> Safety measures in medical microbiology diagnostic laboratories

Guideline for enforcing the Containment Ordinance (CO) in the analysis of clinical samples





Schweizerische Eidgenossenschaft Confédération suisse Confederazione Svizzera Confederaziun svizra Federal Office for the Environment FOEN Federal Office of Public Health FOPH

Swiss Confederation

> Safety measures in medical microbiology diagnostic laboratories

Guideline for enforcing the Containment Ordinance (CO) in the analysis of clinical samples

2nd updated edition, April 2015; first published in 2008

Published by the Federal Office for the Environment FOEN and by the Federal Office of Public Health FOPH Bern, 2015

Legal status of this publication

This publication is an implementation guide issued by FOEN and FOPH in their capacity as supervisory authorities, and is addressed primarily to the enforcement authorities. It seeks to clarify undefined legal concepts contained in the relevant Acts and ordinances so as to facilitate consistent enforcement practices. Authorities who give due consideration to these guides can safely assume that federal law is being correctly implemented. Alternative approaches are, however, permissible provided they comply with the legal requirements. Guides of this kind (until now also referred to as guidelines, instructions, recommendations, handbooks, enforcement aids, etc.) are published by FOEN in the series entitled "The environment in practice".

Publisher

Federal Office for the Environment (FOEN) The FOEN is an office of the Federal Department of Environment, Transport, Energy and Communications (DETEC). Federal Office of Public Health (FOPH) The FOPH is an office of the Federal Department of Home Affairs (FDHA)

Authors

Felix Gmünder (Basler&Hofmann) Thomas Binz, Samuel Roulin, Urs Spahr (FOPH)

In collaboration with:

Susanne Biebinger, Carmen Spycher, Martin Gschwind, Barbara Wiesendanger, Karoline Dorsch, Mauro Tonolla, Marisa Dolina, Werner Wunderli, Sabrina Leuenberger

In-house consultant

Graziella Mazza, Soil and Biotechnology Division

Suggested form of citation

Gmünder F., Binz T., Roulin R., Spahr U. 2015: Safety measures in medical microbiology diagnostic laboratories. Guideline for enforcing the Containment Ordinance (CO) in the analysis of clinical samples. 2nd updated edition, April 2015; first published in 2008. Federal Office for the Environment, Bern. The environment in practice no. 0815: 22 pp.

Design

Valérie Fries, 3063 Ittigen

Cover picture

Susanne Biebinger, State Laboratory of the Canton Basel City

Link to PDF file

<u>www.bafu.admin.ch/uv-0815-e</u> It is not possible to order a printed version.

This publication is also available in German, French and Italian.

© F0EN 2015

> Table of contents

Abstracts Foreword				
1	Introduction	8		
1.1	Content, purpose and significance	8		
1.2	Scope of the specifications	9		
2	Assignment of activities to classes	10		
3	Safety measures	11		
3.1	Use of a microbiological safety cabinet (MSC)	11		
3.2	Commentaries on individual clinical samples 3.2.1 Clinical samples from the lower respiratory	12		
	tract	14		
	3.2.2 Blood cultures	14		
	3.2.3 Blood samples	15		
	3.2.4 Skin swab (anthrax)	15 15		
	3.2.5 Stool, rectal swab 3.2.6 Urine	15 15		
	3.2.7 Biopsies, CSF, puncture specimens	15		
3.3		10		
010	measures in safety level 3	16		
4	Waste disposal	18		
5	Transport	19		
	iography reviations, figures and tables sary	20 20 22		

> Abstracts

This implementation guide explains the various safety measures according to the Containment Ordinance (CO) that must be observed when performing analyses of clinical samples. The safety measures are basically derived from the classification of the activities into classes. According to the type of sample and the pathogen in question, the safety measures stipulated by the CO may, however, be substituted or omitted. The present implementation guide is intended to provide guidance for this. It also contains references to the handling of wastes and to transport.

Diese Vollzugshilfe erläutert die verschiedenen Sicherheitsmassnahmen gemäss Einschliessungsverordnung (ESV), die für die Durchführung von Analysen von klinischen Probematerialien einzuhalten sind. Die Sicherheitsmassnahmen leiten sich grundsätzlich von der Zuordnung der Tätigkeiten zu Klassen ab. Je nach Art der Untersuchungsproben und Krankheitserreger können die gemäss ESV vorgesehenen Sicherheitsmassnahmen jedoch ersetzt oder weggelassen werden. Die vorliegende Vollzugshilfe soll als Anleitung dazu dienen. Weiter verweist sie auf den Umgang mit Abfällen und auf den Transport.

