	Registration AW-96-14-02e	
	General directive for the Safety concept for activities	
Title	involving pathogenic and genetically modified organisms at the Paul Scherrer Institute	AW-96-13-01
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Summary:

This general directive outlines the most important statutory and operational instructions regarding activities involving pathogenic and genetically modified organisms at the Paul Scherrer Institute, and governs the relevant responsibilities. It also refers to basic codes of conduct adopted in order to protect personnel and the environment from the hazards presented by biological samples.

This directive is binding on every person working at the Paul Scherrer Institute.

This directive was approved at the Conference of the Directorate (DIRK) on 19th November 2014.

Following the form of wording used in the statutory texts, personal descriptions are shown in the masculine form only. All descriptions always apply equally to women.

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1 Organisation system and structure of responsibilities

1.1 Legal basis and state supervisory authorities

The ESV SR 814.912 ["Einschliessungsverordnung": Swiss Containment Ordinance] is intended to protect human beings, animals and the environment, as well as biological diversity and its sustainable use, from hazards or harm caused by handling organisms, their metabolic products and wastes in contained systems.

The Canton Aargau (Office of Consumer Protection/ Chemicals Safety) is the implementing authority for the ESV and monitors at regular intervals compliance with the duty of care, the duties relating to handling in closed systems as well as the safety measures.

The Federal Coordination Centre for Biotechnology administrates reports and operational processes for the assessment of proposals intended to use genetically modified organisms (GMOs) and pathogenic organisms according to the Containment ordinance (ESV). Information on projects registered is published on the internet.

SUVA (Swiss Industrial Insurance Association) is the implementing authority for the SAMV ["Verordnung über den Schutz der Arbeitnehmerinnen und Arbeitnehmer vor Gefährdung durch Mikroorganismen": Swiss Ordinance on the Protection of Employees from Dangerous Microorganisms]. Further information is available on the website of the Bundesamt für Umwelt, BAFU (Federal Office for the Environment, FOEN).

http://www.bafu.admin.ch/biotechnologie/index.html?lang=en

1.2 Responsibilities

Safety, health protection and environmental protection at PSI is regulated by the general directive AW-01-07-02.

The head of each organisational unit bears the operational responsibility for ensuring that the protection of human beings and the environment as well as industrial safety is guaranteed. It ensures that the safety concepts are implemented and observed and sets out the requisite organisational structure.

The ASI division ("Abteilung Strahlenschutz und Sicherheit", Division for radiation safety and security) is the point of contact for all industrial safety matters to be organised centrally at PSI. The main tasks of this department

include advising, training and supporting the members of the institute with regard to safety at work and health protection (such as occupational hygiene, occupational medicine, biological safety, fire prevention, chemicals safety, hazardous waste management, radiation protection, transport/dispatch of hazardous goods or environmental protection). The current responsibilities within the ASI department can be seen from the organisational chart (https://ecm.psi.ch/asidoc/Organigramme/ORG-03.pdf).

Handling toxic and radioactive substances is regulated in the general directives AW-96-08-09 and AW-23-96-13.

1.3 Biosafety officer (BSO)

The BSO and his deputy are selected by the safety officer in agreement with the safety delegate and the BIO division head. The line manager is responsible for ensuring that the BSO receives the necessary resources (personnel and finance).

The line managers and safety officer are supported by the BSO in relation to safety involving biological samples.

The BSO is the official biosafety officer pursuant to the ESV and the SAMV. The BSO's status, duties and responsibilities are based on the Swiss government's guidelines "Biosafety Officers (BSO). Status, duties and responsibilities".

1.3.1 Job description

The BSO

- a) has responsibility for the concept of biological safety, in particular for drafting regulations for the use of biological samples at PSI.
- b) coordinates the reporting of projects to the *Federal Coordination Centre for Biotechnology*. Ensures that the reports and proposals from line managers and project managers are made to the authorities responsible in a timely manner.
- c) informs, educates, and advises PSI staff about biosafety, and supervises implementation of biosafety guidelines at PSI. The BSO offers the following training: (a) Working in a BSL-2 laboratory with BSL-2 organisms, (b) General introduction to biosafety.
- d) advises the line managers, safety bodies and PSI staff (internally and externally) in relation to biosafety (i.e. in developing a biosafety risk analysis).

