Variables affecting validation

A significant period of time is required to develop a robust sterilization process, this typically includes considerations such as: -

- **Load item positioning and layout**
- **Temperature uniformity during the ‘Sterilization’ phase**
- **Air removal performance**
- **Drying performance**
- **Cooling performance**

Once a process (program, load) has been developed and tested successfully through a ‘Performance Qualification’ (PQ), we typically consider the load ‘Validated’

Once a process (program/load) is validated…

Will it always perform the same..?

Could some external factors affect the ‘Validated State’

YES

The ‘Usual Suspects’

Typical factors that can affect the ‘Validated State’

- Maintenance activities
- Calibration activities
- Operator activities
- Utilities
- What else?

Typical factors that can affect the 'Validated State'

- Maintenance activities
  - Incorrect or lack of maintenance procedures?
  - Manufacturer trained?
  - OEM parts?
  - Master settings for adjustable devices?
  - Leaks (probe damage?)
- Calibration activities
- Operator activities
- Utilities
- What else?

Typical factors that can affect the 'Validated State'

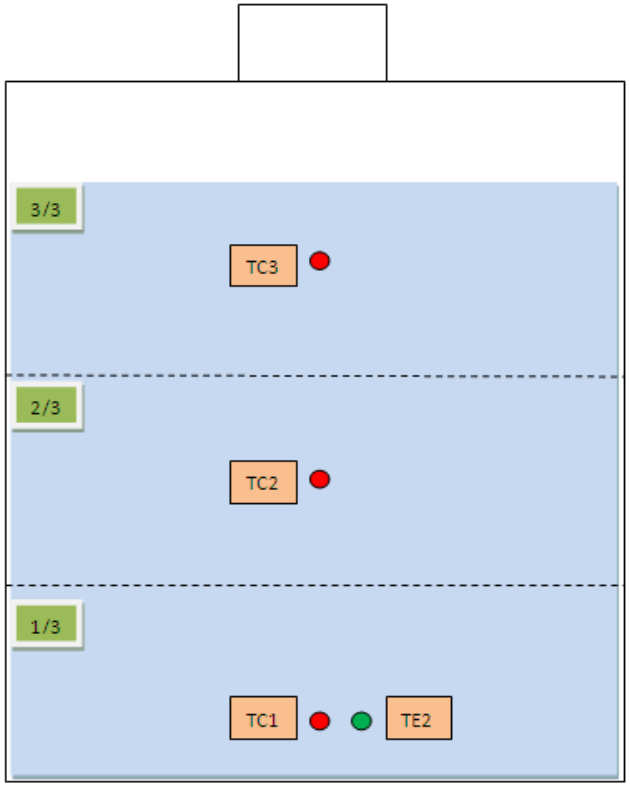
- Maintenance activities
- Calibration activities
  - Correct range for instrument calibration?
  - Correct procedure for instrument calibration?
  - Type and accuracy of test equipment?
  - Adjustment or no-adjustment vs SOP acceptance criteria?
  - Environment?
- Operator activities
- Utilities
- What else?

Typical factors that can affect the 'Validated State'

- Maintenance activities
- Calibration activities
- Operator activities
  - Is there an SOP for the wrapping technique for wrapped items?
  - Are the options on which bag to select for the item, i.e. different brand, different colour?
  - How is the item tapped closed, is there a procedure of the closure technique?
  - Is the orientation and layout of the load as per the validation?
  - Is the chamber hot or cold?
  - What the load staged in a cool area or warm area?
- Utilities
- What else?

