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Equipment Qualification and its Application to Conductivity Measuring Systems

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Abstract

It is only possible to obtain analytical results that are suitable for their intended purpose if the equipment used is capable of producing measurements of the required quality. To ensure that this requirement is met, analysts should define the performance criteria required from instruments, ensure that only suitable instruments are selected for analytical measurements and confirm that these instruments continue to meet these criteria for their entire operational life. This process should be conducted on a formal, documented basis, known as Equipment Qualification. In addition to describing the key elements of Equipment Qualification for all analytical instruments, this paper gives specific guidance on its application to conductivity systems that has never previously appeared in the literature. The benefits of performing Equipment Qualification are highlighted and guidance is given on the selection of Control Standards and why the equipment vendor performing stages of Equipment Qualification can be of benefit to the user. The relationship between Equipment Qualification and Method Validation is discussed, including how these activities play a major role in determining the quality control measures that should be applied to routine analysis.

Keywords

Equipment Qualification; Conductivity; User Requirement Specification; Design Qualification; Installation Qualification; Operational Qualification; Performance Qualification

1 Introduction

All analytical measurements are carried out so that a decision can be made based upon the test result. Confidence in these decisions can only be attained if they are based upon test results that are of sufficient accuracy. The selection of appropriate measuring equipment is a fundamental requirement to obtain analytical measurements that are of a suitable quality to be fit for purpose. Conductivity measurements are no exception to this requirement. Most analysts will conduct an informal process to ensure that the measuring equipment that they use is suitable for their requirements. Such a process may include the following steps:

- Compiling a brief check-list of the functions and accuracy required for their conductivity measuring system.
- Selecting equipment against these requirements – this may be currently owned equipment or equipment to be purchased.

- Checking that this equipment performs correctly before putting it into service – this may involve checking the measurement performance with conductivity standards or checking that an instrument can output data to a PC if its measurements will be transferred to a computer system.

Whilst such informal checks are advantageous to ensure that performance requirements are met, it is of much greater benefit to conduct this process on a formal, documented basis, known as **Equipment Qualification**. In addition to checks performed during the commissioning of a measuring system, Equipment Qualification also documents regular performance checks conducted throughout the equipment's operational life. As well as being a regulatory requirement for some industries, Equipment Qualification gives the following benefits to all analysts:

- Proof that new equipment is fit for its intended purpose. This is achieved by fully defining all of the required characteristics of the measuring system and then proving that the selected equipment meets these requirements before using it for analysis.
- Reduced likelihood of incorrect test results as the equipment's performance has been proved to be suitable for its intended purpose both before it is used for test sample analysis and during its working life.
- A template for troubleshooting any problem that may occur whilst the conductivity measuring system is in service. The Equipment Qualification documentation can act as a checklist for determining and rectifying the source of any measuring problems.

Performing Equipment Qualification on a formal basis may appear to be an onerous task; but this is not the case. In the long run Equipment Qualification results in savings of time and money as it is a key step for analysts to achieve their fundamental goals of not only obtaining conductivity measurements that are correct; but that can also be proven to be correct and fit for purpose.

Equipment Qualification plays a fundamental role in a laboratory's quality system as it assists the development and validation of suitable test methods and helps identify the Quality Control and Quality Assurance measures that will be required to ensure that test measurements are fit for purpose. Equipment Qualification ensures that measuring equipment is capable of generating test measurements that are fit for purpose. However, fit for purpose measurements can only be attained by use of an appropriate test method. The suitability of a test method for a particular application should be verified prior to its use on test samples through a process known as Method Validation. Although a detailed description of Method Validation is beyond the scope of this paper, the relationship between Equipment Qualification and Method Validation is discussed.

This paper describes the individual stages of Equipment Qualification and the benefits that they provide to analysts. As well as including specific details of how to perform Equipment Qualification for conductivity measuring systems, this paper gives guidance applicable to Equipment Qualification for all measurement parameters. Guidance is given

as to when each individual stage of Equipment Qualification should be performed and whether these qualification stages should be performed by the user or the equipment supplier.

