

OPERATING INSTRUCTIONS

ACCORDING TO

§12 GENTECHNIK-SICHERHEITSVERORDNUNG
FÜR GENTECHNISCHE LABORBEREICHE DER
SICHERHEITSSTUFE **S1**

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1. Area of application:

These operating instructions apply in the genetic laboratory of safety level **S1** (Aktenzeichen des Bescheids 54-8451/145 (old: 56-8811.71/145), Sächsisches Staatsministerium für Umwelt und Landwirtschaft) in the group "Physik der weichen Materie" and in the group "Molekulare Biophysik" of the Faculty of Physics and Earth Sciences of the University of Leipzig, Linnéstraße 5 in 04103 Leipzig.

It includes the following rooms:

Anteroom to Room 116, Anteroom to Room 131 a/b, Room 116, 117, 131 a/b, 132 in the semi-basement
Room 309, 310 and 311 in the 1st floor
Room 416, 418, 422 and 426 in the 2nd floor

These rooms are labelled as „**Gentechnik Arbeitsbereich**” S1

2. Responsible People:

Responsible for the genetic laboratory:

Prof. Käs

Tel. 0341 /
9732470

Other project manager

Prof. Seidel

Tel. 0341 /
9732501

Responsible for Biological Safety:

Dr. Dietrich

Tel. 0341 /
9732472

Emergency call / Technical service:

Tel. 0341 /
9734333

Medical Office:

Tel. 0341 /
993848-00

Regulatory Authority:

Sächsisches Staatsministerium für Umwelt und Landwirtschaft

Mrs. Riedel
Mr. Dr. Mücke
Mr. Dr. Maurer

Tel. 0351 /
564-25408
564-25406
564-25400

3. Genetic engineering work:

In the genetic laboratory genetic engineering tasks of the safety level **S1** are performed.

The genetic engineering work includes the production, storage, transportation and disposal of the genetically modified organisms.

The responsible person for the genetic laboratory has to be informed about every incident which differs from the expected process of the genetic engineering work.

4. Potential danger of GMO:

Genetically modified organisms (GMO) of the **risk group 1** means, that if it is handled correctly, in accordance with these operating instructions there is no danger for healthy people and environment. A risk assessment is part of the records referred to the genetic engineering recording regulation. Before starting the work a risk assessment (determination of the danger potential) should be carried out for the planned genetic engineering work, from which the safety level 1 of the genetic engineering work results (§§ 6.7 GenTG; GenTSV, Appendix 2). Here, the representative for Biological Safety (BBS) is helping.

5. Safety measures, behavioral rules and hygienic measures:

All projects should be performed in consideration of the general rules of microbiological techniques and “Gentechnik-Sicherheitsverordnung (GenTSV)”. In particular, the following points should be particularly taken into account:

5.1 Access to the genetic laboratory:

- In the laboratory protective clothing (lab coats) must be worn and sturdy, closed shoes.
- When working with contact of harmful substances suitable protective gloves must be worn.
- In the cell culture inexperienced employees must especially be fully informed, carefully guided and monitored.
- The health status of employees is to be monitored by occupational medical examinations; means initial examination when starting to work and annual check-ups.

S1:



**Wear protective
clothing**



**No eating and
drinking**



No smoking

- a) In the under 1 above-mentioned "genetic engineering workspace S1" designated rooms only those persons who have been further briefed on the necessary security measures on the basis of his operating instructions in a language the employees understand (before starting to work and at yearly intervals) and have confirmed this instruction by signature with date are allowed to work there. This applies to any in the genetic engineering facility operating person, even if they are not involved in the actual genetic engineering work. When new safety-relevant working techniques are introduced, separate instructions must be carried out (§ 12 GenTSV). Female employees are to be instructed about special maternity protection regulations. Students, trainees, etc., who carry out genetic engineering work, are equal to the employees (§ 3 No. 14 Act on Genetic Engineering (GenTG)).
- b) Visitors are only allowed to enter the laboratory rooms in the presence of trained staff. Before guests are responsible for practical work, they are to make the project manager or his representative with the rules in force in the laboratories familiar. This must be confirmed by visits by signature.

