UNIVERSITÀ DEGLI STUDI DI BARI ALDO MORO

Department of Veterinary Medicine

LABORATORY SAFETY MANUAL

DEPARTMENT OF VETERINARY MEDICINE

INDEX

PREFACE

The first evidence of the relationship between work and illness dates back to the 4th century BC, when Hippocrates taught his disciples to always inquire about the profession of their patients to better diagnose illnesses.

In 1700, in Modena, Bernardino Ramanazzi, the "first workers' doctor", published the treatise *"De Morbis Artificum Diatriba"* in which he paid special attention to occupational diseases by relating the working environments and the worker's health. Using an epidemiological approach he evaluated the risk, anticipating some risk prevention, health protection and risk information measures. His precept, expressed in the thirteenth oration of 1711 by the expression «longe præstantius est præservare quam cura» («prevention is far better than cure»), testifies to his preventive vocation.

The legal regulations on workplace hygiene and safety issued up to date are represented by almost a thousand provisions.

The Department of Veterinary Medicine of the University of Bari has numerous laboratories (chemical, biological, anatomical, surgical) attended every day by numerous students, scholarship holders, research fellows, technicians, professors, and guests involved in the various research and teaching activities with the involvement of animals.

Safety in laboratories is an integral part of every research and teaching activity and the implementation of safety measures is the responsibility not only of the Director/Head of the Structure, but also of those responsible for the activities, in relation to the principle that safety must be integrated into the processes right from the design phase.

This Department, therefore, deemed it appropriate to draw up this manual with the aim of providing important information related to safety in our workplaces**.**

1. SAFETY REGULATIONS

Legal foundations

In 1994 the **Legislative Decree no. 626** implemented eight community directives on workplace safety.

Legislative Decree no. 81 of 9 April 2008, is considered the Consolidated Law on safety at work: "Implementation of art. 1 of Law 3 August 2007, n. 123 regarding the protection of health and safety in the workplace" and replaced the previous decree 626/94.

In 2009 the Legislative Decree no. 81 has been revised, integrated and modified in some parts, giving rise to the **Consolidated Legislative Decree of 3 August 2009, n. 106**.

The **Ministerial Decree n. 388** of 2003 (Annex 1) contains provisions on company's first aid, implementing article 15, paragraph 3, of legislative decree 19 September 1994, n. 626, and subsequent amendments.

The particular reality of universities and university structures has made it necessary to draft a Ministerial Decree, dating back to 1998, known as the Ministerial Decree. 363/98, entitled: "Regulation containing rules for the identification of the particular needs of universities and university education institutes for the purposes of the rules contained in Legislative Decree of 19 September 1994, n. 626, and subsequent amendments and additions."

The Ministerial Decree 363/98 that, as mentioned, applies safety regulations to university environments, consists of only 10 articles in which the figures in charge of safety, the responsibilities in staff training and in the management of research activities are indicated.

The University of Bari Aldo Moro has drawn up a regulation (**Regulation on the protection of health and safety in the workplace of the University of Bari Aldo Moro)** on the protection of health and safety in the workplace work that meets the needs:

1. to regulate the matter of health and safety protection in all workplaces of the University of Bari Aldo Moro (hereinafter referred to as University), as well as to make its implementation homogeneous, in application of the Ministerial Decree of 5 August 1998 n. 363 (hereinafter referred

to as Ministerial Decree 363/98) and Legislative Decree of 9 April 2008 n. 81 and subsequent amendments. (hereinafter referred to as Legislative Decree 81/08), pending the issuing of the relevant ministerial implementing decree for the Universities, provided for in the art. 3, paragraph 2, Legislative Decree. 81/08, considering the particular needs and organizational peculiarities of the same;

2. to represent, with its dissemination, the first moment in the information and training process of all University workers regarding safety and health in the workplace, as well as a first contribution to the more general diffusion of the culture of prevention and safety in the University and in the territory;

3. to draw up a University safety organization chart which defines the roles and responsibilities referred to in the regulations cited and attributed within the University's work organization, with a view to adopting conscious and shared behavior by all figures involved.

The management of safety and health at the University of Bari Aldo Moro is entrusted to a series of institutional figures, listed below.

2. INSTITUTIONAL FIGURES

2.1 EMPLOYER

“Pursuant to art. 2, paragraph 1, letter. b), Legislative Decree 81/08 and pending the issuing of the implementing decree for the Universities which considers the particular needs and organizational peculiarities of the same, the employer in the university is the **Magnificent Rector**, President of the Board of Directors", who has the following assignments:

- appointment of the Head of the Protection and Prevention Service (RSPP), an internal or external person with a specific professional qualification (TU, art. 17, non-delegable activity);
- preparation of the risk assessment document with the collaboration of those responsible for teaching or research activities in the laboratory (TU, art. 17, non-delegable activity).
- appointment of the Competent Doctor (MC) to carry out health surveillance in the foreseen cases (TU articles 38, 39, delegable activity);
- appointment of the teachers responsible for teaching and research activities in the laboratory (RDRL) (DM art. 5, figures identified with a formal deed of delegation from the Employer).
- appointment those responsible for radiation protection activities according to resolution No 1069 of 11/21/2006 relating to the regulation for the management of radiation protection;
- participation in the annual safety meeting, organized by the Rector, together with the RSPP, and in which the MC and the Workers' Safety Representatives (RLS) take part.

The Rector, within the limits and conditions established by art. 16, Legislative Decree. 81/08, delegates function and assigns specific tasks to managers or supervisors for the purposes of better implementation of risk prevention and protection measures.

Reference legislation: Ministerial Decree 363/1998 Articles 2 and 4; Legislative Decree 81/08 Art. 18 and subsequent amendments Legislative Decree 106/09

Delegations of the Rector to the General Director (art. 16 Legislative Decree 81/08 - art. 2 L. 240110 - art. 29 Statute University)

The **General Director** (D.G.), based on the guidelines provided by the Board of Directors, is responsible for the overall management and organization of the services, instrumental resources and technical-administrative staff of the University. The D.G. also carries out management, direction and coordination activities of all the University Administration offices.

2.2 MANAGER

According to the art. 2 co. 1 letter D) Legislative Decree 81/08 the **Manager** "is the person who, by virtue of professional skills and hierarchical and functional power, appropriate to the nature of the role conferred on him, implements the employer's directives regarding the protection of health and safety in the workplace, organizing the work activity and supervising it."

Pursuant to and for the specific purposes of the Legislative Decree. 81/08, the Employer identifies the Managers of the Structures for safety purposes as defined by the art. 2 paragraph 5 point 2 of the regulation on the protection of health and safety in the workplace of the University of Bari Aldo Moro:

- Directors of the Teaching and Research Departments
- The General Director (as regards the offices of the Rectorate and Management)
- The Managers of the Administrative Departments
- The Managers of service centers and agricultural and livestock companies, and systems (libraries and museums)
- The Delegated Managers of the decentralized offices
- The managers of all other structures

Important: the Manager must attend a specific training course (Legislative Decree 81/2008 and subsequent amendments - art. 37-c. 7), in which he will receive adequate and specific training and periodic updating in relation to his duties in matters of health and safety at work. The contents of the training include:

a) main subjects involved and related obligations;

b) definition and identification of risk factors;

c) risk assessment;

d) identification of technical, organizational and procedural prevention and protection measures.

Assignments:

- Directs production activities even without the typical powers of the Employer.
- Organizes the work, checks compliance, reports anomalies and intervenes to correct them where his power allows it.
- Adopts all the measures necessary to guard the safety and health of the people working in the structure and supervises the application of these measures by the subjects involved in various capacities (supervisors, managers of teaching/research activities, structured and non-structured workers, students, undergraduates, interns, etc.).

Pursuant to and for the specific purposes of Legislative Decree 81/08, the Employer identifies the Managers of the Facilities (Department Directors) as Managers for safety purposes.

Reference legislation: Legislative Decree 81/08 (Art. 2, Letter d, Art, 18)

2.3 THE MANAGER OF TEACHING AND/OR RESEARCH ACTIVITIES IN THE LABORATORY (R.A.D.R.L.)

An extremely important figure for the management of safety and health in the workplace is the person **responsible for teaching and/or research activities in the laboratory** (R.A.D.R.L.) who shares, together with the employer and the manager (Director of the Department), within the limits of the management and financial powers of the latter, the obligations aimed at guarding the safety and health of the units operating in the laboratory.

Assignments:

- collaborates with the Manager of the Prevention and Protection Service and the Prevention and Protection Service Area, with the competent Doctor and with the other figures required by current legislation in order to assess the risks and identify the necessary preventive and protective measures and made available by the knowledge of technological progress, giving preventive and exhaustive information to the employer for the development of the document on risk assessment referred to in Legislative Decree 81/2008 and subsequent amendments;
- before starting new activities and on the occasion of changes in the organization of teaching or research relevant to the safety and health of operators, identifies all subjects exposed to risk and carries out all the activities indicated in the previous period, so that the risk assessment document is always updated;
- adopts the prevention and protection measures envisaged before the activities at risk are implemented;
- attends training and refresher courses organized by the employer with reference to their activity and specific tasks performed;
- without prejudice to the employer's legal powers regarding the training and information of workers, he/she also provides directly, or with the help of a qualified collaborator, training and informing all exposed subjects on the risks and prevention and protection measures that must be adopted, in order to eliminate them or reduce them to a minimum in relation to knowledge of technological progress, giving preventive and exhaustive information to the employer;
- takes action to supervise the correct application of risk prevention and protection measures by exposed operators, with particular regard to unstructured units (students, undergraduates, interns, research assistants, etc.).

Reference legislation: DM 363/1998 Articles 5 and 6

Note: the role of the **person responsible for the teaching or research activity in the laboratory** (RADRL) can, at the same time, be interpreted by the Manager or by a Person in Charge, depending on the nature of the task conferred on him and the tasks he actually carries out in the company. For example, a researcher who works in a laboratory is certainly a RADRL, responsible, for himself or for others (PhD students, graduate students, etc.), for his own activity, but, often at the same time,

he is a person in charge of a laboratory technician or of the PhD students and graduate students themselves, who are required to observe the directives given by the researcher regarding safety, related to the activity carried out. While a department Director is, as mentioned, a Manager, is also a RADRL, if he personally carries out teaching or research activities in the laboratories, and must fulfill the obligations of the RADRL, in addition to those of the Manager. Obviously, some obligations can be delegated, carefully evaluating the delegate's qualifications, duties and power.

2.4 SUPERVISOR

The **Person in Charge** (Supervisor) is the person who, based on professional skills and within the limits of hierarchical and functional powers appropriate to the nature of the task assigned to him, supervises the work activity and guarantees the implementation of the directives received, checking their correct execution by the workers. and exercising a functional power of initiative - art.2 co. 1 letter And Legislative Decree. 81/08.

According to art. 2 paragraph 5 of the Ministerial Decree. 363/98, the <<……the person who, individually or as a group coordinator, carries out teaching or research activities in the laboratory is considered responsible>>

The supervisor must be identified among the professors, researchers, technical-administrative staff, in relation to the nature of the role held (Head of Activities who, individually or as coordinator of a group, directs the teaching activities (R.A.D.), research (R.A.R.), assistance (R.A.A.) and/or services (R.A.S.).

He is a figure who stands between the workers and the Manager of the specific work activity (administrative, laboratory, research, teaching): in particular, he coincides with the Manager of the work activity when he is present in the work environment in question.

Assignments:

- He has the important obligation to monitor compliance of the workers subordinate to it and of any non-structured worker, with legal obligations and work instructions, including the correct use of equipment, substances and personal (PPE) and collective (DPC) protective devices, if necessary, and the management of emergency situations.
- Informs the direct superior of any failure of workers to comply with obligations.
- Immediately inform the direct superior of any deficiencies related to equipment, PPE or anything else he becomes aware with.
- Must attend a specific training course (Legislative Decree 81/2008 and subsequent amendments - art. 37 - c. 7), in which he will receive adequate and specific training and periodic updating in relation to his health-related tasks and job security. The contents of the training include:
  a) main subjects involved and related obligations;
  b) definition and identification of risk factors;
  c) risk assessment;
  d) identification of technical, organizational and procedural prevention and protection measures.

Reference legislation: Legislative Decree 81/08 (Art. 2, Lett. E, Art, 19)

2.5 WORKER

The Consolidated Law fully involves workers, through the identification of obligations and responsibilities (Legislative Decree 81/2008 and subsequent amendments - art. 20), in the process of managing activities aimed at guarding safety and health in the workplace.

By worker we mean anyone who carries out work within the University organization, with or without pay, even for the sole purpose of learning a trade, an art or a profession - art. 2 paragraph 1 letter. a) Legislative Decree 81/08. Workers belong to:

- Teaching staff;
- Technical – Administrative Staff;

- Researchers;
- Non-structured staff;
- Students who have access to laboratories.

The worker is subjected to rights and duties.