La présente aide à l'exécution énumère les différentes mesures de sécurité qui doivent être prises en vertu de l'ordonnance sur l'utilisation confinée (OUC) lors de l'analyse de matériel clinique. Les mesures de sécurité dépendent des classes de sécurité auxquelles sont attribuées les activités. En fonction du type d'échantillon à analyser et de l'agent pathogène, elles peuvent toutefois être remplacées voire omises. La présente directive doit faciliter la mise en œuvre. Elle contient également des renvois concernant l'élimination des déchets et le transport.

Il presente aiuto all'esecuzione illustra le diverse misure di sicurezza previste dall'ordinanza sull'impiego confinato (OIConf) che devono essere adottate nell'ambito dell'analisi di campioni di materiale clinico. In linea di principio le misure di sicurezza da rispettare sono determinate dalla classe di attività. Tuttavia, in base al tipo di campioni esaminati e ai microrganismi patogeni, le misure di sicurezza previste dall'OIConf possono essere sostituite oppure omesse. Il presente aiuto all'esecuzione fornisce istruzioni al riguardo. Inoltre, contiene indicazioni sulla gestione dei rifiuti e sulle modalità del loro trasporto. Keywords: Containment Ordinance (CO), biosafety, safety measures, diagnostics, laboratories

Stichwörter: Einschliessungsverordnung (ESV), Biosicherheit, Sicherheitsmassnahmen, Diagnostik, Laboratorien

Mots-clés: ordonnance sur l'utilisation

confinée (OUC), sécurité biologique, mesures de sécurité, diagnostic, laboratoires

Parole chiave:

ordinanza sull'impiego confinato (OlConf), sicurezza biologica, misure di sicurezza, diagnostica, laboratori

> Foreword

In putting the Containment Ordinance into practice in human medical microbiological diagnostics, questions have repeatedly been raised about the classification of activities and the required safety measures. Which safety measures can be omitted in which cases and for which pathogens? The present implementation guide is intended to support the cantonal authorities and diagnostics laboratories in answering such questions.

In drawing up this implementation guide, the major contribution was made by the Federal Office of Public Health, which is responsible for issues of human medical microbiological diagnostics. In the elaboration it was able to use the advice and support of Basler & Hofmann, Ingenieure und Planer AG, Zurich. In addition to the FOEN, the Swiss Expert Committee for Biosafety (SECB), the Intercantonal Group ERFA BIO, the Swiss Accident Insurance Fund (SUVA), and experts in laboratory diagnostics, contributed to the preparation and revision of this Guideline.

We would like to take this opportunity to thank all those involved, and particularly the Federal Office of Public Health, for their efforts.

Gérard Poffet Vice Director Federal Office for the Environment (FOEN)

> Introduction

1

1.1 Content, purpose and significance

In this Guideline the Federal Office of Public Health (FOPH) and the Federal Office for the Environment (FOEN) present the safety measures that operators of diagnostic laboratories (analysis of clinical material, medical microbiological diagnostics) must take to protect the population and the environment. The specifications put into practical terms the provisions of the Environmental Protection Law (LPE, SR 814.01), the Law on Epidemics (EpG, SR 818.101) and the Containment Ordinance (CO, SR 814.912). They will be updated periodically to take account of accumulating experience and advances in technology and science.

The protection of employees from microbiological hazards is regulated in the Ordinance on Occupational Safety in Biotechnology (OOSB, SR 832.321). The safety measures that must be taken according to the OOSB for the analysis of clinical material largely overlap with the measures of the CO. However, the OOSB lists additional measures that are specifically for employees (e.g. measures of occupational medicine). SUVA is responsible for enforcing the OOSB.

The target audiences of this document are facilities that handle human-pathogenic microorganisms in contained systems, and the authorities responsible for enforcing the CO and the OOSB.

The facilities are responsible for performing risk identification and assessment of the activities they undertake involving microorganisms, and for determining and adhering to the necessary safety measures.

In accordance with Article 23 CO, the cantonal authorities shall monitor the observance of the obligation to take due care, the contained use obligation, and the safety measures. Facilities in which Class 3 or 4 activities using microorganisms are performed are also subject to the Ordinance on Major Accidents (OMA, SR 814.012) and are required to take further measures to prevent major accidents. When constructing new facilities or when carrying out major building alterations or changes to the business of facilities in which Class 3 or 4 activities are carried out, an Environmental Impact Assessment (EIA) must also be performed. The cantonal authorities are generally responsible for enforcing the OMA and the Ordinance on EIA.

