

Recommendations by the Committee for Hygiene, Construction and Technology

Requirements for construction or reconstruction of a Reprocessing Unit for Medical Devices (RUMED)

Part 1 – Basics

The Committee for Hygiene, Construction and Technology is updating a series of DGSV recommendations on the topic of structural requirements in the RUMED.

I Introduction

In this issue of *Central Service*, the Committee for Hygiene, Construction and Technology of the German Society of Sterile Supply (DGSV) is publishing the first of a series of **revised versions of the Quality Task Group Recommendations Numbers 50, 52, 58 and 61** from 2007 and 2008 on the topic of new construction and/or reconstruction of a Central Sterile Supply Department (CSSD). To reflect the fact that medical devices are reprocessed not only by hospitals, but also by outpatient surgery centres, medical specialists and external reprocessors, we are now employing here instead of CSSD the broader term **Reprocessing Unit for Medical Devices (RUMED)**.

There are no specific or detailed regulations governing this topic in the literature. This present recommendation for construction or reconstruction of a reprocessing unit for medical devices (RUMED) is based on the following regulations as well as on the vast experiences accumulated over the years:

- "Hygiene requirements for reprocessing medical devices"; this is a recommendation jointly compiled by the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the German Federal Institute for Drugs and Medical Devices (BfArM), issued in October 2012; Annex 5 "Overview of requirements for Reprocessing Units for Medical Devices" is of particular relevance.
- Recommendation for medical device reprocessing, framework conditions for uniform administrative action, compiled by: RKI/BfArM Recommendation Project Group, which is part of the Medical Devices Working Group (AGMP)
- DIN 1946:4, 2008 "Room ventilation systems in buildings and premises of the health-care sector"
- Technical Regulation for Biological Substances (TRBA 250 – 2014)

The primary focus of these recommendations is on the structural prerequisites. The main reason for compiling and revising the recommendations was the recurring debate about spatial separation within a RUMED as well as the widespread failure to involve users in the planning activities.

In some cases, it may be necessary to deviate from the recommendations because of the specific circumstances of the various healthcare establishments, or to meet the special needs within the RUMED. Infection control (hygiene) regulations, and possibly local state-level supervisory regulations, must be observed. For example, in some cases it may be necessary to consult the statutory infection control committee when making certain constructional or organizational changes.

The **sequence** of the publications planned is as follows:

- Introduction and fundamentals
- Structural and spatial layout
- Fittings and furnishings
- Technical equipment
- Reconstruction of a RUMED during ongoing operations

The sequence of the publications

I Fundamentals of planning

Hospitals, outpatient surgery centres and medical practices must be able to optimally and flexibly utilize their premises and equipment/fittings, taking account of economic and ecological aspects. In line with the growing number of specialist departments and operations involved, the workload has increased, with attendant need for greater flexibility. Reprocessing medical devices for a third party results in more stringent demands in the workplace, including those related to documentation, and possibly also to equipment and fittings. Besides, there is now a growing trend towards sending those accessories that must be sterile when used, and also flexible endoscopes, to one central department/unit to be reprocessed.

A packing station for laundry sets is no longer needed within the RUMED; if these are used at all, they must be assembled and packed in the laundry.

Conversely, infection control management is needed for detailed and efficient planning (see state-level infection control regulations). This also entails consulting the infection control committee as well as all the relevant in-house parties. **Cooperation** is needed with the following parties from the start of the planning stage:

- RUMED management
- The management of the departments where devices are used
- Hospital infection control officer/infection control nurse, and possibly infection control physician
- Occupational health and safety (OSH) officer
- Head of engineering/medical technology
- Site manager

Before embarking on reconstruction work on a RUMED, it is advisable to contact the following experts, in accordance with the scope of the building measures planned:

- Architects with hospital experience
- Medical technology engineers
- Heating, ventilation and air conditioning (HVAC) engineers
- Possibly, other planning engineers

I Basic evaluation of what is needed for planning, construction or reconstruction of a RUMED

This is based on an inventory (user analysis) and on an analysis of requirements.

First of all, it must be decided where the Reprocessing Unit for Medical Devices is to be located within the hospital or within other healthcare establishments. To make that decision, the following aspects must be borne in mind:

- The routes used for collection and delivery of supplies should be as short as possible (optimal time management)
- Horizontal or vertical link to **main user**.

For large scale RUMEDs preference should be given to a vertical link to the main client, using the greatest number of sterile supplies.

- The RUMED must be a self-contained area to which only authorized personnel may have access
- If services are to be provided to external parties, provision must be made for a driveway that ensures supplies will remain dry.

Floor space required

The **floor space required** will depend on:

- The number of operations, bearing in mind the respective medical disciplines (analysis of requirements)
- The quantity of medical devices and other supplies to be cleaned, disinfected, dried, and possibly packed but not sterilized (shoes, anaesthesia accessories, etc.)
- The quantity of incoming medical devices to be reprocessed, transported, or stored at certain times,

To comply with the amended requirements governing healthcare establishments and reprocessing units for medical devices, proof is now needed that medical device reprocessing is carried out in accordance with quality assurance guidelines, and that this is done in a cost effective manner.

