

Guide to implementing ‘Lifelong Learning’

Lifelong Learning in practice

Contents

1	Background	2
2	Guidelines for Developing Knowledge	2
2.1	Establishing a continuing education programme	2
2.2	Required time commitment	2
2.3	Registering as a qualified employee	3
2.3.1	Basic registration	3
2.3.2	Reregistration	3
2.3.3	Insufficient continuing education	3
2.3.4	Registration from another institute with an establishment licence for animal experiments	4
2.4	Ways to keep your knowledge up to date	4
2.4.1	Theoretical continuing education	4
2.4.2	Practical continuing education	4
3	Guidelines for Establishing Competency	5
3.1	EPAs	5
3.1.1	Establishing EPAs	5
3.1.2	Transfer of EPAs and ‘nesting’	5
3.1.3	Function-specific EPAs	6
3.2	Levels of trust in competency in an EPA	6
3.2.1	Who to train, and when	8
3.3	Assessment	8
3.3.1	Quality of the supervisor and assessor	8
3.3.2	Quality of the assessment	9
3.3.3	Reassessment	10
3.3.4	Developing competency during an experiment	10
3.4	Exceptions in competency assessment	10
4	Maintaining Your LLL Portfolio	11
4.1	Continuing education	11
4.2	Training	11
5	Other Matters	11
6	Implementation Timeline	12
7	Abbreviations and Definitions	14

1 Background

This guide to implementing Lifelong Learning (LLL) provides additional information on how to work out the policy document “‘Lifelong learning” in animal experiments”, with regard to developing knowledge and learning skills. The policy and this guide apply to all persons who design and carry out animal experiments or care for laboratory animals and those who supervise them, under the institutional licences for which the Animal Welfare Body Utrecht (hereafter AWBU) has been appointed the supervisory body.

The AWB will update this guide on the basis of new insights, with the input of LLL coordinators. This implementation guide and any modifications to it go into effect once the starting date has been published on the AWB website and in the AWB newsletter.

2 Guidelines for Developing Knowledge

As indicated in the policy document ‘Lifelong Learning’ in animal experiments, this document gives employees further guidance about possible ways to stay well-grounded and the ways to register these continuing education activities in their personal LLL portfolio.

2.1 Establishing a continuing education programme

Every year, plan your training programme for the coming year with your immediate supervisor or a higher-up, for example during your performance review (P&G at UMC Utrecht or B&O at UU). At a minimum, the report of your performance review or your LLL portfolio should contain the following:

- the date of the meeting with your supervisor,
- the name of your supervisor,
- a brief description of your continuing education activity/activities,
- how each activity can contribute to replacing, reducing, or refining animal experiments,
- how each activity will affect your carrying out or improving your professional tasks,
- the date by which the training is supposed to take place.

2.2 Required time commitment

The minimum time you are expected to spend on developing your knowledge is indicated (in hours) in table 1. In the context of LLL the minimum annual requirement is averaged over three years. If you hold several positions as listed in Table 1, then the position with the greatest number of required hours applies. For example, if a designated veterinarian has completed the required number of hours, they have also satisfied this requirement for their position as a researcher.

Table 1: Minimum requirement (in hours) for registration or reregistration as a qualified person with AWB Utrecht, including the portion that must result in a certificate of participation or exam

	Animal caretaker	Animal technician (MBO-4 or HBO)	Researcher	IvD member	Designated veterinarian
Annual average (hours)	8	8	16	24	24
Per three years	24	24	48	72	72
Share requiring certificate/exam	33%	33%	33%	33%	33%

2.3 Registering as a qualified employee

2.3.1 Basic registration

After completing your training as animal caretaker or animal technician, or as a researcher qualified under Article 9, you must register as a qualified employee with the AWB. Fill out the bilingual [Registration as a researcher](#) form, which can be found on the AWB website, and send it to the AWB along with copies of the necessary diplomas and/or certificates. The AWB will register you as qualified. This registration is valid until the fourth annual registration interview after graduation.

