WFHSS ÖGSV

Sterile Supply Specialist Training Course Level II

TESTING, VALIDATION AND ROUTINE CONTROL OF DECONTAMINATION PROCESSES FOR MEDICAL DEVICES

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2008

Adapted and approved by the wfhss education group (2013)

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Testing, Validation and Routine Control of Decontamination Processes for Medical Devices

1 Foreword

WFHSS Recommendation: Validation of Decontamination Processes

Aside from the requirement to have a quality system, validation of decontamination processes is also mentioned as an essential part of any applicable norm. The ISO-EN definition of validation states:

"Documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specification".

A complete initial apparatus validation including Installation Qualification ("Process of obtaining and documenting evidence that the equipment has been provided and installed in accordance with its specification"), Operational Qualification ("Process of obtaining and documenting evidence that the installed equipment operates within predetermined limits when used in accordance with its standard operational procedures") and Performance Qualification ("Process of obtaining and documenting evidence that the equipment, is installed and operated in accordance with standard operational procedures, consistently performing in accordance with predetermined criteria and thereby yields product meeting its specification") ensures not only that a medical device reprocessor is functioning to the predetermined specifications but also ensures consistency for processes. Requalification ("repetition of part of validation for the purpose of confirming the continued acceptability, of a specified process") in combination with the necessary routine controls assures that the same certainty is maintained if the predetermined process parameters are met within the specified margins. Sterility then can be guaranteed.

Validation of these processes is a critical part of the quality system applied in the department.

This ensures that by monitoring and documenting the steps of the decontamination process, a good qualitative end product is consistently delivered. If all conditions are met, a periodic audit of the quality system, in combination with requalification, makes parametric release of the load possible. Parametric release for steam sterilization implies at least the control of all relevant physical parameters of a process, in combination with periodic vacuum leakage test and daily Bowie-Dick test.

Note: In the event of a non-conformance at any stage of the decontamination process, a risk assessment must be conducted ensuring control measures are identified, established and addressed immediately.

For the central sterilization department, this means a step towards quality release of medical devices reducing the number of procedures with little or no added value, which originate from the past and moreover can create a false sense of safety. Traditions are being replaced by objective physical measurements that are undeniable and that give certainty within the limits of technology. The direct measurement of physical parameters is far more accurate than conducting this through a chemical or biological detour.

Validation makes it possible to found "sterilization" scientific. This is essential if we want to establish decontamination as a discipline. By validation, decontamination may not just evolve into "industrialization" of its production but also to evidence based practice.

Besides validation, a regular calibration of measuring devices remains a prerequisite of good manufacturing practice.

The WFHSS strongly recommends initial and periodic validation of decontamination processes in combination with a regular audit of the quality system. When these principles are applied this will guarantee medical devices fit for purpose and therefore ensure patient safety.

WFHSS Education Working Group

November 2011

2 Definitions

See Module 04: Sterilization

3 Introduction

Most of the Medical Device Acts of the EU member states stipulate that in healthcare establishments only validated cleaning, disinfection and sterilization processes may be used. This is justified on the following grounds: Every effort must be made to ensure that medical devices will not pose any damage to patients, personnel or third parties. The aim of validation is thus to obtain safe and reproducible reprocessing processes for reusable medical devices. The safety level should be on a par with that conferred by newly manufactured single-use medical devices.

Standard definition: **"**Documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications. **"**.

As regards the Reprocessing Unit for Medical Devices (RUMED), this means that:

"Validation serves to furnish documented proof of the ongoing effectiveness of the decontamination process under the operating conditions prevailing at the installation site, using the items encountered in routine operation in their respective packaging and with the reference loads used" (i.e. produces clean, disinfected or sterile devices).

Legal framework for validation of decontamination processes:

- Medical Devices Directive (EU)
- Medical Device Acts of different countries
- Harmonised European and International standards

4 Testing / validation

In principle a distinction must be made between testing the equipment used to reprocess medical devices (MDs) (sterilizers, washer-disinfectors (WDs) and validation of the decontamination processes.

In other words: equipment is tested, while processes are validated.

This means that sterilizers and WDs must be tested after installation. The manufacturer is responsible for this task and it is intended to demonstrate that the equipment will meet the requirements specified in the respective standards also at the installation site. Once these tests have been successfully completed the manufacturer is absolved of any further responsibility.

The operator of the reprocessing unit is responsible for validation of reprocessing processes, and this is done to establish whether the equipment used at the installation site is able to achieve the required results for the respective MDs, with the available operating materials (water quality, detergent, etc.), and in their respective packaging and load (i.e. to clean, disinfect and sterilize them).

5 Steam sterilization

5.1 Testing steam sterilizers

Testing (e.g. after installation = IQ and OQ) of large steam sterilizers (i.e. not process validation) is regulated by EN 285, and that of small steam sterilizers by EN 13060. This includes the type test, factory test and installation qualification.

5.1.1 Type test

While the type test is not the focus of this guideline, it is nonetheless mentioned for the sake of completeness.

