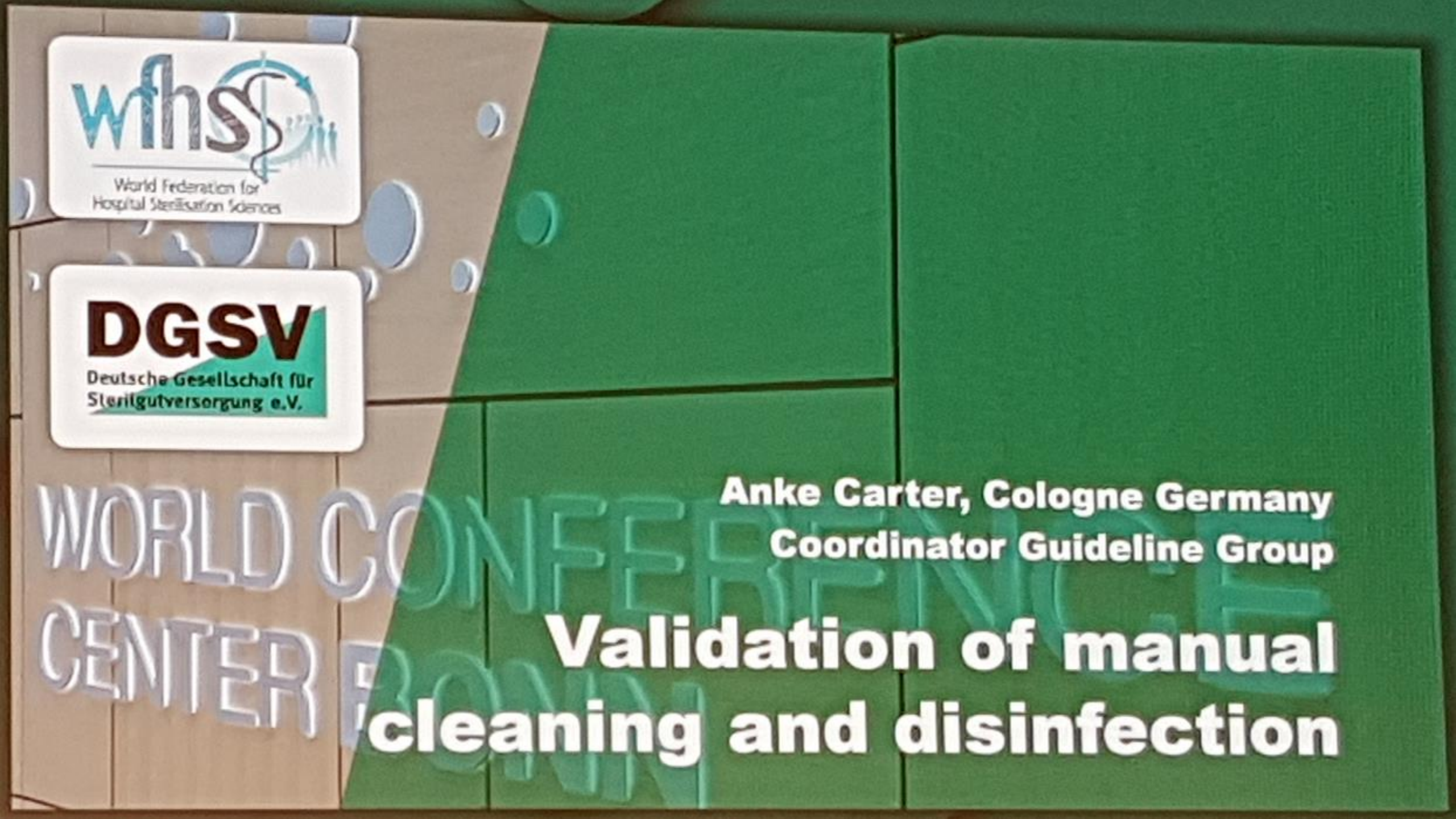


Anke Carter, Cologne Germany
Coordinator Guideline Group

Validation of manual cleaning and disinfection

Validation

ISO TS 11139: „documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications."

Validation of procedures of reprocessing Medical Devices based on Standards

Validated automated processes are:

- Automated Cleaning and thermal disinfection (EN ISO 15883)
- Automated Cleaning and disinfection of flexible endoscopes (DIN EN ISO 15883
- Sealing of pouches (EN ISO 11607)
- Steam sterilization (EN ISO 17665)
- Formaldehyde sterilization (EN 14180)
- Ethylene oxide sterilization (EN ISO 11135)
- H2O2 sterilization (DIN EN ISO 14937

Validation of procedures of reprocessing Medical Devices

Manual processes to be validated

- Manual cleaning and disinfection (Guideline by DGKH, DGSV and AKI)
- Vision control
- Lubrication and Maintenance
- Functional control
- Packaging (DGSV - Guideline)

