



Guideline for Laboratory Bio-Safety Standards (2022-03-04)

Background

ASIIN is regularly conducting accreditation procedures in the area of natural sciences, subjects in which practical laboratory work and/or field experimentation is an essential part.

While conducting these procedures, the auditors assess the quality and quantity of the technical equipment in the laboratories, the safety standards, and containment and confinement measures, respectively. Especially in international procedures, this aspect is always a point of serious discussion.

In order to help auditors to decide if the available technical equipment and facilities are sufficient for adequately teaching students and if the safety standards comply with internationally recognized standards, ASIIN has drafted this guideline. The guideline is based on the OECD Principles of Good Laboratory Practice (1997) the WHO Handbook on Good Laboratory Practice (2009), the WHO Laboratory Biosafety Manual (2004) and the ISO 35001:2019. It describes what laboratory safety standards need to be followed.

Four key regulatory areas of laboratory safety are important and should be carefully assessed during the accreditation process and especially during the on-site visits and discussions with the external assessors:

- (a) Training of students and laboratory staff in the key fundamentals of laboratory, chemical and biological safety, first aid and rapid response to laboratory accidents and safety problems. Establishing and raising awareness of personal responsibility for laboratory safety, personal safety and laboratory personnel. Establish a traceable reporting system and an official safety protocol. These safety instructions need to be repeated on a regular basis like once in a year.
- b) Technical equipment for safe work in laboratories: personal safety equipment and general easily accessible equipment. Responsibility for regular inspection of this safety equipment by students and technical staff.
- c) Basic necessary technical equipment for safe working in laboratories: laboratory areas, separated working areas, fume cupboards, safety cabinets, chemical stores, waste stores and well-documented waste management.
- d) Comprehensive chemical and waste management and safety documentation.
- e) Biosafety and Biosecurity measure implementations. This includes expertise in risk assessment of biological materials, measures to prevent spreading of hazardous biological material by using appropriate biosafety equipment, inactivation procedures (chemical, heat) and constraints to prevent dual use of biohazardous materials.

Importance of Laboratory Safety Standards

Practical laboratory work is essential to promote students' learning of science and scientific skills. However, there are many hazardous substances and instruments used in the laboratories, which causes a significant risk of accidents and presents a danger to human health, and the natural environment. This demands care in order to protect human health, conserve the natural environment and to prevent laboratory accidents.

Teaching and learning of chemistry, biology, pharmacy, and other related sciences involves scientific tests and experiments that take place in laboratories. It involves using hazardous substances and equipment posing risks and health hazards to the users and the environment. Hence, there should be strict safety regulations in place that need to be followed by all people using the laboratories. This includes comprehensive safety practices and trainings, adequate laboratory facilities (non-flammable surfaces, fume hoods, proper ventilation, availability of water, safety signs and exits, etc.) emergency planning, storage and labelling of chemicals, trained safety practitioners, sufficient safety equipment (goggles, gloves, coats, fire extinguishers, fume hoods, eye washers, first aids boxes etc.), and environmentally friendly waste storage and disposal. While German standards such as TRGS 526/DGUV-I 213-850 stipulating an air change rate of 8 for standard laboratory rooms or 600 m³/h airflow per running meter of fume hood may not be directly applicable in every place, they nevertheless can serve as a rough benchmark for assessing the technical adequacy of facilities.

Furthermore, laboratory safety and responsible care for the environment are also key qualifications students will need in their future professional careers.

Personnel

Good Laboratory Practice (GLP) stresses that the number of personnel available must be sufficient to perform the tasks required in a timely and GLP-compliant way. The responsibilities of all personnel should be defined and recorded in job descriptions and their qualifications and competence defined in education and training records. To maintain adequate levels of competence, GLP attaches considerable importance to the qualifications of staff, and to both internal and external training given to personnel. Safety instructions should be repeated in a regular manner.

