ZAMBOANGA CITY MEDICAL CENTER

DOCUMENT REVISION RECORD

Title: **Control of Non-Conformity and Corrective Action**			Doc. No: **: ZCMC-PM-03**	
Rev. No.	DCN #	Brief description of changes	Effectivity date	Originator
0	-	Original Issue	August 1,2014	IQA
1	ZCMC-DCN-2017-0239	**Change title from** Control of Non-Conformance, Corrective and Preventive Action to ***Control of Non-Conformity and Corrective Action*** **Page 1 under 1.0 Scope change from** This procedure is applicable to all products/materials, process and system non-conformances including customer feedbacks/complaints and unmet quality objectives' targets. to ***This procedure is applicable to all products/materials, process and system non-conformity including customer feedbacks/complaints and unmet quality objectives' targets.*** **Page 1 under 2.0 Objective change from** To establish and maintain documented Control of Non conformance, Corrective and Preventive Action procedures to ensure effective implementation of the actions. To ***To establish and maintain documented Control of Non Conformity and Corrective Action procedures to ensure effective implementation of the actions.*** **Page 1 under 3.0 Reference Documents** • Change from ISO 9001:2008 : International Standard Quality Management System Requirements TO ***ISO 9001:2015: International Standard Quality Management System Requirements*** • ZCMC-QM : Quality Manual TO ***ZCMC-QMS Quality Management System (QMS) Manual*** • ZCMC-PM-01 : Control of Documents and Records TO ***ZCMC-PM-01: Control of Documented Information*** **Page 1-3 under 4.0 Procedure** **Change from** All non-conformances detected as a result of defective product/material, unmet goals/ objectives and targets, customer complaints, unsatisfactory results of customer survey, audit findings and service related non-conformances, must be recorded and identified. Investigation of the cause must define the nature and extent of the non-conformance. To ***All non-***	January 10, 2017	IQA

conformity detected as a result of defective product/material, unmet goals/ objectives and targets, customer complaints, unsatisfactory results of customer survey, audit findings and service related non-conformity, must be recorded and identified. Investigation of the cause must define the nature and extent of the non-conformity.

Delete - Any affected personnel upon observance of a non-conformance as stated in item 4.1can raise a Non-conformance Report or inform any member of the involved department about the non-conformance observed.

Change from The involved department shall record the non-conformance into the Non-Conformance, Corrective/Preventive Action Report (NCPAR) Form No. ZCMC- F-NCPAR-01. To ***The involved department shall record the non-conformity into the Non-Conformity and Corrective Action Report (NCAR) Form No. ZCMC- F-NCAR-01.***

Change from For product or material he/she shall identify and segregate the non-conforming product/material and dispose as follows:

a) condemned
b) rework/ repair
c) reject and return to supplier, and/or
d) scrapped

to

For product or material coming from suppliers to Materials Management staff shall identify and segregate the non-conforming product/material and shall be disposed by rejecting and returning to the suppliers.

For product or material such as drugs, medicines, supplies and equipment, this shall be identified, segregated and disposed as follows:

SOURCE	*DISPOSITION*
a. Suppliers	*Reject and return to suppliers*
b. Equipment	*Condemn*
c. Defective of expired medicines, drugs and supplies from pharmacy and Central Supply & Sterilization (CSS)	*Condemn*

Delete Disposition must be reviewed, agreed and implementation must be verified through inspection and/or

