



Recommendation by the Committee for Hygiene, Construction and Technology

Hygiene Requirements in a Reprocessing Unit for Medical Devices (RUMED)

Part 16: Recommendations for cleaning and disinfection policies in Reprocessing Units for Medical Devices

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Demonstrate the significance of **CLEANING AND DISINFECTION POLICIES**

■ Introduction

This recommendation describes the need for **CLEANING AND DISINFECTION POLICIES** 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 a cleaning and disinfection policy.

■ Significance of cleaning and disinfection policies

They are an integral part of the infection control policies and therefore have the same significance as the latter policies; see Recommendation Part 12, *Zentralsterilisation* 05/2020. Cleaning and disinfection policies

- are legally stipulated by the German Protection against Infection Act (IfSG) as constituting a part of the infection control policy. Subordinate regulations specify this requirement.
- are an integral part of quality management in a RUMED.
- describe sequences and work materials.
- assign competencies.
- are binding specifications for the RUMED economic operator (service instructions).
- failure to comply with these provisions may result in disciplinary action.
- describe hygiene procedures in the context of protection against infection and occupational health and safety.
- constitute the basis for verification of compliance with hygiene-related work instructions.
- serve as documentary evidence of personnel induction.
- serve as the basis for regular staff training.
- are evidence in legal disputes.

Include **INFECTION CONTROL POLICIES**

■ Additionally applicable documents for cleaning and disinfection policies

INFECTION CONTROL POLICIES such as e.g.:

- Hand hygiene
- Personal hygiene
- Surface disinfection and cleaning
 - Documentation of the implementation of cleaning and disinfection
 - Documentation of the verification of cleaning and disinfection
 - Verification of hygienic surface cleaning and disinfection, including hygiene rating
- Waste management
- Laundry supply and collection
 - Verification of the hygienic reprocessing of cleaning utensils
 - If necessary, suitability testing of presaturated cleaning utensils for surface/floor cleaning and disinfection

Observe **QUALITY MANAGEMENT** and **OCCUPATIONAL SAFETY AND HEALTH**

Aspects of **OCCUPATIONAL SAFETY AND HEALTH** and of **QUALITY MANAGEMENT** must be observed such as e.g.:

- Qualification of personnel entrusted with cleaning and disinfection
- Induction
- Operating instructions

- Safety data sheets
- Service specifications for cleaning and disinfection of buildings
- Designation of supervisors and contact persons

Specification of the **STRUCTURAL QUALITY** of the cleaning of buildings is a prerequisite for implementation of cleaning and disinfection policies. In general, the following tasks must be undertaken for the entire clinic/practice/facility:

- Designation of suitable rooms for reprocessing cleaning utensils, cleaning trolleys, cleaning machines
- Designation of suitable rooms/areas for storage of cleaning utensils, cleaning trolleys, cleaning machines, detergents, disinfectants
- List of the detergents and disinfectants used, while taking account of material compatibility and the dosing methods employed
- Description of the cleaning methods

The **PROCESS QUALITY** must also be specified, e.g. description of the

- Cleaning methods
- Disinfection methods
- Reprocessing methods for mops, cloths, cleaning machines
- Storage and transportation of reprocessed and of used cleaning mops, cloths, cleaning machines
- Loading cleaning trolleys
- Special services such as laundry collection and, if applicable, laundry supply

■ General contents of cleaning and disinfection policies

The **CLEANING AND DISINFECTION** methods to be implemented must be set out for the individual department and workplace:

where	Which room/working area/zone
what	Which surface
with what	Product/concentration/exposure time
how	Description of measures, e.g. wiping
how often	e.g. each working day or once a week or following contamination (note: "as needed" is meaningless), the time of day or frequency e.g. several times daily after completion of ..., or before The frequency and scope must be specified on the basis of risk analysis and risk assessment. See the recommendation „Requirements for the environmental conditions and their control in Reprocessing Units for Medical Devices (RUMEDs)" Part 1, <i>Zentralsterilisation</i> , 2-2018, Part 2, <i>Zentralsterilisation</i> , 5-2021).
who	RUMED or cleaning service

Procedure in the event of special incidents, e.g. disinfection following contamination of surfaces with pathogens not covered by the spectrum of action of the disinfectants routinely used.

Cleaning and disinfection of medical devices must be regulated in separate standard operating procedures/infection control policies.

■ Formulation/updating of cleaning and disinfection policies

This is the responsibility of the **OPERATOR**.

Formulation of cleaning and disinfection policies should be delegated to **SUITABLE PERSONS** within the respective establishment – primarily to e.g. infection control personnel, hospital infection control consultant, infection control staff in an office-based medical practice and, as applicable, the house-keeping management. The RUMED management must be involved in policy formulation. If building cleaning and disinfection tasks are delegated to external service providers, the latter must be consulted before finalising the policies. Cleaning and disinfection policies must be updated whenever warranted, e.g. when making changes to surface usage, to the process chemicals used or to the working methods.

Define the **STRUCTURAL QUALITY** of surface cleaning and disinfection

Define the **PROCESS QUALITY** of surface cleaning and disinfection

Observe **CLEANING AND DISINFECTION POLICIES** in general

The **OPERATOR** is responsible
Delegate the formulation of cleaning and disinfection policies to **SUITABLE PERSONS**



The policies must be reviewed and updated regularly in accordance with the provisions of the establishment's quality management system.

Define the **FORMAT** of the cleaning and disinfection policies

■ **Cleaning and disinfection policy format**

No specific **FORMAT** is defined. The tabular form has proved useful for cleaning and disinfection policies. Required details:

DOCUMENTARY GUIDANCE

Establishment name/logo
Department/service facility/workstation
Formulation date /author
Revision date/author
Version number
Release/date/released by

Check **UPDATES**

■ **Release of cleaning and disinfection policies**

All cleaning and disinfection policies and their **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 economic operator e.g. of a medical practitioner's office, independent RUMED

MAKE KNOWN the cleaning and disinfection policies

■ **Implementation of cleaning and disinfection policies**

The cleaning and disinfection policies must be **MADE KNOWN** to all staff members of the RUMED and cleaning services, i.e. they must be made available in a suitable form to every staff member.

Staff must be made aware of the cleaning and disinfection policies, new employees have to get an induction 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.

Document **TRAINING** and briefing

Acknowledgement of the plans must be personally confirmed by all those named therein.

■ **References**

1. German Protection against Infection Act (IfSG)
2. German federal state infection control regulations, see website <https://www.rki.de>
3. 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 processing medical devices", see website <https://www.rki.de>
4. 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>
5. Book V of the German Code of Social Law (SGB V)
6. Biological Agents Regulation (BioStoffV)
7. TRBA 250 Biological Agents in Health Care and Welfare
8. DIN 13063 Hospital cleaning – Requirements for cleaning and disinfecting cleaning in hospitals and other health care facilities
9. DIN EN ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes (2016)
10. DIN EN 374-1 Protective gloves against dangerous chemicals and microorganisms
11. List of disinfectants approved by the German Association of Applied Hygiene (VAH)
12. DGSV FA HBT: (Specialist Committee for Hygiene, Construction and Technology of the German Society of Sterile Supply): Requirements for the environmental conditions and their control in Reprocessing Units for Medical Devices (RUMEDs) Part 1, *Zentralsterilisation*, 2-2018, Part 2, *Zentralsterilisation*, 5-2021