



Guiding Principles for Supervision and Assessment of Competence as required under EU and UK legislation

2nd Edition – July 2016

Note:

LASA originally produced guidance on Supervision for Personal Licensees in 2007. This new Guidance however supersedes the (LASA 2013) Guiding Principles on the Supervision Requirements for Personal Licensees. A report by the LASA Education, Training and Ethics Section. (M. Jennings and M. Berdoy eds.).

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Members of the LASA Education, Training and Ethics Section:

Manuel Berdoy (joint convenor), University of Oxford
Elliot Lilley (joint convenor), Research Animals Department, RSPCA
Anne-Marie Farmer, University of Cambridge
Angela Kerton, Imperial College, London
Beverley Law, University of Leeds
Lynda Noddings (observer), Home Office
Patrick Sinnott-Smith, Pfizer
David Smith, previously of AstraZeneca
Clare Stanford, University College, London
Lucy Whitfield, Royal Veterinary College

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Updates:

Guidelines may be updated to reflect changes in practice. Please check on the website that you have the latest version.

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This publication superseded the "*LASA 2007 Guiding Principles on the Supervision Requirements for Personal Licensees. A report by the LASA Education, Training and Ethics Section. (M. Jennings and M. Berdoy eds.)*" which was written before the EU Directive 2010/63/EU

2nd Edition: July 2016 (this publication)

Good training is essential to ensure compliance with ethical and legislative requirements and to facilitate good science and animal welfare. The emphasis in both new EU and UK regulations is on supervision and the demonstration of competence. This document provides a summary of the key principles and responsibilities that need to be addressed when developing processes to deal with these issues at the establishment level. Although this document is designed primarily for use under EU and UK regulations, the principles within may be applicable in countries with different regulatory frameworks.

Responsibilities under the ASPA

- The Holder of the Establishment Licence (PELh) must ensure there is an effective system for training and development, including supervision and assessment of competence for **all** those working with animals.
- The Project Licence holder (PPLh) is directly responsible for ensuring that the appropriate level of supervision is provided for all personal licensees (PILh) working under the authority of their project licence.
- Each Personal Licence Holder (PILh) must keep records of their supervision, competence and continued professional development (CPD).
- The Named Training and Competence Officer (NTCO) provides oversight of the process.
- Additional inputs will come from Animal Welfare and Ethical Review Body (AWERB) the Named Animal Care and Welfare Officer (NACWO) and the Named Veterinary Surgeon (NVS).

Training plans and records

- A training plan/record should be created for each trainee outlining: knowledge/skills required; dates of training; and competence achieved. It should also record reviews of training and competence and any CPD undertaken.
- Training records must be available to the PPLh, NTCO and all other Named Persons, relevant managers and, upon request, made available to the local Home Office inspector or submitted to the Secretary of State.

Trainers, supervisors and assessors

- Must have appropriate, up-to-date, knowledge and be competent in the techniques they are training/supervising/assessing.
- Must be able to impart knowledge and skills, i.e. have appropriate teaching skills.
- Must have sufficient seniority and/or authority with regard to their knowledge and experience.
- The act of supervision, but not the *responsibility*, can be delegated to an appropriately qualified person.

Competence

- The criteria for competence need to be defined so that trainee and trainer understand the standard of performance that is required.
- The focus needs to be on objective assessments of practical skills and knowledge, but attitudes relating to the law, ethics, and the culture of care, are also relevant.
- When assessing competence:
 - it is important to be clear about who is responsible for 'signing off' the trainee as competent, and how this is done;
 - as a general rule, the assessor must be competent in the task being assessed and, if possible, should be a different person from the trainer;
 - assessors need to have sufficient authority to perform their function properly and need to be accountable;
 - re-assessment of competence and/or 'critical self-evaluation' of competence should be built into the establishment's culture;

There must be a process to evaluate the experience, competence and training needs of new staff and those transferring from another establishment in the UK or Europe.

Ensuring an effective process (quality assurance checks)

This could include:

- Random spot-checks of either projects or individuals or targeted checks following retrospective review.
- Periodic review perhaps by an internal, objective, independent 'competency group' comprising PPLhs, representatives of those who conduct procedures and animal care staff.
- Honest, constructive feedback from peers, within a blame-free culture.
- Collaboration between trainers and assessors from different Institutes to review, discuss and formulate suitable and consistent approaches for training and competence assessment.

Good training for those using and/or caring for animals in scientific procedures is recognised as essential to ensure compliance with ethical and legislative requirements and to facilitate good science and animal welfare. This principle is embodied in the EU and UK legislation - Directive 2010/63/EU and the amended Animals (Scientific Procedures) Act, 1986: both state explicitly that staff must be “adequately educated and trained” and “that they shall be supervised in the performance of their tasks until they have demonstrated the requisite competence”. Both pieces of legislation also highlight the importance of applying the 3Rs and minimising the suffering of animals over their whole lifetime. Training that provides the knowledge and skills to do this is essential.