2.3.2 Reregistration

As a registered qualified employee, you can request a reregistration through your department's LLL coordinator at the beginning of every calendar year, during the meeting between the AWB and representatives from each department that takes place between January and April about registering the past year's animal experiments. The coordinator will discuss your LLL portfolio during this meeting with the AWB. Based on your portfolio, the AWB will determine if you have met the requirements in the previous three years, and thereby whether to extend your registration as a qualified person. Therefore, you should apply for reregistration at least every three years.

2.3.3 Insufficient continuing education

If it turns out during the reregistration process that you have not had enough continuing education to meet the minimum requirements, your registration will be revoked. Your name will be deleted from the list, and your status 'inactive'. At this point, you will no longer be qualified to design or conduct animal research, or to care for or carry out procedures on laboratory animals. You can re-activate your registration by spending the required number of continuing education hours, such as by taking a refresher course. Until then, you may carry out certain work tasks under supervision for an agreed-upon period, after receiving permission from the AWB. The AWB will put its permission in writing using the bilingual [Application for internship](#) form.

2.3.4 Registration from another institute with an establishment licence for animal experiments

If you come from another institute to an institute supervised by the AWB Utrecht, then you can bring your LLL portfolio for the past 3 years, and register with us for three years. If you have not maintained an LLL portfolio, or if you have not had sufficient continuing education in the last three years, then the conditions in 3.4.3 above apply. If you have been qualified for less than 3 years, then the conditions for basic registration also apply.

2.4 Ways to keep your knowledge up to date

Below is a list of examples of continuing education that can be put in your LLL portfolio. If you're not sure whether a particular course counts towards the LLL portfolio, ask the AWB.

2.4.1 Theoretical continuing education

Examples of theoretical continuing education include:

- attending congresses, webinars, and seminars in your field that add to your understanding of animal models, the 3Rs or research design,
- attending animal-science congresses, seminars and colloquia,
- taking courses (face-to-face or online) that add to your understanding of animal models, the 3Rs or research design,
- participating in meetings and workshops (face-to-face or online) with 3Rs-related training, competence or job-specific qualifications as a central theme,
- participating in species-specific courses that qualify you to work with an additional species,
- reading articles in laboratory animal science journals and books that upgrade your knowledge in the field,
- using an ARRIVE scan to analyse scientific articles that describe an animal experiment, whether or not they are from the field of laboratory-animal science.¹

2.4.2 Practical continuing education

Examples of practical continuing education include the following:

- learning an EPA that has a theoretical component or otherwise increases knowledge of anatomy, physiology or pathology (the assessor determines the number of hours of professional development in the training course that apply),
- participating in a work visit or excursion to another licensee or establishment licence holder, during which you acquire new information, observe procedures or take a tour.

¹ An ARRIVE scan is a review of an article, checking that it contains all the information necessary to see the real value of the research presented in the article, using the [ARRIVE guidelines 2.0](#).

3 Guidelines for Establishing Competency

As stated in the policy, employees or trainees may perform tasks and/or procedures as part of experiments on animals. The term we use for such a task or procedure is Entrustable Professional Activity (EPA). You may not perform an EPA independently until your competency in it, has been established.

3.1 EPAs

The EPAs in which you are competent go into your portfolio. If you performed an EPA on a work protocol (WP) within 3 years previous of the date this regulation takes effect, then you may add this EPA to your portfolio at level 0, unless you turn out to have insufficiently mastered it. You must be trained and assessed for new EPAs, in accordance with the LLL policy.

3.1.1 Establishing EPAs

An EPA is a professional activity in your everyday work as a qualified employee, which you are entrusted with carrying out independently. You define the activities themselves in consultation with the AWB. You can do this, for example, when filling in table 4 of the WP, in which you summarise the plans for the experimental procedures an animal will undergo. EPAs are classified as 'simple' or 'complex'. This is partly set out in the Experiments on Animals Decree ([article 8](#)) in combination with the Experiments on Animals Regulation ([article 6](#)), as a working out for implementation of the Dutch Experiments on Animals Act (Wod). Here a distinction is made between animal technicians and animal caretakers and thereby a corresponding distinction in the degree of qualification to do simple and complex procedures. In addition, EPAs can be drawn up for the various tasks involved in caring for animals and monitoring their health.

The AWB will make a list of applicable EPAs available. If your EPA is not on the list, please notify the AWB. Refer to a Standard Operating Procedure (SOP). The requirements for the SOP are on the available with the EPA list on the AWB website. The level of entrustment in you is explained for each level in section 3.2 and the assessment procedure in 3.3.

3.1.2 Transfer of EPAs and 'nesting'

Sometimes a complex procedure comprises several simple operations that can also be performed separately at another time. These are known as 'nested' EPAs. If this is the case, then you should make it clear in your SOP. Thus, procedures from another SOP can be incorporated in one SOP (see figure 1). The separate procedures can and must be demonstrated in the assessment of the more complex procedure.

Entrusted Professional Activity (EPA)

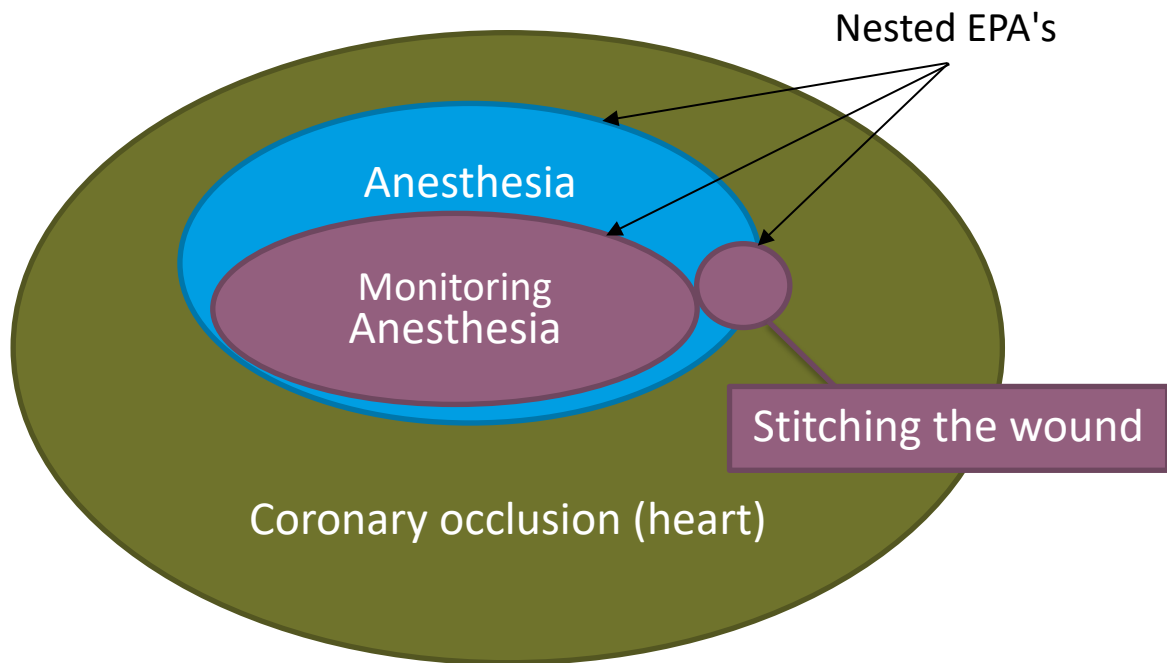


Figure 1: Simple procedures such as suturing a wound, that are part of a complex procedure, such as inducing a focal ischaemic heart attack by occluding a coronary artery. The separate procedures that can be learned individually are nested EPAs in the complex procedure. Someone who can induce a coronary occlusion is presumed to also be able to monitor anaesthesia.

Lastly, a number of EPAs may be combined, such as carrying out a welfare check while caring for animals.

3.1.3 Function-specific EPAs

In addition to competency at the level of a particular procedure, the AWB can also require competency in a number of necessary function-specific tasks. These tasks arise from Dutch or European law, or from recommendations arising from these laws or from other developments in the field, policy documents of the licensee or other relevant sources. These competencies are established by the AWB, disseminated via the newsletter and LLL coordinator, and added to the EPA list. The list will also indicate the deadline by which employees are required to have these competencies.

