Approvals

Signing below indicates agreement that the protocol is ready for execution of the Installation and Operational Qualification for the Inductively Coupled Plasma Spectrometer (ICP) located at 102 Commerce Street in Waynesville, NC.

Project Team Member	Functional Area	Signature	Date
Bryan Elchert	QA Laboratory		7/16/13
Patrick Owen	Engineering		7/22/13
Matt Haynes	Operations		7/22/13
Deborah Durbin	Quality		7/16/13

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.

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I. PURPOSE:

The purpose of this protocol is to certify with documented evidence that the Inductively Coupled Plasma Spectrometer (ICP) 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 ICP Spectrometer 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, ICP spectrometry is used to verify that our products are free of contaminants such as toxic heavy metals. ICP analysis ensures that our products meet USP purity standards.

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 ICP Spectrometer will be documented.

Utility Verification – the voltage and gas pressures to the ICP Spectrometer will be documented and verified to be correct.

Control / Operation Verification – the controls will be verified.

IV. SYSTEM DESCRIPTION:

A. The entire system consists of an ICP Spectrometer, autosampler, and water circulator. The system also requires Argon and Nitrogen gases.

B. Description of Operation

01. The water circulator is started by pressing the "on" button and is stopped by pressing the "off" button.

02. The gas delivery system is started by the opening of regulator valves.

03. The ICP Spectrometer and autosampler are started by pressing the "on" button followed by initiation of the computer software.

V. SCOPE

The Installation and Operational Qualification protocol is intended to certify with documented evidence that the ICP Spectrometer 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 each component of the ICP System.

Equipment/Materials

ICP Spectrometer

Autosampler

Water Circulator

Gas System (Argon and Nitrogen)

Procedure

Perform each item listed below for ICP Spectrometer, Autosampler, and Water Circulator

- Location: Verify that the equipment 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 each component of the ICP System.
- Utilities
  - Electrical Requirements: Verify the components are receiving the specified voltage.
  - Gas Requirements: Verify the components are receiving the specified pressure.

Acceptance Criteria

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

B. OPERATION QUALIFICATION

Objective

The objective of Controls Verification is to document that the ICP Spectrometer operates as needed by Giles. The controls will be operated to test the ability of the ICP Spectrometer to be started and stopped as needed for analysis.

Equipment/Materials

ICP Spectrometer

Autosampler

Water Circulator

Gas System (Argon and Nitrogen)

Procedure

Turn on the water circulator and gases for the ICP Spectrometer. When proper water circulation and gas flow is achieved, turn on the ICP spectrometer and autosampler by pressing the "on" button and initialize the computer software. Calibrate the instrument using standards of known concentration.

Acceptance Criteria

If the ICP Spectrometer initializes and calibrates then the controls are considered to be operationally qualified.

VIII. CALIBRATION

Verify that all instrumentation that requires calibration is calibrated.

- Teledyne Leeman Labs ICP Spectrometer Model #122-00192-1 (Install #64531)

ICP Spectrometer: INSTALLATION QUALIFICATION

A. Installation Qualification

01. Location

a. ICP Spectrometer:

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			
The instrument must be located in an area that is adequately ventilated			

b. Autosampler:

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			
The instrument must be located in an area that is adequately ventilated			

c. Water Circulator:

LOCATION			
Distance Criterion	**Is the current area sufficient to open the access without obstructions (Yes/No)**	**Verified By**	**Date**
Allow sufficient room around the machine for access doors and panels to be opened			
The machine must be located in an area that is adequately ventilated			

d. Gas Tanks:

LOCATION			
Distance Criterion	**Is the current area sufficient to open the access without obstructions (Yes/No)**	**Verified By**	**Date**
Allow sufficient room around the tanks for access.			

Reviewed By: _____ **Date:** _____

FITTINGS & CONNECTIONS			
Connection Criterion	**Are the fittings and connections used correct for proper gas flow (Yes/No)**	**Verified By**	**Date**
Verify 3rd party installation of piping is correct.			
Use correct fittings for the installation and removal of gas dewars.			
Use dual stage regulator to prevent input pressure sag.			

01. Equipment Identification

EQUIPMENT IDENTIFICATION			
Equipment	**Serial or Tag Identifier**	**Verified By**	**Date**
ICP Spectrometer			
Autosampler			
Water Circulator			
Gas Tanks	N/A		
Comments:			

02. Utilities

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

ELECTRICAL			
Specified	**Actual**	**Verified By**	**Date**
210 – 240 V ICP Spectrometer			
210 – 240 V Autosampler			
210 – 240 V Water Circulator			
Comments:			

Reviewed By: _____ **Date:** _____

b. Verify that the system is receiving its specified gas requirement.

ARGON GAS			
Specified	**Actual**	**Verified By**	**Date**
80-90 psi ICP Spectrometer			
Comments:			

NITROGEN GAS			
Specified	**Actual**	**Verified By**	**Date**
80-90 psi ICP Spectrometer			
Comments:			

ICP spectrometer: OPERATIONAL QUALIFICATION

B. Operation Qualification

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

CONTROLS/INDICATORS VERIFICATION				
Description	**Function**	**Did Item function properly (Yes/No)**	**Verified By**	**Date**
ICP SPECTROMETER				
On Button	With line power to the instrument, does pushing the On Button cause the instrument to initialize?			
Program	Does the computer software initialize properly when the instrument is turned on?			
Program	Does the instrument calibrate properly?			
Off Button	With line power to the instrument, does pushing the Off Button cause the instrument to power down?			
AUTOSAMPLER				
On Button	When the ICP Spectrometer is turned on does the autosampler initialize?			
Off Button	When the ICP Spectrometer is turned off does the autosampler power down?			

Reviewed By: _____ **Date:** _____

CONTROLS/INDICATORS VERIFICATION				
Description	**Function**	**Did Item function properly (Yes/No)**	**Verified By**	**Date**
WATER CIRCULATOR				
On Switch	With line power to the circulator, does pushing the On Switch cause the circulator to start?			
Off Switch	With line power to the circulator, does pushing the Off Button cause the circulator to stop?			
GAS TANKS				
On Valve	Does turning the valve to the open position initiate gas flow?			
Off Valve	Does turning the valve to the off position stop gas flow?			
Comments:				

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