Contact must be established between all parties already from the start of the planning stage.

It is advisable to have a direct link to the main client.

The floor space required must always be calculated through analysis of requirements.

- The packaging system selected
 - Automated container decontamination
 - Other packaging materials, bearing in mind the sterilization process used (e. g. Tyvek® packing station)
- Other special requirements related to:
 - Routes and different areas of use
 - User habits
 - Working hours
 - Reprocessing methods
 - Storage of consumable materials
 - Document archival

The floor space requirement should not be calculated on the basis of the number of beds since because of, among other things, the shorter length of hospital stays, outpatient surgical procedures/operations, bed occupancy is not correlated to the quantity and complexity of the medical devices to be reprocessed. It may be helpful to evaluate the OR workload over the past ten years.

A separate room must be allocated for medical device reprocessing. Few exceptions apply.

In principle, subject to the provisions of the KRINKO/BfArM Recommendation a **separate room** must be allocated for medical device reprocessing.

The following exceptions apply:

- For reprocessing medical devices assigned to the semi-critical A and critical A risk group, a temporal separation/different use of the reprocessing zone is possible
- For reprocessing medical devices assigned to critical C risk group, separate rooms must be allocated for the "unclean" and "clean" areas as well as for sterile supply storage

However, practical experiences over many years show that observance of the aforementioned spatially separate areas has proved beneficial when reprocessing large quantities of medical devices (e.g. more than one WD or sterilizer batch /process per day).

Room layout required

The following **terms** are defined here:

Definition of important terms:

- "Area"
- "Zone"

- "**Area**" denotes a structurally separate location within a RUMED; access from one area to another is assured in principle, but may call for a sluice/changing room.
- "**Zone**" describes a certain division within an area; there may be a number of different zones within an area.
- "**Gown sluice**" is a room that connects two areas within a RUMED. A changing room or facilities for donning/storing personal protective equipment (PPE) is needed.

Room allocation

In principle, three **areas** and **additional rooms** are required.

In principle, efforts should be made to have three spatially separate areas as well as additional rooms.

CLEANING AND DISINFECTION AREA (unclean)

- Zone for incoming supplies, possibly with PC workstation
- Manual pre-cleaning section
- Cleaning/disinfection
- Possibly separation between cleaning/disinfection sections (heat-sensitive/heat resistant)
- WD loading zone
- Possibly, trolley washing station/trolley tunnel washer
- Parking bay for transporting/loading trolleys
- Possibly, parking bay for WD loading trolleys
- If there is a vertical link – access to "unclean" elevator (lift)
- Side rooms
 - Possibly, dosage room (dosage centre)
 - Possibly, room for cleaning materials

PACKING AREA (clean)

- Unloading supplies from WD, and release
- PC workstation
- Intermediate storage
- Packing stations, possibly with PC workstation
- Possibly, separate workstations for supplies with low microbial count/supplies to be sterilized, different packing materials/sterilization methods
- Possibly, parking bay for loading trolleys and/or transport racks
- Zone for loading sterilizers
- Side rooms
 - Room for cleaning materials
 - Possibly, store for spare instruments, consumables and supplementary materials

STERILE SUPPLY AREA (clean)

- Zone for unloading sterilizers
- Zone for letting supplies cool down, followed by their release, possibly with PC workstation
- Consignment store
- Possibly, storage zone, possibly area for handing out supplies
- If there is a vertical link – access to “clean” elevator

OTHER ROOMS

- Staff rooms:
 - Recreation room
 - Possibly, staff changing room for departmental clothing
 - Toilet
- Office
 - Document archive
 - Manufacturer’s instructions, validation reports
 - Infection control policies, protocols, etc.
 - Meeting place
 - PC workstation

CONNECTING AREAS

- Sluice in the form of gown sluice for staff between UNCLEAN/CLEAN areas
- Possibly, elevator between user area and UNCLEAN/incoming supplies zone
- Possibly, elevator between CLEAN and user area/sterile corridor.

Staff routes between the areas

- Efforts must be made to provide separate access to the aforementioned areas.
- The cleaning/disinfection area must be entered at least through a “gown sluice”, or better wearing specific “unclean” department clothing; this area must be spatially separated from the other RUMED areas.
- Access from the packing area to the sterile supplies area, with its sterile supply stores, is permitted only after hand disinfection.
- If there is direct access linking the OR department and the sterile supplies area, the same hygiene requirements applicable in the OR must also be observed in that area.

In one of the forthcoming issues of *Central Service*, the material routes within a RUMED as well as the staff and material routes between the RUMED and other areas will be described. Details of the range of equipment and fittings needed in a Reprocessing Unit for Medical Devices will also be given. ■

RUMED personnel use routes are determined by the hygiene requirements.