Recommendations by the Committee for Hygiene, Construction and Technology

Requirements for Construction or Reconstruction of a Reprocessing Unit for Medical Devices (RUMED)

Part 12: Recommendations for an infection control and prevention plan for Reprocessing Units for Medical Devices

Authors: A. Jones (Coordinator), Dr M.-TH. Linner (Coordinator), U. Beilenhoff, M. Schick-Leisten, H. Schunk, R. Stens, A. Wentzler, K. Wiese; Email: hbt@dgsv-ev.de

This recommendation describes the need for an infection control and prevention plan in a RUMED and their significance, while explaining how they are formulated and implemented and giving examples of their content.
Note: This publication is intended as a guide to formulating/revising an infection control and prevention plan.

FRAMEWORK REGULATIONS

Framework regulations as applicable in Germany (in each case in their currently valid version):

- Protection against Infection Act (IfSG)
  - Federal state infection control regulations
  - Recommendations of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO),
- Medical Device Operator Regulation (MPBetreibV)
  - KRINKO-BfArM Recommendation on 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)
- Book V of the German Code of Social Law
- Biological Agents Regulation (BioStoffV)
- TRBA 250 Biological Agents in Health Care and Welfare
- DIN EN ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes (2016)
- DIN EN ISO 14971 Medical devices – Application of risk management to medical devices

SIGNIFICANCE OF AN INFECTION CONTROL AND PREVENTION PLAN

Significance of an infection control and prevention plan

An infection control and prevention plan

- is stipulated e.g. by the Protection against Infection Act (IfSG), federal state infection control regulations, the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO), TRBA 250
- is an integral part of quality management in a RUMED, too
- describes sequences, work materials, space/room usage
- assigns competencies
- is a binding specification for the RUMED operator (service instructions)
- may result in disciplinary action in case of failure to comply with these provisions
- describes hygiene procedures in the context of protection against infection and occupational health and safety
- constitutes the basis for verification of compliance with hygiene-related work instructions
- serves as documentary evidence of personnel induction
- serves as the basis for regular staff training
- serves as evidence in legal disputes

General content of an infection control and prevention plan

An infection control and prevention plan must be formulated such that it can be applied institution-wide and at departmental level.

Depending on the organizational structure of an establishment, it may be beneficial to incorporate parts of occupational health and safety and quality management regulations into the infection control and prevention plan or refer to quality management documentation where applicable.

The infection control and prevention plan includes details of the

- Structural quality e.g.
  - Rooms, equipment, work materials, process media
  - Personnel and their competency/qualifications
    - Safety measures for all persons working by themselves
- Process quality e.g.
  - Personnel hygiene
  - Reprocessing processes
  - Environmental hygiene
  - Logistics
  - Action plan in the face of special incidents and unusual situations
- Outcome quality e.g.
  - Routine control measures
  - Validation/performance qualification
  - Audits

Structural quality

German Statutory Accident Insurance (DGUV) 212-139

Process quality

Outcome quality

Formulation/revision of an infection control and prevention plan

RESPONSIBILITY LIES WITH THE OPERATOR

This is the responsibility of the operator.

Formulation of an infection control and prevention plan may be delegated to suitable persons within the respective establishment. The RUMED management should be involved in policy formulation.

Collaboration with the following parties should be considered: Infection control team, RUMED management, referring bodies such as the endoscopy department/operating room/external clients, engineering department, premises cleaning services, occupational health and safety as well as other interfaces needed.

The infection control and prevention plan must be reviewed and updated whenever warranted as well as at regular intervals in accordance with the provisions of the establishment's quality management system.

Infection control and prevention plan format

INDIVIDUAL DOCUMENTS LISTED IN OVERALL TABLE OF CONTENTS

There is no specific format set out for an infection control and prevention plan. The style should be succinct and precise.

The content should be clearly structured and described in text or tabular form. Presenting topics as individual documents with an overall table of contents has proved useful. List any additionally applicable documents.

The content may make reference to the infection control and prevention plan already in use within the institution (e.g. Chapter – hand hygiene, surface disinfection, emergency measures). If necessary, the information should be tailored to the respective RUMED.

Cleaning and disinfection policies are an integral part of the infection control and prevention plan and can be used as a quick guide.

REQUIRED DETAILS

Required details:

- Establishment name/logo
- Department
- Formulation date/author
- Revision date/author
- Release, date policy adopted
- Released by
- Version number

The infection control and prevention plan must specify the following:

- Who – Competent staff member
- What – Type of measure
- How – Description of the measure
- How often/When – Frequency/time of measure implementation
- With what – Detergent/disinfectant (concentration and contact time, application mode) or equipment/adjuncts (brushes, cloths, etc.)

