24.02.2023

Project leader

OP

Title:	Project leader information RIZ

	Distribution list of original SOP	
Location	**Department**	**Room**
All PIs RIZ		

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	Name	**Signature**	**Date**
Produced by	Maren von Köckritz-Blickwede		
Verified by	Vera Meier		
Approved by	Maren von Köckritz-Blickwede		

1. Content

2. Introduction

Aim of this SOP is to introduce new project leader of the RIZ to regulations in Germany.

3. Contact

President/official operator:	Dr. Dr. h. c. mult. Gerhard Greif Tel no.: 8000 Email: praesident@tiho-hannover.de
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Biological Security Officer (BBS):	Prof. M. von Köckritz-Blickwede Tel no.: 8787 Email: Maren.von.Koeckritz-Blickwede@tiho-hannover.de Dr. Katja-Branitzki-Heinemann Tel no.:6913 Email: Katja.Branitzki-Heinemann@tiho-hannover.de

Management technician biosafety:	Vera Meier Tel no.: 6111 Email: bbs-RIZ@tiho-hannover.de vera.meier@tiho-hannover.de
Company doctor:	*Dr. Michael Glüer Tel no.: 8150*
Representative for working safety:	*Armin Dinter Tel no.: 7874*
Representative for fire protection:	*Armin Dinter Tel no: 7874*
Dangerous goods safety advisor:	*Dr. Andreas Gassner Tel no: 7871*
Technical standby service:	*Tel no.: 7997*
Scientific Director on duty:	*Tel no.: 7998*

4. Overview of the procedures

4.1 General lab safety (important for all!):

(a) Introduction of each project group member

(b) Generation of risk assessments ("Gefährdungsbeurteilungen")

(c) Register all chemicals in DaMaRis

4.2 Does the project work with biological substances e.g. microorganisms or cell cultures?

If yes, follow the next topics:

(d) Protection against infections ("Infektionsschutzgesetz")

(e) Protection against bioorganisms ("Biostoffverordnung")

(i) Targeted ("Gezielt")

(ii) Non-targeted ("Nicht gezielt")

(f) Genetically modified organisms ("Gentechnisch veränderte Organismen")

(g) Epizootic diseases ("Anzeigepflichtige Tierseuchenerreger/ Meldepflichtige Tiererkrankungen")

4.3 Does the project work with human samples or animals?

If yes, follow the next topics:

(h) Human samples ("Ethikkommission")

(i) Animal welfare ("Tierschutz")

4.4 Others

(j) Documentation and quality control

(k) Inactivation procedures

(l) Export of bioorganisms

(m) Import of bioorganisms

(n) Pregnant coworkers

5. Detailed procedures

5.1 General lab safety

(a) Introduction of each group member

Each project leader has to make sure, that every group member is receiving

(1) a proper general introduction to RIZ through RIZ management based on SOP "General operating instructions",

(2) all appropriate e-learning safety instructions, touching the work for this group member

Generelle Sicherheitsunterweisung deutsch:

https://engage-mh.tiho-hannover.de/engage/theodul/ui/core.html?id=f6062df8-9581-44f7-89b9-f7a617209cdd

Generelle Sicherheitsunterweisung englisch:

https://engage-mh.tiho-hannover.de/engage/theodul/ui/core.html?id=cbc9fd67-a1c7-4c23-ac27-d6efbc05649a

PSA:

https://engage-mh.tiho-hannover.de/engage/theodul/ui/core.html?id=7ce2ee5a-1635-40b9-871b-e59992f1519f

Good Scientific Practice

https://engage-mh.tiho-hannover.de/engage/theodul/ui/core.html?id=59d7494a-8e83-42c1-ad97-93d3467f5273

Trouble Shooting Geräte/Labor:

https://engage-mh.tiho-hannover.de/engage/theodul/ui/core.html?id=441123bf-f606-407e-ae9c-654bda44d416

Autoklav/Zentrifugen:

https://engage-mh.tiho-hannover.de/engage/theodul/ui/core.html?id=dc0429c3-f03e-4f1c-94b0-d136525a4ec2

Safety Instruction RIZ-FI:

https://engage-mh.tiho-hannover.de/engage/theodul/ui/core.html?id=176fa7f6-7ca8-4dba-9bcb-c45d6dcfdc29

Project Leader SOP:

https://engage-mh.tiho-hannover.de/engage/theodul/ui/core.html?id=475729f8-1e59-443f-a247-ff3388378430

Gefahrenstoffe:

https://engage-mh.tiho-hannover.de/engage/theodul/ui/core.html?id=dc652788-4457-4501-9cb2-405624f4d95c

Abfallentsorgung:

https://engage-mh.tiho-hannover.de/engage/theodul/ui/core.html?id=16a7a1ba-d24c-470f-98d4-608675df5abb

(3) an introduction to all equipment needed through the RIZ-technicians,
(4) an annual general safety instruction through the BBS or the project leader and
(5) a special hands-on introduction to the respective floor plan.

The management needs to be informed about every update regarding the floor plan. Every two years the floor plan will be revised by the respective project leader.
Long-term group members (more than 4 weeks) have to visit the Company doctor Dr. Glüer prior to starting to work in the labs (see General SOP!). Short-term visitors (less than two weeks) have to be kept under continuous supervision by the project leader or responsible person and need to be registered by the management (see General SOP!).

New coworkers need to be supervised continuously until the project leader decides that the person can work independently.

For S3** and higher biosafety level please contact the biosafety management.

(b) Generation of risk assessments ("Gefährdungsbeurteilungen")

Each project leader must fill out and regularly update risk assessments ("Gefährdungsbeurteilungen") for the working area he/she and the group members will work at:
G:\tiho\Gefährdungsbeurteilungen\Muster Gefährdungsbeurteilungen
These "risk assessments" will be public to every member in the RIZ on:
G:\tiho\Gefährdungsbeurteilungen\80 Research Center for Emerging Infections and Zoonoses\ Gefährdungsbeurteilungen

This risk assessment has to be updated when needed, but latest every two years.
The BBS need to be informed about every update (bbs-RIZ@tiho-hannover.de).

(c) Register all chemicals in DaMaRIS

Every group member has to register all their chemicals in the DaMaRIS system (https://damaris.tiho-hannover.de/) and keep the list up to date. Furthermore, it has to be made sure that all group members have access to the DaMaRIS system via a computer in the lab. Gabriele Wetzel is the responsible person for DaMaRIS. Dr. Andreas Gassner manages new access authorizations.

5.2 Does the project work with biological substances e.g. microorganisms or cell cultures?

Bioorganisms (general lists)

The project leader has to update continuously the organism lists:

(1) RIZ-ZZ BIOSTOFFE_RAUMLISTE; (2) RIZ-ZZBIOSTOFFE GEZIELT; (3) RIZ-ZZ BIOSTOFFE UNGEZIELT;
(4) RIZ-ZZ BIOSTOFFE Personenliste (5) RIZ-ZZ Biostoffe S3 zwei Stern
A modifiable list is available at:
G:\riz\Projektleiter Biosicherheit ZZ
G:\riz\Projektleiter Biosicherheit ZZ\S3 zwei Stern

The project leader has to update continuously the organism lists for work in **RIZ FI:**

1) RIZ-FI BIOSTOFFE Raumliste; (2) RIZ-FI BIOSTOFFE Personenliste; (3) RIZ FI BIOSTOFFE Raumliste

A modifiable list is available in the Projektleiter Biosicherheit FI Folder on:
G:\riz\Projektleiter Biosicherheit FI

An updated pdf-version with the date of update will always be available on:
G:\tiho\Gefährdungsbeurteilungen\80 Research Center for Emerging Infections and Zoonoses\Biostofflisten**.** The BBS and RIZ management (bbs-RIZ@tiho-hannover.de) need to be informed when updates have been made. A good time point for an update will be after a new Biostoffanzeige.
All RIZ members will be informed by e-mail (by BBS) about new available Gefährdungsbeurteilungen.

(a) Protection against infections *("Infektionsschutzgesetz")*

This is a two-step procedure:

(1) For the registration of human pathogens, a **personal permission of each project leader** is needed (**Erlaubnis nach § 44 Infektionsschutzgesetz**). This needs to be obtained by the respective "Gesundheitsamt" of place of residency ("Wohnsitz"). In Hannover, it is the same authority as given under (2). The permission costs 122 Euro per person. An application including information about the pathogens and the planned work, a criminal record certificate ("polizeiliches Führungszeugnis Belegart 0") and certified copy of your University Certificate ("Beglaubigte Hochschulabschlusszeugnis") as well as a letter from a person with § 44 allowance stating that you have worked for min 2 years with human infectious diseases under his/her supervision.

(2) With the permission, each project leader has to register the infection agents that he/she will use for the project at the *Fachbereich Gesundheit, Region Hannover* **30 days before starting** the work (**Anzeige der Tätigkeiten mit Krankheitserregern nach § 49 IfSG**). Send application including § 44 permission, copy of GMO registration of RIZ and information on the work to:

Region Hannover, Fachbereich Gesundheit, Team 53.01
Weinstraße 2, 30171 Hannover

For more information see:
G:\riz\Projektleiter Biosicherheit ZZ\Infektionsschutz\Vorlagen
For S3 Pathogens:
G:\riz\Projektleiter Biosicherheit FI\Infektionsschutz\Vorlagen

A copy of all documents has to be send to BBS and RIZ management (bbs-RIZ@tiho-hannover.de) and saved on G:\riz\Projektleiter Biosicherheit ZZ\Infektionsschutz
or G:\riz\Projektleiter Biosicherheit FI\Infektionsschutz

(b) *Protection against bioorganisms ("Biostoffverordnung")*

Each project leader must register the level 2 bioorganisms (living microorgansims, cell cultures, primary cells, tissue) that he/she will use for the project at the respective authority **30 days before starting** the work (Anzeige gemäß § 16 BioStoffV). Use the following document for registration:

Anzeige BioStoffV Muster. More Infos are found on:
G:\riz\Projektleiter Biosicherheit ZZ\Biostoffverordnung\Vorlagen: Anzeige BiostoffV Muster.

For Level 3 Bioorganims the project leader have to use the document: „Biostofferlaubnisantrag"
G:\riz\Projektleiter Biosicherheit FI\Biostoffverordnung\Vorlagen: Erlaubnisantrag BiostoffV Muster.
Starting the work is not allowed until the authority send the permission.

All documents (separated into targeted and non-targeted work) have to be filled out and send to Vera Meier. If everything is filled out correct, she will send the documents via Dr. Gassner to the respective authority (Staatliches Gewerbeaufsichtsamt Hannover).
Additionally, a copy of the signatured Biostoffanzeige/or Biostofferlaubnisantrag
will be saved by Vera Meier on:

G:\riz\Projektleiter Biosicherheit ZZ\Biostoffverordnung
G:\riz\Projektleiter Biosicherheit FI\Biostoffverordnung

Furthermore for respective risk assessment and documentation at TiHo, the four documents provided by Dr. Glüer G:\riz\Projektleiter Biosicherheit\Biostoffverordnung\Vorlagen\Vorlagen-Biostoff-V-GfdB need to be filled out, signed and send as original to Vera Meier and the digital version to (bbs-RIZ@tiho-hannover.de).

A copy of these signed documents will be saved by Vera Meier on:
G:\tiho\Gefährdungsbeurteilungen\80 Research Center for Emerging Infections and Zoonoses\ Gefährdungsbeurteilungen
All RIZ members will be informed by e-mail (by Vera Meier) about new available Gefährdungsbeurteilungen.

(c) *Genetically modified organisms ("Gentechnikgesetz")*

Each project leader must register the work with level 2 genetically modified organisms (GVO) (microorgansims, cell cultures, animals) as well as the storage of GVO that he/she will use for the project at the respective authority. With obtaining the permission or at the end of a period of **45 days** the work can be started (Anzeige gemäß Gentechnikgesetz).

Cave: For pathogens or work not registered by ZKBS (Zentrale Kommission für Biologische Sicherheit) yet, the time can be longer and starting work is not allowed!

For level 3 the permit of the authority is obligatory (Genehmigung gemäß Gentechnikgesetz). Please contact the biosafety management.

More Info is found on
G:\riz\Projektleiter Biosicherheit ZZ\Gentechnikgesetz\Vorlagen\leere Vorlagen
G:\riz\Projektleiter Biosicherheit FI\Gentechnikgesetz\Vorlagen\leere Vorlagen

All documents have to be filled out and send to Vera Meier. She will send it to the BBS and then via Mr. Dr. Gassner to the University president and finally to the respective authority (Staatliches Gewerbeaufsichtsamt Hannover).

For documentation: See Documentation and quality control (below).

Level 1 GMO work must be documented similar to S2 work. No special allowance/registration in RIZ is needed for that.

In case that a project leader is leaving the TiHo, a new project leader has to be defined in agreement with the BBS, the RIZ management and the president (via Herr Gassner).
Otherwise, all GVO have to be eliminate by the project leader.

(a) *Epizootic diseases ("Anzeigepflichtige Tierseuchen") and animal diseases ("meldepflichtige Tierkrankheiten")*

A classification has to be done by each project leader based on the lists "gezielte und raumbezogene Biostofflisten".

