

Edition: March 2014
GMBI 2014, No. 10/11 of 27.03.2014
Amended on 22.05.2014, GMBI No. 25
Amended on 21.7.2015, GMBI No. 29

Technical Rules for Biological Agents	Biological agents in health care and welfare facilities	TRBA 250
--	--	-----------------

The Technical Rules for Biological Agents (TRBA) reflect the state of the art, the state of occupational health and occupational hygiene as well as other sound work-scientific knowledge relating to activities involving biological agents.

The **Committee for Biological Agents (ABAS)** compiles or adapts the rules and they are announced by the Federal Ministry of Labour and Social Affairs (BMAS) in the Joint Ministerial Gazette (GMBI).

Within its scope of application, TRBA 250 “Biological agents in health care and welfare facilities” sets out in concrete terms the requirements of the Biological Agents Ordinance. If the technical rules are adhered to, the employer can assume that the corresponding requirements under the ordinance have been fulfilled. If the employer chooses another solution, that solution must achieve at least the same level of safety and health protection for employees.

This technical rule updates Technical Rule 250 “Biological agents in health care and welfare facilities” (of April 2012) and was compiled under the overall control of the “Health and welfare services” expert committee (FB WoGes) of the German Social Accident Insurance (DGUV) in application of the cooperation model (see “Leitlinienpapier¹ zur Neuordnung des Vorschriften- und Regelwerks im Arbeitsschutz” [Guidance document on the reorganisation of the rules and regulations in occupational safety and health] of 31 August 2011).

Contents

- 1 Scope of application
- 2 Definitions
- 3 Assessment of working conditions
- 4 Protective measures
- 5 Specific working areas and activities – special and additional protective measures
- 6 Conduct in case of accidents
- 7 Operating instructions and training of workers
- 8 Licensing, notification, record-keeping and information obligations
- 9 Cooperation between employees of various employers – assignment of external companies
- 10 Preventive occupational health care

¹ <http://www.gda-portal.de/de/VorschriftenRegeln/VorschriftenRegeln.html>

Annex 1:	Special isolation units (protection level 4) Part 1: Special isolation units – protective measures Part 2: Special isolation units – important addresses
Annex 2:	Instructions for preparing a hygiene plan
Annex 3:	Guidelines on the use of interns
Annex 4:	Experiences of using safety equipment
Annex 5:	Example of a model “Internal feedback form – evaluation of safety equipment”
Annex 6:	Example of a “Recording and analysis form for needle-stick injuries”
Annex 7:	Information on the correct fit and wearing duration of FFP masks, on the difference between surgical face masks and FFP masks, and on particle sizes in infectious aerosols
Annex 8:	Waste codes for facilities for the care and treatment of humans and animals in accordance with the LAGA Guidelines
Annex 9:	Example operating instructions pursuant to section 14 of the Biological Agents Ordinance
Annex 10:	Rules and regulations, literature

1 Scope of application

1.1 These technical rules apply to activities involving biological agents in areas of health care and welfare facilities in which

- people are medically examined, treated or cared for,
- animals are medically examined, treated or kept for care.

The scope of application includes activities involved in the supply and waste management of the above areas, as well as in sustaining their operations.

Activities involving biological agents within the scope of these rules include professional work involving humans, animals, products, objects or materials if biological agents arise or are released as a result of such work and workers can come into contact with them.

Note: For example, this can occur through inhalation of bio-aerosols, contact with skin or mucous membranes, or cuts and punctures.

These are non-specific activities pursuant to section 2(8) of the Biological Agents Ordinance (BioStoffV).

1.2 These technical rules do not apply to veterinary care of farm and zoo animals as regulated in TRBA 230 “Protective measures for activities involving biological agents in agriculture and forestry and comparable activities” or to activities in accordance with TRBA 120 “Versuchstierhaltung” [Keeping of laboratory animals].

1.3 These technical rules do not apply to laboratories that fall within the scope of application of TRBA 100 “Protective measures for activities involving biological agents in laboratories”. These include, for example, facilities and practices in the field of laboratory medicine, medical microbiology or hygiene and environmental medicine, as well as transfusion medicine laboratories.

It is not strictly necessary to apply TRBA 100 to laboratory activities in doctors’ practices, e.g. in the field of dermatology, urology and internal medicine, or in pharmacies

or dental facilities, provided these activities are minor in type and scale, as such activities are covered by TRBA 250. For example, laboratory activities of this kind include:

- pre-analytical activities such as sample preparation and work-up for analysis (e.g. addition of reagents such as EDTA, centrifuging to extract plasma or for urine sediment);
- the application of simple, rapid laboratory tests and microscopic detection methods;
- the application of indicative diagnostic cultivation methods in closed systems, such as dip culture media, without further diagnostics;
- sample storage and sample packaging for transport.

If further diagnostic work beyond that described above takes place (in particular cultivations), this work is subject to the requirements of TRBA 100. This can also apply to diagnostic investigations in veterinary practices, for example.

The applicable TRBA in the individual case is to be identified within the framework of the risk assessment.

1.4 For example, the activities stated in number 1.1 can take place in the following working areas and facilities:

- hospitals/clinics, doctors' and dentists' practices;
- veterinary hospitals and veterinary practices for small animals;
- rescue services, ambulance services and medical services;
- rehabilitation and residential care facilities;
- working areas in the field of inpatient and outpatient care of the sick and elderly, hospices;
- teaching and research departments in the field of human and veterinary medicine;
- blood and plasma donation facilities;
- anatomy, pathology and forensic medicine;
- practices of nonmedical practitioners;
- working areas in the field of medical cosmetics;
- working areas in which dental components are accepted or disinfected;

and in other working areas in which activities involving biological agents are carried out by members of the medical and paramedical professions.

1.5 The risk assessment pursuant to section 5 of the Occupational Safety and Health Act (ArbSchG) must verify, in each individual case, whether the Biological Agents Ordinance applies to special activities in the areas of health care and welfare facilities set out in number 1.1. If this is the case, the rules described here must be applied.

1.6 If the risk assessment establishes that comparable activities involving biological agents are carried out in working areas outside of health care and welfare facilities, the rules described here should be applied analogously.

Activities of this kind include, for example:

- the examination of excrement by the customs service in order to detect smuggled goods concealed within the body;
 - judicially ordered blood sampling as a measure under the Code of Criminal Procedure (so-called “polizeiliche Blutproben” [police blood samples]);
 - the carrying out of body searches in which contact with bodily secretions or contaminated objects is likely;
 - the taking back of care products that have been lent out, adjusting of prostheses and ostomy care in medical supply stores if contact with potentially infectious materials may occur in the process;
- and
- the transporting of sick persons/patient-transport services including all associated activities involving patients in which unintended contact may occur with bodily secretions, blood or infectious aerosols.

2 Definitions

2.1 **Biological agents** are conclusively defined in the Biological Agents Ordinance.

Pursuant to section 3 of the Biological Agents Ordinance (BioStoffV), biological agents are classified into four risk groups according to the infection risk they present.

For certain biological agents that were classified as risk group 3 and marked with two asterisks (**) in Directive 2000/54/EC, there is only a limited risk of infection for employees as transmission cannot normally occur by the airborne route. For simplicity's sake, these are hereinafter referred to as biological agents of “risk group 3(**)”.

Since, as a rule, these technical rules apply only to biological agents with infectious properties, the term “pathogen” is also used below.

2.2 **Examination and treatment** includes all of the activities involved in diagnosing, healing, curing or alleviating diseases, illnesses or physical injuries of humans or animals or in obstetrics.

2.3 **Care** includes all assistance provided to patients in the performance of habitual and regularly recurring tasks in the course of daily life in which contact with pathogens may occur.

2.4 **Work clothing** is clothing that is worn at work instead of or in addition to private clothing. Work clothing is clothing without a special protective function.

Contaminated work clothing is work clothing that has come into contact with bodily fluids, bodily excretions or body tissue in the course of activities that are subject to these technical rules. Such contamination cannot always be identified with the naked eye.

2.5 **Protective clothing** is clothing that is intended to protect workers from harmful effects at work or to prevent contamination of work/private clothing by biological agents.

2.6 **Potentially infectious materials** are materials that may contain pathogens and may lead to an infection in the event of corresponding exposure.

From experience, such materials include:

- bodily fluids, e.g. blood, saliva;
- bodily excretions, e.g. stool; and
- body tissue.

2.7 Working areas are areas in which activities involving biological agents are carried out. The working area may also include domestic areas, e.g. areas for the activities of care services in private dwellings and in assisted living.

2.8 Needle-stick injuries (NSIs), within the meaning of these technical rules, refer to all punctures, cuts and scratches to the skin caused by piercing or cutting instruments that are contaminated by patient material – regardless of whether or not the wound bleeds. NSIs can be caused by any used medical instrument that is capable of penetrating the skin, such as needles, lancets, cannulas, scalpels or surgical wires.

2.9 Patients are persons that are medically examined, treated or cared for in accordance with these rules. The term also includes persons with different designations in various facilities, e.g. residents, care users, service users.

Diseased animals or animals suspected of being diseased that are undergoing veterinary examination, treatment and care are also referred to as patients.

2.10 Professionally suitable persons are those who are able, because of the training they have completed and their experience, to identify risks of infection and take measures to address them, e.g. doctors, dentists, vets, health care professionals, nurses, medical-technical assistants, midwives, disinfection experts, medical, dental or veterinary assistants, ambulance officers and assistants, and geriatric nurses.

2.11 Notes are further explanations or references to associated areas of law; they do not give rise to a presumption of conformity within the meaning of section 8(5) sentence 3 of the Biological Agents Ordinance.

3 Assessment of working conditions

3.1 Risk assessment

3.1.1 Pursuant to section 4 of the Biological Agents Ordinance, the employer must conduct a risk assessment and document the results prior to the commencement of activities involving biological agents.

The risk assessment forms the basis for determining:

- how exposure can be avoided or, if this is not possible, reduced;
- which safe work processes are to be applied in addition; and
- what measures are to be taken to control unavoidable exposure.

Activities within the scope of application of these technical rules are non-specific activities pursuant to section 2(8) of the Biological Agents Ordinance. The employer must check what hazard workers may be exposed to based on the type of the activity and the infection pathways of the biological agents that are known to arise based on experience and/or that have been diagnosed. This check must take account of the duration of the activity and of how often it is carried out. The risk assessment must include workplace aspects that may affect the safety and health of workers. In particular, these include issues of work organisation, e.g. the qualifications of the persons

carrying out the work, mental loads, and the existence of time pressure. In this context, account must be taken of the human resources, working hours and organisation of work breaks.

3.1.2 The risk assessment is to be checked at least every second year and updated if necessary.

Furthermore, the risk assessment is always to be updated if this is necessitated by changes that could impair the safety of the workers or by new information on hazards.

For example, this information includes:

- findings indicating that the specified protective measures are not appropriate;
- plans to use new working equipment, work processes or workflows;
- the occurrence of new/modified hazards due to infectious diseases, e.g. outbreaks, new pathogens that call for special protective measures;
- findings from accidents, from preventive occupational health care or from diseases that have occurred in workers directly connected with the performed activities.

3.1.3 The risk assessment must be carried out with professional expertise. If the employer itself does not have the necessary knowledge, it must obtain advice from a person with professional expertise. Requirements for professional expertise are stipulated in TRBA 200 "Requirements for professional expertise in accordance with the Biological Agents Ordinance".

3.1.4 In accordance with the specific hazards determined for the activities that are to be carried out, occupational health aspects are to be incorporated into the risk assessment and assessed with professional expertise. As a first priority, this process must involve the appointed medical officer, who must have specific knowledge of the hazards at the corresponding workplaces.

In particular, occupational-health expertise is to be drawn upon for:

a) activities involving risks of infection where

- compulsory preventive occupational health care is to be arranged pursuant to the Ordinance on Occupational Medical Prevention or
- preventive health care is to be offered pursuant to the Ordinance on Occupational Medical Prevention;

b) activities

- that necessitate hygiene measures or special disinfection measures;
- that necessitate the organisation of special first-aid measures or post-exposure prophylaxis;
- for which personal protective equipment must be worn (e.g. protective gloves, respiratory protection); and
- in which exposures of the skin can occur that necessitate skin-protection measures.

3.2 Information gathering

3.2.1 The hazard posed to the workers results from the activities that are carried out and the biological agents that may arise in the process.

The employer must therefore determine which activities are performed and, based on experience, which biological agents may occur in the process.

In the absence of other findings, the possible presence of relevant pathogens (see number 3.3.2) must be expected for activities where contact may occur with:

- bodily fluids, e.g. blood, saliva;
- bodily excretions, e.g. stool; or
- body tissue.

In principle, this also applies to corresponding activities in veterinary medicine.

3.2.2 The binding classifications of biological agents into risk groups can be found in TRBA 460 for fungi, 462 for viruses, 464 for parasites and 466 for bacteria. The classification is determined by the infectious properties of the biological agents; sensitising and toxic effects do not influence the assignment to a risk group and are stated separately.

3.2.3 Specific information on infectious disease pathogens is provided on a national level by

- the Robert Koch Institute (RKI) and
- the Friedrich-Loeffler-Institut (FLI).

Help in carrying out the risk assessment is available in the form of:

- the corresponding Technical Rules for Biological Agents (TRBAs) and the decisions of the Committee for Biological Agents (ABAS);
- industry rules and information documents from the German Social Accident Insurance (DGUV) and the social accident insurance institutions.

Also important are the recommendations of the Commission of Hospital Hygiene and Infection Prevention (KRINKO), which primarily relate to patient protection but also contain aspects of worker protection.

Note: A full list of publications can be found in Annex 10.

3.2.4 In order to estimate the relevance of individual pathogens, it is necessary to consider the epidemiological situation in the catchment area. The gathering of information in medical facilities therefore calls for close cooperation with specialist hygiene personnel pursuant to section 23(8) of the Protection Against Infections Act (IfSG). Apart from this, relevant information can be obtained from the health or veterinary authorities. Current information on the epidemiological situation of individual pathogens is also published online, especially on the sites of the Robert Koch Institute and the Friedrich-Loeffler-Institut.

3.2.5 When patients who are suffering from an infectious disease or who have been colonised with pathogens of infectiological relevance are relocated, transferred or discharged, the employer must ensure that information on necessary protective measures for infection prevention is provided to the facilities that are receiving or providing further treatment to the patients. In the process, account must be taken of the state-specific hygiene regulations based on section 23(8) of the Protection Against Infections Act (IfSG). Care must be taken to ensure the protection of personal data.

3.3 Infection pathways and activity-specific hazards

3.3.1 Depending on the infection pathway, a differentiation is made between the following types of infections:

- **Contact infections** due to pathogens penetrating through broken skin and mucous membranes:
 - direct contact: transmission of pathogens from a colonised/infected person (or animal) through direct physical contact (touching) or through direct contact with infectious bodily fluids, e.g. splashes into the eye,or
 - indirect contact: transmission via contaminated objects. Infections due to, for example, ingestion of food with insufficient hand hygiene.
- **Airborne infections** through the inhalation of pathogen-containing materials into the lungs or after the airborne pathogens strike the mucous membranes of the upper respiratory tract in the form of:
 - droplets (from coughing, sneezing) or droplet nuclei, or
 - other aerosols, e.g. due to the use of rotating instruments, in high-frequency or laser surgery, or in compressed-air or vapour-pressure processes.
- **Injury-related infections** due to the (parenteral) penetration of pathogens into the body via:
 - cuts and punctures or
 - bites and scratches by humans and animals, insect bites.

3.3.2 In particular, the assessment of activity-specific hazards must evaluate the exposure possibilities associated with the activity in conjunction with the specific infection pathways of any pathogens that may be present. Workers that examine, treat or care for persons with blood-borne infectious diseases are therefore subject to an increased risk of infection in activities involving contact with blood, especially if this contact can occur due to injury, e.g. due to needle-stick injuries. On the other hand, a hazard is presented by airborne pathogens from patients with a corresponding infection, e.g. during manipulations in the mouth, nose, throat area or face.

It may also be necessary to consider multiple infection pathways. Some pathogens are transmitted very easily because of their low infective dose or high level of virulence, e.g. noroviruses.

By way of example, table 1 lists the occurrence and infection pathways of some pathogens with examples of activities.

Table 1 Occurrence and infection pathways of some pathogens with examples of activities (not exhaustive)

Material	Pathogens	Risk group	Infection pathways in accordance with no. 3.3.1	Example activities
Blood	Hepatitis B virus (HBV)	3(**)	Injury-related, possibly contact with mucous membrane or previously damaged skin	Operations; establishing parenteral access routes; taking blood samples
	Hepatitis C virus (HCV)	3(**)		
	Human immunodeficiency virus (HIV)	3(**)		
Wound secretion, drained fluid	Staphylococcus sp.	2	Contact	Wound care, changing bandages, drainage care
Respiratory secretions (sputum; tracheal secretions; bronchoalveolar lavage)	Seasonal influenza viruses	2	Airborne, contact	Aspiration; tracheotomy; intubation; extubation, provocation of coughing (physiotherapy, inhalation)
	Corynebacterium diphtheriae	2		
	Streptococcus pyogenes	2		
	Haemophilus spp.	2		
	Mycobacterium tuberculosis complex	3		
Stomach contents, vomit	Noroviruses	2	Airborne, contact	Gastroscopy, nursing measures
	Rotaviruses	2		
Stool	Noroviruses	2	Contact	Operations on the intestines; proctoscopy, colonoscopy; material extraction; nursing measures
	Rotaviruses	2		
	Salmonella enteritidis	2		
	Salmonella typhi	3(**)		
	Campylobacter spp.	2		
	Clostridium difficile	2		
	Hepatitis A virus (HAV)	2		
Hepatitis E virus (HEV)	2			

The Robert Koch Institute's website provides further information on individual infectious disease pathogens in the "Infektionskrankheiten A-Z" (A-Z of infectious diseases) section, as well as expert information on activity-specific hazards in the pathogen-specific "RKI-Ratgeber für Ärzte" (RKI guides for doctors).

3.4 Assignment to protection levels

3.4.1 General remarks

- (1) Activities in health care facilities within the meaning of the Biological Agents Ordinance are to be assigned to a protection level corresponding to their infection risk.

These include workplaces in which people are medically examined, treated or cared for as inpatients or people are medically examined and treated as outpatients (see section 2(14) of the Biological Agents Ordinance).

Note: Appropriate protective measures are also to be specified for activities that need not be assigned to a protection level pursuant to the Biological Agents Ordinance. For example, this includes activities in outpatient care or in veterinary medicine, which are addressed in numbers 5.1 and 5.9 respectively. Since some of the activities carried out here are indeed comparable with those assigned to a protection level, appropriate cross references are made.

- (2) A differentiation is made between four protection levels according to the level of infection risk resulting from the activity. Specific protective measures are assigned to the protection levels.

Since, for activities in health care, there is frequently no concrete knowledge available on the occurring pathogens, the assignment to a protection level is determined based on possible contact with potentially infectious materials, e.g. bodily fluids.

If the infection or colonisation status is known and the patient has an infectious disease or a colonisation, the required degree of protection and, therefore, the assignment to the corresponding protection level are determined by the risk group and properties of the biological agent, e.g. the infective dose and infection pathway, in conjunction with the activity. Account must also be taken of the epidemiological situation.

- (3) Working areas where activities largely of the same protection level take place can also be assigned to this protection level as a whole.

For example, an operating department or the contaminated side of the central sterilisation facility can therefore be assigned to protection level 2 as a whole, since it used largely for activities of protection level 2.