The manufacturer is responsible for the type test and it is composed of a technical and hygienic part. Partial tests should preferably be performed by independent technical and hygiene experts or accredited test bodies. The operator should be given the opportunity to consult the test reports before buying the sterilizer.

5.2 Validation of steam sterilization processes

The purpose of sterilization is to kill or irreversibly inactivate the microorganisms harboured by the items to be sterilized. “Sterile” is defined as “a state that is free of viable microorganisms, including viruses”. But in practice it is not possible to make such an absolute statement, and this can only be viewed as an ideal scenario.

Therefore the requirements of the European pharmacopoeia are used, i.e. a product is deemed to be sterile (see below for Sterility Assurance Level – SAL) if the probability of a single viable microorganism being present on a sterilized product is equal to or less than 10^{-6} (= 1: 1 million) (see also EN 556: Sterilization of medical devices – Requirements for medical devices to be designated “sterile”).

Sterilization is one of the components of the process used to reprocess medical devices. The other components are cleaning and disinfection. Disinfection is intended as a means of reducing the microbial count so that before sterilization it can be assumed that the load of resistant microorganisms (D value = 2.5 min) is almost zero on the MDs.

See also Module : “Fundamentals of sterilization” (Level 1 script)

Various quality management standards designate processes as “special” if the results cannot be fully proven by subsequently testing and checking the product. Sterilization is one example of such a special process since the effectiveness of the process cannot be proven by checking and testing the product. “Sterility” of the end product cannot be demonstrated since such a test would render the product unsuitable for further use (as it would compromise its sterility), but on the other hand it is not possible to investigate the sterility of several million products in order to reasonably conclude that the products are sterile.

In line with European standards[1], when testing sterilizers the practice used for many years now has been to employ a system in which it is demonstrated, by physical tests and recording process relevant parameters, that the sterile supplies had been subjected to an effective and reproducible process.

5.2.1 EN ISO 17665-1 and ISO/TS 17665-2

Title: Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.

This standard defines requirements for validation and routine monitoring of steam sterilization processes. The method is based on checking the **physical parameters** of the process and presupposes that the sterilizer and its installation before validation meet an appropriate specification (in Europe EN 285: Sterilization - steam sterilizers – Large steam sterilizers).

[1] EN 285

5.3 Validation procedure

5.3.1 Prerequisites (framework conditions) for validation

It is not only the equipment that determines ongoing compliance with the pertinent requirements, other factors such as structural and organisational conditions, staff qualifications, manual process steps, etc. also play a role. For that reason certain structural, operational and organisational preconditions must be met, otherwise validation cannot be conducted. Therefore the RUMED operator is called upon to assure compliance with the minimum requirements for the respective RUMED category. Compliance with these requirements is verified when assembling consignments.

Accordingly, the following preconditions must be met before conductance of validation:

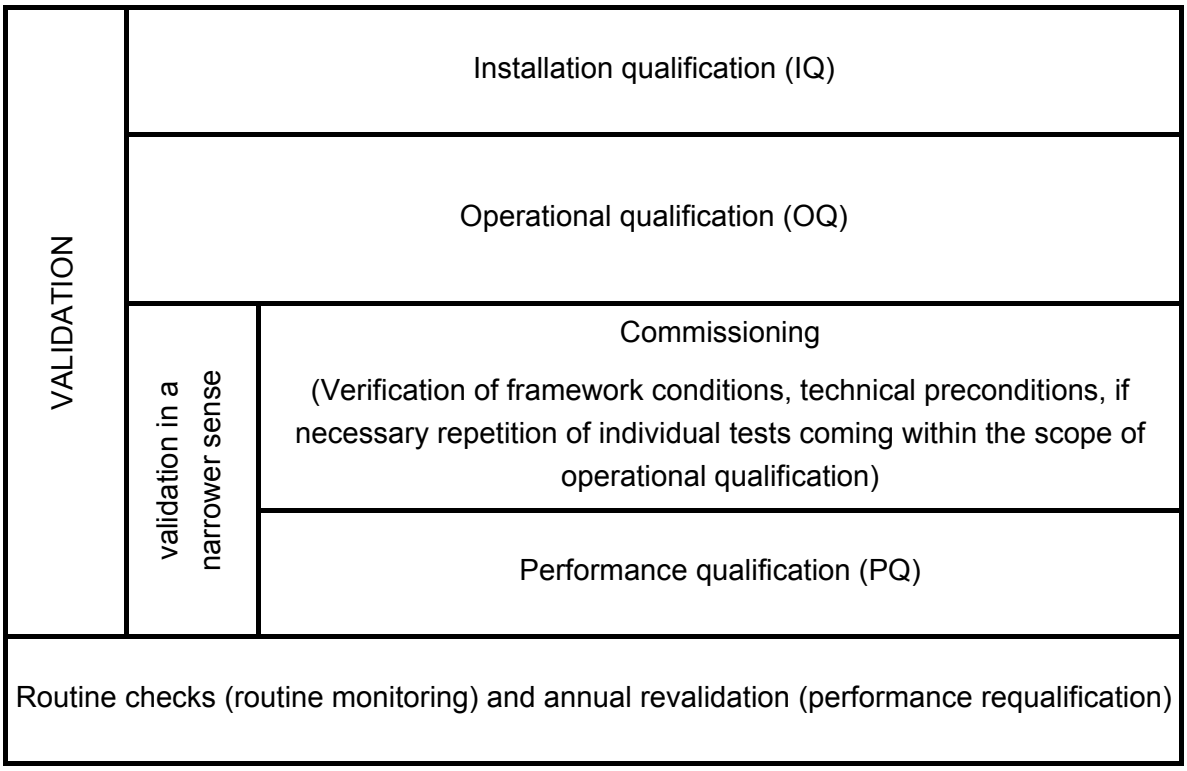
- Structural prerequisites
- Specialist qualifications of management and staff
- Risk assessment and risk assignment for the MDs or MD groups to be reprocessed
- Technical prerequisites for sterilizers
- Suitable operating materials (e.g. demineralised water)
- Appropriate quality assurance measures

