

## Recommendations by the Quality Task Group (104)

# Washer-disinfector performance requalification

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→ **THIS RECOMMENDATION** replaces Recommendations 54 and 55 and is based on the revised Validation Guideline.

→ **DIFFERENT INTENSITIES OF USE** do not lead to amendment of the test interval.

→ **PQ** can be a recurrent test, but can also become necessary due to certain circumstances.

**T**his → **RECOMMENDATION** replaces the two now obsolete Recommendations 54 “Performance Requalification for No Particular Reason” and 55 “Performance Requalification on Changing the Process Chemicals”.

The Quality Task Group has deemed it necessary to revise these recommendations to bring them into line with the amended version of the “Guideline compiled by DGKH, DGSV and AKI for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices”, 5<sup>th</sup> Edition 2017 (termed the Validation Guideline below).

In the introduction to Recommendation 54 it was suggested that the requalification interval should be based on the number of hours a washer-disinfector (WD) was in operation. That viewpoint has not prevailed since, just like any other periodic inspections (e.g. road traffic or passenger elevators), → **DIFFERENT INTENSITIES OF USE** do not automatically lead to amendment of the test interval.

Section 5.4 “Performance Requalification (Repeat Performance Qualification)” of the Validation Guideline makes reference to the normative requirements. Section 6.1.5 of standard DIN EN ISO 15883 describes “normal practice” as conduct of repeat performance qualification on a yearly basis. If the recommended test interval is not observed, written risk assessment must be carried out following identification and evaluation of the existing risk.

The stipulation in the now obsolete recommendations that maintenance be carried out within 4 to 6 weeks before performance qualification (PQ) has been rescinded. Annex 9 of the Validation Guideline makes clear reference to that in the section on the “Relationship between Maintenance and Repeated PQ”, with the statement “The above-mentioned points and references justify the abolition of the 4-week deadline”. That is explained by the advent of modern maintenance concepts that take account of the most diverse aspects of testing and do not necessarily conform to a rigid calendar.

→ **PQ** is not just a recurrent test because there are also circumstances that may warrant earlier testing. These were explained in Recommendation 55 “Performance Requalification on Changing the Process Chemicals”. The Validation Guideline lists other factors in addition to a change in the process chemicals that may result in earlier requalification. In total five factors are mentioned and can be consulted in Annexes 7 to 9 and in the “Information” on recommended activities:

A – Performance Requalification (Repeat Performance Qualification) without special reason – Annex 7

B – Performance requalification if routine monitoring (of the performance of the washer-disinfector) reveals deviations (from the validation results) – Information 8

C – Performance requalification: Introduction of a new medical device or a new load carrier – Information 8

D – Performance requalification: Change of process chemistry – Annex 8

E – Performance requalification: Following maintenance work – Annex 9, Information 9

Unlike in Recommendation 54, this present recommendation does not list the confirmation documentation/checklists needed; instead, attention is drawn to Annex 7 “Performance Requalification (Repeat Performance Qualification) without special reason” of the Validation Guideline.

Likewise, the information in Recommendation 55 on changing process chemicals is addressed in the revised Validation Guideline (see Annex 8 of the guideline) and will not be repeated here.

The Validation Guideline can be consulted on the homepage of the German Society of Sterile Supply (DGSV) ([www.dgsv-ev.de](http://www.dgsv-ev.de)), in the section on “Specialist Information” and can also be saved as a PDF file. ■