2 Components of Equipment Qualification

There are four stages of Equipment Qualification:

- 1. User Requirement Specification (URS)** fully defines all of the conductivity measurements that are required to be made; the required accuracy of analysis; the format that the results must be provided in and all of the ancillary services required from the equipment vendor. This provides a detailed specification, allowing a suitable measurement system to be identified.
- 2. Design Qualification (DQ)** ensures that the equipment manufacturer and vendor have designed their equipment, training, installation service and support services to meet the user's requirements.
- 3. Commissioning the equipment.** This can be sub-divided into two areas:
 - a. Installation Qualification (IQ)** fully documents that the equipment has been installed correctly and that it is suitable for use in the test environment⁽¹⁾.
 - b. Operational Qualification (OQ)** verifies that the measuring system "will function according to its operational specification in the selected environment"⁽²⁾ – i.e. the measuring system will meet all of the requirements detailed in the User Requirement Specification.
- 4. Performance Qualification (PQ)** during the working life of the equipment ensures that test measurements are of suitable quality by identifying if the measuring system is consistently meeting the required quality of performance.

To obtain analytical measurements that are fit for purpose, samples must be collected and handled correctly; the measurement method must be validated and effectively controlled; suitable Calibration and Control standards must be used and all of the personnel involved in this process must be suitably qualified and trained. However, questionable measurements will always be obtained if it cannot be demonstrated that the measuring equipment is

capable of generating fit for purpose measurements. The importance of each stage of Equipment Qualification in achieving fit for purpose measurements is summarised in Fig. 1.

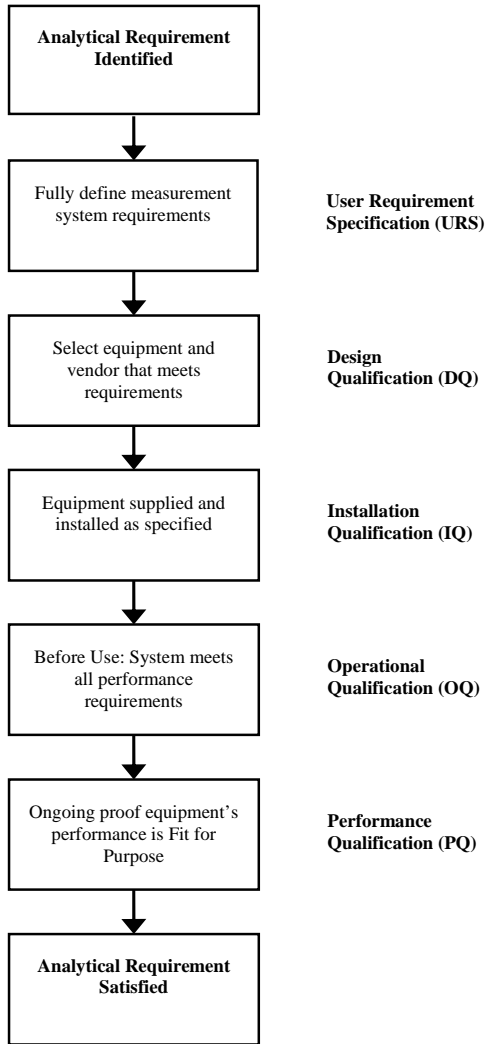


Fig. 1 Relevance of Each Stage of Equipment Qualification to Satisfying an Analytical Requirement

3 User Requirement Specification (URS)

The URS should detail all of the required performance characteristics of the conductivity measuring system. The URS should also specify services required from the supplier, such as training and annual calibration and also take into account likely future additional requirements. Ideally, the URS should be

compiled prior to contact with potential equipment vendors. The URS should specify which characteristics are essential and which are desirable and should cover the following areas:

- **List of all measurement applications.** This will provide a performance specification for the conductivity measuring system and should include:
 - The conductivity range of the samples.
 - The measurement accuracy required.
 - Temperature measurement accuracy and the types of temperature compensation required⁽³⁾.
- **Details of the measuring environment.** Particularly for portable and online conductivity measurement, it is essential to specify the equipment's operating environment in the URS so that a suitable measuring system can be identified. The URS should address the following areas:
 - The physical space that the equipment will be required to operate in.
 - Operating temperature and humidity.
 - The required level of waterproofing, ideally specifying the level of Ingress Protection (IP) Rating required⁽⁴⁾.
 - The equipment's required level of electrical safety certification⁽⁴⁾.
 - For online conductivity sensors, the dimensions of the measurement stream must be specified so that a suitable sensor and housing can be identified.
- **Required format of results.** The desired format may include the following:
 - On screen display
 - Output to a printer
 - Output to an analogue recorder
 - Output to a PC, including compatibility with a LIMS system– this may require additional software.
 - Storage in memory for retrieval at a later stage. Any requirements on labelling memory locations and a time and date function should also be specified.
- **Other functionality requirements.** For conductivity equipment this may include an automated calibration procedure, a calibration interval expiry warning, drift

- control, diagnostic sub-routines and operator identification and passwords.
- **Vendor and manufacturer services and quality requirements.** The URS should specify if the equipment manufacturer and vendor must hold specific quality accreditations, e.g. ISO 9001⁽⁵⁾, and should also specify if any of the following services are required from the vendor:
 - Commissioning of the equipment, including the vendor performing IQ and OQ.
 - Training on the use of the equipment and any related documentation required
 - Periodic re-qualification service for the equipment
 - Maintenance and service contract details.

If written correctly, the URS will provide a definitive list of all of the requirements for the equipment and will provide a comprehensive check-list for assessing potential vendors' equipment and services. The URS is an ideal document to make available to potential vendors so that they can fully understand all of the user's requirements and can therefore ensure that they can supply appropriate products and services.

4 Design Qualification (DQ)

The purpose of DQ is to ensure that the equipment and services provided by the vendor have been designed to meet the user's requirements as specified in the URS. Conductivity measuring systems are almost exclusively purchased as existing, "off the shelf" systems; rather than being designed to meet individual user's specific requirements. However, the following areas should be verified, to ensure that the requirements detailed in the URS will be met:

- The equipment's specification matches or exceeds the requirements outlined in the URS. Care should be taken when interpreting conductivity instruments' accuracy specifications⁽⁴⁾ – a number of manufacturers express measurement accuracy as a percentage of the instrument's full-scale measuring range (f.s.); rather than as a percentage of the measured value. It should also be verified that both the conductivity meter and cell have a suitable linear response range to cover all of the required measurement applications⁽⁶⁾.

- The equipment manufacturer and vendor have an appropriate quality system in place.
- The vendor can provide the commissioning, training, re-qualification, maintenance and servicing described in the URS.

It is relatively straightforward to identify if a vendor meets the first two requirements. The method for identifying if the vendor can provide suitable support services will vary with each application, but is typically done on an informal basis of communication with the vendor and with colleagues with previous experience of the vendor. For conductivity measuring equipment, this can be done as part of the process of selecting suitable equipment and services. Pricing should only become a selection criterion if there is more than one vendor that completely satisfies the URS.

5 Installation Qualification (IQ)

Verifying that the equipment has been delivered and installed correctly can be an onerous task for some analytical equipment; but this is relatively straightforward for conductivity measuring equipment. IQ for conductivity measuring systems should include documented verification of the following areas:

- All of the required items have been delivered as outlined in the user's purchase order and the vendor's delivery note. This should include ensuring that documents such as instruction manuals carry the correct reference number, thus indicating that they are the current issue. For re-programmable conductivity meters, it should be verified that the firmware is the most up to date version.
- The measuring environment is suitable for the equipment's use. This will include ensuring that adequate space is available for operation of the equipment; the operating temperature and humidity are within the equipment's operating range; the equipment can be connected to a suitably rated electrical power supply and computer network connection (if required).
- All of the system's components have been installed in accordance with the manufacturer's instructions.
- No damage has occurred to any items during delivery and assembly.

