



‘Lifelong Learning’ in animal experiments

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1 Background

In accordance with the Netherlands' Experiments on Animals Act (*Wet op de dierproeven*, or Wod), procedures on laboratory animals may only be carried out by people who are qualified and competent, or who are acquiring qualification and competence under the direct supervision of someone who is qualified and competent (Wod: [art. 9](#) and [art. 13f2](#)). Article 13f3c requires licence holders to have on site one or more persons charged with assuring this qualification and competence; as establishment licence holders, UMC Utrecht and Utrecht University have charged the Animal Welfare Body (AWB) Utrecht (*Instantie voor Dierenwelzijn Utrecht* (IvD), [link to text of Wod art. 13f3c](#)) with this task.

In 2016, the AWB Utrecht commissioned a study [2] of the current level of assurance of qualification and competence. The study proposed introducing a registration system. In addition, the 3Rs-Centre and the IvD Platform drew up and worked out recommendations about LLL in research involving experiments on animals in the bilingual document [A guide to Continuing Professional Development in animal experimentation](#) [4], published in collaboration with the National Committee for the protection of animals used for scientific purposes (NCad).

This policy is based on these nation-wide recommendations and the AWB's internal study of the level of assurance. The policy uses the term 'Lifelong Learning', which encompasses the continuing development of both theoretical and practical competence.

2 Purpose

This policy document describes the procedures and requirements that apply to everyone working with laboratory animals. It provides guidance to these people and their supervisors in designing a system for continuous development of professional skills, known as Lifelong Learning (hereafter LLL).

This means:

- Assuring knowledge and competence;
- Frameworks for establishing competence which include:
 - Testing knowledge/attitude/skill;
- Value system for mandatory professional development.

3 Scope

This policy and the supplementary Implementation guide on LLL (hereafter referred to as the implementation guide) apply to all persons who design and carry out experiments on animals, care for laboratory animals, or supervise persons doing this work, under the institutional licence for which the AWB Utrecht has been designated supervisory body.

This policy, the implementation guide and the implementation plan have been communicated and made available to staff of the AWB Utrecht, the laboratory animal coordinators, the representatives of laboratory animal facilities, the principal investigators and study directors of all research, and all employees of Utrecht University (UU) and the UMC Utrecht qualified under the Wod and registered as such. The policy also applies to persons from other institutions registered with the AWB Utrecht, as well as to other institutional licence holders who conduct animal experiments in either of these facilities, who have been designated an internal supervisor by the AWB Utrecht. For interns, the applicable part of this policy is that concerning the path to demonstrating competence.

4 Basic principles

This policy is based on the following principles:

- LLL is an integral part of the qualification to work with laboratory animals (§ 5);
- LLL has been broken down into the knowledge and skills (competencies) necessary for performing professional activities (§ 6);
- An employee may only perform a procedure on an animal if they are qualified (i.e. both knowledgeable and competent) to do so, or are working under the direct supervision of someone who is qualified (§ 6);
- In order to remain registered as qualified, each employee will undergo continuing education and training that promotes the 3Rs (§ 7)

- Every employee is personally responsible for maintaining and registering their own competencies and current knowledge in a portfolio (Implementation Regulations)
- The initial assessment of competence will be done by a person assigned to do so by the designated competence officer (13f3c) (Implementation Regulations)
- Colleagues with corresponding competencies re-assess each other on a regular basis (Implementation Regulations)
- In the application phase of an animal experiment, the principal investigator, in consultation with the AWB, works out in as much detail as possible how the staff members are trained and how much the department is actively promoting professional development.

5 Qualifications

The educational requirements for acquiring qualifications are laid down by law. A detailed description can be read on the website of the 3Rs-Centre and in the publication (in Dutch) by Tiebosch *et al.* (2022) in Biotechniek [6]. The AWB registers the position for which an employee is qualified, in line with articles 2 and 8 (2014 Animal Experiments Decree). The positions that we distinguish and their bases in Dutch and European legislation are shown in table 1 below.