On the other hand, it is not sensible to assign the patient room to a specific protection level as a whole. In addition to activities of protection level 2,

- e.g. taking blood, changing drainage bottles, caring for incontinent patients and residents,

the areas represented by patient rooms are also used for activities of protection level 1,

- e.g. routine cleaning work, as well as for

activities that do not fall within the scope of the Biological Agents Ordinance,

- e.g. serving food.

3.4.2 Description of protection levels

(1) Protection level 1

Activities are to be assigned to protection level 1 if they involve

- no handling of or, very rarely, minor contact with potentially infectious materials, such as bodily fluids, excretions or tissue

and

- no other obvious risk of infection.

Such activities are to be carried out with the minimum protective measures set out in number 4.1.

Example activities of protection level 1:

- X-ray examination, magnetic resonance imaging;
- ultrasound scans;
- ECG and EEG examinations;
- certain physical examinations, e.g. auscultation of a patient with no symptoms of respiratory infection;
- cleaning work on uncontaminated surfaces.

Activities in blood-donor services can be assigned to protection level 1 if, following characterisation of the blood samples, the presence of pathogens of risk group 2 or higher can be ruled out. For example, this is the case if the donor is clinically unremarkable and the sample materials are free of HIV, HBV and HCV. As a rule, one can then proceed on the basis that, although a risk of infection by other pathogens cannot be ruled out, it is nevertheless negligible if the general hygiene measures are complied with.

(2) Protection level 2

As a rule, activities are to be assigned to protection level 2 if

- there may be regular and not merely minor contact with potentially infectious materials, such as bodily fluids, excretions or tissue,

or

- there is another obvious risk of infection, such as via an airborne infection or via punctures and cuts.

For activities involving bodily fluids and excretions that are known to contain pathogens of risk group 3(**), the risk assessment must check whether it is possible to assign the activities to protection level 2 or whether, in the individual case, it is necessary to assign them to protection level 3, e.g. if there is a risk of splashes contaminating skin or mucous membranes.

For example, activities assigned to protection level 2 include:

- puncturing, injecting, taking blood;
- establishing vascular access routes;
- taking samples for diagnosis;
- endoscopy/cystoscopy;
- catheterisation;
- operating;

- carrying out autopsies;
- stitching and dressing wounds;
- intubation, extubation;
- aspiration of respiratory secretions;
- changing nappies and clothing contaminated with faeces;
- washing, showering, bathing incontinent patients;
- handling persons who are a danger to others with a risk of bites or scratches;
- dental treatment;
- acceptance and disinfection of contaminated components in dental laboratories;
- handling used instruments (cannulas, scalpels);
- handling infectious or potentially infectious waste;
- handling (taking off, discarding, collecting) used laundry from patients and residents that is contaminated with bodily fluids or excretions;
- cleaning and disinfecting contaminated surfaces and objects;
- working on contaminated medical products (incl. medical devices), aids (e.g. orthopaedic shoes) and other objects if these have not been disinfected prior to commencement of the activities due to insufficient accessibility or for another plausible reason;
- exchanging syringes in drug outpatient clinics.

(3) Protection level 3

Activities are to be assigned to protection level 3 if the following criteria are met:

- a) Biological agents of risk group 3 are present that can cause an infection even at a low concentration

or

high concentrations of biological agents of risk group 3 may occur

and

- b) activities are performed that make transmission possible, e.g. risk of aerosol formation, splashes or injuries.

This also applies in the event of suspicion to that effect.

In exceptional cases, this can also apply to biological agents of risk group 3(**) (see number 3.4.2 paragraph 2).

The treatment of a patient with open tuberculosis during the infectious phase is to be assigned to protection level 3 due to the high risk of infection via aerosols.

(4) Protection level 4

Activities within the framework of the examination, treatment and care of patients who are or are suspected of being infected with a highly contagious, life-threatening pathogen (biological agent of risk group 4) are to be assigned to protection level 4. Biological agents of risk group 4 include, for example, the Ebola, Marburg and Lassa viruses.

4 Protective measures

In order to combat a possible risk to workers due to pathogens, the employer must arrange the necessary protective measures. These measures are based on the classification of the activities into one of the four protection levels according to their risk of infection pursuant to number 3.4. Unless exemptions are set out in number 5, the minimum protective measures in number 4.1 are to be observed for all activities within the scope of application of these rules.

For activities that are assigned to protection levels 2 to 3, this general minimum standard is to be supplemented by further protective measures in accordance with numbers 4.2 to 4.3. Number 4.4 includes all specific protective measures of protection level 4. If necessary, the protective measures of protection levels 2 to 4 are to be adapted to the activity and workplace based on the results of the risk assessment.

Number 5 addresses special working areas and activities for which additional protective measures may be necessary or for which some measures can also be dispensed with. This section deals with the protective measures for activities in outpatient care and veterinary medicine, for which no protection levels need be specified according to the Biological Agents Ordinance.

4.1 Minimum protective measures

4.1.1 Hand-washing station

- (1) The workers are to be provided with easily accessible hand-washing stations with running hot and cold water, dispensers for skin-cleaning agents, and disposable towels.
- (2) The washbasins are to be fitted with taps that can be operated without hand contact. Suitable taps include, for example, single-lever household mixer taps with an extended lever that can be operated using the wrist, or self-closing (push-button) washbasin taps.
- (3) If the requirements under paragraph 2 did not apply until these technical rules were announced, retrofitting is necessary only in connection with a renovation or significant redesign of the hand-washing station.
- (4) Paragraph 1 does not apply to rescue and ambulance vehicles.

4.1.2 Hygienic hand disinfection

- (1) Where hygienic hand-disinfection facilities are present, disinfectant dispensers are to be provided. The minimum requirements for hygienic and safe use of these dispensers must be observed.
- (2) For reasons of worker protection, staff must perform a hygienic hand disinfection before leaving the working area if any of the following have occurred:
 - patient contact,
 - contact with potentially infectious materials or surfacesor
 - removal of the protective gloves.

Note: For patient-protection reasons, hygienic hand disinfection is also carried out before patient contact and/or before activities that are to be carried out aseptically.

4.1.3 Skin protection and care

- (1) In principle, hand washing places a burden on the skin and is therefore to be reduced to a necessary minimum. Please note that disinfection takes priority over cleaning. Activities in damp conditions lead to an increased burden on the skin. The employer must check whether it is possible to reduce burdens of this kind. In particular, gloves must be worn only for as long as necessary.
- (2) The employer must provide suitable skin-protection and skin-care products. It must compile a skin-protection plan for the selection of preparations for skin cleaning, protection and care, and staff must be trained on their regular and correct use.

Protective and surgical gloves must be applied only to dry hands because of the risk of skin damage and perforation.

Where airtight protective gloves are worn for a prolonged period, it may also be sensible to wear glove liners made of cotton or other fabrics with comparable properties (absorbency, skin tolerance).

Notes: Staff with skin damage in the area of the forearms and hands are to be advised to present themselves to the medical officer.

For more information, see TRGS 401 "Risks resulting from skin contact – identification, assessment, measures".

4.1.4 Surfaces

Surfaces (floors, work surfaces, surfaces of equipment) must be easy to clean and resistant to the cleaning agent, as well as, where applicable, to any disinfectants that are used.

4.1.5 Hygiene plan

For the individual working areas, the employer must prepare – and monitor adherence to – a written hygiene plan specifying measures for preventing an infection risk in addition to suitable structural requirements in accordance with the risk assessment. The hygiene plan must include rules on disinfection, cleaning and sterilisation, as well as on supply and waste management. In the process, one document would ideally combine, on the one hand, the occupational safety and health requirements set out in sections 9(2) and 11(1) of the Biological Agents Ordinance and, on the other, the patient-protection requirements pursuant to sections 23 and 36 of the Protection Against Infections Act. Annex 2 provides instructions for preparing a hygiene plan.

4.1.6 Food and beverages

Workers must not consume or store food and beverages in workplaces where there is a risk of contamination by biological agents. The employer must provide easily accessible break rooms or break areas (separated areas within rooms of the workplace) for this purpose.

4.1.7 Jewellery and fingernails

For example, the following items must not be worn on the hands or forearms in the event of activities requiring hygienic hand disinfection:

- jewellery;
- rings, including wedding rings;
- wristwatches;
- piercings;
- false nails;
- friendship bracelets.

Fingernails are to be kept cut short and round and should not extend beyond the fingertip.

Note: Painted nails can compromise successful hand disinfection. Whether employees must go without nail varnish is therefore to be decided within the framework of the risk assessment.

4.1.8 Changing rooms and work clothing

Pursuant to section 9(1) number 4 of the Biological Agents Ordinance, the employer must ensure that changing rooms separated from the workplace are available if work clothing is required; the work clothing is to be changed and cleaned regularly and as needed. Employees must use the changing rooms provided.

4.1.9 Diagnostic samples

Diagnostic samples for shipment are to be packed according to the regulations set out in the transport legislation. At the same time, patient samples (from persons or animals) with a minimal probability of containing pathogens are exempted from the dangerous goods regulations that apply to transport by road (ADR²) and rail (RID³), provided the packaging meets certain conditions. If the samples have been shown to contain pathogens or if the presence of such agents is suspected, the corresponding packaging and labelling provisions under the transport legislation apply (P620 for category A substances that pose a risk of infection and P650 for category B substances that pose a risk of infection). The requirements both for exempted diagnostic samples and for category B samples up to risk group 2 are covered by Deutsche Post AG's "Regelungen für die Beförderung von ansteckungsgefährlichen Stoffen - Brief national" [Regulations for the carriage of infectious substances – domestic letter].

Note: Patient samples assigned to category B that contain pathogens of risk group 3, as well as patient samples assigned to category A, are not approved for postage.

An overview of the applicable transport regulations can also be found in the brochure "Patientenproben richtig versenden" [Correct shipment of patient samples] from the German Social Accident Insurance Institution for the Health and Welfare Services (BGW).

4.1.10 Training and professional suitability

The employer may assign activities within the scope of these technical rules only to persons who have completed training in health care professions or who are trained and supervised by a professionally suitable person.

The supervision requirement is satisfied if

² ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

³ RID: Regulation concerning the International Carriage of Dangerous Goods by Rail

- a) the supervisor supervises the person requiring supervision until the supervisor is convinced that they have mastered the assigned activity, and
- b) the supervisor subsequently carries out spot checks to ensure that the assigned activity is being carried out correctly.

Note: See annex 3 “Guidelines for the use of interns” for information on employing interns.

4.1.11 Protection of young people at work and maternity protection

The employer may assign young people and expectant or nursing mothers to carry out activities involving biological agents only insofar as this is compatible with the provisions of the Act on the Protection of Young People at Work and the Maternity Protection Act and its associated regulations, especially the maternity protection ordinances.

4.2 Protective measures for activities of protection level 2

The following protective measures are to be observed in addition to the measures set out in number 4.1.

4.2.1 Surfaces (disinfection)

In addition to the requirements set out in number 4.1.4, surfaces (work surfaces and adjacent wall surfaces, floors, surfaces of installed equipment, surfaces of devices and apparatus that may come into contact with biological agents) must be resistant to disinfectants.

Note: Depending on the expected contamination, this requirement may be satisfied for wall surfaces by, for example, correctly painting them with coating materials or coating systems of class 2 wet scrub resistance⁴.

4.2.2 Toilets

- (1) In hospitals, practices and other facilities in which activities of protection level 2 are regularly carried out, separate toilets must be provided for workers and patients. Care must be taken to ensure that the toilet rooms are of sufficient size and are available in a number that is appropriate to the number of workers.

Note: See Technical Rule for Workplaces ASR A4.1 “Sanitärräume” [Sanitary rooms] for information on calculating the number of toilets and on the design of toilet rooms.

- (2) If, until these technical rules were announced, it was not necessary to set up separate toilets because of a right of continuity, paragraph 1 applies only in the event of a renovation or significant redesign of the sanitary area.
- (3) For reasons of hygiene and protection against infections, toilets used by workers must be cleaned and, if necessary, disinfected as required, but at least every working day.

Note: Studies have shown that pathogen-containing aerosols can be released in the flushing process.

⁴ DIN EN 13300 “Water-borne coating materials and coating systems for interior walls and ceilings”

4.2.3 Minimising aerosols

All processes used must be carried out in a way that minimises the formation of aerosols. Examples of this include:

- capturing smokes that are harmful to health when using medical lasers and high-frequency cauterising equipment;
- using corresponding extraction technology during dental treatment procedures; and
- covering the ultrasound bath or fitting it with an extraction system during the cleaning of instruments.

4.2.4 Access restriction

Access to working areas that are assigned to protection level 2 as a whole must be restricted to authorised persons. For more information, see number 3.4.1 paragraph 3.

4.2.5 Prevention of needle-stick injuries

- (1) Where used medical instruments and devices are handled, measures must be taken to minimise the risk of injury or infection for workers.

In this regard, it is essential to adopt an integral approach to minimising the risk of needle-stick injuries (NSIs) that makes use of all technical, organisational and personal measures. This includes issues of work organisation and the establishment of safety awareness, the procedure for recording NSIs, and the implementation of follow-up measures.

- (2) The employer must employ a sufficient number of professionally suitable personnel in order to prevent punctures and cuts, e.g. due to operating errors because of haste.

Furthermore, protective measures are to be specified according to the ranking described in the following paragraphs.

- (3) Priority is to be given to selecting suitable and safe work processes and equipment that render the use of pointed and sharp medical instruments superfluous. For example, these include:

- needle-free infusion systems with a check valve for connection to venous access points for injecting medications and taking blood samples;
- plastic cannulas for drawing bodily fluids without the use of needles;
- blunt cannulas for rinsing root canals in endodontics;
- blunt round-bodied needles for suturing less-dense internal connective tissue/fasciae/muscles.

- (4) Should it be necessary to use pointed and sharp medical instruments, it is essential to use working equipment that has a safety mechanism (hereinafter “safety equipment”), complies with numbers 1 to 7 below, and presents no or only a minor risk of punctures and cuts, provided this is technically possible and necessary for preventing a risk of infection.

1. Safety equipment is to be used for the following activities or in the following working areas with an increased risk of infection or accident:

- treatment and care of patients who have been shown to be infected with pathogens of risk group 3 (including 3**) or higher;
 - treatment of patients who are a danger to others;
 - activities in rescue services and the emergency department;
 - activities in hospitals or clinics in law enforcement.
2. Notwithstanding point 1, safety equipment is to be used for all activities where there is or can be assumed to be a risk of infection due to possible puncture injuries. In particular, these activities include:
- taking blood samples,
 - making other punctures to extract bodily fluids,
 - establishing vascular access routes.
3. For all other activities that do not fall under points 1 and 2, the employer must assess the risk of accident and infection in the risk assessment and take appropriate measures. If a risk of infection must be assumed and this cannot be minimised through organisational and personal measures, priority is to be given to the use of safety equipment.
- Note: At the same time, it should be remembered that it is not helpful to use both safety equipment and conventional instruments in one working area for comparable activities. This could lead to operating errors and reduced acceptance of the safety equipment by workers.*
4. Safety equipment for the prevention of punctures and cuts must have the following properties:
- It must put neither patients nor workers at risk.
 - It must be easy to use and application-oriented.
 - The safety mechanism is an integral part of the system and is compatible with other accessories.
 - The activation of the safety mechanism must:
 - be self-triggering or allow single-handed operation;
 - be possible immediately after use;
 - rule out subsequent use;
 - be indicated by a clear signal (tactile, visible or audible).
5. The safety equipment must be selected specifically for the application, especially from the point of view of manageability and acceptance by employees.

In the selection process, the employer must consider the following approach:

- inclusion of users and employee representatives;
- gathering of information on safety equipment that is currently available on the market, including generally available experiences of dealing with safety equipment (see annex 4 “Experiences of using safety equipment”);
- selection preferably using practical specimens with users’ involvement;
- evaluation of practical in-house experience with promising safety equipment, e.g. in one department. One option is to accompany this with the use of feed-

back forms (see annex 5 “Example of a model ‘Internal feedback form – evaluation of safety equipment’”).

6. During the introduction of safety equipment, it is to be ensured that employees are able to use this correctly. It is also necessary to provide information on the safety equipment and its handling in practical applications.
 7. The effectiveness of the implemented measures is to be verified. This also includes a process for the complete recording and analysis of NSIs in order to identify technical and organisational causes of accidents and to allow remedial action to be taken (for more information, see annex 6 “Example of a ‘Recording and analysis form for needle-stick injuries’”).
- (5) Used cannulas must not be reinserted into the cannula cover (protective cap). They must also not be bent or snapped off, unless this manipulation is intended to activate a built-in protective device.

The safety mechanism must not be overridden by manipulation.

If activities are performed

- that call for repeated use of the medical instrument according to the technical state of the art, e.g. for local anaesthesia in dentistry,

and

- in which the cannula must be reinserted into the cannula cover,

this is permissible, provided a process is used that allows safe reinsertion of the cannula into the cannula cover with one hand, e.g. using a protective-cap holder.

The process to be used must be specified in work instructions in accordance with section 14(4) numbers 2 and 3 of the Biological Agents Ordinance.

- (6) Used pointed and sharp medical instruments, including those with a safety mechanism, are to be collected by the user in sharps bins immediately after use.

The sharps bins must safely enclose the waste. Furthermore, the bins are to be positioned as close as possible to the place in which the pointed, sharp or fragile medical instruments are used. The contents must not be transferred from one bin to another.

The sharps bins must have the following properties:

- They are disposable and can be securely sealed.
- They prevent the contents from escaping, e.g. when exposed to pressure, impacts or falls.
- They are impenetrable.
- Their characteristics are not impaired by moisture.
- The container size and filling hole are adapted to the items that are to be disposed of.
- They do not open during the stripping off of cannulas.
- They are clearly identifiable as sharps bins and cannot be mixed up (colour, shape, labelling).

- The sharps bins are adapted to the disposal concept and syringe systems that are used (stripping device for various cannula connections).
- Their maximum fill quantity is stated and their fill level can be identified.

Note: DIN EN ISO 23907 describes the test requirements that sharps bins of this type must meet.

Full sharps bins are to be disposed of safely.

4.2.6 Provision and use of personal protective equipment (general)

- (1) Pursuant to section 8(4) number 4 of the Biological Agents Ordinance, the employer must additionally provide sufficient quantities of personal protective equipment (PPE), including protective clothing, in accordance with numbers 4.2.7 to 4.2.10 whenever structural, technical and organisational measures are not sufficient to exclude or adequately reduce the risk due to pathogens.
- (2) The PPE is to be selected based on the results of the risk assessment. Employees are to be suitably involved in selecting the PPE. The use of stressful PPE is to be restricted to the absolutely necessary level and must not be a permanent measure.
- (3) The employer must clean and/or disinfect, repair and, if necessary, properly dispose of the PPE provided, including suitable protective clothing. It must take the necessary steps to ensure that PPE can be taken off safely and stored separately from other pieces of clothing when employees leave the workplace.
- (4) Employees must use the PPE provided for as long as a risk is present.

4.2.7 Protective clothing

- (1) Protective clothing provided by the employer must be worn if contamination of work clothing is to be expected during the performance of an activity. For example, contact with bodily fluids or excretions is to be expected during the care of patients
 - with incontinence or
 - with secretory wounds.
- (2) The selected protective clothing must cover the work clothing at all of the points that could be contaminated as a result of the activity. Liquid-tight protective clothing or footwear provided by the employer is to be worn to protect against possible soaking of clothing and/or footwear.
- (3) If the work clothing becomes contaminated during the performance of activities for which protective clothing need not be worn according to the risk assessment, the work clothing must be changed and must be disinfected and cleaned by the employer as if it were protective clothing.
- (4) Protective clothing or contaminated work clothing must not be taken home by the employees for cleaning. Worn protective clothing is to be stored separately from other clothing. Employees must not enter break or stand-by rooms while wearing protective clothing or contaminated work clothing.

