

Recommendations by the Quality Task Group (65): Computer-Assisted Batch Documentation

Update of Recommendation 21 from Issue 2/2002

The use of computer-assisted documentation provides for more effective and efficient management of routine tasks in the Central Sterile Supply Department (CSSD). Networking of several workstations, with integration of washer-disinfectors, heat sealing machines and sterilisers, is still today a topical issue in the everyday CSSD setting, even some eight years after publication of the first Recommendation on that subject.

A → **BATCH DOCUMENTATION SYSTEM (BDS)** is the best form of process documentation to ensure that the quality management requirements governing medical device reprocessing are met (for example those stipulated in the recommendation jointly drafted by the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) from November 2001).

Using BDS, it is possible to record and document all procedural steps undertaken through the entire reprocessing chain. All activities unfolding from the time the medical devices enter the decontamination zone through the process protocols related to washer-disinfectors, heat sealing machines and sterilisers to even the manual sub-steps can be depicted in modern batch documentation systems and saved to a harddisk. Medical devices are → **RELEASED** on the PC after completion of the individual sub-steps. Hence, one can at all times verify which staff member had prepared a particular tray or set at which time point and had released it for further processing or use. A label that is printed out and affixed to every set/tray before or after sterilisation can be used, without any major effort, to document medical device reprocessing, and even transfer this to the patient's file. Thanks to the latest technology, it is now possible to scan the barcode of the various sets into patient files. For the purpose of recording costs, this is also a factor that should not be underestimated.

What is needed?

To begin with, the hardware (PC, printer, scanner, etc.) must be available. A decision must be taken on whether to link the batch documentation system to the existing server or arrange for a special server to that effect. Software (programs for use in the CSSD) should be purchased only after in-depth study and comparison of the various commercially available systems. The hospital's IT Department should definitely be included in the → **PROCUREMENT** process. An important aspect to be borne in mind here is compatibility with other, in some cases existing, computerised systems and programs, in particular the interfaces to the equipment used in the CSSD. The needs of the operating room (OR) should also be taken into consideration. One must therefore avoid opting for a unilateral solution, investing instead in computerised systems that are → **COMPATIBLE** with patient and OR documentation. This will also enable the end user (OR) to establish at any time where a specific tray is and when it will be available again.

Advantages of computer-assisted documentation

The advantages of a computer-assisted batch documentation system, apart from serving as a source of evidence of the medical device reprocessing steps carried out, are as follows:

- The location of a set/tray or an individual package can be identified by computer at all times. This can be important when organising OR schedules for the subsequent day
- Tray lists can be updated by authorised personnel without any delays. Likewise, tray lists can be viewed by OR staff on the computer screen and printed out if necessary

→ **A BATCH DOCUMENTATION SYSTEM (BDS)** is the best form of process documentation.

→ **PARTIAL RELEASE** via BDS is possible on PC. Less effort is necessary for documentation.

→ **WHEN PURCHASING**, definitely bear in mind the equipment used for reprocessing

→ **BEAR IN MIND COMPATIBILITY** with existing computerised systems when purchasing

- The use of a set/tray or individual packages as well as their date of expiry can be verified without any major additional effort. Generation of automated recall messages once the expiry date is reached makes it easier to keep abreast of expiry dates
- The service life of the various instruments can be tracked on the computer if each new instrument is assigned an individual number (Tracking – in this respect please also consult Recommendation 60 by the Quality Task Group in Issue 2/2009 of *Central Service*). Thanks to individual tracking facilities, repairs can be documented and the repair time verified, inter alia. Withdrawal of an instrument and its replacement by a new instrument can also be recorded and documented on the computer
- Procurement of new instruments can be greatly expedited, while maintaining an overview of the existing inventory.
- When briefing new staff members it is possible to verify from the computer data which sets have been packed on several occasions by a new staff member and identify where there is need for more instruction. Illustration of instruments also make it easier for new personnel to become familiar with working practices. This is particularly true for old or customised instruments for which no article number can be identified

Finally, consistent use of a computer-assisted batch documentation system contributes, in addition to continuous documentation of medical device reprocessing, to verifiable quality assurance as part of a quality management system.

Introduction of computer-assisted batch documentation into the CSSD

A computer-assisted batch documentation system should be introduced following systematic in-depth preparation over a sufficiently long period of time. The CSSD management should as far as possible be familiar with the system before it is commissioned. → **MASTER DATA must be recorded in a well-conceived and structured manner.** Any mistakes made at this early stage of working with the computerised system can often be eliminated at a later date only with major investment. Professional assistance should possibly be sought when first recording the master data since this is a very time-consuming process. Once all medical devices have been registered (master data input), an activity that takes a lot of time, a batch documentation system will make it easier to gain an overview of all instruments reprocessed and used in a CSSD.

→ **MASTER DATA** input is important and time-consuming, and professional assistance should possibly be sought

IT and the CSSD staff

The name of each CSSD staff member using the computer-assisted batch documentation system is first of all recorded in the user master data. The authorisation granted to each staff member to use the computer system is specified in the master data. This is important because e.g. not every staff member is authorised to amend tray or packing lists or release batches for use. This information is stored in the system, thus minimising potential errors. As such, it is easy to initially integrate personnel into the system. But this does not mean that staff can yet operate the system. There is considerable need for → **TRAINING** in how to use computers and barcode readers, etc. Often, many CSSD staff members will never have used a computer and must thus overcome any anxieties in that respect; these should be taken very seriously. Already during the planning stage training should be provided to CSSD staff so that incidents and errors are avoided as far as possible once the system is in operation. Once they are properly briefed and trained, CSSD staff will be able to confidently and competently use the new equipment.

→ **TRAINING STAFF** is extremely important. Often, initial anxieties have to be overcome

Summary and outlook

The use of a → **COMPUTER-ASSISTED BATCH DOCUMENTATION SYSTEM** for medical device reprocessing makes it easier to perform routine everyday tasks in the CSSD, in particular as regards compliance with documentation requirements and provision of evidence of the various steps of the reprocessing chain. However, all this is possible only when users have received in-depth and intensive training in use of the system. It is, no doubt, easier to implement a comprehensive quality management system when

→ **A BDS** makes it easier to perform everyday tasks, meet documentation requirements and provide evidence of reprocessing steps carried out

→ **PAPERLESS DOCUMENTATION** is possible with BDS subjected to certain preconditions

→ **COMPILE A CATALOGUE OF REQUIREMENTS** before purchasing a BDS so that all relevant requirements are observed.

this is backed up by a BDS than it is when such a facility is not available. To cost the services rendered by a CSSD (internal or for external clients), additional modules can be purchased for virtually all known systems. These permit printout of delivery notes and invoices for clients. Much importance is now assigned to transparency as regards the costs incurred for reprocessing and, in all probability, this will become more important in the future. When using a computer-assisted batch documentation system these data on CSSD services can be called up or calculated at any time. → **PAPERLESS DOCUMENTATION** is being used in some CSSDs already today after agreement with the supervisory authorities. If measures are in place to ensure that data are not lost and continue to be readable even after 30 years, a vast amount of paper-based documentaton, and hence the numerous shelves in the hospital archives, can be dispensed with. This makes it much easier to document reprocessing activities and, not least, makes it easier to locate reprocessing data when and if needed.

Finally, a tip for CSSD management when it comes to purchasing a BDS: at the time of making a purchase, please bear in mind the requirements addressed by the CSSD to the batch documentation system. It is best to formulate these in writing (in a → **CATALOGUE OF REQUIREMENTS**) to ensure that nothing is forgotten. ♦