Table 1: *The various qualifications for working with laboratory animals to which this policy applies, and the relevant Dutch and European legislation underlying them. The letters in the European legislation represent the various types of position.*

Position	Position in Dutch law*	Position in European Directive**
Animal caretaker	Art 13f2a	Art 23.2a,c,d
Animal technician (Dutch MBO-4 or HBO)	Art 13f2b	Art 23.2c,d
Scientist	Art 9	Art 23.2b
Designated veterinarian	Art 14	Art 25
Animal welfare officer	Art 13f3a	Art 14.1a
Animal information officer	Art 13f3b	Art 14.1b
Designated competence officer	Art 13f3c	Art 14.1c

In addition, the AWB registers which species these qualifications apply to, and includes this information in the registration of a person's qualification.

Since species-specific training modules are not recognised separately by the legislature, the AWB Utrecht recognises animal species-specific modules that are:

* The Dutch law specifies the qualifications for positions. In particular, differences between animal caretaker and animal technician are explained in article 8 of the Experiments on Animals Decree (*dierproevenbesluit*) and article 6 of the Experiments on Animals Regulation (2014).

** Qualifications for positions in European law are described in article 23 section 2 of Directive 2010/63/EU regarding the protection of animals used for scientific purposes.

- accredited by the Federation of European Laboratory Animal Science Associations (FELASA);
- recognised by the Training & Education working group (created by the IVD Platform);
- approved by an independent certification or examination committee, which recognise within an accredited institution or by the AWB itself.

6 Knowledgeable and competent

All qualified persons in the positions listed in section 5 above must demonstrably continue to develop their knowledge and must demonstrably have the appropriate competencies. The following sections and figure 1 explain what we mean in more detail, as well as how to meet these requirements.

