



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 (visual)	B	B	B	X	X(D)
		6.10.3 (Annex C)			O	X	O
2 Thermometric							
2.1 Thermal disinfection							
— Chamber walls	4.3.1.2, 4.3.1.3, 4.3.3.2 and 5.9.2	6.8.3	X	X	O	X	O
— Load carrier	4.3.1.1, 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

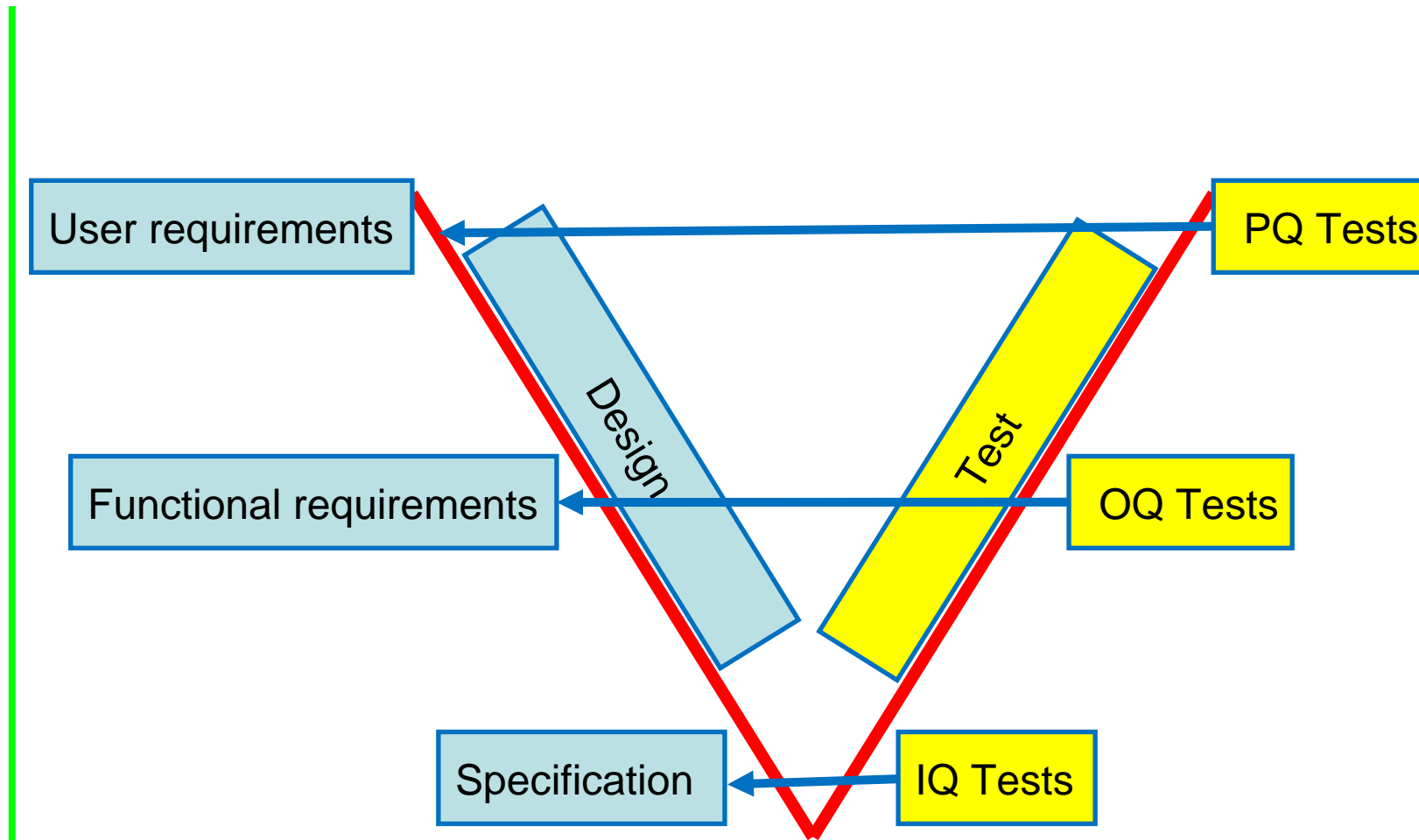
Table E.1 — Suggested tests

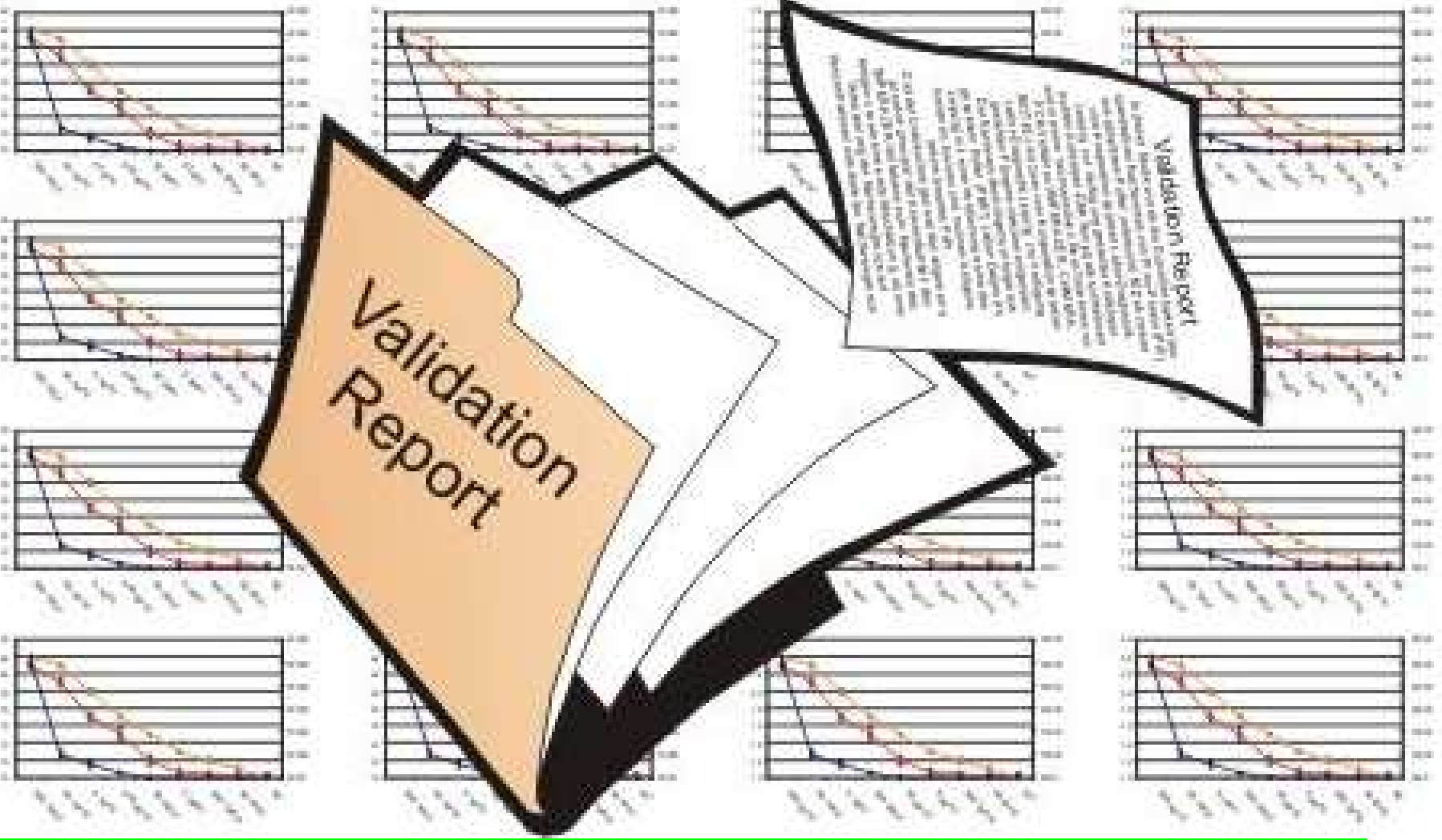
Test	Requirements according to	Test according to	Installation Qualification	Operational Qualification
Safety Tests and checks	See Clause 11		XX	-
Steam quality tests				
- Non-condensable gases	13.3.2	22.1	X	X
- Dryness value	13.3.3	22.2	X	X
- Superheat	13.3.4	22.3	X	X
- Contaminants	see Table E.2	*	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>^a 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