More specifically, the emphasis in EU and UK legislation and accompanying guidance is on the demonstration of competence and the importance of supervision in attaining competence.

Establishments will therefore require a robust framework within which training, supervision and assessment of competence can take place, with clear standards that define competence in knowledge-based and practical

This document focuses on the training requirements for personal and project licensees carrying out procedures likely to cause pain, suffering, distress or lasting harm. In the UK, formal training of prospective personal and project licensees is initially delivered through mandatory attendance of accredited modular training courses¹. These courses provide an introduction to the 3Rs², ethical, legal and practical issues, basic information about animal care, welfare, biology etc. relevant to the species and the theory relating to regulated procedures using living animals. They are not designed to produce people who are fully competent in the practical skills they require and, after their completion, personnel must apply for a personal licence before being able to develop their competencies through on-the-job training (under supervision), together with other forms of continuous professional development (CPD)³.

The intention of the Directive to facilitate free transfer of individuals, between establishments and across member states, relies on the principle that competence in one country will be accepted as competence in another. This presupposes that standards of training and competency are (or will become) equivalent and transparent throughout Europe. To facilitate this process, guidance for member states on training, supervision, and the development and assessment of competence, has been produced by an EC Expert Working Group⁴.

¹ The previous Home Office modular structure (UK Modules 1 – 5, pre 2015) has been adapted to reflect the training modules and deliver the learning outcomes listed in the EC Education and Training Framework (see footnote 4 below for reference). However, much of the content has remained similar. Courses under this new structure are also more closely aligned with accredited training in Europe, which also has been adapted to comply with the EC Education & Training Framework (e.g. FELASA accredited courses).

² 3Rs: Replacement, reduction and refinement (e.g. see www.nc3rs.org.uk/the-3rs)

³ The Institute of Animal Technology sets standards for training and competence for animal technologists and further CPD advice can be found at www.felasa.eu/recommendations/guidelines/guidelines-for-continuing-education-for-persons-involved-in-animal-experime/.

⁴ EC Education and Training Framework
http://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/education_training/en.pdf

This LASA document, was developed specifically for the UK by the LASA Education, Training and Ethics Section (ETES), in conjunction with UK trainers, members of accrediting bodies and others with an interest in training and assessment. It builds upon the EC guidance by summarising principles of good practice for supervision and competence assessment but does not cover the content or methods of delivery of training courses since these are covered elsewhere. The Appendices provide some examples of Directly Observed Practical Skills (DOPS) templates. They are not intended to be prescriptive and it is recognised that they will not be suitable in all circumstances: they are provided here as an example of the principles of how techniques can be assessed.

Details of the training-related responsibilities of different roles in UK establishments are given below.

The **Holder of the Establishment Licence (PELh)**, or **Named Person Responsible for Compliance (NPRC)**, where the establishment licence is held by a corporate body, has ultimate responsibility for education and training at an establishment. They are responsible through the **Named Training and Competence Officer (NTCO)** for making sure that all staff are adequately educated and trained and that they are supervised until they are competent. Thus, the PELh needs to ensure that an effective system for management of all aspects of training and development, including supervision and assessment of competence, is in place. Other individuals with defined responsibilities under the **Animals (Scientific Procedures) Act 1986 as amended in 2013 (ASPA)** are:

- The **Named Training and Competence Officer (NTCO)** “makes sure that everyone dealing with animals is adequately educated and trained and that they are supervised to ensure that competence is demonstrated and maintained.”
- The **Project Licence Holder (PPLh)** must ensure that: “the appropriate level of supervision is provided for all personal licensees carrying out regulated procedures under the authority of their project licence.”
- The **Personal Licence Holder (PILh)** must comply with the standard conditions on their licence. Standard conditions 17 and 20 state that a PILh must receive appropriate training and supervision and maintain a record of all supervision and declarations of competence details.

It is important to recognise that the responsibility for supervision of personal licence holders during the development of competence may differ from that of a PhD supervisor or a line manager.

The licensee will be working under a project licence and the Project Licence holder is directly responsible for ensuring that the appropriate level of supervision is provided for all personal licensees carrying out regulated procedures under the authority of their project licence (project licence standard condition 6).

Animal Welfare and Ethical Review Bodies (AWERBs) are likely to include education and training issues in their remit, and the **Named Animal Care and Welfare Officer (NACWO)**, **Named Veterinary Surgeon (NVS)** and the **Named Training and Competency Officer (NTCO)** are likely to have an input.

Home Office inspectors can ask to check records of training and supervision.

Trainers running mandatory modular courses have a role in informing PILhs and PPLhs about their responsibilities, regarding training and supervision, early in their training. They should emphasise that competence is normally required for professionals in any sphere, that modular training is only an introduction, and that PILhs need to develop and maintain their competence in all of the relevant subjects and practical skills.

Prospective PILhs need to understand that they will be working under supervision until assessed as competent to work alone and that they need to ensure that they are familiar with

the local processes in this respect. These issues should be referenced in any pre-course materials and the **accrediting bodies** should also make it clear, in their documentation, that these issues need to be covered. The assessment of applicants should include questions relating to supervision responsibilities and training records.

