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Reprocessing Validation Recommendations for Reusable Medical Devices:

Category	Cleaning Validation Requirements [1]	Disinfection Validation Requirements [2]	Number of TA Replicates [3]
Non-critical & non-patient contacting	Cleaning can be combined with disinfection validation. Visual inspection results can be used to assess cleaning efficacy.	1 PDC, LLD	3
Non-critical & patient contacting: Low Risk [4]	N/A – Cleaning can be combined with disinfection validation and visual inspection results can be used to assess cleaning efficacy.	1 PDC, ILD, Residuals	3
Non-critical & patient contacting: Higher Risk [4]	1 PDC, 1 analyte, residuals, NDC, NSC, PSC	1 PDC, ILD, Residuals	3
Semi-critical	3 PDC, 2 analytes, residuals, NDC, NSC, PSC	1 PDC, HLD, Residuals	6
Surgical Instruments	3 PDC, 2 analytes, residuals, NDC, NSC, PSC	1 PDC, HLD, Residuals	6
Critical	3 PDC, 2 analytes, residuals, NDC, NSC, PSC	Sterilization (preferred) or HLD (1 PDC) & Residuals if the device is not compatible with sterilization. Sponsor must justify performing HLD.	6
Flexible Endoscopes	3 PDC, 2 analytes, residuals, NDC, NSC, PSC	Sterilization (preferred) or HLD (1 PDC) & Residuals if the device is not compatible with sterilization.	9
Robotics	3 PDC, 2 analytes, residuals, NDC, NSC, PSC	1 PDC, HLD, Residuals	9

References:

AAMI TIR30, AAMI TIR12, 2015 FDA guidance – *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, ISO 17664-2, ISO 15883-5, AAMI ST98 (current draft).

[1] Cleaning validations must include multiple simulated-use cycles prior to the validation test to assess for soil accumulation and to bring the devices into a used condition. It is best practice to use the same device for disinfection validations (if needed).

[2] For European markets, thermal disinfection is often performed as an intermediate step prior to sterilization.

[3] Number of replicates may be adjusted but will need to be scientifically justified. Failure to meet cleaning validation criteria may inquire a larger sample size.

[4] Note: Some non-critical devices can represent a higher level of risk for the presence of residuals below visually detectable levels, and in these cases the qualitative or quantitative detection of analytes can be appropriate. At least 1 analyte should be tested when the device falls into this category. When deciding if a cleaning validation is necessary for a non-critical device, the MDM should follow a risk-based approach to potential contamination and HAI.

PDC: Positive Device Control NDC: Negative Device Control PSC: Positive Sample Control NSC: Negative Sample Control

LLD: Low-level Disinfection ILD: Intermediate-level Disinfection HLD: High-level Disinfection