean manufacturing philosophy and a key prerequisite for continuous improvement of people and processes.

First, proposed by Walter Shewhart and later developed by William Deming, PDCA cycle became a widespread framework for constant improvements in manufacturing, management, and services.

PDCA is a simple four-stage method that enables teams to avoid recurring mistakes and improve processes.

According to the Standard, the PDCA cycle can be briefly described as follows:

Plan: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organisation's policies, and identify and address risks and opportunities; clauses 4 to 7 inclusive in the Standard

Do: implement what was planned; clause 8 of the Standard

Check: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results; clauses 9 and 10 of the Standard

Act: take actions to improve performance, as necessary. Clauses 9 and 10 of the Standard

Appendix 2

2 Risk-based thinking explanation

Risk-based thinking refers to a coordinated set of activities and methods that organisations use to manage and control the many risks that affect its ability to achieve objectives. Risk-based thinking replaces what the old standard used to call preventive action.

Risk has always had an implicit role in ISO standards, but newer versions are giving risk a more prominent place in quality and environmental management standards. Updated standards like ISO 9001:2015 and 14001:2015 require companies to apply risk-based thinking to a variety of processes across planning, operations and performance evaluation.

Risk-Based Thinking Defined

In the context of ISO 9001:2015, risk-based thinking replaces what was called preventive action in the previous standard version. Where ISO once gave preventive action a separate clause, it now incorporates risk throughout. Risk-based thinking requires companies to evaluate risk when establishing processes, controls and improvements in a Quality Management System.

It's important to note that risk isn't limited to negative possibilities. Companies can also use risk-based thinking to pinpoint opportunities, which represent the positive side of risk.

Areas where risk appears in the new standard requirements include:

- **Organisational context:** When establishing the context of the organisation, ISO requires companies to identify risks that could impact quality objectives. They also need to evaluate the risk of producing nonconforming outputs, which can vary depending on the type of good or service provided.
- **Leadership:** Management must commit to addressing risks and opportunities that could affect service quality.
- **Planning:** This section of the standard requires not just to identify risks and opportunities, but also create plans for how to address them.
- **Operation:** The Standard requires the organisation to implement and control the actions identified during planning steps.
- **Performance evaluation:** At this point, an organisation is expected to track and analyse the risks and opportunities identified.
- **Improvement:** Organisations must make improvements based on any changes in risk.

The new high-level structure for ISO standards is based on the Plan-Do-Check-Act (PDCA) cycle for process improvement, corresponding with proven risk management approaches.