Complementary Technical Directive to LEX 1.5.1: Safety Concept as Defined by the ContainO and OPTM for Laboratories Working with Biological Material

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The English version is provided for information purposes only and has no legal force. Only the French version is legally binding

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1. General Provisions

1.1. Scope and Validity of the Concept

This safety concept is mandatory for implementing legal requirements related to activities involving pathogenic, genetically modified, or exotic organisms in controlled environments. All concerned units and individuals must comply with the concept within their areas of responsibility.

1.2. Safety Objectives

The development of a biological safety concept is based on three key factors:

a) Activities involving biological materials carry inherent risks to humans, animals, and the environment that can never be completely ruled out.
b) Biological material is rarely used on its own. It may be combined with chemical hazards (e.g., toxic substances, nanomaterials), physical hazards (e.g., radioactivity, lasers), or mechanical hazards (e.g., sharp objects).
c) Conducting experiments involving biological material requires appropriate infrastructure and specialized equipment.

Thus, only a comprehensive safety approach can achieve the goal of creating an environment where staff can work safely and feel comfortable. Ultimately, it is also about taking all necessary measures to ensure that neither the environment nor external individuals - such as visitors, third-party company employees, staff family members, or the general public - are put at risk.

1.3. Definitions

For the purposes of this document, the following definitions apply:

ContainO: Ordinance on Handling Organisms in Contained Systems (**Containment Ordinance**).

OPTM: Ordinance on Protection of Workers from Risks Related to Microorganisms.

MAO: Ordinance on Protection against Major Accidents.

OPRoMa: Ordinance on Maternity Protection.

Release Ordinance, RO: Ordinance on the Handling of Organisms in the Environment.

CFST: Federal Coordination Commission for Occupational Safety.

ECOGEN: Federal electronic database used for entering notification and authorization procedures according to the ContainO.

Biosafety Officer (BSO): "Person responsible for biosafety". The role of the BSO is related to activities that require notification under the ContainO. The name of the BSO for a given activity is indicated on the Ecogen notification/authorization.

Project Leader: Person responsible for activities subject to notification under ContainO. Generally, the Project Leader is also the head of the unit.

OHS: The Occupational Health and Safety Service of EPFL.

DSE: Safety and Operations Domain of EPFL.

EPFL Biosafety: A group of individuals within the OHS Service composed of biosafety specialists.

COSEC: Safety Correspondent at EPFL, appointed by the head of the unit.

SIS: The "Security, Intervention, and Safety" Service of EPFL.

GIU: Emergency Intervention Group of EPFL.

2. Organization and General Responsibilities for Safety at EPFL

2.1. Civil Liability

The organization of safety at EPFL is defined by LEX 1.5.1, titled " Directive concerning occupational health, safety and security at EPFL." This document governs occupational health and safety (OHS) measures and outlines the responsibilities of various parties, including the EPFL Directorate, Vice Presidencies, DSE (Safety and Operations Domain of EPFL), Faculties, and research units.

The EPFL Directorate is responsible for safety, including biological safety, across the institution's campuses.

The Directorate ensures operational safety measures to protect humans, the environment, and workplace conditions[1]. It establishes the necessary organizational structure to implement the school's safety program. It defines the organizational structure required for this purpose.

EPFL is, by principle, responsible towards third parties. It may act against employees who intentionally or through gross negligence violate safety regulations and, as a result, cause damage to the school or to third parties for which EPFL is liable. The principle that applies to

[1] Article 7, paragraph 2bis, of Ordinance 3 October 1st, 2015, relating to Health protection (OLT 3, RS 822.113) explicitly states « Assigning such tasks to a worker does not relieve the employer of their obligation to ensure health protection. »

all individuals at EPFL responsible for safety aspects is that criminal liability arises from compliance with the safety guidelines applicable in their area of responsibility. Only individuals who, by virtue of their position, can eliminate hazards by intervening personally can be held criminally responsible as guarantors. This occurs when they fail to intervene where it was necessary and where they had the possibility to do so.

2.2. Organization and Responsibilities for Biological Safety at EPFL

The use of genetically modified, pathogenic, or exotic organisms can pose risks both to the users, to the population and to the environment. The appropriate safety measures that must be taken to minimize these risks are defined by two ordinances: the OPTM[2] (Ordinance on Protection of Workers from Risks Related to Microorganisms) and the ContainO[3] (Ordinance on Handling Organisms in Contained Systems).

The OHS service defines the biosafety needs and establishes general rules in accordance with the legal requirements described in the ordinances. To ensure workplace safety and health protection, it has the authority to prohibit work involving biological hazards if the situation is deemed critical.

Point 1(c) of Annex 4 (Article 12) of ContainO defines the assignment of at least one person to monitor biological safety within a company.

The roles, qualifications, and duties of the individuals responsible for biological safety are described in Annex 4 of the ContainO (Point 1c) and in the guidance document 'Management of Biological Risks in Contained Environments' published by the FOEN[4].

At EPFL, biological safety monitoring is carried out by the ‘EPFL Biosafety’ team and by the biological safety officers (BSOs) of the units working with genetically modified, pathogenic, and/or exotic organisms.

2.2.1. Tasks and Responsibilities of ‘EPFL Biosafety’

‘EPFL Biosafety’, integrated within the OHS Service, is composed of a coordinator and biosafety specialists.

‘EPFL Biosafety’:

- Develops and updates the ‘EPFL Safety Concept for Laboratories Working with Biological Materials. The safety concept is validated by the head of the OHS service and the head of the DSE department.
- Publishes the basic rules regarding work in biological laboratories and the proper disposal of microbiological waste.
- Prepares and provides mandatory training for users of Biosafety Level 2 and 3 (BSL 2 and BSL 3) laboratories, as well as for auxiliary staff.
- Prepares and delivers training/information sessions for the BSOs of the units.

[2] Ordinance of August 25,1999 on the protection of workers against risks related to microorganisms (OPTM, RS 832.321)
[3] Ordinance of May 9, 2012 on the use of organisms in contained systems (ContainO, RS 814.912)
[4] Federal Office for the Environment FOEN, Managing biological risks in contained systems, 2021, The environment in practice No 2118: 17 pp

- Develops and updates the environmental impact assessment file according to the MAO[5] for BSL 3 laboratories.
- Supports Project leaders and/or BSOs in risk assessments
- Supports Project leaders and/or BSOs in administrative procedures (notifications and/or authorization requests) related to organisms and activities subject to notification under ContainO.
- Advises Project leaders and BSOs on the implementation of biosafety rules within their unit.
- Supports units regarding regulations on the transportation of biological materials.
- Establishes safety data sheets for organisms.
- Maintains the biological hazard registry across all EPFL sites.
- During audits, ensures that activities and microorganism management comply with ContainO. It also verifies that activities are properly reported, and that notifications or authorization requests reflect the activities of the research unit.
- In collaboration with the SIS service, organizes access control regulations, ensuring that only authorized personnel can access Biosafety Level 2 and 3 areas.

'EPFL Biosafety', is the point of contact for cantonal, federal authorities, SUVA, and others. It is present during audits conducted by these authorities.

2.2.2. Duties of the Project leader

The Project leaders must be aware of the project activities and the associated risks. He/She informs the staff about the health risks related to the use of biological materials.

He/She must ensure that the work methods and procedures implemented are safe (in accordance with the risk assessment) and that the safety measures specific to the group's activities are in place.

The Project leader is the person who notifies the federal authorities about the use of genetically modified, pathogenic, or exotic organisms. The declaration of the use of such organisms and the type of activity conducted is mandatory.

The person responsible for a project involving genetically modified, pathogenic, or exotic organisms appoints a biosafety officer (BSO). Together, they submit the project to 'EPFL Biosafety' for evaluation according to the provisions of the ContainO.

With the approval of 'EPFL Biosafety' and its administrative support, they will notify the federal authorities according to the current procedure.

The Project leader ensures that the laboratory staff implements:

- Safety provisions and principles of good microbiological practices
- Proper disposal of microbiological waste
- Internal guidelines for the shipment or transportation of biological materials

At EPFL, in principle, this role of Project leader is assigned to the head of the unit. If this is not the case, responsibilities and tasks must be clearly defined between these two roles.

