PHILIPPINE HEART CENTER
East Avenue, Quezon City

ISO 9001:2015
Quality Management System

QUALITY MANUAL

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	Document Title **TABLE OF CONTENTS**	Revision Number: 0
		Page: 1

TITLE	POLICY NUMBER	PAGE NUMBER
Quality Manual	QMS-QM- 001	1-34
Document Control	QMS-QM- 002	1-9
Document Coding	QMS-QM- 003	1-6
Internal Quality Audit	QMS-QM- 004	1-7
Control of Non-Conformance and Corrective Actions	QMS-QM- 005	1-10
Management Review	QMS-QM- 006	1-6
Risk Management	QMS-QM- 007	1-8
List of Appendices		
Document Request Form	1	
Quality Objective Plan	2	
Quality Objectives and Plans Monitoring	3	
Corrective and Action Request	4	
Masterlist of Forms	5	
Risk Registry	6	
Minutes of the Meeting	7	
Masterlist of Quality Records and Evidences	8	
Masterlist of Documents	9	
Masterlist of External References	10	
Masterlist of External Forms	11	
Breakthrough Report Form	12	

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	Document Title **QUALITY MANUAL**	Revision Number: 2
		Page: 1 of 34

REVISION HISTORY

Rev No.	Review Date	Description of Change	Date of Next Review
0	September 2017		
1	May 2018	Numbers and bullets formatting, removed redundancies, summarized the performance evaluation processes	May 2021
2	October 2018	Summary of performance evaluation process Integration of all QM 001-007, ISO 9001:2015 Standards	October 2021

Reviewed by:	**Quality Management Team**	Approved by:	**JOEL M. ABANILLA, MD** Executive Director

FOREWORD

The Quality Manual is a compilation of the essential policies and procedures of Philippine Heart Center (PHC). This manual outlines routine procedures thereby promoting effective and efficient operations at all levels. Policies, procedures and other information stated therein are derived from policies approved by the Executive Director, statutory, regulatory and other official requirements. Documentation of the organization's policies and procedures promotes the standardization of its functions.

The purpose of this Quality Manual, then, is twofold: first, to provide statements of policies and procedures for general guidance in conducting operations; and second, to provide specific instructions and guidelines for those personnel who are responsible for the preparation of necessary documents, forms and other materials involved in the provision of quality services to customers and stakeholders.

The Top Management is responsible for coordinating the development of policy guidelines to ensure consistent formatting, coordination of revisions or additions to the organization's policies and procedures, and the distribution of this information.

It is the responsibility of the office head to disseminate information pertinent to the functions of subordinates and to ensure that the employees are aware of, understand and comply with all issued policies and procedures in this Quality Manual

JOEL M. ABANILLA, MD

Executive Director

INTRODUCTION

This Quality Manual demonstrates and documents the Philippine Heart Center's commitment to maintaining a high level of quality and strong customer service within an environment that has safety as a priority, is focused on customers and fosters continual improvement.

1. Scope

1.1. General

This manual covers the overview of the Quality Management System (QMS) set by Philippine Heart Center.

1.1.1. This Manual applies to PHC processes as a Tertiary Specialized Hospital delivering Medical, Nursing, Education, Training and Research and Hospital Support Services. The established, documented and implemented QMS specifies requirements that will demonstrate its ability to consistently provide services that meet customer satisfaction in compliance with applicable regulatory requirements, thereby enhancing customer satisfaction.

2. Introduction to Philippine Heart Center

HISTORY

The Philippine Heart Center is a government corporation organized and existing under and by virtue of Presidential Decree No. 673.

Inaugurated on February 14, 1975, the Philippine Heart Center was dedicated to the Filipino people as an institution committed to caring for patients with heart and related ailments.

Since then, the Center has stood as a testimony to the commitment to save lives and alleviate thousands who suffer from cardiovascular diseases, a leading cause of death in

the Philippines. The Center has brought renewed hope especially to those who otherwise could not afford specialized medical care.

Now on its fourth decade of dedicated service, the Center continues to bring increased optimism not just to Filipinos but to the people of the Asia-Pacific region as well as other countries who look to this medical facility as a wellspring of a healthier and longer life. The Center has gained a reputation as one of the busiest Congenital Heart Surgery centers in the region where patients from as far as South Pacific Islands and the Middle East travel to the Philippines and receive quality service at reasonable prices.

As symbolized by its four-heart logo, the Center offers a comprehensive program of patient care, education and training, research, and public information. The Center extends the best and most efficient medical services to its patients by maintaining a pool of well-trained and highly-experienced physicians and other medical personnel who utilize some of the latest in technology and procedures in cardiovascular science.

Another cornerstone of the institution is researches in improving the prevention, diagnosis, and treatment of heart ailment. An equally important mission is the training of medical staff, nurses, and paramedical personnel. Completing its fourfold objective is the task of informing the public about the risk factors as the healthy lifestyle that guarantee longer, more productive lives through the Center's public information and community service program.

At the moment, the Philippine Heart Center is heavily involved in improving its facilities to keep up with world-class standards, expanding its capacity and upgrading its human and technological resources to meet the increasing demand for its services. Amidst this self-imposed act of renewal, the Center remains in focus in terms of its primary mission: to care for those who need the best of what medical science with a social conscience has to offer.

2.1. Mission, Vision, Objectives and Core Values of Philippine Heart Center

Our Mission

We shall provide comprehensive cardiovascular care enhanced by education and research that is accessible to all.

Our Vision

The PHILIPPINE HEART CENTER is the leader in upholding the highest standards of cardiovascular care, a self-reliant institution responsive to the health needs of the Filipino people by 2022.

PHC Strategy Map: Beyond Better 2017-2022

Our Objectives

To provide compassionate and expert patient care.

To provide world-class education and training.

To conduct Internationally-acclaimed research.

To responsibly disseminate scientific and lay information to the public.

Our Values

We believe that by sharing the following values, we shall remain true to our Mission:

Patient-focused Care

We shall uphold the highest commitment to each one of our patients, giving each of them utmost priority and ensuring everyone has everything he needs to get well, including our dedicated care and attention.

Compassion

Our patients shall know us not only for our expertise but also for our sensitivity and compassion. We try always to remember that our patients need not just cure but healing and nurturing. Their overall wellness is what we seek.

Integrity

We shall conduct ourselves in the highest standards of professionalism and ethics. We shall uphold fairness and honesty in all our dealings with our patients, partners and suppliers. We believe that it is only in so doing that we preserve our right to serve the Nation and our Countrymen.

Respect

We give what is due in every transaction or relationship. We earn respect by likewise according the respect each one deserves, not by demanding it.

Excellence

We seek excellence in everything we do by striving to be better each day. We shall be the experts in our fields of endeavor and we will not rest until we have shared this expertise with others who have the same passion for excellence. We believe our patients and the Filipino people deserve no less.

3. References, Terms and Definitions

3.1. References

For the purposes of PHC QMS, the terms and definition given in ISO 9001:2015 apply:

3.1.1. **Quality Management Systems** – management system to direct and control an organization with regards to quality.

3.1.2. **Top Management** – person or group of people who directs and controls the organization. Refers the organization's Executive Committee, Executive Director and Assistant Directors who are in direct reporting to the Board of Trustees with the Secretary of Health as Chairman.

3.1.3. **Continual Improvement** – recurring activity to increase the ability to fulfill the requirements

3.1.4. **Audit Criteria** – set of policies, procedures or requirements used as reference

3.1.5. **Audit Evidence** – records, statements of fact or other information which are relevant to the audit criteria ad are verifiable

3.1.6. **Non-conformity (NC)** – non-fulfilment of a requirement

3.1.7. **Risk** – effect of uncertainty on objectives; often described by an event, a change in circumstance or a consequence. It is characterized and is measured in terms of its consequence and likelihood.

3.1.8. **Likelihood** – is the chance that an event might happen. It can be defined, determined, or measured objectively or subjectively, and can be expressed either qualitatively or quantitatively.

3.1.9. **Consequence (Impact)** – is the outcome of an event and has an effect on objectives. A single event can generate a range of consequences which can have both positive and negative effects on objectives.

3.1.10. **Risk assessment** – is a process involving risk identification, risk analysis and risk evaluation

3.1.11. **Risk identification** - is a process that is used to find, recognize, and describe the risks that could affect the achievement of objectives.

3.1.12. **Risk analysis** - is a process that is used to understand the nature, sources, and causes of the risks that you have identified and to estimate the level of risk. It is also used to study impacts and consequences and to examine the controls that currently exist.

3.1.13. **Risk evaluation** - is a process that is used to compare risk analysis results with risk criteria in order to determine whether or not a specified level of risk is acceptable or tolerable.

3.1.14. **Risk Source** – is where a risk originates

3.1.15. **Risk Treatment** – is a risk-modification process. It involves selecting and implementing one or more treatment options

3.1.16. **Control** – is any measure or action that modifies a risk. It includes any policy, procedure, practice, process, technology, device or method that modifies or manages risk

3.1.17. **Risk Owner** – person or entity with the accountability and authority to manage a risk

3.1.18. **Risk Register** – the documented information used to review and monitor the context of the organization and its corresponding risks, opportunities and action plan

3.1.19. **QMS** – Quality Management System

3.1.20. **CAR** – Corrective Action Report

3.1.21. **IQA** – Internal Quality Audit

3.1.22. **Soft Copy Document** – refers to unprinted document stored in computers

3.1.23. **Master Copy** – is the controlled soft copy of PHC's QMS documented information under the strict control of the Document Controller in coordination with the Management Services Office.

3.1.24. **Controlled Copy** - copy of QMS documented information and records under the custody of the document controller.

3.1.25. **Uncontrolled Copy** – All printed/ hard copy of QMS documented information and records.

3.1.26. **Obsolete Copy** – are documented information that are outdated and are for disposal from archive files.

3.1.27. **Revised Documents** – documented information and records with partial or complete revision or changes

3.1.28. **Internal Documents** – documents internally generated/originated in the organization

3.1.29. **External Documents** – documents, specifications, requirements and other written information from suppliers, clients, government and system standards which are not created in the organization.

3.1.30. **Distribution** – issuance of approved documents for the implementation of system

3.1.31. **Distribution List** – is a summary of service holding a copy of registered document

3.1.32. **Confidential Document** – refers to document with limited accessibility and usage to public

3.1.33. **Customer** – refers to client and could be used interchangeably

3.1.34. **PHC** – Philippine Heart Center

3.1.35. **Process Owner** – the individual who has the ultimate responsibility for the performance of a process in realizing its objectives and has the authority to make any necessary changes

4. Context of the Organization

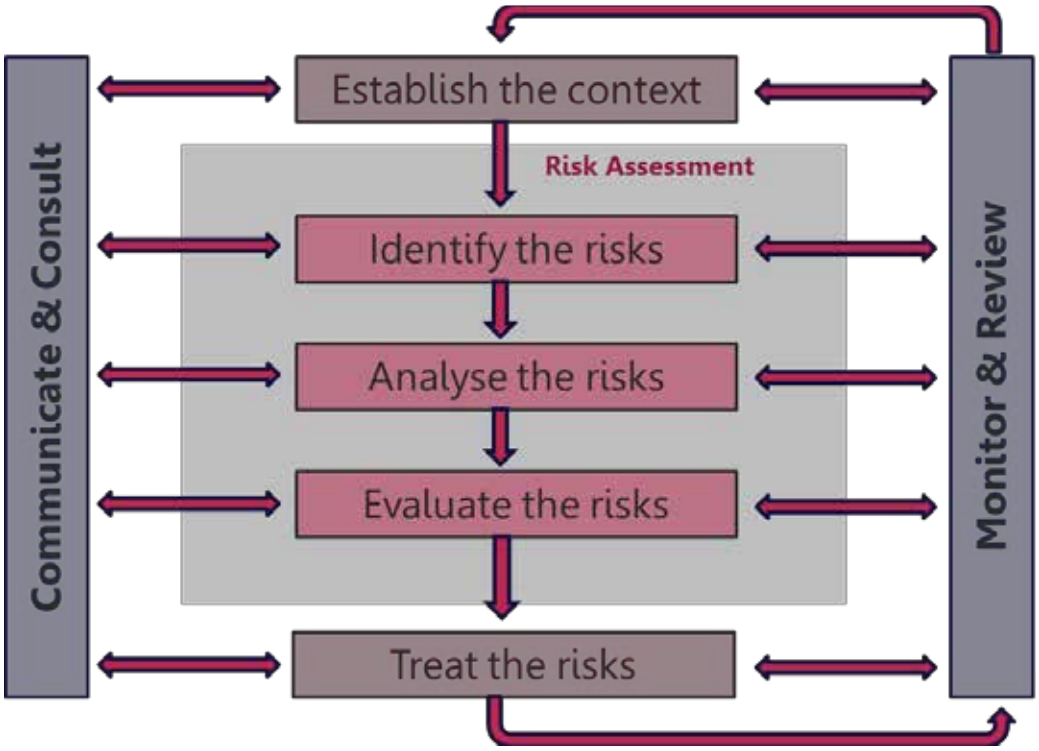
4.1. The PHC shall determine internal and external issues that are relevant to its purpose and its strategic direction and that can affect its ability to achieve the intended results of its QMS. PHC shall monitor and review information about these internal and external issues.

4.2. PHC shall determine relevant interested parties and their relevant requirements that can affect or potentially affect QMS. PHC shall monitor and review information about these interested parties and their relevant requirements.

