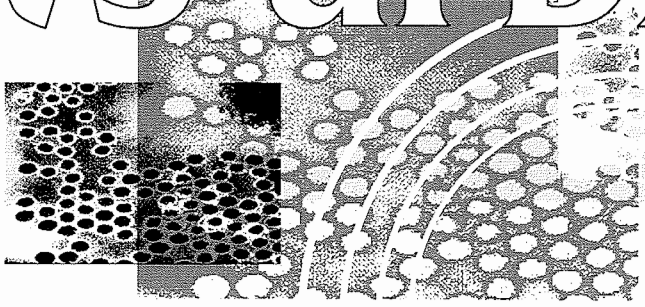
NEWS-UPDATE



What's New in Standardisation

EN 285:2006

Ernst Dennhöfer, Cologne

The second edition of EN 285 was unanimously adopted when put to the final vote. More than 300 amendments had been made to the standard. The current version supersedes EN 285:1996 and has a transition period of 30 months. Within this period of time manufacturers can opt to use either the previous or the amended version. The new version of the standard gives the steriliser manufacturers more responsibilities within the framework of the existing legal regulations than has been the case hitherto.

EN 285 stipulates requirements and associated tests for large steam sterilisers. Hitherto, EN 285 required type and factory tests, however, the (European) directive concerning medical devices stipulates that type tests be carried out only in certain cases. Therefore, as per a provision of the European Commission, EN 285 may no longer advocate type testing. Nor does EN 285 contain hardly any requirements regarding the composition of a steriliser, in particular relating to specifications and test methods in respect of reliability, batch time, operating materials' consumption and service life of the steriliser.

The requirements set out in EN 285 deal with the load to be sterilised. Since the load actually used at the time of process development is generally no longer available, the standard specifies test loads. These test loads are representative of the majority of loads encountered in the healthcare setting. However, extra test loads that are not described in EN 285 are needed for heavy objects with long and/or narrow lumens.

A steriliser that complies with EN 285 must automatically control the sterilisation process and automatically detect and signal certain faults; furthermore, it must also ensure that deviations from the process parameters defined by the manufacturers are not repeated. An automatic air detector can be used to detect such faults.

The Bowie-Dick test continues to be valid. To date, a hold time of 3.5 minutes at 134 °C has been prescribed. Now the temperature-time combination specified as per prEN ISO 11140-3 by its manufacturer is valid for the indicator. Hence, there is no longer such a thing as a standard Bowie-Dick test and the steriliser manufacturer must stipulate a suitable test system.

The tests with biological indicators using a partial and full load of textiles are discontinued without any replacement. It is also planned to replace the biological-indicator tests in the rubber load with the hollow-device tests described in EN 867-5. It is expected that the corresponding draft will be approved in a few weeks' time. Once this draft has been adopted, the amendment will be incorporated into the current version of EN 285.

One of the problems arising when implementing EN 285:1996 resides in the fact that air pockets are formed at locations in the test pack which cannot be exactly predicted. Therefore the requirements governing the temperature measuring chain have been tightened and in future 7 sensors are to be used for thermoelectric measurements as opposed to the current three. Likewise, more stringent requirements are being addressed to the composition of the standard test pack; for sterilisers with a capacity of 1 StU a small 4 kg test pack rather than the 7 kg standard test pack is used.

Moreover, the "theoretic" temperature of the saturated steam calculated from the chamber pressure must be weighted like a measured temperature. Saturated steam has the same temperature throughout the chamber. To date, the temperature values prevailing in the load were compared with the lowest temperature in the chamber. Traditionally, it was always assumed that this lowest temperature was to be measured in the flow pipe. It was by all means possible that a low temperature was not detected within an air pocket since the temperature of the condensate at the beginning of the plateau time was also lower than the temperate in the chamber. In future the manufacturer must specify a reference measuring point at which the same temperature will prevail as in the chamber.

The amendments to EN 285 have also implications for process validation because in general the tests set out in EN 285 are carried out as part of operational qualification (OQ), if the manufacturer declares that the steriliser meets the requirements enshrined in EN 285.

The standard will be published in the languages of the different CEN member states. ✦