[5] Ordinance 27 February 1991 on Protection against Major Accidents (MAO, RS 814.012)

2.2.3. BSO: Qualifications, Tasks, and Responsibilities

The BSO is appointed by the Project leader for projects notified in Ecogen. According to the guidance provided by the FOEN[4], the role of the BSO should be independent from that of the Project leader to avoid conflicts of interest that could lead to a biological risk situation.

The Project leader must provide the BSO with the necessary resources in terms of time and money to carry out their tasks and must ensure their participation in training related to biological safety. Each BSO must have practical knowledge in biology and specific knowledge of the biological hazards present in their unit. They must also attend specific training for the BSO role (offered externally or organized by 'EPFL Biosafety').

At EPFL, the tasks and responsibilities of unit BSOs are:

- Informing, advising, and training the staff of their research group (including external guests) on the specific methods used in the laboratory and the proper use of equipment
- Ensure the dissemination of the directives established by 'EPFL Biosafety'
- Knowing the procedures in case of a biological accident
- Ensuring compliance with biosafety rules
- Organizing the periodic cleaning plan for BSL 2 laboratories
- Establishing an inventory of organisms used and/or stored in the laboratory
- In coordination with the Project leader, communicating significant changes to an activity that may require a reevaluation of the risk and/or an update of the notification/authorization to 'EPFL Biosafety'
- Writing and maintaining a safety concept specific to the activities announced in their unit

The role of the BSO is defined in the job description of the employee to whom this role has been assigned.

The BSO may also serve as the safety correspondent at EPFL (COSEC).

3. Responsibilities in Biological Security

Point 1(c) of Annex 4 to Article 12 of ContainO defines the assignment of at least one person to the prevention of improper use of organisms. « Improper use of organisms » means the handling of organisms subject to a containment obligation which illegally and intentionally endangers or harms humans, animals, the environment or biological diversity and their sustainable use (Art. 3, letter j, ContainO).

At EPFL, unit heads are responsible for the biological security of the organisms used in their projects. They implement all necessary measures to minimize the risk of improper use of organisms.

The heads of the units are responsible for the acquisition, use, storage, and transfer of any biological material that poses a risk of misuse. They must inform the dean of their faculty and obtain their approval before acquiring or using such material. The same procedure applies if the course of their experiments leads to the generation of such organisms. 'EPFL Biosafety' must also be informed.

4. Risk Assessment

4.1. Internal Procedures for Projects Subject to Notification/Authorization Under ContainO

Activities involving biological material may, depending on the nature of the material or the environment in which it is used, be subject to a notification or authorization procedure under the ContainO (Articles 8-10) and OPTM (Articles 5 and 6).

The purpose of the description below is to ensure the proper execution of the notification and authorization request processes according to ContainO.

For the use of genetically modified or pathogenic organisms in non-contained environments, a separate dossier must be prepared in accordance with the ODE[6] .

4.1.1. Notification of a New Activity

The head of the unit reports any use of biological material or organisms to 'EPFL Biosafety' and provides the following information electronically (by email: biosafety@epfl.ch or via ticket: https://go.epfl.ch/support-ohs):

- The title of the activity
- The name of the head of the unit and the BSO
- A description of the activity or activities (e.g., the description found on the project's website or the summary of a funding application to the Swiss National Science Foundation)
- A representative list of organisms used or newly introduced, with typical examples from a biosafety perspective. This list must cover the range of organisms used in the project. All group 3 organisms that might be used must be mentioned
- The list of rooms where the activities will take place, or the list of new rooms or rooms that will no longer be used
- The method of waste inactivation

'EPFL Biosafety' determines whether the submission of notifications or authorization requests to the federal authorities is required.

If it is not necessary to submit a notification or authorization request to the federal authorities, an internal risk assessment must nevertheless be conducted and documented to determine whether specific safety measures need to be implemented.

'EPFL Biosafety' enters the notification/authorization dossier into the electronic database Ecogen. The unit head validates the dossier via email/ticket. The information is then transmitted to the Federal Biotechnology Office, which verifies the completeness of the notifications and authorization requests. Complete dossiers are subsequently forwarded to the relevant federal offices. The relevant federal offices provide their decision within 90 days of confirming that the dossier is complete. The procedure varies depending on the activity class. Authorizations for class 3 activities are valid for a maximum of five years.

4.1.2. Modification of an Activity

Any significant modification of an activity that involves a re-evaluation of the risk must be reported.

[6] Ordonnance du 10 septembre 2008 sur l'utilisation d'organismes dans l'environnement (ODE, RS 814.911)

An update to the notification/authorization is required when:

- New organisms[7] from groups 1 and 2, with properties different from those observed in the organisms initially declared, are used or generated
- New organisms from group 3 are used
- New steps that create a new risk or an additional risk are introduced
- A new type of installation is required for work with the organisms
- If the use of organisms tested in a contained environment is planned in a non-contained environment, a new procedure and the opening of a new dossier according to the Release Ordinance must be carried out
- A renewal request for class 3 authorizations

The notification/authorization must also be updated in the case of administrative changes such as:

- A change in the head of the unit or BSO
- A change in the unit's address or a move to a new site
- The cessation of the activity
- The use of additional premises or other premises that were not previously declared

The unit head or BSO promptly communicates all the above-mentioned changes to 'EPFL Biosafety', so that the new information can be entered into Ecogen.

4.2. Management of Organisms

A biological agents management plan must be established by each unit.

The responsibility for managing the organisms lies primarily with the units that declare the use of these organisms in a notification/authorization.

The management plan must include at least:

- A risk assessment
- Handling procedures for the organism
- Procedures in case of an accident
- A storage organization plan
- An inventory of organisms

Units may use organism safety data sheets (see paragraph 4.2.1) as a reference document for developing the organism management plan.

4.2.1. Safety Data Sheet for Organisms

'EPFL Biosafety' publishes safety data sheets for organisms used in the various units of EPFL. Each sheet includes:

- A general description of the organism (name, biological characteristics, pathogenicity and toxicity, hosts, mode of transmission, infectious dose, presence of toxins)
- A risk assessment (hazards in the laboratory context, risky handling procedures, viability and stability, sensitivity to disinfectants)

[7] If new organisms are used and an authorization has been granted for the omission of one or more safety measures, it is necessary to ensure that the authorization is extended to include the new organisms, provided that the same safety measures can also be omitted for handling these organisms.

- Safety instructions (good microbiological practices, personal protective equipment, procedures in case of an accident)
- Key instructions in case of an accident for EPFL's Emergency Intervention Group (GIU)

All the safety data sheets published by 'EPFL Biosafety' are available to all EPFL BSO, the OHS service, and the GIU.

5. Training

The DSE (Safety and Operations Domain of EPFL) organizes basic safety training courses (FOBS)[8]. All EPFL staff members must, at a minimum, complete FOBS Level 1 (FOBS 1): fire safety, first aid, and occupational hygiene. Personnel working in laboratories are required to complete FOBS 2: laboratory hazards and risks, safety equipment, chemical management, and waste management.

Users of BSL 2 and/or BSL 3 laboratories must complete FOBS Level 3 - Biological Risks. This training provides general principles on good microbiological practices in BSL 2 and BSL 3 laboratories. Without this training, laboratory access rights are not granted.

Support staff (e.g., cleaning teams, emergency response teams) must also complete mandatory training to access BSL 2 laboratories; training specifically tailored to each job category is organized by 'EPFL Biosafety'.

5.1. Training provided by the BSO for BSL 1 laboratories

Users (including students, guests, and visitors) of BSL 1 laboratories must be trained by the BSO of their respective unit.

This training must cover at a minimum the following aspects:

- Good microbiological practices specific to the laboratory context
- Waste management and inactivation procedures
- Consultation and updating of the organism inventory

5.2. Training provided by the BSO for BSL 2 and BSL 3 laboratories

Users (including guests and individuals external to the research unit) of BSL 2 and BSL 3 laboratories must be trained by the BSO of their respective units.

Each group working with pathogens establishes specific procedures based on the organism management plan. This training aims to introduce the specific features of the laboratory to the various users.