The whole training process (including assessment) needs to be open and transparent so that trainees fully understand what they need to achieve, and are fully aware of what and how they need to change if they do not succeed. **Good communication** between all concerned (particularly the PPLh and PILh, the supervisor/s and assessor/s) is essential, and the establishment's training framework should aim to facilitate this and ensure consistency across the organisation.

Supervision needs to cover the development of practical skills necessary for handling of animals, performance of procedures, monitoring of animals, recognition of pain, distress and discomfort and humane killing of animals (see EC Education and Training Framework for further details⁵). Good supervision re-enforces and enhances these learning outcomes and contributes to the maintenance of the establishment's culture of care. Conversely, inappropriate supervision can have serious negative consequences for the animals and the research, and may promulgate out-of-date or poor practice. It is therefore not an issue to be taken lightly and the NTCO will need to have oversight of the processes in place.

3.1 The supervision process

The importance of good training, supervision and the attainment of competence should be emphasised during the induction process for new staff and it should be made clear at an early stage that people are expected to ask for help and advice.

Timely reminders should also be given for someone to be trained and to update their training records; whenever new skills or new species are introduced or when competence in a particular skill needs to be updated or refreshed (e.g. after long periods of absence or other significant breaks in work).

Each trainee should have a **training plan** and/or **record** agreed locally between the NTCO, PPLh and PILh, which should:

- Outline the knowledge-based and practical skills they require.
- Provide a clear indication of the standards that define competence in each skill, linked to the species in which the procedures will be used, and the level of supervision required in each case (see below).
- Provide a record of the dates when training was provided, when work was done under supervision and the dates when competence was achieved.
- Incorporate regular reviews of training, competence, CPD and their personal development plan (see 4.4.).

Training records may be kept by the individual member of staff and/or centrally at the establishment, but must be available to the NTCO, PPLh, NPRC, other managers and, upon request, made available to the local Home Office inspector or submitted to the Secretary of State.

Examples of training and supervision plans are given in **Appendix 1**. The supervisor initially needs to be present when the trainee carries out procedures in order to provide direct supervision, advice, and to intervene if there are problems. The level of continuous 'hands on' supervision required may then decrease, gradually, as the trainee develops their skills. The speed at which this transition takes place will vary, subject to the ability of the individual and their pace of learning.

⁵ EC Education and Training Framework
http://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/education_training/en.pdf

3.2 Selecting a supervisor

A PPLh cannot delegate the responsibility for ensuring that PILhs are adequately supervised, but the process of supervision can be delegated to an appropriately qualified person. The selection of the 'right' individuals as supervisors is crucial - the essential qualities are that they should:

- Have appropriate and up to date knowledge and be competent in the techniques they are training/supervising.
- Be able to impart knowledge and skills to others, i.e. have appropriate teaching skills.
- Have sufficient seniority and/or authority with regard to their knowledge and experience and the local arrangements for training, supervision and assessment of competence.
- Understand the reasons why training and supervision are important.
- Have good interpersonal skills.
- Know their own limitations.
- Be committed to ensuring good practice as well as ensuring compliance with the law.

It is unlikely that there is one 'best' person to supervise all the requisite competencies. The most appropriate in each circumstance will depend on:

- The type of skill to be developed.
- The level of knowledge, understanding and practical ability of the trainee.
- The supervisor having current PIL authority for, and skill in, the technique or procedure to be supervised, so that they can step in if there are problems. The local management structures and available resources.

The NTCO, in conjunction with the NACWO and/or NVS, should be able to provide advice and/or identify someone with the required skills. Establishments/research groups may also find it useful to keep a list of people who are capable of providing good supervision for specific (and specialist) techniques or competencies. The Home Office inspector may also be a helpful source of such advice.

In some cases, there may be only a few people in the country carrying out highly specialist procedures, which can make training, supervision and assessment of competence difficult. Communication with experts in the technique is essential and a customised approach should be adopted to suit the situation. Information sources, such as Compmed and Vets On Line (VOLE), can be useful sources of advice for identifying specialists in particular techniques. It would be useful to develop a register of where specialist expertise is available.

For example, when learning a specialist technique, it may be possible to send the scientist and an animal welfare person (e.g. vet/senior animal care worker) to an expert for advice, training and assessment. Once they are trained and competent, they would be able to train/ supervise others, in-house. Alternatively, an expert could be brought in to carry out training and to assess the trainee's performance of the procedure. It is inevitable that circumstances will vary but, if possible, an independent view of the level of competency should be sought, for example from a vet or other competent person, even where there is limited expertise available for a specialist technique.

4.1 Defining competence

The criteria for competence required for each practical skill needs to be defined and made available so that benchmarks can be set within the establishment for assessment of competence and determination of the successful completion of the supervision period. This will enable consistent judgements to be made by trainers/supervisor and assessors within establishments and, when more widely agreed, consistency between establishments should be achievable. Assessment criteria will also be required for informing trainees about what is expected of them. They also provide transparency and clear justification, for both trainer and trainee, when someone requires ongoing supervision, training and assessment. It is important that all competence criteria are clearly defined, transparent and widely disseminated, so that judgements and agreement can be reached as to the detail of the assessments and level of competence required. This will also help to facilitate the movement of personnel between research programmes and/or establishments.