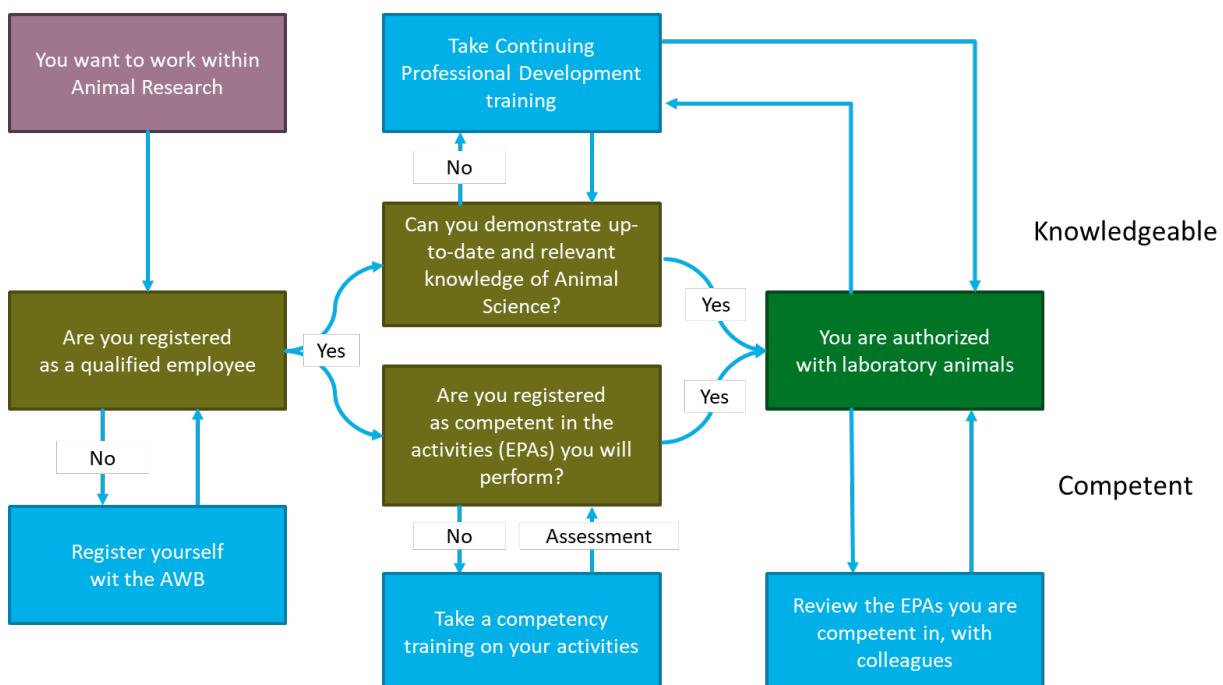


Figure 1: Flow chart of the requirements for working with laboratory animals.

6.1 Knowledgeable

In the context of this policy, a person is considered knowledgeable if they have had the appropriate education, have experience, and continue to improve their knowledge of and skills in doing animal experiments. This is also called education in the 3Rs principle (Replacement, Reduction and Refinement). The NCad recommendations mention theoretical continuing education and training. We have combined these two in the term continuing professional development or CPD. According to the framework of this policy, without this demonstrable theoretical knowledge you may not design or conduct animal experiments, regardless of qualification.

6.2 Competent

You must be competent to do every task you perform involved with an animal experiment, from writing a work protocol (WP), for example, to administering an injection or performing an invasive procedure. Thus, competency can be established for each separate task, also called an ‘entrustable professional activity’ (EPA), described further on in this document.

6.3 Complementarity

To learn new skills, you sometimes need additional theoretical knowledge of the anatomy, physiology or pathology of an animal or the theoretical background of a task. This means that improving an existing competency or learning a new one contributes to your knowledge as well.

7 Knowledge Development

Knowledge development is worked out in more detail in the Implementation Regulations. Its underlying principles are as follows:

- The number of hours required to spend on developing knowledge depends on the position or qualification. These requirements can be modified by the AWB if dictated by developments at national level.
- Every employee will put together their own education/training programme, in accordance with the prevailing policies in their department, in consultation with someone such as their supervisor and/or LLL coordinator.
- The employee will ensure that it clear whether they are maintaining their knowledge.
- The LLL coordinator will assist the AWB in supervising employee knowledge development and is the liaison between staff members and the designated competence officer.
- Every year, the AWB will consult with the LLL coordinator to determine if an employee has worked sufficiently on their knowledge, based on their educational/training programme for the last 3 calendar years.
- If a staff member’s knowledge development is insufficient, the AWB is authorised to temporarily deactivate their qualification to design and/or perform animal experiments. The AWB will inform both the staff member involved and their supervisor, so that the impact on ongoing and planned experiments is clear.

8 Competency and competence

The positions that can be held that involve experiments on animals (see table 1) entail tasks and/or procedures for which competency registration is considered relevant. These ‘entrustable professional activities’ or EPAs [4] are relevant procedures that are necessary to properly carry out animal experiments, and in which the employees concerned are registered as competent. EPAs have been divided into:

- Procedural competencies: EPAs that characterise practical procedures with animals;
- Function-related competencies: EPAs that characterise the tasks associated with a particular position.

Details regarding the need for learning, supervision, training, (re)assessment and exceptions have been elaborated in the Implementation Regulations.

8.1 Competency

An employee can be competent in the practical performance of animal experiments at several levels. In this policy we distinguish 6 levels, which are shown in figure 2.

