Dear *Central Service* Readers,

The Quality Task Group (AKQ) issued a total of 126 recommendations between 1998 and 2022. While some of these recommendations continue to be valid, others are no longer fully applicable due to new developments in science, regulations or standards.

So far, all recommendations are available on the website of the German Society of Sterile Supply (DGSV) and perhaps it is not always easy for the reader to evaluate the content of older recommendations.

The Quality Task Group has therefore begun revising the recommendations. Topics that are no longer of relevance will gradually be placed in an archive, so that they can still be consulted for research purposes but will be clearly separated from currently valid recommendations.

If you have suggestions about the hitherto recommendations or would like to propose new topics, please email us anytime at **qualitaet@dgsv-ev.de.**

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Recommendation by the Quality Task Group (43:2023)

Validation of steam sterilization processes in large sterilizers

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This recommendation, which is kept intentionally brief, sets out the most important points for preparation and conduct of process validation that must be documented later in the validation report.

Defintion

Validation serves as **DOCUMENTED PROOF** of the consistent effectiveness of the sterilization process.

Validation serves as **DOCUMENTED PROOF** of the consistent effectiveness of the sterilization process under the operating conditions prevailing at the installation site with the supplies to be sterilized in routine operation in the respective packaging with the loading patterns used.

General remarks on validation

The validation comprises the **MAIN ELEMENTS...**

INSTALLATION QUALIFICATION,

OPERATIONAL QUALIFICATION,

PERFORMANCE QUALIFICATION.

The **MAIN ELEMENTS** comprise installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ).

- **INSTALLATION QUALIFICATION** makes a statement on the condition of the piece of equipment to be tested (sterilizer).
- **OPERATIONAL QUALIFICATION** provides evidence that the process is, in principle, able to sterilize. That evidence is furnished using a standardized load in accordance with DIN EN 285.
- **PERFORMANCE QUALIFICATION** provides evidence that the defined sterilization conditions are consistently achieved throughout the actual product to be sterilized.

Only **QUALIFIED VALIDATION ENGINEERS** may be appointed.

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Preparation for validation

Before starting the validation process, the applicable legal, regulatory and normative requirements must be verified and compliance with them assured.

A **CONCEPT FOR CONDUCT** has proved to be of use.

Due to the manifold provisions and requirements to be taken into account, compilation of a **CONCEPT FOR CONDUCT** has proved to be of use. This includes, in particular, a planning meeting on site with the validation engineer. In addition to the validation engineer, representative(s) of the Reprocessing Unit for Medical Devices (RUMED) management, of the engineering department and, possibly, of the infection control team should attend that meeting.

Below are examples of the points that must, at least, be addressed:

- Schedule for conduct of validation (routine operation)
- Sterilization programmes required (costs and operational safety)
- Minimum technical requirements for equipment
- Operating media (steam quality)
- Quality assurance measures (standard operating procedures, training certificates)
- Specification of the test configurations (reference loads)

In preparation for performance qualification, the worst-case configurations for routine operation must be determined, assigned to the appropriate programme and documented. This documentation also includes a designation for identification of the supplies to be sterilized. In addition, the **MANUFACTURER'S INSTRUCTIONS** for sterilizing these supplies are needed.

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Tips on establishing the worst-case configuration

The issue is about ensuring steam penetration, simultaneous achievement of the sterilization temperature and drying under the most demanding conditions related to the following:

- Narrowest lumens
- Longest lumens
- Trays with the heaviest weight
- Large number of plastic materials in trays (e.g. plastic trays and devices)
- Chamber load with the heaviest weight
- Individual instruments with the heaviest weight
- All sterilization barrier systems in use (including container types)
- Possibly, also loaned instruments

Conduct

A member of the **RUMED MANAGEMENT** must be present during performance qualification, which is conducted by the validation engineer.

The **RUMED MANAGEMENT** must be present.

Following conduct of testing, the process(es)/programmes must be evaluated using, inter alia, the following criteria:

- Reproducibility of the processes
- Process outcome as per DIN EN285 and DIN EN ISO 17665

The above process evaluation must be set out in **DOCUMENTATION** (validation report). The following documents, inter alia, must be archived:

The evaluation must be set out in **DOCUMENTATION**.

- Details of the equipment tested (type, servicing, etc.)
- Description of the test configurations, including photographic documentation, sensor positioning
- Recordings of the test processes, with all process parameters (batch protocol)
- Recordings of the measurement results (sensor values)
- Assessment and evaluation of the measurement results (including temperature, hold time, pressure)
- If objects/instruments have been inoculated – Assessment of biological indicators (laboratory reports)
- Drying results of all sterile supplies/sets tested
- The results of additional tests, e.g. steam composition
- Summary evaluation and release for routine operation, action if objections: measures to be taken

The **VALIDATION REPORT** must be checked and signed by the RUMED management.

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Performance requalification

The decision to conduct **PEFRORMANCE REQUALIFICATION** can be taken on the basis of the data collected in the validation report, after a specified period of time, or following significant changes (see DIN EN ISO 17665, 12.5), for example:

The decision to conduct **PEFRORMANCE REQUALIFICATION** has to be taken.

- Changes to parts of the sterilizer that impact the process
- Introduction of new sterilization barrier systems
- Changes to the operating media (water, steam, etc.)
- Changes to the loading configuration

If no significant changes have been made, DIN EN ISO 17665 recommends that performance requalification be conducted annually.

References

1 EN ISO 17665-1:2006: Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices; Beuth Verlag GmbH, 2006.

2 Deutsche Gesellschaft für Krankenhaushygiene e.V. (DGKH): Empfehlung für die Validierung & Routineüberwachung von Sterilisationsprozessen mit Sattdampf für Medizinprodukte; 2009.

3 EN 285: Sterilization – Steam sterilizers – Large sterilizers ; German version EN 285:2015+A1:2021.

4 DIN 58946-7 Sterilization – Steam sterilizers – Part 7: Edificial preconditions, requirements for the services and the operation of steam sterilizers used in health care facilities.