PURPOSE:

1. To establish a systematic monitoring and reporting procedure for adverse drug reactions (ADR) and adverse drug events (ADE) in order to avoid future drug related problems
2. To improve therapeutic outcomes by avoiding potential ADRs and ADEs
3. To provide guidelines on how to address ADRs and ADEs when they occur in order to maximize patient safety.

LEVEL:

All Physicians, Nurse, Pharmacists and other Healthcare Professionals

DEFINITION OF TERMS:

Adverse Drug Reaction- is a response to a drug which is noxious and unintended and which occurs at doses normally used for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function.

These reactions include circumstances that:

a) Requires discontinuing the drug (therapeutic or diagnostic)
b) Requires changing the drug therapy
c) Requires modifying the dose (except for minor dosage adjustments)
d) Necessitates admission to a hospital
e) Prolongs stay in a health care facility
f) Necessitates supportive treatment
g) Significantly complicates diagnosis
h) Negatively affects prognosis
i) Results in temporary or permanent harm, disability, or death

Adverse Drug Event - is an injury resulting from the use of a drug. Under this definition, the term ADE includes harm caused by the drug (adverse drug

reactions and overdoses) and harm from the use of the drug (including dose reductions, discontinuations of drug therapy and drug administration errors.)

High-risk Patient- includes but are not limited to pediatric patients, geriatric patients, patients with organ failure (e.g., hepatic or renal failure), and patients receiving multiple drugs.

Alerting Orders- include the use of "tracer" drugs that are used to treat common ADRs (e.g., orders for immediate doses of antihistamines, epinephrine, and corticosteroids), abrupt discontinuation or decreases in dosage of a drug, or stat orders for laboratory assessment of therapeutic drug levels.

POLICY:

1. It is the policy of Riverside Medical Center Inc. (RMCI) to establish a monitoring and reporting system for ADRs and ADEs. This system should establish the following:
   1.1. An ongoing and concurrent (during drug therapy) surveillance system based on the reporting of suspected ADRs by pharmacists, physicians, nurses, or patients.
   1.2. A prospective (before drug therapy) surveillance system for high-risk drugs or patients with a high risk for ADRs.
   1.3. A concurrent surveillance system for monitoring alerting orders. Alerting orders include the use of "tracer" drugs that are used to treat common ADRs (e.g., orders for immediate doses of antihistamines, epinephrine, and corticosteroids), abrupt discontinuation or decreases in dosage of a drug, or stat orders for laboratory assessment of therapeutic drug levels.

2. The data collected will aid the Pharmacy and Therapeutics Committee (PTC) in its assessment of drug use, individual patient incidents related to drug use, and drug

interactions, and will provide the basis for medical and nursing staff education that may minimize the occurrence of adverse reactions.

3. The fundamental role of this reporting system is to enhance patient safety by learning from failures of the healthcare system.

4. Monitoring for ADRs and ADEs is implemented throughout the duration of the patient's hospital stay.

APPROVAL:

	Name/Title	Signature	Date
Prepared by:	**STEPHANIE CAMILLE O. SAMONTE, RPh.** Inpatient Clinical Pharmacist		01/11/22
Verified:	**MA. MADELYN N. LACSON, RPh., RN** Inpatient Pharmacy Supervisor		1/11/22
	MIRIAM HOPE D. BRAVO, RPh. Inpatient Pharmacy Manager		1/11/22
Reviewed by:	**DENNIS C. ESCALONA, MN, FPCHA, FPSQua** Quality Assurance Supervisor		01/11/2022
Recommending Approval:	**PRINCESS M. ABELLON, MBA** Pharmacy Division Officer		1/11/2022
	HENRY F. ALAVAREN, MD, FPSMID, FPSQua Total Quality Division Head		1/12/2022
Approved:	**GENESIS GOLDI D. GOLINGAN** President and CEO		2/12/22

DOCUMENTATION:

Revised Policy

DISSEMINATION:

Policies and Procedures Manual

REFERENCE:

University of Toledo "Adverse Drug Reaction Reporting Policy" 2019

Qmentum International "Medication Management" 2016

ASHP Guideline on Adverse Drug Reaction Monitoring and Reporting w]

PURPOSE:

To discuss the processes involved in the reporting of adverse drug reactions.