		test as applicable. Records of accepted non-conforming product or material and of rework or repairs must be recorded. **Corrective Action** **Change from** Corrective action shall be taken to eliminate or prevent the non –conformance recurrence. This can be initiated by any staff responsible for non-conformance/s as a result of non-conformance as described in item 4.1. to ***Corrective action shall be taken to eliminate or prevent the non –conformity recurrence. This can be initiated by any staff responsible for non-conformities as a result of non-conformity as described in item 4.1.*** **Change from** The department concerned of the non-conformance shall be responsible for the timely investigation on the probable root cause of the problem, the formulation of correction as necessary and implementation of corrective action needed to eliminate its recurrence. Application of controls to ensure the effectiveness of the action taken shall be determined. These shall be recorded in the Non-conformance, Corrective/Preventive Action Report (NCPAR). (ZCMC-F-NCPAR-01) to ***The department concerned of the non-conformity shall be responsible for the timely investigation on the probable root cause of the problem, the formulation of correction as necessary and implementation of corrective action needed to eliminate its recurrence. Application of controls to ensure the effectiveness of the action taken shall be determined. These shall be recorded in the Non-Conformity and Corrective Action Report (NCAR) (ZCMC-F-NCAR-01)*** Add - ***For results of Failure Mode and Effects Analysis (FMEA) with "very high severity" and with the effect of "death with legal issues" and with Risk Priority Number (RPN) of 25 and above, the corrective action will be recorded on the said FMEA including evaluation and its effectiveness.*** ***(Refer to documented information on FMEA form).*** Delete: ***Preventive Action*** ***The determination of preventive action to eliminate the cause of potential non-conformities in order to prevent their occurrence may be done through the following but not limited to results of meeting/s, internal and external audits, customer satisfaction surveys and analyzed data.*** ***Proposed preventive action and controls to be applied to ensure its effectiveness shall be discussed by the Department Heads. Relevant Information on preventive actions taken shall be discussed during the regular Management Review meetings. The finalized preventive action shall be recorded in***		

		the Non-conformance, Corrective/Preventive Action Report (NCPAR) Form No. ZCMC- F-NCPAR-01. **Under Customer Complaints** **Change** Non-conformance, Corrective/Preventive Action Report (NCPAR). Customer Complaints Handling Procedure refer to Filing Complaint - ZCMC - WI - PACCU-02. ***To Non-conformity and Corrective Action Report (NCAR).*** **Under Verification** Change Corrective and preventive actions implemented shall be logged by the assigned personnel in the corrective/ preventive action monitoring log Form No. ZCMC- F-NCPAR-02 and will be monitored and regularly updated to verify its effectiveness. Refer to item 4.7 (Follow up) of Internal Audit Procedure ZCMC-PM-02. To *Corrective actions implemented shall be logged by the assigned personnel in the corrective action monitoring log Form No. ZCMC- F-NCAR-02 and will be monitored and regularly updated to verify its effectiveness. Refer to item 4.7 (Follow up) of Internal Audit Procedure ZCMC-PM-02.* Change The Quality Management Representative or the Department head shall approve the verification. To ***The ISO Chair or the Department head shall approve the verification.*** **Under 5.0 Responsibility** 5.1 Change It is the responsibility of the QMR to ensure that the above procedure is implemented. To It is the responsibilities of the Medical Center Chief and ISO Chair to ensure that the above procedure is implemented. 5.2 Change Records are filed and maintained as per control of documents and records procedure-ZCMC-PM-01. To ***Records are filed and maintained as per Control of Documented Information -ZCMC-PM-01.*** **Under 6.0 Records** ▪ ZCMC - F- NCPAR-01 - Non-conformance/ Corrective/ Preventive Action Report (NCPAR) to ***ZCMC - F- NCAR-01 - Non-conformity and Corrective Action Report (NCAR)*** ▪ Change from ZCMC - F- NCPAR-02- Corrective/ Preventive Action Monitoring Log to ***ZCMC - F- NCAR-02 - Corrective Action Monitoring Log***		

