Recommendations by the Committee for Hygiene, Construction and Technology

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

Part 6: Technical Building Systems (TBS)

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Introduction

Part 6 of the publication Requirements for Construction or Reconstruction of a Reprocessing Unit for Medical Devices (RUMED) focuses on the technical building systems (TBS), without room air conditioning in a RUMED. The room air conditioning (heating, ventilation) will be addressed in a seperate publication.

Technical requirements
Guidance

It serves as guidance for new construction or reconstruction of a RUMED with regard to the **technical requirements** to be met for the supply and disposal of the different media needed. The regulations listed here (e.g. DIN, recommendations, guidelines and other legal, normative technical regulations), must always be applied in their currently valid version.

Note: This publication is not a planning template.

General requirements

Basic requirements

Media supply within a RUMED is essential for its operation and an important subject-when planning that department. Today, at a time when technical building systems must meet increasingly more complex demands, while at the same time having to assure the security of supply despite growing cost pressures, planning is of key importance. The systems should be tailored as far as possible to the needs of the RUMED, with inbuilt redundancy, while also assuring economical installation and operation. Such needs must be ascertained through close cooperation between the project managers, RUMED management and planning engineers.

Planning media supply in the RUMED can be broken down into the general categories of heating/ventilation/sanitation (HVS) and electrical installations (E). These different categories and their aspects of relevance for the RUMED operation are described below.

Compressed air/vacuum

Aspects:

- Quality: medical or technical as required
- Presentation: centralized – decentralized
- Medical compressed air is classified as a medicinal product (air for medical use) based on the European Pharmacopoeia and is subject to special provisions
- Pressure reduction via pressure regulator; application pressure specified by the manufacturer of the medical device/equipment manufacturer

Medical compressed air (5–10 bar)

Must be possible to dismantle, disinfect and sterilize

Compressed air pistols

– Application:

- Medical device packing station
- Air motor test station

- Manual processing cycle for additional drying
- Endoscope additional drying

Possibly for endoscope leakage test instruments

Technical compressed air (6–10 bar)

- Possibly for washer-disinfectors
- Possibly for sterilizers

Vacuum

- Generated centrally or in sterilizer

Steam

Steam capacity
Economic efficiency

Aspects:

- Centralized or decentralized steam generation
- Quality:
  - Heating steam (not for sterilization)
  - Pure steam as per DIN EN 285
- Steam pipes with gradient and condensate trap

Note material and quality for pipeline networks

Sterilizers

- Integrated steam generator/electric steam generator (demineralized water supply)
- Steam converter (demineralized water supply for pure steam generation)
- Pure steam for sterilization of centrally generated steam

In accordance with local conditions/ equipment manufacturers

Washer-disinfectors

- Preferably, heating steam, alternatively electric heating
- Condensate return for heating steam

In accordance with local conditions/ equipment manufacturers

Safety exhaust pipe for pressure vessels

- Sterilizers
- Steam generators

Pressure Vessels Regulation

Dosage systems

Automated processes (WD/EWD/large-chamber WDs/container tunnel washers

Economic efficiency
Ergonomics
Occupational safety
Fire protection
Hazardous Substances Regulation

- Centralized media supply for detergents/disinfectants
  - Location of room (short pipes)
    - Self-contained room
    - Note accessibility
  - Container monitoring
  - Collecting basin tailored to output
  - Hose pipes in empty conduits (replace hose pipes regularly)
  - or CrNi steel pipeline network (provision for cleaning/disinfection of pipeline)
  - Monitoring of microbiological quality e.g. by checking final rinse water
- Decentralized media supply from dispensing unit
  - Note accessibility
  - Container monitoring
  - Collecting basin tailored to output
- Media supply for disinfectants
  - Monitoring of microbiological quality e.g. by checking final rinse water

Eye washes, preferably disposable containers

Manual processes

- Surface/instrument disinfectants and instrument detergents
  - Decentralized dispensing units
  - Alternatively, manual dosage

