Information on the requirements for validation and the validation report

Preliminary publication on the 6th Edition of the Guideline compiled by German Society of Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI) for validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices

Guideline Group of DGKH, DGSV and AKI

Information on the validation report

For the first time ever the below-mentioned standard DIN 58341 sets out normative requirements in Annex A, "Requirements and content of validation reports". Therefore, Annex 1 "Structure and content of the documentation (validation folder)" of the current Guideline of the DGKH, DGSV and AKI for validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices, 5th Edition from 2017, is to be withdrawn.

The forthcoming 6th Edition of the Guideline will point out that in future validation reports are to be primarily produced in electronic format.

Information on the requirements for validation

In July 2020, the standard DIN 58341 "Requirements for validation of cleaning and disinfection processes" was published. This contains detailed requirements for validation of automated cleaning and thermal disinfection, automated cleaning and disinfection of thermolabile endoscopes as well as of manual cleaning and chemical manual disinfection. It also sets out requirements for the stipulated level of knowledge of the Medical Devices Operator Ordinance (MPBetreibV). With reference to that, this annex gives an overview of the content of the training courses for qualification of validators (validation engineers).

The Guideline of the DGKH, DGSV and AKI for validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices is being currently revised and contains important points now published here in advance.

DIN 58341 describes in Section 5 the "Requirements for conduct of validation", including the following requisite knowledge:

- Knowledge of medical devices
- Knowledge of standards and regulations
- Knowledge of work equipment and auxiliary materials for cleaning and disinfection processes
- Knowledge of test and measuring instruments used for validation
- Knowledge of microbiology
- Knowledge of chemistry
- Knowledge of hygiene
- Knowledge of devices and processes

The new Annex 2 of the forthcoming 6th Edition of the Guideline of DGKH, DGSV and AKI for validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices presented here specifies how, depending on the respective measure (IQ / OQ / PQ / requalification), proof of the requisite qualification can be furnished.

The new Annex 2 has been compiled in collaboration with members of the three Guideline Groups: "Guideline of the DGKH, DGSV and AKI for validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices", "Guideline for validation of automated cleaning and disinfection processes for reprocessing thermolabile endoscopes" and "Guideline for validation of manual cleaning and manual chemical disinfection of medical devices".

Annex 2: Requirements for qualification of validators in compliance with DIN 58341

Introduction

With the publication of DIN 58341, detailed requirements were defined for validation of automated cleaning and thermal disinfection, automated cleaning and disinfection of flexible endoscopes as well as for manual cleaning and chemical manual disinfection. Furthermore, requirements are set out for the stipulated level of knowledge of the Medical Devices Operator Ordinance (MPBetreibV). With reference to that, Annex 2 now gives an overview of the content of the training courses for qualification of validators (validation engineers).

Obligations of the economic operator

At the time of awarding a contract, the economic operator must, in compliance with MPBetreibV, Section 5 and Section 8, ensure that the requirements addressed to the validator are met.

The contract for conduct of validation/requalification can be awarded to

- an independent organization, or
- an organization responsible for the manufacture/supply/installation of devices or process chemicals, or
- internally to the economic operator themselves.

In all cases, a declaration must have been made that the validator is not subject to any instructions with regard to professional assessment.

Note

- By exemption of the validator from Section 106 of the Trade Regulation Act
- Based on DIN EN ISO 17025, accredited test laboratories do not need to make any additional declaration regarding the fact that validators are free of instructions.

When choosing an organization to conduct validation the operator may request, before awarding the contract, the corresponding evidence as set out in the column "Achieved e.g. by means of" from the table below. The requirements differ for IQ, OQ, PQ and requalification.

Furthermore, DIN 58341 stipulates that those entrusted with validation must have installed "a quality management system, for example in accordance with DIN EN ISO 13485". Comparable proof of competency, for example in accordance with the standard DIN EN ISO 17025 for accredited test laboratories, can also serve as proof of compliance with the requirements.

Before awarding the contract, the operator must verify whether all these requirements are being met by the validator entrusted with this task.

Keeping knowledge up to date

Time- and event-related update of knowledge must be implemented and documented. Note: the economic operator must request proof of knowledge when awarding the validation / requalification contract.

For certified (DIN EN ISO 13485) or accredited (DIN EN ISO 17025) institutions /organizations, audits are regularly conducted by external bodies that must provide proof to the economic operator that the organization entrusted with validation has a continuously effective QM system in place.

Time related:

- At least every two years

Event related:

- For section a) *general knowledge*, following any change to relevant standards or regulations
- For section b) *device-specific knowledge for process-related changes*

Table documenting the general and device-specific knowledge required for qualification of validators

The following table presents in detail the general and device-specific knowledge required.

General knowledge											
				Reprocessing method			Validation steps				
Requirements in compliance with the standard or based on the standard	See DIN 58341	Achieved e.g. by means of	Knowledge required by validator	Washer-disinfector (WD)	Endoscope washer-disinfector (EWD)	Manual	Installation qualification (IQ)	Operational qualification (OQ)	Performance qualification (PQ)	Requalification
Knowledge of the content and application of a QM system must be assured in compliance with DIN EN ISO 13485.	4.3	▪ Certification in compliance with DIN EN ISO 13485 ▪ Accreditation in compliance with DIN EN ISO 17025 ▪ Appropriate course/training ▪ Modules corresponding to the DGSV training courses FK1 and FK2	Is able to explain the term "quality" and its relationship to medical device reprocessing	X	X	X	X	X	X	X
			Knows the legal requirements for the quality management system for medical device reprocessing	X	X	X	X	X	X	X
			Knows the need for, and basic structure of, a quality management system handbook	X	X	X	X	X	X	X
			Knows the significance and need for procedures and work instructions	X	X	X	X	X	X	X
			Knows the requirements for a quality management system in relation to the medical devices circuit and documentation	X	X	X	X	X	X	X
			Knows the significance of documentation for medical device reprocessing and validation	X	X	X	X	X	X	X
X = required - = not required											

				Reprocessing method			Validation steps			
Requirements in compliance with the standard or based on the standard	**See DIN 58341**	**Achieved e.g. by means of**	**Knowledge required by validator**	**Washer-disinfector (WD)**	**Endoscope washer-disinfector (EWD)**	**Manual**	**Installation qualification (IQ)**	**Operational qualification (OQ)**	**Performance qualification (PQ)**	**Requalification**
			Is able to explain the term "validation" and the need for validated processes	X	X	X	X	X	X	X
			Is able to explain the term "certification"	X	X	X	X	X	X	X
			Knows the term "audit" in relation to QM and certification (RUMED /validation company)	X	X	X	X	X	X	X
			Is able to name and explain the criteria for preparation of validation	X	X	X	X	X	X	X
			Is able to name examples of medical devices and load patterns that are difficult to reprocess	X	X	X	X	X	X	X
			Is able to describe validation methods and understands documentation of the results	X	X	X	X	X	X	X
Knowledge of risk management (DIN EN ISO 14971 and VDI 5700)	4.4	▪ Certification in compliance with DIN EN ISO 13485 ▪ Accreditation in compliance with DIN EN ISO 17025 ▪ Appropriate course/training ▪ Training according to VDI 5700 Sheet 2	Knows the term and the significance of risk management in relation to validation	X	X	X	X	X	X	X
			Knows reasons for refusing validation contracts	X	X	X	X	X	X	X
Knowledge of how to select the most appropriate real-life instruments and loads, dwell times, knowledge of processes and of the programmes used, reprocessing circuit, interpretation of information from DIN EN ISO 17664	5.2	▪ Modules corresponding to FK1 ▪ Expertise course in endoscopy ▪ Supplementary robotics module (if robotic instruments are used)	Is able to name the materials, and their properties, most commonly used at present to manufacture reusable medical devices	X	X	X	–	–	X	X
			Is able to name the most important steps in instrument production and their impact on instrument use and appropriate reprocessing (surface composition of surgical instruments with regard to the requirements for use, design features, functional use, appropriate reprocessing, inspection and care)	X	X	X	–	–	X	X
			Is able to explain the shape and design features of surgical and microsurgical instruments with regard to functional use, and explain how to recognise damage, carry out visual inspection and functional testing as well as explain the applicable criteria	X	X	X	–	–	X	X

