WFHSS ÖGSV

Sterile Supply Specialist Training Course Level II

Constructional Requirements for a Reprocesing Unit for Medical Devices

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Constructional Requirements for a Reprocessing Unit for Medical Devices (RUMED)

1 Introduction

In recent years medical device reprocessing has been increasingly centralised. The aim here was, and is, to assure:

- better equipment and apparatus utilisation (optimal use of energy)
- enhanced process standardisation and automation
- uniform reprocessing conducted according to the state of the art by specially trained staff
- enhanced implementation of a quality-management (QM) system

In turn, this means:

- provision is made for legally stipulated process validation as well as for
- enhanced occupational protection.

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In summary, centralised reprocessing is seen as being safer, more economical, more rational and more environmentally friendly.

When designing a RUMED (reprocessing unit for medical devices), constructional, spatial, technical and organisational structures as well as staff qualifications and procurement of instruments and equipment must be taken into account.

The constructional requirements to be met by RUMED Categories (I – II – III) are tailored to the risk groups to which the medical devices to be reprocessed in the RUMED belong.

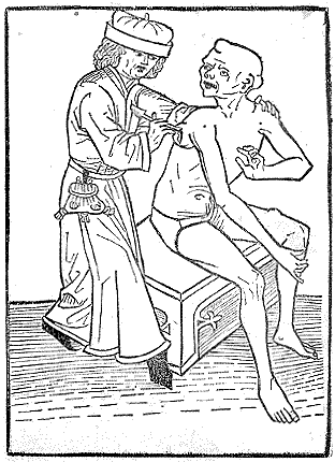
The aim is to plan and implement a process-oriented medical device circuit of the highest quality possible, so as to provide patients with safe treatment and nursing care within the various departments.

The sterilisation unit, including the sterile supplies' store (warehouse), should be situated as closely as possible to the main site of use. It is recommended to provide a direct connection route between the sterile supplies' store and the main site of use or, if this is not possible, to at least assure good and short transport routes and connections.

Since in general more than 80 % of the supplies to be reprocessed originate from a hospital's surgical department (operating rooms – OR), it is advisable to situate the RUMED in the direct vicinity of the ORs. Furthermore, preference should be given to a vertical over horizontal

access (transport routes, lifts /elevators). A direct lift connection to the OR assures swift and efficient material turnover, promoting a certain amount of flexibility and cooperation. Whereas in hospitals in the past the RUMED was generally an integral part of the surgical department, today, because of the risk of contamination posed when reprocessing supplies, the RUMED is preferentially situated outside the surgical department, but efforts should be made to provide for access via sluices to the unclean area of the RUMED and for direct return of supplies to the sterile OR store.

2 Category I RUMED



In Category I RUMEDs only medical devices (MDs) belonging to the non-critical, semi-critical A, critical A risk groups as well as hand and angle pieces (which really belong to semi-critical group B) may be reprocessed.

Examples of institutions with RUMED I: homes for the elderly / nursing homes, rehabilitation centres, medical practitioners' offices (doctors' surgeries) [apart from endoscopy (Cat. II) and surgical activities (Cat. III)]

A dedicated area (e.g. within the treatment room) must be made available.

Provision must be made for **spatial** or **at least for** temporal **zone separation.** This means preference must be given to spatially separate unclean, clean and sterile areas and, in principle, there should also be temporal separation of the various activities following appropriate decontamination of working surfaces. This regulation is aimed at ensuring that, for example, independent medical practitioners can continue to reprocess their own MDs

3 Category II RUMED

In Category II RUMEDs MDs belonging to the semi-critical B risk groups may be reprocessed in addition.

Examples of institutions with RUMED II: independent medical practitioners conducting endoscopy (gastroscopy/colonscopy), decentralised reprocessing units for medical devices in tertiary-care hospitals (e.g. reprocessing of anaesthesia accessories).

For new endoscopy units – centralisation and separate unclean/clean premises are recommended;

A dedicated room must be made available with unclean, clean and sterile **zone separation.**

MDs belonging to the semi-critical B risk group must be reprocessed in a washer-disinfector.