- The response of the equipment to the initial application of power is as expected.

IQ should always be performed by the equipment vendor, as familiarity with the equipment is essential to specify all of the items of equipment and make the assessments required for IQ. Users will not have this familiarity with equipment that they have not previously used.

6 Operational Qualification (OQ)

The purpose of OQ is to verify that the measuring system performs in accordance with the specifications agreed by the user and vendor, in the environment that it will be used for test measurements. OQ for conductivity measuring systems should include documented verification of the following areas:

- Each of the required instrument's functions in its relevant sub-menu performs correctly. For more advanced instruments, this may include checking the available temperature compensation options, checking GLP functions such as time and date stamp and operator passwords and checking that measurements can be outputted to the instrument's display, printer or to a PC.
- The instrument can process input signals correctly.
 - Conductivity inputs are checked by connecting certified, traceable resistors to the sensor input socket.
 - Temperature inputs are checked by connecting a certified, traceable resistance thermometer simulator to the sensor input socket.
- A cell constant can be assigned to the conductivity cell by monitoring its measurement of a certified, traceable conductivity standard. Most conductivity instruments have an automated routine for performing this task.
- After assignment of the cell constant, suitable readings are obtained in Control Standards. The allowable tolerance for these measurements will depend upon the sample measurement criteria defined in the User Requirement Specification. The Control Standard tests will verify that the measuring system is capable of generating test measurements that are fit for purpose. A range of Control Standards should be

selected that cover the entire range of intended samples' conductivity values. The selection requirements for Control Standards are detailed in Section 8.

- The conductivity meter and cell can measure temperature to the required accuracy. The temperature measurement should be compared with a certified Reference Thermometer over the entire temperature range that the equipment will be used for test sample measurements.
- The test measurements are provided in the required format – this may be output to the conductivity meter's display screen, to a printer or to a PC or LIMS system.

The resistors, resistance thermometer simulator and reference thermometer used during OQ should be calibrated by a calibration laboratory that holds accreditation for performing this activity – preferably a laboratory accredited to ISO 17025⁽⁷⁾. The calibration certificates for this equipment should be included in the OQ report.

It is not necessary to verify that all of the instrument's functions perform in accordance with the manufacturer's specifications – only those functions which will be utilized by the user for the applications specified in the URS need to be checked. For example, if a conductivity instrument has an output that is compatible with analogue recorders then it is only necessary to check this function if the instrument will be used with an analogue recorder. As well as covering immediate requirements, the URS should also give details of likely future requirements and correct performance of these functions should also be covered in OQ.

Protocol development and performance of OQ requires a high degree of expertise in using the conductivity instrument. In addition, specialised, certified input simulators are required to perform this activity. These simulators are expensive to purchase and have certified by an accredited laboratory. OQ should always be performed by the equipment vendor, as they have the appropriate instrument expertise and equipment to perform this activity at a fraction of the cost of the user's labour to perform this task.

In addition to demonstrating that equipment is fit for its intended purpose before it is used for critical test measurements, a properly-structured vendor OQ has other considerable benefits for the user:

- The OQ documentation is a valuable tool for compiling the Standard Operating Procedure (SOP) that will govern the equipment's use. The SOP will document the method for taking test sample measurements. This will be almost identical to the OQ method for measuring Control Standards. Access to the vendor's OQ documentation allows users to compile their SOPs much faster than if they only have access to the instrumentation's manuals. This leads to considerable savings of time and money in putting the equipment into service.
- The OQ documentation can be used as an aid to training operators how to use the equipment correctly.
- If a fault occurs with the equipment during its working life, IQ and OQ can be repeated to rapidly identify the cause of the fault. Their modular, systematic structure means that these documents are a powerful troubleshooting tool.
- Suitable checks to be performed for the equipment's Performance Qualification can be based upon the testing carried out during OQ.
- **System Suitability Checks with Control Standards** should be performed with each batch of test samples. The routine use of Control Standards will also ensure compliance with the principles of good laboratory practice⁽⁸⁾ and is an essential element of effective Quality Control of conductivity measurements.
- **Periodic Re-Qualification** of the conductivity measuring equipment. The use of Control Standards provides a straightforward, holistic check of the entire measurement system's performance. However, the detailed, modular checks performed during the Commissioning OQ should be repeated at regular intervals so that the performance of each component of the measuring system can be verified in isolation. The Re-Qualification frequency depends upon the robustness of the measuring system, the criticality of the test measurements and the ramifications of any decisions made based upon the test measurements. It is recommended that Re-Qualification should be performed at least annually and more frequently for conductivity equipment used for critical measurement applications. The equipment vendor should conduct such Re-Qualifications, as they will have the appropriate equipment and expertise to execute this task, as well as providing an assessment of the measuring system that is independent from the user.

