Recommendations by the Quality Task Group (47): Insights Gleaned from Workshops at the 10th DGSV Congress: Manufacturer's Instructions for Decontamination

The workshop "Manufacturers' standard operating procedures – a real help or a source of confusion?" was repeated thrice at the 10th Congress of the German Society of Sterile Supply (DGSV). Here it came to light that the users would like to receive more precise instructions for decontamination and storage of medical devices (MDs) from many manufacturers. Some manufacturers only provide information on manual processes, advising "brush thoroughly, rinse thoroughly, etc." Some examples were shown, especially those of manufacturers based outside Germany. Often, the information provided by these foreign MD manufacturers are not tailored to the process cycles used in Europe, or in Germany, for washer-disinfectors, steam sterilisers, packaging materials or process chemicals.

Users want to subject the MDs to ➜ **AUTOMATED REPROCESSING USING MILDLY ALKALINE DETERGENTS**, and, if they are to be used in a sterile condition, to steam sterilisation, in order to meet quality assurance requirements. Standardisation of validated process steps is being aspired to for cost reasons and in the interest of minimising the possibility of errors (wrong programme, wrong detergent). There is a consensus that ➜ **MANUAL PROCESSES** are not validable strictly speaking, but rather can only be assured on the basis of standard operating procedures and staff training.

➜ **AUTOMATED REPROCESSING USING MILDLY ALKALINE DETERGENTS AND STEAM STERILISATION** meet quality assurance requirements.

➜ **MANUAL PROCESSES** are not validable.

Since MD decontamination begins already after they are used, i.e. in the OR, ➜ **INSTRUCTIONS FOR PRECLEANING** such as "wipe off course residues", "rinse" and on transportation would be desirable. There are transport trays e.g. for optical instruments, some are also suitable for automated reprocessing, but others are totally unsuitable because the water collects inside them.

➜ **INSTRUCTIONS FOR PRECLEANING** would be desirable.

Some manufacturers provide detailed instructions, with diagrams, for dismantling modular instruments.

Precleaning may be absolutely indispensable for heavily contaminated or filigree MDs. Therefore all manufacturers should specify whether ➜ **PRECLEANING IN AN ULTRASOUND BASIN** is possible without causing any damage and what type of detergents or combined detergents and disinfectants are suitable or unsuitable.

➜ **THE POSSIBILITY OF PRECLEANING IN AN ULTRASOUND BASIN** should be specified by all manufacturers.

However, no information is given on how the MDs are to be positioned in the WD. Why is that so? Do the WDs have different inserts and connection possibilities so that the MD manufacturers are not able to elaborate of the plethora of options available? Often, the adapters, LuerLock fittings, etc. needed are missing in the WD. Likewise, divergent instructions are given for partial loads. Should the non-occupied connection facilities be closed or not? If they are not closed, does this lead to a major in pressure? Must channels that should not come into contact with water be closed? Must closures be removed again before sterilisation? It would be very desirable if such ➜ **DISMANTLING AND CONNECTION INSTRUCTIONS** could be given on site, e.g. in an MIS insert, as well as information on material tolerability profiles, designation of decontamination cycles and maintenance intervals. In general all new MDs should also be demonstrated in the CSSD and the CSSD should be involved in reaching any ➜ **DECISIONS ABOUT PURCHASES**!

➜ **DISMANTLING AND CONNECTION INSTRUCTIONS** should be given on site.

➜ **DECISIONS ABOUT PURCHASES** should only be taken after demonstration of a new MD in the CSSD and involving the CSSD personnel.

A knowledgeable consultant suggested that the user himself should define his own load patterns, and possibly should monitor the cleaning pressure levels. However, to date most users do not have the know-how or equipment to do so.

There have been complaints that the data provided on process chemicals are not sufficient. Queries such as e.g.: at what concentration is which pH value reached? What role does the cleaning water play?, have been raised time and again.

Only general instructions are checked off in the matrix to standard EN ISO 17664, e.g. "suitable for automated cleaning with alkaline detergents", but the user would ideally like to receive ➜ **MORE PRECISE PRODUCT INFORMATION, LIKE TESTED AND LISTED DETERGENTS**, e.g. for the particularly delicate instruments used in ophthalmology.

➜ **MORE PRECISE PRODUCT INFORMATION, LIKE TESTED AND LISTED DETERGENTS,** would be helpful for the user.

The application instructions given by the manufacturers of disinfectants often fail to point out that the disinfectant efficacy declines after several loads in line with increasing contamination of the solution, or any instructions given are liable to misinterpretation. Likewise, simple control methods are not cited.

Only incomplete or no instructions are given by the manufacturers for assembly, maintenance of non-standard functional checks and care as well as for packaging and storage.

The non-German manufacturers should at least specify as an alternative to ➜ **STEAM STERILISATION** a sterilisation process commonly used in Germany, e.g. a vacuum instead of a gravitation process.

➜ **FOR STEAM STERILISATION** a process commonly used in Germany should be specified by non-German manufacturers.

In general, ➜ **IMPLANT ACCESSORIES** (screws, plates, etc) are delivered in an unsterile condition and are processed and sterilised on the user's premises. Are the control measures adequate? Would it not be possible to supply the screws and plates in a sterile state? Or does this come down to the doctors' typical expectation of having an ample range at their disposal? It would be desirable if the parts could be coded, packed separately and supplied by the manufacturer in a sterile condition, together with storage instructions.

➜ **IMPLANT ACCESSORIES** should be packed seperately and supplied in a sterile condition.

MD manufacturers cannot in general ➜ **CLASSIFY REPROCESSABLE MDs** as stipulated by the Robert Koch Institute (RKI) since the type of use in a special operation (nature of the residues) and the intended reuse must be borne in mind. For risk assessment, MDs can be classified as semi-critical or critical depending on their use.

➜ **A CLASSIFICATION OF REPROCESSABLE MDs AS STIPULATED BY THE RKI** cannot be provided by the manufacturer.

The discussions at the workshops revealed that there is still much agreement to be reached, on the one hand, between the manufacturers of MDs, process chemicals and WDs and, on the other hand, the users.

Users should formulate their requirements and pass these on to the distributors. Sometimes it can also be beneficial to try out a decontamination process in the real life setting, if delicate materials, cables, etc. are involved, because the prevailing conditions can differ to some extent from those in the laboratory tests. If no agreement is reached and there is no possibility to change to other suppliers, the only course of action remaining is to contact the Federal Institute for Drugs and Medical Devices (BfArM).

To round off, it was proposed that a matrix be designed and the discussion continued at the next DGSV Congress, to which the manufacturers, too, should be invited. ✦