

Medical Device Reprocessing in Germany – 17 years of Medical Devices Act

DGSV Congress, 7 – 9 October 2010, Fulda

Gudrun Westermann

More than 400 delegates had travelled to Fulda to attend the German Society of Sterile Supply (DGSV) congress and gain the latest insights into medical device reprocessing. The principle topic on the agenda was "17 years of MPG" (German Medical Devices Act) and, reflecting that sentiment, the speakers of the first series of lectures on Thursday morning immediately addressed that legal regulation. Prof Mielke from the Robert Koch Institute (RKI) directed his attention to the term "expertise", while stressing that the expert had to be in a position to estimate the risks posed by his actions. That, of course, was something that called for good basic knowledge and continuing professional development. Mielke named other topics being currently dealt with. He stated that a welcome approach, for example, would be to have fewer detergent-process combinations so as to simplify the validation process. Another important topic was practical implementation and material compatibility of prion-active cleaning processes, an area where more research was needed. Supervision by the competent authorities should be simplified at international level. In that context the establishment of a help desk would be also advisable, so that users could get assistance on classification of medical devices; beneficial would also be definition of parameters to help decide whether single-use devices could prove to be a good alternative.

17 years of MPG – what is new?

Dr. Siegemund from the German Federal Ministry of Health (BMG) elaborated on MPG in detail. MPG transposes the European directives governing medical devices (MP) into German law. The responsibility for the safety of MDs is borne first by the manufacturers, but the operators of medical device reprocessing premises also have responsibilities in that respect. For example, the operator can not hold the manufacturer responsible for mistakes made during medical device

repairs or reprocessing. That is also one of the main reasons for compiling the German Medical Devices Operator Ordinance.

Dr. Johmann from the German Central State Body for Health Protection with Regard to Drugs and Medical Devices (ZLG) spoke about the consequences of the 4th Amendment to MPG and the Accreditation Body Act (AkkStelleG). Both of these came into force in 2010, which means that new legislation now applies in some areas. In a recognition procedure laboratories have to have compliance with the minimum requirements enshrined in EU directives verified by ZLG. This obligatory recognition replaces the voluntary accreditation provided for hitherto in MPG. The accredited laboratories are listed on the ZLG website – 98 to date.

If a laboratory voluntarily wants to maintain or attain accreditation status, so as for example to play an active and acknowledged role in markets outside the European Union, it has to comply with the Accreditation Body Act. As from January 2010, each Member State is allowed to maintain only one accreditation body, of which the European Commission has to be informed. Therefore the company Deutsche Akkreditierungsstelle GmbH (DakKS) was set up in Germany. DakKS works closely with ZLG; for example, inspection is still carried out by ZLG. Joint committees are also planned. The topics to be addressed by such committees include e. g. minimum scope of test reports.

Quality Assurance, Certification, Validation – the Experiences

On Friday Dr. Kießling from the Technical Inspectorate of the Rhineland (TÜV Rheinland) reported on experiences with certification. He, too, began with the legal aspects, giving a review of the various legal acts and recommendations, starting with MPG, which was introduced in 1994, to the RKI/BfArM Recommendation (a recommendation jointly compiled by

the Robert Koch Institute and the Federal Association for Drugs and Medical Devices), while highlighting that due to central management of medical device procurement and reprocessing, widespread use of electronic data processing (EDP) and new standards the background on which the legal acts and recommendations was based had once again changed in some cases.

Kießling then went on to describe common shortcomings. In the case of computerised systems, for example, it is important that proof of functionality is furnished and that they are also suitable for use with the respective reprocessing systems. Often it is not possible to elucidate who has been responsible for inputting the master data and at what time this was done. Likewise, often packing lists make no reference to missing or defective instruments. Kießling stated that data had to be archived for 30 years – a very long period of time bearing in mind the rapid developments seen in the EDP sector. Therefore one has to ensure that data can be read at a later stage.

