CHAPTER

1

Definition of Qualification and Validation

INTRODUCTION

Validation: The term validation has been defined by many different authors. Although the wording may be different, the sense is always the same. One of today's commonly accepted definitions of validation was given by the FDA and it defines validation as 'Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.'

Qualification: Qualification is defined as the "action of proving that any equipment works correctly and leads to the expected results." Qualification is also part of validation and is product-specific.

Qualification is often a part (the initial stage) of validation, but the individual qualification steps alone do not constitute process validation.

There are four stages of qualification:

1. Design qualification (DQ);
2. Installation qualification (IQ);
3. Operational qualification (OQ); and
4. Performance qualification (PQ).

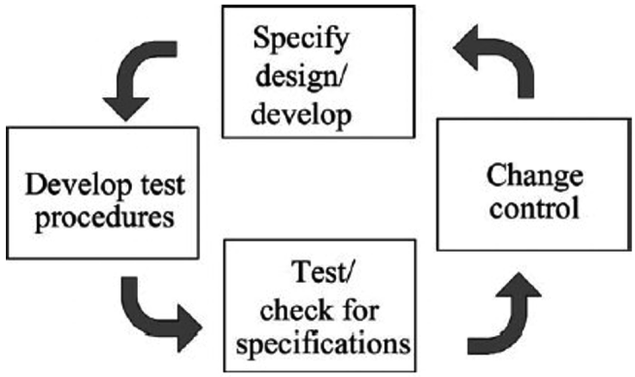

Fig. 1.1: Principle of qualification and validation. *Source:* Ref. 55.

Relationship between Validation and Qualification

Validation and qualification are essentially components of the same concept.

- The term qualification is normally used for equipment, utilities and systems.
- Validation is used for processes.

In this sense, qualification is part of validation.

TYPES OF VALIDATION

Process validation or simply called validation may be conducted at different points during the life cycle of a product. The types of process validation are defined in terms of when they occur in relation to product design, transfer to production and release of the product for distribution.

1. Prospective Validation
2. Concurrent Validation
3. Retrospective Validation
4. Revalidation

1. **Prospective Validation**

Prospective validation is conducted before a new product is released for distribution or, where the revisions may affect the product's characteristics, before a product made under a revised manufacturing process is released for distribution.

Criteria for performing the prospective validation:

- Facilities and equipment should meet GMPs requirements
- Personnel has to be trained properly
- Critical processing steps and processing variables should be identified and provisional operational control limits for each critical test parameter should be provided using pilot laboratory batches (10 x)

Points to be considered

- Different lots of raw materials should be used.
- Batches should be run in succession on different days
- Batches should be manufactured in equipment and other facilities meant for commercial production.
- Critical process variables should be set with in their upper and lower limits during process operation.
- If failure occurs it should be subjected to process requalification and subsequent revalidation.

2. **Concurrent Validation**

Concurrent validation is used for establishing documented evidence that a facility and processes do what they purport to do, based on information generated during actual imputation of the process.

Concurrent validation is a subset of prospective validation and is conducted with the intention of ultimately distributing product manufactured during the validation study.

In-process tests that can be monitored in solid and liquid dosage forms are:

- Powder-blend uniformity
- Moisture content
- Particle/granule size distribution
- Weight variation
- Content uniformity
- Disintegration time/dissolution time
- Tablet hardness
- pH value
- Colour/clarity
- Viscosity/density
- Average unit potency

Selection of the in-process test process parameters should be on the basis of the critical processing variables to be evaluated.

3. **Retrospective Validation**

Retrospective validation is the validation of a process based on accumulated historical production, testing, control, and other information for a product already in production and distribution.

This type of validation makes use of historical data and information which may be found in batch records, production log books, lot records, control charts, test and inspection results, customer complaints or lack of complaints, field failure reports, service reports, and audit reports.

Historical data must contain enough information to provide an in-depth picture of how the process has been operating and whether the product has consistently met its specifications.