See the lists at G:\riz\Projektleiter Biosicherheit ZZ or FI
(1) RIZ-ZZ BIOSTOFFE_RAUMLISTE; (2) RIZ-ZZ BIOSTOFFE_GEZIELT; (3) RIZ-ZZ_BIOSTOFFE_UNGEZIELT;
(4) RIZ-ZZ BIOSTOFFE Personenliste (5) RIZ-ZZ Biostoffe S3 zwei Stern
(6) RIZ-FI BIOSTOFFE Raumliste; (7) RIZ-FI BIOSTOFFE Personenliste

The TiHo as public facility has a general allowance to work with animal pathogens ("**meldepflichtige Tierkrankheiten**"). The work with them only needs to be documented. See the list here: https://www.bmel.de/DE/Tier/Tiergesundheit/Tierseuchen/_texte/MeldepflichtigeTierseuchen.html

General work and the specific pathogens with "**anzeigepflichtige Tierseuchen**" must be registered with the responsible authorities (here: LAVES) (Anzeige gemäß Tierseuchenverordnung): See the list here: http://www.bmel.de/DE/Tier/Tiergesundheit/Tierseuchen/_texte/AnzeigepflichtigeTierseuchen.html
Registration: http://www.gesetze-im-internet.de/tierseucherv/BJNR021230985.html
Registered/responsible persons at RIZ: Prof. Maren von Köckritz-Blickwede.

Inform them and the BBS (bbs-riz@tiho-hannover.de) about all used pathogens prior to start the work.

Furthermore, the pathogen list "Anzeigepflichtige Tierseuchenliste-LAVES_Raum"on G:\riz\Projektleiter Biosicherheit FI\Tierseuchen anzeigepflichtig needs to be updated and send to LAVES via Mail by the BBS (bbs-riz@tiho-hannover.de).

Storage and Experiments with Epizootic diseases needs to be documented according to the "Tierseuchenerregerverordnung" (Tierseuchenerregerverordnung, TierSeuchErV).
The documentation according to § 9 has to be done immediately and continuously.
The documentation must be reliably and verifiable.
All Epizootic diseases and bioorganisms need to be registered by LabControl ID.
This LabControl ID needs to be documented in the Epizootic diseases documentation.

Authorities:
Dezernat 31 – Tierseuchenbekämpfung und Beseitigung Tierischer Nebenprodukte

Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittelsicherheit (LAVES); Postfach 3949
26029 Oldenburg; Tel: +49(0)441/570 26-260; Fax: +49(0)441/570 26-179
Mail: jonas.guese@laves.niedersachsen.de

A copy of all documents has to be saved on
G:\riz\Projektleiter Biosicherheit FI\Tierseuchen anzeigepflichtig and send to
bbs-RIZ@tiho-hannover.de.

Just for information: Frau Dr. Doil, Veterinäramt, is not responsible for allowance, but for controlling/inspection.

5.3 Does the project work with human samples or animals?

(a) Human samples ("Ethikkommission")

Each project leader which needs to work with human samples needs an ethical permission prior to start of the work. Please contact "Ethikkommission der MHH" (https://www.mh-hannover.de/3371.html).

If human fresh blood from healthy volunteers is needed please contact Prof. Dr. Maren von Köckritz-Blickwede.

(b) Animal welfare ("Tierschutz")

For all issues regarding experimental work with animals the *Tierschutzbeuftragte* Prof. Wendt and Prof. Brehm need to be contacted.

See more information on: http://interner-tiho-bereich/kommissionen-gremien-ausschuesse-beauftragte/tierschutzbeauftragter/

5.4 Others

(a) Documentation and quality control

Each project leader is responsible for proper quality control (purity of organisms) and documentation of lab work of all group members.

Storage of GMO needs to be documented according to the "genetic-recording-regulation" (Gentechnik-Aufzeichnungsverodnung, GenTAufzV). The documentation according to § 3 Abs. 7 GenTAufzV has to be done immediately and continuously. Before beginning of genetic work, the project leader initiates a document according to GenTAufzV (e.g. on basis of the blank form Z) and finally confirms the accuracy by his signature.

All GVO and bioorganisms need to be registered by LabControl ID associated with the according number of the GVO and name of project leader. This LabControl ID needs to be documented in the Z-form/documentation.
The form Z are stored on
G:\riz\Projektleiter Biosicherheit ZZ\Gentechnikgesetz.
G:\riz\Projektleiter Biosicherheit FI\Gentechnikgesetz.

BBS and RIZ management will control the documentation and have the right to delete samples without proper labelling.

For traceability it is strongly required to use the same individual ID in the Z-form, the lab book and LabControl for every particular sample.

The identity and purity of the used organism needs to be regularly confirmed. For this purpose, a regular testing for e.g. mycoplasma contamination in cell cultures or PCR-based testing of specific genes is necessary. The usage of new donors, recipients and vectors justifies a new genetic work, which needs to be separately registered with the authorities.

(b) Inactivation procedures

Each project leader is responsible for proper inactivation of their samples and the respective documentation (including quality control) prior to transfer of inactivated bioorganisms to another lab or disposal of organisms.

S2: Reference-based inactivation is ok. However, for GMO work special allowance by Gewerbeaufsichtsamt is required for each project.

S3: Prior to disposal / shipping of S3 ** or S3 organisms or the transport of these organisms from the S3 ** / S3 laboratory to another laboratory, permission must be obtained from the BBS, the RIZ manager for each individual process. The authorities (Gewerbeaufsichtsamt) need to be involved (3-fold validation is required).
Some general information is here:

G:\riz\Projektleiter Biosicherheit ZZ\Inaktivierungsmethoden.

The BBS needs to be inform via Mail about every new inactivation method
via (bbs-RIZ@tiho-hannover.de).

(c) Export/ transfer of bioorganisms

Prior to export/ transfer of bioorganisms to another lab (even another TiHo institute), the respective project leader has to make sure that the recipient agrees to comply with all applicable laws, regulations, policies, and guidelines in its storage and use of the receiving biological material (see letter draft “letter to receive biological material from RIZ”) in “Projektleiter Biosicherheit\Import_Export” folder.

Every export/ transfer needs to be registered in the list: import export samples. All concerning documents needs to be stored in the group specific Export and Import folders. Both is located on G:\riz\Projektleiter Biosicherheit ZZ\Import-Export and G:\riz\Projektleiter Biosicherheit FI\Import-Export

(d) Import of bioorganisms

General sample deliveries:

All import processes are requested through bbs-RIZ@tiho-hannover.de.

The project leader must be stated on the deliveries as contact person and needs to take care that only instructed and trained co-workers opens the deliveries. Samples, that are delivered from outside into the RIZ and are assigned as biological security level 2 or higher need to be unpacked under a bio-safety bench in ZZ and for level 3 in FI-Building. During that you need to wear always the Personal protective equipment. After unpacking the outer package needs to be disinfected and/ or autoclaved before disposed. The sample needs to be transferred into a new and clean primary container and can afterwards be stored or processed. This procedure serves to avoid transfer any infectious contaminations of the packaging material into the laboratories.

Every import needs to be registered in the list: import export samples.
All concerning documents needs to be stored in the group specific Import and Export folders.
Both is located on G:\riz\Projektleiter Biosicherheit ZZ\Import-Export.
For Import in the FI Building on G:\riz\Projektleiter Biosicherheit FI\Import-Export.

Official procedure for Non-EU samples stepwise:

(1) Generally there is an allowance for the import of samples of category 1 and 2 for diagnostic/ scientific samples in RIZ available (Number DE 03 201 0043 21, AZ 42300_2_TiHo, vom 16.02.2016, Fachbereich Öffentliche Ordnung, Gewerbe- und Veterinärangelegenheiten, Dr. Gabriele Doil, Tel. 0511-168-31154).
(2) In addition, prior to import, it needs to be asked for a separate allowance for the import of all respective samples (“Einfuhrgenehmigung”) at the respective institution depending on the state (“Bundesland”) of arrival:

Niedersachsen: Dr. Andrea Berkenhoff, LAVES Niedersachsen: andrea.berkenhoff@laves.niedersachsen; Tel. 0511-28897-916) or Ms. Gühl (Tel 0511-28897-912).

NRW (delivery via airport): Landesamt für Natur-, Umwelt- und Verbraucherschutz NRW, Fachbereich 87, Leibnizstrasse 10, 45659 Recklinghausen; Tel.: 02361-305-3265; E-mail: einfuhr-nrw@lanuv.nrw.de

The following information need to be sent for permission: number and volume of samples, all information available e.g. animal species, inactivation procedure, etc.; flight number, place of origin, sender/user with addresses.

(3) When all permissions have been received, the allowance (*Einfuhrgenehmigung*) and the filled GVDE document (“Gemeinsames Veterinärdokument für die Einfuhr”) needs to be sent to the respective boarder control (“Grenzkontrolle”) minimum 24 h prior to arrival.

(4) Depending on the permission, finally the "Amtstierarzt" Ms. Dr. Doil needs to be informed about the arrival of samples.

(e) Hausapotheke

If medical products for treatment of animals are needed, the respective SOP "Hausapotheke" needs to be considered. The "Hausapotheke" is exclusively allowed to be used for official business reasons, not for private reasons. Medicinal products are only allowed to be handled after consultation of one of the respective officially registered veterinarians from RIZ for RIZ-Hausapotheke. The responsible persons are Dr. Susanne Röhrs and Dr. Claudia Schulz.

(f) Weekend work

Weekend work and work after 8pm is only allowed after agreement with the project leader. In case of emergency the project leader or a representative person need to be available as contact person. The access to RIZ building after 8pm or before 6am and at weekends needs to be documented at the security service in the foyer of the building 231.

(g) Teaching

Teaching activities in the FI building are principally not allowed.

Teaching activities need to be kept to an absolute minimum in the RIZ building and needs to be related to current scientific projects registered in RIZ. Teaching activities have to be done under constant physical presence of the supervisor. The teaching of groups needs to be organized in separate rooms and the RIZ head has to give special allowance before starting any kind of teaching activities.

(h) Accidents

In case of all accidents, the project leader needs to inform the DWL directly. dwl-riz@tiho-hannover.de

A biohazard accident report needs to be written and handed out to the BBS and RIZ management.
This report needs to include the following information: Date, time, room, microorganisms involved, equipment involved, decontamination procedure, injured person, first aid procedure, causative reason, level of training of persons involved, steps taken afterwards to avoid accidents in the future.
A template is available on**:** G:\riz\Projektleiter Biosicherheit\Unfallberichte Accidents

(i) Pregnancy of a coworker

In case of pregnancy of a coworker please contact immediately the medical doctor "Betriebsarzt" Dr. Glüer and the representative for working safety ("Beauftragter für Arbeitssicherheit") Herr Dinter, as well as the BBS and RIZ management.
See more information at: http://www.tiho-hannover.de/interner-tiho-bereich/arbeitssicherheit-gesundheitsschutz-suchtberatung-und-umweltschutz/betriebsaerztlicher-dienst/

(j) Project leader meetings

There is a project leader meeting in the RIZ-FI seminar room together with the scientific manager, RIZ management and the BBS once per month, where general biosafety issues are discussed.
The meeting is obligatory for all project leader and updates regular on safety issues need to be given.

If PIs cannot attend, they have to inform themselves about the given information by reading protocols.

(k) Consultation of BBS for new GMO approvals

6. Further questions

For further assistance please contact the BBS or RIZ management.

General operating instructions

03.03.2024

SOP

Title: General operating instructions fot the ZZ building (S2-laboratories for genetic work in accordance with GenTSV as well as BioStoffV and TRBA 100)

SOP No.: 001v07b
Pages: 19
Version: 07b

	Name	***Signature***	***Date***
Created by	RIZ Management-Team		
Verified and revised by	RIZ Management-Team		
Authorized by	Maren von Köckritz-Blickwede		

1. Content

2. Contact

Official operator:	President of TiHo Tel no.: 8000 Email: praesident@tiho-hannover.de
Director for Scientific Administration and Biosafety, Management S2 labs Epizootic diseases coordinator	Prof. M. von Köckritz-Blickwede Tel no.: 8787 Email: Maren.von.Koeckritz-Blickwede@tiho-hannover.de
Management S3** labs	Dr. Katja Branitzki-Heinemann Tel no.:6913 Email: Katja.Branitzki-Heinemann@tiho-hannover.de
Lab Management	Email: labormanagement-riz-zz@tiho-hannover.de Stephanie Geveke Tel.: 6134 Email: stephanie.geveke@tiho-hannover.de Gabi Wetzel Tel.: 6143 Email: gabriele.wetzel@tiho-hannover.de
Biological Security Officer (BBS): Biological Security Management	Prof. Dr. Maren von Köckritz-Blickwede Dr. Katja Branitzki-Heinemann Email: bbs-RIZ@tiho-hannover.de
Projekt Management	Email: Projektmanagement-RIZ@tiho-hannover.de
Sekretary	Email: riz-geschaeftszimmer@tiho-hannover.de
Technology Technical standby service	Email: Technikmanagement-RIZ@tiho-hannover.de 7997
First aid	Stephanie Geveke, Gabi Wetzel
Company doctor	Dr. Michael Glüer (Tel.: 8150, 0172-5134414)
Occupational safety specialist/ Fire protection representative Fire protection assistants	 Armin Dinter (Tel.: 7874) Stephanie Geveke, Gabriele Wetzel, Rouwen Stucke
Hazardous substance coordinator Dangerous goods coordinator	Dr. Andreas Gassner *(*Tel.: 7871) Silke Staats (Tel.:7875)
Scientific Director on duty	7998, 0170/1156566. Email: dwl-riz@tiho-hannover.de

3. Introduction

Aim and target group

This SOP is intended to ensure proper handling of infectious material and its waste of safety level 2. This applies to every employee who uses the rooms/laboratories of the RIZ-ZZ (Building 231).

Hazard designation:

Genetic work of biosafety level 2:

Safety level 2 is assigned to genetic engineering work with microorganisms and cell cultures for which a low risk to human health or the environment can be assumed according to the current state of scientific knowledge.

Responsibility and qualification

The laboratory management and the Biological Safety Officer (BBS) must be informed immediately of any changes, incidents and malfunctions in the laboratory.