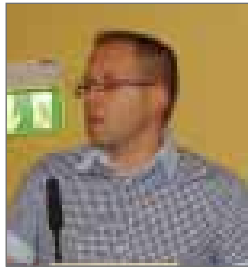
The most common validation problems encountered relate to the packaging, with appropriate validation documentation seen only in exceptional cases.

Marion Peißker and Angelika Schlepp from the DGSV board of directors spoke about problems currently encountered 17 years after the coming into force of MPG. The DGSV wants to assist in laying the foundation for improving the quality of medical device reprocessing. For example, it has compiled recommendations for everyday working practices and updated them in accordance with the prevailing legal and normative requirements. The DGSV has also formulated other guidelines in cooperation with the German Society of Hospital Hygiene (DGKH) and the Working Group Instrument Preparation (AKI), e. g. a packing guideline is planned for 2011.

DGSV has also drawn up framework training syllabuses for reprocessing person-



Marion Peißker



Marco Tomiczek



Klaus Müller



Christian Jäkel



Stefan Staschik

nel. Mrs. Peißker stressed that the practice of assigning staff members whose skills were not wanted elsewhere to the sterilisation department was something that could no longer be tolerated. The government authorities now stipulate that reprocessing staff should attend such specialist training courses. Mrs. Schlepp pointed out that establishments in which only one staff member had successfully attended Specialist Training Course I failed to comply with the legal requirements. On the other hand, attending a specialist training course makes sense only if the attendee has already built up practical experience.

Unresolved problems are still encountered for example in office-based medical practitioners' premises. Often there is a failure to understand why staff now has to attend a course on reprocessing bearing in mind that, after all, medical device reprocessing is something that had been performed for years. However, there have also been positive developments in this area. For instance by now many premises meet the structural requirements to assure proper reprocessing and have also introduced a quality management (QM) system. An important aspect is that any standard operating procedures (SOPs) available are also observed. Because of time pressure and staff shortages that is not always the case. Likewise, packing lists are also often incomplete.

Mrs. Peißker finished off with a remark about the lack of recognition. Rarely is thanks expressed but, conversely, criticism is readily forthcoming. But good collaboration is needed also to ensure that a proper approach was taken to purchasing new MDs.

Marco Tomiczek from Berlin reported on his experiences of validation of washer-disinfectors (WDs). Good preparation is vital. All WDs have to be listed, documentation has to be prepared and, in some cases, repairs carried out in advance.

For operation qualification the WDs have to meet certain prerequisites, e. g. they have to be calibrated and provision made for temperature indicators.

For performance qualification instruments harbouring soils from all medical disciplines are needed. The reference loads have to be checked in all WDs. Tomiczek continued by stating that one should not make any inferences from one WD to the next. Furthermore, test instruments with a defined test soil are needed. Minimally invasive surgical (MIS) instruments are tested using loggers and gap process challenge devices (PCDs).

There were problems, for instance, with punches that could not be dismantled and also with flexible intramedullary reamers; reprocessing of these had in the meantime been outsourced.

Validation is followed up now by annual performance requalification, which in the department described is carried out before servicing since it was assumed that following servicing the equipment will be fully functional.

Biocompatibility – what implications does this have for reprocessing?

Dr. Ute Müller from BMP Labor for medical material testing in Aachen spoke about the implications that biocompatibility had for reprocessing. EN ISO 10993 is the principle standard regulating verification of MD biocompatibility. Biological assessment is binding for issuance of the conformity declaration, and is always the case for devices that have direct body contact.

Certain features of a device have to be checked depending on their intended use. In the case of a device coming into contact with intact skin, cytotoxicity, i.e. the potential to elicit sensitisation and irritation, have to be investigated. If the device also comes into contact with blood, blood compatibility has to be demonstrated using human blood.

What implication does this now have for reprocessing? Armed with impressive photos, Mrs. Müller demonstrated how the features of devices can be altered to some extent when the device is reprocessed. Cleaning processes can alter surfaces, thus meaning that the safe use of the device can no longer be guaranteed.

