Recommendation of the Quality Task Group (118)

Hygiene aspects when dealing with external persons in the RUMED

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1. Introduction

Medical device reprocessing makes stringent demands on product quality and safety and therefore calls for consistent quality, safety and hygiene management.

Often, there is a need for external persons to work in the Reprocessing Unit for Medical Devices (RUMED); such tasks include technical activities, training, inspections, audits and reference visits.

The health of **EXTERNAL PERSONS** in the **RUMED** can be endangered through exposure to biological agents or they themselves can present a danger.

These "**EXTERNAL PERSONS**" are e.g. employees from other departments or also persons who within the meaning of employment legislation and occupational health and safety are not employees, such as visitors, trainees, servicing technicians, cleaning personnel, validation engineers or auditors, and whose health could be endangered through exposure to biological agents or who themselves could present a risk (e.g. by introduction of microorganisms or contamination).

The German Biological Agents Regulation (*BioStoffV*), Section 3, classifies biological agents into four risk groups based on their infection risk. Medical device reprocessing activities undertaken in the cleaning and disinfection area of the RUMED are generally classified as belonging to protection level 2. **HAZARD ASSESSMENT** which must be regularly conducted (recommended once annually) is a suitable implementation and monitoring mechanism to that effect.

HAZARD ASSESSMENT as per the Biological Agents Regulation should be carried out once annually.

Certain exposures (e.g. aerosol exposure in the case of open tuberculosis) may be assigned to the higher protection level 3 (see German Technical Regulation on Biological Agents [*BGR 250/TRBA 250*]). Based on the Protection Level Classification, regulations incorporating technical, organizational and personal **PROTECTIVE MEASURES** must therefore be specified and also declared as mandatory for "external persons".

PROTECTIVE MEASURES are also mandatory for external persons.

Likewise, the hygiene requirements specified by the German Protection against Infection Act (IfSG) and the infection control regulations of individual German federal states as well as internal RUMED regulations (infection control policy) must be observed. Issues around maintaining hygiene standards in the packing area and sterile supplies area must be addressed as well.

With this recommendation the Quality Task Group aims to create awareness of the role of "external persons" with regard to occupational health and safety and hygiene. Important goals include:

- Protection of the medical device reprocessing area (e.g. against additional external contamination)
- Protection of "external persons" against infection and accidents (e.g. needle stick injuries, inhalation of toxic and/or infectious agents)
- Documentary evidence of the measures taken by the RUMED management

2. Regulatory fundamentals

2.1 Occupational health and safety (OSH)

Risk assessment (hazard assessment) of the working environment must be carried out in all areas of a RUMED.

Measures to minimize the identified risks must be specified, implemented, documented and checked for efficacy. On entering the department and before commencing their activities, "external persons" must receive **INDUCTION** in the following:

External persons must receive **INDUCTION** before entering the department and before commencing their activities.

- On-site occupational health and safety as well as hygiene regulations
- Self-protection measures
- Contamination avoidance measures: " External to internal and internal to external carryover of contamination"

Within the meaning of the Biological Agents Regulation, this can be illustrated on the basis of the hazard assessment stipulated for "external persons". Hazard as-

sessment must be carried out by an expert. If the employer does not have the necessary expertise, they must obtain expert advice. The expertise requirements are set out in *TRBA 200* "Requirements for professional expertise in accordance with the Biological Agents Regulation".

Since the RUMED management can in general perform hazard assessment only to the extent permitted by its own expertise, it is advisable to enlist the services of occupational health and safety experts, safety officers, etc. and jointly formulate measures.

TRBA 250 specifies in concrete terms the requirements of the Biological Agents Regulation (*BioStoffV*). It sets out the current status of the safety, occupational medical, hygiene and ergonomic requirements when handling biological agents.

2.2 Hygiene

A risk-based infection control/hygiene policy should be in place to ensure the hygiene requirements stipulated by the various regulations for the RUMED and its environmental conditions are implemented. In addition to other hygiene requirements, this must also take account of how to deal with "external persons".

3. Recommended action when performing tasks within the RUMED

The scope of the protective measures should be tailored to the risk presented to RUMED personnel (in particular in the cleaning and disinfection area) as well as to minimizing risks for "external persons".

