Guiding Principles for Supervision and Assessment of Competence as required under EU and UK legislation
Guiding principles for supervision and assessment of competence as required under EU and UK legislation

Note:
This Guidance supersedes 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.).

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Members of the LASA Education, Training and Ethics Section:

Manuel Berdoy (joint convenor), University of Oxford
Maggy Jennings (joint convenor), Research Animals Department, RSPCA
Anne-Marie Farmer (observer), Home Office
Angela Kerton, Imperial College, London
Beverley Law, University of Leeds
Patrick Sinnett-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 from time to time to reflect changes in practice. Please check on the website that you have the latest version.

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Summary

Good training is recognised as 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 in developing processes to deal with these issues at establishment level.

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.
- The Project Licence holder (PPLh) is directly responsible for ensuring that the appropriate level of supervision is provided for all personal licensees under the authority of their project licence.
- The Personal Licence Holder (PILh) must keep records of supervision and competence.
- The Named Training and Competence Officer (NTCO) provides oversight of the process.
- Additional inputs will come from Animal Welfare and Ethical Review Bodies (AWERBs) the Named Animal Care and Welfare Officer (NACWO) and 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.
- Training records must be available to the NTCO, PPLh, Named Person Responsible for Compliance (NPRC), other managers and upon request submitted to the Secretary of State or made available to the local Home Office inspector.

Trainers and supervisors

- Must have appropriate and up to date knowledge and be skilled and competent in the techniques they are training/supervising.
- Must be able to impart knowledge and skills, i.e. have appropriate teaching skills.
- Must have sufficient seniority to command respect and be authoritative with regard to their knowledge and experience.
- The process of supervision, but not the responsibility for this, can be delegated to an appropriately qualified person/s.

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, may also be 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 culture.
- There must be a process to evaluate the experience and training needs of new staff and those transferring from another establishment in the UK or Europe and where necessary provision for practical assessment of competence.

Ensuring an effective process (quality assurance checks)

Approaches to this include:

- Random spot-checks of either projects or individuals or targeted checks following retrospective review.
- Structured periodic review perhaps by an internal ‘competency group’ comprising PPLhs, representatives of those who conduct procedures and care staff.
1. Introduction

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 new EU and UK legislation - Directive 2010/63/EU and the amended Animals (Scientific Procedures) Act, 1986 both explicitly state 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, and training to provide 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 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 courses. These only provide an introduction to the ethical, legal and practical issues. They are not designed to produce licensees fully competent in the practical skills they require, and after completion personnel must go on to develop their competencies through on-the-job training under supervision, together with other forms of continuous professional development (CPD).

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 throughout Europe. To facilitate this, guidance for member states on training, supervision, and the development and assessment of competence, is being produced by an EC Expert Working Group. This LASA document, 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, builds upon the EC guidance by summarising principles of good practice for supervision and competence assessment. (It does not cover the content or methods of delivery of training courses since this are covered elsewhere). In the Appendices it provides examples of some ‘competency assessment templates’. These have been designed to help think through how competency in different types of techniques could be assessed. They are not intended to be prescriptive and it is recognised that they will not be suitable in all circumstances.

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1 At the time of writing in 2013, a modular framework for training across the EU is being developed. The current HO modular structure may change as a result though the content is likely to be similar.

2 The Institute of Animal Technology sets standards for training and competence for animal technologists.
2. Responsibilities

A summary of the training related responsibilities of different roles in UK establishments is 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. S/he is 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, s/he 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”.
- **The Personal Licence Holder (PILh)** has standard conditions on their licence (standard conditions 17 and 20) which state that supervision and competence is required and must be recorded.

**It is important to recognise that the responsibility for supervision of personal licence holders (PILhs) 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 (PPLh) 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.

**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)** and **Named Veterinary Surgeon (NVS)** 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 of 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 multiple choice questions (MCQ) database used for assessment of applicants should include questions relating to supervision responsibilities and training records.

The whole training process (up until 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) is essential, and the establishment’s training framework should aim to facilitate this and ensure consistency across the organisation.
3. Supervision

Supervision needs to cover the development of practical skills in handling of animals, performance of procedures, monitoring of animals and recognition of pain, distress and discomfort (see EC EWG learning outcomes documents when published). 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 negative consequences, 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.

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 s/he requires;
- provide a clear idea 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 that training has been provided, supervision and the dates competence is achieved;
- incorporate regular reviews of training, competence, CPD and his/her 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 made available to the NTCO, PPLh, NPRO, other managers and upon request submitted to the Secretary of State or made available to the local Home Office inspector.