3.2 Levels of trust in competency in an EPA

We differentiate 6 levels of trust in the ability (competence) to carry out an EPA, from level 5 (not yet competent in practice) to level 0 (complete trust that one is competent to work independently). If you are present at a procedure, but have not (yet) acquired the practical competence, you are considered competent at level 5. Level 0 is the minimum level at which you can perform a procedure reliably and independently, and to be allowed to sign off the entrustment level. Especially in the run up to level 4, but later as well, the AWB encourages training methods using animal-free alternatives such as virtual reality, plastinates or cadavers of animals killed for other reasons. For help and advice, you can contact

the [3Rs-Centre](#). Table 2 and Figure 2 explain in more detail how to increase your competency and the points for assessment.

Table 2: Levels of competence of EPAs with descriptions of the training requirements and the assessment points. The supervisor can allow a trainee to skip levels, but must however always make an interim assessment.

Level	Description
5	<p>Trainee observes an EPA and works on the theoretical and practical basis without using animals.</p> <p>An employee or intern, now called the trainee, who has not yet provided proof of either a theoretical background or the ability to physically perform a given competency, first demonstrates one or both. No live animals are used to teach this EPA.</p>
4	<p>Trainee performs the EPA with their supervisor.</p> <p>The trainee, who is learning an existing EPA but one that is new for them, and who has sufficient knowledge and skill to work with animals, begins at level 4. The EPA or parts of it are performed under constant supervision and coaching.</p>
3	<p>Trainee performs the EPA under direct supervision.</p> <p>The trainee knows all the steps and performs the entire procedure themselves, with the supervisor observing and coaching the crucial steps. The supervisor may be performing other tasks in the immediate vicinity while the trainee is carrying out this procedure.</p>
Assessment	<p>There is always an assessment and discussion using an assessment model before the trainee is entrusted with the EPA at level 2 or 1.</p>
2	<p>Trainee performs the EPA with supervision at an appropriate distance.</p> <p>The trainee performs the procedure independently, but the supervisor is close enough to be called over to intervene. The time within which the supervisor can be at the spot will depend on the procedure, but is never more than 10 minutes. The supervisor remains directly responsible and checks the result.</p>
1	<p>Trainee performs the EPA, with the supervisor reachable for consultation.</p> <p>The trainee carries out the procedure independently, with the supervisor available for consultation (this may be by telephone). The trainee and supervisor together are responsible and may sign off on procedures.</p>
Assessment	<p>The trainee is assessed, in order to be entrusted with the EPA at level 0. An assessor is involved as well as the supervisor.</p>
0	<p>Employee performs the EPA independently.</p>

