

FELASA recommendations for the education and training of persons carrying out animal experiments (Category B)

Report of the Federation of European Laboratory Animal Science Associations Working Group on Education of Persons Carrying out Animal Experiments (Category B) accepted by the FELASA Board of Management

FELASA Working Group on Education of Persons Carrying out Animal Experiments: T. Nevalainen (Convenor), I. Dontas, A. Forslid, B. R. Howard, V. Klusa, H. P. Käsermann, E. Melloni, K. Nebendahl, F. R. Stafleu, P. Vergara & J. Verstegen

FELASA, BCM Box 2989, London WC1N 3XX, UK

Preamble

The Council of Europe Convention, Article 26, makes it a general requirement that 'persons who carry out, take part in or supervise procedures on animals, or take care of animals used in procedures, shall have had appropriate education and training' (CE 1986). Elsewhere the Convention refers to competence. EU directive Article 14 states that 'persons who carry out experiments or take part in them ... including duties of a supervisory nature, shall have had appropriate education and training' (Official J EC 1986).

Article 14 further directs that 'persons carrying out or supervising the conduct of experiments shall have received instruction in a scientific discipline relevant to the experimental work being undertaken and be capable of handling and taking care of laboratory animals; they shall also have satisfied the authority that they have attained a level of training sufficient for carrying out their tasks' (Official J EC 1986).

FELASA has elaborated on this concept by subdividing the levels of competence involved into Categories A, B, C, and D. Recommendations addressing three of these categories have already been published by FELASA working groups (FELASA 1995, 1999). The current working group has prepared recommendations for the education and training of Category B persons, who are responsible for carrying out experimental and other scientific procedures on living animals.

The Council of Europe resolution on education and training of those concerned with the use of animals for scientific purposes also deals with Category B; this was approved by the European Union (EU 1992) and the Council of Europe Multilateral Consultation Body (CE 1993). While adopting the topics proposed in this resolution, the present working group has structured them differently within the Directive's framework.

Currently, the implementation of education and training requirements of persons working in this category varies between countries. This document proposes a standard, adoption of which will create greater uniformity in general levels of competence and facilitate the interchange of persons through harmonized and mutually acceptable criteria.

Correspondence to: T. Nevalainen, NLAC, University of Kuopio, PO Box 1627, 70211 Kuopio, Finland. E-mail: Timo.Nevalainen@uku.fi

Note: Reprints of this Report are available free of charge (while stock lasts) from the Secretary, FELASA, BCM Box 2989, London WC1N 3XX, UK

Duties of Category B person

The working group defines the duties of a Category B person as follows:

- (1) To be aware of European and national laws and guidelines relating to the conduct of experimental or other scientific procedures on animals.
- (2) To be aware of and respect societal ethics in relation to animal research.
- (3) To understand and respect the general rules of the animal facility, where procedures are carried out.
- (4) To understand the theoretical background of tasks he/she is expected to do, so as to safeguard animal well-being and ensure the relevance of scientific findings.
- (5) To be competent in handling and other techniques he/she is expected to carry out.
- (6) To be able to recognize pain and discomfort and to assess the welfare status of animals with which he/she is working.
- (7) To be aware of the need for, and capable of taking, appropriate action when adverse outcomes occur during or following procedures.
- (8) To be knowledgeable concerning the uses of laboratory animals and be competent to take appropriate measures to minimize interfering factors when a procedure is conducted.

Competence

In this document, competence is not defined by the duration of any particular period of training and education, but rather as a person's ability to carry out his/her duties. The working group considers that assessment is necessary at the end of training to measure the competence attained.

In practice, it has been found that a course of approximately 40 h duration, half of which involves practical work closely supervised by a suitable, competent person, would normally be sufficient to establish a basic level of competence in a new candidate. All procedures carried out during training must be

restricted to those absolutely necessary for the requirements of the trainee. The contents of the programme may be tailored to increase its relevance to the task at hand, and some components may be excluded or added because of this. It may be appropriate to restrict attainment of competence to one species or to a group of species or group of procedures. Subsequently, competence should be extended by additional training.

