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Integrated European Checklist for Laboratory Biorisk Management in Handling of High Consequence Risk Group 3 and 4 Agents (ECL-Biorisk)

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[6] http://www.rki.de/Quandhip/EN/Home/Homepage_node.html

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Table of Checklist Contents

Table of abbreviations (in order of appearance)

ELC- Biorisk: Integrated European Checklist for Laboratory Biorisk Management in handling of high consequence Risk Group 3 and 4 agents

BSC: Biological safety cabinet

BSL: Biosafety level

EU: European Union

QUANDHIP: Quality Assurance Exercises and Networking on the Detection of Highly Infectious Pathogens

ENP4Lab / EuroNetP4 Laboratory: European Network of P4 laboratories

ERINHA: European Research Infrastructure on Highly Pathogenic Agents

ETIDE: European Training in Infectious Disease Emergencies

CEN: Comité Européen de Normalisation

CWA: CEN Workshop Agreement (Biorisk Management Guidelines)

EQADeBa: Establishment of Quality Assurances for Detection of Highly Pathogenic Bacteria of Potential Bioterrorism Risk

ENHPB: European Network for Highly Pathogenic Bacteria

EN: European Norms

BMS: Building management system

HEPA: High efficiency particulate air

HVAC: Heating, Ventilation and Air-Conditioning

RPE: Respiratory protective equipment

TV: Television

PPE: Personal protective equipment

UPS: Uninterruptible power supply

FFP: Filtering face piece

PP: Polypropylene

PE: Polyethylene

PC: Polycarbonate

PMP: Polymethyl pentene

The European biosafety and biosecurity **checklist** controlling biorisks associated with the Design, Maintenance and Operation of BSL3 & 4 facilities and support of designated personnel was applied for self-evaluation and the indicated results are confirmed::

Authorization				
Authorized Personnel	**Name**	**Signature**	**Position**	**Date**
Biosafety				
Biosecurity				
BSL3/4 laboratory Manager				
Institute Director				
Other				

Introductory notes

1. This management tool is designed to guide the implementation of a biorisk management system that ensures robust biosafety and biosecurity practices associated with the design, commissioning, routine operation and decommissioning of BLS3 and 4 laboratories.
2. This document (ECL-Biorisk version 01-January-2015) was developed and agreed between 29 European BSL3-laboratories and 6 European BSL4-laboratories working together in the EU funded Joint Action “Quality Assurance Exercises and Networking on the Detection of Highly Infectious Pathogens” (QUANDHIP).
3. The current draft has been updated from checklist documents produced by the EuroNetP4 Laboratory and QUANDHIP projects. It has also taken into consideration recommendations produced by other European initiatives, listed as follows:

   - Biosafety Europe Coordination, harmonization and exchange of biosafety and biosecurity practices within a pan-European network. It also provided the backdrop to the national legislative and regulatory framework of many European States involved with handling high consequence pathogens.

   - ERINHA – a pan-European research infrastructure organized and designed to reinforce the European co-ordination and capacities for the study and surveillance of highly pathogenic agents.

   - ETIDE – provided the design and implementation of multidiscipline training programs for health care workers including laboratory workers, clinicians, nurses and first responders dealing with high consequence viral and bacterial pathogens.

   - CEN. CWA 16393: 2012 **-** Laboratory biorisk management guidelines for the implementation of CWA 15793:2008

   - European Network for Highly Pathogenic Bacteria, EU funded project EQADeBa
4. This document does not aim to replace any national regulations but provide a tool for self-assessment against internationally accepted rules and procedures for the handling of high-risk biological agents. It could also be used to demonstrate the implementation of biosafety and biosecurity for inter-laboratory cooperation on high-risk biological agents.
5. In the framework of the Joint Action QUANDHIP, the checklists produced by both, the Euronet-P4 laboratory project and the EQADeBa project, have been integrated and harmonized for handling of risk group 3 and 4 infectious agents.
6. This comprehensive document is designed to be an ‘aid-memoir’, and user-friendly self-assessment tool for identifying the infrastructural and operational requirements for handling high consequence pathogens. In addition, the document provides informative guidance for the design, building, maintenance or upgrade of appropriate European facilities. It also seeks to inform and contribute to the design of appropriate training programs aimed at improving the knowledge and competence of personnel and inform the decision-making process associated with biorisk and biosecurity management practices.
7. The consolidation of the existing network’s laboratory checklist will ensure European laboratory preparedness and deployment of resources able to manage natural and deliberate outbreaks of high consequence pathogens in facilities designed and managed according to biosafety and biosecurity best practice.
8. The BSL 3 and BSL 4 hazard classification does not necessarily determine the precise handling of biological hazards in the laboratory setting, as the final laboratory area designed is dependent upon the nature of the work being undertaken and procedures that are being used during the manipulation of the organism (e.g. animal handling, large scale production, molecular analysis etc. The containment levels described are designed to provide the minimum containment and operational requirements needed

for the safe handling of the microorganisms in the laboratory setting.

9. Finally, the use of the term ‘containment’ refers to the management of high consequence pathogens in the laboratory environment, designed to prevent exposure of laboratory workers and people and animals in the outside environment to the agents being used. This is achieved by the combination of using the principles of primary and secondary containment.
    1. Primary containment: Defined as the protection of the worker and immediate environment through a combination of good microbiological practices or techniques and the use of appropriate primary containment devices, e.g. Class III microbiological safety cabinets.
    2. Secondary containment: Defined as protecting people and the environment outside the laboratory by combining appropriate laboratory design and operating procedures, e.g. access restriction, air handling and safe disposal of waste.

Pre-phrase

Organizations responsible for aspects of design, building, operation and maintenance of high containment laboratories require increasingly robust biosafety and biosecurity practices, able to identify risks and introduce infrastructure and operational controls that prevent unintentional and intentional release of pathogens that could be the source of local and community outbreaks of highly infectious diseases. It has been recognized that there has been a need to consolidate and harmonize best practices undertaken by a large number of stakeholders, all responding to increasingly stringent regulatory systems operating their country. The original checklists developed during the projects ENP4Lab and EQADeBa identified and recommended 'best practice' for the design, management and operation of BSL3 and BSL4 facilities. These documents formed the basis for the construction of this document. This consensus document does not set out prescriptive requirements, as this has to be determined individually through undertaking risk assessment of work being planned, together with the types of laboratory environment being considered.

