

Policy on competency in animal procedures: training and continuous professional development

Radboud University of Nijmegen

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1. Introduction – it's all about competency

- The latest European Directive 2010/63/EU was implemented in the Dutch legislation (Experiments on Animals Act = Wet op de Dierproeven = Wod) in 2014. The revision reinforces commitment to the **three Rs** and includes conditions for the approval of projects and the competency of staff members carrying out animal procedures, as referred to in Section 13f of the Wod and Article 24-1c of the European Directive 2010/63/EU:
 - All staff members who carry out work involving animal experiments should be adequately educated/trained and competent before they are allowed to design projects and animal experiments, carry out animal procedures, take care of or kill animals.
 - Until they have demonstrated the required competency, they can only perform these tasks under supervision of a competent person.

- The concept of Continuing Professional Development (**CPD**), also known as *Life Long Learning*, applies to all staff members and investigators who carry out procedures on animals or design animal experiments.
 - Section 10(1) of the Wod stipulates that the number of laboratory animals used in animal experiments is to be kept to a minimum and that these animals must experience as little pain and distress as possible. In order to comply with that, the animal facility must ensure that all staff members and investigators concerned are sufficiently competent in their functions at all times.
 - The objective of CPD is to ensure that relevant information is exchanged and that “best practices” are known, understood, and applied whenever possible.
 - It requires that all staff members and investigators concerned continue their learning/training, in addition to the initial training (“at school”) in areas relevant to their animal research activities. Section 13f3c of the Wod stipulates that the license holder has to appoint Designated Competency Officers (DCO’s) to ensure that staff members are adequately educated, competent, continuously trained and supervised until they have demonstrated the requisite competency.
- The CPD affects all researchers, animal caretakers and animal technicians working in animal research facilities.
 - **The Animal Welfare Body (AWB)** of the Animal Research Facility (Centraal Dierenlaboratorium – CDL) of the **Radboudumc** has **developed a system that governs the registration of people involved in animal research, the training in and assessment of competency in execution of animal procedures, and includes the concept of Continuing Professional Development.**
 - This document concerns researchers designing projects and animal experiments (Wod section 9), animal caretakers (Wod section 13f2), animal technicians (also section 13f2), attending veterinarian (Wod section 14), and members of the AWB (in particular Wod section 13f3c).

The crux of the matter

Persons working with laboratory animals should always be trained and competent in order to ensure animal welfare and scientific quality of animal experiments.

2. Responsibilities

Designated competency officers, DCO (AWB member, attending veterinarian): They ensure that all staff members working with animals are adequately educated and qualified to perform procedures on animals. Education and qualification include both theory, to retain qualification (continuing education), and practice, to acquire or retain skills (practical competencies).

At Radboudumc, education and qualification of the animal caretakers/technicians is coordinated by the designated veterinarian. This coordination includes supervision on keeping training records for caretakers/technicians. Training records are kept in an e-learning system used in the Radboudumc. It contains a “quality passport” which states all relevant basic procedures for each unit. For animal caretakers/technicians all these procedures need to be evaluated by a designated trainer and signed by the team coordinator once every two years or any time sooner depending on upcoming experiments. The designated trainer is evaluated by the team coordinator, and the team coordinator is evaluated by the attending veterinarian; evaluations are confirmed by signing off for it. In addition there is a portfolio stating all (non-basic) extra competencies, which are also evaluated and signed off for, comparable to the basic competencies as mentioned above.

The education and qualification of researchers and academic students is coordinated by the AWB. This coordination also involves supervision on training records for researchers, which is done in iVentionLES. All competencies are linked to the specific technical procedures (e.g. intravenous injection mouse, subcutaneous injection rat, etc.) for which these competencies were assessed.

The coordination does not necessarily involve storage of training records for students, since students are not allowed to work without supervision and their direct supervisors remain responsible for their actions.

Animal caretakers, technicians: They provide support in practical assistance or conduct practical procedures for researchers during the execution of animal experiments in the animal facility. They are encouraged to communicate with researchers, attending veterinarian and AWB about potential opportunities to implement 3Rs (culture of care) or potential risks regarding the welfare of animals, and intrinsically linked to this, the scientific quality. They are in fact indispensable for the proper implementation of the principle of *Culture of Care*.

