Recommendations by the quality task group (115)

Routine tests for monitoring automated cleaning and disinfection processes

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The quality of automated cleaning and disinfection is assured, depending on the process, by periodic and batch-related routine tests in addition to validation (KRINKO/BfArM Recommendation, Section 1.4). What does that mean for routine working practices in the Reprocessing Unit for Medical Devices (RUMED)?

EN ISO 11139, Section 3.238, roughly describes the term "routine test" as follows: "A technical operation conducted periodically to establish that the operational performance of the equipment or process remains within the limits established during validation".

The **CONDUCT OF TESTS** is advocated in the KRINKO/BfArM recommendation.

Annex 3 of the KRINKO/BfArM Recommendation advocates **CONDUCT OF TESTS** during ongoing operations for stable process sequences and in the event of complaints or malfunctions.

In addition to the use of test objects (if applied) and stipulation of intervals for test object use, it also makes reference to verification of the cleaning results based on residual protein tests. The checklist "Batch-related tests" also refers to visual inspection for cleanliness, possibly e.g. for medical devices belonging to the Critical B risk group "with reference to a cleaning indicator".

Recommendations on the **MOST APPROPRIATE TESTS** are based on risk assessment.

Recommendations are given on the **MOST APPROPRIATE TESTS** based on risk assessment of the washer-disinfector (WD), technical equipment and of the main process parameters. These are targeted to parametric release, which comprises batch protocols and visual inspection for cleanliness and dryness. But additional risk factors can be used to determine process assurance, e.g.:

- What errors are not detected by parametric checks/detected by the WD's internal monitoring system? (e.g. incorrect dosing is detected but the use of an incorrect canister is not)
- How can an error be detected? (it may be necessary to verify this, e.g. by means of process indicators)

PARAMETRIC DATA are generated in every batch by standard-compliant washer-disinfectors.

Standard-compliant washer-disinfectors (WDs) generate in every batch **PARAMETRIC DATA** on the process sequence, including on the A0 value, pressure, dosage amount of chemicals and water. This data must be compared with the validation or requalification data and evaluated.

Supplementary routine tests may be needed because not all process malfunctions are apparent from the batch protocols. Likewise, missing information in the batch protocols may warrant additional testing.

SUITABLE TEST METHODS AND PCDS must be defined by the operator.

Where the operator is concerned, this means that at the time of validation **SUITABLE TEST METHODS AND PCDS** must be defined for batch or periodic tests as well as their use intervals during ongoing operations for stable process sequences and in the event of complaints or malfunctions. The operator must formulate a routine test policy. The test results are documented and evaluated.

Test intervals should also be established in accordance with the risk, while also considering the merits of conducting testing whenever warranted (e.g. dropped loading trolley).

The RUMED personnel entrusted with conduct, documentation and evaluation of periodic testing must be appropriately trained to assure safe operation of the measuring equipment and implementation of the analytical methods. All competencies must be clearly defined.

MEASUREMENT EQUIPMENT must be serviced and calibrated in accordance with the manufacturer's instructions.

In the event of any uncertainty, assistance can be obtained from specialists such as validation engineers, the manufacturer's engineers or from other experts. If **MEASUREMENT EQUIPMENT** is used for individual tests it must be serviced and calibrated in accordance with the manufacturer's instructions.

Consideration must also be given to the process chemicals used as some of the active ingredients can be adversely affected during storage. These must be stored in accordance with the manufacturer's instructions and the expiry date must be observed.

The following table gives tips on suitable tests. Batch-related and periodic tests are listed for the main process steps, and test intervals recommended. Periodic tests should be conducted at least as often enough as to permit ascertainment of the cause of any unsatisfactory test results as well as remedial action. The duration of the problem should be identified, its potential cause and only very few medical devices, or none at all, which were reprocessed with the faulty process should already have been placed in circulation.

Table 1 Periodic tests

Process steps	Potential verification methods	Interval (batch-related or periodic)
Cleaning performance	Check batch protocol (process parameters)	Batch-related
	Visual inspection	Batch-related
	Process indicators ▪ Artificial test soil that is highly resistant to removal by the test parameter (programme, chemical product, crevices, lumens) ▪ Note manufacturer's instructions	Batch-related or periodic (optional)
	Pressure logger	Periodic (optional)
	Rotating arm measurement (in WDs where this test is not available)	Periodic (optional)
	Note foam formation (in WDs without pressure monitoring)	Periodic (optional)
	Protein measurement (note instructions supplied by test manufacturer)	Periodic (optional)
Disinfection performance / residue-free rinsing	Check batch protocol (A_0 value)	Batch-related
	pH value measurement	Periodic (optional)
	Electric conductivity of rinse water	Periodic (optional)
Drying performance	Visual inspection ▪ Compare with results in validation report	Batch-related

In addition to the routine tests, the validation guideline also specifies daily routine tests, examples of which summarized in Checklist 9 of the guideline [3].

References

1. KRINKO-BfArM Recommendation: Recommendation for hygienic processing practices for medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) from 2012
2. EN ISO 15883-1:2014-10 Washer-disinfectors – Part 1: General requirements, terms and definitions and tests.
3. Guideline for validation and routine monitoring of automated cleaning and disinfection of heat-resistant medical devices as well as advice on selecting washer-disinfectors", compiled by the German Society for Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI): 2017
4. EN ISO 11139:2019-05 Sterilization of health care products – Vocabulary of terms used in sterilization and related equipment and process standards