Curriculum

A. Legislation, ethics and the 3Rs

To have knowledge of and understand

- (1) European and national laws concerning the use of animals for scientific purposes.
- (2) Responsible attitudes to the use of laboratory animals.
- (3) Principles of the 3Rs—Reduction, Refinement and Replacement.
- (4) The availability and applicability of alternative and complementary methods.

B. The basic biology and husbandry of relevant laboratory animal species

1. Basic biology

- *to have knowledge of the structure and function of the main organs and systems sufficient for the procedure to be conducted*
- *to have knowledge of the physiology and biochemistry sufficient for the procedures to be conducted*
- *to be aware of normal ranges of physiological parameters and to understand biological variability*
- *to be aware of behavioural and physiological characteristics relevant to the procedures to be conducted*
- *to have sufficient knowledge of breeding, and of relevant genetic techniques (e.g. transgenic and knockout) for the procedures to be undertaken*
- *to be aware of the existence of circadian rhythms and their practical consequences*

2. Husbandry

- *to have knowledge of environmental requirements in relation to housing and caging systems, and of European and national regulations, guidelines and/or codes of practice*
- *to be aware of the interaction between an animal and its environment*
- *to be aware of the way in which environmental enrichment contributes to an animal's behavioural and socialization needs*
- *to have knowledge of relevant animal care routines and standards*
- *to be aware of the way in which biological characteristics relate to care and husbandry practices*
- *to know how laboratory animals are classified according to their microbiological status*
- *to understand the importance of proper hygiene in laboratory animal facilities with respect to disease prevention and control, and its consequences for experimental results and animal well-being*
- *to understand the relationship between microbial challenge and animal health, and their impact on experimental results*
- *to have knowledge of nutritional requirements and feeding practices*
- *to be aware of the availability of different formulations, types of special diets and different feeding regimes*
- *to be aware of the effects of nutritional status on experimental results, including variation in composition of the diet and the effects of over- and under-feeding*
- *to be aware of factors affecting the selection of special diets and feeding regimes*
- *to understand the necessity for a constant supply of potable water and the various means of presenting this*
- *to have knowledge of the availability and suitability of different types of litter and nest materials*

C. Assuring the physiological needs and welfare of animals without compromising scientific integrity of the investigation or procedure

1. Physiological needs

- *to understand which factors should be*

considered in assessing an animal's well-being

- *to be knowledgeable of an animal's behavioural and environmental needs in relation to its well-being*
- *to be able to observe and interpret the behavioural characteristics of relevant species*
- *to understand how to maximize well-being in relation to the housing and care of relevant laboratory species*

2. Welfare

- *to be able to assess the level of stress, distress or suffering that an animal is experiencing*
- *to know the importance of regular human contact in avoiding unnecessary distress in laboratory animals*
- *to understand the need to minimize variability between animals as a means of minimizing the numbers of animals required and to know measures appropriate to achieving this insofar as well-being is concerned*
- *to recognize the signs of ill-health in animals of relevant species*

3. Scientific integrity

- *to be informed about how the scientific validity of a study may be affected by interference with an animal's social behaviour*
- *to understand why it is important to acclimatize laboratory animals to husbandry routines before experimental studies begin*
- *to be informed of the importance of measures to minimize stress in relation to the housing of relevant laboratory species*
- *to be informed of the influence of environmental complexity on biological variability, and its effect on individual animals*
- *to understand the importance of an animal's health in relation to its welfare and to the scientific validity of the investigation*
- *to know the advantages of conditioning animals before commencing experimental studies*

