Recommendation of the Committee for Hygiene, Construction and Technology

Requirements for the construction, reconstruction and operation of a Reprocessing Unit for Medical Devices (RUMED)

Part 15 Contingency concept for a RUMED to deal with expected and unexpected operational disruptions

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Introduction

A contingency concept should be formulated to deal with any operational disruptions in a Reprocessing Unit for Medical Devices (RUMED) and thus assure the ongoing and timely security of supply to users/clients. This must take account of the breakdown of the technical infrastructure and equipment, disruption of supply media and human resources as well as structural damage (e.g. water damage) and building and conversion measures.

BREAKDOWN, DISASTER/ACCIDENT AND MALFUNCTION

The terms **BREAKDOWN, DISASTER/ACCIDENT** and **MALFUNCTION** are often used synonymously.

The situations in which operational disruptions and breakdowns restrict RUMED operations should be continually documented. These reasons must be analysed and measures introduced into everyday operations to reduce the breakdown rates. This procedural approach contributes to a continuing improvement process as part of quality management and serves as a basis for the formulation of a contingency concept.

The cited laws, standards, recommendations, guidelines and other regulations must all be used in their currently valid version.

Note: This publication is not a planning template and makes no claim to completeness.

Fundamentals and objectives

CONTINGENCY CONCEPT

A specific **CONTINGENCY CONCEPT** must be formulated for every RUMED before the occurrence of a breakdown. The contingency concept must be continually updated. The aim is to assure the security of the ongoing supply of reprocessed medical devices to all RUMED clients (e.g. operating room (OR), clinical departments, external clients).

This always calls for internal regulations or also contractual agreements with external service providers or cooperation partners.

NORMATIVE FUNDAMENTALS

The contingency concept layout must be integrated into the quality management system. Some of the applicable **NORMATIVE FUNDAMENTALS** include, e.g.:

- DIN EN ISO 9001
- DIN EN ISO 13485
- DIN EN ISO 14971
- VDI 5700
- DIN ISO 31000

RISK MANAGEMENT

The systematic approach taken for **RISK MANAGEMENT** includes the following aspects:

- Risk analysis of potential triggers of malfunctions and associated influencing factors/causes
- Risk assessment with
  - Probability of occurrence
  - Probability of detection and potential implications for the security of supply
- Risk management with risk prevention measures/minimisation

Organizational approach for the formulation of a contingency concept

Cooperation between the following participants is essential for the formulation of the contingency concept:

COOPERATION WITH IN-HOUSE PARTNERS of the medical establishment:

- Operator
- Quality management
- RUMED management
- Competent persons in the various in-house interface departments e.g.:
  - OR
  - Endoscopy suite
  - Other functional departments
  - Engineering department.
  - Logistics
  - IT
  - Infection control team
  - Possibly, others, e.g. cleaning services, human resources

COOPERATION WITH IN-HOUSE PARTNERS

COOPERATION WITH EXTERNAL PARTNERS

- RUMED's external clients
- Servicing firms for equipment, IT, media, etc.
- Suppliers
- Possibly, others, e.g. planning engineers

COOPERATION WITH EXTERNAL PARTNERS

Contingency concept content – event related (whenever warranted)

The potential reasons for operational disruptions in a RUMED can be identified as far as possible and solutions put in place to assure the security of supply.

REASONS

Reason for malfunction	Potential solution	Remarks
Manpower shortages and personnel absences	▪ Change the working (shift) times ▪ Hire skilled temporary staff ▪ Arrange for skilled replacement staff from other establishments	▪ Pay attention to qualifications ▪ Carry out induction ▪ Regulate release of medical device (MD) reprocessing processes ▪ Have infection control policies/standard operating procedures (SOPs) countersigned ▪ Observe occupational safety and health regulations
Breakdown of ultrasonic cleaner	▪ Intensify manual cleaning ▪ Hire replacement machine	▪ An SOP must be available ▪ The manufacturer's information for use (IFU) must be available
Breakdown of washer disinfector (WD)/WD for endoscopes (equipment/media)	▪ Use other WDs/AERs available in the RUMED instead ▪ Change the working (shift) times ▪ Change availability/supply of MDs	▪ Ensure suitability of replacement equipment ▪ Validated processes
	▪ Manual cleaning and disinfection for semi-critical A+B and critical A MDs	▪ Validation of manual working steps required beforehand ▪ Process chemicals must be suitable and available /note expiry date! ▪ SOPs and documentation/process release must be assured
	▪ Order and reprocess loan instruments before planned disruption of services	▪ Note delivery times
	▪ Make contract with external service provider/cooperation partner	▪ Note interfaces, documentation and transport conditions, etc.

