Sterile Supply Specialist Training Course Level II

QUALITY MANAGEMENT IN THE RUMED

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Quality management in the RUMED (with special respect to the requirements for conducting validation of decontamination processes)

1 Introduction

Medical device reprocessing, like the entire healthcare system, is subject to continuously changing demands on the quality of its organizational set-up and its products, i.e. the services rendered.

Quality management measures are prescribed for all hospital departments, including the RUMED, and when properly implemented they provide each organization with the requisite legal safety. Quality management measures, as applied today in virtually all businesses and organizations, also give the institution’s operator, management and employees a sense of organizational security.

Whereas the formerly used term 'quality assurance', referred to safeguarding the respective standard, the main focus of 'quality management', as used today, is on assuring the ongoing development of an organization and, as such, its adaptation to continuously changing demands.

Specialist Course I (SC I) already gave a general overview of the principle instruments of a QM system, including the various definitions and QM instruments.

In general, QM systems are applied across the entire spectrum of an enterprise. ISO standards 9001:2000 gives general evidence on the requirements addressed to a QM system and on the organizational measures to be taken to ensure a valid QM system. ISO 13485 specifies other requirements for manufacture or maintenance of medical devices in addition to those set out in ISO 9001

While the QM instruments presented below are intended as a means of ensuring conformance with the general requirements, they are also designed such that a

RUMED can be easily integrated into an overall system if, at any time, the establishment of such a global QM system pursuant to ISO 13485 or ISO 9001 is intended.

For the sake of completeness, it must also be pointed out that there are other basic standards that are also valid here. For hospitals in their entirety, assessment systems can also be applied to assess the effectiveness of QM measures.

Systems such as the *Joint Commission International* (JCI) or *Cooperation for Transparency and Quality in Healthcare* (KTQ®) issue assessment catalogues but, as pointed out, these are applicable to the entire hospital rather than to individual departments. However, if a RUMED has introduced a QM system pursuant to ISO 9001 or ISO 13485 and the instruments for continuing development of the RUMED have been consistently applied, it can be assumed that if such a system is evaluated on the basis of JCI or KTQ compliance with the provisions of the latter will be assured.

For more information on the systems or legal provisions, please visit:

http://www.iso.org/iso/en/ISOOnline.frontpage

http://www.jcaho.org/

Abbreviations used in this Script

RUMED	Reprocessing Unit for Medical Devices
QM	Quality Management
SC I, II	Specialist Course
PPE	Personal protective equipment

NOTE: This script has been written especially in respect to Austrian legislation and guidelines. Though the principles of QM are the same worldwide the preconditions in other countries might be different. So the requirements and guidelines should be taken as an example.

2 Legal fundamentals

The legal fundamentals have already been explained in several sections of previous training courses. Here attention is now drawn to those extracts of the basic legal regulations that give information on designing **Processes and Procedures** in

healthcare institutions. The following regulations must be borne in mind as the legal basis for process management. As an example the Austrian legislation shall be listed here:

European Medical Devices Directive

Austrian Medical Device Act

Article 93 *(1) Cleaning, disinfection and sterilization of medical devices in healthcare institutions (attention drawn to the use of "**suitable validated processes**"*

Article 95 *Quality management measures for installation, commissioning, using, maintenance, disinfection and sterilization of medical devices in healthcare institutions*

Hospital Act (Federal Health Gazette – BGBL – Article 5 b Quality Assurance)

1) The hospitals' legal authorities are obliged to assure the quality of the hospital. Measures must be designed such that they meet the scientifically recognized quality assurance benchmarks and provide for regular comparative testing of the quality with that of other hospitals.

2) .. must ensure that the preconditions are met for internal quality assurance measures. These measures must include the structural, process and outcome quality.

These fundamental rules, which already include the most important process management elements, are intended as guidance to the relevant topics in this Script.

1) *Requirements for process development (....meet scientifically recognized benchmarks of quality assurance and permit regular comparison of quality)*
2) *Requirements for process measurement (..."**suitable validated processes")***
3) *Requirements for process quality: (...must include structural and process requirements).*
4) *Requirements for the process outcome (...must include the outcome quality).*

3 Principles of process management

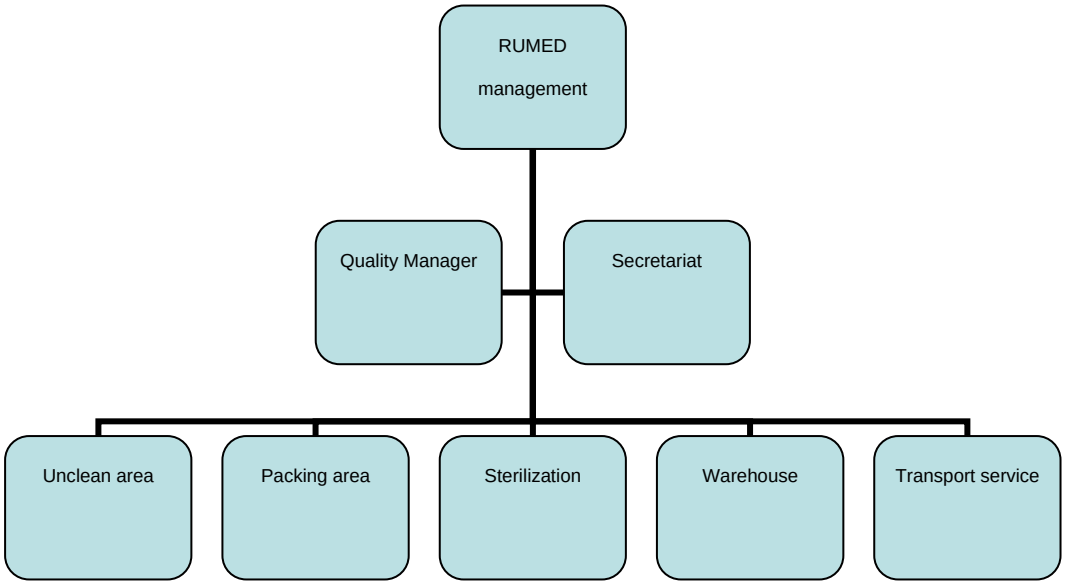
Previous QM systems put major emphasis on the functional notions of small sub-organizations and staff. The current state of the art in the QM setting is based on the rationale that all measures must be targeted towards the processes unfolding within an organization.

Initial appraisal of an organization is always based on how the structural and procedural organization is designed.

