



# **Guiding Principles on the Supervision Requirements for Personal Licensees**

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**Updates:**

Guidelines may be updated from time to time to reflect changes in practice. If you have received a hard copy of this report, please check on the website that this is the latest version.

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## Summary

Good supervision during training of personal licensees working under the Animals (Scientific Procedures) Act, 1986 is central to the development of core skills and attitudes, such that legal, scientific and animal welfare requirements are satisfied. The Home Office considers this to be so important that the supervisory requirements are stated as standard conditions on the personal and project licence, with an additional condition applied to personal licences as appropriate. However, there is little detailed guidance on what supervision should entail. Flexibility with regard to how supervision is implemented is deliberate to accommodate the varying practices that arise from differing circumstances at establishments. Nevertheless, there are common principles of good practice that can be adapted to fit the requirements of all establishments. This LASA guidance on supervision has been developed from the discussions at a LASA workshop attended by trainers and others with an interest in this issue. The key points are listed below, with further detail in the full report.

### Responsibility for supervision – the legal framework

- The **Certificate Holder** has ultimate responsibility for education and training (which includes responsibility for ensuring that appropriate supervision is provided).
- The **Project Licence Holder** *is responsible for the supervision, training, conduct and performance of personal licence holders working under his or her project licence.* While project licence holders cannot delegate responsibility for training and supervision they can delegate its conduct to someone with the appropriate skills (see selection of supervisors below).
- The **Personal Licence Holder** has a responsibility to accept supervision and training arrangements.
- The **Ethical Review Process** has a role in advising on training and assessment of competence and its remit therefore includes supervision.

### The Supervision Process

- Each establishment should ensure that there is a robust framework within which training and supervision can take place, with benchmarks that define competence in knowledge-based and practical skills. Achieving consistency in all of these processes is essential.
- Each personal licensee should have:
  - a formal training plan outlining their personal objectives and the practical and knowledge-based skills s/he requires;
  - a clear idea of the criteria for competence in each skill;
  - records of training and competence;
  - regular reviews of training, competence and their personal development plan.

### Qualities required of a good supervisor

- A supervisor (whether the project licensee or delegated member of staff) should:
  - have appropriate and up to date knowledge and practical skills (both with respect to the competencies to be acquired and his or her teaching skills) as well as a current personal licence authority for the technique/procedure to be supervised;
  - know their own limitations and arrange supervision by someone with the necessary competence;
  - understand the reasons why training and supervision are important;
  - be authoritative with regard to their knowledge and experience;
  - have good interpersonal skills.

### Trainers and accrediting bodies

Trainers should inform project and personal licence applicants of their responsibilities with respect to training and supervision early in the modular courses and make sure these issues are covered in training and accreditation materials.

## 1. Introduction

Good training for those caring for and/or using animals in scientific procedures is recognised as essential to ensure compliance with ethical and legislative requirements and to facilitate good science and animal welfare. Thus, UK and EU legislation, the Animals (Scientific Procedures) Act, 1986 and Directive 86/609<sup>1</sup>, require that staff are appropriately trained and that individuals are 'competent', though the nature of training and competence is not defined.

Training in any skill, whether practical or knowledge-based, aims to develop an individual's competence. This is reflected in the 'conscious competence' learning model that is widely accepted and implemented in training theory and practice<sup>2</sup>. The trainee starts from a state of unconscious incompetence where they are unaware of their lack of knowledge or skill, or of its relevance. Training develops them through a state of conscious incompetence (where they begin to learn a skill but have to think about every action and are conscious of all their mistakes), to conscious competence (where they are competent but still have to think about every action and are unlikely to be able to teach others) and finally, unconscious competence where the skill becomes so practised that it becomes 'second nature'.