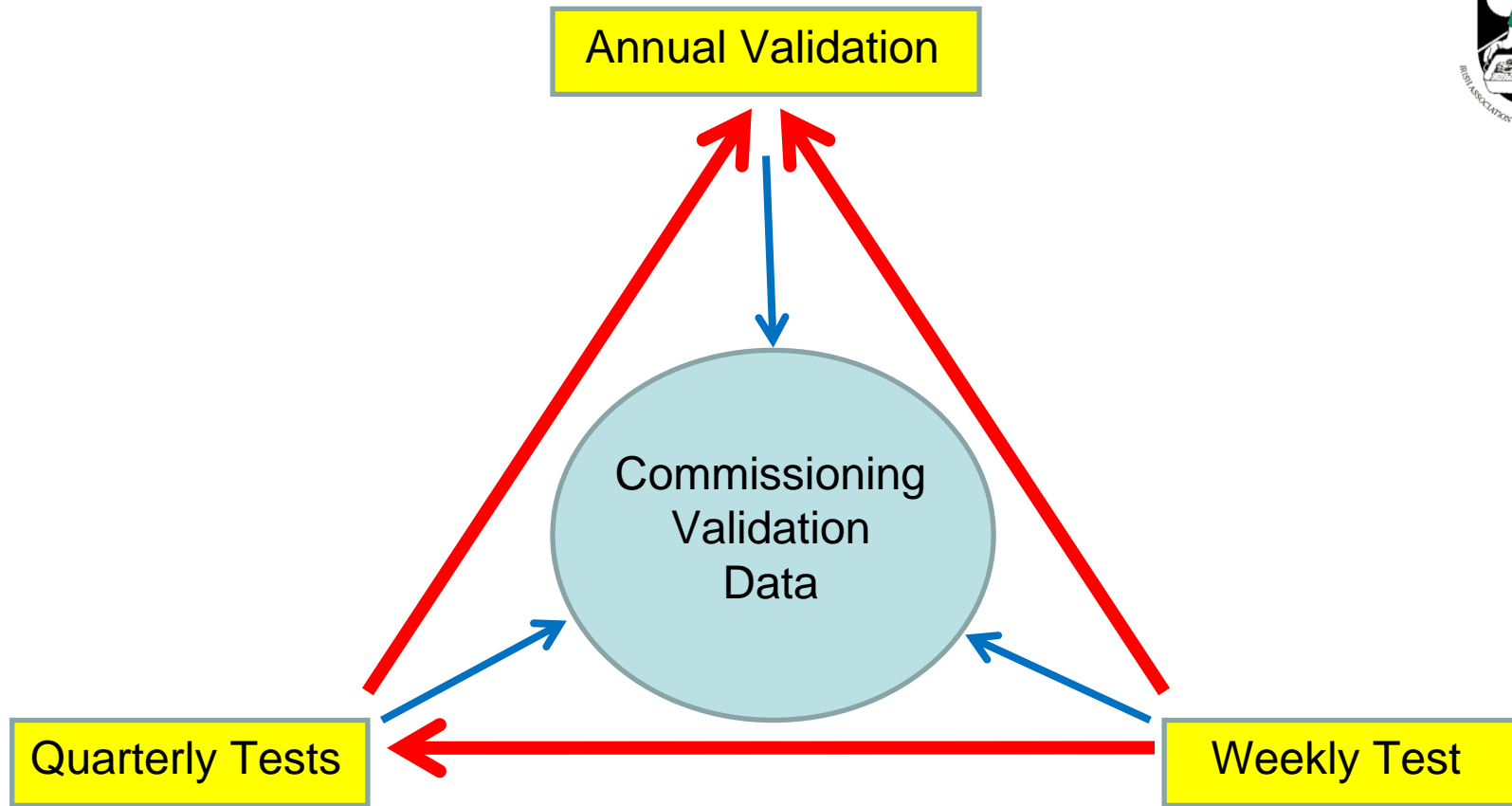
Steam quality

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