- e) documents the maintenance and the functional check of the autoclaves and safety cabinets. The documents are archived digitally on the server of the Safety section (9670).
- f) organises access to the BSL-2 laboratories in collaboration with the safety headquarters.
- g) is charged to prepare emergency measures in collaboration with the emergency officer.
- h) together with the safety officer, coordinates with other areas involved in safety at work and health protection (such as radiation protection, chemicals safety, security (access), etc.).
- i) issues directives for decontamination of biological materials together with the safety officer and supervises the storage facilities for biological materials.
- j) instructs persons who work with BSL-2 materials or in BSL-2 laboratories.
- k) communicates with the Swiss authorities on all issues concerning biosafety at PSI together with the safety officer and communicates accidents and/or injuries involving biological materials to the authorities.
- I) takes care of his own continuous education and training.
- m) keeps the following lists: (a) Persons with access rights for BSL-2, (b) Persons approved to work in BSL-2, (c) Persons who are under medical supervision. The lists are archived digitally.

1.3.2 Competencies

The BSO is authorised to:

- a) issue directives on the use of biological samples at PSI, in consultation with the PSI safety officer.
- b) prohibit the storage or use of biological samples at PSI, in consultation with the safety officer and the line managers, if the statutory provisions have not been maintained, or if the hazard seems too high in his opinion. Prohibition in the latter case is permitted without previous consultation with the safety officer if there is any immediate danger.

- c) delegate his responsibility as official BSO to local persons at PSI, by agreement with the safety officer.
- d) issue and publish instructions regarding the disposal of biological sample waste at PSI, in consultation with the safety officer.
- e) request information from all the people dealing with biological samples at PSI.
- f) communicate independently, orally and in writing, with the authorities and other external offices, by agreement with the safety officer, as long as this does not result in any legal or financial obligations on the part of PSI.

1.4 Special responsibility of line managers and project managers

a) Carry out a risk assessment of new projects

Line managers discuss the Biosafety Level (BSL) of their projects with the BSO. The regulations in the ESV provide the basis for this. In cases of doubt, the decision is made by the BSO.

b) Registration of projects

All new projects or changes to projects that may alter the risk class must be registered before the project gets started. The BSO or his deputy should be contacted to fill in the appropriate forms (class 1 or class 2). Ideally several reports from one laboratory are summarised. Line managers or project managers are permitted to register their projects independently but must inform the BSO. All projects are published by the Federal Office for the Environment under the name of the line manager or project manager responsible.

c) Inform personnel of the risks and safety measures

The biosafety legislation and applied guidelines documented on the PSI biosafety webpage give a theoretical biosafety briefing, especially to all new PSI members. The project manager or line manager is responsible for informing all persons working in the lab of potential hazards of particular organisms in use and for practical training and supervision in the laboratory.

d) The line managers are responsible for the availability of personal protective equipment, in particular lab coats, gloves and protective glasses. They are responsible for maintenance of the infrastructure (electricity, water, heating, light, ventilation, etc.).

- e) The project manager or line manager or beamline manager informs the persons involved about the internal regulations concerning the dispatch and transport of biological material. The Gefahrguttransporte (dangerous goods carriage) Group and the BSO are on hand to provide advice.
- f) Lay down a hygiene plan for all laboratories used (except for BSL-2 laboratories)

This plan should define who cleans relevant lab benches and apparatus, how often and with what disinfectants.

g) **Keep records of all activities (preferentially in digital form)** for 10 years.

2 Classification of activities

To determine the risk stemming from planned activities with organisms in closed systems, the extent and the probability of damaging effects for humans, animals and the environment as well as for biological diversity and its sustainable use must be estimated.

The class of an activity usually corresponds to the grouping of the organisms (see BAFU/FOEN website) but may be different!

Class 1: activities with no risk or a negligible risk;

Class 2: activities with a low risk;

Class 3: activities with a moderate risk;

Class 4: activities with a high risk.

Activities in class 1 and 2 must be reported, while activities in class 3 and 4 require a permit.

Risk assessment is carried out by line managers or project managers with the help of the BSO or his deputy. The BSO decides which classification a project is registered under.

For activities in class 1 and 2, the leakage of pathogens and GMOs must be minimised; for activities in class 3 and 4, any release must be prevented.

At PSI, only activities in class 1 and 2 are allowed.

