Recommendations by the Quality Task Group (55): Performance Requalification on Changing the Process Chemicals

In principle, the operator must be able to make changes to his validated processes in order to take advantage of any technical progress achieved. Such improvements include e.g. new trolleys, innovative medical devices calling for automated decontamination, changes to the equipment, programme sequence or to the process chemicals.

The authors of the DGKH, DGSV and AKI *Guideline for validation of automated cleaning and disinfection processes for heat-resistant medical devices* have compiled and adopted a joint recommendation on this topic. It will be incorporated, together with other supplementary information, into the revised guideline at a later date. The scope of the tests required is, of course, greater than in the case of performance requalification (PRQ) carried out for no particular reason.

1. General instructions

The procedure described below refers exclusively to performance requalification (PRQ) on changing, adding or discontinuing process chemicals. The scope of performance requalification will depend on the type and extent of changes. The tests are conducted with the reference loads used for initial validation. The standard operating procedures must take account of any changes to the preliminary tasks. The following may be affected by a ➜ **CHANGE**:

➜ **DETERGENT, NEUTRALISING AGENT, RINSE AID WATER QUALITY** may be affected.

a) Detergent: a different detergent and/or other use concentration
b) Neutralising agent: a different neutralising agent and/or change to the use concentration or discontinuation
c) Rinse aid: a different rinse aid and/or change to the use concentration or discontinuation. If applicable, changes may be needed for the preliminary rinse.
d) Water quality: water quality apart from the preliminary rinse

The ➜ **MANUFACTURER** of the new process chemicals must make available all the documentation featured in the Guideline:

➜ **THE MANUFACTURER** of the new process chemicals must make all documentation available.

– Product description and dosage recommendation
– Safety data sheet
– Methods for checking the use concentration
– Information on the toxicological safety of any residual amounts of process chemicals remaining on the medical devices
– Methods to detect undershooting of the limit values defined as toxicologically safe for any residual amounts of process chemicals remaining on the medical devices, e.g. in the final rinse water

2. Evaluation (Points 3.1 – 3.4):

– If similar or better ➜ **RESULTS** are obtained for all test batches compared with the initial validation, the process can be deemed to be validated by carrying out performance requalification.

➜ **THE RESULTS** must be compared with those obtained for initial validation and evaluated.

– If poorer results are obtained compared with the initial validation or previous performance qualification exercises, risk analysis, with due attention to any consequential measures needed, must be carried out. The need for changes to ➜ **ROUTINE CONTROL** must be checked.

➜ **ROUTINE TESTS** may need to be changed.

3. Changing the process chemicals

3.1 Changing the detergent

Within the framework of operational qualification fault signals (alarm messages) generated in the event of underdosage or an empty-status message may have to be re-

set since these could be affected by the type and composition of the process chemicals. The following must be borne in mind additionally:
– Dosage precision
– Process chemicals' residues

If the detergent is changed while retaining the set programme cycle, the pressure must be checked, see Guideline 5.2.3.2. The pressure curve must be compared with the pressure curve obtained at the time of initial validation. Any major deviations or fluctuations are an indication of an unfavourable influence being exerted on the cleaning mechanical action.

The cleaning performance is verified with reference loads similar to the instruments used for initial validation. At least two batches are needed with instruments harbouring contamination as encountered in everyday use in addition to at least 5 Crile clamps placed in the same position as during initial validation. The clamps are visually inspected and then subjected to a protein test.

If ➜ **HOLLOW DEVICES** or micro-instruments that are deemed to be particularly critical are to be reprocessed, these must also be checked. To that effect, at least three hollow devices featuring everyday soils (e.g. Verress needle, shaft of an MIS scissors, suction device, etc. as used for initial validation) must be visually inspected and subjected to a protein test. The results must be compared with the results obtained for initial validation.

➜ **HOLLOW DEVICES** must be checked if they are to be reprocessed.

3.2 Changing, adding or discontinuing the neutralising agent

When changing, adding or discontinuing the neutralising agent a check must be made to establish whether the residual quantities of process chemicals in the last rinse water are below the limit values specified by the manufacturer of the process chemicals and that the pH value of the last rinse water is within the neutral range or within the range of the rinse water supplied. The following must be checked additionally:
– Dosage precision

3.3 Changing, adding or discontinuing a rinse aid

When changing, adding or discontinuing a rinse aid the following must be checked:
– Dosage precision
– Drying of surfaces that are particularly difficult to dry
– Influence exerted on the cleaning pressure during the various phases of the programme cycle. If a marked influence can be noticed (see above), tests must also be carried out for verification of the cleaning performance (e.g. residues of the rinse aid during precleaning of the next process cycle).

3.4 Changing the water quality

Since the quality and composition of the water has a major influence on the results (e.g. cleaning performance, absence of stains) obtained for the cleaning process, the ➜ **WATER** must be viewed in the same light as other process chemicals. If any changes are made to this, the following tests must be carried out within the framework of performance requalification:
– in the cleaning step: cleaning performance and cleaning pressure
– in the penultimate rinse step: residues of process chemicals in the rinse water (this point is omitted if it is not possible to measure the conductivity.)
– In the final rinse step: residues of process chemicals in rinse water. ✦

➜ **WATER** must be viewed in the same light as a process chemical.