Retrospective validationmethod:

- Collect commercial values of in-process data and end product testing results.
- Organize these data in chronological order.
- Include data from at least 20–30 batches for analysis.
- Isolate critical processing steps data.
- Subject the data to statistical analysis and evaluation.
- Draw the conclusions on the state of control of the manufacturing process
- Issue a report of findings.

4. **Revalidation**

Repeated validation of an approved process (or a part thereof) to ensure continued compliance with established requirements.

Revalidation should be performed following a change that could have an effect on the process, procedure, quality of the product and/or the product characteristics.

ADVANTAGES OF VALIDATION

i. Process parameters and controls are determined during the validation of any process or system.
ii. It helps to determine the worst case and risks that may arise during the manufacturing of the quality products.
iii. Validation helps to investigate the deviations caused during the process.
iv. Deep study and understanding of the system and equipment are made possible due to the validation.
v. The risk of the regulatory non-compliance is minimized after the validation.
vi. A validated process required less process control and the finished product testing.
vii. Batch to batch variation is minimized due to the validation of processes, systems and equipment.
viii. Reduces the production cost of the product.
ix. Increases the production of manufacturing facility due to the minimized rework and rejection.
x. Decreases the chances of the failure of the batches.

STREAMLINING OF QUALIFICATION AND VALIDATION PROCESS

Approach to Process Validation: In all stages of the product lifecycle, good project management and good archiving that capture scientific knowledge will make the process validation program more effective and efficient. Process validation involves a series of activities taking place over the lifecycle of the product and process.

Stage 1: Process Design

Stage 2: Process Qualification

Stage 3: Continued Process Verification

Stage 1: Process Design

Process design is the activity of defining the commercial manufacturing process that will be reflected in planned master production and control records. The goal of this stage is to design a process suitable for routine commercial manufacturing that can consistently deliver a product that meets its quality attributes.

Stage 2: Process Qualification

During the process qualification (PQ) stage of process validation, the process design is evaluated to determine if it is capable of reproducible commercial manufacture. This stage has two elements:

- Design of the facility and qualification of the equipment and utilities and
- Process performance qualification (PPQ).

During Stage 2, CGMP-compliant procedures must be followed. Successful completion of Stage 2 is necessary before commercial distribution. Products manufactured during this stage, if acceptable, can be released for distribution.

Stage 3: Continued Process Verification

The goal of the third validation stage is continual assurance that the process remains in a state of control (the validated state) during commercial manufacture.

An ongoing program to collect and analyze product and process data that relate to product quality must be established. The data collected should include relevant process trends and quality of incoming materials or components, in-process material, and finished products. The data should be statistically trended and reviewed by trained personnel. The information collected should verify that the quality attributes are being appropriately controlled throughout the process.

QUALIFICATION AND VALIDATION PROTOCOLS

As a minimum the protocols should include the following significant background information:

- The objectives of the study
- The site of the study
- The responsible personnel
- Description of SOPs to be followed
- Equipment to be used; standards and criteria for the relevant products and processes
- The type of validation
- The processes and/or parameters
- Sampling, testing and monitoring requirements
- Predetermined acceptance criteria for drawing conclusions.
  - There should be a description of the way in which the results will be analysed.
  - The protocol should be approved prior to use. Any changes to a protocol should be approved prior to implementation of the change.

STEPS IN VALIDATING A PROCESS

1. Develop validation protocol
2. Conduct installation qualification
3. Conduct operational qualification
4. Conduct performance qualification
5. Analyze results and reach conclusions
6. Monitor and control process
7. Purpose: To ensure process remains within established parameters under anticipated conditions
8. Investigate deviations from established parameters
9. Take corrective action
10. Consider whether revalidation is necessary.
11. Changes in process or product.

