Recommendation by the Quality Task Group (128)

Personnel Qualifications in the Reprocessing Unit for Medical Devices (RUMED)

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MEASURES are needed to ensure the currently specified knowledge continues to stay aligned with the state of the art.

Introduction

PERSONNEL QUALIFICATIONS are one of the most important control elements in medical device reprocessing in order to assure the legally stipulated process quality.

For that reason, the required personnel qualifications are enshrined in legislation. In the case of Germany, the applicable legal requirements are set out in the following (Status 03/2024):

1. Medical Devices Operator Ordinance (*MPBetreibV*) Section 5(2)

"Specific requirements"

"…only those who have up-to-date knowledge of the respective activity based on suitable training and relevant professional experience may exercise this activity."

2. *KRINKO / BfArM Recommendation*

"…. reprocessing shall be executed according to the generally recognized rules of technology, taking account of the state of the art in science and technology."

Here, several references are made to Annex 6 (Personnel expertise) and Annex 8 (Endoscopy), Chapter 2.5 (Equipment and personnel requirements).

What is required is "…..specialist continuing training, e.g. based on the specialist training courses set out in the qualification guidelines of the German Society of Sterile Supply (DGSV)."

"With regard to the expertise requirements, attention is also drawn to the information offered by public corporations and the specialist societies, e.g. DGSV."

A number of **MEASURES** are needed to ensure the currently specified knowledge continues to stay aligned with the state of the art in science and technology.

Personnel qualifications

Legal protection of the operator/institution

The operator bears responsibility for reprocessing (German MPBetreibV §8 Sect. 4).

The responsible person may only commission persons, companies or facilities with the reprocessing who themselves or their employees who carry out the reprocessing fulfil the requirements according to § 5 with regard to the reprocessing of the respective product.

1. Legal protection of superiors (e.g. RUMED management)

The mangement always bears joint responsibility for the actions of its employees to the extent that it cannot prove that it has fulfilled its organisational responsibility to assure its employees are appropriately qualified.

Section 278 *Federal Health Gazette* (BGB) Responsibility of the party liable for a third party

"The party liable shall be liable for the mistakes of their legal representative and the persons they use to fulfil their obligation to the same extent as for their own mistakes."

2. Ensuring a consistently high process quality standard
3. Risk management
4. Qualified employees are able to contribute to process optimization
5. Motivated staff
6. Client satisfaction

Employee Data / Training Plan

Name: _____

Start date: _____ Initial conversation on: _____

Interim conversation on: _____ Final conversation on: _____

Induction plan

1st month		
Topic	**Time period**	**Remarks**
e.g. Packing Basic Tray induction checklist		
e.g. Repeat of Packing Basic Tray induction checklist		
e.g. Peel-Pack Station induction checklist		
Etc.		

2nd month		
Topic	**Time period**	**Remarks**
...		
...		
...		

Month 3–? Depending on induction period

Continuing training/external training		
Topic	**Time period**	**Remarks**
z.B. Fachkunde 1		
z.B. FK 2 und Praxisanleiter		

Induction in sterilizers (on completion of FK 1)		
Topic	**Time period**	**Remarks**
...		
...		

Check of qualifications/working methods based on the Qualification Status Checklist	
Date of check	**Checked by:**
...	

Structural measures

1. Trained supervisors

Trained supervisors assure a high quality of induction and training.

2. Oversight of staff

A FILE comprising all important documents should be maintained for each staff member.

A FILE comprising all important documents should be maintained for each staff member in order to have good oversight of each employee's induction and qualification status.

- e.g. Induction plan to ensure structured induction
- Archival of the signed induction concepts
- Annual training plan
- Archival of continuing training certificates
- Archival of the minutes of conversations (initial, interim and final conversations)
- Documentation of errors and conclusions drawn on the need for further training
- Regular effectiveness tests of the training measures (see point 5)

3. Induction plans/checklists

INDUCTION CHECKLISTS are archived in the employee's file, thus serving as documentary proof if required for audits or inspections.

INDUCTION CHECKLISTS:

- should set out detailed information on the knowledge imparted
- serve as a common thread
- ensure the seamless transfer of internal, process-relevant and technically relevant information
- may include device instructions (medical devices may only be operated or used by persons who have the necessary training or knowledge and experience.)
- are signed by the practice supervisor and employee
- are archived and serve as proof. (e.g. for audits or inspections)

4. Training plan

Training in the following topics should be undertaken annually:

- Process sequences
- Theoretical principles of medical device reprocessing (note: §5 MPBetreibV requires up-to-date knowledge)
- Mandatory instructions (e.g. hygiene, accident prevention measures, fire protection)
- Personal protective equipment (PPE)

5. Effectiveness tests

THE QUALIFICATION STATUS of even experienced employees should be regularly checked.

Gaps in specialist knowledge/expertise or in the execution of the daily processes pose an underestimated risk to the process quality. To detect this on time, the **QUALIFICATION STATUS** of even experienced employees should also be regularly checked, for example on the basis of a checklist.

7. Assessment of complaints

Complaints are an important quality management (QM) component. They offer a timely insight into the current process quality and help to detect errors early on and take suitable remedial measures.

To that effect, complaints should be promptly evaluated (for example on a daily basis) and addressed by taking appropriate improvement measures if required.

References

1. MPBetreibV: Ordinance on the installation, operation and use of medical devices (Medical Devices Operator Ordinance), last revised by Art. 7 V v. 21.4.2021 I 833
2. KRINKO/BfArM Recommendation: Hygiene requirements for reprocessing 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), Federal Health Gazette 2012 · 55:1244–1310 DOI 10.1007/s00103-012-1548-6

Packing Basic Instruments Training Checklist

New employee's name: _____
Mentor's name: _____
Induction period: _____
Remarks/focus: _____

Content/goals	Demonstrated/ explained Employee's signature	Demonstrated/ explained Mentor's signature	Understood/ properly carried out Employee's signature	Understood/ properly carried out Mentor's signature
Functions of the „Packing" module (if software is used) 1. Manual set search 2. Actual/target number 3. Article numbers/alternatives 4. Management of remarks 5. Remarks to be confirmed 6. Cancellation of (reprocessing) operation(s) 7. Reprints of labels/accompanying documents				
Management of missing instruments 1. _____ 2. _____				
Inspection for cleanliness 1. Joints 2. Cables 3. Forceps 4. Cautery accessories 5. Lumened/hollow (visual or with pipe cleaner) 6. Management of recleaning				
Inspection for surface changes 1. What is pitting corrosion? ▪ How do you recognise this? ▪ Cause of pitting corrosion? ▪ Possible consequences of pitting corrosion if corroded instruments are not quickly removed? 2. What is extraneous rust? ▪ Differentiation from pitting corrosion? ▪ How is extraneous rust managed? 3. What is stress cracking corrosion? ▪ Where does this mainly occur? ▪ What causes it and how can it be prevented? 4. etc. _____				
Functional testing 1. Needle holders ▪ Check contours of hard metal insert ▪ Check needle holder for correct closure ▪ When must the hard metal insert be replaced?				

2. Scissors
   - What types of scissors are there?
   - How do the cutting samples vary between the different types of scissors?
   - How is the cutting test properly done?
3. etc. _____

Care

1. Instrument oil
   - Areas to which applied
   - Application
2. Power systems oil
   - Areas to which applied
   - Application
3. etc. _____

Repairs management

1. Reason for repairs
2. Management of defective instruments
   - Labelling
   - Dispatch for repair
   - etc. _____

Error management /management of complaints

_____
_____
_____

Packaging

1. Check container properly before closing
2. Proper packaging in fleece/ non-wovens
3. etc. _____

_____
Date/supervisor's signature