This training must cover at a minimum the following aspects:

- Information on the pathogens used in the laboratory
- Procedure for the use of personal protective equipment (PPE)
- Procedure for using the microbiological safety cabinet and other instruments in the laboratory
- Procedure for disinfecting surfaces and equipment
- Procedures for the inactivation of solid and liquid waste
- Procedure for the transport of pathogens

[8] https://www.epfl.ch/campus/security-safety/en/trainings/

- Procedure for the storage and use of organism inventory
- Procedure in case of an accident

Organism safety data sheets, describing the characteristics of pathogenic agents and possible symptoms in case of infection, are provided by the BSO to inform each user about the specific organisms handled in the laboratory.

Users of BSL 3 laboratories are required to attend an annual refresher course[9] organized by "EPFL Biosafety".

6. Safety Measures and Behavioral Rules

6.1. Infrastructures

6.1.1. Premises

Faculties define the infrastructure they require. In collaboration with the DSE, they establish the specifications for special-purpose rooms, considering specific safety measures (technical, operational, and organizational).

Facilities where biological activities take place must comply with the standardization guidelines issued by the DSE. The technical requirements outlined in these documents are based on the safety measures specified in Annex 3 of the OPTM, Annex 4 of ContainO, and the CFST[10] guidelines. The OPTM may request additional measures if necessary to ensure the protection of staff. The different DSE departments consult the 'EPFL Biosafety' team when establishing standardization documents ("*cahiers de normalization")* for biological laboratories.

No room can be designated for biological activities of level 2 or 3 without validation from the DSE.

The OHS service participates in the planning and installation of BSL 2 and BSL 3 laboratories. 'EPFL Biosafety' verifies the compliance of BSL 2 and BSL 3 installations according to the OPTM and ContainO criteria before they are put into operation. It participates in the acceptance of the premises at the end of the work and is involved in any modification projects or technical interventions.

For level 3, 'EPFL Biosafety' prepares the environmental impact study file according to the MAO and defends it with the General Directorate of the Environment (DGE) of the Canton of Vaud. It is also responsible for submitting the plans to SECO for approval in accordance with Article 37 of OLT 4[11].

[9] According to Article 11, paragraph 1 of the OPTM, information and training must be repeated regularly and, if necessary, adapted to the evolution of risks.

[10] https://www.ekas.admin.ch/fr/centre-dinformations/directives-de-la-cfst

[11] Ordinance 4 of 18 August 1993 relating to the Labour Act, Industrial enterprises, approval of plans and operating permits (OLT 4, RS 822.114)

6.1.1.1. Access Control for BSL 2 Laboratories

Access to BSL 2 laboratories is controlled by a CAMIPRO card reading system. Each EPFL member has their own CAMIPRO card, which serves as an identification card across the entire EPFL campus.

Users of the BSL 2 laboratories on the Ecublens campus request activation of access rights to an BSL 2 room on their CAMIPRO[12] card through the AxS[13] access management system. The request is accepted after a validation process involving: the BSO responsible for the room, the unit manager, and 'EPFL Biosafety'. Access to an BSL 2 room is only possible if the requester is registered or has completed the mandatory training "FOBS3 - Biological Risks".

When a person's access request is accepted, an automatic notification informs the EPFL Occupational Medicine team to assess the person's medical fitness to carry out the planned activities.

Access for support staff is directly controlled by 'EPFL Biosafety', which requests the activation of the CAMIPRO card via email to the Alarm and Engagement Center (CAE).

'EPFL Biosafety' has access to the complete list of individuals who are authorized to access the BSL 2 laboratories. Each BSO can request the list of individuals who have access to the laboratory(ies) they are responsible for.

6.1.1.2. Access Control for BSL 3 Laboratories

Access to BSL 3 laboratories is controlled by biometric systems managed by the Alarm and Response Center (CAE). Access is granted only after specific training and the approval of 1) EPFL Occupational Medicine; 2) the BSO; 3) "EPFL Biosafety"; and 4) the SV Faculty.

6.1.1.3. Signage of the Work Area

Door safety sheets indicate the most critical hazards present in each room, the corresponding safety instructions, and the emergency contacts. They are created and issued by the safety correspondents (COSEC) and are reviewed during safety audits by OHS staff. The door sheets specify: the highest-risk hazards specific to each room, the obligations and prohibitions related to the activities carried out there, the room supervisor, the COSEC, the BSO, and the emergency contacts.

The door sheet is prepared by the COSEC responsible for the room. It must be updated once a year or whenever the activities conducted in the room change.

For BSL 2 and BSL 3 laboratories, the door sheet must indicate the biological safety level, the "Biohazard" symbol, a list of the main organisms handled, and the required personal protective equipment (PPE).

In addition to the door sheet, a "Biohazard" label and a "No entry for unauthorized persons" label must be affixed to the main entrance door of BSL 2 and BSL 3 zones.

6.1.2. Fixed Installations

DSE-EXPL is responsible for the implementation, proper functioning, and maintenance of technical installations, including all electrical systems that are an integral part of the building

[12] https://www.epfl.ch/campus/services/camipro/

[13] https://camipro-axs.epfl.ch/axs/public/workflow_new.xhtml?filterid=235152

(e.g., *Ex* cabinets for chemical storage, fume hoods, or laboratory ventilation systems are typically considered fixed technical installations).

Any intervention on a fixed installation within a level 2 or 3 facility may only be carried out after approval from “EPFL Biosafety”.

Users are required to alert the Alarm and Response Center (CAE) to number 3400 (021 695 40 00) as soon as any installation is not functioning properly.

6.1.3. Instruments and Equipment Belonging to the Units

The Project leader (or by delegation, their COSEC or the BSO) must ensure compliance and quality of work equipment at the time of acquisition. They are particularly responsible for providing users with the instruction manual and the equipment’s declaration of conformity.

They must also organize a maintenance plan and regularly check the condition and proper functioning of instruments that may pose a microbiological risk to the user (e.g., microbiological safety cabinets, incubators, centrifuges, autoclaves). If necessary, they are responsible for repairing or replacing the equipment. Depending on the operational structure of the faculties, this task may be delegated to the faculty’s technical service.

Users are required to inform the COSEC (or the faculty’s technical service) as soon as an instrument is not functioning properly.

‘EPFL Biosafety’, as part of its mandate to monitor BSL 2 and BSL 3 laboratory infrastructure, verifies the proper functioning of equipment that may present a microbiological risk to the user, especially microbiological safety cabinets and any devices capable of generating aerosols.

☞ *Annex 1. Maintenance plan and responsibilities for equipment upkeep*

6.2. General guidelines of biological laboratory work

6.2.1. Safety Sheet (Biosafety Cards)

‘EPFL Biosafety’ defines the standard rules for working in biological laboratories, based on applicable legal texts and existing guidelines. These general directives are published in the form of "safety sheets”.

These rules must be integrated into the safety concept of each research unit and, if necessary, supplemented according to the specific activities of the laboratory concerned.

BSOs may use the "Biosafety Cards" as a framework for training users of biological laboratories.

☞ *Annex 2-4: Safety Cards*

6.2.2. Use of the Class II Biosafety Cabinet

The presence of at least one biosafety cabinet (BSC) is required in BSL 2 and BSL 3 laboratories. Proper handling, correct use, and regular maintenance of microbiological safety cabinets are essential to ensure the protection of individuals and the environment, as well as the quality of research or test results. These procedures are described in detail in a separate technical sheet.

☞ *Annex 5: General Guidelines for the Use of Class II BSC (Biosafety Cabinet)*

6.2.3. Biological Safety during Centrifugation

To prevent the formation of harmful aerosols during centrifugation and the spread of organisms to other areas, BSL 2 and BSL 3 laboratories must be equipped with centrifuges that have aerosol-tight rotor covers. Users must be familiar with and adhere to the manufacturer's guidelines for centrifuges.

6.2.4. Prevention of Infectious Diseases Transmitted by Human Samples

To prevent infectious diseases, for which pathogens can be transmitted through blood or other bodily specimens, special safety precautions apply to this type of sample. Annex 6, "Human Samples", outlines the risks associated with handling such samples and provides safety guidelines (good microbiological practices, personal protective equipment, accident procedures).