Officers are authorized to issue instructions and act in an advisory capacity; ultimate responsibility lies with the respective project managers.

4. Requirements

Quality control and maintenance

Maintenance of the autoclave is ensured by a maintenance contract with the company Schlumbohm-Medizin-Labor-Technologie GmbH, Hamburg, Germany.

Twice a year a documented decontamination control of the autoclaved material is performed.
Solid waste: Spore stripes Geobacillus Stearothermophilus
Liquid waste: MagnaAmp, Geobacillus Stearothermophilus
Textile: Spore stripes Geobacillus Stearothermophilus
In addition, a vacuum test and a Bowie & Dick test (SteriClin) are performed weekly on the autoclave by the lab management.

Continuous verification

All authorized persons are instructed in this SOP before starting their work and afterwards receive job-related verbal instruction from the Biological Safety Officer (BSO) or the project leader once a year. This follows the floor plans and is executed or controlled by the respective project leader. This instruction is mandatory for persons with authorized access and must be recorded in written form. Visitors who work

only for one day at the RIZ must be under the constant supervision of the respective project leader or instructed person or have received instruction on site and this must be documented.

Immediately after starting work, everyone who works longer than four weeks at the RIZ needs to consult the TiHo company doctor **(**Dr Michael Glüer*)*. Depending on the organisms used in the project as well as the risk assessment of the used rooms, he will advise on examinations or more specifically vaccinations. An annual vaccination against influenza is recommended for all employees. Blood can be drawn annually to establish a serum bank, but this is optional. This medical consultation must be repeated depending on the project. At the latest after 36 months or in the event of significant changes in the handling of new pathogens or a higher biosafety level, a follow-up examination must be carried out.

Management needs to confirm that every employee is instructed once a year in the fire protection measures at his/her workplace. Particular attention must be paid to:

- - The location and escape routes of the emergency exits
- - The location of the assembly point
- - The location of the nearest fire alarm
- - The location of the nearest fire extinguishers
- - The switching off of particular equipment
- - The closing of fire protection closures
- - The evacuation procedure
- - Fire protection assistants

Access to the S2-area

For working times between 20:00 and 06:00 and at weekends, the security service together with the project leader have to be informed. Further requirements must be followed when working alone, see chapter 6.
Access cards are personal and cannot be transferred.
Before entering the S2-area, all persons who are not listed on the employee list (e.g., guests, external craftsmen, students) need to register and sign the list in the social room on the ground floor (0062).

Persons without completed training and those taking teaching courses require special authorization from the RIZ management to stay in the S2 area. The responsible project leader must apply for the special authorization. These persons may only work in the S2 area under constant supervision.

Children under the age of 18 are not allowed to enter. A family room is available in the TiHo Tower.
Private guests (family members or other guests) may only enter the RIZ-ZZ under supervision after registering with RIZ Management and receiving their consent.
Before access, everyone has to register on the list in the social room at the ZZ.

Guests are not allowed to use computers with which they could have access to internal data.

Bringing along pets

The keeping of and bringing along of pets is forbidden in the building.

5. Maintenance

If technical defects occur, please contact Labormanagement-RIZ-ZZ@tiho-hannover.de or Technikmanagement-RIZ@tiho-hannover.de

6. Risks for humans and environment as well as protective measures and behavioral rules including behavior in the event of accidents

Risks for humans and environment

Microorganisms of risk group 2 as well as genetically modified organisms (GMOs), which are assigned biosafety level 2, can cause infections or illnesses when exposed to the human body. A sensitization or toxic potential can also not be excluded.

Contact with/ingestion of infectious material is possible due to inhalation of aerosols, swallowing of contaminated specimen materials, penetration of pathogens into existing or injury-related skin damage or when the sample is splashed over the eye and mucous membranes.

During a lot of laboratory activities (e.g., pipetting, vortexing, decanting, plating) aerosols (the finest, invisible, floating droplets) can occur, which can cause infections if humans are exposed to them.

The release of GMOs can lead to environmental burden.

Protective measures and behavioral rules

Working with genetically modified organisms of risk group 2 is only allowed in genetic laboratories of biosafety level 2 or higher.

Only instructed persons have access to the laboratory, the instructions must be documented by signature. The document is submitted to Vera Meier for safekeeping. As different project managers are responsible on each floor, if rooms are used across different floors, instruction must be obtained from one responsible project manager on each floor. If equipment is used on more than one floor, a room briefing by a person defined by the RIZ management is required.

Sturdy, closed, slip-resistant shoes and skin-covering trousers/clothing should be worn in the laboratory rooms. Protective clothing must be worn when entering the laboratories. This consists at least of a clean lab coat and protective gloves, which must be disposed of properly after use. Clean lab coats may be worn when changing labs in the corridor area, provided the BSL area is not left and no office/changing

room/restroom or printer room is entered. If additional protective clothing, such as arm sleeves or safety glasses, is necessary to protect the employee during certain activities, this shall be determined by the project leader in the hazard assessment. In the laboratories, all equipment and objects should be handled with non-contaminated gloves. Declared glove-free zones, the hand wash basin, telephones, door handles, and transport boxes are to be touched without gloves.

Lab coats must be changed immediately in case of contamination and at least once a month on a regular basis.

Windows and doors must be kept closed.

Pipetting with the mouth is forbidden. Only pipetting aids are to be used for pipetting.

During centrifugation use tight closing centrifuge tubes. During centrifugation of aerosol-transferable S2-organisms and S2 GMOs, a bioseal cover must be used additionally.

Syringes and cannulas should only be used when absolutely necessary. After use, the cannulas are to be collected in a container provided for this purpose.

Care must be taken during all work to ensure that no avoidable aerosols are produced. Work that may generate aerosols containing pathogens must be carried out under a Class II safety cabinet. This work must not be performed under a fume hood. The fume hood is only used for working with hazardous chemical substances.

Laboratories must be cleaned up after work, and the work surfaces must be cleaned and disinfected/decontaminated (see hygiene plan). Only the equipment and materials that are actually needed should be placed on the work tables.

Moving equipment to other laboratories is only allowed after agreement with the RIZ management.

The decontamination measures listed in the hygiene plan must be strictly followed for contaminated work equipment.

After completion of the work, the S2 organisms must be properly stored or properly destroyed (see under "Proper disposal").

Eating, drinking, smoking, chewing gum, and applying cosmetics are prohibited in the laboratories.

Alcohol is not allowed in the entire RIZ building.

The wearing of headphones is prohibited. Music may only be loud so that alarm signals are not overheard.

Genetically modified organisms as well as pathogenic microorganisms are only allowed to be transported internally in closed boxes protected against breakage. The transport containers need to be handled from the outside without gloves.

For experimental purposes, risk group 2 organisms may be handled outside the safety cabinet for short periods of time if they are not transferable via aerosol. This work takes place in specially designed low-walled containers (tray or tub). S1 work can be performed without special containers.

Work with aerosol-transmissible organisms of risk group 2 is to be carried out exclusively within the safety cabinet.

Cleanliness and order in the workplace are top priorities.

In the event of pregnancy or immunodeficiency of an employee, the project leader and the company physician must be informed immediately so that appropriate occupational safety measures can be initiated.

The eye showers in each laboratory must be tested for functionality every 14 days and the emergency body showers every month by the employees working in the laboratories. Corresponding documentation of the tests must be kept in the laboratories.

The ventilation system runs permanently. If there is a failure of the ventilation system, management will immediately notify all employees so that appropriate arrangements can be made.

Working alone after regular working hours (6 a.m. - 8 p.m.) and at weekends is permitted, but must be coordinated with the project leader. Everyone must personally ensure a "buddy system", i.e., another person from the family or colleagues must be informed that one is working alone in the laboratory and should also be reachable in case of an emergency.

In accordance with the Working Hours Act https://www.gesetze-im-internet.de/arbzg/each employee must observe rest periods and breaks and also record all working hours (especially in the case of activities longer than 8 h per day).

First aid

There are three fire extinguishers on every floor as well as two first aid boxes. Every laboratory is equipped with an emergency eye shower as well as emergency body shower. Please note the first aid plan in the appendix.

Emergency call

Fire department	**Tel.: 0-112 (Control center)**
Accidents:	**Tel.: 0-112 (Control center)**
Poison center:	**Tel.: 0551-19240 (Göttingen)**
Trauma surgery ambulance of the MHH Carl Neuberg Str. 1	**Tel.: 0511-532-0**

Injuries and contamination with microorganisms must be reported to the project leader immediately. (Forms at "G:\riz_RIZ Allgemein\Formulare und Vorlagen\Verbandbuch Meldung RIZ_20201028.docx" or in the secretariat. Scan it and send it by mail to the secretariat). In addition, a witness must confirm the incident. If necessary, contact a doctor (“Durchgangsarzt”!) or emergency services.

An accident including accidental contamination with biological materials must be documented by the project leader and involved persons. Refer to:
"G:\riz\Projektleiter Biosicherheit ZZ\Unfallberichte Accidents\Formblatt_Dokumentation Unfall Biostoffe.docx"

If you need to see an accident insurance doctor because of an accident at the RIZ and sick leave is taken, an accident report must be written; see:
See for employees:
https://www.tiho-hannover.de/fileadmin/01_Verwaltung/Dez2_Personal/Formulare/Informationen_und_sonstige_Formulare/Dienstunfall/Unfallanzeige-AUV.pdf
See for students:
https://www.tiho-hannover.de/fileadmin/01_Verwaltung/Abfallwirtschaft_Umweltschutz/Arbeitsschutz/Unfallanzeige_Studierende_.docx

The following emergency measures must be carried out as part of first aid:

- In case of skin contact, the contaminated skin area should be disinfected thoroughly with disinfectant solution and then cleaned in accordance with the hygiene plan.
- In case of eye contact, the eye must be cleaned intensively for at least 5 minutes under running water (eye showers are available in every laboratory unit).
- In case of mild burns or scalding, the affected skin area must be immediately kept under running water for at least 10 minutes.
- If further symptoms occur after undertaking these emergency measures, a medical specialist ("Durchgangsarzt") must be consulted immediately.
- After intense contact with any pathogens (e.g. swallowing, inhaling, incorporation through injuries), contact the MHH accident and emergency department.
- The emergency services must be contacted in case of serious injuries.

Behavior in the event of accidents involving genetically modified organisms and reporting obligations § 5 GenTNotfV

If, in the event of an accident or fire, it cannot be ruled out that genetically modified organisms of risk group 2 have left the scope of the operating instructions (the approved rooms of the S2 facilities), there are reporting obligations in accordance with § 5 GenTNotfV.

If genetically modified organisms of risk group 2 are released (e.g. leakage, spillage, breakage, etc.), warn employees, block the area if necessary and (in case of fire after informing the fire department) immediately inform the **scientific management on duty (DWL)** Tel: **0170/ 11 56 566. or 7998**, the responsible project manager and the BBS**(Prof. Dr. M. v. Köckritz Blickwede or Dr. Katja Branitzki-Heinemann**).

Eliminating the hazardous condition must be carried out under personal protection (lab coat, if need be safety glasses, gloves, to be found in the laboratory in each case).

Cleaning and disinfection are to be carried out in accordance with the hygiene plan.

Doors must be kept closed until the decontamination measures have been completed. The entry of unauthorized persons must be prevented.

All contaminated objects (even lab coats) need to be stored in appropriate containers (closable, disinfected from the outside, liquid-tight), collected, and autoclaved.

An accident including accidental contamination with biological materials must be documented by the project leader and involved persons; see: "G:\riz\Projektleiter Biosicherheit ZZ\Unfallberichte Accidents\Formblatt_Dokumentation Unfall Biostoffe.docx"

Fire

In case of fire, an acoustic warning signal is emitted in the building by the fire alarm. The locations of the fire extinguishers can be found in the escape plan (see appendix).

If fire is detected, the fire brigade must be alerted immediately. Push button fire alarms have proven to be the fastest alarming devices. Furthermore, the fire brigade must be alerted by telephone (emergency number). Hannover fire brigade 112 (public telephone) or 0112 (in-house line).

The following information is required:

- Who is calling? Name, position, number to ring back
- Where is the fire? Bünteweg 17, RIZ, floor
- What is burning? Office, library, laboratory etc.
- Why is it burning? Explosion, technical defect...
- Are people in danger? Number of injured persons, severity of injuries
- Indication of special hazards (animals, hazardous substance, pressurized gas cylinder and others)

The fire brigade should be waited for and picked up by pilots at the driveway at the entrance and led to the fire site.
After the arrival of the fire brigade, the fire officer in charge manages all the firefighting and rescue measures. His instructions are to be followed. Observe the first aid plan.

Observe the fire and emergency procedures and the escape and rescue plan (see appendix).

Immediate measures

After alarming the fire brigade, make sure that no person is endangered. Therefore, the following guiding principle applies: Rescue of people takes precedence over firefighting. The first thing to do is to ensure that all persons in the danger area leave immediately. Close doors and windows to prevent drafts and smoke. In smoke-filled rooms, proceed in a stooped position; breathable air is still present near the floor for longer. Do not use elevators in case of fire. Cool burns under running water if possible. Do not

remove clothing residues from burn wounds. Do not apply ointments. Cover large burns in a sterile manner. Facial and eye burns should remain uncovered. Unconscious persons should be placed in the "recovery position". Continuous monitoring of vital functions is urgently required here, if necessary administer breaths. If there are no injured or helpless persons, fight the fire.

