



facultad deveterinaria

BIOSECURITY PLAN

December 2024

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ABBREVIATIONS

GLP Good Laboratory PracticePPE Personal Protective Equipment

• **FVULE** Faculty of Veterinary Medicine of León

ISO standard
 OECD
 OEBA
 Standard of the International Organisation for Standardisation
 Organisation for Economic Coperation and Development
 ULE Subcommittee for Animal Experimentation and Welfare

• WHO World Health Organisation

• **SOPs** Biosafety Standard Operating Procedures

PRL Prevention of Occupational Risks

• **ULE** University of León

• WOAH World Organisation for Animal Health

LQCI Laboratory Quality Stepwise Implementation
 PONBs Biosafety Standard Operating Procedures



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BIOSECURITY PLAN OF THE FACULTY OF VETERINARY MEDICINE OF THE UNIVERSITY OF LEÓN

The practical training, care and research activities carried out at the Veterinary Faculty of n (FVULE) include exposure to physical, chemical and especially biological risks, so it is necessary to know the critical points and comply with the necessary safety measures to protect the health and safety of students, staff, animals and visitors to the Faculty of Veterinary of León. For this reason, the Biosafety Plan of the FVULE has been developed, with the aim of managing and ensuring that all staff comply with the protocols established to prevent the transmission of diseases and mitigate risks, in accordance with biosafety national and international regulations.

In this Plan, the term "BIOSECURITY" should be understood in a broad sense that integrates biosafety and biosecurity. Although they address different risks (accidental for biosafety and intentional for biosecurity), both seek to minimise the potential for exposure and release of hazardous agents. By integrating biosafety and biosecurity practices, laboratories and institutions can create safer environments through a combination of practice, training and accountability (Clevestin, 2009). So, they share several key elements in their implementation: -inventory control of biological materials, -responsibilities and compliance with safety and protection standards, -incident notification, -periodic evaluation and review of protocols, and -education and training.

The scope of this Plan includes all the facilities where activities related to the degrees taught by the Faculty of Veterinary Medicine are carried out, mainly laboratories and clinical classrooms where practical and care training tasks are carried out (Annex I, as well as research laboratories). It should be noted that external internships are also included, which require differentiated treatment depending on the activities carried out in each case.

BIOSECURITY COMMITTEE OF THE FACULTY OF VETERINARY MEDICINE

COMPOSITION

The Biosafety Committee of the Faculty of Veterinary Medicine is composed of:

President: Dean of Faculty

Members:

A representative of the Molecular Biology Department

A representative of Biomedical Sciences Department

A representative of the of Food Hygiene and Technology Department

A representative of the Animal Production Department

A representative of the Animal Health Dept Department

A representative of the Veterinary Medicine, Surgery and Anatomy Department

A representative of Support Staff

A representative of the students

A Prevention Delegate for the Faculty of Veterinary Medicine

Head of the Veterinary Hospital

Head of the Animal Welfare and Research Service

Head of the Teaching Farm

Secretary: Secretary of the Faculty

The current composition of the Biosafety Committee of the Faculty of Veterinary Medicine is shown in Annex II.

FUNCTIONS

Without prejudice to the functions attributed by the regulations to other bodies of the University, the functions of the Biosafety Committee of the Faculty of Veterinary Medicine include, among others, the following:

- Prepare the FVULE Biosecurity Plan proposal, as well as any necessary modifications and revisions, for approval by the relevant bodies.
- Approve the Biosafety Protocols of each of the facilities and their modifications, in accordance with the provisions of this Plan, which must be incorporated into the Plan, once approved.
- Advise those responsible for the installations on the implementation of preventive measures.
- Promote appropriate training for all persons affected by the scope of this Plan.
- Promote joint actions leading to better protection of people's health and safety.
- Supervise and monitor compliance with the protocols contained in the Biosafety Plan.
- Draw up an annual report of the meetings and activities carried out.
- Update the FVULE Biosafety Plan including new legislation and recommendations from national and international bodies on biosafety.
- Approve its Operation Regulations.
- Appoint the FVULE Biosafety Coordinator.

The Biosafety Plan has been drawn up by the Biosafety Committee of the Faculty of Veterinary Medicine and is available to all users on the FVULE website, where the reports on the proposed actions and improvements will be added.

