Recommendations by the Quality Task Group (37) Guide to Compilation of Standard Operating 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** (SOP = QOPs) – also known as "Instructions")

The SOPs must be compiled for all medical device processing steps within the meaning of the German Medical Devices Act (MPG), Medical Devices Operator Ordinance (MPBetreibV) and the Guideline of the Robert Koch Institute (RKI). Procedures will be elaborated on in a forthcoming recommendation.

➜ **PROCEDURES AND STANDARD OPERATING PROCEDURES** are part of a quality management system.

The SOPs must be displayed for consultation by employees in a central location as well as in the relevant working areas. Employees are obliged to observe the provisions of a SOP as they would those of any service instructions.

The ➜ **REASON** for basing working practices on SOPs is to ensure that hygiene and technical/functional requirements are being complied with. The wording of such SOPs should be brief, succinct and generally comprehensible. It is aimed at quality assurance and reproducibility by ensuring uniform working practices, preservation of the value of the instrumentation and increasing economic efficiency.

➜ **THE REASON FOR USING SOPs** is fulfillment of hygienic and technical/functional requirements.

The CSSD management is ➜ **RESPONSIBLE** for compilation of SOPs, in cooperation with staff members and the Quality Assurance Officer.

➜ **RESPONSIBILITY** for compilation of SOPs lies with the CSSD management.

When drawing up SOPs that have a bearing on other departments (e.g. surgical or transport departments), the assistance of the respective management must be sought.

Structure of a Standard Operating Procedure

Structure of a SOP

- Header and Footer
  - Logo
  - Title / designation
  - Registration number such as QM of the entire organisation
  - Name of person responsible for compilation
  - Date compiled
  - Revision number
  - Released by / on
  - Number of pages
- Standard Operating Procedure
  - Aim
  - Scope
  - Work flow patterns
    - As text / table or flow chart
  - Other applicable documents (optional)

The following recommendation is intended as an aid to compilation of a Standard Operating Procedure.

Automated cleaning and disinfection of motor systems and accessories

Example of an SOP

1. Aim:

On completion of this working step, cleaned and disinfected medical devices must no longer pose a risk of infection.

2. Scope

Unclean side of CSSD

3. Work Flow Patterns:

3.1. The supplies are placed on a support system for automated motor processing in accordance with the manufacturer's instructions.

3.2. One must ensure that drilling tubes are not kinked and that they are placed in large loops. All items must be placed on the tray such that they do not inflict mutual damage.

3.3. Having arranged the supplies, place the support systems on the washer-disinfector insertion carts. The loading instructions must be observed!

3.4. The mesh trays must be loaded in a manner that avoids formation of spray shadowing. One must ensure that no items project beyond the edges so as to avoid risk of injury to CSSD staff.

3.5. Fit the insertion carts into the machine.

3.6 Before closing the door, make one final visual check and ensure that the rotary arms are not impeded.

3.7 Before pressing the Start button, verify that the prescribed programme has been selected.

4. Other Applicable Documents:

– Operating Instructions:
– Motor system
– Support system
– Washer-disinfector

Remarks:

Deviating from this example of a SOP, any ➜ **WORKING PRACTICES SPECIFIC** to the respective establishment can be taken into consideration.

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➜ **SPECIFIC WORKING PRACTICES** must be considered.