Many of the concerns stem from the fact that there are limited publications containing robust scientific data that directly underpins the design of BSL3 and 4 facilities. This lack of information is compounded by the knowledge that current security and operating practices vary in many parts of the world. This document does not replace national or European legislative requirements but provides users with a checklist outlining the basic requirements needed to be considered for establishing an initial design, building, operation, maintaining or upgrading of BSL3/4 facilities. The document outlines areas of importance when considering the selection of personnel, their training and continuous professional development programs covering biosafety and biosecurity practices. It can be used as a tool for self-evaluation to assess current biorisk management systems. It also provides a valid and robust set of tools able to demonstrate to third parties consistent biorisk management systems that provide confidence for sample exchange in the framework of diagnostic and research activities, personnel transfer, as well as for accreditation processes.

How to use the document

The document is divided in several chapters. The chapters include tables with specific check boxes applicable for various biocontainment levels. Dots with different intensity of grey to white indicate the importance of specific recommendations (black- mandatory; light grey- optional; white- not required, or NA- not applicable).

Table Key	● mandatory	◯ optional	O not required	NA – not applicable

"Discretionary" could be mandatory if required by national laws, guidelines or regulations.
At the end of each chapter, there is room for description of other regulations on specific items. Please indicate the item and describe if applicable.

In case, recommendations given by individual check points are not in accordance with your national regulations, please mark and describe at the end of the checklist.

1. Biorisk management systems

1.1 Since the original ENP4Lab & EQADeBa were founded, both networks have contributed to the establishment of the Biorisk Management Guidelines (CWA 15793:2011). This document specifies the requirements for establishing a robust biorisk management system that will enable individuals and organizations to develop and implement a biorisk policy that establishes objectives and processes to achieve the desired policy commitments and improve performance. It provides a comprehensive risk based approach that takes into account the legal requirements and current knowledge on biosafety and biosecurity.

1.2 Effective management of BSL3 and 4 facilities should aim to be built on the concept of continual improvement through a cycle of planning, implementing, checking and reviewing (i.e. Plan, Do, Check and Act). It has proved essential to establish comprehensive structures that outline clear management and operational responsibilities for BSL3 and 4 systems. These include: biosafety, engineering and maintenance of all plants and systems, scientific direction and oversight. The responsibilities and reporting lines should be documented and should include plans for communication and authorizations. Several laboratories are also required to meet external standards to conduct their defined role in the provision of clinical or national reference functions.

1.3 It is recommended that impartial and independent reviews of facility design and operations become part of overall management processes. Such reviews would ideally not only be undertaken through regulatory demands but as part of regular management processes at intervals of approximately 3-5 years. In addition, where significant changes are undertaken in the infrastructure of facilities or in the operational status, an independent review body with experience in BSL3 and/or 4 facilities should be established to advise and monitor adherence to the appropriate biosafety and biosecurity regulatory requirements. It is also recommended that, at an early stage of laboratory design, a review body of experienced biosafety professionals, bioengineers and scientists should be established in order to act as external reviewers throughout the project management process.

1.4 As part of this review it is recommended that the biorisk management structure of any high containment facility, dealing with high consequence agents, should also refer to the comprehensive guidance outlined by CWA 15793:2011. This document contains an extensive and globally agreed list of the areas considered important when reviewing biorisk management systems within laboratory and institute facilities.

1.5 Therefore, it is recommended that the BSL3/4 harmonized checklist is used in conjunction with the robust series of biorisk guidelines published in January 2013.

1.6 This document does not replace any national regulations or laws regarding biosafety and biosecurity.

1.7 Recent adaptation of the CWA Guidelines into a user friendly online program allows interrogation of the criteria and enables the user to focus on those details requiring further development in the planning, execution and operation of new facilities or upgrading of existing ones. Together with detailed checklist outlined in this document “users” can further enhance their understanding of their facility and operational needs according to the BSL3/4 agents and procedures being considered. An online program summarizing the CWA Guidelines has been established by the Public Health Agency of Sweden and can be accessed through the following web address http://www.sakrabiorisker.se.

1.8 This checklist is recommended to form part of a self-assessment process to identify or monitor biocontainment needs. Further development can provide a basis for future certification/approval processes conducted by national competent bodies or other recognized organizations. It is also agreed that many of the laboratories have to meet the requirements of other regulations such as hazardous materials and animal procedures authorizations. The details are not covered in this checklist and should be consulted as part of any ongoing project management system.

2. Laboratory design and infrastructure

Using the appropriate processes during the design of a new specialist laboratory or conversion, upgrading or review of existing ones ensures that facilities, equipment and processes are designed and operated in a safe and secure way according to the biorisk, and best practices in biosafety and biosecurity. An interdisciplinary team approach is recommended. This team should visit and interact with existing facilities at an early stage. It is recommended that a multidiscipline team is composed and should include individuals experienced in BSL 3/4 design, biosafety and biosecurity.

As recommended by the CEN document, laboratory infrastructure and operational management require that the facilities, equipment and work undertaken are designed and maintained to ensure safe and secure operation, in accordance with all performed risk assessments, including biorisks. The laboratories should be located in a secured area and access should be restricted to authorized personnel.

Item	BSL 3	BSL 4 Suited	BSL 4 Cabinet	General access & facility requirements
2.1	●☐	●☐	●☐	Containment laboratories should be located away from external building envelope walls.
2.2	●☐	●☐	●☐	Separation of the containment area from public areas by a secured door.
2.3	●☐	●☐	●☐	Technical control centre situated adjacent to containment laboratory.
2.4	●☐	●☐	●☐	Access limited to authorized personnel.
2.5	●☐	●☐	●☐	Laboratory room doors have appropriate signage (e.g., biohazard sign, containment level, contact information, entry requirements, agents being used).
2.6	●☐	●☐	●☐	Size of door openings allows passage of all anticipated equipment.
2.7	●☐	●☐	●☐	Clean and dirty changing areas labelled.
2.8	●☐	●☐	●☐	Doors to the containment laboratory mechanically lockable. *Note: this does not apply to areas within the containment laboratory*.
2.9	●☐	●☐	●☐	Doors provide restricted access by installation of a controlled access system (e.g. card key) or equivalent, which register entry.
2.10	●☐	●☐	●☐	Electronic locking systems backed-up with a physical key-lock system.
2.11	●☐	●☐	●☐	Office areas located outside of containment laboratory. *Note: Data entry stations for data collection can be within containment laboratory provided they are located away from laboratory work areas.*