Electrical

Current

Clarify requirement
Equipment requirements
Contingency concept

- General supply 230 V, 400 V
- Safety equipment power supply 230 V, 400 V (emergency power supply generally not needed)
- With overvoltage protection
- Potential equalization/static /static dissipation measures as specified by installation/equipment manufacturer

Lighting

See publication 4 + 5

- Room illumination
- Workstation lighting
- Safety lighting

Information technology (IT)

See publication 4 + 5

- Documentation stations
- Equipment process documentation

Communication

See publication 4 + 5

- Telephones
- Intercom systems

Building control technology (BCT)

Clarify requirement

- Fault messages
- Measurement and control technology (MCT)
- Remote maintenance modules
- Fire protection
- Fire detectors, impermeable inspection flaps for fire detectors installed in ceiling cavity

Drinking water

Aspects:

Information to user

Shut-off devices for each water pipe and/or piece of equipment, with labelling

e.g. German Association for Gas and Water (DVGW), DIN, VDI

Preferably CrNi steel (stainless steel) pipeline networks

All pipes must be rinsed out and undergo microbiology testing when first installed

Minimize contamination risk (Legionella)

Insulation of hot and cold water pipes

No dead pipes

Drinking water, hot/cold

- Quality based on Drinking Water Regulation in respect of
  - microbiological
  - chemical aspects
- Installed in compliance with the regulations
- Temperatures
- Hardness grade (water treatment may be needed)
- Non-return valves for connected equipment
- Hot water circulation pipes (DVGW*** conform)
- Assure drinking water quality for new/reconstructed premises (before handover to user)

Water fittings

- Non-touch operation (e.g. single lever mixer)
- Sensor control (note contamination risk)
- Wall fittings more hygienic than stand fittings (cleaning)
- Jet control, preferably lamellar jet control

Hand washbasins/sinks

Regular replacement needed

- No overflow
- Do not direct water jet into siphon
- Sink with lever drain or standpipe if needed
- Hand washbasin without stopper

Softened water

In accordance with local conditions/equipment manufacturers

- Drinking water of reduced hardness grade as per the needs of the operator or equipment manufacturer

Demineralized water

Note silicate/silicic acid breakthrough

- Generation of softened water of drinking water quality to reduce the water conductivity value
- Limit values
  - Sterilization steam generation as per DIN EN 285

  - Conductivity value ≤ 5 µS/cm
  - Inert gas reduction
- WD/EWD/large-chamber WD/ control tunnel washer as per DIN EN ISO 15883 and/or equipment manufacturer's specifications
  - Conductivity value ≤ 15 µS/cm or as specified by equipment manufacturer
- The following must be noted, too:
  - Evaporation residues, silicates, iron, cadmium, lead, other heavy metal residues, chlorides, phosphates, pH value, appearance and hardness (sum of alkaline earth ions)
  - Degassing

Waste water

- Floor drain/trolley washing station, possibly in cleaning and disinfection area
  - Preferably, fitted with side drain for connection of nearby basin or rinsing unit
  - Cockroach grid (clean regularly)
- Waste water connections for equipment (WD, sterilizer, etc.)
- Hand washbasins
- Sinks
- If necessary, sanitary area/recreation rooms

Waste water temperature (note pipeline quality and local waste water regulations)

Cooling sterilizer vacuum pumps

- Preferably, via in-house cold water circuit (cold water chiller)
  - Emergency supply – drinking water connection

Room air conditioning

Aspects:

- Heating
- Cooling
- Ventilation
- Humidification and dehumidification
- Measurement and control technology (MCT)

