

Quality Standard for Education and Training in Laboratory Animal Science

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Disclaimer:

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0. INTRODUCTION

The acknowledgement of the ethical purposes of the Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (hereinafter referred to as Directive 2010/63/EU) represents the cornerstone of this Standard regarding Laboratory Animal Science Education and Training (hereinafter referred to as the LAS E&T Standard) to ensure the protection of animals and the quality of science.

The LAS E&T Standard has been developed taking into account the needs of, and the cultural differences between the Member States of the European Union (hereinafter referred to as EU Member States), while recognising the goals of the Directive 2010/63/EU. This approach acknowledges the great variety of education and vocational training traditions and methods in Member States. This tool aims to promote the necessary transparency and common understanding and trust.

The LAS E&T Standard takes into consideration the recommendation of the European Parliament and Council of 18 June 2009 on the establishment of a European Quality Assurance Reference Framework for Vocational Education and Training (EQARF/EQAVET).

The LAS E&T Standard is a voluntary scheme, which may be used by LAS E&T Providers to improve the quality and increase effectiveness of their education and training offer.

The LAS E&T Standard aims to facilitate mutual recognition and implementation of the internationally established principles of Replacement, Reduction, and Refinement (hereinafter referred to as 3Rs principles) in LAS Education and Training.

The LAS E&T Standard is intended to facilitate the functions and legal duties of the Animal Welfare Body, including promoting a culture of care within the establishment.

The LAS E&T Standard promotes modern teaching methods (e.g. eLearning) and encourages the development of deeper learning and critical thinking, according to the Expert Working Group “Working document on the development of a common education and training framework to fulfil the requirements under the Directive 2010/63/EU” (hereinafter referred to as Expert Working Group Document).

1. SCOPE AND APPLICATION

This Standard provides requirements to meet the need of promoting quality in LAS Education and Training on all animal species and for all levels of professional expertise, from basic to advanced. It also aims to satisfy the requirements for competence of all those involved in the use and care of animals for scientific purposes and to facilitate the free movement of personnel, as set by the Directive 2010/63/EU and the Expert Working Group Document.

The requirements of this Standard are general and conceived to be applied by any Providers of education and training services in LAS in Europe, independently from their legal status, size, and organisational structure.

2. LEGISLATIVE FRAMEWORK, INTERNATIONAL STANDARDS, AND OTHER RELEVANT DOCUMENTS

1. Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes
2. EFQM Excellence Model
3. ISO 9001:2015 Quality management systems

4. ISO 10015:1999 - Quality management — Guidelines for training
5. Working document on the development of a common education and training framework to fulfil the requirements under the Directive 2010/63/EU
6. European Quality Assurance Reference Framework for Vocational Education and Training (EQARF/ EQAVET)

3. TERMS, DEFINITIONS, AND ACRONYMS

Terms	Definitions
Animal Welfare	How an animal is coping with the conditions in which it lives. An animal is in a good state of welfare if (as indicated by scientific evidence) it is healthy, comfortable, well nourished, safe, able to express innate behaviour, and if it is not suffering from unpleasant states such as pain, fear, and distress. Good animal welfare requires disease prevention and veterinary treatment, appropriate shelter, management, nutrition, humane handling and humane slaughter/killing. Animal welfare refers to the state of the animal; the treatment that an animal receives is covered by other terms such as animal care, animal husbandry, and humane treatment (definition adopted by the OIE International Committee for inclusion in the Terrestrial Animal Health Code).
Animal Welfare Body	The body that animal breeders, suppliers and users set with the primary task of focusing on giving advice on animal-welfare issues. The body should also follow the development and outcome of projects at establishment level, foster a climate of care and provide tools for the practical application and timely implementation of recent technical and scientific developments in relation to the principles of replacement, reduction and refinement, in order to enhance the life-time experience of the animals (from Recital 31 of Directive 2010/63/EU).
Critical thinking	The intellectually disciplined process of actively and skilfully conceptualizing, applying, analysing, synthesizing, and/or evaluating information gathered from, or generated by, observing, experiencing, reflecting, reasoning, experimenting or communicating, as a guide to belief and action. In its exemplary form, it is based on universal intellectual values that transcend subject matter divisions: clarity, accuracy, precision, consistency, relevance, sound evidence, good reasons, depth, breadth, and fairness (National Council for Excellence in Critical Thinking, 1987).

