Recommendations by the Quality Task Group (99)

Recommendations for validation preparation of steam sterilization processes in large sterilizers – Part 2

Authors: T. Appel, D. Diedrich, S. Eberhardt, B. Früh, M. Kamer, S. Krüger, M. Schick-Leisten, E. Schmidt, T. Schwibbe, K. Wiese
E-mail: qualitaet@dgsv-ev.de

Sterile barrier system

Each sterile barrier system used must be taken into account at the time of validation of the steam sterilization processes. Mixed loads are assembled to create the reference loads and these include the entire range of ➜ **STERILE BARRIER SYSTEMS** used. In addition, the packaging processes must be validated separately.

➜ **ALL STERILE BARRIER SYSTEMS USED** must be included in the reference load.

These include

The packaging includes foil/paper packaging, containers, non-woven packaging. The packaging system must be specified for the MDs and must comply with ISO 11607-1 and ISO 11607-2 [1] (see ISO/TS 17665-1 Section 7.2).

Risk

These ➜ **PACKAGING SYSTEMS** have specific properties to be borne in mind when testing:

- Containers – additional weight/condensate
- Foil/paper and non-woven packaging – porous items – risk of overheating
- Foil/paper and non-woven packaging – no thermal capacity to promote condensate evaporation.
- All packaging types – steam penetration

➜ **SPECIFIC PROPERTIES OF THE PACKAGING SYSTEMS** have to be borne in mind when testing.

Use of loan trays

Before loan trays are reprocessed a corresponding tray already included in the scope of validation must be identified to ensure that the loan tray, too, can be reprocessed using a validated process. If the loan tray/system makes higher demands on the sterilization process than the trays included in the reference load assembled annually, this ➜ **LOAN TRAY/SYSTEM** must be ordered specifically for the purpose of validation and then accordingly subjected to validation.

Risk

Loan trays/systems are often very complex and cannot always be represented by the respective institution's reference load.

➜ **LOAN TRAYS/SYSTEMS** must be ordered specifically for the purpose of validation in certain cases.

"Shortfalls" concept

Many RUMEDs have ➜ **MUTUAL ARRANGEMENTS** with other reprocessing departments to cover any shortfalls. But there may be major differences in the sets as well as the sterile barrier systems used by the two partners, and that must be taken into consideration during validation.
All discrepant issues between the two RUMEDs must be noted and borne in mind for validation.

➜ **IF MUTUAL ARRANGEMENTS** exist to cover shortfalls the sets as well as the sterile barrier systems of the partner department must be taken into consideration during validation.

Steam and water quality

The water used for steam generation must be free of impurities. The acceptance criteria governing the feed water constituents are regulated in standard EN 285 [2].

Apart from steam generation, during which dirt can get into the steam because of the feed water, the material components used to convey the steam into the sterilizer chamber may also be the source of problems when generating pure steam. The chamber steam constituents can be determined by means of ➜ **CONDENSATE ANALYSIS**; the acceptance criteria are also set out in EN 285.

Validation

Based on EN ISO 17665, validation comprises the following three phases:

1. Installation qualification (IQ)
Documentary evidence that the sterilizer has been built and installed to specification, and that all supporting services (i.e. utilities such as electricity, water, and steam) are available and connected properly.

2. Operational qualification (OQ)
Documentary evidence that the installed equipment operates within predetermined limits when used in accordance with its operational procedures.

3. Performance qualification (PQ).
Documentary evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby meets its specification.

Checklist

Below is a template for a checklist that can be used prior to validation. This is a useful orientational guide to the procedures involved and can be modified to suit the individual circumstances. ■

➜ **CONDENSATE ANALYSIS** can be used to determine the chamber steam constituents.

Phases of validation

References

1 EN ISO 11607-1:2014-11 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
2 EN 285:2016-05 Sterilization – Steam sterilizers – Large sterilizers

What	Definition	Status	Comment
Arrange validation date with the validation engineer	– Clarify any unresolved issues – Changes arising over previous year		
Reference load	– Defined – Notified to/requested from clients (OR)		
Loan instruments	Noted		
Shortfalls concept with respect to other RUMEDs	Noted		
Sterile barrier system	– Paper/foil pouch – Non-woven – Container		
Programmes			
Test/inspection parameters (Bowie & Dick, etc.)			
Routine checks implemented			
Servicing	Implemented		
Water analysis as per EN 285			
Preliminary briefing on validation day	– Scheduling – What changes have been made to reference load and why (e.g. new MDs with higher demands on process)?		
Final briefing	Irregularities in the process		
Release of validation report			