Quality Management is the key to standardization and validation of procedures

Responsibility for Validation of processes

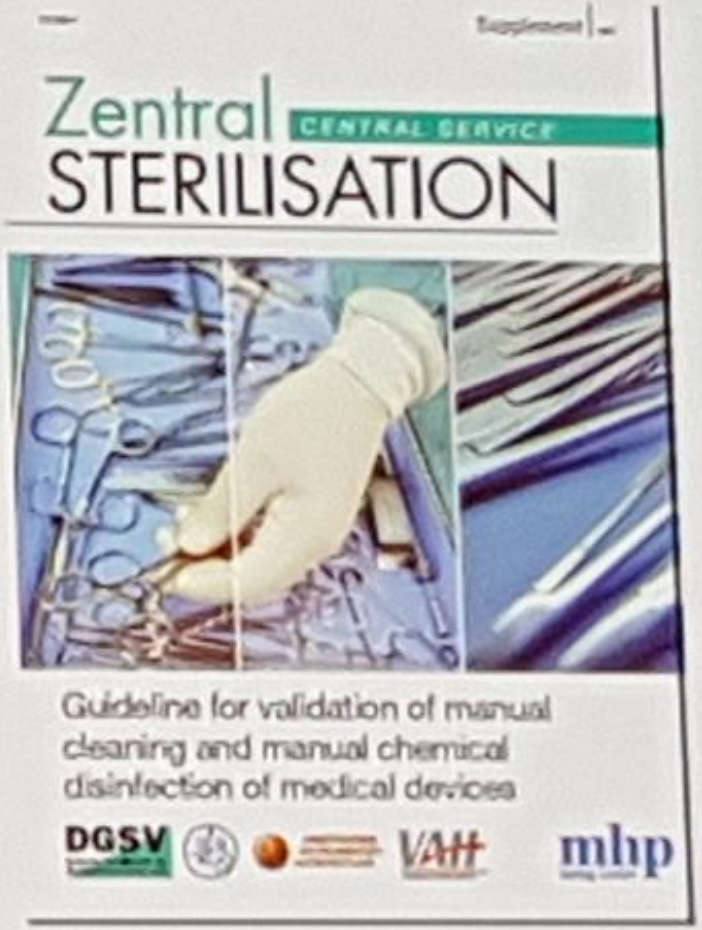
- The Hospital or the Central Service provider are responsible for validation
- There has to be profound knowledge of the procedure of validation, therefore validation has to be a part of the education for CSSD Managers and staff
- Validation of automated processes is carried out with support of technicians who know about the function of the washer-disinfectors, sterilizers and sealing machines
- Validation of manual processes depends largely on the personnel working in CSSD

Validation of manual cleaning and disinfection processes

- Basic requirement for the validation of manual cleaning and disinfection is an implemented Quality Management System
- Further requirements
  - technical
  - organizational
  - information from the manufacturer,
  - medical devices - compliant with DIN EN ISO 17664
  - process chemicals
  - risk assessment and classification of medical devices
  - application of validated detection methods to verify quality characteristics

Guideline for the validation of manual cleaning and chemical disinfection 0f medical devices

The success of performing manual cleaning and disinfection has been in the past in general not checked. Against this background, and with the experience of developing the guidelines for the validation of the automated cleaning and disinfection processes this guideline for the validation of manual cleaning and chemical disinfection has been written. It provides information and background of legal requirements for operators for the set up of Standard Operating Procedures and for their validation for the first time.



The guideline was developed by

German Society for Hospital Hygiene (www.dgkh.de)

German Society for Sterile Supply (www.dgsv-ev.de)

Instrument Reprocessing Working Group (www.a-k-i.org)

supported by the Association for Applied Hygiene (www.vah-online.de)

Objectives for the Guideline

- Standardization: Provision of working materials for the creation of operator-specific standard operation procedures for manual cleaning and disinfection of medical devices depending on the design and classification of medical devices.

- Verification: Provision of methods and acceptance criteria for the review of operator-specific standard operating procedures regarding the results of the cleaning and disinfection as well as identification of chemical residue after manual cleaning and disinfection.

- Validation: Provision of means and methods for carrying out the validation of manual cleaning and chemical disinfection.

Scientific research and publication

Before publishing the Guideline studies were carried out

Studies on the manual processing of medical instruments (exploratory investigation on behalf of the guideline-group of DGKH, DGSV and AKI)

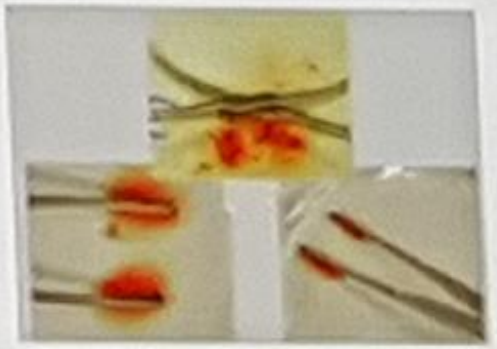
J. Gebel[1], P. Haubrich[1], S. Gemein[1], B. Hornei[2],
A. Carter[3], M. Exner[1]
1: Institute of Hygiene and Public Health at the University of Bonn
2: MVZ society for medical care centers GbR Cologne
3: MMM Group, Planegg

Authors in consultation with the guideline-group

Study in a laboratory

Instruments used for testing

Surgical instruments	Classification categories
surgical forceps	Critical A
dissecting forceps	Critical A /semicritical A
Crile-forceps	Critical B
Volkman spoons	Critcal A



*Classification categories acc. to Spaulding and RKI/BfArM

Summary of results of laboratory tests

- Instruments of category "critical B" have, compared to "semi-critical A" and "critical A" instruments, have a significantly higher demand for cleaning and disinfection
- Different Standard Operating Procedures (SOPs) are needed for instruments of different design
- Manufacturers of instruments have to provide detailed reprocessing recommendations
- There was a large variation in results depending on the reprocessing procedures, thus a standardization of procedures is urgently needed
- Independent testing of the combination „instrument – processing procedures“ is highly recommended

Field tests in hospital CSSDs

- Trials without standard operating procedure (SOP)
- 10 CSSDs participated in the first trial
- Cleaning and disinfecting Crile forceps following their own standards, using their own chemicals and using their own cleaning equipment (e.g. brushes)

- Trials with a provided standard operating procedure (SOP)
- 9 CSSDs participated in the second trial
- Cleaning and disinfecting Crile forceps following instructions stated in the SOP using their own chemicals and using their own cleaning equipment (e.g. brushes)

Summary of results of the field trials (CSSD)