Release of the infection control and prevention plan

RELEASE OF THE INFECTION CONTROL AND PREVENTION PLAN

The infection control and prevention plan and updates/amendments must be released or adopted.

- Release or adoption by the hospital/clinic Infection Control Team (in accordance with the requirements of the federal state infection control regulations)

or

- Release by the operator e.g. of a medical practitioner's office, independent RUMED

Implementation of an infection control and prevention plan

The infection control and prevention plan must be made available in a suitable form to every staff member.

Documented training

New employees must be made aware of the infection control and prevention plan content and all staff members must receive training at regular intervals and after updates. The training frequency is determined by the federal state regulations and the establishment's quality management policies. Training must be documented.

EXAMPLES OF INFECTION CONTROL POLICY CONTENT

Examples of infection control and prevention plan content

Personnel hygiene

Hand hygiene

Hand hygiene

- General
  - See KRINKO Recommendation "Hand hygiene in healthcare institutions" and TRBA 250
    - Hand washing
    - Hand disinfection
    - Skin protection/care
      - Skin protection policy
    - Glove policy
- RUMED – special
  - Hygienic hand disinfection before
    - Donning departmental clothing
    - Entering the packing/sterile supply area
    - Unloading washer/disinfectors (WDs), washer disinfectors for flexible endoscopes (WD-E), continuous tunnel washers (CTWs)
    - Packing/assembling medical devices
    - Packaging processes for medical devices to be sterilized
    - Packaging processes for medical devices that must have only a low microbial count when used,
    - Loading sterilizers
    - Unloading sterilizers
    - Consignment assembly
  - Hygienic hand disinfection after
    - Exiting the cleaning/disinfection area
    - Coming into contact with residual soils/contamination (e.g. picking up dropped items)

Working clothes/departmental clothing/protective clothing

Working clothes

- Working clothes
  - RUMED – special
    - Departmental clothing
      Different colour-coded departmental clothing is usually worn in the cleaning/disinfection area and the packing/sterile supply area of the RUMED and may only be worn in the permitted area. If this is not possible because of spatial and/or organizational constraints, only the protective clothing is doffed and hand disinfection carried out on exiting the cleaning/disinfection area. Ensure that the departmental clothing is completely covered by the protective clothing when working in the cleaning/disinfection area.

Shoes

    - Shoes
      - Shoes should be changed on switching between the cleaning/disinfection area and packing/sterile supply area
      - Shoes must undergo disinfectant cleaning at the end of each working day

- The occupational health and safety requirements for shoes are identified and stipulated during risk assessment.
- If there is a risk of shoes becoming wet the employer must provide watertight shoes. — DGUV 112-991

- Protective clothing/personal protective equipment (PPE) — Personal protection equipment
  - Closed, contamination-proof storage
  - Cleaning/disinfection area:
    - Gown with long, fluid-resistant sleeves and closed all round (TRBA 250, 5.4.8) — If the departmental clothing is not fully covered, it may be necessary to replace it.
    - Disposable gloves (chemically and microbially resistant). For manual precleaning, cleaning and disinfection of medical devices, wear disposable gloves with long cuff made of material tailored to the risk encountered, e.g. nitrile (DIN EN 374). — Specify glove replacement intervals
    - Orofacial mask
    - Protective goggles/visor
    - Ear protection
      - Provide from 80 dB(A), mandatory from 85 dB(A) — DGUV 212-621
  - Packing/sterile supply area:
    - Disposable gloves (for surface disinfection: nitrile)
    - Thermal protective gloves, if necessary, specify reprocessing interval
    - If necessary, protective goggles when drying lumens

Occupational health and safety — **OCCUPATIONAL SAFETY**

- Vaccination
  - In accordance with the occupational health and safety requirements
- Action in the event of injuries with potential infection risk
- First aid/accidents (e.g. first aid kit, eye wash)
- Staff members with infections/allergies
  - Consult the occupational health physician
- Standard and specific occupational medicine services

Examples of measures/action in the various areas/zones — Depending on the establishment's organizational structure, the cited examples can be described in the infection control and prevention plan or in the quality management system.

- Incoming supplies
  - Medical devices to be reprocessed
    - Specify access, storage space, if necessary, parking bay for transport trolleys
  - Consumables
    - Remove transport packaging before acceptance
- Incoming area for loan trays/loan instruments
- Cleaning/disinfection area
  - Description of medical device reprocessing processes
  - Management of work materials e.g. water/compressed air pistols, cleaning accessories
- Packing/sterile supply area
  - Description of medical device reprocessing processes
- Repairs
  - Dispatch of medical devices
  - Dispatch of defective flexible endoscopes
  - Returns
- Explants
  - Reprocessing of explants is not permitted in the RUMED. Management of explanted implants must be regulated. — Explants are not medical devices
- Storage
  - Consumables
    - Fleece, paper, foil, indicators, etc.
    - Note expiry date
    - Observe storage conditions (temperature/humidity, etc.)
  - Consumables
    - Chemicals (detergents/disinfectants, etc.)
    - Note expiry date
    - Observe storage conditions (temperature/humidity, etc.)