4.2.8 Protective gloves

- (1) Protective gloves must be worn for activities that are to be expected to lead to contact between the hands and potentially infectious materials.

For example, activities involving possible hand contact with bodily fluids or bodily excretions include:

- changing bandages,
- taking blood,
- inserting bladder catheters,
- washing incontinent patients.

(2) The following types of gloves are suitable:

- liquid-tight, unpowdered and hypoallergenic medical gloves⁵ with an accepted quality level (AQL) of ≤ 1.5 for possible contact with bodily fluids and excretions;
- liquid-tight, unpowdered and hypoallergenic protective gloves that are additionally resistant to cleaning agents and disinfectants⁶ and have an extended cuff to allow them to be folded over during cleaning and disinfection work to prevent contaminated cleaning fluid from running back under the glove.

Note: The wearing of liquid-tight gloves for a significant proportion of the working time constitutes working in wet conditions (see number 4.1.3 “Skin protection and care” for further information). For more information, see TRGS 401 “Risks resulting from skin contact – identification, assessment, measures”.

Depending on the activity, additional glove properties may be required.

4.2.9 Eye and face protection

Eye or face protection provided by the employer must be worn if splashing or spraying of potentially infectious materials or liquids is to be expected during an activity and technical measures do not constitute sufficient protection.

For example, this may apply in the case of:

- surgical procedures, e.g. in vascular surgery, orthopaedics (cutting work on bones);
- endoscopic investigative procedures;
- punctures of arteries;
- intubation, extubation, care and changing of tracheal cannulas;
- dental activities such as removing tartar with ultrasound;
- cleaning of contaminated instruments by hand or with ultrasound;
- activities in pathology, e.g. during work using hand-operated equipment or during compression of the chest of a deceased person due to lifting and relocation.

The following are examples of suitable types of eye and/or face protection:

- glasses with earpieces and side guards, e.g. with corrective lenses;
- over glasses;

⁵ DIN EN 455 Parts 1 to 3 “Medical gloves for single use”

⁶ DIN EN 374-1: Protective gloves against chemicals and micro-organisms, as well as DIN EN 420: Protective gloves – General requirements and test methods

- goggles;
- visor, face shield.

Depending on the exposure conditions, it may also be necessary to wear respiratory protection, such as an FFP2 mask⁷, e.g. when pathogen-containing aerosols are released.

4.2.10 Respiratory protection

- (1) In order to achieve the required minimisation of risk due to airborne pathogens, respiratory protection is worn once all other technical and organisational measures have been exhausted (especially the protection of employees by vaccination and hygiene measures). If patients are treated who are suspected of having a disease caused by airborne pathogens, the employer must define a company-specific concept for protecting employees against airborne infections within the framework of the risk assessment.

Note: In regard to a pandemic situation, see ABAS Decision 609 “Arbeitsschutz beim Auftreten einer nicht ausreichend impfpräventablen humanen Influenza” [Occupational safety and health in the event of an outbreak of human influenza that is insufficiently preventable by vaccination].

- (2) The employer must provide suitable FFP masks for the purposes mentioned above.

Notes: Filtering face pieces (FFPs) can reduce the quantity of infectious aerosols in inhaled air by up to 92% in the case of FFP2 masks and by up to 98% in the case of FFP3 masks.

In addition to the filter properties, the tightness of the mask’s fit has a particularly decisive influence on its effectiveness. The stated reduction values apply only in the case of an optimum fit, which can be achieved only through careful, correct application of the mask. As a rule, wearing a well-adjusted FFP2 mask constitutes suitable protection against infectious aerosols, including viruses, as it can be assumed that these are bound to the smallest droplets or droplet nuclei.

- (3) Masks of at least class FFP2 are to be worn if patients are infected with airborne pathogens and if activities must be performed on or near these patients.

Notes: For example, such activities include caring for and nursing patients with diseases caused by airborne pathogens, especially if the employees may be exposed to the patients’ coughs in the process.

The wearing of FFP2 masks can be dispensed with in individual cases if the employee concerned is known to have sufficient immune protection, e.g. due to vaccination.

A surgical face mask is not a form of respiratory protection and cannot protect the wearer from inhalation of aerosols but does effectively protect the mouth and nose from contact with contaminated hands. If activities are performed on patients that are suffering from airborne diseases and the patient is wearing a surgical face mask, it is usually sufficient for the person treating them to simul-

⁷ FFP: filtering face piece

taneously wear a surgical face mask as a suitable hygiene measure. This does not apply if the pathogen is assigned to risk group 3.

- (4) The correct putting on of FFP masks is to be demonstrated and practised. It is helpful to test the tightness of fit using suitable methods (fit test) during training.

Note: Refer to annex 7 for information on the correct fit and wearing duration of FFP masks, as well as on the difference between surgical face masks and FFP masks. Beard hairs in the area of the sealing line between the breathing mask and the skin of the face can impair the protective effect of the protective mask. This is to be pointed out to individuals with beards.

4.3 Protective measures for activities of protection level 3

The following protective measures are to be observed in addition to the measures set out in numbers 4.1 and 4.2.

4.3.1 Assignment of activities

Activities of protection level 3 must only be assigned to employees with professional expertise that have been inducted and trained based on the work instructions.

Note: Requirements for professional expertise are specified in TRBA 200 "Requirements for professional expertise in accordance with the Biological Agents Ordinance".

4.3.2 Restriction of the number of employees

The number of employees performing activities of protection level 3 is to be kept to a necessary minimum.

4.3.3 Separation

If necessary, areas in which activities of protection level 3 take place are to be separated from the other working areas by an anteroom, an airlock area or a similar measure.

4.3.4 Personal protective equipment

In addition to the PPE according to numbers 4.2.6 to 4.2.10, it may be necessary to use special PPE for activities of protection level 3.

It is necessary to wear respiratory protection of at least class FFP2 when treating a patient with open pulmonary tuberculosis during the infectious phase.

Note: For more information, please refer to the recommendations of the German Central Committee against Tuberculosis entitled "Tuberculosis Infection Control", published in 2012 in the online publication "Pneumologie".

4.4 Protective measures for activities of protection level 4

4.4.1 Special isolation units

The examination, treatment and care of patients infected with a pathogen of risk group 4 are carried out in a special isolation unit (treatment centre/patient ward of protection level 4). The protective measures that must be observed here are set out in concrete terms in annex 1 part 1. Information on these treatment centres can be found in annex 1 part 2.

4.4.2 Occurrence of suspect cases

In order to ensure minimum protection for employees caring for persons suspected of having a disease while outside of a special isolation unit, the risk assessment for emergency departments and rescue services must specify what personal protective equipment is to be kept ready and used. Annex 1 part 1 number 1.4 can provide some guidance for selecting the personal protective equipment (PPE).

The personnel concerned must be trained on the correct use of this protective equipment.

Where possible, patients are to remain at the place of discovery (practice, rescue station, emergency department, ward, etc.) in case of suspicion and are then to be transferred immediately to a facility with a special isolation unit according to the specified procedure in the respective federal states. Persons who have come into contact are gathered in a separate area.

5 Specific working areas and activities – special and additional protective measures

5.1 Outpatient care

5.1.1 Home care

- (1) Home care of persons in need of care (“care users”) by outpatient care services includes activities within the framework of
 - **general care**, e.g. washing and showering, dental hygiene, assistance with going to the toilet or caring for incontinent persons, assistance with eating, assistance with dressing and undressing,and
 - **therapeutic care**, e.g. injections and infusions, taking blood samples, changing bandages, administering medicines, drainage and wound care, inserting and changing catheters, medical assistance,which may also include activities in the area of
 - **intensive care**, e.g. port care, changing and care of tracheal cannulas, ventilation therapy, special wound care, insertion and care of gastric feeding tubes, care of fistulas of the kidney, gall bladder and bowel.
- (2) Some of these activities, e.g. assistance with dressing and undressing, are comparable with activities of protection level 1, but many are comparable with activities of protection level 2, as they may lead to contact with potentially infectious materials such as blood, excreta, secretions, excretions.

Note: See number 3.4.2 paragraphs (1) and (2).

- (3) While delivering care, employees perform activities in the domestic areas of persons requiring care. These may be private households or, to an increasing extent, new forms of dwelling such as shared accommodation with outpatient assistance in which, for example, dementia sufferers are looked after. The conditions within these private living areas are therefore to be included in the risk assessment.

- (4) Protective clothing, personal protective equipment and work equipment are usually provided in the staff rooms of the outpatient service. If activities such as the cleaning of contaminated work or protective clothing or PPE are also carried out here, these premises must also be included in the risk assessment.
- (5) The employer must prepare **work instructions** containing stipulations for the handling of work clothing and personal protective equipment, as well as for the necessary hygiene and disinfection measures.
- (6) Work clothing is to be worn during **care activities**. If contamination of work clothing is to be expected, then the protective clothing provided by the employer must be used in conjunction with the necessary personal protective equipment in each instance (protective gloves, liquid-tight aprons, FFP masks⁷ as respiratory protection if infectious aerosols may be released). The employer must specify which protective clothing and personal protective equipment (PPE) is to be worn for which activities. It must also specify when a surgical face mask is necessary as a form of contact protection.
- (7) Unless it is a disposable product, any contaminated protective clothing or PPE is to be disinfected and cleaned by the employer using suitable methods. Contaminated work clothing is to be handled in the same way.

Containers are to be provided for collecting contaminated work clothing (e.g. a sufficiently resistant laundry bag that can be washed along with its contents) and for collecting used, reusable protective clothing or PPE.

- (8) The required hygiene measures, especially hygienic hand disinfection, are to be implemented according to the work instructions. Furthermore, skin-protection and skin-care products are to be made available to the employees.

Notes: Hand disinfection should be carried out close to the activity. Medical disinfectant bottles that fit into white coat pockets have proven to be effective for this purpose.

Disinfectants must be selected taking account of their possible harmful effects on health, along with their purpose and spectrum of activity.

Use of the available washing facilities in the care user's domestic area should be contractually ensured.

- (9) Safety equipment (safety lancets, instruments with a safety mechanism for drawing blood) – as described in number 4.2.5 – is to be used to prevent punctures and cuts.
- (10) The bins described in number 4.2.5 paragraph 6 are to be brought along and used for disposing of used pointed and sharp working equipment. Used cannulas must not be reinserted into the cannula cover. Instruments with an activated safety mechanism must also be disposed of in a corresponding fashion.

Note: It might be possible to dispose of the bins via the care user's household waste. See annex 8 – waste code 180101 for further information.

- (11) If reusable contaminated working equipment cannot be disinfected/treated on-site, suitable transport containers must be available for the equipment.
- (12) If special infection risks arise as a result of an illness/infection of the care user/patient, further protective measures are to be specified within the framework of the risk assessment, taking account of the infection pathway.

5.1.2 Activities in staff rooms

- (1) The following measures are to be complied with if, within the **staff rooms**, the outpatient care service provides a central area in which contaminated work clothing is washed, protective clothing or PPE is disinfected and cleaned, contaminated working equipment is treated, and/or contaminated waste is collected centrally for disposal.
- (2) The working area in which the aforementioned activities take place must have surfaces (floors, work surfaces, surfaces of work equipment) that are easy to clean and that are resistant to the cleaning agents and disinfectants used.
- (3) Contaminated laundry must not be sorted prior to washing. The filled laundry bag is to be put unopened into a suitable washing process.
- (4) The employer must provide the following:
 - a hand-washing station as described in number 4.1.1;
 - disinfectant dispensers for hygienic hand disinfection as described in number 4.1.2; and
 - skin protection and care products as described in number 4.1.3.
- (5) Contaminated waste is to be collected and disposed of according to the requirements of the Working Group of the German Federal States on Waste (LAGA).

Note: See number 5.6 and annex 8.

5.2 Maintenance

5.2.1 Maintenance is understood to mean servicing, inspection and repair. Maintenance work constitutes a hazardous activity as it often involves work that is unfamiliar and that may have to be carried out in exceptional conditions, e.g. narrow spaces, time pressure. Employees tasked with maintenance work are therefore to be given separate training before commencing work.

Note: See section 9(2) of the Ordinance on Industrial Safety and Health (BetrSichV).

5.2.2 Equipment that is or may be contaminated with biological agents must be cleaned and disinfected – wherever possible – prior to maintenance work. Work must not be authorised until this cleaning and disinfection is complete. If disinfection is either not possible or insufficiently possible, the employer must prepare special work instructions stating the necessary protective measures.

If multiple companies are involved in maintenance, account must be taken of the remarks on cooperation between various employers (number 9).

5.3 Cleaning work

Cleaning work in working areas of health care and welfare facilities includes all regular cleaning and disinfection measures intended to maintain the desired state of hygiene.

For example, cleaning work includes:

- cleaning thoroughfares (stairs, corridors);

- cleaning and disinfecting treatment rooms and operating theatres;
- cleaning patient rooms, including the sanitary facilities;
- preparing beds;
- cleaning vehicles and means of transport (e.g. rescue or ambulance vehicles).

In health-care facilities pursuant to the Biological Agents Ordinance (see number 3.4.1), these activities are to be assigned to a protection level within the framework of the risk assessment. For example, cleaning a ward corridor generally corresponds to an activity of protection level 1; on the other hand, cleaning and removing blood contamination from operating theatres corresponds to protection level 2.

Note: See documents from the accident insurance institutions on cleaning and disinfection work in health care for further information.

5.4 Processing of medical devices

5.4.1 The processing of medical devices is aimed at ruling out a risk of infection for patients, users and third parties. Within the meaning of these technical rules, it includes the following process steps:

- preparation for cleaning,
- cleaning,
- disinfection and, if necessary,
- sterilisation.

The processing of medical devices contaminated with bodily fluids usually corresponds to activities of protection level 2. This particularly applies to the processing of medical devices that are used invasively. Depending on the infection pathways, additional protective measures must be taken, if necessary, for instruments that have been used on patients with known diseases resulting from pathogens of risk group 3.

Note: For information on basic hygiene and infection-prevention requirements for the processing of medical devices, see the latest version of the recommendations entitled “Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten” [Hygiene requirements for the processing of medical devices] from the Commission of Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and from the Federal Institute for Drugs and Medical Devices (BfArM).

5.4.2 The following preventive measures are required at the location where the contamination arises, e.g. in the operating theatre or procedure/functional room:

- Where possible, and provided they are disposable, pointed and sharp instruments are to be disposed of immediately on-site in a safe manner or put down separately on a sieve/kidney dish.
- Where possible, disposable items, such as scalpel blades, needles and cannulas, are to be removed from the sieves/kidney dishes using tools such as tweezers or tongs.

- Swabs and compresses are to be disposed of immediately in a waste bin during the operation.
- All instruments that require manual processing must be collected separately.
- Instruments used for minimally invasive surgery (MIS) that must be dismantled for processing are to be handled separately and – if possible – put onto the MIS cleaning trolley as soon as they are dismantled.

Note: The greatest infection risk is associated with preparing the instruments for cleaning, since at this stage these are still contaminated with blood, other bodily fluids or body tissue.

5.4.3 Since manual cleaning poses a significantly higher risk of injury, preference is to be given to the use of purely mechanical cleaning and disinfection where possible. Some instruments require mechanical cleaning and manual disinfection in order to ensure the removal of any coarser build-ups. Disinfection reduces the quantity of pathogens.

5.4.4 Potentially infectious instruments are to be processed in a room that is separated from direct patient care. The room must have a ventilation facility. A suitable workplace extraction system must be provided if instruments contaminated with blood, secretions and/or pieces of tissue are mechanically pre-cleaned in processes that produce aerosols (e.g. air or water from pressure guns). The room must not be used for other purposes such as open storage or changing clothes, or as a social room.

If processing is carried out in a central sterilisation facility, the facility's input side (contaminated side) and output side (clean side) are to be separated from one another spatially or by organisational means. The input side must be big enough for short-term storage of the items that are to be processed. Protective clothing must be taken off and the hands must be disinfected before employees leave the contaminated side.

5.4.5 The instruments should preferably be cleaned and disinfected in the closed system of a cleaning/disinfection device in order to minimise the risk of injury and contamination and to protect employees from contact with the disinfectant. At the same time, prior repacking of contaminated instruments is to be avoided through organisational and technical measures. From the point of view of occupational safety and health, the procurement process should give preference to instruments that can be processed mechanically unless this is incompatible with functional requirements.

5.4.6 The formation of aerosols is to be minimised in the manual cleaning of instruments, especially in the case of stuck-on/dried-on material. In order to prevent contamination by potentially infectious materials, cleaning must not be carried out under a strong jet of water. If instruments must be cleaned with a brush, brushing must only be carried out under the surface of the water in the cleaning basin because of the risk of splashing. Soaking water is to be changed regularly, especially after the cleaning of instruments used with patients who are known to be infected. If (additional) instruments are washed in the ultrasound bath, this must be covered or fitted with an extraction system.

5.4.7 Dental, orthopaedic or other medical devices that may be contaminated and that are intended for further processing must be disinfected by the submitter, e.g. the dental practice or orthopaedic practice, prior to submission.

Note: For more information, see the latest version of the announcement entitled "Infektionsprävention in der Zahnheilkunde – Anforderungen an die Hygiene"

[Infection prevention in dentistry – hygiene requirements] from the Commission of Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute.

5.4.8 The following personal protective equipment must be worn:

When putting contaminated and, where applicable, manually precleaned instruments into the cleaning/disinfection device (mechanical treatment):

- Liquid-tight protective clothing (white coat).
- Liquid-tight disposable gloves.

When cleaning and disinfecting instruments or equipment manually:

- Liquid-tight protective clothing (long-sleeved coat).
- Liquid-tight, long-cuffed protective gloves. The protective-glove material should be selected according to the cleaning agent and disinfectant or the potentially infectious material.
- Eye protection and surgical face mask; a face visor can optionally be used instead of safety goggles.
- Cut-proof or cut-resistant gloves for activities on sharp edges of equipment.

Depending on the exposure conditions, it may also be necessary to wear respiratory protection, e.g. FFP2. For example, this may apply to instruments that have been used on persons suffering from tuberculosis.

5.4.9 Special protective measures are necessary for the cleaning, disinfection and sterilisation of instruments that have been used on CJD or vCJD patients or patients with comparable spongiform encephalopathies, or in cases where such a disease is suspected.

Note: See annex 7 to the KRINKO recommendations referred to in 5.4.1.

5.5 Handling used laundry

5.5.1 Used laundry that arises in activities pursuant to number 3.4.2 paragraph 2 or 3 is to be collected directly in the working area in sufficiently resistant and sealed containers, which must be clearly labelled. Correct collection and labelling necessitates coordination between the working areas in which the laundry arises and the laundry facility.

Note: Details on collection can be found in the documents from the accident insurance institutions on the risk of infection due to the handling of used laundry.

5.5.2 In particular, collection includes the following:

- a) Separate collection of laundry that must be put into a special washing process.
- b) Separate collection of wet laundry (heavily contaminated with bodily fluids or bodily excretions) in sealed containers.
- c) Foreign bodies are to be removed from laundry before it is discarded.