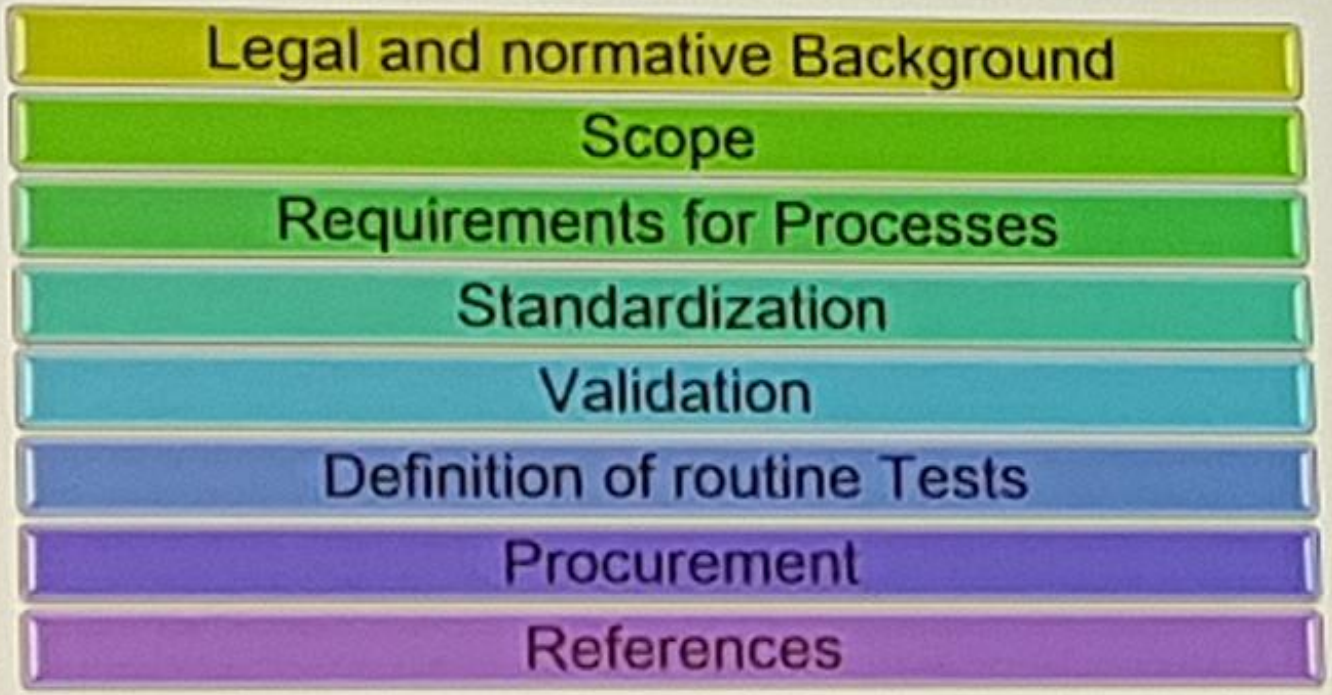
Summary of results of the field trials

- Results of field tests with well-trained personnel are comparable with those of a non-validated test of WD's with the same specimens (CSSD 2005)
- Manual cleaning and disinfection takes a lot of staff time (8-15 minutes /instrument)
- Optimization potential through standardization and validation of the processes is apparent

Working with the guideline

- Read and understand the guideline
- The Annexes contain the necessary information to carry out the standardization and validation
- The test matrix for the validation contains a complete overview of tasks
- The checklists can be used as a template for the creation of own checklists
- Perform standardization of processes
- Perform validation of processes
- Write Validation Report