External persons may include:

- Field service personnel (manufacturers of medical devices, equipment, chemical products)
- Engineers/technicians (in-house / external engineers/technicians e.g. installers, mechanical engineering technicians)
- Validation engineers
- Auditors (e.g. certification body, occupational health and safety, government agencies)
- Cleaning personnel
- Consultants (e.g. planning engineers, QM advisors)
- Visitors
- Guest visitors, trainees

All measures are tailored to the **RISKS** that could emanate from the respective activities and should apply equally to in-house personnel and "external persons". They are based on the nature and intensity of exposure or contact. More stringent requirements must be addressed to an "external person" coming directly into contact with a medical device (MD) in the packing area than to a person entering the packing area for only a brief moment, e.g. to check a device function (no direct contact with the MD).

The **POTENTIAL RISKS ARISING FROM ACTIVITIES** determine the scope of the protective measures, which then apply equally to in-house personnel and "external persons".

If external persons must bring necessary equipment (tools, etc.) from outside into the RUMED it must be assumed that this equipment had already been used at another site and will later be used elsewhere.

Materials/implements repeatedly used in the RUMED should if possible be left long term in that department, e.g. ladders, cleaning utensils, basic tools.

3.1 General recommendations

Within the **CLEANING AND DISINFECTION (C&D) AREA** of the RUMED "external persons" and their equipment must be protected against exposure to or contact with potentially infectious materials.

Within the **C&D AREA** external persons must be protected.

On the other hand, within the **PACKING AREA OR STERILE SUPPLIES AREA** contamination of these areas by external persons and/or their equipment must be avoided. The equipment brought into the RUMED must be of unquestionable hygiene status and be

Within the **PACKING AREA OR STERILE SUPPLIES AREA** contamination of these areas by external persons and/or their equipment must be prevented.

- clean
- disinfected (to the extent advisable and feasible e.g. cameras, laptops, mobile phones)
- secured against falling out, leakage, etc.
- brought into the RUMED in a hygienically safe state.

The amount of materials introduced should be kept to a minimum.
Depending on the scope of the work activities, the following must be clarified or prepared before an "external person" visits:

- Regulations when entering sluices, including conduct of hygienic hand disinfection before entering the RUMED
- Provision of departmental clothing, departmental shoes and, where applicable, personal protective equipment (PPE)
- Issuance of access authorizations/tokens/keys to those having to frequently enter or exit the RUMED and associated areas
- Clarification of any access needed, e.g. to equipment, machines, work surfaces
- Provision of accessory materials, e.g. ladders, tables, transport trolleys

Employers of external persons must teach their staff about correct hygiene and self-protection practices. External persons who have no employer/insurance protection must receive appropriate induction. The RUMED must instruct external persons about any specific behavioural rules and regulations in place.

It may be possible to dispense with measures within the cleaning and disinfection (C&D) area if the latter is not in operation and terminal disinfection was carried out after the last work shift in the C&D area.

A clean working environment ("island") must be arranged for e.g. validation engineers and technicians.

- Provision of a disinfected or covered surface (e.g. table, trolley).
- For tasks carried out at floor level the surface should be covered with cleaning covering material.

It may be possible to omit certain protective measures within this "island" (e.g. when programming loggers, etc.)

3.2 Recommendation of measures for cleaning and disinfection areas

	Remove jewellery, watch, rings from hands and wrists	Hygienic hand disinfection before entering the department	Visitor gown: no specific requirements	Disposable gown (PPE), water resistant	Hair covering	Oronasal mask	Goggles	Disposable gloves	Departmental clothing	Departmental shoes (shoe change)	Hygienic hand disinfection on leaving the area
	Cleaning/disinfection area with potentially infection material										
No direct contact e.g. observation of processes	+	+	+	-	+	0	0	0	0	0	+
Direct contact	+	+	-	+	+	+	+	+	+	+	+

„+" = required; **„0"** = may be required depending on the risk assessment results; **„-"** = not required but can be done voluntarily

