

# Recommendations by the Quality Task Group (32) How Quality Management is Structured in CSSD Practice

One of the central requirements of the recommendation of the Robert Koch Institute (RKI) "Hygienic processing of medical devices" of November 2001 is the following:

**How should processing be carried out in the CSSD?**

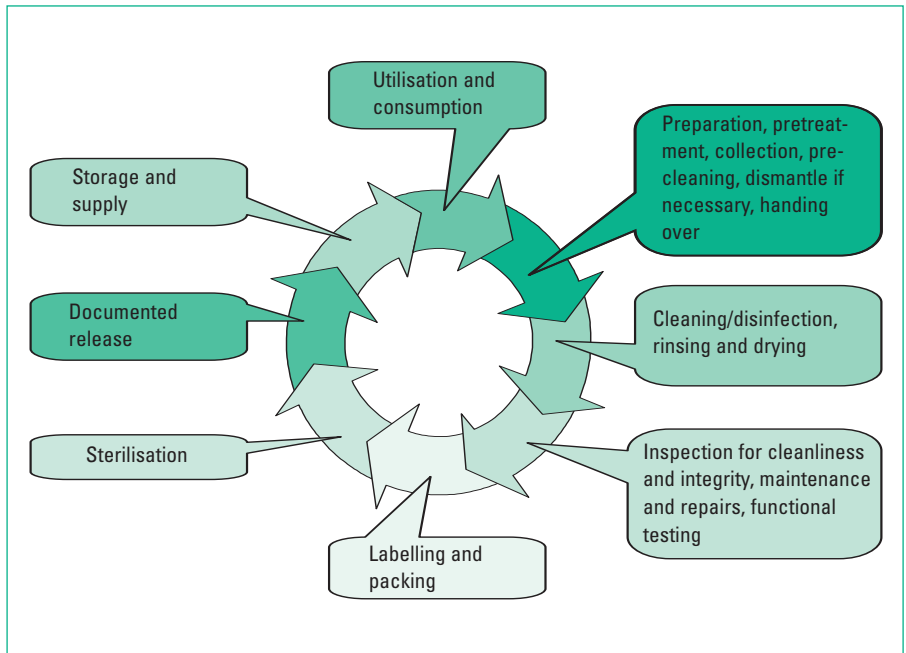
*By using validated processes it must at all times be possible to demonstrate ongoing effectiveness of all processing steps in a reproducible manner. This demand can be met only by providing a quality management (QM) structure for the CSSD.*

Often, it is easier to validate the technical procedures used in processing than it is to validate the myriad manual tasks. The only solution to this dilemma at present – indeed, this is a legal obligation – is to describe these steps within the framework of quality management and, using specification documents, to set them out in writing in the form of → **PROCEDURES AND INSTRUCTIONS.**

→ **EXAMPLES OF INSTRUCTIONS AND PROCEDURES** are compiled

In the course of the year working groups composed of members of the Quality Task Group of the German Society for Sterile Supply (DGSV) will focus on these present problems. Our goal is to draft examples of Procedures and Instructions and publish them in this present journal. Here it should be borne in mind that these Instructions can merely serve as examples because, while the stipulations are the same throughout Germany, the contents of such Instructions will be determined by the structure of the respective CSSD. One example that can serve to highlight this is the issue of how medical devices are made available for processing. If Instructions are to be compiled for handing over medical devices for processing, the transportation pathway must be included. There are various possibilities for organising transport by the collection and delivery service, by using lifts, etc.

But a common feature throughout, something that is also stipulated in the RKI guideline, is the processing steps, which can be depicted as a circuit if one includes device utilisation outside the Central Sterile Supply Department. This circuit is known to many of you as a processing circuit, medical device circuit, instrument circuit or as a quality circle.



By viewing the CSSD as a service provider it becomes clear that medical device processing is its main task. Using quality management terminology, this is called a core (or key) process. All steps of this core process must be set out in writing, so that proof can be furnished that they serve to assure quality. In addition, the non-core processes required for conducting the key process must be described. Examples of a non-core process are procurement of the materials needed for processing, daily commissioning of washer-disinfectors, heat-sealing equipment and sterilisers. It is not enough to simply perform these tasks, rather they must be planned in advance, → **INSTRUCTIONS** must be compiled and later execution of these tasks must be documented in an appropriate form.

Here a few examples of other documented specifications needed for demonstrable quality assurance during the processing procedure:

- Procedure – How to deal with MDs when CJD/vCJD suspected
- Instruction – Packing instrument trays
- Instruction – Repairs requirement
- Instruction – Periodic checks of washer-disinfectors

Before a medical device can be processed for the first time in a CSSD, it must be assigned to one of the specified risk groups in accordance with the RKI recommendation. To that effect, it is advisable to compile an Instruction for → **CLASSIFICATION OF MEDICAL DEVICES** as per the RKI recommendation.

This article gives a brief introduction to the topic of QM in everyday CSSD practice. Possibly due to delays caused by Christmas, concrete recommendations by the Quality Task Group are not yet available. In forthcoming issues of Central Service you will be able to read periodically recommendations on the subject of QM structure in practice. ◆

## Core process and non-core processes in a CSSD

→ **WRITTEN INSTRUCTIONS** must be compiled for each step in the circuit

→ **DEVICES MUST BE CLASSIFIED** before being processed for the first time