Competence	The quality or state of having sufficient knowledge, judgment, skill, experience, or strength required to carry out a particular duty.
Context	The situation (influences and events) within which something exists or happens.
Criterion	A principle or standard by which something may be judged or decided.
Customer	A party that receives or consumes products (goods or services) and has the ability to choose between different products and suppliers (e.g. beneficiaries of Education & Training in LAS).
Deeper learning	The competence that allow a person to master core academic content, think critically and solve complex problems, communicate effectively, work collaboratively, learn how to learn, develop academic mindsets (from https://hewlett.org/library/deeper-learning-defined/).
Driver	Something that makes things progress, develop, or grow stronger.
Expertise	A high level of knowledge and skill, acquired by training, study and practice.
Laboratory animal	Any vertebrate animal (mammals, birds, fish, amphibians reptiles and cyclostomes) produced for or used in research, testing, or teaching. In addition to vertebrate animals, cephalopods are also included in this definition. Art 1 Directive 2010/63/EU.
LAS E&T Provider	Any organisation or individual providing education or training services in Laboratory Animal Science.
Leadership	Setting unity of purpose and direction within an organisation providing conditions, which people are engaged to achieve specific objectives in.
Mutual recognition	Agreement between two organisations (e.g. Member State Competent Authorities) to recognise each other's processes or programmes. Mutual recognition may occur between higher education institutions, quality or accrediting agencies or professional bodies (Expert Working Group Document).
Partnership	An agreement between organisations to work together.
People	The personnel of an organisation (e.g. LAS E&T provider), regarded as a significant asset in terms of skills and abilities.
Process	A series of actions taken by an organisation in order to achieve specific results.
Product	A good idea, method, information, object or service created as a result of a process to serve a need or satisfy a want. It has a combination of tangible and intangible attributes (benefits, features, functions,

	uses) that an organisation offers a customer for purchase.
Quality	The standard of something as measured against other things of a similar kind; the degree of excellence of something. The quality of products and services includes not only their intended function and performance, but also their perceived value and benefit to the customers.
Quality Management System	A set of policies, processes and procedures required for planning and execution (production/development/service) in the core business area of an organisation (i.e., areas that can affect the organisation's ability to meet customer requirements).
Requirement	A quality or qualification that one must have to be allowed to do something or to be suitable for something. A thing that is needed or wanted.
Resource	An economic or productive factor required to accomplish an activity, or as means to undertake an enterprise or a business and achieve desired outcomes.
Service	A valuable action, deed, or effort performed to satisfy a need or to fulfil a demand.
Society	An organisation of people who have the same interest or aim.
Stakeholder	A party that has an interest in an organisation and can either affect or be affected by its business. Stakeholders are investors, employees, customers and suppliers, as well as the policy makers, the community and any relevant association.
Standard	Something considered by an authority or by general consent as a basis of comparison. An approved model.
Strategy	The blueprint of decisions in an organisation that shows its objectives and goals, reduces the key policies, and plans for achieving these goals. It defines the business to carry on, the type of economic and human organisation it wants to be, and the contribution it plans to make to its stakeholders, customers and society at large. The knowledge of the goals, uncertainty of events and need to take into consideration the likely or actual behaviour of others.
Sustainability	The capacity required to service Providers to satisfy the current needs without compromising the ability of future generations to meet their own needs.

4. CONTEXT DRIVERS

Several context drivers influence the decisions of LAS E&T Providers in designing, promoting, delivering, monitoring, evaluating and following up their training offer, in the case in point:

- a. Fulfilment of legislation/legal requirements, including compliance with the 3Rs Principles
- b. Ethics and transparency in LAS E&T
- c. Availability of financial resources and their use in a transparent and adequate manner
- d. Level of competence of LAS educators/trainers
- e. Market demand for competent personnel across the EU (mobility)
- f. Demand for training by professionals operating or willing to operate in the LAS sector (certification of competences)
- g. Latest scientifically proven innovations in the LAS and LAS E&T sector
- h. Scientific recommendations and guidelines from LAS associations and/or their umbrella organisations in the EU MS
- i. LAS E&T Providers' demand for external recognition and/or accreditation of their training offer in the LAS sector
- j. Management strategies adopted by LAS E&T Providers for the market competitiveness (e.g. Quality assurance system, or authorisation/registration)
- k. Collaboration and networking of LAS E&T Providers
- l. Possible legal role and functions of the Animal Welfare Body.

5. PRINCIPLES AND FUNDAMENTAL CONCEPTS

The LAS E&T Quality Standard is based on the following principles and fundamental concepts:

- a. LAS E&T quality standards are adopted on a voluntary basis.
- b. LAS E&T offer is validated by a recognised or official body.
- c. LAS E&T Providers apply pre-defined, publicly available regulations, meeting societal requirements.
- d. LAS E&T Providers should adopt a flexible methodological approach to ensure the fulfilment of training requirements set by the Directive 2010/63/EU and the Expert Working Group Document.
- e. LAS E&T Providers collect, analyse and use relevant information for the effective management of their E&T offer and other activities including inputs and feedback from relevant stakeholders.
- f. LAS E&T Providers ensure the implementation of a quality management system aimed to continuous improvement of their E&T offer through regular monitoring and assessment.
- g. LAS E&T Providers ensure the information on use (and justification for use) of live animals.
- h. LAS E&T Providers comply with the EU and national laws on health and safety at work, social security, data protection.

6. THE LAS EDUCATION AND TRAINING QUALITY STANDARD CRITERIA

6.1. Leadership

LAS E&T Providers' management has clear vision, mission and values to ensure the fulfilment of the scopes of Directive 2010/63/EU, assures appropriate communication, and promotes the proactive engagement of the staff.

LAS E&T Providers' management clearly states that the programmes are aligned with the present quality standards and promotes their dissemination within the organisation.

LAS E&T Providers' management ensures the development and delivery of the training offer by taking into account the factors and context drivers influencing the quality of LAS E&T at local, national and European level.

LAS E&T Providers' management promotes a risk-based thinking approach, applying it to all processes at any level.

6.2. Strategy

LAS E&T Providers design courses aimed at improving animal welfare and the quality of the research in the framework of the Directive 2010/63/EU and facilitating the expected changes.

LAS E&T Providers design training courses (in terms of contents, related learning outcomes and duration) starting from the analysis of their beneficiaries' learning needs. Providers define the specific learning objectives and identify the most appropriate training methods to achieve the expected results, in line with the "Working document on the development of a common education and training framework to fulfil the requirements under the Directive 2010/63/EU".

LAS E&T Providers map the training process, evaluate and manage any possible risks through preventive and corrective actions to guarantee the achievement of the learning objectives.

6.3. People

LAS E&T Providers involve human resources adequately prepared to manage the entire training process. Human resources ensure a multidisciplinary approach for the quality of the LAS E&T offer. They are included in continuous education programmes also to assure innovation and scalability of processes, methods, and contents.

LAS E&T Providers select and recruit trainers with documented experience on the course topics and proven soft skills for training management. LAS E&T Providers also ensure that training is consistent with the scopes of the Directive 2010/63/EU.

6.4. Partnerships

LAS E&T Providers proactively set up, and constantly renew partnerships with relevant stakeholders at national and European level.

Strategic partnerships support LAS E&T Providers on a wide and flexible range of activities in order to create and enlarge the network of people having the required expertise, implement innovative practices, promote development and modernisation of course content, learning methodologies and management approaches (including communication and dissemination of the education and training outcomes achieved).

LAS E&T Providers assess the impact of the established partnerships, to strengthen their capacities, but also to produce high quality innovation.

6.5. Processes, Products & Services

LAS E&T Providers design, manage and improve processes, products, and services to generate increasing value for customers and other stakeholders.

LAS E&T Providers define the target (e.g. Functions A, B, C, D as described in the Directive 2010/63/EU) and the structure (species-orientated or discipline-orientated programmes) of the training programmes, paying attention to the targeted course level (i.e. basic vs advanced).

LAS E&T Providers design programmes structured in modules (or units) of defined duration, thus facilitating the possibility for the beneficiary to combine modules of the same programme provided by different organisations in different Member States, also to enhance their professional development and cultural experience.

LAS E&T Providers define the duration of the education and training programmes adopting the ECTS (European Credit Transfer System) scheme, if relevant.

LAS E&T Providers adopt a variety of training methodologies consistent with the course learning objectives and appropriate to achieving the desired level of competence. They select methodologies also in line with different learning styles and with the Directive 2010/63/EU (including the 3Rs Principle) and the “Working document on the development of a common education and training framework to fulfil the requirements under the Directive 2010/63/EU”. Methodologies include - but are not limited to - classroom or instruction-led training, sub-group exercises, hands-on training, role-playing, eLearning, case studies, assignments.

LAS E&T Providers ensure the availability of facilities and instrumental resources suitable to achieve the learning objectives in compliance with the legislation on laboratory animal welfare.

LAS E&T Providers recruit participants through transparent and inclusive procedures.

LAS E&T Providers define the prerequisite level of competence that candidates should demonstrate upon application, based on the desired learning outcomes.