The following documentation must be available at this stage:

- Written information on the layout of the RUMED showing responsibilities and competencies (e.g. in the form of an organigram)
- Information from the sterilizer manufacturer for the operator (as per EN ISO 15883), e.g. operating instructions, calibration protocols, programme specifications
- MD manufacturer's instructions for reprocessing (if possible)
- Loading configurations
- Standard operating procedures (SOPs) for all reprocessing steps
- Operations' logbook
- Infection control (hygiene) policy (incl. R/D policy)
- Maintenance schedule
- Routine control schedule
- Evidence of qualifications and training
- Release criteria and documentation

Pursuant to EN ISO 14937, validation comprises several steps:

- Installation qualification (IQ): Proof that the sterilizer, with its accessories, was supplied and installed in conformance with the pertinent specifications.
- Operational qualification (OQ): Proof that the installed equipment functions within specified limit values when used as per the operating instructions.
- Performance qualification (PQ): Proof that the equipment, when installed and operated as per the operating instructions, continues to operate as per the pertinent criteria, thus producing products that meet their specification (are "sterile").



5.3.2 Installation qualification (IQ)

During installation qualification a check is carried out to verify if the sterilizer was delivered as ordered, installed and supplied with operating materials and that it can be safely operated. This is a purely technical test. Once the equipment has been installed and connected, installation qualification must be performed by the manufacturer in collaboration with a technical expert designated by the respective establishment and the results documented. IQ comprises e.g.:

- A check of the documentation supplied, including the type test documentation if applicable
- Doors and seals
- Escape of liquids or gases
- Operating materials
- Safety mechanisms
- Design (e.g. solder seams)
- Display and recording equipment (measurement precision of instruments, calibration)
- If applicable, a check of other technical specifications (e.g. as per tender)

5.3.3 Operational qualification (OQ)

The results of installation qualification should be available before operational qualification.

If not otherwise contractually agreed, operational qualification should be instigated by the manufacturer while preferably appointing an independent infection control expert. If the

results of installation and operational qualification are positive, the prerequisites for acceptance of the equipment by the establishment will have been met.

The minimum scope of testing is as follows:

- A check to verify that the sterilizer meets the minimum requirements for validation (vacuum test, B&D test, empty chamber profile)
- A check of supply water and steam quality
- A check of precision of measuring and recording equipment
- Verification of ambient conditions (ambient temperature and ambient humidity).
- Verification of reproducibility (in general threefold repetition of the test performed with the standard test pack)

5.3.4 Process validation (in a narrower sense)

5.3.4.1 Commissioning

Commissioning is broken down into two parts:

1) Technical commissioning: This is intended to demonstrate that the sterilizer and the room in which it is installed meet the given specifications and that calibration of instruments is within specified limits.

If operational qualification had been conducted more than three months previously as well as in the case of validation of "old equipment" that does not meet the pertinent specifications (see below), these parts of operational qualification are performed at the time of commissioning.

2) Operational / organisational commissioning: This entails verification of whether the prerequisites as per 4.3.1 set out as operational / organisational requirements have been fulfilled.

See as well Module 07 "Quality management in the RUMED"

5.3.4.2 Performance qualification (PQ)

Performance qualification furnishes proof that the specified conditions have been reproducibly met at all sites of the sterilization load, i.e. that the sterilizer is able to produce sterile products using the items encountered in routine operation in their respective packaging and with the respective loads and programmes used.

The requirements are deemed to have been met as per the standard (EN 285) if

- the temperature measured at every site within the sterile supplies and chamber is within the sterilization temperature range (lower range = sterilization temperature; upper range = sterilization temperature + 3 K)
- the temperature measured at various measuring points, including the theoretical temperature (= saturated steam temperature at the prevailing pressure) does not differ by more than 2 K
- the temperature fluctuation at any measuring point is $\leq \pm 1$ K

- the equilibration time (= interval elapsing until the sterilization temperature is reached at all measuring points) is
  - ≤ 15" (for ≤ 800 l chamber volume) or
  - ≤ 30" (for > 800 l chamber volume).

