Safety Instruction

Genetic Engineering Facility 92/14 (S1)

Katharina Achazi

March, 8 2021

Legal Background - Genetic Engineering Facility 92/14

Regulation on Biological Agents (BioStoffV)

→ Protection of employees against biological agents

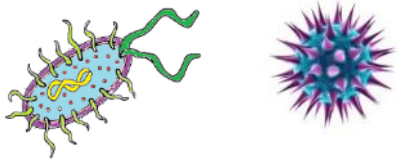
Legal Background - Genetic Engineering Facility 92/14

Regulation on Biological Agents (BioStoffV)

→ Protection of employees against biological agents

What are biological agents?

- **Human materials** e.g. body fluids & tissue
- **Cell cultures** e.g. from humans, animals or insects
- Living **(micro-) organisms:** bacteria, fungi, single-cell organisms, parasites
- **Viruses**
- **Prions** (misfolded "infectious" proteins)
- **Technical engineered biological units**



Biological agents *can have* ***sensitising***, ***toxic*** *or other* ***adverse effects***

Legal Background - Genetic Engineering Facility 92/14

Regulation on Biological Agents (BioStoffV)

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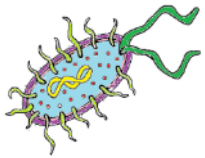


*Biological agents can have **sensitising**, **toxic** or other **adverse effects***

Risk assessment to assign them into **Risk Groups**

Legal Background - Genetic Engineering Facility 92/14

Regulation on Biological Agents (BioStoffV)

→ Protection of employees against biological agents

German Genetic Engineering Act (GenTG), Safety Regulations (GenTSV) & Ordinance on Records (GenTAufzV)

→ Protection of the environment from harmful effects of genetic engineering

Legal Background - Genetic Engineering Facility 92/14

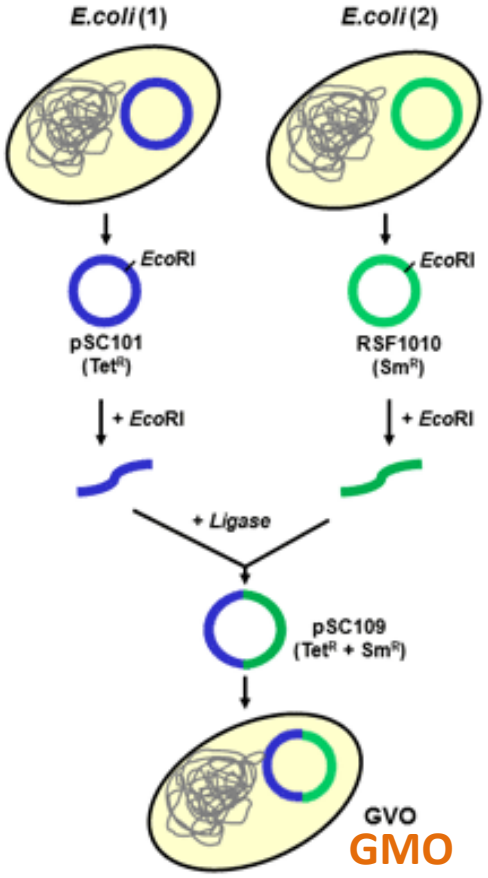
German Genetic Engineering Act (GenTG), Safety egulations (GenTSV) & Ordinance on Records (GenTAufzV)

→ Protection of the environment from harmful effects of genetic engineering

What is genetic engineering?

Specific modifications of a genome

→ **G**enetically **M**odified **O**rganism



Legal Background - Genetic Engineering Facility 92/14

German Genetic Engineering Act (GenTG), Safety egulations (GenTSV) & Ordinance on Records (GenTAufzV)

→ Protection of the environment from harmful effects of genetic engineering

What is genetic engineering?

Specific modifications of a genome

→ Genetically Modified Organism

GMOs have to be handled in a **Genetic Engineering Facility** under a **safety level** corresponding to their **risk group** assignment and work has to be **documented**

Legal Background - Genetic Engineering Facility 92/14

Regulation on Biological Agents (BioStoffV)

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Occupational Safety and Health Act (ArbSchG)

→ Ensure and improve the health of all employees

Legal Background - Genetic Engineering Facility 92/14

Occupational Safety and Health Act (ArbSchG)

→ Ensure and improve the health of all employees

How to ensure and improve the health of all employees?

- **Technical measures**
- **Organizational measures** to supplement technical measures
- **Personal protective equipment** if technical measures are not sufficient
- **Instruction and information**
- **Preventive measures for emergency situations**

Legal Background - Genetic Engineering Facility 92/14

Occupational Safety and Health Act (ArbSchG)

→ Ensure and improve the health of all employees through health and work safety measures

How to ensure and improve the health of all employees?

- **Technical measures**
- **Organizational measures** to supplement technical measures
- **Personal protective equipment** if technical measures are not sufficient
- **Instruction and information**
- **Preventive measures for emergency situations**

Safety Measures based on Risk Assessment

Legal Background - Genetic Engineering Facility 92/14

Who is responsible?

Operator
Freie Universität Berlin &
respective **Professors**

Ensures overall safety
- *In case of genetic engineering delegation of tasks to competent* **Project Manager** *and* **BBS**

Project Manager (Projektleiter: **PL**)
Katharina Achazi

Plans, manages and **supervises** work in the genetic engineering facility → **personal liability**

Biological Safety Officer
(Beauftragter für biologische Sicherheit: **BBS**)
Bernhard Loll (AG Wahl)

Monitors the **Project Manager** & **supports** the **Operator**

Biolab users **YOU**

Ensure your own safety & the safety of others

Legal Background - Genetic Engineering Facility 92/14

Classification into **Risk Groups**

Genetic Engineering Facility

Safety Measures

Legal Background - Genetic Engineering Facility 92/14

Classification into **Risk Groups**

Genetic Engineering Facility

Safety Measures

Classification into **Risk Groups**

respective **Safety Level**

RG 1	**unlikely** to cause **human disease** *(e.g. non-pathogenic strains of E. coli like K12)*	**Level 1**
RG 2	cause **human disease**; **unlikely to spread** to the community; **effective prophylaxis** or **treatment** available *(e.g. pathogenic strains of E. coli)*	**Level 2**
RG 3	cause **severe human disease**; **risk of spreading** to the community**,** effective **prophylaxis** or **treatment** available *(e.g. SARS-CoV-2)*	**Level 3**
RG 3**	**as RG 3** but **low risk** of transmission **via aerosols** *(e.g. HIV, HBV, HCV)*	**Level 2/3****
RG 4	cause **severe human disease**; **risk of spreading** to the community**, NO** effective **prophylaxis** or **treatment** available *(e.g. Ebola virus)*	**Level 4**

Classification into Risk Groups

How to know the risk group?

