

Recommendation of the Committee for Hygiene, Construction and Technology Requirements for construction, reconstruction and operation of a Reprocessing Unit for Medical Devices (RUMED)

Part 14: Measures for construction or reconstruction during ongoing work in a Reprocessing Unit for Medical Devices

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■ Preliminary remarks / Introduction

Reconstruction of a RUMED during ongoing work can have various consequences:

- Spatial restrictions
- Changes of working conditions for staff
- Lower production output
- Internal or external RUMED clients may experience an impact on their operating room (OR) schedules, availability of medical devices, etc.

This publication describes measures to be observed when undertaking construction or reconstruction work in a RUMED in order to minimize disruption to the RUMED activities.

This recommendation is not a comprehensive planning template. The situation of each individual RUMED must be considered.

Reconstruction or construction measures in a RUMED during ongoing work call for detailed preparation, cooperation between all parties involved and close supervision by designated persons.

The diagramme below gives an overview of the various topics to be addressed and organized (Figure 1).

In view of the outlined complexity, contact should be established with all potentially involved persons and trades well in advance of the planned measures.

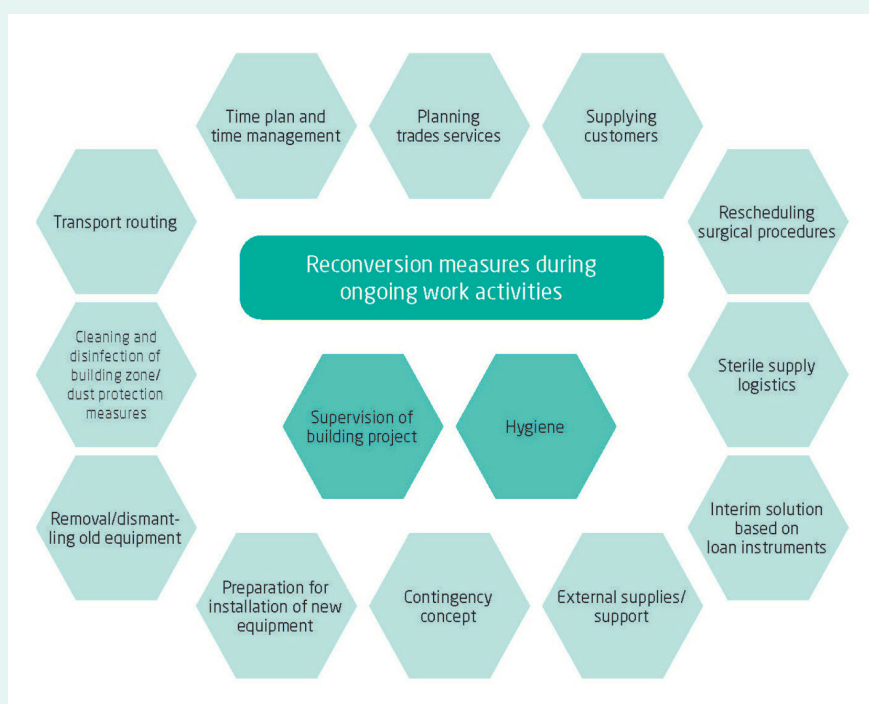


Fig. 1: Aspects to be considered when planning building/rebuilding works during ongoing RUMED work activities

■ Planning RUMED construction or reconstruction measures during ongoing work activities

Some of the prerequisites to be met:

- Quality management system, incl. hygiene/infection control policies
Standard operating procedures and procedural instructions
- **CONTINGENCY CONCEPT** taking account of the available media, transport routes and personnel deployment

DOWNTIMES must be set out in a **CONTINGENCY CONCEPT**.

The following are needed to plan the measures to be taken in the RUMED:

- **APPOINTMENT** of participating persons,
 - Within the hospital or department:
RUMED management, hospital technical department, main client e.g. OR, cleaning service, infection control team (infection control nurse/hospital infection control consultant), logistics (collection and delivery services)
 - Skilled contractors, planning engineers/planners and, possibly, project managers whose expertise can help systematically implement and thus expedite procedures and reduce overall costs.
 - Possibly, other persons

APPOINTMENT of participating persons

Figure 2 gives an overview of the above.

Supervision and monitoring of construction measures

These tasks should be assigned to a person familiar with the conditions prevailing on site and with the appropriate competence and powers, e.g. staff member(s) of the in-house engineering department, hospital infection control team in collaboration with the RUMED management. For construction measures lasting several days, shift work must be organized or it must be possible to reach at least one responsible person.

