

Recommendations by the Quality Task Group (84)

Quality assurance in reprocessing (Part 2)

Revision of Recommendations 13, 16 and 17

Part 1 (Recommendation 80; *Central Service 4/2013*) described the essential requirements for quality assurance. Part 2 now focuses on quality assurance for procurement of medical devices which have been designated for reprocessing by the manufacturer, while also explaining the various procedural steps involved.

→ **BEFORE PROCUREMENT** a number of points should already be observed.

I Procurement of reprocessible instruments

In the interest of quality assurance, the following points should be observed already before → **PROCUREMENT** of instruments:

- Is reprocessing possible in principle?
- Are all manufacturer's instructions prescribed by EN ISO 17664 available?
- Is automated cleaning and disinfection possible?
- Have the KRINKO/BfArM Recommendations [1] (Chapter 1.2, 1.2.2, 2.2.2) been clarified prior to procurement? For example:
 - Reprocessing: preferably automated cleaning and disinfection; preferably moist-heat sterilization
 - Material compatibility
 - Cleaning in an alkaline medium
- Is it possible to implement the recommended cleaning and disinfection procedure using the processes already available in the CSSD (programmes, loading racks, process chemicals, etc.)?
- Can the sterilization processes available in the CSSD be used?
- Are further purchases needed to ensure proper reprocessing (e. g. new loading racks)?
- Are subsequent costs incurred (e. g. performance requalification due to special circumstances)?
- Must staff training be provided (possibly by the manufacturer)?

→ **CAREFUL INSPECTION** of new and repaired instruments is necessary.

I Factory-new instruments and instruments returned for repair

Each new instrument, or instrument returned for repair, received in the CSSD must be carefully → **INSPECTED** and handled, bearing in mind the following points:

- Remove protective caps, protective films as instructed
- Inspect for transport damage
- Clean as instructed by the manufacturer, e. g. to eliminate any residues persisting from the manufacturing process or transport
- Distribute the instruments or store as directed

→ **VALIDATED PROCESSES** are necessary to assure quality.

I Cleaning and disinfection

Validated processes are used to assure the quality of cleaning and disinfection. The use of such → **VALIDATED PROCESSES** for medical device reprocessing is stipulated by Section 4(2) of the Medical Devices Operator Ordinance (MPBetreibV). This applies for

both automated and manual processes. Preference must be given to automated cleaning and disinfection over manual processes. Thermal disinfection processes are superior to chemical disinfection processes.

The requisite routine tests and validation activities must be set out in the **QUALITY MANUAL**, with details of responsibilities, competences and conduct.

In practice thermal, chemothermal and manual disinfection methods are used. Validation guidelines have been compiled to facilitate process validation. Such guidelines are available for automated cleaning and thermal disinfection processes for medical devices, for manual cleaning and manual chemical disinfection of medical devices as well as for automated cleaning and disinfection processes for reprocessing heat-sensitive endoscopes [2, 3].

The Quality Task Group has issued recommendations for certain, special, instruments and associated automated cleaning and disinfection. These are as follows: Recommendation 40 – 05/2005, Recommendation 45 – 04/2006, Recommendation 70 – 03/2011, Recommendation 71 – 04/2011, Recommendation 72 – 05/2011, Recommendation 74 – 01/2012 and Recommendation 76 – 03/2012.

Recommendation 62 – 05/2009 can be consulted for guidance on conduct of manual cleaning and disinfection. That recommendation was compiled following the «Wish-Wash» Workshop held at the German Society of Sterile Supply (DGSV) Congress in Fulda in 2009.

The insights gained from the workshop led to formulation of the guideline for validation of manual cleaning and manual chemical disinfection [4].

Resources and specifications

- Manufacturer's service log book for equipment
- Validation reports
- Standard operating procedures (SOP)

I Inspection, functional testing, care, packaging

Procedural steps

- Visual inspection of decontaminated medical devices
- Functional testing and care
- Replacement of defective instruments
- Packing of trays according to packing lists and packing of individual instruments
- Labelling of packaging

Resources and specifications

- Manufacturer's product data sheets (e. g. packaging material, care agents)
- Packing lists and, as applicable, photographic documentation
- Guideline for validation of packaging processes [5]

I Sterilization and provision

Procedural steps

- Conduct of sterilizer routine tests as per standard operating procedure (SOP)
- Conduct of daily steam penetration test (Bowie & Dick test), see Recommendation 18 from 05/2001
- Selection of suitable sterilization programmes
- Sterile supply release
 - Verification of correct process cycle (temperature, pressure, time) on the basis of the batch documentation
 - Visual inspection of integrity of packaging and labelling
 - Evaluation of chemical batch control, if this specified as a batch-related routine check at the time of validation
- Storage, transport and provision of sterile supplies as per the valid standards

→ **IN THE QUALITY MANUAL** the requisite validations and routine test must be set out.

Resources and specifications

- Manufacturer's service log book for equipment
- Validation reports
- SOPs

I Summary

All points addressed above are an integral part of quality assurance in reprocessing departments.

→ **REPRODUCIBILITY** of all procedural and working steps must be assured.

Daily working practices must be executed such that the → **REPRODUCIBILITY** of all procedural and working steps is assured.

Ultimately, a committed approach to quality assurance helps to enhance patient safety and conserve resources.

I References

1. Hygiene requirements for processing 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), Federal Health Gazette 2012-55:1244–1310.
2. Guideline for validation and routine monitoring of automated cleaning and disinfection of heat-resistant medical devices as well as advice on selecting washer-disinfectors, compiled by the German Society for Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI), 3rd Edition October 2008. Central Service Suppl. 2, 2008.
3. DGKH, DGSV, AKI and DEGEA (German Society of Endoscopy Nurses and Assistants): Guideline for validation of automated cleaning and disinfection processes for reprocessing heat-sensitive endoscopes. Central Service Suppl. 3, 2011.
4. DGKH, DGSV, AKI and VAH (Association of Applied Hygiene): Guideline for validation of manual cleaning and manual chemical disinfection of medical devices. Central Service Suppl., Oct. 2013.
5. DGSV and ZLG (Central State Body for Health Protection with Regard to Drugs and Medical Devices): Guideline for validation of packaging processes pursuant to EN ISO 11607-1, Central Service Suppl 2, 2011.

The Quality Task Group Recommendations and guidelines can be downloaded from the DGSV homepage (www.dgsv-ev.de).