These aspects will be addressed in a separate publication

List of References

- DIN EN ISO 7396-1«Medical gas pipeline systems and vacuum»
- ZLG* «Aide mémoire 07121401 «Medical gas»
- ZLG EFG** VoteV15004 «Limit value for water in air for medical use in hospital pipeline systems»
- European Pharmacopoeia «Monograph "Air for medical use"»
- DruckbhV «German Pressure Vessel Regulation»
- TRB «German Technical Rules for the Pressure Vessel Regulation - Pressure vessels»
- TRR «German Technical Rules for the Pressure Vessel Regulation – Pipelines»
- BetrsichV «Regulation concerning safety and health in providing work equipment and using it in the workplace, concerning safety during operation of systems requiring inspection and organization of workplace health and safety»
- Directive 97/23/EC «Machines/Pressure Equipment Directive»
- Directive of the German Federal Institute for Materials Research and Testing (BAM), and of the Robert Koch Institute (RKI) and of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO) «Requirements for design, features and operation of decentralized disinfectant dispensing units»
- TrinkwV «German Drinking Water Regulation»
- DIN 2000 «Centralized drinking water supply – Guidelines for requirements for drinking water, planning, construction, operation and maintenance of plants»
- DIN EN series 806 «German Technical Rules for drinking water installations»
- DIN series 1988 «German Technical Rules for drinking water installations»
- DIN EN 1717 «Protecting drinking water from contamination in drinking water installations and general requirements for safety equipment to protect drinking water against contamination from backflow»
- VDI 6023 «Hygiene in drinking water installations; requirements for planning, implementation, operation and maintenance»
- DVGW*** «Various rules of the German Association for Gas and Water (DVGW)
- EnEV «German Energy Savings Regulation»
- DIN EN 285 «Sterilization – Steam sterilizers – Large steam sterilizers»
- DIN VDE 0100 «Regulations for the erection of power installations with rated voltages of up to 1000 V»

* ZLG: German Central State Body for Health Protection with Regard to Drugs and Medical Devices

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*** DVGW: German Association for Gas and Water

- DIN VDE 0101 «Power installations with rated voltages of over 1 kV»
- DIN EN 62271-200 «High-voltage switchgear and switch devices»
- VDE 0532 «Power transformers»
- DIN VDE 0100-710 «Special installations and locations – medical facilities»
- DIN VDE 0100-718 «Safety lighting systems»
- DIN EN 1838 «Emergency lighting»
- DIN EN 62305 «Lightning protection»
- DIN EN 12464-1 «Lighting of indoor workplaces»
- ASR 7/3 «Artificial lighting»
- ASR 7/4 «Safety lighting»
- TAB «Technical connection regulations of the energy supply company»
- VDEW «German Electricity Industry Association»
- UVV «German Accident Prevention Regulations»
- DIN EN 50173-1 «Information technology – Generic communications cabling systems – Part 1: General requirements and office areas»
- DIN EN 50174-2 «Information technology – Installation of communications cabling systems – Part 2: Installation planning and practices in buildings»
- DIN EN 50098-1 «Information technology cabling of building complexes Part 1:ISDN basic connection»
- DIN EN 50310 «Application of measures for grounding and potential equalization in buildings with information technology installations»
- DIN EN 60728-11 «Cable networks for television signals, sound signals and interactive services – Part 11: Safety requirements for cable networks for television signals, sound signals»
- DIN VDE 0833-1 «Alarm systems for fire, intrusion and hold up – Part 1: General specifications»
- DIN VDE 0833-2 «Alarm systems for fire, intrusion and hold up – Part 2: Requirements for fire alarm systems»
- DIN VDE 0833-3 «Alarm systems for fire, intrusion and hold up – Part 3: Requirements for intrusion and hold up alarm systems»
- DIN VDE 0833-4 «Alarm systems for fire, intrusion and hold up – Part 4: Requirements for voice alarm systems for fire, intrusion and hold up»
- DIN VDE 0834-1 VDE 0834-1 «Paging systems for hospitals, care homes and similar establishments – Equipment requirements, installation and operation»
- DIN VDE 0834-2 VDE 0834-2:2000-04 «Paging systems for hospitals, care homes and similar establishments – Environmental conditions and electromagnetic compatibility»
- DIN 14675 «Fire alarm systems – Installation and operation»
- TR BOS «Technical directive for buildings' radio systems»
- Technical connection conditions for fire alarm systems by the responsible fire department»
- Data sheet for fire departments in the different German Federal States»