New medical devices, too, are known to fail toxicity testing. Other important causes of toxicity are disinfectants and detergents, sterilisation processes, residues as well as material and device changes, which can also occur during reprocessing. It is therefore important that thorough risk assessment be carried out for each device.

Surgical instruments– what is the impact of MPG?

Klaus Müller, from Bausch, explained how MPG had impacted on surgical instruments. He drew attention to DIN regulations listing instrument dimensions and the permitted deviations. If repairs are needed, restoration of functionality is a basic requirement; of importance in legal terms is, however, conformity in respect of the structural features. In that regard it is particularly important to ensure that original parts are used for repairs. Bausch went on to state that if these features were changed when the instrument was repaired, this would amount to the same thing as commissioning.

Material compatibility is also an important topic. Alkaline cleaning can cause problems for new instruments. Bausch showed photos of Ferrocell handles which had been damaged due to alkaline cleaning. Soils that have penetrated deeply into the handles can be released again in a vacuum. In the meantime new materials that are more resistant to alkaline cleaning have come onto the market.

In view of the vast variety of topics to be borne in mind when purchasing and reprocessing instruments, Bausch advocated that an officer be appointed to take charge of medical devices.

Loaned instruments – what must be borne in mind?

Gerhard Kirmse, from Aesculap, talked about his experiences with loaned instruments. At Aesculap some 33,000 instruments are loaned each year; 22 staff members are responsible for that task alone. In legal terms no distinction is made between in-house and loaned instruments; they are subject to the same requirements. This system calls for good organisation for both parties involved. Therefore standardisation is advisable, beginning at the time of placing an order. A vast amount of information is needed to place an order, and this has to be obtained from various departments of the hospital; e. g. also data related to patients such as their height. It is therefore beneficial if the same person always places orders and will also be available to answer any queries.

The manufacturer supplies the tested medical device with documentation as per EN ISO 17664. Nonetheless, the operator (of a medical device reprocessing unit) should not make any assumptions about this, alone because of the possibility of damage or loss sustained during transportation. The set should as a rule be cleaned, disinfected, tested and sterilised in the hospital. Enough time should be allowed for this, and it is advisable that, as a standard approach, sufficient time be allotted for delivery (e. g. 48 hours before the scheduled operation). If the set is being used for the first time, time must also be allowed for briefing staff and, if necessary, recording related data. It is not only surgical staff who has to be briefed, this is also needed for CSSD staff.

Kirmse summarised the problems frequently encountered with loaned instruments. These range from failure to keep to deadlines and missing documentation through inadequate cleaning to damage and missing information that went unnoticed or was not reported to the manufacturer. All these problems can result in delays and cancelled operations in the respective hospital as well as in the next hospital and should therefore be given due consideration.

Although transport safeguards are being continually optimised, problems are often encountered in this respect too, in particular if no provision is made to safeguard the instruments when returned, thus resulting in their being damaged.

Kirmse finished off by stating that the number and complexity of loaned instruments would rise further. The system has many advantages but the expenditure involved should not be underestimated. Procedures at hospital and manufacturer level have to be well organised and tailored to each other.

Liability – MPG as “supplementary penal provisions”

Dr. Christian Jäkel, physician and lawyer from Lübben, reported on liability avoidance. Pursuant to MPG, unsuitable MDs should not be placed on the marked or put to use; failure to observe this constitutes a criminal offence. When reprocessing MDs the prevailing requirement is that no mistake be made with regard to risks that can be fully controlled. That also results in a reduction in the burden of proof for the damaged party. For example, failure to disinfect one's hands constitutes a gross treatment error, leading to shifting of the burden of proof.

Jäkel drew attention to the Experience Report published by the German Ministry of Health which calls for an improvement in reprocessing practices. A better understanding of the importance of proper MP reprocessing has to be inculcated and, likewise, supervision by the state authorities needs to be improved. Hence greater pressure is being applied at various levels.