In the UK, the formal training of personal licensees is delivered through mandatory attendance of accredited modular training courses. These courses have to cover a great deal of information in a relatively short time and are not designed to produce fully competent licensees. Indeed, they could not do so within a practical timescale, or within the existing legal framework which, with a very few exceptions, prohibits the use of animals to acquire practical skills. Courses can only provide *an introduction* to the ethical, legal and practical issues. This was emphasised in a recent report on modular training produced by the Animal Procedures Committee Education and Training Sub-Committee (APC ETSC)<sup>3</sup> (APC 2006). After completion of a modular training course personal licensees must develop their proficiency in the knowledge and practical skills required (see [Appendix 1](#) for the 7 core competencies listed in the APC ETSC report) including any project-specific issues not covered by modular training. This requires on-the-job training, together with other forms of continuous professional development (CPD).

In the case of scientific procedures on animals, good supervision during on-the-job training is central to the development of core skills and attitudes such that legal, scientific and animal welfare requirements are satisfied. The Home Office consider this to be so important that the supervisory requirements are stated as standard conditions on personal and project licences (standard conditions 17 and 14 respectively) with an additional condition applied to personal licences as appropriate. However, there is little formal guidance as to what supervision should entail and practices vary in process, quality and effectiveness between establishments. There is unlikely to be one system of supervision that fits every situation, since establishments, projects and personal licensees can differ widely. Nevertheless, some common principles of

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<sup>1</sup> Directive 86/609 specifically requires that persons carrying out or supervising ...experiments have received instruction in a (relevant) scientific discipline; are capable of handling and taking care of laboratory animals; and ... *have attained a sufficient level of training and competence*. In the UK, the need for personal licensees to "*undergo appropriate training and achieve and maintain competence in the regulated procedures applied to the protected animals*" and the responsibility of the project licence holder and Certificate holder in this respect, are set out in the [Guidance on the Operation of the Animals \(Scientific Procedures\) Act, 1986](#) (Home Office 2000, The Stationery Office, London). See chapters for personal and project licence holders, and holders of the Certificate of Designation and the Appendices B to E.

<sup>2</sup> See [www.businessballs.com/consciouscompetencelearningmodel.htm](http://www.businessballs.com/consciouscompetencelearningmodel.htm).

<sup>3</sup> Animal Procedures Committee Education and Training Sub-Committee, Review of Modular Training. February 2006 [www.apc.gov.uk/reference/apc-education-modular-training.pdf](http://www.apc.gov.uk/reference/apc-education-modular-training.pdf).

good practice were developed from a LASA workshop in December 2005 attended by trainers and others with an interest in the issue, these are summarised in this report.

## 2. Principles of Good Practice

### 2.1 Legal responsibilities

The responsibilities for ensuring appropriate supervision are set out in the [Guidance on the Operation of the Animals \(Scientific Procedures\) Act 1986](#) (HO 2000) [hereinafter referred to as the Guidance] and the most important points are summarised below. **It is particularly important to recognise that the responsibilities relating to supervision of personal licensees during the development of competence are completely different from those of a PhD supervisor or a line manager.**

- The **Project Licence Holder** has the key responsibility and is required “*to undertake overall responsibility for the supervision, training, conduct and performance of personal licence holders working under his or her control*” [see Guidance para 2.47]. S/he is responsible for ensuring that the appropriate level of supervision is provided for all personal licensees carrying out regulated procedures under the authority of the project licence [see standard condition 14, Guidance para 3.12].

The Home Office regards this as an important responsibility for project licence holders and expects them “*to be able to demonstrate that appropriate supervision and training are actively provided for the personal licensees working under their direction and control*” [see Guidance para 2.84].

- The **Personal Licence Holder** has a responsibility to accept supervision. S/he is subject to such supervision requirements as may be stated in the licence or which the project licence holder may deem necessary in order to ensure that regulated procedures are performed competently [see standard condition 17].

The Secretary of State requires that “*the personal licensee accepts supervision and training arrangements put in place by the project licence holder, or by competent personal licensees nominated by the project licence holder*” [see Guidance para 2.83].

The personal licensee is also required to keep records of their supervision and declarations of competence by the project licence holder [standard condition 21 and Guidance para 6.19.]. The personal licensee can only perform techniques unsupervised if the training records show that they are competent.

Both project and personal licensees should be aware that, as part of the inspection process, Home Office inspectors can ask to check records, including those relating to training and supervision.