The following points must be observed when using fire extinguishers:

- o Press the valve in pulses;
- In case of big fires, use several fire extinguishers;
- Extinguish the fires from the front to the back and from the bottom to the top;
- Extinguish dropping and flowing fires from the top to the bottom;
- When firefighting outside you must extinguish with the wind;
- After extinguishing the fire, be aware of possible re-ignitions. Therefore, always keep an extinguishing agent reserve on hand; if necessary get a new fire extinguisher;
- Be careful when opening closed doors! Air access can lead to the formation of pilot flames;
- When not involved in rescue measures or firefighting, you should act as follows: Immediately leave hazardous areas via the escape routes (do not use elevators as an escape route!) and go to the assembly point;
- If the escape routes are cut off due to fire or smoke, you must attract the attention of the fire brigade (scream and wave at the window of a lit room);
- The presence of all persons from the fire area at the assembly point must be checked;
- Injured persons and hazards must be pointed out to the fire brigade;
- Inform the management of the institute and the management of the university

Escape routes

The main escape routes are the routes to the two staircases. Observe the escape plan (attached).

Transport of infectious materials

The transport of infectious materials within the building is only permitted if it is indispensable for experimental purposes or if it serves to inactivate the material by autoclaving.

Transport for experimental purposes

Transport takes place in double-packed, unbreakable, liquid-tight containers that can be disinfected from the outside and are handled without gloves.

Leading to inactivation

The autoclaved items are brought to room 0044 in break-proof, sealable containers that can be disinfected from the outside and autoclaved. Storage of autoclaved material in Room 0044 is prohibited.

Biologically contaminated liquids are collected in the safety cabinet in a unbreakable container with disinfectant provided and transported for inactivation as required in unbreakable, sealable, liquid-tight containers that can be disinfected from the outside.

Biologically contaminated solid materials need to be transported to inactivation in autoclave bags in unbreakable, sealable containers that can be disinfected from the outside.

The used autoclave needs to be in the same building.

Appropriate disposal

Autoclave

All biological material, excluding domestic waste, is autoclaved.

An exception is made for the liquid waste produced by the flow cytometer. This is collected at the fume cupboard in room 2008 and chemically inactivated there by trained persons.

Caution: Separate rules apply to hazardous materials (see "Hazardous materials").

The autoclave may only be used after instruction by the responsible employee. The operation of the autoclave is subject to the supervision of the RIZ lab management. Accumulating waste must be transported in the **closed**, break-proof, **autoclavable container** with lid.

There are two autoclaves on the ground floor (room: 0044) and another autoclave on the second floor (room: 2042). For contaminated waste, only the Schlumbohm autoclave on the ground floor is used.

The autoclaving process to kill the microorganisms takes place after a fractionated pre-vacuum at **121 °C for at least 20 minutes**. The autoclaved waste can then be disposed of with the general household waste.

All autoclaving procedures of waste are documented.

- All equipment (glass vessels, spatulas) used in microbiological or genetic engineering work must always be considered contaminated and autoclaved after the work. Liquid waste, e.g., from

plasmid preparations, cell culture, etc., is transferred to a break-proof vessel and then autoclaved.

- The persons named in the autoclaving plan are responsible for autoclaving the contaminated waste.
- Autoclave test tapes or chemical indicators must be used to check for proper heating during each autoclaving procedure.
- After autoclaving, the disposable material and liquid waste can be disposed of with general household waste or wastewater.
- Disposal is carried out by the room attendants.

Other methods for inactivation

Handling of biological substances in other lower safety areas outside of the RIZ is only permitted after inactivation and consultation / permission of the project leader! The project leader is responsible for the proper inactivation of biological material. For GMOs, the inactivation method must be approved by the Gewerbeaufsichtsamt (Trade Supervisory Office).

Import and export of biological material

Only after consultation / permission from the project leader! Keeping records is obligatory!

Hazardous waste

Hazardous chemicals need to be disposed of via special chemical waste procedures and not via the autoclave to avoid hazardous fumes. Please contact the RIZ management before disposal, Silke Staats (Tel.: 0511-953-7875) or Dr. Andreas Gassner (Tel.: 0511-953-7871). **The project leader is responsible for the proper inactivation of biological material.**
The contact for hazardous substances at the RIZ is Laboratory Management ZZ.

Some test materials and liquid waste that are contaminated with biological material must be chemically inactivated (without autoclave) and must be disposed of separately as special chemical waste in the respective chemical waste containers in accordance with the TiHo regulations: formaldehyde, methanol, or phenol-chloroform waste (by microscopy, isolation of DNA / RNA). For liquid waste from KingFisher, special regulations exist.

The contact person at TiHo is Dr. Andreas Gassner (waste management, environmental, hazardous materials and radiation protection officer, 953-7871).

The separation of **halogen-containing** (HCl etc.) and **halogen-free special waste** (ethanol, methanol etc.) is important. **Phenol-chloroform waste** is also collected separately. This hazardous waste is all separated into solid or liquid waste. **Formaldehyde waste** is disposed of by the Institute of Pathology.
The respective special waste is disposed of in declared waste containers.

Special waste administration times:
Tuesdays 11:00 to 11:30 and 14:00 to 14:30 at the garages of the craftsmen at Bünteweg 17
by Silke Staats (953-7875).

7. Utilization

Technical problems

In case of technical problems, please contact the RIZ management. Outside core working hours, a technical on-call service has been set up specifically for the RIZ: 0511-953-7997. The persons assigned to the on-call service are appropriately trained in handling and eliminating fault reports in the RIZ.
In general, the on-call service must prevent major damage and not carry out any repairs outside core working hours.

Furthermore, a Scientific Director on duty (DWL) can be reached for emergencies outside core working hours on the following telephone number: 0170/1156566.

Storage of data (storage and recording)

Hazardous materials/ chemicals

All hazardous materials must be registered in DaMaRIS (username:80zzgast password: zzgast80). Everyone must inform themselves in each case about the hazards by means of the operating instructions in DaMaRIS before using hazardous substances.

GenTAufzV

Storage needs to be documented in accordance with the genetic recording regulation (Gentechnik-Aufzeichnungsverordnung, GenTAufzV). Documentation must be carried out immediately and continuously in accordance with § 3 Abs. 7 GenTAufzV.

Before the start of genetic engineering work, the project manager initiates the preparation of the records in accordance with GenTAufzV on the basis of Form Z and confirms their accuracy by signing them. The approval granted must be attached to these records.

All GMOs and bio-organisms must be registered with a LabControl ID, which is linked to the name of the project leader.
This LabControl ID must be documented on the Z form or in the respective genetic engineering records. The Z form should be signed and stored on the server:
G:\riz\Projektleiter Biosicherheit ZZ\02_Gentechnikgesetz.
Each project leader is responsible for documentation.

BBS and RIZ management may control documentation and has the right to dispose of and delete samples without appropriate labeling.

The use of new donors, recipients and vectors usually establishes further genetic engineering work, which must be reported separately. The identity of the organisms used must be checked regularly if this is necessary for the assessment of the hazard potential.

This includes the regular performance of a mycoplasma test for the cell cultures.

Permanent cultures may only be stored in a -80 °C chest, a -150 °C chest, or in the N2 tank (Room 0046; 0048) in labeled second containers. The labeling of the cultures must clearly indicate the organism, vectors contained, and the user. Containers stored elsewhere or incompletely labeled will be destroyed without any consultation with the project leader.

Production, storage, consumption, and destruction of GMOs are documented in tabular form by the person conducting the experiment and are accessible to the project leader at all times (Form Z).

Records must be kept until completion of the work and for 30 years thereafter.

The process parameters of the autoclaving procedures are documented via the instrument software. The autoclaving processes are checked every six months by the lab management or an instructed person.

§7 BioStoffV

All biomaterials used must be listed in the targeted and/or non-targeted "biomaterial list". In addition, the rooms in which the specific biomaterials are used must be documented. The biosubstance lists and the risk assessments contain information about the classification of the biosubstances in accordance with § 3 BioStoffV into risk groups and information about the sensitizing, toxic, or otherwise hazardous effect on health. Each working group is obliged to inform about new biomaterials, to document, and evaluate the biomaterial in the context of the risk assessment.

G:\tiho\Gefährdungsbeurteilungen\80 Research Center for Emerging Infections and Zoonoses\Biostofflisten\RIZ ZZ (For access by all users)
RIZ ZZ BIOSTOFFE GEZIELT
RIZ ZZ BIOSTOFFE UNGEZIELT
RIZ ZZ Biostoff Raumliste

G:\riz\Projektleiter Biosicherheit ZZ (For updating, access only for project managers)
RIZ-ZZ BIOSTOFFE GEZIELT
RIZ-ZZ BIOSTOFFE PERSONENLISTE
RIZ ZZ BIOSTOFFE RAUMLISTE
RIZ-ZZ BIOSTOFFE UNGEZIELT

Further informations

The following information must also be taken into account
→G:\tiho\Gefährdungsbeurteilungen\80 Research Center for Emerging Infections and Zoonoses\Gefährdungsbeurteilungen
→G:\riz_RIZ_ZZ\SOP: 011v04 E Projectleader
→Information about the certain biological material can also be found in the biomaterial database.
https://www.dguv.de/ifa/gestis/gestis-biostoffdatenbank/index.jsp

9. Related documents

Hygiene plan

Skin care plan

Autoclaving plan

10. Appendix

First aid plan

Escape plan

In case of fire or emergency Status: 2016

Keep calm! **Recognize** what happened
Judge the situation
Act according to the situation

In every instance, put your own safety first!
Personal safety comes before safety of objects!

Rescue! → Evacuate injured persons; look after your own safety →First aid
→ Alarm other persons in danger area
→ If necessary shut down electricity, gas, water; **use emergency stop**.

Ask for help! **How to make an emergency call:**

Emergency calls can be made from all TiHo telephones to the following numbers:

0 -112 Fire brigade/rescue service

Poison-emergency-call at the University of Göttingen (around the clock): 0 - 0551 19240

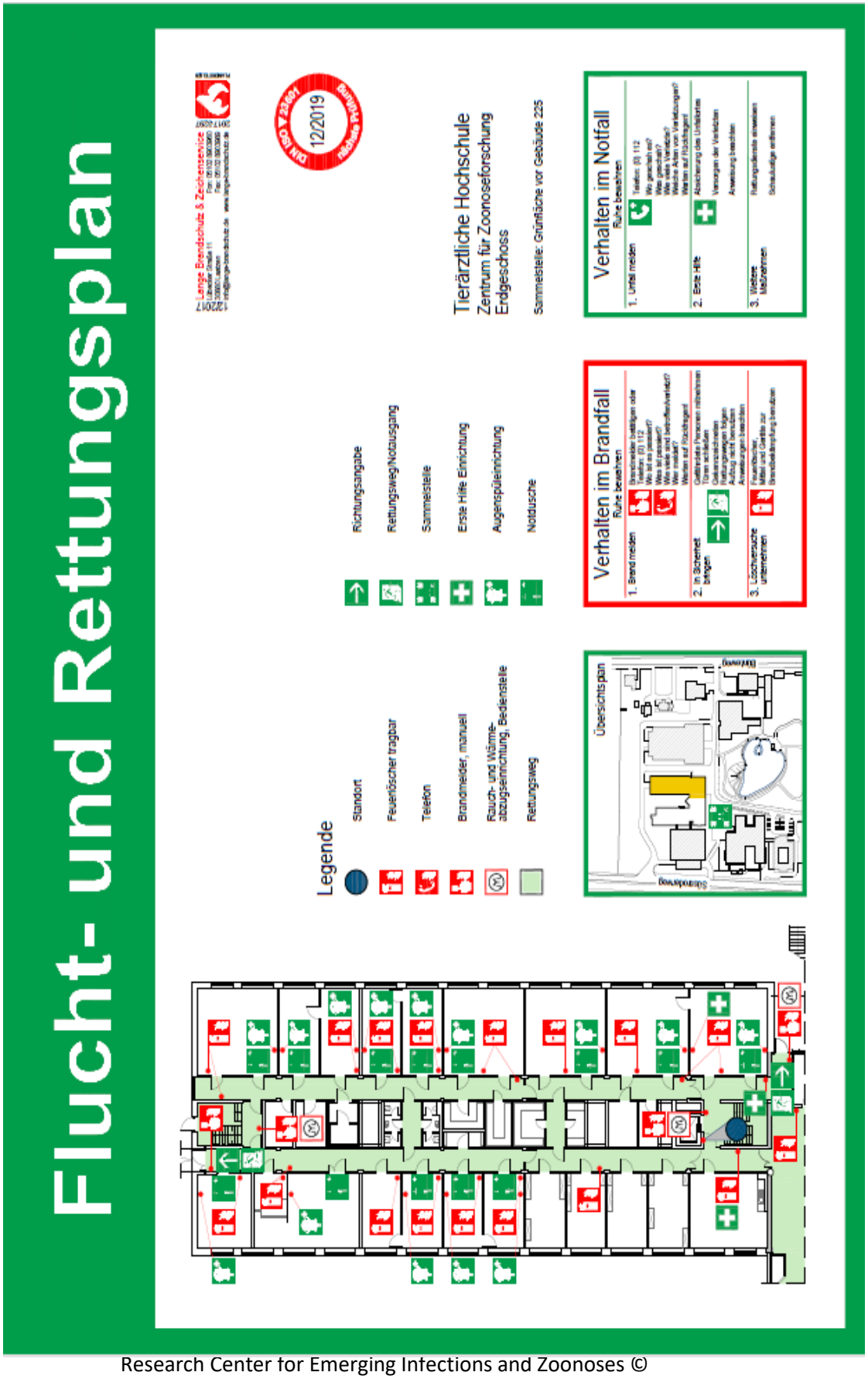
Your **emergency call** should always be made according to the following scheme:

Where did it happen	define area as well as possible
What happened	Fire, chemical burn, collapse
How many injured	Number
What kind of injuries	Type and place on body
Who is calling	Name and telephone number (own telephone number)
Wait	Never end the call before the rescue coordination center does so, they could have more questions.