Risk Registers, are accomplished by process owners after considering internal and external issues. These are reviewed at least once a year upon Management's direction when there are major changes for the organization

The Risk Assessment approach of PHC is described in Figure 1 below (as adapted from ISO 31000):

Figure 1: Risk Assessment



4.3. The Scope of the QMS of PHC has considered the following:

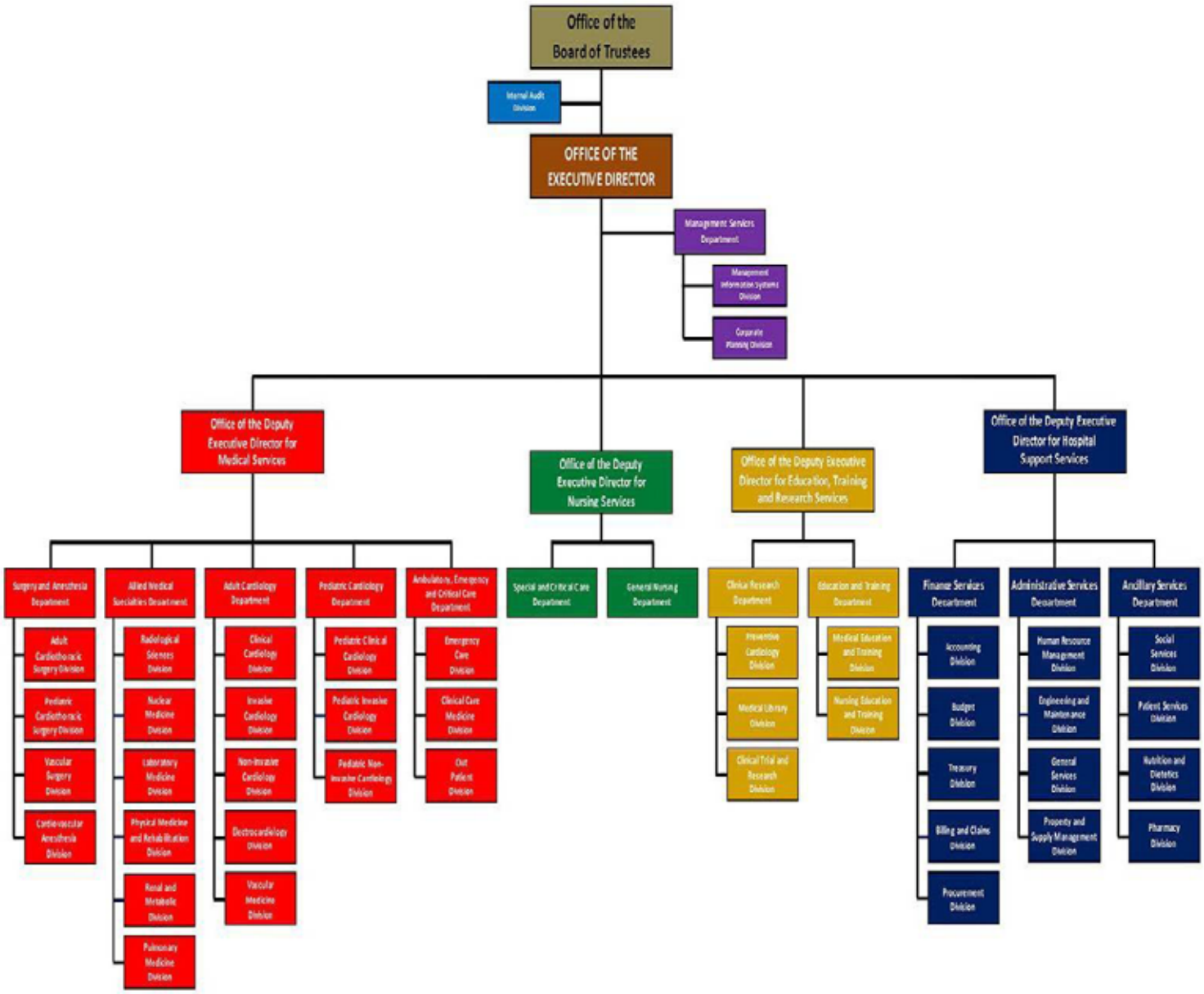
4.3.1. the internal and external issues
4.3.2. the requirements of relevant interested parties
4.3.3. the service of the organization

4.4. PHC shall establish, implement, maintain and continually improve its QMS, including the processes needed and their interactions.

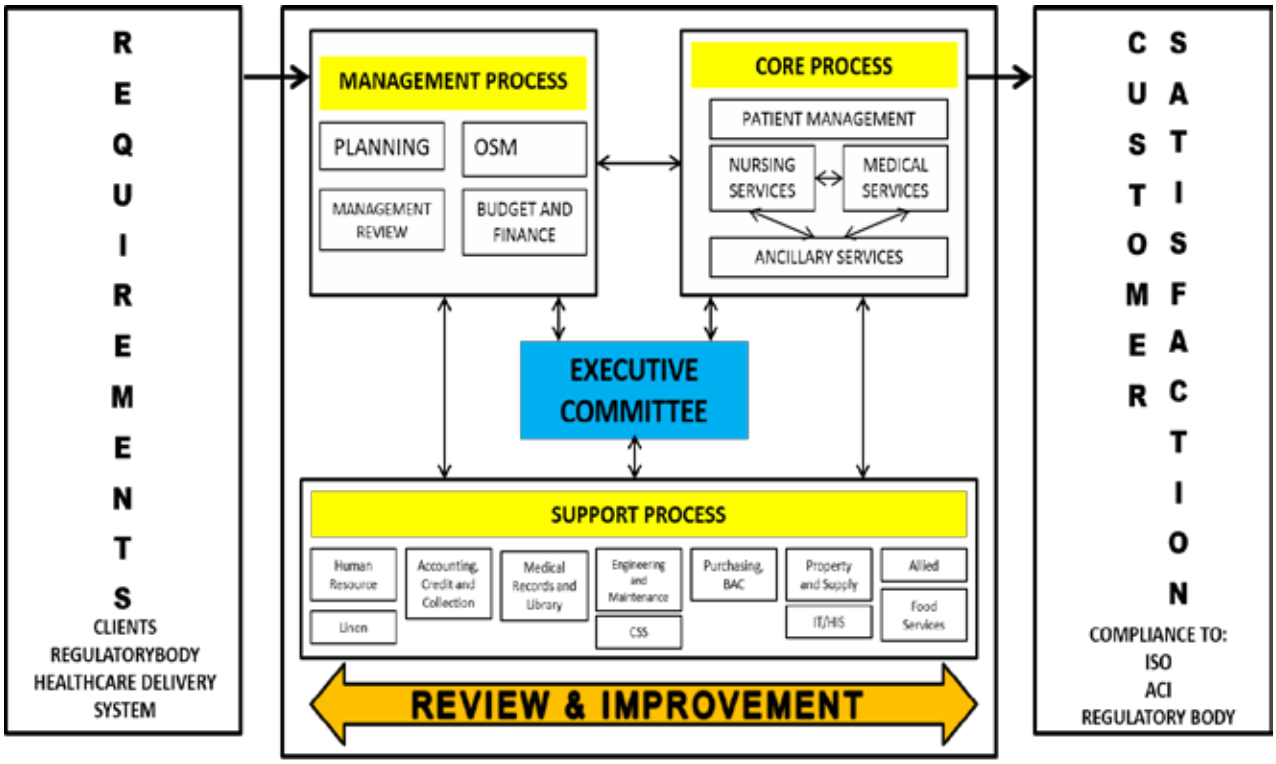
The Sequence and interaction of these processes is illustrated in the Process Map of PHC (Figure 2.)

More detailed processes' descriptions and process interactions can be provided by referring to PHC's documented information.

PHC Organizational Chart



Process Map of the Philippine Heart Center



4.4.1. Management Process

The Management Process includes Planning Operations, Finance, Monitoring and Assessing Performance vis-à-vis its objectives, and Managing Improvements of the core and support processes.

4.4.2. Core Process

The Core Processes relate to the provision of PHC's major services addressing its client's needs and requirements. The core processes describe all the processes that are necessary for PHC to realize and deliver the desired and expected service to its customers. These includes general hospital operations like patient management, i.e. emergency, in-patient, out-patient, and admitting services, and ancillary services, i.e. therapeutic and diagnostic services and infection control

4.4.3. Admitting Services

Philippine Heart Center's Admitting Services includes the processes of the Admitting Section and Social Service Division. Its processes generally focus on securing accurate information relevant to patients' data upon admissions and discharges. It also facilitates timely and precise communication of the information to medical and nursing personnel and other hospital clientele with discretion and prudence. It also coordinate with other departments and patient-patient care areas regarding patient's admission, transfer, discharge and other related services.

4.4.4. Emergency Services

This covers the collaborative processes of the Medical and Nursing Services under its umbrella. Its process involves triaging and assessing to be able to provide immediate medical care to cardiac patients.

4.4.4.1. In-Patient Services

The In-Patient Services of PHC provides direct and in-direct care to patients whose condition warrants admission. The interplay of the nursing and medical services processes is involved under this.

4.4.4.2. Out-Patient Services

The Out-Patient Services of PHC delivers integrated medical and nursing services to patients who, at the moment, do not require admission to a hospital. It encompasses a wide range of services including primary and preventive care. Patients enter In-Patient Care mainly from this area, after referral from the attending physician.

4.4.4.3. Ancillary Services

This delivers a wide-range of healthcare services which provides support to the processes under the Emergency, In-Patient and Out- Patient Services. These services are classified to Therapeutic

(Pharmacy, Physical Medicine and Rehabilitation, Nuclear Medicine, Medical Specialties, Nutrition and Dietetics and Blood Bank) and Diagnostic Services (Laboratory Medicine, Cardiovascular Radiological Science). The hospital's Infection Control Committee also falls under this service.

Please refer to the respective Manuals of Pharmacy, Physical Medicine and Rehabilitation, Nuclear Medicine, Medical Specialties, Nutrition and Dietetics and Blood Bank and Laboratory Medicine, Cardiovascular Radiological Science and Hospit al's I nf ect ion Cont rol Committee for details.

4.4.5. Support Process

The Support Processes ensure that the requirements of the Management and Core Processes are addressed to provide efficient and effective support services which include management of human resources, procurement, facility and equipment, central supply, information technology (HIS), admitting section and quality management.

Refer to the Policy Manuals of the Hospital Support Services for details.

4.4.6. To the extent necessary, PHC shall maintain documented information to support the operation of its processes through its Quality Manual, Quality Policy and Objectives

4.4.7. To the extent necessary, PHC shall retain documented information to have confidence that the processes are being carried out as planned through records, monitoring reports etc.

5. Leadership

5.1. The Top Management of PHC refers to its Executive Committee (ExeCom). The Top Management is reporting to the Board of Trustees with the Secretary of Health as its Chairman.

The Top Management of PHC provides evidence of its leadership and commitment to the development and implementation of the QMS and continual improvement of its effectiveness by:

5.1.1. taking accountability for the effectiveness of the QMS

5.1.2. ensuring that the quality policy and objectives established for the QMS are compatible with PHC's mission, vision and strategic direction

5.1.3. ensuring the integration of QMS to PHC's processes

5.1.4. promoting risk-based thinking and process-based approach

5.1.5. ensuring that resources needed for the QMS are available

5.1.6. communicating the importance of QMS

5.1.7. ensuring that the QMS achieve its intended results

5.1.8. engaging, directing and supporting persons to contribute to the effectiveness of the QMS

5.1.9. promoting improvement initiatives

5.1.10. supporting other relevant management roles

The Top Management of PHC shall also demonstrate leadership and commitment with respect to customer focus by ensuring that:

5.1.11. customer and applicable statutory and regulatory requirements are determined, understood and consistently met

5.1.12. the risks and opportunities that can affect conformity of the services and the ability to enhance customer satisfaction are determined and addressed

5.1.13. the focus on enhancing customer satisfaction is maintained

5.2. Quality Policy

The Quality Policy of PHC:

The Philippine Heart Center commits to provide the highest standard of comprehensive Cardiovascular Care, Education and Research.

We commit to satisfying all relevant statutory and regulatory requirements.

We commit to continually improve our processes.

The Quality Objectives of PHC

To uphold this commitment of providing the highest standard of comprehensive Cardiovascular Care, Education and Research, PHC shall:

5.2.1. Continuously improve services to be able to provide expert patient-care with compassion
5.2.2. Establish programs to enhance knowledge, skills and risk-based thinking
5.2.3. Advocate patient-focused care, respect, integrity, compassion, excellence, teamwork and accountability to advance the interest of the stakeholders
5.2.4. Invest in human resource as its most valuable resource

The Quality Policy is maintained as documented information, disseminated as a separate document and is communicated, understood and implemented throughout the organization. It is also available to relevant interested parties, as appropriate.

5.3. The Top Management of PHC has assigned the responsibilities and authorities pertaining to QMS.

The ISO Team is primarily responsible and authorized for the development of QMS, its implementation and direction, including management of changes if applicable (e.g. transition).

To ensure engagement of people, the responsibility assignments are:

5.3.1. All members of the organization: ensuring QMS conformity
5.3.2. ISO Team: ensuring processes with intended outputs
5.3.3. ISO Team: ensuring performance of QMS
5.3.4. ISO Team: ensuring promotion of customer focus
5.3.5. ISO Team: ensuring integrity of QMS is maintained

Responsibilities and authorities are also well defined in personnel *Job Descriptions.*
Reporting Structure is defined in *PHC's O rganizat io nal Chart .*

The QMS Audit Team's role is to:

5.3.6. Determine whether the QMS is effectively implemented and maintained through audits

5.3.7. Prepare audit plan, coordinates and implements PHC's audit program

5.3.8. Identify the necessary resources for managing PHC's audit program

5.3.9. Provide input to management review regarding the results of audits

5.3.10. Monitor and maintain actions taken to non-conformities raised during audits

The QMS Document Controller

5.3.11. Ensures that the requirements for retaining documented information are established and implemented

5.3.12. Coordinates and oversees activities related to managing organizational knowledge

6. Planning

6.1. PHC shall consider the outputs from Section 4.1 and Section 4.2 above for planning actions to address risk and opportunities.

Options to address risk can include avoiding the risk, taking the risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequence, sharing the risk or retaining the risk by informed decision.

The opportunities detected or recognized are means to improve and or adopt new practices, open new services and new customers, building new teams and partnerships, using new technology and other desirable possibilities to address PHC's and its customer's and stakeholder's needs.

Refer to Corporate Risk Register and the various Risks Registers of the Various Process Owners.

6.2. The Top Management shall establish its quality objectives in coordination with its Office of the Strategy Management and cascaded to all relevant function levels within the organization. It defines its quality objectives through the Office, Department and Division Breakthroughs which are in conformity with the PHC's Strategic Performance

Management System (SPMS), the Performance Governance System and Accreditation Canada International.

The Performance Indicators defined in the Breakthroughs assesses the quantitative and qualitative performance of each personnel.

Refer to Manual of Office of Strategy Management for Details

Also Refer to Documented Information of the Performance Governance System (PGS), Accreditation Canada International (ACI) and the Strategic Performance Management System (SPMS) for more details

The PHC quality objectives shall:

6.2.1. Be consistent with the quality policy
6.2.2. Be measurable
6.2.3. Take into account applicable requirements
6.2.4. Be relevant to conformity of products and services and to enhance customer satisfaction
6.2.5. Be monitored
6.2.6. Be communicated
6.2.7. And be updated as appropriate

PHC shall maintain documented information on the quality objectives.

6.3. PHC shall determine need for changes to its QMS based on :

6.3.1. Change in scope or certification
6.3.2. Change in products or services
6.3.3. Major change in the organizational structure
6.3.4. Major change in process or procedures

These changes shall be carried out in a planned manner considering:

6.3.4.1. The purpose of the changes and their potential consequences
6.3.4.2. The integrity of the QMS
6.3.4.3. The availability of resources
6.3.4.4. The allocation or re-allocation of the responsibilities and authorities

Risk assessment as described in Sections 4.1 and 4.2 will be accomplished as part of planning of changes to ensure that the organizational context and risks arising from these changes are considered.

7. **Support**

PHC determines and provides the resources needed to implement, maintain and continually improve the QMS. Resource allocation is done with consideration of the capability and constraints on existing internal resources, as well as what needs to be obtained from external providers. The organization ensures that its financial resources are properly allocated through the conduct of annual planning and budgeting where all operating units are involved.