SUPERVISION AND MONITORING of construction measures

These persons should

- Provide introduction (in particular on hygiene/special aspects of occupational safety and health) and organize
 - Access to sanitary facilities
 - Recreation/smoking areas
- Identify, explain and report hazards and deviations (communication channel/medium)

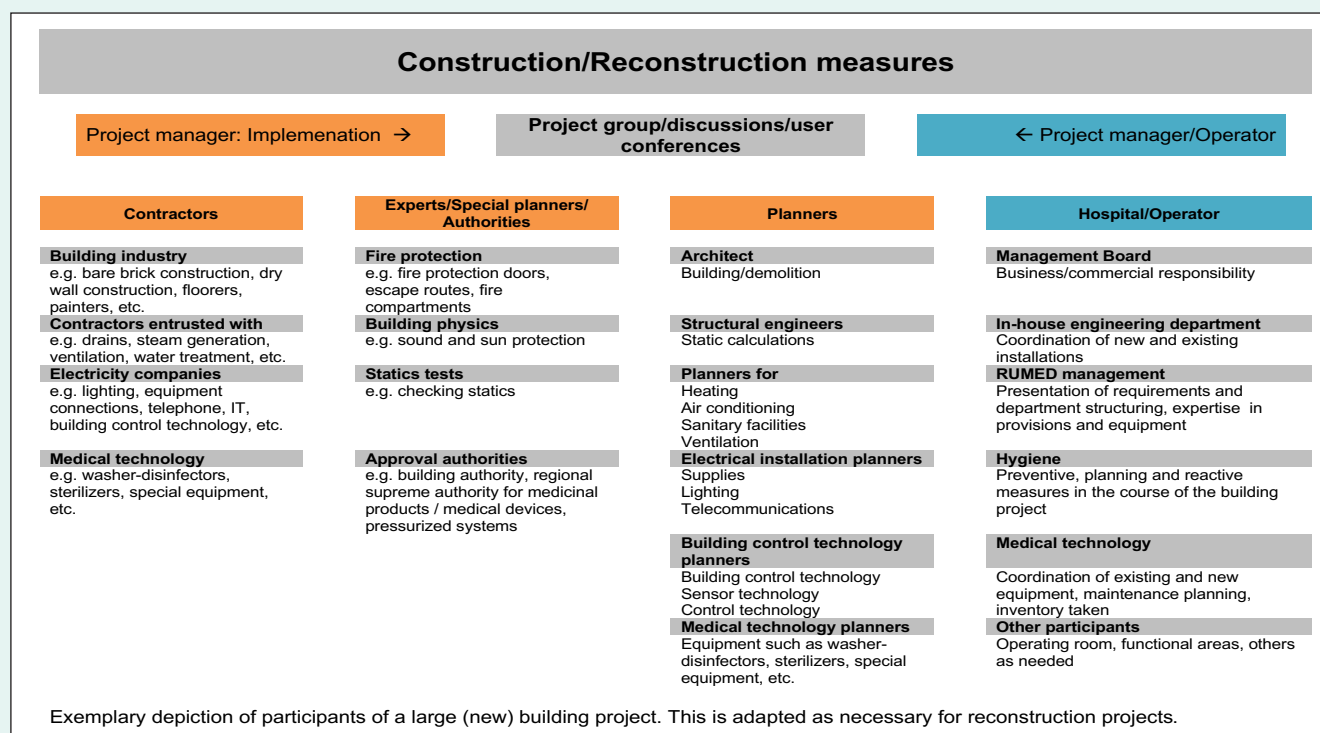


Fig. 2: Competencies when planning construction works



TRANSPORT ROUTING

Planning fundamentals

- Construction and installation plans, furnishing plans (floors plans and elevation drawings, preferably in 3D presentation)

■ Planning content

Transport routing

Specify the implications of **TRANSPORT ROUTING** within the RUMED and the applicable transport routes (“clean”, “unclean”, “external”) and set them out in a building installation plan, showing the logistical routes for departments still in operation.

- Personnel
- Collection and delivery of medical devices for the RUMED
 - Dirty medical devices
 - Reprocessed medical devices (sterilized or with only low microbial count)
- Accessibility for other related departments (e.g. patient routes)
- Access to building site for
 - Contractors
 - Transport routes for construction materials/tools
 - Transport routes for supply and collection of large machinery, incl. floor and elevator (lift) load capacity calculations

ESCAPE ROUTES

Occupational safety and health inspections and **ESCAPE ROUTES** must also be considered.

If there are different building stages, all aspects must be presented separately for each building stage. In this way it will be possible to identify and eliminate in advance any problematic intersections (e.g. intersections between building site routes and departmental routes).