Ensure that the rescuer can find the location where it happened. It is necessary that one person is waiting for them outside the building (in front of the building or on the street) and brings them to the injured person. This can save seconds!
Provide assistance! All persons are obliged to help!
Alarm siren: Long siren (wail) = fire alarm.

Call the fire brigade immediately via emergency call. When they arrive, they have to be instructed by people who are familiar with this area and the risks. Until the fire brigade arrives, you should use the fire extinguisher considering your own safety. All people who do not need to help have to be evacuated from the danger area.
Employees should also take care of guests.

Assembly point in case of an alarm is for all persons the entrance area of Lehrgebäude I (Pylorus). The project leaders have to count their staff to see if there are still persons missing in the building.
Accident & Emergency Department, Hannover Medical School (MHH): Tel. no.: 0 - 532 2052


Flucht- und Rettungsplan
Tierärztliche Hochschule
Zentrum für Zoonoseforschung
Erdgeschoss
Sammelstelle: Grünfläche vor Gebäude 225
Verhalten im Notfall
Verhalten im Brandfall
Übersichtsplan
Legende
Standort
Feuerlöscher tragbar
Telefon
Brandmelder, manuell
Rauch- und Wärmeabzugseinrichtung, Bedienstelle
Rettungsweg
Richtungsangabe
Rettungsweg/Notausgang
Sammelstelle
Erste Hilfe Einrichtung
Augenspüleinrichtung
Notdusche
12/2019

General instruction manual RIZ-FI

08.03.2023

SOP

Title: General instruction manual

(Laboratory and animal husbandry units of building 238)

SOP No.: 501v06a E
Pages: 25
Version: 06-A

	Name	***Signature***	***Date***
Created by	RIZ Management-Team		
Verified and revised by	Dr. Katja Branitzki Heinemann		
Authorised by	Prof. Maren von Köckritz Blickwede		

1. Content

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Biosafety Specialists BSL3 :	Prof. Dr. Maren von Köckritz-Blickwede Dr. Katja Branitzki-Heinemann Project-specific further named specialized persons
Company doctor:	*Dr. Michael Glüer (*Tel no.: *8150)*
Officer for working safety/ Fire protection representative:	*Armin Dinter (*Tel no.: *7874)*
Dangerous goods safety advisor	*Dr. Andreas Gassner (*Tel no.: *7871)*
Technical standby service:	Tel no.: *7997*
Scientific Director on duty:	Tel no.: *7998*

3. Introduction

3.1 Purpose of the operating manual

This instruction manual specifies in the following, information, rules of behavior and instructions for tasks to be performed in the rooms of the RIZ (FI, building 238) of the University of Veterinary Medicine Hannover, Foundation. It should not only serve the purpose of recognizing and documenting biological and technical hazards, but also to protect oneself against them. Complying with these instructions should minimize the occurrence of pathogens and the risk of accidents among members of staff. Furthermore, it is stipulated what must be done in the event of an emergency and which tasks and information networks must be complied with.

Moreover, the responsibilities for various working sectors and decision-makers are named.

These instructions are based on the following legal requirements, regulations and manuals: General operating manual of the RIZ-FI, Genetic Engineering Act and associated regulations, Biomaterials Regulations, Infection Protection Law, Ordinance on Hazardous Substances, Safety at Work Law, Technical regulations (TRBA 100, 105, 120, 310, 450, 460, 462, 464, 466, 500), comments from the Central Commission for Biological Safety (ZKBS).

3.2 Definitions according to the genetic engineering safety regulations

3.2.1 Operator

Those operating genetic engineering facilities in accordance with § 3 No. 9 Genetic Engineering Act (GenTG) are private persons or legal entities that set up or operate genetic engineering facilities, that carry out genetic engineering operations or genetically-engineered releases or bring genetically-engineered products on the market in accordance with the Genetic Engineering Act. As a rule, the operator is represented by the legally held liable head of the institution. At this institute, the Head of Scientific Administration and Biosafety, Professor von Köckritz-Blickwede is the responsible person.

3.2.2 Authorised officer for biological safety

The tasks of the authorised Bio Safety Officer (BBS) derive from § 18 Genetic Engineering Act (GenTG).
The authorised Bio Safety Officer is authorised and required to

- monitor the fulfilment of the tasks of the project leader related to the safety of genetic engineering work, in particular through the control of genetic-engineering facilities at regular intervals, by notifying identified deficiencies and by checking the removal of these deficiencies.
- to advise the operators, the works council and the responsible persons upon request:
- on risk assessment in accordance with § 6 Paragraph 1 Genetic Engineering Act
- on the acquisition of facilities and resources and the introduction of procedures for using genetically modified organisms
- on choosing and testing personal protective equipment and

- before putting facilities and resources into operation and before introducing procedures for using genetically modified organisms.

The Biosafety Officer (BBS) gives a written annual report to the operator about the taken and proposed measures.

The simultaneous carrying out of the duties of a project leader and those of a BBS within the scope of the same genetic-engineering work is prohibited.

Primarily, the BBS is assigned an advisory and scrutinizing function, whereby he has no direct powers of authority. The operator has, however, to ensure that the BBS is able to immediately present his proposals and concerns to the responsible office.

The BBS can be relieved of possible liability issues through his supervisory role and where appropriate through a written warning. He is not allowed to be discriminated against as a result of performing tasks assigned to him.

3.2.3 Projekt leader

The project leader heads the direct planning, coordination or supervision of the genetic engineering work. In accordance with § 3 No. 8 GenTG, only that person can be employed as a project leader who has proved expertise in relation to genetic technological work as required in § 15 GenTSV. In accordance with § 14 GenTSV, he is responsible for:

- the adherence to safety regulations of §§ 8 - 13 as well as pest-, animal pest-, animal protection-, species protection- and plant protection legal regulations;
- when genetic technological work has started, if the tasks are properly registered at the Government Trade Supervisory Body in the case of S2-work and that a response has been acquired or in the case of S3-work, the appropriate permission has been obtained;
- the implementation of regulations and directives from the authorities including collateral clauses;
- adequate qualification and instruction of the members of staff;
- carrying out briefings for the members of staff in accordance with § 12 Paragraph 3 as well as providing medical examinations by a company medical doctor and keeping records of these as well as recording any possible accidents;
- providing detailed information of the BBS concerning the genetic technological work and the necessary precautions to be taken in accordance with §§ 8 - 13;
- that in the case of danger for the named legally protected interests in § 1 No. 1 of the Genetic Engineering Act, suitable measures shall be met to eliminate this danger;
- informing the operator of any matters without undue delay that do not correspond to the expected course of genetic technological work and by which there exists the suspicion of endangering the named legally protected interests in § 1 No. 1 of the Genetic Engineering Act.

Further delegation of tasks which arise from the allocated duties here is permissible. The responsibility for performing the obligations remains however by the project leader.

3.3 Definitions according to biomaterials regulations

3.3.1 „Experts“ (Fachkundige Personen)

The expert in accordance with § 2 Paragraph 11 BioStoffV in connection with TRBA 200, protection level 3 is required for work requiring permission. From the Government Trade Supervisory Body Hannover, regular attendance at the BSL-3-Worcshop “Expert” for obtaining and maintaining the qualification is officially recognised. These workshops are carried out under the auspices of the Working Group National Biorisk Management (ANBIOM) as well as the German Centre for Infection Research (DZIF) of the Hannover Medical School (MHH).

3.4 Further official channels

3.4.1 Biosafety Management

The biosafety Management is responsible for equipping, setting up and maintaining the stables and laboratories. The management coordinates projects and project leaders as well as the corresponding documents and files (e.g. compiling SOPs and risk assessment by the project leaders). Therefore, they initiate, for example, meetings before an animal experiment or a laboratory project which is about to begin and grant a temporary entry permit to the areas to be used in the building 238. Also, the biosafety management carries out the compiling of a work schedule and the planning for the animal keepers (in consultation with the project leaders). They are there to offer support in an advisory capacity regarding the compiling of risk assessments and also the choice of personal protective equipment and they specify the disinfection measures in consultation with the project leaders. Furthermore, the Biosafety Management organizes the obligatory courses for new members of staff as well as first-aid courses and fire prevention drills. The exfiltration of sample material must be approved by the Biosafety Management. The Biosafety Management coordinates maintenance appointments in consultation with the project leaders and assesses which decontamination measures (concerning equipment and rooms) must be met beforehand.

3.4.2 Research Direktor in Charge („Diensthabender wissenschaftlicher Leiter (DWL)“)

The Research Director on duty (DWL) is a member of staff from the University of Veterinary Medicine Hannover, Foundation and is the person who, in an emergency, is responsible outside regular working hours as the first contact partner for the members of staff in the building (see emergency plan). Several Research Directors on duty can be simultaneously defined for the different areas of the building if the project requires this. The respective DWL must have sufficient local knowledge and experience but also sufficient experience in the field of biosafety in the respective area in order to be able to meet decisions in the case of emergencies. Moreover, he/she has to provide proof of having completed a training course and regularly (at least every two years) a refresher course in first aid. He/she has to carry on his/her person an emergency pack when on duty. This consists of a mobile phone switched on in case of an emergency (please look at the notice board), the FI building plans and the emergency telephone list as well as an overview of the current ongoing experiments and pathogen cards.

3.4.3 Technical on-call service

In the event of a technical problem in building 238 (FI) during normal working hours, Mr. Randolf Schorsch (Tel. No.: 0511/953 6917) or Mr. Dmitrij Haas (Tel. No.: 0511/953 6941) is available as contact partner. Outside the core working times, a technical on-call service is set up specially for the RIZ (building 231 and building 238) by the University of Veterinary Medicine Hannover, Foundation (Tel. No.: 0511/953 7997). Those persons associated with the technical on-call service are appropriately trained in dealing with and eliminating error messages for the buildings 231 and 238.

Generally, the technical on-call service has to avert greater damage occurring and **does not carry out repairs** outside core working hours.

3.5 Provisions of the infection protection act (Best. des Infektionsschutzgesetzes)

3.5.1 Permission

In accordance with § 44 Infection Protection Act (IfSG), the person who wishes to carry out tasks with pathogens in the risk groups 2 (specifically), 3 or 4, requires a permission from the responsible authority (the health authority at the abode of the applicant). This permission in accordance with § 44 is not required for the person who is working under the supervision of the one who has been granted permission or who, in accordance with § 45 does not require permission.

3.6 Provisions of the infectious animal diseases regulations (Bestimmungen der Tierseuchenerregerverordnung)

3.6.1 Permission

In accordance with § 2 Infectious Animal Diseases Regulations (TierSeuchErV), the person who wishes to carry out tasks with animal pathogens requires permission from the responsible authority (LAVES is the responsible authority). In accordance with § 2, this permission is not required for the person who does not require permission in accordance with § 3.

4. Organisational structure

4.1 Building 238 RIZ FI

Building 238 (FI) not only includes laboratory units but also livestock units of various safety levels (GenTSV) and protection levels (BioStoffV), also technical areas. A building plan is found in the annex of this document.

In the animal husbandry area, a distinction is made between the outside, non-infectious containment (supply corridor) and the inside, infectious containment (stable areas, disposal corridor and pathology with the adjacent rooms).

The laboratory area, due to the fact that the individual rooms are not gas proofed and are separated from one another by separate sluices (the exception being the insectarium S3e laboratory area), is, in each case, regarded from a hygienic point of view as one area. Therefore, the biosafety measures comply with the project with the highest requirements in this area.

Classifying the activities with certain pathogens is decided upon according to the respective project and pathogen (risk assessment) in consultation with the project leader, the Biosafety Management and the BBS for the defined animal husbandry area, laboratory wings and laboratories.

Infection areas:

- South laboratory wing – S3 (double HEPA filtering of the exhaust air)
- North laboratory wing - S3e (double HEPA filtering of the exhaust air, showering possibility on leaving the area)
- S2 Animal Husbandry units (simple HEPA filtering of the exhaust air)
- S3 Animal Husbandry units (double HEPA filtering of the exhaust air, showering possibilities when leaving the area)
- Pathology and disposal corridor (double HEPA filtering of the exhaust air, showering possibilities when leaving the area)

Supply areas:

- Supply corridors, stable and adjacent rooms
- Wastewater disposal facilities and digester
- Steam boiler
- Ventilation areas S2 Animal Husbandry
- Ventilation areas S3 Animal Husbandry
- Ventilation areas S3 und S3e laboratories

4.2 Duties and responsibilities for biosafety in the building 238 (FI)

For compiling and implementing a biosafety concept as well as complying with the legal fundamental principles and for communicating with the responsible authorities, the following organizational units, contact partners and duties are decided upon in the University of Veterinary Medicine Hannover, Foundation.

The President of the University of Veterinary Medicine Hannover, Foundation is named as operator of the genetic engineering facility and has to take care, by means of the organizational structures and delegating of tasks, that the safety of humans and the environment are guaranteed. For this purpose, the Head of Scientific Administration and Biosafety, Professor von Köckritz-Blickwede is named and represents the operator in these matters. Additionally, a Biological Safety Officer (BBS, see Appointing Persons) is named. He/she advises the operator as well as the project leaders in questions relating to biological safety, work safety and genetic engineering law. Furthermore, the specialist staff for work safety, the company doctor and the Dangerous goods safety advisor act as advisers (see Responsible Persons).

The operator makes the required financial and personnel resources available so as to be able to carry out the organization and biosafety management.

Fundamentally, the operator is held liable to third parties. However, members of staff who act willfully and knowingly or who are grossly negligent, can also be made responsible.