				Reprocessing method			Validation steps			
Requirements in compliance with the standard or based on the standard	See DIN 58341	Achieved e.g. by means of	Knowledge required by validator	Washer-disinfector (WD)	Endoscope washer-disinfector (EWD)	Manual	Installation qualification (IQ)	Operational qualification (OQ)	Performance qualification (PQ)	Requalification
			Is able to name instruments in accordance with their functions and shape (in the case of endoscopes, name the body region in which used)	X	X	X	–	–	X	X
			Knows that medical devices must be classified before reprocessing and is able to name the groups as well as the implications for reprocessing	X	X	X	–	–	X	X
			Is able to give an overview of the medical devices circuit with regard to their use and reprocessing	X	X	X	–	–	X	X
			Is able to describe various types of surface changes and their causes	X	X	X	–	–	X	X
			Is able to detect and define contaminants, damage, surface changes and name their possible causes	X	X	X	–	–	X	X
			Is able to name the processes currently available for automated cleaning and disinfection of motors	X	–	X	–	–	X	X
			Knows the requirements for automated cleaning and disinfection of anaesthesia medical devices, etc.	X	–	X	–	–	X	X
			Knows the importance of the manufacturer's reprocessing instructions for minimally invasive surgical (MIS)/microsurgical instruments and is able to name the important parameters for cleaning and disinfection of MIS/microsurgical instruments	X	–	X	–	–	X	X
			Knows the importance of the manufacturer's reprocessing instructions for robotic instruments and is able to name the important parameters for cleaning and disinfection of robotic instruments	X	–	X	–	–	X	X
			Knows the importance of the manufacturer's reprocessing instructions for flexible endoscopes and is able to name the important parameters for cleaning and disinfection of flexible endoscopes	–	X	X	–	–	X	X

				Reprocessing method			Validation steps			
Requirements in compliance with the standard or based on the standard	**See DIN 58341**	**Achieved e.g. by means of**	**Knowledge required by validator**	**Washer-disinfector (WD)**	**Endoscope washer-disinfector (EWD)**	**Manual**	**Installation qualification (IQ)**	**Operational qualification (OQ)**	**Performance qualification (PQ)**	**Requalification**
Knowledge: German MPDG[1], MPBetreibV[2], KRINKO/BfArM Recommendation[3], AKI[4] Brochures, Guideline of the DGKH[5], DGSV[6] and AKI, knowledge of the medical devices circuit, Drinking Water Regulation and relevant information from the VDI	5.3	▪ Modules corresponding to FK1 ▪ Modules corresponding to FK2 ▪ Course for validators e.g. DGSV	Knows the significance of legal acts, regulations, standards, guidelines and recommendations as well as the content thereof of relevance for conduct of validation	X	X	X	X	X	X	X
Work equipment and auxiliary materials, accessories and their key aspects (process engineering) Process engineering: work bench systems (incl. dosage mechanisms, loading racks for ultrasonic cleaners, precleaning equipment, compressed air, auxiliary materials/ accessories, e.g. brushes, water pistols)	5.4	▪ Course for validators e.g. DGSV ▪ Modules corresponding to FK1 ▪ Expertise course in endoscopy	Is able to explain manual cleaning and disinfection	–	–	X	–	–	X	X
			Is able to name the various types of precleaning (e.g. ultrasonic, brushing, rinsing)	X	X	X	–	–	X	X
			Is able to name the work equipment and auxiliary materials for manual precleaning and knows their function and use (e.g. brushes, magnifying lamps, adapters)	X	X	X	–	–	X	X
			Is able to assess whether the work equipment and facilities meet the requirements for manual precleaning	X	X	X	–	–	X	X
			Knows that this work equipment and auxiliary materials must be cleaned and disinfected each time used	X	X	X	–	–	X	X
			Knows how high the water or air pressure may have to be set or reduced	X	X	X	–	–	X	X
			Knows the significance of the correct dosage and exposure time of the cleaning and disinfection solutions used and is able to assess whether these solutions were prepared with suitable materials. The validator is able to assess whether the timers are appropriate and whether the specified exposure times were observed during the processes	–	X	X	–	–	X	X