Reason for malfunction	Potential solution	Remarks
Breakdown of heat sealing device	▪ Make provision for spare heat sealing device or spare parts with validated sealing process(es) ▪ Change packaging (e.g. nonwoven packaging)	▪ Validate process on site ▪ SOP must be available ▪ Manufacturer's information for use must be available
Breakdown of steam sterilizer (equipment/media)	▪ Use other sterilizers available in the RUMED instead ▪ Change (shift) working times ▪ Change availability/supply of MDs	▪ Ensure suitability of replacement equipment
	▪ Order and reprocess loan instruments before planned disruption of services	▪ Observe delivery times
	▪ Order sterile single-use instruments	
	▪ Make contract with external service provider/cooperation partner	▪ Note interfaces, documentation, and transport conditions, etc.
Breakdown of small sterilizer	▪ Hire replacement machine	▪ Validation must have been carried out for the planned load/packaging
Breakdown of low-temperature sterilizer	▪ Make contract with external service provider/cooperation partner	▪ Note interfaces, documentation and transport conditions, etc.
Breakdown of server, PC, software failure, documentation of process data	▪ Use suitable, stand-alone data loggers for process documentation ▪ Manufacturers' system-specific emergency modules	▪ Make provision for protection systems, redundancy systems
Breakdown/malfunction of communications media, e.g. telephone, DECT system, fax	▪ In-house regulation	
Supply bottlenecks/disruption of consumables supply chain	▪ Draw up list of suppliers, incl. email addresses, contact persons	▪ Consider validated processes ▪ Suitability of replacement devices ▪ Observe manufacturer's information for use
Breakdown of water-treatment system	▪ Redundancy system ▪ Water treatment with mixed-bed resin cartridges	
Breakdown of HVAC systems	▪ Agree action with engineering dept. and infection control team	▪ Use fly grid if window ventilation used
	▪ Close down service and make contract to outsource MD reprocessing to external service provider	▪ Supply greatly restricted or impossible because of lead times; inform in-house/external clients immediately ▪ Note interfaces, documentation and transport conditions, etc.
Disruption because of structural damage e.g. water damage, fire damage	▪ Agree action with engineering dept. and infection control team ▪ Possibly, block off certain areas	
	▪ Make contract with external service provider/cooperation partner	Note interfaces, documentation and transport conditions, etc.
Disruption because of building/rebuilding work	▪ Create additional RUMED areas e.g. by renting a mobile RUMED or using other suitable rooms within the medical establishment	▪ Validation required ▪ Utilization period must be known ▪ Medical device supply and collection routes must be clarified
Disasters/ other damaging events	▪ Refer to the orders put in place by the medical establishment's operator ▪ Consult disaster plan	▪ Observe statutory provisions

Contingency concept content – consequence-related

CONSEQUENCES

A consequence-related approach appears advisable to minimize the processing efforts involved.

Measures should be separated into the following categories when processing the various breakdown scenarios:

With regard to the **POSSIBILITY OF SUPPLYING** reprocessed medical devices, different scenarios may apply:

IS SUPPLY POSSIBLE?

- No supply
- Full or partial supply by using substitute resources within the RUMED itself
- Partial or intermittent supply by external service providers or cooperation partners
- Full supply by an external service provider or cooperation partner

With regard to the possibility of using **RESOURCES WITHIN THE RUMED** or outsourcing services:

CAN RUMED CALL UPON ANY RESOURCES OF ITS OWN?

- Which reprocessing steps can still be carried out in the RUMED?
- Which reprocessing steps must be delegated to whom?
- Which details of documentation and changes must still be clarified for transport, etc.?

The contingency concept must set out the **CONSEQUENCES** arising from the respective measures for the:

IMPACT ON?

- RUMED personnel
- In-house clients
- External clients

and with regard to the:

AVAILABILITY of reprocessed medical devices in terms of the time and products

AVAILABILITY OF SUBSTITUTE MEASURES?