LAS E&T Providers assess prior knowledge and skills of the participants in order to optimise the customisation of the LAS E&T offer, according to the learning objectives of a specific training initiative.

LAS E&T Providers implement a Quality Management System described in a policy and associated procedures as appropriate. The system defines processes and performance indicators to allow monitoring, manage risks, and identify issues and opportunities for improvement.

LAS E&T Providers provide participants with exhaustive and consistent training materials to support preparatory phases (i.e. pre-readings) and training delivery; materials also include those for hands-on-training. They develop procedures to ensure animal welfare and biosecurity in educational activities. LAS E&T Providers design and/or adopt solutions to facilitate the participation of people with physical and sensorial disabilities, people from minority ethnic groups and gender equality.

At the end of the E&T paths, LAS E&T Providers assess and certify participants’ exit knowledge and skills in a way that allows the full understanding of the acquired knowledge and skills by third parties (e.g. potential employers). Candidates have the opportunity to recover any gap emerging from the intermediate assessments with the aim to achieve the learning goals established for each specific training.

LAS E&T Providers define mandatory minimum attendance levels to access to the final exam in order to ensure appropriate learning outcomes. Programmes include ongoing self-assessments and self-evaluations to enable students to determine their progress. Programmes should record pass rates for each cohort of students. Providers foresee appeal process for participants who have failed their exams.

6.6. Customer Results

LAS E&T Providers design programmes that allow customers to gain the three categories of knowledge, skills and competence:

Knowledge:

Includes both theoretical and factual knowledge and described as:

- i) Understanding of the knowledge required for the candidates’ role.

- ii) Understanding of the knowledge base and a critical awareness of forefront developments in the candidates' area
- iii) Understanding of techniques applicable to their own area of practice.
- iv) Application of evidence-based knowledge, together with the ability to evaluate critically current literature and research in the candidates' area.
- v) Understanding of how established techniques and methods are used to create and interpret knowledge in the area relevant for the candidates.
- vi) Evaluate methodologies and techniques, and develop critiques of them and, propose new approaches where appropriate.

Skills

Include cognitive skills (use of logic, intuitive and creative thinking) and practical skills (including use of method, materials and instrumentation):

- i) The ability to integrate knowledge and handle complexity, formulate sound judgements with incomplete or limited information, including reflection on social and ethical responsibilities, and apply this knowledge and these skills in both common and complex clinical and professional situations.
- ii) The ability to clearly communicate the conclusions and the rationale underpinning them, to colleagues and to external stakeholders.
- iii) Apply knowledge, and understanding, and problem solving abilities in new or unfamiliar environments within the broad area of the field of interest.
- iv) Continue to advance their knowledge and understanding, and to develop new skills to a higher level.

Competence:

Refers to the Candidates' ability to integrate knowledge, skills and attitudes, and apply them effectively, responsibly and autonomously to the area of interest, and being able to respond effectively to contingencies, change and the unexpected:

- i) Demonstrate independent learning ability required for continuing professional development in a manner that can be largely self-directed or autonomous.
- ii) Demonstrate self-direction and originality in tackling and solving problems, and act autonomously in planning and implementing tasks in the relevant area of interest.
- iii) Perform independently and accept responsibility at a required level.

LAS E&T Providers regularly assess the impact of the training delivered, measuring-changes occurred in meeting the competence requirements of all those involved in the use and care of animals for scientific purposes.

6.7. People Results

LAS E&T Providers achieve and sustain outstanding results that meet or exceed the needs and expectation of their people. The Providers measure people perceptions and performance (e.g. satisfaction, motivation, empowerment, communication, carriers, engagement, leadership, teaching, training management, results).

6.8. Society Results

LAS E&T Providers define, adopt and monitor short, medium and long-term strategies to guarantee the environmental, social, and economic sustainability of their business as well as of each training

process. This sense of purpose, and real application of the sustainability principles constitute a determining pull factor for LAS E&T Providers.

They build up the foundations of sustainability by training their people to see things differently and to think differently before acting differently, respecting the main pillars of the environmental, social, and economic sustainability. They also promote a “culture of sustainability” in LAS E&T among their customers, partners, competitors and relevant stakeholders.

Sustainable development can be the product of engagement and integration of people, customers, and society.

LAS E&T Providers communicate about, and actively demonstrate their leadership in sustainability.

LAS E&T Providers embrace to heavily influence global efforts with the aim to create a sustainable future both within education and training in LAS, and on a much-widened scale too.