				Reprocessing method			Validation steps			
Requirements in compliance with the standard or based on the standard	See DIN 58341	Achieved e.g. by means of	Knowledge required by validator	Washer-disinfector (WD)	Endoscope washer-disinfector (EWD)	Manual	Installation qualification (IQ)	Operational qualification (OQ)	Performance qualification (PQ)	Requalification
			Knows how high the water or air pressure may have to be set or reduced	X	X	X	–	–	X	X
			Knows the significance of the correct dosage and exposure time of the cleaning and disinfection solutions used and is able to assess whether these solutions were prepared with suitable materials. The validator is able to assess whether the timers are appropriate and whether the specified exposure times were observed during the processes	–	X	X	–	–	X	X
			Knows the role of ultrasound in precleaning and is able to assess whether the loading pattern has been observed. Knows that the medical devices must be positioned on a tray rack and that the ultrasound bath frequencies and exposure times specified by the manufacturer must be observed at certain temperatures. Is able to assess whether the process chemicals used are suitable for the intended use	X	X	X	–	–	X	X
			Knows the importance of the separation of unclean working steps from the post-disinfection steps and is able to assess the hygiene level of the work circuit	–	X	X	–	–	X	X
			Knows the requirements for the process water (drinking water and demineralized water) and the quality of the compressed air used	X	X	X	X	X	X	X
			Knows the significance of visual inspection after the precleaning step and knows which soils are particularly difficult to remove in an automated process and must have been removed after precleaning (e.g. ointments, bone cement, glues)	X	X	X	–	–	X	X
			Is able to assess whether any cloths/ compressed air used for drying meet the requirements	–	X	X	–	–	X	X

1 German Medizinprodukterecht-Durchführungsgesetz (MPDG)
2 German Medical Devices Operator Ordinance (MPBetreibV)
3 KRINKO/BfArM Recommendation: Hygiene requirements for reprocessing medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO) and the Federal Institute for Drugs and Medical Devices (BfArM)
4 Working Group Instrument Reprocessing
5 German Society for Hospital Hygiene
6 German Society for Sterile Supply
7 Association of German Engineers (VDI)

				Reprocessing method			Validation steps			
Requirements in compliance with the standard or based on the standard	**See DIN 58341**	**Achieved e.g. by means of**	**Knowledge required by validator**	**Washer-disinfector (WD)**	**Endoscope washer-disinfector (EWD)**	**Manual**	**Installation qualification (IQ)**	**Operational qualification (OQ)**	**Performance qualification (PQ)**	**Requalification**
Specialist knowledge of the work equipment and measuring systems used for validation Measurement and control technology, selection of appropriate measuring instruments, proper handling of measuring equipment/ instruments Measurement methods and their influencing factors and limitations Expertise in evaluating the measurement results	5.5	▪ Course for validators e.g. DGSV ▪ Proof based on accreditation/approval in compliance with DIN EN ISO 17025 ▪ Training in measurement and control technology: skilled worker's certificate e.g. as - Electronics engineer for automation technology - Electronics engineer for operational technology - Mechatronics engineer	Has knowledge of sensor technology and its application	X	X	-	-	X	X	X
			Has knowledge of calibration of test and measuring instruments	X	X	-	-	X	X	X
			Has knowledge of evaluating the test and measurement results	X	X	-	-	X	X	X
			Has knowledge of measurement uncertainties of the test and measuring instruments	X	X	-	-	X	X	X
			Has knowledge of the evaluation software to be used	X	X	-	-	X	X	X
Basic knowledge of microbiology must be assured Knowledge of sampling and sample dispatch (laboratory) and evaluation	5.6	▪ Modules corresponding to FK1 and ▪ Course for validators e.g. DGSV	Knows the difference between bacteria and viruses in terms of size, morphology, spore formation (bacteria), reproduction, incl. growth curves in closed systems (bacteria), behaviour in the environment	X	X	X	-	-	X	X
			Knows the terms quantitative and qualitative pathogen identification (bacteria)	X	X	X	-	-	X	X
			Knows the terms contamination, infection, pathogen source, pathogen transmission routes, incl. examples	X	X	X	-	-	X	X
			Has knowledge of the requisite sampling	X	X	X	-	-	X	X
			Has knowledge of sample transport	X	X	X	-	-	X	X

