

Recommendations by the Quality Task Group (44) Compilation of Procedures

To provide for transparent and reproducible medical device processing in the CSSD, the CSSD must devise a quality management system, while describing all relevant working practices in → **PROCEDURES** (Ps= QPs) **AND STANDARD OPERATING PROCEDURES** (SOPs= QOPs) – also known as “Instructions”.

Recommendations 37 published in *Central Service* 1/05 gave a guide to compilation of standard operating procedures. In the Quality Manual, Procedures take precedence over Standard Operating Procedures. Like the Standard Operating Procedures, the Procedures must be displayed in a central location for consultation by employees and their observance must be monitored. → **PROCEDURES** are structured according to the following clearly defined rules:

1. Title

Procedures describe all the quality-relevant processes that apply for a particular area: "Procedure 007 – Taking Back Used Supplies" (unclean side).

2. Scope

Scope defines the department, persons and places affected by the Procedure. For example: "This Procedure is valid for the unclean side of the CSSD".

3. Aim

The aims to be achieved must be formulated such that their intent is clear at first glance. For example: "The aim of this Procedure is to assure a consistently high standard of quality and care".

4. Competencies

The CSSD management and representatives are responsible for drafting Procedures. Amendments may be made only by appointed persons.

5. Definition and Abbreviations

This section lists the definitions explaining the Procedures. The aim is to use uniform language. For example: "CSSD = Central Sterile Supply Department; WD = Washer-disinfector ...

6. Other Applicable Documents

Item 6 lists the relevant Standard Operating Procedures as well as the manuals, decontamination instructions, regulations drafted by the Robert Koch Institute (RK), standards, etc. Reference can also be made to other procedures. For example: "Procedure 001 – Collection and Delivery Service".

7. Documentation of Amendments

Amendments to Procedures must be documented here, together with the date and signature as well as the revision number. The amended passages must be clearly highlighted.

→ **PROCEDURES AND STANDARD OPERATING PROCEDURES** are components of Quality Management.

Structure of a Procedure

8. Distribution List

The distribution list should be designed such that Quality Management and all departments coming within its purview are featured. For example: "CSSD, OR, Engineering Department, Collection and Delivery Service, ..."

9. Enforcement

A new or amended Procedure becomes valid on being signed by the persons who drafted, edited and released it. Alternatively, amendments can be documented, and signed, at a central location. Personnel must be informed as soon as a new or amended Procedure becomes valid. Compliance with the Procedure must be monitored.

10. Processes and Competencies

Flow charts can be used to depict processes and competencies.