Researchers: Researchers need to register as section 9 (“artikel 9”) with the local AWB to be allowed to write a project and/or design experiments involving experimental animals. They are not automatically declared competent to independently conduct procedures on live animals. They need to take training from (demonstrably) competent staff member in the relevant practical procedures. Training records are to be created and stored (in iVentionLES). Once the training is completed the competency will be assessed and signed off by a designated competency officer (AWB member, attending veterinarian or senior competent technician). In order to reach this level of competency, any relevant training can be supervised by a designated trainer from the CDL or a by a researcher that is proven competent. Until this process is completed researchers shall not perform practical procedures on or with animals without direct supervision. Researchers are responsible for archiving their own training and CPD records.

Students: Students/trainees need to register with the local AWB before being involved in animal studies (indicating who their supervisor is and what kind of work they will be doing). They shall not perform any procedure on or with animals without supervision. When a student or a trainee is performing an animal procedure, the supervisor should be in the same room or within physical reach. For basic non-surgical procedures the section 9/13f2-qualified trainer (researcher/technician) needs only be reachable by telephone with the ability to be on-site within five minutes, once the student is sufficiently trained. The procedures that will be taught to the student must be recorded in a training record and signed by the supervising (qualified) person. These records are to be archived (uploaded) in iVentionLES under the name of the person in question. If the technique has not been performed during a certain period of time, a refresher training may be necessary before continuing to perform these techniques in experimental animals.

Supervisors: Supervisors are ultimately responsible for their students and trainees. Supervisors should be qualified and registered as art. 9 or art.13f2 with the local AWB, and be able to spend ample time with the trainee(s) in the facility.

Trainers: Responsible for the training of others in a particular biotechnical procedure. Once a trainer has mastered a technique, (s)he should ensure to keep this training expertise. For basic training (handling, dosing, blood sampling) each unit in the facility has its own designated trainer(s). This person is a highly qualified and experienced animal technician and has proven practical and educational skills. He/she is authorized by the designated competency officer. In case of advanced (specialized) techniques, e.g. stereotactic brain surgeries for virus injections,

experienced and skilled researchers can also act as trainers (a situation where the assessment needs to be done by some-one else).

General: For training purposes one should preferably use surplus animals, which (still) requires a valid license: a) CDL project license for general training, or b) any other project license that allows specific procedures to be trained.

The crux of the matter

The designated competency officers (AWB members, veterinarian) are responsible for proper training of people working with animals and they can delegate parts of that responsibility to others with proven competencies. These others will be assigned persons with required expertise.

3. Registration with the local AWB

- It is essential that the educational status of all persons involved in the care or use of laboratory animals is documented.
 - Registration as student/trainee, researcher art. 9, guest researcher, art. 13f2
 - This information is archived by the local AWB
 - All documentation needs to be in order before work with animals can be initiated.
 - These registration documents also need to be available for NVWA inspection (Dutch authorities)
- Documentation is coordinated by means of registration forms standardized for specific requirements/roles.
 - Always download the most current version of the documents and forms that are available on the Radboudumc Animal Research Facility Website: [here](#)
 - Once the relevant forms are completed, they should be sent to the AWB [email here](#)
 - Once you submit all appropriate documents (appropriate copy of documents and forms) you will receive a confirmation that you are registered.

- After registration you will receive an invitation to participate to a mandatory introductory workshop (Workshop 'Welcome to the CDL'), also explaining about access to the digital Laboratory Execution System (iVentionLES) and access to the building.

The crux of the matter

Every person working with live animals needs to be registered with the local AWB.

4. Competency Training and Assessment

a. Competency concept

Every person working unsupervised with research animals must be competent because:

- Competency is essential for the implementation of good laboratory and research practices
- Competency is required by the three Rs principles; refinement obliges us all to minimize animal suffering and distress, in particular avoidable stress caused by amateurism
- Competency of all stakeholders ensures the general public that the work is done with the skills and respect it deserves

Within the context of animal research, competency refers to a set of capabilities associated with a specific procedure. A competent person can:

- Organize and prepare the necessities and activities required for the procedure
- Perform a certain procedure at an acceptable skill level (as assessed by the AWB, following a set of criteria, see below)
- Respond appropriately to unexpected situations related to the procedure
- Apply the skills and knowledge of a certain procedure in new situations where appropriate
- Meet expectations regarding the necessary communication with colleagues

All animal caretakers, technicians and researchers tasked with a (set of) procedure(s) are required to meet the standard of competency set by the AWB before they are allowed to carry out these procedures unsupervised. Note that competency does not imply or require that the person is able to train others; that is the highest level of training which is required to act as trainer.