Structure and Content

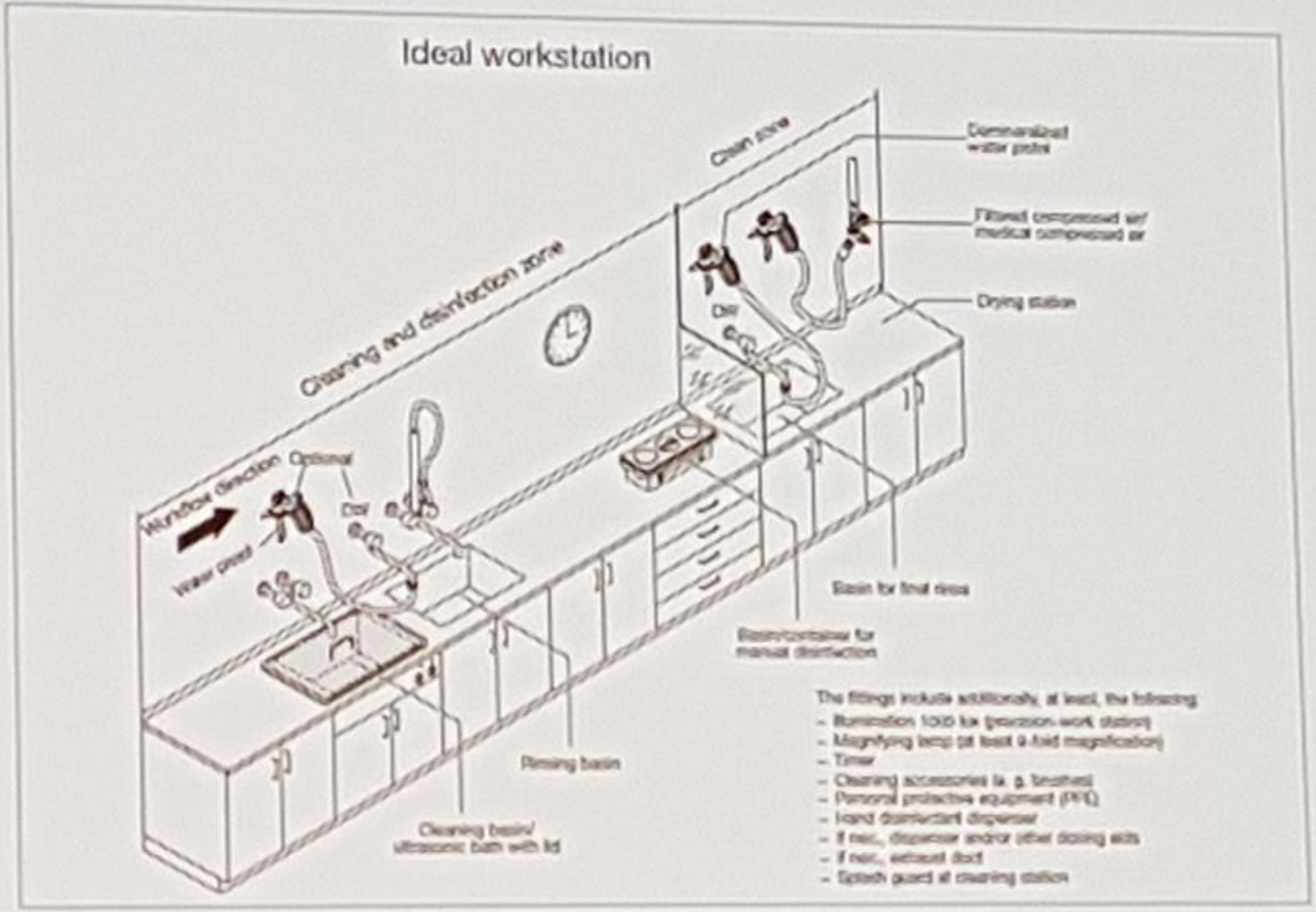


14 Annexes

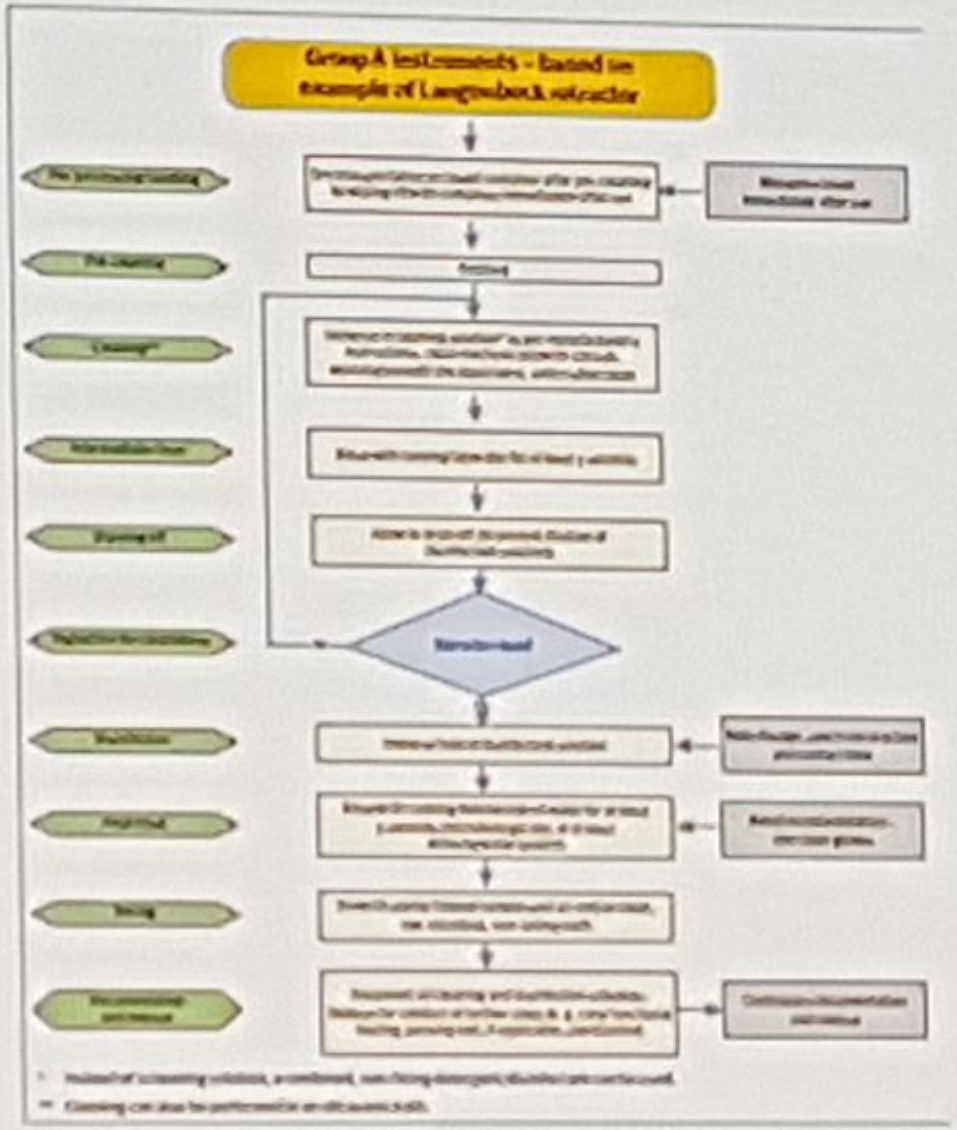
contain information for operators about various subjects

- Contents of EN ISO 17664
- Workstation example
- Determination of a processing procedure
- Flow Chart Group A instruments
- Flow chart Group B instruments with joints
- Flow chart Group B hollow instruments
- Qualification needed by validation personnel
- Verification of Cleaning
- Acceptance criteria for assessment of efficacy
- Process chemicals
- Chemical water quality
- Ultrasound to supplement cleaning
- Using water and compressed air pistols
- Dosage equipment for disinfectants