Each sterilization process (programme) and each type of sterilizer load[2], loading pattern and packaging must be defined and documented.

During performance qualification the pressure within the chamber and the temperature at the coldest site within the chamber (mainly the temperature of the exhaust line) during each and every sterilization cycle must be continually displayed and recorded by display and recording equipment incorporated into sterilizer, so as to produce a reference for product release.

The manufacturer cannot be held liable for any problems occurring during performance qualification which are attributable to the nature of the MDs to be reprocessed at the respective site or to the loading configuration, unless a contrary contractual agreement was made.

5.3.4.3 Qualification of the test body

In the run up to validation the question raised time and again is: “Who is entitled to conduct testing or validation”. To that effect, please note the following:

In many countries testing is not essentially subject to any statutory supervision, i.e. in principle any one is allowed to test anything. But the question is whether the test engineer/expert is capable of doing so, i.e. has the necessary specialist qualifications and requisite expertise/experience and disposes of the necessary test equipment. Even if that is the case, other questions must be answered: is such a person authorised to that effect, i.e. is he authorised to conduct such tests also from a legal perspective and are his tests or test reports recognised? Is the person entrusted with interpreting or evaluating the test results authorised to that effect and capable of doing so? Can the test engineer or “evaluator” be held liable for damage resulting from incorrect tests or incorrect evaluations?

This means that the term ‘testing’ is not used in a standard sense and that the operator must ensure that the test engineer / evaluator has the requisite qualifications, otherwise he is guilty of “negligence in choice of contractor”. Conversely, anyone conducting such tests, validation, etc. without being entitled to or capable of doing so is guilty of “engagement negligence”, i.e. he has taken on a task which he is not at all able or authorised to discharge.

As regards the evaluation authorisation, the situation is somewhat more complex, with the “expertise” being the chief determinant, i.e. the evaluator must not only be conversant with the technical aspects of a test, etc, he must also be aware of the implications of the

[2] for which the process is valid

interpretation/evaluation/decision (i.e. what implications do the results have for a successful sterilization outcome / for the patient / what is tolerable, when is danger in default?).

Example: A service engineer employed by a sterilizer manufacturer/distributor will no doubt have the technical/specialist competence needed for testing sterilizers, but he can hardly be held responsible for deciding whether a sterilizer can continue to be operated or taken out of service.

In Europe there exists an EU directive about Accreditation. This means that test, inspection or certification bodies accredited pursuant to this act are authorised throughout Europe to conduct those test, inspection or certification tasks contained within the scope of accreditation. Accreditation of a test body is thus synonymous with a quality seal and guarantees technically correct, independent test reports.

5.3.5 The run up to validation

First a contract must be drawn up by the establishment's senior management (e.g. a hospital's management). This ensures that the necessary financial, human and time resources will be allotted. In larger institutions setting up a quality circle (validation committee, validation circle, validation working group, etc.) has proved beneficial. This facilitates coordination, assignment of duties and ensures motivation is not lost.

5.3.5.1 Technical requirements

Cooperation between the RUMED, engineering department and service engineer (and possibly validation body) is generally needed to ensure the technical requirements of ONR 112069 are met. The technical prerequisites of the sterilizer, the feedwater treatment, etc. (see 2.2.1 commissioning) and availability of the requisite documentation should be checked.

5.3.5.2 Organisation/responsibilities

Clear assignment of competencies and responsibilities is a precondition for reprocessing in line with the dictates of quality assurance. Using an organigram to that effect has proved beneficial. Experience has shown that shortcomings are found at precisely this juncture, for example often the person in charge does not have the corresponding expertise (advanced training) and is hardly or never present in the RUMED; the RUMED management is not assigned responsibility; the person responsible for validation has not received proper training or someone who does have this expertise is not entrusted with validation. These drawbacks must be overcome first of all.

5.3.5.3 Standard operating procedures

Standard operating procedures (SOPs) must be compiled for all reprocessing steps (see specimen in annex).

Particular attention must be paid to manual steps since these partial processes cannot be validated, rather they can only to be "standardised as far as possible". This applies e.g. to MDs that may not be subjected to automated reprocessing. The manufacturer should specify the action needed. Pursuant to EN ISO 17664 the manufacturer is obliged to specify a process for reprocessing a medical device designated for reuse. If no (or only unsuitable, i.e.

not in the national language), manufacturer's instructions are available, one must decide whether the MD can be reprocessed in a responsible manner (in general this is possible in the case of MDs assigned to risk group A, as per the Robert Koch Institute (RKI) classification system. If that is not the case, alternative options must be discussed (other manufacturer, other type of device, etc.)