- Possibly, substitute with single-use medical devices
- Possibly, change the sterile barrier systems
- Possibly, make changes to "unclean" and "clean" transport
- Possibly, make changes to documentation

Communication channels used for a contingency concept

The RUMED should define the **COMMUNICATION CHANNELS** to ensure the contingency concept is accessible to the following parties:

COMMUNICATION CHANNELS

- Economic operator
- In-house clients e.g.
  - OR management/OR coordinator or also physicians, anaesthetists, accident and emergency department, endoscopy suite, etc.
- External clients, e.g.
  - Economic operator, OR management/OR coordinator, other clients
- In-house interface departments e.g.: engineering dept., IT, infection control team, in-house cleaning services
- External interface departments e.g. other contractually bound RUMEDs or service providers

Finding external service providers for a contingency concept

Contact should be made with a number of potential **EXTERNAL SERVICE PROVIDERS,** with whom various aspects should be clarified in advance and then contractually agreed.

EXTERNAL SERVICE PROVIDER

These external services may be RUMEDs in other medical establishments or independent/commercial service providers. These must provide proof of having in place a quality management system (*see KRINKO-BfArM Recommendation**)

A **CONTRACT** must always be made with the selected service provider/cooperation partner. This should set out all the relevant points, including how services are to be provided, service documentation and reimbursement of costs. The lead time needed to start providing services must be taken into account.

CONTRACT WITH SERVICE PROVIDER/COOPERATION PARTNER

*Recommendation for hygienic processing practices for medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM).

IMPORTANT TOPICS

IMPORTANT TOPICS INCLUDE:

- Capacity for reprocessing additional medical devices
  - Available equipment
  - Personnel
- Operating times, shift times and potential time slots during which medical devices can be reprocessed for the outsourcing RUMED
- Deployment of personnel from the outsourcing RUMED to the partner service provider engaged to implement the contingency concept option. (In agreement with employee representatives)
  - Occupational safety and health as well as insurance coverage e.g. when personnel from the outsourcing RUMED are working externally on the premises of the contractual partner or service provider
- Software system and current version as well as interface options
  - Possibility of VPN connection, install corresponding equipment dummies and label templates for the reprocessing process
  - External service provider can take charge of packing lists
  - Permanent, current packing lists, regular back-up
- Additional cleaning measures due to prolonged transport/ /waiting times before the contaminated medical devices are reprocessed
- Validation of all reprocessing steps
  - Record all additional medical devices expected and their sterile barrier systems
- Logistic types/transport systems: see guideline for storage and transport
  - Spatial distance to potential partner, specific aspects of transport e.g. routes prone to high traffic volumes and traffic jams
  - Logistics and, possibly, also hired transport trolleys and vehicles in good condition
  - Replacement drivers/vehicles
  - Teach drivers how to manage transportation of contaminated and reprocessed medical devices and also how to respond to accidents
  - Insurance (theft, damage, defective deliveries, accidents)
  - Handover location for contaminated medical devices with personal handover and documentation
  - Handover location for delivery of reprocessed medical devices with personal handover and documentation
  - Monitoring of temperature/humidity at the time of assembly and transport of sterilized medical devices (prevention of condensate formation)
  - Suitable storage facilities and areas to assure the logistics needed when reprocessing services are outsourced to an external partner or service provider

Business management aspects as well as practical factors are important when opting for one or several partners/service providers. Reliable and effective reprocessing and supply must be given top priority in any case.

References:

1. Guideline for storage of reprocessed medical devices and transport for supply and collection of reprocessable medical devices between the RUMED and user
2. Guideline compiled by the German Society of Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI) for validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices
3. Guideline for validation of automated cleaning and disinfection processes for reprocessing heat-sensitive endoscopes (DGSV, DGKH, AKI, DEGEA, DGVS)
4. Guideline for validation of packaging processes as per DIN EN ISO 11607-2:2020 (DGSV)
5. Guideline for validation of manual cleaning and manual chemical disinfection of medical devices (DGSV, DGKH, AKI, VAH)
6. EN ISO 9001 Quality management systems – Requirements
7. EN ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes
8. EN ISO 14971 Medical devices – Application of risk management to medical devices
9. VDI Directive 5700 Risk management for medical device reprocessing – Measures for risk control
10. ISO 31000 Risk management – Guidelines