The focus needs to be on the objective assessment of practical skills, but knowledge and attitudes relating to the law, ethics, the 3Rs, the scientific process, local 'rules' and the culture of care, are also relevant and need to be taken into account.

A useful approach is to break each particular procedure down into its individual components (at an appropriate level of detail), covering both the theory and practical elements (e.g. handling, restraint, asepsis, pre and post-operative care, euthanasia, experimental outcomes and data quality) and to assess each of these separately. This may simplify the process of managing training for a large number of persons, as some of these assessments (eg handling) are common to many trainees and can be done early on in training; others (eg anaesthesia) will be needed only by a limited number of learners, so may be done at a later stage. Some examples are given in **Appendix 2**. Trainees then need to **understand the standard of performance** that is required for each component. They need to know why things are done in a particular way as well as what should be done. The end result should always be that each PILh has a signed and dated record of competence for each technique they plan to use and of the species with which competence was achieved.

Some prospective licensees may never achieve the level of competency required in one or more procedure or species for a variety of reasons; for example, their physical dexterity may not be adequate. This needs to be recognised and, rather than providing unlimited extensions of the training and supervision periods, the trainee should be redeployed to procedures that better match their particular skill set.

4.2 Competence of trainers, supervisors and assessors

Not all those who are competent to perform a technique will necessarily be good trainers, supervisors or assessors of others. They may need additional training, to develop their communication skills, for example. It follows that there also needs to be provision for 'training for the trainers' and 'training for the assessors' with the expectation that only those 'competent to train' or 'competent to assess' should undertake training and assessment respectively. The NTCO (with the support of the PELh, other 'named persons' and appropriate resources) should be responsible for establishing the training framework and identifying trainers for each technique or procedure.

4.3 Responsibility for assessment of competence

It is important to be clear about who is responsible for 'signing off' the trainee as competent, and how this is done. The PPLh is ultimately responsible for ensuring PILhs are supervised. However, the actual training, supervision and observing of an individual carrying out a procedure or husbandry task, and verifying that it is being done in a competent way, can be delegated to someone who is competent to train and undertake the procedure.

The assessor must be able to determine whether or not the task being assessed is being undertaken competently and, if possible, should be a different person from the trainer. It may be appropriate for different aspects to be assessed by different people to ensure the assessor has the right skills and avoid placing an undue workload on any one individual. For example, the animal handling skills could be assessed by an experienced NACWO or senior animal technologist, anaesthetic techniques by a vet and the actual procedure e.g. oral gavage, by an experienced PILh.

As with supervisors, assessors need to have sufficient authority to perform their function properly and need to be accountable (if a trainee signed off as competent subsequently has problems, this could reflect on the trainer/supervisor/assessor).

All those concerned need to understand that assessors will only sign-off people as competent if they are confident that the required standards have been achieved.

4.4 Maintaining competence and the need for reassessment

Competence is not a steady-state – it can change and therefore consideration of the need for reassessment needs to be part of the establishment culture. Staff should be encouraged into adopting a culture of 'critical self-evaluation' and to make sure they do not perform techniques if they are uncertain about anything. The trigger for reassessment must not **only** be the occurrence of an 'extreme event' i.e. as a result of unexpected outcomes or deaths. There are several more appropriate categories of trigger for example:

- A time-fixed event e.g. linked to annual appraisal or project review (interim, retrospective); or linked to 'risk factors' such as complexity of technique, severity of procedure, or performance pressures.
- A long time interval since the technique was last performed.
- Use of a new or modified technique, including refinement or new equipment.
- A change in data quality or something not going right, e.g. one or more adverse events observed by a colleague or animal care staff.

There needs to be a balance between the optimum time for periodic review and resources that are available to carry out reviews and any consequent re-assessment/re-training. The ideal situation would be to encourage a self-assessment culture which encourages trainees to ask themselves:

- Do I feel that I can do the technique?
- Would I be comfortable with someone else watching me?

- Would I be happy if a Home Office inspector watched me?

This self-appraisal approach should be encouraged at all stages of the training, supervision and competence process and become part of the culture of care.

4.5 Dealing with poor performance

It is also important that establishments have a mechanism in place to **ensure that incompetence of any member of staff (or inability to gain competence) is recognised, reported and dealt with quickly**. All those working with animals have a responsibility to take action if they feel there is a lack of competence. In most cases an informal approach to the NACWO, NVS or NTCO will lead to remedial action. Establishments should provide a further mechanism to allow confidential reporting (e.g. to the PELh perhaps through the AWERB or an anonymous whistleblowing procedure).