QUALIFICATION AND VALIDATION REPORTS

- Reports should reflect the protocols followed and include at least:
  - The title and objective of the study
  - Reference to the protocol
  - Details of material, equipment, programmes and cycles used
  - Procedures and test methods.
- The results should be evaluated, analysed and compared against the pre-determined acceptance criteria. The results should meet the acceptance criteria; deviations and out-of-limit results should be investigated. If these deviations are accepted, this should be justified. Where necessary further studies should be performed.
- The departments responsible for the qualification and validation work should approve the completed report.
- The conclusion of the report should state whether or not the outcome of the qualification and/or validation was considered successful.
- The quality assurance department should approve the report after the final review. The criteria for approval should be in accordance with the company's quality assurance system.
- Any deviations found during the validation process should be acted upon and documented as such. Corrective actions may be required.

VALIDATION MASTER PLAN

The VMP (Validation Master Plan) serves as the validation roadmap, setting the course, justifying the strategy, outlining the preliminary test and acceptance criteria and documenting the necessary programs that ensure a continuing state of validation.

The VMP should be authored for its audience, including the organization's quality, engineering, and regulatory departments, the FDA, and potential outside contractors. Each group looks for different elements. Outside contractors want a Deliverables List on which to base quotes and define the scope of work; the FDA looks for the pre-approved intention to comply with Federal regulations; while in-house quality, engineering, and regulatory departments look for an accurate representation of systems and corporate policies. The VMP should address all of these concerns.

Box 1.1: Typical VMP contents

1. Introduction
2. Scope
3. Facility description
4. Commissioning
5. Qualification
6. Process validation
7. Computer system validation

(*Contd*.)

(*Contd*.)

8. List of required protocols and procedures
9. List of required standard operating procedures
10. Equipment and utility system descriptions
11. Computer system description
12. Other cGMP programs
13. References

Listed below are the headings for the major sections of a VMP followed by a description of the purpose and the suggested content:

1. **Introduction:** This section should include the company name, location, division or subsidiary name (if applicable) and business sector served. A short overview of the project provides the reader with the necessary background from a macro standpoint. A cross reference to the relevant company Quality Assurance Policy is appropriate here.
2. **Scope:** This section defines the breadth and reach of the validation effort covered by the VMP. A brief description of the installation, whether single- or multi-product, and a breakdown of installed equipment as new or existing should be included here.
3. **Facility Description:** Whether the project is a new building, extension, or remodeling of a current building, the facility characteristics are listed here. The number of floors, the inter-connectivity of process and utility systems, isolation means, and the design product and personnel flow used to minimize cross- contamination are identified. Be sure to note any room classification (cleanroom certification levels) and specialty surfaces and finishes integral to achieving the required product quality. Process Flow Diagrams (PFDs) are useful here, depicting the anticipated personnel, raw material, process, and waste material flow. The emphasis here is on design considerations to eliminate cross contamination of material.
4. **Commissioning:** Documented here is the selection criteria governing what equipment and utility systems will undergo Commissioning. As Commissioning is not part of the Validation Program and is not regulated by the FDA, people often wonder why they should include this section at all. The reason is the FDA is just as interested in the rationale behind why one system is not validated while another is. The VMP needs to answer that question, identifying support utilities that do not need to be validated because they do not directly affect product quality. It also demonstrates thoroughness, showing the FDA that all systems have been examined for product quality impact. To maximize the usefulness of commissioning, the system should be tested within the anticipated operating range of the respective OQ.
5. **Qualification:** The selection criteria governing what equipment and utility systems will undergo Qualification is discussed here. Individual definitions of IQ, OQ, and PQ, may be included. Company policies, regulatory references,

and published guidelines used in this selection process should be addressed. This discussion may include considerations such as product contacting surfaces, critical/non-critical instrumentation, direct and indirect systems, and downstream processing, among others. A discussion of protocol and final report formats may be included here, with either a reference to existing protocol development procedures, or a description of the format to be utilized. Final Reports may be generated as attachments to the protocols themselves, or as separate documents.