These specifications should ensure uniform enforcement practice. Deviation from these specifications is permissible if the statutory provisions can be fulfilled in other ways.

1

9

1.2 Scope of the specifications

The specifications apply to medical microbiology diagnostic laboratories that handle human-pathogenic microorganisms of Group 2 (low-risk microorganisms) and Group 3 (moderate-risk microorganisms; classification according to Annex 2 CO).

The specifications can also be used for diagnosis of Group 2 and 3 animal-pathogenic microorganisms.

Research activities and the handling of Group 4 human-pathogenic microorganisms are not the subject of these specifications.

> Assignment of activities to classes

Risk identification and assessment must be performed for any activity involving pathogenic organisms (Art. 5 para 2 CO). The first stage is to assign the organisms into one of four groups. This classification can be performed using the organism lists published by the FOEN (Art. 26 CO), or using the criteria given in Annex 2.1. CO. The second stage of risk identification and assessment assigns the activity to a class, taking into account the criteria listed in Annex 2.2 CO.

Analyses of clinical material for pathogenic microorganisms (medical microbiology diagnostics) are generally assigned to Class 2 (Annex 2.2 Section 2.2 para 2 CO). However, analyses of microorganisms of Groups 1 and 2 from clinical material may be allocated to Class 1 if the organisms are demonstrated using direct or indirect methods without propagation and methods that involve slight proliferation exclusively in closed vessels (Annex 2.2 Section 2.2 para 1 letter b CO).

The culture of Group 3 pathogenic microorganisms for diagnostic purposes should generally be assigned to Class 3 (Annex 2.2 Section 2.2 para 2 CO) if it is associated with an increased risk for humans, animals and the environment. Culturing Group 3 pathogenic microorganisms for diagnostic purposes is associated with a higher risk if, for example:

- open, grown cultures of microorganisms subject to airborne transmission are being handled (differentiation step for definitive diagnosis)
- the activity is performed in a reference laboratory (e.g. development of methods, strain typing, collection and exchange of reference strains or their handling)
- clinical samples or cultures of Group 3 microorganisms are being handled for quality assurance of the analyses, or as part of validation procedures

The inoculation and workup¹ of clinical samples that may contain Group 3 microorganisms² subject to airborne transmission is a Class 2 activity.

¹ See Chapter 7, Terms

² e.g. for diagnostics of Group 3 bacteria, fungi or viruses. These include: Brucella sp., Bacillus anthracis, Burkholderia mallei and B. pseudomallei, Francisella tularensis, Mycobacterium tuberculosis complex, Yersinia pestis, Coxiella burnettii, Histoplasma capsulatum, Coccidioides immitis, Chlamydia psittaci and certain species of Rickettsia, as well as SARS and monkeypox virus.

3

> Safety measures

In every case, there are general safety measures that must be followed when handling pathogenic microorganisms in diagnostic laboratories (Annex 4 Section 1 CO). The most important aspects of general safety measures are:

- > Observing the principles of good microbiological practice (Annex 3 Section 1 SAMV [OOSB] and Annex 4 Section 1 letter e CO)
- > Employing a biosafety officer³
- > Complying with a safety concept⁴
- > Employing sufficient staff and ensuring they have adequate safety training.

The class of the activity determines which special safety measures must be followed at the corresponding safety level (Annex 4 Section 2.1 CO).

In addition to classifying the activities, risk identification and assessment also forms the basis for deciding which organism- and activity-specific safety measures are required in individual cases, and which can be omitted, replaced or altered in accordance with Article 12 para 3 letter a CO, if the Federal Office responsible issues a corresponding authorisation. The authorisation requires proof that the safety of humans, animals and the environment is still guaranteed. In the following sections we outline the conditions under which special safety measures of level 2 and 3, substantiated and with FOPH authorisation, may be omitted, substituted or altered.

3.1 Use of a microbiological safety cabinet (MSC)

In accordance with the CO, Class 2 activities should take suitable measures to minimise aerosols, which activities at higher classes should avoid completely (CO, Annex 4 Section 2.1 Table, Safety Measures 22).

