

Checkliste KD01202048

Internal Biosafety Audit

Procedure is describe in Internal Biosafety Audit Procedure [KD01202052](#)

Based on checklists according to the "Einschliessungsverordnung" (ESV) of BAFU.

General data for audit	
Date	
Participants (name)	
Inspected rooms (Building, room number, Biosafety Level)	

1. General details

Nr.	Basic Data Laboratory/Group	
1.1	Department Institut Group	
1.2	Sub-BSO (Name)	
1.3	PI (Name)	
1.4	Reported activities (ECOGEN-NR, BSL) Reported activities in progress	
1.5	External User	

2. General Safety measures

Nr.	Safety measures	fulfilled		
		Yes	No	?
2.1	Are operating instructions and rules of conduct available?	☐	☐	☐
2.2	Are appropriate internal training sessions on biosafety conducted regularly?	☐	☐	☐
2.3	Are all projects at Ecogen registered and kept up to date?	☐	☐	☐
2.4	Is there at least one sub biosafety officer (BSO)?	☐	☐	☐
2.5	Are washing and decontamination facilities provided for employees?	☐	☐	☐
2.6	Are eyewash stations available?	☐	☐	☐
2.7	Are the monitoring measures and equipment properly monitored, inspected, and maintained?	☐	☐	☐
2.8	If necessary, is the presence of viable organisms used in the work outside the primary physical containment barriers tested?	☐	☐	☐

2.9	Are appropriate storage facilities used for potentially contaminated equipment and materials?	☐	☐	☐
2.10	Are effective disinfectants and procedures in place in case of an accidental release of organisms?	☐	☐	☐

3. Good Laboratory Practice (GLP)

Nr.	Safety measures	fulfilled		
		Yes	No	?
3.1	Are the doors and windows of the work areas always kept closed?	☐	☐	☐
3.2	Is eating, drinking, smoking, using snuff, applying makeup, and storing food in the work areas prohibited?	☐	☐	☐
3.3	Is mouth pipetting strictly prohibited?	☐	☐	☐
3.4	Are syringes and needles used only when absolutely necessary?	☐	☐	☐
3.5	Are syringes and needles disposed of safely in sharps containers?	☐	☐	☐
3.6	Is it ensured that no avoidable aerosols are generated during all work activities?	☐	☐	☐
3.7	Are hands thoroughly washed after completing a work step or when leaving the laboratories? Are they washed after any potential contamination?	☐	☐	☐
3.8	Are the work areas kept tidy and clean?	☐	☐	☐
3.9	Are only the necessary materials and equipment kept available?	☐	☐	☐
3.10	Are the workspaces cleaned after completion of work?	☐	☐	☐
3.11	Are supplies stored only in designated rooms or cabinets?	☐	☐	☐
3.12	Is the identity of the microorganisms used regularly verified?	☐	☐	☐
3.13	Does the frequency of the checks correspond to the level of risk?	☐	☐	☐
3.14	Are the inspection results evaluated?	☐	☐	☐
3.15	Are employees instructed in the handling of GMOs specific to their workplace (before starting work and at least once per year)?	☐	☐	☐

3.16	Are inexperienced employees in microbiology informed about potential hazards, instructed, and adequately supervised?	☐	☐	☐
3.17	Is pest control implemented (rodents and insects)?	☐	☐	☐
3.18	Is access to the laboratory by animals prohibited?	☐	☐	☐

4. Additional safety measures (research and development laboratories, analysis of clinical material)

4.1 Building

Nr.	Safety measures	Biosafety Level		fulfilled		
		1	2	Yes	No	?
4.1.1	Is the work area separated?	No	Yes	☐	☐	☐
4.1.2	Are there operable windows?	No	No	☐	☐	☐
4.1.3	Is the work area sealed in such a way that fumigation is possible?	No	No	☐	☐	☐
4.1.4	Are biohazard warning signs posted at the entrance to the controlled area?	No	Yes	☐	☐	☐
4.1.5	Are devices located outside or in Biosafety Level 1 areas, but used for organisms of group 2 or higher (e.g. freezers), labeled with the biohazard warning sign?	Yes	Yes	☐	☐	☐
4.1.6	Is access to the work area restricted (entry only with a key/access card/code, list of authorized personnel, etc.)?	No	Yes	☐	☐	☐
4.1.7	Is access to the work area provided via an airlock?	No	No	☐	☐	☐
4.1.8	Is the airlock equipped with facilities for disinfection and handwashing (touch-free operation)?	No	No	☐	☐	☐
4.1.9		No	No	☐	☐	☐

	Is a viewing window or another device for observing the work area available?					
4.1.10	Are alarm systems in place for persons working alone?	No	No	☐	☐	☐
4.1.11	Are devices available to facilitate communication with persons outside the work area?	No	No	☐	☐	☐
4.1.12	Is an atmospheric negative pressure maintained in the work area (including the airlock) compared to the immediate surroundings?	No	No	☐	☐	☐
4.1.13	Is a separate room ventilation system installed?	No	No	☐	☐	☐
4.1.14	Is the work area supplied with directed airflow ventilation?	No	Yes	☐	☐	☐
4.1.15	Is the circulation of air into other areas of the building prevented?	No	Yes	☐	☐	☐
4.1.16	Does the design of the room ventilation prevent reverse airflow and positive atmospheric pressure in the laboratory in the event of an incident?	No	No	☐	☐	☐
4.1.17	Is an alarm device provided for the event that negative pressure can no longer be maintained?	No	No	☐	☐	☐
4.1.18	Is the room ventilation system connected to a backup power supply?	No	No	☐	☐	☐
4.1.19	Is the room ventilation system operable from outside the area (in case of fumigation)?	No	No	☐	☐	☐