Others within the establishment with associated responsibilities are:

- The **Certificate Holder** has ultimate responsibility for education and training at an establishment. Standard condition 19 for Designated Scientific Procedures Establishments states: “*The certificate holder shall take steps to provide such education and training as is necessary for all licensees and others responsible for the welfare and care of protected animals at the establishment*”. Thus, s/he needs

to ensure that an effective system for management of all aspects of training and development, including supervision, is in place.

- The **Ethical Review Process (ERP)** has a role in advising on how all staff involved with the animals can be appropriately trained and how competence can be ensured [see Guidance Appendix J para 7.7]. Supervision therefore also comes within the ERP's remit.

Training and supervision form the basis for the development of competent licensees, assuring high standards of science and animal welfare and helping to create and maintain a local culture of care. It is essential for all establishments to recognise the importance of this and set out a robust framework within which these activities can take place.

## 2.2 The supervision process

The nature of the supervisory process depends on the competency being developed, the needs of the individual and the organisation and management practices of the establishment. The process should address the development of practical skills as set out in the APC ETSC core competency (v) animal handling and relevant techniques and (vi) recognition of pain, distress and discomfort (see [Appendix 1](#)). It should also encompass issues relating to law, ethics, local 'rules' and the scientific process (competencies i, ii, iii, and vi respectively), all of which are relevant to the implementation of ASPA and affect the local 'culture of care'.

The importance of good training, including supervision and CPD, should be emphasised in 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. A training plan should be agreed between the project licence holder and the personal licensee at the outset, and should then be reviewed by them periodically [see Guidance para 2.83]. The type of training and level of supervision provided is determined by this plan which should identify goals and record achievements and competencies.<sup>4</sup> It should also remind licensees of the need for further supervision whenever they start with a new technique or when they start using a technique after a significant lapse in time. Examples of training plans and associated levels of supervision are given in [Appendix 2](#).

A record of supervision is required as a standard condition on the personal licence, as is a declaration of competence from the project licence holder. With respect to the latter point, it is important to be clear about who is responsible *in practice* for 'signing off' the trainee, and about how this is done.

It is also important for all establishments to have a mechanism in place to ensure that incompetence in any member of staff is recognised and reported; 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 Named Animal Care and Welfare Officer (NACWO) or Named Veterinary Surgeon (NVS) will lead to remedial action. Establishments should provide a further mechanism to allow confidential reporting (e.g. to the Certificate holder perhaps through the ERP).

Establishments should aim to achieve consistency in all of these processes and records.

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<sup>4</sup> Helpful guidance on setting up a formal and robust system of ensuring that staff are appropriately developed, with training plans and records of competencies is provided by Investors in People [www.investorsinpeople.co.uk](http://www.investorsinpeople.co.uk).

### 2.3 Defining competence

The level of competence required for the core competencies, including those associated with practical skills, knowledge and attitudes, needs to be defined so that competency, and hence completion of the supervision period, can be assessed. Setting benchmarks for competence will enable consistent judgements to be made within establishments. If such benchmarks are more widely agreed, consistency between establishments should be achievable. This could facilitate the movement of personal licensees between research programmes and/or establishments.

An example of how procedures can be broken down into a set of testable skills for assessing overall competence is given in Box 1.

#### Box 1: Criteria used to judge competence in blood sampling from a rabbit

The licensee must demonstrate that s/he

- can recognise the normal demeanour and appearance of a healthy rabbit
- can recognise signs of ill-health, pain or distress in rabbits
- can determine that the method proposed should cause the least pain, suffering, distress and lasting harm for the purpose
- has determined that appropriate project and personal licence authorities exist for the proposed procedures
- has knowledge of blood sampling routes and techniques so that the least invasive, most appropriate is selected
- can select and prepare equipment (correct needle size, clippers/scissors, surgical swabs)
- can pick up and handle a rabbit in a way that the animal is supported and does not indicate distress
- can prepare the sampling site with minimal distress to the animal
- can consistently insert a needle and withdraw blood successfully without causing adverse effects (pain, haematoma, bleeding)
- 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)
- knows 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.