6. **Process Validation:** This section addresses the selection criteria governing what equipment and utility systems need to undergo Process Validation. Company policies, regulatory references, and published guidelines utilized in the selection process should be addressed. One such criteria is if the "results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated….". Also included is a discussion on the appropriate Cleaning Validations (CV) required to verify inter- and intra-campaign cleaning methods. If this is to be a finished product, Packaging and Sterility validation needs to be addressed.
7. **Computer System Validation:** A separate section should be devoted to the discussion of Computer Validation, whether that is in the form of a Programmable Logic Controller (PLC) or a Distributed Control System (DCS). Computer Validation criteria also should be discussed, and whether the installed control system is to be 21 CFR 11 compliant, i.e., secure audit trails, authority checks, etc.
8. **List of Required Protocols and Procedures:** Include here a tabular representation of the equipment and utility systems, and the required protocols and procedures associated with each. This is the essence of the VMP because it defines the validation requirements for the project, and can be used to determine resource loading. This table can subsequently be used as a "Deliverables List" if the validation effort is contracted outside of the organization.
9. **List of Required Standard Operating Procedures (SOPs):** This should take the form of a tabular representation of the installed equipment and utility systems and the required SOP associated with each, similar to the List of Required Protocols and Procedures. This will help identify the level of SOP generation necessary to complete validation activities. These will generally take the form of Operation, Maintenance, and Cleaning SOPs.
10. **Equipment and Utility System Descriptions:** An overview of the particular system should be given, aligned with the Basis of Design documentation. A listing of proposed Qualification tests (IQ/OQ/PQ) should be identified with a brief description of the procedure and how the associated Acceptance Criteria will be determined. As the VMP should be developed early in the planning stage, many system specifics will be in the draft phase and subject to change. To avoid duplication of effort and unnecessary revisions, do not assign numeric-specific Acceptance Criteria in the VMP. Those details will

be fully delineated in the respective Qualification and Validation protocols that will follow. Keep in mind the intent of the VMP as a scope and guidance document. System specific acceptance criteria fall under the auspices of the individual protocols.

11. **Additional cGMP Programs:** The VMP is meant to be a Validation Life Cycle document. It should cover the activities and requirements from project inception to testing completion and on through a program of continuous monitoring and evaluation. Associated with this effort are Quality Assurance/ Quality Control procedures meant to support and update the validation effort. These programs include, but are not limited to:
    - Document/Change Control
    - Standard Operating Procedures
    - Calibration
    - Revalidation
    - Operator Training
12. **References:** All company policies and procedures, as well as any applicable local, state and federal regulations, and industry standards referenced should be listed.

QUALIFICATION

USER REQUIREMENT SPECIFICATION

User Requirement Specification (URS) is a list of all requirements of buyer regarding the equipment to be purchased. URS is prepared by the equipment user department. It is sent to equipment manufacturer to make it as desired criteria.

Following points should be included in a pharmaceutical user requirement specification:

1. **Introduction:** A brief introduction of the equipment should be written.
2. **Overview**
    i. *Intended Use:* Write the use of the equipment in the manufacturing.
    ii. *Capacity:* Write the required capacity if the equipment in the liter or kgs.
    iii. *Space Availability:* Write the available space for installation of the equipment including height, width and height in mm.
    iv. *Accuracy of Instrument:* Write the desired accuracy of the instrument in decimal places if applicable.
    v. *Cleaning Requirements:* Instrument should be easy to clean. Write, if there is any specific cleaning requirement.
    vi. *Equipment Specific Requirements:* For example, required quality of Stainless Steel (SS) as SS-308, SS-316 or SS-316L if applicable.
3. **Operational Requirements**
    i. *Functional Requirements:* Specify all technical requirements for the equipment.
    ii. *Operation:* Write the operational requirements.

iii. *Control System:* Specify ON, OFF or other specific equipment control requirements.
iv. *Power:* Write the requirements on power failure as autostart or manual.
v. *Safety:* Write the requirements of safety guard and MCB trips on short circuit or overload.
vi. *Environment:* Temperature and humidity of the area where the equipment will be installed.
vii. *Other Requirements:* Write the other requirements as the metal of construction (MOC) of non-contact parts and specific requirements of seals and tubing.