SCOPE:

Applies to all Pharmacy Division staff of Dr. Pablo O. Torre Memorial Hospital

PERSON RESPONSIBLE:

Clinical Pharmacists, Nurses, Physicians, Clinical Department Heads, Managers, Clinical Coordinator and Clinical Staff

GENERAL GUIDELINES:

1. Monitoring for ADRs and ADEs is done for all patients admitted to Dr. Pablo O. Torre Memorial Hospital.
2. Clinical Department Heads, Managers, Clinical Coordinator shall schedule and facilitate clinical staff attendance on the training regarding the reporting of ADRs and ADEs.
3. Compliance to the procedure outlined in this document shall be ensured.

PROCEDURE:

1. Upon admission, high-risk patients are identified by thorough assessment either by the admitting physician or attending physician. These assessments are to be recorded in the patient's medical record (e.g. in the patient's Clinical Data/Medical History, Doctor's Progress Notes).
2. The Pharmacist-on-the-floor in coordination with the Nursing Service Division and Medical Staff shall observe pharmacovigilance practices. Profiles of high-risk patients and alerting orders are to be double-checked prior to filling of

prescriptions and medication administration. Risk factors and potential for ADRs and ADEs are also double-checked and these includes:

2.1. Medication trough levels
2.2. Drug Allergies
2.3. Patient's laboratory values and records
2.4. Double-checking High-alert medication orders

3. In accordance with the hospital's policy on Medication Reconciliation, the patient's medication profile should be timely reconciled in order to minimize the risk for ADEs involving medication duplications, medication discontinuation and inappropriate doses.
4. Whenever an ADR or ADE occurs, any member of the medical, nursing, or pharmacy staff may initiate the report using the ADR/ADE report form (Appendix A).
5. The report should be initiated within 24 hours after the reaction is recognized and must be completely filled as much as possible.
6. The information on the report form will include:
   6.1. Date of Report
   6.2. Date of Reaction/Date of Event
   6.3. Patient Location/Nursing Unit
   6.4. Patient Name
   6.5. Diagnosis (if known)
   6.6. Known allergies/hypersensitivities
   6.7. Drug suspected of causing reaction.
      a) Complete name of the drug (generic and brand)
      b) Manufacturer
      c) Batch and Lot Numbers of suspected drug
   6.8. For ADE- circumstance of the event (e.g. administration error)
   6.9. Dose given and date/time dose given
   6.10. Other concurrent drugs used within 24 hours (i.e., prescription, OTC, herbal, etc.)
   6.11. Description of reaction

6.12. Treatment of reaction and response
6.13. Reporter's ID number and signature
6.14. Attending Physician's Verification (name and signature)
6.15. Pharmacist's verification (name and signature)

7. The clinician who witnessed the reaction and initiated the report must notify the attending physician regarding the nature of the reaction.
8. The physician will examine the individual, order necessary intervention, if needed, and will complete the medical section of the Adverse Drug Reaction Report. The attending physician and direct care clinicians (e.g. residents and nurses) are to record the ADR or ADE in the patient's chart.
9. The ADR and ADE Report form is then documented and compiled by the Inpatient Pharmacy Department.
10. The Pharmacy Division in coordination with the Pharmacy and Therapeutics Committee (PTC) should review and analyze the reports and make programs to address problems identified (e.g. Training program on high-risk medications such as high-alert medications).
11. The PTC will review adverse drug reactions that have been reported to the Pharmacy. One or more of the following actions may be taken:
    11.1. The information may be provided to the manufacturer if the adverse reaction is not well known, or if the drug was only recently released for use.
    11.2. Medical or Nursing Staff may be informed of the reaction as part of the educational function of the Pharmacy, and of the PTC. Related information (recommended treatment of the reaction, ways to avoid the reaction, etc.) will also be provided. This will be done by a memo, the Drug Information bulletin, Medical Staff Bulletin, or other means.
    11.3. Depending on the nature of the reaction and its frequency, a drug utilization review may be initiated, and the committee may re-evaluate the inclusion of the drug in the Hospital Formulary.
    11.4. Depending on the severity and type of reaction, a report should be filed with the Food and Drug Administration (FDA).

