



# Validation



MML



MML



# Validation





Validation is the process of checking if something satisfies a certain criteria





National Hospitals Office Code of Practice for  
Decontamination of Reusable Invasive Medical Devices





EN ISO 15883 part 1,2 & 5 for  
Washer Disinfectors

EN ISO 285 for Steam Sterilizers

EN ISO 17665 part 1 for  
Sterilization of health care products  
Moist heat

EN ISO 14937 for  
Low temperature Sterilizers







## EN ISO 15883 Washer Disinfectors

Part 1 **General requirements, terms, definitions and tests**

Part 2 **Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.**

Part 5 **Test soils and methods for demonstrating cleaning efficacy**



Type One, Single chamber

Type Two, Multi chamber

Types of load to be processed

Instruments, containers, lumen devices, MIS.

Loading carriages for types of loads

Loading equipment Automatic / Manual

Independent monitoring system

Tests required during commissioning / PQ test

Table A.1 — Summary of test programmes for WDs

| Brief description of test | Requirements subclause                       | Test subclause      | Type test | Works test | Operational qualification | Performance qualification | Routine test |
|---------------------------|--|---------------------|-----------|------------|---------------------------|---------------------------|--------------|
| 1 Cleaning efficacy       |  |                     |           |            |                           |                           |              |
| 1.1 Chamber               | 4.2.1.1                                      | 6.10.2              | X         | B          | X                         | B                         | B            |
| 1.2 Load carrier          | 5.1.10                                       | 6.10.2              | X         | B          | X                         | B                         | B            |
| 1.3 Load                  | 4.2.1.1                                      | 6.10.2              | X         | B          | X                         | B                         | X(Q)         |
|                           |  | 6.10.3<br>(visual)  | B         | B          | B                         | X                         | X(D)         |
|                           |  | 6.10.3<br>(Annex C) |           |            | O                         | X                         | O            |
| 2 Thermometric            |  |                     |           |            |                           |                           |              |
| 2.1 Thermal disinfection  |  |                     |           |            |                           |                           |              |
| — Chamber walls           | 4.3.1.2,<br>4.3.1.3,<br>4.3.3.2 and<br>5.9.2 | 6.8.3               | X         | X          | O                         | X                         | O            |
| — Load carrier            | 4.3.1.1,<br>4.3.1.3                          | 6.8.2               | X         | X          | X                         | B                         | O            |







