



RIVERSIDE MEDICAL CENTER, INC.



METRO PACIFIC HEALTH
THE HEART OF FILIPINO HEALTHCARE

DEPARTMENT: Total Quality Division		POLICY NUMBER: DPOTMH-APP-TQD-P035-(02)	
TITLE/DESCRIPTION: Non-Conformity Report			
EFFECTIVE DATE: May 30, 2023	REVISION DUE: May 29, 2026	REPLACES NUMBER: DPOTMH-TQD-QA-SOP003	NO. OF PAGES: 1 of 10
APPLIES TO: All Divisions		POLICY TYPE: Administrative	

PURPOSE:

1. This policy establishes the course to correct the cause(s) of non-conformance's or potential non-conformance's in the Quality Management System, Services, and/or Operational processes in Riverside Medical Center, Inc. (RMCI).
2. To ensure that nonconforming outputs/services are identified and controlled to prevent its unintended use or delivery.

DEFINITIONS:

Non-Conformity-Defined as deviation in terms of quality and safety during the execution operational processes, client's/patient's care, strategic objectives and business goals. Whenever there is a deviation in quality, a non-conformance report (NCR) is issued.

Quality Management System-Refers to a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. A QMS helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis.

RESPONSIBILITY:

Initiator, Total Quality Division, Human Resource Division, Departmental Supervisor, Department Head

POLICY:

1. Non-conforming outputs/service shall be properly identified (e.g. lack of materials, medication errors, unmet TAT, unsafe patient care, etc.) and isolated or intervened when appropriate to prevent its unintended use or delivery to the next process or service provision.
2. Inform related parties through oral or written means to:
 - 2.1 Review previous processes for similar problems.
 - 2.2 Provide containment action.
 - 2.3 Check on-going and future processes to ensure conformity and/or determine the effectiveness of containment action.
3. Non-conformity report shall be classified according to risk level on the risks registry. All NCR categorized as medium and severe should undergo Root Cause Analysis (RCA) using the **Root Cause Analysis form**.





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4. All non-conformance's shall be discussed during unit/section/department meetings, analyzed with the use of Cause and Effect Diagram, Ishikawa or Fishbone Diagram, 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.
5. All Non-Conformity Report shall bear a specific control number and classified as confidential.
6. The Corrective Action process shall be initiated upon detection of non-conformity or in the presence of unmet targets. Corrective Action/s that will reflect on the RCA form shall be initiated as a result, but not limited to the following:
 - Internal (patient and non-patient care) 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
7. All HR-related non-conformities shall be forwarded to Human Resources Division.
8. The Originator and Process Owner shall accomplish the NCR form and follow the following guidelines.





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PROCEDURE (SOP):

PART 1: Non-Conformity Report

1. The Initiator shall accomplish the data as to:
 - 1.1 Date and Time of Incident
 - 1.2 Person Involved
 - 1.3 Classification of Non Conformity
 - 1.4 Brief Description of Non Conformity (Incident Report Form can be added for description)
 - 1.5 Name/s, signatures and contact details needs to be indicated for follow up purposes.
2. The Supervisor (or immediate superior) shall accomplish the data as to:
 - 2.1 Immediate action/s taken
 - 2.2 Name and Signature of the Supervisor
3. The Department Head shall accomplish the data as to:
 - 3.1 Possible root cause/s of the non-conformity
 - 3.2 Recommend possible solution/s or measure/s to prevent the non-conformity in recurring
4. Forwards the NCR form to the Total Quality Division Office.
5. TQD enters the NCR to the Risk Registry and classify according to risk level.





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PART 2: Root Cause Analysis (RCA) Data

2. The TQD representative shall write the following on the space provided:
 - 2.1 Department involved in the NCR.
 - 2.2 Name and Designation of the person involved in the NCR.
 - 2.3 Date of the incident
 - 2.4 Date when the RCA was conducted.
3. The TQD representative shall write the following on the space provided:
 - 3.1 Description of the incident
 - 3.2 List of RCA Team
4. The TQD representative shall write the following on the space provided:
 - 4.1 Possible Cause/s of the incident
 - 4.2 Utilize Cause and Effect Diagram (attached a copy)
5. The TQD representative shall write the following on the space provided:
 - 5.1 Answer the following questions with YES or NO and provides explanation as needed.
 - 5.2 Identify Risk Reduction taken
 - 5.3 Establish and Enumerate Prevention Strategy





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PART 3: Solution Review and Follow up

3. The TQD shall monitor the implementation of the corrective action/s and makes a report accordingly.
 - 3.1 New target date- the date the Action is targeted to be fully implemented
 - 3.2 Status of the action taken- effectiveness of the actions taken
 - 3.3 Closed (Effective)- if the actions corrected the nonconformity
 - 3.3.1 Closed (Not Effective)- if the actions were not effective to correct the Non-conformity.
A new CAR form shall be created by the Originator and to be issued to the Process Owner.





