

## Pharmatherm Validation Specialists

### **PharmaTherm Technical Note: Steam Sterilization 20th May 2014**

#### **HTM 2010 Sterilization: 1994 with drawn in the UK.**

HTM2010 withdrawn and replaced by the document (CFPP) 01-01 in May 2012. Technically, HTM 2010 was archived in November 2011.

#### **Replacement standard (CFPP) 01-01 in May 2012:**

The replacement document for HTM2010 is a Choice Framework for Local Policies and Procedures (CFPP) 01-01. The document covers the entire range of decontamination equipment used in hospital sterile supply units, such as sterilizers, washer/disinfectors and ultrasonic washers. The Choice Framework for Local Policies and Procedures (CFPP) 01-01 does not provide any guidance on laboratory sterilizers.

The Choice Framework for Local Policies and Procedures (CFPP) 01-01 incorporated two standards (Essential Quality Requirements and Best Practice – See Part A of the CFPP).

It should be noted that the (CFPP) 01-01 document relates to England only as Northern Ireland, Scotland and Wales have made provisions for their own standard.

#### **Service Providers:**

Service providers are currently struggling with which standard to apply and the approaches towards autoclave validation: HTM's as previously used for autoclave validation verses the (CFPP) 01-01 standard. Pharmatherm would recommend that the EN 285: 2006 +A2:2009 standard is applied in all cases.

#### **What has changed:**

From an initial review CFPP 01-01: Part C the following test regimes have been updated / changed.

**CFPP 01-01: Part C brings some changes to the validation schedule:**

- Seven temperature sensors rather than three should be used for Porous Load Small and Full load thermometric tests (Ref: EN 285 16.2.3.6)
- A Hollow Load test is now listed on the validation schedule for Porous Load machines (Ref: CFPP 01-01 Part C 2.81)

The use of seven temperature sensors in the Small and Full load thermometric tests test pack was implemented in EN 285 Ref 16.2.3.6. in 2009 and as such all of PharmaTherm's test protocols have reflected this change since 2009.

**PharmaTherm wrote to the IMB 02/02/14:**

PharmaTherm wrote to the HPRA Health Product Regulatory Authority (formerly IMB Irish Medicines Board) for looking for clarification on which standard should be applied for autoclave validation.

PharmaTherm can advise that the auditors have been requesting information relating directly to the CFPP 01-01: Part C during recent audits.

**PharmaTherm would recommend that:**

Pharmaceutical companies based in Ireland subject to HPRA (IMB) audits should review the following with the respective heads of Engineering, Validation and Quality Departments.

- References to the standard HTM 2010 should be removed from all site protocols.
- References in protocols should reference EN 285: 2006 +A2:2009 Sterilization - Steam Sterilizers Large sterilizers.
- A decision to implement the new standard CFPP 01-01: Part C should be made.
- Site SOP's should be reviewed and updated to reflect the changes to the current standards in place.

**How do we get a copy CFPP 01-01: Part C:**

Please contact us directly for a copy of the new standard CFPP 01-01: Part C

Alternatively log onto the web site to down load.

Please Contact PharmaTherm for further validation advice or quotation however large or small the project maybe. We aim to provide a competitive validation service. Please 'don't delay and contact PharmaTherm today' email: [info@pharmatherm.ie](mailto:info@pharmatherm.ie)

See the Pharmatherm website please log onto [www.pharmatherm.ie](http://www.pharmatherm.ie)



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