Assignments:

- observe the instructions given by the Director and the RDRL;
- correctly use work equipment, dangerous substances and preparations, means of transport, as well as safety devices;
- not to remove or modify the safety, signaling or control devices;
- immediately report to the employer, to the Head of the prevention and protection service (RSPP) or the Head of teaching and/or research activities in the laboratory (RADRL) the deficiencies of the PPE and DPC as well as any possible dangerous conditions they come to his attention.
- communicate the pregnancy status to the Director and the RSPP as soon as possible.
- not to carry out operations or maneuvers that are not within their competence or that may compromise their own safety or that of other workers;
- participate in education and training programs organized by the employer.

UNIBA Regulation «Each worker must take care of his own safety and health and that of other people present in the workplace, on whom the effects of his actions or omissions may fall, in accordance with the training received and the instructions and means provided by the employer. All workers are required to comply with the provisions of A 20, Legislative Decree 81/08, and collaborate in the correct implementation of safety measures in compliance with the obligations imposed on them by current regulations and in accordance with the provisions given by the employer, by the managers of the structures and by the supervisors".

Rights:

- receive information and training on risks and prevention measures;
- receive information on the meaning of the health checks concerning him;
- be trained in the use of PPE;
- be trained and instructed in the use of equipment, machines, etc.
- obtain a copy of the health and risk record (upon termination of the employment relationship or upon request);
- be represented by an RLS;
- be consulted on risk assessment and planning of prevention measures;
- participate in the continuous improvement of health and safety conditions;
- being able to move away and be protected in the event of serious, immediate danger that cannot be avoided.

Reference legislation: Legislative Decree N°81/08 and subsequent amendments N°106/09; DM N°363/98 IMPORTANT

Pregnant women, immunosuppressed individuals or those undergoing particular therapies (for example immunosuppressives), individuals with liver cirrhosis, etc., must inform the facility manager, who evaluates the opportunity for the individual to remain in the facilities in question.

Pregnant workers must communicate their condition in writing to the Director and the RSPP as soon as possible so that they can be excluded from any work at risk to themselves and the unborn child (M09IO05). Please note that female workers at risk of exposure to ionizing radiation are obliged to communicate their pregnancy (Art 8 paragraph 2 Legislative Decree 151/2001).

2.6 WORKERS' SAFETY REPRESENTATIVES (RLS)

“The R.L.S. of the university, identified pursuant to art. 47 Legislative Decree. 81/08, is the person belonging to the teaching or technical-administrative staff, elected or designated by the OO.SS., provided that they are in service, who represents the workers, as defined in paragraph 4) of this

article, with regards to the protection of health and safety at work. Subjected to agreement during decentralized negotiation, the R.L.S. can be integrated with student representatives. The duties of the R.L.S. are established by the art. 50 Legislative Decree 81/08. The figure of the R.L.S. is incompatible with those of R.S.P.P., A.S.P.P., M.C., M.A., E.Q. and coordinator and delegates of Sistri.

The primary function is to guarantee workers the exercise of their rights of participation and control in matters of health and safety at work, with particular reference to fundamental choices made by the employer.

He must have adequate training and, in any case, not less than that required by article 37 of Legislative Decree 81/08. He is consulted on the designation of the person in charge and the employees of the prevention service, fire prevention activities, first aid, evacuation of workplaces and the competent doctor. He has consultative and supervisory duties. He can access the workplaces and receives information and company documentation related to risk assessment and related prevention measures, as well as those related to dangerous substances and preparations, machines, systems, organization and work environments, accidents and occupational diseases.

He promotes the development, identification and implementation of prevention measures suitable to protect the health and physical integrity of workers.

He makes observations during visits and checks carried out by the competent authorities, by which he is normally heard.

He is consulted in advance regarding risk assessment, identification, planning, implementation and verification of prevention in the company or production unit. He is consulted on the organization of the training referred to in article 37 of Legislative Decree 81/08.

2.7 HEAD OF PREVENTION AND PROTECTION SERVICE (RSPP)

The Head of the prevention and protection service (hereinafter referred to as R.S.P.P.) is the person in possession of the skills and professional requirements referred to in the art. 32 Legislative Decree.

81/08 designated by the employer, to whom he responds, to coordinate the Risk Prevention and Protection Service (S.P.P.).

The RSPP, within the Department, has a consultative and proactive role with the function of providing technical support to the employer in terms of risk prevention. RSPPs must be in possession of a certificate of attendance, with verification of learning, in specific training courses suited to the nature of the risks present in the workplace and relating to work activities.

Assignments:

- Identify risk factors, evaluate them and identify measures for the safety and health of working environments, in compliance with current legislation and based on specific knowledge of the organization of the workplace;
- Develop preventive individual and collective protection measures
- Develop safety procedures for the various activities of the structure;
- Propose information and training programs for workers;
- Participate in consultations regarding health and safety protection;
- Provide workers with safety information;
- Attend refresher courses.

Reference legislation: Legislative Decree N°81/08 and subsequent amendments N°106/09 articles. 31, 35; DM 363/98 art. 4 (d)

2.8 PREVENTION AND PROTECTION SERVICE EMPLOYEE (A.S.P.P.)

The person in charge of the prevention and protection service is the person in possession of the professional skills and requirements, pursuant to art. 32 Legislative Decree. 81/08 and is appointed by the Rector.

The risk prevention and protection service is, by definition, the set of people, systems and means external or internal to the company aimed at preventing and protecting workers from professional risks.

The University's SPP is structured as follows:

1. **Competent Doctor (M.C.)** (art. 38 of Legislative Decree 81/08) is, by definition, a doctor in possession of one of the qualifications and educational and professional requirements referred to in article 38, who collaborates with the employer for the purposes of risk assessment and is appointed by the same to carry out health surveillance and for all the other tasks referred to in the articles. 38-40 of the decree.

Its function is to promote and maintain the highest level of physical, mental and social well-being of workers in all activities through:

- prevention of health changes caused by working conditions
- protection of workers in the workplace from health hazards
- placement and maintenance in an environment suitable for their physiological and psychological capabilities.

Collaborates with the Employer and the RSPP for risk assessment, also for the purposes of health surveillance where necessary; to the training and information activities of workers; for the part of its competence, to the organization of the first aid service.

The competent doctor is appointed by the Employer to carry out Health Surveillance and collaborates with him on the risk assessment. The employer ensures the competent doctor the necessary conditions of autonomy to carry out his work.

Reference legislation: Legislative Decree 81/08 (Art 38 and 39)

2. **Licenced doctor (M.A.)** is, by definition, the doctor responsible for the medical surveillance of workers exposed to ionizing radiation, whose qualifications and specializations are recognized according to the procedures and methods established in the Legislative Decree. 230/95 and subsequent amendments.

3. **Qualified Expert (E.Q.)** the person who possesses the knowledge and necessary training both to carry out measurements, examinations, checks or assessments of a physical, technical or

radiotoxicological nature, and to ensure the correct function of protective devices, and to provide all the other indications and formulate measures aimed at guaranteeing the physical surveillance of the protection of workers and the population.

Assignments:

- Design of protective barriers.
- Classification of work environments.
- Evaluation of the individual dose of exposed workers and particular groups of the population.
- Examination of the suitability of the protective equipment used.
- Examination of the technical characteristics of X-ray equipment.
- Verification of the effectiveness of radiation protection devices and techniques.
- Environmental surveillance of radiation protection.
- Report on worker safety based on the provisions of Legislative Decree N°81/08. He can also ensure quality controls on X-ray equipment.

Reference legislation: art. 79 by Legislative Decree 230/95; Legislative Decree N°81/08 and subsequent amendments No. 106/09

These three figures are appointed by the Rector to whom they respond.

2.9 EMERGENCY EMPLOYEES

The **firefighting** and emergency situation management officer is the person who, in the event of serious and immediate danger in the workplace, has as priority duty the disabled people who may be present in the structure, and to take care of the evacuation of the workplaces, rescue and physical safety, primarily of the disabled people who may be present in the structure.

The **first aid officer** is the person designated to collaborate in the management of emergency situations that may occur in the University's workplaces.

These two figures are proposed by the manager of the structure and are formally appointed by the Rector.

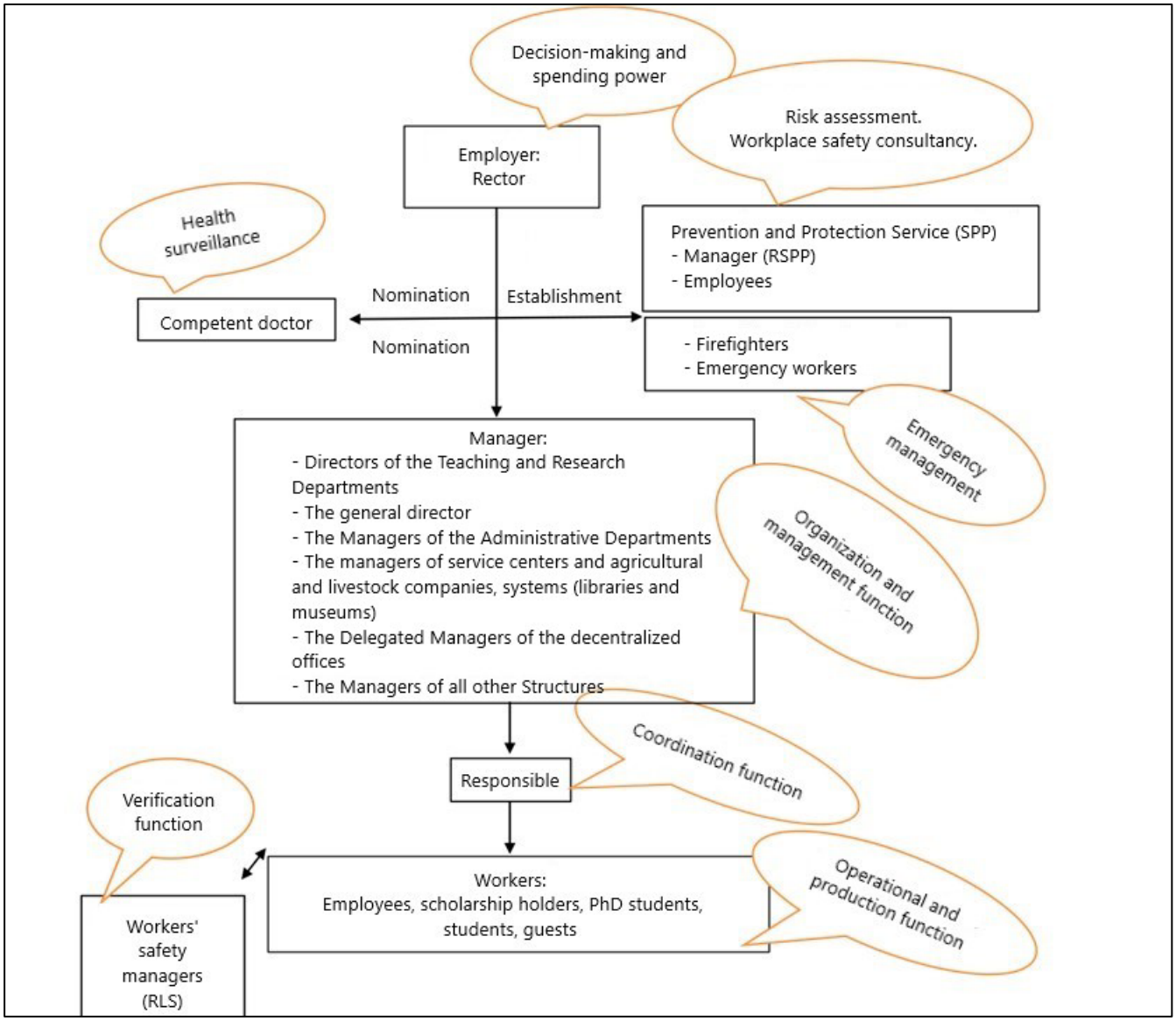
Reference legislation: Ministerial Decree 15 July 2003, n. 388 Regulation containing provisions on company first aid, implementing article 15, paragraph 3, of legislative decree 19 September 1994, n. 626, and subsequent amendments (Annex 1).

Liability towards third parties

Legislative decree 81/2008 imposes prevention rules on employees of contracting companies or self-employed workers for which every laboratory manager must implement prevention and protection measures against the risks that may arise from the work activity also towards third parties.

In particular, with regard to responsibilities towards employees of cleaning companies, during the time intervals in which cleaning is carried out in the laboratories there must be no presence of biological materials, dangerous substances and radioactive materials that could constitute a danger. Suitable measures must also be adopted during maintenance operations.

The following diagram summarizes the figures present within the university organization:


Decision-making and spending power
Risk assessment. Workplace safety consultancy.
Employer: Rector
Health surveillance
Prevention and Protection Service (SPP)
- Manager (RSPP)
- Employees
Nomination
Establishment
Competent doctor
Nomination
- Firefighters
- Emergency workers
Emergency management
Manager:
- Directors of the Teaching and Research Departments
- The general director
- The Managers of the Administrative Departments
- The managers of service centers and agricultural and livestock companies, systems (libraries and museums)
- The Delegated Managers of the decentralized offices
- The Managers of all other Structures
Organization and management function
Coordination function
Responsible
Verification function
Workers:
Employees, scholarship holders, PhD students, students, guests
Operational and production function
Workers' safety managers (RLS)

3. SAFETY IN THE LABORATORY

Laboratories are places where the activities that are carried out involve the use of machines, work appliances and equipment, systems, prototypes, or other technical means, like chemical or biological agents. Laboratories also include places or environments where activities are carried out outside the built-up area of the headquarters (e.g., archaeological, geological campaigns, etc.). The laboratories are divided into:

- Teaching laboratories;
- Research laboratories;
- Service laboratories.

All the activities that take place in a laboratory expose the worker to risks of various nature: mechanical (fall from slipping, cutting...) chemical and/or biological.

The general measures to protect the health and safety of workers in the workplace are listed in the art. 15 of Legislative Decree 81/08.

Definitions

- **Danger** art. 2, letter r, Legislative Decree 81/08: intrinsic property or quality of a given factor having the potential to cause damage. Danger is an intrinsic property (of the situation, object, substance, etc.) not linked to external factors; it is a situation, object, substance, etc. which due to its properties or characteristics has the ability to cause harm to people.
- **Risk** art. 2, letter s, Legislative Decree 81/08: probability of reaching the potential level of damage in the conditions of use or exposure to a specific factor or agent or their combination. Risk is a probabilistic concept; it is the probability that a certain event capable of causing harm to people will occur. The notion of risk implies the existence of a source of hazard and the possibility that it turns into damage.
- **Prevention** art. 2, letter n, Legislative Decree 81/08: the set of provisions or measures necessary, also according to the particularity of the work, experience and technique, to avoid or reduce professional risks while respecting the health of the population and the integrity of the external environment.
- **Risk assessment** Art. 2, paragraph 1, letter q: global and documented assessment of all risks conserning the health and safety of workers present within the organization in which they carry

out their activities, aiming to identify the appropriate measures of prevention and protection and to develop the program of measures aiming to guarantee the improvement of health and safety levels over time.

- **Single Risk Assessment Document (DUVR).**

  Pursuant to art. 28, of Legislative Decree 81/08, the Director of the Facility must develop, with the technical support of the SPP, a single risk assessment document (DUVRI) that contains the global and documented assessment of all risks to the health and safety of the workers present within the organization in which they carry out their work, aimed at identifying the appropriate prevention and protection measures and developing the program of measures aimed at guaranteeing the improvement of health and safety levels over time.

  The obligation to carry out the process of evaluation, control and management of workplace risks essentially concerns the employer, but managers and supervisors who are custodians of important knowledge and bearers of obligations, must still participate in this process.

  The legislator of art. 15 lists the general protection measures in order of priority with which they must be applied.

Wanting to summarize the four principles of safety in the laboratory are:

1. Recognizing chemical, physical, biological and equipment hazards.
2. Assessing the risks associated with exposure to chemical, physical, biological and equipment products.
3. Minimizing risks by paying particular attention to the design and execution of an experiment, providing adoption of all those measures necessary to minimize or eliminate exposure to a risk (use of good laboratory safety practices).
4. Preparation for emergencies.

4. THE CHEMICAL RISK

Title IX of Legislative Decree 81/08 as amended by Legislative Decree 106/09 requires carrying out a chemical risk assessment of every activity that uses substances or preparations hazardous for health and safety: an assessment that is mandatory for the employer in whose activity hazardous chemical agents are used for any purpose.

The Legislative Decree. 9 April 2008, n. 81, in fact, requires the Employer to:

- carry out the assessment of worker exposure risks; update it periodically based on substantial changes that have occurred in the meantime;
- take, based on the findings, all collective and individual prevention and protection measures necessary to minimize the risk.

To minimize the risks deriving from the handling of chemical substances it is essential to:

- ✓ identify the substance
- ✓ consult the product **safety data sheets** present in the laboratory
- ✓ know **the classification and labeling criteria, the numerical acronyms related to the risk phrases (R), safety phrases (S) and danger phrases (P)** specific to the reagent and the indications given for handling, storage and disposal of the reagent
- ✓ use specific **personal protective equipment (PPE) (Annex 2)** and **collective protection equipment (DPC) (Annex 3)**

4.1 Identification

All chemical substances are identifiable not only by their IUPAC name (International Union of Pure and Applied Chemistry) but also by their CAS number. The CAS number is a numerical identifier that uniquely identifies a chemical compound. The Chemical Abstract Service (CAS), a division of the American Chemical Society, assigns these identifiers to every chemical described in the

literature. Chemical substances placed on the European Union market before the 18th of September 1981 are also identifiable by an EINECS number (European INventory of Existing Commercial chemical Substances), while those placed on the European Union market after that date are characterized by an ELINCS number (European List of Notified Chemical Substances).

4.2 Criteria for classification and labeling of chemical agents.

In the past, the classification and labeling of hazardous substances and preparations were regulated by Legislative Decree 52/97 (implementation of Directive 67/548/EEC) and Legislative Decree 65/03 (implementation of Directive 1999/45/ CE), both transpositions of European Directives on Dangerous Substances (DSP), respectively. According to the DSP, chemical agents can be classified according to hazard categories.

On the 20 of January 2009, came into force in the European Union the EC Regulation no. 1272/2008, called CLP (Classification, Labeling and Packaging), which introduced a new system of classification, labeling and packaging of substances and mixtures. It repealed the previous DSPs effective from June 1st, 2015.

The CLP regulation allows the application of the Globally Harmonized System of Classification and Labeling of Chemical Substances, called GHS (*Globally Harmonized System*), developed by the UN, within the European Community.

In order to facilitate the adoption of the GHS system in the various countries and in the various working sectors, the concept of the *building block approach* was introduced that allows even the partial adoption of the hazard categories: harmonization is understood as the adoption of the same elements for everyone, even if they are not transposed in full.

Therefore, products imported from non-EU countries, despite having common labeling elements, may not be fully compliant with CLP regarding the classification and labeling of substances and mixtures, since the degree of implementation of GHS may vary from country to country.

Comparison between the two classification systems: CLP and DSP

Comparing the CLP Regulation with the previous DSPs, some important differentiating elements emerge.

The CLP has introduced several innovations including new definitions and different terminology:

- The substances, based on the nature of the hazard, are no longer divided into hazard categories (there were 15; e.g. flammable, harmful) but into hazard classes (28 in the CLP). Hazard classes in CLP are divided into categories that specify the severity of the hazard. These differences mean that there is not always a correspondence between the old indications (R and S phrases) and the new ones (H and P phrases).
- The hazard indications placed under the pictogram are no longer present in the CLP. They are replaced by a warning which can be given with two words "danger" or "caution".
- Pictograms and danger symbols are modified.
- Risk phrases (R phrases) are replaced by danger indications (Hazard statements). Each danger indication corresponds to an alphanumeric code composed of the letter H followed by 3 numbers; the first number indicates the type of danger (H2=chemical-physical dangers, H3=health hazards, H4=environmental hazards), the next two numbers correspond to the sequential order of definition. The European Union reserved the right to insert additional sentences that would have had no equal in the GSH system. They consist of EUH followed by a three-digit number.
- The precautionary phrases (S phrases) are replaced by safety advice (Precautionary statements). Each safety advice corresponds to an alphanumeric code composed of the letter P followed by 3 numbers; the first number indicates the type of advice (P1=general, P2=prevention, P3=reaction, P4=conservation, P5=disposal), the two subsequent numbers correspond to the sequential order of definition.

CHEMICAL HAZARDS: COMPARISON OF NEW AND OLD LABELS

NEW CLP Pictogram	Number	Hazard Class (CLP)	OLD 'CHIP' Symbol
PHYSICAL HAZARDS			
	GHS-01	• Explosives • Self-reactive substances and mixtures, types A, B • Organic peroxides, types A,B	 Explosive
	GHS-02	• Flammable gases, aerosols, liquids or solids • Self reactive substances and mixtures • Pyrophoric liquids and solids • Self-heating substances and mixtures • Substances and mixtures, which in contact with water emit flammable gases • Organic peroxides	 Highly/Extremely flammable
	GHS-03	• Oxidising gases, liquids and solids	 Oxidising
	GHS-04 NEW	• Compressed gases, liquids and solids • Liquefied gases • Refrigerated liquefied gases • Dissolved gases	No current symbol
	GHS-05	• Corrosive to metals	 Corrosive
HEALTH HAZARDS			
	GHS-06	• Acute toxicity (Cat 1 - 3)	 Toxic/Very Toxic Harmful

	GHS-07 NEW	• Acute toxicity (Cat 4) • Skin and eye irritation • Skin sensitisation • Specific target organ toxicity • Respiratory tract irritation • Narcotic effects	 Harmful/Irritant
	GHS-08 NEW	• Respiratory sensitisation • Germ cell mutagenicity • Carcinogenicity • Reproductive toxicity • Specific target organ toxicity • Aspiration hazard	 No current specific symbol (Use either)
	GHS-05	• Skin corrosion • Severe eye damage	 Corrosive
ENVIRONMENTAL HAZARDS			
	GHS-09	• Hazardous to the aquatic environment (acute) • Hazardous to the aquatic environment (chronic)	 Dangerous for the environment

4.3 Carcinogenic, mutagenic, and reproductive toxic chemicals

These agents are included in three health risk classes which are in turn divided into three categories.

Hazard category	Criteria	Hazard and warning indication
MUTAGENICITY (formerly R46 and R68) ***(increased frequency of mutations in populations of cells and/or microorganisms)***		

Cat. 1A	**It can cause hereditary mutations in human germ cells**	**H340 - Hazard**
Cat. 1B	**It can cause hereditary mutations in mammals or humans but without transmission to offspring**	**H340 - Hazard**
Cat. 2	**Suspected of causing hereditary mutations in human germ cells**	**H341 - Attention**
CARCINOGENITY (formerly R45, R49 and R40) ***(cause or increase the incidence of cancer in humans)***		
Cat. 1A	**Carcinogenic effects on humans**	**H350 - Hazard**
Cat. 1B	**Presumed carcinogenic effects on humans mainly based on animal studies**	**H350 – Hazard**
Cat. 2	**Suspected carcinogenic effects on humans**	**H351 – Attention**
REPRODUCTION TOXICITY (formerly R60 and R61) ***(effects on sexual function or development, on or through breastfeeding)***		
Cat. 1A	**Toxic for human reproduction**	**H360 – Hazard**
Cat. 1B	**Presumed human reproductive toxicity**	**H361 - Attention**
Cat. 2	**Suspected human reproductive toxicity**	

Cat. additional	**Effects on or through breastfeeding**	**H362 - No pictogram and no warnings**

With the Ministerial Circular of 06/30/2011 it was clarified that workers for whom the exposure assessment has highlighted a health risk **regarding carcinogenic and/or mutagenic substances and mixtures of categories 1A and 1B which correspond to the previous categories 1 and 2** (formerly R45, 46 and 49).

Only those exposed to these categories, i.e. those marked with the indications **H340 and H350**, will therefore be included in the register of exposure to carcinogenic and/or mutagenic agents.

4.4 Accident prevention

In the laboratory, the use of dangerous chemicals must be reduced to a minimum.

These products must be stored in closed cabinets (reagent cabinets).

The reagent cabinet must be a **safety cabinet with shelves** (vacuum/fire cabinets) for particular categories of products (acids/bases and toxic substances, flammable substances), equipped with doors that allow them to be closed.

It is recommended to post a sheet of paper containing the following **information** on each cabinet:

- references on where to find the relevant safety data sheets;
- list of products contained with related hazard indications and date of the last update of the list itself;
- indications on maintenance (e.g. carbox filter replacement dates);
- name and telephone number of the laboratory manager.

- Flammable liquids must be housed in fireproof cabinets for exclusive use.

- Highly toxic agents (e.g. carcinogens, CMT) must be stored separately in preferably vacuumed and locked cabinets.

- Knowledge of chemical incompatibilities

The handling of substances that can release dangerous fumes must be carried out exclusively inside a chemical hood (Annex 3)

If you have to work with ethers, remember that in contact with air they form peroxides. Before carrying out a distillation or evaporation, the ether must be tested for the presence of peroxides and, if present, they must be eliminated. Abnormal condensation of highly flammable vapors such as ether can produce an explosive atmosphere.

The worker must communicate to the RSPP:

- ✓ the list of carcinogenic and mutagenic reagents (R45, R46 and R49)
- ✓ the methods of use,
- ✓ the quantities used,
- ✓ the prevention measures adopted (PPE - DPC) Annex 4, 5.

The laboratory manager, as far as possible, **is committed to**:

- avoid carcinogenic substances,
- use them in a closed circuit if possible (under a chemical hood with maximum suction efficiency, > 0.8m/s-2, and using all the appropriate PPE) and ensure that the level of exposure of the workers is the technically lowest level possible, exposure must not exceed the exposure limit values established by law.
- place adequate warning and safety signs,
- provide, with the RSPP, the measurement of carcinogenic or mutagenic agents through chemical risk assessment.