3 Safety measures

3.1 Biosafety level 1, BSL-1

- a) PSI staff adhere to the laboratory rules in Annex 1, which are based on the "Basic rules of good microbiological practice".
- b) The staff are trained by the line managers or project managers.
- c) The work must be carried out in rooms or on working surfaces that are sufficiently large. The furniture and equipment must correspond to the standard for microbiology/biotechnology laboratories.
- d) The walls, ceiling, floor and working surfaces must be resistant to the materials and cleaning solutions used. The thorough weekly clean (floors, emptying the normal waste containers) is carried out by the cleaning staff at PSI.
- e) A washbasin must be present in the working area.
- f) The creation of aerosols must be avoided as far as is possible, especially when using centrifuges or sonicators.
- g) Contaminated effluent and solid waste must be treated in a suitable way so as to inactivate biological material (see section 7: "Disposal of biological waste"). For materials that are also radioactive or chemically active, the requirements in the directives for radiation protection (AW-23-96-13) and chemicals (AW-96-08-09) apply.

3.2 Biosafety level 2, BSL-2

The following applies in addition to the above regulations:

- a) The laboratory must be marked with the biohazard warning symbol. Storage locations for Level 2 microorganisms outside of the BSL-2 laboratory must also be indicated with the biohazard warning symbol. If an instrument is used outside of the BSL-2 laboratory (e.g. centrifuge), it must be temporarily indicated with the biohazard warning symbol and subsequently decontaminated. Details on the use of the biohazard warning symbol are regulated in **Annex 2**.
- b) Access to the BSL-2 laboratories is regulated. All persons who work in this laboratory with BSL-1 organisms are given instruction by the BSO or the laboratory manager. Persons who work with Class 2 microorganisms receive additional instruction. Participation in these instruction events is documented. A list of persons with access

permission / work permission is shown on the door (template in **Annex 3**).

- c) A special hygiene plan applies (**Annex 4**). Implementation of the plan is documented. The regular weekly clean (floors, emptying the normal waste containers) is carried out by the cleaning staff of PSI.
- d) It is only permissible to open the cultures in safety cabinets. These safety cabinets are subject to annual maintenance. The maintenance is documented by the BSO.
- e) An autoclave, which must be regularly checked for functionality, must be present in the building.
- f) Unbreakable containers must be used for samples. Samples must be kept closed during storage and transport. No glassware can be used to cultivate Class 2 microorganisms.
- g) During pregnancy, BSL-2 activities can only be carried out subject to the approval of the BSO and to medical advice.
- h) In case of injuries, PSI Betriebssanität (occupational safety unit) must be notified immediately by dialling 3333 (056 310 3333). It will take the appropriate measures, e.g. call a doctor. A protocol has to be prepared (see section 9: "Accidents/Emergencies").
- i) Contaminated liquid and solid waste must be treated in a suitable way so as to inactivate biological material.

4 Safety regulations for animal care

Animals must be cared for in line with animal protection legislation as well as regulations relevant for the welfare of animals and the quality of the care of laboratory animals. Questions regarding correct animal care as well as ethical aspects of animal care and its necessity must be discussed with the animal welfare officer at PSI. Projects with genetically modified animals (transgenic & knockout animals and cancer models) are subject to the ESV and must be reported to the Swiss Chemical and Biological Safety department ("Kontrollstelle Biosicherheit").

The following applies with regard to transport:

Pathogen-free, genetically modified animals must be transported in the corresponding cages or containers that are secure against escape as prescribed by animal protection regulations. The cages or containers must be clearly labelled (recipient, sender and note: 'Living animals') and the species and number of animals must be stated. Transported animals are counted before and after transport, and any irregularities are clarified immediately.

5 Special safety measures when working with primary tissues (including blood) of humans and primates

- a) The BSO must be informed about any projects involving primary human tissues before such projects begin.
- b) Primary human tissues are potentially infectious. Such material must be handled according to BSL-2 conditions. **Annex 5** must be observed.
- c) Persons working routinely with primary human tissues will be required to take periodic medical examinations and be vaccinated against Hepatitis B.

6 Medical care

- a) A health card will be provided if the employee needs or requests one. This card is then part of that person's HR file. The employee alone decides who should have access to these data. The BSO is merely told who has a health card.
- b) Persons working routinely with primary human tissues (including blood) must be vaccinated against Hepatitis B. This will be organised by the BSO. The costs are borne by the organisational unit.
- c) Persons working with animals should be alert for signs of allergies. Problems that arise must be reported to the BSO and to the Human Resources team, who will organise medical assistance.

7 Disposal of biological material

7.1 Microbiological and tissue culture biological waste

All biological waste (liquid and solid waste) of genetically modified or pathogenic organisms must be autoclaved prior to disposal, or inactivated by an approved chemical disinfectant.