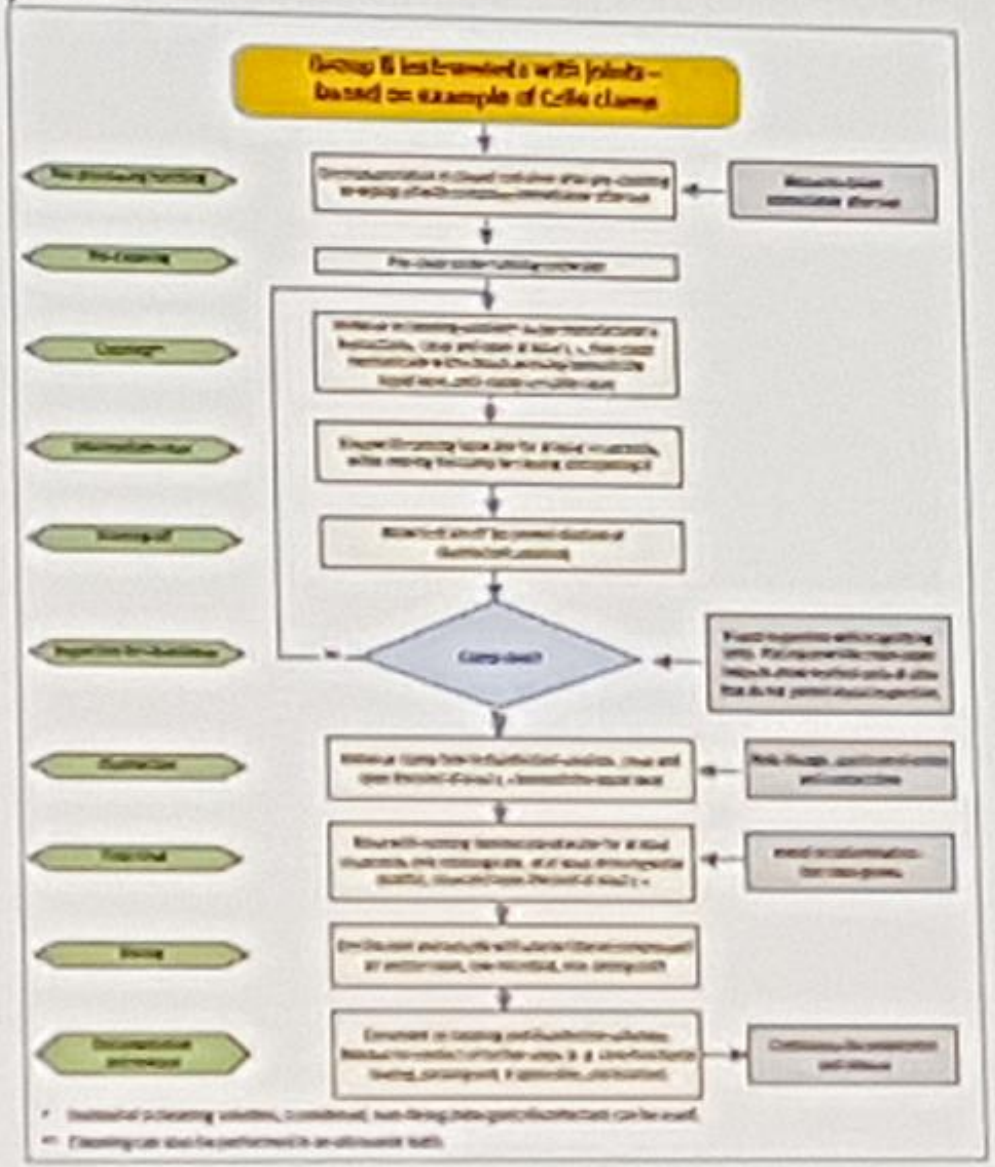
Annex 2: Workstation – example



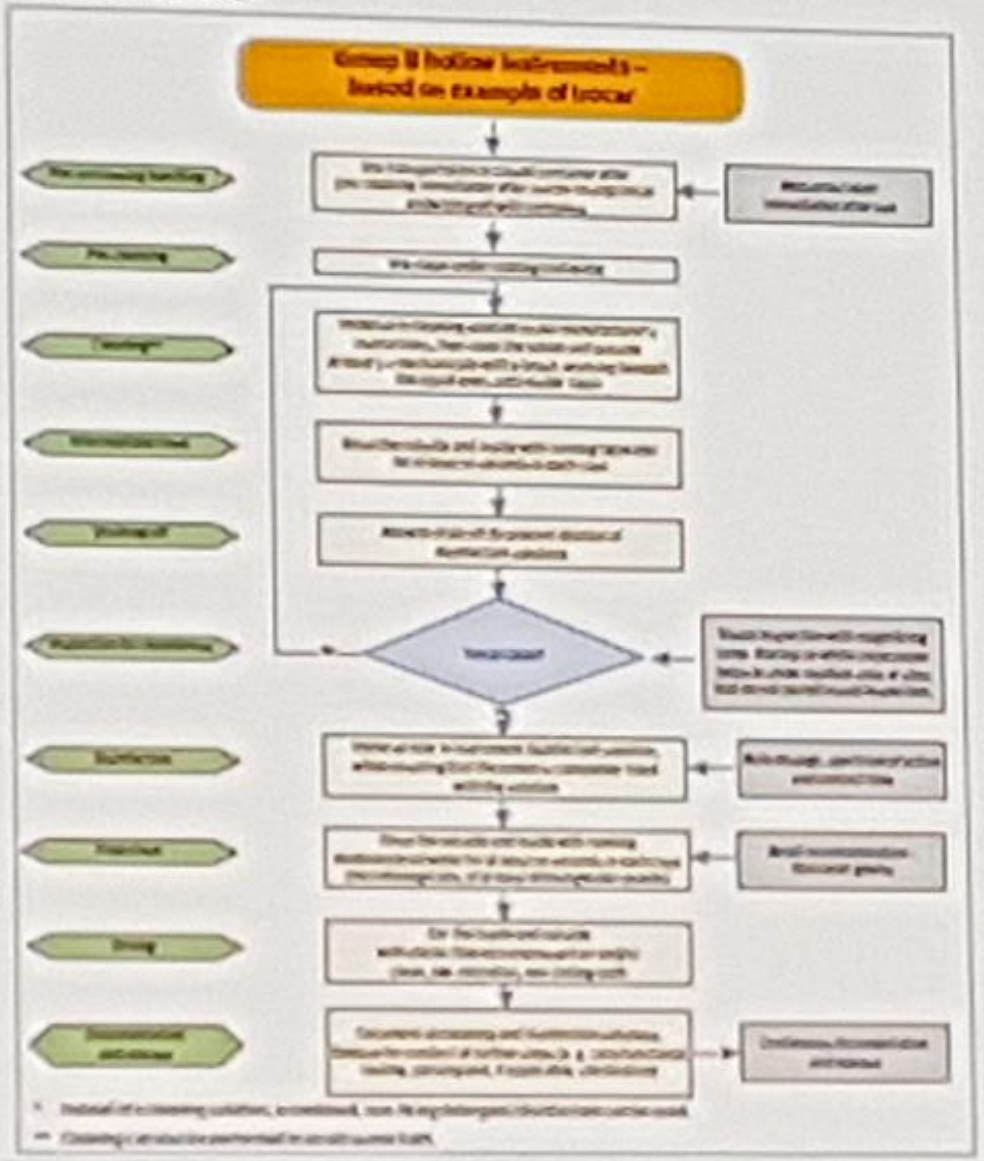
Annex 4: Flow chart: Group A instruments