Refer to Policy Manuals of Hospital Support Services consisting of Financial Services Department, Administrative Services Department and Ancillary Services Department.

- *Financial Services consists of the Accounting Division, Budget Division, Treasury Division, Billing and Claims Division, Procurement Division*
- *Administrative Services Department consists of Human Resource Management Division, Engineering and Maintenance Division, General Services Division, Property and Supply Management Division.*
- *Ancillary Services Department include the Social Services Division, Patient Services Division, Nutrition and Dietetics Division and Pharmacy Division.*

7.1. PHC determines, provides people and ensures their competence for QMS.

Evidence of competence shall be retained as documented information.

PHC maintains organizational knowledge through appropriate documentation (e.g. Standard Operating Procedures, Training Manuals) and HR related processes (training, turnover process, mentoring)

Refer to Manuals of Education, Training and Research Services (Clinical Research and Education and Training Department) and Human Resource Management Division

7.2. PHC determines, provides and maintains the infrastructure and environment processes and to achieve conformity of products and services.

Refer to Manuals of Engineering and Maintenance Division, General Services Division, Property and Supply Division, and Management Information Systems Division.

7.3. PHC ensures that persons doing work under the organization's control are aware of :

a. The quality policy
b. Relevant quality objectives
c. Their contribution to the effectiveness of the QMS including benefits of improved performance
d. The implications of not conforming with the QMS requirements.

This is done through Unit/ Division or Departmental Meetings or posting through the PHC Intranet.

7.4. PHC shall determine the internal and external communications relevant to the QMS

Internal communication details between process interactions are described within the respective policy manuals of the divisions.

These are also posted at the PHC Intranet and its Website. Internal Communications are also made through Office Memorandum. External Communications are those duly signed and emanating from the Office of the Executive Director.

7.5. **Documented information**

PHC's documented information shall be controlled.

Refer to QMS-QM-002: Standard Operating Procedure on Document Control.

8. **Operation**

8.1. PHC shall plan, implement and control the processes in Section 4.4. needed to meet the requirements for the provision of its services and to implement the actions determined in Section 6

Operational planning and control are described within the policy manuals of various Units. Further PHC, determines, maintains and retains documented information to the extent necessary:

- To have confidence that the processes have been carried out as planned
- To demonstrate the conformity of services to their requirements

PHC shall ensure that outsourced processes are controlled (see 8.4).

8.2. Communication with customers include :

a. Providing information relating to products and services
b. Handling enquiries, contracts or orders, including changes
c. Obtaining customer feedback relating to products and services, including customer complaints
d. Handling or controlling customer property
e. Establishing specific requirements for contingency actions, when relevant

Information regarding company profile and services are provided in the PHC website (www.phc.gov.ph). All inquiries, feedback, including customer complaints should be posted in the Contact PHC page. Information are then screened by the Marketing Specialist under the Public Relations Office and forwarded to Patients Services Division and Quality Assurance for appropriate action or reply to the customer.

Other concerns, complaints or feedback are immediately addressed during Board of Trustees Meetings, regular correspondences, ad discussions between PHC and its stakeholders.

8.3. Design and Development:

8.3.1. The services provided by PHC are based on the needs and requirements of its customers and other interested parties. PHC shall establish, implement and a maintain design and development processes to ensure the provision of quality services.

8.3.2. PHC shall consider the following when determining the process for design and development:

a. The nature, duration and complexity of the design and development activities
b. The requires process and applicable design and development reviews
c. The required design and development verification and validation activities
d. The responsibilities and authorities involved in the process
e. The internal and external resource needs
f. The need for involvement of customers and users in the design and development process
g. The documented information needed to demonstrate that design and development requirements have been met

8.3.3. Design and Development Inputs:

PHC shall determine the requirements essential to the products and services to be designed and developed, and shall consider:

a. Functional and performance requirements

b. Information derived from previous similar design and development activities
c. Statutory or regulatory requirements
d. Standards or code of practice that PHC has committed to implement
e. Potential consequences of failure.

8.3.4. Design and Development Controls

PHC shall apply design and development controls to ensure that:

a. The results to be achieved are defined
b. Reviews are conducted to evaluate the ability of the design and development activities to meet requirements
c. Verification of activities are conducted to ensure that the output meets the inputs
d. Validation activities are conducted to ensure that the resulting product or services meet the requirements for the specific application or intended use
e. Documented information of these activities are retained

8.3.5. Design and Development Outputs

PHC shall ensure that design and development outputs:

a. Meet the input requirements
b. Include reference monitoring and measuring requirements, as appropriate, and acceptance criteria
c. Specify the characteristics of the product or service that is essential for their intended purpose and their safe and proper provision
d. Are documented

8.3.6. Design and Development Changes

PHC shall identify, review and control changes made during or after the design and development activities, to the extent necessary to ensure that there is no adverse impact on conformity to requirements. PHC shall retain documented information on:

a. Design and development changes
b. The result of the reviews

c. The authorization of changes

8.4. PHC shall ensure the determination and review of products and service requirements. When there are changes in requirements, PHC shall also ensure relevant information is amended, and that relevant persons are made aware of the changes requirements, when the requirements for products and services are changed.

8.5. PHC shall ensure that all externally provided processes, products and services conform to requirements.

PHC provides timely, cost effective, transparent and competitive procurement services. All procurement of goods and services are in accordance with bid parameters, specifications and applicable laws. Procurement documents contain clear description of goods or services ordered. Procurement documents are reviewed and approved prior to its release to suppliers. Inspection, evaluation and acceptance activities are in place to ensure that all specifications are met.

Performance of approved suppliers and service providers are periodically reviewed and evaluated to ensure their ability to meet PHC's quality requirements. Records of review and evaluation are maintained.

PHC ensures its compliance to the requirement of the implementing rules and regulations of Republic Act 9184 otherwise known as the "Government Procurement Reform Act".

Refer to Policy Manual of Procurement Division, General Services Division, Engineering and Maintenance Division, Property and Supply Management Division.

8.6. Service Provision

8.6.1. PHC shall implement service under controlled conditions.

Refer to Policy Manuals of the Surgery and Anesthesia Department (Adult Cardiothoracic Surgery Division, Pediatric Cardiothoracic Surgery Division, Vascular Surgery Division, Cardiovascular Anesthesia Division)

Refer to Policy Manuals of Allied Medical Specialties Department (Radiological Sciences Division, Nuclear Medicine Division, Laboratory Medicine Division, Physical Medicine and Rehabilitation Division, Renal and Metabolic Division, Pulmonary Medicine Division)

Refer to Policy Manuals of Adult Cardiology Department (Clinical Cardiology Division, Invasive Cardiology Division, Non-Invasive Cardiology Division, Electro Cardiology Division, Vascular Medicine Division)

Refer to Policy Manuals of Pediatric Cardiology Department (Pediatric Cardiology Division, Pediatric Invasive Cardiology Division, Pediatric Non-invasive Cardiology Division)

Refer to Policy Manual of Ambulatory, Emergency and Critical Care Department (Emergency Care Division, Critical Care Division, Out-Patient Division)

Refer to Policy Manuals of Nursing Services consisting of Special Critical Care Department and General Nursing Department.

8.6.2. Patient Charts/ Medical Records are retained to ensure traceability of all diagnosis, medications, treatments, procedures undertaken on patients including progress reports on patient's health and status including dates of admission and discharge.

Further, PHC's Departments also maintain identification and traceability of their outputs through various account folders.

8.6.3. PHC shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by PHC such as *consigned items and rented equipment* .

Refer to Guidelines/Policy Manual of Consignment Committee for Details.

If property is damaged or found unsuitable for use, PHC shall report to the customer or external provider and retain documented information on what has occurred.

8.6.4. PHC shall preserve outputs during service provision to the extent necessary to ensure conformity to requirements. For the case of outputs in the form of documented information this shall include identification, storage, transmission and protection*. Refer to Policy Manual of Medical Records*

8.6.5. PHC shall meet the requirements for post-delivery activities associated with its services considering:

- Applicable statutory and regulatory requirements
- Potential undesired consequences associated with services
- Nature use and intended lifetime of its services
- Patients' requirements and feedback

(Refer to Guidelines of Tele Care System of Nursing Services)

8.6.6. To the extent necessary to ensure continuing conformity with requirements, PHC reviews and control changes of service provision.

PHC retain documented information describing the results of the review of changes, the persons authorizing the changes and any necessary actions arising from the review. These are defined in the various Policy Manuals of the different Departments.

8.7. PHC shall implement planned arrangements to verify service requirements have been met.

PHC shall retain documented information on the release of services which includes evidence of conformity with acceptance criteria and traceability to the person/s authorizing the release.

Documented information includes, but is not limited to, resolutions, memos, turnover documents, minutes of the meeting, discussion or presentation of projects, contracts etc.

8.8. PHC shall ensure that outputs that do not conform to the requirements are identified and controlled to prevent their unintended use or delivery.

PHC shall address the nonconforming outputs with one or more of the following ways:

Correction or immediate action

8.8.1. Return or suspension

8.8.2. Informing the customer

8.8.3. Obtaining authorization for acceptance under concession

The organization shall retain documented information by using one or combination of:

Non-conformity report, Action plan report, resolutions, memos, minutes of the meeting, contracts or contract amendments.

Refer to QMS-QM-005 Control of Non-Conformances and Corrective Action

9. Performance evaluation

PHC shall determine its provisions for monitoring, measurement, analysis and evaluation. The appropriate documented information shall be retained as evidence of results.

Summary of the performance evaluation process is describes as follows:

What to Monitor?	What Method?	What Frequency?	When to Analyze?	Locus of Responsibility
Conformity of Products/Services · Breakthrough Measures · ROPS/ACI Standards · Implementation of Philhealth No Balance Billing · Citizen's Charter for frontline services	a. Division Meetings b. Reports to the ExeCom	Monthly	Monthly	Office of the Strategy Management All Services/Process Owners
Employees' Performance	a. SPMS	Bi-annual	Bi-annual	Human Resource Division
Customer Satisfaction (External)	a. Patient Satisfaction Survey for in-patients, b. Frontline Service Client Satisfaction (out-patient) c. Reports on complaints handling d. Number of complaints received from 8888	Monthly, Quarterly, Annually	Monthly, Quarterly, Annually	Patient Services Division, Quality Assurance
Customer Satisfaction (Internal)	a. Survey Meeting b. Employee Satisfaction Survey c. Reports to ExeCom	Annual	Annual	Human Resource Division

Performance of External Providers	a. Ocular Check b. Reports from end-users to Hospital Support Services	Quarterly	Quarterly	All Services/Process Owners Janitorial Linen Security
Effectiveness of Actions for Risks/Opportunities	a. Audit b. Division Meetings	Annual	Annual	All Services/Process owners

9.1. PHC monitor issues of internal and external interested parties through Patient Satisfaction Survey, Feedbacks/ Complaints received through 888, Exit Interview of out- going personnel, Personnel Satisfaction Survey and Feedbacks received through its website.

Results of these measurements are analyzed and summarized to become an input to the continuous improvement of PHC processes. Results are discussed during management reviews where improvement actions are identified for implementation. Monitoring of all management decisions are conducted by converting recommendations/observations into Action Plans.

Refer to Appendix B to L for Forms related to Quality Objectives (Breakthrough) Monitoring.

9.2. PHC conducts an Internal Quality Audit at least twice a year to verify whether quality activities and related results conform to and is effectively implemented and maintained:

9.2.1. PHC Requirements as stated in:

9.2.1.1. ACI

9.2.1.2. ISO

9.2.1.3. PGS

9.2.2. Regulatory and statutory requirements

Details of the PHC Internal Quality Audit Procedure are discussed in *QMS-QM-004: Standard Operating Procedure on Internal Quality Audit.*

9.3. The Top Management reviews the QMS at least once a year and or at planned intervals to ensure its continuing adequacy, applicability and effectiveness. The review is led by the Quality Management Representative, Deputy Quality Management Representative and Quality Leader. The review evaluates the need for changes to the organization's QMS, including its quality policy and quality objectives.

The review shall consider the following as necessary:

- the status of actions from previous management reviews
- changes in internal and external issues that are relevant to QMS
- the effectiveness of actions taken to address risks and opportunities
- information on the performance and objectives of QMS including trends in:
  - ü client satisfaction and feedback from relevant interested parties,
  - ü the extent to which quality objectives have been met
  - ü PHC's Performance Indicators
  - ü nonconformities and corrective actions/process performance monitoring and measurement result
  - ü audit results
  - ü performance of external providers
- adequacy of resources, and
- opportunities for improvement

The outputs from the management review include but are not limited to decisions and actions related to:

- opportunities for improvement
- any need for changes to QMS
- resource needs.

Results of management reviews are recorded.

Process on Management Review is detailed on *QMS-QM-006: Standard Operating Procedure on Management Review.*

10. Improvement

10.1. The Top Management determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction. These include;

- improving processes and services to meet requirements as well as to address future needs and expectations,
- correcting, preventing or reducing undesired outcomes, and
- improving the performance of QMS

10.2. Nonconformity and Corrective Action

PHC maintains a Corrective Action Procedure to ensure that it reacts to the nonconformity and as applicable, take action to control and correct it or deal with the consequences.

The procedure also provides a system for reviewing, analyzing, determining the causes and if similar nonconformities exist, or could potentially occur, to ensure that appropriate corrective actions are taken.

Records of the nature of the nonconformities and any subsequent actions taken and results of any corrective action are maintained.

Procedure on this is detailed on the *QMS-QM-005: Standard Operating Procedure on Non-Conformances and Corrective Action.*

10.3. PHC shall continually improve the suitability, adequacy and effectiveness of the QMS by considering the results of analysis and evaluation, and the outputs from the Management Reviews, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

10.4. Control of Nonconformity

PHC ensures that service provided which does not meet requirements is identified, controlled where possible to prevent unintended use or delivery to the customer, and corrected if it has been delivered. This procedure includes provisions for:

- identification, documentation, evaluation, segregation (where practical), disposition of nonconforming service, and for notification of the functions concerned;
- assigning responsibility for the review and the authority for disposition of nonconforming service;
- correction of nonconforming service and re-verification/calibration of the affected equipment after correction to demonstrate conformity (if necessary);
- handling of nonconforming service when it is detected after delivery to the customer.

Procedure on this is detailed on the *QMS-QM-005: Standard Operating Procedure on Control of Non-Conformances and Corrective Action Plan*

10.5. Continual Improvement

PHC continually improves the applicability, adequacy and effectiveness of the QMS through the results of audits, analysis and evaluation of data and the outputs from the corrective and preventive action and management review. The organization plans and manages the processes necessary for the continual improvement of the QMS.