2	ZCMC-DCN-2020-0238	**3.0 Reference Documents** **To** **3.0Reference Documented Information** ZCMC-QMS : Quality Management System Manual to ZCMC-QMSM : Quality Management System Manual **Responsible:** Top Management To Top Management/ ISO Chair **Type of Non conformity: Add** Defective/ Product Materials from receipt of delivery of supplies **Responsible:** ISO Chair/ Concerned Heads with findings **4.4 For product or material coming from suppliers to Materials Management staff shall identify and segregate the non-conforming product/material and shall be disposed by rejecting and returning to the suppliers.** **To** **4.4 For product or material coming from suppliers to Materials Management staff shall identify and segregate the non-conforming product/material and shall be disposed by rejecting and returning to the suppliers (ZCMC- F-MM-03 -Inspection and Acceptance Report (Material Management)** **4.6 Corrective Action** **To** **4.6 Correction and Corrective Action** **4.6.1 Corrective action shall be taken to eliminate or prevent the non –conformity recurrence. This can be initiated by any staff responsible for non-conformities as a result of non-conformity as described in item 4.1.** **4.6.2 The department concerned of the non-conformity shall be responsible for the timely investigation on the probable root cause of the problem, the formulation of correction as necessary and implementation of corrective action needed to eliminate its recurrence. Application of controls to ensure the effectiveness of the action taken shall be determined. These shall be recorded in the Non-Conformity and Corrective Action Report (NCAR) (ZCMC-F-NCAR-01)** **4.6.3 For results of Failure Mode and Effects Analysis (FMEA) with "very high severity" and with the effect of "death with legal issues" and with Risk Priority Number (RPN) of 25 and above, the corrective action will be**	July 30,2020	IQA

		recorded on the said FMEA including evaluation and its effectiveness. **(Refer to documented information on FMEA form).** **To** **4.6.1 Correction is an action taken to eliminate the detected nonconformity.** **4.6.2 Corrective action shall be taken to eliminate the cause of the nonconformity and to prevent its recurrence. This can be initiated by any staff responsible for nonconformity.** **4.6.3 The department concerned of the non-conformity shall be responsible for the timely investigation on the probable root cause of the problem, the formulation of correction as necessary and implementation of corrective action needed to prevent its recurrence. Application of controls to ensure the effectiveness of the action taken shall be determined. These shall be recorded in the Non-Conformity and Corrective Action Report (NCAR) (ZCMC-F-NCAR-01)** **4.6.4 For results of Failure Mode and Effects Analysis (FMEA) with Risk Priority Number (RPN) of 25 and above, the corrective action will be documented in the Recommended Action Column of the FMEA (Refer to documented information on FMEA form).** **4.7 Customer Complaints** **4.7.1 Any written report or feedback from the customer which is treated as complaint shall be handled by the Public Affairs and Customer Care Unit (PACCU), and shall be recorded through the Non-conformity and Corrective Action Report (NCAR). Customer Complaints Handling Procedure refer to Filing Complaint - ZCMC - WI - PACCU-02.** **To** **4.7.1 Any written report or verbal feedback from the customer which is treated as complaint shall be handled by the Public Affairs and Customer Care Unit (PACCU), and shall be recorded through the Nonconformity and Corrective Action Report (NCAR) (ZCMC-F-NCAR-01, refer to Filing Complaint - ZCMC - WI - PACCU-02** **4.8 Verification** **4.8.1 Corrective actions implemented shall be logged by the assigned personnel in the corrective action monitoring log Form No. ZCMC- F-NCAR-02 and will be monitored and regularly updated to verify its effectiveness. Refer to item 4.7 (Follow up) of Internal Audit Procedure ZCMC-PM-02.**		

Title: **Control of Non Conformity and Corrective Action**

1.0 Scope

This procedure is applicable to all products/materials, process and system non-conformity including customer feedbacks/complaints and unmet quality objectives' targets.

2.0 Objective

To establish and maintain documented Control of Non Conformity and Corrective Action procedures to ensure effective implementation of the actions.