SIGNPOSTING

The altered **ROUTES** must be:

- signposted
- publicised
- checked

DISMANTLING POSSIBLY, POLLUTION

Other influencing factors on work activities must be noted, e.g.:

- When **DISMANTLING** old components, attention must be paid to potential **POLLUTION** risks
- The extent and, possibly reduction, of noise, dust and odour emissions or vibrations.
 - External air intake by HVAC (heating, ventilation and air conditioning) systems
 - Note risk areas within hospital
- Parking facilities for businesses/contractors

Dust protection

A dust protection enclosure is always needed if the ambient conditions within the RUMED during ongoing work operations could be adversely impacted by the construction measures e.g.:

- Dust from grinding/sanding, drilling or cutting tasks
- Work on pressurised gas lines if sudden emission of medical gases such as compressed air are likely, or
- Dismantling of old equipment

The following measures must be taken before installing dust protection walls

- Cleaning/disinfection area**
Stored supplies must be protected against recontamination or placed elsewhere.
- Packing and sterilization area**
Reprocessed medical devices, supplies stored in cabinets, drawers and on shelves must be protected against recontamination or placed elsewhere. Make provision for a suitable interim storage area.
- Sterile supply store**
If this is affected by the building work taking place in the RUMED, protect the sterile supplies against recontamination by making arrangements for a suitable interim storage area.

REMOVAL OF SUPPLIES from the construction area

Dust protection walls designed as permanent fixtures and reaching as far as the raw ceiling are recommended in principle.

- The quality of the coating used on the front side of the panels in the department still in operation during building work must meet the same requirements applicable throughout the entire department (e.g. melamine resin-coated panels) (Figures 3–5).
- Measures must be taken to minimize dust exposure when installing and removing dust protection structures.

MATERIAL FOR dust protection walls

Dust protection walls with strong plastic foils should only be used for short-term, low-dust measures. These should be installed all around the dust protection en-



Fig. 3*: RUMED side of dust protection wall



Fig. 4*: Building site side - Rear of dust protection wall

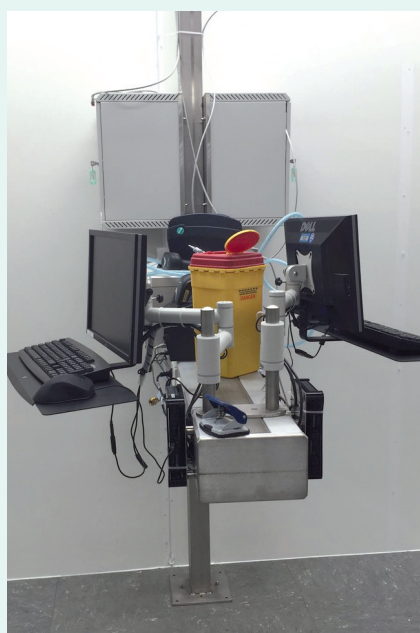


Fig. 5*: RUMED side - with connected media supply

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closure. The foil walls must be able to withstand the different pressure conditions prevailing between the various zones. If continued use of a passage/corridor is intended, foil doors with zip closure should be installed.

Masking tape should be fitted to the vents of HVAC systems that have been taken out of service. The same applies for overflow openings.

If necessary, deactivate the fire alarm system or smoke alarms for this area.

TIME TABLE

Time table, time management and planning contractor services

Downtimes must be minimized. Coordination with other construction measures and with maintenance and servicing deadlines should be organized.

It is advisable to implement in parallel other measures needed, but not directly linked to the construction or reconstruction measures, e.g. flooring and painting work, dismantling of old installations such as unused pipes or cables.

A detailed time table should be drawn up and presented several weeks before the planned construction measures. The time table should be compiled in joint discussions and on-site meetings. These should also be used to discuss and specify hygiene issues and requirements.

These steps can be presented e.g. as a calendar overview in a table or on a **TIME TABLE CHART**, such that the relationship between the various work steps and contractors is clearly identifiable.

- Distribute construction time table among all participants

TIME TABLE CHART

KEY QUESTIONS when planning

The key questions to be considered in the construction time table

- What preparatory discussions should be held with the contractors and businesses as well as with in-house persons and by when ?
- What preparatory measures must be completed by when?
- What disruptions to customer sterile supplies are expected and for how long?
 - What surgical procedures are not possible for what period of time?
 - Is there an emergency plan for supplying medical devices (reserves, external reprocessing, single-use devices)?
- Must emergency patient care or admission of emergency cases by the emergency service be cancelled?
- What special measures are needed by when (RUMED, OR, collection and delivery services, cleaning services, etc.)
 - different working times
 - manpower requirements
- Which areas/zones of the RUMED are affected?
- Which contractors and businesses will be involved and when?
- List of telephone numbers and details of availability of all project participants (update list as building work progresses)
- Must changes be made to the reprocessing steps (e.g. manual cleaning/disinfection)?
 - Must standard operating procedures be updated?
 - Is validation needed?
- Has a time frame been specified for “post-construction tasks”?