11.5. Any other actions that may reduce the risk of recurrence of the adverse reaction, or serve to educate the nursing and medical staff.

REFERENCE:

University of Toledo "Adverse Drug Reaction Reporting Policy" 2019

Qmentum International "Medication Management" 2016

ASHP Guideline on Adverse Drug Reaction Monitoring and Reporting

APPROVAL:

	Name/Title	Signature	Date
Prepared by:	**STEPHANIE CAMILLE O. SAMONTE, RPh.** Inpatient Clinical Pharmacist		5-2-22
Verified:	**MA. MADELYN N. LACSON, RPh., RN** Inpatient Pharmacy Supervisor		5/4/22
	MIRIAM HOPE D. BRAVO, RPh. Inpatient Pharmacy Manager		5/4/22
Reviewed by:	**DENNIS C. ESCALONA, MN, FPCHA, FPSQua** Quality Assurance Supervisor		5/5/2022
Recommending Approval:	**PRINCESS M. ABELLON, MBA** Pharmacy Division Officer		5/5/2022
	HENRY F. ALAVAREN, MD, FPSMID, FPSQua Total Quality Division Head		5/19/2022
Approved:	**GENESIS GOLDI D. GOLINGAN** President and CEO		6/15/22

ANNEX A:

RIVERSIDE MEDICAL CENTER, INC.
Owner and Operator of the Dr. Pablo O. Torre Memorial Hospital
A proud member of the Metro Pacific Hospital Holdings, Inc.

PATIENT NAME:
MRN:
DOB:
AGE:
SEX:

ADVERSE DRUG REACTION REPORTING FORM

REPORT ANY REACTION OR INCIDENCE THAT MAY BE A DETRIMENTAL RESPONSE TO A MEDICATION WHICH IS UNDESIRED, UNINTENDED IN DOSES ACCEPTED IN MEDICAL PRACTICE.

Date of Reaction: _____ Time of Reaction: _____ Location Reaction Occurred: _____
Suspected Cause: (Brand Name)_____ (Generic Name)_____ Start Date: _____
Manufacturer: _____ Lot Number: _____ Batch Number: _____
Concurrent Drugs: _____
Has patient ever received this agent before? □ Yes □ No □ N/A If yes, specify: _____
Any past reaction noted? □ Yes □ No □ N/A If yes, specify: _____
Manifestation of Past Reaction: _____
Known Allergies/Sensitivities: _____

Check appropriate box(es) symptoms/signs

NEURO:	RESPIRATORY:	GI:	CNS:	SKIN:
□ Dizziness □ Confusion □ Paresthesia (location) _____ □ Tingling (location) _____ □ Change in Consciousness □ Tinnitus □ Hearing Acuity □ Fever □ Chills	□ Dyspnea (rate)_____ □ Tachypnea (rate) _____ □ Shallow, slow □ Orthopnea □ Bronchospasm **RENAL:** □ Hematuria □ Oliguria □ Anuria	□ Nausea □ Vomiting □ Diarrhea □ Constipation □ Melena □ GI Upset □ GI Pain **LABS:** □ LFTs □ Scr/BUN □ Neutropenia □ Anemia □ Electrolyte	□ Headache □ Confusion □ Anxiety □ Sedation □ Depression □ Malaise **CV:** □ Hypertension □ Hypotension □ Chest Pain □ Arrhythmias □ Bradycardia □ Tachycardia	□ Rash Site (s) & Type _____ _____ □ Alopecia □ Sloughing- necrosis □ Itching □ Flushing □ Swelling □ Phlebitis □ Erythema

□ Others: _____
□ Joint Pain (location): _____
□ Edema (location): _____
□ Shortness of Breath □ Chills
□ Wheezing □ Seizures
□ Fever □ Shock

Was the Physician Notified: □ Yes □ No

Describe Reaction: (chronological sequence if possible)

_____
_____
_____

Describe Therapy or Treatment Initiated:

_____
_____
_____

Response to Treatment/Outcome of Incident:

_____
_____
_____

Completed by: _____ (Pharmacist Full Name/Signature)

Verified by: _____ (Physician Full Name/Signature/Stamp)

DPOTMH-PHARM-F009 (R1)
Effective Date: 04-01-2022

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(034) 705-0000 / (034) 433-7331

ANNEX B:

RIVERSIDE MEDICAL CENTER, INC.