### 2.4 Selecting a supervisor

Project licence holders cannot delegate the responsibility for ensuring that personal licensees are adequately supervised. However, the *process* of supervision can be delegated to an appropriately qualified person. Often there will not be one 'best' person

to supervise all the requisite core competencies and the most appropriate in each circumstance will depend on:

- the nature of the skill to be developed;
- the supervisor having current personal licence authority for the technique/procedure to be supervised;
- the level of knowledge, understanding and skills of the supervisee;
- the local management structures and resources available.

Supervision is not a task to undertake lightly and the qualities required of a good supervisor are that they should:

- understand the reasons why training and supervision are important;
- have appropriate knowledge and practical skills (both with respect to the subjects to be learnt and teaching skills) and keep up to date in all these aspects;
- know their own limitations;
- have good interpersonal skills;
- be authoritative with regard to their knowledge and experience;
- be committed to implementing the spirit of the ASPA as well as the letter of the law.

The NACWO and/or NVS will usually be able to provide advice or identify someone with the required skills and are often the best people to contact for this information. The Home Office inspector may also be a helpful source of such advice. 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. Good communication between all concerned (the project and personal licensee and the supervisor/s) is essential, and the training framework should aim to facilitate this.

## **2.5 The role of trainers and accrediting bodies**

Personal and project licensees need to be informed of their responsibilities regarding training and supervision (and the advantages of this) early in their training and trainers delivering modular courses are ideally placed to cover these issues in detail. These points should also 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.

Trainers should emphasise that modular training is only an introduction and that personal licensees need to develop their competence in all of the subjects addressed and in relevant practical skills. Prospective personal licensees need to understand that they will be working under supervision until deemed competent to work alone and that they need to ensure that they are familiar with the local processes in this respect.

In Module 5, prospective project licence holders need to be clear that it is their responsibility to ensure that:

- a) personal licensees are adequately trained and supervised until they are competent to carry out work under the project licence;
- b) appropriate records of training, supervision and competence are maintained; and
- c) personal licensees do not exceed their authorities.

The multiple choice questions (MCQ) database used for assessment of applicants should include questions relating to supervision.

**Core Competencies for Personal Licensees - extracted from the APC report****(i) Be aware and knowledgeable about national and international regulations**

Licensees should be able to demonstrate a sound knowledge of the principles of the Animals (Scientific Procedures) Act, 1986 (ASPA), codes of practice and other relevant legislation. They should understand the personal role and responsibilities of the personal licence holder and other named persons working under the Act, and their required interactions. They should be able to implement the requirements as appropriate.

**(ii) Be aware of and respect societal ethics**

Licensees should have a thorough understanding of the ethical basis for the ASPA, indicating how the cost/benefit assessment is made and indicating how the Three Rs relate. They should understand the ethical issues more generally and how these relate to and shape public opinion. They should be able to recognise that there is a spectrum of views in society on animal experiments and the use of animals more generally (not just polarised extremes) and that attitudes change over time.

**(iii) Understand and respect the 'rules' of the animal facility**

Licensees should understand the need to ensure staff health, safety and security under the Health and Safety at Work Act, 1974 and understand local rules and procedures designed to ensure smooth running of the unit, protect animal welfare and safeguard the integrity of scientific studies, including the use of barrier systems and standard operating procedures.

**(iv) Understand and know how to provide for the biology, behaviour and needs of the animals**

Licensees should understand the anatomy, biology, ecology and behaviour of the species and why the animals are motivated to behave in the way that they do. They should recognise, and know how to provide for, physiological and behavioural needs.

**(v) Be competent in animal handling and relevant techniques**

Licensees should be competent in practical aspects such as animal handling, regulated procedures and other techniques used, such that they cause the minimum distress to the animals. They should also be competent in the preparation of dosing solutions, collection, storage and distribution of samples and analysis of data.

**(vi) Be able to recognise and respond appropriately to pain, distress and discomfort.**

Licensees should be able to assess welfare and recognise pain/distress of relevant species. They should be able to identify and respond appropriately to adverse effects and outcomes.

**(vii) Have an appropriate level of understanding of the scientific process and the reasons for the study**

Licensees should understand what they are doing and why they are doing it, in the context of the programme of work authorised by the relevant project licence. They should be able to recognise the purpose of individual procedures and indicate how these relate to the project as a whole. They should have an appropriate level of understanding of the scientific process.

Two Examples of Personal Licensee Supervision and Competency Records

Example 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 current 0 - 4 | Level of supervision future 0 - 4 | PIL (signature) | Supervisor's signature confirming competence to proceed unsupervised | Date competency confirmed |
|--------|----------------------------------|-------------------|----------------------------|---------------------------|------------------------------------|-----------------------------------|-----------------|--|---------------------------|
|        |                                  |                   |                            |                           |                                    |                                   |                 |  |                           |
|        |                                  |                   |                            |                           |                                    |                                   |                 |  |                           |
|        |                                  |                   |                            |                           |                                    |                                   |                 |  |                           |
|        |                                  |                   |                            |                           |                                    |                                   |                 |  |                           |
|        |                                  |                   |                            |                           |                                    |                                   |                 |  |                           |

**Key: Levels of supervision**

- 0 - No supervision required
- 1 - Supervisor aware when procedures are taking place and available for discussion to provide advice if necessary (i.e. by telephone)
- 2 - Supervisor aware when procedures are taking place and available to attend to provide advice if required (i.e. in the vicinity of the establishment)
- 3 - Supervisor aware when procedures are taking place and available for rapid intervention if required (i.e. in the vicinity of the procedure)
- 4 - Supervisor present when the procedure takes place providing direct supervision and advice

**Example 2**

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**

| Title of Course/Seminar                                   | Date Attended | Signed for Attendance |
|---|---------------|-----------------------|
| Modules 1 – 3 (rodent)                                    |               |                       |
| Modules 2 – 3 (carnivore)                                 |               |                       |
| Modules 2 – 3 (minipig)                                   |               |                       |
| Modules 2 – 3 (farm animals)                              |               |                       |
| Module 4  |               |                       |
| Module 5  |               |                       |
| Neuromuscular blocking agent seminar - non-modular course |               |                       |
| 'Awareness' seminar - non-modular course                  |               |                       |

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

|  |         | Level 1<br>Working under supervision |                         | Level 2<br>Competence Assessed |                          |                          | Level 3<br>Competence as Trainer |                          |
|--|---------|--------------------------------------|-------------------------|--------------------------------|--------------------------|--------------------------|----------------------------------|--------------------------|
| Technique  | Species | Date                                 | Signature of<br>Trainer | Date                           | Signature of<br>Assessor | Signature of<br>Licensee | Date                             | Signature of<br>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     |                                      |                         |                                |                          |                          |                                  |                          |

**Assessment of Competence**

Level 1: Records the date that training under close supervision commences.

Level 2: Records the date that competence has been assessed and agreed by the supervisor and the personal licensee. The trainer indicates that competence has been achieved. The personal licensee agrees that s/he feels competent to carry out the technique unsupervised.

Level 3: Records the date when a level of competence has been achieved that allows the personal licensee to supervise and train other licensees.

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

|   |         | Level 1<br>Working under supervision |                         | Level 2<br>Competence Assessed |                          |                          | Level 3<br>Competence as Trainer |                          |
|---|---------|--------------------------------------|-------------------------|--------------------------------|--------------------------|--------------------------|----------------------------------|--------------------------|
| Technique<br>Specialised procedure                          | Species | Date                                 | Signature of<br>Trainer | Date                           | Signature of<br>Assessor | Signature of<br>Licensee | Date                             | Signature of<br>Assessor |
| e.g. pharmacological preparation under terminal anaesthesia |         |                                      |                         |                                |                          |                          |                                  |                          |
| e.g. Implantation of ICV cannula                            |         |                                      |                         |                                |                          |                          |                                  |                          |

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