CASE STUDY

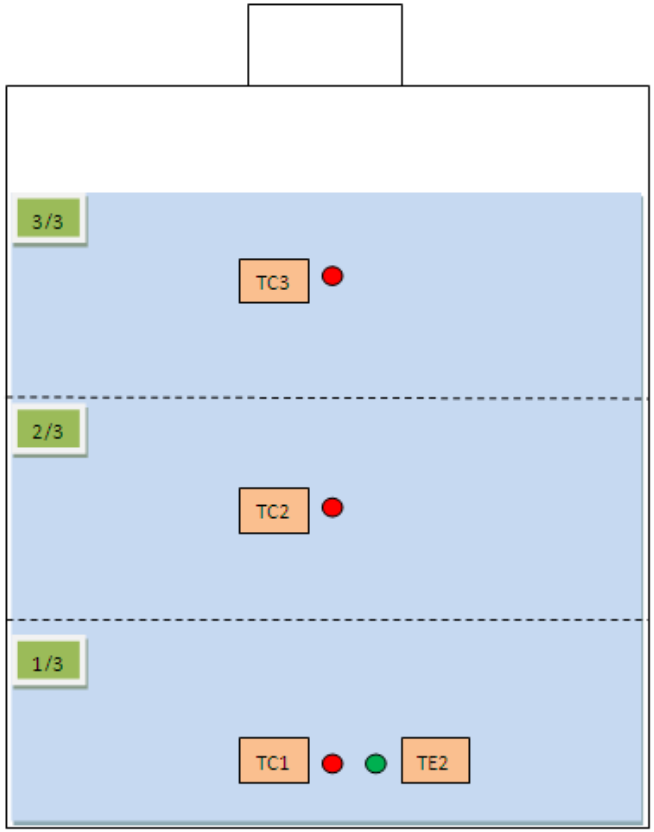
Typical factors that can affect the 'Validated State'



