Recommendations by the Quality Task Group (98)

Recommendations for validation preparation of steam sterilization processes in large sterilizers

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Introduction

In Germany, validation of reprocessing processes has been an established practice for several years now. When process validation was first introduced there was a certain anxiety prior to testing but any such concerns have now been allayed thanks to the recommendations published on this topic by the German Society of Sterile Supply (DGSV). These recommendations are now being updated to take account of new knowledge, legal provisions and normative amendments.

Legal aspects

➜ **VALIDATED STERILIZATION PROCESSES** are stipulated in the German Medical Devices Operator Ordinance (MPBetreibV) .

➜ **THE KRINKO-BFARM RECOMMENDATION** has legal character because of its being references in the MPBetreibV .

In Germany, the legal basis stipulating the use of ➜ **VALIDATED STERILIZATION PROCESSES** is set out in Section 4 of the German Medical Devices Operator Ordinance (MPBetreibV) [1]. In addition to calling for validated processes, the "legal character" of the ➜ **KRINKO/BFARM RECOMMENDATION** [2] is reflected in the following wording: "Reprocessing is deemed to have been properly carried out pursuant to Para. 1(1) if the hygiene requirements for processing medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO) and the Federal Institute for Drugs and Medical Devices (BfArM), have been observed".

Standard EN ISO 17665 [3] defines validation and its purpose as follows: "a documented procedure for furnishing, recording and interpreting the requisite results, in order to demonstrate that a process continually meets the given specifications".

Attention is drawn to that in the introduction to the standard.

"EN ISO 17665 describes the requirements which when met will lead to a moist heat sterilization process endowed with adequate microbicidal activity insofar as that process is intended for sterilization of medical devices. Besides, compliance with the requirements ensures that the (microbicidal) activity is both effective and reproducible, thus fostering well-justified confidence that the probability of a viable microorganism being present on a product after sterilization is low".

➜ **THE MINIMUM REQUIREMENTS** to be met by steam sterilizers are specified in EN 13060 or EN 285, respectively.

The ➜ **MINIMUM REQUIREMENTS** to be met by steam sterilizers are specified for small sterilizers (chamber size less than 1 StU or < 60 l) in the standard EN 13060 [4]and for large sterilizers (chamber size more than 1 StU or > 60 l) in the standard EN 285 [5].

Reference load

➜ **A REFERENCE LOAD MUST** make the highest demands on the sterilization process (worst-case load).

One or several reference load(s) must be assembled on the basis of the list of medical devices used. A ➜ **REFERENCE LOAD** consists of medical devices which, in terms of air removal, steam penetration and drying, make the highest demands on the sterilization process (worst-case load).

- Hollow items
- Items with poorly accessible areas
- Heavy items
- Mixed materials

– Synthetic materials
– Porous items

Hollow items
These include: For example, tubes, cannulas, tubular instruments, devices and equipment parts with open or dead-end lumens.

Risk
They have surfaces that are poorly accessible to the steam or lumens from which it is difficult to remove the air.

Items with poorly accessible areas
These include: Medical devices (MDs) which, because of their design, have poorly accessible areas or areas designed to accommodate protective caps.

Risk
There are surfaces to which the steam has difficulty gaining access or cannot at all access.

Heavy items
These include: Heavy trays and/or heavy individual instruments.

Risk
There is a high probability of considerable condensate formation due to the composition and design of these items. During the sterilization process this condensate does not remain at the place where it arises but, responding to gravity, flows downwards. Effective sterilization cannot be assured at those sites where there is widespread accumulation of condensate. Besides, there may be problems with drying.

Mixed materials
These include: Medical devices with a synthetic coating e.g. cannulated screwdrivers.

Risk
Condensate formation on the inner metallic cannulation surfaces. However, because of the insulation effect of the synthetic handle no further thermal energy can be supplied to evaporate the condensate.
As in the case of heavy items, the use of mixed materials can also lead to increased condensate formation. Synthetic materials generate a lot of condensate but absorb little thermal energy as needed for the drying process.

Synthetic materials
These include: For example, synthetic trays, tubes, silicone mats

Risk
As in the case of mixed materials, these can give rise to accumulation of condensate precipitate, thus compromising the sterilization and drying results.

Porous items
These include: For example, textiles, swabs, compresses, dressings, etc.

Risk
Medical devices containing natural fibres can become overheated during the sterilization process due to thermodynamic compression (see ISO/TS 17665-2, Section 5.2 Microbicidal activity). Therefore items made of natural fibres must be conditioned prior to sterilization to ensure that their relative humidity is more than 40%.

Part 2 will be published in issue no. 5/2016

Components of a reference load

References

1 German Medical Devices Operator Ordinance MPBetreibV, last changed 11/12/14. BGBl I S. 2010
2 RKI/BfArM Recommendation: Hygiene requirements for processing medical devices BGBl 2012. 55: 1244-1310
3 EN ISO 17665-1; -2: Sterilization of health care products – Moist heat: Requirements for the development, validation and routine control of a sterilization process for medical devices
4 EN 13060:2015-03 Small steam sterilizers
5 EN 285:2016-05 Sterilization – Steam sterilizers – Large sterilizers