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TITLE: QUALITY CONTROL FOR MONITORING VALIDITY OF



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1.0 PURPOSE

- 1.1 This documented information aims to provide the instruction for the assurance of quality of test and results.
- 1.2 To determine:
 - a) what needs to be monitored and measured;
 - the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
 - when the monitoring and measuring shall be performed;
 - d) when the results for monitoring and measurement shall be analyzed and evaluated.
- 1.3 To evaluate the performance and the effectiveness of the quality management system.
- 1.4 To retain appropriate documented information as evidence of the results.

2.0 SCOPE

- 2.1 documented information includes analytical quality control measure such as duplicate analysis, positive and negative controls, blanks and sterility checks.
- 2.2 The CWD shall analyze and evaluate appropriate data and information arising from monitoring and measurement.
- 2.3 The results of analysis shall be used to evaluate:
 - a) conformity of products and services;
 - b) the degree of customer satisfaction;
 - c) the performance and effectiveness of the quality management system;
 - d) if planning has been implemented effectively;
 - e) the effectiveness of actions taken to address risks and opportunities;
 - f) the performance of external providers;
 - g) the needs for improvements to the quality management system.

3.0 RESPONSIBILITY

- 3.1 The Laboratory management ensures that all test results generated are accurate and valid.
- 3.2 The Laboratory Analyst must be aware of the potential deviation during the execution of the test method.

4.0 DEFINITION OF TERMS

- 4.1 Quality Assurance includes all activities undertaken by the laboratory to ensure that reliable and accurate testing or measurements results are accurate and reliable.
- 4.2 Quality Control includes those activities that are undertaken to confirm that test and measurements results are accurate and reliable

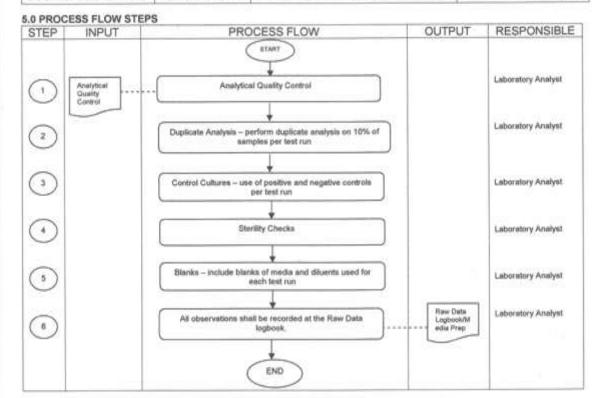
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6.0 PROCESS DETAILS

- 6.1 Analytical Quality Control Procedures
 - 6.1.1 Duplicate Analysis perform duplicate analysis on 10% of samples per test run.
 - 6.1.2 Control Cultures use of positive and negative controls per test run.

Control Cultures for Microbiological Tests

Group	Control Cultures			
	Positive	Negative		
Total Coliforms	Eschericha coli Enterobacter aerogenes	Staphylococcus aureus Pseudomonas sp		
Fecal Coliforms	Eschericha coli	Enterobacter aerogenes		

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		Streptococcus feacalis
Fecal Streptococci	Streptococcus feacalis	Staphylococcus aureus Eschericha coli

- 6.1,3 Sterility Checks incubate a representative portion of each batch of media at 35 ±0.5°C for 24 48 hours and observe for growth. Contamination is indicated by turbidity or growth on plates, determine the cause and reject analytical data for sample tested with these media.
- 6.1.4 Blanks include blanks of media and diluents used for each test run.

6.2 Control of changes

- 5.2.1 The CWD shall review and control for production and service provision, to the extent necessary to ensure continuing conformity with the requirements.
- 6.2.2 The CWD shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

6.3 Release of products and servies

- 6.3.1 The CWD shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.
- 6.3.2 The release of products and services to the customers shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by relevant authority and, as applicable, by the customer.
- 6.3.3 The CWD shall retain documented information on the release of products and services. The documented information shall include:
- evidence of conformity with the acceptance criteria;
- b) traceability to the person(s) authorizing the release.

7.0 RECORDS RETENTION

- 7.1 Active Retention Indefinite retention period for current or active documents for both electronic and hardcopy Master
- 7.2 Inactive/Archival Retention shall be kept for active three (3) years or may request for an extension as deemed necessary (hardcopy), for electronic/soft file, it shall be kept in a separate folder named "Obsolete Master Copy/Original".

8.0 REFERENCE

- 8.1 ISO 9001:2015 QMS Standard
- 8.2 Philippine National Standards for Drinking Water 2007
- 8.3 Standard Methods for the Examination of Water and Wastewater

9.0 ATTACHMENTS

- 9.1 Media Preparation Form
- 9.2 Raw Data Logbook

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