

# Systematic Decontamination: Techniques, Quality and Risk Containment

DGSV Members' General Meeting and Congress, 2–4 October 2008 in Fulda

Anke Carter, Christiaan Meijer, Gudrun Westermann

Since the delegates who took part in the congress of the German Society of Sterile Supply (DGSV) in 2007 were so favourably impressed by the congress venue and hotel, this year's DGSV conference was held once again at the Fulda Congress Centre.

In her customary cordial welcoming speech, Anke Carter, first chairman, thanked the representatives of industry and the members for their impressive turnout. This year the congress was attended by 360 delegates and more than 40 exhibitors. Altogether, the figure for attendees at this event in Fulda exceeded 500.

Prof. Martin Mielke from the Robert Koch Institute (RKI) was in charge of conference moderation. He pointed out that the control of avoidable risks was one of the first duties of medical establishments, but also emphasised that such measures should be in proportion to the degree of risk minimisation achieved. To demonstrate that point, Prof. Mielke critically reviewed the amount of information provided by process and batch control systems in the light of the investments made in process validation.

The first session of the afternoon was opened by Dr. Günter Siegemund from the German Federal Ministry of Health with a report on the medical device decontamination situation in Germany. The

"Experience Report on the Decontamination of Medical Devices in Germany" which was published in March 2008 by this ministry was evidence that the legal regulations were essentially adequate. Dr. Siegemund went on to say that the supervisory activities conducted by the statutory authorities had apparently helped drive this improvement process to a large extent – or, indeed, had set it in motion in the first place. Conversancy with the legal requirements was still poor among office-based medical practitioners, to cite one example.

## Reporting events

Gisela Ininger followed with a talk about how to process event messages with respect to Article 4 of the Medical Devices Operator Ordinance (MPBetreibV). The manufactures, but also the operators and users of medical devices, were obliged to notify any events detected to the respective federal authorities. Such events included malfunctions, changes or a breakdown in performance as well as incorrect designations or operating instructions, but they also included those errors and breakdowns occurring while reprocessing medical devices that should be used in a sterile or low-microbial state. Since the estimation "Event yes/no" was often difficult, the event should always be reported

in cases of doubt. As part of the risk assessment procedure, the competent federal authorities were then obliged to "establish whether there was a justifiable risk and what measures were needed."

Statistics on event processing were published twice yearly on the website of the Federal Institute of Drugs and Medical Devices (BfArM) ([www.bfarm.de](http://www.bfarm.de)). The number of reports thought to be related to medical device decontamination or, to a lesser degree, even confirmed, was less than 0.5%. That could be attributable to, among other things, the fact that operators and users – to cite Frau Ininger – were not particularly "keen on reporting" such events.

She went on to describe event reporting for both reprocessed multiple-use and single-use devices, how these were processed by the authorities and the corrective measures that had been initiated. She was unable to find any evidence to support the conclusion that decontamination of single-use medical devices represented a particular hazard: "In the case of virtually all events relating to single-use devices, the link to the decontamination process can only be supposed."

## Certification and quality management

Dr. Andrea Johmann spoke about reprocessing of "critical C" medical de-



M. Mielke



G. Siegemund



G. Ininger



A. Johmann

vices from a legal, user and reprocessor's perspective. Orderly decontamination was presumed if the recommendation jointly formulated by the Commission for Hospital Hygiene and Infection Prevention at the RKI and by the BfArM governing the hygiene requirements for decontamination of medical devices were observed.

Accordingly, reprocessing of contaminated medical devices called for a quality management system, among other things. In the case of medical devices that were a particular challenge to decontaminate ("critical C"), the recommendations stated that, as a form of external quality control, the quality management system should be certified pursuant to DIN EN ISO 13485 by a body accredited by the competent authority (in Germany this was Central State Body for Health Protection with Regard to Drugs and Medical Devices – ZLG).

In 2002, the Federal Ministry of Health had upon request made clear that observance of the RKI-BfArM Recommendation was not mandatory. "But if the reprocessor deviated from those recommendations, he had to furnish proof that on using the (different) methods chosen by him he was able to fully meet the requirements of Article 4(2) of the Operator Ordinance (MPBetreibV)".

What form of certification was best for the reprocessor or on what certificate could the user rely? The certificate had to be issued by a certification body that had been accredited by the ZLG for decontamination of medical devices, including "critical C" devices in accordance with the RKI-BfArM Recommendation ([www.zlg.de](http://www.zlg.de)). The certificate had to be issued for the setting up and implementation of a quality management system for medical devices as per DIN EN ISO 13485:2007 in the domain of medical device decontamina-

tion, including the "critical C" classification as per the Recommendation. The validity period of the certificate must not have expired. The certificate and annex should document the establishments and medical devices for which the certificate was valid. In general, the certificate featured the ZLG accreditation logo.