- ensure regular cleaning of the premises, equipment and systems and their storage in special locked cabinets and transport in safe conditions
- ensure that waste disposal takes place using air-tight containers labeled in a clear, clean and visible way.

Health Surveillance: The Competent Doctor, in agreement with the Employer, will evaluate when necessary to compile a register of those exposed to carcinogens and mutagens (workers authorized to use the aforementioned products) and subject them to health surveillance. In this regard, the operating methods will be made known by the Competent Doctor who will decide whether it will be appropriate to compile a register also for those potentially exposed (workers who are not authorized to use carcinogenic products but who may accidentally come into contact with the reagent).

4.5 Disposal of reagents

All chemicals known or suspected to be toxic or harmful to the environment must be disposed following hazardous waste disposal procedures. It is necessary to store used chemical compounds and solvents in special containers, marked with labels, which must be disposed of as hazardous waste. No chemical substances that are toxic or harmful to the environment must be eliminated through the sewer system. Where possible, methods capable of reducing the presence of dangerous concentrations of flammable and chemically unstable substances, must be adopted.

4.6 Chemical decontamination procedure

Every laboratory that uses chemicals must have access to a control kit for accidental spills (SPILL CONTROL KIT) strategically placed near work areas so that it is easily accessible in case of emergency.

The SPILL CONTROL KIT must contain the Personal Protective Equipment (Annex 2) indicated below and adsorbent materials appropriately chosen to manage the spillage of 1 liter of liquids or 1 kg of dry chemical products.

PPE:

- protective glasses and visor;
- heavy neoprene or nitrile gloves;
- disposable lab coat for corrosive substances;
- vinyl/plastic shoes/overshoes;
- FFP3 dust mask to be used in case of spillage of solid substances in powder or granules.

ADSORBENT MATERIALS:

- universal inert absorbents for spreading solvents: vermiculite, sawdust, sodium bicarbonate, sand, and clay.
- neutralizer for the spreading of acidic substances: sodium bicarbonate, sodium carbonate or calcium carbonate
- neutralizer for the spreading of basic substances: sodium bi-sulphate.
- bromine neutralizer: 5% solution of sodium thiosulphate and absorbent aggregate.
- hydrofluoric acid spill neutralizer: calcium gluconate

MATERIAL FOR THE CLEAN UP:

- disposable broom, dustpan and spatula for collecting waste and possibly pliers for collecting glass;
- absorbent cloths or gauze;
- container for waste collection: plastic bags, a plastic bucket (5 liter polyethylene) with lid

4.7 IN THE EVENT OF AN ACCIDENT INVOLVING CHEMICAL SUBSTANCES, COMPLY WITH THE FOLLOWING EMERGENCY RULES

- Offer first aid and call external help if necessary.
- Remove clothing and any contaminated PPE, using the necessary precautions;
- Decontaminate any affected skin using the emergency showers provided; if the eyes have been affected, use facial-ocular fountains, eyewash liquids or physiological solution contained in the kit;

- Clean up spills immediately; if the quantity and/or nature of the spilled product allow it, using the appropriate absorbent materials with which the laboratory is equipped;
- If gases, vapors or airborne dust are present, ensure maximum ventilation of the room by opening the windows and using all available means of mechanical ventilation (hoods, wall fans, etc.);
- In the event of unforeseeable exposure to dangerous chemical agents, immediately leave the affected area, isolating it until decontamination by emergency management personnel;
- Immediately notify the Section Manager giving all the information necessary to manage the emergency (dynamics of the events, information on the spilled compound, etc.).

4.8 GENERAL PROCEDURE TO BE IMPLEMENTED IN THE EVENT OF SPILLAGE OF LIQUID PRODUCTS

- always consult the safety data sheet of the product involved
- evacuate the area by moving people away;
- close the doors and ventilate by opening the windows;
- wear the appropriate personal protective equipment present in the kit;
- pour the absorbent substance starting from the periphery of the spill and reaching the inside;
- wait for the powder to solidify;
- remove the absorbed product with a dustpan and spatula;
- in case of glass fragments, collect them with the appropriate dustpan and/or pliers;
- possibly wash with water or other liquid if indicated in the safety data sheet;
- dry and check that the surfaces do not have residual slipperiness;
- adequately store and dispose of used products in the waste container

4.9 GENERAL PROCEDURE TO BE IMPLEMENTED IN THE EVENT OF SPREADING OF POWDER OR GRANULATED PRODUCTS

- always consult the safety data sheet of the product involved;
- evacuate the area by moving people away;
- close doors and windows avoiding creating air currents;

- avoid operations that could develop or raise dust;
- wear the appropriate personal protective equipment present in the kit;
- limit the spreading in order to avoid environmental contamination;
- if required by the safety data sheet, moisten the dust;
- collect dust with damp cloths,
- remove the absorbed product with a dustpan and a spatula;
- in case of glass fragments, collect them with the appropriate dustpan and/or pliers;
- possibly wash with water or other liquid if indicated in the safety data sheet;
- dry and check that the surfaces do not have residual slipperiness;
- adequately store and dispose of used products in the waste container.

5. BIOLOGICAL RISK

Definition: **Biological risk is** "the probability that, in the presence of a biological agent, an undesirable for the health event occurs" and is, therefore, connected with exposure to pathogenic and non-pathogenic organisms and microorganisms, cell cultures, human endoparasites present in the work environment following emission and/or treatment and manipulation.

Legislative Decree 81/08 (title X) defines:

- **biological agent:** any microorganism, even if genetically modified, cell culture and human endoparasite that could cause infections, allergies or intoxications.
- **microorganism:** any **microbiological entity**, cellular or otherwise, capable of **reproduction or transferring genetic material**;
- **cell culture:** the result of the in vitro growth of cells derived from multicellular organisms.

The biological agents are divided into the following four groups based on the risk of infection:

Group 1: (no risk or low individual and collective risk) agent that is unlikely to cause disease in humans;

Group 2: (moderate individual risk, low collective risk) agent that can cause diseases in humans and constitute a risk for workers; it is unlikely to spread in the community; effective prophylactic or therapeutic measures are usually available;

Group 3: (high individual risk, low collective risk) agent that can cause serious diseases in humans and constitutes a serious risk for workers; the biological agent can spread in the community, but effective prophylactic or therapeutic measures are usually available;

Group 4: (high individual and collective risk) biological agent that can cause serious diseases in humans and constitutes a serious risk for workers and can present a high risk of spread in the community; usually, effective prophylactic or therapeutic measures are not available.

In the event that the biological agent being classified cannot be attributed unequivocally to one of two groups indicated above, it must be classified in the higher risk group of the two possibilities.

Reference legislation: Annex XLVI of Legislative Decree 81/08 contains the list of biological agents with the relative attribution to groups 2, 3 and 4.

Furthermore, Annex XLVII reports the specifications on the containment measures and containment levels to be adopted in relation to the classes of biological agents treated (Annex 4).

The most important work activities that may involve ***potential risk of exposure*** to biological agents are the following:

- **Activities in which there is contact with animals and/or products of animal origin;**
- **Activities in health services, including isolation units and autopsy rooms;**
- **Activities in clinics, rooms connected to clinical and surgical activities; microbiological laboratories,**

In microbiological laboratories, the risk associated with the deliberate use of microorganisms must also be considered.

In the laboratory it is necessary to prevent the transmission of pathogens to operators.

Transmissibility	ability to be transmitted from infected to susceptible
Infectivity	ability to penetrate and multiply in the host
Pathogenicity	ability to produce disease following infection
Neutralizability	availability of prophylactic and/or therapeutic measures

The most frequent routes of transmission of pathogens to humans are:

- inhalation of infected aerosols.
- Spillage or splashes of liquids on the skin and mucous membranes
- ingestion (mouth contact with fingers or contaminated objects)
- parenteral inoculation (needles or other contaminated sharp or cutting objects)
- indirect transmission via vectors

FOMITES: all objects are classified as such, both those used specifically in the laboratory and the personal objects of operators (cell phones, electronic devices, pens, etc.) that act as a potential transmission vehicle. It is therefore necessary to minimize the use of these tools, especially personal objects.

In addition to zoonotic agents, veterinary diagnostic and research laboratories must consider a list of pathogenic agents, that are dangerous due to their virulence, transmissibility in the animal population, as well as their repercussions on animal productivity (Annex 4). To avoid the dispersion of these **microorganisms, manipulation in biosafety laboratories level 3 is necessary.**

The employer's obligations, the containment and prevention and protection measures for workers are conditioned by the different levels of hazard of the microorganisms.

The requirements vary depending on whether biological agents from groups 2 and 3 on the one hand and 4 on the other are used, respectively. In the first case, the employer must simply notify the Local Health Unit at least 30 days before the start of the activity; however, in the case of group 4 microorganisms, specific authorization from the Ministry of Health is required.

The use of genetically modified microorganisms is regulated by **Legislative Decree 206/01**.

The risk levels may, therefore, be different and require different safety standards.

The susceptibility of individuals to pathogens changes depending on the physiological state of the operators or following their pathologies. Pregnant women, immunosuppressed individuals, or those undergoing particular therapies (for example immunosuppressives), subjects with liver cirrhosis, etc., are particularly at risk. In these cases, operators must inform the facility manager, who evaluates the opportunity for the individual in question to remain in the facilities.

Measures aimed at reducing the risk of exposure to biological agents are implemented in **CONTAINMENT** measures.

For containment and protection from biological agents, please refer to the Legislative Decree Legislative Decree 81/2008 and 106/09.

5.1 BIOSAFETY LABORATORIES

The classification into 4 risk levels of infectious agents and laboratory activities was introduced for the first time by the Centers for Diseases Control and Prevention, USA, in 1974 in the manual: “Classification of Etiologic Agents on the Basis of Hazard” (CDC. Office of Biosafety, 1974).

This subdivision, taken up by the various editions of the "Biosafety in Microbiological and Biomedical Laboratories" (BMBL) of the CDC, and in the "Laboratory biosafety manual" of the WHO (updated in 2004) still represents a fundamental guideline for the evaluation and classification of the potential biological risk connected to the various biomedical and microbiological activities carried out in a laboratory.

Based on their design characteristics, four biosafety levels have been identified, characterized by the acronym BSL deriving from the English ***B**iological **S**afety **L**evels*, followed by a number.

- Basic laboratories (Biosafety Level 1 and 2)
- Containment laboratories (Biosafety Level 3)
- Maximum containment laboratories (Biosafety Level 4)

Other names PCL 1-4, BL 1-4, P1-4

The assignment of a certain biosafety level must result from a careful risk assessment and must be taken into consideration the pathogens handled, the facilities available, the operational practices and the procedures that are necessary to work safely in the laboratory.

Note: in the Department of Veterinary Medicine, there are laboratories with biosafety levels 1, 2 and 3.

All laboratories must be designed at Biosafety Level 2 or higher as the laboratory personnel, upon acceptance of the sample, may be exposed to agents belonging to a higher risk group than expected.

The guidelines for laboratories with biosafety levels 1 and 2 represent the common basis for laboratories of any biosafety level.

5.1.1 BASIC LABORATORIES: BIOSAFETY LEVELS 1 AND 2

Access

- ✓ Where a biological risk is identified, the international biohazard **symbol** must ALWAYS be displayed on all doors of the laboratories where microorganisms in risk group 2 or higher are handled.
- ✓ Access to the laboratories must be allowed only to authorized personnel.
- ✓ Children are prohibited from entering!
- ✓ No animals are allowed in the laboratory.

The doors of our laboratories display the following sign:

LABORATORIO BIOSICUREZZA 1 E 2

1. **Disinfettare i banchi di lavoro prima e dopo le manualità.**
2. **È severamente vietato pipettare a bocca.**
3. **Non si deve portare nessun materiale alla bocca.**
4. **Tutte le procedure devono essere effettuate in modo da minimizzare la formazione di aerosol o goccioline.**
5. **Non usare aghi ipodermici e siringhe per l'aspirazione di liquidi.**
6. **Il materiale cartaceo utilizzato nel laboratorio deve restare all'interno dello stesso.**

Design and general requirements

- Walls, ceilings and floors must be smooth, easy to clean, impervious to liquids and resistant to chemicals and disinfectants.
- Lighting must be adequate, avoiding reflections and excessively strong light.
- The surfaces of the counters must be joined to the walls with sealing substances, resistant to chemical agents and disinfectants and impervious to water.
- In the laboratories there must be sinks equipped with running water.
- The fire prevention standards must be self-closing and have inspection panels.
- An autoclave must be available in the laboratory or in the same building.

- The ventilation must be mechanical if possible, so as to ensure an incoming air flow without recirculation. If there is no mechanical ventilation, the windows must be openable.

Safety equipment

- safety cabinet (BSC-1 or -2) for processing all samples that may cause aerosols/splash of material (Annex 3)
- Protective clothing is mandatory (lab coat, gloves, and for some procedures mask and protective glasses)

Aerosol

It is a two-phase mixture with a gaseous dispersing phase and a liquid or solid dispersed phase, that has a certain stability character. We distinguish two fundamental types of aerosols:

- of dispersion: powders, sprays
- of condensation: fumes, mists

Dissemination in the form of aerosols represents a significant source of dispersion of infected material in the atmosphere and constitutes one of the most frequent methods of environmental contamination, all the more dangerous as it is not visible.