PHILIPPINE HEART CENTER	Document Type **POLICY**	Document Code: QMS-QM-002
		Effective Date: October 2018
	Document Title **DOCUMENT CONTROL**	Revision Number: 2
		Page: 1 of 9

REVISION HISTORY

Rev No.	Review Date	Description of Change	Date of Next Review
0	September 2018		
1	October 2018	Revised the guidelines in document formatting	October 2021

Reviewed by:	**Quality Management Team**	Approved by:	**JOEL M. ABANILLA, MD** Executive Director

1. OBJECTIVE

This procedure defines the method for preparing, reviewing, approving, maintaining, tracking, and changing documents identified in the individual Document Master Lists.

2. SCOPE

This process applies to all functions and processes defined in the scope of the Quality Management System. This procedure applies to the creation and revision of documents of PHC, from core or operating to support units.

3. DEFINITIONS

Document Controller - This refers to the person/s responsible for the control of all documents and data relating to the requirements of ISO 9001:2015 both in electronic and hard copy.

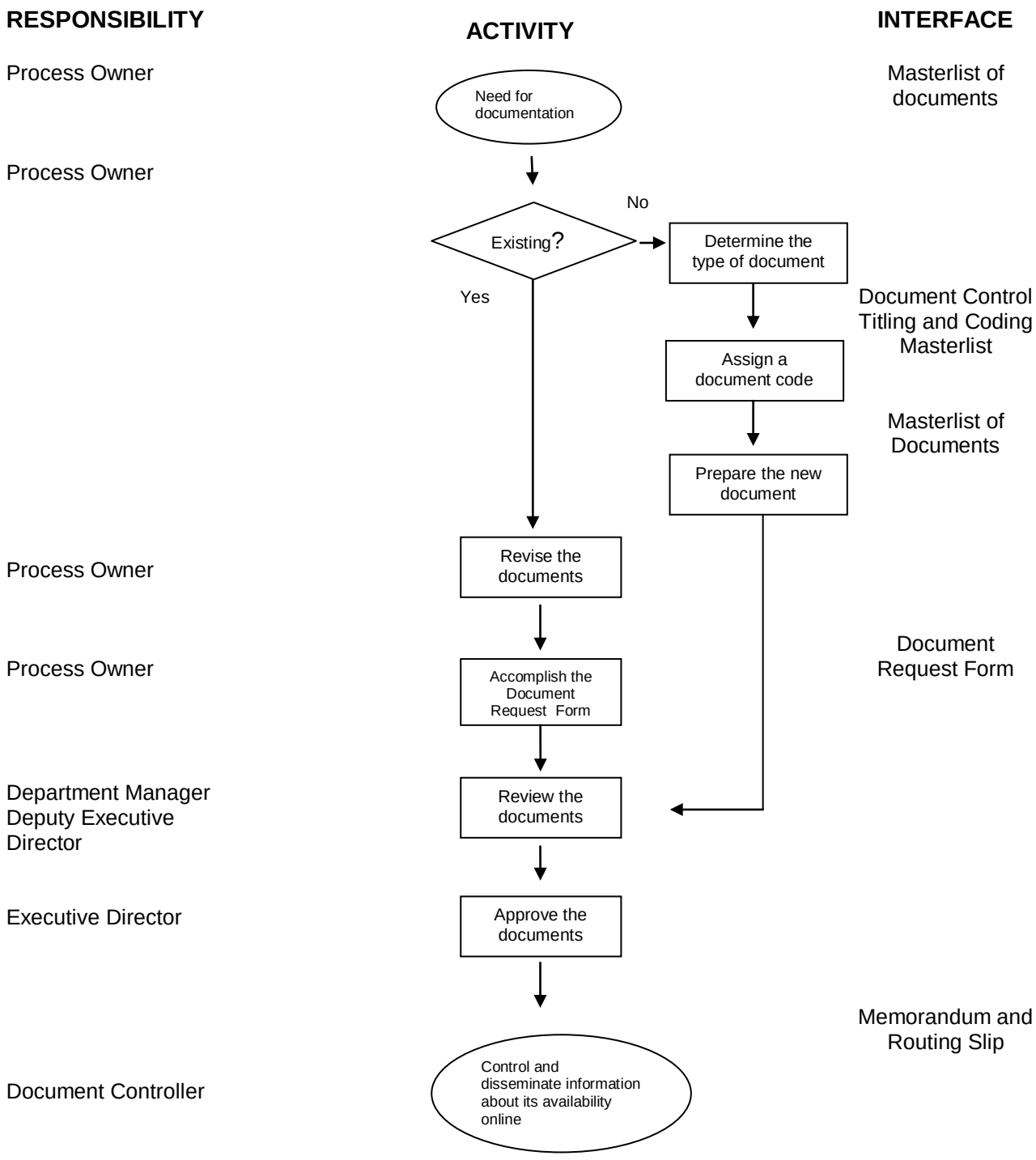
Document - This refers to PHC's procedures, work instructions, manuals, or associated form/s which is used to control the processes that affect the quality of the services provided by the organization.

Document Control Form (DCF) - This refers to the form used to create or change a document.

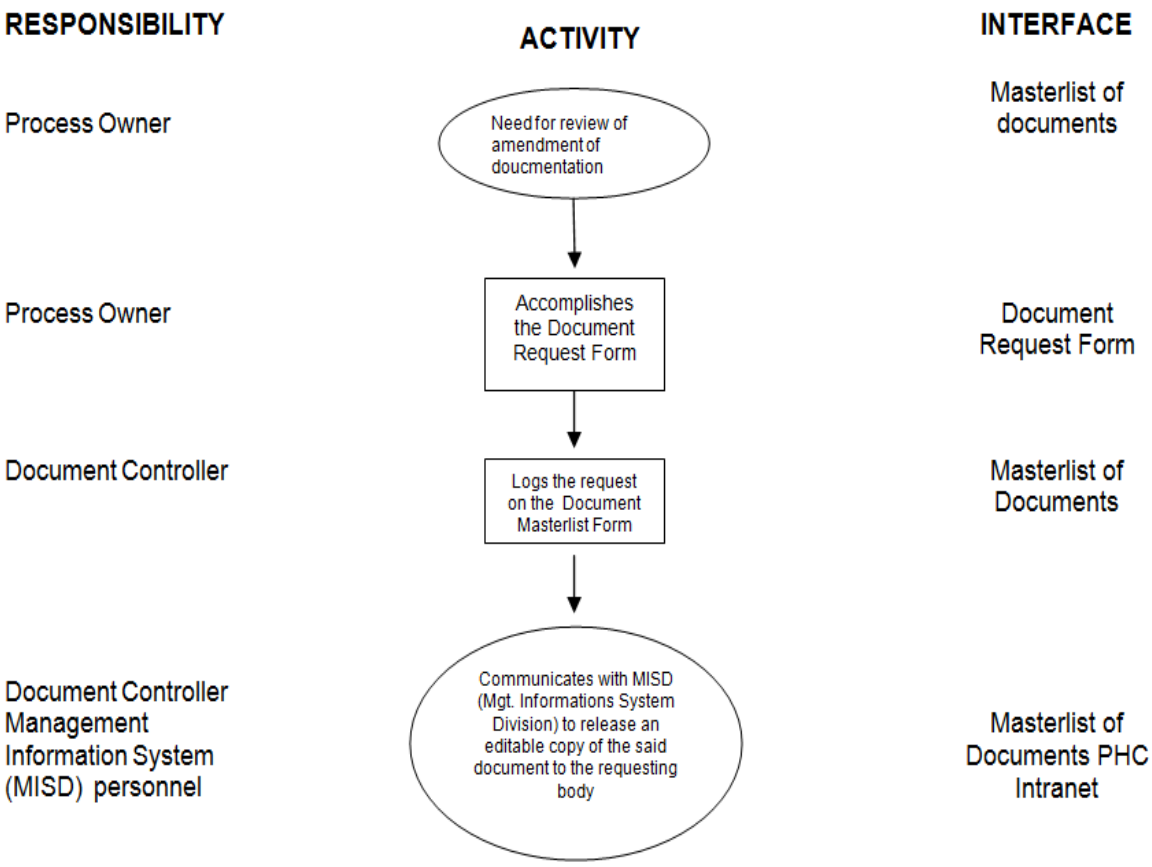
Master List - This refers to the list that identifies PHC's documents and data as well as current revision status

4. PROCEDURES OUTLINE

A. CREATION OR REVISION OF DOCUMENTS



B. REQUESTING FOR DOCUMENTS



5. PROCEDURE DETAIL

5.1. If an opportunity to establish or revise a new document is presented, the process owner or assigned personnel shall review the master list to verify that the creation or revision of the document has not already been done.

5 . 2 . For new documents the following are the general guidelines in formatting:

5 . 2 . 1 . GUIDELINES

5.2.1.1. A table of the summary of the cumulative history of revisions will appear on the first page of each document.

5.2.1.2. For Page 2 and onwards, the “Reviewed by” and “Approved by” footnote/ fields are omitted

5.2.1.3. Generally, Arial font, 1.5 lines paragraph spacing and justified alignment shall be used for the whole document. Font size will vary depending on the location and usage.

5.2.1.3.1. HEADER CONTENT

5.2.1.3.1.1. PHC Logo

5.2.1.3.1.2. Hospital Name – situated below the logo (Arial, 12- point, Bold, All Caps)

5.2.1.3.1.3. Service (Medical/ Hospital Support/ Nursing/ Education, Training and Research) in bold letters, upper case, Arial 11, under Hospital Name

5.2.1.3.1.4. Department – pertains to origin of the policy, typed in regular case (Arial,8), under Service Name

5.2.1.3.1.5. Specific name of the division in regular case (Arial,8), under the Department Name

5.2.1.3.1.6. If a document is specific to an area, unit or section, write its name right after the Division’s name in regular case, Arial 8

5.2.1.3.1.7. Document Type- the type of document, whether Policy, Standard Operating Procedure, Work Instruction, or Guidelines typed in bold, all upper case letter, (Arial, 11)

5.2.1.3.1.8. Document Title – the identification of the document. This should be a unique name/description that is not duplicated by another document, typed in bold, all upper case (Arial, 11)

5.2.1.3.1.9. Titles such as Document Type, Document Title, Document Code, Effective Date, Revision Number, Page, are all typed in regular cases (Arial, 9)

5.2.1.3.1.10. Specific entries in the above-mentioned titles are typed in regular, all upper case, Arial, 9 and as follows:

5.2.1.3.10.1. Document Code: Use two to three letters for Service, Department and Division ownership separated by a hyphen. Hyphens will be used as a standard form, rather than spaces, slashes or underscores.

AAA - Service (MED/NSG/HSS/ETR)
BBB - Department owner CCC - Division
000 – Document/Series number

Note: Please refer to the **DOCUMENT CONTROL TITLING AND CODING MASTER LIST** file which can be found on the ACI and ISO Journey in the PHC Intranet and for new document codes, the process owner shall communicate the addition to the Document Controller through the Document Request Form

For coding Forms and Communications refer to the Coding System Guidelines QMS-QM-003

5.2.1.3.10.2. **Effective Date** – [Month] [Year] – the specific date the policy has been implemented, whether it is its first issuance or the effectivity/ implementation of the revised version example, January 2010.

5.2.1.3.10.3. **Revision Number** - Original documents will be noted as revision 0. All subsequent revisions will be numbered sequentially (1, 2, 3, 4….)

5.2.1.3.10.4. **Page** – general numbering system is used. Each policy shall be numbered as 1 of #, 2 of #, and so on. The number sign '#' represents the total number of pages of a given document.

5.2.1.3.10.5. Use roman numerals (lower case), **i, ii, iii, iv, v, vi**, in paging the following sections:

a. Table of Contents
b. Introduction
c. Vision / Mission
d. Organizational Structure
e. Organizational Chart
f. Physical Lay-Out

5.2.1.3.2. BODY CONTENT

5.2.1.3.2.1. The body of the policy is written in Arial size 10 5.2.1.3.2.2.

5.2.1.3.2.2. Use 1.5 line spacing

5.2.1.3.2.3. Indentions are applied and should be aligned throughout the document. This will apply in numbering format and bullets.

Note: Bullet format to be used is *"outline numbered"* as shown in this guideline.

5.2.1.4. SAVING THE FILE

5.2.1.4.1. Individual policy shall be saved as one file.

Example: Policy on Patient's Complaint shall be saved as "MSO-QA-001-Patients Complaint"

5.2.1.4.2. Soft copy of the file will be submitted to the **Management Information System Division (MISD)** for uploading to the PHC's intranet.

5.2.1.4.3. All uploaded Documents are signed and approved by the concerned Deputy Executive Director and the Executive Director respectively.

5.3. All documentation activities, i.e. creation, revision, review, deletion, etc., shall be communicated to the Document Controller using the Document Control Form

5.4. The Department Manager, Division Chief, process owner or members of a committee assigned for documentation activities shall be the one responsible in ensuring the correct preparation and formatting.

5.5. The Deputy Executive Director or, if applicable, the Chairperson or Leader in a committee assigned for any documentation activity, is responsible in reviewing the proposed document.

5.6. All documents should be approved by the Executive Director

5.7. Final and approved documents shall be registered by the Document Controller and necessary changes in the Master list of Documents shall be made.

6. REQUESTING FOR DOCUMENTS

6.1. When reviewing, amending or deleting a document, the process owner shall request for an editable format of the specific document to the Document Controller.

6.2. Request for an editable format of documents shall be communicated through the use of the Document Control Form.

6.3. The Document Controller shall record the request on the Master list and shall communicate with the HIS personnel for the issuance of the request.

7. CONTROL OF DOCUMENTS

7.1. All documents shall be controlled using the standard coding (refer to QMS-QM-005:Guidelines on Coding System and Document Control Coding Master List)

7.2. Appropriate issue and revision number shall be indicated in the document. Every revision in a document shall be reflected in the revision number for the document.

7.3. Changes in the documentation may be made from time to time. There are also cases when these documents may have to be withdrawn for replacement, or perhaps ultimately for retirement. Typical of these cases are as follows:

7.3.1. A re-issue of the document is needed

7.3.2. Document is no longer in effect

7.3.3. Document has been replaced with another

7.3.4. Contents have been combined with another document

7.3.5. Contents have been split into two or more documents

7.3.6. Document was rewritten with a change in category (e.g., changing procedure into guideline)

7.4. All changes made in the document shall be summarized and entered in the Revision History page.

7.5. Any documents external to the organization that affect the quality of service but are not covered by the QMS or are included by reference shall be controlled by the respective department user. These shall be communicated to the Document Controller and shall be registered in the master list with the latest revision. Examples of such external

documents are manual of standards from ISO and ACI, product or machine specifications etc.

7.6. The Master Copy of all documents is in soft copy and uneditable format and is uploaded in PHC's intranet.

7.7. All printed documents (hard copies) by the Document Controller are considered Controlled Copies.

7.8. A Master List of Documents shall be prepared to indicate copy holders of all controlled documents.

8. DISTRIBUTION

8.1. Master Copies of all documents are uploaded and is readily accessible for viewing via the PHC's Intranet

8.2. Controlled copies of the Quality Manual shall be tagged as "Controlled" and shall be distributed to all Department, Division, Unit and Sections of the organization.

