Recommendations by the quality task group (112)

Unambiguous traceability of medical device reprocessing

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1. Objective

Traceability of the reprocessing process was already addressed in Recommendation 100 of the Quality Task Group [1]. This present recommendation once again focuses on traceability since the new Medical Device Regulation (MDR) [2] has resulted in changes to the legal fundamentals for the manufacturers.

What does that mean for the user in practice?

2. Legal fundamentals

The currently valid MDR, with transition time to May 2020, sets out the legal framework for the manufacture and placement on the market of medical devices (MDs) and points to future national regulations that could require the premises operator to unambiguously identify MDs. In the case of Germany, for example, it is unclear so far whether and how that will be implemented.

THE OPERATION OF MDS will be regulated by national requirements.

As in the past, the marketing and **OPERATION OF MDS** will be regulated by national requirements. In Germany these requirements are enshrined in the Medical Device Operator Regulation (MPBtreibV) [3]. Section 8(1) of MPBtreibV stipulates that a successful reprocessing outcome must be "reproducibly" assured. The recommendation for hygiene requirements for processing medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO) and the Federal Institute for Drugs and Medical Devices (BfArM) known as the KRINKO/BfArM Recommendation [4], gives more specific details while stating that:

The documentation must provide evidence that the respective reprocessing process was carried out in ac cordance with the standard operating procedures (SOPs) in compliance with the parameters set out in the validation protocol (Paragraph 2.2.8 "Batch documentation" of the KRINKO/BfArM Recommendation).

THE BURDEN OF PROOF of proper reprocessing rests with the operator.

Pursuant to current case law, hygiene constitutes a "fully controllable risk" (German Civil Code Section 630h) [5], which implies that in cases of doubt **THE BURDEN OF PROOF** of proper reprocessing rests with the operator. While to date such demands tend to be rarely imposed, keeping records of the process is important in various scenarios. How these records are kept is not regulated and can be in paper or software format.

Table 1: Traceability scenarios

"Example scenarios" for traceability		
Postoperative wound infection – possibly linked to instruments? ■ With which sets was the patient operated? ■ Did other patients, too, have problems? ■ How were the sets reprocessed? ■ Washer-disinfector (WD) batches, correct process sequences and release? ■ Sterilization batch, correct process sequences and release? ■ With the same instruments?	**Creutzfeld-Jacob disease (CJD) subsequently suspected / proven, or notifiable infection, pathogens** ■ With which sets was the patient operated? ■ How was reprocessing? ■ Where are these sets now? ■ Which patients have in the meantime been operated on with these sets? ■ Do these sets still consist of the same instruments?	**Traceability of flexible endoscopes, relevant in cases of outbreak or another event** ■ Patient identity ■ Date and nature of the intervention ■ Physician's name ■ Endoscope identification ■ Name of the person who conducted cleaning ■ Traceability of the various cycles in the automated endoscope reprocessor (AER)

In the case of **MDS BELONGING TO THE CRITICAL C** [6] **RISK GROUP**, traceability of reprocessing of individual instruments is required. For all other risk groups traceability can be assured via the set designation / set code. In certain countries (e.g. the United Kingdom) because of issues around CJD there is also the requirement that instruments must not migrate between sets. But that implies unambiguous identification of individual instruments (serial number or in future a Unique Device Identification [UDI] code).

FOR MDS BELONGING TO THE CRITICAL C RISK GROUP, traceability of reprocessing of individual instruments is required.

All **RECORDS** related to the reprocessing processes must be retained for five years [7]. Here it must be noted that this retention period applies only to medical devise legislation. Other areas such as product liability legislation stipulate retention periods of up to 30 years.

ALL RECORDS RELATED TO THE REPROCESSING PROCESSES must be retained for five years.

As regards the traceability of implants to the patient, only for certain medical devices does *MPBetreibV* contain specific provisions. It requires the generation on an implant pass and location of the implants within three working days. The relevant documentation must be retained for 20 years.