Certification of the quality management system as per DIN EN ISO 13485 was no doubt a challenge, but it had advantages, too, such as: markedly improved in-house communication between the senior management, nursing services/hospital management, purchasing department, engineering department and the Central Service Supply Department (CSSD); as well as clear assignment of competencies and demarcation of responsibilities, enhanced workflow patterns and a better level of qualifications and furnishings. It was not uncommon that quality shortcomings and problems with monitoring

of media (demineralised water, steam supply, ventilation) were detected only during an audit.

Dr. Johann went on to point out that, in the case of single-use devices for which the manufacturer had not provided any decontamination instructions, a reprocessing procedure had first of all to be devised and then confirmed on the basis of validation. That proved to be an overwhelming task for many institutions and they frequently had to reply on external expertise.

### **Standards – background and importance**

Annett Müller, Grad. Eng., outlined the background and role of standards with regard to medical devices. Standards were, she stated, technical regulations that were particularly important for decontamination of medical devices. Using established procedures, the German Standardisation Institute (DIN) drafted such standards at national, European and international level.

The harmonised European standards drafted in recent years by the sterilisation, disinfection and sterile supply services section of the medical standardisation body (NAMed) set out in particular, the requirements to be met by sterilisers with respect to specific sterilants or certain areas of application as well as requirements for washer-disinfectors, packaging and indicators. These harmonised European standards served to bestow a concrete form on the "essential requirements" of directive 93/42/EEC concerning medical devices.

Ideally, standardisation should take place at the same time as the development processes to which it referred. Close interaction between research, development and standardisation was being called for increasingly at a political level. Here DIN viewed itself as assuming the role of project manager and service provider.

### **Requirements for instrument disinfectants**

Friday morning opened with a lecture by Cordula Arnhold on the topic of the requirements to be met by instrument disinfectants. She stated that instrument disinfectants were classified as medical devices or accessories and were covered by the Medical Devices Act (MPG). All disinfectant products had to feature a CE mark; they had similar properties and were subject to uniform test procedures. As such, they could be marketed throughout the EU. Each manufacturer documented efficacy by means of an expert opinion.

The manufacturer was not obliged to have his disinfectants entered into the (official) Disinfectants' Lists. The user was free to opt for a disinfectant of his choice – apart from in the case of statutorily mandated decontamination. However, from a legal perspective, the use of listed products whose efficacy is could be documented on the basis of independent expert opinions was recommended. Disinfectants listed by the German Association of Applied Hygiene (VAH) met all the requirements, since the antimicrobial efficacy of such products would have been documented by two independent expert opinions.

### **Failure Modes and Effects Analysis**

Detlef Mertens spoke about a Failure Modes and Effects Analysis (FMEA) when reprocessing medical devices. FMEA was

used for systematic investigation and evaluation of errors. With the establishment of a QM system in the CSSD, analysis and avoidance of errors was an absolute necessity.

Using FMEA, remedial measures were taken in respect of any errors analysed or evaluated, and safety-related processes and their weak links were displayed in a clearly structured manner. Consistent implementation of such measures led to enhanced customer satisfaction, higher throughput and improved quality of sterile supplies.

### **Computerised documentation systems**

Corinna Frese-Meier reported on process optimisation in the CSSD and OR (surgical department) thanks to computerised systems. Computerised systems for documentation of instrument reprocessing not only helped to improve quality, but also facilitated coordination of sterile supplies with the OR. This, in turn, contributed to optimisation of the decontamination process and utilisation of reprocessed medical devices. The advantages conferred on the OR by computerised links to the CSSD was that more comprehensive information was available on instrument



A. Müller



C. Arnhold



D. Mertens



C. Frese-Meier

management. For its part, the CSSD received additional information on how the instruments were used. As such, the system helped improve OR planning, patient documentation and also clarified and improved the assignment of costs.

#### **Assignment of costs in the CSSD**

Andrea Scharnowski described facilities for identifying hidden costs in the CSSD. To foster an awareness for economical working practices, it was necessary to highlight costs and present them such that they could be understood by everyone. With transparency of how costs were incurred, it was possible to maintain, or even improve, the quality of supplies by optimising workflow patterns that gave rise to fewer costs. Citing a number of

examples, Mrs Scharnowski explained just what was meant by hidden costs: a prolonged reprocessing time of only 10 minutes due to an incorrectly defined process parameter meant that there was a shortage of urgently needed instruments; and increased consumption of process chemicals, of water, electricity and maintenance activities related to the operating time.