X = required
- = not required

				Reprocessing method			Validation steps			
Requirements in compliance with the standard or based on the standard	**See DIN 58341**	**Achieved e.g. by means of**	**Knowledge required by validator**	**Washer-disinfector (WD)**	**Endoscope washer-disinfector (EWD)**	**Manual**	**Installation qualification (IQ)**	**Operational qualification (OQ)**	**Performance qualification (PQ)**	**Requalification**
Basic knowledge of chemistry: ▪ Process chemistry (cleaning, neutralization) ▪ Process water ▪ Sampling of final rinse water ▪ Analytical evaluation on site (e.g. pH value), measurement of conductivity value and its implications	5.7	▪ Modules corresponding to FK1 and ▪ Appropriate FK2 modules and ▪ Course for validators e.g. DGSV	Has knowledge of process chemistry ▪ Detergents: ingredients (e.g. complexing agents, surfactants, enzymes) and their mechanisms of action ▪ Disinfectants: active ingredients, mechanisms of action and possible interaction with other chemical products ▪ Neutralizing agents: ingredients, application criteria and effect ▪ Tolerable residues of process chemicals	X	X	X	–	X	X	X
			Has knowledge of water chemistry: ▪ Industrial and drinking water: chemical constituents and their properties ▪ Assessment criteria for the water quality: pH, conductivity value, vapour residues and constituents (hardening constituents, special cations such as of Fe, Cu, etc., special anions such as Cl, SiO_2 ▪ Water treatment methods: softening, desalination (reverse osmosis), demineralization (distillation, ion exchange, electrodeionization, etc.)	X	X	X	X	X	X	X
			Has knowledge of the microbiology requirements for the final rinse water ▪ Treatment of the final rinse water (sterile filtration, UV light; thermal) ▪ Knowledge of carrying out sampling and of the sampling conditions e.g. aseptic sampling techniques, required neu-tralization of the process chemicals, sample quantity, transport)	–	X	X	–	X	X	X
	5.6		Has knowledge of analysing the cleaning results: ▪ Direct method of staining (e.g. Amido Black) ▪ Sampling through elution with 1% SDS solution (recovery) ▪ Differentiation of qualitative, semi-quantitative and quantitative methods ▪ Haemoglobin detection ▪ BCA, modified OPA and other methods of residual protein determination (mechanisms of interaction and error sources, positive and negative controls) ▪ Photometric measurements ▪ Analytes for non-protein-based soils	X	X	X	–	–	X	X

				Reprocessing method			Validation steps			
Requirements in compliance with the standard or based on the standard	**See DIN 58341**	**Achieved e.g. by means of**	**Knowledge required by validator**	**Automated in washer-disinfector (WD)**	**Endoscope washer-disinfector (EWD)**	**Manual**	**Installation qualification (IQ)**	**Operational qualification (OQ)**	**Performance qualification (PQ)**	**Requalification**
Knowledge of hygiene: occupational safety and health regulations, hygiene policy, management of infectious samples	5.8	▪ Modules corresponding to FK1 ▪ Modules corresponding to FK2 ▪ Course for validators, e.g. DGSV	Is able to name the key hygiene regulations applicable in medical institutions	X	X	X	X	X	X	X
			Knows the aims of hygiene measures	X	X	X	X	X	X	X
			Is able to define the terms cleaning and disinfection and sterilization	X	X	X	X	X	X	X
			Is able to explain hygienic hand disinfection	X	X	X	X	X	X	X
			Knows the significance of, and how to carry out, surface disinfection	X	X	X	X	X	X	X
			Is able to name the key occupational safety and health regulations in the RUMED	X	X	X	X	X	X	X
			Knows the aims of occupational safety and health	X	X	X	X	X	X	X
			Is able to name the occupational safety and health measures in a RUMED and for management of contaminated materials and laboratory samples	X	X	X	X	X	X	X

