

Recommendations by the Committee for Hygiene, Construction and Technology

Requirements for Construction or Reconstruction of a Reprocessing Unit for Medical Devices (RUMED)

Part 11: Heating, ventilation and air conditioning (HVAC) system in a RUMED

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Part 11 of the publication series “Requirements for Construction or Reconstruction of a Reprocessing Unit for Medical Devices (RUMED)” focuses on the heating, ventilation and air conditioning (HVAC) system in a RUMED.

Note: This publication is not a planning template.

■ Fundamental documentary sources

- DIN 1946-4:2018-09 Ventilation in buildings and rooms of health care
- VDI 6022-1:2018-01 Hygiene requirements for ventilation and air-conditioning systems and units
- Workplace Regulation (ArbStättV) (12.08.2004; last amended by Art. 5(1) of 18.10.2017)
- Hygiene requirements for processing medical devices, 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), (2012)
- Hospital hygiene guideline for the planning, execution and operation of ventilation and air conditioning systems in rooms of the health care system issued by the German Society of Hospital Hygiene (DGKH), Hyg Med 2015; 40 – 12
- TRBA 250 Biological Agents in Health Care and Welfare (4th Amendment 2018)

Cooperation is vital between all participants for planning and acceptance, as described in the recommendations previously published by the Committee for Hygiene, Construction and Technology. That calls for close collaboration between the project managers, RUMED management, infection control team, engineering department, architect, planning engineer for technical building services, medical technology department, fire protection, occupational health and safety, and the competent authorities.

Any deviations from the pertinent standards must be justified by an expert and documented.

■ Basic requirements for the heating, ventilation and air conditioning system

Pursuant to DIN 1946-4, provision must be made for a HVAC system when planning a new RUMED.

The following criteria also apply for the “one-room solution”:

The heating, ventilation and air conditioning requirements applicable in the cleaning/disinfection area, equipment-based barrier composed of washer-disinfectors (WDs)/sterilizers differ from those in the packing and sterilization area as well as in the side rooms within the RUMED.

- Contamination transmission from the cleaning and disinfection area into the other areas (internal/external) must be avoided
- Contamination transmission from the outside into the clean areas of the RUMED must be avoided
- Provision must be made for an adequate amount of outside air (no window ventilation)
- Dissipation of thermal and humidity loads (at the site of origin e.g. WD/AER/sterilizer)
- Maintenance of room temperature and relative humidity,

FUNDAMENTAL DOCUMENTARY SOURCES

COOPERATION

INFORMATION on the heating, ventilation and air conditioning system for a RUMED DIN 1946-4

AIRFLOW DIRECTION



- Dissipation of aerosols from the cleaning/disinfection area e.g. steam cleaner/ compressed air pistol (see TRBA 250, Section 5.4.4)
- Dissipation of chemical vapours above the emission sources

Avoidance of drafts and noise also contributes to a comfortable environment for the persons working there.

WHAT IS A HVAC SYSTEM?

■ Functions of a heating, ventilation and air conditioning (HVAC) system

HVAC systems are distinguished on the basis of their function

- **Mechanical ventilation system** – air supply and air removal
- **Partial air conditioning system** – air supply and air removal with heating and/or cooling
- **Air conditioning system** – air supply and air removal with heating, cooling, humidification, dehumidification

Only an air conditioning system or partial air conditioning system with separate extraction of loads above the emission sources are able to meet the specified requirements.

To assure proper operation of a HVAC system, windows must be airtight when they are closed and must not be opened. Doors must also be kept closed

By controlling the supply and exhaust air volumes, different airflow directions can be generated. That prevents transmission of airborne particles/microorganisms between areas with differing hygiene requirements.

Idle mode or shutdown during periods of work inactivity is possible. Here it must be noted that rundown times after the end of operation and the correct time for switching on the system again before resumption of work activities must be programmed. The hours of operation should be documented.

WINDOWS

■ Fundamentals for planning

DIN 1946-4, Table 1, describes a HVAC system for the RUMED, specifying the following:

- Rooms are assigned to room class II
- For room class II two-stage filtration is defined
 - In the HVAC system:
 - At the system input
(ISO ePM1 filter $\geq 50\%$ [formerly F7 filter])
 - At the system output, after all air treatment functions
(ISO ePM1 filter $\geq 80\%$ [formerly F9 filter])
- No terminal filtration is specified
- Room temperature 22°C to 26°C
- Negative air balance in the cleaning/disinfection area (unclean): sum of supply air volume < sum of exhaust air volume
- Positive air balance in the packing /sterilization area (clean): sum of supply air volume > sum of exhaust air volume
- Dissipation of sensitive and latent loads through exhaust air suction above the emission source (WD/AER/sterilizer/steamer, etc.)
- Minimum requirements for the cleaning/disinfection area: outdoor air volume flow > 5 m³/m²/h, often higher requirement due to thermal loads/humidity etc.
- Since no minimum amounts of outdoor air are specified for other areas of the RUMED, it is recommended that provision be made for > 40 m³/h/person (based on the amounts specified for operating rooms (OR))
- The room temperature and humidity must also meet the equipment manufacturer requirements, in particular for electrotechnical equipment as well as the manufacturer's specifications for packaging materials

DIN 1946:4, TABLE 1, REQUIREMENTS

EFFECT ON THE AIR QUALITY

Criteria to be borne in mind (humidity and thermal sources) – Examples:

- Number of persons
- Manual cleaning and chemical disinfection
- Steam cleaner
- Ultrasonic cleaners

- WD-E
- Storage cabinet with drying function
- Sterilizers, possibly with steam generators
- Heat sealing devices
- Light sources
- Battery chargers
- IT equipment
- Solar radiation

If there are lifts/elevators installed within the RUMED, their effect must be taken into account when drawing up ventilation plans.

For operation of gas sterilizers the requirements for air exchange rates must be observed. (German Technical Regulation for Hazardous Substances [TRGS] 513 Issue October 2011, last amended 17.10.2017; Section 5.4.) must be noted.

A positive air-conditioning effect can be achieved by means of the following:

- The process exhaust air from large equipment should be selectively collected and dissipated at the respective site of origin in order to comply with the occupational health and safety conditions and prevent humidity-induced microbial growth
- External solar protection or north-facing window
- No supply air vents directly above workstations (drafts)
- Do not block exhaust air vents with any fixtures or fittings
- Position the supply and exhaust airflow such as to avoid air short-circuits

Draw up a contract setting out responsibilities for all stages of planning, installation, acceptance and operation. Make arrangements for commissioning, inspection and servicing of the HVAC system. Make timely provision for the technical and hygiene acceptance testing.

■ Operation of the HVAC system

- Within the framework of quality management (QM), arrangements are made for cleaning, servicing and periodic technical and hygiene testing and documentation thereof, see VDI 6022-1 Section 7 and DIN 1946-4 Tables 3 and 4
- The system must be operated in accordance with the applicable standard/guideline
- Operation must be documented, see VDI 6022-1 Section 7.1
- Cleaning intervals and methods must be specified for the supply and exhaust air vents

■ Testing

- Pursuant to the provisions of the applicable standard/guideline

LIFTS/ELEVATORS

GAS STERILIZERS

POSITIVE EFFECTS

CONTRACTUAL SPECIFICATION OF RESPONSIBILITIES

TESTING