An MSC is one way to ensure protection against aerosols. It is standard equipment for laboratories of safety level 2 or higher, and the CO prescribes the use of one for activities of Class 2 or higher (CO, Annex 4 Section 2.1 Table, Safety Measure 21).

An MSC should normally be used if there is a possibility that aerosols may arise during a work step. An MSC may be replaced or omitted for Class 2 activities in justified cases. The decision on whether a safety cabinet must be used for particular activities depends on the risk identification and assessment of the activity or work step in individual cases. This should take into account the protective effect of the MSC and criteria for the risk of infection (potential for aerosol or droplet formation, routes of transmis-

 ³ SAEFL (2005). Guideline. Biosafety officers (<u>www.bafu.admin.ch/publikationen/publikation/00597/index.html?lang=en</u>)
 ⁴ FOEN (2008). Guideline Operational Safety concepts according to Containment Ordinance (CO): www.bafu.admin.ch/publikationen/publikation/00094/index.html?lang=en

sion, concentration and infective dose of the organisms etc.). The applicant must in each case provide justification for omitting an MSC, or proof that substitute measures are sufficient to guarantee the protection of humans and the environment.

A safety cabinet need not be used if the presence of Group 3 microorganisms in samples or cultures is not suspected, and if risk identification and assessment has shown that under laboratory conditions, infection of employees by any aerosols generated can be largely ruled out, according to the current state of scientific knowledge.

Detailed further specifications for using MSCs, with examples, are contained in the Guideline for the use of a microbiological safety cabinet when handling human pathogens⁵.

3.2 Commentaries on individual clinical samples

This chapter discusses the use of the safety cabinet for specific clinical samples, workup steps and activities in microbiological diagnostics. Table 1 gives an overview of when a safety cabinet must be used in safety level 2 laboratories, as well as additional work steps that must be performed in safety level 3 laboratories (see Chapter 3.3).

Tab. 1 > Use of safety cabinet for different clinical samples, preparatory stages, and activities in medical diagnostic laboratories (bacteriology, parasitology, mycology, virology), and activities performed in a safety level 3 laboratory

Please note the commentaries in Chapters 3.2.1–3.2.7.

Type of clinical sample	Possible Group 3 and 3** microorganisms ⁶	Use of MSC in level 2 laboratories	Further steps in level 3 laboratories in MSC
Material from the lower respiratory tract: sputum, bronchial lavage etc.	M. tuberculosis complex, F. tularensis, B. pseudomallei, Y. pestis, dimorphous fungi, SARS virus	Required when handling open sample flasks and cultures e.g. for producing microscopic preparations.	Handling cultures of Group 3 microorganisms for further identification, resistance tests etc.
Blood cultures	Brucella sp., B. mallei, F. tularensis, Y. pestis or N. meningitidis (group 2)	Required for handling grown blood cultures for microscopy and initial differentiation.	Handling cultures of Group 3 microorganisms for further identification, resistance tests etc.
Blood samples	p. ex. HIV, HBV, HCV	Recommended ⁷ when handling open sample flasks.	Handling cell cultures containing Group 3 viruses.
Skin swabs	B. anthracis	Required when reading plates if anthrax is suspected.	Handling cultures of Group 3 microorganisms for further identification, resistance tests etc.
Stool, rectal swabs	S. dysenteriae, S. typhi, EHEC	Recommended ⁷ when handling cultures for further identification (typing), resistance tests etc.	-
Urine	M. tuberculosis complex, F. tularensis, B. pseudomallei, dimorphous fungi	Required when handling open sample flasks. Not required for diagnosis of normal urinary tract infections.	Handling cultures of Group 3 microorganisms for further identification, resistance tests etc.
Material such as biopsies, CSF, puncture samples etc.	M. tuberculosis complex, F. tularensis, Y. pestis, N. meningitidis (Group 2), dimorphous fungi	Required	Handling cultures of Group 3 microorganisms for further identification, resistance tests etc.

⁶ For Group 3 microorganisms marked with two asterisks «**», infection via the airways is not normally anticipated.
 ⁷ If no MSC is used, risk identification and assessment must show that infection of employees can be ruled out.

