analytikjena

Equipment Qualification

Meeting Your Demands

Our competent service & support makes it easy for you to choose the right analytical instrument to suit your quality system.

Furthermore, we can support the qualification procedure and offer many service products to make monitoring afterwards even easier.

Inside the brochure you will find more detailed information about Equipment Qualification and the services Analytik Jena can offer.

Equipment Qualification of Analytical Instruments

It is a basic requirement of good analytical chemistry that analytical instruments must be suitable for the purpose for which they are used and that they must be appropriately calibrated. As a consequence, EQ is gaining more and more importance in ensuring the validity of results. Regulatory bodies also seem to be turning their attention increasingly to this area, and manufacturers of analytical equipment are forced to play a significant role in the various steps of EQ.

The section **„Equipment Qualification (EQ)"** is based mainly on the book „Validation and Qualification in Analytical Laboratories" by Ludwig Huber (ISBN:1-57491-080-9). EQ is used as the umbrella term covering the first four steps that ensure an instrument is appropriate for its intended use. The user has the ultimate responsibility for the accuracy of results and for the qualification of his/her equipment. EQ is broken down into:

1. Design Qualification (DQ)

Design qulaification defines the functional and operational specifications of the instrument and details the conscious decisions made in the selection of the supplier.
DQ should ensure that instruments have all the necessary functions and performance criteria that will enable them to be successfully implemented for the intended application and to meet user requirements.
The list below shows the recommended steps that should be considered for inclusion in a Design Qualification.

- Description of the analysis problem
- Description of the intended use for the equipment
- Description of the intended environment
- Preliminary selection of the functional and performance specifications (technical, environmental, safety)
- Preliminary selection of the supplier
- Final selection of the supplier and equipment
- Development and documentation of final functional and operational specifications

Vendor Qualification

As part of the DQ process, the vendor should be qualified; the question is how should this be done? Is an established and documented quality system enough (e.g. ISO 9001), or should there be a direct audit?
The answer is that there may be situations where a vendor audit is recommended: for example, when complex computer systems are being developed for a specific user. However, this is rarely the case for analytical instruments.
If equipment does not include a computer system, a good reputation, one's own experience or good references from other users together with ISO 9001 certification can be sufficient.

2. Installation Qualification (IQ)

IQ ensures that the instrument is received as designed and specified, that it is properly installed in the selected environment, and that this environment is suitable for the operation and use of the instrument.

Before installation:

- Obtain manufacturer's recommendations for installation site requirements
- Check the site for the fulfillment of the manufacturer's recommendations (utilities such as electricity, water and gases plus environmental conditions such as humidity, temperature, vibration level and dust)
- Allow sufficient shelf space for the equipment itself, related SOPs, perating manuals, logbooks and software

3. Operational Qualification (OQ)

Operational Qualification (OQ) is the process of demonstrating that an instrument will function according to its operational specification in the selected environment.
Before OQ testing is done, one should always consider what the instrument will be used for. Testing may be quite extensive if the instrument is to be used for all types of applications and where some of these place great demands on the performance of the system.

4. Performance Qualification (PQ)

PQ is the process of demonstrating that an instrument consistently performs according to a specification appropriate to its routine use.
Important here is the word consistently. The test frequency is much higher than for OQ. Another difference is that PQ should always be performed under conditions that are similar to routine sample analysis.
PQ should be performed on a daily (or at least a weekly) basis, or whenever the instrument is used. The test frequency depends not only on the stability of the equipment but also on everything in the system that may contribute to the analysis results.

1. Define the performance criteria and test procedures.
2. Select critical parameters.
3. Define the test intervals.

5. Maintenance Qualification (MQ)

The MQ describes and documents any maintenance required on the equipment. This includes routine servicing and any repairs necessary. Details of any maintenance contracts are also documented in this section, together with a list of authorized service engineers. In addition, the MQ includes the routine cleaning of the equipment and also its ultimate disposal.

Responsibilities
Who should perform the EQ: the vendor or the user?
This is a frequently asked question. Here it should be noted that the user bears the ultimate responsibility for the accuracy of the analysis results and therefore also for the EQ. What the user does in this respect depends again on the type of equipment, and especially on its intended use.
DQ should always be done by the user. The instrument's functional and performance specifications from the vendor can be used as a source of information, but they should always be adapted to the specific use intended for the system.
As a rule OQ should be done by an authorized service engineer of Analytik Jena. In this case the user does not have to worry about calibrated weights and testing equipment that is certified and traceable to national or international standards.
PQ should always be done by the user, because it very often depends upon a specific application. As PQ is done much more frequently than OQ, this effectively limits the task to the user anyway.

Documentation
On completion of Equipment Qualification, documentation should be available that consists of:
- Design and Vendor Qualification document
- Calibration certificate documenting initial calibration
- Installation Qualification document (IQ protocol)
- List of authorized users
- PQ test procedures and representative results
- List of authorized service engineers
- Log that lists all activities involving the equipments
- Entries on instrument ID in the laboratory's instrument database

Validation
Validation means proving that something does what it is supposed to do. It establishes documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

Qualified Trainings
To optimize the operation of your analytical instrument Analytik Jena includes qualified trainings up to your standard within MQ. Only individual application trainings ensure best measuring results and efficient operation of the analyzer. Furthermore Analytik Jena offers a wide range of services, e.g. user seminars and consultation by telephone or on-site. Our welltrained, globally active staff ensures optimum customer care and support at any time. A strong team of application specialists is available to you at any time to assist you in your everyday laboratory work.

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