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WORK INSTRUCTION:	
Non-Conformity Report	
KEY TASK	PERSON RESPONSIBLE
1. Accomplish data as to: <ul style="list-style-type: none">Date and Time of IncidentPerson InvolvedClassification of Non ConformityBrief Description of Non Conformity (Incident Report Form can be added for description)Name/s, signatures and contact details needs to be indicated for follow up purposes.	Initiator
2. Accomplish the data as to: <ul style="list-style-type: none">Immediate action/s takenName and Signature of the Supervisor	The Supervisor (or immediate superior)
3. Accomplish the data as to: <ul style="list-style-type: none">Possible root cause/s of the non-conformityRecommend possible solution/s or measure/s to prevent the non-conformity in recurring	Department Head
4. Forwards the NCR form to the Total Quality Division Office.	Initiator





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Root Cause Analysis (RCA) Data	
KEY TASK	PERSON RESPONSIBLE
1. Write the following on the space provided: <ul style="list-style-type: none">Department involved in the NCR.Name and Designation of the person involved in the NCR.Date of the incidentDate when the RCA was conducted.	TQD representative
2. Write the following on the space provided: <ul style="list-style-type: none">Description of the incidentList of RCA Team	
3. Write the following on the space provided: <ul style="list-style-type: none">Possible Cause/s of the incidentUtilize Cause and Effect Diagram (attached a copy)	
4. TQD representative shall write the following on the space provided: <ul style="list-style-type: none">Answer the following questions with YES or NO and provides explanation as needed.Identify Risk Reduction takenEstablish and Enumerate Prevention StrategySecure approval of the strategy with name and signature of the RCA Team.	





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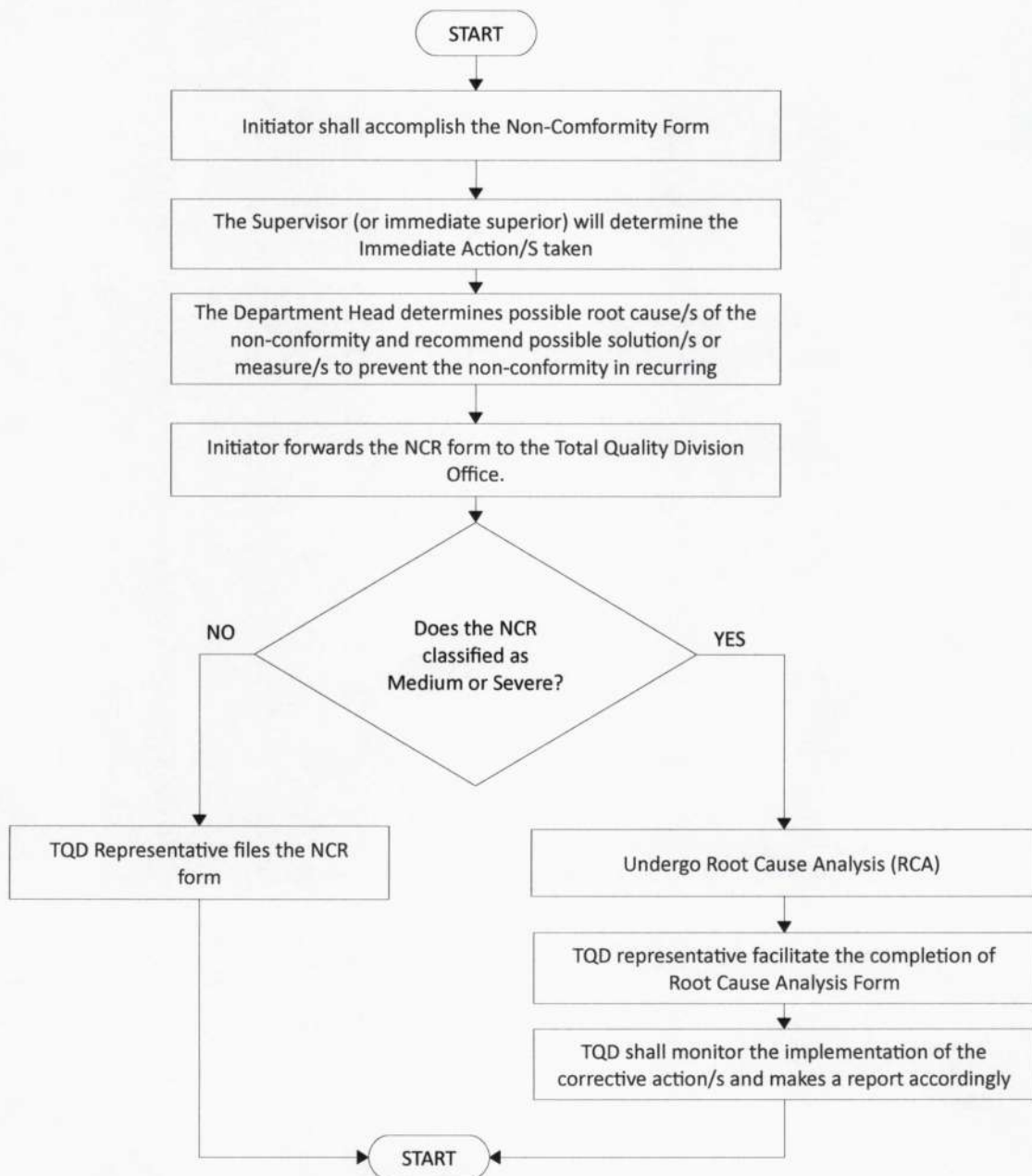
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WORK FLOW:





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FORMS:

1. DPOTMH-QA-F013-01-Non-Conformity Report Form
2. DPOTMH-QA-F015-A-Root Cause Analysis Form
3. DPOTMH-QA-F015-B-Cause and Effect Diagram

EQUIPMENT: N/A

REFERENCES:

1. Maheswari, J. & Charlesraj, V. Paul & Kumar, G & Padala, S P Sreenivas. (2016). A Study on Assessment of Non-conformances Using Multiple Domain Matrix: A Case Study from Metro Projects. Procedia Engineering. 145. 622-629. 10.1016/j.proeng.2016.04.052.





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