3.2.1 Clinical samples from the lower respiratory tract

Clinical samples from the lower respiratory tract, such as sputum, bronchial lavage etc. must be handled in a Class II safety cabinet if the presence of Group 3 microorganisms subject to airborne transmission is suspected. This particularly applies to:

- > Opening sample flasks
- > Dividing clinical samples for normal bacteriology and mycobacteriology
- Direct smears for microscopy (e.g. gram and/or Ziehl-Neelsen staining), or aliquoting for molecular biological verification
- > Heat-fixed slides may be stained and examined microscopically outside the safety cabinet. Depending on the duration of the heat-fixing and staining procedure, the slides may still count as infectious objects and must therefore be inactivated before disposal (phenol-containing stains inactivate mycobacteria)
- Workup of clinical samples (liquifying and centrifuging) for primary culture and slide smears for microscopy
- > Establishing primary cultures
- Making slide smears for microscopy or taking aliquots from enrichment cultures for molecular biological verification.

Centrifugation outside the safety cabinet is permitted only in tightly sealed, unbreakable receptacles in a biological safety centrifuge (the rotor or the individual buckets under airtight seal)⁸.

In safety level 2 laboratories, grown primary cultures may be opened in the safety cabinet for microscopy (verification of acid-proof rods) or for taking aliquots for molecular biological verification. For further identification and resistance tests, the cultures must be transferred to a Level 3 laboratory.

3.2.2 Blood cultures

If growth is determined in a blood culture, and the presence of Group 3 microorganisms subject to airborne transmission or Neisseria meningitidis (Group 2) is suspected, further processing for microorganism identification must take place inside the safety cabinet. Particular caution is required, for example, in the production of microscopic preparations and catalase tests (aerosol formation in frothing). The final identification steps (differentiation, serotyping) of Group 3 microorganisms subject to airborne transmission must be performed adhering to level 3 safety measures.

⁸ FOEN (2008). Guideline Microbiological safety cabinets (<u>www.bafu.admin.ch/publikationen/publikation/01016/index.html?lang=en</u>

3.2.3 Blood samples

Blood samples that are suspected to contain Group 3** viruses (e.g. HIV, HBV, HCV) non-subject to airborne transmission should be opened in an MSC. When processing them on the laboratory bench, other suitable measures should be taken to protect the staff.

Handling cell cultures with Group 3 viruses generally requires adherence to level 3 safety measures. In particular cases, level 2 safety measures may be adequate (e.g. mini-cultures for phenotypic resistance of viruses not-subject to airborne transmission). However, these cultures must also be processed in an MSC.

3.2.4 Skin swab (anthrax)

The clinical samples may be inoculated (primary cultures) or streaked (microscopy) on the laboratory bench. Reading the cultures must take place in the safety cabinet. Further handling of densely grown cultures suspected of containing anthrax must adhere to level 3 safety measures.

3.2.5 Stool, rectal swab

Possible Group 3 pathogens in the stool are not subject to airborne transmission (except for suspected *M. tuberculosis*). Transmission occurs via contact infections (splashes, touch etc.). Establishment of primary cultures can take place on the laboratory bench.

3.2.6 Urine

The same regulations apply to the investigation of urine for acid-proof rods or other Group 3 microorganisms as to clinical samples from the lower respiratory tract. If there is no suspicion of e.g. tuberculosis (i.e. for a normal urinary tract infection), clinical samples and all further investigative procedures may be performed on the laboratory bench.

3.2.7 Biopsies, CSF, puncture specimens

Where microorganisms subject to airborne transmission belonging to group 2 (*N. meningitidis*) or 3 are suspected, clinical samples must be handled in a safety cabinet.

Omission, alteration or substitution of special safety measures in safety level 3

Certain special safety measures may be omitted, altered or substituted in accordance with Annex 4 Section 2.1 Table CO if the Federal Office issues the corresponding authorisation. Table 2 below lists and comments the omission, alteration or substitution of level 3 safety measures in medical microbiology diagnostic laboratories.

Tab. 2 > Comments on special safety measures and their omission, alteration or substitution in medical microbiology diagnostic laboratories

Numbering according to Annex 4 Section 2.1 Table CO.