Official EU/German **lists** and **statements**

- the Central Committee on Biological Safety
- the Federal Institute for Occupational Safety and Health (BAuA)
- GESTIS Biological Agents Database

➢ **Notify me before you bring or buy a biological agent or GMO**

Mandatory Documents:

- **Product data sheet**
- **Material transfer agreement** from non-commercial sources e.g. collaboration partner
- **Certificate of a negative test for HIV, HBV and HCV** for products of human origin

If possible: **Buy cell lines, bacteria or viruses always** from an officially **recognized source or company**

DSMZ

ATCC

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Classification into Risk Groups

Genetic Engineering Facility

Safety Measures

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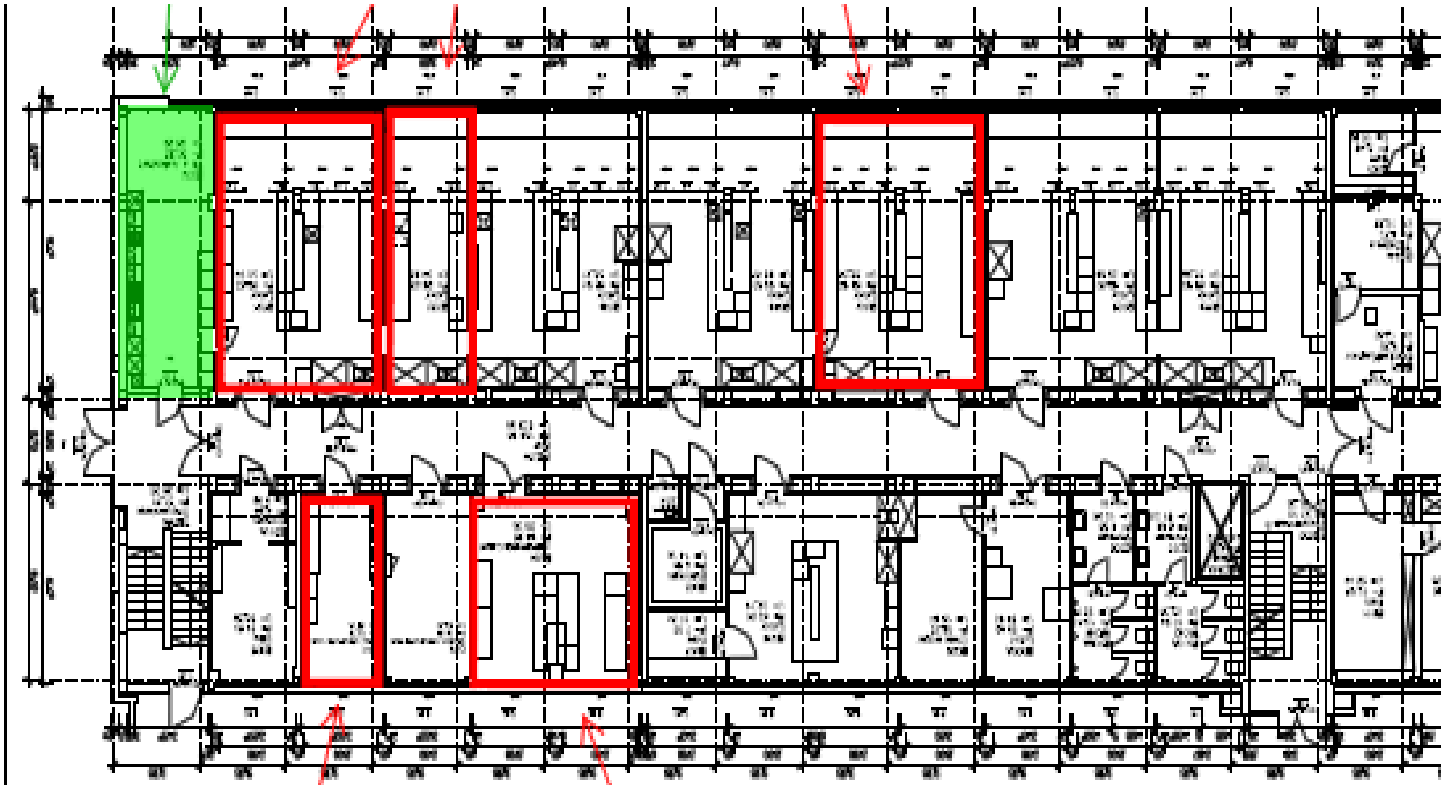
Arnimallee 22 - Safety Level 1 according to *GenTSV*