Facilities and Maintenance

GLP emphasises that facilities and equipment must be sufficient and adequate to perform the studies. The facilities should be spacious enough to avoid problems such as overcrowding, cross contamination or confusion between projects. Utilities (water, electricity etc.) must be adequate and stable.

All equipment must be in working order; a program of validation/qualification, calibration and maintenance needs to be in place. All instruments should be periodically inspected, cleaned, maintained, and calibrated according to standard operating procedures. Records of these activities should be maintained. Calibration should, where appropriate, be traceable to national or international standards of measurement. Keeping records of use and maintenance

is essential in order to know, at any point in time, the precise status of the equipment and its history.

Personal Protective Equipment

The basic personal protective equipment that needs to be available to all persons working in laboratories includes safety goggles, laboratory coats, and hand gloves. It must be worn all the time when working in the laboratory. Students should be trained in the right use of the equipment (e.g. the need to change contaminated gloves before touching a door handle or a keyboard, which also might be used by persons not wearing safety gloves). The personal protective equipment should be stored separately from street clothes.

Technical Equipment

In the laboratories, essential materials such as materials for and equipment for heat and/or chemical inactivation of biological material, water, soap, glass disposal boxes and safety manuals must be available. Besides hand washing, disposal bins for chemicals residue are one of the most important laboratory requirements. Furthermore, disposal bins for biological material (e.g. containing genetically modified organisms) should be provided as well. As the health of the skin suffers from long-time wearing gloves, skin protection products should be provided, and a skin protection plan should be established.

There needs to be a sufficient amount of instruments and material so that students can conduct the experiments in small groups and get personal hands-on experience.

General Safety Practices

There should be a Chemical Hygiene Plan (CHP), which sets forth policies, procedures, equipment, personal protective equipment, and work practices that are capable of protecting employees and students from the health hazards presented by hazardous chemicals used in laboratories.

Before working with organisms or products at biosafety level higher than two, both personnel and students need to be especially trained in order to safely handle biohazardous materials.

A culture of safety needs to be established from the first meeting of the class by setting and explaining the appropriate safety rules of the laboratory to the students.

Safety Knowledge and Skills

Students, teachers, and laboratory assistants must have adequate skills and knowledge of chemical and biological safety, which will ensure avoiding accidents and injuries in the laboratories.

Emergency Planning

Cases of emergencies in laboratories are unpredictable and there should be an emergency action plan.

Storage and Labelling

Lack of proper knowledge about the labelling of substances will lead to accidents. Therefore,

correct labelling and storage of all used substances is very important. Incompatible substances need to be kept separately; this includes transport, storage, use, and disposal.

Chemicals, reagents, and solutions including biological cultures, and materials should be labelled to indicate identity (with concentration if appropriate), expiry date and specific storage instructions. Information concerning source, preparation date and stability should be available.

Hazardous Waste Management

Waste, which is hazardous for both people and the environment, needs to be disposed of safely and correctly. Biological waste, especially consisting of recombinant material, requires appropriate inactivation prior to disposal.

Handling and disposal of wastes should be carried out in such a way as not to jeopardize the handler and the environment. This includes provision for appropriate collection, storage and disposal facilities, and decontamination and transportation procedures.

Policy and Training

The training on storage and handling of biological and chemical materials are crucial to enable laboratory staff to prevent potential accidents and to prepare them to respond in case of accidents. Teachers must undergo all necessary training steps to prepare for emergencies because in some cases the teacher may have to act before medical personnel arrives.

All users need to receive training to ensure that they are apprized of the hazards of chemicals present in their work area.

Furthermore, students should be instructed how to assess the hazards associated with a given task in the lab and to propose appropriate safety measures to ensure adequate protection or to propose alternative problem solutions for achieving the same goals with intrinsically less risk.

References for Biosafety & Biosecurity

<https://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf>

<https://internationalbiosafety.org/resources/biosafety-biosecurity/biosafety-guidelines/>