Approvals

Signing below indicates agreement that the protocol is ready for execution of the Installation, Operational, and Performance Qualification for the HACH DR5000 Spectrophotometer (SN 1396156) located at Giles Chemical QA Laboratory, 102 Commerce Street, Waynesville, NC 102 Commerce Street in Waynesville, NC.

Project Team Member	Functional Area	Signature	Date
Bryan Elchert	QA Laboratory		7/23/13
Patrick Owen	Engineering		7/24/13
Matt Haynes	Operations		7/24/13
Deborah Durbin	Quality		7/24/13

A final summary report that consists of results and conclusions based on the data collected after protocol execution will be written and approved. The executed protocol will be attached behind the report.

TABLE OF CONTENTS			Page #

I. PURPOSE:

The purpose of this protocol is to certify with documented evidence that the HACH DR5000 Spectrophotometer (SN 1396156) is installed and functions as intended. This protocol sets forth the objectives, methodology, documentation, and test activities needed to complete the Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification for the HACH DR5000 Spectrophotometer (SN 1396156) located at Giles Chemical QA Laboratory, 102 Commerce Street, Waynesville, NC.

II. BACKGROUND:

Giles Chemical, a division of Premier Magnesia (Giles), is dedicated to offering high quality Magnesium Sulfate products. To help achieve this goal, UV-Vis Spectrophotometry is sometimes used for quality purposes.

OVERVIEW

No other departments or systems will be affected by the installation or use of this equipment.

The following tests will be performed in this qualification:

Installation Documentation – the serial number or asset tag number of the Spectrophotometer will be documented.

Utility Verification – the voltage to the Spectrophotometer will be documented and verified to be correct.

Control / Operation Verification – the controls will be verified.

Analysis Verification – Verify the analytical capabilities of the Spectrophotometer.

III. SYSTEM DESCRIPTION:

A. The system consists of a HACH DR5000 Spectrophotometer (SN 1396156).

B. Description of Operation

01. The Spectrophotometer is started by pressing the power button.

02. The correct analytical method for the Spectrophotometer is selected based on the analysis to be performed.

03. Samples can then be analyzed.

IV. SCOPE

The Installation, Operational, and Performance Qualification protocol is intended to certify with documented evidence that the Spectrophotometer is installed properly and functions as desired by Giles.

V. ROLES AND RESPONSIBILITIES

1. QA Laboratory

- ❖ Write and issue the protocol
- ❖ Investigate protocol deviation reports
- ❖ Execute the IQ, OQ, and PQ.

- ❖ Review raw data and originate interim notification to Quality Assurance
- ❖ Write and route the final report

2. Quality Assurance
   - ❖ Review and approve the protocol.
   - ❖ Review and approve raw data and notifications.
   - ❖ Review, approve, and store the final report.

VI. TEST PROGRAM

A. INSTALLATION QUALIFICATION

Objective

The objective of the installation verification is to document the proper installation of the Spectrophotometer.

Equipment/Materials

HACH DR5000 Spectrophotometer (SN 1396156)

Procedure

Perform each item listed below for the Spectrophotometer.

- Location: Verify that the instrument is situated to allow sufficient room around the instrument for access doors and panels to be opened.
- Equipment: Document the Model and Serial or Asset Tag number of the Spectrophotometer.
- Utilities
  - Electrical Requirements: Verify the Spectrophotometer is receiving the specified voltage.

Acceptance Criteria

If the voltage is correct, each piece uniquely identified, and sufficient access for all doors and panels is available, the Spectrophotometer will be considered installed properly.

B. OPERATION QUALIFICATION

Objective

The objective of Controls Verification is to document that the Spectrophotometer operates as needed by Giles. The controls will be operated to test the ability of the Spectrophotometer to be operated as needed.

Equipment/Materials

HACH DR5000 Spectrophotometer (SN 1396156)

Procedure

Turn the Spectrophotometer on by pressing the power button.

Select the correct analytical method based on the analysis to be performed.

Samples are then analyzed.

Acceptance Criteria

If the Spectrophotometer powers up, analytical methods can be selected, and samples can be analyzed, the Spectrophotometer is considered to be operationally qualified.