This Manual has the character of the Faculty of Veterinary Medicine's own regulations. All users of the facilities included in Annex I (students, PDI, PTGAS, external staff and users of the services) are obliged to follow the instructions that emanate from it and the protocols established for each facility.

The Biosecurity Plan of the Faculty of Veterinary Medicine is developed on the basis of the following fundamental axes:

- 1) Biosafety Standard Operating Procedures (PONBs).
- 2) Biosafety Protocols Biosafety Manual.
- 3) Good Practice Guide.
- 4) Biosafety Management and Quality Control.

BIOSECURITY COORDINATOR OF THE FACULTY OF VETERINARY MEDICINE

The Biosafety Committee will appoint a Biosafety Coordinator whose mission shall be to oversee the adequate implementation of the provisions of this Biosafety Plan. Specifically, its scope of action is to verify:

- Compliance with national and international biosafety regulations in the different areas of the FVULE.
- That procedures related to the handling of biological, chemical and physical agents comply with safety standards.
- The identification and assessment of risks associated with academic, research and clinical activities.
- The design and implementation of Biosafety Protocols.
- Training of students, teachers and technical staff on biosecurity and good practices.
- FVULE premises and facilities to check that they have adequate biosecurity equipment.
- Conducting internal inspections and audits to ensure compliance with biosecurity measures.
- Prepare detailed reports on biosecurity status and possible areas for improvement.
- Emergency response plans for chemical spills, exposure to infectious agents or animal accidents.
- The promotion of a proactive attitude towards biosecurity at all levels of the faculty.
- The appropriate integration of biosafety principles into curricula and research projects.

The Biosafety Coordinator will be a member of the FVULE with training in Biosafety, Risk Management, handling of biological agents and knowledge of related regulations.

STANDARD OPERATING PROCEDURES FOR BIOSAFETY (PONBs)

The PONBs guarantee the protection of students, teachers, staff and animals at the Faculty of Veterinary Medicine, and constitute the essential pillars for the development of teaching activities, particularly clinical practices, and research.

The PONBs also strengthen compliance with international public health and biosafety standards, while consolidating the FVULE commitment to biosafety and the well-being of the university community. They protect the integrity of the research and clinical treatments conducted at the institution, contributing to the advancement of veterinary science in a safe and ethically responsible context. By ensuring compliance with these regulations, FVULE fosters a culture of responsibility and biosafety awareness, which is transmitted to students as an integral part of their professional training.

Moreover, the "dual-use potential" needs to be considered in this area. Health organisations such as the World Organisation for Animal Health (WOAH, 2024)¹, address this dual potential by balancing scientific innovation with biosafety and biosecurity.

The key PONBs set out in this Plan are detailed below, considering in any case the specific development in the protocols and manuals of the units and facilities of the FVULE, as well as their continuous implementation.

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¹ WOAH (2024). Guidelines for responsible conduct in veterinary research

1) Protection of persons:

- Personal Protective Equipment (PPE): Detailed instructions on when and how to use PPE, (gloves, masks, gowns and eye protection).
- Maintenance of PPE: Guidelines for the proper cleaning, storage and disposal of PPE to ensure that it remains effective.
- PPE inventory management: Procedures for maintaining an adequate supply of PPE, including regular inventory checks.
- 2) Handling and housing of animals:
- Quarantine procedures: Protocols for isolating new or sick animals before they are introduced into shared areas or interact with other animals.
- Animal care: Guidelines for feeding, handling, housing and care to maintain the health and welfare of animals, reducing the risk of injury or transmission of disease to staff.
- Transport protocols: Procedures for the safe transport of animals in and out of the facility, including disinfection and vehicle handling practices.
- Health and treatment records: Maintain records of all animals, including their health status, clinical or surgical procedures performed, and treatments carried out, including the administration of medication.
- 3) Signage and communication:
 - Signage: Indications for access to the different areas and compliance with biosecurity protocols.
 - Dissemination and updating: Communicate and disseminate protocols to staff and ensure that they are regularly updated.
- 4) Cleaning and disinfection of the facilities:
 - Routine cleaning: Indications on procedures for daily cleaning of all areas, including floors, surfaces and equipment.
 - Disinfection protocols: Specifications on methods and products for disinfection of areas after exposure to pathogens.
- 5) Biosafety in laboratories
 - Biological samples: Should be handled in a biosafety cabinet if there is a risk of pathogen transmission.
 - Sterilisation techniques: Use of autoclave to decontaminate equipment and surfaces after working with biological agents.
 - Labelling of containers: Must allow the status of the material and its biohazard to be known.
 - Inspection and maintenance: Permorfed regularly on cabinest, centrifuges, freezers, etc.
 - **6)** Waste management
 - Waste segregation: Instructions for the segregation of biological waste (tissues, fluids, organs, cadavers), sharps, chemical waste and general waste in correctly labelled containers, in accordance with regulations.
 - Sharps containers: Guidelines for safe disposal of needles, blades and other sharps in appropriate containers to avoid injury or contamination.
 - Animal carcasses: Procedures for the safe disposal of animal carcasses, particularly incineration.

