PURPOSE:

1. To establish and maintain an effective and systematic control of documents both internal and external.
2. To ensure that all records are established, accomplished, filed, maintained and preserved under a formal and documented procedure to demonstrate compliance with the document requirements.

LEVEL:

All employees of Dr. Pablo O. Torre Memorial Hospital

DEFINITION OF TERMS:

Document control procedures- provide "chain of custody" quality control for documents that transfer between parties, including internal documents, external documents, and quality records.[1]

Documentation Control Staff- this refers to the person/s responsible for the control of all documents and data of DPOTMH.

Master Copy- is the original issue of the document, or so called the first generation.

Controlled Copy- copy of a document coming from the master document; second generation should be updated for any revision.

External Documents- documents, specifications, requirements and other written information from suppliers, clients, government and system standards which are not created in DPOTMH.

Internal Documents- documents internally generated/originated in DPOTMH.

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Form- a document with blanks for the insertion of details or information.

Distribution- issuance of approved documents for the implementation of Integrated Management System.

Originator- author of the documents

Document Control Register- a list which identifies all DPOTMH documents and includes current revision status.

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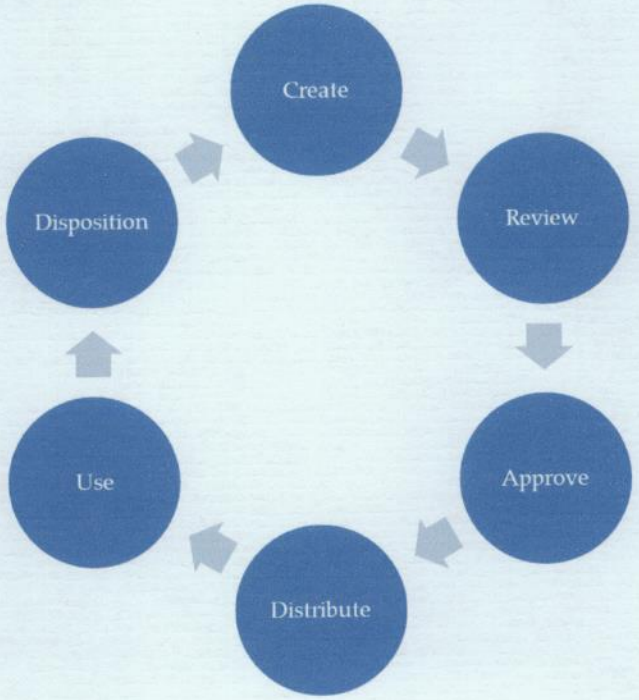
POLICY:

1. All DPOTMH documents that are used to define, direct and control activities that the Quality Management System and healthcare service shall:
   1.1. Be controlled
   1.2. Clearly communicate the rules and provide instructions; and
   1.3. Accurately reflect standards, regulations, and practices.

2. All documents created shall have a "lifecycle" from creation to disposition. It is important to understand this cycle and the various stages when creating and handling documents to ensure that they are managed effectively.



3. **Document Creation**
   Once a need for new or revised documentation has been identified it shall be allocated to the most appropriate individual for action. The individual with responsibility for producing the document must do so by utilising the appropriate

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template available. They shall ensure that all sections including appendices are fully completed in a timely manner, and submitted to the appropriate group, committee or meeting, following consultation. The timescales for doing this will be dependent on the complexity of the document required and the level of risk associated with the document not being available to staff, and also current expiration dates. The requirement for new or additional documents may be based on, but not limited to:

3.1. Legislative requirements;
3.2. Suggestions from workers;
3.3. Suggestions from the established committee (if in place);
3.4. System failures reported or identified during incident investigations;
3.5. Internal or external audit findings;
3.6. Outcomes of workplace inspections and monitoring;
3.7. Industry or organizational best practice; or
3.8. Changes in business activities and or structure.

4. **Document Template:** All documents of the hospital shall follow the templates set by the Total Quality Division with the exception of the Kohlberg Kravis Roberts & Co. (KKR) documents, which shall follow the official format by the Metro Pacific Hospitals Holdings Inc. (MPHHI).
   4.1. The official document templates for Policy, Standard Operating Procedure, Flowchart, and Work Instruction are discussed further in the *TEMPLATES FOR POLICY, STANDARD OPERATING PROCEDURE, FLOWCHART AND WORK INSTRUCTION (Standard Operating Procedure).*

5. **Document Review:** Consultation on new or revised documents is required prior to approval. Evidence of consultation shall be documented through meeting minutes, memorandums or emails and records maintained.
   5.1. Drafted documents shall be watermarked with the word "DRAFT" to differentiate it from the final document.
   5.2. Feedback shall be reviewed and incorporated into draft documents, where relevant.

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5.3. Final draft prepared by the Documentation Control staff shall be routed for approval.