☞ *Annex 6: "Human Samples"*

6.2.5. Personal Protective Equipment (PPE)

The head of the unit must ensure that the required personal protective equipment (PPE) for the activities in their laboratory is available. The BSO checks that the PPE is correctly used. This equipment must comply with current standards and meet the minimum standards set by the School or the Faculties.

For class 1 activities, the standard PPE consists of:

- A white cotton laboratory coat with long sleeves, fastening in the front
- A pair of gloves meeting EN 374-5 standards
- Protective eyewear (safety glasses)

For class 2 activities, the standard PPE consists of:

- A colored, water-repellent fabric laboratory coat with long sleeves, elastic cuffs, and fastening at the back (or a mandarin collar)
- At least one pair of long gloves meeting EN 374-5 virus standards
- Protective eyewear (safety glasses)
- A pair of shoe covers, if a sticky mat is not present at the entrance of the BSL 2 laboratory
- Adaptations to this standard equipment may be required, such as wearing an FFP2 or FFP3 protective mask for class 2 activities that cannot be carried out in a safety cabinet

For class 3 activities, the standard PPE consists of:

- A Tyvek suit
- Shoe covers
- A powered air-purifying respirator (PAPR)
- Double gloves meeting EN 374-5 virus standards

The Biosafety team and the OHS hygienists validate the required protective equipment for class 2 and 3 biological activities.

6.2.6. Isolated Worker

Users of the BSL 2 and BSL 3 laboratories are considered to be lone workers when they work alone outside of standard working hours (night, weekend, public holidays). In this situation, a risk assessment should be done by the Project leader to establish if a monitoring system should be implemented (e.g., call-back procedure to the alarm center).

6.3. Guidelines for Laboratory Cleaning

6.3.1. Disinfection and Cleaning – Hygiene Plan

The hygiene plan ensures personal safety at work and minimizes the spread of organisms into the environment.

Key factors such as the spectrum of activity, product concentration, and contact time are critical for the effective use of cleaning and disinfecting agents. Only disinfectants proven effective against the targeted organisms should be used, and the manufacturer's usage instructions must be strictly followed.

☞ *Annex 7: Disinfection and Cleaning (Hygiene Plan)*

6.3.2. Safety Guidelines for the Cleaning Service

Cleaning staff receive specific training for work in BSL 1 and BSL 2 laboratories.

In BSL 2 laboratories, cleaning personnel are only responsible for sweeping and mopping the floors. Two disinfectants with different active classes are alternated throughout the year to prevent the development of resistant bacteria.

Cleaning staff do not handle or remove any waste from BSL 2 laboratories.

6.4. Storage of Biological Material

The storage of biological material must be organized in a way that ensures:

a) The protection of personnel
b) The protection of the environment

These two objectives are met by limiting the storage of biological materials to confined areas or by using enclosed, access-controlled containers (e.g., -20°C or -70°C freezers, refrigerated cabinets).

Biological material, whether genetically modified or not, that falls under risk group 1, is not subject to specific storage rules.

Risk group 2 biological material is generally stored in refrigerators or freezers located in a BSL 2 laboratory. Eppendorf-type tubes must be placed in clearly labeled plastic or cardboard boxes. Ideally, these boxes are secured with Parafilm or adhesive tape. Falcon tubes, Petri dishes, or cultures in flasks or bottles should be stored in plastic boxes or bags that can be easily sealed.

Risk group 2 biological material may be stored in freezers outside of an BSL 2 laboratory if:

- All primary containers holding infectious material are packed in a second, leak-proof layer (double containment principle). The outer packaging must also be clearly labeled with the "Biohazard" symbol or wording.
- The freezer door must display: i) a storage map of the infectious materials, ii) the "Biohazard" pictogram, iii) the "Authorized personnel only" pictogram, and iv) a list of individuals authorized to access the infectious material.

Risk group 3 biological material must always be stored in a BSL 3 laboratory. As with group 2 organisms, double containment is required.

6.5. Potentially Hazardous Waste

With the support and expertise of DSE and the 'EPFL Biosafety' team, the Logistics Unit (DSE-INT) is responsible for the disposal of waste generated at EPFL. It manages the storage, collection, and transport of waste. On associated campuses, waste disposal is overseen by the operational directors. The rules for disposing of hazardous waste (biological, chemical, and radioactive) are established by the relevant specialists within the Occupational Health and Safety (OHS) service.

Faculties are responsible for sorting and storing special waste until it is collected by DSE-INT or disposed of through a specialized process. They define internal waste management procedures and provide suitable storage facilities.

The waste producer (research group or unit) remains responsible for the waste until its final disposal.

6.5.1. Genetically Modified Organism Waste - Risk Group 1

According to ContainO, genetically modified organisms (GMOs) in risk group 1 must be safely disposed of. A risk assessment should determine the most appropriate method of inactivation, which may include autoclaving, off-site incineration, freezing, or chemical treatment. Generally: solid waste is collected in dedicated UN 3245 containers and transported via a special service to the Tridel incineration plant. Liquid waste is treated with an approved TP 2[14] biocide (e.g., Virkon or bleach). After treatment, the liquid is disposed of as chemical waste under OMoD code 18 01 06. Agar cultures are autoclaved in leak-proof trays and then disposed of as biomedical waste or collected in UN 3245 containers for special transport to Tridel for incineration[15].

6.5.2 Biological Material Waste - Risk Groups 2 and 3

All biological waste, whether solid or liquid, generated from class 2 biological activities is, in principle, destroyed by autoclaving. However, based on a risk assessment, liquid waste may in some cases be inactivated using an approved TP 2 biocide. Solid waste that has been autoclaved is disposed of through the biomedical waste stream. Liquid waste, whether inactivated by chemical treatment or autoclaving, is disposed of according to the procedure for chemical waste (OMoD code 18 01 06).

In certain situations (e.g. presence of toxic, non-autoclavable materials or absence of an autoclave in the building), contaminated material may be removed via special transport under OMoD code 18 01 03. Special transport may also be used for solid cultures (e.g. agar plates), but only with prior authorization from federal and cantonal authorities.

All biological waste generated from class 3 biological activities is primarily inactivated by autoclaving. The only exception concerns toxic or radioactive chemical waste, for which inactivation procedures are adapted based on both the biological material and the specific chemical or radioactive component.

[14] Annex 10, Ordinance of 18 May 2005 on the Placing on the Market and Handling of Biocidal Products (OBP, RS 813.12)

[15] DETEC (Swiss Federal Department of the Environment, Transport, Energy and Communications) Ordinance on the Lists for Waste Shipments (814.610.1)

6.6. Transportation of Hazardous Materials

6.6.1. In-Building Transportation

The DSE (Safety and Operations Domain of EPFL) establishes guidelines and instructions regarding the transport of hazardous materials within EPFL. Specific rules for the transport of genetically modified and/or potentially infectious/pathogenic organisms are established by 'EPFL Biosafety'.

Unit heads (or by delegation, the BSO) are responsible for implementing these rules. They must ensure that appropriate transport equipment is provided, particularly for the transport of biological liquids or organisms from risk group 2. It is strictly forbidden to carry potentially hazardous biological materials on one's person.

During transport, organisms from risk group 2 must be double packaged. The outer packaging must be leak-proof and capable of withstanding a fall from a height of 1.2 meters without opening or breaking, thereby preventing the leakage of liquids or hazardous biological material. The "Biohazard" pictogram must be clearly visible on the packaging.

6.6.2. Transportation on Campus[16]

The principles outlined above remain in effect with the following additional restrictions: in the event of an accident, no release into the environment must be possible, and genetically modified biological material from risk group 1 must also be double packaged. Biological material from risk group 3 must be triple packaged.

6.6.3. Transportation on Public Roads

Organisms from risk group 2 and above are considered dangerous goods, and their transport on public roads is regulated by the Ordinance on the Transport of Dangerous Goods by Road[17]. It is forbidden to transport infectious substances using public transportation. 'EPFL Biosafety' is the competent authority for questions regarding the transport of pathogenic organisms. Through inspections, DSE-OHS and 'EPFL Biosafety' ensure that transport regulations are followed.