All laboratory techniques, even the most common, cause the formation of aerosols.

Some examples of the most important causes of dispersion of pathogenic aerosols in the air are the following:

- centrifugation
- flaming (sterilization by flaming causes in the first phase a micro-explosion and the projection of infected particles on the operator's hand and surrounding areas)
- mixing
- agitation
- expulsion of liquids

- opening containers of infected material with internal pressure different from that of the surrounding environment
- inoculation of materials intranasally in animals
- collection of infected tissues from animals and eggs
- handling high concentrations or large volumes of infected materials

Given the very small size of the particles that compose them, they spread rapidly in the environment: they contaminate people, surfaces and instruments, they can creep into ventilation channels, quickly reaching other laboratories, offices and hospitalizations even far from the place of origin. Following the inhalation of pathogenic aerosols, not only the operator can be contaminated, but also the colleagues present in the same room and other staff present in the building. A drastic reduction of aerosols is achieved by using modern equipment that complies with current regulations (centrifuges, biohazard hoods, automatic pipettors, etc.) designed with safety.

5.1.2 CONTAINMENT LABORATORIES: BIOSAFETY LEVEL 3

Biosafety level 3 laboratories are designed to be suitable for handling risk group 3 microorganisms and/or large volumes or high concentrations of risk group 2 microorganisms that pose a risk of aerosol spread.

Access

- Access to the laboratory is permitted exclusively to authorized personnel with specific training.
- Appropriate signage must be affixed to the laboratory access door(s) containing the intended use of the room, specific prohibition signs, obligations, warnings, the list of biological agents used, access rules for authorized staff.
- The laboratory doors must always remain closed while carrying out work activities.

Design and general requirements

The containment laboratory with biosafety level 3 must present all the requirements described for the basic laboratory and in addition the following modifications:

- laboratory with filter room, (specify better)
- double entrance door,
- separate air conditioning and air without recycling,
- internal negative pressure [HEPA (high efficiency particulate air) filters at outlet]
- The doors of the filter area can be self-closing and interlocking so that only one door opens at a time.

5.1.3 MAXIMUM CONTAINMENT LABORATORIES: BIOSAFETY LEVEL 4

A maximum containment laboratory is designed to work with risk group 4 microorganisms.

The operation of such laboratory must be under the control of the national health authority or other competent authorities.

5.2 GOOD LABORATORY PRACTICES

Regardless the method, the purpose of decontamination is to protect the laboratory worker, the environment, and every person who enters the laboratory or who handles laboratory materials that have been carried out in the laboratory. Regardless of the disinfectant used, it is good practice to:

- Clean the surfaces at the beginning of work.
- Clean any object (e.g. pens, phone) if it has been touched with used gloves.
- Clean all surfaces at the end of each shift.
- The use of disposable liners may reduce equipment cleaning intervals, but it does not replace the need to clean the surfaces or equipment. Clean the counter surface underneath whenever the covering is discarded.

- In case of organ stains or dried blood, leave in contact with the disinfectant for at least 20 minutes. Never use a knife or other instrument to scrape dried blood or body fluid from surfaces, to avoid percutaneous injury or facilitate the formation of aerosols. All contaminated materials, specimens and cultures must be decontaminated before disposal or cleaning for reuse.

BIBLIOGRAPHY

CDC MMWR (2012) Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories VOL. 61.

BIOSAFETY MANUAL in laboratories, 3rd EDITION AIREPSA 2005 (Published by WHO).

ANNEX 1

Ministerial Decree of 15 July 2003, n. 388 - Regulation containing provisions on company first aid, implementing article 15, paragraph 3, of legislative decree of 19 September 1994, n. 626, and subsequent amendments

Published in the Official Journal 3 February 2004, n. 27

SUMMARY

THE MINISTER OF HEALTH

THE MINISTER OF LABOR AND SOCIAL POLICIES

THE MINISTER FOR THE PUBLIC SERVICE

THE MINISTER OF PRODUCTIVE ACTIVITIES

Having seen articles 12, paragraph 1, letters b) and c) and article 15, paragraph 3 of the legislative decree of 19 September 1994, n. 626, and subsequent amendments, that delegate to the Ministers of Health, Labor and Social Security, of the Public Function and of Industry, Commerce and Crafts, the task of identifying the minimum characteristics of first aid equipment, the requirements of the personnel involved and their training, in relation to the nature of the activity, the number of workers employed and the risk factors;

Having seen the act of direction and coordination of the Regions for the determination of emergency health care levels, approved by decree of the President of the Republic of 27 March 1992, published in the

Gazzetta Ufficiale no. 76 of 31 March 1992;

Having seen the law of 23 August 1988, n. 400, and in particular article 17, paragraphs 3 and 4;

Having seen the decree of the Minister of Health of 15 May 1992, published in the Gazzetta Ufficiale no. 121 of 25 May 1992, concerning the criteria and requirements for the codification of emergency interventions;

Having seen the legislative decree of 30 December 1992, n. 502, and subsequent amendments;

Having seen the act of understanding between the State and the Regions containing the approval of the guidelines on the health emergency system of 11 April 1996, published in the Gazzetta Ufficiale no. 114 of 17 May 1996;

Having consulted the permanent consultative commission for accident prevention and workplace hygiene, referred to in article 26 of legislative decree 19 September 1994, n. 626;

The agreement of the Permanent Conference for relations between the State, the regions and the autonomous provinces of Trento and Bolzano has been acquired; Having acquired the opinion of the Superior Health Council;

Having heard the opinion of the Council of State expressed by the consultative section for regulatory acts at the meeting of 26 March 2001;

They adopt the following regulation:

Art. 1 - Classification of companies

1. The companies or production units are classified, taking into consideration the type of activity carried out, the number of workers employed and the risk factors, into three groups.

Group A:

I) Companies or production units with industrial activities, subjected to the obligation of declaration or notification, referred to in the Article 2 of Legislative Decree of 17 August 1999, n. 334, thermoelectric power plants, nuclear plants and laboratories referred to in articles 7, 28 and 33 of the legislative decree of 17 March 1995, n. 230, mining companies and other mining activities defined by the legislative decree of 25 November 1996, n. 624, underground works referred to in the decree of the President of the Republic of 20 March 1956, n. 320, companies for the manufacture of explosives, powders and ammunition;

II) Companies or production units with more than five workers belonging to or attributable to INAIL tariff groups with an accident index of permanent disability greater than four, as deduced from the national INAIL statistics relating to the previous three-year period and updated on 31 December of each year. The aforementioned INAIL national statistics are published in the Gazzetta Ufficiale;

III) Companies or production units with more than five permanent workers in the agricultural sector.

Group B: companies or production units with three or more workers that do not fall into group A.

Group C: companies or production units with fewer than three workers that do not fall into group A.

2. The employer, having consulted the competent doctor, where applicable, identifies the category to which his company or production unit belongs and, only if it belongs to group A, communicates it to the Local Health Unit Company competent in the territory in which it carries out the work

activity for the preparation of the necessary emergency interventions. If the company or production unit carries out work activities included in different groups, the employer must refer to the activity with the highest index.

Art. 2 - Organization of the first aid

1. In group A and group B companies or production units, the employer must guarantee the following equipment:

a) first aid box, kept at each workplace, adequately kept in an easily accessible and identifiable place with appropriate signs, containing the minimum equipment indicated in Annex 1, that is part of this decree, to be integrated on the basis of the risks present in the workplace and upon indication of the competent doctor, where applicable, and of the health emergency system of the National Health Service, and of which the completeness and correct state of use of the aids contained therein is constantly ensured;

b) a means of communication suitable for rapidly activating the emergency system of the National Health Service.

2. In group C companies or production units, the employer must guarantee the following equipment:

a) medication package, kept at each workplace, adequately guarded and easily identifiable, containing the minimum equipment indicated in Annex 2, that is part of this decree, to be integrated on the basis of the risks present in the workplace, of which the complete and correct state of use of the aids contained is constantly ensured, in collaboration with the competent doctor, where applicable;

b) a means of communication suitable for rapidly activating the emergency system of the National Health Service;

3. The minimum content of the first aid kit and the medication package, referred to in annexes 1 and 2, is updated by decrees of the Ministers of Health, Labor and Social Policies taking into consideration technical-scientific developments.

4. In group A companies or production units, including consortium members, the employer, having consulted the competent doctor, when required, in addition to the aforementioned equipment in paragraph 1, is required to guarantee the connection between the internal first aid system and the health emergency system referred to in the decree of the President of the Republic of 27 March 1992 and subsequent amendments.

5. In companies or production units that have workers who work in isolated places, other than the company headquarters or production unit, the employer is required to provide them with the medication package referred to in Annex 2, that is part of this decree, and a suitable means of communication to connect with the company in order to quickly activate the emergency system of the National Health Service.

Art. 3 - Requirements and training of first aid workers

1. First aid workers, designated pursuant to article 12, paragraph 1, letter b), of legislative decree of 19 September 1994, n. 626, are trained with theoretical and practical instructions for the implementation of internal first aid measures and for the activation of first aid interventions.

2. The training of designated workers is carried out by medical personnel, in collaboration, where possible, with the emergency system of the National Health Service. In carrying out the practical part of the training, the doctor can avail of the collaboration of nursing staff or other specialized personnel.

3. For Group A companies or production units, the contents and minimum time of the training course are shown in Annex 3, that is part of this decree, and must also include the discussion of the specific risks of the activity carried out.

4. For group B and group C companies or production units, the contents and minimum time of the training course are shown in Annex 4, that is part of this decree.

5. Training courses for first aid workers completed by the date of entry into force of this decree are valid. The training of designated workers must be repeated every three years at least as regards too the practical intervention skills.

Art. 4 - Minimum equipment for first aid interventions

1. The employer, in collaboration with the competent doctor, where applicable, on the basis of the specific risks present in the company or production unit, identifies and makes available the minimum equipment and personal protective equipment for internal first aid and emergency workers.

2. The equipment and devices referred to in paragraph 1 must be appropriate with respect to the specific risks associated with the company's work activity and must be kept in efficient and ready-to-use conditions and kept in a suitable and easily accessible place.

Art. 5 - Repeals

The ministerial decree of 2 July 1958 is repealed.

Art. 6 - Entry into force

This decree comes into force six months after its publication in the Gazzetta Ufficiale of the Italian Republic.

This decree, bearing the seal of the State, will be included in the official collection of regulatory acts of the Italian Republic.

It is the obligation of anyone responsible to observe it and to have it observed as state law.

Rome, 15 July 2003

The Minister of Health Sirchia

The Minister of Labor and Social Policies Maroni

The Minister for the Public Service Mazzella

The Minister of Productive Activities Marzano

Seen, the Keeper of the Seals: Castelli

Annex 1 - MINIMUM CONTENTS OF THE FIRST AID KIT

Disposable sterile gloves (5 pairs).

Visual Splash Guard Visor

1 liter bottle of povidone iodine cutaneous solution with 10% iodine (1).

500 ml bottles of physiological solution (sodium chloride - 0.9%) (3).

Sterile gauze compresses 10 x 10 in individual bags (10).

Sterile gauze compresses 18 x 40 in individual bags (2).

Disposable sterile drapes (2).

Disposable sterile dressing tweezers (2).

Pack of medium size elastic net (1).

Pack of cotton (1).

Packs of ready-to-use plasters of various sizes (2).

Rolls of plaster of 2.5 cm (2).

A pair of scissors.

Tourniquets (3).

Ready-to-use ice (two packs).

Disposable bags for the collection of medical waste (2).

Thermometer.

Device for measuring blood pressure.

Annex 2 - MINIMUM CONTENTS OF THE MEDICATION PACKAGE

Disposable sterile gloves (2 pairs).

125 ml bottle of povidone iodine cutaneous solution with 10% iodine (1).

250 ml bottle of saline solution (sodium chloride 0.9%) (1).

Sterile gauze compresses 18 x 40 in individual bags (1).

Sterile gauze compresses 10 x 10 in individual bags (3).

Disposable sterile dressing tweezers (1).

Pack of cotton (1).

Pack of ready-to-use plasters of various sizes (1).

Roll of plaster of 2.5 cm (1).

Roll of hemmed bandage of 10 cm (1).

A pair of scissors (1).

A tourniquet (1).

Ready-to-use ice pack (1).

Disposable bags for the collection of medical waste (1).

Instructions on how to use the aforementioned aids and provide first aid while waiting for the emergency service.

