

Recommendations by the Quality Task Group (43) Recommendations for Validation of Steam Sterilisation Processes in Large Sterilisers

The topic of process validation was addressed in three editions of *Central Service* in 1999. Current everyday practices require that this information now be updated. While the earlier articles still pondered whether "validation" was at all necessary and why equipment was not delivered already in a "validated" state, such issues are now no longer raised. In the meantime there have been several publications that have dealt with the practical implementation of process validation. Hence there is no need to "reinvent" validation. Rather, what is given here is a summarised presentation of the most important aspects. With the kind permission of Spectaris* we have based this article on the guide published by that association.

Definition

Validation serves to furnish documented proof of the ongoing effectiveness of the sterilisation process under the operating conditions prevailing at the installation site, using the sterile items encountered in routine operation in their respective packaging and with the reference loads used.

General Remarks on Validation

The principle elements consist of installation qualification, operational qualification and performance qualification. In the standard DIN 58946 T6 installation qualification and operational qualification are subsumed under the term "commissioning" and performance qualification is designated as "performance testing".

INSTALLATION QUALIFICATION provides information on the composition of the equipment to be investigated (steriliser).

OPERATIONAL QUALIFICATION furnishes proof that the process is, in principle, capable of carrying out sterilisation. This proof is obtained by running a standardised load as per DIN EN 285.

PERFORMANCE QUALIFICATION furnishes proof that the defined sterilisation conditions are being continually assured throughout for the actual device.

Practical Sequence of Events for Validation

Before embarking on the project of validation, the relevant requirements stipulated in legislative acts, guidelines and standards must be checked and observed.

In view of the manifold aspects and requirements to be borne in mind, formulating an → **IMPLEMENTATION CONCEPT** has proved useful. In this respect, it is advisable to hold a planning discussion on site with the manufacturer's validation expert. Apart from the validation expert, the following departments should participate in this discussion: CSSD management, OR, Engineering Department and possibly the Infection Control Team.

The following points must at least be explained:

- Implementation schedule (routine operation)
- Sterilisation programmes required (costs and operational safety)
- Minimum technical requirements for the equipment
- Operating materials (steam quality)

* Deutscher Industrieverband für optische, medizinische und mechatronische Technologie e.V., Fachbereich Großsterilisation

What is the role of validation in steam sterilisation processes?

Principle elements of validation

Installation qualification

Operational qualification

Performance qualification

→ **AN IMPLEMENTATION CONCEPT** should be formulated in a planning discussion.

Minimum technical requirements

- Quality assurance measures (standard operating procedures)
- Specification of configurations to be tested (reference loads)

The quality assurance measures include, inter alia:

- Standard operating procedures

As preparation for performance qualification, the configurations required for everyday operations must be determined, assigned to the respective programme and documented. This documentation must also entail designation of the devices to be sterilised so that they can be identified. In addition, the → **MANUFACTURER'S INSTRUCTIONS** indicating how such items must or can be sterilised, are needed.

→ **MANUFACTURER'S SPECIFICATIONS** for sterilisation of medical devices have to be obtained.

Implementation

Implementation for installation qualification, operational qualification and performance qualification. A member of the CSSD management must be present during performance qualification, which is carried out by a validation expert.

Having carried out testing, the process(es) (programmes) must be evaluated in accordance with the following criteria:

- Process reproducibility
- Occupational safety
- Sterilisation effect

This assessment of the processes must be → **DOCUMENTED** in the validation file, and should comprise:

→ **WITHOUT THE RELEVANT DOCUMENTATION** validation has not been carried out!!!

- Packing lists for the packing units for the respective reference load with release for routine sterilisation
- Description of the configurations tested
- List of all processes tested, while specifying all process parameters
- Record of measurement results (original measurements)
- Evaluation of biological indicators (laboratory reports)
- Dryness results for all packaging checked
- Evaluation of the measurement results (inter alia, temperature, hold time, pressure)
- Evaluation of measurements results
- Summarised assessment and release for routine operation
- The results of additional tests, e.g. of the steam composition

Revalidation

A decision to carry out → **REVALIDATION** can be taken either on the basis of the data collected at the time of validation as per the specified period of time or because of any essential changes that have taken place. If no major changes have been made, DIN 58946 T6 recommends that requalification be carried out on an annual basis. ♦

→ **ANNUAL REVALIDATION** is recommended.