Biological waste (cell culture plates, media solutions, contaminated pipettes and containers, used gloves etc.) must be stored separate from regular waste (paper, cardboard etc.). Solid biological waste is collected in special bins with two autoclavable plastic bin-liners and a lid. Large flasks and bottles of waste culture medium (maximum volume per bottle 2 litres) must be collected. Sharps (needles, scalpel blades etc.) must be collected in disposal plastic sharps containers, which are then autoclaved. Glass pipettes must be collected in a suitable container. Sharps must be collected in certified boxes and disposed of as hazardous waste (LVA code 18 01 01).

Containers from risk category 2 laboratories are marked with the *biohazard* warning symbol.

Full bins and baskets must be taken to the autoclave room by a lab member and placed in the area for contaminated waste. After autoclaving, the solid waste is disposed of with the regular waste. Autoclaved or inactivated fluids can be emptied into a sink.

Strategies for inactivating biological waste are explained in **Annex 4** (disinfection and cleaning).

7.2 Animal waste

Genetically modified animals must be inactivated and must not be used as feed animals.

Cadavers must be packed in plastic (bags) and stored in a -20°C cadaver freezer for disposal. Cadavers are collected and incinerated by a disposal firm.

Cadavers from risk category 2 projects (e.g. virus--infected) must be double packed, labelled as biohazardous and autoclaved before being placed in the freezer for collection.

Cadavers (infected or not) containing radioactive isotopes with short half-lives are packed in plastic, stored in a -20°C freezer in an isotope laboratory type C until the isotope has decayed below a specific activity of 1 LE or an absolute activity below 100 LE and are then transported for incineration as above.

Cadavers (infected or not) containing radioactive isotopes with long half-lives (> 60 days half-life) are packed in plastic, stored at -20°C and sent for incineration together with other radioactive waste in the special-waste incinerator (ask the Radiation Protection Officer).

8 Transport of biological materials outside PSI

The line managers or project managers are responsible for the correct importing and exporting of biological samples. The current instructions can be found at http://www.efbs.admin.ch/index.php?id=146&L=3. The BSO and the Gefahrguttransporte (dangerous goods carriage) Group are on hand with advice.

8.1 Export

- a) There are restrictions on the import of biological materials into certain destination countries. The recipient must send the sender a copy of any import permit required, which must be attached to the package.
- b) Some biological materials fall under the definition of *Dangerous Goods*, e.g. infectious agents, genetically modified organisms, and require special packing and accompanying documents. The classification of such materials prior to transport will be carried out with the help of the BSO or staff from the *Gefahrguttransporte* (dangerous goods carriage) Group.
- c) Radioactive materials may not be shipped from PSI without permission of the Radiation Safety Officer. The procedure for such transport is described in VART01 (<u>https://ecm.psi.ch/asidoc/VA/VART01.pdf</u>), which provides notes on the correct transport process.

8.2 Import

- a) The import of some so-called *animal products* from countries outside of the EU requires a permit. The *Gefahrguttransporte* (dangerous goods carriage) Group at PSI can provide advice on permits.
- b) You need a specific import permit for each country. A copy of the appropriate permit must be sent to the supplier of the products, who must attach it to the package before sending.

9 Accidents / Emergencies

9.1 Emergency planning

How to proceed in the case of accidents and emergencies is documented in PSI regulations (see AW-NFO-98-01).

The telephone numbers of the persons responsible are listed in **Annex 6**. This list is available in the BSL-2 laboratory.

9.2 Accidents / Injuries

All accidents resulting in injured persons must be reported immediately to the safety headquarters by telephone by dialling 3333 and to the line manager. In the case of projects in risk group 2, the BSO and his deputy must also be informed. The BSO reports every incident (self-treated injuries, material damage) and accidents (injuries requiring medical care) to the safety officer.

In the case of injuries, PSI Betriebssanität (occupational safety unit) is automatically notified by dialling 3333. PSI Betriebssanität prepares a protocol. In the case of projects in risk group 2, the BSO receives a copy. A decision is made by the BSO/PSI Betriebssanität as to whether further medical assistance is required.

9.3 Spills of liquids

In case of a spillage of biological material, use a *spill kit* for decontamination (such as that in OFLG 1st floor elevator room on the Aare side).

A spill kit contains: gloves, paper, Bomix, masks.

The procedure in the event of spillage of fluids is regulated in **Annex 7**. These instructions are available in the laboratory.

The person who caused the spillage is responsible for decontamination (unless he is injured).

In the case of projects in risk group 2, the BSO must be informed.