8.3. Controlled copies of certain types of documents relevant to specific processes shall be tagged as "Controlled" and shall be selectively distributed to process owners.

8.4. The Document Control Form and Master list shall be accomplished accordingly to ensure proper tracking and to prevent unauthorized access of documents.

8.5. Obsolete documents and records shall be tagged as "Obsolete" and shall be archived and stored or disposed in accordance to the National Archive of the Philippines General Records Disposition Schedule :

8.5.1. The Master Copy of obsolete documents shall be removed from the intranet and shall be stored as reference in PHC's Hard Drive upon its effectivity date.

8.5.2. Controlled copies of obsolete documents shall be removed from the active file upon its effectivity date.

8.5.3. Controlled copies of obsolete documents shall be destroyed using a shredding machine.

8.6. The originating Department Manager is responsible in informing all concerned that a document was created, reviewed, revised or deleted through a memorandum or meeting.

Refer to Annex A for the Document Request Form

PHILIPPINE HEART CENTER	Document Type **POLICY**	Document Code: QMS-QM-003
		Effective Date: October 2018
	Document Title **DOCUMENT CODING**	Revision Number: 2
		Page: 1 of 7

REVISION HISTORY

Rev No.	Review Date	Description of Change	Date of Next Review
0	September 2017		
1	October 2018	Included the guidelines in coding Forms, Communications, Job Order and Purchase Order and Requests	October 2021

Reviewed by:	**Quality Management Team**	Approved by:	**JOEL M. ABANILLA, MD** Executive Director

I. Objectives

To provide specific guidelines on the coding system for documents and records within the Quality Management System.

II. Scope

These guidelines shall apply to all documents and records generated within the Quality system. Covered by these guidelines are new, as well as existing, documents and records.

III. Responsibility

Every concerned Process Owner (Policy-maker) who will create a new document or record and/or use an existing document or record shall be responsible for the implementation of these guidelines.

IV. Guidelines

1. Quality Manual (c/o ISO-QMS Team)

The Quality Manual shall be identified by the following code:

QMS-QM-001 where

QMS - Quality Management System
QM - Operations Manual
001- - Document number

2. One Hospital Policy

The One Hospital Policy are documents describing the multidisciplinary approach to providing safe and effective healthcare services in relation to the 15 Standards of Accreditation Canada International.

All documents under this shall be identified by the following code:

PHC-ACI-AAA-000 where

PHC - Philippine Heart Center
ACI - Accreditation Canada International (ACI)

AAA - ACI Standard
(ACS- Ambulatory Care Standard, EDP- Emergency and Disaster Preparedness)

000 - Document Number

3. Standing Committees

All hospital-assigned committees shall be identified by the following code:

PHC-COM-AAA-000 where:

PHC - Philippine Heart Center

COM - Standing Hospital Committee

AAA - Name of Committee

000 - Document Number

4. Management Services Department

All offices under the Management Services Department shall be identified by the following code:

DO-MSD-AAA-000 where

DO - Director's Office

MSD - Management Services Department

AAA - Division

000 - Document Number

5. Office of the Strategy Management (OSM)

All documents under this office will be identified by the following code:

PHC-DO-OSM-000 where:

PHC - Philippine Heart Center

DO - Director's Office

OSM - Office of the Strategy Management

000- Document Number

6. Documents from Process Owners

All documents under the different Services, Departments, Divisions and Sections shall be identified by the following codes:

AAA-BBB-CCC- 000 where:

AAA - Service **(MED/NUR/HSS/ETR)**
BBB - Department owner
CCC - Division
000 - Document Number

Example: **NUR-DSA-SPE- 000** where:

NUR - Nursing Service
DSA - Department of Special and Critical Care
SPE - Division of Specialized Care
000 - Document Number

Refer to the Document Control Titling and Coding Masterlist

7. Forms and written communication

7.1. Forms

All forms will be identified by the following codes:

AAA-FRM-000-0000, where:

AAA - Process Owner's Code
FRM - Form
000 - Series Number
0000 - Effectivity Year

Example: **QMS-FRM-001-2018** (Document Control Form), where:

QMS - Quality Management System (originator)
FRM - Form
001 - Document Number
2018 - Effectivity Year

7.2. Communications

7.2.1. Memorandum

All memoranda entered in PHC's online Memorandum System shall be automatically assigned the following codes:

AAA-M:000-0000 where:

AAA - Originator's Code
(Director's or any of the Deputy Executive Directors' Office)

M - Memorandum (Memo)

000 - Document Number

0000 - Year Issued

Example: DO-M:001-2018, where:

DO - Director's Office

M - Memo

001 - Document Number

2018 - Year Issued

7.2.2. Routing Slip

All routing slip will be identified by the following codes:

AAA-BBB-CCC-RS-000-0000, where:

AAA - Service (Medical/ Hospital Support Services/ Nursing/ Education Training and Research)

BBB - Department

CCC - Division/ Specific Unit or Section

RS - Routing Slip

000 - Document Number

0000 - Year of Issuance

Example: **NUR-CLA-ER-001-2018**, where:

NUR - Nursing Service

CLA - General Nursing Department

ER - Emergency Room

001 - Document Number

2018 - Year of Issuance

7.2.3. Letters

All letters will be identified by the following codes: AAA-BBB-LT--000-0000, where:

AAA-BBB-LT-000-0000, where:

AAA - Service (Medical/ Hospital Support Services/ Nursing/ Education Training and Research)
BBB - Department
LT - Letter
000 - Document Number
0000 - Year of Issuance

Example: **MED-PED-LT-001-2018**, where:

MED - Medical Services
PED - Pediatric Cardiology Department
LT - Letter
001 - Document Number
2018 - Year of Issuance

7.2.4. Minutes of the Meeting

All minutes of the meeting will be identified by the following codes:

AAA-BBB-CCC-MOM-000-0000, where:

AAA - Service
BBB - Department
CCC - Division
MOM - Minutes of the Meeting
000 - Document Number
0000 - Year of Issuance

Example: **ETR-CRD-MLD-MOM-001-2018**, where:

ETR - Education, Training and Research
CRD - Clinical Research Department
MLD - Medical Library Division
MOM - Minutes of the Meeting
001 - Document Number
2018 - Year of Issuance

8. Job Order

All requests entered in PHC's online Job Order System shall be automatically assigned a code.

9. Purchase Request and Purchase Order

All Purchase Requests and Orders are assigned codes by the Purchasing Division.

PHILIPPINE HEART CENTER	Document Type **POLICY**	Document Code: QMS-QM-004
		Effective Date: October 2018
	Document Title **INTERNAL QUALITY AUDIT**	Revision Number: 2
		Page: 1 of 7

REVISION HISTORY

Rev No.	Review Date	Description of Change	Date of Next Review
0	September 2017		
1	October 2018	Included description of responsibilities of the Quality Assurance Officer, Unit QA and Representatives and revised the procedures on the conduct of audit	October 2021

Reviewed by:	**Quality Management Team**	Approved by:	**JOEL M. ABANILLA, MD** Executive Director

I. **OBJECTIVE**

1. To determine whether the quality management system of the Philippine Heart Center conforms with:
   1.1. requirements of the ISO 9001:2015 International Standards
   1.2. other existing regulatory and statutory requirements relevant in the delivery of safe and quality patient care.
2. To ensure that these requirements and standards of care are effectively implemented and maintained

II. **SCOPE**

1. The internal audit process shall include the medical services, nursing care, medical ancillary units, administrative units and support services relevant to the implementation and sustainability of quality patient care.

III. **RESPONSIBILITY**

1. ISO Over-all Chairman/Coordinator

2.1. Has the overall task of ensuring that internal audits are conducted at planned intervals
2.2. Reviews the results or audit findings submitted by the Lead Auditor
2.3. Approves the summary of internal audit findings PRIOR to submission to Office of Executive Director
2.4. Updates the organization about any new requirements or standards for application to the organization

2. Lead Auditor

2.1. Prepares the Audit Plan
2.2. Determines the Audit Criteria for the respective services to be audited
2.3. Leads the Opening Meeting and Closing Meeting during internal audits
2.4. Summarizes and analyzes the Audit Findings
2.5. Submits the Final Summary Report of IQA Findings to the QA Officer
2.6. Presents the Internal Audit Findings during Management Reviews

3. Internal Auditor

3.1. Actively participates in the audit process as required

3.2. Reviews the audit criteria and standards relevant to the type and basis of audit to be conducted

3.3. Prepares & submits the findings to the Lead Auditor in the time allotted

3.4. Shall participate in the analysis and summarization of the audit findings

3.5. Shall confer with the Lead Auditor any concerns pertaining to the actual conduct of the audit

3.6. Prepares the CAR on the audit findings he/she had submitted

4. Respective Unit QA Representative

4.1. Shall participate in meetings or workshops scheduled by the QA Office

4.2. Shall assist the Unit in ascertaining the compliance of the Unit to the standards, or regulatory and statutory requirements prescribed

4.3. Encourage to be observers during audit, and become a qualified internal auditor

5. Auditee

5.1. Shall abide with the scheduled audit itinerary

5.2. Shall cooperate and provide the documents required with the internal audit process

5.3. Shall promptly accomplish the CAR issued to the Unit, should there be any audit findings

IV. **Procedures on the Conduct of the Internal Audit**

1. An **Internal Quality Audit** shall be conducted at planned intervals, *preferably twice a year*, to include the services as described above.

2. The **Notice of Internal Audit**, together with the **approved Audit Plan** / **Audit Itinerary** shall be sent to the Units concerned, at least thirty (30) calendar days PRIOR to the conduct of scheduled Internal Audit.

2.1. The **Audit Plan / Audit Itinerary shall include** the

2.1.1. Purpose of the Internal Audit

2.1.1.1. Scope of Audit and Audit Criteria per Unit

2.1.1.2. Assigned Auditors

2.1.1.3. Date and Time of Audit, and

2.1.1.4. Other arrangements made for this Audit, if any

2.2. The **Audit Plan is prepared by the Lead Auditor**, and shall be submitted as follows:

2.2.1. **Final Review by the ISO QMS Coordinator**

2.2.1.1. **Final Approval by the Office of the Executive Director**

2.3. All the concerned Department Heads, Division Chiefs, Unit Heads and respective QA Representatives are enjoined to attend the Opening Meeting and Closing Meeting.

2.3.1. During the **Opening Meeting**, introduction of auditors to auditees and time mand schedule are tackled

2.3.2. During the **Closing Meeting**, the Lead Auditor shall present the audit findings. Appeals for consideration and explanation on the audit findings can be done by the Auditee during this session.

2.4. **Conduct of Audit** is through interview, observation, and examination of documented information required by the standards and regulatory and statutory requirements relevant to the service.

2.5. The Internal Auditors shall gather accordingly any available objective evidence, both deficiencies and conformances, relevant to the process and procedure under audit.

2.6. At the end of EACH day of audit, the internal auditors shall discuss, validate and summarize their audit findings. The Auditee may present additional evidences at the end of each audit day to explain and rectify any findings or non-compliance observed.

2.7. A Summary of the Final Report on the Internal Audit Findings shall be submitted by the Lead Auditor after two (2) working days to **ISO QMS Coordinator** for review and final approval.

2.8. The **ISO QMS Coordinator** shall submit this Summary of Audit Findings to the Office of the Executive Director within three (3) working days, for his information and for his perusal during the Management Review.

V. **Procedure on Documentation of Audit Findings and Issuance of Corrective Action Request (CAR)**

1. Audit Findings shall be categorized as follows:

1.1. **Non- Conformities (NC)**

1.1.1. Failure to fulfil one or more requirements of the management system standard

1.1.2. a situation that raises significant doubt about the ability of the Unit quality management system to achieve its intended outputs.

1.1.3. A completed CAR shall be accomplished to give the detailed plan of corrective actions; the implementation of effectiveness of corrective actions shall be verified in the next internal audit

1.2. **Minor Nonconformities (Min)**

1.2.1. Lapse in some of the requirements of the management-system standard;

1.2.2. Requirements are not fulfilled completely BUT this does not jeopardize the effectiveness of the management-system element (i.e. chapter of the standard).

1.2.3. The Unit must return to the QA Office the filled up CAR giving the details of INTENDED corrective actions; The implementation and effectiveness of corrective actions will be verified in the next audit.

1.3. Opportunities for Improvement (OFI)

1.3.1. Aspects that would lead to management system optimization with respect to a requirement of the standard.

1.3.2. The requirements of the standard regarding the process element have been fulfilled but that there are still areas for potential improvement of

system effectiveness and efficiency. Implementation by the organization is recommended.

1.4. Positive Aspects (P)

1.4.1. Positive aspects of the management system meriting special mention

2. After the Summary of Audit Findings have been duly validated by the Team Leader, and reviewed by the Lead Auditor, the Internal Auditors shall issue two copies of Corrective Action Request (CAR) for each audit finding.

3. This CAR must be received by the concerned UNIT within five (5) working days from date of issuance of CAR.

4. The accomplished CAR shall be returned by the concerned UNIT within 14 days from time date of receipt of CAR.

5. The respective QA Representatives of each Unit/Service shall follow up on the action plan submitted by the Dept Managemer/ Division Chief / or Unit Head

6. Closure of CAR shall be monitored by the Lead Auditor and the effectiveness of the action plans shall be verified by the Internal Auditors during the next audit

VI. **Selection & Evaluation of Internal Auditors**

1. Competencies and Skills

1.1. Shall have undergone workshops/training on auditing management systems and currently employed by the institution

1.2. Able to communicate clearly and respectfully

1.3. Able to do task management

1.4. .Displays team working abilities

2. Evaluation of Internal Auditors

2.1. After each IQA, the internal auditors shall be evaluated by each Team Leader

2.2. The Team Leaders and all the other intenal Auditors shall be individually evaluated by the Lead Auditor

2.3. An evaluation Tool for Internal Auditors shall be provided

3. Related Documented Information

3.1. Annual Audit Plan – QMS-IQA-FRM-001-2018

3.2. Audit Itinerary – QMS-IQA-FRM-002-2018

3.3. Audit Checklist - QMS-IQA-FRM-003-2018

3.4. Audit Report - QMS-IQA-FRM-004-2018

3.5. Summary of Audit Findings - QMS-IQA-FRM-005-2018

3.6. Evaluation of Internal Auditors - QMS-IQA-FRM-006-2018

PHILIPPINE HEART CENTER	Document Type **POLICY**	Document Code: QMS-QM-005
		Effective Date: October 2018
	Document Title **CONTROL OF NON-CONFORMANCES AND CORRECTIVE ACTION**	Revision Number: 2
		Page: 1 of 10

REVISION HISTORY

Rev No.	Review Date	Description of Change	Date of Next Review
0	September 2017		
1	October 2018	Revised the statement with regards to who will retain the original CAR and where to submit a duplicate copy	October 2021

Reviewed by:	**Quality Management Team**	Approved by:	**JOEL M. ABANILLA, MD** Executive Director

I. Objectives.

1. This policy establishes the course to correct the cause(s) of non-conformances or potential non- conformances in the Quality Management System, Services, and/or Operational processes at Philippine Heart Center in accordance with the Quality Manual.