Item	BSL 3	BSL 4 Suited	BSL 4 Line	Section 2 continued: General access & location requirements facilities
2.12	●□	●□	●□	Anteroom door(s) located between the clean and dirty areas prevented from opening simultaneously with either the containment laboratory door or the clean change entry door. *Note: Interlock, visual or audible alarms, or protocols are all acceptable means*.
2.13	●□	●□	●□	Doors to the shower area and containment laboratory are interlocked and cannot be opened at the same time.
2.14	●□	●□	●□	Interlocked doors, if present, must have manual overrides for emergency exit.
2.15	●□	●□	●□	Entry to laboratory zone is provided with changing areas that separate personal and laboratory clothing suitable for that zone (i.e. "clean" changing area separated from "dirty" changing area).
2.16	●□	●□	**NA**	Entry to laboratory only possible via anteroom with airtight doors (e.g. inflatable or compression seal).
2.17	**NA**	●□	**NA**	Suit facility (animal or laboratory): Entry to hazard zone equipped with a suit change area, a chemical shower on the containment barrier (i.e., between the laboratory and suit change area) and water shower on exit from the zone (i.e. between "dirty" and "clean" change areas).

3. Biological safety cabinets (BSCs) and BSC lines

Item	BSL 3	BSL4 Suited	BSL 4 Line	Biological safety cabinets
3.1	●☐	**NA**	●☐	Biosafety Cabinets Class I, II, and III as available are in-situ tested in accordance with the EN 12469-2000(6) at least once a year.
3.2	●☐	●☐	**NA**	Interlock testing strategies (i.e. Class II Type B2 BSC internal cabinet supply fan and exhaust fan tested, if BSC are connected to central air ventilation), which ensure that internal supply fan shuts off whenever exhaust fan fails.
3.3	●☐	●☐	●☐	Checked by service and self-check: Presence of alarms for the detection of exhaust failure at the BSC tested by simulation of alarm conditions. *Note: Tested once a year by service*.
3.4	●☐	●☐	●☐	Checked by service: Presence of integrity-tested? HEPA filters installed into air supply system as a method of back draught protection. The exhaust ductwork is tested in situ by particle challenge testing using scanning method. *Note: Acceptance criteria: particle penetration not to exceed 0.01%.*
3.5	**NA**	**NA**	●☐	Integrity of HEPA filter housings with inlet and outlet bubble tight dampers installed into supply ductwork, where HEPA filters are used as back draught protection, and exhaust ductwork tested in situ to EU standards.
3.6	**NA**	**NA**	●☐	Back draught protection is required on supply, and exhaust air ductwork located between containment perimeter and HEPA filter or bubble tight back draught damper and is tested in situ.
3.7	**NA**	**NA**	●☐	Pressurization relationships across adjacent areas are verified (i.e. clean change to dirty change, dirty change to laboratory). Manometer readings are available outside and inside of lab. Checked and recorded daily. *Note: Acceptance criteria for inward directional airflow (under normal operations) need to be visually demonstrated (e.g. by holding a smoke pencil at each door leading to adjacent areas).*
3.8	**NA**	**NA**	●☐	Control systems are tested for fail-safe operation by failure of system components, (i.e. exhaust fan failure, supply fan failure, power failure [where possible]. This is to include audible/visual alarm testing. Tested twice a year at service. *Note: The sustained reversal of airflow across containment barrier is to be prevented.*

4. Containment barrier – Heating, Ventilation and Air Conditioning

Item	BSL 3	BSL4 Suited	BSL4 Line	Heating, Ventilation and Air Conditioning (HVAC)
4.1	●☐	●☐	●☐	100% outside air supplied.
4.2	●☐	●☐	●☐	Directional inward airflow by under pressure provided such that air will always flow towards areas of higher containment in cascade.
4.3	●☐	●☐	●☐	Visual pressure differential monitoring devices provided at entry to containment laboratory. Independent of the building management system.
4.4	●☐	●☐	●☐	Containment barrier provided with filters of efficiency equal to that of HEPA filtration.
4.5	●☐	●☐	●☐	Alarm (visual or audible) provided in the laboratory and outside laboratory area (i.e., to warn others and maintenance personnel) to signal air handling systems failure.
4.6	●☐	●☐	●☐	Supply air duct provided with back draught protection (i.e. HEPA filter; bubble tight back draught damper).
4.7	●☐	●☐	●☐	Supply air HEPA filtered.
4.8	NA	NA	●☐	BSL-4 suit one should add that the connection between the suit and the breathing air hose has to be HEPA filtered
4.9	●☐	●☐	●☐	Supply air system independent of other laboratory areas.
4.10	●☐	●☐	●☐	Supply air system interlocked (e.g. fans, dampers, electrical) with exhaust air system, to prevent sustained laboratory positive pressurization.
4.11	●☐	●☐	●☐	Exhaust air in series double HEPA filtered.
4.12	●☐	●☐	●☐	HEPA filters installed into the supply and exhaust system to conform to national standards.
4.13	●☐	●☐	●☐	Supply HEPA filter housings designed to withstand structural change.
4.14	●☐	●☐	●☐	Exhaust HEPA filter housings designed to withstand structural changes and provided with a method of isolation and decontamination.
4.15	●☐	●☐	●☐	Exhaust air system independent of other laboratory areas.

Item	BSL 3	BSL 4 Suited	BSL 4 Line	Section 4: Continued Heating, Ventilation and Air Conditioning (HVAC)
4.16	●□	●□	●□	Supply and exhaust systems located outside of containment accessible for repairs, maintenance, cleaning and inspection.
4.17	●□	●□	●□	Supply and exhaust air ductwork that is outside the containment perimeter (e.g., between containment perimeter and HEPA filter or bubble tight back draught damper) sealed airtight.
4.18	●□	●□	●□	Airflow control devices and duct sensors to be located downstream of the exhaust HEPA filter and upstream of the supply bubble tight back draught damper or HEPA filter, or if located upstream, duct penetrations to be sealed.
4.19	●□	●□	●□	Bubble tight back draught dampers and HEPA filters located in close proximity to the containment perimeter.
4.20	●□	●□	●□	Efficient vector control (e.g. Rodents and insects).