10 lt. Duran bottle

Heating to 120ºC

Product probe placement: Case Study



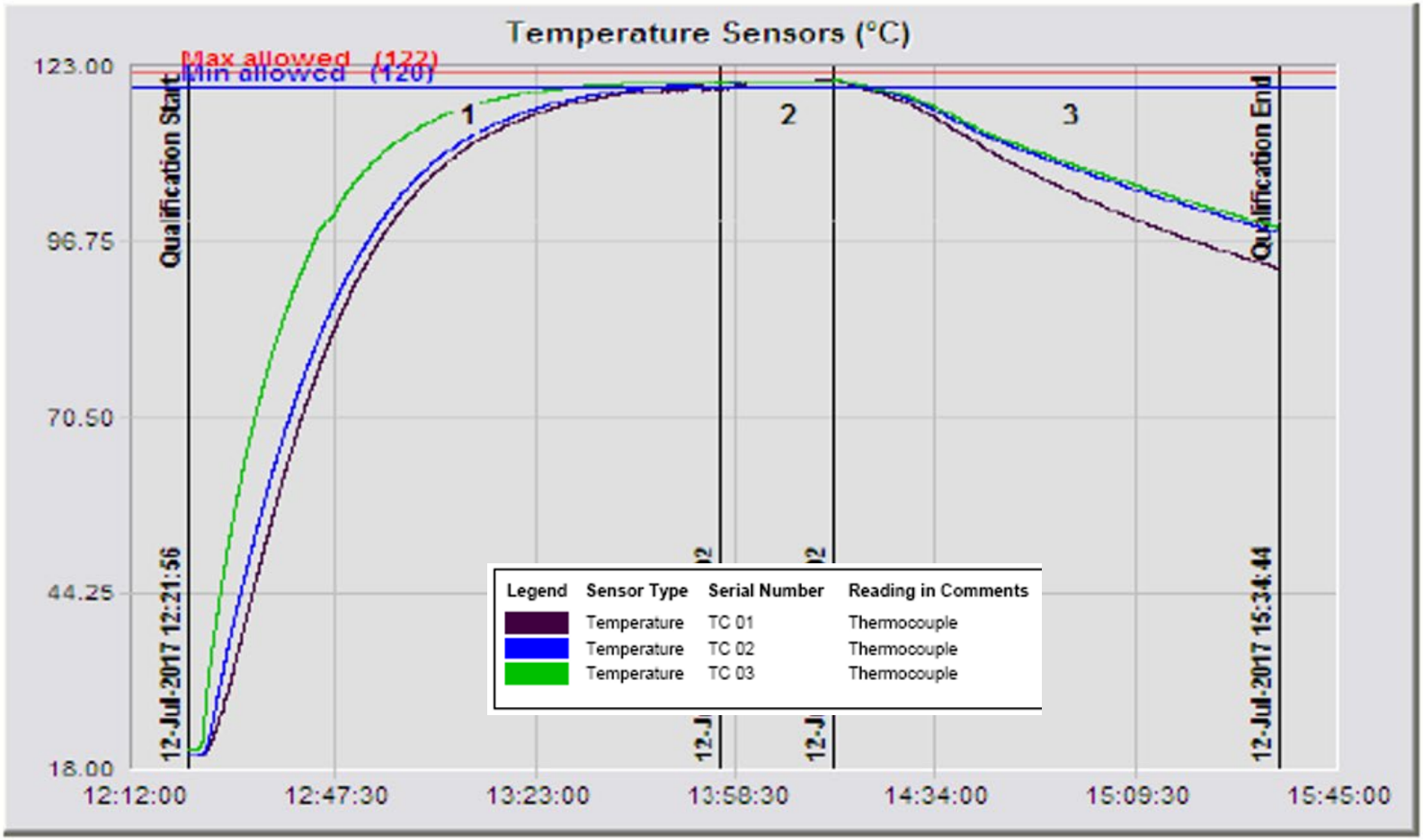
Heating to 120ºC

Fastest Thermocouple:**TC3**

Slower Thermocouple:**TC1**

Δt between faster and slower: **20:16 min**

Product probe placement: Case Study



Heating to 120ºC

Typical factors that can affect the 'Validated State'

- Maintenance activities
- Calibration activities
- Operator activities
- Utilities
  - What is the status of the steam quality, how frequently has this been tested?
  - Has the steam been tested with the load at maximum, i.e. all equipment connected to same header a max demand?
  - Is the steam supply adequately trapped at point of use?
  - Could condensate backup in the plant steam line to the jacket?
  - Vacuum pump water temperature fluctuations?
- What else?

CASE STUDY

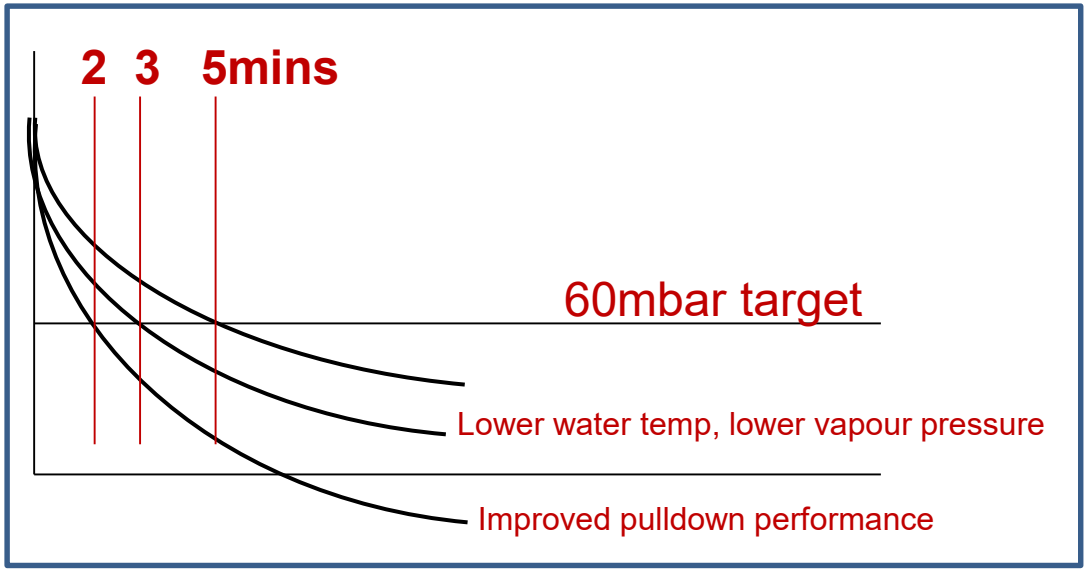
Typical factors that can affect the 'Validated State'

Could system demand affect the quality, flowrate and pressure of the steam at the point of use?

CASE STUDY

Vacuum Pump Performance vs water temperature

A change in water temperature to the vacuum pump will have an affect on vacuum performance and ultimate vacuum achieved



Typical factors that can affect the ‘Validated State’

- Maintenance activities
- Calibration activities
- Operator activities
- Utilities
- What else?

Thank you.