See also Modules: "Quality management in the RUMED and "Process-oriented medical devices circuit"

5.3.5.4 Classification of MDs into risk groups as per RKI system

See Module 02: "Fundamentals of MD reprocessing"

5.3.5.5 Packing lists

Packing lists must be available for all sets. Layout diagrams are recommended, in general photos are taken of the sets and these are helpful in practice.

5.3.5.6 Loading patterns

The loading patterns / configurations must be defined for the individual sterilizer. The configuration is understood to mean the combination of supplies, packaging, sterilization programme and arrangement in the sterilizer. It is of course not possible to accommodate every possible combination of the different sets; indeed, the recommendation is to keep to a minimum the number of loading patterns. This can be accomplished in the healthcare setting only by defining rough patterns, e.g.:

Example:

Sterilizer 1 (4 sterilization modules (StMs):

Configuration 1: 134 °C programme: full load: 4 StMs instruments in containers (with valves in lid and floor) and internal wrapper, total weight max. 12 kg.

Configuration 2: 134 °C programme: full load: lower level: 2 StMs instruments in cassettes (with valves in lid and floor) and internal wrapper, total weight max. 12 kg; upper level: 2 StMs instruments packed separately in double paper foil packaging in mesh trays.

Configuration 3: 121 °C programme: partial load: lower level: 2 StMs 2 separately packed anaesthesia supplies in double paper foil packaging in mesh trays.

Making graphics or photos or the approved configurations has proved beneficial.

Based on the loading patterns during PQ the validation expert will choose the most challenging configuration (if applicable combining two or more of the loading patterns to a worst case configuration, intended to cover all the possible challenges that might occur in practice.

5.3.5.7 Training schedule

The training schedule does not mean documentation of participation in past training seminars, but rather the long-term measures taken for organising training, advanced training

and continuing professional development. This schedule should indicate who should participate in which training session and when. Conductance of such training seminars must be documented, and department meetings, etc. can also be classified as such.

5.3.5.8 Maintenance schedule

Here too one should always clarify what a maintenance schedule is supposed to mean. Like all schedules/plans, it entails making long-term plans for equipment servicing activities. Separate maintenance schedules can be compiled for each item of equipment or one schedule for all equipment. Tests (not to be confused with routine checks, which must be conducted by the operator of the equipment as an ongoing quality control measure) can also be viewed as maintenance, hence a combined maintenance and test plan drawn up. In any case it is important that this schedule should indicate when which servicing tasks (tests) are to be carried for which equipment and by whom.

5.3.5.9 Routine checks' schedule

This should specify which routine checks (e.g. vacuum test, B&D test) are to be performed how often and who is responsible for them. The routine checks' schedule can also be made available in the form of an SOP.

5.3.5.10 Batch and release documentation

It is important that the persons authorised to release supplies are specified and that a list of signatures (or initials) is maintained. Of course it is not just the person(s) authorised to conduct release that must be specified, but also the prerequisites for release.

If there is no national regulation the required qualification for releasing batches has to be specified by the management of the RUMED.

5.3.6 Revalidation

Initial validation is followed by revalidation at yearly intervals. A distinction is made between

- recommissioning and
- performance requalification

5.3.6.1 Recommissioning

It is intended to confirm that the data recorded during commissioning are still valid.

It is carried out if the data recorded for routine process monitoring or performance requalification shows unacceptable deviations from the data recorded at the time of initial validation.

Likewise, recommissioning is needed if the sterilizer has not been used for a long period of time or following changes or servicing tasks that could affect the sterilization process (e.g. replacement of the vacuum pump).

Responsibility for conductance of recommissioning (whether recommissioning must be performed) and definition of the test scope is borne by the responsible test body.

5.3.6.2 Performance requalification

It must be performed at least once yearly as well as always when, because of changes to the sterilizer load, the measured values for the sterile supplies are not within limits specified during performance qualification.

Performance requalification may be necessary on

- introduction of a new or modified device
- introduction of a new or modified loading configuration,
- or introduction of a new or modified type of packaging
- as well as when changes are made to equipment and process parameters (programme changes),

if lack of concordance has been noted with respect to

- a validated reference load
- a previously validated device, packaging or loading pattern combination.

Responsibility for conductance of performance requalification and definition of the test scope is borne by the person in charge, who must be suitably qualified. The decision as to whether performance requalification must be performed or not should be taken jointly with the test body entrusted with validation.

In general process validation (performance requalification) entails repetition of at least one of the loads (reference load) used for initial validation.

In some countries (e.g. Austria, Germany, Switzerland) guidelines are available in which it is accurately described how validation of steam sterilization processes has to be conducted.

5.4 Routine control

For validated sterilization processes including yearly requalifications based on thermoelectric measurements, checks with biological indicators are no longer needed. However, a functional routine control system is important.