4.6 Assessment of staff transferring from another establishment in the UK or Europe

All establishments *must* have a mechanism for ensuring that any incoming member of staff who is likely to be involved in animal work - either caring for animals, planning projects, carrying out procedures or killing animals – is captured within the training framework. This may be more difficult in academic establishments where there may be a rapid throughput of people. HR departments and all relevant senior managers need to be made aware of the requirement for training, which should be advertised in staff induction packs, on intranet sites and in other easily accessible information.

It is helpful to have a single point of contact to whom all new starters can be directed on arrival. The NTCO is likely to be the most appropriate person, given their role. Also, the HO Guidance states that the NTCO should ensure that everyone planning to work with animals under ASPA at their establishment is made known to them at an early stage in order that they can discuss their training needs with them.

In order to assess the competence of new staff, information on the skills they have and the work they have done (including when they last undertook the work) is essential: face to face discussion is recommended for this process. A list of qualifications, taken on trust, is inadequate; veterinary and medical qualifications should not obviate the need for this process. It would be helpful to develop a standardised format for training records to facilitate transference across Institutions and Member States. The following information is the minimum needed:

- Details of previous training (e.g. Federation of Laboratory Animal Science Associations (FELASA) accredited training modules) including the training provider, when and where training was carried out, and level of competencies achieved.
- How long the individual has been involved with animal work and how long since they last performed the tasks/techniques they want to use.
- A list of publications to indicate the use of *in vivo* techniques.
- Whether they understand the national legislation in the country where they will be working.
- Their ability to understand and communicate in the local language (if the primary language is different).

In addition, all new starters/transfers-in will need an induction to introduce them to local rules and working practices. A new person needing to work in more than one unit within the establishment should undergo the induction training for each unit. The establishment will also want to appraise and confirm their practical competency in order to make sure they are familiar with local rules and standards.

4.7 Ensuring an effective process

Establishments need to take training and competency seriously, ensuring that competency is confirmed rather than just assumed.

Training needs to be seen as a core process, which is an accepted part of a culture of professional compliance and normal employee induction. The whole system for ensuring competence needs to be 'fit for purpose', with consistency in all practical processes and records. There must be some method of quality assurance (QA) to ensure that the system is achieving the intended outcomes with respect both to the practical aspects (training, supervision, assessment and ongoing monitoring) and to the record keeping and other documentation. This could be done by one or more of the following approaches:

- Spot-checks, which could be random or targeted, selecting one project or one person from each research group to 'audit': these could be carried out when looking at the outcomes of retrospective review, for instance.
- Periodic review, perhaps by an internal 'competency group' comprising PPLhs, representatives of those who conduct procedures and care staff.
- Encourage honest, constructive feedback from peers, in the context of a blame-free culture.
- Collaboration between trainers and assessors from different Institutes to review, discuss and formulate suitable and consistent approaches for training and competence assessment.

This QA function could be coordinated centrally by the NTCO and reviewed by the AWERB.

Appendix 1. Examples of Personal Licensee Supervision and Competency records

Tables 1.1 to 1.3 show three different formats of supervision records (note the differing levels of supervision) and an example of a form to record training is shown in table 1.4.

TABLE 1.1

NAME:

PIL NO:

DATE GRANTED:

PPL No	Technique title and species used	Date of procedure	Supervised by (print name)	Supervised by (signature)	Level of supervision See Key below	PIL (signature)	Supervisor's signature confirming competence to proceed unsupervised	Date competency confirmed /reassessed

Levels of supervision, key: S – under direct supervision; 0 - No supervision required; T – Competent to train; A - Competent to assess

TABLE 1.2

		Level 1 Working under supervision		Level 2 Competence Assessed			Level 3 Competence as Trainer	
Technique	Species	Date	Signature of Trainer	Date	Signature of Assessor	Signature of Licensee	Date	Signature of Assessor
Animal handling and restraint	Mouse							
	Rat							
Oral administration of substances	Mouse							
	Rat							
Intraperitoneal administration of substances – small animals	Mouse							
	Rat							
Subcutaneous administration of substances	Mouse							
	Rat							
Withdrawal of blood from superficial blood vessels	Mouse							
	Rat							

TABLE 1.3

Name: Ms PIL

PIL Number: IAE000000

Date Granted: 16/02/2015

Technique	Comments	Species	Competency Level*	Trainer / PPL Holder	Date	Trainee Acknowledgment	Date	Review Date
Biopsy of superficial tissues or tail tip removal	ear notching for identification and genotyping	Mouse	4 – Supervisor present	Prof. PPL name/signature	18 Nov 2015	Ms. PIL name/signature	20 Nov 2015	18 Nov 2017

*** T – Trainer 0 – No longer requires supervision 1 – Supervisor aware/available for discussion 2 – Supervisor aware/available to attend
 3 – Supervisor aware/available for rapid attention 4 – Supervisor present**

Table 1.4. Record of *in vivo* training courses or seminars attended

Title of Course/Seminar	Species (where relevant)	Date Attended	Signed for Attendance	Certificate awarded
Advanced anaesthesia for surgical or prolonged procedures (EU Module 21)				
Design of procedures and projects (level 1) (experimental design) (EU Module 10)				
Neuromuscular blocking agent seminar - non-modular course				
Assessor Course – non-modular course				

Note: In the UK competence in practical techniques using living animals, that could cause pain, suffering, distress or lasting harm will be achieved, under supervision, when a licensed person begins their work.