BIOSECURITY MANUAL AND PROTOCOLS

BIOSECURITY MANUAL

The Biosafety Protocols are drawn up for the different facilities and are included in their respective **Manuals**, respecting the provisions established by the ULE's Occupational Risk Prevention Unit, as well as by the Ethics Committee and the Subcommittee for Animal Experimentation and Welfare of the ULE.

The Biosafety Manuals serve as a reference, based on scientific evidence and specific biosafety regulations, for the correct development of the FVULE's activities. The purpose of these guidelines is to -manage and identify the risks to the safety and health of people, animals and the environment involved in the use of chemical and biological agents, -guarantee respect for the dignity, integrity and identity of people, -promote the welfare of animals used as models in research and teaching practices, -establish appropriate prevention measures and -inform all users in the different facilities and premises of the FVULE.

The Biosafety Manuals for Laboratories, Veterinary Hospital, Necropsy Room and Teaching Farm are attached in Annex III. Each manual specifies the specific Biosafety protocols for each of the activities and facilities adapted to the peculiarities relating to the risks inherent to them, as well as the Guide to Good Practices:

Manual on Safety and Good Laboratory Practice
Handbook on Safety and Good Practice in the <u>Veterinary</u> Hospital
Manual of Safety and Good Practices in the Necropsy Room
Manual on Safety and Good Practices on the Teaching Farm

BIOSECURITY PROTOCOLS

The specific Protocols shall be drawn up by those responsible for the different facilities and activities affected by the scope of this Biosafety Plan on the basis of the respective risk assessments and other reports relating to the safety and health of people and shall be approved by the Biosafety Committee.

The Biosafety Protocol should follow a common structure in all scenarios (activities and facilities) and contain the following information.

- Identification of the facility and biosafety officer
- Identification of specific risks
- Patients / samples (sorting and reception)
- Rules to be followed by users
- Waste management
- Mechanism for the control of biosafety standards
- Emergency procedure

The common format template for Biosafety Protocols is provided in Annex IV of this plan.

GOOD PRACTICE GUIDELINES

The "Good Laboratory Practices" (GLP) are defined as the quality system focusing on the organisational processes and conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. They were initially

developed by the Organisation for Economic Co-operation and Development (OECD)², and also establish standards covering all aspects of daily laboratory activity, such as the design of test and storage areas, cleaning and disinfection, calibration of equipment, handling of animals, and recording and archiving of the essay results.

The World Health Organisation (WHO) also recognises the importance of GLP, and in that context has developed its own guidelines and standards for laboratories conducting tests on drugs, vaccines and other medical products³. WHO promotes the adoption of GLP in member countries' laboratories to ensure that safety and efficacy studies of medical devices meet global quality standards. The key principles of GLP according to the WHO are as follows:

- 1. Laboratory Organisation and Responsibilities
- 2. Quality System and Quality Assurance
- 3. Facilities and Working Conditions
- 4. Equipment, Materials and Reagents
- 7. Handling of Samples and Test Substances
- 5. Documentation System and Protocols
- 8. Conducting the Study
- 9. Final Report and Review
- 10. Audit and Compliance

In order to integrate these principles of GLP in the European Union, Directive 2004/9/EC on the inspection and verification of good laboratory practice was published in 2004, which establishes the obligation for EU countries to designate the authorities responsible for GLP inspections in their territory. In Spain this Directive has been transposed by *Royal Decree 822/1993 of 28 May 1993, which establishes the principles of good laboratory practice and their application in the performance of non-clinical studies on chemical substances and products,* as amended by *Royal Decree 1369/2000*.