5.4.1 Indicators

A distinction must be made between the following indicator types:

a) bioindicators

b) chemical indicators

c) physical indicators (are rather seldom used in the healthcare sector)

5.4.1.1 Bioindicators

These consist of a germ carrier inoculated with bacterial spores (e.g. for steam sterilization: *Geobacillus stearothermophilus*). The bioindicators are exposed to the sterilization processes

and then either transferred to an appropriate culture medium or they are self contained (i.e. the culture medium is already enclosed). After incubation at the temperature suited to the respective test organism, the culture is inspected for presence or absence of bacterial growth.

5.4.1.2 Chemical indicators

The sterilization process gives rise to a chemical reaction (e.g. colour change) in the indicator.

Treatment indicators (EN ISO 11140 -1: Type 1):

These are intended to demonstrate that the supplies were exposed to a sterilization process. A colour change does **not** mean that all parameters for the particular process were complied with or that the process was effective (i.e. that the supplies are sterile). Treatment indicators (adhesive tapes for paper packaging, indicators integrated in composite film) serve merely to distinguish between sterilized and non-sterilized supplies.

Indicators for the Bowie & Dick test (EN ISO 11140 - 1: Type 2):

These are special indicators suited only to this test.

Integrating indicators (EN ISO 11140 - 1: Type 5):

In the event of a complete colour change of these integrated indicators it can be assumed that all parameters required for effective sterilization (e.g. for steam sterilization: saturated steam, temperature, time) were observed. However, here too no guarantee is given that the supplies are sterile, as per the definition of this term. This type of indicator is used e.g. for batch control systems (see below).

5.4.2 Practical implementation of routine checks

5.4.2.1 Vacuum test (VT)

The automated vacuum test must be conducted at least once weekly as per the operating instructions. The test helps establish whether the sterilizer chamber is sufficiently leak-proof when under vacuum. The vacuum test is one of the preliminary tests performed before reprocessing **(see Specialist Training Course 1 Script).**

Criterion: pressure rise ≤ 13 mbar / 10 min.

If the vacuum test is not successful:

Perform B&D test:

B&D test successful: notify service engineer, sterilization can be continued

B&D test unsuccessful: see below

5.4.2.2 Bowie & Dick test (B&D test)

A **Bowie & Dick test** is also a preliminary test and must be performed daily *before* reprocessing (If applicable, *after* running a blank load). A successful B&D test attests to rapid and uniform penetration of steam into the test pack and is used to release the sterilizer for the day's sterilization activities. Before the steam can penetrate the test pack, the air must be removed from the sterilizer chamber and from the supplies to be sterilized.

[Additional information: Originally, a laundry pack (standard test pack) was used for the B&D test, as continues to be reported in the standard governing the B&D test as well as for other tests as per EN 285. This standard test pack consists of unbleached cotton towels, folded and measuring 22 x 30 cm and placed in a pile measuring 25 cm in height. An indicator sheet as per EN ISO 11140-3 is placed in the centre of this pack (around DIN A 4 size).]

Criterion: uniform colour change across the entire surface (or as per the manufacturer's instructions)

The B&D indicator must be evaluated by trained staff.

Alternative B&D tests

Today virtually only "alternative systems" (e.g. helix model or single-use test packs), which must meet the criteria of EN ISO 11140-4, are used for the B&D test.

The commercially available systems operate according to three principles:

a) **difficult air removal from porous supplies**: the latter are small single-use test packs made of layers of paper or cardboard with special indicator sheets in the centre of the pile or comparable reusable systems with piles of cardboard for which the indicators are replaced.

b) **difficult air removal from a hollow body**: in this simulation test, a helix model, after evacuation of the chamber the steam must penetrate through a tube with an internal diameter of 2 mm and 4 m length into the receptacle, containing a suitable indicator strip.

c) The following systems are a special version of the systems outlined in Item b). They also consist of a hollow body, but using an electronic display as an indicator. This display shows whether the process was successful or not, either directly on the system and/or through evaluation of data recorded by the system's computer program. The advantage of such a reusable system resides, inter alia, in its tracking facilities, appropriate documentation and ability to detect shortcomings before occurrence of faults (comparison of measurement curves).

For RUMEDs that primarily sterilize porous materials (e.g. surgical drapes), a system listed in Item a) will have greater power. For RUMEDs where hollow bodies tend to be the devices presenting the greatest challenge to air removal, a hollow body test model will be more suitable.

Reasons for uneven colour change:

- leaks and hence air penetration into the sterilization chamber
- inadequate vacuum depth generated during air removal phase

- non-condensable gases in steam

If B&D test unsuccessful:

Repeat and, if applicable, conduct vacuum test (this might provide insights into cause)

If test unsuccessful again: take sterilizer out of service and notify service engineer.

Documentation

The results of the B&D test must be documented. The sterilizer may be released for routine operation only after a positive test result. It is not necessary to preserve the indicator itself since, inter alia, the colour could change (colour reversion). But the test result must be recorded with the respective staff member's signature (initials).

5.4.2.3 Batch control systems

In principle compliance with the critical process parameters must be verified by comparing the data recorded by the sterilizer's continuous recorder (pressure-temperature curve) with a "specimen curve" generated during validation. The latter must be made available by the test body and must contain information for evaluation purposes (tolerances).