Animal caretakers are considered sufficiently capable by their education, and their practical competencies will be assessed at least once every two years.

Students and trainees may only execute procedures under supervision of a trained professional. After an appropriate training (resulting in training records) they can work with their supervisor nearby (with the ability to be on-site within five minutes). Their competency will not (does not need to) be assessed by the DCO's unless invasive procedures are going to be performed without their supervisor in the same room (but always nearby, with the ability to be on-site within five minutes). On top of this BSc students are only allowed to perform non-surgical procedures.

In order to ensure competency, persons new to a procedure are required to follow competency trainings and to successfully complete a competency assessment. For people with previous experience, the level of training may be different but the assessment will always have to take place (see Figure 1).

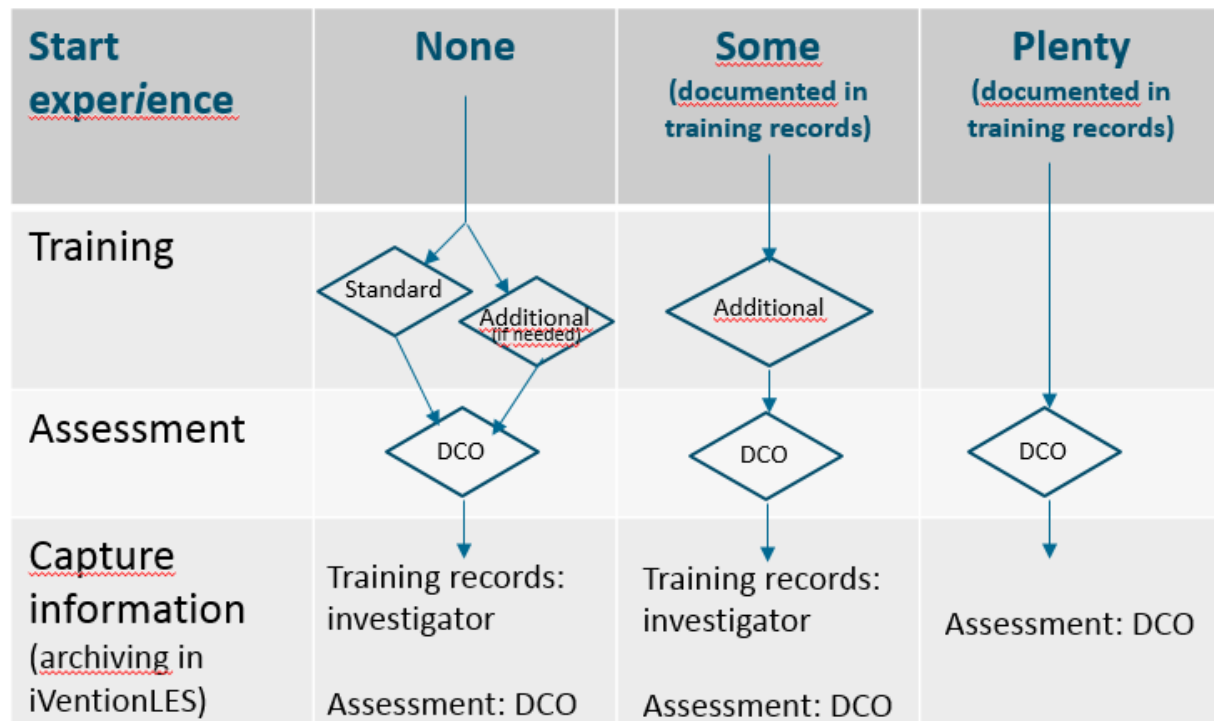


FIGURE 1. Overview documentation competencies for investigators.

b. Designated Competency Officers

Competency assessments are conducted by the Designated Competency Officers (DCOs) or assigned DCOs; authorized trainers such as senior technicians and experienced scientists with special expertise.

The DCOs do not (always) provide the practical training themselves, but they will decide whether further training is needed. They will assess practical competency, and sign off on the outcome.

c. Competency Training

i. Competency Training

Assigning a competent trainer

A competent trainer is someone who has reached the highest level of training for the procedure that needs to be performed. He or she is very experienced and has the educational ability to transfer the required knowledge. The AWB members and veterinarian are responsible for the appointment of trainers.