7 Performance Qualification (PQ)

The purpose of PQ is to verify that the measuring system consistently performs adequately for its intended purpose over its entire operational life. Suitable PQ will ensure that maximum confidence is achieved for all of the analytical test measurements obtained using the measuring system. This activity should always be performed by the user. PQ should be viewed as a process rather than an event and should be an integral part of the SOPs and other Quality Assurance documentation that governs the conductivity instrumentation's use. There are three main areas to effective PQ of conductivity instrumentation:

- **Simple, visual inspections** should be performed on a regular basis. For laboratory and portable instruments this will be covered by recording that the equipment has been checked daily or prior to each use. For online conductivity systems, these inspections should be written in to maintenance schedules as it may only be possible to inspect online conductivity cells during shutdown periods.
- **Fault Identification:** The IQ and OQ documentation provide an ideal checklist of tests to be performed to identify the cause of faults. Fault identification should only be performed by authorized, qualified personnel. In many instances, the user may not have the diagnostic tools and expertise required to identify faults and the equipment vendor will be required to conduct this activity. The user should ensure that the vendor provides a written report of any work undertaken.
- **Fault Rectification:** Any corrective measures that are taken should be documented and the equipment should be

If any unacceptable equipment performance is detected by PQ, the measuring equipment should be removed from service and the cause of the out of Specification performance should be investigated and rectified, as outlined in the Quality Assurance and Quality Control systems that govern the conductivity equipment's use. Documented procedures should be in place that address the following areas:

re-qualified before it is returned to service. Details of any maintenance and service contracts should be documented so that only authorised, qualified personnel attempt to perform any repairs.

- **Investigation of recent sample measurements:** All sample measurements taken since the previous acceptable System Suitability Check must be investigated as their quality cannot be relied upon. In some instances it may be possible to repeat the conductivity tests on retained samples.
- **Performance Analysis:** PQ results, Re-Qualification reports and Fault Identification and Rectification Reports should be assessed on a regular basis. This will enable the user to ensure that the PQ employed achieves its aim of providing maximum confidence in all test measurements; that any trends in performance are identified; and that suitable preventative maintenance is put in place.

8 Selection of Control Standards for OQ and PQ

The Control Standards used for OQ and PQ should comply with the following criteria⁽⁸⁾:

- They should have a similar conductivity value to the test samples. If this is not the case, the System Suitability Check will not give any indication of the equipment's ability to measure the samples' conductivity to the required degree of accuracy.
- Their matrix should be the same as the samples' matrix. As conductivity analysis is virtually exclusively performed on aqueous samples, the Control Standards should also be of aqueous matrix.
- They should be of a high specification. For most conductivity measurement applications, Control Standards with a specification of $\pm 1\%$ of the nominal value are readily available.
- They should be certified as being traceable to Primary Standards by a Certificate of Analysis that fully documents the traceability and Uncertainty of Measurement associated with their assay. Ideally, the Control Standards' manufacturer should be accredited to ISO 17025⁽⁷⁾ for their conductivity measurement, as this provides independent verification of the

manufacturer's traceability and Uncertainty of Measurement claims.