Building

3.3

	•	
4	Access to the workspace via airlock	 Description/Purpose: Access must be via a room separated from the level 3 area. The external (clean) side of the airlock must be separated from the internal side by a barrier such as a bench or at least a visual boundary (line on the floor). Only one of the two airlock doors may be open at a time. In emergencies, it must be possible to override reciprocal locking of the airlock (if installed) from inside or outside. The protective clothing, shoes and shoe covers worn in the level 3 area may not be worn outside. They must be decontaminated before leaving the level 3 area. Conditions for changing, replacing or omitting this safety measure: Omission of a proper airlock may be permitted if Group 3 microorganisms not subject to airborne transmission are handled, and the laboratory can be entered via an unused level 2 room. Alternatively, a separate zone for changing clothes can be demarcated in the laboratory.
5	Shower facilities in the airlock	Description/Purpose: In medical diagnostic laboratories, routine use of a shower on exit from a safety level 3 laboratory is uncommon. However, there must be opportunities for decontamination of contaminated parts of the body. The showers for chemical or fire emergencies are not suitable for biological decontamination, since they do not decontaminate and because the associated aerosolisation of any microorganisms present increases the risk of infection for the employee. If such an emergency shower must be used in the event of an incident, the resulting water must be collected so that it can be decontaminated before being discharged into the sewerage system (see Safety Measure 30). Conditions for changing, replacing or omitting this safety measure: Depending on the risk, this measure may be omitted based on a risk analysis by the applicant without permission from the responsible Federal Office. This applies in particular to activities such as exclusive handling of human pathogens, since the aerosols produced by the shower actually increase the danger of infection for the employees. However, suitable alternative measures must be available. In particular, opportunities must be available for decontamination of contaminated parts of the body (see Safety Measure 6), e.g. a washbasin with collecting container that can also be equipped with a movable shower head. Such an arrangement for personal decontamination must be available in the level 3 workspace.
7	Viewing window or other arrangement for observation of the workspace	Description/Purpose: The entire workspace of the controlled area must be visible from the outside or be monitored with a video camera as an alternative. Conditions for changing, replacing or omitting this safety measure: Omission of a viewing window or video surveillance may be permitted if e.g. structural conditions make these impossible. In this case, a dead man's switch (automatic alarm for immobility) must be used as the minimum alternative measure.

11	Workspace to be sealed to enable fumigation	Description/Purpose: Fumigation of the workspace should ensure that it can be effectively decontaminated. Conditions for changing, replacing or omitting this safety measure: Cleaning of contaminated areas (especially after spillage of live microorganisms) may be carried out with other effective and validated methods of inactivation. The workspace can be made airtight with adhesive tape or sealant for the period of fumigation; ventilation channels should be closed with flaps. This is especially important when handling microorganisms subject to airborne transmission.
12	Negative pressure in the workspace with respect to the immediate surroundings	Description/Purpose: As a rule, the air pressure should be 20 to 50 Pa less than that in surrounding areas. The pressure can be decreased step-wise from the airlock to the internal rooms of the level 3 area. The ventilation must be designed by an expert. There are two accepted methods for maintaining the negative pressure: active control (with airtight doors) and flow-regulated systems (with non-airtight doors and air flow towards the controlled area). Conditions for changing, replacing or omitting this safety measure: Omission may be permitted if handling Group 3 microorganisms not subject to airborne transmission.
14	Exhaust air from the workspace filtered through a HEPA filter	Description/Purpose: The exhaust air must be filtered with high efficiency particulate air (HEPA) filters. For work involving bacteria, filter class H12 is sufficient; work involving viruses requires filter class H14. Pre-filters (F9) extend the service life of the main filters. The filter units are best placed in the controlled area (inside or outside the workspace). Conditions for changing, replacing or omitting this safety measure: Omission may be permitted if handling Group 3 microorganisms not subject to airborne transmission.
Equ	ipment	
20	Workspace with complete, self- contained equipment	Description/Purpose: All facilities and equipment necessary for Class 3 operations and activities are located in the controlled area. Procedures of classes 1 and 2 and those that do not fall under the CO/OOSB may only be executed outside the level 3 area. Conditions for changing, replacing or omitting this safety measure: Omission may be authorised if the appropriate facilities and equipment are inactivated or decontaminated using validated methods prior to discharge.
23	Autoclave	Description/Purpose: The autoclave may not be required for Class 3 activities if cultures and other contaminated waste can be inactivated on site using

other methods of inactivation with validated and comparable effects. A permit from the responsible Federal Office must be obtained for this purpose. A different location for the autoclave may also be proposed (outside the workspace, but in the building). **Conditions for changing, replacing or omitting this safety measure:** Safe transport of waste from the workplace to the autoclave must be ensured, or the alternative inactivation method must be validated

and achieve a comparable effect to that of inactivation by autoclaving.