Table 2: Extract from the German Medical Device Operator Regulation (MPBetreibV)

Medical devices subject to specific traceability requirements MPBetreibV, Annex 3 of Section 15 (1) and (2)
1. Active implantable medical devices
2. The following implantable medical devices:
2.1 Heart valves
2.2 Non-absorbable vascular prosthetic devices and stents
2.3 Hip and knee joint replacement
2.4 Vertebral replacement systems and intervertebral disc prosthesis
2.5 Breast implants

Traceability to the patient is not specifically mandated for any other medical devices. But it is recommended that in the event of product recall at least records establishing a link between implant systems (or article numbers) and patients should be available (e.g. in the surgical reports).

3.Expectations regarding traceability

Apart from the legal fundamentals, there are various expectations of efficient medical device management vested in traceability.

RAPID LOCATION OF SETS within the Reprocessing Unit for Medical Devices (RUMED) or the entire hospital is crucial in advance of major operations. The frequency of use is also a key element for compliance with the requisite provisions for MDs subject to a restriction of the total number of reprocessing cycles or for which specified maintenance intervals apply. Records of the frequency of repairs and maintenance are useful for cost control purposes as these assure optimal management of stocks and can serve as the basis for decision-making around procurement of new devices or of repairs.

RAPID LOCATION OF SETS is an advantage in terms of efficient medical device management.

In the case of missing instruments being able to verify when the instrument was last traced back to the set is helpful in refining the search and, as applicable, in assigning costs.

As part of the documentary obligation, the parameters of key processes and the medical devices undergoing these processes must be recorded. It would be desirable to have in place **AN INTERFACE CONNECTION** between the operating room (OR) and RUMED documentation system so as to avoid duplication of effort. That would obviate the need for registration once again of the sterile supplies in the OR and would link the patient records to the existing data. Likewise, any instrument damage noted, as well as complaints, could thus be immediately processed and forwarded to the RUMED.

AN INTERFACE CONNECTION between the OR and RUMED documentation system is helpful to obviate the need for re-registration.

The electronic systems in place are intended as a means of permitting analyses and of thus enhancing efficiency. In general the instruments and sets used are scanned per barcode. In that way data on the available stocks can be retrieved in the system and instruments made available for operations, thus considerably reducing the workload.

Part 2 will be published in issue no. 3/2019.
References: http://bit.ly/ZT0219-Rec-References

Table 3: Typical traceability issues

Issue	Task definition	Possibilities	Advantages	Disadvantages
Individual instruments	Unambiguous identification of Individual instruments difficult and may result in ambiguous evidence of cleaning and disinfection (loss, assignment to incorrect departments)	Only identification in terms of type and/ or department, evidence of SOP (possibly, inscription with department)	▪ Reduced workload	▪ Reprocessing not 100% reproducible
		Enclose barcode stickers (or place in original peel pack after use)	▪ Individually identifiable ▪ Standard readability	▪ Can be lost
		Read out Data Matrix code, or similar, on the instrument	▪ Cannot be lost ▪ More secure individual proof	▪ Others scanners needed
Divided trays	For logistical reasons or because of (inadequate) connection facilities one tray is divided between two WDs	Avoid division	▪ No organizational investment	▪ Possibly, process delays
		Assign to only one process	▪ No organizational or logistical investment	▪ Errors may not be noticed / assigned
		Assign to both processes	▪ Proper reproducibility of the processes	▪ Greater administrative investment ▪ Not possible in all systems
Containers	No evidence of cleaning and disinfection (separate process), containers have no direct patient contact	Evidence of SOP	▪ Reduced workload	▪ Cleaning / disinfection not 100% reproducible
		Barcode on tank and lid Possibly, assignment when packing	▪ Direct assignment to batches	▪ See divided trays ▪ Increased workload ▪ Less reduction of potential risks
Pooled articles	e.g. lamp handles, cables, bowls are collected and cleaned and disinfected separately	Evidence of SOP	▪ Reduced workload	▪ Cleaning / disinfection not 100% reproducible
		Barcode on all items, assignment when packing	▪ Direct assignment to batches	▪ See divided trays ▪ Increased workload ▪ Less reduction of potential risks
Manual processes	Precleaning, ultrasonic cleaning, manual cleaning and disinfection, visual inspection and functional testing, packing as well as processes related to loading and unloading WDs and sterilizers Alternatively: Manual steps of the reprocessing process	Evidence of SOP	▪ Reduced workload	▪ Cleaning / disinfection not 100% reproducible
		Individual release in the IT system	▪ Proper reproducibility of the processes	▪ Greater investment ▪ Not possible in all systems