5.2 General instructions:

- a) Before starting work, each employee of the laboratory has to inform himself about the location and function of disinfectants, body and eye showers, first aid equipment, fire-fighting equipment as well as escape routes.
- b) The genetic laboratory is to be kept clean and tidy. The bench space should only bear work-related material and equipment.
- c) Within the genetic laboratory, desk work places are restricted only to journalize experiments. On the write-workplaces neither genetic engineering work nor office work beyond the logging should be carried out.
- d) The doors to the genetic laboratory should be closed during genetic engineering work. Windows may be opened for ventilation purposes only if no genetic engineering experiments are performed.
- e) Pipetting aids must be used.
- f) Syringes, Scalpels, needles, etc. shall only be used if necessary. For disposal, they are to be collected in puncture proof autoclavable containers and autoclaved.

For cannulas are those to use with stripping aperture. Needles must not be put back in the envelope or kinked. Appropriate containers must be provided at the individual workstations before beginning work.

- g) In all cases, the formation of aerosols should be avoided. Such aerosols may form while decanting, shaking, stirring, centrifuging, inoculating, or pipetting of solutions or while keeping solutions under high pressure.

Possible measures to prevent aerosol formation:

- use closed vessels or apply encapsulated work processes
 - keep sufficient waiting time for lowering of aerosols before opening the vessels
 - avoid bubble formation
 - comply short height of drops during decanting and pipetting (liquid should run as slowly as possible down the wall of the vessels)
 - do not blow out pipettes, do not spray the contents of syringes/cannulas in the airspace
 - where necessary, work under the fume hood
- h) The operating instructions from the manufacturer for the different devices such as autoclave, safety cabinet, incubators, and centrifuges must be followed
- j) Transportation of genetically modified organisms within the institute must be done using specific, fail-safe containers, labeled with "Container for transport of genetically modified organisms" (e.g., white plastic containers with red screw cap)
- k) The storage of genetically modified organisms should take place in liquid nitrogen in laboratory 117 and in the -80°C freezer in Lab 422. The cryo tubes should be clearly labeled and the cell culture-file must be updated immediately in accordance with storage
- l) Gas cylinder storage is not permitted. Compressed gas cylinders must be secured by chains against toppling over
- m) In the working area protective clothing (disposable gloves, protective goggles) must be worn

5.3 Hygienic Measures:

The instructions of the hygiene plan as part of the operating instructions are binding for all laboratories of safety level 1.

- a) All work benches should be disinfected after completion of the work by wiping with disinfectant specified in the hygiene plan. For the disinfection of surfaces greater than 1m² no 80% ethanol should be used because of its high flammability. If larger surfaces must be disinfected (see hygiene plan) a non-alcoholic disinfectant should be used.
- b) After completion of the work and before leaving the laboratory hands must be disinfected with disinfectant, washed with soap and greased with skin care cream (see skin care plan). To dry ones's hands disposable tissues should be used.
- c) Tools and instruments should be cleaned regularly:
1. centrifuges should be disinfected immediately by the respective user in case of contamination, by wiping out the rotor chamber and the rotors with disinfectant (see hygiene plan)
 2. The surfaces of the work benches should be disinfect by wiping after each use by the respective user with disinfectant (see hygiene plan)

- d) In particular, on electrically powered equipment and compounds linked to open flames/hot surfaces the explosion protection must be observed when using chemical disinfectants (see manufacturer's instructions)
- e) The occurrence of vermin should be reported to the project manager for the initiation of appropriate control measures

5.4 Prohibition:

- a) Nutrition, stimulants, and cosmetics must not be stored within the genetic laboratory. For storage, room 313 at the first floor respectively the rooms 427 and 428 at the second floor are available.
- b) It is not permitted to eat, drink or smoke in the genetic laboratory.
- c) Mouth-pipetting is prohibited. Pipetting aids must be used.
- d) Exhaust devices (membrane pump or water pump jet) may only be used for liquids which may contain genetically modified organisms (GMO's) if with suitable measures (e.g. interposing a sterile filter or a washing bottle with disinfectant) an escape of genetically modified organisms is prevented
- e) Storage of GMO's or other biological materials in the floors is prohibited.