- *to be familiar with the benefits obtained by training experimental animals and ways of achieving this*
- D. Handling, conduct of basic techniques and euthanasia*
1. Handling/Behaviour
 - *to understand the principles and importance of correct handling and normal behaviour in respect to their proposed use*
 - *to be capable of selecting appropriate restraining method*
 - *to be capable of selecting and applying appropriate identification methods*
 2. Administration of substances
 - *to know how most commonly used compounds are distributed and eliminated following administration by different routes*
 - *to be capable of administering compounds and selecting an appropriate route of administration depending on experimental design*
 - *to be competent in the correct techniques (and recognizing known side effects) of oral, subcutaneous, intramuscular, intraperitoneal and intravenous administration of compounds*
 3. Sampling techniques
 - *to know methods for removing and collecting body fluids, faeces and urine*
 - *to be able to demonstrate correctly how to collect blood, faeces and urine*
 - *to be aware of reasons for restricting the frequency and volume of sampling*
 - *to be able to discuss advantages and disadvantages of these methods*
 - *to demonstrate correct methods for the storage of biological samples*
 4. Euthanasia
 - *to be able to define euthanasia and list the reasons for its conduct*
 - *to be able to explain the four most commonly used methods of euthanasia*
 - *to be able to select an appropriate method(s) in accordance with the experimental design*
- *to know which methods are unacceptable*
 - *to be able to perform and confirm euthanasia using a chemical or a physical method*
5. Data collection
 - *to understand and demonstrate how to prepare a protocol for animal experiment*
 - *to understand and demonstrate the collection and storage of data in accordance with the principles of Good Laboratory Practice (GLP)*
- E. Recognition of a lack of well-being and of other complicating factors*
1. Recognition of well-being and health
 - *to be able to observe and assess the state of health in relevant species*
 - *to understand biological variability in normal healthy animals*
 - *to be aware of literature sources of physiological data of relevant species*
 2. Recognition of pain, suffering or distress
 - *to be able to recognize signs of pain, suffering and distress, and to be familiar with the concept of humane endpoints and with the necessity to pre-determine them for procedures*
 - *to be aware of principal stressors in relevant species*
 - *to be able to evaluate the severity of a procedure and to understand severity limits*
 3. Recognition of ill-health
 - *to be able to recognize signs of ill-health in relevant species and to know the appropriate actions to be taken*
 - *to have knowledge of health monitoring and disease prevention or control in relation to relevant species and procedures*
 - *to understand the importance of latent diseases*
- F. Anaesthesia, analgesia and basic principles of surgery*
1. Methods of anaesthesia
 - *to understand the definition of anaesthesia*

- to have knowledge on indications for general and local anaesthesia
- to have knowledge on the main routes of general anaesthesia
- to have knowledge of the anaesthetic agents most commonly used, their specific indications and contraindications

2. Preoperative care

- to be aware of the importance of preoperative physical examination and the implications of food restriction
- to be aware of the importance of pre-anaesthetic medication as a means of ensuring an animal's well-being and smoother anaesthesia induction
- to have knowledge of the most commonly used tranquilizers and anticholinergic agents and to be able to administer them correctly
- to be competent in the preparation of an animal for surgery

3. Maintenance of anaesthesia

- to be able to assess the depth of anaesthesia in relevant species
- to be aware of the importance of monitoring the progress of anaesthesia and to be capable of maintaining appropriate records
- to be aware of common anaesthetic emergencies and capable of responding promptly
- to be competent in the use of anaesthetic machines
- to have knowledge of the principal drugs administered for the reversal of anaesthesia

4. Postoperative care—analgesia

- to be able to closely monitor an animal postoperatively with respect to respiration, pulse, temperature, surgical site and general condition
- to be able to recognize and promptly treat post-anaesthetic emergencies
- to have knowledge of the benefits of analgesia and to be competent in administering analgesic agents

- to have knowledge of the characteristics and duration of effect of the analgesics commonly used

5. Basic principles of aseptic surgery

- to understand the importance of maintaining sterility in the operating theatre and to be competent in the conduct of aseptic procedures
- to be competent in the preparation and proper sterilization of surgical instruments and material packs