2. To ensure that nonconforming outputs/services are identified and controlled to prevent its unintended use or delivery.

II. Scope.

This is applicable to all departments divisions, units/ sections, providing services governed by the requirements specified within the PHC Quality Management System.

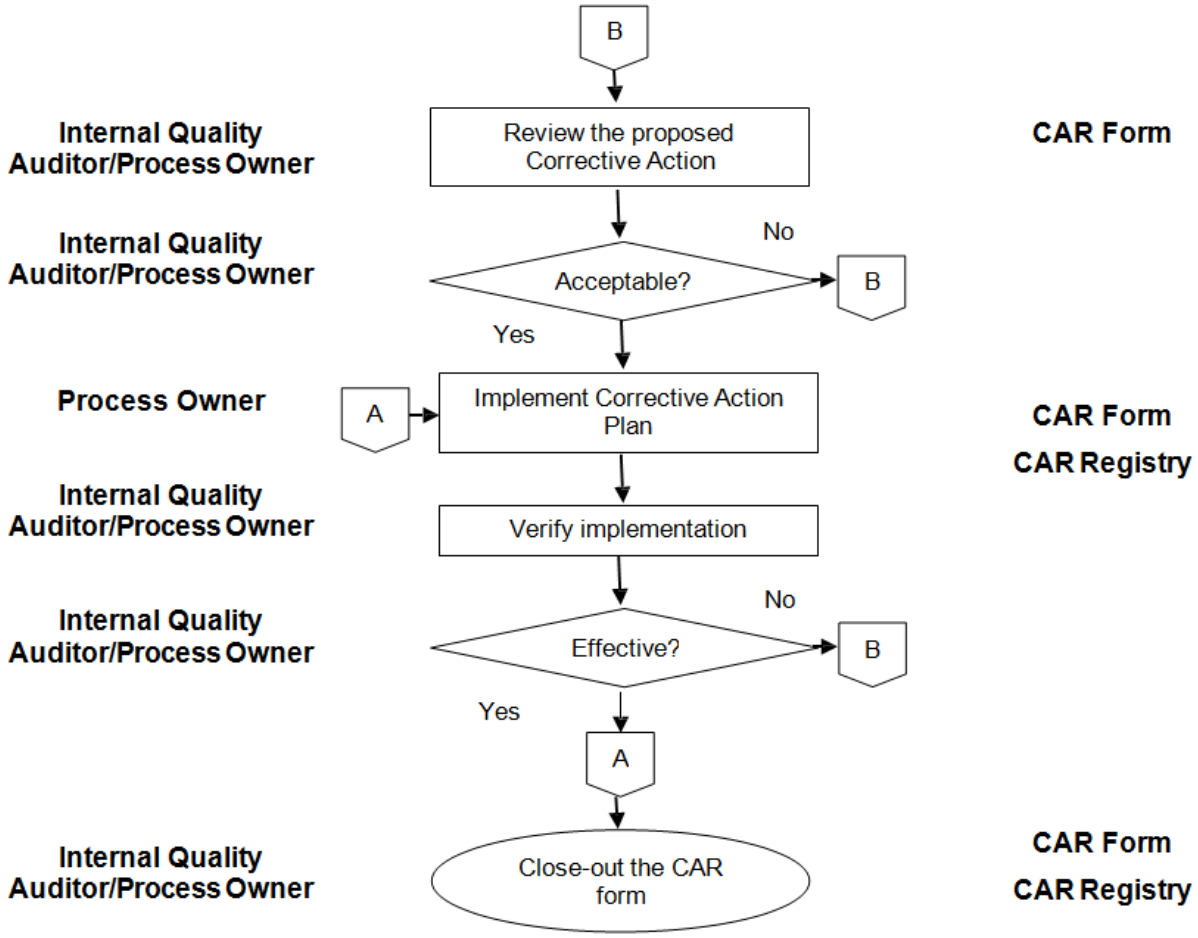
III. Definitions.

Originator. This refers to the person who will be the advocate of the Request for Action process from initiation until close out phase.

Corrective Action. This refers to the action taken to eliminate the cause of a detected non-conformance, unmet targets or other undesirable situation in order to prevent recurrence.

Non-conformance. This refers to non-fulfillment of a specified requirement of the QMS

RESPONSIBILITY	ACTIVITY	INTERFACE
Internal Quality Auditor/Process Owner	Non-conformance is observed/ Target is unmet	IQA Findings Report
Internal Quality Auditor/Process Owner	Formulate Corrective Action Request Form (CAR)	IQA Findings Report CAR Form
Internal Quality Auditor/Process Owner	Check completeness of form	CAR Form
Internal Quality Auditor/Process Owner	Issue/Initiate CAR	CAR Form
Internal Quality Auditor/Process Owner	Log in CAR Registry	CAR Registry
Internal Quality Auditor/Process Owner	Follow-up with Process Owners within 5 days after issuance	CAR Registry
Internal Quality Auditor/Process Owner	Review Corrective Action	CAR Form CAR Registry
	Acceptable? — No → B	
	Yes → A	


B
Internal Quality Auditor/Process Owner
Review the proposed Corrective Action
CAR Form
Internal Quality Auditor/Process Owner
No
Acceptable?
B
Yes
Process Owner
A
Implement Corrective Action Plan
CAR Form
CAR Registry
Internal Quality Auditor/Process Owner
Verify implementation
Internal Quality Auditor/Process Owner
No
Effective?
B
Yes
A
Internal Quality Auditor/Process Owner
Close-out the CAR form
CAR Form
CAR Registry

IV. Guidelines

1. Non-conforming outputs/service shall be properly identified (e.g. error in billing, lack of materials, etc.) and isolated or intervened when appropriate to prevent its unintended use or delivery to the next process.
2. Inform related parties through oral or written means to:
   2.1. Check previous processes for similar problems.
   2.2. Provide containment action.
   2.3. Check subsequent processes for conformity and/or effectiveness of containment action.
3. All non-conformances shall be discussed in meetings, analyzed and given appropriate actions. All actions and agreements made during the meeting shall be documented for discussion during Management Review to provide evidence of action plans to address issues.
4. The Corrective Action process shall be initiated upon detection of non-conformity or in the presence of unmet targets.

   Corrective Action Request (CAR) shall be initiated as a result, but not limited to, the following:

   - Internal and external quality audit findings
   - Action items from Management Reviews of Quality System effectiveness
   - Facilities audit findings
   - Suppliers' quality audits
   - Service and process problems identified by employees
   - Unmet Breakthrough or KPI targets
   - Non conformance/ unmet targets as identified performance evaluation process (page 31-35 QMS-QM-001)
5. Originator shall secure and accomplish, in duplicate, the CAR form by using any of the following methods:
   5.1. Accessing and accomplishing the CAR form directly thru the PHC Intranet
   5.2. Securing and accomplishing the hard copy of the CAR form from the Lead Auditor
   5.3. The originator shall retain the original copy and will issue a copy to the Quality Assurance Office for CAR Registry.

5.4. The originator will issue one accomplished CAR form to the concerned process owner and will retain and control a copy.

6. The Originator and Process Owner shall accomplish the CAR and follow the following guidelines:

6.1. PART 1: **Non-Conformity Data**

6.1.1. The Originator/auditor shall accomplish the data as to:

6.1.1.1. Date Issued- the date the CAR to be issued to the process owner

6.1.1.2. Originator's name/Designation- the complete name or designation of the Originator/s

6.1.1.3. Unit/Department- the unit or department of the Originator/s

6.1.1.4. Phone- local number of the assigned unit of the Originator/s

6.1.1.5. Email- email address of the Originator/s

6.1.1.6. Department- unit or department where the nonconformity was found out

6.1.2. The Originator/auditor shall put a tick mark on the appropriate box to how the CAR is intended to.

6.1.2.1. Correct a Non-conformity/ eliminate source of non- conformance

6.1.2.2. Prevent a potential Nonconformity/ mitigate risk

6.1.3. The Originator/auditorshall put a tick mark on the appropriate box the description of the Non-Conformance.

6.1.3.1. IQA Related- non conformance was detected during the Internal Quality Audit

6.1.3.2. Supplier-Related- non conformance was detected by the client or customer

6.1.3.3. 3rd Party Audit Related- non conformance was detected by the certifying body

6.1.3.4. Process/Procedural-related- non conformance was detected by the process owner from his own unit or department

6.1.3.5. Customer Satisfaction related- non conformance was derived from customer's complaint

6.1.3.6. KPI/ Quality Objective Review Related- non conformance detected was related to the Key Performance Indicators (KPI) or Quality Objective

6.1.3.7. Other than the above mentioned

6.1.4. The Originator/s shall write the Audit Finding and the Objective evidence on the space provided.

6.1.5. The Originator/s shall write the ISO Clause number and the title of the Clause related to the Audit Finding.

6.1.6. The Originator/s shall write the type of Non-conformity/ Opportunity for Improvement

6.1.6.1. Major- the absence or the total breakdown of a system to meet the requirements of a clause of ISO 9001 or other related documents.

6.1.6.2. Minor- a failure to meet one requirement of a clause of ISO 9001 or other reference document or a single lapse in following the organization's Quality Management System.

6.1.6.3. OFI- are observations which, if not addressed early enough, or if just left to continue may result to a deviation against the QMS requirements.

6.1.7. The Process Owner shall write the Immediate Action or Correction related to the nonconformity on the space provided.

6.1.8. The Originator/s shall affix his/her signature over printed name on the Acknowledged by space provided including the date it was signed

6.2. **PART 2: Cause Analysis Data**

6.2.1. The Process Owner shall write the following on the space provided:

6.2.1.1. Cause of Non-Conformance based on his/her Root Cause Analysis

6.2.1.2. separate sheet for the Root Cause Analysis may be attached to the form if necessary.

6.2.1.3. Date the Cause of Non Conformance was written

6.2.1.4. Responsible Officer- name of the Process Owner who led the conceptualization of the Root Cause Analysis

6.2.1.5. Estimated Close Out Date of the CAR form

6.3. **PART 3: Solution Data**

6.3.1. The Process Owner shall write the Action Plan to address the Nonconformity Finding and fill up the following on the space provided:

6.3.1.1. Activities- specific actions to be taken

6.3.1.2. Responsible Person- the designation of the person/s responsible to implement the action plan

6.3.1.3. Target Date of implementation of each Activities

6.3.1.4. Actual Date the activity was implemented

6.3.1.5. Result of the actions taken

6.3.2. The Originator/s shall affix his/her signature on the space provided.

6.4. **PART 4: Review of Action Plan**

6.4.1. The immediate/service head shall review the action plan and shall place a tick mark if accepted (effective) or not accepted (not effective). If not accepted, he/she shall write the reasons on the space provided.

6.4.2. The immediate/service shall write his/her name on the Reviewed by and write the date it was accomplished.

6.5. **PART 5: Follow Up**

6.5.1. The Process Owner shall follow-up the implementation of the action plan and writes the following on the space provided:

6.5.1.1. Status- the current status of the implementation process

6.5.1.2. Initials/Responsibility- the signature of the Process Owner countersigned by the Originator

6.5.1.3. Date it was accomplished

6.6. **PART 6: Verification**

6.6.1. The Lead Auditor shall verify the effectiveness of the implemented actions and shall fill up the following on the space provided:

6.6.1.1. Number of visits- number of follow-up made by the Originator to the Process Owner

6.6.1.2. Date visited- date the Originator followed-up the Process Owner

6.6.1.3. Objective evidences- the evidences showed by the Process Owner in the implementation of the Action Plan

6.6.1.4. New target date- the date the Action is targeted to be fully implemented

6.6.1.5. tatus of the action taken- effectiveness of the actions taken

6.6.1.6. Close (Effective)- if the actions corrected the nonconformity

6.6.1.7. Close (Not Effective)- if the actions were not effective to correct the nonconformity. A new CAR form shall be created by the Originator and to be issued to the Process Owner.

6.7. **PART 7: Close Out**

6.7.1. The Originator/s and Process Owner shall complete the CAR form and fill up the following on the space provided:

6.7.1.1. Originator's name

6.7.1.2. Date of Close Out

6.7.1.3. Process Owner's name

6.7.1.4. Date of Close Out

7. The Originator shall issue a hardcopy of the accomplished CAR Form to the process owner within three (3) working days from the time the non-conformity was detected or the audit findings is finalized.

7.1. The Originator shall be responsible in discussing the non-conformity findings to the process owner.

8. The Process Owners are given five (5) working days to submit their Corrective Action Plan/s to the originator.

9. For Internal Audit related findings, the Lead Auditor shall list down all CARs issued in a registry and update the CAR registry with the proposed corrective action and status of action plans.
10. If action plan is not accepted, the CAR is again forwarded and/or referred to the Responsible Unit for amendments.
11. Records of the nature of nonconformities and any subsequent actions taken shall be maintained.