5.4. The signatories of the document shall signify his/her agreement by affixing their signature.

5.5. The review shall ensure that the following is considered:

a) The continuing suitability and relevance of the documentation;
b) The accuracy and clarity of the documentation;
c) Compliance with current legislative requirements;
d) The effectiveness of the document in achieving desired outcomes;
e) Identified areas requiring improvement;
f) The creation of any new documents and removal of obsolete documents; and
g) The status/ currency of any attachments/ references included in the documents.

6. **Document Approval:** Any document shall be approved before release and distribution. Drafted documents shall go through a series of document reviews and approval gates where stakeholders provide comments, corrections, and changes.

6.1. New or revised final draft documents shall be verified by the person in higher authority (e.g. Supervisor or Manager if the document author is a rank and file employee), reviewed by the Quality Assurance Supervisor, recommended for approval by the respective Division Officer, Total Quality Division Officer, Chief Medical Officer/ Chief Operating Officer and subsequently approved by the President and CEO.

7. **Document Control Register:** A Document Control Register shall be maintained by the Documentation Control staff for all DPOTMH documentation created or modified.

7.1. The Document Control Register shall include the following information:

a) Document number;
b) Document type;

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c) Document title;
d) Issue date;
e) Revision number;
f) Description;
g) Review date; and
h) Owner.

8. **Distribution:**
   8.1. Controlled copies of the documented information shall be tagged as "Controlled" and shall be distributed to all Department, Division, Unit and Sections of the organization.
   8.2. Controlled copies of certain types of documents relevant to specific processes shall be tagged as "Controlled" and shall be selectively distributed to process owners.
   8.3. The Document Control Form and Master list shall be accomplished accordingly to ensure proper tracking and to prevent unauthorized access of documents.

9. **Records storage:** All Master Copy documents are to be stored in the Total Quality Division's (TQD) steel cabinet and will be made available to all workers via the Hospital's Communicator e-Library. These files are stored on an electronic server system which is regularly backed up, archived and maintained by the Information Technology Department.
   9.1. The Master Copy of all documents is in soft copy and editable format and is kept in the Documentation Section.
   9.2. All printed documents (hard copies) by the Documentation Control Staff are considered Controlled Copies.
   9.3. Controlled copies are to be given to the originator for safekeeping and for easy access if a need arises.
   9.4. A library of external documents shall be maintained in the TQD Office and can be accessed by employees following the protocols for requesting documents.

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10. **Records Retention:** Records shall be retained in the TQD office within five (5) years.

11. **Document Revisions:** Policies, SOPs, Flowcharts and work instructions shall be formally reviewed every three years in order to ensure it is still up to date. Should there be a need for revision before the 3-year rule, the procedure for *Revision of Documents* shall be followed.

12. **Document Obsoleting:**
    - 12.1. Documents shall be considered obsolete when:
        - a) The document has been revised or superceeded
        - b) A re-issue of the document is needed.
        - c) Document is no longer in effect
        - d) Document has been replaced with another
        - e) Contents have been combined with another document
        - f) Contents have been split into two or more documents
        - g) Document was rewritten with a change in category (e.g. changing policy into procedure)
    - 12.2. Obsolete documents and records shall be tagged as "Obsolete" and shall be archived and stored or disposed in accordance to Data Privacy Act of 2012:
    - 12.3. The Master Copy of obsolete documents shall be stored as reference in the Documentation Section of Total Quality Division until a revised and updated copy has been replaced.
    - 12.4. Controlled copies of obsolete documents shall be removed from the active file upon its effectivity date and replacement.
    - 12.5. The originating Department Manager/Supervisor is responsible in informing all concerned that a document was created, reviewed, revised or deleted through a memorandum or meeting.

13. All documents shall be controlled using the standard coding system organized by the Documentation Section (*refer to Standard Operating Procedure on Assigning Document Code*).

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14. 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.

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

16. 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 Documentation Control Staff and shall be registered in the Document Control Register. Examples of such external documents are manual of standards from ISO and ACI, DOH/ PhilHealth forms, product or machine specifications etc.

17. **Stamping:** Stamping is one way of controlling documents as to identification and usage. The Documentation Control Staff shall be responsible for determining the stamp to be used in each document.

18. Revision of documents shall be initiated immediately once there is a change in the standard practice of the area.

DOCUMENTATION:

Revised Policy

DISSEMINATION:

1. Policies and Procedure Manual
2. Unit Meeting or Orientation
3. Hospital Communicator (E-library)

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REFERENCES:

Document Control | Processes and Practices. (n.d.). Workflow Management Software by Integrify. Retrieved May 13, 2022, from https://www.integrify.com/document-control/

ISO 9001 Requires that you maintain control of documents. (n.d.). 9000 Store. Retrieved May 13, 2022, from https://the9000store.com/articles/iso-9000-tips-document-control-requirements/

Guidance on the requirements for Documented Information of ISO 9001:2015. (n.d.). ISO. Retrieved May 13, 2022, from https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/documented_information.pdf

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