10 Education

The line manager or project manager is responsible for proper introduction of employees to safe performance of BSL-1 activities at PSI. Employees who are involved in a BSL-2 project or work in a BSL-2 laboratory receive additional instruction from the BSO. Persons who work with biomaterials must certify in writing to have read and understood the laboratory rules (**Annex 1**). The code of conduct for staff working in biological laboratories at PSI is published at regular intervals. The BSO is responsible for the organisation of regular seminars on biosafety. Documentary evidence of training and instruction received is regulated such that line managers are informed at all times about the status of the employee's training.

Annex 1 - Laboratory rules

These laboratory rules are based on the "Safety concept according to ESV and SAMV for Level 2 laboratories" and apply at PSI to BSL-1 and BSL-2 laboratories.

Basic rules for safe working in a laboratory used for microbiology or molecular biology

- Windows and doors of the working areas are closed during work.
- It is forbidden to eat, drink, smoke or use snuff in the workrooms; cosmetics are not to be applied there. Foods must not be kept in the working area.
- A laboratory coat or other prescribed protective clothing must be worn while working with toxic or carcinogenic materials or with microorganisms in workrooms.
- Contaminated gloves must be cleaned or replaced immediately.
- When using gloves, care must be taken to ensure that that no organisms or hazardous substances are dispersed as a result of telephoning, opening doors of whatever kind, using water taps etc.
- The wearing of eye protection is not necessary for work in a safety workbench.
- Protective clothing must be removed when leaving the working areas.
- Mouth-pipetting is forbidden; pipetting aids must be used.
- The use of syringes and cannulae must be kept to the absolute minimum. They must be disposed of properly¹ after use.
- During all manipulations, care must be taken to ensure that aerosol formation is prevented as far as possible.
- Upon completing the work and before leaving the working area, an employee must wash his hands carefully and, if appropriate, disinfect and moisturise them, paying attention to protection of the skin.
- The working areas should be cleared up and kept clean. The benches must be disinfected before and after use according to the hygiene concept. Only the

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See also the template *Measures to prevent infectious diseases transmissible by blood* and the SUVA publication "Verhütung von Berufskrankheiten in diagnostisch-mikrobiologischen Laboratorien" (Prevention of occupational diseases in diagnostics/microbiological laboratories) / Order number: 2869/27d

Order address: http://www.suva.ch/waswo/

equipment and materials actually needed should be kept on the workbenches. Stocks are stored only in the designated areas or cupboards.²

- The identity of the microorganisms used is checked if there is a certain probability of contamination by pathogenic organisms or if it is required to assess the potential risk.
- With regard to work involving microorganisms, employees are to be instructed verbally and in relation to the particular place of work (according to their prior knowledge) before the commencement of the work.
- Vermin must be eliminated regularly.
- The keeping and use of personal items (e.g. bags, mobile telephones etc.) in the working area must be kept to a minimum.
- Contaminated equipment must be autoclaved or disinfected before being cleaned.
- Waste containing pathogens must be collected according to the requirements of the disposal concept and rendered inactive by autoclaving or disinfection.
- If infectious material is spilled, the contaminated areas must be shut off and disinfected immediately. Safety-related laboratory incidents must be reported immediately to the biosafety officers.
- First-aid instructions for accidents involving pathogenic organisms must be accessible immediately in the working area. All injuries must be reported to the relevant managers and to the biosafety officers.
- Expectant and nursing mothers must not work with infectious human pathogenic microorganisms or materials containing such microorganisms. The exceptions are set out in the Mutterschutzverordnung (Swiss Maternity Protection Ordinance).³

² The guidelines of EKAS ["Eidgenössische Koordinationskommission für Arbeitssicherheit": Federal Coordination Commission for Occupational Safety, FCOS] must be observed:

⁻ Chemische Laboratorien (Chemical laboratories) (EKAS guideline no. 1871)

⁻ Brennbare Flüssigkeiten - Lagern und Umgang (Flammable liquids - storage and handling) (EKAS guideline no. 1825)

Säuren und Laugen (Acids and alkaline solutions) (EKAS guideline no. 6501)
 Order address: http://www.suva.ch/waswo/

Exceptions are possible if an occupational health specialist examines the working situation and detects no additional danger. Regarding the legal background, see Art. 62 of Ordinance 1 to the Labour Act dated 10th May 2000 (ARGV1; SR 822.111) and Art. 10 and 17 of the Ordinance by the EVD dated 20th March 2001 (on dangerous and onerous tasks during pregnancy and maternity (Mutterschutzverordnung; SR 822.111.52)).