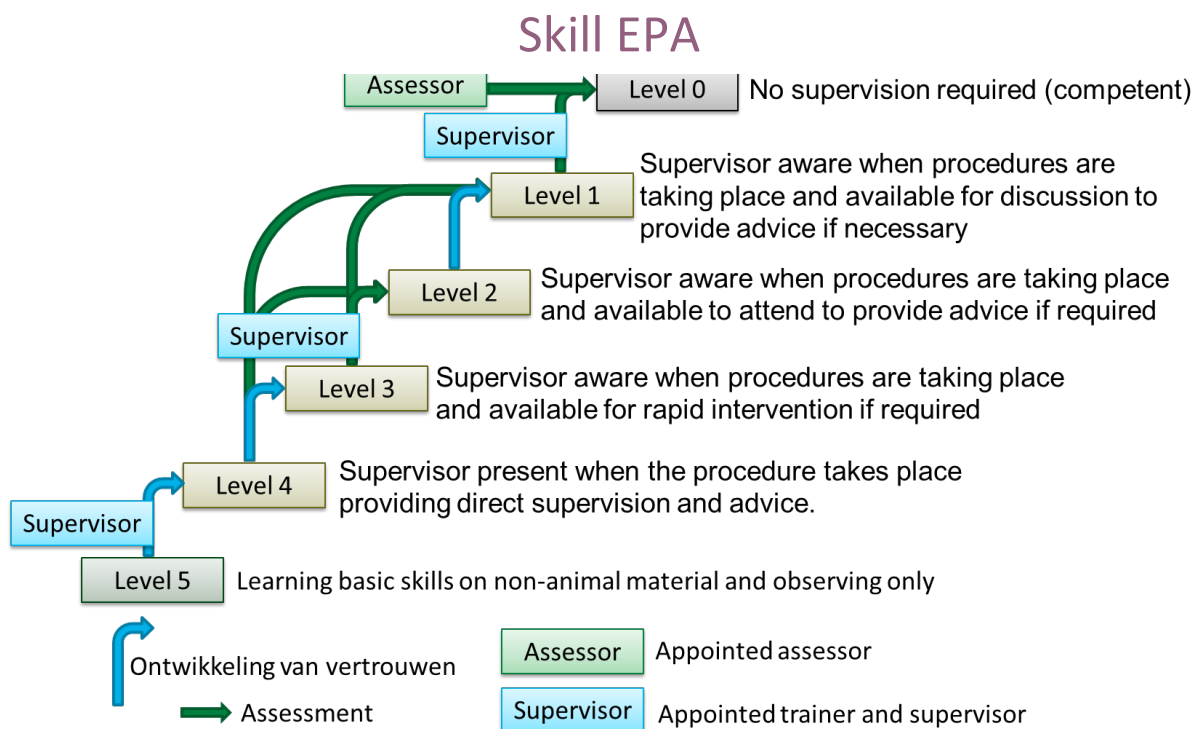


Figure 2: chart of competency development in employees and interns (trainees). Depending on their level, the trainee receives assistance or supervision. Progressing to the next level is based on informal internal assessments by the supervisor and formal assessments by an assessor. Levels between 4 and 1 can be skipped in the case of simple techniques. A supervisor or assessor must be appointed by the designated competency officer. The supervisor or the AWB may require the trainee to demonstrate basic skills before being allowed to begin an EPA training, in which case the trainee is still at level 5.

3.2.1 Who to train, and when

The policy states that only EPAs that are necessary must be learned, and therefore the need to learn a skill must be established before someone is taught this EPA and animals are used for that purpose. The AWB will decide, if desired in consultation with the supervisor and the trainee. The decision is based on criteria such as the number of times the EPA is expected to be performed, availability of other competent staff, the trainee's experience with similar EPAs, etc.

A competency is established twice, once to allow someone to work at level 1 or 2 and again to establish trust in their competency (level 0) to perform an EPA. The criteria for both assessments are the same, except that the full independent level does not need to be acquired for level 2 or 1. While at levels 2 and 1, a trainee gains experience until they can be entrusted to carry it out independently, in the supervisor's opinion. An assessor will then finally evaluate whether the trainee is competent (level 0). See figure 2 of the policy.

3.3 Assessment

3.3.1 Quality of the supervisor and assessor

Only training courses and assessments by appointed supervisors and assessors are recognised by the AWB. Supervisors and assessors are appointed by the competence officer. They have demonstrable

knowledge of skills training and assessment. Moreover, the supervisor has mastered the EPAs to be trained at level 0. In preparation for setting up a training programme for supervisors and assessors, the DCO will appoint provisional assessors and supervisors. Supervisors and assessors are appointed for three-year terms, which are automatically extended if the supervisor/assessor has performed at least two trainings or assessments in these three previous calendar years (regardless of which EPA). This only applies to new trainings for level 2 or 1, or assessments for level 0 (see green arrows in figure 2), no peer-to-peer reassessments.

The appointment as supervisor and assessor applies to every EPA you have mastered (level 0). You may train an employee or trainee in the same EPAs. You may also assess an employee or trainee in these EPAs, as long as they were trained by someone else. In addition, you can be asked to assess EPAs that correspond with the EPAs in which you are competent, such as:

- inserting a cannula in a different blood vessel to one you are experienced in;
- an operation involving transplant of a different donor organ to one you are experienced with, in which the construction of anastomoses is crucial;
- placing an electrode in the brain stereotactically, while your experience is in inserting a brain cannula.