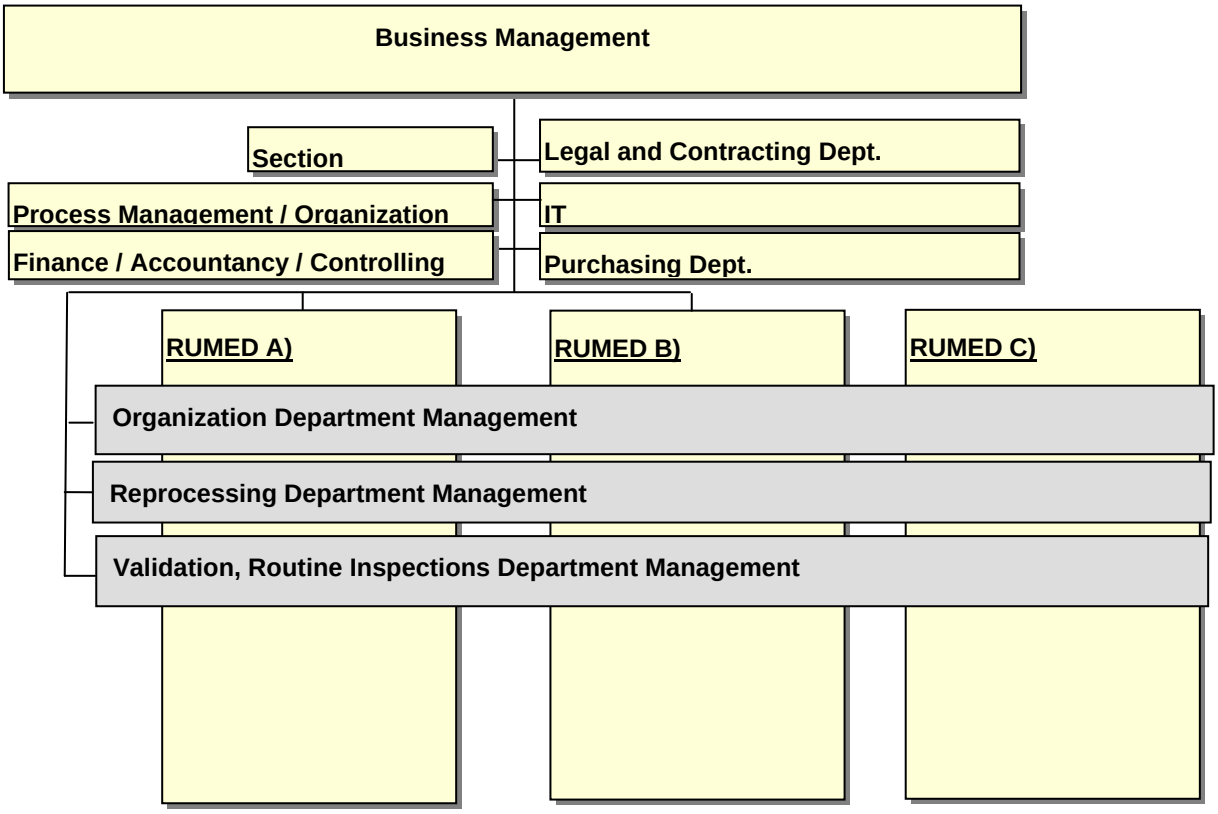
3.1 Structural organization

The structural organization denotes the structure of the individual departments and functional units and how they interact to achieve the results of the organizational unit and how they are embedded into the surrounding organization. The easiest way to depict the structural organization is to use an organigram. These come in many forms, but the most common is the

Line organigram

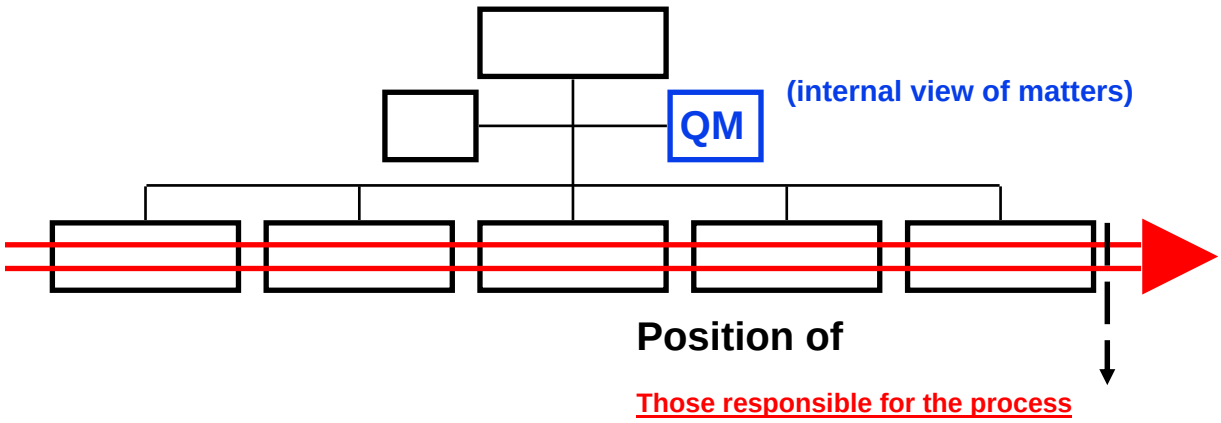


For larger, overlapping organizations the **matrix organigram** is an option.



3.2 Procedural organization

Once this task has been accomplished, it will be much easier to identify and depict all procedures unfolding in this organigram.



An enterprise's performance is measured by the customer only on the basis of the tangible results achieved for value-adding processes - hence how the core processes are managed is a feature that distinguishes the enterprise from its competitors.

3.1 Process types

Core processes consist of an enterprise's direct and indirect value-adding procedures, which are viewed and managed as a single entity. Core processes are designated as such since they define the core business of an organizational unit. One can also get an idea of what core processes are by asking, "....with what do we earn our money?"

Examples of typical core processes in a RUMED are:

- Sterile supply reprocessing
    - Steam processes
    - Gas processes
- Possibly, laundry distribution
- Reprocessing for other organizational units
- etc.

Support processes are those procedures unfolding within an organization which directly support the defined core processes.

Examples of typical support processes are:

- Warehousing
- Procurement
- Servicing, maintenance
- Training, continuing professional development
- etc.

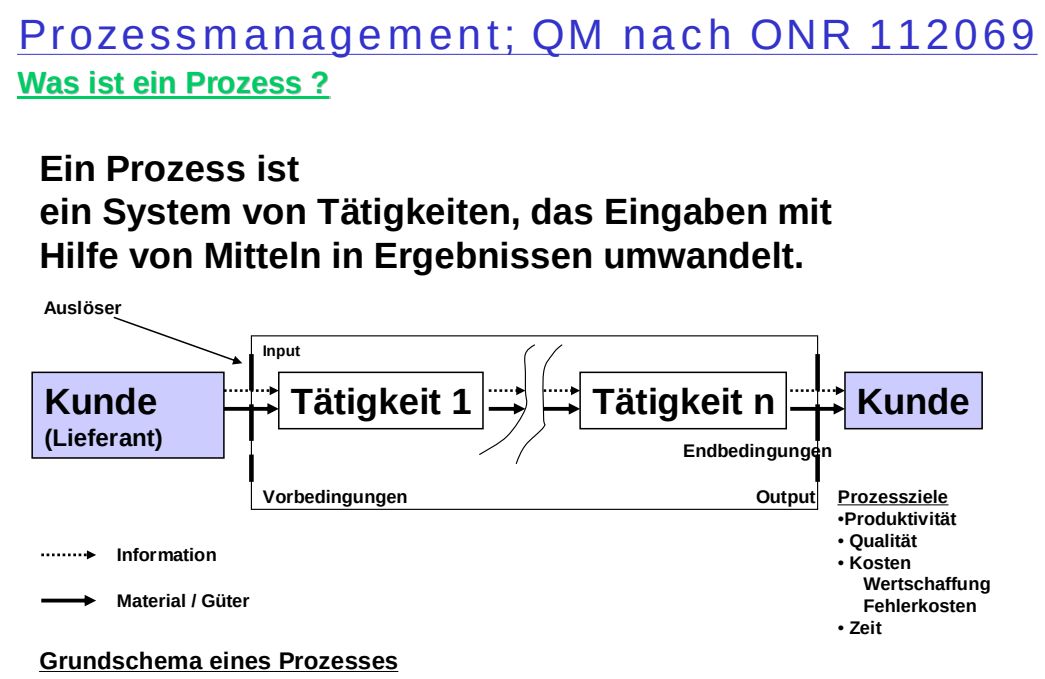
Management processes are those procedures unfolding within an organization which help guide the enterprise or organizational unit.

Examples of management processes are:

- Management of the RUMED
- Planning of resources
    - Human resources planning
    - Activity planning
- Corrective measures
- Controlling process
    - Finance controlling
    - Process controlling
- Document management
- Data recording management, etc.

3.2 Definition of a process

This now brings us to process definition



Process management; QM as per *ONR 112069*

What is a process?

A process is

a system of activities which uses

resources to transform inputs into outputs.

Trigger	Input			
Customer (supplier)	**Activity 1**	**Activity n**		**Customer**
			Input conditions	Process targets Productivity Quality Costs Value creation Error-related costs Time
	Preconditions		Output	
	Information			
	Materials/supplies			

Basic schema of a process

Here, one must bear in mind that there are always two lines in a process:

1) The value-creation component, i.e. juxtaposition of the activities that ultimately contribute to the process outcome (in the case of the reprocessing process, to the sterile supplies)
2) The information chain running parallel to the action steps (in the reprocessing process, e.g. this takes the form of the accompanying papers)

Using the form proposed below and the aforementioned process analysis, the detailed elements of a process can be worked out.

Form for process development

Process name:	**Code:**
Associated main process	**Number of process runs per year**
Trigger, input:	**Output:**
What triggers the process, what information, adjuncts are available?	*What is available as outcome at the end of the process?*
Objectives	
What is the process supposed to achieve?	
Process measurement:	
With which key figures is the process quality measured?	
Roles (who is involved):	
Who is involved?	
Interfaces:	
To which processes are there intersecting points or contextual dependencies/ relationships?	
Process description:	
What are the main tasks that must be accomplished to achieve the process targets**?**	

3.3 Evaluation of processes

Procedure:

1. Determination of status quo => Who are we?, Where are we positioned?
   (analysis of strengths / weaknesses, future risks and chances)

2. Mission, Q Policies => What is our mission?, What can the customer expect?

3. Strategy formulation => How do we intend getting there?

4. Ascertainment of core processes (see 6.3)

5. Depiction of ACTUAL procedures => What is the current process procedure?

6. Modelling of the overall process model => Which processes must be borne in mind for a global management system?

7. Modelling of TARGET procedures => What alternatives are there to process enhancement?

8. Appointment of person responsible for the process and definition of process parameters

9. Monitoring and Controlling => How is the process running and how can it be further enhanced?

10. Guiding the organization through applied process management

Evaluation must take account, in particular, of the following aspects:

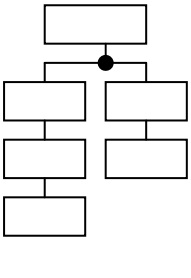
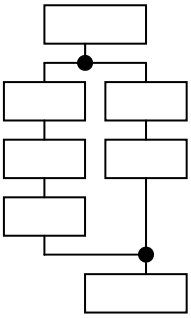
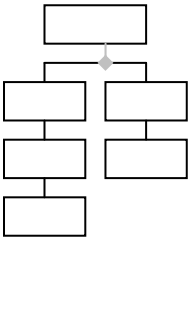
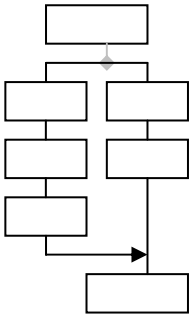
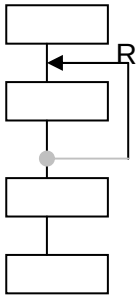
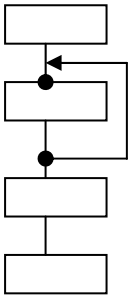
1) Economic feasibility: Instructions should be clear and unambiguous, and the level of detail should be such that the instructions serve to support staff,
2) Social effectiveness: Process instructions usher in a process of change. The involvement of staff in the process design and further development must be enlisted.

Working materials: Due attention must be paid to the working procedures and working materials (IT, working environment, working materials)

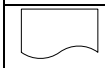
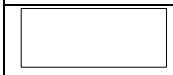
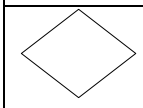
3.4 Depiction of processes

Since process depiction involves juxtaposition of activities (see definition in 6.4), depiction in the form of flow charts is the most popular method. To that effect, the logic elements listed below may be used.

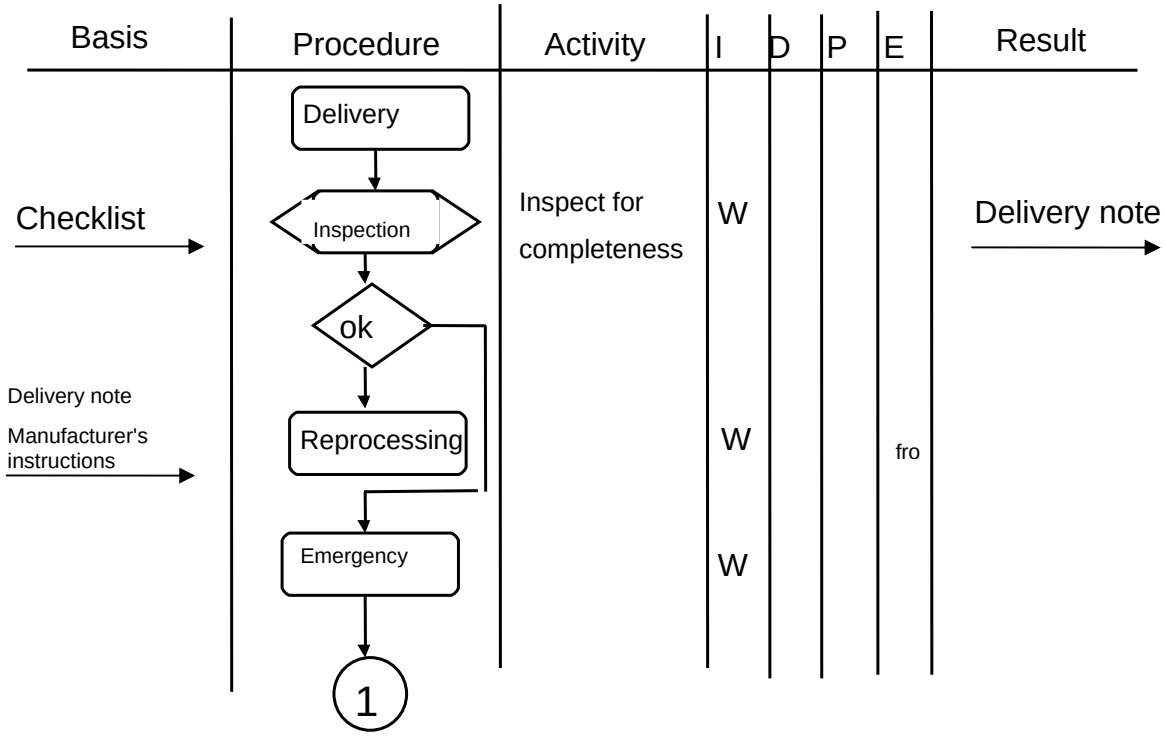
Overview of the basic forms used to depict flow charts

						
Chain	AND branch	AND logic element (after AND branch)	OR branch	OR logic element (after OR branch)	OR feedback	AND feedback

Examples of flow chart symbols

	Start
 and	AND logic element
	Document
	Activity
	Branch
 or	OR logic element

- Below is a simple depiction method that can also be used without a computer



Description:

1) In the 'Basis' column are given all documents used as a basis for the respective process step (instructions, checklists, manufacturer's instructions, etc.)
2) In the "Procedure' column the respective action steps are defined
3) In the 'Activity' column additional details can be defined (what is to be tested, what test criteria apply, etc.)
4) In the 'Responsibilities' column (IDPI) , the person responsible for this process step is defined. Thanks to the IDPI breakdown, it is possible to assign several responsibilities for a single step, whereby IDPI denotes the following:
    a. I = Implementation responsibility
    b. D = Decision-making responsibility
    c. P= Participating employee (i.e. staff member(s) working with person bearing implementation responsibility)

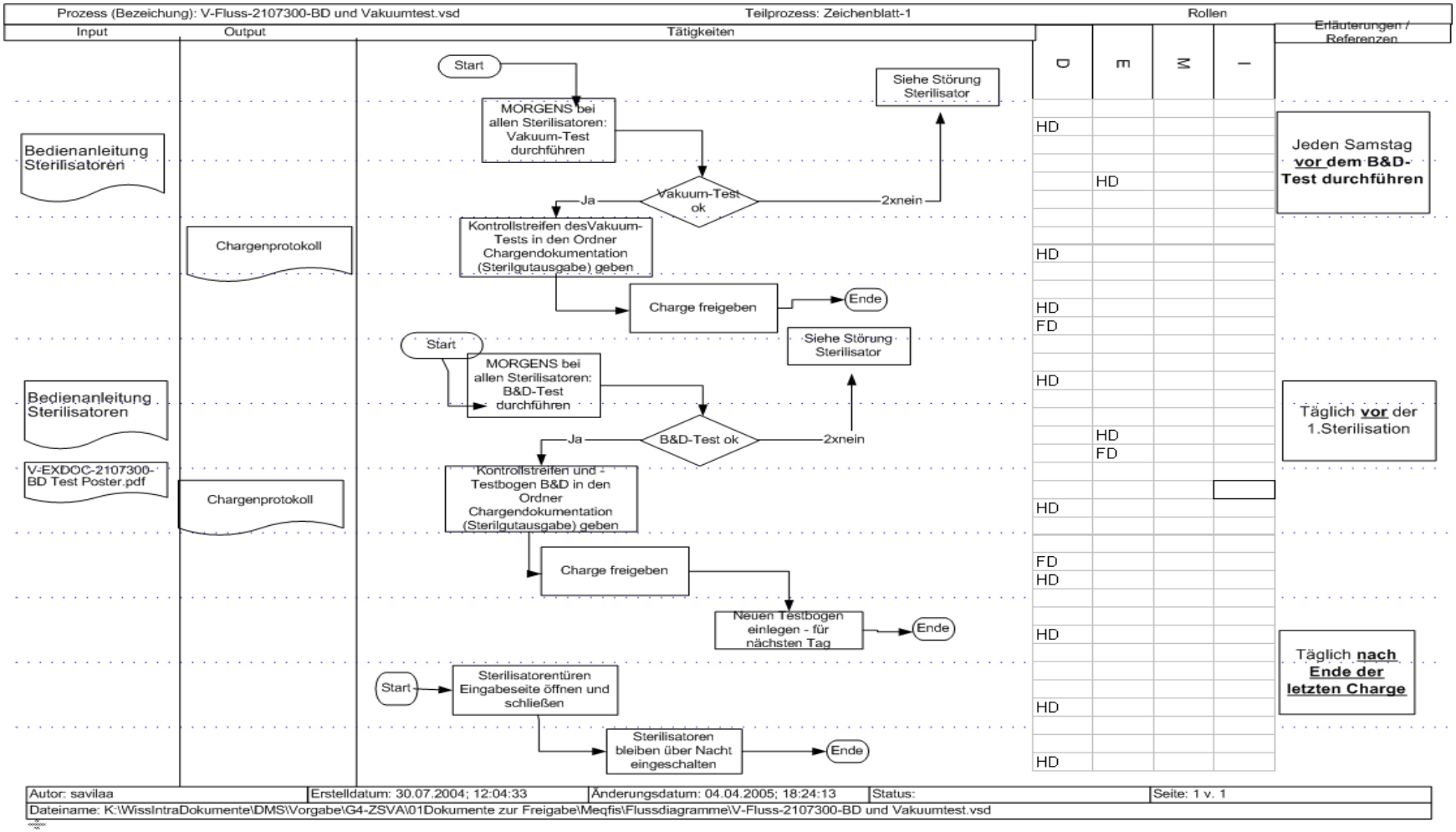
d. I = Information (i.e. who should be informed of outcome)

5) In the 'Outcome' column are listed all documents (recordings) serving as evidence of implementation.

The two columns 'Basis' and 'Outcome' define the information chain, as described in Section 6.4.

Access to a computer for process definition will permit the following, essentially more detailed, depiction, but the basic structure is the same.

3.5 Flow chart



3.6 Method of working with specified documents

All process definitions serve as **Instruction Documents** i.e. each process is released through the signature of the person responsible for the process and the management of the organizational unit. If a change is made to the structural or procedural organization, first a new process specification is immediately defined, then released, and as such passed on to the employees, who must now comply with it.

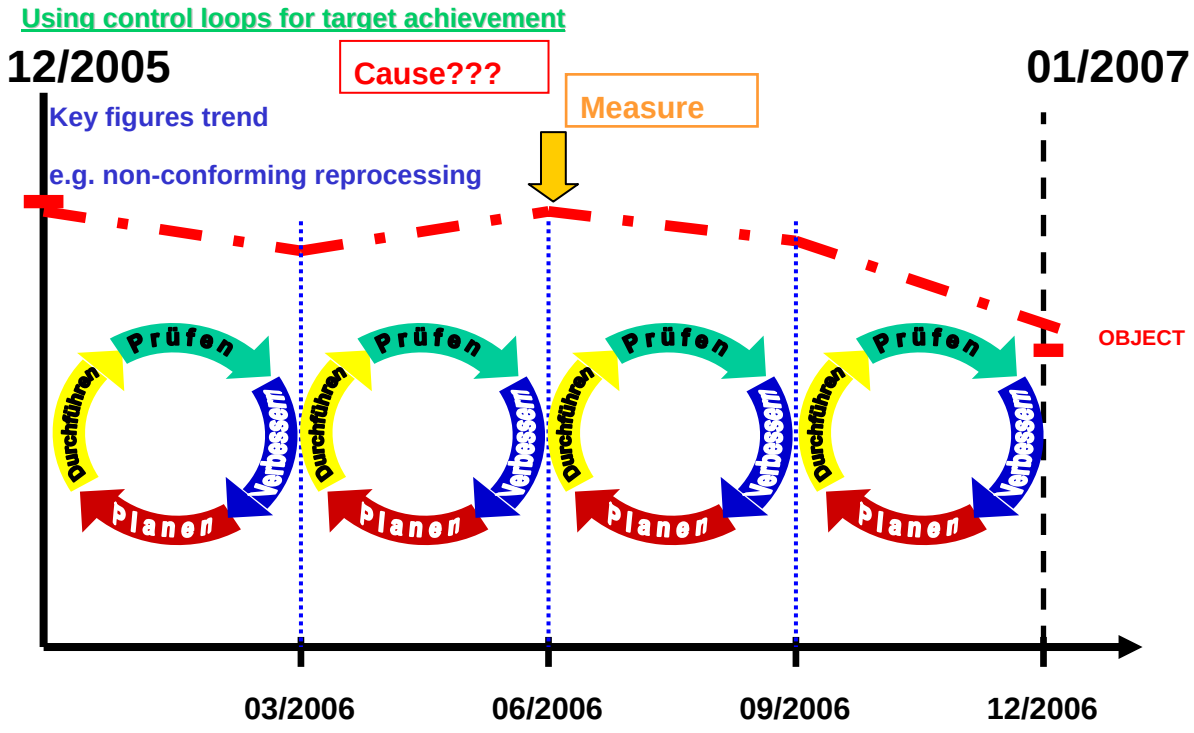
This procedural approach confers the following advantages as from the time of introduction of the process definitions:

1) Regulation of structural and procedural organization based on uniform rules
2) Depiction of the structural and procedural organization to the outside world
3) Registration of quality costs, avoidance of error-related costs
4) Reduction of product liability risks
5) Identification of weak links, deviations and potential quality problems
6) Control of processes, risks
7) Coverage of the needs of the 5 interest groups

Process management is a tool for
business management controlling

3.7 Business management controlling

A well-established process management (as described in 6.5) is characterized by the fact that the organization has defined, depicted and introduced all relevant processes, and equipped the core processes with the corresponding key figures. Thanks to this instrument, the organization is able to develop further in a selective and structured manner.



Prüfen = Test

Verbessen = Improve

Planen = Plan

Durchführen = Implement

3.8 'Special process'

The term 'special process' is used in quality management if one cannot measure the process outcome, i.e. the product quality. Hence, sterile supply reprocessing constitutes a 'special process'.

In such a case, all process steps must be expertly regulated, organized, monitored and documented such that it can be assumed that, when all instructions are observed, the product quality equates with sterile products.

4 Austrian guideline ONR 112069

The ONR 112069 is taken as an example

Austrian guideline ONR 112069 on validation and routine monitoring of moist-heat sterilization processes for medical devices is divided into 3 parts

Part 1

Part 1 is the general part and contains the following:

1 Introduction

2 Legal fundamentals

3 Principles of process management

3.1 Structural organization
3.2 Procedural organization
3.1 Process types
3.2 Definition of a process
3.3 Evaluation of processes
3.4 Depiction of processes
3.5 Flow chart
3.6 Method of working with specified documents
3.7 Business management controlling
3.8 'Special process'

4 Austrian guideline ONR 112069

Part 1
Part 2
Part 3
4.1 Implementation of ONR 112069
Re 1) General information
Re 2) Structural/spatial situation
Re 2.2) Fittings and furnishings
Re 2.3) Organization
JOB DESCRIPTION
Re 2.4) Staff qualification / training
Re 2.5) General hygiene (infection control)
Re 2.6) Occupational safety

Re 3) Quality assurance / management

Re 3.1) General
Re 3.2) Washer-disinfectors (WDs)
Re 3.3) Sterilizers
Re 3.4) Sterile supply storage
Re 3.5) Standard operating procedures (SOPs)
Re 3.6) Documentation
4.2 Measurement analysis, improvement
4.3 Customer-related processes

5 Annex

5.1 Standards
5.2 Links

Part 2

Part 2 describes 'Further Specifications'. It contains the following:

1 Introduction

2 Legal fundamentals

3 Principles of process management

3.1 Structural organization
3.2 Procedural organization
3.1 Process types
3.2 Definition of a process
3.3 Evaluation of processes
3.4 Depiction of processes
3.5 Flow chart
3.6 Method of working with specified documents
3.7 Business management controlling
3.8 'Special process'

4 Austrian guideline ONR 112069

Part 1
Part 2
Part 3
4.1 Implementation of ONR 112069
Re 1) General information
Re 2) Structural/spatial situation
Re 2.2) Fittings and furnishings
Re 2.3) Organization
JOB DESCRIPTION
Re 2.4) Staff qualification / training
Re 2.5) General hygiene (infection control)
Re 2.6) Occupational safety

Re 3) Quality assurance / management

Re 3.1) General
Re 3.2) Washer-disinfectors (WDs)

Re 3.3) Sterilizers
Re 3.4) Sterile supply storage
Re 3.5) Standard operating procedures (SOPs)
Re 3.6) Documentation
4.2 Measurement analysis, improvement
4.3 Customer-related processes

5 Annex

5.1 Standards
5.2 Links

Part 3

For the RUMED, Part 3 is the most relevant since it sets out organizational aspects of the RUMED. Fields with a grey background are MUST fields, i.e. these requirements must be met at the time of validation. It is therefore advisable to first define the processes in order to render visible the connections between them, since the provisions of ONR 112069 will generally be formulated by different areas (management, engineering department)

Part 3 relates to the structural and procedural organisation as well as to RUMED fittings and furnishings. Part 3 is designed like a checklist and contains the following:

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Quality management in the RUMED (with special respect to the requirements for conducting validation of decontamination processes)

Part 3

4.1 Implementation of ONR 112069

Re 1) General information

Re 2) Structural/spatial situation

Re 2.2) Fittings and furnishings

Re 2.3) Organization

JOB DESCRIPTION

Re 2.4) Staff qualification / training

Re 2.5) General hygiene (infection control)

Re 2.6) Occupational safety

Re 3) Quality assurance / management

Re 3.1) General

Re 3.2) Washer-disinfectors (WDs)

Re 3.3) Sterilizers

Re 3.4) Sterile supply storage

Re 3.5) Standard operating procedures (SOPs)

Re 3.6) Documentation

4.2 Measurement analysis, improvement

4.3 Customer-related processes

5 Annex

5.1 Standards

5.2 Links

4.1 Implementation of ONR 112069

The following chapter takes a closer look at, and interprets, the provisions of ONR 112069-3 from a QM perspective, while giving exemplary solutions.

Commissioning

General specifications and preconditions General specifications

Re 1) General information

In the specifications given under General Information, risk assessment of medical devices as proposed by the Robert Koch Institute (RKI) guideline is verified. Accordingly, the RUMED is divided pursuant to wfhss guideline Nr. 04 (RUMED concept).

Name and address of operator:	
Highest risk class of medical devices (MDs) to be reprocessed	☐ semi-critical A ☐ semi-critical B ☐ critical A ☐ critical B ☐ critical C
Accordingly, to be assigned to RUMED category pursuant to wfhss guideline Nr. 04	☐ I ☐ II ☐ III
Responsible for sterilization:	

Furthermore, the RUMED management's responsibility is verified.

Re 2) Structural/spatial situation

See as well Module 05 “Constructional requirements for RUMEDs”

	yes	no	Remarks
Dedicated premises available			RUMED II, III
Spatial zone division in unclean / clean / sterile			RUMED II
Structural zone division in unclean / clean / sterile			RUMED III (new construction)
Only structural division in unclean + clean / sterile			TARGET for RUMED III (also old construction)
Sluice unclean / clean			RUMED III (new construction, at least gown sluice)
Sluice clean / sterile			RUMED III (if adjacent to OR)
Unclean area: Available surface area adequate			RUMED II, III

Clean area: Available surface area adequate			RUMED II, III
Separate changing rooms for clean / unclean area			
Structural defects			
RUMED adjacent to operation unit			
Sterile supply storage	☐ RUMED ☐ operation unit ☐ others:		

To answer these questions, status plans must be drawn up by the Technical Business Management and displayed in the RUMED. To ascertain whether the available surface area is adequate, the Workplace regulation must also be consulted since it is here that the basic conditions are defined. If may also be necessary to consult the respective safety officer and the occupational medical service.

The following parameters on spatial conditions should be complied with (spatial ratios formulated on the basis of commissioning)

	yes	no	Remarks
Room aeration / deaeration facility available?	☐	☐	
Rel. ambient humidity on loading side > 30 %	☐	☐	

Re 2.2) Fittings and furnishings

	yes	no	Remarks
Handwashing basin available in unclean area?			
- Appropriate fittings available?			
Ultrasonic cleaner available?			
- Routine inspection (if applicable)?			Type:
Washer-disinfectors (WDs) available?			as from semi-critical B MDs
- WD capacity adequate?			
- WD processes validated?			
Rotary sealer available			as from critical A MDs
- Routine inspection?			Type:
Sterilizers available			as from critical A MDs
- Large steam sterilizer(s)			Number: ☐ as per EN 285
- Small steam sterilizer(s)			Number: ☐ as per EN 13060
- Low temperature sterilizers?			Type: Number:

For this block it is advisable to draw up an equipment list. In doing so, enter the basic parameters, such as capacity, year of manufacturer, basis for installation tests from the Technical Documentation. Submit any test reports on the installation tests or past tests.

To reduce the scope of commissioning for the inspector, or to help the RUMED decide whether the appliances lend themselves to validation of a reprocessing process, the RUMED should at the outset clarify, while consulting the respective hospital's technical services, the following issues from Section B 'Commissioning'.

Technical preconditions for validation of sterilizers supplied before EN 285 and 13060 respectively came into force:

	yes	no	Remarks / values
Is the test steam sterilizer fitted with an **absolute pressure measurement facility** to record the pressure in the sterilizer chamber	☐	☐	
Is the test steam sterilizer equipped with an automatic **Bowie & Dick** test program?	☐	☐	
Is the test steam sterilizer equipped with an automatic **vacuum tes**t program?	☐	☐	
Are the test steam sterilizer programs equipped with a **pulsed (fractionated) vacuum process** or equivalent process?	☐	☐	
Are the **connections** needed to install the test measuring instruments available?	☐	☐	
Does the steam sterilizer have a recording facility for long-term measurement of the chamber pressure and temperature	☐	☐	☐ analogue ☐ digital ☐ electronic
Two mutually independent temperature sensors for control and display/recording with connection as per EN 285 and 13060 respectively?	☐	☐	
Fault signalling and process interruption in the event of			
• deviations from process parameters (> 1K)	☐	☐	
• malfunctions in operating materials supply	☐	☐	
• pressure drop in door sealing cables	☐	☐	
Measuring instrument available to display chamber pressure / temperature and sleeve pressure?	☐	☐	
Batch counter available	☐	☐	

	yes	no	Remarks / values
Mutual interlocking doors for double door machines?	☐	☐	
Are the pipelines for the sterilant made of stainless steel?	☐	☐	
Defined sampling point available for steam condensate?	☐	☐	

Fields where 'yes' is displayed in the background are mandatory specifications

Re 2.3) Organization

	yes	no	Remarks
Is there an up-to-date organigram available?			RUMED III
Are there written specifications on responsibilities and competencies?			RUMED II, III
Has release competence been regulated?			
Has special release competence been regulated?*			
Is permanent expert supervision (manager or deputy manager) assured on site?			e.g. on -call service
Does the unit reprocess MDs for other establishments?			
- What is the RUMED classification for that establishment?			
- To which RKI risk groups do the MDs belong?			
- Do contracts exist?			

*Example for special release: Paper for the printer has run out in the drying stage

It is advisable to assemble all the requisite instructions and documents in a QM manual. The basic organizational issues, such as the organigram or written assignment of responsibilities and competencies, can already be addressed in the introduction to this QM manual.

Job descriptions are also advantageous for definition of competencies and responsibilities. The job descriptions are designed for the respective employees and regulate all relevant topics such as duties, competencies, powers and proxies. Below is an example of a job description, highlighting the most important elements.

Example for job description

Sheet 1/1	JOB DESCRIPTION	

1) Job holder
2) Area or project
3) Abbreviation for item 2
4) Job designation

5) Signatory powers

6) Supervisor (disciplinary)
7) Deputy supervisor (disciplinary)
8) Supervisor (specialist)
9) Deputy supervisor (specialist)
10) Subordinate positions
11) Job holder will be replaced
12) Job holder replaces

13) Job objectives

14) Requirements profile

15) Specialist duties assigned to job holder

Besides, duties not mentioned here but, as per their nature belong to this area, must also be discharged

16) Process responsibility in line with quality management

17) Responsibility for systems, functions and procedures

18) Signature with date:

Area supervisor Job holder

Distribution list: Original: **Supervisor** Copy: **Job holder, QM**

Re 2.4) Staff qualification / training

	yes	no	Remarks
Manager / deputy manager:	Name:		
Basic qualification depending on national regulations			
Specialist training			See RUMED concept (wfhss guideline No. 03)
Specialist Course 1			Or equal education
Specialist Course 2			Or equal education
Specialist Course 3			Or equal education
Not less than one year's experience of medical device reprocessing			

In addition to the job descriptions, a requirements profile can also be compiled for each position within the organization. The requisite level of knowledge and experience will be defined in the requirements profile. The requirements profile will then make it much easier to identify the need for any additional training or continuing professional development (CPD); a requirements profile is a good basis for selecting new employees.

Regular staff meetings are another way of recording any need for training or CPD. Such meetings can be held between the staff member and supervisor away from routine activities.

Employees			
Number of additional employees			
How many of them have completed at least Specialist Course 1 or equal education			

Evidence of participation in training courses must be documented in the interest of the staff member and respective supervisor. All measures, duration, trainer and knowledge imparted must be duly recorded.

Experience has shown that maintaining individual training records for employees is very beneficial. Each training seminar is recorded in this log and confirmed by the trainer. This has the advantage that, when changing employment, each employee can present the log to the next supervisor and proceed on the basis of the already completed training courses.

By keeping a record of training and, possibly, a requirements profile, it will be very easy to compare this with the level of knowledge needed for a (new) position.

Training

	yes	No	Remarks
Is there a training schedule available?			
- Is this up to date?			
Has the training content been defined for new employees?			
- Hygiene (infection control) training?			
- Occupational safety training?			
- Equipment training?			
Are induction records available?			
How is the existing level of knowledge ascertained?			
Spot checks are carried out to ascertain employees' level of knowledge			

Re 2.5) General hygiene (infection control)

	yes	No	Remarks
Is there a hygiene (infection control) policy (folder) available?			
Cleaning and disinfection policy available?			
- Is this up to date?			
- Are the products available?			
- Listed (approved) products?			
Instructions on personal hygiene?			
Instructions on hand hygiene?			
Instructions on changing rooms / sluices?			

The RUMED operator must

a) list all working materials used

b) define, and provide training in, the hand hygiene measures needed

c) define instructions for changing working clothes in the clean room area and assure documented employee induction.

Re 2.6) Occupational safety

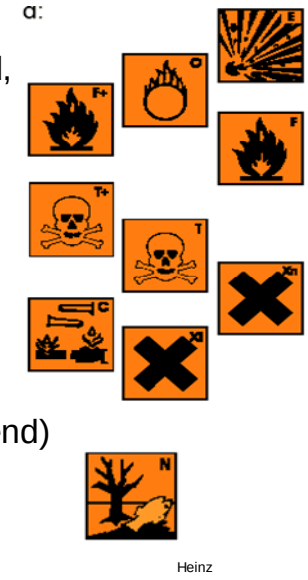
	yes	No	Remarks
Is hepatitis B vaccination offered?			
Are safety data sheets available for the chemicals used?			
Are there leaflets available on the action to be taken in the event of incidents involving biological substances?			
Is there a system in place for reporting incidents involving biological substances?			
Is personal protective equipment (PPE) available?			
Gloves			
- Gowns			
- Aprons			
- Orofacial masks			
- Goggles			
Is there an adequate supply of PPE available?			
Is PPE used properly?			
Is training in occupational safety provided annually?			

ARBEITNEHMERSCHUTZ

Gefahrenstoffe

Gefahrstoffe sind Stoffe und Zubereitungen, die eine oder mehrere gefährliche Eigenschaften aufweisen.
Gefährlichkeitsmerkmale sind:

- explosionsgefährlich, • brandfördernd,
- hochentzündlich
- leichtentzündlich, • entzündlich
- sehr giftig, • giftig,
- ätzend
- reizend,
- sensibilisierend
- krebserzeugend
- fortpflanzungsgefährdend (reproduktionstoxisch, fruchtschädigend)
- erbgutverändernd
- umweltgefährlich
- gesundheitsschädlich



Heinz

Hazardous substances are substances and preparations which exhibit one or more hazardous properties.
Hazardous properties include:

- Explosive • combustible
- highly explosive
- slightly explosive • inflammable
- highly toxic • toxic
- corrosive
- Irritant
- sensitizing
- carcinogenic
- teratogenic
- mutagenic
- hazardous to the environment
- hazardous to health

Request the safety data sheets from the manufacturer for all working materials listed above (see Item a). The safety data sheets give information on the nature and constituents of the substances, storage conditions, measures to be observed when handling the substances and PPE (personal protective equipment) to be used.

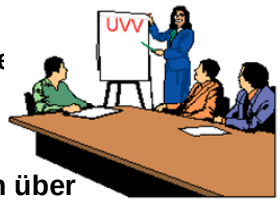
ARBEITSMITTEL, ARBEITSSTOFFE

Betriebsanweisung

Für gefährliche Arbeiten mit Werkzeugen, Maschinen, Arbeitsstoffen und Verfahren sind Betriebsanweisungen erforderlich.

Betriebsanweisungen sind Grundlage für die Unterweisung.

Betriebsanweisungen sowie Anleitungen müssen auch in der Sprache des Bedienе vorhanden sein.



Betriebsanweisungen müssen mind. Angaben über

- **die normalen Einsatzbedingungen,**
- **die bestimmungsgemäße Verwendung,**
- **das Verhalten bei Betriebsstörungen und**
- **die Herstellerhinweise aus der Bedienungsanleitung enthalten.**

Heinz

WORKING MATERIALS, OPERATING MATERIALS

Operating Instructions

Operating instructions are required when using dangerous implements, machinery, working materials and processes

Operating instructions serve as the basis for employee induction.

Operating instructions as well as manuals must be available in the operator's language.

Operating instructions must contain information on at least

- Normal use conditions
- Intended use
- Action to be taken in the event of malfunctions and
- The manufacturer's instructions from the operating manual

Appropriate instructions must be compiled on reporting and recording accidents and near incidents, and staff trained accordingly.

ALLGEMEINES

Meldung von Arbeitsunfällen

Was ist eine Arbeitsunfall ?

Ein Arbeitsunfall ist eine Unfall, der Ihnen während der Arbeit am Arbeitsplatz oder am Weg zur und von der Arbeit passiert

Was ist bei einem Arbeitsunfall zu tun ?

Erste Hilfe
Ärztliche Behandlung (falls nötig)
Meldung an den Arbeitgeber (an Vorgesetzten)

Warum ist die Meldung so wichtig ?

- Dadurch haben Sie Anspruch auf die bestmögliche Behandlung.
- Bei bleibenden Schädigungen besteht Anspruch auf Umschulung oder Rente (Kosten von der AUVA).
- Es können in Zukunft weitere Gefahren vermieden werden
- Durch die Meldung von Beinaheunfällen können schwerere Unfälle vermieden werden !

Heinz

GENERAL

Reporting accidents at work

What is an accident at work?

An accident at work is an accident you experience in the workplace or on the way to/from work

What action is needed in the event of an accident at work?

First aid

Medical treatment (if necessary)

Report to employer (to supervisor)

Why is this report so important?

- It entitles you to the best treatment possible
- If there is lasting damage, you will have a right to retrain or claim an invalidity pension
- It helps to ward off other dangers in the future
- By reporting near accidents, serious accidents can be avoided!

Re 3) Quality assurance / management

Re 3.1) General

	yes	no	Remarks
Has risk classification of MDs as per RKI been carried out?			
Are the manufacturer's instructions on reprocessing available?			as far as available (necessary)
Is consideration given when purchasing MDs to whether they can be reprocessed?			
- Are there written instructions to that effect?			
Are there written instructions on:			
- Document compilation			
- Document inspection			
- Document release			
Are test reports on previous tests available?			
- WD			
- Sterilizer(s)			
Is a maintenance schedule available?			
- WD			
- Sterilizer(s)			
- Ultrasonic cleaner			
- Sealing device			
- Steam generator			
- Water **R**everse **O**smosis system			
Are these instructions followed and documented?			

The risk assessment procedure and classification of medical devices in terms of their amenability to reprocessing are described below.

The conditions to be met for document release addressed in this block of topics are described in detail below.

Another point to be mentioned in this block is that already at the time of purchasing instruments, consideration must be given to whether, and how, such devices can be reprocessed. This means that the RUMED management must be involved in the hospital's procurement process.

Classification into risk groups as per RKI:

See Module 02: Fundamentals of Medical Device Reprocessing

The checklist above also states that maintenance schedules must be drawn up for all equipment and systems used in the reprocessing process. The onus to formulate maintenance schedules is on the person(s) responsible for the various systems. However, the hospital's engineering department should also be involved in setting maintenance intervals, defining tasks and maintenance strategies.

When reviewing maintenance activities, attention should also be paid to ensuring regular calibration of measurement and signalling equipment, because functional display facilities are essential for assessment of the sterilization results and, hence, for batch release.

Re 3.2) Washer-disinfectors (WDs)

	yes	no	Remarks
Is there a routine inspection schedule?			
Are routine inspections carried out?			
- with respect to blockage (endoscope, MIS instruments, etc.)			
- with respect to cleaning			☐ Visual inspection ☐ Cleaning indicator ☐ Protein detection
- with respect to disinfection			☐ Regular thermometric tests ☐ Visual temperature check (display of the WD) ☐ others:
- Dosage of process chemicals			☐ Line on canister ☐ Documentation of change of chemicals ☐ others:
- Inspection of rotary arms on loading and unloading			as far as possible
Is batch documentation carried out?			
- Sufficiently comprehensive and continuous?			

Re 3.3) Sterilizers

	yes	no	Remarks
Is there a routine inspection schedule?			
Are routine inspections carried out?			
- Vacuum test (at least weekly)			
- Steam penetration test (Bowie & Dick test) – daily			

- Signalling of compliance with the sterilization cycle specifications			e.g. periodic thermoelectric tests
Is batch documentation carried out?			
- Batch control system (PCD)			
- Sufficiently comprehensive and continuous?			

To ensure that routine tests are performed in a representative manner and yield comparative results, the procedure used for each individual test must be described in test instructions. The same format used for (standard) operating instructions (SOPs) is used for the test instructions too. But there is one important difference in the test instructions: definition of the acceptance and rejection criteria, i.e. what is the cut-off test result that determines whether a test was not passed, or whether it was passed and the system can continue to be used.

Re 3.4) Sterile supply storage

	yes	**no**	**Remarks**
Store while protected against dust?			
Shelf life defined?			

Re 3.5) Standard operating procedures (SOPs)

	yes	**no**	**Remarks**
Are there standard operating procedures for:			
Management of medical devices after use			
- How medical devices are managed (transported) after use			
- Max. time MDs allowed to wait until reprocessed?			hours
Pretreatment in the place of use (e.g. OR)			
Transport of contaminated MDs			
Taking charge of incoming supplies in the RUMED (incoming inspection)			
Dismantling instructions			
Manual precleaning			
Ultrasonic cleaning			
Washer-disinfectors (WDs)			
- Loading instructions for WD			
- Program selection			
- Inspection			
- Release criteria			
- Procedure for non-compliance with			

release criteria			
- Procedure in the event of malfunctions			
- Procedure in the event of faults			
Functional test			
Care			
Packaging			
Sterilizer(s)			
- Loading instructions for sterilizer			
- Program selection			
- Inspection			
- Release criteria			
- Procedure for non-compliance with release criteria			
- Procedure in the event of malfunctions			
- Procedure in the event of faults			
Transport of sterile MDs			
Storage			
Use			
Handling sterile supplies			

The structure of standard operating instructions (SOPs) was already described, and practical exercises carried out, in Specialist Course I (SC I). To explain how SOPs are matched to the various demands set out in the validation guideline, the specimen SOP used in SC I is now given again below.

Hospital "Specimen"	STANDARD OPERATING PROCEDURE	Doc. No:	AA-XY
	Title: Preparation of a surface disinfectant solution	Revision:	00
		Valid as from:	

1. Purpose

This standard operating procedure describes the preparation of surface disinfectants for XY area

2. Scope / work place

Specify the area where the solution is to be prepared and used

3. Terms

ml = millilitre

l = litre

4. Competences

Specify who is responsible for this task

5. Procedure

As a standard practice, a 0.5 % solution is to be prepared.

Other concentrations are specified for certain application areas by the suitably qualified nurse on duty

5.1 Receptacles

- Cleaning basin, green, from the cleaning trolley
- Disinfectant (5 l container with dosing pump)
- Dosing beaker, small, with precise graduations (markings)

5.2 Method

- The solution must be freshly prepared each morning
- Dosing table is stuck inside the cabinet above water tap in the "Unclean Disposal" room
- Fill 8 l water (cool) into the basin (markings on inside rim of basin)
- Then dose the disinfectant with the dosing pump into the small measuring beaker
- Check that it is exactly 40 ml
- Now add the 40 ml to the water

5.3 Application

The solution may only be used for one day

An already-used cloth must never be dipped into the solution

Surfaces are wiped off moist

6. Personnel protection

- When preparing the solution gloves, orofacial mask and goggles must be worn.
- Gloves must always be worn when applying the solution
- Each staff member shall be briefed on the hazards posed by working materials
- Each staff member shall be familiar with first aid measures, based on the safety data sheet.

7. Troubleshooting

Check the expiry date

After accidents or near accidents, take the action outlined in the valid service instructions of the respective institution.

8. Additional documentation

- Hygiene (infection control) policy
- Service instructions
- Safety data sheet

But SOPs can also be compiled in other formats. Packing lists or photographic documentation of set assemblies have the same character as the SOP given above by way of example. The SOP format that best reflects its purpose and appropriateness should be chosen.

Regardless of the format, the issue status and release notes should always be given so that validity can be verified at all times.

Re 3.6) Documentation

	yes	no	Remarks
Is the following documentation available?			
Surface disinfection			
WD routine inspections			
WD batch documentation			
Sterilization routine inspections			
Sterilization batch documentation			
- parametric release			
Malfunctions			
Errors / near errors			
Servicing, internal			
Servicing, external			
Inspections/ tests, internal (e.g. internal audits, assessment of training needs)			
Inspections/ tests, external (e.g. Technical Inspectorate, validation, external audit, health inspection)			
Feedback from clients or others			

In quality management a distinction is made between documents (specified documents) and records. Records are documents compiled on the basis of individual process steps and serve as proof of orderly conduct of working practices.

Terms Employed in Quality Management

DOCUMENTATION

- Definition of standards
- Definition of responsibilities
- Documentation for tracking
- Important for product liability

RECORDS

- Test records
- Important for product liability
- Important for validation

When preparing records it is important that the insights they provide are preserved, because records can at a later date prove that tests, release, etc. have been appropriately carried out. As such, records are important if product liability issues are raised. One must not forget either that computerized data are also records, i.e. for computerized data the following must be specified: who is authorized to work with the program, how data are to be stored and on which data storage media. This is important because over time computerized data can also become illegible. The retention period for records is regulated, on the one hand, by the Product Liability Act or, if the data can be related to the patient, the retention period for patient documentation applies. Which regulations apply must be determined in cooperation with the respective hospital's legal department.

4.2 Measurement analysis, improvement

Monitoring and measuring

Management of non-conforming products

Monitoring and measurement are described in detail in standards ((Bowie & Dick tests, vacuum test, validation)

Management of non-conforming products is a particularly important aspect of medical device reprocessing. Non-conforming means: "Not in conformance with the requirements". It must therefore be determined how measures can be implemented to ensure that a non-sterile product will not be used either or even be forwarded to the customer.

The most common way to do so is to use process indicators.

4.3 Customer-related processes

The products (i.e. medical devices) in a RUMED are the property of the customers and are used by the customer to render his/her services. Therefore every RUMED should also ask who the customers are, what needs do the customers have, and a communications process with all customers should be established. If process analysis is properly conducted, the RUMED employees will be able to appreciate just how complex are their own core processes and how they are integrated into the customers' processes. As already described above, the interfaces to the customer are a key component of the process which must be continually monitored. Here information is received from the customer indicating whether one's own processes are functioning properly. Communication with the customer is an important input for optimization of one's own processes, using the process controlling principle described in Section 6.4.

5 Annex

5.1 Standards

Sterilizers are Class IIa medical devices (pursuant to Article 10, Annex IX, 93/42/EEC) for sterilization of medical devices in the health care sector

It is important that the operator of sterilizers, too, is familiar with the relevant standards.

The significance of standards has been underpinned by the Medical Devices Directive 93/42/EEC and the corresponding harmonized Austrian Medical Devices Act (MPG). They stipulate the (minimum) state of the art, which must be observed by the manufacturer when designing, producing, operating or using medical devices.

5.2 Links

EU directives online	http://europa.eu.int/eur-lex/
Robert Koch Institute	www.rki.de
Austrian Society for Sterile Supply	www.oegsv.com
Working Group Instrument Preparation	www.a-k-i.org