



Equipment Validation

Current guidelines and standards

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Services

Back to basics

- What tests should we perform and how often?
- What standards should we work to?
- What are the current guidelines and standards?

Is the HTM series relevant to us?

- HTM's are internal guidance documents for the NHS
- They predate many of the current standards and acknowledge this stating
“HTM should not be regarded as a substitute for the standards themselves when ascertaining compliance with the EU directives or the UK regulations that implement them”

While long considered to be best practice, the current HTM series is not as relevant as it once was.

HSE Code of practice

- Relevant for all HSE departments
- References EN standards
- Has test schedule from HTM series

EN Standards

- En standards are no longer allowed to be prescriptive.
- They can detail requirements to be met but not prescribe how to meet them.
- For healthcare applications a prescriptive approach would probably be beneficial.
- Test schedules in the standards are described as “recommended” or “suggested.”
- ENs ARE NOT COMPULSARY!

Medical Device Directives

- While Standards are not compulsory, Directives are for manufacturers.
- You are only a manufacturer if you sell products on the open market and are CE marking them.
- Do these directives apply to Hospitals if they are supplying internally?
- Supplying other hospitals as part of HSE/trust or group?
- Should we meet the requirements anyhow?

Medical Device Directives

- Products complying with an EN standard are presumed to meet the requirements of the MDD as detailed in annex ZA of the standard.
- Therefore if you follow the relevant standards you will be compliant with the relevant sections of the MDD's.

Vocabulary and phrases used in standards

- Justify
- Shall
- Recommended
- Suggested
- May be considered
- Optional
- Informative

IS EN ISO 14937- 2000

General requirements for characterisation of a sterilising agent and the development, validation and routine control of a sterilisation process for medical devices.

IS EN ISO 14937-2000

- 9.1 The purpose of validation is to demonstrate that the sterilisation process established in process definition can be delivered effectively and reproducibly to the sterilisation load. Validation consists of a number of identified stages;
- installation qualification (IQ)
- operational qualification (OQ) and
- performance qualification (PQ.)

Routine monitoring and control

- 10.1 The purpose of routine monitoring and control is to demonstrate that the validated and specified process has been delivered to the product.

EN Standards

IS EN 285-2006

- Supersedes EN 285-1996
- Gives details of test methods and requirements for validation.
- Requires records that sterilisers comply with the standard be established, maintained and declared.
- Tests detailed and their methods "...may be used in type tests, works tests, in validation and re-validation tests, or in periodic and routine tests..."
- Gives recommended tests for type and works tests; suggested tests for installation and operational tests are detailed in the appendix.
- For validation and re-validation references ISO 17665

IS EN ISO 17665-1

Sterilization of health care products -moist heat-

- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
(Supersedes EN 554:1994.)
- prEN ISO 17665-2 Guidance on the application of ISO 17665-1

IS EN ISO 17665-1

- Section 10: Routine monitoring and control states that routine monitoring and control SHALL be performed on each operating cycle.
- It gives information on the type of factors to be monitored but does not detail particular tests or test intervals.
- It requires records to be kept in accordance with IS EN ISO 13485 (Medical devices – Quality management systems – Requirements for regulatory purposes.)
- IS EN ISO 17665-2 will detail tests and their schedule

IS EN ISO 17665-1

- Responsibility and authority for meeting the requirements to be specified.
- Requires IQ, OQ, PQ and revalidation
- Validation to be performed to a documented procedure.
- The user/manager would normally be considered responsible for quality and compliance with current standards and best practice in the absence of evidence to the contrary.

IS EN ISO 17665-1

Routine monitoring and control

- Operational Status SHALL be verified by evidence from periodic tests of factors such as (but not limited to) the following.
- A) air leakage into the steriliser chamber:
- B) Quality of saturated steam.....
- C) Automatic control
- D) Steam penetration
- E) Sterilisation process

IS EN ISO 17665-1

Routine monitoring and control

- For saturated steam, the data SHALL include (if applicable):
 - A) sterilisation temperature, chamber pressure and theoretical steam temperature during the plateau period
 - B) Duration of the plateau period.
 - C) The chamber temperature and the chamber pressure for at least each stage of the operating system.
 - D) The results obtained from a process challenge device
 - E) temperatures and or pressures in a process monitoring system, if used as part of process control.
- 12.4.1 Requalification of a sterilisation process shall be carried out for the defined product and specified equipment at defined intervals and after the assessment of any change (see 12.5.) The extent to which requalification is carried out shall be justified.

Steriliser test schedules

Test schedule	prEN 17665-2	HTM 2010	Draft Irish Code
Daily	<ul style="list-style-type: none"> ●Bowie and Dick (S) 	<ul style="list-style-type: none"> ●Bowie and Dick 	<ul style="list-style-type: none"> ●Bowie-Dick
Weekly	<ul style="list-style-type: none"> ●Vacuum leak test (S) ●Air detector function ●Bowie and dick 	<ul style="list-style-type: none"> ●Safety Checks ●Vacuum Leak Test ●Air detector function ●ACT ●Bowie and Dick 	<ul style="list-style-type: none"> ●Safety checks ●Vacuum leak test ●Air detector function test ●ACT ●Bowie-Dick

Steriliser test schedules

Quarterly

prEN 17665-2	HTM 2010	Draft Irish Code
<ul style="list-style-type: none"> • Weekly + • Small load thermometric (7 thermocouples and pressure required from EN 285) 	<ul style="list-style-type: none"> • Weekly + • Vacuum with probes • Verification of calibration • Small load thermometric (3 thermocouples and pressure Required) • Vacuum no probes 	<ul style="list-style-type: none"> • Weekly + • Vacuum • Vacuum with probes • Verification of calibration • Small load thermometric • Vacuum no probes

Steriliser test schedules

Annual tests

prEN 17665-2	HTM 2010	Draft Irish Code
<ul style="list-style-type: none"> •Quarterly + •Steam quality (NCG, Superheat, Dryness and Contaminants) •Air detector <ul style="list-style-type: none"> Small load Large load •Large Thermometric •Hollow load •Product test •Verification of calibration 	<ul style="list-style-type: none"> •Quarterly + •Yearly safety checks •Steam quality (NCG, Superheat and Dryness) (contaminants are in HTM 2031) •Air detector small load •Air detector large load •Large Thermometric •PQ as required 	<ul style="list-style-type: none"> •Quarterly + •Steam quality <ul style="list-style-type: none"> NCG Superheat Dryness •Air detector <ul style="list-style-type: none"> Small load Large load •Large Thermometric •PQ as required

IS EN ISO 15883: Washer-Disinfectors

- Parts 1,2,3 and 5 ratified. Part 4 covering chemical disinfection of Endoscopes still at prEN stage.
- Details are given of test methods and performance requirements. A test program is given in table A.1 in Annex A.
- Annex A is informative and the test program is described as “recommended”

Instrument WD test schedules

Daily Tests

IS EN 15883	HTM 2030	HSE code of Practice
<ul style="list-style-type: none">●Cleaning efficacy by visual inspection (optional ninhydrin)●Spray system (recommended but with no frequency indicated)	<ul style="list-style-type: none">●ACT●Check spray arms and nozzles●Remove and clean strainers and filters.	<ul style="list-style-type: none">●Check spray arms and nozzles●Remove and clean strainers and filters

Instrument Washer test schedules

Weekly tests

IS EN ISO 15883	HTM 2030	HSE Code of practice
● No Tests detailed	<ul style="list-style-type: none">● Weekly safety● Daily tests● Water hardness● Water conductivity (rinse)● Cleaning efficacy by residual soil detection	<ul style="list-style-type: none">● Weekly safety● ACT● Daily tests● Water hardness● Water conductivity and hardness● Cleaning efficacy by residual soil detection

Instrument Washer test schedules

Quarterly tests

IS EN ISO 15883	HTM 2030	HSE
<ul style="list-style-type: none"> ●Cleaning efficacy 1 with soil and 3 protein residue ●Thermometric tests (1 cold and 3 hot with up to 10 probes) ●Door interlock ●Chemical dosing ●Verification of Calibration ●Rate of rise 	<ul style="list-style-type: none"> ● Weekly safety checks ●Cleaning efficacy Chamber wall and load carrier in duplicate, load tested once ●Thermometric test for thermal disinfection 7 probes tested in triplicate ●ACT ●Verification of calibration 	<ul style="list-style-type: none"> ● Weekly safety checks ●Cleaning efficacy ●Thermometric test for thermal disinfection ●ACT ●Verification of calibration

Instrument Washer test schedules

Annual tests

IS EN ISO 15883	HTM 2030	HSE
<ul style="list-style-type: none">• There are no annual tests detailed but the following are PQ tests.• Soil test and protein residue• Chamber wall thermometric• Load dryness• Process residue• Load carrier alignment	<ul style="list-style-type: none">• Yearly safety checks• ACT• Verification of calibration• Water system• Drainage• Doors and door interlock• Fault interlock• Water vapour discharge• Aerosol discharge	<ul style="list-style-type: none">• Yearly safety checks• ACT• Verification of calibration• Water system• Drainage• Doors and door interlock• Fault interlock• Water vapour discharge• Aerosol discharge

Instrument Washer test schedules

Annual tests

IS EN ISO 15883	HTM 2030	HSE
<ul style="list-style-type: none">• The following are optional tests• On fault condition• Door interlock• Water quality• Rinse water• Air quality• Reproducibility• Fault indication	<ul style="list-style-type: none">• Chemical dosing• Load carriers• Air quality• Cleaning efficacy• Over temperature• Thermometric tests• Load dryness• Process residues	<ul style="list-style-type: none">• Chemical dosing• Load carriers• Air quality• Cleaning efficacy• Over temperature• Thermometric tests• Load dryness• Process residues

Summary

- prEN 17665 and HTM 2010 have slightly different test methodologies and it may be possible to mix both
- IS EN ISO 15883 and HTM 2030 have quite different approaches and to meet the testing requirements of both would be excessive
- The HTM series is currently being revised and will reflect the new EN standards more closely if published
- It is important that roles are clearly defined and every stake holder is informed in writing of their responsibility and authority.

ANY QUESTIONS?

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