In addition, the use of chemical indicators (EN 867-5, to be replaced by EN ISO 11140-6) might be useful.

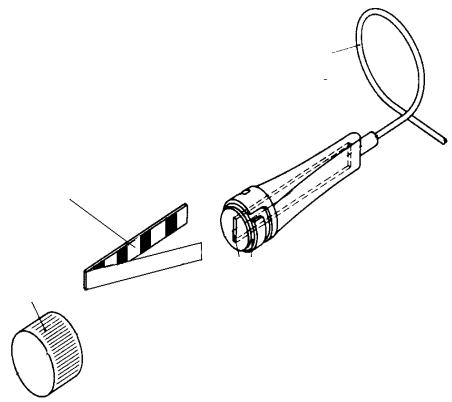


Fig. 1: Batch control process challenge device (helix model - example)

When using a batch control system – as opposed to a "traditional" variant where an indicator is placed in each item of packaging – only one single indicator is used per batch. Appropriate documentation and the use of treatment indicators to distinguish between sterilized and non-sterilized supplies as well as the clear colour change ensure that only inspected sterile supplies leave the RUMED. There is no need then to check the indicators of containers, tray, etc. at the point of use, with only the integrity of the packaging and, possibly, the expiry date having to be checked.

If the indicator points to unsuccessful sterilization, the respective supplies will not be sterile. Check loading pattern and packaging, and if necessary repeat sterilization or perform technical /hygienic test or repair.

5.5 Release

Validation of sterilization processes is also aimed at parametric release, i.e. batches can be released on the basis of parameters displayed or recorded by the sterilizer. Hence the printout (or curve) for every batch must be checked to ensure that data recorded during validation are complied with. That is the basis for release, any batch control systems with chemical indicators can also contribute to release but on their own they do not constitute a criterion on which release can be based.

Supplies may only be released by authorised persons who have commensurate training. These persons must be trained in how to evaluate batch logs and read / interpret indicators and evidence of this must be available.

Batch documentation and that related to preliminary tests must be preserved for at least 10 years. Computerised documentation is acceptable but provision must be made to ensure it continues to be legible after 10 years. There is no need to preserve indicators since colour reversion over time cannot be ruled out. However, the test results must be documented.

5.6 Small sterilizers

Mandatory validation as set out in the European Medical Devices Directive applies for all sterilization processes (regardless of whether it is conducted with a small or large sterilizer. Citation by Jack van Asten: "*After all, the microbes don't know whether they are in a small or big sterilizer*").

Small sterilizers are regulated by EN 13060. Old sterilizers without a fractionated vacuum facility, batch recording or test connection, should be replaced at the first opportunity by sterilizers that comply with this standard.

Today small steam sterilizers are found almost only in rehabilitation centres, homes for the elderly and nursing homes as well as in outpatient departments and medical practitioners' offices (i.e. mainly category I RUMED). Validation of small sterilizer processes is a topic that continues to be controversial since it calls for a relatively large investment.

The following are minimum requirements for category I RUMEDs:

- personnel must have commensurate training,
- the corresponding SOPs and documentation must be available,
- thermoelectrical testing of the sterilizers must be performed annually as per EN 13060, using a load that as far as possible approximates the supplies routinely sterilized.

An alternative approach would be to outsource MD reprocessing to establishments, e.g. hospitals, which have already been validated or change over to single-use devices (which today are often of a good quality).

6 Sterilization processes with formaldehyde

6.1 Testing FO sterilizers

Testing of FO sterilizers is regulated by EN 14180.

Testing comprises:

***Microbiological testing*:** Process challenge devices (PCDs) as per EN 867-5 must be used. They simulate the most difficult type of device to be sterilized (long hollow devices with narrow lumens).

The number of PCDs to be used depends on the composition, type of filling (load) and packaging used for the sterile supplies. For chambers of less than 60 litres, at least five bioindicators, and 10 bioindicators for chambers over 60 litres, must be used in the PCDs.

***Physical testing*:** For thermoelectric testing data recorders with at least five thermocouples and a pressure sensor must be used to keep sight of the temperature distribution in the sterilizer chamber and sterile supplies.

6.2 Validation of sterilization processes with formaldehyde

The international standard EN ISO 25424 regulates validation of sterilization processes with formaldehyde.

This stipulates that preconditions (technical, operational, organisation) must be met as in the case of validation of steam sterilization processes. The scope of sterilizer commissioning (OQ) includes: leak test, functional testing, thermoelectric tests of partial load and full load, testing for dryness. For performance qualification (PQ) representative everyday configurations are subjected to thermoelectric and microbiological tests.

6.3 Routine control

- Check of sterilization parameters (temperature, time, pressure, humidity, If applicable, gas concentration)
- A suitable chemical indicator must be used for each sterilization load (in case of sterilizers which are not compatible with the standard or not validated processes the use of a biological indicator in each batch is recommended).
- Recommendation: continuous biological validation with bioindicators in corresponding PCDs (see Fig. 1) at least every three months.