Waiving training (not the assessment)

- Very experienced people that can show proof of their training (preferentially training records)
- Guest researcher: an expert invited to perform a technique that is not known in-house

Training in the absence of a competent trainer

- For competent persons to refine their techniques
- For competent persons to adapt their methods to newest technology
- For trainers to refresh their skills
- In the end assessment is still required

d. Competency Assessment

i. Competency assessment

The assessment should test a current level of competency in terms of skill and knowledge, and compare that with the competency standard established for the procedure. In addition to showing competency, the assessment should identify areas of strength and areas that could still be improved. The method of and criteria for assessment has been described in universal training record: *appendix A*.

Competency is only assessed by the (assigned) DCO. The trainer may be present, but he or she should not assist the person being assessed, and he or she should not be involved in deciding the outcome of the assessment. Exceptions to the rule that the assessor is not the same person as the trainer are situations concerning simple procedures like s.c. dosing, or situations with specialized techniques requiring very special knowledge of the assessor.

The competency assessment should include multiple factors associated with the procedure:

- Knowledge and Understanding (incl. peri-operative care, positioning of animals, etc.)
- Skills
- Attitude

Knowledge and understanding: the person must be adequately educated and trained. Good science depends on understanding what you are doing and why.

For instance, if the person is to perform a subcutaneous injection, he/she should be able to restrain the animal and inject it. The assessment will go beyond the injection itself as it is important for the person to know what is the maximum volume that can be injected, to understand the importance of the injection medium temperature, have knowledge about possible injection sites, and restraining methods. If blood needs to be collected, the DCO can assess knowledge of what is the maximum volume allowed for that particular species or alternative collection sites.

Skills: are required for properly performing an animal procedure. This involves:

- manual dexterity (how the person holds and operates the syringe)
- catching and restraining the animal

- adequate motor skills, which will depend on the procedure performed. In the case of surgery and i.v. dosing, fine motor skills are required.

Attitude: it is possible to see someone's attitude while performing an animal procedure. The attention to carefully preparing for the procedure, being prepared for possible problems, and attitude towards the animal. Is the Culture of Care being respected throughout?

Assessment Criteria:

In summary you need to be trained (and records of this training need to be kept) for each procedure, and your practical skills will be assessed before unsupervised execution of the procedure is allowed. The Assessment Criteria are summarized in the following 'generic assessment checklist'. Guided by these points, a person's competence is determined.

Generic assessment checklist:

- **Making proper preparations,**
- **Performing the procedures correctly,**
- **Understanding of the technique (theory behind it) and means used (including injection fluids).**
- **An eye for animal welfare (3 Rs), including aftercare, and acting accordingly,**
- **Ability to self-reflect on the manner of execution**

Upon completion of the assessment, the DCO should be certain that the person examined is able to execute the procedure correctly, responsibly, and independently (if applicable), and that the person is confident that he or she is able to do so in the absence of any direct supervision. The DCO should be able to support the outcome of this decision with observable criteria that a trainee can use to further improve. In case of invasive procedures a stepwise (surgical) protocol should be available - and uploaded in iVentionLES under Notes of the Work Protocol in question - allowing the DCO to pre- and review the procedures.

If the DCO is convinced that the person tested is fully competent to perform the procedure, the DCO will sign-off on their competency (in the applicable system). If the DCO does not believe the person to be adequately competent, follow-up training requirements should be discussed.

ii. Re-assessment

Re-assessment of competency may be required with:

- High-risk procedures
- Substantial interval between execution of procedures (either because of uncommon techniques, or because a person has been on an extended leave)
- Modifications of an experimental technique
- Animal welfare concerns
- Unanticipated or adverse events

The re-assessment of the skills of the CDL animal technicians follows a fixed time schedule organized by the designated veterinarian. Re-assessment of the skills of scientists is up to the decision of the DCOs (and in the future there will be an 'valid until date' linked to the practical skills that were approved, the option has been created in iVentionLES).

iii. Outcome records

The current regulations are very clear about our task in capturing/documenting training and competencies. This must be done logically and completely so that it can be monitored. At the Animal Research Facility in Nijmegen we have the iVention Laboratory Execution System (iVentionLES) with the option to upload training records on a personal basis. In the same documentation system it can be indicated (by the DCO's) for which procedures a person has been declared competent. This is the method to document the training and competencies of researchers (art 9).

