Technical Note 43172

# Easy and Rapid System Qualification using the iCAP Series Qualification Kit

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## Key Words

iCAP 7000 Series ICP-OES, iCAP Q Series ICP-MS, System Qualification, Qtegra ISDS, Pharmaceutical Industry

## Goal

To demonstrate how the iCAP Series Qualification Kit can ensure a smooth and rapid qualification of the system to get production labs up and running in the shortest possible time frame.


## Introduction

System qualification ensures that the instrument and the procedures used with it are fit for purpose. The qualification process instils confidence in instrument performance and subsequent analytical results, with regular tests performed by service personnel and the instrument operator verifying continuing system performance.

The system qualification process commences long before an instrument is built; starting with the initial Specification Qualification (SQ) and Design Qualification (DQ) that provide evidence that quality is specified and designed into the final product by the manufacturer. Thermo Fisher Scientific is responsible for the research, development and manufacturing of the Thermo Scientific™ iCAP™ Q Series ICP-MS and Thermo Scientific™ iCAP™ 7000 Series ICP-OES, respectively. The production facilities for these instruments have been awarded accreditation to the ISO 9001:2008 Quality Standards. All Thermo Scientific instruments are designed and manufactured in accordance with the requirements of this standard.

The process for instrument qualification after manufacture and delivery of a new system is defined by Installation Qualification (IQ) and Operation Qualification (OQ). Both IQ and OQ processes are performed following instrument installation, by specially trained and certified personnel alongside a customer representative.

IQ checks the equipment and control systems against the vendor defined standards of operating environment, physical connection, safety and functional parameters prior to initial utilization of the system. It thus confirms that the system is installed correctly.

OQ defines functional tests and compares them against vendor specification. This is ideally performed following successful completion of the IQ. OQ is the process of ensuring that the instrument meets specifications over all intended operating ranges.

Performance Qualification (PQ) is an additional component of the qualification step for analytical instruments. PQ requires test criteria specific to a given application or method. The analytical tests and testing interval must be defined and undertaken by the customer in accordance with any applicable protocol of the laboratory. Typically, this is specified in Standard Operation Procedures (SOPs).

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Figure 1 depicts all the processes involved in the system qualification of an analytical instrument.

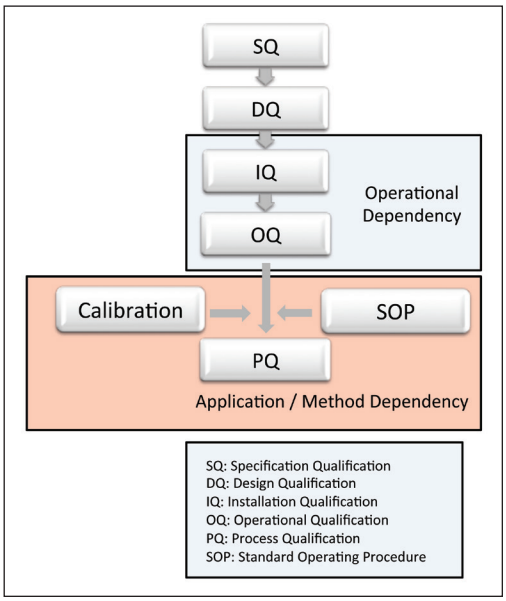


Figure 1: The entire qualification process from initial design to analytical operation.

Figure 2 gives an overview of the different qualification tests, explaining the responsibilities of both manufacturer and user.

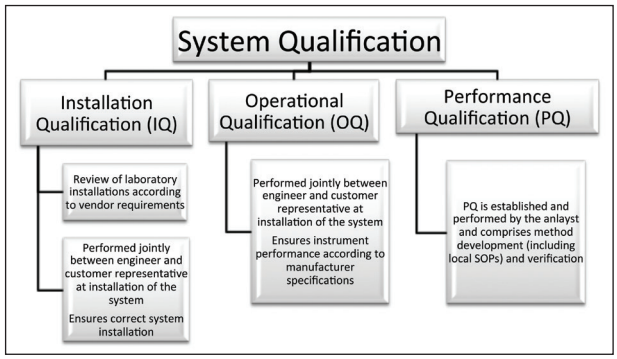


Figure 2: The system qualification process.

## The iCAP Series Qualification Kit

The new Thermo Scientific™ iCAP™ Series Qualification Kit contains the required material for the successful qualification of an iCAP 7000 Series ICP-OES or an iCAP Q Series ICP-MS system in a laboratory. The respective kits contain all the necessary documentation and solutions for completion of IQ/OQ for either instrument. The tests themselves are completed upon installation of a system by a specially trained and certified field service engineer and in parallel are verified and approved by the customer representative.

Furthermore, the kit contains detailed information on the qualification process for a new instrument and describes the compliance of the Thermo Scientific™ Qtegra™ Intelligent Scientific Data Solution™ software to the guidelines set out in Part 11 in Title 21 of the US Code of Federal Regulations (FDA 21 CFR Part 11), defining the storage and protection of electronic records and use of electronic signatures.

As outlined previously, Performance Qualification is the sole responsibility of the user. Therefore, applicable test criteria for PQ are not included in the iCAP Series Qualification Kit. However, drawing upon the extensive experience of the Thermo Scientific Application team, the Qualification Kit contains a summary of best practices for new users of plasma based instrumentation.

As a reference for the development of methods suitable for elemental impurities analysis, the iCAP Series Qualification Kit also contains a number of application notes describing field-proven methodologies for a variety of samples.

## Compatibility

The iCAP Series Qualification Kit is available for the iCAP 7000 Series ICP-OES or the iCAP Q Series ICP-MS systems, both operating on the Qtegra ISDS software platform. This new modular software easily integrates different instrument types, leveraging the potential in a laboratory as operators can seamlessly switch between different instrument types.

## Conclusions

The iCAP Series Qualification kit ideally complements an iCAP 7000 Series ICP-OES or iCAP Q Series ICP-MS, as it provides a complete set of materials for a successful new instrument implementation. By combining Installation and Operational Qualification (IQ/OQ) with practical guidelines for effective day-to-day operation of the system and helpful information for the development of analytical methods, newly installed instruments will be up and running quickly and smoothly ensuring faster validation and expedited time to production.





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