

Installation Qualification and Operational Qualification

Introduction

LECO's Installation Qualification (IQ) and Operational Qualification (OQ) service ensures your instrumentation and software is installed correctly and functions according to LECO's specifications. It also confirms that all functionality operates as intended by LECO. IQ documentation is supplied in a standard checklist format, and it includes all items delivered and installed. The OQ service uses NIST traceable standards supplied by LECO for system validation to ensure accuracy and precision of the installed system. The results of the IQ/OQ are fully documented and include analysis data and statistical analyses that satisfy government and internal laboratory requirements (e.g., FDA).

IQ/OQ is performed on-site at your facility by a certified LECO service engineer, specially trained to validate LECO instrumentation.

Future OQ's can be performed by a certified LECO service engineer for a fee or included in a service contract.

Installation Qualification (IQ)

This qualification is performed on site and during the time of installation. It documents the key aspects of the installation and verifies compliance with LECO's specifications and safety parameters. In order to qualify for an IQ Certificate, this procedure must be performed by a certified LECO service engineer. This IQ procedure includes the following protocols.

- Verifying installation location meets LECO requirements before the instrument is installed
 - Location meets floor space requirements
 - Power requirements are met
 - Gas supply requirements are met
 - Environmental operating conditions are met
- Unpacking of instrument to check for damage and cross-checking contents with packing list
- Documenting the computer hardware/operating system
- Checking the installation of the software and its basic accessibility
- Installing the instrument and options per LECO's installation procedure
- Verifying all connections to peripheral units and that communication is operational
- Documenting the instrumentation controlled by the software
- Checking basic communication with the instrument
- Recording all firmware versions and LECO serial numbers
- Tagging the instrument with IQ sticker
- Recording the calibration dates for equipment used during IQ
- All manuals, relevant outputs from the instrument, and certificates of conformity are gathered and placed in IQ/OQ binder for transfer to end user

Operational Qualification (OQ)

Operational qualification is performed subsequent to installation, after major maintenance or modification of the instrument, or can be based on a customer-specified quality schedule. It documents that the instrument performs consistently throughout the LECO-specified operating ranges.

In order to qualify for an OQ Certificate, this procedure is to be performed by a certified LECO service engineer.

OQ validation is performed on the instrument as a system. LECO's specified protocols are used to show that the accuracy and precision of the system meet our required specifications. These protocols include the following.

- Testing of configuration menus, instrument control, and data transfer
- Activate software logging
- Set-up of user logins and application access
- Employing automated System Check-Out feature within software and verifying status
 - Leak checks, etc
- Testing of all user administration settings, security settings, audit trails, and data integrity/security
- Instrument-specific protocols verifying the analytical parameters defined by LECO
 - Calibration
 - Accuracy
 - Precision
 - Linearity
- Tagging the instrument with OQ sticker
- Recording the calibration dates for equipment used during OQ
- All relevant outputs from the instrument are gathered and placed in IQ/OQ binder for transfer to the end user

At the end of the IQ and OQ you are supplied with complete documentation contained in an IQ/OQ binder, including installation checklist, operational checklist, validation data, pass/fail documentation, manuals, relevant outputs from the instrument, certificates of conformity, and copies of the protocols used during the qualification procedures. At the completion of the OQ the LECO service engineer will provide instrument familiarization training and review the operation and calibration, confirming the end user's ability to properly operate the instrument.