For the qualified technicians and caretakers working for the CDL, the Radboudumc system "Online Leeromgeving" is used to document training and competencies. Their basic competencies (routine procedures and unit depending) are reassessed with a maximum of 2 years interval. Other non-basic competencies (e.g. heart transplantation) are reassessed whenever experimental techniques are requested by a research group.

The crux of the matter

The competency of every person working with live animals needs to be trained, assessed and documented. The documentation/archiving is done in iVentionLES.

5. Continuing professional development (CPD)

The starting point of CPD is that persons registered with the AWB to perform or design animal experiments received extensive basic education and training (prior to CPD), while the knowledge required is maintained and updated via continued and refresher training, making it possible to retain the authorization conferred on a member of staff. It has also been determined that staff members involved in animal experiments have to keep training their practical skills in order to update and maintain the competence required. This training or re-training may involve both a theoretical component – *an explanation of the anatomy of the cheek of the mouse, for example* – and a practical component – *the performance of a cheek puncture to take blood from the submandibular vein*.

Requirements are imposed in relation to the authorization and competence of staff members who are involved in animal procedures.

Culture of Care: In a Culture of Care, laboratory animals are provided with the best possible care and treatment and both are safeguarded in the organization. To be able to guarantee the quality of research and the responsible use of laboratory animals, it is important that staff members involved in every aspect of animal experiments are able to further expand and maintain their knowledge and skills, develop a critical outlook and require high standards of each other - in a positive manner. The Culture of Care is the optimal climate for all of the above.

Naturally, individual staff members are responsible for retaining and maintaining their capacity and competence too. This applies to animal caretakers, animal technicians and researchers, but also to the 'designated competence officers' who often form part of the Animal Welfare Body.

Where theoretical continued and refresher training is concerned, Continuing Professional Development (CPD) may involve a wide range of activities, ranging from conference and symposium attendance, lectures and workshops, up to and including literature reviews and e-learning. Where practical skills are concerned, CPD may consist of skills training, at the establishment or elsewhere, in combination with e-

learning modules, where possible. For a complete overview of CPD see the guide to Continuing Professional Development in animal experimentation (a pdf containing both the Dutch and English version): <https://www.ncadierproevenbeleid.nl/documenten/publicatie/19/25/leven-lang-leren/lven-lang-leren>

