

## Recommendations by the Committee for Hygiene, Construction and Technology

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

## Part 4 – Room furnishings and equipment for a RUMED

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### I Introduction

Part 4 of the publication "Requirements for construction or reconstruction of a Reprocessing Unit for Medical Devices (RUMED)" focuses on equipping and furnishing the rooms and is a continuation of Parts 1, 2 and 3 of this series of publications. Based on experiences from everyday practice, it summarizes and characterizes by way of example the limited number of rather unspecific provisions given in the pertinent recommendations/guidelines/standards on furnishing and equipping a RUMED.

No information is provided on fire protection, structural physics, structural engineering or the various utility installations (e.g. gas, water and electricity connections, etc.)

### I Basic requirements

#### *Structural aspects*

- General requirements
  - Surfaces
    - Resistant to detergents and disinfectants
    - Accessible for cleaning and disinfection
  - Transport trolley wheels - resistant to detergents and disinfectants
  - Cabinets with veneer finish to the ceiling
  - Cabinets with dustproof locks in the packing area, sterile supply area, materials' store
  - Doors with inspection windows (apart from staff changing rooms/toilets)
  - Intercom system for external communication as well as communication within the RUMED
  - Outer doors assuring restricted access
- Wall surfaces/floors/surfaces/joints
  - Smooth and even
  - R10 anti-slip treatment for the cleaning/disinfection area (ASR A1.5/1,2); following risk assessment R9 may be suitable
  - Few joints
  - Joint sealing
  - Chamfered skirting board
  - Floor – threshold-free access
  - Ramming protection (height tailored to transport trolleys)
  - Accessible for cleaning/disinfection
  - Easy to clean/disinfect
  - Resistant to
    - Detergents and disinfectants and other chemicals used in the relevant areas (written evidence of material compatibility)
    - Humidity/heat
    - Mechanical stress tailored to use

#### *Planing aids for equipment*

#### *General requirements*

#### *Restricted access*

#### *Room equipment – observe details*

- Wall/ceiling paint and coating tailored to expected use
  - Wet abrasion resistance
  - As per EN 13300 class 2
  - As per EN ISO 19998 class 1/2
- Lighting (ASR A3.4 lighting)
  - Workstation 1000 lx
  - For other areas 500 lx
- Cables concealed or enclosed in ductwork; outer surface amenable to wet disinfection
- Ductwork and shafts with close-fitting access openings
- Avoid condensate formation (appropriate insulation)
- For new projects and reconstruction close cooperation with the infection control team or hospital chief infection control officer
- Position dosing equipment such that contamination from pathogenic liquids from the outlet is prevented
- All furnishings must be installed such that traffic routes, escape and reuse routes are not impeded (e.g. wall-mounted dispensers, fire extinguishers, etc.)

*Number of employees?  
Organization of changing –  
centralized/decentralized?*

#### **Changing rooms**

- Room size and furnishings tailored to number of persons
- Separation between used departmental clothing, clean departmental clothing and personal clothing
- Appropriately equipped hand washbasin
- Non-touch facilities for depositing items (shoes, laundry, waste)

*Hygiene requirements*

#### **Staff recreation rooms**

- Room size and furnishings tailored to number of persons
- Hand washing facilities
- In the cleaning/disinfection area, changing rooms and recreation room
- Non-touch fittings
- Hot/cold water
- Disposable towels from dispensers
- Dispensers for wash lotion
- Facility for skin-protection and skin-care products

#### **Hygienic hand disinfection**

- Hand disinfectant dispensers installed at the entrance/exit of each room, and additionally based on risk assessment

*Departmental clothing/PPE*

#### **Departmental clothing (to be worn only in respective department)**

- Closed storage facilities for departmental clothing (cabinet or enclosed in packaging on a shelf)
- Shoes on racks or shelves

#### **Personal protective equipment (PPE)**

- Facility for contamination-proof storage of clean PPE
- Facility for depositing used PPE
- Possibly, storage for reused PPE (specify in infection control policy)

*Coordination RUMED – IT  
Avoid cable mess*

#### **IT hardware**

- Enclosed IT components, including cabling
- Wireless radio technology IT accessories (e.g. scanner, printers)
- Surfaces amenable to wipe disinfection

The **“RUMED with spatial separation“ concept** gives details of how to equip and furnish a RUMED.

The **“RUMED one-room solution“ concept** gives details of how to equip and furnish a RUMED in medical institutions which reprocesses a limited number and type of medical devices.