Particular care should be taken when selecting Control Standards for low conductivity measurement applications, as it has been identified that accurate, aqueous, low-level conductivity standards with proven stability are not readily available⁽⁹⁾. However, the authors have published comprehensive stability data for low-level, aqueous conductivity standards that allays these concerns⁽¹⁰⁾.

9 Equipment Re-Qualification

The checks performed during the commissioning of the measuring equipment should be periodically repeated during the working life of the equipment as part of the PQ described in section 7. In addition to this requirement to regularly Re-Qualify the equipment, if the operation of the instrument undergoes any significant changes during its service then it may be necessary to repeat all or part of the commissioning qualification phases:

- If the equipment is relocated then the Commissioning IQ and OQ should be repeated to ensure that the equipment has been correctly re-assembled and that it continues to meet its performance criteria in its new measurement location.
- If any parts are replaced then it will be necessary to repeat elements of the Commissioning qualification. If the conductivity sensor is replaced then it is sufficient to repeat the elements of OQ that are directly dependent on the sensor's performance – i.e. verifying that the conductivity and temperature measurements are of the required accuracy.
- If the conductivity instrument's firmware is upgraded then the relevant sections of OQ should be repeated after they have been updated to account for the firmware modifications.
- If a new test measurement application is introduced this should be compared with the original URS. If the new application falls outside these performance criteria then the URS should be modified and the equipment Re-Qualified to demonstrate compliance with the extended performance requirements. In some instances, it may be necessary to use a supplementary conductivity sensor with the existing conductivity meter or a

completely new measuring system may be required to comply with the new measurement requirements.

- If the equipment fails PQ tests and corrective maintenance or repairs are performed on the equipment then it will be essential to Re-Qualify the equipment before it is returned to service.

10 Who should perform Equipment Qualification?

The execution of each stage of Equipment Qualification requires expertise, familiarity with the equipment and access to specialist tools and equipment. The user will not have the knowledge and equipment required to conduct all of the stages of Equipment Qualification. Subsequently, DQ should be performed by the user and vendor working in partnership and IQ, OQ and Re-Qualification should be performed by the equipment vendor:

- **DQ** – if the supplier is provided with a copy of the URS, they will be in a position to provide evidence that the equipment is of a suitable specification and that all of the support and training services that they will offer will meet the requirements outlined in the URS. However, the user is ultimately responsible for ensuring that the supplier's proposals conform to the URS.
- **Commissioning IQ and OQ.** Compiling the Commissioning documentation requires an intimate knowledge of the measuring equipment. The user will not be familiar with the components of the measuring system and therefore will not be able to evaluate if they have been delivered and installed in good condition. Hence, IQ must be performed by the equipment supplier. As users will be unfamiliar with new equipment, it would require a considerable amount of time for them to identify the equipment's functions and performance characteristics and to compile the OQ documentation to prove that the equipment is functioning correctly. The user may not have access to the specialised equipment required to perform this activity, such as certified resistors and resistance thermometer simulators. The commissioning OQ should be performed by the equipment supplier as they will have the relevant expertise and equipment to conduct these tasks. Typically, equipment suppliers will be providing this service to a number of clients and so their costs associated with

compiling the qualification documentation will be spread over a number of instruments. This means that the supplier will be able to perform commissioning OQ faster and cheaper than the user.

- **Re-Qualification** required as part of the routine, ongoing PQ or after a change to the equipment or its measuring environment. The equipment supplier will have the required expertise and equipment to perform Re-Qualification and will provide an assessment that is independent from the user.

Although the equipment vendor may perform some of the elements of Equipment Qualification, it remains the user's responsibility to ensure that suitable Equipment Qualification is carried out. The user should verify that, to the best of their knowledge, the vendor has performed their contracted activities correctly and that the Equipment Qualification as a whole is fit for purpose⁽¹¹⁾.

11 Relationship between Equipment Qualification, Method Validation and Quality Control

Equipment Qualification merely demonstrates that measuring equipment is **capable** of producing test measurements that are fit for purpose. The test method employed on the samples must also be suitable for its application if the results are to be fit for purpose. The same rationale used in the initial stages of Equipment Qualification should be applied to test methods, i.e. they should be validated prior to their use on samples to demonstrate that they are capable of generating results that are fit for purpose.