C. PERFORMANCE QUALIFICATION

Objective

The objective of performance testing is to document that the Spectrophotometer can perform the Total Organic Carbon (TOC) analysis required by Giles.

Equipment/Materials

HACH DR5000 Spectrophotometer (SN 1396156)

Blank Sample (Deionized water)

Reagent Blank Sample (Deionized water with reagents added)

TOC Standard of Known Concentration (10 ppm)

Procedure

Prepare 3 samples, a blank sample, a reagent blank sample, and a TOC Standard of known concentration (10 ppm). Analyze the three samples using HACH Method 10129 for the Low Range (0.3-20 ppm) analysis of Total Organic Carbon.

Acceptance Criteria

- The test result of the Blank Sample is 0 ppm
- The test result of the Reagent Blank Sample has a value of 0.8 ppm or less.
- The test result of the 10 ppm TOC Standard of Known Concentration has a value of 9.1-10.9 ppm for a 95% Confidence Limits of Distribution.

VII. CALIBRATION

Verify that all instrumentation that requires calibration is calibrated.

HACH DR5000 Spectrophotometer (SN 1396156)

VIII. REFERENCE

DR5000 Spectrophotometer Procedures Manual, November 05 Edition 2

Spectrophotometer: INSTALLATION QUALIFICATION

A. Installation Qualification

01. Location

a. Spectrophotometer:

LOCATION			
Distance Criterion	**Is the current area sufficient to open the access without obstructions (Yes/No)**	**Verified By**	**Date**
Allow sufficient room around the instrument for access doors and panels to be opened			

02. Equipment Identification

EQUIPMENT IDENTIFICATION			
Equipment	**Serial or Tag Identifier**	**Verified By**	**Date**
Spectrophotometer			
Comments:			

03. Utilities

a. Verify that the system is receiving its specified utility requirements.

ELECTRICAL			
Specified	**Actual**	**Verified By**	**Date**
110 – 120 V Spectrophotometer			
Comments:			

Reviewed By: _____ **Date:** _____

Spectrophotometer: OPERATIONAL QUALIFICATION

B. Operation Qualification

01. Controls Verification – to document that the Spectrophotometer controls work properly

CONTROLS/INDICATORS VERIFICATION				
Description	**Function**	**Did Item function properly (Yes/No)**	**Verified By**	**Date**
SPECTROPHOTOMETER				
Power Button	With line power to the instrument, does pushing the Power Button cause the Spectrophotometer to start up?			
Method	Is the desired method available from the list of stored programs?			

Spectrophotometer: PERFORMANCE QUALIFICATION

C. Performance Qualification

01. TOC Analysis

TOC ANALYSIS				
Sample	**Concentration (ppm)**	**Acceptable (Yes/No)**	**Verified By**	**Date**
SPECTROPHOTOMETER				
Blank				
Reagent Blank				
10 ppm Standard				

Reviewed By: _____ **Date:** _____

ATTACHMENT I - PROTOCOL DEVIATION REPORT LOG

Log each Protocol Deviation Report in the table below. Attach the PDRs to this Attachment.

PDR #	DESCRIPTION	DATE INITIATED	DATE RESOLVED
Comments:			

IX. PROTOCOL DEVIATION REPORT (PDR)

General Information

System Name: _____ Protocol Number: _____

Deviation Report Number: _____ Protocol Step & Page No.: _____

Instructions

InstructionsThe validation specialist assigns a sequential report number for each deviation with a specific protocol. For example, 001, 002, etc. can be easily referenced in a report.

1. Reference the relevant protocol number, step and page number of the noted deviation above.
2. Complete the below listed sections. If necessary, use additional pages and attach any supporting info.
3. Include the original PDR(s) with the protocol as an attachment. Summarize the impact of the deviation in the Validation Report.

Description of Deviation:

Investigation Evaluation and Results:

Corrective Action and Resolution:

Overall Investigation Review:

Prepared By: _____ Date: _____

ATTACHMENT III - SIGNATURE IDENTIFICATION LOG SHEET

Identify in the table below any personnel involved in the execution of this protocol.

Name	Affiliation	Signature	Initial	Date