5. Building management and emergency alarm systems

The control system should have independent alarm and monitoring capability. Control systems for high containment facilities should be designed, constructed and tested to standards as defined by EN61508 and EN61511. Where the control system performs no safety related functions, EN61508, EN61511 may not be suitable for use as design standards. In this instance, the safety criticality of the system should be determined by the use of a suitable documented risk assessment and if no safety related functions are required an alternative national design standard can be used as appropriate.

Systems should fail to a safe condition, i.e. one that does not result in a release.

The alarm system should alert to changes in conditions, which could lead to an emergency situation based on the criticality of the system it is monitoring. The alarm system should monitor direct conditions and not from the BMS and be maintained on a separate power feed or computer system.

6. Laboratory integrity including surface finishes and casework

Item	BSL 3	BSL 4 Suited	BSL 4 Line	Room integrity, finishes and casework
6.1	●□	●□	●□	1. Integrity of containment surfaces tested visually and with a smoke pencil or other visual aid. 2. Floors, walls, and ceiling clear of cracks, chips and wear. 3. Wall/floor and wall/ceiling joints intact. *Acceptance criteria: Integrity of all penetrations (i.e. equipment, services, etc.) and seals (i.e. around doors, windows, autoclaves, etc.) on the containment barrier*.
6.2	O □	●□	●□	Integrity of containment tested by pressure decay testing.
6.3	●□	●□	●□	Doors, frames, casework, bench tops working surfaces impervious. *Note: The use of organic materials should be avoided.*
6.4	●□	●□	●□	Surfaces scratch, stain, moister, chemical, impact and heat resistant.
6.5	●□	●□	●□	Continuity of seal between floor and wall.
6.6	●□	●□	**NA**	Bench tops have no open seams and can contain spills, perimeter frame prevents leak of fluids to the floor.
6.7	●□	●□	**NA**	Benches, doors, draws, door handles etc. have rounded rims and corners..
6.8	●□	●□	**NA**	Drawers have catches that prevent them from being pulled out of chest.
6.9	●□	●□	●□	Interior surfaces and coatings to be gas and chemical resistant (e.g. will withstand chemical disinfection, fumigation).

7. Containment perimeter

Item	BSL 3	BSL 4 Suited	BSL 4 Line	Containment perimeter requirements
7.1	●□[1]	●□	●□	Double-door barrier autoclave with bioseal located on containment barrier; maintainable parts of autoclave to be preferably located outside of containment for ease of maintenance. *Note: The technical requirements for autoclaves should be regulated by national standards or acceptance of international rules.* *Note: In cabinet lines autoclave needs to be integrated.*
7.2	●□[1]	●□	●□	Barrier autoclave equipped with interlocking doors, and visual or audible alarms to prevent both doors from opening at the same time.
7.3	●□	●□	●□	For material that cannot be autoclaved (e.g. heat sensitive equipment, samples, film), other proven technologies for waste treatment (e.g. incineration, chemical, or gas) provided at containment barrier are used.
7.4	●□	●□	●□	All penetrations sealed at containment barrier.
7.5	**NA**	**NA**	●□	All conduit and wiring penetrating cabinet line are sealed at the containment barrier.
7.6	●□	●□	●□	Windows positioned on containment barrier are sealed in place and window-glazing material provides the required level of security.
7.7	●□	●□	●□	Installation of observation windows on containment barrier.

[1] Due to national laws a double-door barrier autoclave might not be required for BSL3, instead an autoclave accessible near to the BSL3 laboratory area and an adequate description of material packaging and transportation to the autoclave would be sufficient. Check here if applicable: □

8. Personnel and chemical shower plant operation and laboratory services

Item	BSL 3	BSL4 Suited	BSL4 Line	Laboratory services (i.e. water, drains, gas, electricity and safety equipment)
8.1	●☐	**NA**	●☐	Hand washing sinks with 'hands-free' capability are located near the point of exit from the laboratory or in the anteroom or on final exit.
8.2	●☐	●☐	●☐	If present, hand-washing sinks are provided with 'hands-free' capability.
8.3	●☐	●☐	●☐	Domestic water branch piping serving laboratory area(s) are provided with backflow prevention and isolation valve, and are located in close proximity to the containment barrier.
8.4	●☐	●☐	●☐	Drain lines and associated piping, including autoclave condensate are separated from areas of lower containment and connected to an effluent sterilization system.
8.5	●☐	●☐	●☐	Sealed drains connected to an effluent sterilization system are sloped towards the sterilization system to ensure gravity flow. Considerations should be given to the installation of valves to isolate sections of piping for in situ decontamination; the effluent sterilization system (e.g., piping, valves, tank) to be heat and chemical resistant consistent with application.
8.6	●☐	●☐	●☐	Emergency eyewash facilities.
8.7	●☐	●☐	●☐	Emergency shower equipment.
8.8	●☐	●☐	●☐	Drainage traps provided to required deep seal depth in consideration of air pressure differentials.
8.9	●☐	●☐	●☐	All waste water is collected and inactivated chemically or thermally.
8.10	●☐	●☐	●☐	Open floor drains and gullies not provided, except if essential (e.g., body shower and animal rooms).
8.11	●☐	●☐	●☐	Provision of independent power supply.
8.12	●☐	●☐	●☐	Lighting switches and fittings sealed to protect against ignition of vapors by sparking.
8.13	●☐	●☐	●☐	All equipment tested and certified safe for use.

9. Emergency provision, plans and responses

The plans for emergency events including security incidents should include mitigation measures as well as failures of safety system, which ideally will have more than one mitigation step. Scenario exercises should be regularly rehearsed between users, on-site support services and off-site emergency services to ensure effective communication of risk and evaluation of procedures.

Item	BSL 3	BSL 4 Suited	BSL 4 Line	Emergency provision
9.1	NA	●☐	**NA**	Compressed breathing air provided to positive-pressure personal protective equipment (i.e., for connection to the air hose of suits), equipped with breathing air compressors and back-up cylinders (sufficient for making safe and evacuation per person); air hose connections to be provided in all areas where suits are worn, including chemical shower and suit change room.
9.2	●☐	●☐	●☐	Validated RPE should be provided on the 'clean' side of the decontamination shower in the event that support workers are required to enter the laboratory during emergency/rescue operations.
9.3	●☐	●☐	●☐	Battery driven emergency lighting provided sufficient for making safe evacuation.
9.4	●☐	●☐	●☐	Laboratory to be equipped with a communication system between containment area and outside support area.
9.5	●☐	●☐	●☐	Life safety systems, lighting, HVAC systems, BSCs, security systems and other essential equipment to be supported with emergency back-up power.
9.6	●☐	●☐	●☐	Circuit breakers located outside bio containment area.
9.7	●☐	●☐	●☐	Flammable liquids should not be stored, otherwise an approved safe cabinet should be used.
9.8	●☐	●☐	●☐	Gaseous cylinder should be stored outside the containment.
9.9	●☐	●☐	●☐	System (e.g., fax, computer) provided for electronic transfer of information and data from laboratory area to outside laboratory perimeter. *Note: Paperwork from the containment laboratory may be removed after appropriate decontamination, i.e. autoclaving.*
9.10	●☐	●☐	●☐	Work area monitored (e.g., closed circuit TV) from outside laboratory.
9.11	●☐	●☐	●☐	System provided for recording entry and exit of laboratory workers that can be examined.
9.12	●☐	●☐	**NA**	Gaseous or vaporous decontamination of rooms must be possible.
9.13	●☐	●☐	●☐	Staff within working area trained in first aid procedures and rehearsed with emergency scenarios.
9.14	●☐	●☐	●☐	Emergency exercise conducted at least once a year.

Item	BSL 3	BSL 4 Suited	BSL 4 Line	Contingency Planning
9.15	●☐	●☐	●☐	Have established fumigation and decontamination procedures using validated disinfectants.
9.16	●☐	●☐	●☐	Emergency and evacuation procedures, including list of contacts and their phone numbers displayed or readily available.
9.17	●☐	●☐	●☐	Input and inspection provided by security or law enforcement agencies.
9.18	●☐	●☐	●☐	Completion of up to date threat assessment and security practices
9.19	●☐	●☐	●☐	Provision of biorisk and biosecurity training programs.
9.20				Safety exercises or drills conducted regularly with internal and external emergency responders, including:
	●☐	●☐	●☐	personnel incidents (i.e. exposure, needle stick, physical illness)
	●☐	●☐	●☐	equipment failure (i.e. centrifuges, autoclave, effluent treatment plants)
	●☐	●☐	●☐	infrastructure failure responses (i.e. emergency lighting, fire detection, ventilation system failure)
	●☐	●☐	●☐	natural events (i.e. power failure, flooding, equipment failure,)
	●☐	●☐	●☐	unintentional threats (i.e. accidental release)
	●☐	●☐	●☐	intentional (i.e. bomb threats)
				evacuation and transfer of personnel to designated medical center (clinic/hospital) for treatment (emergency evacuation training and execution strategies of patients and 1st responders)
9.21	●☐	●☐	●☐	Contingency planning in response to multiple adverse events.
9.22	●☐	●☐	●☐	First aid emergency response training (i.e. corrosive chemicals, gaseous release, first responder responses).
9.23	●☐	●☐	●☐	Liquid effluent treatment system is in place.
9.24				Incineration
	●☐	●☐	●☐	On-site (in the area of the facility, in-house transportation)
	●☐	●☐	●☐	Off-site (transport through public areas)

10. Planned preventative maintenance, calibration and certification records

All the engineering systems - incinerator, autoclave, PPE, BSC, effluent - should be regularly maintained with documented pre-planned shutdown periods. Alarm testing should be included in this programme. Plant and system requirements or scientific scheduling may drive the scheduling, however this should be set and any variation reviewed by responsible persons.

Item	BSL3	BSL4 Suited	BSL 4Line	Laboratory equipment and services requirements
10.1	●☐	●☐	●☐	Operation of water supply backflow preventers verified.
10.2	●☐	●☐	●☐	Backflow prevention for other services (e.g. gases) verified to ensure that system would operate as specified.
10.3	NA	●☐	NA	Compressed breathing air and systems verified. Systems verified for switchover to backup system and to test the response of the alarm.
10.4	NA	●☐	NA	Operation of positive-pressure personal protective equipment (i.e. suit) tested to ensure that the suit would operate as specified.
10.5	NA	●☐	NA	Water and chemical shower systems tested to ensure that systems operate as specified and to test the response of the disinfectant tank low-level alarm.
10.6	●☐	●☐	●☐	Water shower systems tested to ensure that systems operate as specified and to test for effluent tank critical alarm states.
10.7	●☐	●☐	●☐	Standby power and UPS systems tested under appropriate load conditions to ensure that the systems will operate as specified.
10.8	●☐	●☐	●☐	Battery driven emergency lights checked on a regular basis.
10.9	●☐	●☐	●☐	Operation of interlocking doors to be verified to ensure that doors cannot be opened at the same time.
10.10	●☐	●☐	●☐	Operation of security systems (e.g. controlled access, closed circuit TV) verified to ensure that the system would operate as specified.
10.11	●☐	●☐	●☐	Operation of communication and electronic paper transfer systems (e.g. intercom, telephone, fax) verified to ensure that the system operates as specified.
10.12	●☐	●☐	●☐	Operation of decontamination systems (e.g. autoclaves, fumigation chambers, liquid effluent) verified for operation as specified and microbiologically tested using representative loads; resistance of test organism representative of organisms likely to be encountered.
10.13	●☐	●☐	●☐	Drains and associated piping leading to liquid effluent treatment systems (including associated vent lines) tested in accordance with European Standards.

Item	BSL3	BSL4 Suited	BSL 4Line	Decontamination and waste management
10.14	●☐	●☐	●☐	Decontamination strategy of equipment and work surfaces with appropriate disinfectant after work with infectious substances.
10.15	●☐	●☐	●☐	Decontamination strategy and procedures after overt spills, splashes or other contamination with infectious materials.
10.16	●☐	●☐	●☐	Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, or national regulations.
10.17	●☐	●☐	●☐	All cultures, stocks and other regulated waste are decontaminated daily before removal for disposal by an approved decontamination method (such as autoclaving).
10.18	●☐	●☐	●☐	All potentially contaminated waste materials (e.g. gloves, lab coats, etc.) from laboratories are decontaminated before disposal or reuse. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to the means of decontaminating equipment. If waste is transported out of the laboratory, it should be sealed and not transported in public corridors.
10.19	●☐	●☐	●☐	Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records maintained.
10.20	●☐	●☐	●☐	Procedures for decontamination of the whole laboratory, parts of it or single instruments are developed and applicable. Adequate decontamination equipment is available.
10.21	●☐	●☐	●☐	Autoclaves and other pressure vessels are regularly inspected.
10.22	●☐	●☐	●☐	There is an adequate organization for the collection and disposal of general household rubbish.
10.23	●☐	●☐	●☐	Validated methodology for gaseous decontamination of rooms.
10.24	●☐	●☐	●☐	Validated liquid effluent treatment systems are used for decontamination of liquid waste streams from sinks, showers, autoclave chambers etc.
10.25	●☐	●☐	●☐	Access to effective incineration for processing biomedical waste and animal carcases.
10.26	●☐	●☐	●☐	Validated procedures for sample inactivation and transfer to the outside of the containment are in place.

11. Commissioning and decommissioning

A new, converted, refurbished or decommissioned facility requires an organization to implement a formal process of commissioning or decommissioning to ensure that the facility components, equipment and operating systems are constructed and perform as intended.

Commissioning aims to ensure the operational integrity and performance of the building as designed and specified.

Item	BSL 3	BSL 4 Suited	BSL 4 Line	The check list defines operational requirements to assure expectations of facility are achievable
11.1	●□	●□	●□	Availability of a complete set of drawings and specifications of intended use and work to be performed.
11.2	●□	●□	●□	Integrated systems plans and testing.
11.3	●□	●□	●□	Complete list of and testing profiles of all equipment testing.
11.4	●□	●□	●□	Component testing and validation.
11.5	●□	●□	●□	Verification of the structural integrity of facilities according to the design criteria and regulatory requirements.
11.6	●□	●□	●□	Certification/compliance notification by national authorities
11.7	●□	●□	●□	Measures for decommissioning including the decontamination of the facility are fixed and agreed with national authorities

Decommissioning of a facility: A plan needs to be developed to carry out the process of decontamination and disposal safely.

12. Preventative maintenance programme

The development of the planned preventative plan by users and service personnel should include a system to review incidence of faults and reactive maintenance to adjust according to preempt failures and adjust intervals for required maintenance. The plan should be reviewed, updated and implemented on a regular basis. Involved personnel must be instructed accordingly.

13. Operator Checks

In addition to the detailed planned preventative maintenance, between servicing periods, the users will conduct some general internal safety checks. The checking of room cascade pressures, control panel status, should be part of the daily routine. The condition of and the correct flows in the biosafety cabinet are examples for the sort of checks that should

be recorded in the Standard Operating Procedures (SOPs) as entry requirements.

14. Personal Protective Equipment (PPE)

The type of personal protective equipment for the various styles of BSL 3 laboratories that use BSC class II or III or BSL 4 cabinet lines or air fed suits are very different and the integrity of the suit is a critical procedure before and after use. In each case there is a need to have robust training programmes that reflect the level of experience, type of work being undertaken and competence level of personnel. PPE should be cleaned, disinfected, fit-tested and stored under clean and sanitary conditions. Both the physical checks on PPE and usage of PPE should be recorded. The breathing air system of the suit also requires testing of switch over and alarm states. All respirators require robust maintenance, disinfection, visual and fit test and storage protocols to ensure the correct operation for purpose.

Item	BSL3 design using BSC Class II	BSL 3 design using BSC Class III	BSL4 Suite	BSL 4 Line	Personal protective equipment
14.1	●□	●□	●□	●□	Full change out of street cloths. Protective laboratory clothing (wrap around gowns, aprons, scrub suits, laboratory shoes).
14.2	●□	●□	NA	NA	Complete coverage of lab cloths. Protective laboratory clothing (fluid resistant overalls or backwards closed coats, water-repellent aprons, shoe covers).
14.3	●□	●□	●□	●	Disposable gloves (i.e. double gloved working practices), outer gloves should be changed and/or decontaminated in “dirty” area and not reused.
14.4	NA	NA	●□	NA	Positive pressure respiratory protection (i.e. for connection to the air-hose of suits), equipped with breathing compressors and back-up cylinders (sufficient for 30 minutes per person). Air-hoses provided in all work areas, including chemical showers and changing areas.
14.5	●□	NA	NA	NA	HEPA filtered positive pressure respiratory protection battery powered or FFP3 masks.
14.6	●□	●□	●□	●□	Safety glasses, goggles and shields (visors). (i.e. manipulations involving liquid nitrogen, deep-freeze extraction, chemical usage etc.).
14.7	●□	●□	●□	●□	Physical containment devices (i.e. centrifuge safety cups or sealed rotors).
14.8	NA	●□	●□	NA	Hepa filtered downdraught necroscopy tables with appropriate respiratory protection.

14.9	●□	●□	●□	●□	Heat resistant gloves (i.e. unloading autoclaves in adjacent or designated areas associated with containment areas).
14.10	●□	●□	●□	●□	Designated storage provided for RPE including safe storage of spare parts.
14.11	●□	●□	NA	●□	For the emergency team protective overall suits (e.g. category III, type 3B) with HEPA filtered respirators (e.g. TH 3P) and in case of chemicals additional gas filters (A-organic compounds, B-inorganic gases, E-acidic gases, or K-ammonia, amines)

15. Personnel recruitment, competence, and training

The organization requires a comprehensive proficiency programme in biorisk management that ensures all personnel are competent to undertake their designated functions through having defined training and continuous professional development programmes.

Recruitment

Item	BSL 3	BSL4 Suited	BSL4 Line	Areas
15.1	●□	●□	●□	Employment history
15.2	●□	●□	●□	Security checks
15.3	●□	●□	●□	Basic knowledge
15.4	●□	●□	●□	Technical competency profile
15.5	●□	●□	●□	General health monitoring
15.6	●□	●□	●□	Plan for vocational adjustment in place and implemented
15.7	●□	●□	●□	Competency status and needs documented
15.8	●□	●□	●□	Recognized biosafety training
15.9	●□	●□	●□	Recognized biosecurity understanding and training
15.10	●□	●□	●□	Demonstrate ability to perform tasks under supervision and unsupervised
15.11	●□	●□	●□	Maintenance and presentation of records and registrations of professional bodies
15.12	●□	●□	●□	Health status and monitoring programme appropriate to agents in use and programs in place (i.e. immune status, pregnancy)
15.13	●□	●□	●□	Vaccination status and suitability
15.14	●□	●□	●□	Emergency response capabilities

Maintenance, training, and competence

Item	BSL 3	BSL4 Suited	BSL4 Line	Areas
				Evidence of recognized training and development programs designed and delivered for all disciplines involved with high containment that are monitored, assessed and recognized by professional bodies, regulators and other European high containment facilities and institutions. (a-g)
15.15	●□	●□	●□	a. Biosafety and biosecurity for all personnel (Scientists, technical staff, engineers, biosafety professionals and managers)
15.16	●□	●□	●□	b. Emergency responses to accidents, fire, and evacuation and role of occupational health
15.17	●□	●□	●□	c. Laboratory access and operational practices
15.18	●□	●□	●□	d. Equipment
15.19	●□	●□	●□	e. Hazard and microbiological practices
15.20	●□	●□	●□	f. Risk assessment
15.21	●□	●□	●□	g. Regulatory framework
15.22	●□	●□	●□	Evidence of records and learning, outlining proficiency and competency, evaluated both to improve training methods and ensure changes in knowledge and behaviors has taken place.
15.23	●□	●□	●□	Evidence of evaluation and monitoring mechanisms of training programs aimed to provide staff with the knowledge and skills to reduce risk.

16. Operational procedures and special practices

A Standard microbiological and work practices

The competency of personnel should be assessed against standardized methods being used and outlined in SOPs. This ensures evidence of compliance and monitors effectiveness and consistency of training and operational practice.

Item	High Containment Laboratory (BSL3/4 suited and line)	Areas for implementation
16.1	●□	Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for this purpose only.
16.2	●□	Mechanical pipetting devices supplied and used.
16.3	●□	Work surfaces in BSC II and III are decontaminated daily according to standard operational procedures and considering appropriate applied disinfectants (e.g. peracetic acid requires an evacuation of the air from the BSC) and immediately after any spill of viable material according to laboratory regulations and emergency plans.
16.4	●□	The performance of autoclaves is monitored for each run and operational effectiveness routinely checked by the appropriate chemical, physical and biological indicators.
16.5	●□	Hygienic and skin protection plans are implemented.
16.6	●□	Incompatible chemicals are effectively separated when stored or handled.
16.7	●□	The working space is adequate for safe operation.
16.8	●□	All chemicals are correctly labelled with names and warnings with hazard warning charts prominently displayed.
16.9	●□	Separate changing rooms are provided for male and female staff.
16.10	●□	There is accommodation (e.g. lockers) for street clothing for individual members of the staff.
16.11	●□	Drinking water is available outside the laboratory facility.
16.12	●□	There is provision of facilities outside containment area for staff recreation, food consumption etc.

B Handling infectious material

Item	BSL 3	BSL4 Suited	BSL4 Line	Areas for consideration
16.13	●□	●□	**NA**	All open manipulation, involving infectious materials, is conducted in biological safety cabinets within the containment module. No work in open vessels is conducted on the open bench. Clean up is facilitated by using plastic-backed paper towelling on non-perforated work surfaces within biological safety cabinets.
16.14	●□	●□	●□	Material containing live pathogens must be packed in safe containers with subsequent decontamination procedures of the containers before removal from containment into designated secure areas (e.g. refrigeration, liquid nitrogen storage areas).
16.15	●□	●□	●□	Designated restricted biosafe / biosecure areas available for the storage of highly pathogenic agents which are certified and /or approved by national bodies.
16.16	●□	●□	●□	For the handling of infectious cultures, no glassware should be used. It must be substituted by plastic ware. Recommendable plastics are either single-use (polypropylene PP, polyethylene PE or alike) or re-usable and autoclavable (polycarbonate PC or polymethyl pentene PMP). Flasks used for the cultivation of dangerous pathogens should be leak proofed (thus screw-capped).
16.17	●□	●□	●□	Use of validated inactivation procedures for agents being used.
16.18	●□	●□	●□	Validated transfer protocols of inactivated material or non-inactivated material with proper packaging to outside of the high containment facility are in place.

C Handling of sharps

Item	High Containment Laboratory (BSL3/4 suited and line)	Areas for consideration
16.19	● ☐	Policies for safe handling of sharps are instituted when these instruments cannot be avoided. (Note: *A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, microscope slides, and scalpels that might not be avoided in case of animal work*)
16.20	● ☐	Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for animal work.

D Compressed gas cylinders

Item	High Containment Laboratory (BSL3/4suited and line)	Areas for consideration
16.21	● ☐	Central tube supply. (If yes, the following sub questions are dispensable)
16.22	● ☐	The contents of all containers are correctly described on the labels.
16.23	● ☐	Each portable gas container is legibly marked with contents correctly colour-coded.
16.24	● ☐	Bottle carriers are provided.
16.25	● ☐	Compressed-gas cylinders and their high-pressure and reduction valves are regularly inspected and maintained.
16.26	● ☐	A pressure-relief device is connected when a cylinder is in use.
16.27	● ☐	Protection caps are in place when cylinders are not in use or are being transported.
16.28	● ☐	All compressed gas cylinders are secured so that they cannot fall.
16.29	● ☐	Cylinders and liquid petroleum gas tanks are kept away from sources of heat.
16.30	● ☐	Personnel are trained to properly use and transport compressed and liquid gases.

17. Biosecurity

Increasingly, facilities handling infectious agents do not only need a biosafety program but also a biosecurity plan in place. While biosafety deals with all aspects of containment to prevent any exposure to and accidental release of pathogens, biosecurity is implemented to prevent the theft, misuse or intentional release of pathogens. Whether it is for the advancement of science or the diagnosis of agents causing disease or the misuse of these technologies, there is unfortunately a dual use potential in the nature of the work

(i.e., procedures, equipment, etc.) that is done with these agents. There are many international recommendations and position papers, which can provide further assistance with the management of biological threats.