Examples of training and supervision plans are given in Appendix 2. The supervisor initially needs to be present when the trainee carries out procedures to provide direct supervision and advice stepping in if there are problems. The level of continuous ‘hands on’ supervision required may then decrease, gradually, as the trainee develops his/her skills and the speed at which this transition takes place will vary, subject to the ability of the individual and his/her pace of learning.

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/s. The selection of the ‘right’ individuals as supervisors is crucial - the qualities required are that they should:

- have appropriate and up to date knowledge and be skilled and competent in the techniques they are training/supervising;
- be able to impart knowledge and skills to others, i.e. have appropriate teaching skills for the techniques;
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- have sufficient seniority to command respect and be authoritative 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 implementing the letter of the law.

There will probably not be 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 resources available.

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 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 very 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 and information sources such as Compmed and Vets On Line (VOLE) can be a useful source 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 specialist techniques, it may be possible to send the scientist and an animal welfare person (e.g. vet/senior care worker) to a specialist for advice, training and assessment, then once 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. Circumstances will, inevitably vary, but if possible an independent view of the level of competency should be sought, for example from a vet, even where there is limited expertise available for a specialist technique.
4. Competence

4.1 Defining competence

The criteria for competence required for each practical skill needs to be defined so that benchmarks can be set within the establishment for assessment of competence and completion of the supervision period. This will enable consistent judgements to be made within establishments, and if more widely agreed, consistency between establishments should be achievable. This should 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 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 assess each of these. Some examples are given in Appendix 1. 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 to be carried out and of the species with which competence was achieved.

There may be some prospective licensees who are never going to 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 period, the staff member should be refocused on an area appropriate to 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 teaching and the development of communication skills, so there also needs to be ‘training for the trainers’.

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. Someone needs to have ultimate responsibility for observing an individual carrying out a procedure or husbandry task and verifying that it is being done in a competent way.

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. 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 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 people off 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 ‘critical self evaluation’ 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 between when the technique was last performed;
- use of a new or modified technique or new equipment;
- a change in data quality;
- 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 available resources to carry out reviews and any consequent re-assessment/re-training. The ideal situation would be to encourage a self-assessment culture which encourages people to ask themselves: a) do you feel that you can do the technique; b) would you be OK about someone else watching you; and c) would you be happy with an Inspector from the Home Office watching you? 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 for all establishments to have a mechanism in place to ensure that incompetence in 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 or NVS will lead to remedial action. Establishments should provide a further mechanism to allow confidential reporting (e.g. to the PELh perhaps through the AWERB).

### 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 or carrying out procedures – is captured within the training framework. This may be a particular problem in academic establishments where there may be a rapid throughput of people, so HR departments and all relevant senior managers need to be made aware of the requirement for training. These should also be
advertised in staff induction packs, on intranet sites and in other easily accessible information.

**It is most 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 and the fact that the HO Guidance states that they should ensure 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 is essential, and face to face discussion is recommended. A list of qualifications to take on trust is insufficient; 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. FELASA 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; and
- his/her ability to understand and communicate in the local language (if the primary language is different).

In addition, whatever their previous training, 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 manage risk and protect both the individual and the establishment.

### 4.6 Ensuring an effective process

**Establishments need to take training and competency seriously and be stronger in this respect, ensuring that competency is confirmed rather than just assumed.**

Training needs to be seen as a core value which is an accepted part of a professional compliance culture 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) (other than incidents of non-compliance) 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 either or both of the following approaches:

- spot-checks which could be random, or targeted, selecting one project or one person from each research group to ‘audit’, perhaps when looking at the outcomes of retrospective review;
- structured periodic review perhaps by an internal ‘competency group’ comprising PPLhs, representatives of those who conduct procedures and care staff.

This QA function could be coordinated centrally by the NTCO and reviewed by the AWERB.
Appendix 1

Examples of competence assessment templates

The templates in this Appendix are offered as examples of the criteria and process that can be used to assess competence. The colour coding indicates the different roles that could be involved in the assessment process. It is recognised that the tables may not be appropriate in all situations but they are provided as a ‘guide to thinking’.

**Blue text:** animal centred competencies which can be assessed by a senior animal technologist/vet before progressing to carrying out an actual procedure

**Green text:** technique centred competencies which can be assessed by the module provider and the supervisor before progressing to carrying out an actual procedure and assessment of this.

**Black text:** the action of carrying out the procedure and the monitoring associated with that procedure which should be assessed by the supervisor as nominated by the PPLh.