Annex 2 - Meaning and use of the "biohazard" warning symbol

This annex is based on the "Safety concept according to ESV and SAMV for Level 2 laboratories", Annex 8, FOEN 2008

1. Purpose

The "biohazard" warning symbol draws attention to the risks due to Group 2 pathogenic or genetically modified organisms and serves to reduce the dispersal and uncontrolled multiplication of organisms and to protect people from unintentional infection.⁴

The warning symbol is aimed at three different groups of people, with a different purpose in each case:

- 1. It reminds employees that infectious organisms are present in a certain working area and that contamination is to be expected.
- 2. It serves to warn plant personnel without the necessary knowledge not to enter the designated area or touch instruments and containers marked in this way.
- 3. It serves to draw the attention of the emergency services to the protective measures to be taken.

2. Principles for application

The "biohazard" warning symbol is used as follows:

- 1. It is used sparingly to retain its signalling effect.
- 2. It is positioned in the entrance area to the Level 2 rooms.
- 3. It is also attached to equipment (e.g. to the incubator) or positioned in working areas <u>inside</u> an already marked room if there is a possibility of a higher biohazard risk there <u>compared with</u> the immediate surrounding working area.
- 4. It is attached to the second or third layer of packaging of a sample contained in a pack which is impermeable to liquids if this sample is stored, processed or transported <u>outside</u> a marked room.
- 5. It is attached temporarily to equipment (e.g. to a centrifuge) <u>outside</u> a marked laboratory if work involving Group 2 organisms is being done there as an exception.

The ESV provides for the use of the biohazard warning symbol for laboratories of Safely Level 2 and higher.

6. It is attached to doors of freezers located <u>outside</u> a marked room, if Group 2 organisms are kept there.⁵

3. Special case: handling marked waste bags

Commercially available, autoclavable waste bags for biological waste carry a warning symbol. After this waste has been autoclaved and inactivated, the "biohazard" warning symbol on the bags is no longer applicable. So this is clear, autoclaved waste bags must be identifiable as "autoclaved". To this end, they are equipped with heat-sensitive indicators.

Inactivated waste must not be disposed of with the industrial waste until the "biohazard" warning symbol is no longer visible. To this end, it is hidden by a second layer (e.g. by a container) in order not to unjustifiably unsettle third parties in the disposal chain.

These requirements are set out in more detail in section 7 of AW-96-14-02.

4. Appearance and form of the warning symbol and safety symbol



European biohazard warning symbol⁶



International biohazard symbol (with or without text)

If the insides of the freezers are subdivided into compartments with different doors, the warning symbol is attached to the various internal doors.

⁶ Order address: Sicherheit/Safety (sicherheit@psi.ch)

Annex 3 – BSL-2 Lab with Limited Access

Room No.:

People with permission to work with organisms of BSL-1:

Name	Start	Organism
Philipp Berger	1st January 2014	mammalian / insect cells

People with permission to work with organisms of BSL-2:

Name	Start	Organism
Philipp Berger	1st January 2014	Lentivirus / BacMam

Annex 4: Disinfection and cleaning (hygiene plan)

1. Applies to the following premises

Room No.	Organisms	Laboratory manager
OFLG 125	BSL-2	BSO

2. Notification and spreading of information

The hygiene plan is displayed in the laboratory. Compliance is documented.

3. Significance

Compliance with the hygiene plan helps towards personal safety at work and preventive health care as well as the quality of research.

The cleaning agents and disinfectants used at PSI are selected so that they fulfil the designated function in the hygiene plan, i.e. ensuring the effectiveness⁷ and user-friendliness required. The criteria of occupational safety, health protection and environmental protection are taken into account when products are selected.

Generally, the following applies:

- Always work with suitable (household) gloves when handling disinfectants (allergising potential).
- Only use cold water to make the disinfectant solution (to prevent vapours which could irritate mucous membranes) – if necessary, mix in the laboratory fume hood.
- Observe the dilution / concentration required for use.
- Adhere to the contact times required for disinfectants to act.
- Active life of instrument disinfectants according to the manufacturer's information (renew daily if disinfectant is mixed with cleaning agent).
- Surfaces to be disinfected should normally be wiped, not sprayed.
- After wiping on disinfectant: use the surfaces as soon as the disinfectant has dried.
- An unused, measured solution of surface disinfectant (e.g. 0.5% solution) can be kept in a closed (storage) container (e.g. spray-bottle) according to the manufacturer's information (usually 14 -28 days).

Users must be able to demonstrate the effectiveness of a disinfectant (to third parties) – either because they follow the instructions on use exactly or because there is microbiological evidence of inactivation under the given conditions.