4. **Compatibility and Support**
   i. *Utilities:* Available power supply on which instrument shall be operated. The requirement of the uninterrupted power supply (UPS) and other specific utility requirements.
   ii. *Availability:* Continuous operating time of the equipment in hours or working shifts.
   iii. *Supporting Documents:* Requirements of operating manual, circuit diagrams, warranty letter, change part list, spare part list etc.
5. **Abbreviations:** List all abbreviations used in this user requirement specification document.
6. References
7. Approval

	Name & Designation	Department	Signature	Date
Prepared By				
Checked By				
Approved By				

FACTORY ACCEPTANCE TEST

Factory Acceptance Test (FAT) is done at the equipment manufacturing site of the vendor before the shipping. A proper FAT can help to minimize the problems occur during the installation of the equipment at the site.

A FAT protocol can be written as follows:

1. **Purpose:** Write the purpose of the FAT protocol as "to ensure that the equipment is designed as per the specification" and "to check the basic performance of the equipment".
2. **Scope:** Write the scope of this protocol as "this protocol is applicable to the equipment manufactured by ABC Ltd."
3. **Procedure:**
   - Write the full procedure to carry out the Factory Acceptance Test.
   - Write the procedure to check the operation of the equipment.
   - Write the action to be taken when any deviation is observed.
   - List of documents to be checked.

4. **Documentation:** Write the instructions for the documentation that is to be done during the Factory Acceptance Test.
5. **Acceptance Criteria:** Equipment and accessories should be according to the purchase order. Equipment should be as per the pre-designed parameters.
6. **Verification Sheet:** Include all tests and parameters those should be verified during the factory acceptance test.
   - *Make:* Write the make of the equipment.
   - *Model:* Write the model of the equipment here.
   - *Capacity:* Write the required capacity of the equipment.
   - *Design:*
     - Parts of the equipment and their design & specification.
     - Write the material of construction (MOC) of all parts as SS-308 or SS-316
     - Include the quantity and other details of the specific parts of the equipment.
   - *Control Panel:* Write quantity and specific requirements to be included in control panel like auto or manual, emergency stop etc.
   - *PLC:* Write make, model and quantity of the PLC panel.
   - *Temperature sensors:* Write type, make, model and quantity of the temperature sensors.
   - *RH sensors:* Write make, model and quantity of the RH sensors.
   - *Safety Features:* Write the type of emergency stop, guards on moving and electric parts etc.
   - *Documents:* List of required documents like MOC certificate, manuals, calibration certificates and warranty cards etc.
7. **Observed deviations:** Write the deviations observed during this verification, their investigation, corrective action and if those are acceptable or not.
8. **Approval**

	Name & Designation	Department	Signature	Date
Prepared By				
Checked By				
Approved By				

SITE ACCEPTANCE TEST (SAT)

Site Acceptance Test can determine whether or not systems are meeting the desired and required specifications. The main purpose of site acceptance testing is to give an overall evaluation of a systems compliance and to ensure this compliance meets the requirements of the business involved.

Site acceptance tests are related to factory acceptance tests, in that they work by inspection and dynamic forms of testing to system components. The SAT (site acceptance tests) are written by the client themselves and this verifies the functionality of the equipment being tested. They are also, as their title suggests, tested on site. The test will show whether the equipment meets, does not meet, or exceeds the expectation of performance.

The factory acceptance tests (FAT) are inspections that use the same principle, are more focused on whether the user requirements meet specification, and be executed by not only the client but the client representative. They take both the manufacture and the user into account and are, like their title suggests, tested at the factory/place of manufacturing.

In the biotech, medical and pharmaceutical fields, these tests are common knowledge. Site acceptance test documents need to be completed routinely in order for systems to meet GMP requirements. Without the SAT tests, it is difficult to see if these requirements are successfully complied with.

The SAT is a test of not only efficiency but quality. It is up to senior management and committed staff to keep a track of system software levels across different departments. By conducting an SAT, quality assurance is met, along with good manufacturing practice, safe quality risk management and efficient quality control checks.

There are various elements of a Site Acceptance Test that will be included in the test to ensure its success. These include: Finishing visual checks, main components visual checks, internal box pressure and ventilation setting checks, the functionality of utilities to be checked, the interlocks to be checked in relation to functionality, a hot test for dispensing systems, calibrator verifications, safety devices checks and tests of the operator's training and ability.