PHILIPPINE HEART CENTER	Document Type **POLICY**	Document Code: QMS-QM-006
		Effective Date: October 2018
	Document Title **MANAGEMENT REVIEW**	Revision Number: 2
		Page: 1 of 6

REVISION HISTORY

Rev No.	Review Date	Description of Change	Date of Next Review
0	September 2017		
1	October 2018	Revised the inputs and outputs of the review	October 2021

Reviewed by:	**Quality Management Team**	Approved by:	**JOEL M. ABANILLA, MD** Executive Director

I. **OBJECTIVE**

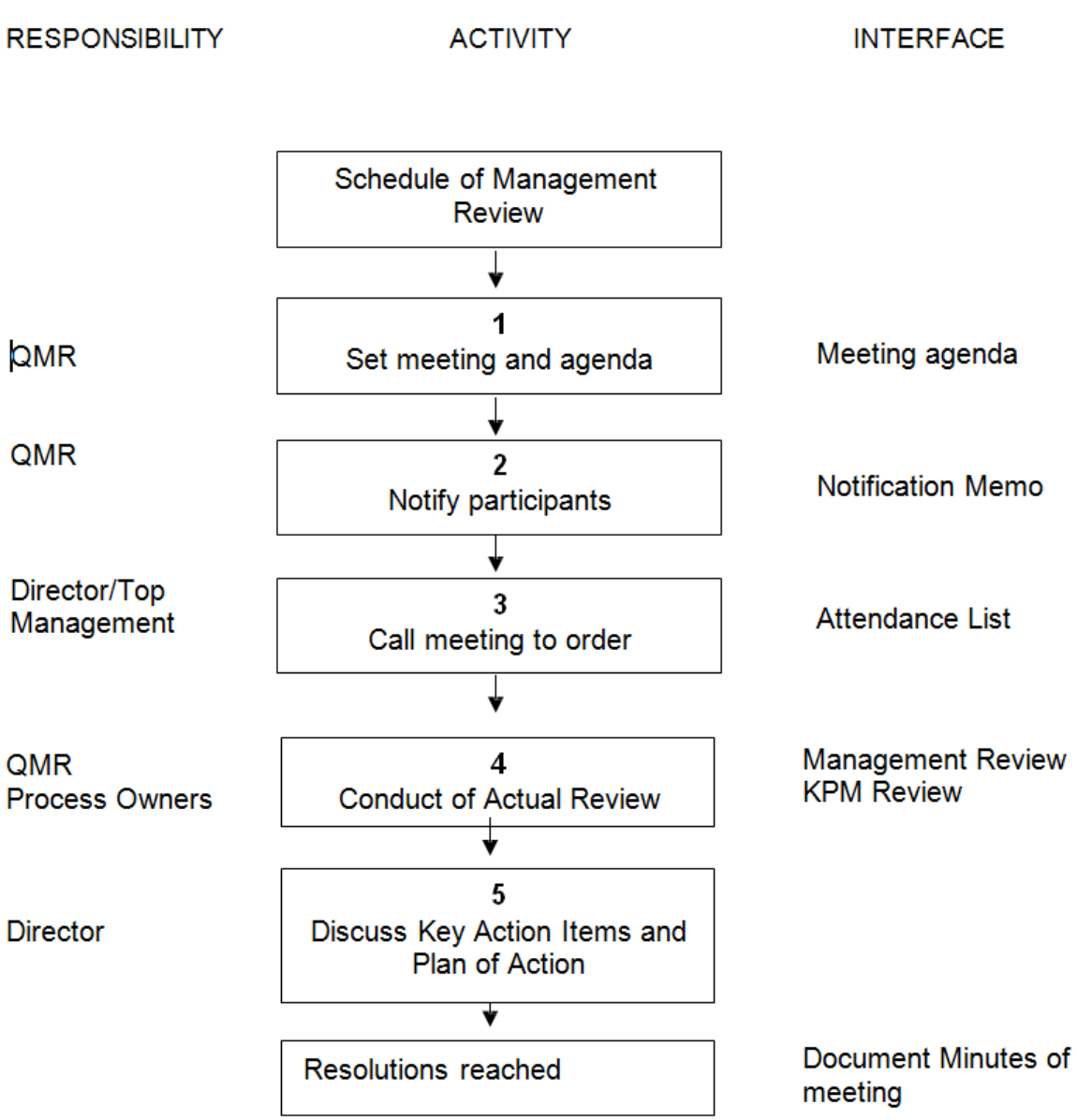
To ensure that management conducts periodic reviews of the quality system to determine its suitability and effectiveness in meeting customer's needs.

To establish a standard method for documenting management reviews of the quality management system and set up a venue where the effectiveness of quality management system can be discussed and evaluated.

II. **SCOPE**

This applies to all organizations defined in the scope of the Quality Management System.
The procedure starts from the preparation of the agenda up to the filing of minutes of actions and decisions arrived at during the meeting.

III. **PROCEDURE OUTLINE**



IV. **PROCEDURES DETAIL**

1. QMR gets approval of the Executive Director for the schedule of the Management Review meeting, and sets the agenda.

1.1. The Management Review shall serve as platform for the exchange of new ideas, with open discussion, presentation of performance status, evaluation of inputs, and resolution of quality matters.

1.1.1. Participants for Management Review meeting includes:

1.1.1.1. Executive Committee (ExeCom)

1.1.1.1.1.□□□□□□ Executive Director

1.1.1.1.2.□□□□□□ Deputy Executive Directors

1.1.1.2. Department Managers

1.1.1.3. Division Chiefs

1.1.1.4. Supervisors

2. A General Management Review meeting shall be conducted at least once a year as directed by the QMR and Executive Director, and shall be attended by the given participants (refer to 5.1.2).

2.1. In line with this, a monthly meeting conducted by the Department Manager/ Division Chief/Supervisor is being held monthly to discuss results of the Key Performance Measures. This is to monitor the suitability, adequacy and effectiveness of the quality management system in satisfying the requirements of ISO 9001:2015, set Breakthrough Targets and relevant government regulations leading to ultimate customer satisfaction.

2.2. Agenda for the Management Review shall consider the following as necessary:

2.2.1. Status of actions from previous management review

2.2.2. Changes in the internal and external issues that are related to QMS

2.2.3. Effectiveness of actions taken to address risks and opportunities

2.2.4. Information on the performance and objectives of QMS including trends in:

2.2.5. Client satisfaction and feedback from relevant interested parties

2.2.6. The extent to which quality objectives have been met

2.2.7. PHC's performance indicators and conformity of products and services

2.2.8. Non-conformities and corrective actions monitoring

2.2.9. Audit results

2.2.10. Monitoring and measurement results

2.2.11. Performance of external providers

2.3. Adequacy of resources, and

2.4. Opportunities for improvement

3. The Review shall also include appraising improvement opportunities in processes elsewhere defined in the QMS and services related to customer satisfaction and resources needed.
4. Participants for the Management review shall be informed through a notification memo at least one week prior to schedule of Management Review. Memo would also indicate materials needed for the discussion.
5. Approved agenda shall be taken up one by one. Special attention is given to noted areas for improvement. Proposed corrective and preventive actions for improvement are discussed and reviewed.

    5.1. Outputs of this review shall include any decisions and actions related to:

        5.1.1. Improvement of the effectiveness of the quality management system and its processes

        5.1.2. Improvement of product related to customer requirements, and

        5.1.3. Allocation of resources needed

6. The findings, plan of action and resolutions reached are fully documented in the Minutes of the Management Review.
7. Dissatisfaction raised from the Management Review will be discussed to the corresponding Process Owner on the monthly meeting
8. Inputs, outputs, discussion and action plans can be extracted from minutes of the ExeCom and Department Meetings.

PHILIPPINE HEART CENTER	Document Type **POLICY**	Document Code: QMS-QM-007
		Effective Date: October 2018
	Document Title **RISK MANAGEMENT**	Revision Number: 2
		Page: 1 of 8

REVISION HISTORY

Rev No.	Review Date	Description of Change	Date of Next Review
0	September 2017		
1	October 2018	Revised the inputs and outputs of the review	October 2021

Reviewed by:	**Quality Management Team**	Approved by:	**JOEL M. ABANILLA, MD** Executive Director

I. OBJECTIVES

1. To outline PHC's underlying approach to identified risks and opportunities in relation to the requirements and issues of internal and external interested parties.
2. To document the roles and responsibilities of the Top Management, Department Managers, Division Chiefs and other key committees and individuals
3. To outline key aspects of the risk management process
4. To identify the main reporting framework and procedures

II. SCOPE

This applies to all functions and processes defined in the scope of the Quality Management System.

III. DEFINITION AND APPROACH TO RISK MANAGEMENT

1. **Risk (Risk Event)** – the possibility that an uncertain event, action or set of circumstances which, if to occur, would have a material adverse or beneficial effect on achieving the set objectives of the institution. It is characterized and is measured in terms of its likelihood and impact.
2. **Institutional Risk**- risks that affect the institution as a whole
3. **Strategic Objective**- is the Breakthrough of the department/ division/ unit/ section, a defined objective or target, aligned with PHC's Mission, Vision, Objectives and Strategy Map, that an area must achieve within a specified timeline
4. **Risk Owner**- is the process owner, the individual or group who will be in charge of implementing the actions to address the risks
5. **Likelihood**- is the probability of the occurrence of the Risk Event
   - **5.1. Very Likely**- Not having doubt of occurrence (score = 5)
   - **5.2. Likely**- likely to occur and certain (score = 4)
   - **5.3. Possible**- Likely to Occur but not certain (score = 3)
   - **5.4. Unlikely**- unlikely to occur, not certain (score = 2)
   - **5.5. Rare**- Inconceivable that the event will occur (score = 1)
6. **Impact** -is the consequence of the Risk Event

6.1.1. Catastrophic (score = 5)- the outcome could threaten lives, of patients and/ employees, or results in financial, human, operational or physical losses or damage

6.1.2. Major (score = 4)- could result to:

6.1.2.1. failure to achieve desired output

6.1.2.2. failure for an area to effectively function and deliver services

6.1.2.3. violation of laws, rules and regulations or breaches in accountability requirements, legislative/contractual obligations

6.1.2.4. sustained negative image to the public'

6.1.3. Moderate (score = 3)- could threaten the efficient function of the process but can be dealt with internally or delay the delivery of services or could result to public criticism or negative image or feedback from clients

6.1.4. Minor (score = 2)- poses no threat in the processes and could be dealt with by routing operation and controls and has no regulatory consequences

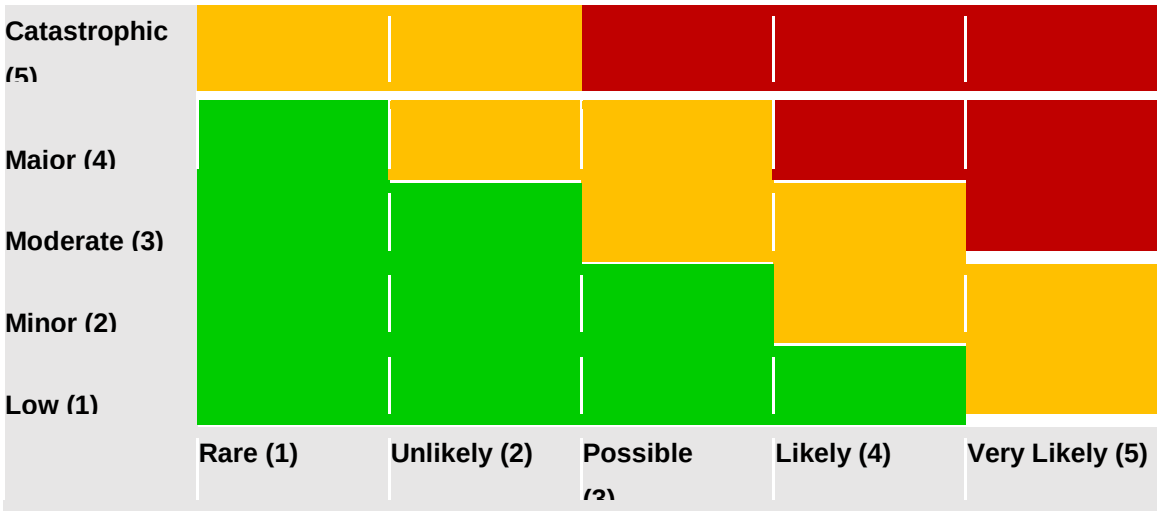
6.1.5. Low (score = 1)- quality degradation is barely noticeable and has no discernible impact at all

7. Risk Rating –is the product of the likelihood and the impact scores of a risk (likelihood score x impact score), the value beneficial in guiding risk owners in prioritizing risk events

8. Risk Response Plan – are strategies or activities to address the Risk Event/s identified

9. Risk Profile - a way of mapping the identified Risk Events

by using the identified Impact and Likelihood Scores



10. PHC's intention is not to fully eliminate risks from its activities, but rather to enable the Top Management or Process Owners to mitigate and manage it appropriately, within the established risk appetite.

11. **Risk Appetite** - describes the general action or pursuit of the organization towards an identified risk, it is set as High, Moderate or Low

11.1. Is set as either: critical, high, moderate or low

H	High risk: Executive Committee Members (Deputy Executive Directors), Executive Director and Immediate Board attention required.
M	Moderate risk: Management's (Deputy Executive Director, Department Managers and Division Chiefs) attention is required
L	Low risk: First Level Managers and Division Chiefs' attention is required. Manage by routine procedures, review of Policies/SOPs

IV. RESPONSIBILITIES

1. Top Management

1.1. Ensuring that institutional/strategic risk descriptions, for which they are responsible, are maintained

1.2. Implementing policies on risk management and internal control within the areas for which they are responsible to ensure risks are managed effectively

1.3. Identifying and evaluating the strategic risks faced by the Institution-including the financial and non-financial implications of those risks

1.4. Providing adequate information in a timely manner to the Board of Trustees on the status of risks and controls

1.5. Undertaking a review- at least annually- of the effectiveness of the system of risk management

2. Process Owners

2.1. **Process Owners** are the immediate risk owners and are responsible for:

2.1.1. Ensuring the delivery of mitigating actions

2.1.2. Keeping the risk description up to date

2.1.3. Reporting on progress at least every two (2) years to align with the Internal Audit Process Cycle

2.1.4. The escalation or referral or transfer of risks through the identified risk interdependencies:

2.1.5. Ensuring the incorporation of risk identification into Strategic Planning Initiatives

3. RISK MANAGEMENT

3.1. Risk Management is the planned and systematic approach to identifying, analyzing, evaluating and treating risks at all levels of the organization

3.2. It involves the determining of the acceptable level of exposure to risk, which enables the achievement of the identified objectives across the organization. The process provides the assurance that:

3.2.1. objectives at all levels are more likely to be achieved,

3.2.2. damaging events are less likely to occur, and

3.2.3. beneficial events are more likely to occur.

3.3. PHC's approach to risk management supports the Top Management and Risk Owners in determining actions for prioritization. The approach is aligned to the development of the organization's Strategic Planning Initiatives.

4. RISK AND INTERNAL CONTROL

4.1. The system of internal control is in conjunction with the planning and budgeting process and is designed to manage and mitigate the risk

5. REVIEW OF EFFECTIVENESS

5.1. The Internal Audit Team and the risk owners are responsible for reviewing the effectiveness of the internal control of the organization, based on information provided during internal audit and independent monitoring reports.

5.2. For each risk identified, the Audit Team or Risk Owner will:

5.2.1. Review the previous report and examine the area's track record on risk management and internal control

5.2.2. Consider the internal and external risk profile of the coming year and consider if the current control are likely to be effective

5.2.3. Consider the objectives and targets of their area

5.2.4. Consider the timely identification, assessment and reporting of significant risks;

5.2.5. Prioritize the risks and the allocation of resources to address areas of high priority

5.2.6. Consider the effectiveness of the control environment

V. PROCEDURE

a. The risk management process of PHC is dynamic and is designed to adapt to developments and any changes in the risk profile over time

b. It is based on a structured and systematic process which takes into account the internal and external risks of PHC.

c. The main elements of the risk management process are as follows:

3.1. Communicate and consult – with internal and external interested parties, as appropriate, at each stage of the risk management process

3.2. Establish the context- establish the internal and external issues if interested parties

3.3. Identify Risks- identify where, when, why and how events could prevent, degrade, delay or enhance the achievement of objectives

3.4. Record risks- document the risks that have been identified in the risk register

3.5. Analyze risks- identify and evaluate existing controls. Determine consequences and likelihood and the level of risk

3.6. Evaluate risks- compare estimated levels of risk against the pre-established criteria and consider the balance between potential benefits and adverse outcomes. This enables decisions to be made about the extent and nature of treatments required and priorities

3.7. Treat risks- develop and implement specific cost-effective strategies and action plans for increasing potential benefits and reducing potential adverse outcomes

3.8. Monitor and Review- risks and effectiveness of the treatment measures need to be monitored

3.9. It can be applied at any level within the organization, strategic or operational level, specific projects or process, or units recognized as risk areas.