Annex 5: Flow chart: Group B instruments with joints



Annex 6: Flow chart: Group B hollow instruments



Annex 9 - Acceptance criteria for process challenge devices

- All process challenge devices (PCDs) must be visibly free of test soils
- Semi-quantitative or quantitative testing for protein residues is performed only for visibly clean instruments.
- Protein per PCD as bovine serum albumin (BSA):

- Limit value: > 150 µg must not be reached/exceeded
- Alarm value: > 80 ≤ 150 µg
- Guide value: ≤ 80 µg

Group	Model Instruments	Methodology	Guide Value
1	Instruments without joint and without cavity: sharp spoon, wound retractor	Visual inspection	< 10–15 µg/per 4–5 cm²
2	Instruments with joint: scissors, clamps	At least semi-quantitative protein detection after elution in PE bag	< 75 µg per instrument (up to a length of 15 cm) < 100 µg per instrument (for a length of more than 15 cm)
		Elute as for Crile clamp PCD, but using only the working end with joint	< 50 µg per instrument
3	Sliding-shaft instruments: punches, rongeurs	Quantitative protein detection after elution of the entire instrument in PE bag	< 100 µg per instrument
		Partial elution of working end into test tube, supplemented by ultrasound	< 50 µg per instrument
4	Instruments with cavity (tubular instruments): MIS instruments	Quantitative protein detection e. g. shaft of a dismantable instrument, only interior sampled (flush out):	< 75 µg per instrument (up to 4 mm internal diameter) < 100 µg per instrument Schaftrohr (more than 4 mm internal diameter)
		Working elements separately (e. g. eluted in tube closed at both ends)	< 50 µg per working element
		Only jaw region with joint in test tube, supplemented by ultrasound	< 40 µg per jaw region with joint
5	Microinstruments	Quantitative protein detection after elution of entire instrument	< 50 µg per instrument < 20 µg per instrument (ophthalmology instruments)

Structure and content of the guideline

7 Checklists

to support documentation during validation

- Organizational prerequisites
- Structural prerequisites
- Batch Documentation
- Validation report cover page
- Operational Qualification
- Performance qualification
- Daily routine checks of manual workstation

Structure and content of the guideline

1 Test Matrix	The test matrix Validation of manual cleaning an disinfection processes assists the operator to plan and review the individual steps of validation
	Provides information on inspection intervals to support the planning of the operator

Test matrix: Validation of manual cleaning and disinfection processes									
Test Objects	Test Requirements		Number of Tests						
Designation	Criteria	See guideline/ document	Validation Installation qualification	Validation Operational qualification	Validation Performance qualification	Performance requalification for no specific reasons	Performance requalification for a specific reason		Routine check
Structural separation or division into zones	Installation suitable for intended purpose	Cl.[1] 1 and 2 F = Checklist	1 x after installation			omitted	a. b. c. d.	x x ○ ○	omitted
Personnel qualifications	Demonstrably qualified to conduct manual cleaning and disinfection; records of instructions available	MPBetreibV, Cl. 1	1 x after installation			Verification	a. b. c. d.	○ ○ x x	omitted
Installation of workstations at operator's premises	Installation suitable for carrying out manual cleaning and disinfection	Annex 2 Cl. 2	1 x after installation			Verification	a. b. c. d.	x x ○ ○	omitted
Ultrasound	Equipment manufacturer's instructions, operator requirements	Annex 12 DIN Cl. 2 Cl. 3	1 x after installation	1 x after installation	3 x	1 x	a. b. c. d.	○ x ○ ○	Cl. 7 as per SOP
Dosing equipment/dosing aids	Equipment manufacturer's instructions, operator requirements	Annex 14 DIN Cl. 2 Cl. 3	1 x after installation	1 x after installation	1 x	Annual calibration	a. b. c. d.	x x ○ ○	
Drying cabinet	Medical device and equipment manufacturer's instructions, operator requirements	DIN Cl. 2 Cl. 3	1 x after installation	1 x after installation	1 x	1 x	a. b. c. d.	○ ○ x ○	
Other equipment for cleaning and/or disinfection	Medical device and equipment manufacturer's instructions, operator requirements	DIN Cl. 2 Cl. 3	1 x after installation	1 x after installation	1 x	1 x	a. b. c. d.	○ ○ x ○	
Media supply (e. g. water, compressed air)	Medical device and equipment manufacturer's requirements, operator requirements	Annex 11, Annex 13, Cl. 2, Cl. 3	1 x	1 x	omitted	1 x	a. b. c. d.	○ x ○ ○	Cl. 7
Detergents, disinfectants	Medical device and process chemicals' manufacturer's instructions, CE mark	Annex 15 Cl. 1, Cl. 3	1 x	1 x	omitted	1 x	a. b. c. d.	○ x x ○	Cl. 7
For no specific reasons: Based on re-validation and routine tests For specific reasons: a. Structural changes to processing circuit b. Change of media supply c. New SOP d. New staff x = required ○ = not required									