Issues can be rectified before they have the potential to cause damage or harm, which also allows for projects to be kept on track and, if applicable, on budget. Site acceptance tests aren't just used in the pharmaceutical fields. They stem across all borders of engineering, even into traffic signal equipment! By conducting an SAT all users are able to acknowledge a system is doing its job right.

DESIGN QUALIFICATION

Documented evidence that the premises, supporting systems, utilities, equipment and processes have been designed in accordance with the requirements of GMP

Design qualification should provide documented evidence that the design specifications were met. DQ should ensure that instruments have all the necessary functions and performance that will enable them to be successfully implemented for the intended application and to meet business requirements.

While IQ, OQ, and PQ are being performed in most regulated laboratories, DQ is not so well known to many laboratories. It is rarely performed officially in those cases where the equipment is planned for use in multiple applications, not in a specific one.

DQ is performed in most laboratories but are not called DQ. DQ is officially required by Annex 15 of the EU Guide for Good Manufacturing Practices. Therefore inspectors from Europe and from other PIC/S member countries are quite familiar with the term and may ask for DQ documents. An FDA inspector may ask for documented user requirements.

The main purpose of DQ is to ensure that:

- The right type of equipment is selected for specific tasks,
- The equipment will have the right functional and performance specification, and
- The vendor meets the user firm's qualification and support criteria.

DQ should be performed

- When a new instrument is being purchased, or
- When an existing instrument is being used for a new application not previously specified.

INSTALLATION QUALIFICATION

Installation qualification establishes that the instrument is delivered 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.

Installation qualification should provide documented evidence that the installation was complete and satisfactory.

The purchase specifications, drawings, manuals, spare parts lists and vendor details should be verified during installation qualification.

Control and measuring devices should be calibrated. The main purposes of IQ are to ensure that:

- Equipment has been received as purchased
- The equipment meets the physical hardware specification
- The selected environment meets the vendor’s environmental specifications
- Individual hardware modules and all accessories are properly installed and connected to each other
- The software is completely installed on the designated storage device
- Computer systems are properly configured for the intended use
- The instrument functions in the selected environment, and
- All equipment hardware and software are registered in some kind of a laboratory equipment database.

Protocol

1. Develop an operating procedure for IQ.
2. Generate a database for equipment.
3. Ask the vendor to perform IQ as part of the installation.
4. Correct installation of software should be verified for computer systems. Develop an installation verification master file.
5. An installation check with known chemical standards should be performed for complex modular systems.
6. Document IQ. If IQ was done by the vendor, the IQ document should also be signed by the vendor and user.

OPERATIONAL QUALIFICATION

Operational qualification is the process of demonstrating that an instrument will function according to its operational specification in the selected environment.

OQ should be carried out after initial installation; after instrument repair and after other major events, such as upgrades; and at regular intervals during routine use.

OQ is an important part of the overall equipment qualification process. The careful selection of test items, the test procedures, and acceptance limits is extremely important, because if set too stringently, the instrument's test may have an unnecessarily high failure rate and/or the maintenance efforts will be too intense. If the limits are too relaxed, the equipment will not prove itself fit for its purpose.

The general procedure to qualify an instrument for operation is as follows:

1. Define the intended use and the functional and operational specifications (use criteria as defined during DQ).
2. Develop test procedures and protocols.
3. Define acceptance criteria.
4. Perform the tests.
5. Check if test results meet acceptance criteria
6. Document the results.
7. Develop criteria and steps for requalification, e.g., after repair.
8. Develop procedures in case the equipment does not perform to specifications.

PERFORMANCE QUALIFICATION

Performance qualification (PQ) is the process of demonstrating that an instrument consistently performs according to a specification appropriate for its routine use.