4.1.20	Is the exhaust air from the work area filtered through HEPA filters?	No	No	☐	☐	☐
4.1.21	Can used HEPA filters be sterilized before replacement or removed without contact, immediately sealed airtight, and then sterilized?	No	Yes	☐	☐	☐
4.1.22	Are any floor drains properly sealed?	No	Yes	☐	☐	☐

4.2 Equipment

Nr.	Safety measures	Biosafety Level		fulfilled		
		1	2	Yes	No	?
4.2.1	Are the workbench surfaces resistant to acids, alkalis, solvents, and disinfectants?	Yes	Yes	☐	☐	☐
4.2.2	Is the floor surface resistant to acids, bases (alkalis), solvents, and disinfectants?	No	No	☐	☐	☐
4.2.3	Is the work area fully equipped with its own dedicated equipment?	No	No	☐	☐	☐
4.2.4	Is a microbiological safety cabinet available and appropriately positioned?	No	Yes	☐	☐	☐
4.2.5	Are measures taken to prevent aerosol formation?	No	Yes	☐	☐	☐
4.2.6	Is an autoclave available, and is it installed in an appropriate location?	Yes	Yes	☐	☐	☐
4.2.7	Are centrifuges with aerosol-tight lids (e.g. with O-rings) used?	No	Yes	☐	☐	☐
4.2.8		No	Yes	☐	☐	☐

	Are the sterilization temperature and cycle duration recorded by the autoclave?					
4.2.9	Are shower facilities provided?	No	No	☐	☐	☐

4.3 Work organization

Nr.	Safety measures	Biosafety Level		fulfilled		
		1	2	Yes	No	?
4.3.1	Are the inspection and maintenance of the autoclave and other equipment ensured and carried out regularly?	Yes	Yes	☐	☐	☐
4.3.2	Is the sealing integrity of the centrifuge cups checked?	Yes	Yes	☐	☐	☐
4.3.3	Is centrifugation performed using closed centrifuge tubes or cups?	Yes	Yes	☐	☐	☐
4.3.4	Are individuals entering the work area informed about the activities performed there?	Yes	Yes	☐	☐	☐
4.3.5	Is dedicated protective clothing worn in the work area?	Yes	Yes	☐	☐	☐
4.3.6	Are clothing and personal protective equipment (PPE) that may be contaminated with microorganisms cleaned and disinfected if necessary?	Yes	Yes	☐	☐	☐
4.3.7	Are protective clothing and normal clothing stored separately in appropriate facilities?	Yes	Yes	☐	☐	☐
4.3.8	Are gloves worn?	No	Yes	☐	☐	☐

4.3.9	Is all skin contact with rDNA and microorganisms avoided?	Yes	Yes	☐	☐	☐
4.3.10	Are workspaces regularly disinfected?	No	Yes	☐	☐	☐
4.3.11	Are workspaces disinfected after a spill has occurred?	Yes	Yes	☐	☐	☐
4.3.12	Are microorganisms in the drainage systems of sinks, pipes, and showers inactivated?	No	No	☐	☐	☐
4.3.13	Are microorganisms in contaminated materials, waste, and contaminated equipment inactivated?	Yes	Yes	☐	☐	☐
4.3.14	Is waste containing organisms collected separately from other waste?	Yes	Yes	☐	☐	☐
4.3.15	Are syringes and needles safely disposed of using sharps containers?	Yes	Yes	☐	☐	☐
4.3.16	Is waste properly labeled (e.g. indicating the type of waste and biohazard symbol from level 2 onwards)?	Yes	Yes	☐	☐	☐
4.3.17	Is the internal transport of organisms, organism-containing materials, and waste properly carried out using closed, leak-proof, and break-resistant containers?	Yes	Yes	☐	☐	☐
4.3.18	Is the external transport of organisms, organism-	Yes	Yes	☐	☐	☐

	containing materials, and waste carried out in compliance with ADR/SDR using closed, leak-proof, and break-resistant containers?					
4.3.19	Are the organisms stored in secure containers inside the facility?	Yes	Yes	☐	☐	☐
4.3.20	Are measures in place to prevent stored organisms from entering the wastewater system (e.g. in the event of a power outage)?	Yes	Yes	☐	☐	☐
4.3.21	Is there an instruction requiring that any employee injuries must be reported immediately to the project leader and the biosafety officer (BSO)?	Yes	Yes	☐	☐	☐
4.3.22	Are all employees aware of this regulation?	Yes	Yes	☐	☐	☐
4.3.23	Is protective clothing worn exclusively within the work area and taken off before leaving the area?	Yes	Yes	☐	☐	☐



Agreement (with deadline):

Recommendations:

BSO	Nicole Meili	Sub-BSO	
BSO Stv.	Giulio Marcionelli	PI	