4. Hygiene plan

What	When	With what	How	Remarks
Surface, instrument, item	Frequency, timing, interval	Materials, cleaning agents and disinfectants to be used	Task, e.g. clean, disinfect, sterilise / by wiping, washing, spraying, soaking etc.; necessary personal protective equipment	
Cleaning of the hands	When leaving the laboratory	Soap	Wash hands	
Hygienic disinfection of the hands	After contamination	Isopropyl alcohol	Wash hands	
Laboratory clothing	After 14 days of use or after contamination	PSI cleaning	In the case of contamination, decontaminate beforehand with 70% EtOH	
Safatu cabinat	Daily after use, or after contamination	70% EtOH	Wipe	
Safety cabinet	Have HEPA filter checked every 2 years and replace if necessary	Service	Maintenance agreement	
Laboratory glass	After contact with organisms	70% EtOH	Rinse	
Working surfaces	Daily after use, or after contamination	70% EtOH	Wipe	
Refrigerator	Annually and after contamination	70% EtOH	Wipe	
Incubator(s)	Annually and after contamination	70% EtOH	Wipe	
Centrifuge(s)	Annually and after contamination	70% EtOH	Wipe	
Washbasins	Annually and after contamination	70% EtOH	Wipe	
Floor	No contamination: cleaning, as agreed, by cleaning staff	Standard cleaning agents PSI cleaning		
Floor	After contamination: cleaning not by cleaning staff	70% EtOH	Wipe (by person responsible)	
Waste involving risk of injury	As required	Autoclaving	Disposal in puncture-proof plastic containers which can be closed tightly and are then autoclaved.	
Biological waste (solid)	As required	Autoclaving	Disposal in autoclavable bags which are then autoclaved.	
Biological waste (effluent)	As required	1% Bomix	Incubate for 30 minutes, then regular drain	
Waterbath	As required	70% EtOH	Wipe	

5. Instructions for the use of disinfectants

Trade name / substance	Applications ¹⁾	Spectrum of activity, organisms ²⁾	Dilution required for use in %	Contact time	Other papers ³⁾ Remarks
70% EtOH (ethyl alcohol)	Disinfecting of hands Disinfecting of surfaces	B; Mb; F; eV	70%	10 min.	
Javelle water	Supernatant cultures (prokaryotic)	B; Mb; F; e&ueV eV	0.5	30 min.	
Bomix plus	Supernatant cultures (eukaryotic, viral)	B; F; eV	1%	30 min.	
ASEPTOMAN	Disinfecting of hands	B; Mb; F; eV	100%	1 min.	Isopropyl alcohol

- 1) Disinfection of hands / disinfection of surfaces / disinfection of instruments / supernatant cultures
- 2) **B:** Bactericide / **Mb:** Mycobacteria (tuberculocide) / **F:** Fungicide / **e&ueV:** Enveloped and unenveloped viruses / **eV:** Only enveloped viruses /

Bs: Bacterial spores

3) Instructions on use / data sheet / safety data sheet (indicate where they are kept)

6. Organisms used

The hygiene plan applies specifically to the rooms listed on the title page. Work with the following BSL-2 organisms is carried out in these rooms:

Organisms		
Lentivirus	VSVg baculovirus	

7. Instructions to the cleaning staff

The cleaning staff is instructed on how the BSL-2 laboratory is to be cleaned.

8. Weekly maintenance plan

- Refill EtOH canister
- Empty waste bottles
- Check CO2
- Check water level in all incubators and refill
- Check waterbath
- Refill tips, glass pipettes
- Replace yellow bags
- Remove trash from tables

Week	Who	Date	Signature

Annex 5: Measures to prevent infectious diseases transmissible by blood

1. Background

This leaflet is aimed at people employed at PSI who work with blood and other body fluids, especially laboratory personnel and cleaning service staff.

Infectious diseases, pathogens of which are contained in the blood, can be transmitted by blood or other body fluids which contain blood: e.g. through stab wounds, cuts, splashes into the eyes and onto the mucous membranes of the mouth as well as through contact with broken skin (open wounds).

Blood and body fluids containing blood must always be regarded as infectious!

The only people who work in working areas with a high risk of infection are those who have been instructed about possible dangers from infectious diseases in the course of their work, measures to prevent exposure, hygiene regulations, the wearing and use of protective equipment and protective clothing, and action in the event of incidents. Stab wounds and cuts are prevented by technical means and appropriate equipment.

Employees who, on the basis of experience, are exposed to a higher risk of stab wounds and cuts from items contaminated with blood or who have foreseeable contact with blood are **inoculated against Hepatitis B** at PSI.