G. Occupational health and safety

1. Zoonoses and dangerous pathogens

- to have knowledge of the health status of research animals, the principal pathogens affecting them and related hazards for humans

2. Hazardous chemicals

- to have knowledge of the main hazards associated with the handling of the most common categories of gases, solvents, acids, alkali and salts employed in biomedical research and testing
- to have knowledge of the main hazards connected with handling drugs and other pharmacologically-active test substances
- to be able to correctly interpret the symbols and warnings appearing on the labels of pharmacologically-active substances
- to be aware of the potential danger of inappropriately mixing different chemicals

3. Biohazards

- to be aware of hazards related to the handling of viruses and genetically modified organisms
- to be aware of hazards presented by material contaminated by microorganisms
- to be aware of the hazards inherent in biological material of human origin

4. Allergies

- to understand how allergy arises
- to be able to recognize early signs suggesting the development of allergy

5. Precautions and personal protection

- to know relevant European and national legislation and local procedures relevant to occupational health and safety
- to be aware of health care programmes for personnel exposed to chemical and biological hazards
- to have knowledge of the basic principles of hygiene and asepsis
- to be able to properly operate health and safety equipment (hoods, masks, etc.)
- to be able to implement appropriate precautions to minimize potential risks in relevant situations

6. First aid

- to know the local procedures to follow in case of an accident
- to be aware of what can be done and what has to be avoided while waiting for help

7. Waste disposal and public health legislation

- to have knowledge of national legislation relating to the environment and its protection
- to have knowledge of local procedures for waste disposal
- to be able to classify different kinds of hazardous waste
- to be able to properly process material before disposal
- to have knowledge of local procedures for the correct disposal of animal carcasses

Alternative ways to achieve Category B competence

The working group recognizes that satisfactory education and training can be achieved in a variety of ways. An apprenticeship scheme was considered to be the most appropriate means of achieving competence for Category B persons. The advantage of the apprentice approach is that the supervisor can tailor learning to the individual's needs, is able to supervise the learning of practical skills and gets almost simultaneous feedback. This programme is dependent on the availability of suitable instructors.

Another means of developing competence, is by use of free-standing courses. In this situation it is more difficult to structure the material presented and the teaching of practical elements requires particular care. Courses may make more efficient use of skilled presenters. Suitable parts of curricula for Categories A and C may contribute to this process.

One way of combining these approaches is the 'sandwich' or 'day-release' course, where presentation of theory is interspersed with the acquisition of practical skills in the workplace.

Updating of competence through continuous education

All training becomes obsolete unless it is used and updated continuously. A mechanism should be introduced to ensure that competence remains up-to-date, by appropriate further training. National Competent Authorities should be encouraged to ensure that this is done.

Assessment of competence

No award recognizing competence should be granted without a thorough evaluation of the candidate. In the case of Category B it is necessary to assess not only theoretical knowledge, but even more so the practical skills learned. Following training according to these FELASA recommendations, a successful outcome to assessment should take the form of a diploma which would explicitly describe both the theoretical and practical elements of competence achieved and which would be universally accepted within Europe.

References

- Commission of the European Communities. *Educational and Training Needs of Those Working with Laboratory Animals. Guideline Document*. Brussels, February 1992
- Council of Europe (1986) *European Convention for the Protection of the Vertebrate Animals used for Experimental and other Scientific Purposes*. Article 26, Strasbourg
- Council of Europe (1993) *Resolution on Education and Training of Persons Working with Laboratory*

-
- Animals*, Appendix 2. Adopted by the Multilateral consultation on 3 December, Strasbourg
- FELASA (1995) FELASA recommendations on the education and training of persons working with laboratory animals: Categories A and C. *Laboratory Animals* **29**, 121–31
- FELASA (1999) FELASA guidelines for the education of specialists in laboratory animal science (Category D). *Laboratory Animals* **33**, 1–15
- Official Journal of the European Council (1986) *Legislation*. Article 14, Strasbourg