Equipment Qualification (IQ, OQ, PQ): demystification and practical application
Objectives

• Realize that regulatory bodies such as CSA are turning their attention increasingly to the area of Equipment Qualification by having clear statements in their standards

• Comprehend the different steps of Equipment Qualification and their implications

• Generate a practical and compliant methodology to handle equipment requalification

• Assume ultimate responsibility for initiating and implementing the required qualifications in a timely manner using the available and recommended resources

• Incorporate this process in the departmental policies and procedures as part of an ongoing Quality and Risk Management
Equipment Qualification

- Very common in different types of industries
- Confusing, not widely understood in health care
- Essential part of a sterilization quality system that incorporates extensive testing, verification, and documentation
- Establishes that equipment meets minimum requirements and functions as desired
- Required to not only provide assurance of the current state of control, but must also substantiate the existence of procedures and practice that maintain the equipment in continuous working order
- Provides data on “in-use” equipment to support and verify the suitable operation and performance of different types of equipment
- Protects operators and employees from hazards
What is Validation/ Commissioning Verification/ Qualification

• Validation
A process that provides an appropriate amount of assurance through testing that critical processes in producing a product can be shown to be operating in the correct sequence

• Commissioning
A process that will ensure installed equipment or systems perform in conformity with their intended design.

• Verification
Evidence that establishes or confirms the accuracy of something at a single point in time.

• Qualification
The process of insuring equipment or system are properly installed or properly operating and properly performing a process
Stages of Equipment qualification

- Design Qualification
- Installation qualification
- Operational qualification
- Performance qualification
- Routine Monitoring
Section 12—Sterility assurance

12.1.1
Sterility assurance shall include:

a) careful adherence to written procedures (e.g., decontamination, sterilization, handling, and storage);

b) testing and monitoring of critical points in the process to ensure that procedures and processes are working correctly;

c) accurate documentation; and

d) an effective recall procedure so that problems can be quickly identified, appropriate action taken, and patient safety assured.

Notes:

1) Sterility assurance refers to the integrated system of tests, controls, and backup procedures intended to ensure that reprocessed medical devices are sterile when delivered for use. In Canada, the testing and monitoring program for sterility assurance is based on a validated system that includes the following elements:

a) Installation qualification (IQ). IQ confirms that the sterilizer has been installed and connected to the required services according to the sterilizer manufacturer's specifications and local regulations (see Clause 12.3);

b) Operational qualification (OQ). OQ has two aspects: it verifies that the sterilizer meets the manufacturer's operating specifications, which includes calibration of temperature and pressure sensors as well as verification of safety features and alarms; OQ also verifies that the sterilizer consistently produces the necessary process conditions for sterilization by repeated testing with a process challenge device (PCD). Operational requalification verifies that the sterilizer is working properly. It is performed at least annually and following repairs or other significant occurrences (see Clause 8.4);

c) Performance qualification (PQ). PQ testing accounts for setting-specific variables by verifying that packs and loads can be successfully and consistently sterilized using routine processes, products, people, and equipment as applied in the healthcare setting (see Clause 8.5);

d) Routine monitoring. Routine monitoring provides ongoing confirmation that equipment and processes are working as expected (see Clauses 8.6 and 8.7), and includes the following aspects:

i. Monitoring the physical parameters of every load (Clause 12.6.2.1);

ii. Monitoring every package with chemical indicators (Clause 12.6.3.2);

iii. Monitoring sterilizer efficacy with biological indicators (Clause 12.5.4);

Validation is a documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications. In Canada, validation testing is performed by manufacturers of devices, sterilizers, and packaging to demonstrate that a sterilization process is efficacious; this is done before approval for sale and in some other special circumstances. Canadian healthcare settings perform sterilization process monitoring, or verification testing, as described in this Clause; Canadian healthcare settings do not conduct validation.

2) See Clause 4 and Annex D of CSA Z314.0 for detailed information regarding quality management systems, risk management, and sterility assurance.
Qualification Plan – for all types

1. Purpose
2. Scope
3. Responsibilities
4. Equipment Description
5. Operational Specifications
6. Acceptance Criteria
7. Testing Results
8. Discrepancies/Corrective Actions
9. Conclusions/Final Report
Design Qualification

Is used as a start-up activity before the equipment is purchased and installed.

DQ defines:

- the functional and operational specifications of the equipment vendor

- ensures that equipment will have all the necessary functions and performance criteria that will allow the equipment to be successfully implemented for the required application.
IQ, OQ, and PQ—What are they?