6.7. Use of Radioactive Sources

EPFL must ensure that the use of radioactive sources or devices generating ionizing radiation complies with federal legislation[18, 19] and current guidelines. It entrusts the radiation protection experts of the OHS team with the supervision of authorization requests[20], user training, waste management, dosimetric monitoring, and the verification of protective measures. The radiation protection measures implemented by OHS are described in the technical directives supplementing LEX 1.5.1 and on the OHS website.

[16] Campus refers to all EPFL buildings located on the sites of Ecublens, Neuchâtel, Geneva, Sion, and Fribourg, as well as the streets and access routes connecting these buildings. On the Ecublens site, however, major roads such as Avenue du Tir fédéral, Route de la Sorge, Avenue François-Alphonse Forel, and the Route cantonale are excluded, as they are considered public roads.

[17] Ordinance on the Carriage of Dangerous Goods by Road (SDR)

[18] Radiological Protection Ordinance 814.501 (RPO)

[19] Radiological Protection Act 814.50 (RPA)

[20] Federal Office of Public Health - Supervision and Authorization

6.8. Use of Nanoparticles

The technical directive supplementing LEX 1.5.1 "Working with Nanomaterials" defines the conditions of use, and the precautionary measures associated with handling nanoparticulate materials. It is available on the OHS website.

6.9. Use of Chemicals

OHS defines the conditions for the use (safety equipment, personal protective equipment, waste management) and storage (premises, secure cabinets, types of containers) of chemical products in accordance with CFST directives. These conditions are described in the technical directives supplementing LEX 1.5.1, available on the OHS website.

6.10. Combined Use of Biological Materials and Other Hazards

The combination of biological hazards with other hazards (chemical, radioactive, nanoparticles, laser) can result in increased risk for unit personnel or the nearby environment. It is the responsibility of the unit head to anticipate these risks and establish a risk assessment process. Support from OHS and 'EPFL Biosafety' is available to help evaluate the risk level associated with the combination of different hazard types.

'EPFL Biosafety' and EPFL Radiation Protection work closely together to assess the risk arising from the labeling of potentially pathogenic organisms or laboratory animals with radioactive isotopes. These two teams must make decisions regarding experimental containment, organism inactivation, and waste management.

7. Unit-Specific Safety Concept

With the support of the unit head, the BSOs of BSL 2 and BSL 3 laboratories develop their own safety concept. This concept is based on the general rules established by 'EPFL Biosafety', but it considers the risks associated with the specific activities of the laboratory. The BSOs must be able to present the unit's safety concept during internal or external inspections or audits.

The safety concept must include:

- List of Notifications/Authorizations (☞ *Annex 8*)
- Description of laboratory methods and processes with the specific safety measures associated with them
- Rules for the use of equipment and facilities
- Training concept for new staff
- Principles for managing microorganisms used by the unit
- Waste disposal plan (☞ *Annex 9*)
- Equipment maintenance plan (☞ *Annex 1*)
- Hygiene plan (☞ *Annex 7*)
- Emergency contact numbers (☞ *Annex 10*)

The annexes can be adapted to develop the unit's safety concept. The organism sheets may also provide useful information for establishing the safety concept.

8. Medical Surveillance

The Project leader informs their staff about the health risks associated with the use of the biological materials being handled and the actions to take in case of an accident or exposure.

The Project leader must also inform female staff to contact EPFL Occupational Medicine in case of confirmed or planned pregnancy.

The Project leader can request OHS to conduct an exposure assessment in the workplace.

Staff exposed to biological risks level 2 and 3 will be required to attend an entry and medical fitness examination by EPFL Occupational Medicine. If the person fails to attend the medical examination after the first reminder, their access will be revoked, and the activity will be prohibited.

EPFL Occupational Medicine determines the individual's medical fitness for the planned activity, sets any necessary conditions, and informs them of the applicable medical preventive measures. The assessment is based on the laboratory hazard register and the safety sheets of the organisms.

In the case of maternity, risk assessment according to the maternity protection ordinance is conducted by EPFL Occupational Medicine and EPFL Occupational Hygiene.

In case of an exposure accident, the affected person is required to report the accident using the "Incident Manager" portal (https://go.epfl.ch/incident-management). EPFL Occupational Medicine ensures the follow-up of the situation.

9. Emergencies

The SIS (Emergency Services) manages all emergency aspects on campus. It establishes intervention teams available 24/7 and organizes the training of responders. These teams are specially trained by ‘EPFL Biosafety’ to handle biological risks on campus.

All emergencies are coordinated by the Alarm and Engagement Center (CAE), with the emergency contact number 115 (021 693 30 00 for non-EPFL phones).

Emergencies involving acute infection risks are handled by the GIU for evacuation to the CHUV Emergency Department.

Finally, any accident or incident is reported to OHS through the "Incident Manager" portal (https://go.epfl.ch/incident-management).

10. Final Provisions

This document must be revised during structural reorganizations or when new biological risks not covered by this biosafety concept emerge on the EPFL campus.

10.1. Entry Into Force

The following three Lex have been consolidated into this technical directive:

- 1.5.3 (Directive regarding the internal procedure for projects subject to notification/authorization according to the ContainO, Release Ordinance, and OPTM), effective from 12.09.2011
- 1.5.4 (Directive regarding the management of organisms), effective from 12.09.2011

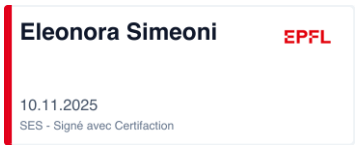
- 1.5.11 (EPFL Safety Concept for laboratories working with biological material), effective from 01.01.2017

Version	Modifications	OHS Validation	DSE Validation	Date
2.0	Adaptation of the safety concept according to the implementation guide "Management of Biological Risks in Contained Environments"			28.08.2024
2.1	Minor revisions: Isolated worker rule; Annex 3 and 6	E. Simeoni		
		S. Karlen		
			E. Du Pasquier	

Dr. Eleonora Simeoni

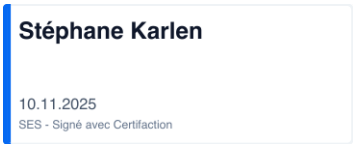
Head of Unit, OHS-PR

Institutional Biosafety Officer



Dr. Stéphane Karlen

Head of OHS Service



Dr. Eric Du Pasquier

Director of DSE

Annex 1

Maintenance Plan and Responsibilities for Equipment Maintenance

This document must be adapted to the specificities of the unit. Please adjust/delete the parts in green.

1. Purpose

Properly functioning equipment ensures the quality of results, the safety of employees, and, in general, the protection of humans and the environment. To achieve this, equipment must be regularly maintained. Maintenance is part of the upkeep of equipment; it keeps it in good technical condition. The overall maintenance of equipment generally also includes cleaning and disinfection; however, these two aspects are addressed separately in the hygiene plan.

Overview of Equipment and Maintenance Responsibilities:

This table presents a list of all equipment directly related to safety or regularly used for work involving organisms from groups **2 and 3**.

Concern		**Where**	**When**	**Who**
Equipment	Equipment No.	Room number	Maintenance Frequency	Responsible person
Biological Safety Cabinet				
Centrifuge				
Incubator				
Autoclave				
…				

2. Access Regulations for Personnel Performing Equipment Maintenance

Visitors may only enter and work in level 2 or 3 laboratories after obtaining prior authorization from the BSO or the laboratory head, being accompanied by a competent person, and being informed of the potential existing hazards.
When performing maintenance or repairs in level 2 and 3 laboratories, personnel must be appropriately trained, and protective measures may need to be implemented.

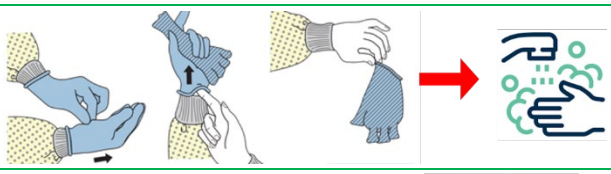
Written/Approved by	
Date	

Annex 2

Occupational Health and Safety

Guidelines for Biosafety Level 1 laboratory (BSL1)

BSL1 laboratory is only for **risk group 1** organisms!

