

# Experience Report on Medical Device Decontamination

German quality standards in everyday practice against a background of non-uniform European standards

*Nikou Ghassemieh*

The current state of affairs has been successfully reviewed, indicating that the German model used for decontamination of medical devices has to a large extent proven its merit. This is the conclusion drawn by the report published by the German Federal Ministry of Health. The report was based on an investigation of compliance with the existing legal regulations in everyday practice and reflects in concrete terms the requirements governing decontamination. Its conclusion is unequivocal: the German system and decontamination practices meet the approval of the majority of those surveyed.

This report was compiled in order to review the existing standards: for over five years now anyone in Germany who reprocesses medical devices for reuse in the medical setting must comply with the newly formulated provisions of the German Medical Devices Act (MPG) and the Medical Devices Operator Ordinance (MP-BetriebV), as supplemented by the Recommendation jointly formulated by the Robert Koch Institute (RKI) and the German Federal Institute for Medical Devices and Medicinal Products (BfArM). Since medical device decontamination entails stringent quality requirements to assure patient safety, the German Federal Ministry of Health has now for the first time conducted a consultation to review the experiences relating to the existing regulations. In the course of this survey, government agencies, associations, organisations and experts, etc. were interviewed. Overall, some 80 responses were received by the Federal Ministry and were evaluated to compile the report. The findings were first published in April.

## **Risk classification proven to be a successful model**

In the overall evaluation the report concludes that the combination of standards

and recommendations has guaranteed safe decontamination of medical devices in Germany. Systematic evaluation based on risk classes has proven a success. Differentiation between single- and multiple-use medical devices – as carried out for example in some European countries such as the United Kingdom or France – for medical device decontamination has been rejected. The report states that there is no factual or convincing argument for prohibition of single-use devices.

## **Shortcomings as regards implementation in everyday practice**

The report has identified three areas where there is need for improvement: qualification of decontamination practices, continuing professional development and supervision.

## **Quality management system is obligatory**

The report lists emergency measures to provide for continuous quality improvement in the interest of patient safety. In concrete terms, it first of all makes reference to reprocessing of particularly critical medical devices that are difficult to sterilise. To achieve high standards of quality for such "Critical C" devices, the establishment of a quality management system will be obligatory in the future. This system is intended in principle as a means of assuring that each individual device is inspected as part of the decontamination process used for medical devices classified as belonging to the "Critical C" risk group. This entails 100% inspection of quality, safety and functional capabilities. In order to ensure that this approach will serve to achieve the best possible quality standard, the system to be introduced must be additionally certified by a Notified Body accredited by the Central State

Body for Health Protection with Regard to Drugs and Medical Devices.

## **Ambulatory sector lagging behind**

Apart from quality assurance, shortcomings have been identified as regards conformance with the RKI/BfArM Recommendation. In that regard the experience report has noted major differences between the outpatient and inpatient setting. Furthermore, the report discusses mechanisms for describing the recommendation in more concrete terms. While no emergency measures have been proposed here, it has been pointed out that the Federal Ministry of Health will request the Commission for Hospital Hygiene and Infection Prevention at the RKI to study the commentaries made by the parties concerned on the RKI/BfArM Recommendation. Any action needed is to be discussed up to the end of the year or a new version of the recommendation is to be formulated.

## **Shortcomings as regards the supervisory personnel**

To assure, and further improve, compliance with the requisite standard, statutory supervision is to be accorded greater importance in future. In their commentaries to the Federal Ministry of Health, numerous users have drawn attention to the variations in the provision of supervisory personnel made available to the different federal states. For example, criticism is addressed to the fact that the remit of supervisory staff is often too wide and that such agencies suffer from staff shortages. As regards expertise, interviewees point out that in several cases persons who do not belong to a medical profession are deployed to assess the quality of the reprocessing outcome. Hence a specific qualification was not always assured here. This situation was further compounded

by the fact that the different states had, in some cases, different levels of training. The report announces that this topic will be addressed at a political level with the aim of bridging these gaps in the quality of supervision. The BfArM has been entrusted with the task of conducting a representative study to collect tangible data on the quality of reprocessed medical devices throughout Germany.

#### **External reprocessors as a guarantor of high quality**

Regardless of these shortcomings, many commentaries also applaud the RKI/BfArM Recommendation for its exemplary role. For example, it has been unanimously agreed that when complied with, this recommendation provides for orderly de-

contamination. In general the fact that the external reprocessors began to implement the recommendation at an early stage has been met with approval. The material and human resources available are viewed as being above average. The quality of reprocessing is convincing.

#### **German practices as a model for Europe**

At present the Commission is compiling a report on decontamination practices within the European Union. The combination of standards and recommendations as used in Germany can serve as an example of the best practice. In particular, the positive experiences gleaned from systematic evaluation as per risk classes can serve as a model at European level.

That Germany was one of the few EU countries to at an early stage recognise the need to, in the interest of comprehensive patient safety, link technical progress to binding framework conditions can serve as a beacon for other European countries. After all, several countries do not yet have specific regulations governing decontamination. This will give rise to risky and uncontrolled reprocessing of unsuitable medical devices. Such a practice is alarming in terms of patient safety and calls for action – the German mix of laws and regulations can at the same time serve as a model and guide here. ♦