Laundry that contains foreign bodies that present a risk of injury must not be handed over to the laundry facility.

5.6 Disposal of waste

- 5.6.1** Waste is assigned to individual waste codes according to the Waste Catalogue Ordinance (AVV) based on European requirements. On the national level, the disposal of waste is governed by the “Vollzugshilfe zur Entsorgung von Abfällen aus Einrichtungen des Gesundheitsdienstes” [Guidelines for the disposal of waste from health care facilities] from the Working Group of the German Federal States on Waste (LAGA), as well as by regulations that are specific to individual federal states. At the same time, special requirements from the viewpoint of occupational safety and health and infection prevention must be taken into account for employees both of the facility and of the disposal companies.

Note: Guidance can be found in the brochure “Abfallentsorgung – Informationen zur sicheren Entsorgung von Abfällen im Gesundheitsdienst” [Waste disposal – information on the safe disposal of waste in health services] from the German Social Accident Insurance Institution for the Health and Welfare Services (BGW).

- 5.6.2** Activities carried out within the framework of collecting, packaging, making available, transporting and treating medical waste from the examination, treatment and care of persons or animals are generally to be assigned to protection level 2. Separate consideration is to be given to activities in the disposal of medical waste containing biological agents of risk group 3 or 4. Here, the necessary measures are to be specified on a case-by-case basis, taking account of the local conditions, by the facility's waste management officer in coordination with the person responsible for hygiene and, if necessary, the medical officer or occupational safety specialist, depending on the severity of the risk of infection.
- 5.6.3** If filled waste bins are stored temporarily pending subsequent disposal, the collection sites must be designed so that the type of storage prevents a hazard from arising. The waste bins must be selected according to the disposal requirements (strong enough for transport, moisture-resistant, can be securely sealed) and labelled in a universally identifiable manner. In the case of internal transport of waste to central storage and handover locations, it is to be ensured that waste is prevented from escaping. At the same time, the structure of the internal collection and transport system is to be coordinated with the disposal routes available outside of the facility.
- 5.6.4** Waste assigned to waste codes 180101, 180104, 180201 and 180203 is to be collected immediately in containers that can be securely sealed at the location where the waste arises and transported to the central collection point without being sorted or transferred to other containers. The waste must not be sorted or transferred at the collection point either.
- 5.6.5** Waste assigned to waste codes 180102, 180103* and 180202* is to be collected in tear-proof, moisture-resistant and leak-proof containers and transported to the central collection point in suitable, securely sealed containers without being sorted or transferred to other containers. Contamination of the outside of the collection vessels is always to be avoided. Should contamination nevertheless occur, suitable disinfection measures are to be taken. Waste assigned to waste codes 180103* and 180202* must only be ground down in disinfection systems approved by the Robert Koch Institute and, if appropriate, must only be compacted afterwards.

- 5.6.6** The central collection point must be designed to allow disinfection of the surfaces and to prevent hazards to employees or third parties due to storage of the waste. Pests must be prevented from entering. In addition, when waste assigned to waste codes 180102, 180103* and 180202* is stored, pollution by dust and odours must be prevented by ventilation, and cooling must be used to prevent gas formation in the collection containers.

Notes: Information on the collection and transport of waste within the facility can be found in the “Collection – Storage” column of the table in annex 8 to these technical rules.

Municipal waste management regulations and special waste-disposal requirements for doctors’ practices and other health care facilities must still be adhered to. It is therefore advisable to obtain information on special procedures from the local municipality’s commercial waste advisory service. Further information can be found in the brochure referred to in 5.6.1: “Abfallentsorgung – Informationen zur sicheren Entsorgung von Abfällen im Gesundheitsdienst” [Waste disposal – information on the safe disposal of waste in health services].

5.7 Multidrug resistant pathogens

- 5.7.1** Pathogens with antibiotic resistance – so-called multidrug resistant (MDR) pathogens – do not differ from equivalent pathogens without this resistance in terms of their infection pathways, pathogenic effects, environmental properties or sensitivity to disinfectants. Strict compliance with the general hygiene measures is therefore sufficient with regard to occupational safety and health. Barrier/isolation measures alone cannot be used to substitute general hygiene measures that are either inadequate or not strictly complied with.
- 5.7.2** No personal protective equipment is necessary when activities are carried out that do not involve contact with bodily fluids, e.g. when entering the patient room to distribute food, and in which this is not expected to occur accidentally, e.g. due to uncontrolled coughing in patients with a tracheotomy. Should contact with bodily fluids nevertheless occur within the framework of these activities, e.g. because the patient is about to fall out of bed, then the risk of transmission of MDR pathogens can be avoided by changing any contaminated work clothing. Hand disinfection is necessary on leaving the room.
- 5.7.3** Where contact with bodily fluids is foreseeable in activities involving patients carrying MDR pathogens, protective measures are necessary to protect the employees and to prevent the pathogen from spreading within the facility. These measures must be specified based on individual risk analyses. Where contact with the mucous membranes of the nose and mouth has been ruled out, surgical face masks can generally be dispensed with as a form of contact protection. See number 4.2.10 “Respiratory protection” for information on activities that lead to the production of aerosols.
- 5.7.4** In principle, the occurrence of MDR pathogens is always to be expected in working areas of health care facilities. If MDR pathogens are demonstrated to be present in an area, the training sessions pursuant to the Protection Against Infections Act (IfSG)

and the Medical Hygiene Ordinance (MedHygV)⁸ are to be ensured. This also includes prompt communication with relevant persons that are involved in patient care.

5.7.5 Protective clothing kept ready in the patient room must be protected against dust and contamination.

5.7.6 From an infection prevention perspective, the requirements on waste disposal and laundry processing do not go beyond those for other waste in health care facilities.

Note in relation to number 5.7: *National and regional networks for multidrug resistant (MDR) pathogens⁹, e.g. in Bavaria, Lower Saxony or North Rhine-Westphalia, can offer valuable assistance in training and communication, as they seek to standardise MDR pathogen management and raise awareness of this area in health care facilities. They provide some specific information (FAQs, leaflets, patient transfer forms), mostly on websites, and coordinate the network activities of local health care facilities, which can then actively collaborate in the network.*

5.8 Pathology – performing dissections and processing untreated samples

5.8.1 Information for the risk assessment

(1) The field of pathology is characterised by work on potentially infectious tissues or organs within the framework of necropsies, post-mortem examinations, autopsies and dissections in order to establish the cause of disease or death, as well as for scientific purposes. The type and quantity of pathogens and the infectivity are often not yet known.

It is also to be noted that, in addition to autolytic decomposition processes, death is quickly followed by the onset of putrefaction and decay processes, which are associated with pronounced multiplication of microorganisms. This primarily involves intestinal bacteria (of which some are of risk group 2). Furthermore, this is frequently accompanied by the growth of moulds.

(2) Necropsies always include opening the cranial, thoracic and abdominal cavities where the condition of the body permits this. Opening the body increases the probability of contact with potentially infectious materials. In principle, there is a risk of infection for employees in the event of direct contact with the bodies, body parts or bodily fluids. Bodily fluids such as blood and lymph may escape and aerosols may be formed when whole organs, liquid-filled intestines, bladders and cysts, or lymph nodes are cut open. Puncturing and cutting tools are used, leading to a risk of infection via cuts and needle-stick injuries.

5.8.2 Requirements for premises and technical equipment

(1) The dissection room must be entered through an anteroom with the following equipment:

- a facility for separately putting on and taking off the specific dissection clothing and/or street clothes (separate clean/contaminated areas);

⁸ “Verordnung zur Hygiene und Infektionsprävention in medizinischen Einrichtungen” [Ordinance on Hygiene and Infection Prevention in Medical Facilities]

⁹ e.g. methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant Enterococci (VRE)

- a hand wash basin and disinfectant dispenser (according to numbers 4.1.1 and 4.1.2);
- suitable collection containers for disposing of used PPE.

In the veterinary field, a disinfection facility for the surgical boots is to be provided – if necessary – at the entrance to the contaminated side.

- (2) There should be visual contact between the dissection room and other rooms. Facilities must be available for communicating with the outside world, e.g. by telephone or intercom.
- (3) The pathology department must have suitable rooms for storing already autopsied and not yet autopsied bodies. For example, two cold storage rooms would be one suitable solution.

In pathology departments, it is advisable to have possibilities for direct access via short routes and to avoid 'through traffic' for infection prevention reasons.

- (4) The dissection room is to be equipped with stainless-steel dissection tables surrounded by profiled edges with strongly rounded inner corners; the tables must also have drains and an adequate gradient. To minimise splashes, the drainage nozzles should reach right down to the drainage channel, which, in turn, should be sunk into the floor and covered with a flush-fitting, removable metal grille.

Surfaces in the dissection room must meet the requirements set out in number 4.2.1.

- (5) If dissections with a special risk of infection are to be expected in addition to routine examinations, a separate dissection room must be provided wherever possible. This should have its own anteroom. One secondary possibility is to separate activities by timing or organisational measures.
- (6) Aerosol formation must be minimised, especially if an infection by airborne pathogens is suspected. For example, extraction systems on bone saws help to minimise aerosol formation. If steps involving further processing of removed tissues or organs take place in the dissection area, microbiological safety workbenches (MSWs) or pathology workbenches with a displacement ventilation system are to be used depending on the size of the specimen.
- (7) If work is to be carried out on body segments, facilities such as special vices are to be provided to fix these in place in order to minimise risks of injury as a result of the segments slipping.

5.8.3 Handling of instruments and materials

- (1) Suitable facilities must be available for putting instruments down repeatedly during the dissection. For example, this could be on a mobile side table or on an instrument tray positioned in a stable manner on the dissection table.
- (2) Pointed and sharp instruments are to be collected in puncture- and fracture-resistant containers in accordance with number 4.2.5 paragraph 6.
- (3) Infectious waste from the dissection is to be collected either using suitable disposal containers that are easy to disinfect and have smooth inside surfaces or using disposable containers; in both cases, the containers must have a sealable lid. Disposal must be carried out in accordance with number 5.6.

- (4) Working equipment and work surfaces must be cleaned and disinfected once the dissection is complete. Disinfection must be performed using suitable, effective and recognised substances. Should precleaning steps be necessary in an individual case, these must be carried out with a reduced-pressure water jet and/or disposable wipes.

Note: See number 5.4.6 for information on the manual cleaning of instruments.

- (5) Sample-transport containers for passing on to subordinate areas must be fracture-resistant, tightly sealable, liquid-tight, permanently labelled and easy to disinfect. The use of open sample dishes is to be avoided.
- (6) Direct contact with potentially infectious materials is to be avoided as far as possible. Provision is to be made for the use of corresponding tools.

5.8.4 Personal protective equipment (PPE)

- (1) The required personal protective equipment includes a protective gown, suitable face protection (face shield, visor), surgical shoes and liquid-tight protective gloves (equipped with cut-protection features if necessary).

It is advisable to identify protective clothing (e.g. through its colouring) as being specifically for dissections. It must not be worn outside of the pathology department.

- (2) Liquid-tight and disinfected aprons or disposable aprons must be worn for analysis steps in which large volumes of liquid may arise, for example.
- (3) The surgical shoes must be liquid-tight and slip-resistant, as well as having a sufficiently pronounced tread. Surgical boots are required in veterinary medicine because of the unavoidable contamination of the floor with blood and bodily fluids during the dissection of large animals.

Notes: If large volumes of liquids are expected, as is typical in veterinary pathology, a washing station for boots and aprons is to be installed in the dissection area with a depositing wall for aprons and boots, provided these are used multiple times. This requirement does not apply if a disposable apron is worn over the work coat and disposable overshoes are used instead of surgical boots and disposed of in a collection bin immediately after use.

- (4) If hazards due to biological agents of risk group 3, e.g. *Mycobacterium tuberculosis*, are to be expected and sufficient technical/structural protection is not possible, it is necessary to wear respiratory protection in accordance with number 4.2.10 in addition to the face visor.

Note in relation to number 5.8: *Protective measures analogous to those in pathology are to be adopted when opening carcasses for targeted on-site removal of organs for diagnostic purposes.*

5.9 Veterinary medicine – veterinary hospitals and veterinary practices for small animals

5.9.1 Scope of application, activities

- (1) This section, number 5.9, applies to:

- outpatient and inpatient examination, treatment and care of small animals and pets, including the carrying out of home visits with or without a mobile practice vehicle;
 - activities in livestock hospitals in the field of higher education;
 - inpatient examination, treatment and care of horses;
 - inpatient processing of samples (unless this falls within the scope of TRBA 100) and treatment of materials from livestock/equine practice in practice rooms.
- (2) Table 2 (see number 5.9.7) provides a non-exhaustive overview of relevant activities, occurring pathogens and infection pathways.

5.9.2 Assessment of activities within the framework of the risk assessment

- (1) The following activities are comparable with activities of protection level 1 in human medicine:
- general examinations and vaccinations, castrations/operations where zoonosis is not suspected;
 - taking blood samples, as the transmission of pathogens via the patients' blood is of lesser significance than in human medicine.
- (2) The following activities are usually comparable with activities of protection level 2 in human medicine:
- activities in which there may be regular and not merely minor contact with potentially infectious materials, such as faeces, urine or other bodily fluids or tissues;
 - activities in which there is an obvious risk of infection, e.g. via an airborne infection, bites or scratches.
- (3) Activities involving possible contact with highly pathogenic agents of risk group 3 represent rare exceptional cases, e.g. in the case of:
- influenza A (H5N1) outbreaks with agents that are pathogenic to both animals and humans,
 - psittacosis or
 - Q fever (occasionally present in dogs and cats).

Here, if the conditions correspond to those described in number 3.4.2 paragraph 3, the activities may be compared with protection level 3 in human medicine.

5.9.3 Minimum protective measures

In principle, the minimum protective measures specified in number 4.1 also apply in relation to veterinary hospitals and veterinary practices for small animals. In the veterinary scope of application, however, the following stipulation applies in place of 4.1.5:

The employer must at least compile a cleaning and disinfection plan for the individual working areas that lays down the basic measures described in annex 2. In hospitals and in practices specialising in surgery, a written hygiene concept is required. In any case, the occupational safety and health requirements pursuant to section 9 of the Biological Agents Ordinance and the requirements of patient protection can be combined into one document. Adherence to the specified measures is to be ensured. In a similar way to human medicine, it is advisable to specify risk-based measures in order

to prevent outbreak situations or to address specific areas of activity or the presence of specific pathogens.

The minimum protective measures in the veterinary field also include the measures set out in number 4.2.1 (Surfaces).

5.9.4 Protective measures for activities comparable with protection level 2

In addition to the minimum protective measures set out in number 5.9.3, the following protective measures are to be adhered to; these are to be adapted to the specific activity and workplace.

- (1) The employer must only assign employees with corresponding qualifications to carry out activities comparable with protection level 2. These employees are: vets, veterinary assistants, veterinary/technical assistants or other employees with corresponding experience and corresponding further training in these fields.
- (2) The formation of aerosols is to be kept to a minimum in all of the processes that are used. Examples of this include:
 - capturing smokes that are harmful to health when using medical lasers and high-frequency cauterising equipment;
 - using corresponding extraction technology during veterinary dental treatments;
 - covering the ultrasound bath during the cleaning of instruments.
- (3) Puncture-resistant, liquid-tight, securely sealable and fracture-resistant containers are to be used for disposing of used pointed and sharp working equipment. These are to be provided as close as possible to the location at which waste arises. The contents must not be transferred from one container to another. If possible, used cannulas must not be reinserted into the cannula cover.

Note: See number 4.2.5 paragraph 6 for further requirements of the containers.

- (4) If the risk potential is comparable, the measures set out in numbers 4.2.6 to 4.2.10 are to be taken into account for the provision and use of personal protective equipment (PPE).

Examples of activities for which number 4.2.8 requires the wearing of protective gloves or medical gloves include:

- cleaning stalls used for small animals,
- inserting bladder catheters,
- opening or rinsing abscesses,
- handling wounds,
- laboratory activities that pose a risk of infection.

Examples of activities for which number 4.2.9 requires the wearing of eye or face protection, as well as a surgical face mask, include:

- dental scaling using ultrasound,
- preparation of bronchoscopes.

- (5) If home visits for small animals and pets are carried out regularly on a larger scale, the employer must stipulate the following in work instructions:

- Use of work clothing and personal protective equipment.
 - Necessary measures for hygiene and disinfection, including the provision of suitable transport containers for reusable contaminated working equipment, e.g. ear specula and bulb-headed cannulas, as well as for surgical instruments.
 - Implementation of hand hygiene. Here, the stipulations for hygienic hand disinfection are of particular relevance.
- (6) If treatment is given to wild animals, the possible infection potential must be taken into account. The measures already described are to be applied as necessary.

5.9.5 Protective measures for activities comparable with protection level 3

In addition to the measures set out in numbers 5.9.3 and 5.9.4, the following protective measures are to be adhered to; these are to be adapted to the activity and workplace.

- (1) Where activities of protection level 3 are to be expected, animal health aspects must be taken into account and the relevant veterinary authorities must be involved.
- (2) As a minimum, spatial separation of the activities from less hazardous activities is to be ensured by organisational measures. Access is to be restricted to the necessary personnel.
- (3) Additional personal protective equipment may be necessary; in particular, respiratory protection measures are to be considered.

5.9.6 Conduct following accidents

- (1) Number 6 is only applicable insofar as its provisions are relevant to veterinary medicine. At the same time, consideration must be given to the presence in treated animals of agents that are pathogenic to humans (zoonotic agents).
- (2) All occupational accidents, including bites, cuts, punctures or scratches, are to be documented in the accident book.

Note: Larger injuries should be presented to the accident insurance consultant. This also applies to smaller injuries if signs of inflammation appear.

- (3) Employees that might have contaminated themselves with pathogens (zoonotic pathogens or pathogens with zoonotic potential, e.g. MRSA) should document this in the accident book as soon as they become aware of it. The employer is to be informed.

5.9.7 Treatment of instruments

Note: Although used instruments are processed for reuse, these instruments are not medical devices. Therefore, number 5.4 does not apply to veterinary medicine.

Pathogens in the blood itself very rarely pose a risk of zoonosis in practices. A hazard can arise due to pathogens that may be released through contact or injuries or through aerosol formation during processing.

- (1) The following preventive measures should already be taken at the place of use, e.g. in the operating theatre or procedure/functional room:
 - Where possible, pointed and sharp instruments are to be disposed of immediately on-site in a safe manner – provided they are disposable.

-
- If they are not disposable, items are to be put down separately on a sieve or kidney dish wherever possible.
 - Disposable items, e.g. scalpel blades, needles and cannulas are to be removed from the sieves/kidney dishes using tools if possible.
- (2) If instruments are processed regularly on a larger scale, this should preferably be carried out in the closed system of a cleaning/disinfection device in order to minimise the risk of injury and contamination and to protect employees from contact with the disinfectant.
- (3) Especially in the case of stuck-on/dried-on material, the following measures are to be applied in order to minimise the formation of aerosols during the manual cleaning of instruments:
- Cleaning must not be performed under a strong jet of water.
 - If instruments must be cleaned with a brush, this is only to be done under the surface of the water in the cleaning basin.
 - The soaking water is to be changed regularly, especially after the cleaning of instruments used on patients who are known to be infected.
 - If cleaning is carried out in the ultrasound bath, this must be covered.
- (4) The following may be necessary as PPE for the manual cleaning and disinfection of instruments:
- Liquid-tight protective clothing (long-sleeved coat/apron).
 - Liquid-tight, long-cuffed protective gloves.
 - The protective-glove material should be selected based on the cleaning agent/disinfectant and the potentially infectious material.
 - Eye protection and surgical face mask; a face visor can optionally be used instead of safety goggles.
 - Boots.
- (5) Special protective measures are necessary for the cleaning, disinfection and sterilisation of instruments that were used on TSE/BSE patients or patients with comparable spongiform encephalopathies or in cases where such a disease is suspected.