Appendix 2. Examples of competence assessment templates

The templates in this Appendix illustrate **the process and criteria** that can be used to assess competence. The first three examples (2.1 to 2.3) also highlight the different roles that could be involved in the assessment process. Tables 2.4 and 2.5 illustrate some marking systems (graded, with criterion, or binary). Tables 2.6 and 2.7 combine several of those aspects and integrate some general elements. The aim of a Competence Assessment Template, also called a Directly Observed Practical skills (DOPS) template, is to allow an objective and transparent way of assessing performance in a practical task. The assessment includes elements of underpinning knowledge, the technical/manual skills to carry out the task and can also include 'attitude' in the sense of behaving within a framework of professional 'norms' for the environment (e.g. culture of care).

Some General Key points

- A Competence Assessment Template is not an SOP (Standard Operating Procedure) for the technique. Rather, it examines 'performance standards': i.e., it is intended to assess whether the task carried out was 'fit for purpose'. Being output-driven, rather than process-driven, allows for diversity/variation in the precise technique, provided that it satisfies the 'meets expectations' standards (see example 2.6 below).
- The elements of the task are set out so that everyone is marked using the same criteria. This promotes consistency of assessment with relatively minimal training.
- The "meets expectations" (i.e. a 'pass') level of performance is explained for the benefit of student and assessor. Students are aware of the assessment form when they start training, so that they know what they are aiming for. Feedback can be given on the form to help development.
- Students ask to be assessed when they feel ready and can do so several times during training.
- The form constitutes a permanent record of the assessment to back up the competency entry in a database. It can also be passed on to the next Institute to help their NTCO make a judgement on how the person was performing. This will aid movement of staff because the standard of performance and the criteria used to judge it are transparent to everyone. The standard of working of each Institution is evident too from the criteria that are set out.

In the next three examples (2.1 to 2.3), the colour coding indicates the different roles that could be involved in the assessment process.

Blue text: animal-centred competencies.

Green text: technique-centred competencies.

Black text: the action of carrying out the procedure and the monitoring associated with that procedure.

2.1 Blood sampling from a conscious [insert species]

Individuals must demonstrate that they:

- a) can recognise the normal demeanour and appearance of a healthy [insert species]
- b) can recognise signs of ill-health, pain or distress in [insert species]
- c) can determine that the method proposed should cause the least pain, suffering, distress and lasting harm for the purpose (including use of local anaesthesia)
- d) know how to determine that authorities exist for the proposed procedures
- e) have knowledge of blood volumes, blood sampling routes and techniques so that the least invasive, most appropriate is selected
- f) can select and prepare equipment (correct needle size, clippers/scissors, surgical swabs)
- g) can pick up, handle and restrain a [insert species] in a way that the animal is supported and does not indicate distress
- h) can prepare the sampling site with minimal distress to the animal
- i) can consistently insert a needle and withdraw blood successfully without causing adverse effects (pain, haematoma, bleeding)
- j) know how to provide appropriate aftercare, including a range of methods for haemostasis, to provide for expected and unexpected events (e.g. can decide on appropriate monitoring intervals)
- k) know (and can recognise) the adverse effects, what to look for and how and when to deal with these, including whom to contact for assistance and how to contact those individuals
- l) know how to handle the sample to ensure adequate labelling ,thorough mixing, handling and storage
- m) know how to keep appropriate records (e.g. cage labels, PIL records, sample labelling)

2.2 Surgical procedures with recovery - bile duct cannulation in a rat

Individuals must demonstrate that they:

Preparation/ Legal/Local rules

- i. know how to determine (and has checked) that appropriate licence authorities exist for the proposed procedures and knows all relevant local policies (e.g. SOPs)
- ii. know the requirements regarding health and safety (e.g. can choose appropriate PPE, procedure for sharps, gas scavenge, etc.)
- iii. can determine that the method proposed should cause the least pain, suffering, distress and lasting harm
- iv. know what pre-experimental preparation is required (e.g. re booking facilities, staff, animal ordering, medicines, pre-study meeting etc.)
- v. are able to prepare a surgical checklist and recovery score sheets/records
- vi. can determine that the method proposed should cause the least pain, suffering, distress and lasting harm
- vii. know how to arrange for post-op care and of the need to communicate with staff about this.
- viii. know whom to contact if advice is required at any stage (e.g. bodyweight data accessible to NACWO)
- ix. are able to maintain a safe working environment – and tidies up afterwards!