EN ISO 285 for Steam Sterilizers

EN ISO 17665 part 1 for  
Sterilization of health care products Moist heat



Chamber size

Single ended or double ended, left or right door

Cycles 134°, 121°, 115°, Extended drying. etc

Loading carriages for types of loads

Loading equipment Automatic / Manual

Independent monitoring system

Tests required during commissioning / PQ test

Metal load dryness test, etc



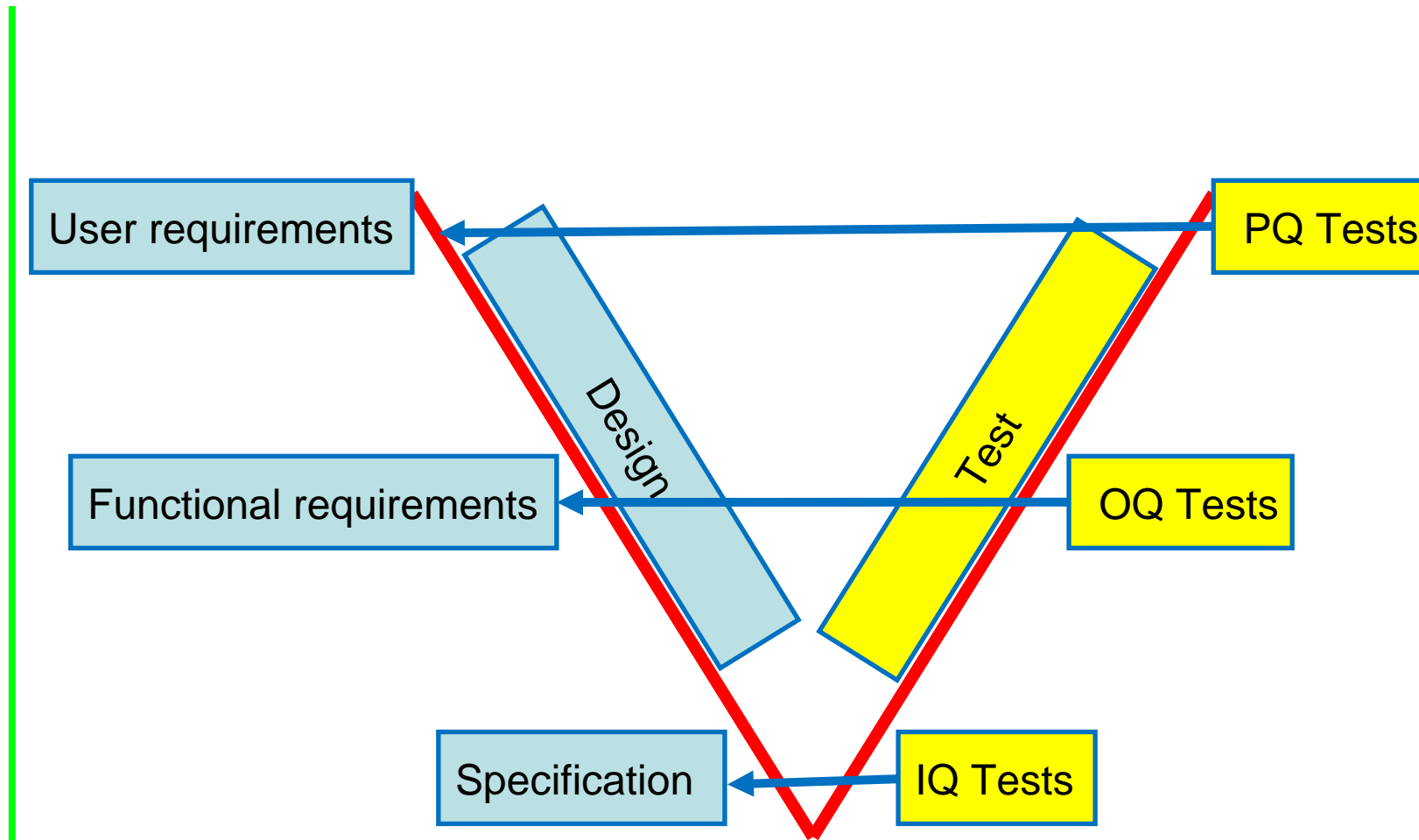
Table E.1 — Suggested tests

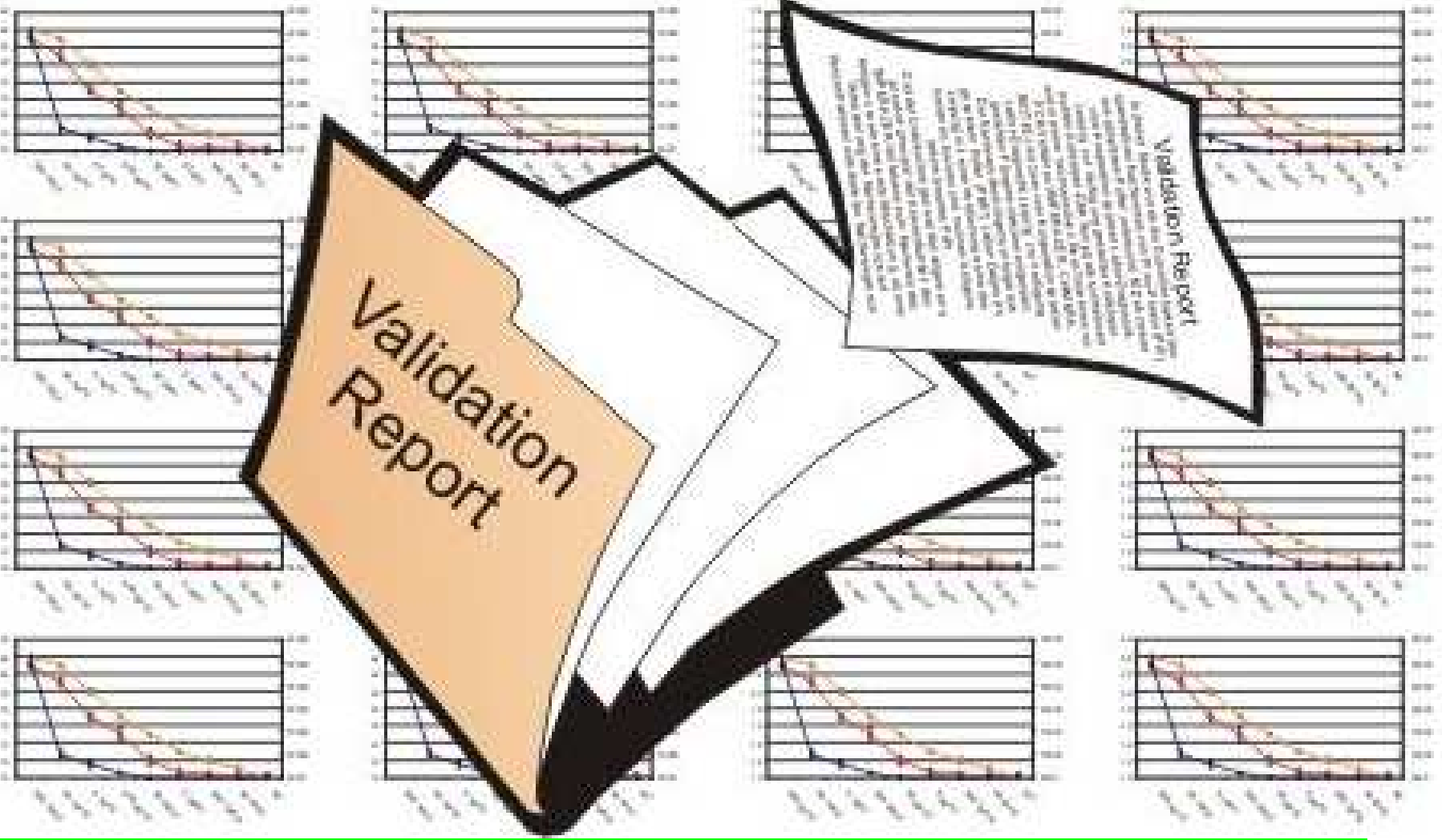
| Test                              | Requirements according to | Test according to | Installation Qualification | Operational Qualification |
|-----------------------------------|---------------------------|-------------------|----------------------------|---------------------------|
| Safety Tests and checks           | See Clause 11             |                   | XX                         | -                         |
| Steam quality tests               |                           |                   |                            |                           |
| - Non-condensable gases           | 13.3.2                    | 22.1              | X                          | X                         |
| - Dryness value                   | 13.3.3                    | 22.2              | X                          | X                         |
| - Superheat                       | 13.3.4                    | 22.3              | X                          | X                         |
| - Contaminants                    | see Table E.2             | *                 | X                          | X                         |
| Thermometric tests                |                           |                   |                            |                           |
| - Small load                      | 8.3.1.2                   | 16.1              | -                          | XX                        |
| - Full load                       | 8.3.1.3                   | 16.2              | -                          | XX                        |
| Microbiological test, rubber load | 8.2                       | 15                | -                          | X                         |