BIOSECURITY MANAGEMENT AND QUALITY CONTROL

BIOSECURITY MANAGEMENT

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Evaluating the effectiveness of biosafety protocols involves monitoring, supervision and verification of the correct implementation of control measures. In this regard, the World Health Organisation has published several editions of the "Laboratory Biosafety Manual", from 1983 to the latest version in 2023. It states that safety and security of laboratory operations are essential components for compliance with the International Health Regulations⁴ and the prevention of serious threats to public health. The handbook includes sustainable developments on biosafety in the framework of risk assessment, training and improvement of working practices, to foster a responsible safety culture that complies with regulations. Moreover, it is relevant to note that the methodological approach for risk assessment proposed in the Manual is aligned with the occupational health and safety

² OECD (2005), Good Laboratory Practice: OECD Principles and Guidance for Compliance Monitoring.

³ Handbook: Good Laboratory Practice (GLP): *Quality Practices for Regulated Non-clinical Research and Development*. World Health Organization, 2005

⁴ International Health Regulations 2005 World Health Organisation, 3rd Edition

management system of the standard ISO $45001:2018^5$, as well as with ISO $35001:2019^6$ "Biological risk management for laboratories and other related organisations". These ISO standards set out requirements and guidelines to ensure safe and healthy workplaces through continuous process improvement.

The list in Annex V refers to the international and national legal instruments, agreements and specifications adopted by international organizations related to Biosafety and Biosecurity.

BIOSECURITY QUALITY CONTROL

The design of the Biosafety Plan must include a quality control system that allows for an objective evaluation of the effectiveness of the protocols and to detect which measures should be improved or implemented. The updating of the PONBs must also be adapted to new legislation, the appearance of infectious diseases and recommendations from international and national bodies, or from the University itself, such as the Occupational Risk Prevention Unit.

The WHO has developed a Laboratory Quality Stepwise Implementation (LQSI) tool⁷ for effective implementation of a clinical laboratory quality management system. This tool sets out four progressive phases with key objectives and activities: - initial engagement and planning, - implementation of core processes, - strengthening and expansion of the quality management system, and - preparation for accreditation and sustainability. In addition, LQSI includes a series of checklists that serve as practical guides for implementing each phase and provides different templates designed to be practical and adaptable, offering questions and sections that guide step-by-step verification.

In a veterinary school it is essential to develop and implement internal biosecurity audits and biosecurity checklists to ensure adherence to biosecurity protocols and to provide a safe environment for students and staff, animals and the community (Humblet and Saegerman, 2023).

Internal Biosafety Audits

Internal biosafety audits must be carried out at least once a year in FVULE premises, laboratories and facilities. The objectives, areas and processes are detailed in the following table:

	✓ Ensure animal welfare: Comply with regulations on safe and ethical animal handling.
	✓ Protecting human health: Preventing zoonoses
Specific Objectives	✓ Avoid environmental pollution: Ensure proper disposal of
	biological and chemical waste.
	✓ Strengthening the quality of education: Providing a safe and
	regulated environment for practice and learning

⁵ ISO technical standards 45001:2018. (2018). Occupational health and safety management systems-requirements with guidance for use.

⁶ ISO 35001:2019 Biorisk management for laboratories and other related organisations. 2019.

⁷ World Health Organization (2014). Laboratory Quality Stepwise Implementation Tool (LQSI).

Key Areas	 ✓ Laboratories ✓ Veterinary hospital (consultation, surgery, hospitalization, diagnostic imaging, necropsies, etc.) ✓ Quarantine areas for potentially infectious animals ✓ Stables, boxes ✓ Teaching Farm ✓ ULE Animal Research and Experimentation Service
	✓ Chemical and biological warehouses
Processes	 ✓ Documentary review: Protocols, biosafety manuals, records ✓ Physical inspection: infrastructure, equipment, cleanliness and signage ✓ Direct observation: Verify biological agents and animal handling practices. ✓ Interviews: Consult staff on practice and emergency management. ✓ Reporting and follow-up: Provide a detailed report with findings and corrective actions.

A **responsible person** in each area/laboratory/facility will be designated for this purpose. Several criteria are included in the audit, developed as **Checklists** based on the recommendations of the Biosafety Standard Operating Procedures Manual of the Veterinary Faculty of Liège⁸. This generic methodology is adaptable to each sector and will be passed on to those responsible for each area/laboratory/facility (facilities, laboratories, etc.) in order to implement it themselves. The results of the self-monitoring and its follow-up will be systematically transmitted to the Biosafety Coordinator and the Biosafety Committee of the FVULE.