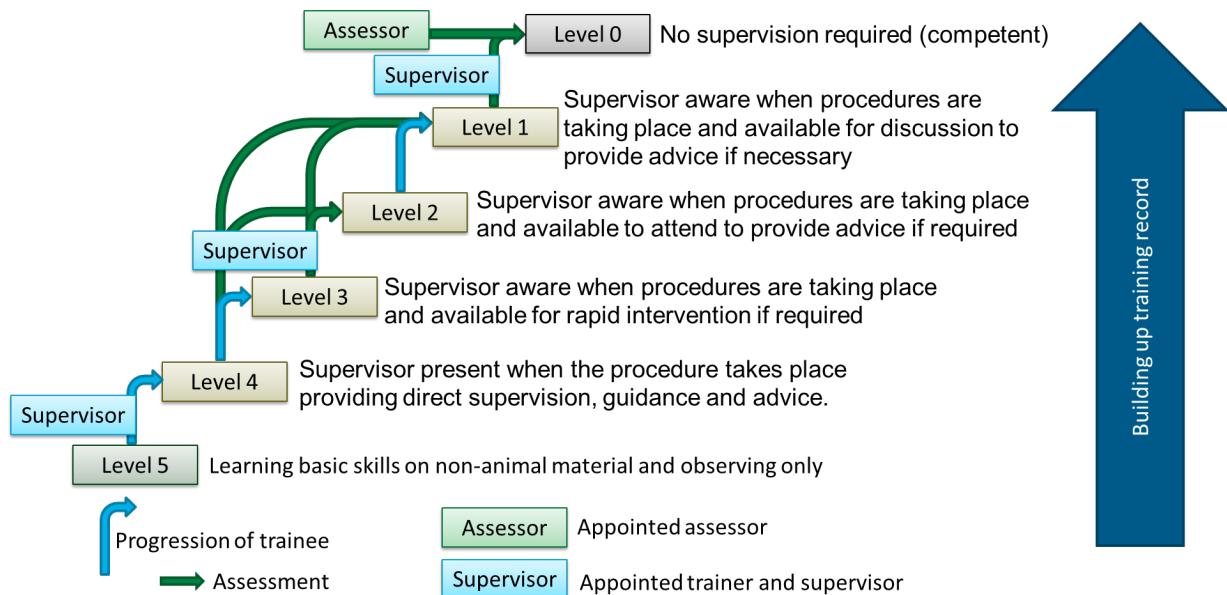


Figure 2: chart of competence development in regular employees and trainees (stagiaries). Trainees receive support or supervision depending on their level. Promotion to a higher level is determined on the basis of informal internal assessments by the supervisor and formal assessments by an assessor. Levels of simple techniques may be skipped between level 4 and 1.. A supervisor or assessor must be appointed by the designated competence officer. The supervisor or the AWB may require the trainee to demonstrate basic skills before allowing them to begin an EPA training. In this case, the trainee remains at level 5.

8.2 Supervision, training and (re)assessment

A person cannot be competent in an EPA without having had training.

Figure 2 shows the supervision and assessment path of this training. This path applies to all techniques. An employee passes through several levels, starting with requiring direct supervision, then moving to greater independence with supervision at an appropriate distance, until the employee can work independently. This process takes place with a supervisor appointed to this employee and task, who teaches the employee the skill (competency), determines at intervals if the employee has mastered it and gives feedback. After an initial assessment, the employee can continue training under a level of supervision appropriate to the procedure, until they reach level 0, where they can carry the EPA out independently. This competency is determined by an appointed assessor, who in principle is not the same person as the trainer.

Supervisors and assessors are appointed by the AWBU. They can be appointed if they are demonstrably competent both in the technique to be trained and in teaching and assessing others.

Employees with the same competencies at level 0 will regularly assess each other.

8.3 Job-related competence

In addition to competency in particular procedures, the AWB can also require competency for a number of job-related tasks that are required in Utrecht. These tasks arise from Dutch or European legislation, or from advisory documents generated by it, as well as from other developments in the field, policies of the licence holder or other relevant sources.