A1 Blood sampling from a conscious [insert species]

An individual must demonstrate that s/he:

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) knows how to determine that authorities exist for the proposed procedures

e) has 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) knows 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) knows (and can recognise) the adverse effects to look for and how and when to deal with these, including who to contact for assistance and how to contact those individuals

l) knows how to handle the sample to ensure adequate labelling and thorough mixing

m) knows how to keep appropriate records (e.g. cage labels, PIL records)
An individual must demonstrate that s/he:

**Preparation/ Legal / Local rules**

i. knows 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. knows the requirements surrounding 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 for the purpose

iv. knows the pre-experimental preparation required (e.g. re booking facilities, staff, animal ordering, medicines, pre-study meeting etc)

v. is 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 for the purpose

vii. knows how to arrange for post-op care and of the need to communicate with staff about this.

viii. knows whom to contact if advice is required at any stage (e.g. bodyweight data accessible to NACWO)

ix. is 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 scavenge equipment

xiv. can recognise appropriate anaesthetic depth

xv. can identify, dilute and apply appropriate analgesia for the animal

xvi. is able to choose the most appropriate route for continuing pain relief (e.g. oral)

**Surgical preparation and aseptic technique**

xvii. is able to prepare the surgical area appropriately, maintaining sterile field throughout the procedure, using drapes, sterile consumables (with assistant if necessary)

xviii. is able to select appropriate instruments, consumables and equipment for the procedure and sterilise them appropriately

xix. is able to prepare themselves (as the surgeon) appropriately for aseptic procedure

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Performance of procedure

i. knows the regional anatomy relevant to the surgical procedure and what to do when encountering unexpected variations

ii. is 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. is 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. is able to describe the likely adverse effects and know what to do about them (see above re pre-surgery plan)

vi. is 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 to avoid unnecessary pain, suffering, distress or lasting harm

viii. knows how to update appropriate records (e.g. animal records, cage labels, personal records)

ix. understands species biology with regard to post-operative housing and care

x. Understands the need for timely removal of sutures or wound clips

Scientific output

xi. is able to provide a bile sample that is suitable for the purposes of the study and understands the appropriate processing and storage
A3 Non-recovery procedures - cardiac puncture in rat

The first four competency bullet points below are in common with the bile duct surgical procedure:
- Preparation/ Legal / Local rules
- Animal
- Anaesthesia
- Scientific outputs

Specific competency criteria for this procedure:
1. be able to state why this technique is being used and how much blood is likely to be withdrawn
2. be aware of the need to communicate within the establishment to facilitate tissue sharing from the carcase if possible
3. be able to select appropriately sized needle and syringe
4. be able to select/prepare appropriate tubes for blood, according to requirements for anticoagulant
5. know how to select appropriate anaesthetic and assess sufficient anaesthetic depth for non-recovery procedure
6. know the local anatomical landmarks with regard to selection of the appropriate approach to blood sampling from the heart and can consistently insert the needle into the heart at the first attempt
7. know what to do if the first attempt is unsuccessful i.e. how to re-direct needle and when to stop
8. know how to confirm death after exsanguination and/or how to apply a humane method of killing then confirm death
9. know the appropriate method of disposal of the carcase
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A4: Competency assessment score sheets

Below is an example of a surgical competency assessment taken from a competency webinar[3]; the score sheets are a potentially useful approach.

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

<table>
<thead>
<tr>
<th>Skin Incision</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rough with tissues, excessive traction, forceps frequently slips off, repeats incising leaving jagged edges</td>
<td>Handle tissues reasonably well, occasional slipping of forceps, minor trauma to tissues</td>
<td>Handles tissues well with appropriate traction, makes incision confidently with one smooth motion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal wall incision</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>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</td>
<td>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.</td>
<td>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</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Placement of retractors</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Uncertain, many unnecessary moves, constantly changing placement of retractors without progress, major tissue trauma, does not use gauze</td>
<td>Slow, but reasonably well places with some unnecessary moves, uses gauze with inappropriate placement</td>
<td>Confidently and smoothly placed retractors and gauze allowing for good exposure</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