3.3.2 Quality of the assessment

To ensure the quality of the assessment, we use assessment forms for procedures. This method is referred to in European directives as *Direct observation of procedural skills* (DOPS) after the DOPS [database](#) of the UK's Laboratory Animal Science Association (LASA). It enables the objective and transparent gathering of information that makes it possible to assess the trainee's degree of independence, and consequently the degree of confidence that can be put in the quality of the procedure carried out by the trainee. The quality criteria for this assessment are listed in Table 3. The DOPS form and any modifications to it are made in consultation between the supervisor and assessor. If there is no assessment form available, it will be made available before the training course. The assessment model is always shared with the trainee before the training courses (or as early in the training process as possible).

Table 3: Quality requirements for assessment

Valid	On the basis of the assessment, a person can be entrusted with the EPA without any likely risks to the animal's welfare or the quality of the experiment.
Reliable	The moment of assessment or a change of assessor has no effect on the chance of passing.
Transparent	It is clear to all how and with what points for attention the assessment takes place, and what can and cannot result in trust.
Workable	The assessment is easy to carry out with limited observation, and does not involve disproportionate expenses or equipment requirements.

To establish trust in a valid way, the assessor evaluates theoretical knowledge, skill and attitude (table 4).

Table 4: Conditions for trust.

Theoretical knowledge		The candidate has the necessary knowledge to carry out the action.
Skill		The candidate has the skills necessary to carry out the action.
Attitude	Integrity	The candidate is open, honest and shows respect for the animal.
	Trustworthiness	The candidate works accurately and predictably.
	Modesty	The candidate knows their limitations and asks for help if necessary.

3.3.3 Reassessment

The idea underlying reassessment assumes that you are still competent, but that mutual reassessment will allow colleagues to give each other tips for refinement and will limit deviations from the SOP. A reassessment is peer-to-peer, done by colleagues, which means that another person at level 0 besides an assessor or supervisor may carry out the reassessment. For reassessment, use the AWB's reassessment form and keep the completed form for your LLL portfolio.

The following guidelines apply to reassessment:

- **If you perform a procedure at least twice per year:** have yourself reassessed by a colleague within two years of your last assessment. This reassessment will also record how often you have carried out the EPA since their last assessment, which creates a track record.
- **If you last performed a procedure between one and five years ago:** have yourself immediately assessed by a colleague the next time you carry it out.
- **If you have not performed a procedure in the last five years, or if you or your reassessor have doubts about your competence:** request a training and assessment plan from an appointed supervisor, who in this case can also act as an assessor. Until competency is proven again, it will be listed at level 3, 2 or 1 in consultation with the supervisor.

3.3.4 Developing competency during an experiment

You can work on developing competence within an ongoing experiment, but only after receiving permission from the AWB, with the training explicitly mentioned in the work protocol of the experiment involved. In particular, you can do training from level 2 to 1, as well as the level 0 exam (for the sake of reduction) during experiments. It must be clear that this does not pose a risk to the integrity of the experiment – for example because it has exclusion criteria (or additional ones) that ensure there is no risk – and that the groups are large enough to compensate for the additional risk of drop-outs. If there is no explicit mention of training during the experiment, a work protocol can only proceed if those carrying out EPAs are competent in them at level 0.

3.4 Exceptions in competency assessment

In the following situations, you and the DCO will agree on where training in a competence takes place, and/or how competences are established:

1. If an EPA was or is being learned elsewhere, or is adopted from elsewhere.
2. If a new EPA is being developed in-house.

3. If only one person within the institute has mastered an EPA.
4. If an EPA has only been mastered by one or more specialists (medical or otherwise) who do not have the qualifications to work with laboratory animals.
5. If an EPA is being carried out by a guest researcher employed by an external licensee.

4 Maintaining Your LLL Portfolio

You are responsible for keeping your own LLL portfolio up to date, using existing educational software. If this software is not yet available, you can find [Excel spreadsheets](#) on the AWB website or keep a record of your LLL activities yourself. Besides some basic information, such as your name and employee number, your LLL portfolio contains records of activities which make it possible to assess whether you are sufficiently knowledgeable and competent to stay registered to design and carry out experiments on or to work with laboratory animals. You should keep certificates and other proof of acquired knowledge and competencies in such a way that they are easy to find if the AWB needs to check your LLL portfolio.