Insofar as not defined otherwise in this operating manual, the central organization and monitoring of biosafety as well as animal husbandry in the building 238 (FI) lie fundamentally in the responsibility of the operator and the Head of Biosafety RIZ Professor von Köckritz-Blickwede.

The project leaders are responsible for the risk evaluations and occupational safety standards of their projects (see SOP Project leaders).

5. Biosafety plan

5.1 General Regulations/ Entry to the building 238 (FI)

The entry of persons to the building 238 (FI) is categorically only possible after submitting a detailed project plan and all required permits from the authorities by the project leaders as well as authorization of the project by the operator or the Head of Scientific Administration and Biosafety (Professor von Köckritz-Blickwede) and can as a result of this be granted. Those persons who are authorised access receive a personalised chip card with specified rights. Working alone in the building (with the exception of the office wing) is categorically not allowed and only permitted in exceptions after the risk has been assessed by the project leader, BBS and Biosafety Management (see separate SOP for working alone and weekend work). **Generally, security and the Scientific Director on duty (DWL) should be informed about working in the building between 20:00 and 06:00 or in the entire building at weekends and on public holidays and this should occur in consultation with the project leader.** After finishing work in the case of working alone, the member of staff has to report back (buddy system), see 5.3. and 5.4.). Moreover, each person who has an access right (exception guest access) to the building has to have been trained as a first aider as well as having completed a regular fire protection training course. Both courses are offered regularly.

Before starting the activity in the building, a medical examination has to be carried out in which the wearing of breathing protection, susceptibility to infections and skin status are dealt with.

Insofar as vaccines are available, it is recommended that members of staff are vaccinated against the pathogens with which they are going to work. This recommendation applies for all members of staff who stay in areas in which these pathogens are worked with.

All members of staff who would like to enter an infectious area must record their name, date, time of entering/time of leaving in a logbook in the FI lobby. The logbook provided for that purpose serves in the case of a fire identifying the whereabouts of persons who have not/have left/were unable to leave the building.

In all infectious areas as well as supply areas, the project-related and general hygiene plans must be followed. Smoking, eating, wearing cosmetics and drinking are strictly forbidden. Working under the influence of substances which influence the concentration or alertness are forbidden. In the case of a pregnancy or the diagnosis of an immunodeficiency, the project leader as well as Biosafety Management must be informed immediately thereof. Categorically, in the changing sluices, jewelry and watches are taken off. Should these items accidentally be taken into the laboratory area, they must be disinfected and sluiced after written permission from the Biosafety Management.

In all supply and infection areas, personal protective equipment (PPE) specific for any one area must be worn which has to be changed using the sluices (see 5.7.). Every member of staff must take care that

pathogens are not spread between the rooms or to the outside. For this purpose, the given Biosafety Regulations must be followed.

Also, the technical area must only be entered by instructed members of staff who have received instructions to wear PPE.

Use of the toilets in all areas must be defined depending on the related project, as if need be, a personal decontamination before using the toilet has to take place. Additionally, specific instructions are displayed on the toilet door.

All members of staff have to strictly comply with a previously stipulated quarantine period after working in the stables as well as in the laboratory due to animal pathogen regulations. For the areas which are used by the Reference Laboratory for Classical Swine Fever Virus (CSFV), a quarantine period of 48 hours (since the last entering of the units) to other areas where animals are kept has to be adhered to. This relates to swine and other cloven-hoofed animals (e.g. on farms or in zoos). Additionally, a written undertaking ("Verpflichtungserklärung") must be signed by every member of staff which is to be found in the annex of this SOP.

5.1.1 Entry of guests

Unauthorised persons such as workmen, scientists or guests must only enter the infection area of the building 238 (FI) under escort and supervision of authorised persons. This must be discussed beforehand with the project leaders as well as the Biosafety Management and authorised by them.

The general regulations of the building 238 (FI) also apply for guests. Members of staff of the University of Veterinary Medicine must always have their staff card with them. This should be left in the closed sluice areas on entering the infection area. Guests, if appropriate, are handed out a guest card. The "taking along" of an unregistered person is strictly forbidden. Should the "taking along" of an unregistered person be discovered, this will lead to one's own card being blocked. The Biosafety Management is responsible for blocking cards. Loss of staff cards must be reported immediately to the Biosafety Management.

External scientific guests who are intending to work with human pathogens must present confirmation from their institution/institute/university of a medical examination carried out by a company doctor as proof that the person is physically able to work in the respective area.

5.2 How to Proceed in the Event of a Breach of Occupational Health and Safety Regulations and Biosafety Regulations

All employees should take care of one another for reasons of safety at work and biosafety. This also serves the purpose of preventing accidents and the release of pathogens. If in individual cases, the employee is no longer able to comply with the regulations, e.g. owing to an accident, this must be reported to the Biosafety Management. "Not being able to comply with" regulations and guidelines can have different reasons. Here, are exemplarily listed, being overworked, stress, deadlines, missing equipment or private reasons of the members of staff. Work-related reasons must be analysed immediately after being reported and eliminated. In the event of private reasons, for example, signs of addiction, other illnesses or also politically motivated behavior not conforming to the laws, the Head of Scientific Administration and Biosafety (Professor von Köckritz-Blickwede) must be informed by other members of staff/colleagues. Depending on the situation, the person concerned should be interviewed in the presence of the company doctor, a specialist for occupational safety or a Staff Council Representative to discuss a plan of action.

If applicable, the operator, DWL and the BBS have to be notified. The person concerned is not allowed to work in certain areas in the FI building until further notice until his/her medical condition has improved and a renewed work permit from the Head of Scientific Administration and Biosafety (Professor von Köckritz-Blickwede) as well as the project leaders has been presented.

It is important to bear in mind that knowingly working under the influence of substances in the laboratory area and stable area is strictly forbidden. Thereby, not only are drugs such as alcohol meant but possibly also medication by which possibly occurring side effects must be taken into consideration. If applicable, the company doctor must be consulted.

Working with fever or other restrictive disease-related conditions is strictly forbidden. If a member of staff has feelings of nausea, dizziness or fever while working in the laboratory or stable area, he/she must immediately inform a colleague (if applicable by phone) and leave the laboratory/stable.

5.3 Buddy-system in the animal husbandry area

Working with large animals and/or with zoonotic agents is associated with an increased risk for all members of staff. For this reason, all care-related and experimental-related work in the stable area must always be performed with two persons being present in the building who are in contact with each other by phone. Thereby, one reachable person by phone can also be in the office or in the break-room for the animal care takers and the contact can remain guaranteed by the camera system. In the case of experimental work with animals when taking samples or in pathology, at least two persons must always be present.

Outside working hours (20:00 until 06:00 hours/at the weekend/on Public Holidays), additionally, the security service in the RIZZ ZZ building must be informed about those persons entering or leaving the FI building.

5.4 Buddy System in the laboratory area

Also, in the laboratory area when working with zoonotic agents, there is a high risk of contamination/infection. Therefore, in this case there must be a second person reachable in the building (by phone) to regularly check the medical condition of the staff member (above all when working in a protective suit) and to be able to support him/her in an emergency. Working alone (e.g. changing medium in cell culture) can, after appropriate risk assessment and consultation with the project leader and Biosafety Management as well as the DWL, be carried out. Hereby, the working times must be defined beforehand with the project leader and the project leader must be notified when entering and leaving the laboratory area.

Outside working hours (20:00 until 06:00 hours/at the weekend/on Public Holidays), additionally, the security service in the RIZZ ZZ building must be informed about those persons entering or leaving the FI building.

5.5 Training / Safety instructions

The particular working conditions and practices in building 238 (FI) require specific safety instructions and structured training of the members of staff before work begins. The training/instructing is carried out and documented by previously instructed and experienced members of staff and/or the Biosafety Management in consultation with the project leader. If a member of staff has not entered an infection

area for six months, the training/instructions relating to a specific project must be refreshed in consultation with the project leader. Depending on the area, different contents, and of varying intensity, have to be conveyed.

After the training/instruction, work initially takes place under the supervision of the already instructed and experienced members of staff from whom project-related techniques and special features are learned.

Alongside the training units, particular qualifications for carrying out scientific work in the FI building are required. These are a completed training as a Biological Technical Assistant (BTA), Medical Technical Assistant (MTA) or Veterinary Medical Technical Assistant (VMTA), Animal Care Taker or a university degree (in Biology or a similar subject), (Veterinary) Medicine, as well as proof of knowledge and experience (at least three months) in the S2 area. If members of staff have already worked in the S3 area, working under supervision is not applicable. The training units must be completed however.

The contents of the training shall be adapted to the respective area to be trained and include:

General rules and principles FI building

1. Fire protection and behavior in emergencies
2. Finding your way around FI and special dangers
3. Personal protektive equipment (PPE)
4. Handling samples, disposal and sluice procedures
5. Project-related risk assessments including executing collateral clauses on dealing with biomaterials
6. First aid (refresher course at least every two years)

Technicians/ Technical on-call service → members of staff of the technical on-call service as well as project-related technicians receive technical instructions (Mr. Schorsch or Mr. Haas) as well as instructions on biosafety (Biosafety Management).

Cleaners → Cleaners receive separate instructions including safety training for the specific areas which have to be entered.

In all S3 areas, the sectors follow an active training phase which include working at least five times under supervision. The training phase can be extended as required and is defined by the RIZ Head of Biosafety and the project leaders depending on the project.

5.6 Personal Protective Equipment (PPE)

Personal protective equipment must be adapted in the respective areas to the specific project and pathogen. The respective areas are entered via the sluices for persons. Within the sluices, line markings (with line marking tape) / the sluices (showers) separate the sterile from the non-sterile side. Here, clothing and/or shoes have to be changed before going behind the line/entering the shower. Before entering the animal enclosures (via the supply corridors S2 and S3) and pathology/disposal corridor, everyday clothes must be **completely** removed and afterwards clean laboratory attire (underwear, socks, outer garments, shoes) must be put on. In the laboratory area, street clothes (outer garments, shoes) are discarded and the area is entered in work clothes (S3) or additional special protective clothing (S3e).

As soon as an aerosol occurs in the context of the task with infected (animal) material, the wearing of an FFP-3 mask and goggles or alternatively a ventilated fume hood with corresponding filters is obligatory. In the event of wearing an FFP-3 mask, in accordance with ARBMEDVV, a medical examination is obligatory before use. The following must be observed: the FFP3 masks must be worn for a maximum of 120 min at a stretch. After wearing for 120 minutes, a 30-minute break is stipulated. The disposable masks are collected in an autoclave bag after use and disposed of via the autoclave by the animal care takers. The hoods are decontaminated in accordance with the hygiene plan.

Thereby, the **DGUV (German Social Accident Insurance (deutsche gesetzliche Unfallversicherung)) Regulations 112-190** regarding the use of breathing protection equipment and the corresponding working time restrictions have to be taken into consideration.

5.7 Routes to the various areas

5.7.1 S2 Animal husbandry (Supply Corridor, Stall Area)

As described under PPE, the supply corridor is entered after a complete change of clothes in laboratory attire. When entering the stable, the laboratory attire is taken off on the sterile side of the changing room (excluding underwear). Here, gloves are put on. On the other side of the changing room, an overall, boots, as well as further project-specific PPE (e.g. apron, protective googles, hood, FFP-3 mask) are got ready. **Wearing a pair of clean gloves,** the protective equipment is placed **in front of the overall and boots** and the stable is entered (without entering the disinfection bath so as to avoid unnecessary amounts of disinfectant in the animal husbandry area).

When leaving the stable, the members of staff pre-clean their boots with water and enter the sluice with the prepared disinfectant bath wearing their boots (see hygiene plan). The boots are taken off and then put to dry next to the dip. The members of staff steps with his socks and stable protective equipment onto the plastic mat. There he sees to his protective equipment, takes off his gloves, and subsequently washes/disinfects his hands in accordance with the hygiene plan. With clean socks or barefoot, he then enters the clean blue area and puts on his laboratory attire. Before entering another stable area, it is necessary to proceed as described above.

After completing all work, showering in the sluices for persons (a hygiene shower) is recommended and depending on the project is specified by the project leaders and Biosafety Management. Changing clothes and shoes (street clothes) as well as cleaning and disinfecting hands are obligatory in accordance with the hygiene plan when leaving the outer containment.

The procedure can be adapted to the specific project.

5.7.2 S3 S3 Animal husbandry (Supply Corridor, Stall Area)

As described under PPE, the supply corridor is entered in laboratory attire after a complete change of clothes. When stepping over into the S3 supply corridor, shoes are changed again. The stable sluice in the S3 area is equipped with a shower. Before entering the shower sluice from the sterile side of the sluice for persons, the **entire laboratory attire** is taken off and the non-sterile area is entered via the shower sluice. The PPE (underwear, disposable overall/suit, breathing protection, socks, boots, gloves) meeting the needs of the specific project are placed there, wearing **a clean pair of gloves,** and the stable is entered

((without entering the disinfection bath so as to avoid unnecessary amounts of disinfectant in the animal husbandry area).

When leaving the stable, the members of staff pre-clean their boots with water and enter the sluice with the prepared disinfectant bath wearing their boots (see hygiene plan). The boots are taken off and then put to dry next to the dip. The member of staff steps with his socks and protective equipment onto the plastic mat. There he takes off his entire protective equipment and underwear, takes off his gloves, and subsequently washes/disinfects his hands in accordance with the hygiene plan. Afterwards, he takes a shower and puts on his laboratory attire on the sterile side.

Taking a shower when leaving the area is obligatory!

5.7.3 S3 Pathology/ Disposal corridor

Every single opening of stable doors in the disposal corridor and using the pathology area must be permitted by the Biosafety Management.