Learn how to use the scientific instruments at your disposal and consult the Material and Safety Data Sheet (MSDS) of each chemical used in your experiments.	
Locate close-by emergency equipment (chemical and biological spill kits, eyewash stations, chemical showers).	
Lab coat in cotton, long sleeves. Remove it when leaving the lab. Wear clothes that protect your legs. No open shoes. Tied hair. Plants are not permitted in the laboratory.	
Wear adapted gloves for protection against chemicals or microorganisms. Remove gloves when leaving the lab, opening doors, calling elevators, using a keyboard, answering the phone etc.	
Do not reuse disposable gloves. Ensure glove removal does not cause contamination of the hands. After disposing the gloves, thoroughly wash your hands with soap and water!	
Safety glasses for activities that may produce spills/splashes. Face shield against UV.	
No eating, drinking, applying cosmetics, and storing food for human consumption in the laboratory.	
Perform all procedures to minimize the creation of splashes and/or aerosols (pipette slowly and gently). Mouth pipetting is prohibited. Use mechanical pipetting devices.	
Clean surfaces after completion of work and after any spill and before disinfecting!	

Occupational Health and Safety

Sort out the waste:

Sort out household waste according to the various categories: paper, cardboard, batteries, plastics, electronics etc.

Separate household waste from laboratory waste. Domestic trash is for non-contaminated objects (no chemicals, no biological material, no sharps)

Laboratory waste: separate liquid from solid

Solid contaminated with biological material without GMO

Solid contaminated with GMO

Collect liquid waste into a plastic container.

Label the liquid waste and choose the corresponding OMoD code.

Use a cap with a disruption disk to prevent from overflowing and blowing up.

Respect chemical incompatibilities for liquid waste.

	Oxidizers	Flamm-ables	Corrosive Acid	Corrosive Base	Health Hazard/ Toxic
Oxidizers					
Flamm-ables					
Corrosive Acid					
Corrosive Base					
Health Hazard/ Toxic					

Use of needles and syringes or other sharp instruments:

DO NOT put fingers inside container

DO NOT remove needle

DO NOT bend or break needle

DO NOT recap needle

- Make sure that all activities involving genetically modified material are notified to the Office of Biotechnology (contact biosafety@epfl.ch)

Annex 3

Occupational Health and Safety

Guidelines for Biosafety Level 2 laboratory (BSL2)

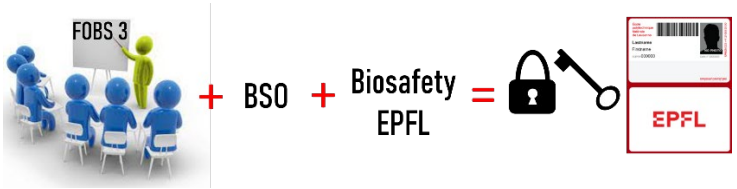
Risk group 2 organisms must be handled in a BSL2 room.

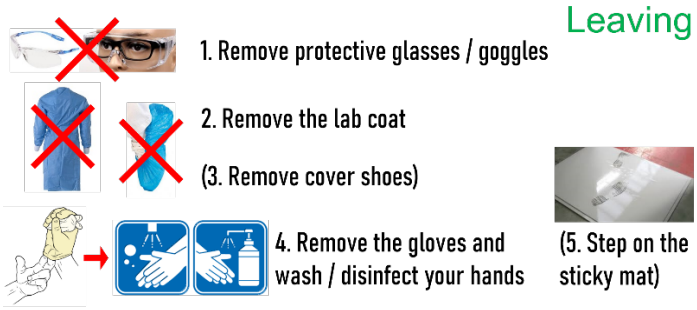
Basic rules described in BIO Safety Card BSL1 apply.

All BSL2 activities must be notified to the Office of Biotechnology, and derogations to standard BSL2 safety measures must be authorized by the federal authorities. Contact biosafety@epfl.ch.

BSO and Biosafety EPFL validate the CAMIPRO rights to access the BSL2 room.

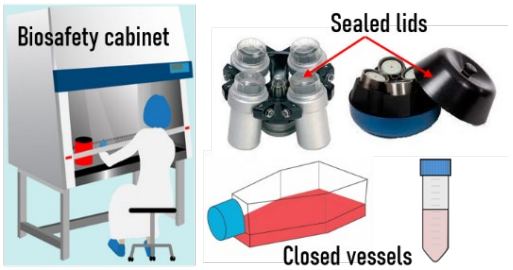
The “FOBS 3: biological risk” training is mandatory.





All activities must be confined:

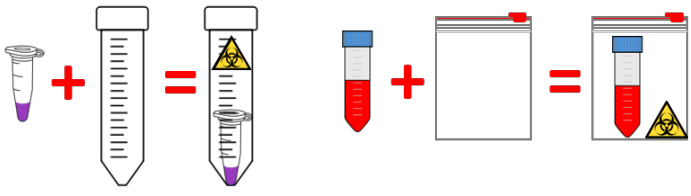
- Cultures are set in closed vessels
- Solid waste bag inside the biosafety cabinet must be closed before to be trashed in the main solid waste bin
- Buckets or rotors equipped with sealed lids. In case of centrifugation problems (improper balance, tube damages), wait 30’ to allow aerosols sedimentation before opening the lids
- FFP2 or FFP3 respiratory masks must be considered in the absence of primary containment



Risk group 2 samples are double-packaged for internal transport.

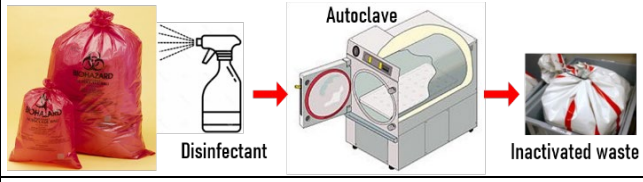
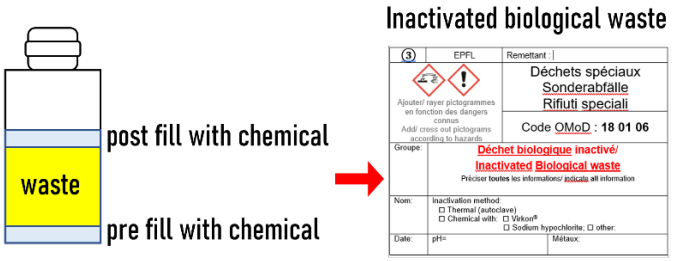
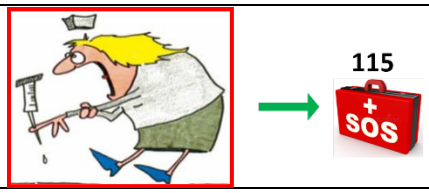
The external packaging must be unbreakable and waterproof.

Risk group 2 samples that are not stored inside a BSL2 room must be double-packaged.



Occupational Health and Safety

Waste containing risk group 2 organisms must be inactivated before elimination:

Solid waste: autoclave When ¾ full, close the bags and decontaminate the outside before leaving the BSL2 room.	
Liquid waste: chemical inactivation or autoclave. Chemical inactivation: add the appropriate decontaminant to liquid waste, let it react at least overnight before elimination. Autoclave: do not add any solvent or disinfectant to liquid solutions that must be autoclaved. Inactivated liquid waste must be eliminated as special waste (code OMoD: 18 01 06).	
In case of biohazard spill outside the biosafety cabinet: • All users must quit the BSL2 lab immediately • Put on the door the biohazard spill alert notice • Call 115 for assistance.	
In case of accident (ex: injury, spill in the eyes): • Use the appropriate emergency equipment (eyes washer, disinfectant, …) available in the lab • Call 115 for assistance	

Guidelines for Prion-like proteins

Introduction

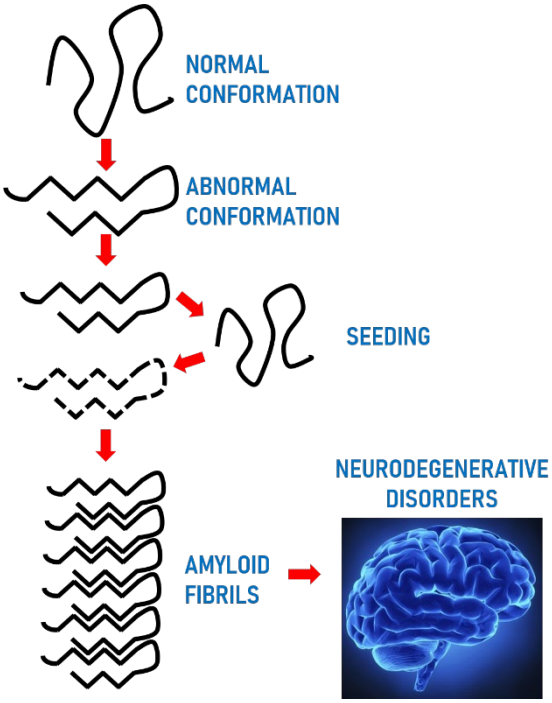
Recent studies in experimental models demonstrate that certain misfolded proteins associated with neurodegenerative diseases can induce misfolding of cognate native proteins and propagate across neural systems, thus displaying some of the properties of prions.