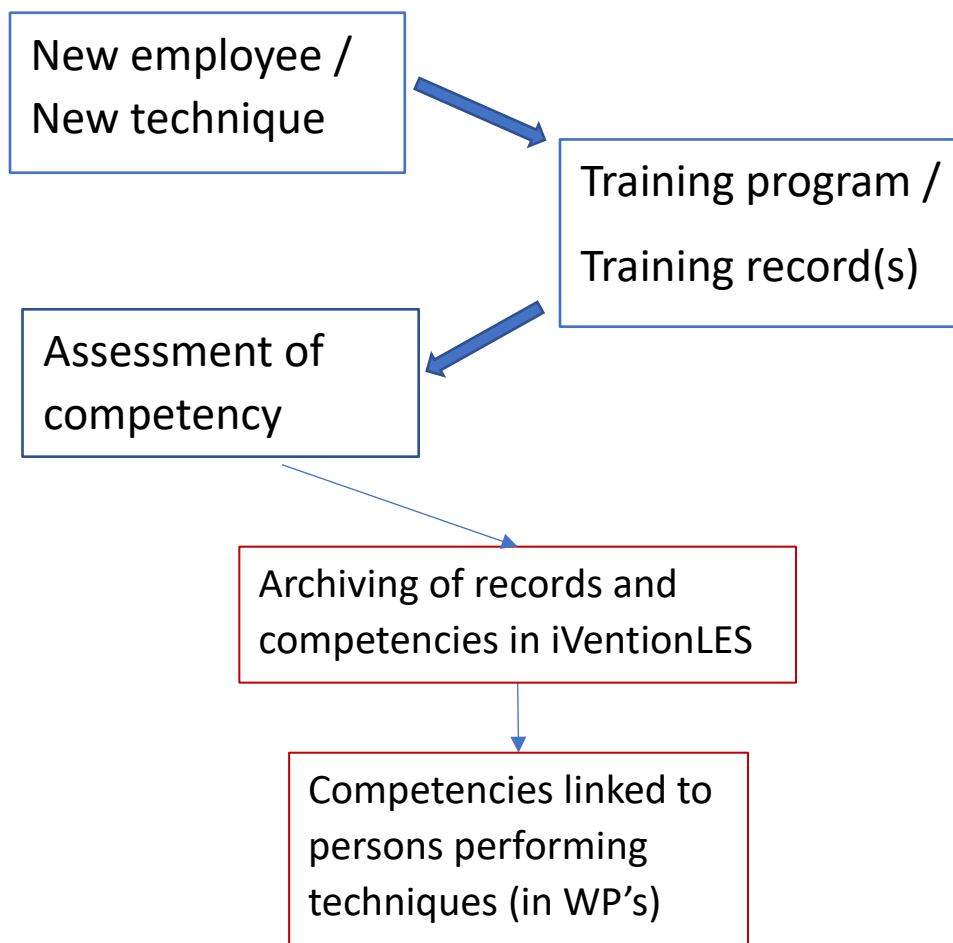
The crux of the matter

Continuing Professional Development applies to all staff members and investigators who carry out procedures on animals or design animal experiments.

6. Summary of this policy

The workflow in a nut shell:

- Technicians and caretakers follow a (re-) training program organized by the veterinarian; their training records are archived by the veterinarian (and Online Leeromgeving)
- Student/scientist that needs training receives training from experienced CDL-technicians (basics), CDL-trainers or (their) experienced supervisors; their training records are kept and uploaded in iVentionLES
- AWB (including veterinarian, senior technicians) will assess competency, performed according to a SOP
- In Work Protocols these competencies are linked to procedures the student/scientist/technician is going to perform



7. Glossary/Abbreviations (definitions/explanations that can help to understand this document)

Animal caretakers – staff members with expertise and competency necessary to take care of and kill (laboratory) animals (section 13(f)(2a) of the Wod

Animal technicians – staff members with the expertise and competency necessary to carry out animal procedures (section 13(f)(2b) of the Wod

Researcher – staff members who designs the project and animal experiment and is required to comply with the rules stipulated in respect of expertise and competency (laid down in the 2014 Animal Experiments Decree (Dierproevenbesluit, 2014). Researcher as referred to in section 9 of the Animal Experimentation Act (Wod, in Dutch).

AWB – Animal Welfare Body. The Animal Welfare Body (Instantie voor Dierenwelzijn IvD, in Dutch) helps to ensure a responsible animal experimentation policy within the Radboud University and Radboudumc. The AWB acts on behalf of the Radboud University to oversee the execution of animal experiments and the welfare of laboratory animals, in accordance with the Animal Experimentation Act.

CDL – Centraal Dierenlaboratorium. It is the animal research facility of Radboud university and medical center, which comprised four teams: Team 1, Team 2, Team 3 (PRIME) and (Farm/Breeding Pavilion).

CPD – Continuing Professional Development (=lifelong learning, theoretical and/or practical)

Culture of care – it implies that laboratory animals are provided with the best possible care and treatment, and both are safeguarded in the research institute.

Designated Competency Officer (DCO) – designated person(s) responsible for checking education, competency and CPD of working with experimental animals. This includes assessing one's competency in laboratory animal procedures. The DCO's of Radboudumc are the members of the AWB and attending veterinarian of CDL.

Assigned DCO – a person who has been appointed as DCO by the AWB and veterinarian based on the level of experience and the educational ability to transfer the required knowledge.

Education: a prior formal relevant training that leads to a diploma.

Practical competency: the knowledge and practical skills to carry out a specific procedure in animals adequately and responsibly.

Three Rs / 3Rs – Guiding principle for ethical use of animals in research; Replacement (avoid or replace the use of animals), Reduction (use fewer animals to obtain relevant data or obtain more information from the same number of animals), Refinement (utilization of methods to alleviate or minimize potential pain, suffering, or distress, and generally improve the wellbeing of the animals used in experimentation).

Wod – Wet op Dierproeven; Dutch Experiments on Animals Act, revised in 2014.

Appendix A

Training Record

Name of trainee:

Procedure	Training dates	Trained by	Level of training (1-5)	Remarks (ready for assessment?)

Explanation of the training levels 1-5 is given in the scheme below. To be allowed to work independently at level 2, 1 or 0, there must first be an assessment of skills at that level.