| Bowie and Dick test               | 8.3.2                     | 17                | -                          | XX                        |
| Air leakage flow rate             | 8.3.3                     | 18                | -                          | XX                        |
| Air detector                      |                           |                   |                            |                           |
| - Small load                      | 8.3.4.2                   | 19.2              | -                          | XX                        |
| - Full load                       | 8.3.4.3                   | 19.3              | -                          | XX                        |
| - Function                        | 8.3.4.4                   | 19.4              | -                          | XX                        |

Table E.1 (continued)

| Test  | Requirements according to | Test according to | Installation Qualification | Operational Qualification |
|---|---------------------------|-------------------|----------------------------|---------------------------|
| Load dryness tests  |                           |                   |                            |                           |
| - Small load, textiles  | 8.4.1                     | 20.1              | -                          | X                         |
| - Full load, textiles   | 8.4.2                     | 20.2              | -                          | XX                        |
| - Metal   | 8.4.3                     | 20.3              | -                          | X                         |
| Dynamic pressure test   | 10                        | 23                | -                          | X                         |
| <p>XX tests which are suggested</p> <p>X tests which may be considered</p> <p>- tests which need not be performed during IQ and/or OQ</p> <p><sup>a</sup> Compliance should be tested in accordance with acknowledged analytical methods.</p> |                           |                   |                            |                           |