Contrarily to prions, infectivity of these misfolded proteins (named prions-like proteins) has not been demonstrated in humans so far. However, this issue has not been deeply explored and there is a series of critical questions to be addressed to assess the real risk of transmission/ infectivity.

Due to their proteopathic seeding ability, a precautionary approach must be adopted when manipulating prion-like containing samples, and prion-like proteins are classified as **risk group 2** pathogens.

In the context of occupational exposure in laboratory setting, major risks would be accidental parenteral inoculation, and aerosol inhalation. Mucous membrane contamination should also be considered as a potential route of transmission.

Guidelines for biosafety level 2 (BSL-2) environment should thus be followed (see Biosafety Card for BSL2). Additional indications are addressed in this document.



Post exposure management

- Contamination of **unbroken skin** with samples containing prion-like proteins: wash with detergent and abundant quantities of warm water (avoid scrubbing), rinse, and dry. Brief exposure (1 minute) to Dakin's solution (sodium hypochlorite 0.4% - 0.5%) can be considered for maximum safety.

- **Needle sticks or lacerations**: gently wash under running tap water with warm soapy water (avoid scrubbing), rinse, dry. Brief exposure (1 minute) to Dakin's solution (sodium hypochlorite 0.4% - 0.5%) can be considered for maximum safety. Then cover with a waterproof dressing.

- **Splashes into the eyes, mouth, or nose**: irrigate with either saline (eye) or tap water (mouth and nose) for 15-20 minutes.

Report the laboratory accident by the EPFL event manager.

Sharp Objects

The use of sharp material (e.g. needles) should be minimized. Blunt-ended forceps and needles should be used whenever possible.

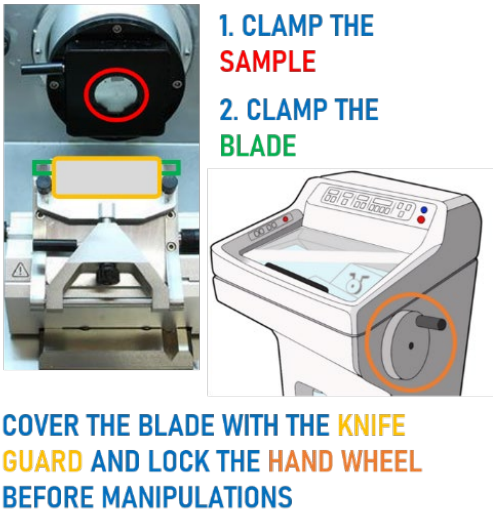
Histopathological examination of tissues

Cryostat

Non-fixed samples (group 2 samples) have to be processed with a cryostat which is placed in a BSL-2 laboratory. Since tissue sectioning cannot be performed in a biosafety cabinet, users must wear the standard PPE for a BSL-2 laboratory and an FFP2 mask when cutting not fixed samples.
Fixed samples (group 1) can be processed in a BSL1 laboratory.

The sample should be clamped BEFORE clamping the blade. The blade should be covered with the knife guard and the handwheel locked before changing the sample and prior to any other manipulation and in case of breakdown or malfunction. The blade for the microtome should be disposed after each use.

The internal part of the cryostat will need to be cleaned with an alcohol-based disinfection wipe. All external surfaces potentially contaminated must be treated with a wipe soaked in a solution of Hellmanex III and rinsed just after with an alcohol-based disinfection wipe.



Slides staining and mounting

Fixation of slides containing fresh frozen tissues must be performed in a BSL2 laboratory. Once fixed, slides can be manipulated in BSL1 laboratories.
Because of conflicting results between different studies from the literature, the ability of formalin to complete inactivate prion-like proteins aggregates is still debated. Even if the risk is very low, formalin fixed samples should be handled with precautions following good microbiological practices. Operators must: 1) always wear a lab coat, gloves, and safety goggles; 2) decontaminate surfaces at the end of the working session.

Storage

Slides with **non-fixed** tissues must be stored as BSL2 samples (double envelop principle).
Whenever possible slides with fixed tissues should be stored in a sealed container.

Waste

Material	Treatment	Packaging
Solid (including sharp objects) and semi-solid waste; animal carcasses	No specific inactivation in house, waste is transported to TRIDEL for incineration	30 L or 60 L blue boxes certified UN 3291 with OMoD code 18 01 03
Liquid waste	NaOH 1M	Plastic containers suitable for liquid waste with OMoD code 18 01 06
Surfaces / objects	1% Hellmanex III* (Z805939, Sigma Aldrich), 2% SDS solution *	

*Trash the tissues used to clean the surfaces and objects in a blue box

Annex 5

Use of the Class 2 Biological Safety Cabinet

1. Context

Class 2 Biological Safety Cabinets (BSC), type A1/A2, ensure protection for people, products, and the environment.

The application of good microbiological practices is also necessary in the biological safety cabinets, as they protect only against contamination by aerosols, but not against contamination by contact.

2. Hazards to Humans and the Environment

There is a risk of biological products being disseminated outside the biological safety cabinet in the event of improper handling or actions.

3. Safety Measures and Behavioral Rules

The BSC should not be placed too close to doors or under ventilation (airflow).

Before starting work, ensure the equipment is turned on according to the manufacturer's recommendations.

The BSC does not provide protection against harmful vapors and gases unless a carbon filter is installed. In the absence of a carbon filter, if toxic chemical materials are used, an assessment must be performed by OHS.

For optimal use of the BSC, the following instructions must be followed:

- Avoid disturbing the airflow as much as possible
- Do not make quick or abrupt movements
- Only introduce large equipment into the biological safety cabinet when absolutely necessary and remove it immediately after use
- Do not store unnecessary objects inside the biological safety cabinet; only bring the equipment and materials essential for the task
- Do not use a Bunsen burner

All equipment that leaves the BSC must first be cleaned and disinfected.

The work surface of the biological safety cabinet must be cleaned and disinfected once work is completed.

A small bin with an autoclavable bag must be placed inside the BSC. All contaminated or potentially contaminated materials (pipettes, Petri dishes, gloves, etc.) must be disposed of in this bin. When the bag is full, it must be sealed and disinfected before being removed

from the BSC.

Liquid waste will be separated from solid waste and disposed of in an appropriate container inside the BSC or suctioned into a reservoir with a suction pump connected to the BSC.

4. Failures and Risks

Safe operation is only possible when the green light indicator is on, and the front window is lowered. Never ignore alarm signals (visual or audible).
In case of an alarm or complete shutdown of the BSC while working with biological materials presenting a biological risk, stop working, secure the work (e.g., close tubes, flasks, bottles, waste bags, etc.), and immediately inform the BSO.

5. Inspections / Maintenance

The biological safety cabinet in BSL 2 laboratories must be inspected annually by a specialist. In BSL 3 laboratories, the inspection must be done twice a year. In BSL 1 laboratories, an annual inspection is recommended but not mandatory.