Table 2 Occurrence and infection pathways of some pathogens in veterinary medicine with examples of activities (not exhaustive)

By way of example, the following table lists the occurrence and infection pathways of some pathogens with examples of activities.

On its website, the Robert Koch Institute provides further information on individual infectious disease pathogens in the "Infektionskrankheiten A-Z" (A-Z of infectious diseases) section, as well as expert information on activity-specific hazards in the pathogen-specific "RKI-Ratgeber für Ärzte" (RKI guides for doctors).

Materials	Pathogens	Risk group	Infection pathways in accordance with no. 3.3.1	Example activities	Frequently affected species
Saliva	Rabies virus	3(**)	Bites; possibly contact with mucous membrane or previously damaged skin	Putting down animals suffering from rabies	Dogs, cats, among others (as of 2013, Germany is free of terrestrial sylvatic rabies)
Faeces	Echinococcus granulosus	3(**)	Contact	Contact with faeces during examination and treatment activities on the animal, cleaning of stalls, faecal analyses	Dogs
	Salmonella spp.	2			Pigeons, reptiles
	Cryptosporidium spp.	2			Dogs, cats
	Giardia spp.	2			
	Toxoplasma gondii	2			Cats
Urine, amniotic fluid	Leptospira spp.	2	Contact	Urine analyses	Dogs
	Brucella canis	3		Helping animals to give birth	
Respiratory/ tracheal secretions	Chlamydophila felis	2	Airborne, contact	Intubation, extubation, dental scaling using ultrasound	Cats
	Avian strains of Chlamydophila psittaci	3			Psittacidae, birds
	Pasteurella spp.	2			Rabbits, cats, dogs
Skin/ wounds	Staphylococcus pseudintermedius	2	Contact	Wound care, taking scrapings	Dogs, cats
	Staphylococcus aureus	2			
	Cowpox viruses	2			Rats, cats
	Bartonella henselae	2	Scratch		Cats
	Trichophyton spp./ Microsporum spp.	2	Contact		Guinea pigs, cats

6 Conduct in case of accidents

6.1 Specification of measures

6.1.1 Pursuant to section 13 of the Biological Agents Ordinance, the employer must specify the necessary measures that are required in the case of accidents before an activity of protection levels 2 to 4 is commenced in order to minimise the effects on the safety and health of employees and other persons.

6.1.2 For employees whose activities put them at risk of punctures and cuts by used pointed and sharp medical instruments or of other contact with bodily fluids, especially contact with mucous membranes, it is necessary to specify measures to be taken following needle-stick injuries or corresponding contact in order to avoid and limit infection. The measures are to be specified in coordination with the medical officer or another professionally suitable person.

6.1.3 In particular, the measures to be implemented include:

- Immediate implementation of local emergency measures (disinfection, decontamination).
- Investigation of the infectivity of the index patient, which requires the consent of the affected persons.
- Designation of a body that specifies and implements prophylaxis measures (e.g. PEP¹⁰) in the event of exposure to HIV, HBV or HCV.
- Survey of the serostatus of employees in the event of possible exposure to HIV, HBV or HCV (serological check) to detect infection.
- Specification of corresponding procedures if, in the event of accidents, a hazard due to other biological agents must be expected (e.g. patients with TSE, accidents in microbiological laboratories or animal experimentation units).

Note: Details of recommended approaches and conduct, especially those following needle-stick injuries, can be obtained from the accident insurance institutions.

6.1.4 Employees are to be trained on the specified measures. In particular, please note that every accident identified in number 6.1.2 must be reported and that, where a serological check or PEP is needed, employees are to consult the relevant body immediately after the accident.

Note: Specifically, the suitable body is the accident insurance consultant. It is advisable to appoint a local accident insurance consultant.

6.2 Documentation and analysis

6.2.1 The employer must establish at the facility an internal procedure for the complete recording of accidents¹¹. In particular, all needle-stick injuries and other incidents of contact between skin or mucous membranes and potentially infectious materials are to be documented and reported to the body identified by the employer.

¹⁰ PEP: post-exposure prophylaxis

¹¹ For more information, please refer to the documentation obligation laid down by the German Accident Prevention Regulation "Principles of Prevention" (DGUV Vorschrift 1).

- 6.2.2** These details must be analysed in accordance with section 11(5) of the Biological Agents Ordinance with a view to identifying technical or organisational causes of accidents, and remedial measures must be specified (see annex 6 “Example of a ‘Recording and analysis form for needle-stick injuries’” for more information).
- 6.2.3** Employees and their representatives are to be informed of the results, but individual apportioning of blame is to be avoided.

7 Operating instructions and training of workers

7.1 Operating instructions and work instructions

7.1.1 Pursuant to section 14(1) of the Biological Agents Ordinance, the employer must prepare written operating instructions and update these in the event of substantial changes to working conditions. This is not necessary if the only activities performed involve biological agents of risk group 1 without sensitising or toxic effects. The operating instructions are to be prepared for the specific working area, activity and substance based on the risk assessment and the specified protective measures. In particular, the operating instructions must include the following items:

- Risks associated with the activity for employees:
 - biological agents that occur and their risk groups;
 - relevant infection or uptake pathways.
- Necessary protective measures and code of conduct:
 - exposure-prevention measures;
 - correct use of sharp or pointed medical instruments;
 - hygiene measures, with reference to the hygiene plan where applicable;
 - wearing, use and taking off of personal protective equipment;
 - conduct in case of injuries, accidents, incidents and emergencies.
- First-aid measures, including information on post-exposure prophylaxis if necessary.
- Disposal measures for contaminated waste.
- Information on preventive occupational health measures, including immunisation.

7.1.2 The operating instructions are to be drafted in a form and language that employees can understand and are to be announced at a suitable location in the workplace and put out or hung up for inspection. It is possible to combine the operating instructions and hygiene plan.

For example, suitable locations include the workplace, the nurses’ room, the examination room, the vehicle for employees of outpatient care services, or the rescue or ambulance vehicle.

See annex 9 for example operating instructions and annex 2 for the structure of a hygiene plan.

7.1.3 In addition to the operating instructions, work instructions are to be prepared for activities of protection levels 3 and 4 and must be available at the workplace. Work in-

structions are also required for activities involving an increased risk of infection, e.g. in the case of

- activities in which experience shows there to be an increased risk of accident;
- activities in which serious infections are to be expected in the event of an accident; or
- maintenance work on contaminated devices.

Where patients are medically examined, treated and cared for outside of outpatient and inpatient health care facilities¹², the employer must specify in work instructions how to handle personal protective equipment and work clothing, as well as the required hygiene and disinfection measures.

7.2 Training

7.2.1 Employees that carry out activities involving biological agents must be trained on the risks that arise and the required protective measures based on the operating instructions and the facility's hygiene measures (hygiene plan). This also applies to external companies (maintenance, repair and cleaning staff) and other persons (e.g. interns).

The training must be designed to improve employees' awareness of safety. Implementation of the training content must be monitored.

Employees are also to be informed of the conditions under which they are entitled to preventive occupational health care pursuant to the Ordinance on Occupational Medical Prevention (ArbMedVV).

7.2.2 Employees must be given a general occupational health consultation within the framework of the training. This must involve the doctor appointed to carry out preventive occupational health care. For example, this involvement may take the form of training the persons who provide the training or of collaborating in the preparation of suitable teaching materials for preventive occupational health care.

The topic areas on which the employees must be informed and advised are to be specified based on the results of the risk assessment. Among others, they relate to:

1. Possible activity-related health risks as a result of the biological agents that are used or that are present.

In particular, account must be taken of:

- a) the typical infection or uptake pathways or those associated with the activity;
- b) the possible disease patterns and symptoms;
- c) medical factors that may lead to an increased risk, such as
 - diminished immune defence, e.g. due to an immunosuppressant treatment or a disease such as diabetes mellitus;
 - the presence of chronic obstructive respiratory diseases in conjunction with activities involving potentially sensitising biological agents;

¹² Activities that are not performed in workplaces but rather in the private sphere, e.g. in home care for the sick and elderly

- impaired barrier function of the skin;
 - another individual disposition; or
 - pregnancy and breastfeeding; and
- d) the possibilities for prophylactic vaccination.
2. The compulsory code of conduct, e.g. with regard to hygiene requirements, skin protection and skin care, and its consistent implementation.
 3. The medical aspects of necessity, suitability and use of personal protective equipment, e.g. protective gloves, protective clothing, respiratory protection, including handling, maximum wearing times, replacement cycle and possible physical stresses.
 4. The first-aid and post-exposure prophylaxis measures, as well as the procedure in case of cuts and punctures.
 5. The necessary (compulsory or optional) preventive occupational health care, the scope and benefit of such examinations, and possible vaccinations.
 6. The offer of occupational health care when a disease occurs if a causal connection with the activity is suspected.
- 7.2.3** The training is to be provided before the commencement of activities, as well as in the event of significant changes to working conditions, and at least once a year. It must be specific to the workplace and activity and must be delivered orally in a form and language that the employees can understand.

The content and scheduling of the training sessions must be documented, and the trained persons must give their signature as confirmation.

7.3 Employees' obligations

Employees must carry out the work in a way that prevents, wherever possible, a risk to themselves or third parties by biological agents by applying technical, organisational and personal measures insofar as they are able to in accordance with the training given and work instructions prepared by the employer. The provided personal protective equipment must be used as intended.

8 Licensing, notification, record-keeping and information obligations

8.1 Licence

Pursuant to section 15(1) of the Biological Agents Ordinance, a licence from the competent authority is required in order to commence activities of protection level 4 in a special isolation unit (patient ward of protection level 4) for the first time. The licence covers the structural, technical and organisational requirements that the Ordinance sets out for the protection of employees and other persons against the risks posed by biological agents. The licence is to be applied for in writing along with the documents required according to section 15(3) of the Biological Agents Ordinance.

8.2 Notification

The employer must notify the competent authority of the admission of an infected patient to a patient ward of protection level 4, as well as of the discontinuation of the activity requiring a licence, and in doing so must provide the information required by section 16 of the Biological Agents Ordinance.

8.3 Informing the authority

Pursuant to section 17(1) of the Biological Agents Ordinance, the competent authority is to be informed immediately of every accident and incident in the case of activities involving biological agents of risk group 3 or 4 that may entail a serious health risk for employees, as well as of diseases or fatalities that are attributable to activities involving biological agents; the activity performed must be clearly stated. In connection with the application of section 17(1) number 1 of the Biological Agents Ordinance, needle-stick injuries from used cannulas are to be reported as accidents immediately to the competent authority if the infectivity of the index patient is known and they are demonstrably infected with HIV, HBV or HCV.

Note: Reporting the accident to the relevant accident insurance institution is no substitute for informing the competent authority.

8.4 List

8.4.1 Section 7(3) of the Biological Agents Ordinance states that, in the case of activities of protection level 3 or 4, the employer must additionally keep a list of the employees that perform these activities. The list is to include the type of activities and the biological agents present, as well as any accidents and incidents that have occurred. It is to be archived on an individual basis for a period of at least 10 years after the end of the activity.

8.4.2 The employer must

- a) give the employees access to the information in the list relating to them; protection of the personal data is to be ensured.
- b) hand over to the employee an excerpt of the list containing the information relating to them in the event that the employment relationship is terminated; the employer must keep evidence of the information being handed over in the same way as it does for personnel records.

The list of employees can be kept together with the list of biological agents pursuant to section 7(2) of the Biological Agents Ordinance.

9 Cooperation between employees of various employers – assignment of external companies

9.1 Cooperation between employees of various employers

If employees of multiple employers are working at a workplace at the same time, or if an external company is assigned to carry out work, e.g. maintenance or cleaning work, the employers must cooperate on implementing the safety and health requirements in accordance with section 8 of the Occupational Safety and Health Act (ArbSchG). If necessary, mutual provision of information is required and a joint as-

assessment is to be made of the work situation and the hazards it presents. The resulting measures for the protection of employees must be coordinated.

9.2 Assignment of external companies

9.2.1 When assigning an external company, the employer must, acting as the client, assist the external company in the risk assessment of facility-specific risks¹³ and inform it of specific codes of conduct. The client must ensure that activities involving special risks¹⁴ are coordinated and monitored by a supervising person. If necessary, the supervising person can also be appointed jointly by the participating companies. They are to be given the appropriate authority to issue instructions – to employees both of their own and of the other company – for the purpose of averting special risks. For practical reasons, this authority is contractually agreed between the participating companies.

Note: See also the German Accident Prevention Regulation “Principles of Prevention” (DGUV Vorschrift 1).

9.2.2 The contract should also stipulate who is responsible for specifying occupational-safety measures, briefing employees and training in accordance with section 14 of the Biological Agents Ordinance (see number 7 of these technical rules for more information). In principle, the safety measures relating to the equipment requiring maintenance are to be arranged by the employer that bears direct responsibility for the equipment’s operation. The protective measures in relation to the maintenance activities are arranged by the employer that bears direct responsibility for carrying out the work (external company).

The safety requirements and qualification requirements for the maintenance personnel (TRBS 1112 “Instandhaltung” [Maintenance]) should already be specified at the time of the contract being awarded.

10 Preventive occupational health care¹⁵

Preventive occupational health care is governed by the Ordinance on Occupational Medical Prevention (ArbMedVV) and the Occupational Health Rules (AMR) published in connection with that Ordinance.

Preventive occupational health care serves to provide employees with individual medical advice on the interactions between work and physical and mental health. It also allows early detection of work-related health problems, as well as determination of whether an increased health hazard is present when carrying out a specific activity. Blood samples may be taken and physical examinations may be carried out either for diagnostic purposes or as necessary, but not against the will of employees. Vaccinations are to be offered to employees as an integral part of preventive occupational health care, provided the infection risk relates to the activity and is elevated in com-

¹³ For example, risks specific to the establishment include those arising from handling biological agents, such as risks of infection during cleaning work.

¹⁴ For example, special risks can arise from work including non-specific activities involving biological agents of protection levels 2 to 4 or from work that results from the cooperation between employees of various employers.

¹⁵ Number 10 is a contribution from the Committee for Occupational Medicine (AfAMed).

parison to the general population and provided the employee does not already have sufficient immune protection.

The employer must assign the provision of preventive occupational health care to a doctor who specialises in occupational medicine or who has a supplementary qualification in workplace medicine. Wherever possible, this should be the medical officer who has been appointed in accordance with the Occupational Safety Act (ASiG).

Sections 4 and 5 of the Ordinance on Occupational Medical Prevention (ArbMedVV), in conjunction with part 2 of the annex to that Ordinance, set out an exhaustive list of occasions on which compulsory and optional preventive health care must be provided in connection with specific or non-specific activities involving biological agents, as well as when exposure to biological agents has occurred. Over and above the requirements of the annex, the employer must make it possible for employees, if they wish, to receive regular preventive occupational health care pursuant to section 5a of the Ordinance on Occupational Medical Prevention (ArbMedVV).

If compulsory preventive health care is stipulated, the employer must only order the activity to be carried out if the employee has participated in the compulsory preventive health care; however, there is no obligation to allow physical or clinical examinations to be carried out. On the other hand, participation in optional preventive health care is not a prerequisite for carrying out the activity. Furthermore, if employees reject an offer, this does not release the employer from the obligation to continue offering regular optional preventive health care.

Annex 1 Special isolation units (protection level 4)

Part 1: Special isolation units – protective measures

1.1 General remarks

The examination, treatment and care of patients infected with pathogens of risk group 4 correspond to activities of protection level 4. These must always be carried out in a treatment centre (special isolation unit) of protection level 4. In situations where the capacities of these treatment centres are inadequate for caring for persons suffering from or suspected of suffering from a disease, e.g. in the event of bioterrorist attacks with numerous injured persons and/or persons suspected of suffering from a disease, it is necessary to adopt separation measures in accordance with the instructions of the competent health authorities and to adapt these measures to the respective situation. In particular, such situations will not allow the implementation of the structural and technical requirements described in number 1.2 in the wards that are then to be provided.

Notes: Health care facilities intended for activities of protection level 4 are subject to the licensing obligation set out in section 15(1) of the Biological Agents Ordinance (see number 8.1 for more information). A reliable person with professional expertise pursuant to section 11(7) number 3 of the Biological Agents Ordinance must be appointed. Requirements for professional expertise are specified in TRBA 200 "Requirements for professional expertise in accordance with the Biological Agents Ordinance".

The protective measures of protection level 4 must reliably prevent these pathogens from posing an infection risk to employees and third parties. The measures include the following requirements.

1.2 Structural and technical requirements for special isolation units

A treatment centre of protection level 4 must be safely structurally separated from other working areas. This can be achieved by constructing a dedicated building or by fully separating a part of a building with its own entrances and supply routes. The treatment centre is to be designed so that patients can be brought in via an airlock without posing a hazard to third parties.

1.2.1 Patient area and airlock system

The patient area (contaminated area) is to be separated from the outside area (uncontaminated area) by an airlock system with at least two airlock chambers.

The external airlock chamber contains the changing area and a personal shower. It is used for putting on protective clothing and personal protective equipment.

The patient area is entered via the adjoining internal airlock chamber. When a person exits via the airlock, the protective clothing is decontaminated by the disinfection shower installed in the internal airlock chamber.

The airlock chambers should be sufficiently large, and the functional areas of the external and internal airlock must be clearly specified.

In order to prevent the escape of contaminated air, the airlock chambers and patient area must have a negative air pressure cascade relative to the outside area, with the pressure increasing towards the patient area. For practical reasons, at least three

pressure levels are to be provided. The negative pressure present at each stage of the cascade must be easy to verify from both inside and outside and must be monitored by an optical and acoustic alarm.

The airlock doors must be sealed, self-closing and interlocking so that they cannot be opened at the same time. Windows must be sealed, break-proof and non-opening.

1.2.2 Supply and exhaust air systems

The supply and exhaust air systems must be routed separately from other air conditioning (AC) systems in the building. They must have an emergency power supply and a non-return design that is redundant with regard to the central units. The supply and exhaust air systems must be mutually interlocked so that air cannot escape in an uncontrolled manner if fans fail.

The supply air system must be designed so that no contaminated air can escape. The supply air must be fed through a high-efficiency particulate absorption filter and the exhaust air through two high-efficiency particulate absorption filters connected in series; it must be possible to verify the perfect operation of each of the filters in the installed state.

The planning of the air conditioning system must include the concept for final room disinfection (e.g. fumigation), as well as for the safe (low-contamination) replacement of filters. The duct routes should be as short as possible.

1.2.3 Surfaces, disinfection

All surfaces must be impermeable to water, easy to clean and resistant to the disinfectants and chemicals used. They must be of a smooth and seamless nature. The corners and edges of the room should preferably be rounded for the sake of easier cleaning/disinfection.

All points at which supply and disposal lines penetrate through walls, floors or ceilings must be sealed and secured against backflow. Gas pipes are to be protected with high-efficiency particulate absorption filters; liquid pipes are to be protected by pathogen-proof filters. Tightly sealing removable gaskets are to be used preferentially.

It must be possible to hermetically seal the airlock chambers and patient area for the purposes of final disinfection, e.g. by fumigation.