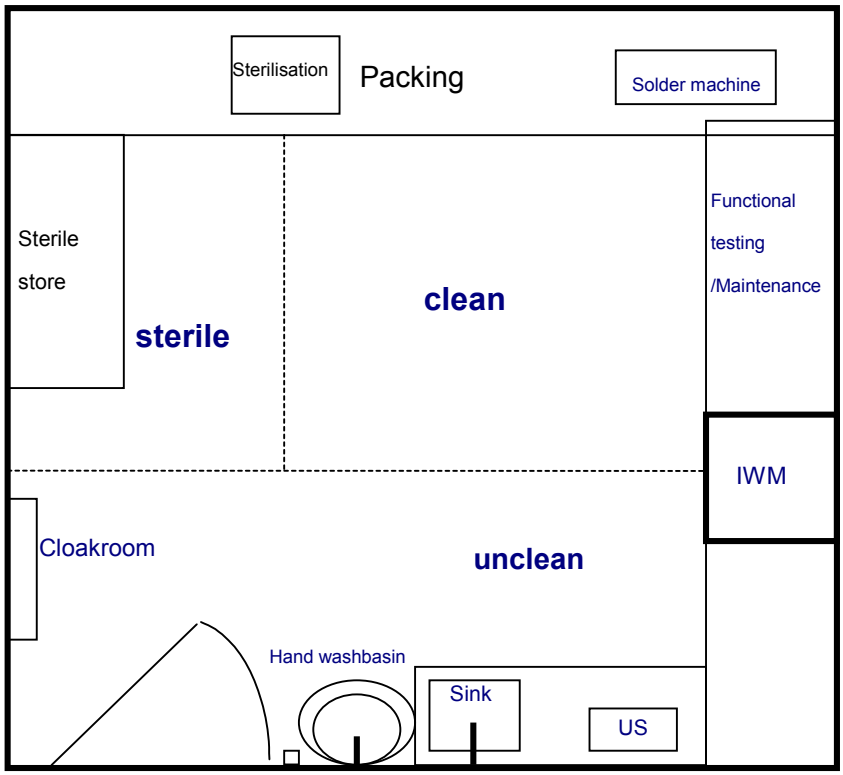


Fig.1: Example of Category II RUMED premises

4 Category III RUMED

In Category III RUMEDs MDs belonging to all risk groups may be reprocessed.

Examples of institutions with RUMED III: hospitals with surgical units.

Dedicated rooms must be made available with unclean, clean and sterile zone separation. Dedicated personnel should be available, and provision made for appropriate changing rooms. This requirement applies for new, extended and converted premises.

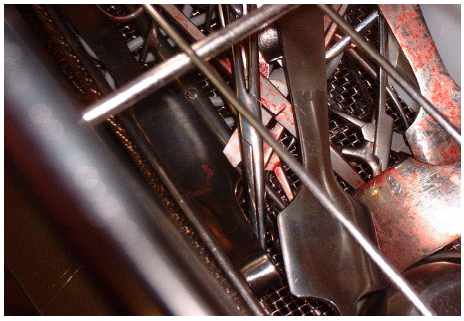
To assure orderly working practices in a RUMED III, provision must be made for the following spatially separate areas accessible only via sluices:

- an unclean area,
- a clean area,
- a sterile supplies' store,
- a room for RUMED management and
- corresponding recreation rooms for staff

Working activities in the various areas must be organised while taking account of occupational safety, assurance of standardised workflow patterns and hygiene. Working activities must be organised such that reprocessed supplies cannot be contaminated by unclean devices (sterile supply circuit). Therefore all unclean materials should be taken charge of and decontaminated in an area that is clearly separated from all manipulations involving clean supplies.

For hygiene reasons, it is therefore necessary that a sufficient surface area be made available for this unit. Space shortage has adverse effects in a sterilisation unit / RUMED!

4.1 Unclean area



In the **unclean area** used and contaminated materials are taken charge of and, as far as possible, cleaned and disinfected in washer-disinfectors.

Efforts should be made to use double-door washer-disinfectors that are installed in the partition wall between the unclean and clean side, and which can be loaded on the unclean side and unloaded on the clean side. For special cleaning and disinfection measures, provision should be made, if necessary, for ultrasound equipment, in which a disinfectant can be used, for immersion procedures with chemical detergents and disinfectants as well as facilities for manual cleaning.

If direct contact with non-disinfected devices cannot be avoided, suitable gloves should be worn.

The following surfaces or rooms are needed:

- incoming materials room
- Surface area for cleaning and disinfection of supplies
- Surface area for cleaning and disinfection of transport supplies
- If applicable, an office
- if applicable, a recreation room

4.2 Clean area

In the **clean area** the cleaned and disinfected supplies

- are subjected to functional testing and maintenance
- sorted in accordance with the user's requirements;
- packed, labelled and
- sterilised.

Double-door sterilizers must be installed in the partition wall separating the clean area and sterile supplies' store.

If surgical drapes are folded and inspected, there is a likelihood of particles being released. In such cases the instruments must be protected (possibly by covering them or making provision for spatial or temporal separation).

For new, extended or converted premises, clean area should meet requirements of ISO class 8 as per ISO 14644-1.