Test matrix (continued): Validation of manual cleaning and disinfection processes								
Test Object	Test Requirements		Number of Tests					
Designation	Criteria	See guideline/ document	Validation Installation qualification	Validation Operational qualification	Validation Performance qualification	Performance requalification for no specific reason	Performance requalification for a specific reason	Routine check
Cleaning result for instruments with everyday soils, in the case of semi-critical and critical B MDs	Acceptance values as per Annex 9	5.2.3.1	omitted	omitted	3 x per SOP but at least 3 instruments	3 x per SOP but at least 3 instruments	a, b, c, d: O x O x	as specified at the time of validation
Cleaning result for instruments with everyday soils, in the case of non-critical, semi-critical and critical A MDs	Acceptance values as per Annex 9	5.2.3.1	omitted	omitted	3 x per SOP but at least 9 instruments	3 x per SOP but at least 3 instruments	a, b, c, d: O x O x	as specified at the time of validation
Disinfectant solution	Compliance with SOP specifications	5.2.3.2	omitted	omitted	1 x per SOP but at least 3 x	1 x per SOP but at least 3 x	a, b, c, d: O x O x	as specified at the time of validation
Disinfection, including final rinse and drying	Observe disinfection process	5.2.3.2	omitted	omitted	3 x per SOP	1 x per SOP	a, b, c, d: O x O x	as specified at the time of validation
	Measure residual chemicals on PCD (Citric clamp)	5.2.3.4	omitted	omitted	3 x per SOP	1 x per SOP	a, b, c, d: O x O x	as specified at the time of validation
	Check for residual moisture	5.2.3.3	omitted	omitted	3 x per SOP	1 x per SOP	a, b, c, d: O x O x	as specified at the time of validation
Documentation and release	Complete documentation and release	4.2.10 Cl. 3	omitted	omitted	depending on task	depending on task	a, b, c, d: x x x x	as specified at the time of validation

For no specific reason: Based on risk evaluation and routine tests

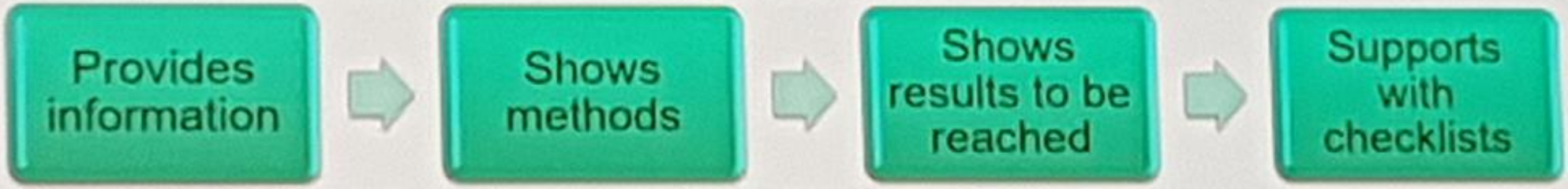
For specific reason: a. Structural changes to processing circuit b. Change of media supply c. New SOP d. New staff

x = required O = not required

Summary

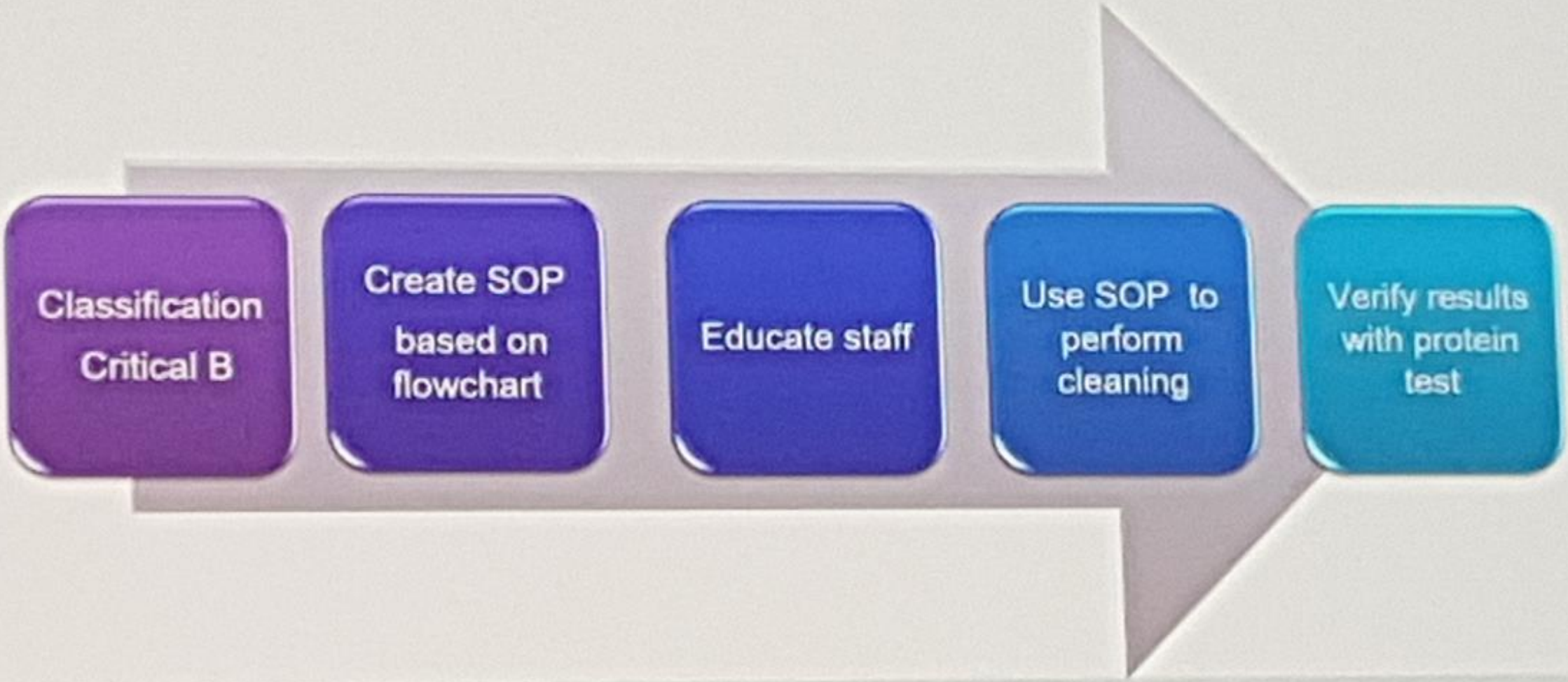
Working with the guideline and validating the processes of manual cleaning and disinfecting is a lot of work! ....But always remember:

All steps of reprocessing Medical devices have to be reproducible and manual cleaning and disinfection has to be as good as automated procedures, thus results need to be checked! The guideline

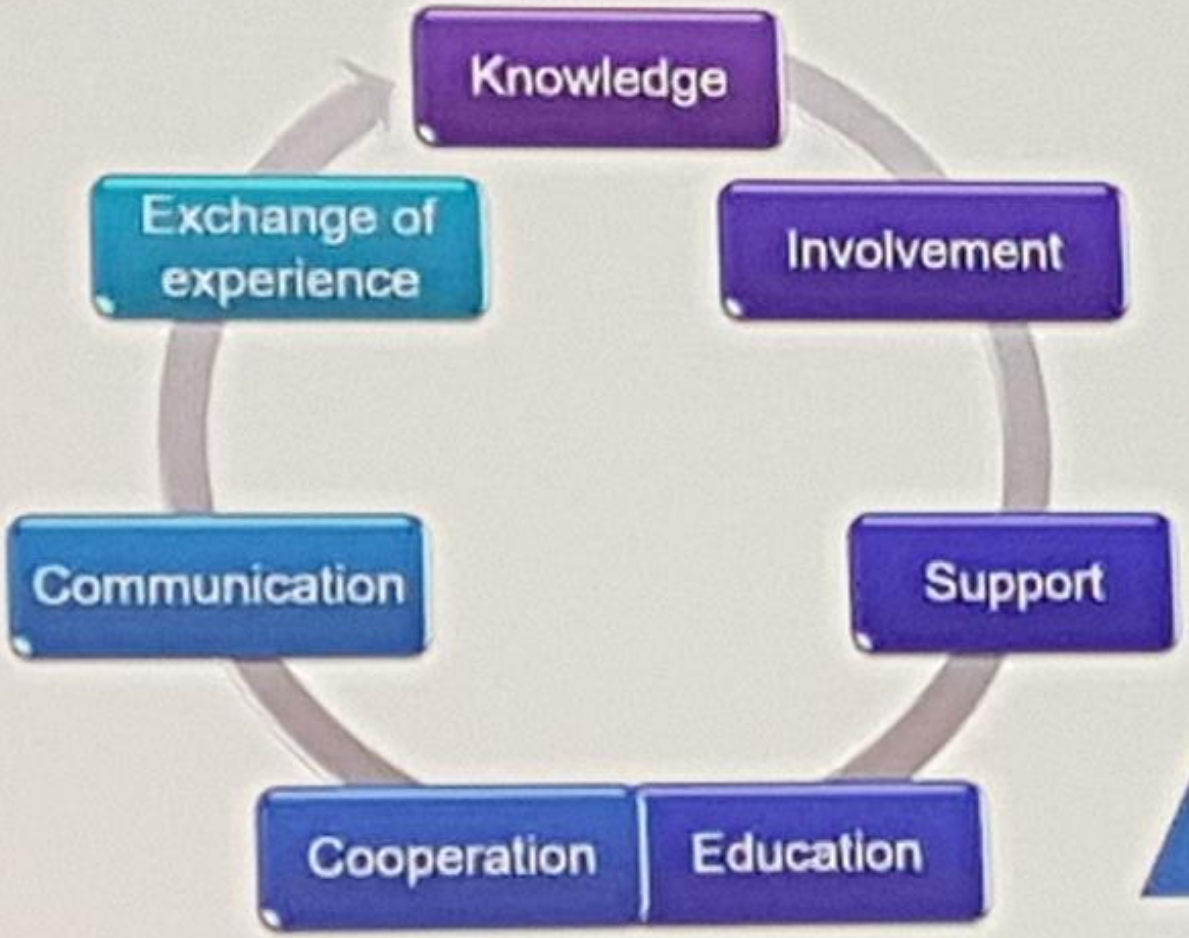


So lets get started and take the first step.....

Standardization and Validation by use of an SOP



The Future of reprocessing



For the wellbeeing

- of patients
- employees
- and everyone concerned