X = required
– = not required

Device-specific knowledge												
				Reprocessing method			Validation steps					
Requirements in compliance with the standard or based on the standard	See DIN 58341	Achieved by means of	Knowledge required by validator	Washer-disinfector (WD)	Endoscope washer-disinfector (EWD)	Manual	Installation qualification (IQ)	Operational qualification (OQ)	Performance qualification (PQ)	Requalification
Expert validation in compliance with DIN EN ISO 15883-1 can only be carried out when adequate technical knowledge of the devices and equipment used is assured. This technical knowledge consists of: ▪ Electrotechnical knowledge ▪ Knowledge of safety functions Electrical: Knowledge of all device-specific safety mechanisms, other electrical functions, structure of the device from an electrical point of view, incl. potential equalization. Process engineering: Special features of the respective washerdisinfector (WD,) incl. the loading racks used, heating type, drying and extraction system, water pipeline network, process chemicals, automatic programme selection, knowledge of disabled functions, water storage, relationship between loading racks and medical devices, performance limitations of the system (what can/may be reprocessed), validation-related information (pressure range of loading racks, worst-case aspects, loading patterns, partial load, programme cycles, what interruptions are possible, solution volumes) must be available from the type test (for IQ, OQ); for PQ the validator must be familiar with the data; knowledge of the standard(s) applicable to the device	5.9.1 5.9.2 5.9.3 5.9.4 6.4.2 6.4.3 6.4.4 6.5.2 6.5.3 6.5.5	Up-to-date knowledge gleaned from appropriate training and commensurate professional experience	Is able to check doors and locking systems as instructed by the manufacturer (if necessary, override and disconnect locking switches)	X	X	–	–	X	–	–
			Is able to check the anti-pinch protection of automatic doors as well as the covers of top-loading machines as instructed by the manufacturer (short circuit, if necessary interrupt/simulate wire break)	X	X	–	–	X	–	–
			Knows that if the WD/EWD doors are open, it must not be possible to start a programme (simulate electrically)	X	X	–	–	X	–	–
			Is able to test the fault alarms, and their function, of the devices to be tested by: ▪ Interruption or short circuit of the measuring chain ▪ Functional testing of the door switch	X	X	–	–	X	–	–
			Is able to check the device-specific dosing level monitoring for detergents and disinfectants for low supply or simulate electrically	X	X	–	–	X	–	–
			Is able to the simulate (e.g. electrically) underdosing	X	X	–	–	X	–	–
			Knows about minimum pressure monitoring as instructed by the device manufacturer	X	X	–	–	X	–	–
			Is able to test the pressure at the medical device connection ports as instructed by the device manufacturer	X	X	–	–	X	–	–
			Is able to measure the water volume in each process step (cold water, hot water, demineralized water) as instructed by the device manufacturer	X	X	X	–	X	–	–
			Is able to check by means of visual inspection the correct installation of filters (water filters, air/HEPA filters) as instructed by the device manufacturer	X	X	X	–	X	–	–
			Knows the special features of the loading racks used and the minimum pressure levels required	X	X	–	–	X	X	X

				Reprocessing method			Validation steps			
Requirements in compliance with the standard or based on the standard	**See DIN 58341**	**Achieved by means of**	**Knowledge required by validator**	**Washer-disinfector (WD)**	**Endoscope washer-disinfector (EWD)**	**Manual**	**Installation qualification (IQ)**	**Operational qualification (OQ)**	**Performance qualification (PQ)**	**Requalification**
Since it must be ensured during validation that the reprocessing process is interrupted before the disinfection step, the validator must have the commensurate knowledge		The manufacturer's information for use (IFU)	Is able to interrupt the programme before the disinfection step	X	X	-	-	X	X	X
			Is able to correctly take a sample of the final rinse water	X	X	-	-	X	X	X
Special functions of the endoscope washer-disinfectors (EWD) specified in DIN EN ISO 15883-4	5.9.5	Up-to-date knowledge gleaned from appropriate training and commensurate professional experience	Is able to the test that endoscope channels are not blocked	-	X	X	-	X	X	X
			Functional testing of the leakage tester for endoscopes (if available)	-	X	X	-	X	X	X
X = required - = not required										