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<table>
<thead>
<tr>
<th>Tissue handling</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rough with tissues, excessive traction, forceps slips off, poor control of coagulation device</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Handles tissues reasonably well, occasional slipping of forceps, minor trauma to adjacent tissues with instruments</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Handles tissues well with appropriate traction</td>
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<table>
<thead>
<tr>
<th>Instrument handling</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tentative/awkward moves or inappropriate use or handled instruments inappropriately</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Competent use of instruments, but occasionally awkward or stiff, handled instruments appropriately most of the time</td>
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<tr>
<td>Fluid movement with instruments. No awkwardness. Used instruments appropriately all of the time</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Instrument knowledge</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Could not name instruments, selected wrong instruments</td>
<td></td>
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<tr>
<td>Could name some, not all instruments; hesitated or changed mind in selecting instruments</td>
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<tr>
<td>Named all instruments; easily selected corrected instruments</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Flow of procedure</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequently stopped operating, seemed unsure of next move</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demonstrated some forward planning, reasonable progression</td>
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<tr>
<td>Obviously planned course, effortless flow from one move to the next</td>
<td></td>
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</tr>
<tr>
<td>Setting up equipment</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>----------------------</td>
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<tr>
<td></td>
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<td></td>
</tr>
<tr>
<td>Deficient knowledge, needs specific instruction at most steps</td>
<td></td>
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<tr>
<td>Knew all important steps</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Demonstrated familiarity with all aspects of set up</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Depth perception</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Constantly overshoots target, wide swings</td>
<td></td>
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</tr>
<tr>
<td>Some overshooting, quickly corrects</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Accurately directs instruments to target</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bimanual dexterity</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Use of one hand, ignores non-dominant hand</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Use of both hands, but does not optimise interactions between hands</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Uses both hands in complementary fashion to optimise exposure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time and motion efficiency</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Uncertain, many unnecessary moves, constantly changing focus of operation, persists without progress</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Slow, but planned and reasonably well organized with some unnecessary moves</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Clear economy of movement, Confident and efficient with safe conduct</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

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Guiding principles for supervision and assessment of competence as required under EU and UK legislation

**Assessment – binary score system**

<table>
<thead>
<tr>
<th>Procedure part</th>
<th>Correct</th>
<th>Incorrect/ Not performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bowel oriented mesenteric border to mesenteric border</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Check for torsions and twists</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Select appropriate needle holder</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Select appropriate suture</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Needle loaded correctly</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Index finger used to stabilise needle holder</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Needle enters bowel at right angles (&gt;80% of bites)</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Single attempt at needle passage through bowel 90% of bites</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Total Score</td>
<td>8</td>
<td>0</td>
</tr>
</tbody>
</table>
Guiding principles for supervision and assessment of competence as required under EU and UK legislation

Appendix 2

Examples of Personal Licensee Supervision and Competency Records

Example 1

<table>
<thead>
<tr>
<th>PPL No</th>
<th>Technique title and species used</th>
<th>Date of procedure</th>
<th>Supervised by (print name)</th>
<th>Supervised by (signature)</th>
<th>Level of supervision See Key below</th>
<th>PIL (signature)</th>
<th>Supervisor’s signature confirming competence to proceed unsupervised</th>
<th>Date competency confirmed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

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

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This example includes a form to record (i) courses attended, (ii) training in common procedures and (iii) training in specialised procedures.

(i) **Record of *in vivo* training courses/seminars attended**

<table>
<thead>
<tr>
<th>Title of Course/Seminar</th>
<th>Date Attended</th>
<th>Signed for Attendance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modules 1 – 3 (rodent)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Modules 2 – 3 (carnivore)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Modules 2 – 3 (minipig)</td>
<td></td>
<td></td>
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<tr>
<td>Modules 2 – 3 (farm animals)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Module 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Module 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neuromuscular blocking agent seminar - non-modular course</td>
<td></td>
<td></td>
</tr>
<tr>
<td>‘Awareness’ seminar - non-modular course</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

November 2013
(ii) Basic *in vivo* Procedures (examples)

<table>
<thead>
<tr>
<th>Technique</th>
<th>Species</th>
<th>Date</th>
<th>Signature of Trainer</th>
<th>Date</th>
<th>Signature of Assessor</th>
<th>Signature of Licensee</th>
<th>Date</th>
<th>Signature of Assessor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal handling and restraint</td>
<td>Mouse</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td></td>
<td>Rat</td>
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<tr>
<td>Oral administration of substances</td>
<td>Mouse</td>
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<tr>
<td></td>
<td>Rat</td>
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<tr>
<td>Intraperitoneal administration of substances – small animals</td>
<td>Mouse</td>
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<tr>
<td></td>
<td>Rat</td>
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<td></td>
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<tr>
<td>Subcutaneous administration of substances</td>
<td>Mouse</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rat</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Withdrawal of blood from superficial blood vessels</td>
<td>Mouse</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rat</td>
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</tr>
</tbody>
</table>

November 2013
(iii) **Specialised in vivo procedures (examples)**

<table>
<thead>
<tr>
<th>Technique</th>
<th>Species</th>
<th>Date</th>
<th>Signature of Trainer</th>
<th>Date</th>
<th>Signature of Assessor</th>
<th>Date</th>
<th>Signature of Licensee</th>
<th>Date</th>
<th>Signature of Assessor</th>
</tr>
</thead>
<tbody>
<tr>
<td>e.g. pharmacological preparation under terminal anaesthesia</td>
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<tr>
<td>e.g. Implantation of ICV cannula</td>
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</tbody>
</table>

November 2013