

Practical instructions for the Validation of cleaning and disinfection methods according to the recommendation of the German Society for Hospital Hygiene (DGKH) and according to the prEN ISO 15883.

Laws, guidelines and recommendations of the expert committees call for suitable validated proceedings at the processing of medical devices, for to guarantee, that no physical dangers for patients, users and third parties start out of processed medical products.

The scientific interest the last years mainly was focussed on the sterilization. The processes of the steam sterilization were examined and discussed as well as low temperature methods, new developments and alternative methods.

The decontamination, that means cleaning and disinfection were neglected more or less, disregarding, that the manufacturers brought new products of cleaning chemistry to the market again and again.

Now is cleaning a topic one can argue about. Clean is a relative concept, if e.g. we are talking about cleanness in the household or cleanness of beaches. But there may not be any discussions about the definition of "clean" in the area of medicine products. Already in 1994 a working group at Tuebingen University Hospital dealt with the topic "Cleaning of Minimal Invasive Surgery Instruments" and developed the so called "Radionuklidmethode", the at the moment only non destructive and quantifying examining method which allows statements concerning the cleaning behaviour of surgical instruments with cavities.

The idea "sterile faulting" on instruments is lead ad absurdum, the latest since the discussion about prions.

The secure decontamination is at least as important in the processing circulation as the sterilization. A in vivo study at SMP in Tübingen shows, that only an effective decontamination enables a safe sterilization.

In Germany, cleaning and disinfection of medical devices is regulated by the Medical Devices Act (MPG), the Medical Devices Operator Ordinance (MPBetreibV), the Recommendation of the Robert Koch Institute (RKI) "Hygiene requirements for processing medical devices " and by prEN ISO 15883-1 and prEN ISO 15883-2 (washer-disinfectors). Specific national regulations apply in other European countries and in Switzerland.

Standard pr EN DIN ISO 15883 and the Recommendation of the German Society for Hospital Hygiene (DGKH), which is based on it, pose many new challenges for the user in the hospital, and raise myriad issues relating to implementation. Taking account of this situation, a working group comprising representatives of industry, science and the practical setting, has been set up to compile a practical guide to validation cleaning and disinfection processes in line with the provisions stipulated in standards, directives and recommendations.

Preconditions for correct technical validation of cleaning and disinfection processes are testing, programming and servicing of the washer-disinfectors, while, of course, referring to the relevant documentation on measured values and programme parameters.

What Does Validation Involve?

The standard gives the following definition for validation: "a documented procedure for furnishing, recording and interpreting the requisite results, in order to demonstrate that a process continually meets the given specifications". In terms of form and scope, validation must be tailored to the device, intended purpose and the state of the art.

Validation serves, first of all, to furnish clear proof that processes, equipment, materials, working practices or systems actually produce the expected results.

Validation should always be carried out according to a validation plan, featuring objectives as well as a schema listing the validation tasks and competences.

The validation results must be summarised in a validation report and a commentary must be given on them.

It is recommended that revalidation be carried at least once annually.

Who is Authorised to Conduct Validation?

Validation may be conducted only by persons who, on the basis of their specialist training and their practical experience of parametric and microbiological testing of washer-disinfectors as well as of their knowledge, especially of pertinent provisions and standards, are capable of conducting validation in an appropriate and reproducible manner. The persons conducting validation must have at their disposal appropriate measuring facilities and have contact with microbiology test laboratories.

Ideally, the technical departments, infection control team and CSSD personnel should engage in close cooperation.

Who is Authorised to Conduct Routine Checks?

Only persons who have been suitably briefed may conduct daily start-up and routine tasks. Such persons must have the knowledge required for routine operation of a washer-disinfector, including of routine assessment of the cleaning results. In Germany, completion of Specialist Training Course I as per the guidelines of the German Society for Sterile Supply (DGSV) is recommended.

Processing in Accordance with Validated Processes

The law requires processing to be conducted while using validated processes. The overall medical device processing procedure involves several manual and processing steps.

Preparation (pretreatment, dismantling, poss. precleaning, e.g. in ultrasound bath) = Manual

Cleaning, disinfection, rinsing, drying = Automated

Inspection of cleanliness and integrity = Manual

Servicing and repairs = Manual

Functional testing = Manual

Wrapping and packing (e.g. with validated devices) = Manual

Sterilisation with validated processes = Automated

Checking, documentation, release = Manual

2.4 Manual

Manual tasks must be carried out in accordance with pertinent standard operating procedures (SOPs). Personnel entrusted with such tasks must be suitably qualified and briefed, e.g. Technical Sterilisation Assistant .

The required equipment for to fulfil all requirements is the prerequisite which has to be controlled before to control the working result of the staff.

Automated

Automated cleaning and disinfection processes as per prEN ISO 15883-2 involve in general cold precleaning (to rinse off coarse, loose particles and water-soluble contaminants) as well as the main cleaning step, subsequent rinsing tasks and final thermal disinfection. The individual steps are carried out in tunnel washers, with tanks or zones being positioned one after the other. A cleaning zone with ultrasound may also be present. There are tunnel washers which partially recycle

solutions, as well as washer-infectors that provide for a complete change of solutions (see 'Commissioning'). In washer-disinfectors that change the water (these are known as automated washer-disinfectors), steps are executed consecutively, with the water exchanged after each step.

The washer-disinfectors must be loaded by trained staff (technical sterilisation assistant) in accordance with standard operating procedures (SOPs).

As stipulated by standard Norm prEN ISO 15883, the following requirements must be met:

All processed devices must be optically clean on completion of the cleaning steps or of the entire process. After the disinfection step, any microorganisms present must have been reduced by at least 5 log₁₀ levels. This can be proven by carrying out temperature measurements on the processed devices or by using biological indicators. There must be no residues of treatment agents on the medical devices which could lead to health or material damage, e.g. surfactant, alkaline or acidic residues. The quality of the operating water, e.g. drinking water, demineralised water, is decisive for rinsing and must be checked.

Technical Preparations

To provide for qualification or validation of the washer-disinfector as prescribed, commissioning must be carried out first of all as per the following list:

Inventory

- Washer-disinfector type
- Machine water supply
- Detergents and how dosed
- Information on thermal disinfection

Error messages
Documentation of the cleaning process
Trolleys for processed items

On the basis of this inventory one can now decide whether it is at all practicable to conduct validation in view of the costs incurred or whether it is necessary to purchase new items. In making this decision, the following aspects must be borne in mind:

- Is optimisation needed or possible in principle?
- Can a facility for dosage monitoring be fitted later?
- Has the washer-disinfector been regularly serviced?
- How old is the washer-disinfector?

The sequence of the process cycles and the cleaning performance should be tested first of all in order to get an overall picture of the condition of the machine. Such a test can be carried out with thermologgers as well as with cleaning indicators, and the results must be documented.

Assembly of Test Materials

Different test materials are needed to verify the cleaning and disinfection results.

Thermologgers

Thermologgers are placed at the following test sites to record the temperature as specified in the standard. In practice, waterproof PT 1000 thermocouples have proved useful because it is much easier to place them in the washer-disinfector than it is to fit thermal wires.

Thermologgers must acquisition and record data in steps of

at least 0.1 K. All data recorded must be taken into account during evaluation.

The thermologgers are used to check the effectiveness of disinfection and to verify the sequence of programme cycles and the effectiveness of disinfection.

Test Soils

Annex B of the standard lists the customary national or standardised test soils used so far for acceptance tests. The type of test soil, method of application and of drying influence the cleaning results. Hence the results of these tests are not comparable when using different test soils.

Two German test soils are listed, and these have also been used as a test challenge for biological indicators as per RKI guidelines:

- a) Defibrinated sheep blood (B 19 B)
- b) Semolina made according to specified recipe (B 19 A)

Defibrinated sheep blood dissolves in cold water and can be removed even by a preliminary rinse. It has not been used in this case for verification of the cleaning performance.

To ensure reproducibility of the results with B 19 A, aliquots of 0.1 g of the soil were spread onto roughened stainless steel coupons as per DIN 10510 (tunnel washers) and allowed to dry. In theory, matching instruments (e.g. tweezers) could have also been used. Aliquots of approx 1 g of the test soil were applied to the chamber walls or door using an 8 x 8 cm template and allowed to dry.

These were evaluated, first of all, by means of visual inspection. In addition, an iodine solution — potassium iodide — was applied to sites that appeared to be free of residues. Any starch residues gave rise to a pronounced blue colour.

That there is no evidence of starch residues is a requirement that must be fulfilled by the cleaning performance.

Cleaning Indicators

In order to ensure a procedure for testing cleaning results which is reproducible and standardized and allows proper evaluation, apart from visual inspection of all instruments, standardized cleaning indicators have to be implemented which reflect realistic conditions.

For testing the cleaning efficacy of washer disinfectors the following devices may be used:

Gap process challenge devices, employing hemoglobin, albumine, fibrin as test soil in correlation with human blood and/or synthetic indicators, using as test soil proteins, lipids and polysaccharides without blood components.

These process challenge devices are used for visual inspection of the cleaning results.

Biological Indicators

The aim and purpose of hygienic and microbiological testing is to rule in or out the presence of microorganisms in water as well as in or on medical devices. Furthermore, biological methods are used for functional testing of washer-disinfectors.

Determination of Residual Protein

Chemical testing for blood on medical devices is a very sensitive method for rendering blood residues (guaicum test) highly visible, even if no contaminant is visible to the human eye. Chemical testing for protein residues can be carried out with the biuret method.

Water Quality

It must be endeavoured to use demineralised water for all processes executed in the washer-disinfector apart from the cold preliminary cleaning step. The guide value for demineralised water is 20 μS when water is flowing into the machine (a value of 10 μS or smaller should be aspired to). Experience shows that following rinsing and thermal disinfection this value should not be above 60 μS . Values above 60 μS are suggestive of entrainment of chemicals. No detergent residues should be present any longer. The presence of any detergent residues containing dissociated compounds can be ascertained by measuring the conductivity. Any residues of alkaline detergents can be determined by measuring the pH value. The standard stipulates that the detergent manufacturer must offer special test methods which ensure that no residues that are detrimental to health will remain on the cleaned medical devices.

Detailed Planning and Time Investment

There is no set time investment when it comes to validation. Depending on the items being processed, a different number of processes will have to be validated (surgical instruments, minimally invasive surgical (MIS) instruments, anaesthesia equipment, etc.).

Validation should be planned such that clients can continue to be supplied with processed devices. The following documents must be available:

- Operating instructions for the washer-disinfector
- Servicing plan, loading configurations
- Classification of the medical devices (MDs) to be processed as per risk evaluation (RKI)

- MD manufacturer's processing instructions (EN ISO 17664)
- Instructions from the manufacturer of the chemicals used for processing
- Pretreatment of defined product groups as per standard operating procedures (SOPs)
- Operations log book
- Schedule for routine checks
- Proof of training courses held

Practical Implementation

Ideally, the validation team should comprise personnel from the CSSD, infection control team and technical departments. The required test materials as well as the devices to be processed for the test load must be assembled.

All cleaning programmes and loading racks used in the respective hospital must, of course, be checked.

It is advisable to run an empty load as the first mechanism for checking each programme so as to highlight any weak points in the washer-disinfector.

The working group recommends that — in the case of tunnel washers that partially recycle solutions — a test be conducted at the beginning and end of a working shift to ensure that optimal cleaning performance was assured in the last cleaning process and that recontamination of the items being processed by a contaminated cleaning solution can be ruled out.

Depending on the items being cleaned and on the size of the cleaning trolley, the different test materials must be distributed on the mesh trays in a definite manner.

Assessment and Evaluation of Performance

Once the entire process has been completed, the cleaning and disinfection performance is assessed using the test materials placed in the washer-disinfector.

The cleaning indicators are evaluated visually and chemically.

The biuret method can be employed as semi-quantitative proof of residual protein. The results are evaluated by comparing the change in colour against a colour table. The cut-off limits are about 25 µg protein.

Residual blood can be determined by mean of analysis with the guaicum test or alternatives with a similar mechanism of action.

Evaluation of the thermologgers shows the temperature curve for the entire process and provides for calculation of the A_0 value.

Compilation of the Validation Report

On completion of validation the validation team compiles a validation report, which contents all essential results of the validation, including the necessary documents, protocols and troubleshooting strategies.

Optimisation Proposals, Risk Classification

Based on the results obtained, the validation team must make proposals for process optimisation. If the cleaning results do not come up to the prescribed standard despite optimisation, a decision on the further course of action is taken on the basis of risk analysis and risk evaluation. Here it must be ensured that any endangerment to patients, users and third parties is ruled out.

As you could see, the validation of decontamination processes can be rendered by persons out of the health care

system, without the support by, may be not absolute independent industrial companies.

In my opinion, this has some advantages:

- Saving money
- Education of staff
- Neutrality of results
- Knowledge of working processes

However, no matter who is responsible for the job, it must be done.

The results of different studies registering nosocomial infections show that validated processes are essential for reducing costs and guaranteeing the safety of the patients.

The question, whether to have validated processes in a hospital, or an increased risk for patients and staff, must never even be raised.