	High Containment Laboratory (BSL3/4suited and line)	Areas for consideration
17.1		**Physical security measures in place**
	●□	Institutional perimeter security
	●□	Facility perimeter security
	●□	Agent security
	●□	Information security (i.e. restrictions associated with data handling, computer access)
	●□	Transportation security systems within facility
	●□	Shipment and transportation of material outside high containment facility (i.e. International transport security - packaging, transportation couriers see 17.4)
	●□	Undertake review or testing of physical integrity of facility
17.2		**Personnel – Suitability and reliability**
	●□	Social and criminal background checks undertaken
	●□	Regular security clearance and operational requirements
	●□	Photo identification for employees and visitors
	●□	Policy on visiting personnel
	●□	Access control and authorization
	●□	Access record of entry and exit
	●□	Access criteria to agents and storage facilities
	●□	Access criteria of equipment
	●□	Biosecurity training programs
17.3		**Pathogen accountability**
	●□	Inventory access and requirements
	●□	Tracking systems for internal procession and personal responsibility
	●□	Inactivation and disposal of cultures
	●□	Inventory controls
	●□	Identification of those responsible for pathogens
	●□	Record keeping and notification process identifying, reporting and dealing with security issues.
	●□	Equipment failure
	●□	The institution has an officially certified sender for packaging, declarations, and labelling for sending of infectious substances.
	●□	Personnel are trained to ship infectious substances according to current national and/or international regulations.
	●□	The sender is certified and updated by IATA/ICAO or ADR or other applicable regulations.
	●□	The institution/sender uses certified shippers/couriers to transport dangerous goods/infectious substances.
	●□	Records kept of outgoing/incoming materials.

18. Summary of required documentations

Item	**High Containment Laboratory (BSL3/4suited and line)**	**Documents**
18.1	● ☐	Standard Operating Procedures (SOPs) for standard practices (i.e. handling infectious material, decontamination & fumigation, work practices, equipment usage & maintenance etc.)
18.2	● ☐	Risk assessments of all aspects of working and operational practices
18.3	● ☐	Biosafety and biosecurity manual
18.4	● ☐	Laboratory evacuation plan (i.e. unplanned incidents, accident)
18.5	● ☐	Security plan
18.6	● ☐	Instruction manuals
18.7	● ☐	Training records for all staff
18.8	● ☐	Commissioning and decommissioning protocols
18.9	● ☐	Local and external inspection and registration reports and certificates
18.10	● ☐	Incident and accident records, investigation and actions
18.11	● ☐	Medical evacuation and treatment plan in the event of high consequence pathogen exposure
18.12	● ☐	Quality assurance management
18.13	● ☐	High consequence pathogen stocks, storage compliance and location
18.14	● ☐	Transportation of high consequence pathogens, protocols relating to national and cross-border exchanges.
18.15	● ☐	Emergency plans (e.g. for infrastructure and systems failure, safety and biosecurity incidents and accidents, security breaches).

19. Items with recommendations which are not in accordance with your national regulations, please describe your approach here:

Item	**Describe shortly your approach**

20. References and further information

Laboratory Biorisk Management Standard CWA 15793:2011

CWA 16393: 2012 - Laboratory biorisk management - Guidelines for the implementation of CWA 15793:2008

BMBL CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition Canada Health Ministry of Health 2004. Laboratory Biosafety Guidelines 3rd Edition

Directive 97/23/EC (PED) 1999: the Pressure Equipment Directive' Official Journal of the European Communities 1997 (L181) 1 et seq., corrigendum in Official Journal of the European Communities 1997 (L265)

Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC)

BS EN 464: 1994 Protective clothing. Protection against liquid and gaseous chemicals, including liquid aerosols and solid particles. Test method. Determination of leak-tightness of gas-tight suits (Internal Pressure Test) British Standards Institution ISBN 0580 22378 7

BS EN 1822-1: 1998 High efficiency air filters (HEPA and ULPA). Classification, performance testing, marking British Standards Institution ISBN 0 580 29837 X

BS EN (IEC) 61508-1: 2002 Functional safety of electrical/electronic/ programmable electronic safety-related systems. General requirements British Standards Institution ISBN 0 580 32719 1

BS EN12469: 2000 Biotechnology - Performance criteria for microbiological safety cabinets

EN61508-6:2002 Functional safety of electrical/electronic/programmable electronic safety-related systems. Guidelines on the application of IEC 61508-2 and IEC 61508-3

EN61511-1:2004 Functional safety. Safety instrumented systems for the process industry sector. Framework, definitions, system, hardware and software requirements

ISO 9001:2008, Quality management systems – Requirements

ISO 14001:2004, Environmental managements systems – Requirements with guidance for use

ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories

ISO/IEC 27001:2005, Information technology –Security techniques –Information security management systems - Requirements

ISO 22000:2005, Food safety management systems – Requirements for any organization in the food chain

ISO/IEC 20000, Information technology – Service management

ILO-OSH 2001, Guidelines on occupational safety and health management systems

ISO 15189:2007, Medical laboratories – Particular requirements for quality

Richmond J Y (editor) Anthology of Biosafety V – BSL 4 Laboratories American Biological

Safety Association 2002 ISBN 1 882 14763 4

OHSAS 18001:2007, Occupational health and safety management systems – Requirements

WHO 2004 Laboratory Biosafety Manual. ISBN 92 4 154650 6

WHO EPIDEMIC AND PANDEMIC ALERT AND RESPONSE 2006 Biorisk management Laboratory biosecurity guidance September 2006 WHO/CDS/EPR/2006.6

WHO 2009 Guidance on Regulations for the Transport of Infectious Substances 2009-2010. Geneva: Division of Epidemic and Pandemic Response.

WHO 2012 Laboratory Biorisk Management Strategic Framework for Action 2012-2016 International Health Regulations WHO/HSE/2012.3

The German Protection against Infection Act (IfSG) and BioStoffV (Biological Agents Ordinance)

Biosafety-Europe Containment level 3 and 4 laboratories Legislative and regulatory framework Austria, Belgium, Germany, France, Ireland, Norway, Sweden Switzerland, The Netherlands and UK