Animal

- x. can recognise the normal demeanour and appearance of a healthy [insert species]
- xi. can recognise signs of ill-health, pain or distress in [insert species]
- xii. can pick up and/or handle and restrain a [insert species] in a way that the animal is comfortable and does not indicate distress

Anaesthesia & analgesia

- xiii. can identify and apply appropriate anaesthesia for the animal and set up an anaesthetic machine and scavenging equipment
- xiv. can recognise appropriate anaesthetic depth and vital physiological signs and/or use monitoring equipment
- xv. can identify, dilute and apply appropriate analgesia for the animal
- xvi. are able to choose the most appropriate route for continuing pain relief (e.g. oral)

Surgical preparation and aseptic technique

- xvii. are able to prepare the surgical area appropriately and to maintain a sterile environment throughout the procedure, using drapes, sterile consumables (with an assistant, wherever possible)
- xviii. are able to select appropriate instruments, consumables and equipment for the procedure and to sterilise them adequately
- xix. are able to prepare themselves (as the surgeon) appropriately for aseptic procedure

Continued...

Performance of procedure

- i. know the anatomy relevant to the surgical procedure and what to do when encountering unexpected variations
- ii. are able to clip the animal and prepare the skin aseptically without causing trauma to the skin
- iii. demonstrates technical and manual dexterity in performing the procedure successfully
- iv. are able to select and apply appropriate wound closure method, such that the wound heals without irritation to the animal or the need for re-intervention

Post operative care and nursing

- v. are able to describe the likely adverse effects and know what to do about them (see above re pre-surgery plan)
- vi. are able to re-assess the animal post-operatively for pain, dehydration, ability to feed
- vii. understands the humane endpoint and is able to apply it appropriately in order to avoid unnecessary pain, suffering, distress or lasting harm
- viii. know how to update appropriate records (e.g. animal records, cage labels, personal records)
- ix. understand species biology with regard to post-operative housing and care
- x. understand the need for timely removal of sutures or wound clips

Scientific output

- xi. are able to provide bile samples that are suitable for the purposes of the study and understands the appropriate processing and storage

2.3:

Non-recovery procedures - cardiac puncture in rat

The first four competency bullet points below replicate the bile duct surgical procedure:

- Preparation/ Legal/Local rules
- Animal
- Anaesthesia
- Scientific outputs

Specific competency criteria for this procedure:

- i. be able to state why this technique is being used and how much blood is likely to be withdrawn
- ii. be aware of the need to communicate within the establishment to facilitate tissue sharing from the carcass if possible
- iii. be able to select appropriately sized needle and syringe
- iv. be able to select/prepare appropriate tubes for blood, according to requirements for anticoagulant
- v. know how to select appropriate anaesthetic and assess sufficient anaesthetic depth for non-recovery procedure
- vi. know the local anatomical landmarks, with regard to selection of the appropriate approach to blood sampling from the heart, and to be able to consistently insert the needle into the heart at the first attempt
- vii. know what to do if the first attempt is unsuccessful: i.e., how to re-direct needle and when to stop
- viii. know how to confirm death after exsanguination and/or how to apply a humane method of killing then confirm death
- ix. know the appropriate method of disposal of the carcass

2.4: Competency assessment score sheets

Below is an example of a surgical competency assessment taken from a competency webinar⁶.

Surgical Scoring assessment for small bowel resection and end to end anastomosis

Skin Incision	1	2	3	4	5
	Rough with tissues, excessive traction, forceps frequently slips off, repeats incising leaving jagged edges		Handle tissues reasonably well, occasional slipping of forceps, minor trauma to tissues		Handles tissues well with appropriate traction, makes incision confidently with one smooth motion
Abdominal wall incision	1	2	3	4	5
	Rough with tissues, excessive traction, forceps frequently slips off, poor hemostasis, does not check for abdominal tissues and organs prior to making an incision, does not lift up muscular layer while extending incision		Handles tissues reasonably well, occasional slipping of forceps, checks for grasping abdominal tissues and organs prior to making an incision, minor trauma to tissues, lifts up muscular layer while extending incision but not high enough.		Handles tissues well with appropriate traction, good hemostasis, checks for grasping abdominal tissues and organs prior to making an incision, lifts up muscular layer while extending incision
Placement of retractors	1	2	3	4	5
	Uncertain, many unnecessary moves, constantly changing placement of retractors without progress, major tissue trauma, does not use gauze		Slow, but reasonably well placed with some unnecessary moves, uses gauze with inappropriate placement		Confidently and smoothly placed retractors and gauze allowing for good exposure

⁶ "Surgical Competency and Assessment" : http://www.vetbiotech.com/webinar_od.php (not currently available; June 2016) Also see: <http://www.alnmag.com/articles/2011/09/how-develop-competency-assessment> (accessed June 2016)

Tissue handling	1	2	3	4	5
	Rough with tissues, excessive traction, forceps slips off, poor control of coagulation device		Handles tissues reasonably well, occasional slipping of forceps, minor trauma to adjacent tissues with instruments		Handles tissues well with appropriate traction
Instrument handling	1	2	3	4	5
	Tentative/awkward moves or inappropriate use or handled instruments inappropriately		Competent use of instruments, but occasionally awkward or stiff, handled instruments appropriately most of the time		Fluid movement with instruments. No awkwardness. Used instruments appropriately all of the time
Instrument knowledge	1	2	3	4	5
	Could not name instruments, selected wrong instruments		Could name some, not all instruments; hesitated or changed mind in selecting instruments		Named all instruments; easily selected corrected instruments
Flow of procedure	1	2	3	4	5
	Frequently stopped operating, seemed unsure of next move		Demonstrated some forward planning, reasonable progression		Obviously planned course, effortless flow from one move to the next