Technical Sterilisation Assistant (TSA) – the protracted course towards attaining a professional job description

Three other afternoon lectures dealt with the topic “Professional job description”. Mrs. Peißker spoke about the current situation in Germany and about personnel requirements. The DGSV specialist training courses have now become established throughout Germany. Despite tightening of the requirements to be met by staff, no changes have been made to the prerequisites and scope of Specialist Training Courses I and II. Nor do the training courses solve all problems. The aim of the DGSV is, and continues to be, the establishment of a professional job

description for the Technical Sterilisation Assistant (TSA). However, in Germany this designation continues to be an activity description only. If the TSA does not have a basic medical qualification, he/she is classified as a skilled worker. However, the body of knowledge imparted in the training courses and demonstrated in examinations goes far beyond the level of knowledge required for a skilled worker. State recognition is therefore urgently needed.

Mrs. Peißker emphasised that this was something that concerned the operators of reprocessing premises, too. But often there is failure to accept this need since such duties have been discharged by staff for a long time and, in particular, operators do not want to have to release staff from their duties to attend training courses because of the financial implications.

Stefan Staschik from Kiel focused on the topic of a professional job description in his final paper compiled on completion of Specialist Training Course III. He described his professional background and how on completion of Specialist Training Course I he realised that the 80-hour teaching period was not really enough to meet the needs of medical device reprocessing.

In his paper he first of all reviewed the current situation at Campus Kiel and put forward arguments explaining why a recognised training scheme was needed for medical device reprocessing. In creating a professional job description, in addition to the content set out in a framework syllabus, there are many other aspects to be borne in mind, e. g. the preliminary requirements to be met by trainees, trainers' qualifications or financial aspects.

The afternoon session was brought to a close with a panel discussion of this topic by the DGSV project group.

Medical Device Reprocessing in Office- Based Medical and Dental Practices

Saturday morning began with various topics related to medical and dental practices. Babette Hartung from the Association of Statutory Health Insurance Physicians of Baden-Württemberg reported on problem areas in such practices. In addition to unsuitable premises the main problems are lack of knowledge and inadequate training of reprocessing staff. Medical device reprocessing is not something in which medical technicians have received



Babette Hartung



Christine Otto



Anke Carter



Jürgen Gebel



Dirk Diedrich

training. Furthermore, the lack of a standardised approach to supervisory activities by the authorities give rise to very divergent conditions in the medical and dental practices.

The Association of Statutory Health Insurance Physicians of Baden-Württemberg therefore has set up a Hygiene and Medical Devices Competence Centre, in which in the meantime the respective associations in other federal states are now participating. The Centre deals with different areas, e. g. infection control policy and management of infectious diseases. Medical device issues addressed include: risk assessment, classification of MDs as well as validation of processes and supervision. There are various leaflets available for download on the Association's website. There is also an Excel tool to enable medical and dental practitioners to easily calculate their own reprocessing costs. The aim of this collaboration is to standardise reprocessing in medical and dental practices and, not least, to achieve uniform supervision by the authorities.

Dr. Udo Beimert, office-based ear, nose and throat specialist from Munich, described instrument reprocessing in his practice. In an ENT practice the principle instruments used are endoscopes. The high throughput means that reprocessing activities are subject to time pressures. Reprocessing involving wipe disinfection with 80 % ethanol is obsolete and should be relegated to the past. Immersion disinfection or thermal disinfection in an WD is better. For immersion disinfection with glutaraldehyde one should bear in mind that this is not only toxic but also sensitising, and this is the case even in concentrations below the limit values.

In the interest of occupational safety, the fine ENT instruments should be pre-disinfected with a non-fixing agent. When reprocessing in a WD at 90 °C for 5 min, an A_0 value of 3000 is achieved.

Beimert described other important

aspects of reprocessing in medical and dental practices: one has to ensure that the instruments are arranged properly in the WD to ensure effective cleaning. Batch control is carried out in his practice with a helix device. WDs have to be serviced once yearly and performance requalification conducted, which is a very onerous task. Furthermore, there are the daily routine checks at the start of the working day. To finish off, Beimert spoke about the importance of documentation. Since in the ENT setting there is widespread contact with lymphatic tissues, it is imperative to assure tracking, also by keeping proper records in the patient file.