ANNEX 2

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Personal protective equipment (PPE) means any equipment intended to be worn and kept by the worker for the purpose of protecting him against one or more risks present in the work activity, likely to threaten his safety or health during work, as well as any complementary or accessory intended for this purpose. **Regulations:** Art. 74 of Legislative Decree 81/08 and subsequent amendments 106/09

PPE must be prescribed only when it is not possible to implement risk prevention measures (reduction of risks at source, replacement of dangerous agents with less dangerous ones, limited use of the same), adopt means of collective protection, methods or procedures for reorganizing the work. The worker is obliged to use these devices correctly, to take care of them and not to make changes to them, reporting specific defects or inconveniences. For some PPE, it is mandatory to undergo training and training programs.

The art. 76 of Legislative Decree no. 81/08 indicates the characteristics that PPE must have in order to be used:

- they must be appropriate for the risks to be prevented and their extent without themselves entailing a greater risk
- they must be adapted to the conditions existing in the workplace
- they must meet the ergonomic or health needs of the worker
- they must be adaptable to the user according to his needs
- they must possess the essential intrinsic safety requirements, i.e. comply with the standards set out in Legislative Decree no. 4 December 1992. 475 (CE marking) and its subsequent amendments.

PPE is classified based on the parts of the body they must protect (Annex VIII of Legislative Decree no. 81/08):

1. head protection equipment
2. hearing protection equipment
3. eye and face protection equipment

4. respiratory protection equipment
5. hand and arm protection equipment
6. foot and leg protection equipment
7. skin protection equipment
8. body and abdominal protection equipment
9. full body protective equipment
10. protective clothing

EQUIPMENT

1. Protective glasses
   - ✓ for chemical protection
   - ✓ for UV rays
   - ✓ for laser rays
   - ✓ for X-rays

2. Visor, face mask
   - ✓ for protection from splashes and aerosols

3. Protective masks (European standard EN149:2001):

   - **hygienic masks** for harmless dust with a diameter >=5 microns (they are not considered personal protective equipment)
   - **FFP1** for protection against harmful dust, water-based aerosols of particulate material (>=0.02 micron) when the concentration of the contaminant is a maximum of 4, 5 times the corresponding TLV (threshold limit value)
   - **FFP1** for protection from organic vapors and acid vapors for contaminant concentrations lower than the respective TLV

- **FFP2** for protection against medium-toxic dust, fibers and water-based aerosols of particulate material (>= 0.02 micron), metal fumes for contaminant concentrations up to 10 times the limit value (good filtration efficiency)
- **FFP3** for protection from toxic dust, water-based aerosol fumes of toxic particulate material with grain size >=0.02 micron for contaminant concentrations up to 50 times the TLV (excellent filtration efficiency)

4. Gloves:
   - disposable material compatible with the substances handled and hypoallergenic material
   - cotton gloves (undergloves)
   - for high temperatures
   - for liquid nitrogen

5. Overshoes
6. Standard work footwear

In any case, in the laboratory you must always work with protective clothing (lab coats) and the need to provide changing rooms with double lockers for each person must be assessed.

ANNEX 3

COLLECTIVE PROTECTION DEVICES (DPC): THE HOODS

The chemical hood

Laboratory fume hoods, commonly called chemical hoods, are the main Collective Protection Devices (CPD) for protecting the health of operators from risks deriving from the use and manipulation of dangerous chemical agents. They aim to reduce at the source the environmental concentration of dust, fumes, gases and vapors of dangerous substances that can be generated during the activities carried out in scientific research and teaching laboratories and protect the operator from splashes, fires or explosions, accidents and damage to health. Hoods are to be considered as a primary protection tool for worker safety.

Correct use of the chemical hood:

- turn on the hood a few minutes before use
- avoid creating air currents near the hood in operation: therefore avoid opening doors and windows, frequent transit of people in the room
- keep only the strictly necessary material under the hood, placing it at least 15-20 cm away from the front opening
- during the activity work with the front glass lowered as much as possible (the more the front glasss is lowered, the less the functioning of the hood is affected by currents present in the room), in any case with a maximum opening no greater than 50 cm from the work surface
- position yourself slightly away from the front opening in order to avoid turbulence
- do not get inside the hood (e.g. with your head) for any reason. At the end of the work, clear and clean the work surface. Each operator must clean the hood, possibly using specific products depending on the substances he uses; this is in order to avoid inappropriate risks for those who will use the hood later

- when the hood is not in use, turn off the extraction and close the front
- all users of the hood must be aware of the emergency procedures to be carried out in the event of an explosion or fire in the hood
- work involving pathogenic microorganisms must be carried out under a biosafety cabinet (biological hood) and not a chemical hood
- do not use the hood as a storage area for material, or as a mean for disposing of reagents through forced evaporation
- do not use the hood sink to dispose of chemical agents or waste. Finally, it is good to remember that a chemical hood with direct air extraction towards the outside (without filter) is not a pollution control device. All contaminants that are removed by the extraction system are released directly into the atmosphere.

The biological hood

A biohazard hood is one of the most important elements of primary physical containment of biological risk during processing (deliberate manipulation or potential risk) to ensure the protection of the operator and the product and to prevent the dispersion of aerosols in the environment.

Absolute air filtration (HEPA filters)

HEPA filters (*High Efficiency Particulate Air* filter) are able to retain 99.999% of particles with a diameter equal to or greater than 0.3 μm present in the air that passes through them. These filters make it possible to decontaminate the air without using chemicals or radiation. The HEPA filter has also the ability to "straighten" the air flow that passes through it at 0.45 m/sec, generating a laminar air flow, i.e. unidirectional and free of turbulence, ideal for creating controlled contamination environments in order to operate on sterile material (e.g. cell cultures, pharmaceutical preparations, and more).

In microbiological safety cabinets the work area is constantly kept under negative pressure compared to the environment in order to protect operators from the risk of biological

contamination. All the air expelled from the cabin is filtered with HEPA filters for environmental protection and then channeled outside the building or recycled in the room. Microbiological safety cabinets (commonly defined as "biohazard" or identified with the acronym MSC for Microbiological Safety Cabinet) are divided into three classes based on their operating scheme.

Cabinet class	**Group of protection**	**Use**
class I		Used in all cases where it is not essential or a priority to protect the product from the air present in the laboratory (e.g. opening of biological samples to be analyzed, as protection for centrifuges or other devices at risk of aerosols, etc.).
class II A and B3	I II	Indicated for medium-low biological risks (pathogens of groups I-II)
class II B1	II III	For pathogens of group II and III and for substances labeled with low-activity radioactive tracers
class II B2	I III	For pathogens of groups II and III, for cell cultures treated with carcinogenic and/or mutagenic substances or labeled with radioactive isotopes.
class III	IV	Indicated for high biological risks (pathogens of groups III and IV)

Class II cabinets, the most widespread, offer a compromise in terms of product-operator-environment protection. Using a front suction barrier, they prevent air from passing from the inside to the outside of the cabin towards the operator (dynamic seal). A vertical laminar flow of sterile air protects the product in the work area. All air is sucked in, HEPA filtered and partly expelled outside, partly recycled after filtration in the work area. Class II hoods are

distinguished, depending on the internal aerodynamics, into 4 types: **Class II type A, B1, B2 and B3. Types B1, B2 and B3** provide for the mandatory expulsion of the air outside the building.

Biosafety class	**Flow characteristics**	**Applications**	
		Non-volatile toxic chemicals, radionuclides	Volatile toxic chemicals, radionuclides
I	Front; expelled through the HEPA filter to the outside or into the room	YES	YES
II, A	70% of air recirculated in the work area through the HEPA filter; 30%, via the HEPA filter, in the room or ducted to the outside	YES	NO
II, B	The exhausted air must pass through a dedicated duct and expelled outside through a HEPA filter	YES	YES (minimum quantity)
II, B2	No recycling; all the exhausted air is expelled outside through a duct and a HEPA filter	YES	YES (minimum quantity)
II, B3	Like II,A, but under negative pressure with respect to the room; the exhausted air is expelled outside through a duct and a HEPA filter	YES	YES (minimum quantity)
III	The incoming and outgoing air passes through two HEPA filters positioned in order	YES	YES (minimum quantity)

Correct use of the biohazard cabinet:

• It is necessary that all those who use the hood are aware of the procedures for correct use.

- Turn on the motorized fan and leave it running for at least 10' before the beginning of the work to stabilize the sterile laminar flow.
- Position the front glass, if it is sliding, at the height set for the protection of the operator.
- Always turn off the UV lamp in the presence of the operator.
- Immediately remove spills or spills of biological material. All potentially infected or contaminated material must be removed from the hood in closed and airtight containers, perfectly clean on the outside and labeled with the biohazard sign; the equipment must be disinfected before being removed from the hood.
- After each use, clean and disinfect the hood. Use a disinfectant proven to be effective against any microorganisms present. E.g. 70% alcohol.
- Close the front glass, turn on the UV lamp for 15'.
- Once a month clean the outside of the hood with detergent and clean inside and under the worktop with a specific decontaminant.
- Do not use the hood if it is not working perfectly and do not open the glass closing panel during use.
- It is important not to create turbulence (opening and closing of doors and windows, passage of people behind the operator, entry and exit of materials from the hood) to avoid the escape of potentially contaminated air towards the outside.
- The grid area (and up to a few centimeters beyond) must absolutely not be obstructed to avoid creating turbulence or holes in the barrier, nor must it be used as a work area to avoid certain contamination of the sterile material by the ambient air unfiltered.
- The biohazard cabinet does not protect the operator from contamination of the hands and arms caused by splashes and aerosols. Overalls with elastic cuffs over which gloves are worn represent the best protection, as long as they are removed with due precautions as soon as the work is finished.

- For safety purposes it is important not to overload the work surface: the air must be able to maintain its flow constant without encountering too many obstacles. Furthermore, all objects and containers introduced or removed from the work area must always be disinfected.
- There are two types of worktops: the perforated one and the closed tray type with front and rear intake grilles.
- The perforated surface, which offers the advantage of keeping the vertical laminar flow constant, offers the best laminarity characteristics, given that at every point on the work surface the air flow descends vertically. It is particularly suitable for cell cultures and for all applications where it is useful to guarantee product sterility.
- The closed work surface is useful for preventing contamination of the cabinet in the event of liquid spills, given that with this solution it is possible to use absorbent sheets spread on its surface without altering the air flow. The objects placed in the central band of the worktop will be hit directly by the flow of sterile air, while the objects placed in the front or rear band of the worktop will be hit by air that has crossed the central band.
- The use of the Bunsen burner inside the biohazard hood should be avoided: the upward current of hot air produced by the flame creates significant turbulence in the laminar flow with consequent risk of cross-contamination of the handled biological material. Furthermore, there is a risk of damage to the HEPA filter and the sterilization of objects by flaming causes a micro-explosion with the projection of infected particles into the areas surrounding the Bunsen, including the operator's hand. For the sterilization of the loops, we recommend the use of electric incinerators, if it is not possible to use disposable material.
- Germicidal lamps cannot replace the daily disinfection of contaminated surfaces, given that ultraviolet radiation only acts on the surface and has very limited effectiveness. Furthermore, it can cause health risks to the skin and eyes, with long-term damage.
- If the hood must be turned off, leave it running at least 25-30 minutes after disinfection to ensure that all the air has been treated through the filter.

Fumigation of microbiological cabinets

Fumigation of the microbiological cabinets is necessary in the following cases:

• before changing the filters

• before any test done in the hood

• at regular intervals, based on the use of the hood.

Formaldehyde is used for fumigation which, being a dangerous substance classified as carcinogenic and mutagenic, must only be handled by specialized personnel, who will implement all the specific protection methods required. This operation also requires protection from neighboring laboratories and offices, that must be notified of the operations being carried out. Furthermore, the room in which the formaldehyde fumigation will take place must be sealed and the air circulation must be stopped if it is produced artificially.

Contaminations inside the hood:

Small contaminations:

Small contaminations inside the hood can be easily managed.

1. Pour 10% sodium hypochlorite on the contamination, let it act for 5-15 minutes, dry with absorbent paper.
2. Remove the contaminated paper and discard it in the biohazard bag without leaving the hood.
3. Wash the surface of the hood with sterile water and clean paper to remove disinfectant residues, then throw the paper into the biohazard bag.
4. Clean any splashes on objects placed inside the hood, as well as on the internal parts of the hood, with paper soaked in 10% sodium hypochlorite or equivalent disinfectant.
5. Remove contaminated gloves and wash hands.
6. Wear clean gloves and place disinfectant items inside the hood.

Major contaminations:

- Massive contamination resulting in abundant spills of liquids with drainage into the front grilles of the hood require more extensive decontamination.
- Decontaminate the surface of all objects inside the hood using 10% sodium hypochlorite or equivalent disinfectant as you remove these objects from the hood.
- Pour 10% sodium hypochlorite onto the hood surface. Pour the disinfectant generously onto the openings of the grilles so that it flows directly into the drain pan.
- Wait 20-30 minutes. The time may vary depending on the pathogen.
- Dry the surface with paper and discard it in a biohazard bag.
- Use clean paper of sterile distilled water to clean the hood surfaces again to remove residual sodium hypochlorite and discard the paper in the biohazard bag.
- Empty the contents of the drain pan into a container containing 10% sodium hypochlorite. To do this, attach a hose to the drain valve. The tube must be long enough to allow the end to be immersed in the disinfectant present in the aforementioned container. This technique allows you to avoid the formation of aerosols.
- Rinse the hood drain tank with water and drain the washing water with the hose into the appropriate container. Remove the drainage tube.
- Remove gloves and wash your hands.
- Wear clean gloves and place objects in the hood.