Method Validation is defined as "the process of defining an analytical requirement, and confirming that the method under consideration has performance capabilities consistent with what the application requires"⁽¹²⁾. Method Validation should only be performed on "equipment that is within specification, working correctly and adequately calibrated"⁽¹²⁾. This means that the commissioning phases of Equipment Qualification should be completed prior to commencing Method Validation. The method performance characteristics that need to be quantified during Method Validation will be dependant on the nature of the analytic

requirement. However, it will always be necessary to determine whether the method generates results of suitable accuracy for the analytical requirement. This means that the Method Validation must include characterisation of the method's Uncertainty of Measurement, as this is the performance characteristic that quantifies the accuracy of the test method. For conductivity measurements, many of the contributory components of the method's Uncertainty of Measurement will be the instrument performance characteristics that are verified during Equipment Qualification, e.g. the conductivity instrument's accuracy for processing conductivity input signals.

For validation of conductivity methods, it is usually required to demonstrate that the method can generate a linear response over the expected conductivity range of the samples. This is done by assessing the results generated when the method is used on conductivity standard solutions that cover the conductivity range of the samples. This analysis is also covered in the Control Standards' checks performed during Operational Qualification. It may be possible to design the Operational Qualification and Method Validation so that

the same suite of Control Standards' analysis may be used for both purposes.

Once the commissioning phases of Equipment Qualification have been completed and the test method has been validated, the laboratory will have measuring equipment and a measurement method that is capable of generating test results that are fit for purpose. However, confidence in the analytical measurements on samples can only be attained if there are adequate Quality Control measures in place for the routine use of the test equipment and method. Equipment Qualification and Method Validation provide the information required to determine what Quality Control measures will need to be employed. As conductivity is a temperature-dependent parameter, Method Validation should identify the degree of control required of the testing temperature to generate fit for purpose measurements. The principal tool used in Quality Control of test methods is a Performance Check using Control Standards. For straightforward analytical techniques, such as conductivity, the same Control Standard test can be used for this purpose as is used to perform the Performance Qualification of the measuring equipment.

12 Conclusion

The aim of any analytical process is to produce test measurements that are fit for their intended purpose. Regardless of the skill and efforts of the analytical personnel, this can only be achieved if the measuring equipment used is capable of producing measurements of the required quality. Equipment Qualification not only ensures that the measuring equipment is suitable for its intended use, but also provides unequivocal evidence that this is the case.

Equipment Qualification's components of fully defining the equipment's required performance, ensuring that suitable equipment is selected and ensuring that the equipment's performance is consistently of the required standard have many benefits for the analyst:

- Attaining the correct result and proof of the correct result (in conjunction with other QA and QC measures)
- Reduced incidence of test measurements that are not of the required quality.
- Rapid identification and rectification of any problems that may occur with the measuring equipment during its entire working life.
- Subsequent long term savings of both time and money.

The IQ and OQ stages of Equipment Qualification require specialist knowledge and equipment. These stages should be performed by the equipment vendor, as this will bring the following benefits to the user:

- Time savings, as the user does not need to gain the detailed knowledge of the equipment that is required to compile and perform IQ and OQ.
- Saving of money – for the labour costs associated with IQ and OQ and the specialised equipment required to perform these functions.

- Independence of the assessment of the equipment's capabilities.

One of the key requirements for effective OQ and PQ is suitable Control Standards. This is required for the Equipment Qualification of all types of analytical instrumentation, but is of particular relevance to the qualification of conductivity systems. The Control Standards must have the same matrix as the samples and must be of a similar conductivity value to the samples. If this is not the case, the Control Standards will not give any meaningful indication of the quality of test measurements.

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* These papers forms part of a comprehensive series of papers that the authors have written covering all of the practical requirements for accurate conductivity measurement. These papers and the authors' book, "A Practical Guide to Accurate Conductivity Measurement" are available via Reagecon's website - www.reagecon.com.

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