5.5 Personal protective equipment:

- a) People must wear a lab coat inside the genetic laboratory. These are washed regularly weekly by the central laundry of the University Hospital.
- b) Lab coats and disposable gloves should be taken off before leaving the genetic working area within the same. Disposable gloves should be disposed of after use. Contaminated gloves must be autoclaved as solid waste before disposal.
- c) To avoid contaminations, protective clothing (e.g. lab coats) should be kept separate from street wear.

6. Behavior in the case of danger:

- Stay calm and avoid hasty blindfold actions!
- Warn endangered people; if necessary, ask them to leave the rooms.
- Stop endangered and dangerous experiments, e.g. if so switch of gas and electricity by pressing the red safety switch on yellow background. Shut-off valves for water are below the laboratory sink.
- In all cases of emergency, the responsible person for the genetic laboratory must be informed!

Any incident that does not correspond to the intended use of the genetic engineering facility (such as the release of GMOs or fire/water damage/etc.) as well as injuries shall be reported to the Saxon State Ministry for the Environment and Agriculture (Surveillance Authority) according to § 21 (para. 3) GenTG.

6.1 Contamination with biological material:

Areas, where biological material is spilled, must be labeled immediately.

If the spilled biological material contains genetically modified organisms, then it must be inactivated immediately, using the following decontamination steps:

- 1) Absorption of material with a tissue paper
- 2) Disposal of tissue paper in autoclavable bags
- 3) Autoclaving of the bag
- 4) Cleaning of the bench surface or the object with a disinfectant

Surfaces:

Wear protective gloves. Spilled Material is to be taken up with tissue paper and to be autoclaved. Thereafter, the contaminated area must be disinfected by whipping with disinfectant (see hygiene plan)

If glass breaks, then the pieces of glass should be disinfected first and then removed using protective gloves and appropriate tools. Wear protective gloves. Spilled Material is to be taken up with tissue paper and to be autoclaved

Devices:

Thereafter, the contaminated device must be disinfected by whipping with disinfectant (see hygiene plan). On electrically powered equipment and compounds linked to open flames/hot surfaces the explosion protection must be observed when using chemical disinfectants (see manufacturer's instructions). In addition, before application of liquids pull the main plug.

Clothing:

Take off contaminated lab coats or street wear and disinfect or autoclave it (see hygiene plan). Thereafter, clothing should be washed.

Skin:

Contaminated skin should be disinfected with sufficient disinfectant (see hygiene plan). After sufficient exposure (see hygiene plan), the affected areas can be rinsed with a lot of water, if necessary.

Eyes:

After eye contact, the eye should be rinsed (fixed eye shower at the laboratory sink, in room 310), eye wash bottles in all laboratories above the sinks. In case of injuries or chemical burns consult immediately the next D-doctor (eye hospital or eye doctor).

Mucosa:

Rinse mucosa with a lot of water. If necessary, consult the next D-doctor.

If, despite these emergency measures other discomfort occurs, then immediately consult the emergency department of the University of Leipzig.

Every accident should be reported to the project manager or BBS.

6.2 Fire:

In case of small fires, these should be extinguished with the help of the fire extinguishing equipment at each floor. Otherwise, the valid fire safety plans should be followed.