W	Work organisation				
30	Inactivation of microorganisms in the effluent from sinks, pipes and showers	Description/Purpose: All wastewater, including condensate from the autoclave, must be inactivated before discharge from the controlled area. Thermal or chemical methods are particularly suitable. This measure ensures that no live microorganisms enter the sewerage system from the wastewater. Hands must be disinfected before washing them. Relevant instructions must be posted over the sink. Conditions for changing, replacing or omitting this safety measure: Omission can only be granted if contamination by the wastewater is prevented by appropriate organisational measures or other alternative means. It may be necessary to separate wash basins from the wastewater system and install collecting containers.			

17

> Waste disposal

4

Waste disposal is regulated in the Table in Annex 4 Section 2.1 CO under Safety Measure 33 (Inactivation of Microorganisms). Waste from Class 2 activities should always be inactivated in the building, unless an autoclave outside the building may be used for inactivation in accordance with Safety Measure 23. Contaminated material, animal carcasses and diagnostic samples resulting from Class 2 activities can be disposed of without authorisation as hazardous waste. In justified exceptional circumstances and with permission from the responsible Federal Office, it is possible to dispose of solid cultures as hazardous waste. This requires evidence of a functional waste management chain. An explanation must also be submitted as to why disposal of solid cultures in the specific case is at least as safe as inactivation on site. Liquid cultures associated with Class 2 activities must always be inactivated on site.

Waste generated by Class 3 activities must generally be inactivated in the workspace. If the waste is to be inactivated outside the workspace, the operation requires a permit from the responsible Federal Office. However, inactivation must in any case be carried out within the building (see also the Table in Annex 4 Section 2.1 Safety Measure 23).

Autoclaving is regarded as the method of choice for inactivation of waste. Alternative methods of inactivation are generally only permissible if they are considered as equivalent and have been validated. If an autoclave is not used for Class 2 activities, approval must be obtained from the responsible Federal Office.

The Statement of the Swiss Expert Committee for Biosafety (EFBS, SECB) on waste disposal in medical microbiology diagnostic laboratories must also be observed. After inactivation of contaminated waste in accordance with Annex 4 Section 2.1 Table CO, the provisions of the Ordinance on Movements of Waste (OMW) may apply.

18

5

5

> Transport

If clinical samples or cultures are sent to other laboratories for further analysis, the national and international regulations on transport (SDR, ADR, GGBV, ICAO) apply to packaging, labelling, accompanying documents and safety measures (see Article 15 CO). The Federal Roads Office and the Federal Office of Transport are responsible for enforcement of these. For intra-company transport (within the same building or on the same premises), suitable safety measures must be laid down in the safety concept.

> Bibliography

CDC and NIH 2007: Biosafety in Microbiological and Biomedical Laboratories, 5th edition U.S. Department of Health and Human Services Public Health Service, Centers for Disease Control and Prevention and National Institutes of Health, Washington DC.

Federal Law. Federal Law of 7 October 1983 relating to the Protection of the Environment, LPE, SR 814.01.

Federal Law. Federal Law of 18 December 1970 on Protection against Contagious Diseases in Humans (Epidemics Law), EpG, SR 818.101.

Federal Law. Ordinance of 9 May 2012 on the Contained Use of Organisms. Containment Ordinance, CO, SR 814.912.

Federal Law. Ordinance of 25 August 1999 on Occupational Safety in Biotechnology, 00SB, SR 832.321.

Federal Law. Ordinance of 19 October 1988 on Environmental Impact Assessment, OEIA, SR 814.011.

Federal Law. Ordinance of 27 February 1991 on Protection against Major Accidents, OMA, SR 814.012.

Federal Law. Ordinance of 15 June 2001 on safety officers for the transport of dangerous goods by road, rail and inland waterways, GGBV, SR 741.622.

Federal Law. Ordinance of 29 November 2002 for the transport of dangerous good by road, SDR, SR 741.621.

Federal Law. Ordinance of 22 June 2005 on the Movement of Wastes, OMW, SR 814.610.

FOEN 2008: Guideline Microbiological safety cabinets (MSC) (www.bafu.admin.ch/publikationen/publikation/01016/index.html?lang=en).

FOEN 2005: Guideline Operational safety concepts according to Containment Ordinance (CO) (www.bafu.admin.ch/publikationen/publikation/00094/index.html?lang=en).

Fleming D.O., Hunt D.L. (eds) 2006: Biological Safety: Principles and Practices, 4th edition. ASM Press. Washington, DC.

Gillespie S.H., Pearson R.D.(eds) 2001: Clinical Parasitology. John Wiley & Sons, Chichester.

Mandell G.L., Bennett J.E., Dolin R. 2005: Principles and Practice of Infectious Diseases. Churchill-Livingstone.

