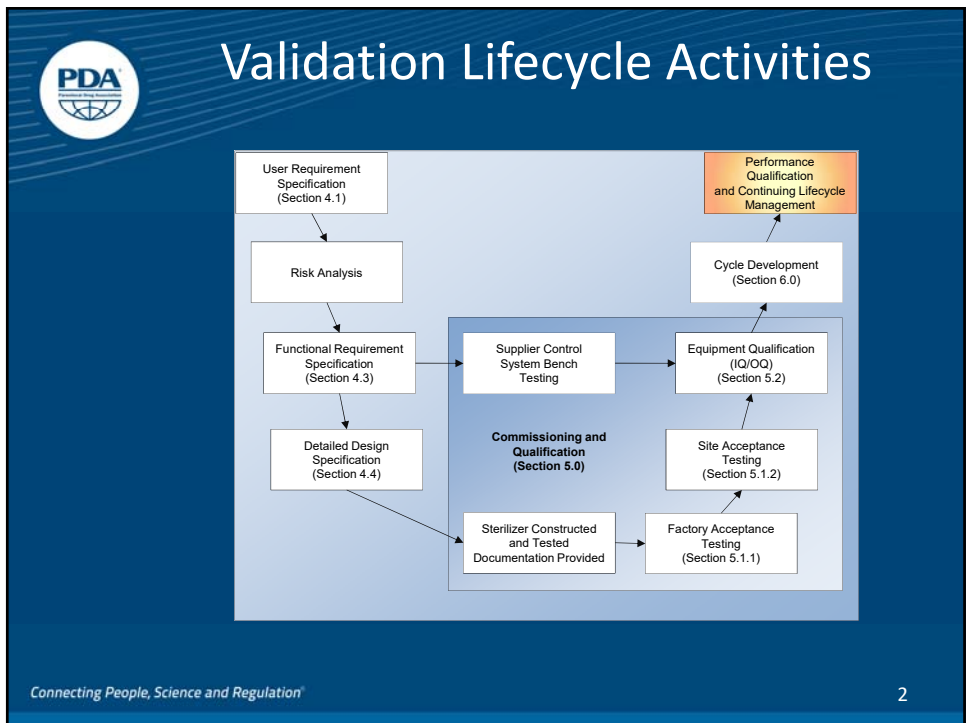


 Technical Report No. 48  
Moist Heat Sterilizer Systems:  
Design, Commissioning, Operation,  
Qualification and Maintenance


**Module Eight**  
**Ongoing Control**  
Section 7.0  
*Maintaining the Validated State*

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## On-Going Control

**On-Going Control**  
After sterilizer qualification, an ongoing monitoring program ensures maintaining the validated state of control

Requalification, maintenance, change control and periodic verification of the cycle should also be considered part of the lifecycle control of the sterilizer

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## On-Going Control

**Change Control**


- Change control procedures should adequately address issues such as a load configuration change or a sterilizer modification.

**Systems Suitability Evaluations**

- Physical evaluations (e.g. chamber integrity or air removal) that can be performed on routine basis to demonstrate ongoing control of system

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## On-Going Control


### Requalification

- A procedural process that requires a written protocol before performance of a test
- Should be performed on a defined periodic basis
- Empty chamber studies evaluate locations throughout a sterilizing unit to confirm uniformity of temperature and pressure conditions

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## On-Going Control

### Control system settings

- Should be reviewed at defined intervals according to internal requirements


### Sterilizer's computer system maintenance

- includes change control for software and hardware, and continuing calibration of critical and key input and output devices

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## On-Going Control


### Sterilizer System Maintenance

- Ensure the equipment is maintained in its qualified state
- Maintenance planning should include what, when, and how to perform preventive maintenance
- Maintenance should be performed in conjunction with calibration

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## On-Going Control


### Sterilizer System Maintenance

- Maintenance planning may typically include:
  - Cleaning of the chamber, racks, shelving, and door
  - Replace chamber exhaust filter
  - Lubricate door gasket (if applicable)
  - Replace door gasket(s)
  - Vent filter is sterilized and/or replaced periodically
  - Replace compressed air inlet filter
  - Steam traps cleaning and functional verification

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## On-Going Control


### Sterilizer System Maintenance

- Verify chamber pressure switches and door interlock function
- Check the compressed air / pneumatic system operation
- Check the steam/clean steam inlet valves and pressure regulators
- Rebuild vacuum pump as needed
- Check water and cooling water pressure and level
- Check water control valve operation

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## On-Going Control


### Sterilizer System Maintenance

- Flush heat exchangers
- Check and replace valve seals/diaphragms
- Verify pressure relief devices function
- Verify other safety switches
- Check clean steam piping and chamber for rousing

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## On-Going Control


### Sterilizer System Maintenance

When corrective maintenance is due to malfunction, change control procedures should be followed

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## On-Going Control

### Calibration

- To detect and report all deviation from specified calibration tolerance limits
- May include adjusting the instrument, or a measurement loop
- Equipment should be calibrated according to a documented program that includes establishing appropriate calibration intervals

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## On-Going Control: Documentation

Maintenance documentation should include sterilizer instruments such as:

- temperature indicators
- pressure indicators
- transmitters
- controllers
- recorders
- limit switches (high temperature and high pressure safety switches)

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## On-Going Control: Calibration

Device measurement tolerances are specified by the instrument manufacturer

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## On-Going Control: Calibration

However, calibration can provide greater than stated accuracy

- An RTD element (as delivered) may be specified to be within  $\pm 0.5^{\circ}$  C at  $0^{\circ}$  C. When the RTD is connected to an adjustable transmitter, the RTD tolerance can be eliminated, thereby providing an installed system accuracy that can be maintained within tighter specifications.

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## On-Going Control: Calibration

### Single Devices

- Measured against a reference standard

### Linear Devices

- Perform at least a two-point calibration
  - Includes low and high point range of use

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## On-Going Control: Calibration

Calibration of a loop takes into consideration the individual characteristics of each device.

However, the collective calibration tolerance is based on a sum of tolerances for all the devices in that loop.

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## On-Going Control: Calibration

Instruments that control and monitor critical and key parameters on a GMP sterilizer must be maintained within specified limits in order to comply with regulatory and process requirements

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## On-Going Control: Calibration

### Record Keeping

- Calibration activities and results should be recorded
  - Typically recorded on a form or
  - Maintained in an electronic database
- Recorded data should include:
  - Device manufacturer, name, tag number and location
  - Operating range and calibration points
  - Identification of procedure used to calibrate the device

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## On-Going Control: Calibration

### Record Keeping

- Accuracy or allowed deviation from standard that triggers an adjustment
- Out-of-Tolerance deviations that trigger an investigation
- The “as found” data and “as left” data
- Identification of the reference standard(s) used to compare field measurements
- Identification of the person(s) that performed the calibration
- Date of calibration
- Date of next calibration

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# On-Going Control: Calibration


## Record Keeping

Calibration records should be reviewed and approved by a subject matter expert, and depending on the organization's policies and practices, the Quality Unit

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# Questions / Discussion

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Moist Heat Sterilizer Systems

End Module Eight

On-Going Control

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