1.2.4 Sanitary room

If a sanitary room is provided for the patient room, this must have at least the same negative pressure at the patient room.

The sanitary room must be connected to a thermal inactivation system for the waste water from the wash basin, shower and toilet. Under some circumstances, the waste water can also be collected in an appropriately installed tank and chemically inactivated. In the case of chemical inactivation, compliance must be ensured with waste water regulations on the discharge of chemicals.

1.2.5 Further patient-room equipment

When occupied, the patient room must allow sufficient freedom of movement for staff. The design must also include sufficient space for the devices needed for treatment.

Within the area assigned to protection level 4 (contaminated area), a laboratory bench unit is permissible for the analytical investigations that are necessary for man-

aging the therapy. The associated equipment must be selected with a view to avoiding aerosol formation. Further diagnostic investigations, including virus analysis, must be carried out in a laboratory of protection level 4 in accordance with TRBA 100.

1.2.6 Waste

Solid and liquid waste arising during treatment is to be autoclaved in a manner that prevents the spread of pathogens. Preferably, this should take the form of a double-ended autoclave that is loaded in the contaminated area and emptied in the uncontaminated area. The automatic locking system must only allow the door to be opened if the sterilisation cycle is complete. Inactivation of contaminated process exhaust air and the condensed water must be ensured.

Note: For liquid waste, it is also permissible to use an equivalent, validated chemical inactivation procedure.

Where it is not possible to autoclave large items, e.g. the mattress, once treatment is finished, the inactivation and disposal can be achieved through proper contract disposal by an approved specialist company. The packaging and transport must conform to the requirements of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).

1.2.7 Emergency power supply, safety lighting, monitoring

An emergency power supply is required for all safety-related facilities. Depending on safety aspects, it may be necessary to have an uninterruptible power supply system.

The treatment centre must be equipped with safety lighting.

A facility must be present for visual monitoring, e.g. via a camera or a continuous visual link. The treatment team must have a suitable means of communication within the treatment centre, i.e. while wearing personal protective equipment, and with the outside world.

1.3 Organisational measures, hygiene measures

1.3.1 Management of the treatment area

Access to the treatment centre must be controlled and is to be restricted to authorised persons and persons with professional expertise who have been briefed and trained based on the work instructions (cf. number 1.3.2).

The procedures for managing the treatment area, starting up the special isolation unit and organising the patient care must be regulated in a binding manner. It is advisable to have replacement staff available and ready for service at all times in the uncontaminated area, so that they can step in immediately in case of emergencies.

The length of work shifts must be stipulated, taking into account the physical stresses arising due to the activity, bodily needs and the length of time taken to enter and exit via the airlock. The medical officer must participate in the drawing up of these stipulations.

1.3.2 Work instructions, hygiene plan, disinfection

Work instructions in accordance with section 14(4) of the Biological Agents Ordinance must be available for all activities that take place in the treatment centre. This relates in particular to:

- the treatment team entering and exiting via the airlock;
- the putting on and taking off of protective clothing, as well as the corresponding disinfection steps;
- the patient entering via the airlock;
- the provision of care to the patient;
- the disposal of liquid and solid waste;
- the procedure in case of accidents;
- the procedure for deceased patients;
- the procedure after treatment is finished; and
- repair and maintenance.

All disinfection measures are to be specified in a hygiene plan, along with all disinfectants and disinfectant processes used. This relates in particular to the:

- disinfection shower;
- decontamination of reusable personal protective equipment, e.g. respiratory protection accessories (respirator, hood, hose, etc.) and, if necessary, boots;
- decontamination and, if necessary, processing of used instruments and equipment;
- decontamination or disinfection of surfaces;
- safe disposal of liquid and solid waste;
- disinfection of beds; and
- stipulations for room disinfection once treatment is finished.

1.3.3 Internal plan for averting risks

There must be an internal plan in accordance with section 13(3) and (4) of the Biological Agents Ordinance setting out the conduct in case of incidents, accidents and emergencies and the corresponding information, reporting and notification obligations.

This plan must also include rules for the prevention of risks that could arise due to the release of highly pathogenic biological agents should a containment measure fail. The plan must contain:

- information on specific risks;
- the names of the persons responsible for implementing the rescue measures;
- information on the extent of safety exercises and the regular carrying out of these exercises.

The plan is to be coordinated with the relevant internal and external rescue and safety workers and must be designed so that the safety workers are able to define their rescue and safety measures.

Warning systems and means of communication must be established for immediately warning employees and alerting the rescue and safety services, and the correct operation of these systems and means of communication must be guaranteed.

1.3.4 Training

Training must be provided regularly and at least once a year to the members of the treatment team, as well as to other affected employees, taking into account the work instructions, the hygiene plan, emergency planning and the preventive occupational health measures. The content of the training is to be recorded in writing, and attendance must be confirmed with a signature.

In order to ensure smooth operation, the members of the treatment team are to be trained regularly and at least once a quarter. In particular, these training sessions should include the set-up of the isolation facility, as well as all safety-related activities arising during the treatment of infected persons. This relates above all to entering and exiting via the airlock.

1.4 Personal protective equipment (PPE)

The following PPE is necessary when treating infected persons:

1.4.1 Respiratory protection

Fan-assisted respiratory protection (TH3P) meeting DIN EN 12941 is to be worn. Depending on the disinfectant used, it may be necessary to supplement the particle protection with corresponding gas filters (combination filters).

Filter devices with fans (e.g. a respirator hood) can be dispensed with in some circumstances depending on the results of the risk assessment (e.g. in the event of significantly reduced contagiousness of the pathogen). In this case, FFP3 filtering face pieces, preferably with an exhalation valve, may be used, possibly in conjunction with eye protection (anti-fog safety goggles, CE Cat III, DIN EN 166).

1.4.2 Body protection

It is compulsory to wear category III, type 3 B disposable protective suits with feet. Work clothing may be worn underneath. It is permissible to wear shoes made of materials that can be disinfected (e.g. clogs). The junction between the sleeves and the gloves must be fixed in place and sealed by taping it up with liquid-tight adhesive tape. If necessary, it may be advisable to wear a disposable plastic apron in order to reduce contamination of the front side of the protective suit.

By way of exception to the aforementioned category III, type 3 B protective suit with a respirator hood for respiratory protection, it is also permissible to use fan-assisted protective suits with built-in respiratory-protection hoods, gloves and feet if they meet the stated requirements.

1.4.3 Hand protection

The hands are to be protected by wearing two pairs of liquid-tight protective gloves that protect against mechanical and biological risks (CE Cat. III, e.g. according to DIN EN 420, 388, 374, AQL \leq 1.5). The upper pair of gloves should preferably be chosen

with cuffs that allow easier masking and sealing at the junction with the protective suit.

1.4.4 Foot protection

Already described in 1.4.2.

1.4.5 Eye protection

Already described in 1.4.1.

Part 2: Special isolation units – important addresses

Treatment, competence and training centres

Since 2003, the German federal states have had a network of Competence and Treatment Centres for the management and care of persons with highly contagious and life-threatening diseases.

In cooperation with other institutions, a Permanent Working Group of Medical Competence and Treatment Centres (STAKOB) was established at the Robert Koch Institute in 2014:

- Treatment centres make available special isolation units with appropriately trained personnel for caring for persons suffering from diseases.
- Alongside this, competence centres act as a source of special expertise in the public health service.
- Training centres provide further training on various topics, e.g. putting on and taking off personal protective equipment correctly.

Further information on the STAKOB and the centres can be found on the Robert Koch Institute's website at www.rki.de under the menu item "Kommissionen" [Commissions] > "Arbeitskreis STAKOB" [STAKOB Working Group].

National Reference Centres and Consiliary Laboratories

National Reference Centres (NRCs) and Consiliary Laboratories (CLs) are appointed based on considerations relating to the epidemiological relevance of pathogens and special diagnostics, but also based on questions of resistance and infection-protection measures.

The NRCs are tasked with monitoring important pathogens. In addition, the CLs provide technical advice on the broadest possible range of pathogens. Further information on the NRCs and CLs can be found on the Robert Koch Institute's website at www.rki.de under the menu item "Infektionsschutz" [Prevention of infection] > "Diagnostik in NRZ und Konsiliarlaboratorien" [Diagnostics in NRCs and Consiliary Laboratories].

Annex 2 Instructions for preparing a hygiene plan

The aim of the hygiene plan pursuant to these technical rules is to prevent the transmission of infections due to microorganisms and to prevent harmful effects that result from necessary cleaning, disinfection, sterilisation, supply and disposal measures.

Necessary preventive measures are to be specified according to the workplace-specific risk. The example below sets out the procedure for preparing an activity-specific hygiene plan of this kind.

Hazard analysis

The first step entails defining the hazard characteristics of a workplace or, where applicable, an area (risk of contamination, infection, intoxication, or sensitisation).

The second step entails specifying who may be at risk and, where applicable, under what conditions.

Preventive measures

Risk-adapted guidelines and codes of conduct must be prepared and prescribed in a binding manner for the specific facility, taking account of the requirements that apply to the workplace/area (laws and ordinances) and drawing on relevant regulations (recommendations, directives, guidelines, standards, etc.). The employees are to be trained accordingly. Specialists (in occupational safety or hygiene) are to be included in the implementation process in an advisory or accountable capacity through written regulations in accordance with the statutory requirements.

Structure of measures

Basic measures: These include basic, universally binding regulations for the areas of hand hygiene, work/protective clothing and cleaning/disinfection measures.

Risk-based measures: Additional regulations may be necessary under specific conditions. Examples of this include:

- a) *pathogen properties* such as virulence (e.g. hepatitis viruses, HIV, tuberculosis pathogens, gastroenteritis pathogens, influenza viruses), toxin formation (e.g. clostridia, staphylococci) or other properties (e.g. defined antibiotic resistance of certain bacteria);
- b) *certain activities* such as operations, injections, punctures, laboratory diagnostics, endoscopies;
- c) *defined areas* such as the kitchen, laundry facility, central sterile supplies department, physiotherapy department, waste management department.

Annex 3 Guidelines on the use of interns

Foreword

Interns are now an indispensable part of everyday working life in a health care facility. Depending on the activity, they may be subject to infection risks to the same degree as regular employees.

Interns are protected by statutory accident insurance under article 2 of Volume VII of the Social Code (SGB VII). The Biological Agents Ordinance (BioStoffV)¹⁶ regulates the protection of employees if they are or may be at risk of biological effects as a result of their work. Section 2(9) of the Biological Agents Ordinance states that, in addition to the groups of persons identified in the Occupational Safety and Health Act (ArbSchG), employees also expressly include "...schoolchildren, students, [and] other persons, especially those working in scientific institutions or healthcare facilities". The definition therefore includes interns from schools that provide vocational training and help students find their vocation, as well as clinical trainees, doctoral candidates, guest students, scholarship holders, etc. In addition to employment relationships and internships for the purpose of vocational training, the scope of the Biological Agents Ordinance therefore also includes other forms of internship relationships in health care facilities. Section 12 of the Biological Agents Ordinance ensures that the Ordinance on Occupational Medical Prevention (ArbMedVV) also applies to this group of persons¹⁷.

These guidelines are intended to help decision-makers ensure adequate occupational safety and health protection. When interns are used, account must also be taken of the necessary implementation of all measures based on the activity-specific risk assessment.

For almost all internships that take place in health care facilities within the framework of the vocational training of health care professionals, it is to be assumed that activities involving infection risks take place and that these also fall within the scope of the Biological Agents Ordinance. These internships are referred to as **vocational internships** ("Berufspraktika").

If internships involving comparable activities are conducted outside of vocational training, these are to be treated analogously to vocational internships. So-called "**trial placements**" or **trial internships** are short-term internships that do not form part of vocational training and, for example, are intended only to give an impression of everyday life in the corresponding profession.

For example, these include work-experience placements during the period of compulsory full-time schooling for children¹⁸ or during young persons' holidays¹⁹.

Interns under the age of 18 who are not undertaking a vocational internship are only permitted to carry out activities that do not involve the direct handling of potentially infectious materials and for which the risks due to pathogens are comparable to those for the general population.

¹⁶ Ordinance on Safety and Health Protection at Workplaces Involving Biological Agents (Biological Agents Ordinance – BioStoffV) of 15.07.2013.

¹⁷ Ordinance on Occupational Medical Prevention (ArbMedVV) of 23.10.2013.

¹⁸ According to section 2(1) of the Act on the Protection of Young People at Work (JArbSchG), a "child" is anyone under the age of 15.

¹⁹ According to section 2(2) of the Act on the Protection of Young People at Work, a "young person" is anyone aged 15 to 17.

In principle, all interns in the health service should be expected to have the vaccination protection recommended for children and young persons by the Standing Committee on Vaccination (STIKO).

1 Vocational internship

1.1 Interns under the age of 18

1. Interns classified as young persons must only have contact with biological agents if this takes place within the framework of their training, if the activity is necessary for achieving their training objective, and if their protection is ensured through supervision by a person with professional expertise (section 22(2) of the Act on the Protection of Young People at Work).
2. For interns under the age of 18, it is advisable to obtain written consent for the internship from the legal guardians.

Note: Young persons whose vocational internship is to last more than two months must be examined by a doctor before the start of the internship. This first examination pursuant to the Act on the Protection of Young People at Work must have taken place no more than 14 months beforehand (section 32 of the Act on the Protection of Young People at Work).

This is not equivalent to preventive occupational health care from a medical officer.

1.2 General requirements

The following points apply to interns aged over 18 and interns aged under 18 who are carrying out a vocational internship.

1. Interns must only perform activities for which there are no prerequisites of professional expertise pursuant to section 11(6) of the Biological Agents Ordinance.
2. Within the framework of the risk assessment, the employer must specify whether it is necessary to arrange or offer preventive occupational health care. In facilities for the medical examination, treatment and care of humans, preventive health care is compulsory if activities are performed that involve regular, direct contact with persons suffering from or suspected to be suffering from a disease or if activities are performed that may regularly involve extensive contact with bodily fluids, bodily excretions or body tissue, especially if these activities entail an increased risk of injury, splashing or aerosol formation (annex part 2(1) number 3c of the annex to the Ordinance on Occupational Medical Prevention).

Within the framework of preventive occupational health care, interns must also be offered the relevant vaccinations. By way of example, the following table lists relevant reasons for vaccination:

Table: Examples of relevant vaccinations with reference to working areas and activities

Working area	Activity	Vaccination
Facilities for medical examination, treatment and care of humans	Activities involving regular, direct contact with persons suffering from or suspected of suffering from a disease	B. pertussis Hepatitis A virus Measles virus Mumps virus Rubivirus
Facilities for the medical examination, treatment and care of humans	Activities that may regularly involve extensive contact with bodily fluids, bodily excretions or body tissue, especially if these activities entail an increased risk of injury, splashes or aerosol formation	Hepatitis B virus
Facilities for the medical examination, treatment and care of children	Activities involving regular, direct contact with children suffering from or suspected of suffering from a disease	Varicella zoster virus (VZV) ¹
Facilities exclusively for the care of humans	Activities that may regularly involve extensive contact with bodily fluids, bodily excretions or body tissue, especially if these activities entail an increased risk of injury, splashes or aerosol formation	Hepatitis A virus Hepatitis B virus

¹: possibly in addition to lines 1 and 2

Depending on the specific internship position, it may be necessary to offer further facility-specific vaccination in individual cases.

3. Prior to commencing the activity, all interns are to be presented to the doctor in good time in accordance with section 7 of the Ordinance on Occupational Medical Prevention. The doctor will inform the interns of the infection risks that the internship entails within the framework of preventive occupational health care. The doctor may also carry out an examination and, if necessary, will determine whether the intern has sufficient immunity to the relevant biological agents.

After the occupational health consultation and, as the case may be, the examination and/or vaccinations are complete, the interns are permitted to carry out defined activities depending on their level of training and knowledge.

4. The doctor should request to see the intern's vaccination certificate.
5. It should be specified which protective measures are to be adhered to for which activities based on the risk assessment pursuant to the Biological Agents Ordinance (this is usually the responsibility of the establishment providing the internship). The establishment providing the internship provides the interns with the necessary personal protective equipment, including the protective clothing. This establishment also ensures the disin-

fection, cleaning and, if necessary, repair of the protective clothing or contaminated work clothing.

6. Before the start of the internship, the interns and legal guardians will receive information on hazards, conduct during the internship, necessary protective measures and vaccinations.
7. Training based on the risk assessment must be ensured at the start of the internship, followed by suitable supervision and support during the internship.
8. The medical officer should be notified of the interns by the corresponding management body, e.g. by the management of the care service and/or by the human resources department, before the start of the internship, with reference to the place of work and the period of the internship.
9. In the case of pregnant interns, the regulations of the Maternity Protection Act (MuSchG) and the Ordinance on the Protection of Mothers at Work (MuSchArbV) also apply.

2 Trial placements and trial internships

1. For interns aged under 18 who are undertaking not a vocational internship but rather a trial placement or trial internship, for example, the establishment providing the internship must specify the activities that cannot entail hazards due to pathogens (**restricted catalogue of activities**).

The following working areas are not suitable: intensive care units and operating departments; TB/HIV wards; areas with patients that have tested positive for MDR pathogens; pathology departments (example list).

2. Since these internships do not include activities that entail an infection hazard, there is no need for preventive occupational health care or to offer vaccinations pursuant to the Ordinance on Occupational Medical Prevention (ArbMedVV). Interns should, however, be made aware of the vaccinations recommended by the Standing Committee on Vaccination (STIKO).

3 Occupational safety and accident prevention measures – responsibility for costs

In accordance with the Occupational Safety and Health Act, the employer must not impose the costs of occupational safety measures or health and accident prevention on employees. As a rule, these costs are the responsibility of the employer, as are the costs for vaccinations offered and carried out within the framework of preventive occupational health care. The internship provider in whose establishment or facility the intern performs the activities is to be seen as an employer unless a different body is responsible for the internship's content and organisation. For example, in the case of vocational internships, the training centre with which the training contract was concluded can act as the employer.

Annex 4 Experiences of using safety equipment

The safety equipment must be selected for the specific application in accordance with number 4.2.5 paragraph 4 point 5. Any existing experiences of using safety equipment are to be taken into account. At the time of publication of these technical rules, the following information could be ascertained:

- The “Verzeichnis sicherer Produkte” [List of safe products] on the portal “www.sicheres-krankenhaus.de” [1] provides a market overview of safety equipment.
- Depending on the purpose and the current state of the art, safety equipment features various safety mechanisms that either require activation by the user after use (so-called active systems) or are self-triggering (so-called passive systems).
- Safety equipment with a safety mechanism that triggers automatically after the intended use has proved to be particularly effective. Examples of this include:
 - disposable safety lancets with a pull-back mechanism;
 - safety pen-type cannulas with automatic shielding;
 - safety venous catheters with a safety mechanism that locks in place when the steel stylet is pulled out of the catheter tube;
 - hypodermic syringes with a locking mechanism.
- If specific areas of application lack commercially available safety equipment that meets the requirements set out in number 4.2.5 paragraph 4 point 4, it is permissible to continue using instruments without a safety mechanism – observing any adapted safety measures – until suitable safety equipment is developed. This must then be documented in the risk assessment. The model risk assessment grid for the disconnection of shunt cannulas [“Raster einer Gefährdungsbeurteilung für das Dekonnektieren von Shuntkanülen”] can serve as a template for this – and by analogy for applications other than in dialysis [2].