  - Supplementary instruments
  - Sterile medical devices
    - Recommended storage period for sterile medical devices DIN 58953-8
    - Storage site, preconditions
  - Transport packaging
- Means of transport
  - Servicing plan
  - See also guideline "Storage of reprocessed medical devices and transport of reprocessed medical devices to and from the site of use/between the RUMED and user" (in German only)
- Waste management
  - Sorting, storage, transport pursuant to
    - European waste code
    - Federal/State Working Group for Waste (LAGA)
    - Municipal Waste Management Regulations
- Laundry supply and collection
  - Supply of fresh laundry
    - Protected against contamination
  - Collection of used laundry
    - Hygienic management of used laundry
    - Closed storage (room/container) until collected
- Office – administration
- Recreation room
- Other side rooms

CLEANING POLICY DISINFECTION POLICY

Examples of cleaning policy and disinfection policy

- Cleaning
  - Surfaces/furnishings
  - Equipment
  - Means of transport
  - Containers
  - Floors
  - Walls (risk classification)
  - Ventilation
  - and ....
- Disinfection
  - Surfaces/furnishings
  - Equipment
  - Means of transport
  - Containers
  - Floors
  - Wall (risk assessment)
  - Ventilation
  - and ……

VISITORS

Recommendation by the Quality Task Group (118)

Visitors/external persons

- See the recommendation by the Quality Task Group (118) "Hygiene aspects when dealing with external persons in the RUMED" (Central Service 2020; 28 (3): 172–175.)
- Access and action to be managed as in a previous infection control and prevention plan whenever possible.
- Competency for induction and control must be specified.

CONSTRUCTION WORK

Construction work

- Action for equipment repairs, surfaces
- Action in the event of reconstruction works

CONTINGENCY PLAN

Contingency plan

- Specify in the infection control and prevention plan or quality management system

Special pathogens

- Regulations on special pathogens (e.g. CJD, vCJD)

Appointment of infection control officers recommended in the RUMED

INFECTION CONTROL OFFICERS

- Nominate person
- Preconditions:
  - Training
  - Regular training at least every two years
  - Release from work for 4h/month
- Specify tasks, e.g.
  - Interface between infection control department and RUMED
  - Information dissemination on hygiene-related topics
  - Run training sessions for staff e.g. hand disinfection, etc.
  - Training regarding infection control and prevention plan and additionally applicable documents
  - Training regarding routine control of outcome quality
  - Conduct of internal audits

Interface between infection control department and RUMED

Interfaces to RUMED need special regulation, e.g.

INTERFACES TO RUMED

- Engineering department
  - For example, heating, ventilation and air conditioning (HVAC) systems, water systems
- Purchasing department
- Information technology (IT)
- External service providers (e.g. cleaning companies)

References

- German Protection against Infection Act (IfSG)
- German federal state infection control regulations see website https://www.rki.de
- KRINKO-BfArM Recommendation 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): “Hygiene requirements for reprocessing medical devices”, see website https://www.rki.de
- Recommendations of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO)
  - Miscellaneous (e.g. hand hygiene, cleaning and disinfection of surfaces, etc.) see website https://www.rki.de
- German Medical Device Operator Regulation (MPBetreibV)
- Book V of the German Code of Social Law (SGB V)
- Biological Agents Regulation (BioStoffV)
- TRBA 250 Biological Agents in Health Care and Welfare
- DGUV 112-991 Use of Foot and Knee Protection
- DGUV 212-139 Emergency numbers for all persons working by themselves”
- DGUV 212-621 Ear protection
- DIN EN ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes (2016)
- DIN EN ISO 14971 Medical devices – Application of risk management to medical devices
- DIN 58953-8 Sterilisation – Sterile supply – Part 8: Logistics of sterile medical devices
- DIN EN 374-1 Protective gloves against dangerous chemicals and microorganisms.
- Recommendation by the Quality Task Group (118) “Hygiene aspects when dealing with external persons in the RUMED”, Central Service, Vol. 28 3/2020
- Guideline “Storage of reprocessed medical devices and transport of reprocessed medical devices to and from the site of use/between the RUMED and user”, Central Service, Vol. 26 Suppl. 2018