## I RUMED with spatial separation – Room furnishings and equipment

### *Cleaning and disinfection area (C+D area)*

- Incoming zone
  - Automatic door drive
  - Admission control
  - Space for storage of deliveries at ergonomic height
  - Wall dispensers for hand disinfectant
  - Wall-mounted facility for glove boxes
  - Waste containers with non-touch lid
  - Documentation station
    - Possibly, hand scanner
  - If needed or as contingency measure washing station for transport trolleys
    - Space for PPE
    - Provision for cleaning utensils
    - Provision for disinfectant dosing unit (surface disinfection)/outlet
    - Possibly, floor drain, take hygiene precautions
    - Space for incoming loan instruments (preferably dedicated room)
  - Delivery side
    - Parking bay for trolleys and storage space for transport packaging
    - Documentation station
    - Wall dispensers for hand disinfectant
    - Wall-mounted facility for glove boxes
    - Waste containers
  - Hygiene barrier of appropriate size between delivery and handing-over zones
    - Storage space at ergonomic height
- Cleaning/disinfection area
  - Worktop for sorting and preparations (table, trolley, etc.)
  - Manual cleaning and disinfection zone (if needed, see "Guideline for validation of manual cleaning and manual chemical disinfection of medical devices", Annex 2, for example workstation
    - The fittings must be tailored to the order in which procedural steps are executed (process-oriented)
      - Only for precleaning/subsequent cleaning
      - Or for manual cleaning and disinfection, incl. rinsing/drying
  - Ultrasonic cleaning (flush-mounted or tabletop device with temperature display and lid, with preferably non-touch operation)
  - Magnifying lamp suitable for wet rooms
  - Possibly, dosing equipment for surface/instrument disinfectants
  - Space for depositing and storing work materials
  - Water pistol (amenable to automated reprocessing) for precleaning,
  - In cases of manual reprocessing – water pistol for final rinse after disinfection, demineralized water with sterile filter
  - Possibly, steamer, always fitted with hood and extractor
  - Loading zone for washer/disinfectors (WDs)/container tunnel washer (CTW)
    - Transport trolley
    - Loading trolley/racks
    - Possibly, automated loading system
  - Storage space/shelf for
    - Loading trolley/racks (standard/MIS/anaesthesia, etc.) as needed
    - Accessories for loading the WDs (e.g. for special MDs, small-items baskets, etc.)
  - Documentation station
    - Possibly, hand scanner with wall-mounted facility
  - Waste bin
  - Wall-mounted facility for glove boxes
  - First aid kit as per health and safety requirements

*TRBA 250 "Biological agents in health care and welfare facilities"*  
*Protection level 2*

*Manual reprocessing required?*

<i>Avoid recontamination by spatial separation</i>	<p><b>Equipment-based barrier – hygiene barrier</b></p> <ul style="list-style-type: none"> <li>– 2-door WDs (heat-resistant MDs)/EWDs (endoscope) <ul style="list-style-type: none"> <li>• Alternatively, multi-chamber washer-disinfector as per EN ISO 15883 (heat-resistant MDs)</li> </ul> </li> <li>– Container tunnel washer (CTW) as per EN ISO 15883</li> <li>– Maintenance access</li> <li>– Return/hatch, lockable (with storage space)</li> </ul> <p><b>Packing area (clean)</b></p> <ul style="list-style-type: none"> <li>– Zone for unloading WDs <ul style="list-style-type: none"> <li>• Unloading MDs <ul style="list-style-type: none"> <li>– Possibly, automated feed-out mechanism</li> </ul> </li> <li>• Release/documentation of reprocessed MDs <ul style="list-style-type: none"> <li>– Possibly, scanner</li> </ul> </li> <li>• Transport trolley</li> </ul> </li> <li>– Packing zone <ul style="list-style-type: none"> <li>• Hand disinfectant dispenser – no dripping/splashing at packing workstation</li> </ul> </li> </ul>
<i>Observe ergonomic requirements</i>	<ul style="list-style-type: none"> <li>• Work tables <ul style="list-style-type: none"> <li>– Anti-glare work surfaces</li> <li>– Height adjustable</li> <li>– IT equipment</li> <li>– Possibly, facilities for standing/sitting</li> <li>– Chamfered base cabinet to floor/or ground clearance of at least 30 cm/or mobile</li> <li>– Sockets</li> </ul> </li> <li>• Magnifying lamp 500 lux, ASR A3.4 Workplace Regulation</li> </ul>
<i>Media supply</i>	<ul style="list-style-type: none"> <li>• Possibly, compressed air pistol (medical compressed air) amenable to automated reprocessing</li> <li>• Storage space/shelf/trolley for cleaned/disinfected supplies and containers for subsequent reprocessing steps</li> <li>• Facilities for storing accessories (care/assembly), enclosed</li> <li>• Possibly, equipment/materials for functional testing of MDs as per the manufacturer's instructions</li> </ul>
<i>Packaging concept?</i>	<ul style="list-style-type: none"> <li>• Racks for soft packaging <ul style="list-style-type: none"> <li>– Reels, pouches, sheets</li> </ul> </li> <li>• Heat sealing machine as per ISO 11607/Part 1</li> <li>• Protected store/warehouse <ul style="list-style-type: none"> <li>– Consumables/packaging</li> <li>– Replacement/reserve MDs</li> <li>– Intermediate storage</li> <li>– Possibly, facilities/shelf/trolley for storing packed supplies</li> </ul> </li> <li>• Zone for loading sterilizer <ul style="list-style-type: none"> <li>– Possibly, trolley for assembling load</li> <li>– Possibly, automated feed-in mechanism</li> </ul> </li> </ul> <p><b>Sterilizer-based barrier</b></p> <ul style="list-style-type: none"> <li>– Sterilizers as per ISO 17665, EN 285 <ul style="list-style-type: none"> <li>• 2-door sterilizer (assures organizational separation)</li> <li>• Maintenance access</li> <li>• Possibly, hatch or doors (lockable) <ul style="list-style-type: none"> <li>– Possibly, returning loading systems</li> <li>– Possibly, transport trolley from CTW</li> </ul> </li> <li>• Possibly, low-temperature sterilizer</li> </ul> </li> </ul>
<i>Transport concept</i>	<p><b>Sterile supply area/consignment store</b></p> <ul style="list-style-type: none"> <li>– Automated feed-out mechanism</li> <li>– Possibly, loading trolley</li> </ul>