Murray P.R., Baron E.J., Pfaller M.A., Tenover F.C., Yolken R.H. (eds) 1999: Manual of Clinical Microbiology. ASM Press, Washington DC.

Public Health Agency of Canada 2004: Laboratory Biosafety Guidelines, Ottawa.

SAEFL 2005: Guideline Biosafety Officers (www.bafu.admin.ch/publikationen/publikation/00597/index.html?lang=en).

SECB 2009: Recommendation of the SECB on the treatment and disposal of waste produced in contained systems, 2009 (updated September 2014) (<u>www.efbs.admin.ch/fileadmin/efbs-dateien/dokumentation/empfehlungen/Empfehlungen 2014/Abfall EF BS E.pdf</u>)

Sewell D.L. 1995: Laboratory-associated infections and biosafety. Clin. Microbiol. Rev. 8:389–405.

Sewell D.L. et al. 2005: Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline – 3rd edition. Clinical and Laboratory Standards Institute, document M29-A3, Vol. 25 No. 10.

Specter S., Hodinka R.L., Young S.A. (eds) 2000: Clinical Virology Manual. ASM Press, Washington DC.

SUVA, Swiss Accident Insurance Fund 2003: Verhütung von Berufskrankheiten in diagnostisch-mikrobiologischen Laboratorien. Lucerne, order no. 2869/27d.

SUVA, Swiss Accident Insurance Fund 2003: Verhütung blutübertragbarer Infektionen in medizinischen Laboratorien. Lucerne, order no. 2869/19.d.

World Health Organization 2004: Laboratory Biosafety Manual, 3rd edition. Geneva.

World Health Organization 2005: Guidance on regulations for the Transport of Infectious Substances, Geneva.

Zuckerman A.J., Banatvala J.E., Pattison J.R. (eds) 2000: Clinical Virology. John Wiley & Sons, Chichester.

> Abbreviations, figures and tables

Abbreviations

ADR

European Agreement concerning the International Carriage of Dangerous Goods by Road

CO

Ordinance of 25 August 1999 on the Contained Use of Organisms. Containment Ordinance, SR 814.912

EHEC

Enterohaemorrhagic Escherichia coli

F9

Class 9 fine particulate air filter (prefilter class for HEPA filters)

FOEN Federal Office for the Environment

FOPH Federal Office of Public Health

GGBV

Ordinance of 15 June 2001 on safety officers for the transport of dangerous goods by road, rail and inland waterways, SR 741.622

H12

Class 12 HEPA filter for bacteria and fungi

H14

Class 14 HEPA filter for viruses

HEPA High Efficiency Particulate Air Filter

ICAO International Civil Aviation Organization

LPE

Federal Law of 7 October 1983 relating to the Protection of the Environment, SR 814.01

MSC

Microbiological safety cabinet

OEIA

Ordinance of 19 October 1988 on Environmental Impact Assessment, SR 814.011

OMA

Ordinance of 27 February 1991 on Protection against Major Accidents, SR 814.012

OMW

Ordinance of 22 June 2005 on the Movement of Wastes, SR 814.610

OOSB

Ordinance of 25 August 1999 on Occupational Safety in Biotechnology, SR 832.321

Pa

Pascal (unit of pressure)

SARS Severe Acute Respiratory Syndrome

SDR

Ordinance of 29 November 2002 for the transport of dangerous good by road, SR 741.621

SR Classified Compilation of Swiss Federal Law

Tabellen

Tab. 1

Use of safety cabinet for different clinical samples, preparatory stages, and activities in medical diagnostic laboratories (bacteriology, parasitology, mycology, virology), and activities performed in a safety level 3 laboratory

Tab. 2

Comments on special safety measures and their omission, alteration or substitution in medical microbiology diagnostic laboratories

13

21

> Glossary

Enrichment

Multiplication by culture methods. This does not include enrichment by centrifugation, as described in Chapter 3.2.1.

Inoculation

Plating of treated or untreated clinical samples onto agar plates or inoculation of liquid and cell cultures.

Open cultures

Cultures without airtight seal (e.g. untaped Petri dishes, agar slopes, cell cultures with loose or opened screw-top lids).

Workup

Treating clinical samples for inoculation onto agar, the inoculation of liquid cultures or cell cultures, or for streaking onto slides for microscopy. See the example of the workup of clinical samples for diagnosing tuberculosis given in Chapter 3.2.1.