Biosafety Checklists

The use of checklists is a simple and effective methodology for

Ensure compliance with biosecurity protocols.

Maintain the cleanliness, disinfection and organisation of the laboratory environment and FVULE premises.

Verify the functionality of equipment and systems to prevent errors or accidents.

Establish a structured format for inspections.

Ensure safe handling of samples.

To achieve a better quality of care and safety for the animals, resulting in improved animal welfare.

To enhance the safety of staff and students by preventing biological or chemical hazards.

To achieve an adequate institutional reputation of the FVULE based on compliance with national and international biosafety standards.

To facilitate the verification by means of Checklists, the templates to be followed, which can be adapted to the different units of the FVULE, are included in Annex VI.

⁸ Biosecurity SOPs applied to the Faculty of Veterinary Medicine, Liège University (2019)

By initiative of the Biosafety Coordinator or the Biosafety Committee, external audits (external validation of biosafety in the FVULE) may be carried out to ensure the proper development of processes and promote continuous improvement of biosafety.



BIOSECURITY PLAN ANNEXES

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ANNEX I:

The facilities covered by this Biosecurity Plan are those in which activities related to the degrees offered by the FVULE are carried out.

- Main Faculty Building (common areas)
- Molecular Biology Department (Biochemistry and Molecular Biology area)
- Biomedical Sciences Department
- · Food Hygiene and Technology Department.
- Animal Production Department
- Animal Health Department.
- Veterinary Medicine, Surgery and Anatomy Department
- Veterinary Teaching Hospital
- Food Pilot Plant
- Teaching Farm
- Animal Welfare and Research Service
- Any other that may be incorporated



ANNEX II:

BIOSECURITY COMMITTEE OF THE FVULE

President: Dean of the Faculty, María Teresa Carbajo Rueda

Members:

- Molecular Biology Dept. Representative: Dr. Alejandro Chamizo Ampudia (substitute Dr. Javier Rúa Aller)
- Biomedical Sciences Dept. Representative: Dr. Sonia Sanchez Campos
- Food Hygiene and Technology Dept. Representative: Carlos Alonso Calleja (alternates Javier Mateo Oyagüe / Marcia de Sousa).
- Animal Production Dept. Representative: Dr. Aroa Suárez Vega
- Animal Health Dept. Representative: Dr. César Bernardo Gutiérrez Martín
- Veterinary Medicine, Surgery and Anatomy Dept. Representative: Dr. José Manuel Gonzalo
- Support staff representative: Dr. Leticia Gonzalez Arias
- Student Representative: Ms. Ana Cabañero García (alternate Ms. Carmen Gail de la Peña).
- Prevention Delegate of the Faculty of Veterinary Medicine: Dr. Luzdivina Vila Fidalgo
- Head of the Veterinary Hospital: Dr. José Antonio Rodríguez-Altonaga Martínez
- Hea of the Research and Animal Welfare Service: Dr. Miguel Fernández Fernández
- Head of the Teaching Farm: Mr. Javier Miguélez

Secretary: Secretary of the Faculty, José Gabriel Fernández Álvarez



ANNEX III:

Safety Manual and Good Practices in the Laboratories
Safety Manual and Good Practices in the Veterinary Hospital
Safety Manual and Good Practices in the Necropsies Room
Safety Manual and Good Practices in the Teaching Farm



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ANNEX IV:

Facility/Laboratory Biosafety Protocol Template Specific information

1. Identification of the facility / laboratory
2. Identification of activities
3. Responsible for biosafety
4. Identification of specific risk
4.1. Identification of biological hazards
4.2. Identification of physical hazards
4.3. Identification of chemical hazards

5. Patients/samples
6. User Rules
C.1. Description of sease restriction to the facilities
6.1. Description of access restriction to the facilities
6.2. Specific clothing standards
6.3. Personal Protective Equipment
6.4. Specific standards for equipment, instruments and material
6.5. Guide to good biosafety practices and behavior
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7. Waste management
8. Procedure for the control of biosafety standard σ
9. Emergency actions

REMARKS

ANNEX V:

National and international legal instruments and bibliographic references

National

- Real Decreto 822/1993, de 28 de mayo, por el que se establecen los principios de buenas prácticas de laboratorio y su aplicación en la realización de estudios no clínicos sobre sustancias y productos químicos. https://www.boe.es/eli/es/rd/1993/05/28/822
- Real Decreto 664/1997, de 12 de mayo de 1997, sobre la protección de los trabajadores contra los riesgos relacionados con la exposición a agentes biológicos durante el trabajo. https://www.boe.es/eli/es/rd/1997/05/12/664/con. (modificado el 25 de noviembre de 2021)
- Ley 8/2003, de 24 de abril, de Sanidad Animal. https://www.boe.es/eli/es/l/2003/04/24/8/con
- Guía técnica para la evaluación y prevención de los riesgos relacionados con los agentes químicos presentes en los lugares de trabajo. INSST (2022). https://www.insst.es/especificas

<u>International</u>

- Directiva 2010/63/UE del Parlamento europeo y del Consejo de 22 de septiembre de 2010 relativa a la protección de los animales utilizados para fines científicos. Diario Oficial de la Unión Europea L 276/34 (2010). https://www.boe.es/doue/2010/276/L00033-00079.pdf
- Directiva 2004/10/CE DEL Parlamento europeo y del Consejo de 11 de febrero de 2004 sobre la aproximación de las disposiciones legales, reglamentarias y administrativas relativas a la aplicación de los principios de buenas prácticas de laboratorio y al control de su aplicación para las pruebas sobre las sustancias químicas (versión codificada) Diario Oficial de la Unión Europea L 50/44 (2004). https://www.boe.es/doue/2004/050/L00044-00059.pdf
- World Health Organization (2001) Handbook: Good Laboratory Practice (GLP): Quality Practices for Regulated Non-clinical Research and Development. https://iris.who.int/handle/10665/66894
- Organización Mundial de la Salud (2005) Reglamento Sanitario Internacional 3º edición
 Ginebra https://iris.who.int/bitstream/handle/10665/246186/9789243580494-spa.pdf
- World Health Organization. (2014) Laboratory Quality Stepwise Implementation Tool (LQSI) https://extranet.who.int/lqsi/
- Organización Mundial de la Salud (2016) Laboratory quality management system: Manual
 https://iris.who.int/handle/10665/44665
- Organización Mundial de la Salud (2023) Laboratory Biosafety Manual, 4th edition Geneva Ginebra, https://iris.who.int/bitstream/handle/10665/365600/9789240059306-spa.pdf
- World Health Organization (2024) Laboratory Biosecurity Guidance. https://www.who.int/publications/i/item/9789240095113

- World Organization for Animal Health (2015) Biosafety & Biosecurity: Standard for Managing Biological Risk in the Veterinary Laboratory and Animal Facilities.
 https://www.woah.org/fileadmin/Home/esp/Health_standards/tahm/1.01.04_BIOSAFETY_BIOSECURITY.pdf
- World Organization for Animal Health. Terrestrial Manual Health Code (2024).
 https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-manual-online-access/
- World Organization for Animal Health (2024). Guidelines for responsible conduct in veterinary research. Paris. https://www.woah.org/app/uploads/2021/03/guidelines-for-responsible-conduct-in-veterinary-research.pdf
- OECD (2005), Good Laboratory Practice: OECD Principles and Guidance for Compliance Monitoring, OECD Publishing, Paris, https://doi.org/10.1787/9789264012837-en.
- OECD (1998-2022) OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, N. 1-24, OECD Publishing, Paris. https://www.oecd.org/en/publications/oecd-principles-on-good-laboratory-practice 9789264078536-en.html
- FAO Biosecurity Toolkit. 2007. http://www.fao.org/docrep/010/a1140e/a1140e00.htm
- ISO 15190:2003, Medical laboratories Requirements for safety. https://www.iso.org/obp/ui/#iso:std:iso:15190:ed-1:v1:en
- ISO 35001:2019, Biorisk management for laboratories and other related organisations. https://www.iso.org/standard/71293.html
- ISO 45001:2018. Occupational health and safety management systems-requirements with guidance for use. https://www.iso.org/standard/63787.html
- ISO 15189:2022. Clinical laboratories Requirements for quality and competence, https://www.iso.org/obp/ui/#iso:std:iso:15189:ed-4:v1:es