Kitchen E032

Measurement rooms E031/E030

Measurement & bacterial culture rooms E027



Cell culture E002

Cell culture & autoclave room E004

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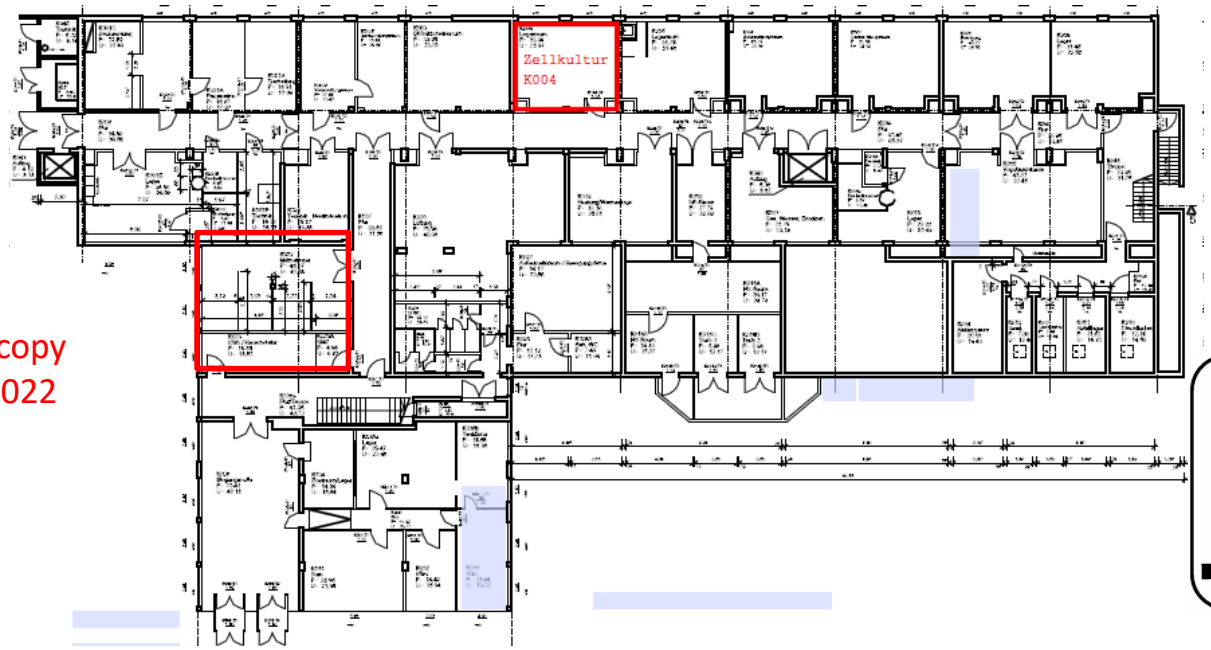
Takustr. 6 - Safety Level 1 according to *GenTSV*

~~K004: **Exceptional permit** to **isolate cells from foreskin** for people with **special instruction** and **health certificate** according to *BioStoffV*~~ BIO II

K004 is **NOT** a **safety level 2 lab** according to *GenTSV*, **NO** handling of RG 2 GMOs

Cell culture K004



Microscopy room K022

Autoclave room 321 (3. floor)

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How to get Access?

- **Register with project manager** (me)
- **Personal instruction** based on the **biolab agreement** & **operating instructions**, **hygiene plans** & **emergency plan** by **project manager** (me) or deputy
  - *extra instruction mandatory if you plan to work with **RG 3**** bio agents*

- **Attend annual safety instruction**
- **Visit FUBs medical doctor** for a **health check,** advice & vaccination
  - *health check mandatory for work with bio agents from RG 2 or higher*

Access to the facility **only for instructed persons** including cleaning and technical personal

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What are your resposnibilities?

- **Register biological agents** and **GMOs** with **project manager** (me) and **chemicals** with Elisa Quaas or Johanna Scholz (CLAKS) prior to work
- Notify **project manager** (me) immediately in case of injuries or accidents
- If you are pregnant, let **project manager** (me) or **BBS** (Bernhard Loll) know
- **Do not work alone** or **out of FUB`s regular working hours**
- **Document risk assessment** and every **experiment** and **storage**
  - in the lab journal
  - additionally for **bio agents** in the **bio agents list** & for **GMO**s fill **Formblatt Z**

    → documents need to be stored for at last **10 years** in the facility
- Be a **good** and mindful **lab fellow**
- Follow **Rules of good laboratory practice** and all other safety rules

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What is "Formblatt Z"?

- ***Risk assessment and documentation of genetic engineering experiments and GMOs***

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Formblatt Z

AUFZEICHNUNG FÜR EINE GENTECHNISCHE ARBEIT NACH GENTAUFZV

1. **Name und Anschrift des Betreibers**
   Freie Universität Berlin – Das Präsidium – (Körperschaft des öffentlichen Rechts)
   Kaiserswerther Str. 16-18, 14195 Berlin
2. **Lage der gentechnischen Anlage**
   Arnimallee 22 und Takustr. 6, 14195 Berlin
3. **Nr. der Anlage:** 92/14
4. **Projektleiter (ggf. weitere PL)**
   Dr. Katharina Achazi
5. **Beauftragter für die Biologische Sicherheit** [A]
   Dr. Bernhard Loll
6. **Ab Sicherheitsstufe 2:** Bei Umgang mit humanpathogenen Organismen Personen, die in der gentechnischen Anlage tätig sind [A]
7. **Nr. der Arbeit:**
8. **Thema der Arbeit (bei weiteren S1-Arbeiten Beschreibung und Zielsetzung** [B])
9. **Sicherheitsstufe** S1 ☐ → S2 ☐ → S3 ☐ → S4 ☐
10. **Datum des Bescheides oder der Eingangsbestätigung:** 05.03.2014
11. **Zeitpunkt des Beginns und Abschlusses der gentechnischen Arbeiten**
    Beginn: Abschluss:
12. **Besondere Vorkommnisse** [A]

bei Platzmangel gesondertes Blatt verwenden
bitte Anlage verwenden

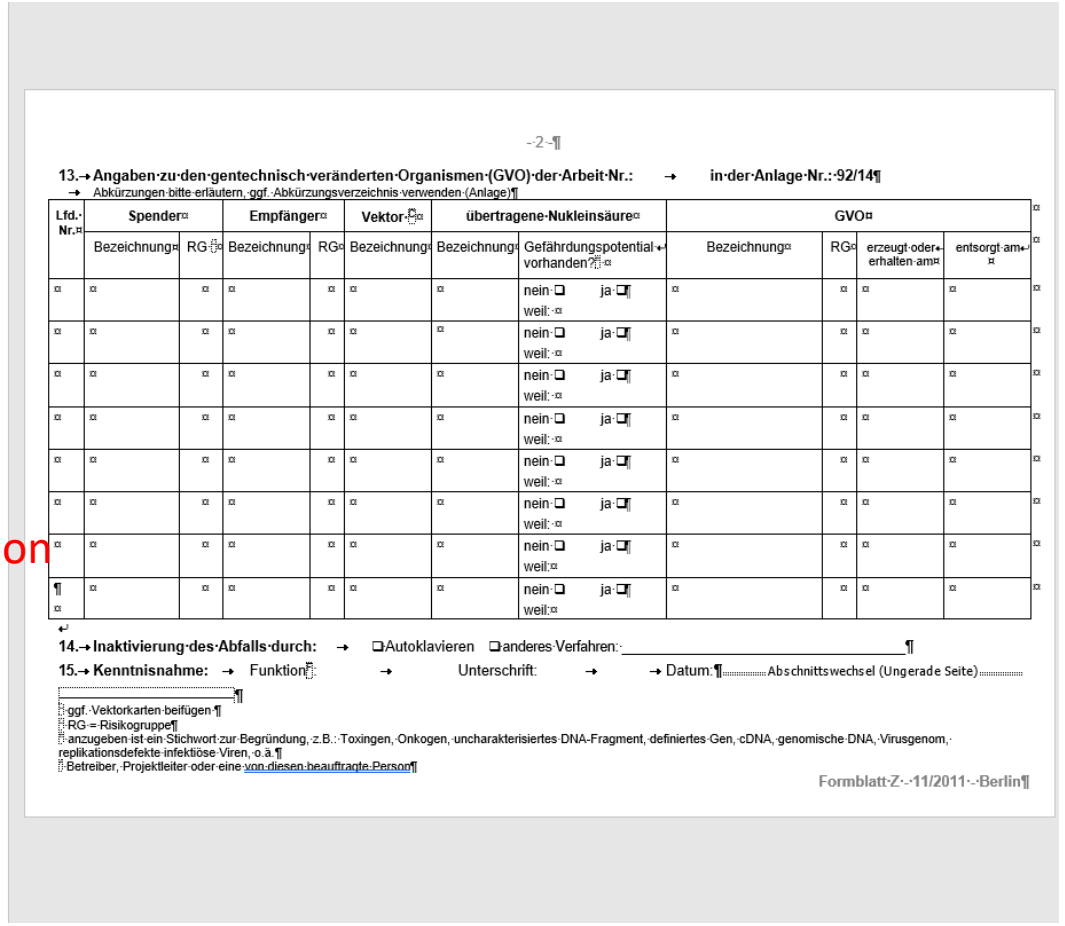
prefilled until No. 6

consecutive number

short title → detailed description of project on an extra page

Safety level

Start date



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13. Angaben zu den gentechnisch veränderten Organismen (GVO) der Arbeit Nr.: → **in der Anlage Nr.: 92/14**
Abkürzungen bitte erläutern, ggf. Abkürzungsverzeichnis verwenden (Anlage)

Lfd. Nr.	Spender		Empfänger		Vektor	übertragene Nukleinsäure		GVO			
	Bezeichnung	RG	Bezeichnung	RG	Bezeichnung	Bezeichnung	Gefährdungspotential vorhanden?	Bezeichnung	RG	erzeugt oder erhalten am	entsorgt am
							nein ☐ ja ☐ weil:				
							nein ☐ ja ☐ weil:				
							nein ☐ ja ☐ weil:				
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							nein ☐ ja ☐ weil:				
							nein ☐ ja ☐ weil:				

14. Inaktivierung des Abfalls durch: → ☐ Autoklavieren ☐ anderes Verfahren: _____

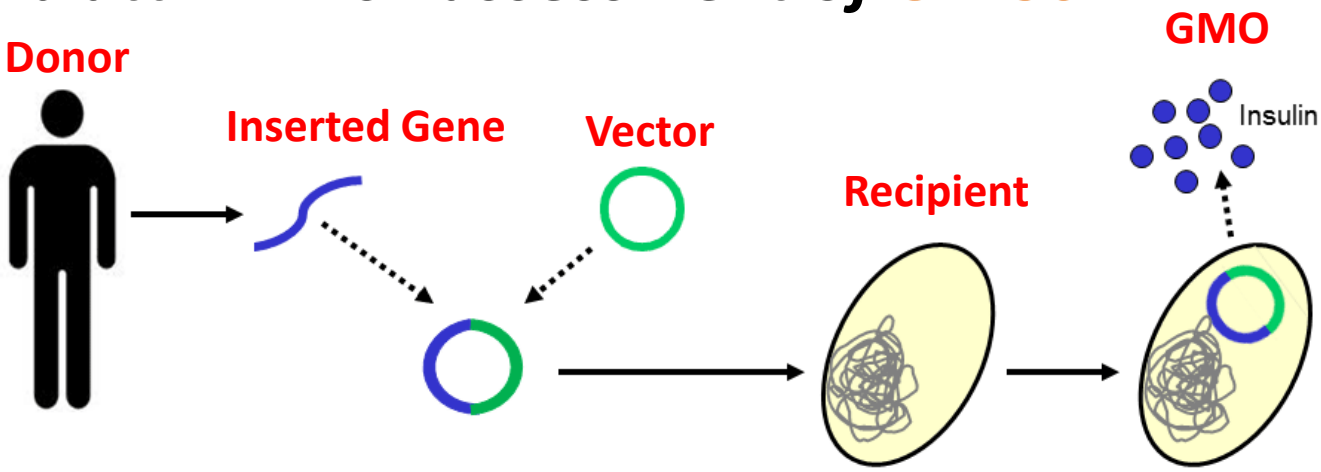
15. Kenntnisnahme: → Funktion: → Unterschrift: → → Datum: Abschnittswechsel (Ungerade Seite)

ggf. Vektorkarten beifügen
RG = Risikogruppe
anzugeben ist ein Stichwort zur Begründung, z.B.: Toxingen, Onkogen, uncharakterisiertes DNA-Fragment, definiertes Gen, cDNA, genomische DNA, Virusgenom, replikationsdefekte infektiöse Viren, o.ä.
Betreiber, Projektleiter oder eine von diesen beauftragte Person

Formblatt Z - 11/2011 - Berlin

Genetic Engineering Facility 92.14

Formblatt Z – Risk assessment of GMOs



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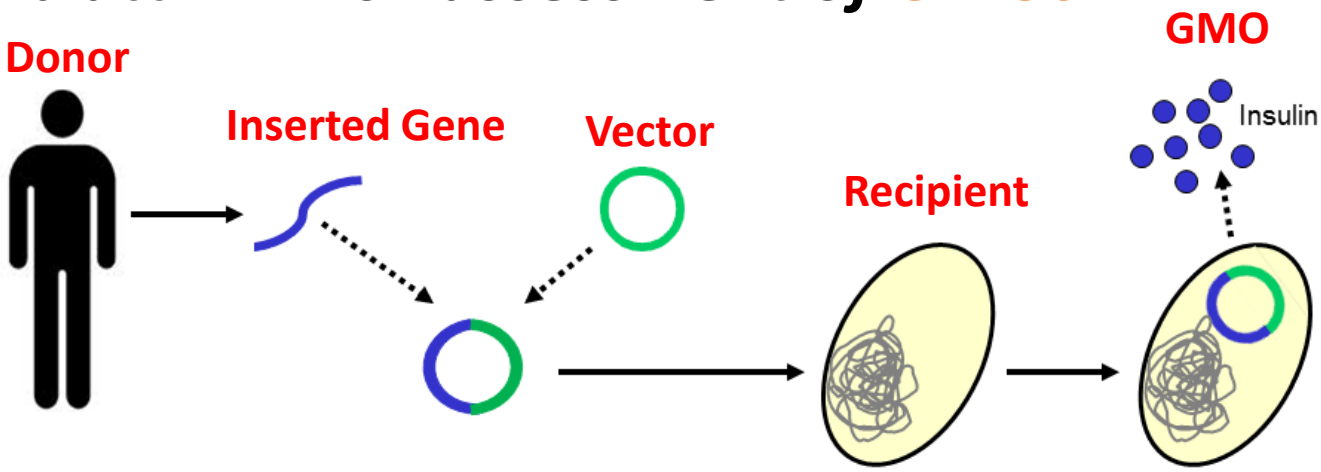
Formblatt Z – Risk assessment of GMOs



Donor	**Gene**	**Vector**	**Recipient**	**GMO**
Human no risk RG: 1	Insulin gene no risk: sub-genomic and no hazardous gene product RG: 1	Plasmid X no risk: listed in official list as RG: 1	E. Coli K12 no risk: listed in official list as RG: 1	Insulin producing E. Coli K12 with Plasmid X no risk RG: 1

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Formblatt Z

Donor Recipient Vector Inserted Gene GMO

Lfd. Nr.	Spender		Empfänger		Vektor	übertragene Nukleinsäure		GVO			
	Bezeichnung (name)	RG	Bezeichnung (name)	RG	Bezeichnung (name)	Bezeichnung (name)	Gefährdungspotential vorhanden?	Bezeichnung (name)	RG	erzeugt oder erhalten am (produced)	entsorgt am (discarded)
							nein ☐ ja ☐ weil:				

RG: risk group

Potential risk, and if no reason why:

Combination of donor, recipient and vector

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Formblatt Z

Anlage zu den Aufzeichnungen Arbeit Nr.: ..... Anlage Nr.: 92/14 .....

Verzeichnis der verwendeten Abkürzungen:

Abkürzung	Erläuterung

abbreviations

Anlage zu Formblatt Z - 11/2011 - Berlin

Anlage zu den Aufzeichnungen Arbeit Nr.: ..... Anlage Nr.: 92/14 .....

Beschreibung der weiteren Arbeiten der Sicherheitsstufe 1 einschließlich Zielsetzung und Risikobewertung:

a) Allgemeine Beschreibung des Vorgehens

Describe procedures

b) Konkretes Vorhaben

Describe project in detail

c) Zusammenfassung der Risikobewertung nach § 6 Abs. 1 GenTG

Summarize risk assessment

Anlage zu Formblatt Z - 11/2011 - Berlin

Legal Background - Genetic Engineering Facility 92/14

Classification into Risk Groups

Genetic Engineering Facility

Safety Measures

Safety Measures

Rules of good laboratory practice

- Laboratory doors and windows must be closed
- Use personal protective equipment: coat, gloves, protective glasses
- Wear no synthetics and wear always long trouser & closed shows

- Eating, drinking, smoking, applying of cosmetics is forbidden in the labs and lab writing spaces
- Do not store jackets, bags, food & drinks in the lab or lab writing spaces
- Mouth pipetting is prohibited
- Avoid aerosol formation → *use sterile workbench, closed centrifuge tubes*
- Avoid use of needles and sharp items → do not recap needles

- Hands must be disinfected and washed according to the hygiene plan
- Keep laboratory tidy and clean

Safety Measures

Waste separation

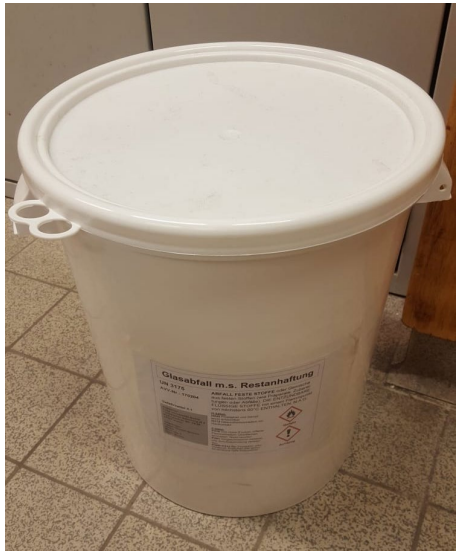
- **Waste separation** and **disposal of chemicals according to institute rules**

Recycling waste
(foil, plastic containers, …)

Residual waste
(paper towels, …)

paper
(no paper towels)

Solvent waste
(see label)



Glass/solid waste contaminated with chemicals

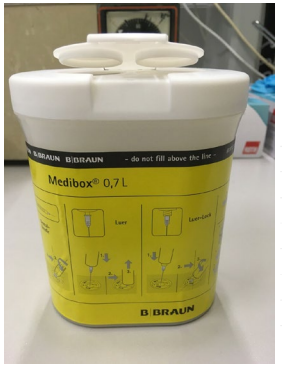
Safety Measures

Waste separation

- **Waste separation** and **disposal of chemicals according to institute rules**

- **Waste contaminated** with **bio agents or GMOs** *(bio waste)* is collected separately and **is autoclaved** before disposal

- Collect **sharp items contaminated** (needles, glass pipettes, glass slides, etc.) in **sharp items containers** → *do not put needles back in the cover*



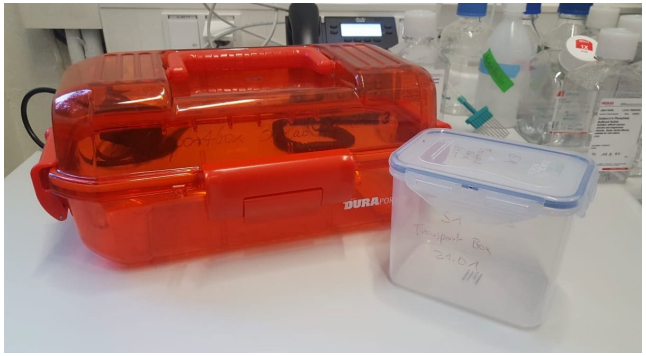
Safety Measures

Transport of waste and samples

- **Decontaminate items before leaving the lab**
  → no gloves outside of the labs
- **Inside the facility: appropriate containers**, e.g. bucket, waste bin or plastic box
- **Outside the facility: unbreakable, tightly closed** plastic **box, outside the university additionally** use a second layer (**paper box)** filled with **paper towels** to absorb any leaking liquid

➢ ***Make sure that the lab you sent the sample to is allowed to handle it***

Bio waste bins and transport bucket



transport containers

Safety Measures

Skin care

- **Wear gloves as long as necessary, but as short as possible**
- **Use skin care products** → *see hygiene plan*

Health check

- voluntary: gloves > 2 h/day
- obligatory: gloves > 4 h/day

Safety Measures

How to handle…
…liquid Nitrogen

- Always wear **safety glasses** and **gloves**
- Store and handle in **well-ventilated places**
- **Only** open cell container if **ventilation** is **on**
- Leave the room immediately, if a lot of liquid nitrogen is released!
- **Never use the elevator** with liquid nitrogen!
- Never attempt to manipulate the storage dewar!

…the autoclave?

- Use the autoclave only with introduction
- Liquids need to be autoclaved with open lid
- Wait with opening until autoclave has cooled down

Safety Measures

What to do in case of emergencies?

See emergency guide in each lab!

Keep calm !

☎ 112 or **55112 rescue service**

Emergencies (accidents, fire, etc.)

Follow instructions!

first-aid box: in lab E027, in office E001, in lab K004

first-aiders: Katharina, Elisa, Johanna (-54300)

Stand: 01.01.2020

Notfallplan für die gentechnische Anlage Nr. 92/14

Verhaltensmaßnahmen im Notfall

1. Ruhe bewahren!

2. Brand bzw. Unfall melden

Notfall/Erste Hilfe	→	→ 112
Notruf über Leitwarte FU	→	→ 55112
Ersthelfer	→	→ 54300
Feuerwehr:	→	→ 112
Polizei	→	→ 110

• **Projektleiter**	→	→ **Katharina Achazi**
Dienstl. Telefonnummer	→	→ 838-59145
Private Telefonnummer	→	→ 015203150552
• **BBS:**	→	→ **Bernhard Loll**
Dienstl. Telefonnummer	→	→ 838-57348
Private Telefonnummer	→	→ 0177/3503488

3. Inhalt der Meldung
   - **Was** ist passiert?
   - **Wo?** In welchem Gebäude/Stockwerk/Raum ist es passiert?
   - **Sind Menschen in Gefahr?**
   - **Wer** meldet? **(Name, Rufnummer)**

4. Weitere Maßnahmen
   - **Gefährdete Personen warnen und hilflose Personen in Sicherheit bringen**
   - **Türen und Fenster schließen**
   - **Löschversuch unternehmen**
   - **Gekennzeichneten Fluchtweg benutzen**
   - **Im Brandfall keinen Aufzug benutzen**

Spaltenumbruch

Role of conduct in case of emergency

1. Stay calm!

2. Report fire or accident

Emergency/First Aid	→	→ 112
FU emergency call	→	→ 55112
First aid helpers	→	→ 54300
Fire guard	→	→ 112
Police	→	→ 110

• **Project supervisor**	→	→ **Katharina Achazi**
official phone	→	→ 838-59145
private phone	→	→ 015203150552
• **BSO**	→	→ **Bernhard Loll**
official phone	→	→ 838-57348
private phone	→	→ 0177/3503488

3. Content of notification
   - **What** has happened?
   - **Where?** In which building/floor/room did it happen?
   - **Are people in danger?**
   - **Who** is calling? **(name, phone number)**

4. Additional measures
   - **alert other individuals working in the lab that there is a fire, try to rescue helpless individuals**
   - **close doors and windows**
   - **attempt to confine and/or extinguish the fire**
   - **use the labelled escape route**
   - **in case of fire do not use the elevators**

Safety Measures

What to do in case of an accident?

- **Take care for your own safety first**
- **Disinfect** contaminated **surfaces** & **instruments** (S1/Bio I: 70% EtOH, *BIO II: Meliseptol*) →
- **Remove** big **amounts** of **fluid** first with **cellulose paper**
- **Disinfect skin** with **Sterilium** (no open wounds), **rinse eyes** & **mucus membranes** with **water** → eye/body shower
- **Contaminated objects** (paper towels, lab coat & normal clothes) must be **autoclaved** in suitable containers
- **Treat injuries** immediately → if necessary call **(55)112**, a first aid helper **(54300)** or see a doctor
- Notice the doctor about hazardous substances/bio agents/GMOs
- **Report** all **injuries** to **me** (PL) or the **BBS** **without delay** and **document**

Freie Universität Berlin

COVID-19 prevention measures

- **Wear a mask** at all times *(no synthetic mask while working with solvents or fire)*
- **Maintain** a **distance of** at least **1.5** meters to other persons, if this is not possible wear a FFP2 mask
- **Obey** the **max. number of persons per room** indicated & **book labs in advance** via Wiki calendar (Measurement/ Biolabs AG Haag)
- **Wash/disinfect hands** regularly
- **Record your presence** in each lab/room every day
- **Follow signs**, **posters** & **announcements** and check information from university (https://www.fu-berlin.de/sites/coronavirus) → Phase 2
- **Stay at home, if you have symptoms**, you are a contact person or you have corona (report to university and your boss)

Fachbereich Biologie, Chemie, Pharmazie

CO

- **Wear**
- **Main**

this is

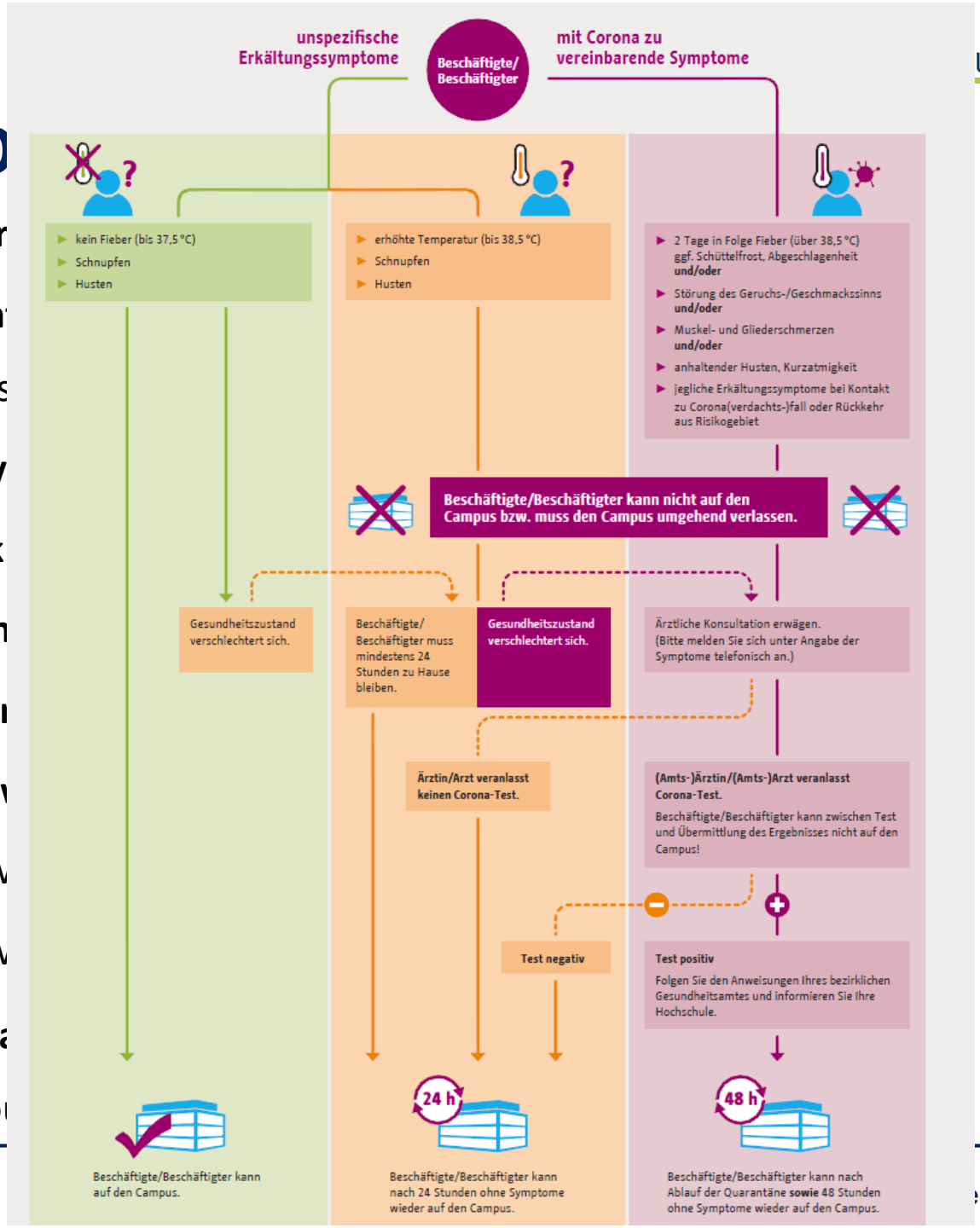
- **Obey**
- **Book**
- **Wash**
- **Reco**
- **Follo**

https://w

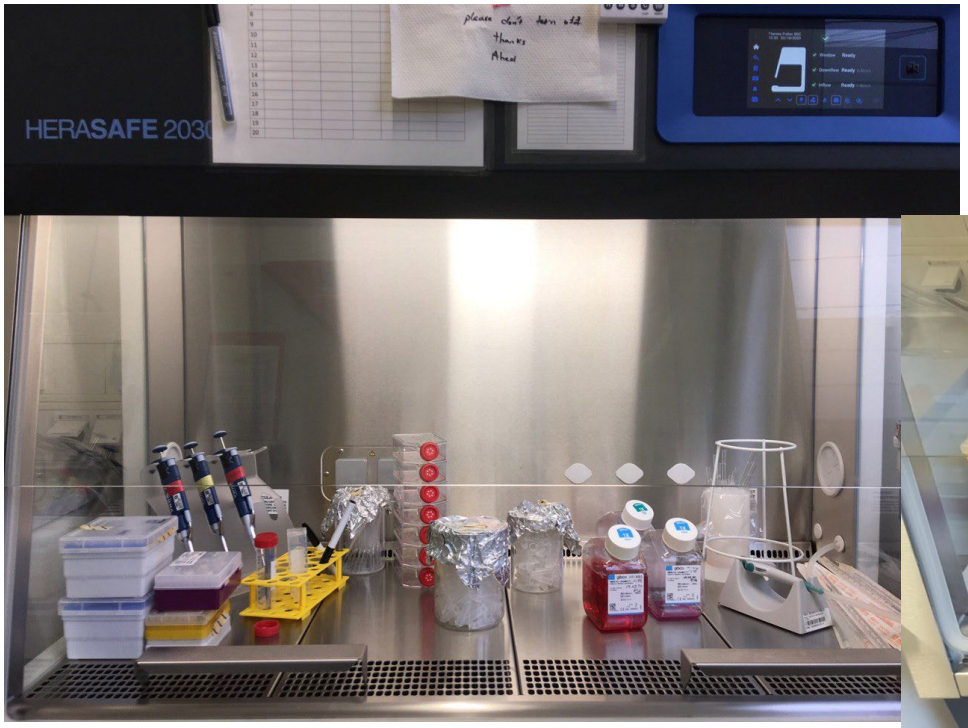
https://w

- **Stay a**

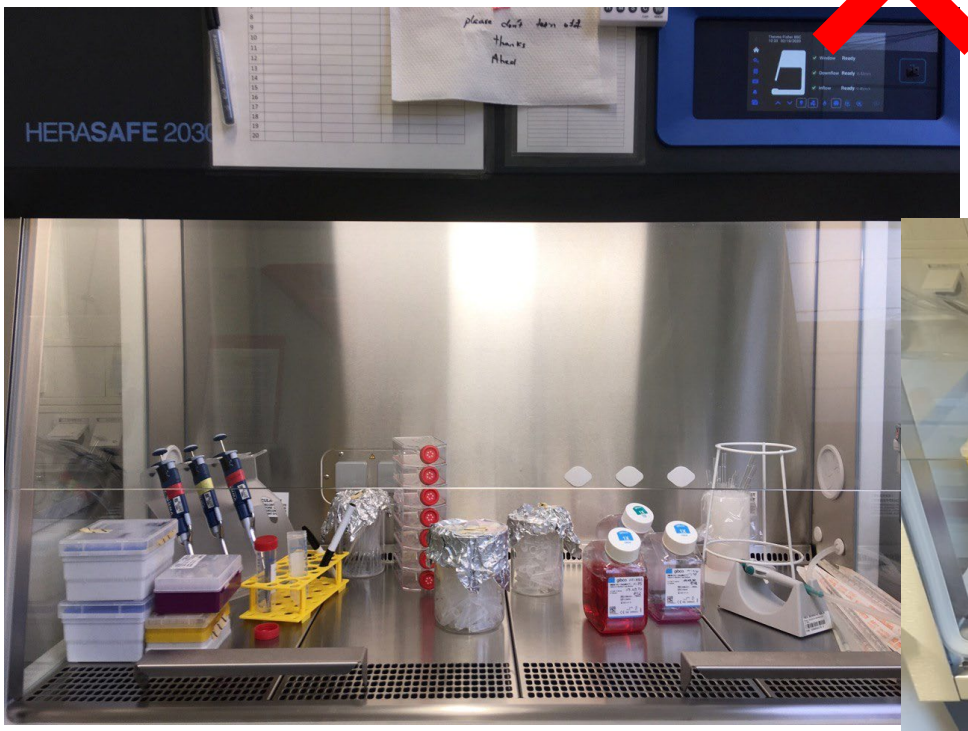
or yo



Safety Measures - Do`s and Dont`s



Safety Measures - Do`s and Dont`s



Safety Measures - Do`s and Dont`s

https://www.youtube.com/watch?v=KqaWM5Dd15c

Safety Measures - Do`s and Dont`s

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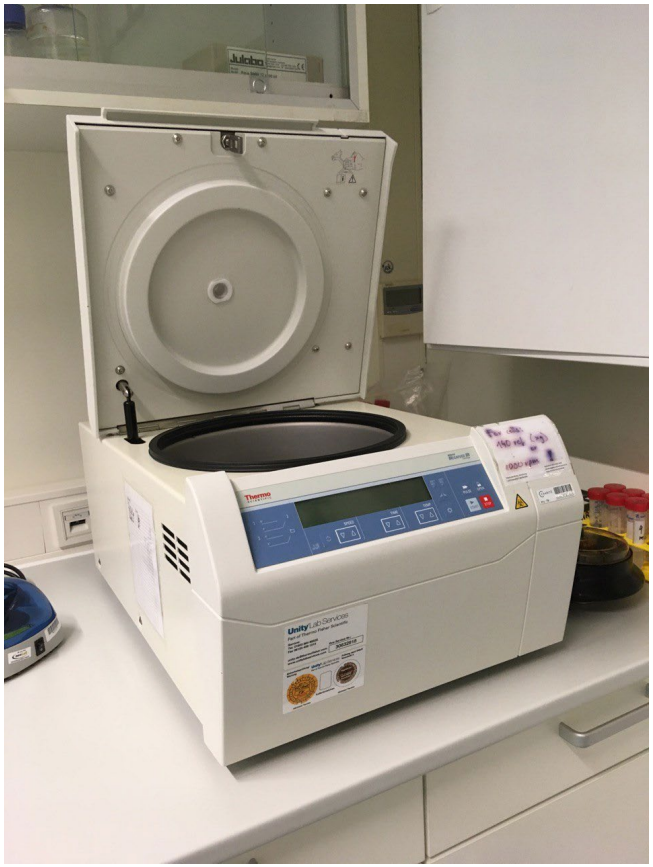
Safety Measures - Do`s and Dont`s



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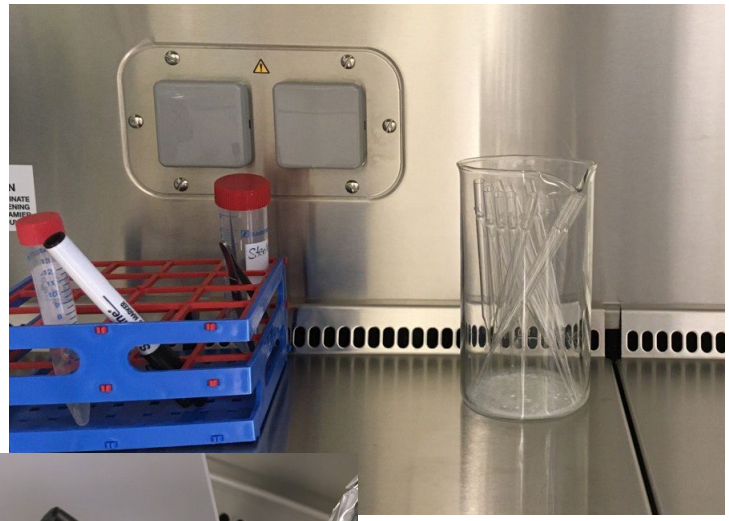

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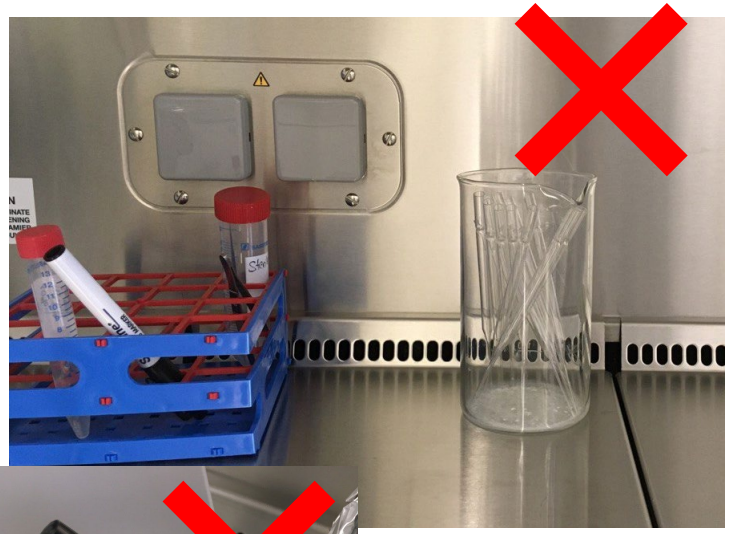

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Safety Measures

Relevant **safety documents** can be found directly in the lab as print outs, in my office E001 and the Haag wiki:

https://wikis.fu-berlin.de/display/tas/Biolab+Safety

Further safety information is provided by the departments homepage

and the homepage of the occupational safety service
https://www.fu-berlin.de/sites/baas/index.html

Thank you for your attention!