Setting up equipment	1	2	3	4	5
	Deficient knowledge, needs specific instruction at most steps		Knew all important steps		Demonstrated familiarity with all aspects of set up
Depth perception	1	2	3	4	5
	Constantly overshoots target, wide swings		Some overshooting, quickly corrects		Accurately directs instruments to target
Bimanual dexterity	1	2	3	4	5
	Use of one hand, ignores non-dominant hand		Use of both hands, but does not optimise interactions between hands		Uses both hands in complementary fashion to optimise exposure
Time and motion efficiency	1	2	3	4	5
	Uncertain, many unnecessary moves, constantly changing focus of operation, persists without progress		Slow, but planned and reasonably well organized with some unnecessary moves		Clear economy of movement. Confident and efficient with safe conduct

2.5: Assessment – binary score system

Procedure part	Correct	Incorrect/ Not performed
Bowel oriented mesenteric border to mesenteric border	1	0
Check for torsions and twists	1	0
Select appropriate needle holder	1	0
Select appropriate suture	1	0
Needle loaded correctly	1	0
Index finger used to stabilise needle holder	1	0
Needle enters bowel at right angles (>80% of bites)	1	0
Single attempt at needle passage through bowel 90% of bites	1	0
Total Score	8	0

2.6: Directly Observed Practical skills (DOPS) Assessment:

Injection into tail vein - Mouse

Assessment criteria/Components of the task:

- a) Check Personal & Project Licence authority; personal training record
- b) Choose Suitable PPE (mask or flow-hood, gloves)
- c) Confirm animal's identification, cage label
- d) Choose suitable equipment: needle, syringe, equipment to warm the tail
- e) Handle and restrain mouse correctly and sympathetically
- f) Preparation of suitable site for injection
- g) Know suitable volume for injection
- h) Appropriate handling of dose; all bottles/tubes clearly labelled
- i) Correctly amend cage label/records
- j) Demonstrate a professional attitude towards performing the procedure

Grading/Threshold statements

“Below expectations” [BE]

- Failure to check legal authorities, cage labels, animal identification
- Failure to choose suitable PPE
- Poor animal handling, or risk of injury; animal showing signs of distress
- Unsuitable site, volume or preparation for dosing
- Incorrect operation, timing or application of warming (eg heat box)

Requirements for “borderline” [Bo]

- Able to catch and handle mouse but perhaps hesitantly
- Poor choice/preparation of suitable equipment and/or site; dose volume
- More than 2 attempts needed to give dose

Requirements for “meets expectations” [ME]

- Correctly checks Licence authorities and animal's identification
- Dose & equipment prepared & ready; tidy, safe workspace
- Correctly removes mouse from cage, handle empathetically, body supported; feet allowed to touch floor of cage before release
- Correct use of warming equipment and/or restrainer
- Able to dose into tail vein within 2 attempts; correct haemostasis
- Correct needle & syringe size chosen; appropriate handling of dose
- Cage label/record updated

Requirements for “exceeds expectations” [EE]. As “meets expectations” and

- Confident, capable and empathetic animal handling
- Explain reasons for choice of equipment with respect to 3Rs
- Excellent manual dexterity in handling and sampling

**2.7: Directly Observed Practical Skills (DOPS) Marking Sheet for:
Injection into tail vein (Mouse)**

	Level (e.g. ME)	Feedback/comments
<i>Legal & compliance:</i> Check PIL & PPL Correct PPE/flow hood operation Confirm animal's identification Amend cage label/record ⁷		
<i>Animal Welfare:</i> Empathetic, safe animal handling Correct use of warming and restrainer Correct site & haemostasis applied		
<i>Procedural:</i> Choice and use of suitable size syringe, needle/butterfly Appropriate handling dose material Injection given <3 attempts		
<i>Professionalism:</i> Dose administered in timely manner Workspace left tidy Communicates/Knows own limits		
<i>3Rs:</i> Demonstrates understanding of refinements (e.g. frequency, volumes).		

Candidate's name:

Assessor's name:

Assessor's signature:

Date:

Requirement to be assessed as COMPETENT: One borderline score or better.

Candidates scoring "Below expectations" on any point OR two borderline scores are recommended to "continue supervision"

GLOBAL RATING: COMPETENT
(Circle)

CONTINUE SUPERVISION

⁷ Record could be personal (e.g. lab note book) or any other record required by SOP or local practice



LASA
PO Box 524
Hull HU9 9HE
Telephone: 08456 711956
Fax: 08456 711957
E-mail: info@lasa.co.uk
Web: www.lasa.co.uk