Recommendations by the quality task group (120)

Guide to compilation of standard operating procedures

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This recommendation replaces the previous version of *AKQ Recommendation 37* from 2005: Guide to compilation of standard operating procedures.

For many years now Book V of the German Code of Social Law [1] has stipulated that all hospitals and other healthcare institutions must apply quality assurance (quality management) measures. Quality management is imperative in the medical device reprocessing setting.

A LIVED QUALITY MANAGEMENT SYSTEM serves as a guarantor of the reprocessing quality required.

A LIVED QUALITY MANAGEMENT SYSTEM that is observed and implemented (lived) by all personnel in the Reprocessing Unit for Medical Devices (RUMED) not only legally underpins reprocessing but also serves as a guarantor of the reprocessing quality required.

To demonstrate this, all relevant process steps must be described in process descriptions and Standard Operating Procedures. Routines checks, etc. must be set out in check lists (documentation).

In the event of a patient suit it must be demonstrated that **MEDICAL DEVICE REPROCESSING WAS PERFORMED IN ACCORDANCE WITH THE STATE OF THE ART IN SCIECE AND TECHNOLOGY.**

In the event of a patient legal suit, as decreed by the **REVERSAL OF THE BURDEN OF PROOF**, it may be necessary to demonstrate that medical device reprocessing was performed in accordance with the state of the art in technology, as stipulated in the German Medical Device Operator Regulation (*MPBetreibV*) [2]. Evidence that working practices were based on SOPs can, among other things, help to demonstrate this.

In terms of the QM-specific documents, in the German-speaking countries a distinction is made in principle between process descriptions and (Standard) Operating Procedures.

The conventional abbreviations are as follows:

- Process descriptions
- (Standard) operating procedures → SOPs = OPs = QOPs

Process descriptions

A process description describes a process in general and may be of relevance across departments. “Process description” is not a term conventionally used in QM standards and is thought to derive from descriptions of “documented processes” in standards.

Compilation of a Procedure will be addressed in a forthcoming recommendation by the Quality Task Group.

Standard operating procedure (SOP)

The use of SOPs help to demonstrate compliance with all the hygienic and technical requirements legally specified for medical device reprocessing. SOPs underpin the **QUALITY ASSURANCE AND REPRODUCIBILITY** of processes through uniform (standardized) workflow practices and contribute to the value retention of instruments and to economic efficiency.

SOPs underpin the **QUALITY ASSURANCE AND REPRODUCIBILITY** of processes through uniform (standardized) workflow practices.

SOPs describe the correct implementation of all relevant work steps in the respective workplace, thus ensuring that all staff members are able to perform the process steps to a similar standard of quality. In this way manual steps, in particular, can be standardized and hence considerably enhance process safety (fewer errors).

SOPs must be compiled to complement a Procedure for all relevant steps of the reprocessing process. In Germany the regulatory framework applicable here is the KRINKO/BfArM Recommendation [3], Medical Devices Act (MPG) [4], Medical Devices Implementation Act (MPDG) [5], Medical Device Operator Reg-

ulation (MPBetreibV) and currently valid standards (e.g. DIN EN ISO 17664 [6]). **The wording should be brief, succinct and easily comprehensible.**

MODEL STANDARD OPERATING PROCEDURES are given below for the various reprocessing steps.

MODEL SOPS for reprocessing steps.

- Donning of departmental clothing
- Hygienic separation of "unclean and clean" areas
- Proper precleaning immediately after use
- Cleaning (automated/manual)
- Disinfection (automated and/or manual)
- Process release after cleaning and disinfection processes
- Cleanliness inspection
- Functional testing
- Instrument care
- Packaging processes
- Sterilization
- Release after sterilization

In general, the responsibility for **COMPILATION OF ALL RUMED QM DOCUMENTS** lies with the RUMED management. The management may be supported by RUMED personnel, the quality assurance officer (QAO) of the RUMED, the hospital or economic operator. As part of interface management (e.g. surgical department, transport), the input of the competent persons in the various departments should be sought for document compilation.

The RUMED management is responsible for **COMPILATION OF ALL RUMED QM DOCUMENTS.**

RUMED personnel must have unhindered access to the applicable SOPs. The competent person ensures that staff have understood the content of the relevant SOPs and duly confirm that (e.g. with their signature).

All quality management updates or amendments must be documented in writing. Amendments can be easily incorporated using an amendment index, whereby the updated documents are assigned a new version number.

All staff must be informed about these **UPDATES/AMENDMENTS** and must document the same. Since these provisions are instructions, they must be observed and implemented by staff.

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Structure of a standard operating procedure

The format chosen when compiling QM documents will depend on the specifications of the respective establishment. There are standard layouts and breakdowns that can be used to that effect.

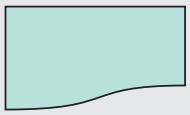
The SOP could include the following:

- Header and footer
- Logo (if applicable)
- Title/document designation
- Registration number such as QM of the entire organization
- Definitions of abbreviations
- Scope
- Aim
- Workflow patterns (as text / table or flow chart)
- Other applicable documents
- Current updates
- Compiled by
- Date compiled
- Released by/on
- Revision number
- Number of pages

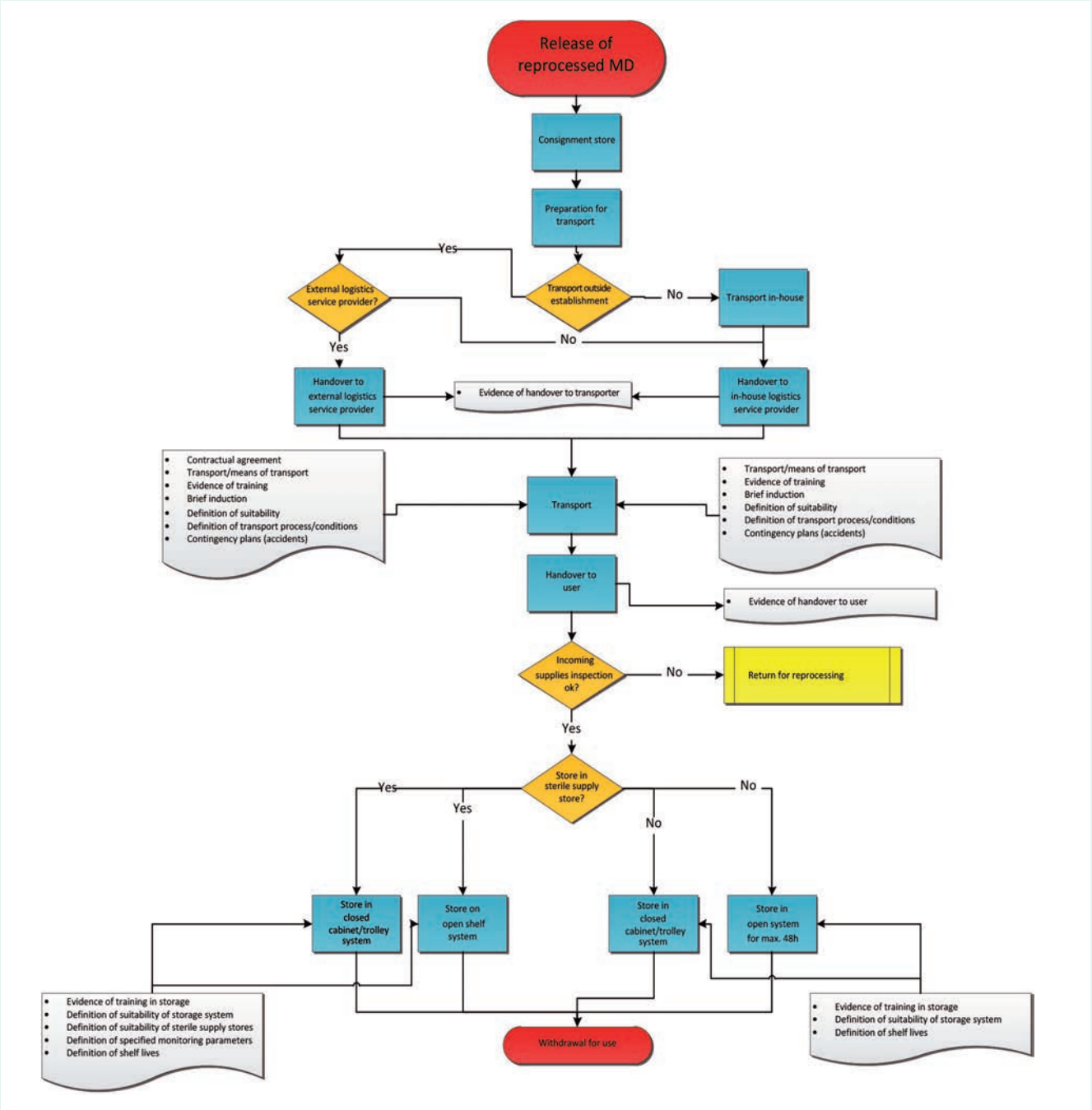
For clear definition of competences, workflows and tasks, graphic representation of processes, e.g. with **FLOW CHARTS**, is useful. These can be used to depict structures, sequences, competences and work steps.

FLOW CHARTS can be used to depict processes.

Standardized symbols enhance clarity when implementing flow charts, thus improving acceptance.

Table with visualization examples			
Start/endpoint:		Decision:	
Work step:		Document:	

Model SOP based on flow chart



(Source: DGSV guideline – Storage of reprocessed medical devices and transport of used medical devices to the RUMED and of reprocessed medical devices to the site of use)

Example of standard operating procedure in text format

LOGO

Standard Operating Procedure xx

1 Aim and scope

Example:
This standard operating procedure (SOP) regulates the management of contaminated medical devices (MDs) and is part of the process step *Cleaning* and *Disinfection* of Procedure "Example 1".
It ensures that cleaned and disinfected MDs will not present any infection risk.

The SOP applies to the unclean area of the RUMED.

2 Abbreviations and definitions

Abbreviations (examples):

StU	Sterilization unit
Steri	Sterilizer
TSA	Technical Sterilization Assistant
PQM	Process and Quality Management Department
MD	Medical Director
MB	Management board
MDs	Medical devices
WD	Washer-disinfector

Definitions and demarcations:

Complete only if demarcations and definitions are needed!

3 Other applicable documents

Document any references to pertinent acts, directives and regulations.
Otherwise, "None"

Example:
Manufacturer's instructions (DIN EN ISO 17664):

- Motor system
- Support system
- Washer-disinfector (WD)

4 Description

Variant 1: Tabular view (example)

No.	Work step	WHO	Remarks/documents
	What must be done and How	Designate compe-tence/function	Concretization of work step
1	The supplies are placed on a support system for auttomated motor processing in accordance wit the manufacturer's instructions.	RUMED staff member, trained to at least DGSV Specialist Course I level	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.
2			

Variant 2: Continuous text (if necessary, in combination with tabular representation)

Continuous text can be entered here. The above table can be flexibly adapted if necessary or also used in combination with continuous text for emphasis.
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Compiled by:	Released by:	Release date:	Version:
			01

References:

1. Book V of the German Code of Social Law (SGB) – Statutory Health Insurannce – (Article 1 of Act of 20 December 1988, Federal Health Gazette (BGBl). I p. 2477)
2. MPBetreibV – Regulation on the installation, operation and use of medical devices
3. KRINKO/BfArM Recommendation: 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)
4. German Medical Devices Act (MPG)
5. Medical Devices Implementation Act (MPDG)
6. DIN EN ISO 17664 – Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices