



[**PEAK** Protected]

IQ/OQ Certification

Installation Qualification/ Operation Qualification

Providing assurance in your laboratory's results

Peak Scientific gas generators define the industry benchmark for reliable, consistent and convenient gas supply for analytical instruments in laboratories the world over.

However, sometimes it is not enough that your laboratory gas generator performs to the manufacturers' standards; it also needs to meet the strict regulatory requirements outlined by the Food and Drug Administration (FDA) or equivalent EU regulatory bodies.

Here at Peak Scientific, we understand the increasing need for validation and regulatory compliance. With customer service and support at the very core of everything we do, we have developed a comprehensive Installation and Operational Qualification certification, for customers who require this additional certified assurance for their analytical applications.

The Peak Scientific IQ/OQ certification is tailored to your specific gas generator and provides you with a cost-effective and efficient solution to achieve and maintain compliance.

In addition to our highly trained, dedicated Service Engineer completing the Installation and Operational validation, we will also provide full certification to document this process, ensuring accurate proof of compliance.



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IQ/OQ Certification

What is Installation Qualification (IQ)?



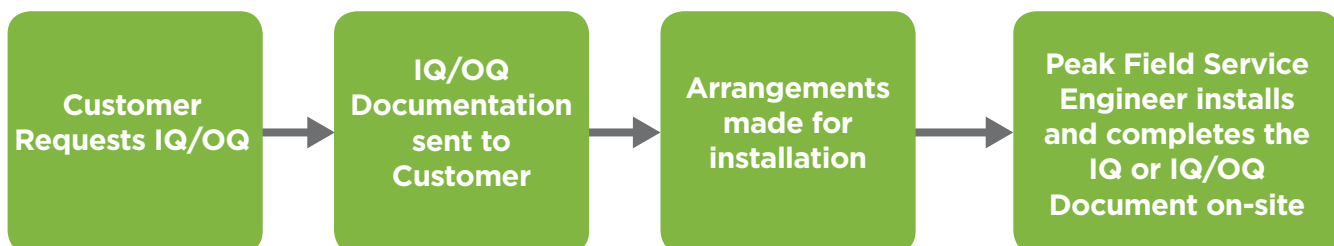
IQ is the pre-installation detail of the equipment, its component parts and its location onsite. Its main aim is to identify if the gas generator is fit for specific purpose and to prove and certify that it can perform its intended function to the expected and required standard.

Once your dedicated Service Engineer has completed the review of the installation and configured it correctly, you can be assured that the equipment is going to operate the way in which it was designed to do.

Your certified IQ/OQ Peak Scientific Engineer will:

- Compare equipment received with the purchase order including: accessories, firmware, and additional documentation such as operation manuals
- Check the gas generator for possible damage during the delivery process
- Assess the environment that the gas generator will be placed making sure there is adequate ventilation for the equipment
- Review hazard and safety precautions for area of use, including materials that may come into contact with the generator and/or personnel
- Perform an installation functionality check and create an installation report
- Record all relevant activities and actions as well as sign all relevant documentation
- Complete a certificate of conformity

IQ/OQ Process Flow



What is Operational Qualification (OQ)?

Once the gas generator has been installed, your Service Engineer can complete an Operational Qualification to verify that the equipment functions according to the generator's specifications. The Service Engineer is able to verify the performance criteria of the instrument outlined by Peak Scientific and confirm the instrument satisfies its agreed metrics.

Your certified IQ/OQ Peak Service Engineer will:

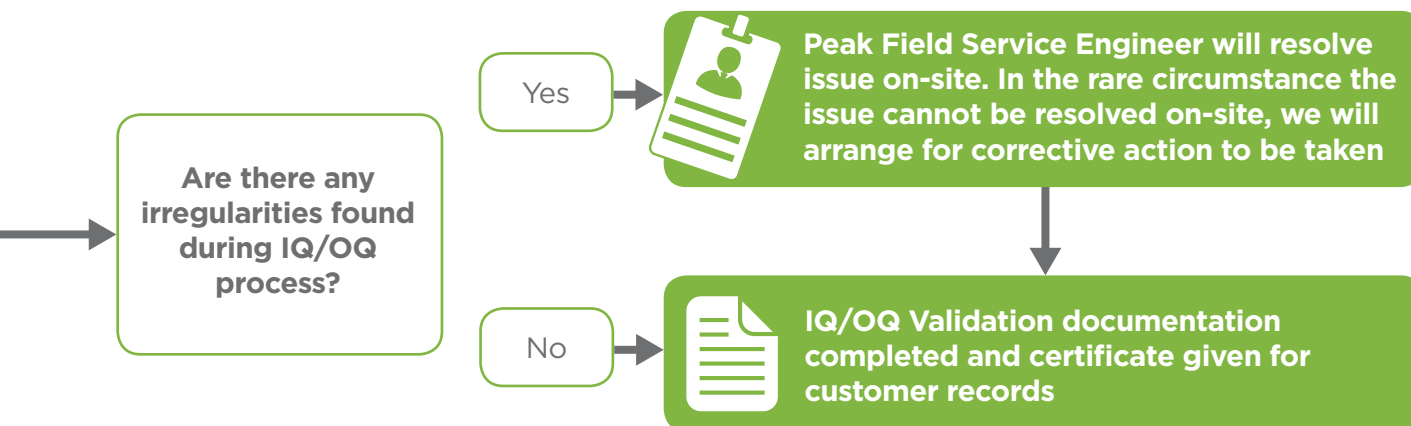
- Assure the gas generator is functioning to the acceptable standard by testing the generator's specification parameters and ranges against the technical specifications of the equipment
- Perform familiarization training with the generator to ensure your team are able to use it as intended, safely and with confidence
- At the completion of the OQ all of the operational tests will be documented, the results validated, all relevant certificates completed and signed



When should I carry out an OQ?

Peak Scientific would recommend an OQ certification is performed at the following times:

- Equipment installation or relocation of the gas generator
- On a periodic basis in accordance with your standard operating procedures
- After a major repair
- Before a previously installed system is to be used in a regulated test environment for the first time



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No matter your laboratory size or specific analytical application, Peak Scientific can assist you in improving and verifying your laboratory's performance. With a local direct presence in over 20 countries across every continent around the world, Peak Scientific has highly trained and fully certified Field Service Engineers on hand to assist you soon after your instrument delivery, minimizing any delay or downtime and maximizing your laboratory productivity.



To discuss our IQ/OQ services please speak to your local Peak Representative or for further information please contact our dedicated service team on: protected@peakscientific.com.