3.0 Reference Documented Information

- ISO 9001:2015 : International Standard Quality Management System Requirements
- ZCMC-QMSM : Quality Management System (QMS) Manual
- ZCMC-PM-01 : Control of Documented Information
- ZCMC-PM-02 : Internal Quality Audit
- ZCMC-WI-PACCU-02 : Filing Complaint
- ZCMC - F- NCAR-01 :Non-conformity and Corrective Action Report (NCAR)
- ZCMC - F- NCAR-02 : Corrective Action Monitoring Log

4.0 Procedure

4.1 All non-conformity detected as a result of defective product/material, unmet goals/ objectives and targets, customer complaints, unsatisfactory results of customer survey, audit findings and service related non-conformity, must be recorded and identified. Investigation of the cause must define the nature and extent of the non-conformity.

4.2 In the issuance of the nonconformity report, the following should be observed:

Type of Non conformity	Responsible
a. Unmet Quality Objectives/Target	Top Management/ ISO Chair
b. IQA Findings	IQA Auditors
c. Customer Complaints	Public Affairs & Customer Care Unit (PACCU)
d. Customer Satisfaction	Public Affairs & Customer Care Unit (PACCU)
e. Service Nonconformity	Department Head
f. Defective/ Product Materials from receipt of delivery of supplies	Materials Management
g. External Audit Findings	ISO Chair/ Concerned Heads with findings

4.3 The involved department shall record the nonconformity into the Non-Conformity and Corrective Action Report (NCAR) Form No. ZCMC- F-NCAR-01.

4.4 For product or material coming from suppliers to Materials Management staff shall identify and segregate the non-conforming product/material and shall be disposed by rejecting and returning to the suppliers (ZCMC- F-MM-03 -Inspection and Acceptance Report (Material Management)

4.5 For product or material such as drugs, medicines, supplies and equipment, this shall be identified, segregated and disposed as follows:

SOURCE	DISPOSITION
a. Suppliers	Reject and return to suppliers
b. Equipment	Condemn
c. Defective of expired medicines, drugs and supplies from pharmacy and Central Supply & Sterilization (CSS)	Condemn

4.6 Correction and Corrective Action

4.6.1 Correction is an action taken to eliminate the detected nonconformity.

4.6.2 Corrective action shall be taken to eliminate the cause of the nonconformity and to prevent its recurrence. This can be initiated by any staff responsible for nonconformity.

4.6.3 The department concerned of the non-conformity shall be responsible for the timely investigation on the probable root cause of the problem, the formulation of correction as necessary and implementation of corrective action needed to prevent its recurrence. Application of controls to ensure the effectiveness of the action taken shall be determined. These shall be recorded in the Non-Conformity and Corrective Action Report (NCAR) (ZCMC-F-NCAR-01)

4.6.4 For results of Failure Mode and Effects Analysis (FMEA) with Risk Priority Number (RPN) of 25 and above, the corrective action will be documented in the Recommended Action Column of the FMEA (Refer to documented information on FMEA form).

4.7 Customer Complaints

4.7.1 Any written report or verbal feedback from the customer which is treated as complaint shall be handled by the Public Affairs and Customer Care Unit (PACCU), and shall be recorded through the Nonconformity and Corrective Action Report (NCAR) (ZCMC-F-NCAR-01), refer to Filing Complaint - ZCMC - WI - PACCU-02

4.8 Verification

4.8.1 A follow-up check shall be conducted minimum of two (2) to seven (7) days after the implementation of the corrective action/s even without prior announcements to verify of the committed action is implemented and preferably minimum one (1) month after, another follow-up check will be done to evaluate the effectiveness of the implemented action.

4.8.2 For FMEA recommended action the effectiveness of actions will be evaluated preferably six (6) months after its implementation. The result of the verification will be logged in the Nonconformity and Corrective Action Report (ZCMC-F-NCAR-02) and Corrective Actions Monitoring Log (ZCMC-F-NCAR-02) for monitoring and updating as necessary.

4.8.3 The ISO Chair or the Department head shall approve the verification.

4.8.4 All necessary changes brought about by the implementation shall be reflected in the affected documented procedure or relevant work instructions as applicable.

5.0 Responsibility

5.1 It is the responsibilities of the Medical Center Chief and ISO Chair to ensure that the above procedure is implemented.

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