When entering this area via the sluices for persons in pathology, a complete change of clothes is required and the area is entered via a shower sluice. Afterwards, the PPE (underwear, disposable overall/suit, if applicable, breathing protection, socks, boots, gloves) meeting the needs of the specific project are placed there.

The disposal corridor /pathology can in the event of animal transport also be entered via the stable area. Additionally, boots must be changed at least once in the disposal corridor and the further PPE for working in pathology meeting the needs of the specific project must be placed there. Both must be placed in the disposal corridor/pathology beforehand.

Thereby, attention must be paid to the fact that the stable doors must only be opened/closed from the stable side and that in the event of passing through the disposal corridor, one person on the stable side must close the door again.

When leaving pathology, the members of staff, if applicable, pre-clean their boots with water and enter the prepared disinfection bath wearing their boots (see hygiene plan). The boots are taken off and then put to dry next to the dip. The member of staff steps with his socks and protective equipment onto the plastic mat. There he takes off his entire protective equipment and underwear, takes off his gloves, and subsequently washes/disinfects his hands in accordance with the hygiene plan. Afterwards, he takes a shower and puts on his street clothes on the sterile side.

Taking a shower when leaving the area is obligatory!

5.7.4 Leaving the stable/pathology with full protective clothing

When leaving the stable, the members of staff clean their boots and suit with water and enter the prepared disinfectant bath wearing their boots (see hygiene plan). Afterwards, they enter the shower in which they disinfect the PPE by means of portable pressure spraying equipment (project-specific, in an emergency) and afterwards rinse with water. Then, the members of staff can enter the sterile area of the changing room, take off their PPE and put on their laboratory attire.

5.7.5 S3 Laboratory

Jackets, street shoes as well as personal possessions (e.g. handbags) are put in the locker room (room no.: 00042) and locked in a personalised locker. Wearing laboratory shoes, the S3 area with restricted entry is entered where the shoes are left (room no.: 07094). In the sluice for persons (room no.: 00052), the street outerwear is exchanged for laboratory attire. The laboratory shoes are put on immediately before entering the laboratory wing at a “sluice line” (marking in the floor area of the sluice for persons). The project-specific PPE is stored in lockers on the corridor of the S3 area and put on before entering the laboratory. The laboratory attire consists at a minimum of a laboratory coat with back fastener, as well as gloves. Further project-related PPE (e.g. sleeves, a second pair of gloves, FFP3 breathing protection mask) are put on in the laboratories.

Numerous pieces of project-related PPE for once only use are always taken off in the laboratory after finishing activities.

In the changing room, the hands are disinfected and washed, the laboratory attire is taken off and the street outerwear is put on.

5.7.6 S3e Laboratory

Jackets, street shoes as well as personal possessions (e.g. handbags) are put in the locker room (room no.: 00042) and locked in a personalised locker. The corresponding changing cubicle (ladies/gents) in the restricted entry S3e area is entered in laboratory shoes and in street outerwear. After taking off street outerwear and laboratory shoes, the shower sluice is passed through. The other side of the changing cubicle (after leaving the shower) is divided into a sterile and non-sterile side by means of line marking tape. On the non-sterile side, the project-specific PPE (overall/protective suit, breathing protection/respirator, shoes and gloves) are put on. Further project-related PPE (e.g. sleeves, a second pair of gloves) are put on in the laboratories.

As the laboratory rooms are not separated by further sluices from the laboratory corridor (with the exception of the insectarium), the PPE for the area depends on the risk assessment of the project with the highest requirements.

When leaving the laboratory, some of the external PPE layers are disinfected at exposed points (see hygiene plan). The outer pair of gloves is left in the laboratory. The inner pair of gloves is disinfected again.

In the changing room, the PPE is taken off on the non-sterile side in accordance with the PPE instructions (displayed) and remains there. After disinfecting one’s hands in accordance with the hygiene plan, the shower sluice is passed through in laboratory attire. Now the laboratory attire can be removed and the street outerwear be put on again.

In this area, showering with jets is possible and can be stipulated by the Biosafety Management depending on the project. In this case, an entire change of clothing is necessary before passing through/using the shower sluice.

5.8 Centrifuges

In the case of centrifugation of genetically modified organisms (GMOs) from risk group 2 upwards, aerosol-tight rotors or bucket rotors must be used. The centrifuge test-tubes must be loaded on the safety workbench and sealed with a leak-proof cap. After centrifugation, the tubes must be opened in the safety workbench. A corresponding SOP is available for this step. Each member of staff is instructed before use on site.

In the event of the centrifuge displaying any error message, the regulations of an "emergency" apply, as it cannot be ruled out that sample test-tubes have got broken in the centrifuge. Elimination of the hazardous condition must always be done with self-protection measures (laboratory coat, gloves, disposable apron, which are in the laboratory). In the event of human pathogenic bacteria, protective googles and FFP-3 masks must additionally be worn.

5.9 Sluices

All samples which are taken in the stable are packed double in seal proof and break proof containers and disinfected in accordance with the project-related adapted hygiene plan in the stable sluice (observe the treatment time!)

All samples are brought to the outside by the animal care takers/animal sluices in a sealed transport vessel after being disinfected again (observe the treatment time!) for further processing.

Sealed telephones are decontaminated in the same way as samples and can be removed from their case after the disinfection process in the supply corridor.

5.9.1 Samples and Material from the Stall Area

All samples which are taken in the stable are packed double in seal proof and break proof containers and disinfected in accordance with the project-related adapted hygiene plan in the stable sluice (observe the treatment time!)

All samples are brought to the outside by the animal care takers/animal sluices in a sealed transport vessel after being disinfected again (observe the treatment time!) for further processing.

Sealed telephones are decontaminated in the same way as samples and can be removed from their case after the disinfection process in the supply corridor.

5.9.2 Spray sluices

In building 238 (FI), there are four spray sluices for the spraying of specific samples:

- from pathology in the S3 supply corridor
- from the S3 and S3e laboratory wing leading out of the building
- via the disposal corridor out of the cage laundry leading out of the building

The spraying sluices can only be used after instruction by experienced, instructed personnel and authorization by the Biosafety Management/BBS. Sluicing of infectious sample material requires separate authorization by the Biosafety Management/BBS.

All samples are either packed double, seal proof and break proof in the laboratory, in the appropriate animal stable or in pathology. Afterwards, the repackaging material is disinfected from the outside depending on the project (e.g. dip, spraying or wiping disinfection) so that the secondary vessels only have to be sprayed with water before being taken out via the spraying sluices or the disinfection of the vessels takes place directly in the sluice by means of using a suitable disinfectant in a defined validated sluice program.

Use of the spraying sluices is described in an equipment-specific SOP.

5.9.3 Material sluices

In the FI building, there are two adjoining rooms in the respective laboratory areas (room no.: 00054 and 00024) in order to be able to bring in and take out equipment and material. These sluices also serve the purpose of evacuating persons in an emergency (see 4.2.).

The material sluices can be used after instruction by experienced members of staff and authorization by the Biosafety Management.

5.9.4 Shower sluices

Shower sluices are installed in the S3 stable areas, pathology and the personal sluices to the S3e laboratory area.

The shower sluices can be used after instruction by experienced members of staff and authorisation by the Biosafety Management.

5.9.5 Autoclave

Autoclaves from the company Schlumbohm are l in each laboratory area as well as in the cage laundry. These consist of double-door autoclaves of the model LAB.STM 6.900.2.HSD.E (cage laundry) and the model LAB.STM 6.700.2.HSD.E (laboratory areas). The thermal inactivation of the item to be sterilised occurs at temperatures of at least 121 °C or 134 °C and was validated by the manufacturer by means of temperature data logging. Each autoclave cycle is documented.

In the inner containment of the animal husbandry area and in the laboratory areas, waste is categorically collected in the autoclave bags, decontaminated via the autoclaves and thus taken out of the areas.

The autoclave can only be used after instruction by experienced members of staff and authorisation by the Biosafety Management.

Using the autoclaves is described in an equipment-specific SOP.

5.10 Cleaning/Disinfecting/Disposal

The **hygiene plan** must always be followed. All cleaning agents and disinfectants may have to be adapted to the pathogen spectra (depending on the project-specific risk assessment).

5.10.1 Animal husbandry area

As a general cleaner, Lerades (chlorine cleaner) is made available centrally. After disinfecting at the end of an experiment in the stables and in pathology, VennoVet (formic acid) is used. Dependent on the pathogen spectrum, the disinfectant used at the end is performed by means of cold fogging with 1+1 Wofasteril SC Super / Alcapur E (all areas except for S2 are validated). The exact procedure is stipulated for each project in a separate hygiene plan (gas injection concept).

The supply corridor and the animal sluice are wet cleaned and disinfected after housing livestock.

Depending on the project requirement, all occupied stables are wet cleaned at least once a day.

5.10.2 Pathology/ Disposal Corridor/ Digester

Pathology is extremely complex due to the technical setup, total size of the room as well as the adjoining rooms and the possible overlapping of several project and pathogens. If pathology is occupied, the emergency pathology is available in the event of an emergency dissection. The extraordinary use of the dissection rooms must be notified to the Biosafety Management immediately.

All work must be carried out as aseptically as possible in order to protect each surface (particularly equipment such as digesters, spraying sluices etc.) from contamination. This only has to be observed for the facilities and materials in pathology during dissection which are actually used - all other pieces of equipment are brought to the dissection hall in the adjacent storage room.

In pathology, a digester from the company PRI is installed. After ending an animal experiment, animal carcasses (at least weighing 200 kg, maximal 800 kg) are put in it and hydrolysed by means of an alkaline solution. The resulting liquid waste (hydrolysate) is taken by an external company to the animal carcass disposal plant. After putting material into the digester at any one time, the surfaces are cleaned and afterwards sprayed with disinfectant.

The digester can only be used after instruction by experienced members of staff and authorisation by the Biosafety Management/BBS.

Using the digester is described in an equipment-specific SOP.

The cleaning and disinfection takes place in a similar manner to that in the stables and is analogously adapted to the pathogen spectrum. **After use and during disinfection, pathology is not allowed to be used by all users.**

Clearance is given by the Biosafety Management.

5.10.3 Laboratory areas

Accumulating waste from numerous activities within the laboratories is collected in autoclaved plastic bags (solid waste) or break proof, sealable bottle (liquid waste) and repacked in sealable metal containers. After careful disinfection from the outside, the waste is transported to the autoclave within the respective containment where the thermal inactivation ultimately takes place.

In the event of an emergency, the area can be disinfected by fumigation with hydrogen peroxide (H_2O_2). The process is validated by an external company.

5.10.4 Work clothes

A large amount of work clothes (also underwear) are collected in the building 238 (FI) in autoclave bags, autoclaved and afterwards washed at 60 °C.

5.10.5 Chemical waste

Chemical waste must be separated from infectious waste and disposed of in accordance with the disposal regulations of the University of Veterinary Medicine (TiHo).

5.10.6 Thermal waste water treatment plant

The wastewater disposal in the stable areas of the building 238 (FI) is performed by a vacuum system. In each floor inlet there is a stainless steel bath which collects wastewater. After reaching a certain level, the wastewater is sucked up and taken to two storage tanks in the cellar and, from there, taken through the exposure level of the thermal wastewater treatment plant. The wastewater treatment plant is able to accommodate 2 m^3/h wastewater and can thermally inactivate the wastewater from the stable- and laboratory areas at 121 °C or 134 °C. After completing the process, the inactivated water is directed to the city's wastewater. The temperature and flow rate are documented.

6. Emergency plan

When working with biological and chemical substances, various high-risk scenarios can occur. Low risk incidents can be eradicated from the person who caused them. Categorically, unplanned release, spillage etc. or inoculation with pathogens should be defined according to the listed scheme below and should be reported to the scientific director on duty, the project leader, the BBS and the Biosafety Management. Furthermore, an unplanned release of water, gases or a fire can occur. These incidents are associated with a high risk and must be categorised as an accident/emergency. For the purpose of estimating the risk in the event of an unplanned incident, a matrix is provided for the members of staff to follow.

Principally, the Government Trade Supervisory Body has to be informed regarding every incident.

	Tierseuchenerreger		Humanpathogene Erreger	
Risikogruppe Sicherheitsstufe Ereignis	2	3	2	3
Verschütten	Niedriges Risiko			
Verspritzen				
Versprühen				
Inokulieren				
Großflächige Verletzungen				Hohes Risiko

6.1 Technical emergency facilities in building 238 (FI)

In the stables and in pathology, loudspeakers have been installed which can be used centrally from the break-room for the animal care takers and one office of the Biosafety Management in the event of an emergency. The data from the camera systems also installed in these room are transferred to a computer in the break-room of the animal care takers and to the office of the Biosafety Management. The camera system serves the purpose, on the one hand, of observing the animals during the animal experiments without anyone having to be there. On the other hand, the second person, who has to remain in the building for the safety of the person alone inside the stable, can at all times convince himself of the health condition of the person in the stable via the camera system (Buddy Stem, cf. 5.3).

In the event of a fire, technical systems are installed in building 238 (FI) to warn members of staff of dangers and to prevent a fire spreading. As soon as smoke detectors, sprinkler heads, handheld warning systems or fire detectors are activated, the fire brigade will be automatically informed. Moreover, a warning signal is emitted and a repeated recorded announcement is made to leave the building immediately in compliance with the laboratory and stable-specific biosafety measures. Additionally, all members of staff receive training regarding the instructions for each specific area and the drill. In certain areas, a fire is extinguished by a high pressure water mist fire extinguisher (feeding areas, ventilation storeys, certain cellar areas and laboratory area). As soon as this is activated or smoke forms, the corresponding area must be immediately left without exception.

6.1.1 Technical emergency

In technical emergencies, technical personnel can be contacted within normal working hours and outside working hours, a technical on-call service can be contacted (see Technical On-Call Service).

