Recommendations by the Quality Task Group (80)

Quality assurance in reprocessing

In 2000 and 2001, Recommendations 13, 16 and 17 were published by the Quality Task Group under the title «Quality assurance on the clean and unclean side of a CSSD». In the meantime, and in particular because of the issues addressed in the amended KRINKO/ BfArM Recommendation – Recommendation for hygienic reprocessing practices for 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) – it must be stated from the outset that quality assurance is an inherent component of the quality management system applied for medical device reprocessing. A well-established quality management system lays the foundation for ➜ **QUALITY ASSURANCE**.

➜ **QUALITY ASSURANCE** is based on a well-established quality management system.

Quality assurance does not begin only after the used instruments have been dealt with. Rather, ➜ **PREPARATIONS** are already made for reprocessing while handling the instruments in the operating room (OR). In doing so, the user must observe the «Hygiene requirements for medical device reprocessing» [1].

➜ **PREPARATIONS FOR REPROCESSING** are already made in the OR.

Unused as well as used medical devices must be appropriately prepared for transport to the reprocessing site (e. g. opened and dismantled). Suitable mechanisms must be used to secure sensitive instruments (e.g. instruments with optics) during transport.

➜ **STANDARD OPERATING PROCEDURES** (SOPs) must be compiled to describe the activities and procedures needed.

➜ **STANDARD OPERATING PROCEDURES** must be compiled to describe all the necessary activities and procedures.

Appropriate management of medical devices after use helps not only to eliminate or reduce additional procedural steps and costs arising from damage sustained during transport, it also prevents and limits danger to personnel in the Central Sterile Supply Department (CSSD) (Chapter 7 of the German Technical Regulation on Biological Substances (TRBA 250) in the healthcare and welfare setting).

Documentation for formulation of a quality assurance concept

There are myriad regulations to be borne in mind for formulation of a quality assurance concept for medical device reprocessing, while additional documents provide useful tips. In Germany, various regulations, including the legal provisions of Book V of the German Code of Social Law (SGB), German Medical Devices Act (MPG), Medical Devices Operator Ordinance (MPBetreibV), Protection against Infection Act (IfSG), guidelines by the Employers' Liability Insurance Associations such as e.g. the Accident Prevention Ordinance (UVV), German Technical Regulation on Biological Substances (TRBA 250), German Technical Regulation on Hazardous Substances (TRGS 555), as well as the introduction of a quality management system for medical device reprocessing serve as the ➜ **BASIS FOR QUALITY ASSURANCE**.

➜ **QUALITY ASSURANCE** is based on various legal regulations.

Furthermore, there are regularly updated lists issued by the Robert Koch Institute (RKI) on equipment, processes and disinfectants to be used in the event of an epidemic. A list compiled by the Association for Applied Hygiene (VAH) provides information on disinfectants for disinfection of hands, surfaces, instruments and laundry for routine clinical activities.

The pertinent ➜ **STANDARDS** must also be observed, e. g. EN ISO 15883 regulating validation of automated cleaning and disinfection processes, EN ISO 11607 on packaging processes and those for sterilization processes (e. g. EN ISO 17665 for steam sterilization). The supporting ➜ **GUIDELINES** compiled by the German Society for Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI) also provide practical advice on implementation of validation [2].
Service log books, operating instructions and validation documentation must be available for all equipment used in a reprocessing unit (e. g. washer/disinfector, rotary sealer, sterilizer).
The RKI/BfArM Recommendation governing «hygiene requirements for medical device reprocessing» is cited in Article 4 MPBetreibV, thus conferring on it a quasi-legal character: «Medical device reprocessing is assumed to be conducted in the prescribed manner if …» that Recommendation is observed. Any ➜ **DEVIATIONS** from that must be explained and justified.
The recommendations by the DGSV Quality Task Group focus, in particular, on practical issues and give tips for implementation and application of the legal regulations, recommendations and directives for reprocessing medical devices.
The AKI's «Value-Retaining Instrument Reprocessing» section deals primarily with value retention and material behaviour of instruments. This group gives advice on how to prevent damage to medical devices.
The Medical Devices Act (MPG) stipulates that medical device manufacturers must supply ➜ **DETAILED REPROCESSING INSTRUCTIONS** for each device pursuant to EN ISO 17664. The CSSD/reprocessing unit management must be in possession of such instructions and must have access to all the aforementioned documents when formulating a quality assurance concept. All reprocessing personnel must have the requisite qualifications (Article 4 MPBetreibV).
Such expertise can be acquired by successfully attending the specialist training courses organized by the DGSV and obtaining the corresponding certificates.