Ute Wurmstich from Wedemark spoke about cleaning and disinfection of dental instruments. First she asked how the basic dental instruments were classified and stressed that classification as per the RKI-BfArM Recommendation had to be conducted before first using the instruments. This could ultimately help save time and resources – for example semi-critical instruments could be released after thermal disinfection.

Wurmstich explained that there was a rise in the number of modern techniques used in dental practices, e. g. insertion of implants, surgical procedures. The role of cleaning and disinfection should be given more prominence in the reprocessing chain. Transmission instruments are a particular problem in dental practices (angled hand-pieces and turbines), because measures have to be taken to ensure that they are also cleaned and disinfected on the inside. Preference should therefore always be given to automated reprocessing.

Christine Otto, Leipzig, spoke about reprocessing in medical practices and expressed concern that the existence of nosocomial infections in such medical practices is still being denied. Among the duties conducted in such a practice, top priority is not accorded to reprocessing.

Apart from a lack of time, there is the issue of inadequate knowledge on the part of staff. Rapid developments in reprocessing, calling for continuing professional development, are often underestimated. Otto reported that at present no supervision is carried out by the authorities in Saxony, and this meant that less importance is ascribed to staff training in this sector.

She pointed out that a long list of prerequisites have to be met before processes can be validated; this is all the more difficult if one has to start almost from the beginning since even the very basic conditions are not assured.

Standardised Manual Reprocessing – working towards a guideline

Anke Carter and Dr. Jürgen Gebel reported on the progress made by the working group that has compiled a guideline for standardised manual cleaning. This working group comprising members of the DGSV, DGKH and AKI, has been in existence since 2008. Its aim is to draft basic requirements for compilation of standard operating procedures tailored to the individual operator. Furthermore, test methods are to be developed to verify these SOPs in respect of the cleaning and disinfection results obtained as well as with regard to residues of chemical substances. Carter and Gebel reported on the first findings of a cleaning study in which 10 hospitals have participated. These revealed that, among other things, there is widespread variance in manual cleaning practices. The use of ultrasound greatly improved cleaning results, but these continued to vary greatly, hence standardisation is urgently needed.

Even when cleaning and disinfection were conducted in accordance with an SOP, the final measures conducted varied greatly, as did the results achieved. Other studies are now to be carried out to ex-

plorable suitable approaches and operating procedures, so that an appropriate recommendation can ultimately be compiled.

Risk Management – VDI guideline under preparation

In the last lecture of the conference Dirk Diedrich, Münster, spoke about the guideline compiled by the Association of German Engineers (VDI) on risk management for medical device reprocessing. The guideline is aimed at listing potential hazards and at formulating recommendations for risk reduction during MD reprocessing. This guideline can be of interest to manufacturers, test bodies and supervisory agencies as well as to us-

ers. The main focus here is on functional testing. The aim is to identify hazards that adversely impacted on the intended use and/or posed a risk to personnel. By way of example, Diederich cited an endoscopic forceps with internal movable surfaces where cleaning could not be controlled.

More than 60 recommendations have been drafted by the working groups. Of these, 22 focus primarily on cleaning/disinfection and sterilisation, 15 on product design, 5 on other reprocessing steps (packing, transport, storage, labelling, etc.) and 3 on sterilisation.

Hence the process of drafting a VDI guideline, ongoing since January 2010, is akin to that used for standards. The

guideline is to be published in the characteristic VDI structure (two columns: German/English). Furthermore, development of software to be used with the existing database (with filter functions) is planned. The aim is to have the draft guideline adopted in 2011.

In addition to the lectures, like every year delegates had the opportunity to attend a total of four workshops. Special summaries of the findings of the workshops will be reported in forthcoming issues of *Central Service*.

Next year's congress, at which the DGSV can look forward to celebrating the 15th anniversary of its foundation, will be held once again in Fulda from 3 to 5 October. ◆