The following surfaces or rooms are needed:

- Surface for maintenance, sorting and packing heat-resistant and heat-sensitive supplies
- Store for packed supplies, for packaging materials, accessories, detergents, maintenance supplies
- If applicable, an office
- If applicable a recreation room
- Staff changing room

4.3 "Sterile area"

Following sterilisation supplies are withdrawn from the sterilizer on the sterile side, the sterile supplies are transported to the sterile supplies' store, where they are stored together with single-use supplies. Efforts must be made to protect supplies against dust by storing them in cabinets. If necessary, supplies are handed out at the site of use or distributed to the user.

The following surfaces or rooms are needed:

- Sterile supplies' store
- Material hand-out area
- Staff changing rooms/sluice

This room should be dry, have only low dust content and be well ventilated, it should meet the corresponding cleaning and disinfection requirements (e.g. the internal surfaces - walls, floors and ceilings - should be smooth and free of cracks), it should not be used as a main thoroughfare and be accessible only via sluices. A room air ventilation system with three-stage incoming air filtration is needed for the sterile supplies store only in cases where supplies cannot be protected against dust. In such a case, the entire room is classified as being "protected against dust".

See also chapter "Fundamentals of Sterilisation"

For hygiene and economic reasons, stocks should be tailored to need.

The office for RUMED management should provide a good overview of the entire premises, but on the other hand allow for communication with visitors and other persons from outside the department without these persons having to gain entry. This could be done, for e.g. via an intercom.

The following rooms are needed for staff

- Staff changing rooms with showers, toilets and appropriate fittings as well as
- Staff recreation room with appropriate fittings.

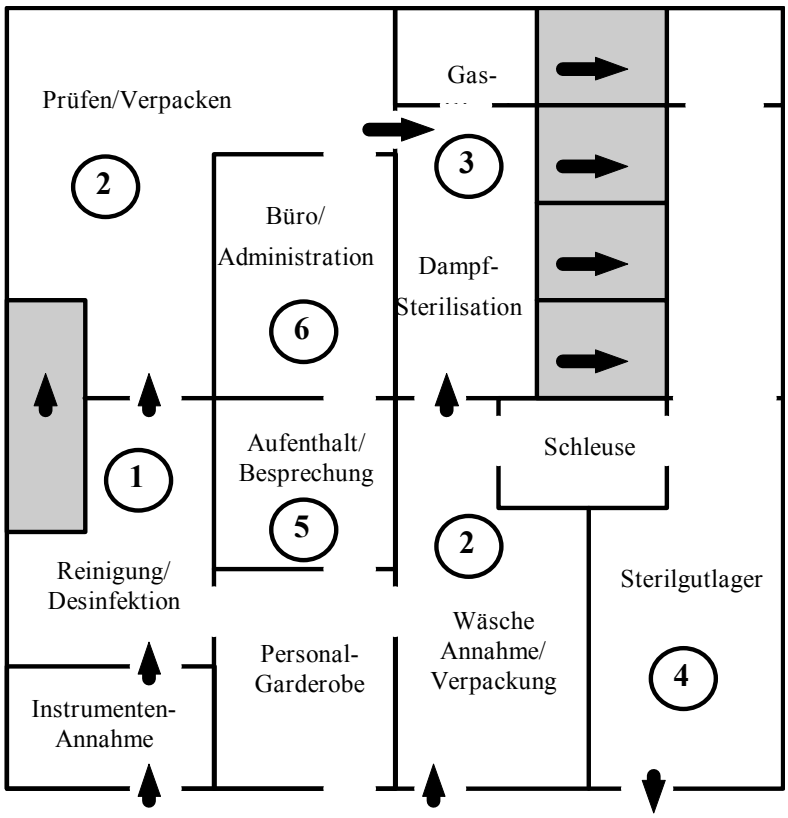


Fig.2: Example of a layout for a Category III RUMED premises (central sterilization)

1 = cleaning/disinfection incoming instruments

2 = inspection/packing incoming laundry/packing

3 = gas/steam sterilization

4 = sterile supplies' store

5 = recreation/meeting room staff cloakroom

6 = office / administration

1. **Disinfection and cleaning zone**
2. **Packing room and materials' store**. In addition to having enough working space, sufficient space should also be available for the supplies to be sterilized and for packaging materials
3. **Sterilisation zone**. This should be spatially separated and provide for strict separation of unsterile and sterile supplies
4. **Sterile supplies' store**. Here it should be possible to store the sterile supplies in well-organised manner
5. **Staff room**
6. **Office**

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The script has been proof read and authorized by the wfhss education group

6 References

(1) Richtlinie für Krankenhaushygiene und Infektionsprävention: Robert Koch Institut, G. Fischer Verlag.

(2) Leilinie der ÖGSV: Aufbereitung von Medizinprodukten in/für Einrichtungen des Gesundheitswesens (www.oegsv.com > guidelines)

7 Learning objectives

The student should

- be able to name the constructional requirements for the various RUMED categories
- be able to name the various areas of a RUMED III premises as well as the rooms needed