➜ **STANDARDS** for process validation have to be observed.

➜ **GUIDELINES** provide practical advice on implementation of validation.

➜ **DEVIATIONS** from the RKI/BfArM Recommendation must be explained and justified.

➜ **DETAILED REPROCESSING INSTRUCTIONS** must be provided by medical device manufacturers.

Documentation

Quality assurance is legally stipulated (e. g. SGB V, MPG, MPBetreibV) and, as such, is a mandatory requirement for medical device reprocessing.
➜ **DOCUMENTATION** of a quality management system in a quality management manual constitutes an important element of quality assurance:

➜ **DOCUMENTATION** constitutes an important element of quality assurance.

Procedures and Instructions

- All workflow patterns and working steps must be described in detail in (standard) operating procedures (SOPs), while taking account of the pertinent regulations.
- Workplace descriptions must be compiled. Any deviations or special instructions must be explained and justified.
- Occupational safety requirements and their exact implementation must be defined and documented (e. g. as regards when to use protective clothing).
- The applicable hygiene (infection control) measures must be set out in SOPs (e. g. hand disinfection, surface disinfection) and be observed.

Other applicable documents (examples)

- Expert opinions, manufacturer's instructions as well as technical leaflets, warranties, reprocessing instructions must be appropriately filed and updated as required.
- Safety data sheets for all process chemicals used must be filed and accessible to users. Operating instructions must be compiled and staff informed about hazards and safety instructions.
- A valid cleaning and disinfection policy must be compiled and made accessible to all employees.

Validation, periodic tests, routine tests and technical maintenance

- Technical and hygiene tests must be defined at the time of validation and documented in a validation report.
- Schedules must be drawn up for conduct of environmental tests

➜ **CHECKLISTS** facilitate conduct of prescribed tests.

Conduct of the prescribed tests must be documented. The use of ➜ **CHECKLISTS** is recommended to that effect. Summary examples of the minimum content to be covered by the documentation is set out in the guidelines on process validation for medical device reprocessing [2] and these can be consulted for tips on conduct of validation. Such documents serve as evidence that the prescribed reprocessing steps and processes have been reproducibly observed and are checked at regular intervals.

Staff training and induction

Written records must be maintained on regular staff training and induction, showing the training content, list of participants and trainer.

Summary

All the issues mentioned above are an inherent component of quality assurance in reprocessing departments, but by no means is that list to be viewed as being exhaustive. The prevailing circumstances and other special requirements must be observed and described on an individual case basis.

➜ **REPRODUCIBILITY** of all routine procedures and workflow patterns must be ensured.

➜ **GOOD TEAM WORK** is necessary for living quality assurance.

The ➜ **REPRODUCIBILITY** of all routine procedures and workflow patterns must be ensured.

Every quality assurance concept must be based on the premise that quality can be assured only when working as a functional team. Therefore well-coordinated ➜ **INTERACTION** with all the relevant departments is vital.

Last but not least: living quality assurance promotes patient safety, staff satisfaction and better utilization of resources. ■

References

1 RKI/BfArM Recommendation: Hygiene requirements for medical device reprocessing, Nov. 2012

2 Guideline compiled by the German Society for 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 as well as advice on selecting washer-disinfectors, 3rd Edition 2008