7 Sterilization processes with ethylene oxide (ETO)

7.1 Testing ETO sterilizers

Testing of these sterilizers (type test, works test, and installation qualification) in Europe is regulated by EN 1422: Sterilizers for medical purposes — Ethylene oxide sterilizers — Requirements and test methods.

7.2 Validation and routine control of sterilization processes with ethylene oxide

Validation of sterilization processes with EO is regulated by EN ISO 11135: Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.

8 Cleaning and disinfection processes

8.1 Testing washer-disinfectors (WDs)

In the past the main focus of washer-disinfector tests was on the disinfectant action, with the effectiveness of cleaning being largely ignored. Only in recent years has more importance been attributed to cleaning and its relevance enshrined in international standard EN ISO 15883 Parts 1-6.

This standard series defines technical requirements for WDs as well as performance criteria and test methods.

EN ISO 15883 Part 1: General requirements, definitions and tests (valid for all WDs)

Part 2: Requirements and tests for washer-disinfectors for surgical instruments, anaesthetic equipment, hollowware, utensils, glassware, etc. (= instrument WDs)

Part 3: Requirements and tests for washer-disinfectors for human waste containers (= bedpan WDs)

Part 4: Requirements and tests for washer-disinfectors for thermolabile reusable instruments, including endoscopes (= endoscope WDs)

CEN ISO/TS 15883 Part 5 (Technical Specification): Test soils and methods for demonstrating cleaning efficacy of washer-disinfectors

The cleaning efficacy is a main focus of the tests described in this standard.

So e.g. for surgical instruments in Sweden reactivated cattle blood, in Austria and Germany reactivated sheep blood as test soils are used for demonstrating cleaning efficacy of the Washer-Disinfectors under test, all of which are quite a challenge for a WD.

Remark: A curious aspect of this international standard is that its annexes list all national test soils and test methods. Since this situation is unsatisfactory and comparability of the WDs is not assured, Part 5 is being currently revised in order to define uniform test methods for the WDs specified in Parts 2 – 4.

8.2 Validation of cleaning and disinfection processes

There is no international standard for validation of automated cleaning and disinfection processes but in some countries guidelines of national professional associations are available (e.g. Austria, Germany).

But in principle the validation procedures for cleaning-disinfection processes are of course similar to the ones for sterilization.

9 References

(1) Applicable CEN and ISO Standards

(2) ONR 112069 (Technical Specification of the Austrian Standards Institute): Leitlinie für die Validierung and Routineüberwachung von Sterilisationsprozessen mit feuchter Hitze für Medizinprodukte + Anhänge

(3) Österreichische Gesellschaft for Steriligutversorgung (Austrian Society for Sterile Supply): ÖGSV-Leitlinie für die Prüfung, Validierung und Überwachung von maschinellen Reinigungs-/ Desinfektionsverfahren für Medizinprodukte. (www.oegsv.com > guidelines)

(4) Robert Koch Institut (RKI): „Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten“. Bundesgesundheitsbl 2012 · 55:1244–1310, Springer Verlag.

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Adapted and approved by the wfhss education group (September 2013)

Annex:

Hospital "Specimen"	**STANDARD OPERATING PROCEDURE**	**Doc. No.:**	**XY – 00**
	Title:	**Revision:**	**00**
		Valid as from:	

Time and again the question is asked: How do I compile a procedural directive or standard operating procedure (SOP)?

The main points are:

1. SOPs must be drafted such that they can be understood by the staff member executing the respective task.
2. It should be possible to update them with minimal effort (document register, filing, archival)
3. The persons authorised to compile and release SOPs must be defined.
4. Documentation management is essential.

This must indicate:

- who compiled the SOP and when
- who reviewed the SOP and when
- who released the SOP and when
- version and revision date .
- SOPs' distribution list.

Saved in IT system under document number

Access granted only to authorised persons (password)

The person in charge must ensure that only the currently valid SOPs are used.

	Name	**Date**	**Signature**
Compiled by			
Reviewed by			
Released by			

Distribution list:

Each SOP should have the same layout

Example:

Purpose:

- Why and for what purpose the SOP was compiled

Scope of validity:

- For which departments or working areas the SOP is valid

Terms and abbreviations:

- All expressions and abbreviations must be clearly explained so that they can be understood by all staff members

Competence:

- State clearly who has to perform task and who is responsible for whom

Procedure:

- Precise, brief, but detailed and unambiguous, work instructions,

Personnel protection:

- Use personal protective equipment and point out hazards posed by respective working procedure

  Information on action in the event of accidents or near accidents.

Reporting faults:

- Precise details of action needed in the event of equipment faults or problems with working procedures (what do I do if....)

Other valid documentation:

- Generate links between different SOPs, while incorporating manufacturer's instructions, infection control policy, information circulars, regulations, etc.

Amendment protocol (history chart)

Revision	Date of revision	Reason for amendment