Annex 5 Example of a model “Internal feedback form – evaluation of safety equipment”

For in-house review of the testing of promising safety equipment, e.g. in one department.

Date:			
Activity:			
Department:			
Safety device: (company; make; model)		Frequency of use (per shift):	

Please mark the appropriate answer with a cross (1 = statement is correct, ..., 5 = statement is not at all correct). If the question does not apply to the product used, put a cross under **N**.

	1	2	3	4	5	N
1. The device requires no significant change to the application technology.						
2. The device takes no longer than another device.						
3. The safety mechanism triggers automatically.						
4. The safety mechanism can be activated with one hand.						
5. The activation of the safety mechanism can be identified visually/acoustically/by touch.						
6. The safety mechanism operates reliably.						
7. The device can be handled correctly even while wearing gloves.						
8. The device allows good visibility of the aspirated fluid.						
9. It is easy to learn how to use.						
10. The device does not put the patient at risk.						

Do you believe that the device significantly increases your safety?

Yes No , because

If you know of various safety devices, which would you use in preference?

Do you have any further questions or information relating to safe working in your activity or with this device?

Annex 6 Example of a “Recording and analysis form for needle-stick injuries”

A questionnaire for identifying possible organisational and technical causes of accidents following a needle-stick injury (NSI) should contain the following points. Individual apportioning of blame is to be avoided (for more information, see number 4.2.5 paragraph 4 point 7 and number 6.2).

At the same time, this sheet is not used for internal management purposes following NSIs (accident insurance consultant, medical officer, laboratory tests). These measures are set out in number 6.1.

Incident: File number or similar for identifying the accident, date of accident

Injured person: Record of

- Sex
- Age
- Professional experience (years)
- Length of service at the company (years)
- Vocation in which person originally trained
- Activity being performed at the time of the accident

Sequence of events: Brief description of how the accident occurred

- Time of accident
- Time elapsed since starting work
- Type of injury
- Instrument that caused the injury (state exactly)
- Injured part of body
- Was the person wearing PPE? What type?

Possible causes of accident (more than one answer can be given):

- Time pressure
- Distraction due to environmental factors
- Interruption by other persons
- Unexpected movement of the patient
- Working environment: technical or organisational deficiencies, confined spaces
- Fatigue
- Overloading
- Insufficient training/knowledge of application
- ...

The following measures may remedy the situation:

- Technical:
- Organisational:
- Personal:
- Other:

Annex 7 Information on the correct fit and wearing duration of FFP masks²⁰, on the difference between surgical face masks and FFP masks, and on particle sizes in infectious aerosols

1 Information on the correct fit of FFP masks

Testing with excess pressure: after the filtering face piece is put on, the exhalation valve is to be closed (if there is one). Breathing out slightly creates a perceptible excess pressure in the mask. If the air flows past the sealing edge, the mask must be readjusted. If it is not possible to close the exhalation valve, this method cannot be applied.

Testing with negative pressure: the filtering face piece is to be enclosed with both hands. Breathing in deeply and holding the breath creates a negative pressure in the mask. If air flows in past the sealing edge, the mask must be readjusted.

The so-called “fit test” is even better suited than the tests described above and is therefore recommended. This test allows a mask’s seal to be determined qualitatively or quantitatively on the mask’s wearer [1].

Note that when the wearer has a beard in the area of the sealing line of respiratory protective devices, the anticipated protective effect cannot be achieved due to the poor seal.

2 Information on the wearing duration and reusability of FFP masks

FFP masks only exhibit slightly increased breathing resistance and are lightweight [2]. They belong to respiratory protective device group 1. In health care facilities, it can be assumed that the mask filters do not clog with dust during wearing; i.e. the inhalation resistance remains in the normal range. In individual cases, an FFP3 mask is nevertheless to be assigned to group 2 if, for example, heavy physical work is carried out or adverse climatic conditions are present. Such cases are to be identified within the framework of the risk assessment pursuant to the Occupational Safety and Health Act. If respiratory protective devices of group 2 must be worn, it is compulsory to provide preventive occupational health care in accordance with the Ordinance on Occupational Medical Prevention (ArbMedVV).

According to the Ordinance on Occupational Medical Prevention, employees are to be offered preventive occupational health care in the case of activities that require them to wear group 1 respiratory protective devices. See reference [3] for information on the short-term wearing of group 1 respiratory protective devices for up to 30 minutes. For further information on the wearing duration of respiratory protective devices, please refer to the documents from the accident insurance institutions on the “Use of respiratory protective equipment”.

FFP masks are to be disposed of after use for hygiene reasons.

In the event that FFP masks are not available in sufficient quantities during a pandemic and it is only possible to resort to already-used masks, these may also exceptionally be used multiple times under the following conditions, albeit for no longer than one work shift (see [4] for more information):

- The hands are to be disinfected before and after the mask is taken off; contamination of the inside of the mask is to be avoided.
- The mask is stored dry in the open air after use (not in closed containers!).

²⁰ FFP: filtering face piece

- The mask is subsequently used by the same wearer (access by other persons must be ruled out).

3 Difference between filtering face pieces (FFPs) and surgical face masks

Filtering face pieces (FFPs)

Filtering face pieces are respiratory protective devices that are tested according to and meet the requirements of the European standard DIN EN 149. This standard differentiates between three device classes: FFP1, FFP2 and FFP3. The use of respiratory protective devices is governed by the Ordinance on Safety and Health Protection when Using Personal Protective Equipment at Work (PPE Usage Ordinance; PSA-BV).

The decisive factor for a respiratory protective device's protective effect is its total leakage. This is made up of the filter transmission and the leak rate arising due to leakages between the mask's sealing line and the wearer's face. In accordance with DIN EN 149, both properties are tested in FFP masks. FFP1 masks have the lowest protective effect, while FFP3 masks have the highest.

The following values are to be used for total inward leakage (total leakage) for the individual devices according to the DIN EN 149 test procedure (permitted values for eight of the 10 arithmetical means, where one value was determined per test person):

FFP1 max. 22%

FFP2 max. 8%

FFP3 max. 2%.

Another positive aspect of using filtering face pieces to protect employees against airborne pathogens is their good retention capacity even with respect to particles with sizes $< 5 \mu\text{m}$ and their defined maximum total leakage (if used correctly!).

Surgical face masks

The surgical face mask is predominantly used in primary medical care, outpatient and hospital care and treatment, and in care work; it is a medical device. Above all, patients are protected against splashes from the person treating them if that person is wearing a surgical face mask. The European standard [5] for surgical face masks does not apply to masks that are solely intended for the personal protection of staff.

Tests carried out by the Institute for Occupational Safety and Health (IFA) of the German Social Accident Insurance (DGUV) on commercially available surgical face masks pursuant to the European standard DIN EN 149 [2] for respiratory protective devices show that the total leakage of many surgical face masks is significantly higher than the permitted values for filtering face pieces (FFPs). Only a few surgical face masks meet the essential requirements (filter transmission, total leakage, breathing resistance) for a filtering face piece of the device class FFP1 [6].

Surgical face masks can effectively prevent macroscopic droplets in the patient's phlegm from falling on the wearer's oral and nasal mucosae.

Surgical face masks protect the wearer's nose and mouth against contact with contaminated hands.

For further information on the differences between surgical face masks and FFP masks, please refer to reference [6] and the bibliography of ABAS Decision 609.

4 Information on particle sizes in infectious aerosols

From the point of view of protecting employees' health, the following points mean it is not sufficient to specify simple safety distances of 1 to 1.5 metres from the person who is coughing based on the assumption that pathogens transmitted primarily through droplets would fall to the floor quickly.

1. Aerosols consisting of solid or liquid particles suspended in air represent a distribution of particles of several orders of magnitude. Even if a significant proportion of the particles are the size of a droplet with a diameter of 100 μm , it can be assumed that smaller particles ($< 5 \mu\text{m}$ or $< 2.5 \mu\text{m}$; see below), typically referred to as (airborne) "droplet nuclei", are present at the same time. Smaller particles remain in the air longer and can spread throughout the room via air movements.
2. Even large droplets with a diameter of 100 μm take 6 seconds to fall to the floor from a height of 2 m. Droplets with a diameter of 10 μm take 10 minutes to fall the same distance; droplet nuclei with a diameter of 1 μm take 16.6 hours [7].
3. Recent studies on indoor exposure in waiting rooms show that the proportion of small, i.e. respirable, particles may be greater than previously expected:
 - In a study by W. Yang et al., various particle fractions were collected in waiting rooms of health care facilities, as well as in aeroplanes, during the 2009–10 flu season and analysed for the presence of RNA from the influenza A virus using molecular biology methods [8]. On average, 64% of the particles containing the influenza A virus were found in the $< 2.5 \mu\text{m}$ fraction, which can remain in the air for several hours.
 - F. M. Blachere et al. investigated the incidence of influenza A RNA in aerosol samples from waiting areas of a hospital emergency department [9]. 46% of the particles found to contain influenza A were in the $> 4 \mu\text{m}$ size range; 49% were in the 1–4 μm size range; and 4% were in the $< 1 \mu\text{m}$ range. In other words, more than 50% of the particles containing influenza A were in the respirable fraction; for this reason, the authors draw particular attention to the potential "airborne" infection pathway.

The use of respiratory protection therefore plays a greater, i.e. more effective, role in the prevention of infections by airborne pathogens than the distance recommendations mentioned earlier.

Annex 8 Waste codes for facilities for the care and treatment of humans and animals in accordance with the LAGA Guidelines²¹

The waste types marked with an asterisk (*) in the waste catalogue are hazardous within the meaning of section 48 of the German Recycling Act (KrWG).

AVV ²² waste code Waste code 18 01 01	AVV designation: Pointed or sharp objects		Waste classification: Non-hazardous
Waste definition: Pointed and sharp objects, also referred to as "sharps".			
Places where waste arises	Constituents	Collection – Storage	Disposal
Entire area of patient care	Scalpels, cannulas from syringes and infusion systems, objects that pose a similar risk of cuts and punctures.	Collection at the place where the waste arises in puncture- and fracture-resistant disposable containers, no transferring, sorting or pre-treatment.	No sorting! If necessary, disposal together with waste of waste code 18 01 04.
Notes: It is difficult to safely disinfect the cannula cavities. Also applies analogously to waste code 18 02 01.			

AVV waste code Waste code 18 01 02	AVV designation: Body parts and organs including blood bags and blood preserves		Waste classification: Non-hazardous
Waste definition: Body parts, organ waste, containers filled with blood and blood products			
Places where waste arises	Constituents	Collection – Storage	Disposal
E.g. operating theatres, outpatient facilities with corresponding activities.	Body parts, organ waste, blood bags, containers filled with blood or liquid blood products.	Separate collection at the place where waste arises, no mixing with municipal waste, no transferring, sorting or pre-treatment, collection in carefully sealed disposable containers (suitable for incineration), limited storage to prevent gas formation.	Separate disposal in approved incineration plant, e.g. toxic waste incineration plant; individual blood bags: may be emptied into the drainage system (taking account of hygiene and infection-prevention aspects). Adhere to municipal waste water regulations.
Notes: This classification applies only to waste that is not classifiable under waste code 18 01 03*. Extracted teeth are not body parts for the purposes of this waste code.			

²¹ LAGA: Working Group of the German Federal States on Waste

²² AVV: Abfallverzeichnisverordnung (Waste Catalogue Ordinance)

AVV waste code Waste code 18 01 03*	AVV designation: Other waste whose collection and disposal is subject to special requirements in order to prevent infection.		Waste classification: Hazardous waste
Waste definition: Waste contaminated with reportable pathogens if it is feared that the disease will spread as a result (see text!).			
Places where waste arises	Constituents	Collection – Storage	Disposal
E.g. operating theatres, isolation units in hospitals, microbiology laboratories, clinical/chemical laboratories and laboratories carrying out serological tests for infections, dialysis wards and centres when treating persons known to be carrying a hepatitis virus, pathology departments.	<p>Waste contaminated with pathogen-containing blood, secretions or excreta or that contains blood in liquid form.</p> <p>E.g.: vessels filled with blood or secretions, waste from operations that is soaked in blood or secretions, used dialysis systems from the treatment of persons known to be carrying a virus.</p> <p>Microbiological cultures from, for example, institutes of hygiene, microbiology and virology, laboratory medicine, doctors' practices carrying out a corresponding activity.</p>	<p>Pack into tear-proof, moisture-resistant and leak-proof containers at the place where waste arises. Collection in carefully sealed disposable containers (suitable for incineration, with type approval).</p> <p>No transferring or sorting.</p> <p>Limited storage to prevent gas formation.</p>	<p>No recycling!</p> <p>No compaction or crushing.</p> <p>Disposal as hazardous waste with disposal certificate: disposal in approved incineration plant, e.g. toxic waste incineration plant.</p> <p>Or: disinfection using methods approved by the RKI, followed by disposal as for waste code 18 01 04.</p> <p>Caution: restriction in the case of certain pathogens (CJD, TSE).</p>
Notes: Also pointed and sharp objects, body parts and organ waste from patients with corresponding diseases. Also applies analogously to waste code 18 02 02*.			

AVV waste code Waste code 18 01 04	AVV designation: Waste whose collection and disposal is not subject to special requirements in order to prevent infection, e.g. linen, plaster casts, disposable clothing		Waste classification: Non-hazardous
Waste definition: Waste contaminated with blood, secretions or excreta, such as dressings, plaster casts, disposable linen, nappies, disposable items, etc.			
Places where waste arises	Constituents	Collection – Storage	Disposal
Entire area of patient care	<p>Dressings and plaster casts, nappies, disposable linen, disposable items (e.g. syringe bodies), etc.</p> <p>Waste slightly contaminated with cytostatic drugs, such as swabs, sleeve covers, gloves,</p>	<p>Collection in tear-proof, moisture-resistant and leak-proof containers.</p> <p>Transport only in carefully sealed containers (in conjunction with reflux tanks where applicable).</p> <p>No transferring (not</p>	<p>Combustion in approved waste incineration plant (household waste incineration) or other approved thermal treatment.</p> <p>Containers with larger quantities of bodily fluid may be emptied into the</p>

	respiratory protection masks, disposable white coats, plastic/paper materials, wipes, empty cytostatic drug containers following intended use (ampoules, syringe bodies without cannulas, etc.), air filters and other slightly contaminated material of safety workbenches. Not: Separately collected, uncontaminated fractions of paper, glass, plastics (these are collected under their own waste codes).	even in the central storage location), sorting or pretreatment (except placing in compaction container).	drainage system, taking account of hygiene and infection prevention aspects (adhere to municipal waste water regulations). Alternatively, it is to be ensured through suitable measures that no liquid substances escape.
--	---	--	--

Notes: This classification applies only to waste that is not attributable to waste code 18 01 03*. Also applies analogously to waste code 18 02 03.
 This waste represents a mixture of a multitude of wastes to which other waste may be added that does not especially require monitoring and that, from an economic perspective, cannot reasonably be disposed of separately because of the small quantity involved.
 A separate declaration is not necessary if waste of this waste code is collected and disposed of within the framework of municipal waste disposal by the public waste disposal organisations.

Waste code 18 02 01

Pointed or sharp objects except those that fall under 18 02 02*
 Disposal as for waste code 18 01 01



Waste code 18 02 02*



Waste whose collection and disposal is subject to special requirements in order to prevent infection.
 This includes animals used for scientific purposes and other waste from human medical research and diagnostics and from veterinary medical practices and clinics whose disposal is not regulated by the Animal Carcass Disposal Act (TierKBG), as well as litter and excrement from animal experimentation facilities, provided it is to be expected that infectious diseases, especially those identified under waste code 18 01 03*, will be transmitted or animal diseases or epizootic diseases will spread through animal carcasses, animal body parts, blood, bodily secretions or excreta from diseased animals. Please refer to the Biological Agents Ordinance and the Technical Rules for Biological Agents TRBA 120 "Versuchstierhaltung" [Keeping of laboratory animals] and TRBA 230 "Protective measures for activities involving biological agents in agriculture and forestry and comparable activities".
 The requirements of the EWC waste code 18 01 03* are to be adhered to.

Waste code 18 02 03

Waste whose collection and disposal is not subject to special requirements in order to prevent infection.
 Disposal as for waste code 18 01 04.

Annex 9 Example operating instructions pursuant to section 14 of the Biological Agents Ordinance

Person responsible: Signature:	<p>Operating instructions pursuant to section 14 of the Biological Agents Ordinance</p> <div style="background-color: #e0e0e0; padding: 5px; margin: 10px auto; width: 80%;"> <p style="text-align: center; margin: 0;">Home for the elderly</p> <p style="text-align: center; margin: 0;">Incontinence care, assistance in going to the toilet, changing dirty bed linen</p> </div>	Revised:
DESCRIPTION OF RISKS		
	Above all, pathogens are to be expected that may lead to diseases of the gastrointestinal tract. In addition to this, other pathogens that can be transmitted via bodily excretions may represent a hazard.	
RISKS TO HUMANS		
	The pathogens can be transmitted by contact with stool/urine or contaminated objects or laundry, such as bedpans, bed linen.	
PROTECTIVE MEASURES AND CODE OF CONDUCT		
	<ul style="list-style-type: none"> – Wear provided work clothing (washable at 60°C) – suitable protective clothing is to be used (disposable white coat, waterproof apron) if contamination is to be expected. – Containers are available for collecting contaminated work clothing and protective clothing. – Wear provided disposable gloves (name:). – Wear a surgical face mask when disposing of vomit or stool. When assisting persons who are vomiting, wear FFP2 masks wherever possible, as they can protect against inhalation of fine bio-aerosols (including protection against noroviruses). – Any pointed, sharp working equipment that is found must be collected in the labelled, puncture-resistant containers. <p>Adhere to the hygiene and skin-protection plan:</p> <ul style="list-style-type: none"> – Use hand disinfectants! Caution: Use antiviral product (name:) in the event of norovirus infections! – Jewellery/rings are not permitted on the hands and forearms during these activities! – Wash dirty/contaminated skin, especially if spore-forming organisms such as <i>Clostridium difficile</i> are to be expected. – Use disposable (paper) towels for drying; use skin protection and care products. – Cleaning and disinfection of work surfaces; in the event of norovirus infections, use product provided for this purpose (name:)! – Disinfectant: Observe application times; avoid spraying! – Comply with the provided preventive occupational health care! <p>Food and beverages must only be stored and consumed in the break rooms.</p>	

CONDUCT IN CASE OF DANGER	
	<p>After soiling/contamination, disinfect any affected areas, cleaning up any coarse soiling beforehand with a disposable cloth.</p> <p>Take further protective measures if necessary. Inform the manager!</p>
FIRST AID	
	<p>Accident insurance consultant:</p> <p>Medical officer:</p> <p>Document incidents in the accident book.</p> <p>Emergency number/ambulance control centre: (0) 112</p>
PROPER DISPOSAL	
	<p>Collect potentially contaminated materials in rubbish bins with lids and sufficiently sturdy plastic bags, then dispose of them immediately as household waste.</p>

Annex 10 Rules and regulations, literature

10.1 Rules and regulations

10.1.1 Acts, ordinances, technical rules, European directives

(see <http://www.gesetze-im-internet.de> for further information)