Fire report about fire department	0-112
House alarm (hit window, press alarm button)	
Building control center of the University	34333



7. First aid:

First aid equipment is located in room 116 (cell culture lab, semi basement), in room 310 (first floor) and in room 422 (second floor).

Injuries

1. as far as possible, wounds should be disinfected and tied
2. Injuries must be reported immediately to the project manager or the BBS.
3. If a serious health hazard is suspected, the next D-doctor should be consulted
4. Accidents / injury report as soon as possible also to SMUL (Ms. Riedel: 0351/564-25408)
5. Injuries related to genetic engineering work must be recorded and must be attached to the records of the genetic engineering work (folder at the BBS). These records must be kept at least 10 years in case of S1.

Inhaling or swallowing of genetically modified organisms

If it came to the inhalation or ingestion of modified organisms despite careful work, so immediately the project should be informed and medical advice (occupational physician) should be requested whether and how a treatment is required.

The project manager and the attending doctor must be informed, which organisms in what quantity were absorbed

8. Correct waste disposal:

Autoclaving:

The autoclave may be operated only by trained personnel. The prescribed program sequence must be adhered to. When autoclaving liquids, the cover may only be opened when the liquid temperature has dropped sufficiently to the atmospheric pressure associated with the boiling temperature (for example, water: about 80 degrees). (*Bumping is an unpleasant, sometimes dangerous physical phenomenon. Overheated liquids give their heat content explosively free.*)

Solid and liquid wastes containing genetically modified organisms should be inactivated prior to disposal. This is accomplished by autoclaving at 121 ° C, 1 bar for 20 min. For this purpose, the autoclave in room 116 (vestibule) and the autoclave in room 418 is available. The effectiveness of the autoclave is supported by yearly maintenance and inspection followed by the appropriate documentation.

Solid contaminated wastes are collected in vapor permeable autoclavable bags until inactivation. These bags need to be open up during sterilization so that the water vapor can enter. After autoclaving, these bags can be disposed with the general disposal

Liquid contaminated disposals remain in the glass bottles and must be autoclaved/ prior to disposal. The inactivated liquids are collected in appropriate labeled containers and their disposal is organized by the person responsible for biological safety (BBS).

9. Notes on general rules:

All laws and technical rules can be viewed by the employee in room 315

- **laws**

GenTNotfV	Gentechnik-Notfallverordnung	GenTG	Gentechnikgesetz
GenTAufzV	Gentechnik-Aufzeichnungsverordnung	BiostoffV	Biostoffverordnung
GenTSV	Gentechnik-Sicherheitsverordnung	IfSG	Infektionsschutzgesetz
GenTAnhV	Gentechnik-Anhörungsverordnung	GefStoffV	Gefahrstoffverordnung
GenTVfV	Gentechnik-Verfahrensverordnung		
GenTBetV	Gentechnik-Beteiligungsverordnung		
ZKBS	Verordnung über die Zentrale Kommission für die Biologische Sicherheit		

- **technical rules**

[TRBA](#) Technische Regeln für Biologische Arbeitsstoffe

10. Notes on specific rules:

Duty of notification

The project manager or BBS must be informed about each incident which does not correlate with the expected course of the genetic engineering work.

Instructions

Before starting the work and at regular intervals (at least annually), the employees have to be trained on the basis of operating instructions. Content and time of the instruction must be recorded in written form and confirmed by the instructor with signature.

Duty of recording

In the complex genetic engineering work at safety level 1 are permitted. This work must be recorded as specified. As the information on the donor and recipient organism, on the genetically modified organism, on the vector and on the transferred gene is an essential part of the risk assessment of genetic engineering work, these information must be included in its own records and wrote down in Form Z (online available via the Office for Environmental Protection and Occupational Safety of the University of Leipzig for the recording of the genetic engineering work). The records of the genetic engineering work must be countersigned by the project manager or the BBS. After completion of the respective genetic engineering work the records are kept for at least 10 years.

Leipzig, 19.10.2018

project leader

BBS