Ongoing activities may include the following:

1. Preventive instrument maintenance
2. Regular calibration
3. Full or partial OQ checks
4. Daily check of critical performance characteristics, for example, baseline noise of a UV detector if limit of detection is critical
5. Daily system suitability testing
6. Analysis of blanks
7. Duplicate analysis
8. Analysis of QC samples
9. Procedures to detect, record, and handle errors and other unforeseen events
10. Regular security checks
11. Changes to the system in a controlled manner and controlled requalification after the change, if necessary
12. Internal audits
13. Participation in proficiency testing schemes
14. Ongoing training programs for employees.

General Procedures

1. Develop an equipment logbook.
2. Develop maintenance procedures (with the help of the vendor).
3. Develop procedures and acceptance limits for performance testing (criteria: regulations, instrument type, application, performance requirements).

REQUALIFICATION

Requalification means ensuring that the equipment is still in the qualified state after a change and periodical assessment of the equipment within defined time intervals.

Strictly speaking, requalification is not mentioned in Annexure 15 of the EU guidelines to GMP, which is the guidance document for qualification in Europe. But revalidation is described and since qualification is considered to be a subset of validation, a requalification also is required. There is no setting of time standards. But it should be stipulated when a periodically recurring requalification has to be carried out. These requirements should not be taken and met on a general basis but system-related and risk-based. In many cases this is every 3 to 5 years. But in the case of a fully automated system for the visual inspection of parenterals for example, it could be scheduled already every 1 to 2 years. It is very important that this requalification is not understood as a repetition of qualification.

Usually, no new tests or measurements are necessary insofar as the equipment concerned was not changed. Here, requalification is rather a review of data from routine operation. Hence, the quality-related equipment or specification parameters are to be considered and analysed as well as the changes in the equipment and the deviations that took place in the period considered.

An analysis of the logbook should also be part of this evaluation. The document should end with a conclusion that informs about the equipment's state: equipment still is considered to be qualified: Yes/No.

MAINTAINING STATUS FOR CALIBRATION

The quality of the products manufactured by any enterprise can directly be associated with the accuracy of the instruments producing them. If the instruments are not calibrated properly, or if they are damaged and need repair work, they will surely affect the end products. ISO calibration lists out the general requirements for the competence of testing and calibration laboratories. All the labs must adhere to service specifications developed by the International Organization for Standardization.

It is important to remember that instruments and equipment will not always stay calibrated. At some point, the level of calibration will go down and it will affect the final measurements and quality of the products. The instruments and equipment must be kept in excellent condition at all times. Preventive maintenance and repair, and recalibration of the instruments are performed regularly.

Variables determining how frequently instruments should be calibrated or re-calibrated:

i. **Manufacturers' Recommendations:** Every manufacturer mentions the ideal time frame of when you should recalibrate an instrument. Follow these instructions and specifications to the letter and you will face minimum maintenance issues. It is extremely important to remember that critical measurements may call for greater frequency.

ii. **Annually or Biannually:** Some instruments need to be re-calibrated once or twice every year. It depends on how often the critical measurements are taken. Additionally, the amount of damage sustained by the instruments during use also plays a role.

iii. **After a Damaging Incident:** If any instrument was damaged in an accident, if it was dropped hard or if it sustained any kind of injury, you must calibrate it immediately. Events where the instruments sustain damage usually experience a sharp impact that directly affects their readings. Check if the calibration was altered and carry out the necessary calibration procedures.

iv. **As Demanded by Projects:** When you carry out certain assignments, you have to use certified and calibrated test equipment, irrespective of how big or small the project is. When assignments call for such calibration based on project requirements, you must follow it.

v. **Before or After a Major Project:** Some major projects require extremely accurate measurements. This means that the instruments must be calibrated before the project starts. However, it doesn't end there. You must calibrate all the instruments that were used after the project comes to an end. Post-project calibration will show you if the testing that you conducted is indeed reliable or not, if the correct and consistent measurements were observed throughout the project.

vi. **Semiannually, Quarterly or Monthly:** Some instruments, based on their use and functions, need to be calibrated frequently. If you deal with critical measurements quite frequently, it would be ideal that you conduct frequent and consistent calibration check-ups, like every month or every three to six months.