

# Installation Qualification and Operation Qualification (IQ/OQ)



**Be confident your results will be accurate and compliant everyday.**

It is not enough that your lab's instruments perform to manufacturer's standards. More importantly, they need to meet the regulatory requirements of your lab everyday. PerkinElmer's team of service experts understand the increasing need for validation and regulatory compliance and has designed a complete Installation and Operational Qualification (IQ/OQ) program including an extensive Log Book for complete instrument history. This complete program provides a permanent record identifying

selected key activities performed and verified during installation, before the instrument is put into service for actual analysis. The IQ/OQ documentation is specifically designed to your instrument including your company name, address, instrument serial number, purchase order number and an individualized protocol number. This is more than a simple instrument performance verification—our IQ/OQ program produces the thorough audit trail of system performance you need to meet validation requirements imposed by internal and external regulatory groups giving you the confidence in your instrument everyday.

## Key Capabilities

- ▶ Our IQ/OQ program produces the thorough audit trail needed to meet internal and external validation requirements
- ▶ Documented tests confirm proper installation and operation
- ▶ Log book for recording instrument history ensures your instrument follows good GLP and GMP guidelines
- ▶ More factory-trained service people than anyone else in the industry, available globally

**Ensure you're ready to go right from the start**

**Installation Qualification (IQ)** provides formal checks and documentation to confirm that the instrument and its components have been supplied as ordered and properly installed in your lab environment (Figure 1). Upon delivery, the shipment will be visually inspected and reviewed for completeness followed by installation of all hardware, software and peripherals. Once completely installed, the system will be turned on to confirm all modules and systems work correctly. Finally, all information determined is then documented within the protocol.

For the Installation Qualification PerkinElmer's Customer Support Engineers will:

- Compare equipment as received with purchase order including software, accessories, spare parts, and documentation such as tutorials, manuals and operating procedures
- Check equipment for any damage during shipping
- Check that the documentation supplied is of the correct issue
- Establish that the laboratory environmental requirements are appropriate for the instrument (power, bench, lighting, accessibility etc.)
- Review all hazards and safety precautions, including materials that may come in contact with the instrument
- Install hardware including all tubing, columns, cables for power, data flow and instrument control
- Install or confirm factory installation of software on the computer following the installation instructions
- Configure peripherals, e.g., printers and equipment modules
- Document equipment tutorials, manuals and operating procedures
- Perform installation functionality check and prepare installation report
- Activate utilities and pre-condition instrument (e.g. warm-up, leak-test, flow controls etc.)
- Check that the response to the initial application of power is as expected and record deviations
- Record all relevant activities and actions and sign all required documents
- Locate the certificates of conformity and place them in the appropriate protocol appendices

**Confidence your instrument is ready to run**

Once the instrument has been installed, **Operation Qualification (OQ)** will demonstrate that the instrument will function according to its operational specifications. The Service Engineer will ensure the system is functioning to acceptable limits by testing relevant instrument specifications, parameters and ranges as determined by PerkinElmer's Instruments Performance Verification (IPV). At the completion of the OQ all of the operation tests are documented, the results are noted, and all relevant certificates are completed and signed. Once the instrument is validated, the Service Engineer will provide instrument familiarization training to confirm that you are ready to run your instrument that very day. The Service Engineer will also review and explain the contents of the

Installation Qualification and Operational Qualification of the PerkinElmer Series 200 LC Autosampler		
<h2 style="margin: 0;"><i>Certification</i></h2>		
The Installation Qualification and Operational Qualification final report for the PerkinElmer		
Series 200 LC Autosampler Serial number 123N4567890		
has been reviewed and was found to meet the requirements necessary for the instrument to be used in the customer's laboratory.		
FINAL REPORT		
Reviewed by (Name and Title)	Signature	Date
Authorized PerkinElmer Representative		
Authorized Customer Representative		
Customer QA Representative (if applicable)		

Figure 1. IQ/OQ Certification confirms all formal checks and documentation have been completed.

