## Approvals

Signing below indicates agreement that the validation protocol for the Installation and Operational Qualification of the Quincy Labs 20GC Drying Oven located at Giles Chemical QA Laboratory, 102 Commerce Street in Waynesville, NC has been completed and approved.

| Project Team Member | Functional Area | Signature | Date |
|---|---|---|---|
| John Safi | QA Laboratory | | 7/22/14 |
| Patrick Owen | Engineering | | 7/22/14 |
| Matt Haynes | Operations | | 7/22/14 |
| Deborah Durbin | Quality | | 7/22/14 |

This document contains the final summary report that consists of results and conclusions based on the data collected after protocol execution. The executed protocol is attached behind the report.

## TABLE OF CONTENTS

## I. PURPOSE:

The purpose of this protocol is to certify with documented evidence that the Drying Oven is installed and functions as intended. This protocol sets forth the objectives, methodology, documentation, and test activities needed to complete the Installation Qualification (IQ) and Operational Qualification (OQ) for the Quincy Labs 20GC Drying Oven 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, product samples sometimes must be efficiently dried for laboratory analysis for quality purposes.

## III. 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 Drying Oven will be documented.

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

Control / Operation Verification – the controls will be verified.

## IV. SYSTEM DESCRIPTION:

A. The system consists of a Quincy Labs 20GC Drying Oven.

B. Description of Operation

01. The Drying Oven is started by pressing the power button.

02. The Drying Oven heats up to desired temperature.

## V. SCOPE

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

## VI. ROLES AND RESPONSIBILITIES

1. QA Laboratory
   - ❖ Write and issue the protocol
   - ❖ Investigate protocol deviation reports
   - ❖ Execute the IQ and OQ.
   - ❖ 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.

## VII. TEST PROGRAM

### A. INSTALLATION QUALIFICATION

Objective

The objective of the installation verification is to document the proper installation of the Drying Oven

Equipment/Materials

Quincy Labs 20GC Drying Oven

Procedure

Perform each item listed below for the Drying Oven.

- Location: Verify that the equipment is situated to allow sufficient room around the equipment for access doors and panels to be opened.
- Equipment: Document the Model and Serial or Asset Tag number of the Drying Oven.
- Utilities
    - Electrical Requirements: Verify the Drying Oven 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 Drying Oven will be considered installed properly.

## B. OPERATION QUALIFICATION

Objective

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

Equipment/Materials

Quincy Labs 20GC Drying Oven

Procedure

Turn the Drying Oven on by pressing the power button.

Verify that the Drying Oven reaches desired temperature.

Acceptance Criteria

If the Drying Oven powers up and reaches the desired temperature then the Drying Oven is considered to be operationally qualified.

## VIII. CALIBRATION

Verify that all instrumentation that requires calibration is calibrated.

**Drying Oven: INSTALLATION QUALIFICATION**

**A. Installation Qualification**

**01. Location**

a. Drying Oven:

| LOCATION | | | |
|---|---|---|---|
| **Distance Criterion** | **Is the current area sufficient to open the access without obstructions (Yes/No)** | **Verified By** | **Date** |
| Allow sufficient room around the oven for access doors and panels to be opened | YES | JS | 7/18/2014 |

**02. Equipment Identification**

| EQUIPMENT IDENTIFICATION | | | |
|---|---|---|---|
| **Equipment** | **Serial or Tag Identifier** | **Verified By** | **Date** |
| **Drying Oven** | G2-6409 | JS | 7/18/2013 |
| **Comments:** | N/A | | |

**03. Utilities**

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

| ELECTRICAL | | | |
|---|---|---|---|
| **Specified** | **Actual** | **Verified By** | **Date** |
| 110 – 120 V Drying Oven | 116.0 | JS | 7/18/2013 |
| **Comments:** | N/A | | |

**Reviewed By:** _____ **Date:** _____

**Drying Oven: OPERATIONAL QUALIFICATION**

**B. Operation Qualification**

**01. Controls Verification** – to document that the Drying Oven controls work properly

| CONTROLS/INDICATORS VERIFICATION | | | | |
|---|---|---|---|---|
| **Description** | **Function** | **Did Item function properly (Yes/No)** | **Verified By** | **Date** |
| **DRYING OVEN** | | | | |
| Power Button | With line power to the instrument, does pushing the Power Button cause the Drying Oven to heat up? | YES | JS | 7/18/2013 |
| Temperature Setting | With the Drying Oven powered on does it reach the desired temperature? | YES | JS | 7/18/2013 |

**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: | | | |

## X. 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 |
|---|---|---|---|---|
| John Safi | Quality Lab | John Safi | JS | 7/22/14 |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |