Recommendation of the Quality Task Group (121)

Quality assurance in the RUMED through well-targeted personnel qualification

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Introduction

In any organization the personnel represent an important resource. In the medical device reprocessing setting qualified personnel work more efficiently, thus safeguarding resources (medical device quality and value retention) and reducing disruptions in the overall supply chain process (e.g. postponement of surgical procedures). The qualitative and legal requirements are constantly evolving and personnel are a decisive factor in keeping abreast of these challenges.

The Reprocessing Unit for Medical Devices (RUMED) management is entrusted with the task of formulating a concept for personnel development tailored to the structures of the individual department and this is deemed to be an integral part of the organizational development. In that respect, it is imperative that **EACH STAFF MEMBER SHOULD BE SUPPORTED** to maximize their abilities and skills. Apart from personnel support, process observation and quality control are additional quality assurance tools.

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Furthermore, the quality management (QM) standard DIN EN ISO 13485 [1] explicitly calls for a process to determine and implement the necessary training (6.2. Human Resources). Pursuant to the QM standard, it must be ensured that personnel are not only trained but are also aware of the relevance and importance of their activities. Implementation of a well-targeted personnel qualification is also necessary if certification of the RUMED in accordance with DIN EN ISO 13485 is to be achieved and retained.

Personnel development

The complexity increases in line with the number of medical specialty departments catered to and the range of medical devices and staff members. Highly qualified staff and their integration into a closely monitored process observation system are of key importance and an indispensable prerequisite. **MEASURES TAILORED TO THE INDIVIDUAL STAFF MEMBER'S DEVELOPMENT** and the targets to be achieved are set out in an action plan. Examples of the points included in the action plan are as follows:

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- **Measures for target achievement**
  - Staff qualification
  - Describe requirements profile
  - Define competence and qualification
  - Analyse educational/training needs
  - Adapt the training and support measures to the staff member's qualification level
  - Evaluate the staff member's qualification level using reproducible criteria
  - Use all available human resources
  - Conduct structured, competence-oriented discussions with staff
  - Promote the capacity for teamwork and the team spirit

Personnel qualification

A high standard of training and regular briefings are of paramount importance. The greater and more complex the range of medical devices reprocessed in a RUMED, the greater will be the need for in-depth induction of new staff.

To that effect, the KRINKO/BfArM Recommendation [2] states: "It shall be ensured that the **RESPONSIBLE STAFF MEMBER** is really able to discharge their task in line with their position and qualification (QM; MPBetreibV [3], Specialist knowledge required)."

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Induction targets

The targets of in-depth induction must not be restricted to learning about process sequences. A staff member must also be aware of why the process steps are to be executed as specified and understand the consequences of any deviations from the prescribed procedures. Only then will they be aware of the great responsibility vested in them to ensure all activities are executed with meticulous care.

PILLARS OF EFFECTIVE INDUCTION

A well-targeted and **EFFECTIVE INDUCTION** process is based on three vital pillars:

1. Induction in the proper execution of all important process steps
2. Transfer of background knowledge (why must this process step be executed exactly in accordance with these specifications?)
3. Preparation for training as a Medical Device Reprocessing Specialist (FMA-DGSV®), or Sterilization Assistant (FK-I)

Staff members thus trained will have extensive knowledge and grasp of the different processes involved. These abilities will help staff identify with the mastered activities and increase their motivation.

Structured induction

IT IS RECOMMENDED TO QUALIFY MENTORS through the course "Practical Guidance in the RUMED" (compiled by the DGSV)

Structured induction of new staff is a key component of quality assurance in the RUMED. It is therefore **RECOMMENDED TO DESIGNATE QUALIFIED MENTORS**, who have successfully undertaken the course "Practical Guidance in the RUMED" (compiled by the DGSV), to work in the various areas of the RUMED involved in the practical training of new staff and trainees. Job descriptions and work release periods are a precondition for ensuring that practical guidance can continue to be delivered during the working day despite the difficult framework conditions. The Education Committee of the German Society of Sterile Supply (DGSV) has developed outline curricula for this training and corresponding training courses are being offered by approved training centres.

The induction concept should be structured as follows:

1. Training content e.g. presented as checklists for the different work areas:
   - Definition of learning goals and demands to be met by staff
   - Definition of the individual induction period (for example, see Table 2 Specimen Induction Concept)
   - Means of evaluating the learning progress
2. Conduct of initial, intermediate and final discussions
   These provide for close communication and timely response to any problems
4. Participation in training courses e.g. Medical Device Reprocessing Specialist (FMA-DGSV®), or Sterilization Assistant (FK-I).

Retention of personnel qualifications and knowledge update

Knowledge that is not regularly applied will increasing decrease and may even be lost over time. Continuing education and training ensures specialist knowledge is retained and updated, thus contributing to specialist qualification of personnel. A number of ways this can be assured are outlined below.

- Regular in-house training (IHT)
- The most important topics that should be regularly repeated are set out in an annual IHT plan (for example, see Table 3 Specimen IHT Plan)
- In addition to the practical part, each IHT should review/contain the specialist knowledge related to the specific topic
- The annual plan should allow space for topical issues (e.g. training in new instruments or process changes)
- As dictated by quality assurance, the assimilation of the imparted knowledge must be verified and documented (e.g. brief confirmation)
- Participation in external training courses
- Refresher course/knowledge update (offered by training centres)
- Guest visits to other departments (e.g. operating room [OR] or endoscopy suite) promote mutual understanding

References

1. EN ISO 14385 Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016); German Version EN ISO 13485:2016
2. 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)
3. Regulation on the Installation, Operation and Use of Medical Devices (German Medical Devices Operator Regulation — MPBetreibV)

Overview of advanced personnel qualification

- Training as Medical Device Reprocessing Specialist – FMA-DGSV®
- Accreditation of staff members who have successfully completed training as Medical Device Reprocessing Specialist – FMA-DGSV
- Specialist Training Course II (FK II)
  "Technical Sterilization Assistant with expanded functions" This qualification allows shift managers, deputy managers and, in small departments, also managers (depending on the range of medical devices reprocessed) to independently take decisions in line with their competences.
- Supplementary module "Reprocessing flexible endoscopes" enables staff who have successfully completed Specialist Training Course I to acquire knowledge in reprocessing flexible endoscopes.
- Practical Guidance in the RUMED for RUMED staff familiar with practical guidance tasks
- RUMED validation course
- Management course
  This course is aimed at those who are new to the field of RUMED/CSSD management and/or those who wish to expand their management skills in specific areas. Participants who have successfully completed the "Management of a RUMED" will be able to assume management functions in accordance with the state of the art in science and related disciplines.

Table 1 Specimen Qualification Matrix from DGSV e. V.

	Basic qualification	Specialization
Entry-level employee	Specialist Training Course I	Supplementary module "Reprocessing flexible endoscopes"
FMA DGSV®	3-year training comprises: Specialist Training Course I Specialist Training Course II Expertise in endoscope reprocessing Validation course	Practical Guidance in the RUMED Management Training Course for management of a RUMED
RUMED shift management	Specialist Training Course II	Practical Guidance in the RUMED Process validation for reprocessing medical devices
RUMED management/deputy RUMED management	Management Training Course for management of a RUMED or Specialist Training Course III (to 2020)	

Table 2 Example for personnel induction concept (This table does not claim completeness.)

Central area of RUMED – Checklist for personnel induction on "unclean side"				
New staff member's name:		Mentor's name:		
Induction period:				
Content/targets for above period:				
Content/targets	Demonstrated/ explained Staff member's signature	Demonstrated/ explained Mentor's signature	Understood/ properly executed Staff member's signature	Understood/ properly executed Mentor's signature
Induction to WD 1. Explanation of display 2. Emergency Off (red switch + main switch) 3. Programme selection automated + manual 4. Programme interruption (procedure) 5. Replace coarse filter 6. Action following error messages such as: ▪ Replace fine filter (inform management) ▪ Fill DOS 1–3				
Induction to CTA (continuous tunnel washer) 1. Explanation of display 2. Emergency Off 3. Safety pull cord in the chamber 4. Error reset if pull cord activated 5. Programme selection 6. Error acknowledgement (2x acknowledge + Code 111111)				

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Content/targets	Demonstrated/ explained Staff member's signature	Demonstrated/ explained Mentor's signature	Understood/ properly executed Staff member's signature	Understood/ properly executed Mentor's signature
Routine checks of WD 1. Clean course and fine filters (Important! Before removing coarse filter, inspect margin with toothbrush for transfixion wires that would otherwise fall into pump) 2. Chamber interior + door seals 3. Rotary arms of WD 4. Rotary arms of loading trolley 5. Conduct of protein tests 6. Documentation of protein test results 7. Filling level with chemical products (only WD 2 + 3)				
Routine checks of CTA 1. Coarse filter in the chamber 2. Fine filter in technical unit 3. Clean door channel (clean side + unclean side) 4. Intervals for cleaning fine filter in technical unit 5. Chamber interior + door seals 6. Rotary arms of container trolley				
Tasks discharged by early shift 1. Check demineralised water (execute + document) 2. 1 min at workstation 1: Run water to obtain fresh, cool water for the ultrasonic bath 3. Place ultrasonic bath in operation ▪ Action if dosing unit defective ▪ How to manually prepare a solution? (using what?) ▪ What does outgassing mean? 4. Conduct routine checks 5. Each first week of the month, protein tests in all WDs + programmes + feedback to management 6. Check grey microseals and replace if necessary 7. Dismantle inspection filters, clean and reassemble 8. On Fridays, replace or clean the filter in the Elan 4 + cleaning device + in the 4x red ports for mini hollow drills 9. Explain replacement of filters in the cleaning adapter for micromotors (interval monitored by management) 10. Wash supplies 11. Each first Monday of month Sono-Check ▪ Execute ▪ Document				

Table 3 Example IHT (This table does not claim to completeness.)

Logo	Annual IHT Plan 2020	Revision Status
		Revision: 1
Compiled by: Mr/Ms XXX	**Checked by:** Mr/Ms XXX	**Released by:** Mr/Ms XXX
Date: xxx	**Date:** xxx	**Date:** xxx
Calendar Year	**Topic of Training**	**Delivered on:**
1 CW	IHT: Proper closure of an instrument container	
3 CW	IHT: Proper handling of non-woven packaging	
4 CW	IHT: Control of sterilizer release	
6 CW	IHT: Instrumentation science	
7 CW	IHT: Sinner's Circle	
9 CW	IHT: Proper inspection of instruments for cleanliness and corrosion	
11 CW	Training in hygiene/infection control delivered by hygiene specialist	
13 CW	IHT: Consignment assembly	
15 CW	IHT: Loading a sterilizer	
16 CW	IHT: Loading patterns for different WD racks	
18 CW	IHT: Packing an instrument tray	
19 CW	IHT: Dealing with missing instruments	
20 CW	IHT: Preclearing for automated reprocessing	
23 CW	IHT: Batch release of automated WDs	
24 CW	IHT: Preclearing in ultrasonic bath	
27 CW	IHT: Handling containers for single-use wipes/cloths	
30 CW	IHT: Instrument care	
31 CW	IHT: Soldering workstation: proper handling of foil-bag packaging, routine checks, heat sealing devices	
32 CW	Description of a laparoscopy procedure + reprocessing of the minimally invasive surgical (MIS) instruments used	
34 CW	IHT: Routine checks of sterilizers	
35 CW	IHT: Proper conduct of functional testing	
37 CW	IHT: Specialist terms and specialist knowledge	
39 CW	Surgical techniques and instruments for hip replacement	
41 CW	Occupational safety and health (OSH) / OSH file	
43 CW	IHT: Surgical techniques: Transurethral resection of the bladder and prostate and instruments used	
46 CW	Training in hygiene/infection control delivered by hygiene specialist	
47 CW	Back-friendly working posture	
49 CW	Training: "Unclean-side" accessories	
51 CW	IHT: Management of loaned sets	
52 CW	IHT: Reprocessing motor systems	