- CSA Z 314.03-09 Section 12—Sterility assurance
  - 4 parts to testing and monitoring
    - IQ—Installation Qualification
    - OQ—Operational Qualification
    - PQ—Performance Qualification
    - RM—Routine Monitoring
IQ-Installation Qualification

Performed on installation or when equipment is moved

- By manufacturer in conjunction with facility representative(s)
  - e.g. Engineering, Physical Plant

- includes assessment and verification according

- to the manufacturer’s installation specifications:
  - Power
  - Steam and water quality and capacity
  - Sewer and drains
  - Ventilation
  - Environment (lighting, floors, ceilings, walls)
  - Physical installation (level, square, appropriate materials and clearances)
OQ- Operational Qualification

Demonstrates and provides documentation that the equipment operates within its operational specifications when used under defined operating procedures and in a certain environment

- Test and record
  - the operation of equipment security systems
  - sequence of operations, all modes of operation to meet user requirements
  - equipment alarms and any other specific requirements of the equipment

- Document the verification of
  - any applicable equipment parameters,
  - sensors, switches, control devices,
  - logic circuits, gauges,
  - any preventative maintenance requirements.
OQ- Operational Qualification of sterilizers

Documented verification that the sterilizer:

• performs as intended throughout the anticipated operating ranges

• is able to achieve and maintain the required sterilization conditions during the sterilization cycle(s)

• is programmed and operating correctly, and is able to meet all of the manufacturer and user requirements.

• involves verifying the parameters/settings
  • (e.g. general system options, cycle length, sterilization temperature, leak testing, or air removal, alarms )

• Documented records -Operational qualification report
OQ- Operational Qualification of sterilizers

Performed by manufacturer at installation:

- For steam autoclaves:
  - Via Process Challenge Devices... (PCD, test pack)
  - 3 consecutive negative tests for all of the predetermined acceptance criteria

- For low temperature sterilizers:
  - Manufacturers’ specific kits for different models of sterilizers and types of cycles
PQ – Performance Qualification of sterilizers

Performance qualification protocol maps out process and indicates that:

- the equipment must consistently perform in a reliable and reproducible manner according to design specification and user defined requirements appropriate to normal production conditions

- the sterilization cycle(s) can repeatedly achieve the required Sterility Assurance Level (SAL)

- the process, under anticipated conditions, consistently produces a conforming product

- the performance is satisfactory over time
  - i.e. carried out long enough to prove that the equipment is under control and turns out product of specified quality consistently

Performance qualification report

- documented verification that the sterilizer can perform effectively and reproducibly based on the approved process method and specifications
IQ, OQ, PQ (and routine monitoring)

- All tests require:
  - Written instructions
  - Actual steps documented
  - Results recorded
Performance Qualification (Section 12.5)

- Performance Qualification (PQ) has 2 parts
  - Product
  - Load
Performance Qualification (Section 12.5)

- Performance Qualification of **Products** (12.5.2.1)
  - Establish product “families” \(^1\)
    - Sets with similar sterilization requirements and/or limitations
      - Time, temperature, resistance to sterilant penetration
      - Size, weight, number of items
      - e.g. Wrapped complex ortho sets, Major instrument sets in sterilization containers
  - Assign every set to a family
  - Within each family, identify the most challenging set
  - Test the set...

Performance Qualification  (Section 12.5)

- Test the set
  - 12.5.2.5 – Textiles, basins sets, instrument sets
  - 12.5.2.7-Complex or multi level trays

- Set becomes the PCD

Figure 1. Placement of Bi's and Ci's in a complex orthopedic tray.

Fig 1 is from: Swensen, Donna.  *Product Quality Assurance Testing: One Hospital’s Experience*.  Biomedical Engineering and Technology.  March/April 2008. pp 135-139
Routine Monitoring (Section 12.6)

Periodic confirmation that processes are working

- i.e. sterilization process does kill microorganisms

Performed by MDRD e.g.

- Daily Biological Indicator in a PCD
Requalification

A repeat of some or all of the equipment qualification tests to provide assurance that the utility or equipment continues to operate in a qualified state of control

- Knowing that requalification is part of your qualification program is a first good step

- The next steps include:
  - figuring out what aspects need to be re qualified
  - determining when it should be performed and by whom
  - making sure the decisions are compliant with regulations and best practices in order to demonstrate compliance
Criteria for Requalification

• How to identify Equipment required in the Requalification Program

• Systems / Equipment Impact and critically assessment

• System / Equipment Classifications
  • Direct Impact
  • Indirect Impact
  • No Impact
Operational Requalification

- Requalification (Section 12.4.2)
  - In response to significant events
    - As specified by sterilizer manufacturer e.g.
      - Major repairs
      - Sterilizer relocation
      - Changes to services (e.g. steam or water supply)
    - Unexplained sterilization failure
  - At least **annually**
Assessment for Equipment Requalification

- Does the function / operation of the equipment directly impact product quality, patient and employees safety?
- Would malfunction impact directly on product quality, patient and employees safety?

IN STERILIZATION

THE ANSWER IS YES
Who ... Responsibilities

Who should perform the EQ (Equipment Qualification): the vendor or the user?

IQ

for a small, low-cost instrument, = the user,

Large critical equipment such as sterilizers, washer disinfectors etc... = the vendor

OQ

As a rule should be done by the vendor.

• the user does not have to worry about calibrated weights and testing equipment that is certified and traceable to national or international standards.
  • Some low temperature sterilization companies offer this service

PQ

should always be done by the user, because it very often depends upon a specific application.
How to prepare

Lets make it a requalification week / month

- Prepare a Qualification Plan (QP)
  - A high level document, which establishes an umbrella validation plan for the entire project and is used as guidance to the project team for resource and technical planning

- Documentation matrix
  - Collect, review and update related documentation to the equipment (procedures, change control, historical production data, process deviations).
  - May be done as part of the Risk Assessment Process to identify which items of equipment require requalification
Requalification group - Role

- The Requalification group is responsible for:
  - generating a protocol as per Standing Operating Procedures
  - to obtain approval and documented evidence of the requalification activities
  - provides guidance to the identified impacted departments
  - reviewing the summary reports and taking the appropriate actions as requested.
Requalification Master Plan

- A document that highlights:
  - the requirements for equipment requalification
  - lists equipment that will require requalification
  - the specific format to be used for all documentation.

- Continued qualification includes:
  - managing and evaluating changes to the equipment
  - periodic verifications (e.g., performance verification), calibration
  - preventative maintenance,
  - maintenance work orders
  - a periodic review of performed critical changes/repairs
  - identification of events that could trigger requalification - RED FLAGS/Indicators
  - using a risk-based evaluation to determine the extent of the requalification
Requalification Indicators

Maintenance Triggers for Qualified Equipment

- change in operating parameters
- change or replacement of key components in the system
- new accessories or components are added to previously qualified equipment
- loss of product quality
- upgrades to equipment
- change in location
Requalification of “Old” Equipment

What about "old manufacturers" who have not performed equipment qualification on old in-use equipment?

- not always possible to have all details for all components of the qualification for old equipment

- the manufacturer should however have data that verifies the operating parameters and limits for the critical variables of the equipment

- the calibration, cleaning, preventative maintenance, operating procedures and operator training procedures for the use of the equipment should be documented and used as standard operative procedures
Requalification Process

• identify the list of equipment due for re-qualification.

• perform risk assessment for each equipment

• prepare a qualification schedule

• prepare a documentation matrix

• perform qualification

• prepare a re qualification report and conclusion shall be drawn
Remediation program

• Notify any out of trend or failures observed during the requalification program execution.

• Identify actions and/or projects required to fix failures or to bring the equipment / process / system to the acceptable trend.

• Include the actions and/or projects to a remediation program to monitor the completion and progress of those actions and/or projects

• Compare CAPAs Corrective Actions Preventive Actions (CAPAs) with the previous evaluation period to ensure that the equipment are not drifting from normal/acceptable actions.

• Use project schedule to assign and monitor equipment, processes, and systems progress.
How to measure success

• The qualification / requalification program status is kept updated and accessible

• Roadblocks are recognized promptly and constraints are identified and solved in a timely manner

• Action plans are prepared and measures are put in place to keep the program on time.

• “Flash Reports” are produced and shared among departments
This process will help you ...

- address pain points
- resolve deficiencies & citations
- ensure regulatory compliance
- maintain defensible audit trails with qualification & requalification
- assure quality & reliability
- reduce recurring costs
- mitigate risk
Conclusion

Equipment qualification and requalification is defined a discipline

An organized process define the success of this practical approach

Important points to remember

- determining when it should be performed
- finding ways to ensure it gets executed
- figuring out what aspects need to be re qualified
- making sure the decisions you make are compliant with standards and best practices.