SUPPLYING CLIENTS with reprocessed medical devices

Customer supplies/Adjustment of OR schedules

As soon as the date and duration of building-related disruption of customer supplies is known, this must be communicated in writing to OR coordinators, OR managers and (internal/external) client contact persons and the relevant details must be discussed.

These include e.g.:

- Stocking up on sterile supplies e.g. through loan instruments before the start of construction e.g. for emergency procedures, caesarean sections
- Reduce/change work activities in the OR/functional areas
- Change logistics while paying attention to hygiene requirements

Outsourcing medical device reprocessing

Part 15 of this series of publications will focus on **CONTINGENCY CONCEPTS**.

See Part 15 for **CONTINGENCY CONCEPT**

Preparatory measures

The aim is to expedite the building/rebuilding work itself, reduce costs and restore a full complement of RUMED services as soon as possible. Check what construction measures can be taken in advance without disrupting RUMED activities.

Examples:

- Media connections (waste water, water or compressed air pipes, electrical connections)

Measures for HVAC systems

Ventilation engineers and architects must address this issue in collaboration with the in-house engineering department and hospital infection control consultant.

The following information is important for the RUMED:

- Which air inlet/outlet vents must be covered with masking tape?
- Which sections of the HVAC system must be taken out of service and, if so, for how long/until what stage of the construction work?

Before placing the system in service again, the ventilation engineers, architects, in-house engineering department and hospital infection control consultant must specify the measures needed. These include e.g.:

- Inspection of channels (incoming/outgoing air)
- Cleaning/disinfection of channels (incoming/outgoing air)
- Sealing of flaps/access openings
- Reinstall fire protection flaps
- Fit filters
- Cleaning/disinfection of air outlets or air outlet vents
- Functional testing/measurements
- Assign competencies for implementation and documentation

Cleaning

- The RUMED management, infection control nurse/hospital infection control consultant, building project supervisor and contractor must take timely measures for assigning cleaning tasks
 - Making a distinction between rough and fine cleaning
 - Assign competencies or specify management and implementation
 - Removal of covers/protective foil
 - Transport routing
 - Deadline planning in line with completion of building works and on time before resumption of RUMED activities
 - Specify time line for any subsequent improvements
 - For example, consider the time needed for silicone seals to dry
- Specify contact persons and their availability to carry out the cleaning tasks during the respective phases of the building works
- Exchange of information on planned and actual deadlines for
 - Removal of dust protection walls
 - Moving dust protection walls
 - Changing routes
 - Incidents requiring cleaning tasks
 - Downtimes (personnel, equipment)
 - Room or equipment usage
- Acceptance of cleaning contracts/assignments
 - Assign competencies for implementation and documentation
 - Deadlines (singly or jointly)

Final disinfection before handover

The RUMED management, infection control nurse/hospital infection control consultant, building project supervisor and contractor must take timely and jointly agreed measures after completion of fine cleaning for:

- Assignment of disinfection measures (surface disinfection)

PROVISION OF MEDIA supplies in advance

HVAC SYSTEMS

TAKING HVAC SYSTEM out of service

REINSTALLATION

FUNCTIONAL TESTING/MEASUREMENTS

ROUGH AND FINE CLEANING

CONTACT PERSONS for cleaning tasks

ACCEPTANCE OF CLEANING TASKS

FINAL DISINFECTION



DEADLINES FOR DISINFECTION TASKS

ACCEPTANCE OF DISINFECTION TASKS

RESUMPTION OF RUMED ACTIVITIES

FIRE ALARM SYSTEM

- Competencies for implementation, possibly in collaboration with in-house cleaning personnel
- Disinfectants (approved products; in the case of Germany those approved by the German Association of Hygiene [VAH]; dosage, exposure time) and application method (wipe, brush roller machine, etc.)
- Scope of disinfection (specify rooms, surfaces, equipment to be disinfected)
- Personal hygiene, behaviour, induction
- Transport routing
- Specify contact persons and their availability to carry out the disinfection tasks during the respective phases of the building works
- Exchange of information on planned and actual deadlines for
 - Implementation of disinfection tasks
 - End of exposure time = time at which areas can be reused
 - Building work barred from disinfected areas
 - Organize reuse of disinfected rooms by the RUMED
- Acceptance of disinfection contracts/assignments
 - Assign competencies for implementation and documentation
 - Deadlines (singly or jointly)

Resumption of RUMED activities

The area may only be used after release by the competent persons. Agreements must be reached on any validation and device instruction activities needed. Place **FIRE ALARM SYSTEM** or smoke alarms back in service.

Finally, update SOPs, infection control policies and procedural instructions. After release of disinfection measures, cabinets, drawers and work areas can be used again.