2. Rules of conduct for laboratory personnel

To protect oneself and others (especially laboratory personnel and cleaning staff) against infectious diseases which can be transmitted through blood, the **following basic rules of conduct** must be followed:

- Avoid stab wounds and cuts: only place protective covers over used cannulae if absolutely necessary, preferably using a mechanical aid or the one-handed technique, but never with both hands (no two-handed recapping).
- Items contaminated with blood which pose a risk of injury (e.g. used cannulae and sharp disposable utensils) must be disposed of in unbreakable, puncture-resistant and closable containers. Hand over the containers for disposal no more than 2/3 full, tightly closed and marked as a biohazard (LVA code 18 01 01).
- Disposable gloves are to be worn for activities involving possible contact with blood or body fluids. When disposing of the gloves, turn them inside-out, so the outside, contaminated glove surface is on the inside. Wash and moisturise hands.
- Always wear eye protection and a respirator when carrying out tasks which could cause splashes.
- Disinfect and/or sterilise protective clothing and other material which might be contaminated.

3. Rules of conduct for the cleaning staff

People entrusted with cleaning duties should be informed about the dangers of stab wounds and cuts. In particular, these people must be instructed that any refuse bag could contain items/instruments capable of piercing or cutting and that appropriate precautions must be taken when disposing of refuse bags.

- Never press waste bags down by hand.
- When emptying waste bins, never put bare hands or even hands protected by gloves into the bins.
- Only grasp waste bags near to the closure. Waste bins without a liner must be emptied by being tipped over.
- Wear liquid-proof protective gloves and dispose of them after work then wash hands thoroughly and moisturise them.

4. Action following an incident with possible transmission of infection

The following immediate action should be taken after an incident with possible transmission of infection:

- Wash hands and contaminated areas of skin immediately with soap and water and/or disinfect them.
- If the eyes or mucous membranes have been in contact with blood or with body fluids containing blood, rinse them immediately with plenty of water or a physiological liquid.
- In the event of an incident in which there is a risk of infection through blood (stab wound, cut, splash onto a mucous membrane or contact between blood and open, injured skin), proceed according to PSI's emergency planning (telephone 3333).
- Report stab wounds, cuts and splashes⁸ to PSI Betriebssanität (telephone 3333)
 without delay, which then also informs the line manager and the BSO. Contact your line
 managers in the event of any uncertainty or if you have any questions.

Regarded as an accident according to Art. 9 of VUV ["Verordnung vom 19. Dezember 1983 über die Verhütung von Unfällen und Berufskrankheiten": Ordinance governing the prevention of accidents and occupational diseases] and must therefore be reported to the accident insurance fund.

Annex 6: Emergency numbers

1. Emergency numbers

Area of responsibility	Telephone	Body responsi	ble
Emergencies: fire, first aid	3333	Internal services	emergency
Emergencies: poisoning; effect of chemicals	0145 044/ 251 51 51	Toxicological I Centre	nformation

2. People responsible for safety and specialists at PSI

Area of responsibility	Telephone	Contact person & e-mail
Biology, biosafety officer BSO	47 28	Philipp.Berger@psi.ch
Deputy	28 48	juergen.gruenberg@psi.ch
Chemicals	20 11	louis.tiefenauer@psi.ch
Radiation protection	44 87	albert.fuchs@psi.ch
Safety officer	23 50	yves.loertscher@psi.ch
Access authorisation	26 00	siz@psi.ch

Annex 7: Decontamination of spillage

- 1. The waste producer is responsible for cleaning (except if he is injured)
- 2. Prevent access to the contaminated area
- 3. A helper is required when bigger volumes are spilled
- 4. Wear gloves

Soak spilled liquid with paper (dispose of paper in autoclavable bag) Carefully collect broken glass (dispose of in container)
Decontaminate area with 70% ethanol or 2% Bomix
Incubate for 30 minutes
Clean area

Annex 7: Dekontamination von Verschüttungen

- 1. Der Verursacher ist für die Reinigung verantwortlich (ausser er ist verletzt)
- 2. Unfallstelle absperren
- 3. Bei grösseren Verschüttungen Helfer zuziehen
- 4. Handschuhe anziehen

Flüssigkeit mit Papier aufsaugen (Papier in Autoklaviersack entsorgen) Splitter vorsichtig einsammeln (in festem Container entsorgen) Fläche mit 70% Ethanol oder 2% Bomix behandeln 30 Minuten einwirken lassen Fläche reinigen