It was not only salary-related costs that were incurred for new, inexperienced staff members, but also additional costs because of their "unproductivity" during the training period. Studies had revealed that, during their first three months, inexperienced staff members could only meet 50% of the performance for which they were being paid.

If because of perceived time pressures, a decontamination step specified in DIN EN ISO 17664 for a particular medical device was omitted, the result could be very high costs for repairs and purchase of new instruments.

A rigorous QM system with clearly defined targets was needed to identify hidden costs. Processes could be optimised if realistic figures and well-documented facts were available.

#### **Ergonomic features of the workplace**

The afternoon session opened with the important topic of health management in the CSSD and optimisation of the ergonomic features of the workplace. Regula Widmer-Kennel described how this was accomplished within the firm Ster-



A. Scharnowski



R. Widmer-Kennel



M. Franke

dispensable for validation in certain cases, in particular for validation of processes with complex instruments.

In future the validator (firm/person entrusted with validation) would have to define the routine tests to be carried out by the operator. In that manner the validation results could also be properly taken into account.

In general, the new standard accorded the validator greater latitude when it came to evaluation of the results. When put to proper use, this extra scope could on the one hand result in a situation whereby, contrary to the situation seen hitherto, processes for older sterilisers could also be validated and operated in conformance with the standard. But on the other hand, the new regulations also entailed certain risks: incorrect assessment of the results obtained would mean that faulty sterilisation processes would not be identified.

Franke continued by stating that the new standard thus conferred advantages on the CSSD operator provided that the greater scope was properly used. This called for a competent and qualified user who was conversant with the requirements addressed to a modern sterilisation process and was capable of acting as an equal partner vis-à-vis the validator.

#### Indicators of cleaning performance

In his lecture, Emanuel Nagel demonstrated a chemical indicator that, at little

cost or time investment, was able to verify the cleaning performance of washer-disinfectors and document it accordingly (ProCheck-Swab, HS System- und Prozesstechnik GmbH). To date, the practice of verifying the process outcome using chemical indicators was normally used only for steam and other types of sterilisation processes. But reliable disinfection, with ensuing sterilisation if needed, could be assured only for clean instruments. It was thus important to check the cleaning performance, too, on a routine basis.

#### What's new in standardisation

Wolf-Dieter Wegner reported on new aspects of the standards regulating steam sterilisation and packaging, and went on to elaborate on a number of important changes to standards DIN 58946 and DIN 58953, which were being currently revised. These included a check using a hollow-devices' load (Hollow A) as part of the operational qualification, designation of the premises in which decontamination was carried out, as well as a guideline for a partial process used for validation of packaging processes. He stated that the term "Commissioning" had now been replaced by the expressions "installation qualification" and "operational qualification". Conductance of validation and operation of steam sterilisers were

addressed in a new part of DIN 58546 Part 7.

Apart from the lectures, this year's congress offered eight workshops. The topics covered ranged from management of repairs in a modern CSSD (M. Klar, OPAL Service GmbH), reprocessing of motor systems (The Quality Task Group in cooperation with manufacturers), decontamination of delicate instruments (Th.W. Fengler, Cleanical GmbH), new aspects of the guideline for validation of thermal WD processes (Guideline Group), risk management for decontamination of medical devices (T. Kießling, TÜV Rheinland), critical aspects of implementation of a documentation system (N. Mahlke, H. Ferschl, Sterilog GmbH/MMM GmbH) and the conclusions that could be drawn from deposits on surgical instruments in respect of unsatisfactory test results (S. Knoefel, Schnorrenberg GmbH). In addition, Toni Zanette and Anke Carter moderated a panel discussion on the subject of "Regulations for decontamination of medical devices and their implementation into everyday practice".

A summary of the workshops' results was presented on the last day to all delegates.

After three days packed with information, the congress was brought to a close around 13:00 h on Saturday with the presentation of the new DGSV board



E. Nagel



W.-D. Wegner



A. Carter

members who had been elected at the members' general meeting on 2 October 2008. After her term of office is completed at the end of the year, Marion Peißker will take over from Anke Carter as DGSV first chairman. Angelika Schlepp will succeed Josef Graf as second chairman and Ilijas Mislimi will serve as third DGSV

chairman. Maik Roitsch replaces Martin Held as treasurer, and Dr. Maria-Theresia Linner as secretary rounds off the newly elected board of DGSV e.V.

Armed with packed lunches, the congress delegates set off on their journey home on Saturday afternoon, and will hopefully meet, by the latest, at next year's

DGSV congress. This year, too, the majority of delegates had a favourable impression of Fulda as a congress venue, and as such the new DGSV board will no doubt consider organising Congress 2009 once again in Fulda. ♦