In the case of a **technical emergency outside core working times**, the information network is as follows:

1. The security service receives an error message via the building control system “Gebäudeleittechnik (GLT)“.
2. The security service informs the technical on-call service (Tel.: 0511/953 7997).
3. The technical on-call service estimates the situation on site (Where is the error? What has to be done in order to contain the damage?).
4. If action must be taken to avert further damage and the error is to be found in the infectious area, the on-call service contacts the DWL and discusses it with him. If need be, the project leader also working in this area is called in.

6.1.2 Biosafety-/ Medical emergency

In the case of a biosafety/medical emergency, members of staff from the S3 Laboratory Area can be rescued via the material sluice or the changing room sluice. Due to the limited space in the changing rooms in the S3e area, the rescue via the material sluice is preferable, the programming of which can **only in an emergency** be bypassed by an emergency button. Persons from the S2 stable area are to be rescued via the sluice system for personnel in the stable and then via the supply corridor via the S2 animal sluice or the personnel sluice.

For the S3 stable area and pathology in the event of having to wear a protective suit, the animal sluice in the waste disposal corridor is determined as the evacuation route.

In the autoclave room, spill kits and personal protective equipment for the area are placed in readiness for the rescue teams who enter. This prevents a high amount of pathogens escaping to the outside and, on the other hand, the emergency services teams being exposed to health risks by the human pathogens. The first aid measures can then be performed in the sluice and the members of staff stabilised for transport. For this purpose, the affected members of staff are also disinfected externally by first aiders equipped with personal protective equipment and their protective suit is removed (the necessary spraying equipment is positioned in front of the inner door of the animal sluice/emergency exit for pathology). The personal protective equipment (PPE) for all involved parties can either be taken from the spill kits (see 4.3.), from the changing rooms of the animal care takers or pathology. The responsibility of coordinating the rescue or evacuation lies with the Research Director on duty, the project leader and/or Biosafety Management. The emergency services teams should be forewarned that the patients could be externally contaminated with animal pathogens or viral pathogens with human pathogenic potential.

Before pursuing activities, “Pathogen cards” are compiled by the project leaders, describing the risks for the respective project-related pathogens. These cards are left at the main entrance and are handed out to the emergency services teams so that they can take the necessary preventive action.

In an emergency, the emergency services teams arrive in front of the main entrance and from there they are taken by the DWL, the project leader, the Biosafety Management or an instructed person to the person who needs to be medically treated.

In the event of a **biosafety-/medical emergency outside core working hours**, the information network proceeds as follows:

1. The members of staff phone and inform the DWL (0511/ 953 **7998** or 0170/ 11 56 566). In an emergency, the fire brigade or the emergency service should be called directly on the internal phone number 0112.
2. The DWL informs the security service (0511/953 8606) to instruct the ambulance service.
3. The DWL (in consultation with the project leaders) is available in an advisory capacity for the members of staff and the emergency services. In the event of a biosafety accident, the emergency services are handed out an emergency data-sheet with information on the pathogens.
4. All emergency cases should be directed to the Hannover Medical School (MHH).
5. Moreover, the DWL informs the Bio safety officer, the company doctor as well as the President.
6. Information from the Government Trade Supervisory Office concerning incident.
7. Incidents are digitally documented and saved.

6.1.3 Behaviour in Accidents with Spillage of Biomaterials, Event of Accidents ("Havariefälle")

In the case of release of genetically modified organisms of the biological safety level 2 (S2) and higher, as well as biological materials of the risk group 3** and higher in large quantities (e.g. leakages, spillage, breakage etc.), all members of staff in that room have to be warned first. Afterwards, the area is to be cordoned off if appropriate and the responsible persons must be contacted immediately (see previous section "First Aid").

The removal of the risk has to always be carried out with self-protection (laboratory coat, gloves, disposable apron, which are to be found in the laboratory). In the event of human pathogens, additionally, a pair of protective googles and an FFP-3 mask must always be worn.

The cleaning and disinfection occur in accordance with the hygiene plan.

Doors must remain closed until the decontamination measures have been completed. Entry of unauthorised persons must be prevented. The general principle applies- human life is more important than containment.

Numerous contaminated pieces of equipment (also laboratory coats) must be collected in suitable containers (sealable, disinfected from the outside, liquid-tight) and autoclaved.

In the event of any error message on the centrifuge, the regulations of an emergency apply, as it cannot be ruled out that sample centrifuge test-tubes in the centrifuge have been broken. The removal of the hazardous situation must always occur under self-protection (laboratory coat, gloves, disposable apron, which are to be found in the laboratory). In the event of human pathogens, additionally, a pair of protective googles and an FFP-3 mask must always be worn.

6.2 Post exposure prophylaxis

All members of staff are informed about the specific human pathogens including possible occurring symptoms before beginning their activity within the context of the training by means of an emergency data sheet so that every member of staff is sensitised to possible occurring symptoms (in the event of a biosafety accident). In case of a biosafety accident, all patients are transferred to the MHH.

The responsible doctors completely take over all further steps.

6.3 Evacuation and rescueplan

Behaviour in an emergency shall be extensively trained; evacuation plans are displayed in the entire building. A building plan with marked escape routes is added to this document.

Every member of staff in building 238 (FI) is obliged by means of the displayed plans to make himself familiar with the signed **routes with the flight and rescue paths out of the individual areas of a building**. Reporting an evacuation follows as described under “technical emergency facilities”. In the event of an evacuation, everyone must leave the building immediately and gather at the allocated assembly points in the working areas (see evacuation plan).

All members of staff from the **S2 animal husbandry sector and the S3 laboratory area** gather at the allocated assembly point behind the building (south-west side of the building).

All members of staff from the **S3 animal husbandry sector and the S3e laboratory area** gather at the allocated assembly point behind the building (north-west side of the building, **separate from the assembly point described above)**.

Members of staff who are in the **office wing or other non-infected areas**, gather at the assembly point at the east side of the building.

To minimise the spread of diseases in the event of contamination, members of staff shall be decontaminated with a skin-friendly disinfectant at emergency set up decontamination locations. For the escape from contaminated stables and pathology, jet showers filled with 3.5 % VennoVet disinfectant are positioned at the end of the disposal corridor in front of the emergency exit. These should be used to decontaminate rubber boots and aprons.

Furthermore, to protect people and the environment, it must be ensured that no one who was evacuated from the infectious area may leave the premises of the University of Veterinary Medicine Hannover before consulting the DWL (outside working hours) or Biosafety Management (in consultation with the responsible project leaders).

6.4 Spillkits

In the total building 238 (FI) at central points, so-called spill kits in combination with first aid boxes and recuse blankets are to be found. These measures should ensure that quick medical care can be carried out by a first aider. The spill kits are transparent cases attached to the wall. They are sealed and secured in such a way that they can be easily opened. If a spill case is opened, the Biosafety Management should be informed thereof. Using the spill kit is covered in the general FI training.

Content:

1x blanket for covering and warming the patient

Disposable gloves in sizes S, M, L, XL

Disposable protection suits in sizes S, M, L, XL

3x laboratory shoe covers up to shoe size 45

1x cloth with disinfectant (at least 70% alcohol)

3x FFP3 masks

3x pairs of goggles

7. Internal control intervals

7.1 Engineering

In the building, a central monitoring system - building management system (Gebäudeleittechnik GLT) - is installed, within which, error messages are centrally reported and transferred as quickly as possible. Additionally, regular function controls of all technical equipment and large devices are carried out by the technical staff.

7.2 Biosafety

1. For the internal control of the hygiene measures, once annually without being announced, various areas in the laboratory and the stalls are sprayed with “glow check” paint and controlled after a fortnight with the help of a UV lamp. Should traces of paint be found on the sprayed surfaces after a fortnight, an additional training course for the members of staff follows within six weeks. Hereby, it is to note that the results are only discussed internally by the Biosafety Management.

2. Once a year, hygiene checks are carried out in cleaned stalls, in the supply and disposal corridors, pathology, in the showers and at the wash basins.

3. The “spill kits” are inspected once a year by the Biosafety Management or instructed members of staff of the RIZ and the inspection documented.

4. Once a year biosafety relevant themes are presented and current problems discussed. This takes place within the framework of the safety week of the RIZ.

5. In order to monitor the procedures in the areas, the following controls are carried out on a regular basis and documented. Should deficiencies be recognised, the corresponding correction of the fault is checked in a further control at short notice.

- A freezer/refrigerator from each working group is opened and sample vessels are checked for appropriate labelling and documentation.

- On a random basis, selected laboratory strains are controlled for their identity by means of external sequencing. For this purpose, the samples are inactivated beforehand by means of an inactivation method approved by the authorities.
- The instruction documents of the members of staff are checked.
- The notices of the building-/evacuation- and hygiene plans are checked.
- The order and cleanliness in the laboratories is checked at the respective workplaces.

6. The effectiveness of the autoclaves is checked half-yearly with the help of bioindicators and the results thereof documented. A regular control of fractionated vacuums is carried out by means of a Bowie & Dick test by a trained person and documented.

15.09.2023

Hygieneplan SOP

Title: Hygieneplan

SOP Nr.: 002v07
Seiten: 3
Version: 7

	Name	***Signature***	***Date***
Created by	RIZ Management		
Verified and revised by	RIZ Management		
Authorized by	Maren von Köckritz-Blickwede		

Scope of application: Labs in RIZ-ZZ (Building 231)

WHAT		WHEN	WHEREBY	HOW	WHO
Hands	Disinfektion	Before leaving the laboratory, after every contamination	Hand disinfectant Aseptoman® viral or Aseptoman® forte 2 strokes = 3 ml	Rub into the dry hands (in accordance to the put up plan)	Everyone
	Cleaning	After visible pollution, after working with spore-producing microorganisms	Liquid soap from the dispenser	Wash hands with warm water	Everyone
	Care	After disinfection, if neccessary	Moisturising cream Lindesa oder Lindesa F	Rub after disinfection and cleaning into the dried hands	Everyone
Treatment of wounds during labwork		potential and visible injuries	Aseptoman viral or Aseptoman® forte 2 strokes; PVD-Iod if needed	Rinse at 1,5min residence time	Everyone
Working areas		After use	70% Ethanol optional UV-radiation	During ongoing ventilation wipe disinfection on the working surface	Everyone
		After contamination	Optisept® (RKI) 4% 1h	Moistening, exposure time 60 min., wipe	Every user/ polluter
Surface of devices etc.		After contamination	Optisept® (RKI) 4% 1h	Moistening, exposure time 60 min., wipe	Polluter
Centrifuge		After contamination	Optisept® (RKI) 4% 1h	Moistening, exposure time 60 min., wipe	Polluter
Protective clothing		Change after contamination/pollution or min. once a month	Collect in autoclavable bags	First autoclaving, then washing (central laundry)	Everyone
Lab waste, petri dishes		After use/ contamination	In closed autoclavable bags	Autoclaving → household waste	Polluter
Floor		Daily up to weekly (depending on room and pollution)	Universal wipe care	With mop in accordance to the two bucket method	Cleaning staff
		After contamination	Optisept® (RKI) 4% 1h	Moistening, exposure time 60 min., wipe	Polluter
Ceiling and walls		After contamination	Optisept® (RKI) 4% 1h	Moistening, exposure time 60 min., wipe	Polluter
Liquid waste in collecting bottles		**Preventive** Disinfektion before start of work	Antifect extra: 0,5% final 30 min **or** Kohrsolin FF 2% final 2h	Prepare desinfectant in empty container Observe exposure time	Every user
		Sterilisation	Autoklave	Finally autoclaving	Only instructed user

Scope of application: RIZ - Building 231: Labs 2004 + 2008 (Flowcytometrie)

WHAT		WHEN	WHEREBY	HOW	WHO
Hands	Disinfektion	Before leaving the laboratory, after every contamination	Hand disinfectant Aseptoman® viral or Aseptoman® forte 2 strokes = 3 ml	Rub into the dry hands (in accordance to the put up plan)	Everyone
	Cleaning	After visible pollution, after working with spore-producing microorganisms	Liquid soap from the dispenser	Wash hands with warm water	Everyone
	Care	After disinfection, if neccessary	Moisturising cream Lindesa oder Lindesa F	Rub after disinfection and cleaning into the dried hands	Everyone
Working areas		After use	70% Ethanol oder Antifect extra: 0,5% final 1 min	During ongoing ventilation wipe disinfection on the working surface	Everyone
		After contamination	Optisept® (RKI) 4% 1h	Moistening, exposure time 60 min., wipe	Every user/ polluter
Surface of devices etc.		After contamination	Optisept® (RKI) 4% 1h	Moistening, exposure time 60 min., wipe	Polluter
Centrifuge		After contamination	Optisept® (RKI) 4% 1h	Moistening, exposure time 60 min., wipe	Polluter
Protective clothing		Change after contamination/pollution or min. once a month	Collect in autoclavable bags	First autoclaving, then washing (central laundry)	Everyone
Waste, petri dishes, one time material		After contamination	In closed autoclavable bags	Autoclaving → household waste	Polluter
Floor		Daily up to weekly (depending on room and pollution	Universal wipe care	With mop in accordance to the two bucket method	Cleaning staff
		After contamination	Optisept® (RKI) 4% 1h	Moistening, exposure time 60 min., wipe	Polluter
Ceiling and walls		After contamination	Optisept® (RKI) 4% 1h	Moistening, exposure time 60 min., wipe	Polluter
Liquid waste from FACS Attune and Fortessa		When waste tank full up to mark (3/4) or not enough space for next user)	Venno®vet super 2% final	Add 20 ml/l, mix well min exposure time 2h disposal in sink	Change of container: Everyone Inaktivation with Venno®vetonly instructed user