

# Quality Task Group Workshop C at the DGSV Conference in Potsdam: Quality assurance by means of washer-disinfectors in running operation

In Workshop C lectures were given on this topic with a view to improving the quality of automated processing of medical devices, while taking account of the given specifications and available resources. The workshop was based on the activities of the Quality Task Group, which had its last meeting in Osnabrück under the direction of Anke Carter, and in particular on the working group around Anne Gründer-Förster based at the Hans-Susemihl-Hospital in Emden.

- What do we already know?
- Which goals are new?
- How can they be reached?
- Who can help us reach them?

Rather than using a virtual hospital, the workshop focused its attention on Emden Hospital, which is a 394-bed, basic and standard care establishment. With approximately 5,000 procedures each year, covering the inpatient and outpatients domains, some 34,000 sterilisation units (STUs) are processed annually for the departments of traumatology, general and vascular surgery, gynaecology, ENT and maxillofacial surgery. C. Itzen, the hospital's specialist hygiene nurse, gave an overview of the available resources: premises, washer-disinfectors as well as personnel and their qualifications obtained on completion of specialist courses I, II and III organised by the German Society for Sterile Supply (DGSV). She elaborated in particular on the control plans, which had been updated only in July 2002. A routine control plan always entails an intrinsic control concept which is tailored to the individual needs, bearing in mind the applicable specifications and requirements.

B. Früh acted as moderator for the ensuing lectures, giving an overview of the most important provisions from the Medical Devices Operator Ordinance and the RKI Guideline. There are still many issues to be addressed for classifying medical devices (MDs). The decision tree, of which the Quality Task Group presented a revised version at the congress, elicited keen interest (see above). It is important to also take account of the previous as well as the intended use, hence it is not possible to give any binding information for an MD (please also consult the information given on this topic in Issues 3 and 4/2002).

Dr. Brömmelhaus, from the manufacturer Miele, directed his attention to the importance of having washer-disinfectors regularly serviced by the after-sales service; but he did not neglect to also state that only daily cleaning of e.g. trays etc. and functional checks are needed. Further inprocess control mechanisms, said R. Schäpers, BHT, are integrated into the latest washer-disinfector designs which monitor water quantity, temperatures, exposure times, pressure, dosage quantities, etc. and use displays, fault signals or machine standstill to alert the operator to malfunctioning. But they are not a substitute for supplementary checks such as visual inspection for cleanliness and verification of the cleaning performance.

S. Krüger outlined the test methods listed in standard prEN ISO 15883 "Washer-Disinfectors" and how performance verification, also in combination, can be used in existing washer-disinfectors such as with thermologgers, tests based on test soils, water quality and dosage quantities. Furthermore, other tests can be integrated, such as TOSI for checking the spray pattern and protein detection using the biuret method. This topic was further illustrated with many photos in a lecture given by C. Dogs, from Merz, outlining functional testing of a washer-disinfector. The workshop was shown a comparison between the TOSI and radionuclide method in which K. Roth, SMP, outlined the good correlation between the two test procedures.

Workshop C proved to be a popular event and was well attended on both days. Since topics were explored from different angles, they gave rise to many questions and discussions from the practical setting. The Quality Task Group will deal with some of these in the next projects, so that we can continue our joint quest for the key to the still unopened locks.

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# Recommendations by the Quality Task Group (24) Classifying Medical Devices before Processing (Part 3)