Instrument Log Book so you are familiar with the information provided. For Operation Qualification PerkinElmer Service Engineers will:

- Perform basic instrument control functions from both the instrument's keyboard and from the computer (if applicable)
- Perform basic functions of the application software
- Test the equipment hardware for proper functionality
- Perform Instrument calibration as documented in the supplied configuration and Test Certificate
- Document all the operation test results
- Perform familiarization training
- Explain the purpose and contents of the Instrument Log Book and associated documentation

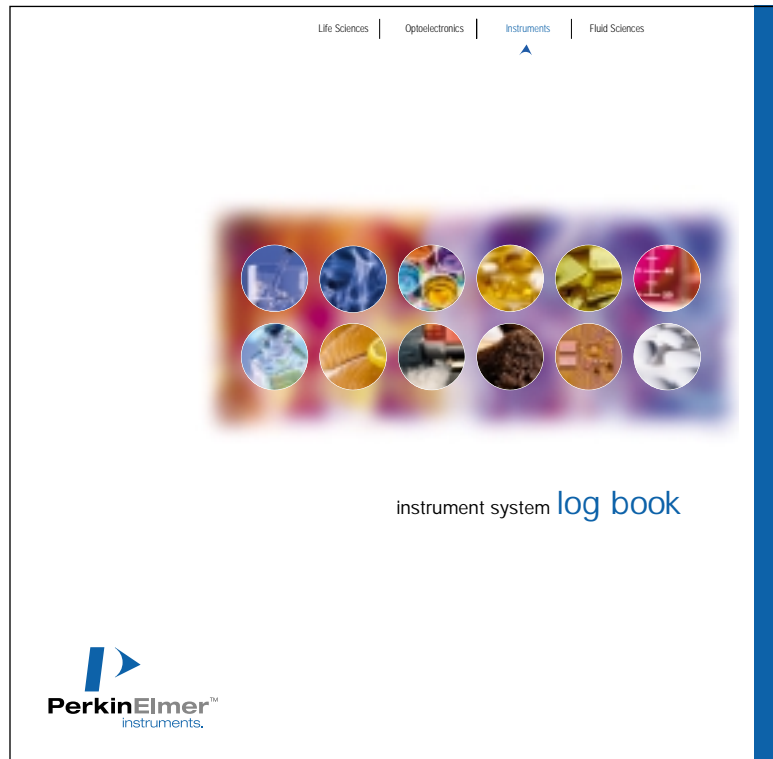


Figure 3. Instrument System Log book ensures a complete record of activities is maintained.


 <b>PerkinElmer</b> <small>instruments.</small>	Model _____
	Serial No. _____
<b>Installation/Operational Qualification</b>	
Protocol No. _____	Date _____
C.S.E. Signature _____	
Customer Signature _____	
<b>Instrument Performance Verification</b>	
Next IPV Due Date _____	

Figure 2. The IQ/OQ sticker affixed to the instrument helps you keep your instrument testing up-to-date.

### Ensure you're in compliance

To help ensure your instrument stays in compliance, the PerkinElmer Service Engineer will affix an IQ/OQ sticker to the validated instrument (Figure 2). This sticker will help you keep your instrument testing up-to-date by noting the compliance date of the instrument and the date the next IPV should be performed.

### Complete Instrument History

#### The Instrument System Log Book

is an integral part of the IQ/OQ program as it ensures a complete record of activities and is maintained for the entire working life of your instrument (Figure 3). With this Log Book, users are able to keep records of all changes, modifications, service, maintenance, parts, etc. All actions with regard to the PerkinElmer system are traceable, a requirement for GLP and GLAP. The instrument Log Book has more than a dozen sections ranging from "who-to-reach at PerkinElmer" to "what reference material was used the last time the unit was serviced". Maintaining an up-to-date Log Book of the overall history of the instrument or system will satisfy GLP and ISO-9000 requirements. If for any reason you need a copy of the PerkinElmer factory generated protocol, these documents are archived electronically to ensure easy access.

### Expert Support Services for your lab

Not only are we prepared to assist with IQ/OQ, PerkinElmer's uptime experts are ready to assist you to maximize your productivity and optimize your lab's performance. Backed by 60 years of leading edge instrumentation experience, PerkinElmer's uptime experts are passionate about exceeding customer expectations, every time. We offer more factory-trained service people than anyone else in the industry, available globally. Our team has expertise across a broad range of technologies so we can support your entire lab. Through our extensive internal global programs such as Six Sigma and ISO certification, we can ensure consistent and reliable support on a global basis. So no matter what your laboratory size or budget, we can assist you in improving every aspect of your lab's performance, from instrument care and repair, training, validation, consulting and more.

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