Owner and Operator of the Dr. Pablo O. Torre Memorial Hospital
A proud member of the Metro Pacific Hospital Holdings, Inc.

DR. PABLO O. TORRE MEMORIAL HOSPITAL

ADVERSE DRUG EVENT REPORT

DATE OCCURRED	DRUG INVOLVED	SEVERITY LEVEL	PREVENTABILITY LEVEL	REPORTED PATIENT REACTION/SYMPTOMS	TREATMENT ORDERED	PATIENT OUTCOME

Severity (S) Levels:

1. No action necessary, reaction minor
2. Change prescription, no treatment necessary
3. Change prescription, treatment instituted
4. Change prescription, provide treatment, requires admission or longer LOS
5. Change prescription, provide treatment, requires transfer to higher acuity unit (ICU/CCU)
6. Change prescription, provide treatment, results in irreversible harm/injury
7. Results in death

Preventability (P) Levels:

1. Unpreventable, Rx appropriate for disease
2. Possibly preventable, different Rx could be ordered
3. Possibly preventable, drug-drug interaction noted
4. Possibly preventable, food-drug interaction noted
5. Preventable, documented patient allergy
6. Preventable, drug known to cause toxicity- no levels obtained
7. Preventable, drug known to cause toxicity – continuous monitoring required not performed
8. Preventable, drug ordered inappropriate for patient disease

Recommendations: (Pharmacy Only)

_____

_____

_____

Completed By:

_____
(Complete Name/Signature/Badge Number/Date)

Verified By:

_____
(Complete Name/Signature/Badge Number//Date)

DPOTMH-PHARM-F008
Effective Date: 02-01-2020

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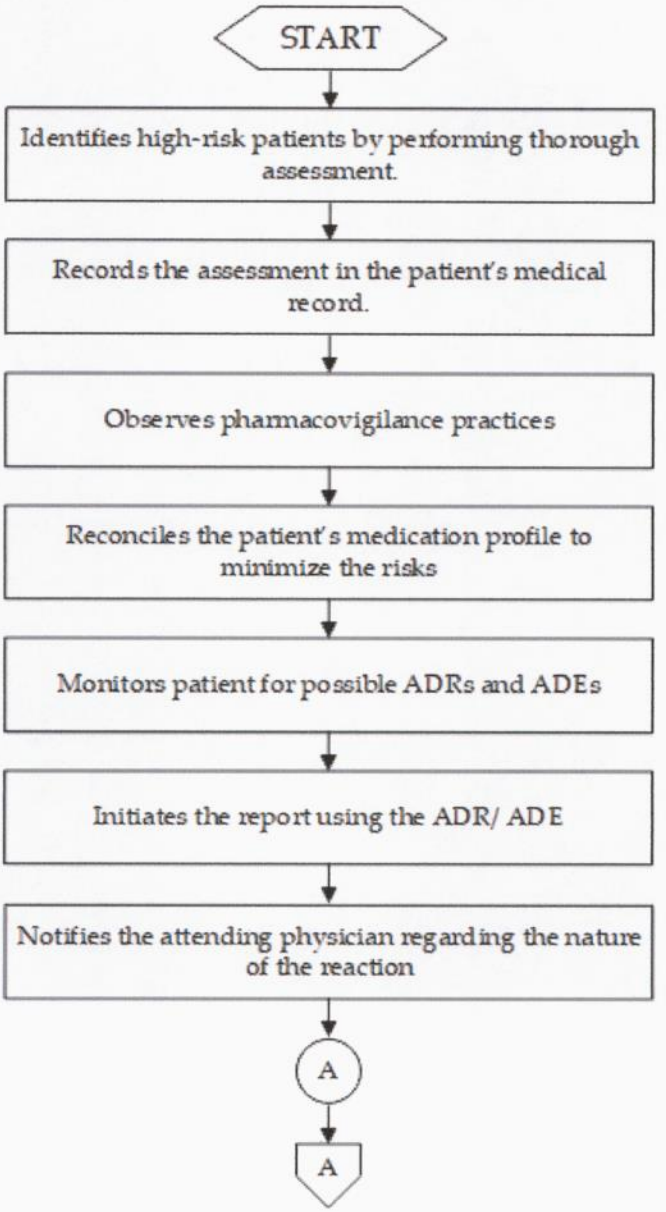
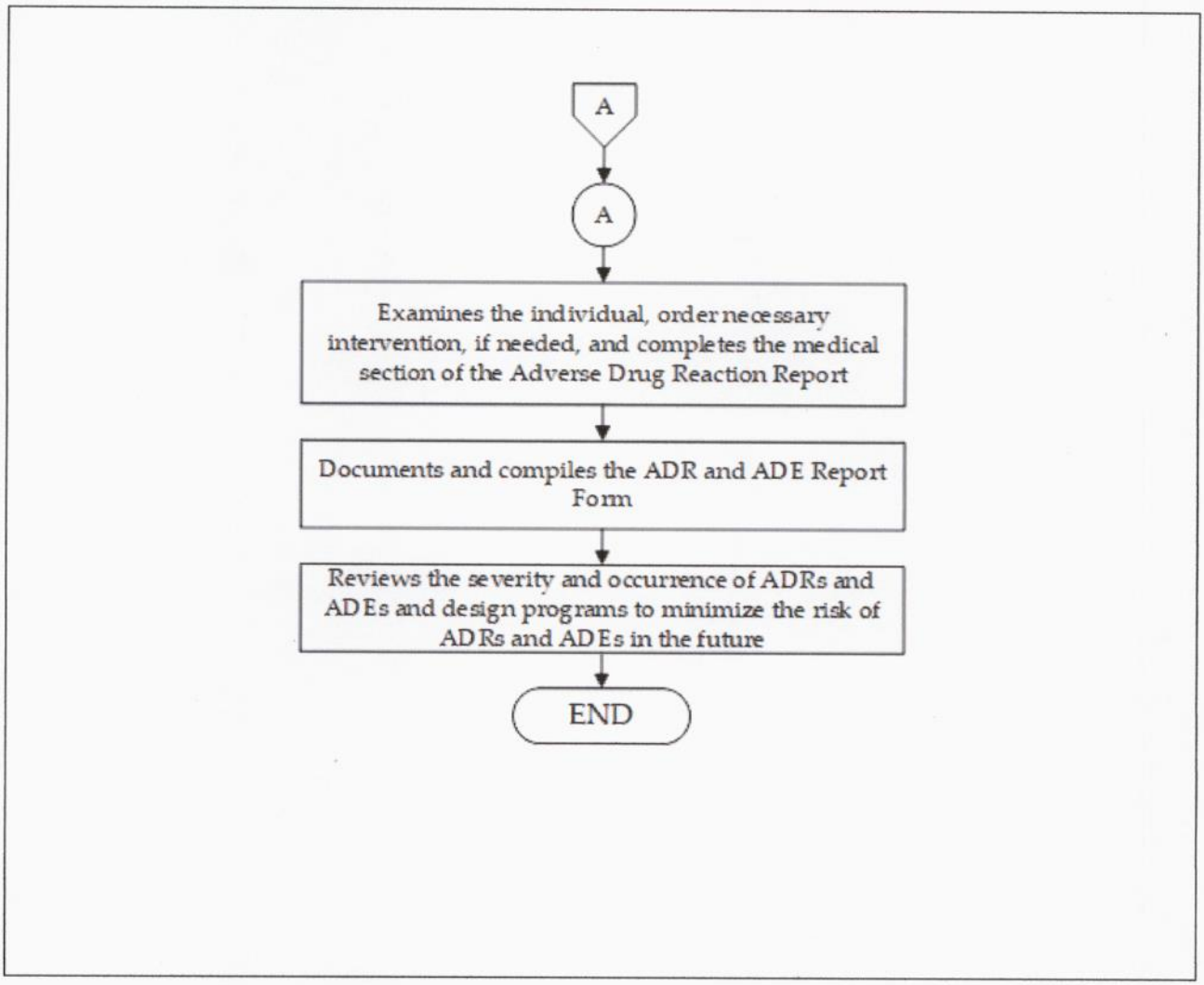
	Effective Date:	05-01-2022
	Document Type:	Flowchart
	Page Number:	1 of 3
	Department/Section:	Pharmacy Division
	Document Title:	**ADVERSE DRUG REACTION AND ADVERSE DRUG EVENT REPORTING**