Annex 6

OCCUPATIONAL HEALTH AND SAFETY

EPFL VPO-SE OHS
BS 196 (Bâtiment BS)
Station 4
CH 1015 Lausanne

Contact: OHS Support
Web site: Biological hazards

Human samples

Group 1 and 2

Eléments clés_Interventions

Organisme	Echantillons humains
Danger spécifique	Ingestion ou inhalation d'aérosols, contact direct des muqueuses avec les échantillons, l'injection ou l'inoculation accidentelle
Laboratoire	NSB 1 ou NSB 2 selon classification de l'échantillon
Produits de décontamination	Virkon, peroxyde d'hydrogène, acide peracétiques
EPI	Blouse de laboratoire, gants, lunettes de protection. En cas de déversement hors poste de sécurité microbiologique, masque respiratoire adaptée.

General description

Name	Human samples
Description	In this datasheet, human samples include plasma, serum, feces, BAL, cerebrospinal fluid, and other similar specimens. This safety data sheet does not refer to blood and to primary human cells isolated from human tissues.

Risk analysis

Hazard	In principle, human samples that origin from individuals with no known or suspected infections are considered biosafety level 1. Therefore, they can be handled in a biosafety level 1 laboratory following good microbiological practices to minimize exposure. A risk assessment is mandatory if human samples originate from patients with **confirmed or suspected infections**. Depending on the outcome of the risk assessment, handling of these samples may require biosafety level 2 (BSL 2) conditions. A risk assessment is also required for samples containing microbiota (e.g. feces, saliva, BAL, etc.) and prion-like proteins. In most cases, the risk group classification is determined by the type of experimental manipulations to be performed.

	Samples that are used to diagnose pathogens require biosafety level 2 conditions.
Critical handling steps	All activities in which human material is handled. Particular critical steps are: 1) manipulations that create aerosols/droplets; 2) usage of needle/sharp objects; 3) work involving animals receiving human samples.
Disinfectants	The usage of broad-spectrum disinfectants is recommended (ex. Virkon, hydrogen peroxide, Peracetic Acid). Attention must be paid to choose disinfectants that are effective also in the presence of organic matter (for examples serum and plasma).
Remarks	For human primary cells please refer to the "Human primary cells" safety sheet.
Risk group	1 or 2

Safety instructions

Handling information	▪ Not for environmental release. ▪ All activities involving known infectious materials are assigned to a BSL 2 lab. ▪ Working steps generating aerosols have to be performed in a biosafety cabinet or a chemical hood (with exception of specific authorized steps). The use of needles, syringes, and other sharp objects should be strictly limited. Open wounds, cuts, scratches, and grazes must be covered with waterproof dressings. ▪ A lab coat and gloves have to be worn. ▪ Centrifuges with aerosol tight lids or buckets must be used if the work is conducted in a BSL 2 lab. Pipet tips with filter protection have to be used. ▪ Eye protection must be used in case of potential risk of exposure to splashes. A respiratory mask must be worn, when aerosols might be produced outside the biosafety cabinet or chemical hood. ▪ The working place must be cleaned after work and decontaminated with the appropriate disinfectant (see above). Working surfaces and equipment have to be cleaned regularly. ▪ Waste has to be inactivated according to regulation (see specificity in the lab notification/authorization). ▪ Hands must be thoroughly washed and disinfected after handling these samples.
Consideration for high-risk group employees	The personal situation has to be discussed with the doctor at the entry medical check or, for pregnancy, at the maternity medical check.
In case of accident	Always call 115 if the accident affects people (wound, spill in the eyes, etc.). If there is a wound, wash thoroughly with water and disinfect with Merfen® or an equivalent disinfectant. In case of spill in the eyes, rinse thoroughly the eyes using the eyes-wash station.
In case of biohazard spill	*Spill outside biosafety cabinet for biosafety level 1 samples:* Clean the spill using paper soaked with appropriate disinfectant (see above). Leave the soaked paper for minimum 10 minutes on the spill before removing everything and doing the final cleaning. For

	cleaning-up large spills, wear the adequate PPE (if necessary, define them with the help of the Biosafety Officer or the COSEC). *Spill outside biosafety cabinet for biosafety level 2 samples:* In the event of a spill **outside** the biosafety cabinet, evacuate everyone from the room. Post a biohazard spill alert on the door and call emergency services (**115**). *If the spill can be managed by the lab members, wait* approximately *30 minutes* for the *aerosols* to *settle* before the cleanup. Before cleaning, wear adequate personal protective equipment: at least, BSL 2 lab coat, gloves, FFP2 respiratory masks, safety glasses and cover shoes. The use of full body protection suits is recommended for large volume spills. Cover the spill using a paper or a towel soaked with appropriate disinfectant (see above) and allow contact for 30 min. Collect the soiled papers and discard them for autoclaving (towels can be autoclaved and re-used). Proceed to the final cleaning. Any accident or incident must be reported to the OHS.

Annex 7

Periodic Hygiene Plan

This document must be adapted to the specificities of the unit.

Applies to the following rooms:

Room No.	Organisms	Head of the Unit

1. Posting and Dissemination of Information

The hygiene plan is posted in the laboratory. Compliance with the plan is documented.

2. Importance

Adherence to the hygiene plan ensures personal safety at work, health protection, and the quality of research. Cleaning and disinfection products are selected to fulfill their intended function as outlined in the hygiene plan - ensuring necessary efficacy and ease of use.

3. Periodic Hygiene Plan

Surface, Equipment, object	Frequency	Cleaning and Disinfection Products or Methods to Be Used
Biological Safety Cabinet		
Work Surfaces		
Refrigerator		
Oven / Incubator(s)		
Centrifuge(s)		
Sinks		
Floors		
Water Bath		

Hygiene Plan

Date	What	By Whom	When (date)	Signature

Written/Approved by	
Date	

Annex 8

List of Notifications/Authorizations

This document must be adapted to the specificities of the unit.

A project notification submitted to the Federal Biotechnology Office contains all necessary information regarding the buildings and premises (building and room identification), the persons responsible or with expertise in the field (project leaders, etc.), the classification of organisms into risk groups, the class of the activity, and the duration of the project.

Notification 1:

Number:	Axxxxxx
Title	
Responsible Person	
Deputy Responsible Person	
BSO	
Deputy BSO	
Class of Activity	

Notification 2:

Number:	Axxxxxx
Title	
Responsible Person	
Deputy Responsible Person	
BSO	
Deputy BSO	
Class of Activity	

……..

Annex 9

This document must be adapted to the specificities of the unit. Please include unit-specific information and delete any parts that do not apply.

Disposal Plan for Level 2 Infectious Waste

1. Purpose

This waste disposal plan governs the handling of waste contaminated with biological products. The inactivation of contaminated waste is a key aspect aimed at minimizing the dissemination of organisms outside the laboratory and thus preventing risks to humans and the environment.

2. Disposal of Infectious Waste Presenting a Risk of Injury (Sharps)

Waste presenting a risk of injury (*sharps*) is disposed of as special waste with OMoD code 18 01 01. If they have come into contact with infectious material, they must first be inactivated by autoclaving.

3. Disposal of Infectious Liquid Waste

Liquid waste is inactivated by autoclaving and/or chemical inactivation using the authorized TP2 biocide: ……

4. Disposal of Semi-Solid Waste

Semi-solid waste (e.g., Petri dishes with agar) is inactivated by autoclaving using solid autoclavable containers.

5. Disposal of Contaminated Materials

Contaminated materials (pipettes, gloves, flasks, etc.) are inactivated by autoclaving in autoclavable bags.

6. Transport of Waste for Autoclaving and Inactivation Room

Materials to be autoclaved are transported to the inactivation room: …… using a mobile transport container.

7. Disposal of Infectious Waste - Code 18 01 03

Waste …… is not inactivated on-site at EPFL but is transported to Tridel with special transport as infectious waste.

Annex 10

Emergency Contact Numbers

This document must be adapted to the specificities of the unit.

Area of Expertise	Phone
Emergency situations: specific events, fire, medical aid	**115**
Emergency situations: technical incidents	**34000**

Unit Safety Contacts

Area of Expertise	Phone	Contact Person and Email
BSO (Biological Safety Officer)		
COSEC		
Radiation Protection		
Unit Head		
…		
…		

Written/Approved by	
Date	