# Periodic Testing



**Daily**

**Weekly**

**Quarterly**

**Annually**



## **Daily**

**15883-1-Washers 6.10.3**

**EN 285 Sterilizers No specified tests.**

**Tests listed in paragraphs 15-23 may be used in periodic testing**

**DD CEN ISO/TS 17665-2-2009**

**Sterilization of health care products-Moist heat**

**Bowie and Dick test- EN 285 8.3.2 17**





## **Weekly**

**15883-1-Washers No specified tests.**

**EN 285 Sterilizers No specified tests.**

**Tests listed in paragraphs 15-23 may be used in periodic testing**

**DD CEN ISO/TS 17665-2-2009**

**Sterilization of health care products-Moist heat**

**Air detector function test**



# Quarterly

## 15883-1-Washers

**6.10.2 Cleaning efficacy test 1**

**6.8.2 Load temperature test.**

**6.8.4 Temperature tests on tanks/chambers**

**6.8.3 Chamber wall temperature test**

**6.3.1 Cycle start interlock**

**6.3.4 Cycle complete door interlocks**

**6.3.3 Door interlocks on double-ended WDs**

**6.9.1 Chemical dispensed volume**

**6.9.2 Indication of insufficient process chemical for a cycle**

**6.6.1 Verification of calibration**



## **Quarterly**

**EN 285 Sterilizers No specified tests.**

**Tests listed in paragraphs 15-23 may be used in periodic Testing**

**DD CEN ISO/TS 17665-2-2009**

**Sterilization of health care products-Moist heat**

**Air leakage flow rate EN285 8.3.3 18**

**Thermometric test small load EN285 8.3.4.2 19.2**



## **Annually**

**EN 285 Sterilizers No specified tests.**

**Tests listed in paragraphs 15-23 may be used in periodic Testing**

**DD CEN ISO/TS 17665-2-2009**

**Sterilization of health care products-Moist heat**

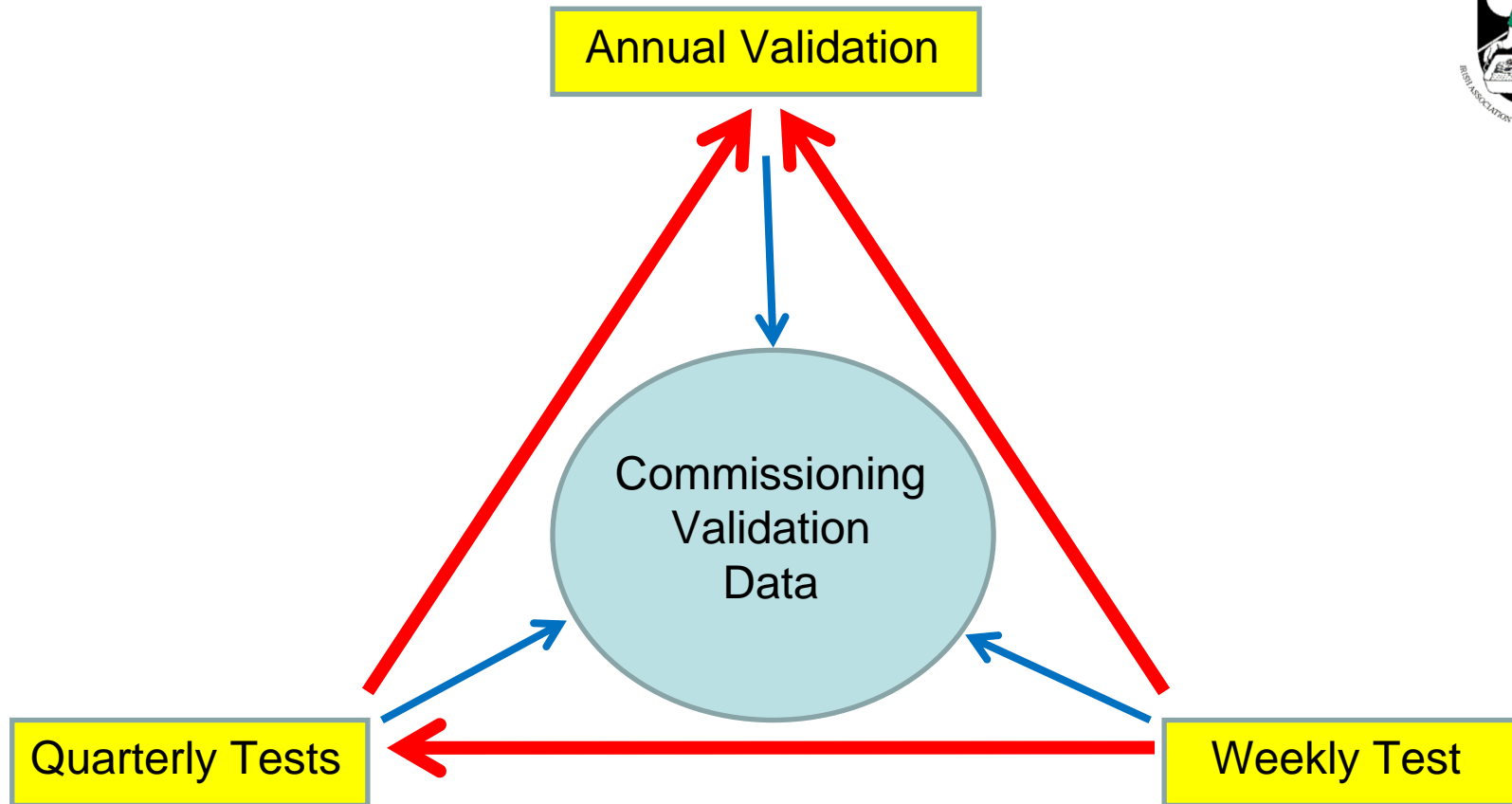
**Steam quality**

**Full load Thermometric test**

**Hollow load**

**Air detector full and small load**

**Product test**





Section 13.4 of the Code of Practice section 3 lists:-

