Dear *Central Service* Readers,

The Quality Committee published 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 any suggestions about the hitherto recommendations or about new topics, you can send them to us at any time at qualitaet@dgsv-ev.de.

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Recommendations by the Quality Task Group (FA Q) 42:2023

The use of test objects to verify the cleaning performance at the time of validation of cleaning and disinfection processes

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The standard **DIN EN ISO 15883 Part 5** stipulates that a defined test soil and soiling method as well as instruments harbouring routinely encountered soils be used for verification of the cleaning performance. The **Guideline Compiled by the DGKH (German Society of Hospital Hygiene), DGSV (German Society of Sterile Supply) and AKI (Instrument Preparation Working Group) for Validation and Routine Monitoring of Automated Cleaning and Thermal Disinfection Processes for Medical Devices** specifies a defined test object (process challenge device) to be used to verify the cleaning performance at the time of validation. This test object meets the requirements for specification of the cleaning performance and with blood as a test soil it simulates the contaminants routinely found on surgical instruments. Using defined test objects, the reproducibility of the cleaning process can be assessed in addition to the minimum cleaning performance and if necessary optimized, for example by modifying the influencing variables or the load specifications. To that end, the test object must be appropriately standardized and manufactured subject to the pertinent quality assurance requirements. In-depth **QUALITY ASSURANCE** understandably sets high standards for the manufacture of the test objects.

QUALITY ASSURANCE

Test object

The material and surface composition must be standardized. That applies especially if the clamps are repeatedly used. The factors that play a role include e.g.: alloy quality, passivated surface, rust, residues, care and sterilization.

Test Soil

As **TEST SOIL**, heparinised sheep blood is used while adding the appropriate amount of protamine sulphate to counteract the anticoagulant effects of heparin. 0.1 ml of this test soil is pipetted into the clamp joint (Fig. 1) and dried under standardized conditions. Neither human nor ovine blood has an absolutely unchanging composition or unchanging coagulation properties. This applies for this test soil too. When manufacturing test objects each blood batch must therefore be checked to ensure it is within the specified tolerance limits. In all cases the **REPRODUCABILITY** of the test results must be assured. Important preconditions for blood of an unchanging quality include the maintenance of the cold chain during blood transportation and observance of the blood shelf life.

TEST SOIL

REPRODUCABILITY

Test objects – release and dispatch of the test objects by the manufacturer

Before releasing the test objects, the manufacturer must check the quality, including the cleaning performance in a defined process. Batch assignment must be assured by the manufacturer's internal quality management system. The test object packaging must be accordingly labelled. To pre-empt occurrence of adverse changes during transportation the shelf life – in relation to the time, temperature and vacuum packaging – must be investigated and defined.

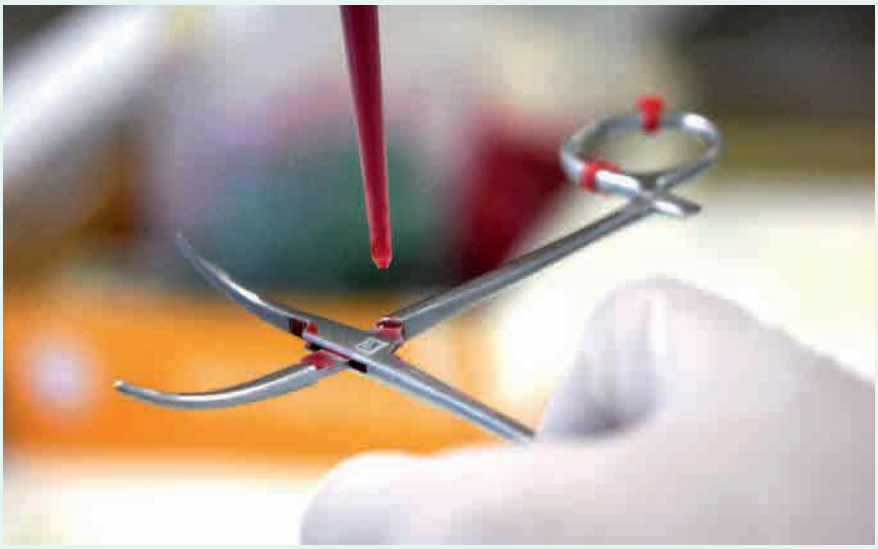

Figure 1: As defined **TEST OBJECT**, a Crile arterial clamp is used as per the guideline

TEST OBJECT

Handling test objects at the time of validation

INSTRUCTIIONS BY THE MANUFACTURER

Before using the test objects, the user/validation engineer must check the expiry date and other **INSTRUCTIIONS BY THE MANUFACTURER**. The positions of the test objects in the washer-disinfector reference load must be documented. The test process is started and the test objects are withdrawn for inspection before the disinfection step. **TESTING** comprises visual inspection for cleanliness and investigation for protein residues using an eluted sample and a quantitative detection method, e.g. biuret, BCA (bicinchoninic acid) or OPA (ortho-phthalaldehyde) method. Immediately after inspection, clean, disinfect and dry the test objects in the washer-disinfector. This helps to avoid rusting of the joint region.

TESTING

LABORATORY

If the test objects are sent for evaluation to a **LABORATORY**, they must be dried at room air temperature immediately after withdrawal from the washer-disinfector and visual inspection, then placed in the return packaging provided, labelled according to positions and dispatched.

Basic remarks

Blood residues are the most common type of contamination found on surgical instruments. But in addition to blood, instruments may also harbour other substances, e.g. fat, mucus, bone meal, drugs, antiseptics, etc. The test object described here serves as a model for testing the cleaning performance in relation to blood soils. Testing is done on site with the specified routine reference loads. These tests may also reveal application errors, e.g. loading errors or process deficits.

TESTING REAL-LIFE INSTRUMENTS

During validation the effectiveness of the cleaning process must be verified additionally by **TESTING REAL-LIFE INSTRUMENTS**, i.e. instruments harbouring routine soils; these are also visually inspected for cleanliness and investigated with a quantitative protein detection method. Especially in view of their specific design and the various operational influences as well as the drying times, additional shortcomings in the reprocessing process may come to light. The validation engineer must take account of these preconditions when carrying out the tests. Here, cooperation with the reprocessing management personnel is absolutely necessary.