FLOWCHART





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APPROVAL:

	Name/Title	Signature	Date
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Verified:	**MA. MADELYN N. LACSON, RPh., RN** Inpatient Pharmacy Supervisor		5/4/22
	MIRIAM HOPE D. BRAVO, RPh. Inpatient Pharmacy Manager		5/4/22
Reviewed by:	**DENNIS C. ESCALONA, MN, FPCHA, FPSQua** Quality Assurance Supervisor		5/5/2022
Recommending Approval:	**PRINCESS M. ABELLON, MBA** Pharmacy Division Officer		5/5/2022
	HENRY F. ALAVAREN, MD, FPSMID, FPSQua Total Quality Division Head		5/19/2022
Approved:	**GENESIS GOLDI D. GOLINGAN** President and CEO		6/15/22

KEY TASKS	PERSON RESPONSIBLE
1. Identifies high-risk patients by performing thorough assessment.	Admitting Physician or Attending Physician
2. Records the assessment in the patient's medical record.	Admitting Physician or Attending Physician
3. Observes pharmacovigilance practices	Pharmacist-on-the-floor and Nurse
4. Reconciles the patient's medication profile to minimize the risks	Physician/ Pharmacist/ Nurse
5. Monitors patient for possible ADRs and ADEs	Nurse
6. Initiates the report using the ADR/ ADE	Clinician who witnessed the reaction (any member of the Medical, Nursing, or Pharmacy Staff)
7. Notifies the attending physician regarding the nature of the reaction	Clinician who witnessed the reaction (any member of the Medical, Nursing, or Pharmacy Staff)
8. Examines the individual, order necessary intervention, if needed, and completes the medical section of the Adverse Drug Reaction Report	Physician
9. Documents and compiles the ADR and ADE Report Form	Inpatient Pharmacist
10. Reviews the severity and occurrence of ADRs and ADEs and design programs to minimize the risk	Pharmacy and Therapeutics Committee

of ADRs and ADEs in the future	
11. Coordinates with the FDA regarding guidelines on how to address ADRs and ADEs especially for new drugs (those that have not been on the market for more than 3 years).	Pharmacy and Therapeutics Committee
12. Verifies reports regarding ADRs and ADEs and coordinate with the Nursing Department and medical staff in monitoring patients for possible ADRs and ADEs	Pharmacists
13. Provides therapeutic advice in an event an ADR or ADE occurs (e.g. dosage adjustments, therapeutic alternatives).	Pharmacists
14. Educates the healthcare staff regarding medications that are high-risk for ADRs and ADEs (e.g. High Alert Medications)	Pharmacists
15. Ensures compliance to the procedure outlined in the policy on Adverse Drug Reaction and Adverse Drug Reporting.	Clinical Department Heads, Managers, Clinical Coordinator and Clinical Staff
16. Schedules and facilitates clinical staff attendance on the training regarding the reporting of ADRs and ADEs.	Clinical Department Heads, Managers, Clinical Coordinator and Clinical Staff

APPROVAL:

	Name/Title	Signature	Date
Prepared by:	**STEPHANIE CAMILLE O. SAMONTE, RPh.** Inpatient Clinical Pharmacist		5-2-22
Verified:	**MA. MADELYN N. LACSON, RPh., RN** Inpatient Pharmacy Supervisor		5/4/22
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	HENRY F. ALAVAREN, MD, FPSMID, FPSQua Total Quality Division Head		5/19/2022
Approved:	**GENESIS GOLDI D. GOLINGAN** President and CEO		6/15/22