9 Abbreviations and definitions

Assessor	Person charged with assessing competency in a professional activity
AWB (Utrecht) Animal Welfare Body Utrecht	Body responsible for carrying out tasks listed in Art. 14c of the Wod (at Utrecht University and UMC Utrecht)
Competent/competency	Skilled in carrying out a particular activity/the ability to carry out a particular activity properly
Competent/competence	Having both knowledge and skills, including the desired attitude, to carry out a function; this person has a general competence
DCO (Dutch FC) Designated competence officer	Person charged on behalf of the licence holder with the task, as specified in sec. 13F3c of the Experiments on Animals Act (Wod), of supervising the qualifications and competence of staff members who work with laboratory animals
DOPS Direct observation of procedural skills	First-hand observation of an action or procedure during an assessment
EPA Entrustable professional activity	A defined professional activity which a qualified person is entrusted to carry out
FELASA Federation of European Laboratory Animal Science Associations	Umbrella organisation of European associations working in laboratory-animal science.
IvD Platform	Association of affiliated AWBs within the <i>Dutch Association for Laboratory Animal Sciences</i> (DALAS)
Knowledgeable	Having up-to-date and background knowledge of the best methods for performing the work tasks with which one is charged
LLL Lifelong learning	Continuing to learn and develop professionally and personally over one's entire lifetime

LLL coordinator	Person charged with the administration of an LLL programme within an organisational work unit or department
LLL portfolio	Portfolio containing both the knowledge and competencies of a staff member
Qualified	Meets the legal minimum requirements for carrying out a professional activity and is knowledgeable and competent
SOP <i>Standard operating procedure</i>	Recorded and documented step-by-step instruction for carrying out a procedure within an organisation
Supervisor	Person charged with teaching a professional activity to a trainee under supervision
Trainee	Person being trained in a professional activity
Wod (Wet op de dierproeven) Experiments on Animals Act	Dutch legislation protecting animals used for education and scientific research
WP Work protocol	Description of a discrete animal experiment in a project licence
3Rs Replacement, Reduction, Refinement	Basic laboratory animal science principles for responsibly conducting experimental research involving animals, in which no animal testing is done if alternatives are available, the number of animals used is limited, and the procedure has been designed for optimal animal welfare

10 Additional documents

1. Lifelong learning Implementation Regulations
2. Tasks and responsibilities in the animal-experiment chain: <https://ivd-utrecht.nl/en/infocentre/document/tasks-and-responsibilities-in-the-animal-experiment-chain>
3. 3Rs info page 'Dutch competency regarding animal experimentation'
<https://www.uu.nl/en/organisation/3rs-centre/education-and-training>

11 Literature

1. *Wet op de dierproeven*, effective as of 01-01-2019 (still in force).
<https://wetten.overheid.nl/BWBR0003081/2019-01-01>
2. Lilian Vlijm (2016), *Borging van Bekwaamheden*, Elective internship Master CRU medicine, IvD Utrecht/UMC Utrecht.
3. 3Rs info page ‘Competency regarding animal experimentation’
<https://www.uu.nl/en/organisation/3rs-centre/education-and-training>
4. 3Rs-Centre ULS and IvD Platform, February 2019, *Leven Lang Leren in het dierexperimenteel onderzoek*, <https://www.ncadierproevenbeleid.nl/documenten/publicatie/19/25/leven-lang-leren/lven-lang-leren>
5. Ilse ten Cate, Huiju Carrie Chen, Reinier G. Hoff, Harm Peters, Harold Bok & Marieke van der Schaaf (2015) Curriculum development for the workplace using Entrustable Professional Activities (EPAs): AMEE Guide No. 99, Medical Teacher, 37:11, 983-1002, DOI: [10.3109/0142159X.2015.1060308](https://doi.org/10.3109/0142159X.2015.1060308)
6. Ivo Tiebosch et al. (2022) *Overzicht van Nederlandse opleidingen die onderwijs verzorgen ten behoeve van de bevoegdheid voor het werken met proefdieren*. Training & Education working group, IvD platform, DALAS: Biotechniek 61-2, ...
7. Directive 2010/63/EU on the protection of animals used for scientific purposes.
https://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/directive/en.pdf

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