ANNEX 4

Legislative Decree N° 81/08 - Annex XLVI

List of classified biological agents

1. Only agents known to cause infectious diseases in humans are included in the classification. Any toxic or allergenic risks present are indicated next to each agent in a specific column. Animal and plant pathogens that are known to have no effect on humans were not taken into consideration. When compiling this first list of classified biological agents, genetically modified microorganisms were not taken into consideration.
2. The classification of biological agents is based on the effect they have on healthy workers. It does not consideration the particular effects on workers whose sensitivity could be modified by other causes such as pre-existing illness, use of medicines, compromised immunity, pregnancy or breastfeeding, factors that are taken into consideration in the health surveillance are referred to in the art. 41.
3. Biological agents that have not been included in groups 2, 3 and 4 of the list are not implicitly included in group 1. For agents whose pathogenicity for humans is known for numerous species, the list includes species most frequently implicated in diseases, while a more general reference indicates that other species belonging to the same genus can have effects on human health. When an entire genus is mentioned in the list of biological agents it is implied that strains and species defined as non-pathogenic are excluded from the classification.
4. When a strain is attenuated or has lost genes known to be virulent, the containment required by the classification of the parent strain is not necessarily applied unless the assessment of the risk posed by it in the workplace requires it.
5. All viruses that have already been isolated from humans and are not yet listed in this Annex should be considered to belong at least to group 2, unless it is proven that they cannot cause disease in humans.
6. Some agents classified in group 3 and indicated with a double asterisk (**) in the attached list may pose a limited risk of infection because they are not normally

airborne. In the case of particular activities involving the use of the aforementioned agents, in relation to the type of operation carried out and the quantities used, it may be sufficient to implement the measures referred to in points 2 and 13 of Annex XLVII and in points 2, 3, 5 of the Annex.

7. The containment measures resulting from the classification of parasites apply only to the stages of the parasite cycle that can be infectious to humans.
8. The list contains indications identifying biological agents that can cause allergic or toxic reactions, those for which an effective vaccine is available and those for which it is appropriate to keep the list of workers who have worked in activities with risk of exposure to these agents for at least ten years. These indications are: **A:** possible allergic effects **D:** the list of workers who have worked with said agents must be kept for at least ten years from the cessation of their last activity involving risk of exposure **T:** production of toxins

BACTERIA and similar organisms

(i) There is currently no evidence of human infection caused by the agents responsible for other TSEs in animals. However, as a precaution it is recommended to apply containment level 3 (**) in laboratories, with the exception of work related to an identified "scrapie" agent for which containment level 2 is sufficient.

Biological agent	Classification	Surveys
Actinobacillus actinomycetemcomitans	2	
Actinomadura madurae	2	
Actinomadura pelletieri	2	
Actinomyces gereneseriae	2	
Actinomyces israelli	2	
Actinomyces pyogenes	2	
Actinomyces spp	2	
Arcanobacterium haemolyticum (Corynebacterium haemolyticum)	2	
Bacillus anthracis	3	
Bacteroides fragilis	2	
Bartonella bacilliformis	2	
Bartonella (Rochalimea) spp	2	
Bartonella quintana (Rochalimea quintana)	2	
Bordetella bronchiseptica	2	
Bordetella parapertussis	2	

Bordetella pertussis	2	V
Borrell*ia* burgdorferi	2	
Borrell*ia* duttonii	2	
Borrell*ia* recurrentis	2	
Borrell*ia* spp	2	
Brucella abortus	3	
Brucella canis	3	
Brucella melitensis	3	
Brucella suis	3	
Burkholderia mallei (pseudomonas mallei)	3	
Burkholderia pseudomallei (pseudomonas pseudomallei)	2	
Campylobacter fetus	2	
Campylobacter jejuni	2	
Campylobacter spp	2	
Cardiobacterium hominis	2	
Chlamydia pneumoniae	2	
Chlamydia trachomatis	2	
Chlamydia psittaci (ceppi aviari)	3	
Chlamydia psittaci (ceppi non aviari)	2	
Clostridium botulinum	2	T
Clostridium perfringens	2	
Clostridium tetani	2	T,V
Clostridium spp.	2	
Corynebacterium diphtheriae	2	T,V
Corynebacterium minutissimum	2	
Corynebacterium pseudotuberculosis	2	
Corynebacterium spp	2	
Coxiella burnetii	3	
Edwardsiella tarda	2	
Ehrlichia sennetsu (Rickettsia sennetsu)	2	
Ehrlichia spp	2	
Eikenella corrodens	2	
Enterobacter aerogenes/cloacae	2	
Enterobacter spp	2	
Enterococcus spp	2	
Erysipelothrix rhusiopathiae	2	
Escherichia coli (with exception to non-pathogenic strains)	2	
Escherichia coli, verocytotoxigenic strains (e.g. O157:H7 or O103)	3 (**)	T
Flavobacterium meningosepticum	2	
Fluoribacter bozemanii (Legionella)	2	
Francisella tularensia (Tipo A)	3	
Francisella tularensis (Tipo B)	2	
Fusobacterium necrophorum	2	

Gardnerella vaginalis	2	
Haemophilus ducrey*i*	2	
Haemophilus influenzae	2	V
Haemophilus spp	2	
Helicobacter pylori	2	
Klebsiella oxytoca	2	
Klebsiella pneumoniae	2	
Klebsiella spp	2	
Legionella pneumophila	2	
Legionella spp	2	
Leptospira interrogans (tutti i s*i*erotipi)	2	
Listeria monocytogenes	2	
Listeria ivanovii	2	
Morganella morganii	2	
Mycobacterium africanum	3	V
Mycobacterium avium/intracellular	2	
Mycobacterium bovis (with exception to the strain BCG)	3	V
Mycobacterium chelonae	2	
Mycobacterium fortuitum	2	
Mycobacterium kansasii	2	
Mycobacterium leprae	3	
Mycobacterium malmoense	2	
Mycobacterium marinum	2	
Mycobacterium microti	3 (**)	
Mycobacterium paratuberculosis	2	
Mycobacterium scrofulaceum	2	
Mycobacterium simiae	2	
Mycobacterium szulgai	2	
Mycobacterium tuberculosis	3	V
Mycobacterium ulcerans	3 (**)	
Mycobacterium xenopi	2	
Mycoplasma caviae	2	
Mycoplasma hominis	2	
Mycoplasma pneumoniae	2	
Neisseria gonorrhoeae	2	
Neisseria meningitidis	2	V
Nocardia asteroides	2	
Nocardia brasiliensis	2	
Nocardia farcinica	2	
Nocardia nova	2	
Nocardia otitidiscaviarum	2	
Pasteurella multocida	2	
Pasteurella spp	2	
Peptostreptococcus anaerobius	2	
Plesiomonas shigelloides	2	

Porphyromonas spp	2	
Prevotella spp	2	
Proteus mirabilis	2	
Proteus penneri	2	
Proteus vulgaris	2	
Providencia alcalifaciens	2	
Providencia rettgeri	2	
Providencia spp	2	
Pseudomonas aeruginosa		
Rhodococcus equi		
Rickettsia akari	3(**)	
Rickettsia canada	3(**)	
Rickettsia conorii	3	
Rickettsia montana	3(**)	
Rickettsia typhi (Rickettsia mooseri)	3	
Rickettsia prowazekii	3	
Rickettsia rickettsii	3	
Rickettsia tsutsugamushi	3	
Rickettsia spp	2	
Salmonella arizonae	2	
Salmonella enteritidis	2	
Salmonella typhimurium	2	
Salmonella paratyphi	2	V
A, B, C		
Salmonella typhi	3(**)	V
Salmonella (other serological varieties)	2	
Serpulina spp	2	
Shigella boydii	2	
Shigella dysenteriae (Tipo 1)	3(**)	T
Shigella dysenteriae, different from Tipo 1	2	
Shigella flexneri	2	
Shigella sonnei	2	
Staphylococcus aureus	2	
Streptobacillus moniliformis	2	
Streptococcus pneumoniae	2	
Streptocoocus pyogenes	2	
Streptococcus spp	2	
Streptococcus suis	2	
Treponema carateum	2	
Treponema pallidum	2	
Treponema pertenue	2	
Treponema spp	2	
Vibrio cholerae (including El Tor)	2	
Vibrio parahaemolyticus	2	
Vibrio spp	2	

Yersinia enterocolitica	2	
Yersinia pestis	3	V
Yersinia ps*e*oudotuberculosis	2	
Yersinia spp	2	

VIRUS

Biological agent	Classification	Surveys
Adenoviridae	2	
Arenaviridae:		
LCM-Lassa Virus complex (Old World Arenavirus):	4	
Lassa virus	3	
Lymphocytic choriomeningitis virus (neurotropic strains)	2	
Lymphocytic choriomeningitis virus (other strains)	2	
Tacaribe Virus complex		
Mopeia virus	2	
Other LCM-Lassa Virus complex (New World Arenavirus)	2	
Guanarito virus	4	
Junin virus	4	
Sabia virus	4	
Machupo virus	4	
Flexal virus	3	
Other Virus of the Tacaribe Complex		ANNEX XLVI
Astroviridae		
Bunyaviridae:		
Bhanja	2	
Bunyamwera virus	2	
Germiston	2	
Oropouche virus	3	
California encephalitis virus	2	
Hantavirus:		
Hantaan (Corean hemorrhagic fever)	3	
Belgrado (also known as Dobrava)	3	
Seoul-Virus	3	
Sin Nombre (ex Muerto Canyon)	3	
Puumala-Virus	2	
Prospect Hill-Virus	2	
Other Hantavirus	2	
Nairovirus:		

Crimean/Congo hemorrhagic fever virus	4	
Hazara virus	2	
Phlebovirus:		
Rift Valley Fever	3	V
Sandfly fever	2	
Toscana virus	2	
Other bunyaviruses known as pathogens	2	
Caliciviridae:		
Hepatitis E virus	3 (**)	
Norwalk-Virus	2	
Other Caliciviridae	2	
Coronaviridae	2	
Filoviridae:		
Ebola virus	4	
Marburg virus	4	
Flaviviridae:		
Australian Encephalitis (Murray Valley Encephalitis)	3	
Central European tick-borne encephalitis virus	3 (**)	V
Absettarov	3	
Hanzalova	3	
Hypr	3	
Kumlinge	3	
Dengue virus types 1-4	3	
Hepatitis C virus	3 (**)	D
Hepatitis G virus	3 (**)	D
Japanese B encephalitis	3	D
Forest of Kyasanur	3	V
Louping ill	3 (**)	
Omsk (a)	3	V
Powassan	3	
Rocio	3	
Russian winter-summer encephalitis (a)	3	V
St. Louis encephalitis	3	
Wesselsbron virus	3 (**)	
Nile Valley virus	3	
Yellow fever	3	V
Other flaviviruses known to be pathogenic	2	
Hepadnaviridae:	2	
Hepatitis B virus	3 (**)	V, D
Hepatitis D (Delta) virus (b)	3 (**)	V, D
Herpesviridae:		
Cytomegalovirus	2	
Epstein-Barr virus	2	
Herpesvirus simiae (B virus)	3	

Herpes simplex virus types 1 and 2		
Herpesvirus varicella-zoster		
Human herpes virus type 7	2	
Human herpes virus type 8	2	D
Human B-lymphotropic virus (HBLV-HHV6)	2	
Orthomyxoviridae:		
Influenza virus types A, B and C	2	V (c)
Orthomyxoviridae transmitted by ticks:		
Dhori and Thogoto virus	2	
Papovaviridae:		
BK and JC virus	2	D (d)
Human papillomavirus	2	D (d)
Paramyxoviridae:		
Measles virus	2	V
Mumps virus	2	V
Newcastle disease virus	2	
Parainfluenza virus types 1-4	2	
Respiratory syncytial virus	2	
Parvoviridae:		
Human parvovirus (B19)	2	
Picornaviridae:		
Hemorrhagic conjunctivitis virus (AHC)	2	
Coxackie virus	2	
Echo virus	2	
Hepatitis A virus (human enterovirus 72)	2	V
Poliomyelitis virus	2	V
Rhinovirus	2	
Poxviridae:		
Buffalopox virus (e)	2	
Cowpox virus	2	
Elephantpox virus (f)	2	
Milker's nodule virus	2	
Molluscum contagiosum virus	2	
Monkeypox virus	3	V
Orf virus	2	
Rabbitpox virus (g)	2	
Vaccinia virus	2	
Variola (mayor & minor) virus	4	V
Whitepox virus (variola virus)	4	V
Yatapox virus (Tana & Yaba)	2	
Reoviridae:		
Coltivirus	2	
Human rotavirus	2	
Orbivirus	2	
Reovirus	2	