4.1 Continuing education

Continuing education is expressed in number of hours of active effort. For each activity you have done, keep track of at least the following:

- the name or a brief description of the activity,
- the date the activity was completed,
- the organisation where the activity was given (if applicable),
- the number of hours (effort) in the activity,
- if a certificate of attendance was issued,
- if there was a test to establish what was learnt, and if so, if you passed this test,
- what you learned and the significance it has for your work tasks involving animals.

Your LLL portfolio must always be available for your department's LLL coordinator. The coordinator shares the data annually with the AWB.

4.2 Training

You enter the EPAs you have mastered, and at what level, in your LLL portfolio. This can be viewed in the competence dossier that each department create. In this dossier levels 4 and 3 are combined, as well as 2 and 1.

5 Other Matters

In the event of uncertainties or ambiguities regarding competence, competency or knowledge, which are not dealt with in this guide, the DCO's decisions will be binding. The DCO makes decisions on behalf of the establishment licence holder. If necessary, the DCO will ensure that any additions to this document are incorporated and adopted by the AWB.

6 Implementation Timeline

The LLL policy will be implemented over a period of 3 years and 9 months. At several points in the process the requirements will be tightened and experiences from previous phases will be considered. These points are shown in figure 3 below.

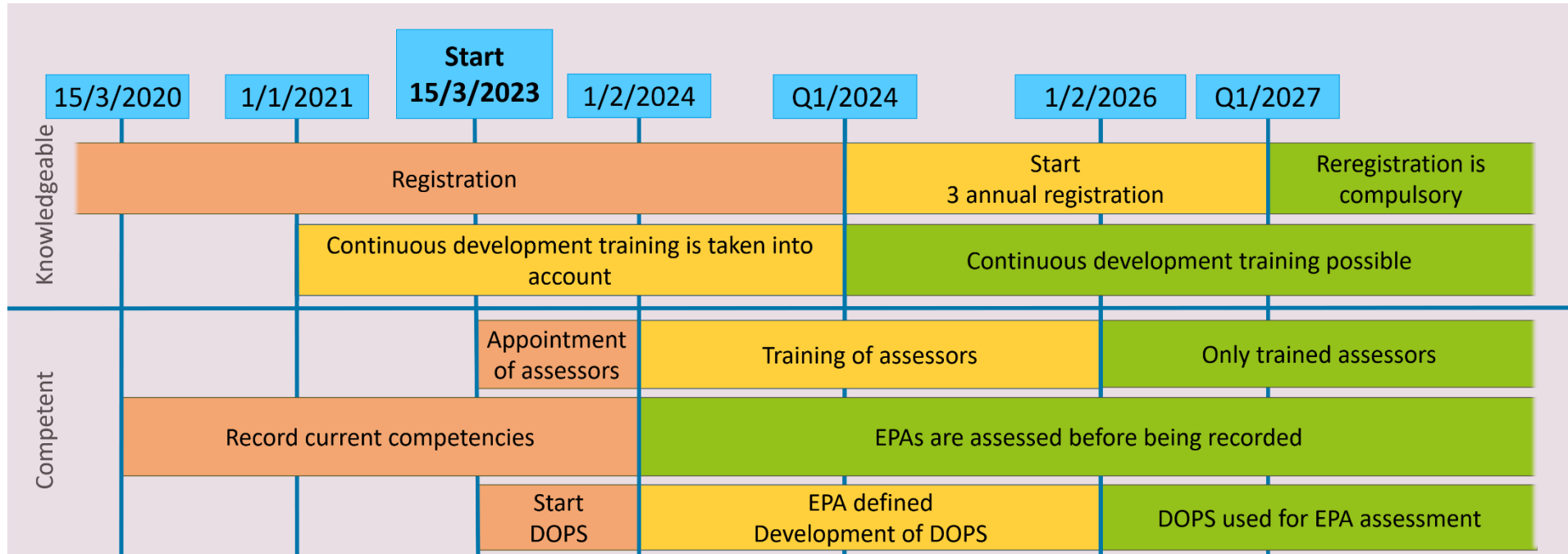


Figure 3: Implementation schedule for LLL policy.