Bibliographic References

- Beeckman, D.S. and Rüdelsheim, P. (2020) Biosafety and Biosecurity in containment: A regulatory overview, Frontiers in Bioengineering and Biotechnology, 8. doi:10.3389/fbioe.2020.00650.
- Biosecurity Unit–Faculty of Veterinary Medicine, ULiège. Biosecurity SOPs applied to the Faculty of Veterinary Medicine, Liège University. (2019). Avaliable on line at: https://www.fmv-biosecurite.ulg.ac.be/generale/medias/PDFs/Manuel Bios SOPs Final.pdf
- Brass, V.H. *et al.* (2017) Biosafety and Biosecurity in veterinary laboratories, *Revue Scientifique et Technique de l'OIE*, 36(2), 701–709. doi:10.20506/rst.36.2.2687.
- Carpenter, C.B. (2018) Safety considerations for working with animal models involving human health hazards, *Animal Models and Experimental Medicine*, 1(2), 91–99. doi:10.1002/ame2.12019.
- Clevestig, P. (2009) *Handbook of Applied Biosecurity for Life Science Laboratories*. Solna: SIPRI, Stockholm International Peace Research Institute.
- Cunha, M.V. and Inácio, J. (2015) Veterinary infection biology: Molecular diagnostics and high-throughput strategies. Springer, New York.
- Dewulf, J. and Van Immerseel, F. (2019) Biosecurity in Animal Production and Veterinary Medicine: From principles to practice. Wallingford: CABI.

- Edwards, S. and Jeggo, M.H (2012). Governance and management of veterinary laboratories. *Rev. sci. tech. Off. int. Epiz.*, 2012, 31 (2), 493-503.
- Faculté de Médecine Vétérinaire de l'Université de Liège (2021) Biosecurité de base.
 Disponible en: https://www.fmv-biosecurite.ulg.ac.be/generale/biosecurite-de-base.php (Accessed: Abril 15 2024)
- Ficociello, B. *et al.* (2022) Who laboratory biosafety manual: A new approach to security, *Annals of Work Exposures and Health*, 67(4), 425–429. doi:10.1093/annweh/wxac086.
- Hiber, L. (2022) *Hospital Biosecurity*, en: Large Animal Medicine for Veterinary Technicians, 2nd ed. Loly and Hopkinson (eds), John Wiley & Sons, Inc, 1-24.
- Humblet, M.-F. and Saegerman, C. (2023a) Internal audits as a tool to assess the compliance with biosecurity rules in a veterinary faculty, *Frontiers in Veterinary Science*, 10. doi:10.3389/fvets.2023.960051.
- Humblet, M.-F. et al. (2017) Observations as a way to assess the compliance of veterinary students with biosecurity procedures, Revue Scientifique et Technique de l'OIE, 36(3), pp. 767–777. doi:10.20506/rst.36.3.2712.
- Katharine M. Benedict, K.M. (2008) Characteristics of biosecurity and infection control programs at veterinary teaching hospitals, *Journal of the American Veterinary Medical* Association 233(5), 767-773.
- Kozlovac J, Schmitt B. (2015). Biosafety principles and practices for the veterinary diagnostic laboratory. *Methods Mol Biol* 1247 31-41. doi: 10.1007/978-1-4939-2004-4_3.
- Nagarajan, P., Gudde, R. and Srinivasan, R. (2021) *Essentials of Laboratory Animal Science: Principles and practices.* Singapore: Springer.
- Stull, J.W. et al. (2018). 2018 AAHA Infection Control, Prevention, and Biosecurity Guidelines. *Journal of the American Animal Hospital Association*, *54*(*6*), 297–326. doi.org/10.5326/JAAHA-MS-6903.
- Swearengen, J.R. and Carpenter, C.B. (2015) Working safely with experimental animals exposed to biohazards. En: Fox JG et al. (eds) *Laboratory animal medicine, 3rd edn*. Elsevier-Academic Press, 1297–1312.
- Wooley, D.P. and Byers, K.B. (2017) Biological safety: Principles and practices. Washington, DC: ASM Press.

