

Regulatory Service Definitions

The following services are generally required for regulated laboratories. These services are also recommended for all labs to establish documentation that your instruments and software are compliant with applicable standards and regulations.

Installation Qualification (IQ)

Establish confidence that your instrument(s) and software are compliant with applicable codes, approved design intentions, and have been setup in accordance with the manufacturer's recommendations. IQ documentation is provided to establish instrument installation qualification.

Operational Qualification (OQ)

Validate the functionality of your instrument(s) and software according to established performance standards and applicable regulations. Performance documentation is provided to establish instrument operational qualification.

Product Verification (PV)

Ensure that your instrument(s) and software perform consistently over time with a specifically-designed verification plate. Resulting performance data is analyzed and coefficient of variation (% CV) is provided with written product verification documentation.

Manufacturer Audit (MA)

Verify that LI-COR Biosciences is performing up to your standards. Complete an on-site audit of LI-COR Biosciences at our headquarters in Lincoln, Nebraska, USA as required by regulatory agencies or your organizational standard operating procedures (SOPs). LI-COR hosts auditors and provides necessary information for auditors and/or regulatory officials.

To schedule an audit, please contact us at regulatory@licor.com.

LI-COR Regulatory Services

LI-COR offers a number of regulatory service packages to provide the services described above. Work with greater confidence knowing your system validation was performed by the manufacturer. LI-COR employs a dedicated regulatory and compliance staff to ensure that LI-COR standards meet or exceed the highest applicable regulatory standards for data acquisition, access control, and more.

IQ/OQ (Limited)

Basic IQ/OQ services for your instrument(s) and software, recommended only for labs that are not externally audited. A certified LI-COR technician will confirm installation and operation of the instrument and complete the appropriate paperwork for certification, demonstrating that the system meets LI-COR standards. Does not include product verification (PV) or manufacturer audit (MA).

IQ Service

The standard installation qualification (IQ) protocol for your instruments and software. A certified LI-COR technician will confirm the installation of the instrument and complete the appropriate documentation, demonstrating that the system has been installed according to LI-COR standards. Recommended for labs that are audited externally.

LI-COR Regulatory Services (Continued)

OQ/PV Service

The standard operational qualification (OQ) protocol for your instruments and software. A certified LI-COR technician will confirm that your instruments and software are performing according to LI-COR standards. Performance verification (PV) will also be completed with standard Plate Verification from LI-COR to ensure consistent performance of instruments and software over time. It is recommended that each instrument owner purchase their own verification plate. No additional charges will be incurred for a Manufacturer Audit. Recommended for labs that are audited externally.

To schedule a regulatory service, contact LI-COR regulatory services at regulatory@licor.com or visit licor.com/regulatory.

LI-COR Regulatory Products

LI-COR offers regulatory products in addition to services to provide complete coverage of installation, operation, and performance verification and validation of your LI-COR instruments and software.

21-CFR Part 11-Ready Software

Secure, database-driven software that ensures traceability for access control, data acquisition, and analysis for regulated labs with a controlled workflow. Trained LI-COR technicians will install the software according to LI-COR standard operating procedures, interface the software with your existing IT infrastructure, and will work alongside your IT personnel to provide training for administration of the software.

For specific 21 CFR Part 11 compliance information, download the Image Studio™ Software 21 CFR Part 11 Compliance Guide at licor.com/21CFRpart11.

Odyssey® Imager Verification Plates

Odyssey verification plates are designed and optimized to confirm consistent performance of your Odyssey CLx or Fc over time.

Odyssey Verification Plate Recertification

Each Odyssey Verification Plate may be sent back to LI-COR for recertification, ensuring that the plate is still performing as designed. Recertification includes cleaning and statistical performance tests against a LI-COR standard to confirm consistent performance over time.

To purchase a regulatory product, contact us at regulatory@licor.com or visit licor.com/regulatory.

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