Periodic testing for washer disinfectors as listed in the HTM2030 table 5b page 45

### **Washer disinfectors Daily tests**

1. Automatic control test
2. Check spray arm rotation for free movement
3. Check spray nozzles for blockage
4. Remove and clean strainers and filters



## **Washer disinfectors Weekly tests –**

1. Weekly safety checks
2. Carry out Daily tests
3. Water hardness
4. Water conductivity
5. Cleaning efficacy test by residual soil detection



## **Washer disinfectors Quarterly tests**

1. Weekly safety checks
2. Automatic control test
3. Verification of calibration of WD instruments
4. Thermometric test for thermal disinfection
5. Cleaning efficacy test





Section 19.4 of the Code of Practice lists:-

Periodic testing sterilizers as listed in the HTM2010 table 4 page 45

**Sterilizers Daily test –**

Bowie-Dick test for steam penetration



## **Sterilizers Weekly tests –**

1. Weekly safety checks
2. Vacuum leak test
3. Air detector function test
4. Automatic control test
5. Bowie-Dick test for steam penetration



## **Sterilizers Quarterly tests**

1. Safety checks
2. Vacuum leak test
3. Vacuum leak test  
(temperature and pressure sensors connected)
4. Automatic control test
5. Verification of calibration of sterilizer instruments
6. Thermometric test for a small load
7. Vacuum leak test (sensors removed)
8. Air detector function test
9. Bowie-Dick test for steam penetration



## **UK Guidance Documents**

HBN13 Sterile Service Departments.

HTM 2010 Sterilizers.

HTM 2030 Washer Disinfectors.

HTM 2031 Steam for sterilization.



# Service Level Agreements



**Frequency of the visits**

**Day and time of testing**

**List all the tests to be carried out**

**Action to be taken in the event of a failure**

**If maintenance is to be included a schedule of tasks**

**If parts are to be included list of parts to be replaced**

**Response time to breakdowns**