ANEXO VI – Checklist Templates

PERSONS		YES	NO	N/A	REMARKS
Dress and equipment	Cleaning and use of basic PPE				
	Type and cleanliness of footwear				
	Personal identification				
	Use of disposable gloves				
Procedure preparation for people	Place of preparation				
	Storage of personal belongings				
	Long hair tied up				
	No wearing of jewellery nor accessories				
	Do not use cell phones				
Entry of people	Hand hygiene upon entering				
	Wearing disposable gloves				
	Wearing apron				
Between two patients	Glove change between patients				
	Hand washing between patients				
Exit of people	Disposal of gloves in appropriate containers				
	Hand hygiene upon exiting unit				
Information and training	At the beginning of each practical session, students are informed of the biosafety rules to be followed				
	A continuous training program is available				

ANIMALS		YES	NO	N/A	REMARKS
General	Cleaning and proper handling of animals				
	Identification of the patient and the type of risk				
Consultation and surgical areas	Records of patients attending for consultation				
	Updated patient records after each consultation or treatment				
	Recording of incident reports (accident, injury)				
Feeding	Fodder availability in the unit				
	Almacenamiento adecuado de forraje				
	Pest control				
Movements of Animals	Control of patient movements				
	Control of contact with hospitalized animals				
	Disinfection of the horse's limbs when leaving the box				

PREMISES		YES	NO	N/A	REMARKS
General	Visible signage in the facilities and in compliance with standard methods				
	Visibility of color lines on the ground				
	Availability of soap for handwashing				
	Availability of paper for hand drying				
	Availability of disinfectant				
	Presence of a waste container for hand drying paper				
	Restricted access areas secured and properly identificated				
Cleaning and disinfection (Method and frequency according to the Protocols)	Laboratory tables and work surfaces				
	Floors and sinks				
	Corridors				
	Consultation waiting area				
	Examination and treatment rooms				
	Surgical rooms				
	Boxes and stables				
	Record of facility cleanliness				
Almacenamiento	Properly marked storage areas				
	Storage of flammable products in suitable cabinets				
	Properly enclosed and secured biological storage areas				
Otros	Use of boot-washer				
	Use of footbaths/foot mats				
	biohazard signage clearly visible				

EQUIPMENT		YES	NO	N/A	REMARKS
General	Visible signage in the equipment and in compliance with standard methods				
	Visibility of color lines on the ground				
	Availability of soap for handwashing				
	Availability of paper for hand drying				
	Availability of disinfectant				
	Presence of a waste container for hand drying paper				
	Restricted access areas secured and properly identificated				
Cleaning and disinfection (Method and frequency in compliance with the Protocols)	Laboratory tables and work surfaces				
	Floors and sinks				
	Corridors				
	Consultation waiting area				
Animal equipment management	Updated equipment registry				
	Equipment labeling with detailed information				
	Medical equipment (X-rays, ultrasound, ultrasound devices monitoring) tested and operational				
	Oxygen tanks, anesthesia machines and pumps tested and functional intravenous lines				
	Protocolized sterilization of the equipment after procedures				
	Updated drug registry				
	Checking the expiration date of drugs				
	Medicines and vaccines refrigerated and stored at appropriate temperatures				

Laboratory equipment management	Up-to-date record of equipment		
	Equipment labelled with detailed information		
	Material registration inventory		
	Reagent record updated		
	Reagent expiration dates checked		
	Operational fume hoods and biosafety cabinets, certified		
	and with the mandatory revisions.		

SAMPLES		YES	NO	N/A	REMARKS
Samples	Updated registry of biological samples				
	Correct labeling of samples with identification, date, type of sample and place of storage				
	Handling of samples keeping the precautions established in the protocols				
	Biological waste (samples, cultures, tissues, etc.) disposed of in appropriate containers				
In the event of an accidental spill	Procedure in the event of an acciental spill				
	Availability of a spill kit at the laboratory				
	Method of hand hygiene after decontamination				

WASTE MANAGEMENT		YES	NO	N/A	REMARKS
Waste management	Biohazardous waste containers available and properly labelled				
	Tissue residues, materials contaminated with blood), deposited in labelled containers				
	Sharp containers available and used far needles, scalpels and other instruments				
	Chemical waste deposited in the appropriate containers				
	Periodic checking of containers for safe disposal				
	Standardized signage of hazards in the containers/ packaging				
	Waste disposal management according to the guidelines of the Waste Management Service of the ULE				

EMERGENCIES		YES	NO	N/A	REMARKS
Emergencies	Safety showers and eyewash stations tested and functional, and conveniently signposted				
	First aid kit with materials and products not expired				
	Procedures manual setting out how to act in specific emergency situations				
	Spill kits are available and functional in case of chemical or biological spills				
	Fire protection equipment in the laboratory				
	Incident reports filled for any accident or spill				