
**OPERATING GUIDELINE No. 544 PURSUANT TO SECTION 12 GENETIC ENGINEERING
SAFETY REGULATIONS FOR LABORATORIES, SECURITY LEVEL 1**

Table of Contents

1. Scope of application
2. Responsible persons
3. Genetic engineering work
4. Potential hazards from GMOs
5. Protective measures, code of conduct and hygienic measures
 - 5.1 Access rules
 - 5.2 Handling requirements
 - 5.3 Additional instructions
 - 5.4 Hygienic measures
 - 5.5 Prohibitions
 - 5.6 Personal protective equipment
 - 5.7 Special regulations
6. Conduct in case of danger
 - 6.1 Leakage or spilling of biological material
 - 6.2 Fire
7. First aid
8. Proper disposal
9. References to general guidelines
10. References to special regulations

1. Scope of application

These operating instructions apply to the genetic engineering facility at IZKF Aachen, Uniklinik RWTH-Aachen. This includes the following rooms:

Room number	Function
3F43-01 (170007)	Lab
3F43-02 (170009)	Lab
3F43-03 (170013 & 170011) not including adjacent rooms	Lab
3F43-04 (170017)	Lab
3F43-05 (170019)	Lab
3F43-06 (170 023 & 170 027)	Lab
3F43-07 (170 032 & 170 030 & 170 033) not including adjacent room	Airlock, storage room, lab
3F43-08 (170024)	Lab
3F43-09 (170026)	Lab/constant-temperature room
3F43-10 (170029)	Darkroom
3F43-12 (170020 & 170022)	Climatic chamber
3F43-13 (170015)	Lab
3F43-14 (170018) not in use	Lab
3F43-15 (170030, 170033)	Lab
3F43-16 (170014)	Autoclave room
3F43-18 (170004) not in use	Lab

The abovementioned rooms are known as “*Genetic Lab S1.*”

2. Responsible persons:

Project manager:	Dr. Denecke, tel. (office: 89918)
Biological safety officer:	Univ.-Prof. Dr. Lüscher, tel. (office: 8885)
Physician on-call:	On-call emergency service, tel. 88729
Company physician:	University physician Dr. Keller, tel. 94444
Safety officer:	Dipl.-Ing. R. Henneke, tel. 80190
Fire safety officer:	Mr. Lammer, tel. 80451
Fire department:	112

3. Genetic engineering work

Genetic engineering work at safety level 1 is performed in the genetic engineering facility. In addition to creating genetically modified organisms, this work also includes the use, reproduction, storage, destruction and disposal as well as internal transport of such organisms.

4. Potential hazards from GMOs

The genetically modified organisms belong to risk group 1. That means when handled properly, according to these operating instructions, they do not pose a risk to healthy people or the environment.

A comprehensive risk assessment is part of the documentation as per the Genetic Engineering Documentation Regulation.

Pregnant women are fundamentally advised to avoid genetic engineering work even if the current state of scientific knowledge indicates “no risk to people or the environment.”

5. Protective measures, code of conduct and hygienic measures

According to the principles of good microbiological engineering and the Genetic Engineering Safety Regulations, the following aspects must particularly be considered:

5.1 Access rules:

- a) Work in the lab may only be performed by persons who demonstrably received instruction about the necessary and project-specific safety measures for each workplace, according to the operating instructions, before the start of work as well as at yearly intervals thereafter, and who have received explicit permission from the project manager to work in the lab.

This applies to all persons working in the genetic engineering facility even if they are not involved in the actual genetic engineering work.

- b) Visitors shall only enter the laboratories when accompanied by trained employees.
- c) Cleaning and maintenance staff may only work in the laboratories if they have been authorized by the project manager and informed of potential hazards. It is sufficient to inform them about the type of work performed in the lab and about the significant behavioural measures. Cleaning and maintenance staff shall have an expert contact person available on site (see Point 2 project manager).

Specifically, the following regulations apply for instructing the cleaning staff:

Instructing cleaning staff on cleaning work in S1 genetic engineering facilities

In S1 genetic engineering facilities, the cleaning staff shall exclusively clean the floors. Only trash cans and paper bins shall be emptied.

Once a year, cleaning staff shall be divided into logical groups, for instance cleaning staff responsible for areas on one floor with genetic engineering facilities, and shall receive instruction from one of the project managers on that floor.

Individuals who are unable to attend or who start work during the year shall receive additional instruction from a trained person, e.g. the head of the cleaning staff. Written work instructions shall also be provided to the cleaning staff.

Instruction sessions shall be documented and signed by the project manager and/or instructor as well as the persons receiving instruction. By signing this document, the cleaning staff also confirms that they have received and will comply with the instructions.

5.2 Handling requirements

- a) Before starting work, each lab employee shall learn about the location and function of disinfectants, body and eye baths, first aid equipment, fire extinguishing equipment as well as escape and rescue paths.
- b) Rooms in the genetic engineering facility shall be kept tidy and clean. Only absolutely necessary equipment and materials may be kept on the desks. Supplies are to be stored in the provided rooms or cabinets.
- c) Use of the office workstations provided in the laboratories shall be limited to documenting experiments. Office workstations may not be used for genetic engineering work or for any office tasks other than documentation.
Catalogues, books, etc., stored at the office workstations shall be kept to a minimum.
- d) Doors to workspaces shall be kept closed during all genetic engineering work.
- e) Pipetting aids shall be used.
- f) Syringes, cannula, razor blades, needles, lancets, etc., that pose a risk of injury may only be used if absolutely necessary. They must be collected in puncture-proof autoclavable containers for disposal and then autoclaved.
Cannula must feature a tear-strip opening. They may not be bent or returned to the sheath. Appropriate containers must be provided at the individual workstations before the start of work.
- g) During all work, it must be ensured that no preventable aerosols are formed. Aerosols can be formed, for instance, when refilling, stirring, working with high-pressure presses, vaccinating, shaking, pipetting, centrifuging and working with ultrasonic technology.

Possible measures to prevent aerosol formation:

- Use closed containers or encapsulated work processes
 - Before opening the containers, allow sufficient wait time for aerosols to sink
 - Prevent bubbles from forming
 - Observe low drop heights during refilling and pipetting processes
 - Do not blow out pipettes; do not spray contents of syringes/cannula into the air
- h) Follow work/operating instructions posted on the individual devices
 - i) Use closed, break-proof and labelled containers for the internal transport of genetically modified organisms. Hallway 3F43 is not an S1 area!
 - j) Genetically modified organisms (bacteria and cell cultures) shall exclusively be stored in the specified incubators and refrigerators.

- k) Gas cylinder storage is not permitted. Pressurized gas cylinders must be installed and handled according to the guidelines in GUV-R 120, "Safety and Health in Laboratories," Point 5.4.3.
- l) The identity of all organisms used must be verified regularly.
- m) Genetically modified organisms shall be stored in the cold storage room (170020), in the freezer or in the nitrogen tank (Room 133052), in clearly labelled containers.
- n) If live animals are kept in the killing facility, a sign barring entry shall be posted on the entry door during this time.

5.3 Additional instructions

- a) [Operating instructions for hazardous substances](#) as per § 14 Ordinance on Hazardous Substances can be found in your Hazardous Substances folder (or on the intranet for UK-Aachen)
- b) Operating instructions and a quick guide are posted by the safety workbench.
- c) [Sample operating instructions for machines](#), devices such as centrifuges, autoclaves, etc., can be found on the intranet for UK-Aachen. A quick guide is posted by the autoclave.
- d) Radiation protection instructions and information for working safely in controlled areas can be found on the web page for [Department 11.3 Radiation protection](#) at [RWTH Aachen](#)
- e) Operating instructions for the animal enclosure area at VTK
- f) Operating instructions, "Use of UV Radiation"

5.4 Hygienic measures:

see also hygiene and disinfection plan

- a) All work surfaces must be cleaned after the work is finished.
- b) After finishing work, always wash your hands.
- c) Working equipment and instruments must be cleaned regularly:
 - ☒ Particularly for electrically operated devices and equipment together with open flames/hot surfaces, explosion protection must be observed when using chemical disinfectants (see also manufacturer's information).
- d) Any occurrence of vermin shall be reported to the project manager so that suitable control measures can be taken.

5.5 Prohibitions:

- a) Food, confectionery and cosmetics may not be kept inside the laboratories. Metal lockers are provided for this purpose in Hallway 3F43.
- b) There is no eating, drinking, smoking or snuff usage permitted within the workspaces. Inside the laboratories, beverages may only be consumed within the marked areas of the office workstations, from "closed" containers (bottles, cups with lids, etc.).
- c) Mouth pipetting is prohibited.
- d) Extraction systems (water-jet pumps) may only be used for liquids that potentially contain genetically modified organisms (GMOs) if corresponding collection containers and a sterile filter are used to prevent GMOs from escaping.
- e) Storing GMOs or other materials along escape or rescue paths is prohibited.

5.6 Personal protective equipment:

- a) Lab coats are to be worn in the genetic engineering work area, and washed as needed.
- b) Lab coats and disposable gloves are to be removed inside the genetic engineering area before leaving this area.

When choosing disposable gloves, consider the manufacturer's chemical resistance information.

Disposable gloves are to be disposed of after use.

- c) In order to prevent contamination, protective clothing is to be kept separate from street clothing.

6. Conduct in case of danger

- Stay calm and avoid sudden, impulsive actions.
- Warn people who are in danger; tell them to leave the room if necessary.
- End threatened or dangerous experiments; turn off gas, power and water if necessary (cooling water must continue to flow).
- Inform the project manager of all emergencies.

6.1 Leakage or spilling of biological material: see also hygiene and disinfection plan

If biological material is spilled, secure the affected area. Leaked or spilled biological material that potentially contains genetically modified organisms must be inactivated immediately.

The following decontamination measures must be taken:

- Surfaces: Wear protective gloves. Collect leaked or spilled material using an autoclavable material (e.g. paper towels) and autoclave it. Then disinfect the contaminated area and remove any broken glass using appropriate tools.
- Equipment: Wear protective gloves. Collect leaked material using an autoclavable material (e.g. paper towels) and autoclave it. Then disinfect the contaminated device and remove any broken glass using appropriate tools.
☒ Particularly for electrically operated devices and equipment together with open flames/hot surfaces, explosion protection must be observed when using chemical disinfectants (see also manufacturer's information).
- Clothing: Remove protective clothing and/or street clothing items and **autoclave**. Then wash the clothing items.
- Skin: Disinfect contaminated skin and rinse with plenty of water after disinfectant has taken effect.
- Eyes: Rinse eyes with plenty of water (eye bath). (Accident outpatient department located in the emergency department on Level -2)
- Mucous
membranes: Rinse mucous membranes with plenty of water. (Accident outpatient department located in the emergency department on Level -2)

6.2 Fire:

Extinguish smaller fires using the fire extinguishers located in the rooms, vestibules and hallways. Otherwise, follow the applicable fire safety regulations.

7. First aid

- Injuries:

- Where possible, disinfect wounds for 0.5 minutes while performing first aid and then bandage them.
- Injuries must be reported to the project manager immediately.
- In the event of exposure or suspected exposure to harmful substances, inform a doctor.
- Injuries associated with genetic engineering work shall be documented by the project manager. These documents must be kept for at least 10 years.

- Inhalation or swallowing of genetically modified organisms:

The project manager must be informed immediately and medical advice must be obtained as to whether treatment is required and if so, what type. The project manager and the doctor providing treatment must be informed about the type and quantity of organisms inhaled or ingested.

8. Proper disposal

see also hygiene and disinfection plan

Solid and liquid waste that contains genetically modified organisms must be inactivated before disposal by autoclaving it. Proper autoclaving must be verified and documented using autoclave tape and by monitoring the autoclave notifications.

Autoclave pouches must be opened wide during the autoclaving process to allow the necessary saturated steam to reach the autoclaved items.

Waste is to be collected in the designated containers until it is inactivated. The collected waste must be inactivated regularly by a trained employee from the department.

9. References to general guidelines

Laws and ordinances

Genetic Engineering Law

Genetic Engineering Safety Regulations and Appendices I-VI

Genetic Engineering Documentation Regulations

GefStoffV – Hazardous Substances Ordinance

BioStoffV - ordinance on safety and health during work with biological working agents – Biological Substances Ordinance

IfSG – law to prevent and fight infections in people – Protection Against Infection Act

MuSchG – law to protect working mothers – Maternity Protection Act

JArbSchG - law to protect working youth – Youth Worker Protection Act

BetrSichV – regulations on safety and health protection when providing and using work equipment, on safety when operating systems that require monitoring and on organizing industrial safety – Industrial Safety Regulations

ArbSchG – law on carrying out occupational safety measures to improve safety and health protection of employees at work – Working Conditions Act

BKV – Ordinance on Occupational Diseases

Technical rules

TRBA 001 – General information and structure of the ordinance on Biological Working Agents – application of technical rules for biological agents (TRBA)

TRBA 100 – Protective measures for targeted and untargeted activities involving biological agents in laboratories

TRBA 250 – Biological agents in health care and welfare facilities, as of November 2003

TRBA 400 – Guideline for risk assessment in relation to activities with biological agents

TRBA 450 – Criteria for the classification of biological agents

TRBA 460 – Classification of fungi into risk groups

TRBA 462 – Classification of viruses into risk groups

TRBA 464 – Classification of parasites into risk groups

TRBA 466 – Classification of bacteria into risk groups

Regulations from accident insurance companies

GUV-V A1 - UVV “Principles of Prevention”

GUV-R 120 “Safety and Health in Laboratories”

GUV-V A4 - UVV “Occupational Medical Precautions”

BGI 504-42 - BG information “Selection criteria for specialized occupational medical care under employer’s liability insurance association Principle G 42, ‘Activities with a risk of infection’”

BGI 504-43 - BG information “Selection criteria for specialized occupational medical care under employer’s liability insurance association Principle G 43, ‘Bioengineering’”

GUV-I 8536 “Preventing Infectious Disease” - Information for healthcare workers

Other publications

List of disinfectants and disinfecting procedures tested and approved by the Robert Koch Institute

BGI 863 / B011 “Safely Working With Microbiological Safety Cabinets”

GUV-R 206 “Disinfection Work Carried Out in the Area of Public Health”

GUV-R 181 “Floors in Workspaces and Working Areas With a Risk of Slipping,” formerly GUV 26.18

Disinfectant list from Verbund für angewandte Hygiene e.V. (VaH)

Regulations can be reviewed in the Legal Division under Occupational Safety or on the [intranet](#). These operating instructions are kept in the Legal Division, Occupational Safety, under No. 544. Please provide this number in the event of any inquiries or changes.

10. References to special regulations

- Notification obligation:

The project manager must be informed of any incident that deviates from the expected course of genetic engineering work.

- Instruction:

Before starting work and at regular intervals (at least once a year), employees must receive workplace-related instruction according to the operating instructions. The content and time of this instruction must be documented in writing and confirmed by the participants by way of a signature.

- Documentation obligation:

Only genetic engineering work at safety level 1 is permissible in the facility. This work must be documented as specified. Since information about the donor and recipient organism, the genetically modified organism, the vector and the transmitted gene are an essential part of risk assessment for genetic engineering work, this information must be included in the documentation. Documentation is to be kept for at least 10 years after the end of the respective genetic engineering work.

- Penalties and administrative fines:

In the event that the rules on genetic engineering law are violated, violations are subject to fines of up to €50,000 and up to 5 years of imprisonment. In addition, violations of statutory genetic engineering liability provisions may be subject to damage compensation claims of up to €85,000,000.