Retroviridae:		
Human immunodeficiency syndrome virus (AIDS)	3 (**)	D
Human T-cell leukemia virus (HTLV) types 1 and 2	3 (**)	D
SIV (h)	3 (**)	
Rhabdoviridae:		
Rabies virus	3 (**)	V
Vesicular stomatitis virus	2	
Togaviridae:		
Alfavirus:		
East American equine encephalomyelitis	3	V
Bederu virus	2	
Chikungunya virus	3 (**)	
Everglades virus	3 (**)	
Mayaro virus	3	
Mucambo virus	3 (**)	
Ndumu virus	3	
O'nyong-nyong virus	3	
Ross River virus	2	
Semliki forest virus	2	
Sindbis virus	2	
Tonate virus	3 (**)	
Venezuelan equine encephalomyelitis	3	V
Western American equine encephalomyelitis	3	
Other known alphaviruses	2	V
Toroviridae:	2	
Non-classified virus:		
Hepatitis viruses not yet identified	3(**)	D
Equine Morbillivirus	4	
Non-classical agents associated with transmissible spongiform encephalitis (TSE) (i):		
Creutzfeldt-Jakob disease	3(**)	D (d)
Variant of Creutzfeldt-Jakob disease	3(**)	D (d)
Bovine spongiform encephalitis (BSE) and other associated animal TSEs	3(**)	D (d)
Gerstmann-Stráussler-Scheinker syndrome	3(**)	D (d)

Notes

a) Tick-borne encephalitis.

b) The hepatitis D virus exerts its pathogenic power in workers only in the event of simultaneous or secondary infection with respect to that caused by the hepatitis B virus. Vaccination against the hepatitis B virus protects *workers not affected by the hepatitis B virus against hepatitis D (Delta) virus*.

c) For types A and B only.

d) Recommended for jobs involving direct contact with these agents.

e) Two viruses can be identified under the rubric, a genus "buffalopox" and a variant of the "vaccinia" viruses.

f) Variant of "Cowpox".

g) Variant of "Vaccinia".

h) There is currently no evidence of human infection caused by other retroviruses of simian origin. As a precaution, level 3 containment is recommended for work involving exposure to this retrovirus.

i) There is currently no evidence of human infection caused by the agents responsible for other TSEs in animals. However, as a precaution, it is recommended that containment level 3(**) to be applied in laboratories except for work related to an identified "scrapie" agent for which containment level 2 is sufficient.

PARASITES

Biological agent	Classification	Surveys
Acanthamoeba castellanii	2	
Ancylostoma duodenale	2	
Angiostrongylus cantonensis	2	
Angiostrongylus costaricensis	2	
Ascaris lumbricoides	2	A
Ascaris suum	2	A
Ba*b*esia divergens	2	
Babesia microti	2	
Balantidium coli	2	
Brugia malayi	2	

Brugia pahangi	2
Capillaria philippinensis	2
Capillaria spp	2
Clonorchis sinensis	2
Clonorchis viverrini	2
Cryptosporidium parvum	2
Cryptosporidium spp	2
Cyclospora cayetanensis	2
Dipetalonema streptocerca	2
Diphyllobothrium latum	2
Dracunculus medinensis	2
Echinococcus granulosus	3(**)
Echinococcus multilocularis	3(**)
Echinococcus vogeli	3(**)
Entamoeba histolytica	2
Fasciola gigantica	2
Fasciola hepatica	2
Fasciolopsis buski	2
Giardia lamblia (Giardia intestinalis)	2
Hymenolepis diminuta	2
Hymenolepis nana	2
Leishmania brasiliensis	3(**)
Leishmania donovani	3(**)
Leishmania aethiopica	2
Leishmania mexicana	2
Leishmania peruviana	2
Leishmania tropica	2
Leishmania major	2
Leishmania spp	2
Loa Loa	2
Mansonella ozzardi	2
Mansonella perstans	2
Naegleria fowleri	3
Necator americanus	2
Onchocerca volvulus	2
Opisthorchis felineus	2
Opisthorchis spp	2
Paragonimus westermani	2
Plasmodium falciparum	3(**)

Plasmodium spp (uomo & scimmia)	2
Sarcocystis suihominis	2
Schistosoma haematobium	2
Schistosoma intercalatum	2
Schistosoma japonicum	2
Schistosoma mansoni	2
Shistosoma mekongi	2
Strongyloides stercoralis	2
Strongyloides spp	2
Taenia saginata	2
Taenia solium	3(**)
Toxocara canis	2
Toxoplasma gondii	2
Trichinella spiralis	2
Trichuris trichiura	2
Trypanosoma brucei brucei	2
Trypanosoma brucei gambiense	2
Trypanosoma brucei rhodesiense	3 (**)
Trypanosoma cruzi	3
Wuchereria bancrofti	2

FUNGHI

Biological agent	Classification	Surveys
Aspergillus fumigatus	2	A
Blastomyces dermatitidis (Ajellomyces dermatitidis)	3	
Candida albicans	2	A
Candida tropicalis	2	
Cladophialophora bantiana (es. Xylohypha bantiana, Cladosporium bantianum o trichoides)	3	
Coccidioides immitis	3	A
Cryptococcus neoformans var. neoformans (Filobasidiella neoformans var. neoformans)	2	A
Cryptococcus neoformans var. gattii (Filobasidiella bacillispora)	2	A
Emmonsia parva var. parva	2	
Emmonsia parva v*a*r. crescens	2	
Epidermophyton floccosum	2	A
Fonsecaea compacta	2	

Fonsecaea pedrosoi	2	
Histoplasma capsulatum var. capsulatum (Ajellomyces capsulatum)	3	
Histoplasma capsulatum duboisii	3	
Madurella grisea	2	
Madurella mycetomatis	2	
Microsporum spp	2	A
Neotestudina rosati*i*	2	
Paracoccidioides brasiliensis	3	
Penicillium marneffei	2	A
Scedosporium apiospermum, Pseudallescheria boydii	2	
Scedosporium prolificans (inflantum)	2	
Sporothrix schenckii	2	
Trichophyton rubrum	2	
Trichophyton spp	2	

References to Annex XLVI:

- Art. 268, co. 3 - Art. 271, co. 1, letter. a) - Art. 279, co. 5

ANNEX 5

Hand washing

Correct hand washing is essential to minimize the risk of contamination before and after work procedures.

Hands should be washed:

- Before and after work procedures
- After handling cell cultures or biological materials
- After removing gloves
- Before and after the breaks (e.g. meals)

Correct hand washing procedure

- Wet your hands and forearms with warm water
- Deposit at least 3 ml of soap in the palm of your hand
- Soap and scrub hands past the wrist for 10 to 30 seconds, cleaning thoroughly between fingers and nails
- Rinse well with warm water until the soap disappears
- Dry with absorbent paper.

If it is not possible to wash your hands immediately, use alcohol or other sanitizers and wash them as soon as possible.

Use of a sanitizer (e.g. alcohol)

- Fill the palm of your hand with a small amount of disinfectant and rub it into your other hand, including the space between your fingers and nails, until the disinfectant dries.
- Repeat the operation for the other hand

In general, laboratory personnel (including students, interns, PhD students, etc.) should be encouraged to have short, tidy nails and not to wear rings or bracelets (to minimize contamination and promote hand hygiene).

NEW PICTOGRAMS INTRODUCED BY THE CLP REGULATION

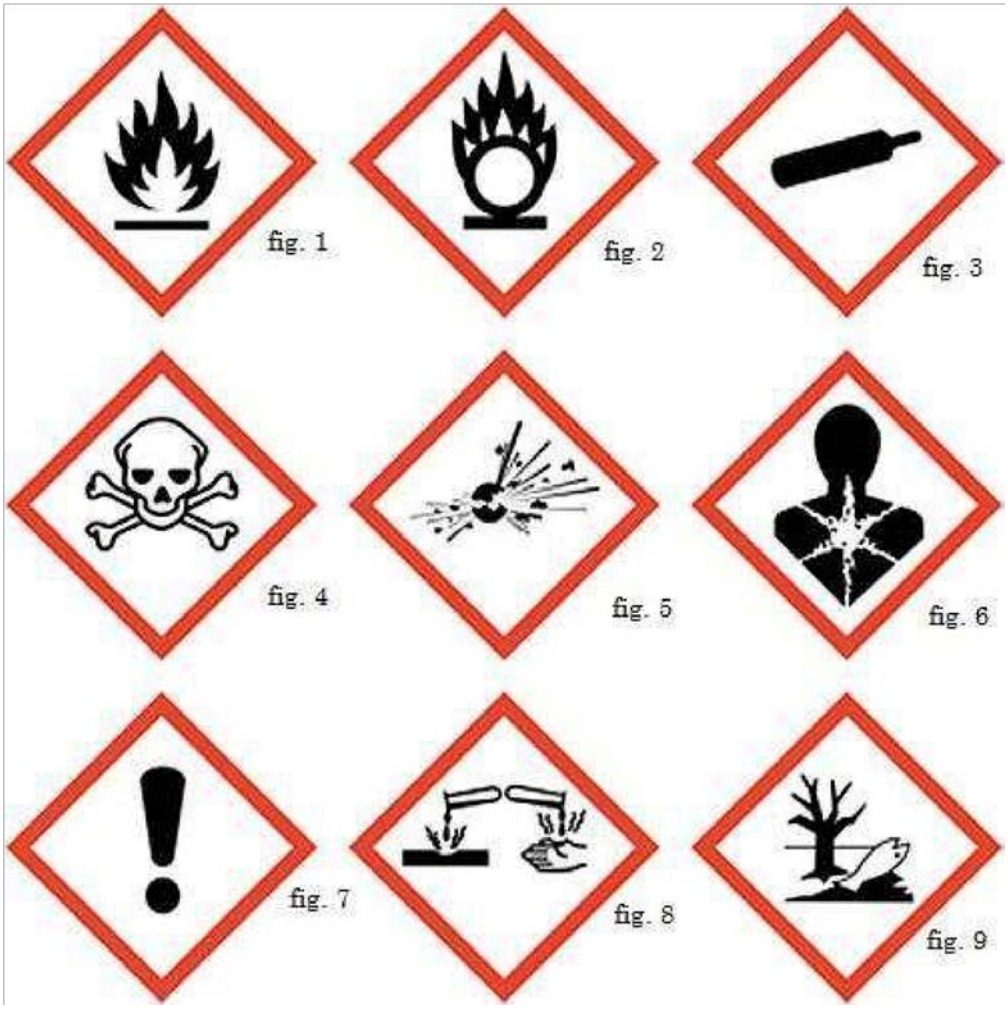


Fig.1 **Flammable.** What it indicates: Highly flammable gas. Flammable gas. Highly flammable aerosol. Flammable aerosol. Highly flammable liquid and vapor. Flammable liquid and vapor. Flammable solid. Where you can find it: e.g., Lamp oil, petrol, acetone.

Fig. 2 **Oxidising**. What it indicates: It can cause or worsen a fire; oxidizer. May cause a fire or explosion; very oxidizing. Where you can find it: for example, bleach, oxygen for medical purposes.

Fig. 3 **Gases under pressure.** What it indicates: Contains gas under pressure; may explode if heated. Contains refrigerated gas; may cause burns or cryogenic injuries. Where you can find it: Gas cylinders.

Fig. 4 **Acute toxicity.** What it indicates: Fatal if ingested. Lethal by skin contact. Fatal if inhaled. Toxic: if ingested. Toxic by contact with skin. Toxic if inhaled. Where you can find it: e.g., Pesticide, biocide, methanol.

Fig. 5 **Explosive.** What it indicates: Unstable explosive. Explosive; danger of mass explosion. Explosive: serious protection hazard. Explosive; danger of fire, blast or projection. Danger of mass explosion in case of fire. Where you can find it: for example, Fireworks and ammunition.

Fig. 6 **Serious health effects.** What it indicates: It can be lethal if ingested and if it enters the respiratory tract. Causes organ damage. It can cause damage to organs. May harm fertility or the unborn child. Suspected of damaging fertility or the unborn child. It can cause cancer. Suspected of causing cancer. It can cause genetic alterations. Suspected of causing genetic alterations. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Where you can find it: for example Turpentine, petrol, lamp oil.

Fig. 7 **Danger.** What it indicates: May irritate the respiratory tract. May cause drowsiness or dizziness. May cause an allergic skin reaction. Causes serious eye irritation. Causes skin irritation. Harmful if ingested. Harmful in contact with skin. Harmful if inhaled. It harms health and the environment by destroying the ozone layer in the upper atmosphere. Where you can find it: e.g. Detergents, bathroom cleaner, coolant.

Fig. 8 **Corrosive.** What it indicates: May be corrosive to metals. It causes serious skin burns and serious eye injuries. Where you can find it: for example drain clearing products, acetic acid, hydrochloric acid, ammonia.

Fig. 9 **Effects on the environment.** What it indicates: Very toxic to aquatic organisms with long lasting effects. Toxic to aquatic organisms with long lasting effects. Where you can find it: for example Pesticides, biocides, petrol, turpentine.

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