VI. GUIDELINES

a. Organize a team

b. Review the general process of the area as guided by the set Breakthrough and list-down Risk Events or error-prone or problematic processes that could affect the identified objective/s

c. Utilizing the Risk Registry Template:

d. State the Strategic Objective (Breakthrough) that is affected by the Risk Event identified

e. Identify the following:

5.1. Risk Event/s

5.2. Risk Assessment:

5.2.1. Risk Owner

5.2.2. Impact

5.2.3. Likelihood

5.2.4. Risk Ranking

5.3. Risk Response

6. Prioritize the identified Risk Events by their Risk Ranking
7. Formulate a Risk Response Plan for each Risk Event Identified
8. Submit to the respective Deputy Executive Director for approval
9. Implement Strategies and Recalculate Risk Ranking according to the timeline stated on the Risk Response Plan

VII. RESOURCE:

Hospital Risk Management Lecture by the Institute of Internal Auditors of the Philippines, Inc.

APPENDIX A. Document Request Form

PHILIPPINE HEART CENTER
East Avenue, Quezon City\

DOCUMENT REQUEST FORM

Document Change and Registration Request Form			
Dept/Div/Unit/Section		Date Requested	

TYPE OF DOCUMENT	NATURE OF REQUEST
☐ Quality Objectives and Plans ☐ Standard Operating Procedures ☐ Work Institutions ☐ External Documents ☐ Guidelines ☐ Forms ☐ Quality Records	☐ Creation ☐ Revision ☐ Obsolete ☐ Registration ☐ Request Copy

AFFECTED DOCUMENTS

Document Code	Document Title	Revision No.	Justification

AFFECTED AREAS
(Areas to be informed/provided copies)

Reviewed by:	Checked by:	Approved by:
Department/Division/Unit/Section/ Head	Document Control Officer	Quality Management Representative

QMS-FRM-001-2018

APPENDIX B. Quality Objective Plan

PHILIPPINE HEART CENTER
East Avenue, Quezon City

Quality Objective Plan

PERIOD COVERED:				
Section A: GENERAL INFORMATION				
A.1 Service/ Department				
A.2 Division/Section/Unit:				
Section B. ACCOMPLISHMENT				
B.1 Quality Objectives				
Section C: GOALS, THRUST & QUALITY POLICY				
C.1 PGS/KP Goals				
☒ Better Health Outcomes in Cardiovascular Diseases in the Country ☒ Responsive Health System ☒ Healthier Filipino Hearts				
C.2 Strategic Thrusts				
☒ Improving Access to quality health facilities				
C.3 Quality Policy				
☒ Provide the highest standard of comprehensive cardiovascular care.				
☒ Satisfy all relevant statutory and regulatory requirements.				
☒ Continually improve our processes.				
Section D: OBJECTIVES				
Quality Objectives Statements	Measurable Target	Frequency of Monitoring	How to measure?	Records/ Evidences
D.1. Breakthrough				
Section E. QUALITY PLAN				
Activities	Timeframe	Budget	Persons Responsible	Related Documents

Prepared by:	Reviewed by:	Approved by:
NAME HERE	NAME HERE	NAME HERE
(Designation)	(Division Chief/Department Manager)	(Deputy Executive Director)

APPENDIX C. Quality Objectives and Plans Monitoring

PHILIPPINE HEART CENTER
East Avenue, Quezon City

Quality Objectives and Plans Monitoring

PERIOD COVERED:				
Section A: GENERAL INFORMATION				
A.1 Service/ Department				
A.2 Division/Section/Unit:				
Section B. ACCOMPLISHMENT				
B.1 Quality Objectives				
Section C: GOALS, THRUST & QUALITY POLICY				
C.1 PGS/KP Goals				
☒ Better Health Outcomes in Cardiovascular Diseases in the Country ☒ Responsive Health System ☒ Healthier Filipino Hearts				
C.2 Strategic Positioning				
☒ Improving access to quality health facilities				
C.3 Quality Policy				
☒ Provide the highest standard of comprehensive cardiovascular care.				
☒ Satisfy all relevant statutory and regulatory requirements.				
☒ Continually improve our processes.				
Section D: OBJECTIVES				
Quality Objectives Statements	**Measurable Target**	**Actual Accomplishment**	**Measurement of Target**	**Achieved? (Yes or No)**
D.1. Breakthrough				
Section E. QUALITY PLAN				
Activities	**Date Accomplished**	**Actual Budget**	**Persons Responsible**	**Results/Outputs**
E.1.				
E.2.				
E.3.				

Prepared by:	Reviewed by:	Approved by:
NAME HERE	NAME HERE	NAME HERE
(Designation)	(Division Chief/Department Manager)	(Deputy Executive Director)

QMS-FRM-003-2018 Page 1 of 1

APPENDIX D. Corrective and Action Request

PHILIPPINE HEART CENTER
East Avenue, Quezon City

CORRECTIVE and ACTION REQUEST ISO 9001:2015	CAR Ref. No. (DCC ONLY) Date Issued

PART 1: What is wrong?	NON-CONFORMITY (NC) DATA		
Originator's Name/ID No.	Unit/Department	Phone	E-mail
This CAR is intended to: ☐correct a NC / eliminate source of non-conformance ☐prevent a potential NC / mitigate risk		Department (where NC exists)	
Description of the Non-Conformance	☐ IQA-Related ☐ Supplier-Related ☐ 3rd Party Audit Related ☐ Process/Procedural-related ☐ Customer Satisfaction Related ☐ Relates to KPI/Quality Objective Review ☐ Others (Please Specify):		

DESCRIPTION OF NON-CONFORMANCE (Existing or potential; specify the objective evidence). Objective evidence:	ISO Clause / Reference: Category (Major/Minor/OFI):
Immediate Action/Correction:	Acknowledged by: Date

PART 2: What is the root cause?	CAUSE ANALYSIS DATA
CAUSE OF NON-CONFORMANCE Note: Attach copy (if necessary) of root cause analysis.	Date: Responsible Officer: Estimated Close Out Date:

PART 3 :What solutions can we formulate?	SOLUTION DATA			
ACTION PLANS	Note: Please use continuation sheet if necessary ACTIVITIES	Resp.Person	Target Date	Actual Date
				CONFIRMATION OF EFFECTS OF COUNTERMEASURES Result:
	"I certify that the aforesaid action plans have been reviewed and authorized for implementation. I, therefore, support the implementation of said action plans".	Signature		

APPENDIX E. Masterlist of Forms

PHILIPPINE HEART CENTER
East Avenue, Quezon City

MASTERLIST OF FORMS

Service: Department: Division: Unit/Section:			
Form Number	**Form Title**	**Effectivity Date (If applicable)**	**Status (Revised/Obsolete)**
Prepared by: Division/Unit/Section/ Head	**Checked by:** Department	**Approved by:** Deputy Executive Director	

QMS-FRM-005-2018

APPENDIX F. Risk Registry

PHILIPPINE HEART CENTER
East Avenue, Quezon City
RISK REGISTRY

Department/Division/Section:

Strategic Objective	Risk Event	Risk Assessment				Risk Response	Effectiveness of Risk Response New Risk Assessment		
		Risk Owner	Likelihood	Impact	Risk Rating		Likelihood	Impact	New Risk Rating

Prapared by:

Process Owner (Designation)

Reviewed by:

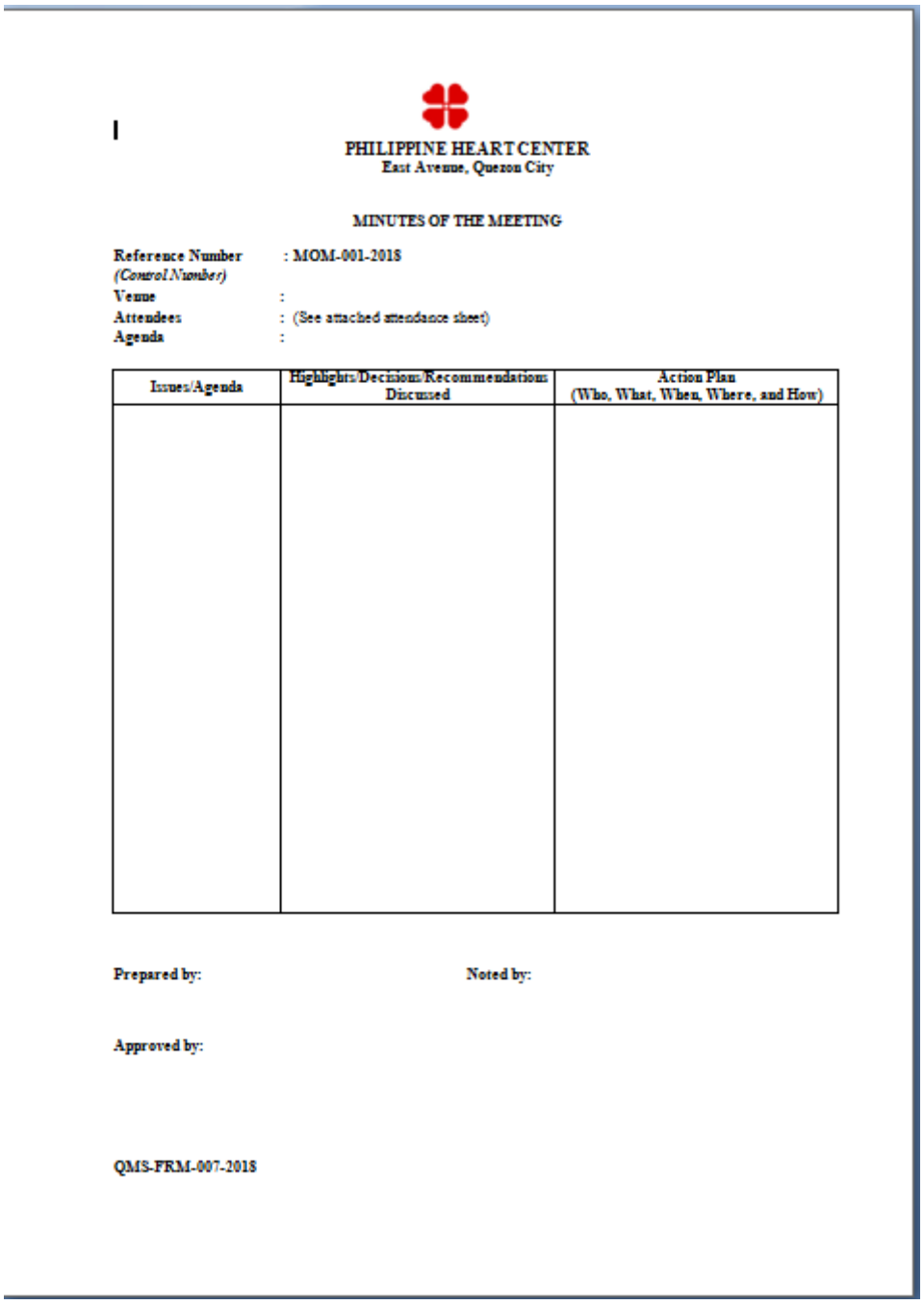
Division Chief/Department Manager

Approved by:

Deputy Executive Director

QMS-FRM-006-2017

APPENDIX G. Minutes of the Meeting



PHILIPPINE HEART CENTER
East Avenue, Quezon City

MINUTES OF THE MEETING

Reference Number : MOM-001-2018
(Control Number)
Venue :
Attendees : (See attached attendance sheet)
Agenda :

Issues/Agenda	Highlights/Decisions/Recommendations Discussed	Action Plan (Who, What, When, Where, and How)

Prepared by: **Noted by:**

Approved by:

QMS-FRM-007-2018

APPENDIX H. Masterlist of Quality Records and Evidences

PHILIPPINE HEART CENTER
East Avenue, Quezon City

MASTERLIST OF QUALITY RECORDS AND EVIDENCES

Service:
Department:
Division:
Unit/Section:

Record Number	Record Title	Person Responsible (Record Keeper)	Location	Retention Period (Active/Storage)	Effectivity Date (If applicable)	Status

Prepared by:	Checked by:	Approved by:
Division/Unit/Section/ Head	Department	Deputy Executive Director

QMS-FRM-008-2018

APPENDIX I. Masterlist of Documents

PHILIPPINE HEART CENTER
East Avenue, Quezon City

MASTERLIST OF DOCUMENTS

Policy/Guidelines/Work Instructions						
Service: Department: Division: Unit/Section:						
Document Number	Document Title	Person Responsible	Location	Retention Period (Active/Storage)	Effectivity Date	Status (Revised/Obsolete)
Prepared by: Division/Unit/Section/ Head		Checked by: Department		Approved by: Deputy Executive Director		

QMS-FRM-009-2018

APPENDIX J. Masterlist of External References

PHILIPPINE HEART CENTER
East Avenue, Quezon City

MASTERLIST OF EXTERNAL REFERENCES

Service: **Department:** **Division:** **Unit/Section:**				
External Reference Number	**Title**	**Location**	**Effectivity Date (Edition/Year Adapted)**	**Status (Revised/Obsolete)**
Prepared by: **Division/Unit/Section/ Head**		**Checked by:** **Department**	**Approved by:** **Deputy Executive Director**	

QMS-FRM-010-2018

APPENDIX K. Masterlist of External Forms

PHILIPPINE HEART CENTER
East Avenue, Quezon City

MASTERLIST OF EXTERNAL FORMS

Service: Department: Division: Unit/Section:			
Form Number	**Form Title**	**Effectivity Date (If applicable)**	**Originator**
Prepared by: Division/Unit/Section/ Head	**Checked by:** Department	**Approved by:** Deputy Executive Director	

QMS-FRM-011-2018

APPENDIX L. Breakthrough Report Form

PHILIPPINE HEART CENTER
East Avenue, Quezon City
Office of Strategy Management

Breakthrough Report

Division:
Report Period:

Department:

Breakthrough	Formula/ description	Target	% Accomplishment (ACC) (Actual/Target or Actual decrease / Target decrease)														
			Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sep	Oct	Nov	Dec	Total/ Average	%ACC	Rating
	Actual Target / No. of Target																◯ G ◯ Y ◯ R
Lead Measure 1																Mean Compliance Actual/Target	
																	◯ G ◯ Y ◯ R

Note: Please attached supporting data

Legend: G (100% and up)
Y (70%- 99%)
R (69% and below)

Prepared by: _____

Noted by: _____