- Occupational Safety and Health Act (ArbSchG)
- Biological Agents Ordinance (BioStoffV) with associated Technical Rules for Biological Agents (TRBA) and decisions of the Committee for Biological Agents (ABAS), including in particular:
 - TRBA 100 “Protective measures for activities involving biological agents in laboratories”
 - TRBA 120 “Versuchstierhaltung” [Keeping of laboratory animals]
 - TRBA 200 “Anforderungen an die Fachkunde nach Biostoffverordnung” [Requirements for professional expertise in accordance with the Biological Agents Ordinance] (in preparation)
 - TRBA 230 “Protective measures for activities involving biological agents in agriculture and forestry and comparable activities”
 - TRBA 460 “Einstufung von Pilzen in Risikogruppen” [Classification of fungi into risk groups]
 - TRBA 462 “Einstufung von Viren in Risikogruppen” [Classification of viruses into risk groups]
 - TRBA 464 “Einstufung von Parasiten in Risikogruppen” [Classification of parasites into risk groups]
 - TRBA 466 “Classification of prokaryotes (bacteria and archaea) into risk groups”
 - ABAS Decision 609 “Arbeitsschutz beim Auftreten einer nicht ausreichend impfpräventablen humanen Influenza” [Occupational safety and health in the event of an outbreak of influenza that is insufficiently preventable by vaccination]

For Technical Rules for Biological Agents (TRBA) and ABAS decisions, see also <http://www.baua.de/trba>

ABAS decision on company first-aiders see: http://www.baua.de/de/Themen-von-A-Z/Biologische-Arbeitsstoffe/ABAS/aus-dem-ABAS/Ersthelfer.html_nnn=true

- Hazardous Substances Ordinance (GefStoffV) with associated Technical Rules for Hazardous Substances (TRGS), including in particular:
 - TRGS 401 “Risks resulting from skin contact – identification, assessment, measures”
 - TRGS 525 “Umgang mit Gefahrstoffen in Einrichtungen zur humanmedizinischen Versorgung” [Handling hazardous substances in human health care facilities]

For Technical Rules for Hazardous Substances (TRGS), see also <http://www.baua.de/trgs>

- Workplaces Ordinance (ArbStättV) with its associated Technical Rules for Workplaces (ASR), including in particular:
 - ASR A4.1 “Sanitärräume” [Sanitary rooms]
 - ASR A4.2 “Pausen- und Bereitschaftsräume” [Break and stand-by rooms]

For Technical Rules for Workplaces (ASR), see also <http://www.baua.de/asr>

- Ordinance on Industrial Safety and Health (BetrSichV) with associated Technical Rules for Operational Safety (TRBS), including in particular:
 - TRBS 1112 “Instandhaltung” [Maintenance]
- For Technical Rules for Operational Safety (TRBS), see also <http://www.baua.de/trbs>
- Ordinance on Occupational Medical Prevention (ArbMedVV)
 - Protection Against Infections Act (IfSG)
 - Ordinance on Hygiene and Infection Prevention in Medical Facilities (MedHygV)
 - Act on the Protection of Young People at Work (JArbSchG)
 - Maternity Protection Act (MuSchG)
 - Ordinance on the Protection of Mothers at Work (MuSchArbV)
 - Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work
 - Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU

10.1.2 Rules, regulations and information from the social accident insurance institutions

(see <http://publikationen.dguv.de> for more information)

- **Accident-prevention guidelines**
 - Principles of prevention (BGV A1, GUV-V A1; in future DGUV Regulation 1)
 - Occupational Physicians and OSH Professionals (DGUV Regulation 2)
- **Rules**
 - “Benutzung von Schutzkleidung” [Use of protective clothing] (BGR or GUV-R 189)
 - “Benutzung von Atemschutzgeräten” [Use of respiratory protective devices] (BGR/GUV-R 190)
 - “Benutzung von Schutzhandschuhen” [Use of protective gloves] (BGR or GUV-R 195)
 - “Desinfektionsarbeiten im Gesundheitsdienst” [Disinfection work in the health service] (BGR or GUV-R 206)
 - “Reinigungsarbeiten mit Infektionsgefahr in medizinischen Bereichen” [Protecting cleaners from infection risks in healthcare facilities] (BGR 208)
- **Information**
 - “Sichere Biotechnologie” [Safe biotechnology] series of information sheets, including in particular:
 - “Fachbegriffe” [Technical terms] (BGI 628)
 - “Einstufung biologischer Arbeitsstoffe: Viren” [Classification of biological agents: viruses] (BGI 631)
 - “Einstufung biologischer Arbeitsstoffe – Parasiten” [Classification of biological agents – parasites] (BGI 632)

- “Einstufung biologischer Arbeitsstoffe – Prokaryonten (Bacteria und Archaea)” [Classification of biological agents – prokaryotes (bacteria and archaea)] (BGI 633)
- “Einstufung biologischer Arbeitsstoffe – Pilze” [Classification of biological agents – fungi] (BGI 634)
- “Zahn technische Laboratorien – Schutz vor Infektionsgefahren” [Dental laboratories – protection from risks of infection] (BGI 775)
- “Neu- und Umbauplanung im Krankenhaus unter Gesichtspunkten des Arbeitsschutzes” [Planning hospital constructions and conversions from the point of view of occupational safety and health] (BGI/GUV-I 8681) with the supplementary module “Anforderungen an Funktionsbereiche” [Requirements of functional areas] (BGI/GUV-I 8681-1)
- Guideline for special preventive occupational health care, entitled “Tätigkeiten mit Infektionsgefährdung” [Activities with a risk of infection] (BGI/GUV-I 504-42)
- DGUV Guideline G 42 for occupational medical examinations, entitled “Tätigkeiten mit Infektionsgefahr” [Activities with a risk of infection] (available from: Gentner Verlag, Abt. Buchdienst, Postfach 101742, 70015 Stuttgart)
- **German Social Accident Insurance Institution for the Health and Welfare Services (BGW)**
(see <http://www.bgw-online.de> for further information)
 - Information document “Diagnostische Proben richtig versenden – gefahrgutrechtliche Hinweise” [Correct shipping of diagnostic samples – information on dangerous goods regulations] – human medicine: order no. TP-DPHuM; and veterinary medicine: order no. TP-DPVetM,
 - “Abfallentsorgung – Informationen zur sicheren Entsorgung von Abfällen im Gesundheitsdienst” [Waste disposal – information on safe waste disposal in the health service] (order no. EP-AE)
- **German Social Accident Insurance Institution for the Energy, Textile, Electrical and Media Products Sector (BG ETEM)**
(see <http://www.bgetem.de> for further information)
 - Information document “Wäsche mit Infektionsgefährdung der Beschäftigten” [Laundry with an infection risk for employees] (S 050, TA 2048)
 - Information document “Infektionsgefährdung und Schutzmaßnahmen in Orthopädienschuhtechnikbetrieben” [Infection risk and protective measures in workplaces for orthopaedic shoe technology] (S 051)

10.1.3 Standards and similar guidelines

- DIN EN 149 Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking
- DIN EN 455 Parts 1 to 4: Medical gloves for single use
- DIN EN 13300 Water-borne coating materials and coating systems for interior walls and ceilings

- DIN EN ISO 23907 Sharps injury protection – Requirements and test methods – Sharps containers

10.1.4 Special literature for individual numbers and annexes

For number 3 “Assessment of working conditions”

- Recommendations of the Commission of Hospital Hygiene and Infection Prevention (KRINKO), see www.rki.de, menu item: “Infektionsschutz” [Prevention of infection], menu item: “Infektions- und Krankenhaushygiene” [Infection control and hospital hygiene], including in particular:
 - “Empfehlungen zur Händehygiene” [Recommendations for hand hygiene]
 - “Anforderung der Krankenhaushygiene und des Arbeitsschutzes an die Hygienebekleidung und persönliche Schutzausrüstung” [Hospital hygiene and occupational safety requirements for hygienic clothing and personal protective equipment]
 - “Anforderungen an die Hygiene bei Punktionen und Injektionen” [Hygiene requirements for punctures and injections]
 - “Anforderungen an die Hygiene bei der Reinigung und Desinfektion von Flächen” [Hygiene requirements for the cleaning and disinfection of surfaces]
 - “Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten” [Hygiene requirements for the treatment of medical products]
 - “Anforderungen an Gestaltung, Eigenschaften und Betrieb von dezentralen Desinfektionsmittel-Dosiergeräten” [Requirements for the design, properties and operation of decentralised disinfectant dispensers]
 - “Infektionsprävention in Heimen” [Prevention of infection in residential care facilities]
 - “Anforderungen der Hygiene an die baulich-funktionelle Gestaltung und apparative Ausstattung von Endoskopieeinheiten” [Hygiene requirements for the structural/functional design and equipment of endoscopy units]
 - “Anforderungen der Hygiene bei Operationen und anderen invasiven Eingriffen” [Hygiene requirements for operations and other invasive procedures]
 - “Anhang zu den Anforderungen der Hygiene beim ambulanten Operieren in Krankenhaus und Praxis” [Annex to the hygiene requirements for outpatient operations in hospitals and practices]
 - “Infektionsprävention in der Zahnheilkunde - Anforderungen an die Hygiene” [Prevention of infection in dental medicine – hygiene requirements]
- Information from the Robert Koch Institute (RKI) on agents that are pathogenic to humans: www.rki.de
- Information from the Friedrich-Loeffler-Institut (FLI) and/or the national reference laboratories for agents that are pathogenic to animals: www.fli.bund.de
- Information from the Committee for Biological Agents (ABAS): www.baua.de/abas
- Information from the German Social Accident Insurance (DGUV) and the social accident insurance institutions: www.dguv.de

For number 4 “Protective measures”

4.1.9 Diagnostic samples

- “Regelungen für die Beförderung von gefährlichen Stoffen und Gegenständen, Teil 1 A und B: BRIEF national” [Regulations for the carriage of hazardous substances and objects, parts 1 A and B: National LETTER] (valid from 01.07.2013), “Versandvorschriften und Hinweise für Einlieferer” [Shipping requirements and information for senders], www.deutschepost.de
- “Regelungen für die Beförderung von gefährlichen Stoffen und Gegenständen, Teil 2: DHL PAKET national” [Regulations for the carriage of hazardous substances and objects, part 2: DHL national PARCEL] (valid from 01.07.2013), www.dhl.de
- Brochure “Patientenproben richtig versenden - Gefahrgutrechtliche Hinweise – aktualisierte Fassung nach ADR 2013” [Correct shipment of patient samples – Information on dangerous goods regulations – Updated version pursuant to ADR 2013] (human medicine: TP-DPHuM), www.bgw-online.de
- “European Agreement concerning the International Carriage of Dangerous Goods by Road” (ADR), 2013, with associated ordinances and packing instructions P620 and P650.

4.2.2 Toilets

- Technical Rules for Workplaces ASR A4.1 “Sanitarräume” [Sanitary rooms]
- Hj. Gebhardt, I. Levchuk, C. Mühlemeyer, K.-H. Lang, final report on the research project F 2159 “Need-related design and equipment of sanitation facilities at workplaces”, BAuA Dortmund/Berlin/Dresden 2013, www.baua.de
- Johnson DL; Mead KR; Lynch RA; Hirst DV, Lifting the lid on toilet plume aerosol: A literature review with suggestions for future research, American Journal of Infection Control 2013, 41 (3):254–8
- S Strauss, P Sastry, C Sonnex, S Edwards, J Gray, Contamination of environmental surfaces by genital human papillomaviruses, Sex Transm Infect 2002; 78:135–138, <http://sti.bmj.com/content/78/2/135.full.pdf+html>

4.2.7 Protective clothing

- ABAS Decision 45/2011 “Kriterien zur Auswahl der PSA bei Gefährdungen durch biologische Arbeitsstoffe” [Selection criteria for PPE in case of risks due to biological agents] of 5.12.2011, www.baua.de/abas

4.2.8 Protective gloves

- DIN EN 455 Parts 1 to 4 Medical gloves for single use
- DIN EN 420 Protective gloves – General requirements and test methods
- DIN EN 374 Part 1 Protective gloves against chemicals and micro-organisms – Terminology and performance requirements
- Online portal “Branchen-Arbeits-Schutz-Informationen-System (BASIS)” [Industrial Occupational Safety Information System], module “Hand- und Hautschutz, Dentaltechnik” [Hand and skin protection, Dental technology], <http://www.basis-bgetem.de/hh>

4.3.4 Personal protective equipment (protection level 3)

- Recommendations of the German Central Committee against Tuberculosis, entitled “Tuberculosis Infection Control”, published in 2012 in the online publication Pneumologie

For number 5 “Specific working areas and activities – special and additional protective measures “

5.7 Multidrug resistant pathogens

- Recommendations of the Commission of Hospital Hygiene and Infection Prevention (KRINKO), see www.rki.de, menu item: “Infektionsschutz” [Prevention of infection], menu item: “Infektions- und Krankenhaushygiene” [Infection control and hospital hygiene], including in particular:
 - “Empfehlungen zur Prävention und Kontrolle von Methicillin-resistenten Staphylococcus aureus-Stämmen (MRSA) in Krankenhäusern und anderen medizinischen Einrichtungen” [Recommendations for the prevention and control of methicillin-resistant Staphylococcus aureus (MRSA) strains in hospitals and other medical facilities]
 - “Kommentar zu den 'Empfehlungen zur Prävention und Kontrolle von MRSA-Stämmen in Krankenhäusern und anderen medizinischen Einrichtungen” [Comment on the “Recommendations for the prevention and control of MRSA strains in hospitals and other medical facilities”]
 - “Hygienemaßnahmen bei Infektionen oder Besiedlung mit multiresistenten gramnegativen Stäbchen” [Hygiene measures in case of infections or colonisation with multidrug resistant gram-negative rods]

5.9.7 Treatment of instruments

- ABAS Decision 603 “Schutzmaßnahmen bei Tätigkeiten mit Transmissibler Spongiformer Enzephalopathie (TSE) assoziierter Agenzien in TSE-Laboratorien” [Protective measures for activities involving transmissible spongiform encephalopathy (TSE) associated agents in TSE laboratories], www.baua.de/abas
- Recommendation of the Commission of Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM), entitled “Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten” [Hygiene requirements for the processing of medical devices], Bundesgesundheitsblatt [Federal Health Bulletin] 2012, 55, p. 1244–1310, or www.rki.de

For annex 1 “Special isolation units (protection level 4)”

- Fock, Peters, Wirtz, Scholz, Fell, Bußmann; “Rahmenkonzept zur Gefahrenabwehr bei außergewöhnlichen Seuchengeschehen” [Framework concept for risk avoidance in case of exceptional epidemic events]; Gesundheitswesen 2001; 63:695-702; Georg Thieme Verlag Stuttgart
- Fock, Koch, Wirtz, Peters, Ruf, Grünewald; “Erste medizinische und antiepidemische Maßnahmen bei Verdacht auf virales hämorrhagisches Fieber” [Initial medical measures and anti-epidemic measures when viral haemorrhagic fever is suspected]; Me. Welt 5/2001

See also current information on the Robert Koch Institute's website.

For information on handling highly contagious, life-threatening diseases, see e.g. <https://hsm.hessen.de/gesundheits/infektionskrankheiten/hochkontagiose-lebensbedrohende-erkrankungen>.

- DIN EN 166 Personal eye-protection – Specifications
- DIN EN 170 Personal eye protection – Ultraviolet filters – Transmittance requirements and recommended use
- DIN EN 374 Part 1 Protective gloves against chemicals and micro-organisms – Terminology and performance requirements
- DIN EN 388 Protective gloves against mechanical risks
- DIN EN 420 Protective gloves – General requirements and test methods
- DIN EN 12941 Respiratory protective devices – Powered filtering devices incorporating a helmet or a hood – Requirements, testing, marking

For annex 4 “Experiences of using safety equipment”

- [1] “Verzeichnis sicherer Produkte” [List of safe products] on the portal www.sicheres-krankenhaus.de from the North Rhine-Westphalia Accident Insurance Provider (Unfallkasse NRW) and the German Social Accident Insurance Institution for the Health and Welfare Services (BGW)
- [2] “Raster einer Gefährdungsbeurteilung für das Dekonnektieren von Shuntkanülen” [Risk assessment grid for the disconnection of shunt cannulas], German Social Accident Insurance Institution for the Health and Welfare Services (BGW), recommendation of the Committee for Biological Agents (ABAS) with Decision 7/2010 on 18.05.2010 in relation to TRBA 250 “Biological agents in health care and welfare facilities”

As well as further opinions of the Committee for Biological Agents (ABAS) in relation to TRBA 250; see www.baua.de/abas, link: “Stellungnahmen des ABAS” [Opinions of the ABAS]

For annex 7 “Information on the correct fit and wearing duration of FFP masks, on the difference between surgical face masks and FFP masks, and on particle sizes in infectious aerosols”

- [1] Auswahlhilfe für Atemschutzgeräte: Der Fittest – ein Muss für Betriebe? [Selection aid for respiratory protective devices: The fit test – a must for workplaces?], C. Thelen, sicher ist sicher – Arbeitsschutz aktuell, no. 2, 2013, p. 74–76.
- [2] DIN EN 149 (August 2009) “Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking”, Beuth Verlag GmbH, Berlin
- [3] “Handlungsanleitung für die arbeitsmedizinische Vorsorge nach dem DGUV-Grundsatz G 26 ‘Atemschutzgeräte’” [Guideline for preventive occupational health care in accordance with DGUV Guideline G 26 “Respiratory protective equipment”] (BGI/GUV-I 504-26, published October 2010); see <http://www.dguv.de/publikationen>

- [4] Institute of Medicine of the National Academies, "Reusability of Facemasks During an Influenza Pandemic: Facing the Flu", April 2006, <http://www.iom.edu/CMS/3740/32033/34200.aspx>
- [5] DIN EN 14683 Surgical masks – Requirements and test methods, published February 2006, Beuth Verlag GmbH, Berlin.
- [6] "Zur Frage des geeigneten Atemschutzes vor luftübertragenen Infektionserregern" [On the question of suitable respiratory protection against airborne pathogens]; Dreller, S., Jatzwauk, L., Nassauer, A., Paskiewicz, P., Tobys, H.-U., Rüden, H., Gefahrstoffe – Reinhalt. d. Luft, 66 (2006) no. 1–2, p. 14–24.
- [7] Kappstein, "Nosokomiale Infektionen" [Nosocomial infections], Georg Thieme Verlag 2009.
- [8] W. Yang, S. Elankumaran, L.C. Marr, "Concentrations and size distributions of airborne influenza A viruses measured indoors at a health centre, a day-care centre and on aeroplanes", J. R. Soc. Interface (2011), 8, p. 1176–1184.
- [9] F.M. Blachere, W.G. Lindsley, T.A. Pearce, S.E. Anderson, M. Fisher, R. Khakoo, B.J. Meade, O. Lander, S. Davis, R.E. Thewlis, I. Celik, B.T. Chen, D.H. Beezhold, "Measurement of Airborne Influenza Virus in a Hospital Emergency Department", Clinical Infectious Diseases 2009, 48, p. 438–440.

Further literature on the performance of FFP masks and surgical face masks:

Evaluating the protection afforded by surgical masks against influenza bioaerosols, Gawn, J., Clayton, M., Makison, C., Crook, B., HSL, Research Report 619, Ed. Health and Safety Executive, UK 2008, see <http://www.hse.gov.uk/research/rrhtm/rr619.htm>

For annex 8 "Waste codes for facilities for the care and treatment of humans and animals in accordance with the LAGA Guidelines"

- Notification 18 of the Working Group of the German Federal States on Waste (LAGA) entitled "Vollzugshilfe zur Entsorgung von Abfällen aus Einrichtungen des Gesundheitsdienstes" [Guidelines for the disposal of waste from health care facilities], revised: September 2009, see <http://www.laga-online.de>