3.3 Recommendation of measures for packing areas and post-sterilization areas

	Visitor gown: no specific requirement	Hair covering	Orofacial mask	Shoe covers	Disposable gloves	Departmental clothing	Departmental shoes (shoe change I)	Hygienic hand disinfection before entering the area
	Packing area, post-sterilization handling area							
Activities **without** contact with MDs (devices/instruments)	+	+	0	0	-	0	0	+
Activities **with** contact with MDs (devices/instruments)	-	+	0	0	-	+	0	+

„+" = required; **„0"** = may be required depending on the risk assessment results; **„-"** = not required but can be done voluntarily

When working outside the "island" validation engineers/technicians must take additional protective measures e.g. wear gloves and always remove them before returning and then perform hygienic hand disinfection. Equipment used outside the "island" should be cleaned using a wipe disinfection method before being returned to the "island". Disinfectant solutions must be made available; if special disinfectants are needed, these should be brought in by the user.

Equipment that became contaminated during use should be disinfected before being removed from the RUMED. It may be possible to *remove* equipment that had been used within the "island" from the RUMED without having to take any additional measures (avoiding contact with contaminated surfaces).

SERVICING AND REPAIR TASKS should if possible be undertaken outside the RUMED'S normal operating hours. If servicing and repair tasks must be carried out while the RUMED is in operation, perform risk assessment. Criteria to that effect can be defined in a risk-based infection control policy

SERVICING AND REPAIR TASKS should if possible be undertaken outside the RUMED'S normal operating hours.

The relevant surfaces and furnishings should be covered while work is in progress. Mobile equipment must be removed from the working area. Normal RUMED activities should not be continued within areas/zones for the duration of servicing /repair activities and surfaces must be cleaned using a wipe disinfection method on completion of such tasks.

Equipment transport crates should undergo wipe disinfection before being brought into the department. Transport trolleys are provided within the RUMED to ensure no trolleys are brought in. No cardboard boxes should be brought into the department. For tasks performed at floor level, the surface should be covered with a clean cover (e.g. fleece).

3.4 Switching between areas

There is no need to change departmental clothing if switching only once between the packing or post-sterilization areas and an external area or the cleaning and disinfection area of a RUMED.

If repeatedly **SWITCHING BETWEEN AREAS** departmental clothing must be changed in accordance with the RUMED regulations. For more prolonged, intensive tasks a disposable gown is generally not enough to provide the effective protection afforded by departmental clothing. Cleaning personnel, servicing technicians and validation engineers should avoid using "visitor gowns".

IF REPEATEDLY SWITCHING BETWEEN AREAS change departmental clothing in accordance with the RUMED regulations.

Regardless of the above, it may be advantageous to have available brief instructions tailored to the various groups of persons and request written confirmation of the same.

References

1. Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG)
2. Hygieneverordnungen der Bundesländer
3. Hygieneanforderungen der jeweiligen Einrichtung
4. Arbeitsschutzgesetz - § 8 Zusammenarbeit mehrerer Arbeitgeber
5. BiostoffV
   · § 2 Begriffsbestimmungen Abs.7/2 Abs.8, Abs. 9/3;
   · § 3 Einstufung von Biostoffen in Risikogruppen
   · § 5 Tätigkeiten mit Schutzstufenzuordnung;
   · § 14 Betriebsanweisung und Unterweisung der Beschäftigten
6. TRBA 250 Biologische Arbeitsstoffe im Gesundheitswesen und in der Wohlfahrtspflege 9.2 Beauftragung von Fremdfirmen
7. TRBA 400 – Handlungsanleitung zur Gefährdungsbeurteilung und für die Unterrichtung der Beschäftigten bei Tätigkeiten mit Arbeitsstoffen
8. TRBS 1112 Instandhaltung – 3.1 Regelungen der Zusammenarbeit
9. Lasi – Leitlinien zu Tätigkeiten mit Biostoffen – 1.4 Wer sind „andere Personen" die gefährdet werden können?
10. DGUV Vorschrift 1 § 6 Zusammenarbeit mehrerer Unternehmen
11. EN ISO 13485 6.4 Arbeitsumgebung und Lenkung der Kontamination
12. AWMF, S1 Leitlinie „Schutzhandschuhe für den Gesundheitsbereich (Kategorie III), AWMF-Register Nr. 029/021
13. KRINKO 'Händehygiene" (2016)
14. TRBA 200 Anforderungen an die Fachkunde nach Biostoffverordnung