Description of the phases:

- **Registration:** If you are qualified, you will be registered as such;
- **Start 3-year registration:** you can ask for re-registration or 3-year registration as long as you have fulfilled the requirements for advancing your knowledge/skills;
- **Re-registration is compulsory:** Re-registration is for 3 years. If you do not have it, or if your initial registration or re-registration has expired, your status becomes inactive;

- *Continuous development training is taken into account: Continuous development activities in this period can count towards an initial re-registration, but only if they were completed within three years of registration;*
- *Continuous development training possible: Continuous development training courses can be taken. It is clear to an employee what activities will help them to develop;*
- *Appointment of assessors: If you want to assess or train someone as an assessor, you will be assigned based on experience and your request, without strict criteria;*
- *Training of assessors: Assessors are trained and reappointed through an internal process;*
- *Only trained assessors: Assessor training is a requirement if you want to assess or train a competency;*
- *Record current competencies: starting in this period, you may designate yourself in cooperation with your LLL- coordinator as competent on all active procedures you carry out independently and without supervision in WP's that start within this period;*
- *Assessments of EPAs: If you want to carry out a professional activity (EPA) independently, but do not yet have a level 0 competency, the EPA must be assessed by an assessor. You will be assessed by a peer if you wish to continue carrying out, or wish to carry out again, an EPA that you have mastered to level 0. You keep track of assessment in your LLL-portfolio.*
- *Start DOPS: We will begin development of Direct Observation of Procedural Skills, together with the assessors in training. DOPS are assessment documents with which assessors and trainers can establish your competency and the degree to which you have mastered an EPA and thus can be entrusted to carry it out;*
- *EPA definition & development of DOPS: EPAs are defined and put into a complete list. The assessors and trainers will develop an SOP and DOPS for all EPAs;*
- *DOPS used to assess EPA: In each experiment it is clear what the EPA is and there is a DOPS with which an assessor can establish if you have mastered it.*

Changes by date:

- *15/3/2020: Reference date for initial competences (3 years before start);*
- *1/1/2021: Starting date for validity of evidence for continuous development training;*
- *15/3/2022: Policy takes effect, this implementation begins, first assessors are appointed, first DOPS developed;*
- *1/2/2024: First assessor trainings start, thereby also the start of implementation and continuing development of DOPS, EPAs must be assessed where not yet established and there is no DOPS required for it yet;*
- *Q1/2024; From now on, you can reregister yourself for three years;*
- *1/2/2026: You may only assess an EPA if you are a trained assessor, and EPAs are assessed based on DOPS;*
- *Q1/2027; without reregistration you are no longer allowed to be actively involved in animal research.*

7 Abbreviations and Definitions

Assessor	Person charged with assessing someone's competence in a professional activity
AWB Platform	Association of affiliated AWBs within the Dutch Association for Laboratory Animal Sciences (DALAS)
AWB (Dutch <i>lvD</i>) 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 (activity)	Competent to carry out an activity
Competent (position)	Having both knowledge and skills to carry out an activity, including the desired attitude
DOPS <i>Direct observation of procedural skills</i>	First-hand observation of an action or procedure during an assessment
EPA <i>Entrustable professional activity</i>	Defined professional activity which a qualified person is entrusted to carry out
FELASA <i>Federation of European Laboratory Animal Science Associations</i>	Umbrella organisation of European associations working within laboratory-animal science.
DCO Designated competency 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 (Dutch: <i>functionaris competenties</i>)
Knowledgeable	Has up-to-date knowledge of one's required work tasks, and of the ongoing developments around it.
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 basic 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 (<i>Wet op de dierproeven</i>) Experiments on Animals Act	Dutch legislation protecting animals used for education and scientific research
WP Work protocol	Description in a project licence of a separate experiment using animals
3Rs Replacement, Reduction, Refinement	Basic principles of laboratory animal science in conducting sound experimental research involving animals, in which animal testing is avoided if alternatives are available, the number of animals used is limited and the procedure has been designed for optimal animal welfare

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