- IT equipment
- Possibly, cabinets, dustproof locks/shelves
- Possibly, cabinet system for handing out supplies, with mutual interlocking system

#### **Other rooms**

- Staff changing rooms
  - Clothes locker, preferably with forced ventilation/lockers for depositing personal clothing/departmental clothing depending on organizational setup. Possibly, separate male/female facilities.
  - Shelves for outdoor shoes
  - Bench/stools
  - Cabinets for departmental clothing or shelves for packed departmental clothing, including hood
  - Shelves for departmental shoes
  - Mirror for checking departmental clothing
  - Facility for depositing departmental clothing
  - Collection containers for departmental shoes
  - Waste containers
- Recreation room
  - Hand washbasin
  - Furnishings as per the Workplace Regulation, ASR A4.2 depending on the organizational setup
- Office
  - Preferably partitions to create separate zones (accessible from outside and from RUMED as communications interface)
  - Office furnishings
  - IT equipment
- Staff sluice to access C+D area
  - Cabinet/shelves for packed personal protective clothing, including orofacial mask/goggles/face shield
  - Shelves for departmental shoes
  - Wall-mounted facility for glove boxes
- Staff sluice to exit C+D area
  - Facility for depositing protective clothing
  - Collection containers for departmental shoes

*Staff changing rooms centralized/decentralized?*

*Recreation room?*

*Administration*

*Hygiene plan*

#### **Side rooms with assignment to cleaning and disinfection area**

- Room for cleaning materials
  - Furnished as per cleaning system
  - Possibly, space for storing cleaning accessories
  - Possibly, outlet/disinfectant dosing unit
  - Possibly, cleaning trolley with accessories and facility for depositing used items/waste
- Room for used/waste materials
  - Possibly, containers for storage of waste for collection
- Dosage centre
  - Equipped as per requirements
  - Safety collecting tray, preferably at floor level
  - PPE/first aid kit as per health and safety requirements

*Cleaning concept*

*Detergent/disinfectant supply*

#### **Side rooms with assignment to packing and sterilization area**

- Room for cleaning materials
  - Furnished as per cleaning system
  - Possibly, space for storing materials
  - Possibly, outlet/disinfectant dosing unit
  - Possibly, dedicated cleaning trolley with accessories and facility for depositing used items/waste

*Cleaning concept*

- Sluice for waste materials
  - Floor markings/transit barrier
  - Container for waste collection in external area
  - Possibly, shelf (e.g. for packaging/loan instruments/repairs)
- Materials sluice
  - Table for unpacking
  - Hatch to materials storage
- Materials storage
  - Cabinets dustproof, veneer finish to the ceiling
- Handover

Optional areas not featured in the drawing will be addressed in the report on technical prerequisites

*Publication in the next issue*

**I RUMED (one-room solution) – Organizational separation of zones**

*References please see p. 247*