University Hospital Essen **Institute for Experimental Immunology and Imaging**	**Operating Instructions** **for the laboratories of the genetic engineering S2 facility of IMCES**	As of: 13.11.2025 Created by: Dr. Mike Hasenberg Translation: Jan-Hagen Krohn Number of pages: 19

OPERATING INSTRUCTIONS

in accordance with §12 Genetic Engineering Safety Ordinance for laboratory areas of safety level 2

- Translation -

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Preamble

This document is an English translation of the corresponding German language Betriebsanweisung, provided for the convenience of users of IMCES laboratories who are more comfortable with English language than German. The translation has been performed using Meta Llama 3.3 70B Instruct, and was completely reviewed and corrected by Jan-Hagen Krohn. Note however that in case of contradictions between the versions, the German version is to be considered authoritative.

Operating Instructions for the Laboratory Area

Safety Level 2

1 Scope

These operating instructions apply to the genetic engineering facility No. 1410, Az. 53.02.01-D-1.20/11, District Government of Düsseldorf, at the Imaging Center Essen (IMCES) at the Institute for Experimental Immunology and Imaging (Medical Research Center (MFZ), Hufelandstr. 55, 45147 Essen), in the following rooms:

Laboratories:	***3.OG:***	*3.029, 3.030, 3.031, 3.032, 3.033, 3.034, 3.035, 3.027*
	1.OG:	1.034, 1.035, 1.036, 1.037, 1.038, 1.039
Autoclave room/kitchen:	***3.OG:***	*3.050*

The laboratories on the 2nd floor of the facility (2.029, 2.030) are used by the research group of Prof. Dr. Daniel Engel for their own research projects. A separate operating instruction exists for this area.

The mentioned rooms are designated as "Genetic Engineering Area Safety Level S2". Additionally, signs with the notice "Access prohibited for unauthorized persons" are posted at the entrance.

2 Responsible persons and important contacts in case of emergencies

Emergency call/Fire department/Emergency doctor:	**0-112**
Reanimation team of the ZNA:	**1001**
Plant fire department (Mon–Fir 7:30–15:00):	3407

Technical control center:	4310
Safety technical service - fire protection (Angela Prinz)**:**	3348
Safety technical service - genetic engineering (Dr. Nora. Koll)**:**	3397
Occupational health service (Beate Anna Streich)**:**	3480/3481
Project leaders	
• Prof. Dr. Gunzer**:**	(0)183-6640
• Prof. Dr. Engel**:**	6055
• Dr. Hasenberg**:**	4387
Biological safety officer (BBS; Prof. Dr. Küppers)**:**	3384

3 Genetic engineering work

In the genetic engineering facility, genetic engineering work of risk levels 1 and 2 is carried out. Genetic engineering work includes the use, deactivation, and disposal, as well as the internal transport of genetically modified organisms (GMOs).

The project leaders must be informed of any incident that does not correspond to the expected course of the genetic engineering work.

4 Hazard potential from GMOs

In the laboratories of the IMCES facility, on the 1st and 3rd floors, work is carried out with genetically modified organisms (bacteria and viruses) of different species, of risk groups 1 and 2 (according to BioStoffV with TRBA), corresponding to individual projects of the IMCES users. All users of the IMCES laboratories must therefore assume that work with maximum risk group 2 is being carried out.

If the behavior corresponds to these operating instructions, there is no hazard to healthy individuals and the environment. A comprehensive risk assessment is part of the documentation according to the Genetic Engineering Documentation Ordinance.

In the entire area of the facility, there is an infection risk for actively (through medication) or passively (through illness) immunosuppressed persons and for persons with open wounds. Therefore, access to the genetic engineering facility and the start of active work by these persons are prohibited. If an immunosuppressive illness (e.g., as a result of medication with immunosuppressants) occurs in instructed, active employees in the facility, this must be reported immediately to the project leader. Active work in the facility is prohibited for the duration of immunosuppression.

Pregnant and breastfeeding women have no access to the rooms of the genetic engineering facility if S2 work is being carried out there or if toxic or carcinogenic chemicals are being handled.

5 Protective measures, rules of conduct, and hygiene measures

According to the principles of good microbiological practice and the Genetic Engineering Safety Ordinance, the following points must be observed:

5.1 Zugangsregelungen

Schutzmaßnahmen und Verhaltensregeln in S2-Räumen

Unauthorized persons must not enter!

No eating and drinking!

No smoking!

Wear protective clothing!

Wear protective gloves!

a) Access to the rooms designated as "Genetic Engineering Area Safety Level S2" is prohibited for unauthorized persons. Only those persons are allowed to enter who work there and have been instructed on the required and project-specific safety measures, based on the operating instructions, before starting their work, and who have the explicit permission of the project leaders to work in the laboratory. Furthermore, annual participation in all relevant safety instructions (genetic engineering and general laboratory work, laser protection, and, if applicable, radiation protection) is mandatory, conducted by a project leader or a competent representative. The safety instructions must be given in a language understandable to the employees.

b) Before starting work, all employees must undergo a medical examination (Beate Anna Streich, Tel. 3480/3481), which must be repeated at regular intervals, coordinated by the occupational health service. This applies to every person working in the genetic engineering facility, even if they are not directly involved in genetic engineering work.

c) Visitors, craftsmen, and service personnel may only enter the laboratory area of the facility in the presence of instructed employees. It must be ensured that employees inform the visiting persons of acute hazards.
If longer-term craft or service work is to be carried out, which cannot ensure that instructed employees are continuously present, a verbal instruction on possible risks and essential measures must be given to the person concerned by an instructed employee of IMCES. This instruction should be based on the "Operating Instructions according to BioStoffV, Release Certificate for Technicians and Craftsmen" and documented in the corresponding documentation form. These instructions must be repeated annually for each person. For detailed questions, the respective project leaders are available on site, by arrangement.

d) Cleaning personnel may only work in the laboratories if they have been instructed by a project leader or an authorized person on possible hazards and measures. Instructions on the kind of work performed in the laboratory, the relevant hazards resulting from that, and the most important behavioral rules, is sufficient. Cleaning and maintenance personnel must wear protective gloves during all work. Project leaders are available on site by arrangement to answer

questions. The initial safety instructions must be carried out by a project leader or a competent representative, and has to be renewed once per year. Cleaning personnel must confirm the instructions by signature.

e) Breastfeeding mothers are not allowed to work actively in laboratories where human pathogenic organisms are handled.

5.2 Handling instructions

a) Before starting work, all employees must inform themselves about the location and function of disinfectants, emergency showers, first aid facilities, fire extinguishers, and escape routes.

b) The rooms of the genetic engineering facility must be kept tidy and clean. Only the necessary devices and materials should be on the workbenches. Supplies, such as consumables, culture media, and, in particular, hazardous substances according to the Hazardous Substances Ordinance, must be stored in designated rooms or cabinets.

c) The special regulations for laboratories (BGI/GUV-I 850-0), in particular for handling compressed gas cylinders and flammable liquids, must be followed.

d) The use of the writing workplaces in the laboratories is limited to protocoling experiments. Neither genetic engineering work nor office work beyond protocoling may be carried out at these workplaces. The catalogs, books, etc. available at the writing workplaces must be limited to what is necessary.

e) The windows and doors of the workrooms must be kept closed during genetic engineering work.

f) In the laboratory, protective clothing (lab coat), long pants, and closed, sturdy shoes must be worn.

g) When working with health-hazardous substances, suitable protective gloves must be worn.

h) When working with vessels containing active biological materials, suitable protective gloves must be worn.

i) When working with liquid nitrogen, suitable protective clothing (insulated gloves, safety glasses, closed shoes) must be worn.

j) Pipetting aids must be used.

k) Syringes, cannulas, needles, lancets, etc. may only be used if absolutely necessary. For disposal, they must be collected in puncture-proof, autoclavable containers with a pouring

spout and autoclaved. Cannulas must not be bent or pushed back into their sheaths. Corresponding containers must be provided at each workplace before starting work.

l) All work with non-aerosol-tight enclosed biological materials of risk group 2 must be carried out under a safety cabinet. An exception is made for a few protocols of the Electron Microscopy Unit (EMU), where work must be carried out outside the safety cabinet to prevent drying out of the samples (see annexes to the operating instructions "Handling of biological materials in cryo-electron microscopy" and "Handling of biological working materials in 'Negative Staining'" [TRANSLATOR'S NOTE: At the time of translation, these documents are not available in English translation, and translation not planned. Users and employees are encouraged to contact Dr. Mike Hasenberg in case of questions.]).

m) All chemical fume hoods in the facility (e.g., in rooms 1.036 and 3.030) are only used for storing and shielding chemical hazardous substances. Active biological material of risk groups 1 and 2 may not be worked with in these fume hoods. Introducing this material into the fume hoods is only permitted after suitable inactivation (e.g., after autoclaving or chemical fixation using aldehydes).

n) When working, care must be taken to avoid creating avoidable aerosols. Aerosol formation can occur, for example, when pouring, stirring, application of high pressure, inoculating, shaking, pipetting, centrifuging, and working with ultrasound (etc.).

Measures to avoid aerosol formation:

- Use closed containers or encapsulated working procedures
- Wait for a sufficient time before opening containers to allow aerosols to settle
- Avoid bubble formation
- Use low drop heights when pouring and pipetting
- Do not blow out pipettes, do not spray the contents of syringes/needles into the air

o) The operating instructions/brief instructions for devices (e.g., centrifuge, autoclave, safety cabinet, microwave, etc.) available at each device must be followed.

p) In some rooms of the IMCES, the windows and sight glasses in the doors have been made opaque to eliminate disturbing light effects for microscopy. These rooms may only be used for work in the dark area (microscopy).

q) For the internal transport of genetically modified organisms, closed, break-resistant, and labeled containers must be used. As a rule, these are gray plastic boxes that can be closed with safety seals and are labeled with "Container for transporting S2 material".

r) Waste disposal

In the laboratories on the 3rd floor, in the area of the light microscopy unit (LMU), all solid waste is collected in autoclave bags, which are located in designated red trash cans with lids.

At least once a week, these bags are sealed with adhesive tape by IMCES staff and decontaminated in the facility's autoclave on the 3rd floor.. After autoclaving, the autoclave bags are placed in red trash bags, consistent with the usual waste color code on the UKE campus, for normal waste disposal and then taken directly to the trash collection containers at the MFZ. If there are sharp or pointed objects in the autoclave bags that pose a puncture hazard, the deactivated autoclave bags are placed in red solid plastic trash cans commonly used on the UKE campus before disposal, for reasons of personal protection.

Liquid waste is routinely collected in closed, autoclavable, and labeled containers (glass bottles with screw caps ("Schott bottles") or suitable plastic containers) of suitable size, which are located at a collection point in room 3.030. At least once a week, this waste is transported by IMCES personnel to the autoclave in break-resistant, closed, and labeled containers and deactivated there. After autoclaving, the liquids are disposed of through the drainage system. Note: if necessary, follow handling instructions for chemicals and dispose of them through chemical waste disposal on the campus.

In the laboratories on the 1st floor of the facility, in the area of the electron microscopy unit, only very rarely, and if at all only small amounts of solid and liquid waste contaminated with active biomaterials are generated, and storage or direct decontamination in the autoclave is not usually sensible. This waste is collected in small autoclavable bags in tabletop trash cans during work. Immediately after completion of work, the bags are sealed and transported in sealed, unbreakable, and labelled containers to an intermediate storage location, either the collection containers for biological waste in the 3rd floor of the IMCES facility or the waste disposal in the genetic engineering facilities of the respective users.

Autoclaving of biological waste for the IMCES facility is carried out in room 3.050, which can be reached from the laboratories on the 1st and 2nd floors via the freight elevator of the MFZ (see route plan).

In the operating instructions for waste disposal at the UK Essen, additional waste containers for disposing of infectious materials are listed. These are only suitable for disposing of potentially infectious patient material in clinical areas and are **not** permitted for disposing of active (GMO) biological materials from scientific laboratories!

s) When working with UV light sources, face protection and closed clothing must be worn. Direct radiation exposure to eyes, skin, and mucous membranes must be absolutely avoided.

t) At the end of each working day, the employee who last leaves the laboratory must check that all electrical devices are switched off and the laboratory rooms are closed.

5.3 Additional instructions

[TRANSLATOR'S NOTE: Not all documents on the following list are available in English. Contact IMCES staff to ask for information if necessary.]

- Skin protection plan – MFZ
- Hygiene plan – MFZ

- Operating instructions for hazardous substances according §20 Gefahrstoff-V-TRGS 555
- Operating instructions „Safety cabinet – 2.029“
- LMU Operating instructions „Akoya PhenoCycler Fusion” – Room 3.034
- LMU Operating instructions „Autoclave” – Room 3.050
- LMU Operating instructions „BD FACS Aria III” – Room 3.029
- LMU Operating instructions „BD FACSymphony A1” – Room 3.029
- LMU Operating instructions „Centrifuges” – Room 3.029
- LMU Operating instructions „Keyence BZ-X810” – Room 3.032
- LMU Operating instructions „Leica SP8 gSTED/FLIM” – Room 3.031
- LMU Operating instructions „Miltenyi UltraMicroscope Blaze” – Room 3.033
- LMU Operating instructions „Molecular Devices ImageXpress Pico” – Room 3.031
- LMU Operating instructions „Olympus BX51” – Room 3.034
- LMU Operating instructions „Perkin Elmer Lumina II” – Room 3.035
- LMU Operating instructions „Safety Cabinets” – Rooms 3.029 and 3.035
- LMU Operating instructions „Visualsonics Vevo 2100” – Room 3.035
- LMU Operating instructions „Zeiss AxioObserver/Apotome” – Room 3.031
- LMU Operating instructions „Zeiss AxioScan” – Room 3.034
- LMU Operating instructions „LSM710/Elyra” – Room 3.032
- EMU Kurzbetriebsanweisung - BioWaveMikrowelle - Raum 1037
- EMU Kurzbetriebsanweisung - Captair-Laborabzug - Raum 1036
- EMU Kurzbetriebsanweisung - Cryo Plunge - Raum 1035
- EMU Kurzbetriebsanweisung - Gefrierultramikrotom - Raum 1031
- EMU Kurzbetriebsanweisung - Glow Discharger - Raum 1035
- EMU Kurzbetriebsanweisung - Kontrastierautomat - Raum 1034
- EMU Kurzbetriebsanweisung - Kritisch-punkt_Trockner - Raum 1037
- EMU Kurzbetriebsanweisung - Kryo-SEM Präparationssystem - Raum 1039
- EMU Kurzbetriebsanweisung - Kryo-TEM Präparationssystem - Raum 1035
- EMU Kurzbetriebsanweisung - Magnetrührer - Raum 1037
- EMU Kurzbetriebsanweisung - Pelco-Chiller - Raum 1037
- EMU Kurzbetriebsanweisung - Sputter Coater Quorum - Raum 1039
- EMU Kurzbetriebsanweisung - Trimmfräse - Raum 1031
- EMU Kurzbetriebsanweisung - UV-Lampe - Raum 1035
- EMU Kurzbetriebsanweisung - Vakuumtrockenschrank_Raum 1034
- EMU Kurzbetriebsanweisung - Vibratom - Raum 1035
- EMU Kurzbetriebsanweisung - Zentrifuge - Raum 1037
- EMU Kurzbetriebsanweisung - Zentrifuge 5430R - Raum 1037
- Operating instructions for hazardous substances, which are available as DAMARIS print-outs in the individual laboratories

5.4 Hygiene measures

The instructions of the hygiene plan are binding for all workplaces of safety level 2 as part of the operating instructions.

a) All work surfaces must be disinfected with the disinfectant specified in the hygiene plan after completion of work (see hygiene plan).

b) After completion of work and before leaving the laboratory, hands must be disinfected with alcoholic disinfectant (see hygiene plan) (rub hands with concentrated solution until the liquid evaporates; exposure time at least 30 s), washed with soap, and moisturized with skin cream (see hygiene plan). Single-use towels must be used for drying.

c) Work equipment and instruments must be cleaned regularly:
   - Centrifuges must be disinfected by the users immediately in case of contamination, but at least once a month, by wiping the rotor room and rotors with disinfectant (see hygiene plan).
   - All surfaces of the safety cabinet must be disinfected routinely, after each use, by wiping with disinfectant (see hygiene plan and operating instructions on the device) by the users. In case of contamination, this disinfection must be carried out immediately, including all contaminated areas, such as the catch basin under the work surface. If a workstation is not used for a longer period, disinfection, including the catch basin, must be carried out at least once a month.
   - The incubator must be disinfected and cleaned at least once a month by wiping the inner surfaces with disinfectant (see hygiene plan). Before cleaning, the power cord must be pulled out, and the device must be brought to room temperature.

d) Especially when using chemical disinfectants on electrical devices and systems in connection with open flames/hot surfaces, protection against explosion must be considered (see also manufacturer's instructions).

e) The occurrence of pests must be reported immediately to the project leaders to initiate appropriate control measures as soon as possible.

5.5 Prohibitions

a) Foodstuff, drinks, tobacco, and cosmetics, must not be stored within the genetic engineering facility.

b) Eating, drinking, smoking, or snuffing is prohibited in any area of the genetic engineering facility. This is only permitted in designated break rooms, which must not be entered wearing laboratory protective clothing.

c) Mouth pipetting is prohibited. Pipetting aids must be used.

d) Suction devices (e.g., membrane pumps) may only be used for liquids that may contain active biomaterials if measures are taken to prevent the escape of biological materials (*e.g.*, by use of a sterile filter). The use of water jet pumps is prohibited!

e) The storage of active biological materials and objects in traffic areas is prohibited.

f) Immunocompromised persons, pregnant women, and persons with cystic fibrosis (mucoviscidosis) are prohibited from entering the genetic engineering facility.

5.6 Personal protective equipment:

a) In the entire IMCES genetic engineering facility, lab coats must be worn, which must be washed regularly. The IMCES provides lab coats in different sizes for its users. The lab coats must be autoclaved before washing (see hygiene plan).

b) Lab coats and disposable gloves must be removed before leaving the genetic engineering facility. This means that the lab coats available in the EMU rooms (1.034, 1.035, 1.036, 1.037, 1.038, 1.039) must remain in the laboratories. The area of the LMU facility (rooms 3.027, 3.029, 3.030, 3.031, 3.032, 3.033, 3.034, 3.035, 3.050) also includes the corridor in front of the laboratories. Storage of general IMCES lab coats is done in the lockers on the corridor. Contaminated gloves must be autoclaved before disposal as solid waste.

c) When choosing disposable gloves, the chemical resistance information of the manufacturers must be observed. Disposable gloves must be disposed of after use.

d) To avoid contamination, protective clothing must be stored separately from street clothing and bags. Separate lockers are available in front of the genetic engineering facility for this purpose.

e) When working with laboratory activities that pose a potential hazard to the eyes, safety glasses must be worn.

5.7 Special regulations:

a) The genetic engineering facility of IMCES on the 1st and 3rd floors is used for conducting experiments of safety levels 1 and 2, as part of the service offered by IMCES. By filling out an IMCES registration form, users define the experimental work they intend to carry out in

the IMCES genetic engineering facility, including its risk potential. The risk group of the work is determined by a risk assessment according to §4 BioStoffV and TRBA 400, which is the responsibility of the users.
Subsequently:

- wt R1 activities can be started immediately without further measures.
- Non-targeted R2 activities require transmission of the internal "IMCES Biosafety Form" to IMCES before starting work.
- Targeted R2 activities must be reported to the District Government of Düsseldorf, Department 56, 30 days before starting work, via the Safety Technical Service of the UME (Dr. Nora Koll, email: nora.koll@uk-essen.de, phone: +49 201/723-3397 (cordless -85596)). Additionally, the "IMCES Biosafety Form" must be transmitted to IMCES before starting work.
- Genetic engineering S1 work requires submission of the internal "IMCES Biosafety Form" to IMCES before starting work.
- Genetic engineering S2 work must be reported to the District Government of Düsseldorf, Department 53.5, before starting work, according to §9 (4a) GenTG, via the Safety Technical Service of the UME (Dr. Nora Koll, email: nora.koll@uk-essen.de, phone: +49 201/723-3397 (cordless -85596)). Additionally, the "IMCES Biosafety Form" must be transmitted to IMCES before starting work.

b) The responsibility of the main project leaders of the IMCES genetic engineering facility (Prof. Matthias Gunzer, Prof. Daniel Engel, and Dr. Mike Hasenberg) includes…

   - ensuring S2 compliance of the laboratories and laboratory equipment.
   - ensuring documentation of S2 use of the facility, on the one hand, through user entries in the IMCES online booking calendar and, on the other hand, through forms that users must fill out and submit to IMCES when using IMCES S2 services.
   - documentation and control of genetic engineering and R2 work, if and only if it is carried out by IMCES personnel as part of “full-service” work.

c) The responsibility for the experimental content and any existing documentation obligation (*e.g.*, according to GenTG §6(3)), including its control, lies with the users, their direct supervisors, and the associated project leaders in the genetic engineering facilities of the users.

d) Through the use of an online booking calendar for all IMCES devices, their use can be assigned to individual users retrospectively. S2 work must be marked as such when booking devices in the online calendar.

e) In general, the retention period for genetic engineering records for S1 work is 10 years (S2

30 years).

6 Behavior in case of emergency

a) Remain calm and avoid hasty, unconsidered actions.

b) Warn endangered persons and, if necessary, instruct them to leave the rooms.

c) Stop endangered and hazardous experiments, turn off gas, electricity, and water (cooling water must continue to run).

d) In all emergency situations, the project leader must be notified immediately.

6.1 Release or spillage of biological material

If active biological material is spilled, the affected area must be secured. Released or spilled biological material, in particular if it may contain GMOs, must be inactivated immediately. The following decontamination measures must be taken:

- Surfaces — Wear protective gloves. In case of contamination with vegetative bacteria, including mycobacteria, and with fungi, including fungal spores, treat the contaminated area with copious amounts of Bacillol® AF. In case of contamination with enveloped and non-enveloped viruses, treat the contaminated area with copious amounts of Dismozon® plus (3.6%). Close off the area during the 15-minute exposure time. Then, take up the released or spilled biological material with multi-layered, dry, absorbent paper towels and autoclave them. Finally, disinfect the corresponding surface again with Bacillol® AF (wiping disinfection with an exposure time of 15 minutes).
  In case of a broken vessel, glass fragments must first be disinfected with Bacillol® AF or Dismozon® plus (3.6%) (see above) and then removed using protective gloves and suitable tools, and autoclaved (120°C, 20 minutes) before final disposal

- Devices — Same procedure as described above for surface decontamination. Specifically when working with electrical devices and systems in connection with open flames/hot surfaces, protection against explosion protection must be considered (see also manufacturer's instructions).

- Clothing — Remove protective clothing or street clothing and autoclave it. Then wash the clothing.

- Skin — Disinfect contaminated skin areas (see hygiene plan) and rinse with plenty of water after sufficient exposure time; in case of contamination of open wounds with active biological materials, disinfect according to the hygiene plan and seek medical advice immediately

- Eyes — Rinse eyes with plenty of water (eye shower) and seek medical advice

- Internal body areas — If active biological materials are inhaled or ingested, seek medical advice immediately

If further complaints occur despite these immediate measures, seek medical advice immediately.

Every accident must be reported immediately to a project leader of the IMCES facility. Additionally, all injuries and accidents must be documented in the online accident book of the UKE (https://intraweb.uk-essen.de/dokuErsteHilfe/default.aspx). Furthermore, all injuries related to genetic engineering work must be recorded in the experimental records. These records must be kept for at least 10 years (S1) and 30 years (S2).

6.2 Fire:

In case of small fires, the fire can be extinguished using the fire extinguishers available in the rooms. Otherwise, the current UKE fire protection guidelines must be followed:

Prevent fire

Fire, exposed lighting, and smoking prohibited!

Behavior in case of fire

Stay calm!

Report fire

Use emergency button
Fire department tel. 0-112

- Who is calling?
- Where is the fire?
- What happened?
- What number of people is affected?
- Wait for response!

Coordination in-house: 4310

Get to safety

Pay attention to warning signals
Warn people at risk
Bring yourself and others to safety
Follow the indicated escape routes
Close doors without locking them
Go to official gathering spot

Attempt to extinguish fire

Use fire extinguishers
Use wall hydrants
Use other facilities and tools to fight fire (e.g., fire blankets)

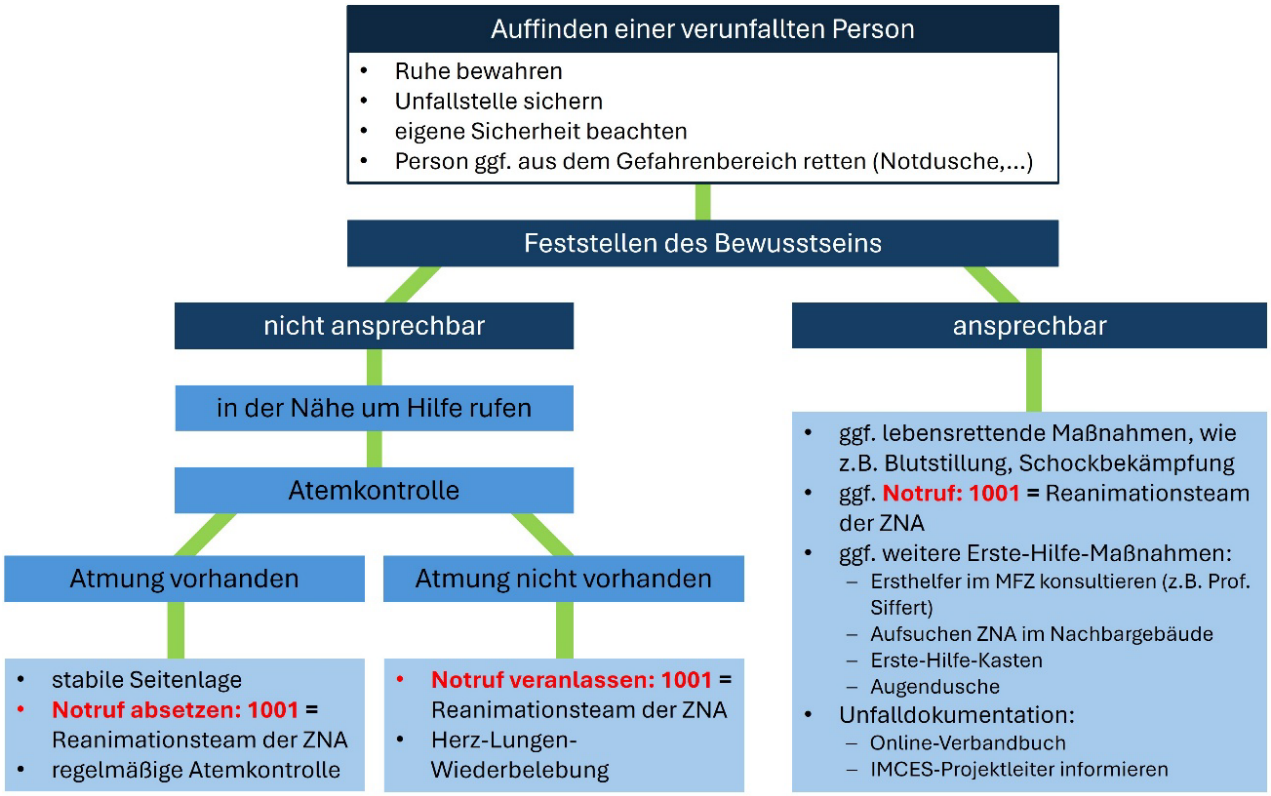
Follow the instructions by fire fighters!

7 First aid

- Injuries
  - As far as possible, wounds should be disinfected and bandaged during first aid. Dispensers for skin disinfectants are available at all sinks.
  - If there is a risk of exposure to health-hazardous substances, a doctor must be notified.
- Inhalation or ingestion of active biological material
  - Immediate medical advice must be sought on whether and how treatment is required. The treating doctor must be informed of which organisms were taken in and in what quantity.

- Scratches and bites when handling animals – If scratches or bites occur when handling animals, the affected skin areas must be cleaned immediately, disinfected with disinfectant (see hygiene plan), and bandaged if necessary. In case of deeper or heavily bleeding injuries, seek medical advice immediately. In case of every scratch or bite, it must be checked whether adequate tetanus vaccination protection exists.

In case of severe personal accidents, the following scheme must be followed:



8 Proper disposal

a) Solid and liquid waste containing active biological materials must be inactivated before disposal. This can be achieved, for example, by autoclaving at 121°C for 20 minutes and under pressure. For this, an autoclave is available in room 3.050.

b) The effectiveness of the autoclave must be checked at least every six months using bioindicators (DIN/EN ISO 11138-3). The result of the effectiveness test must be documented.

c) Waste is collected in designated waste containers until inactivation. Storage of solid waste is done in plastic trash cans with an inserted autoclave bag. Liquid waste is stored in sealable glass containers or autoclavable plastic containers, depending on the volume. Inactivation of the collected waste is carried out at least weekly.

d) After autoclaving, the waste can be disposed of with the general laboratory waste, taking into account any additional chemical or mechanical hazard potential.

e) In the laboratories of the EMU (1st floor), only very small amounts of waste containing active biological materials are generated during corresponding work. The aim is for the users to take this waste to their own genetic engineering facilities in break-resistant transport containers and inactivate and dispose of it there according to their own routine.

9 References to general regulations

[TRANSLATOR'S NOTE: Names of laws etc. are left untranslated.]

Gesetze und Verordnungen

- Gentechnikgesetz (GenTG)
  - Gentechnik-Sicherheitsverordnung (GenTSV), inkl. Anhänge I–VI
  - Gentechnik-Aufzeichnungsverordnung
- Infektionsschutzgesetz (IfSG)
- Biostoffverordnung (BioStoffV) – Verordnung zum Schutz der Beschäftigten vor biologischen Arbeitsstoffen
  - einschl. zugehöriger Technischer Regeln für Biologische Arbeitsstoffe (TRBA)
- Gefahrstoffverordnung (GefStoffV) – einschl. TRGS
  - TRGS 526 „Laboratorien"
  - TRGS 555 „Betriebsanweisung und Unterweisung"
- Arbeitsschutzgesetz (ArbSchG)
- Betriebssicherheitsverordnung (BetrSichV)
  - einschl. noch gültiger Technischer Regeln für brennbare Flüssigkeiten und Druckbehälter
- Mutterschutzgesetz (MuSchG)
- Strahlenschutzgesetz / Strahlenschutzverordnung (StrlSchG/StrlSchV, neue Fassung)
- Tiergesundheitsgesetz (TierGesG) *(ersetzt das frühere Tierseuchengesetz)*

Veröffentlichungen des Robert-Koch-Institutes / Verbundes für angewandte Hygiene

- Liste risikobewerteter Spender- und Empfängerorganismen für gentechnische Arbeiten (BVL-Datenbank)
- RKI-Liste geprüfter Desinfektionsmittel *(jeweils aktuelle Fassung)*
- VAH-Desinfektionsmittelliste

DGUV-Vorschriften, Regeln und Informationen

- DGUV Vorschrift 1 „Grundsätze der Prävention" *(ehemals BGV A1)*
- **DGUV Vorschrift 2 „Betriebsärzte und Fachkräfte für Arbeitssicherheit"*
- DGUV Vorschrift 13 / 14 „Biologische Arbeitsstoffe" *(Nachfolger der UVV BGV B12)*

- DGUV Vorschrift 3 „Elektrische Anlagen und Betriebsmittel“ (falls zutreffend)
- DGUV Information 213-850 „Biologische Arbeitsstoffe im Labor“
- DGUV Regel 109-003 „Arbeiten in Laboratorien“ *(Nachfolger verschiedener BGI/BGR)*
- DGUV Merkblatt zu Sicherheitswerkbänken (ZH 1/48) – in aktualisierter Form integriert in DGUV-Materialien
- Weitere DGUV Informationen aus der Reihe „Sichere Biotechnologie“, u. a.:
  - B001–B009 (Fachbegriffe, Laboratorien, Betrieb, Viren, Parasiten, Bakterien, Pilze, GVO, Zellkulturen)
  - M651 „Richtig pipettieren“
  - M007 „Tierlaboratorien“

DIN- / EN-Normen

- DIN 58956 – Medizinisch-mikrobiologische Laboratorien
- DIN EN 13150 – Labortische, sicherheitstechnische Anforderungen
- DIN EN 12469 – Sicherheitswerkbänke (in Verbindung mit VDI 2083)
- DIN 58946 – Dampfsterilisatoren
- DIN 12924 Teil 1–3 – Laborabzüge
- DIN-Fachbericht 7 „Verminderung des Infektionsrisikos in der medizinischen Mikrobiologie“

The mentioned regulations can be viewed at the Safety Technical Service, Esmarchstraße 10. [TRANSLATOR’S NOTE: Most of these documents will not be available in English.]

10 References to special regulations

- **Reporting obligation:**

  The project leader must be informed of any incident that does not correspond to the expected course of the genetic engineering work.

- **Safety Instructions:**

  Before commencing active work at the IMCES facility, new users and persons who do not comply with the annual safety training cycle due to prolonged inactivity must receive initial workplace-specific training on risks and necessary protective measures. This initial training is conducted by permanent IMCES staff and documented using a standardised form.

- No later than 12 months after the initial workplace-specific training, all people engaged in scientific work at the facility must participate in the annual safety training offered by IMCES. Participation must then be repeated at least once every 12 months (365 days). The annual safety training sessions are conducted by a “Projektleiter” according to GenTG or a suitably qualified representative. The content, location and date of the training shall be documented in writing;

participation is confirmed by the original signature of the persons trained.

- **Documentation obligation:**

- In the facility, genetic engineering work of safety levels 1 and 2 is permitted. This work must be documented according to the law (GenTG §6(3)). Since the information on the donor and recipient organisms, the genetically modified organism, the vector, and the transferred gene is an essential part of the risk assessment of genetic engineering work, this information must be included in the documentation. The documentation must be kept for at least 10 years (S1) and 30 years (S2).

- **This documentation, its storage, and the required regular inspection are the responsibility of the IMCES users and/or their supervisors, and the genetic engineering project leaders in the individual genetic engineering facilities of the users**

- **Penal and fine regulations:**

- In case of non-compliance with the regulations of the Genetic Engineering Act, fines of up to €50,000 and imprisonment of up to 5 years can be imposed. Furthermore, due to genetic engineering liability regulations, claims for damages of up to €85,000,000 can arise.