EU 2010/63
Training, Supervision & Competence
Fraser Darling
7th December 2012
- Output of EC Expert Working Group (EWG) on Education & Training
- Functions of personnel to be trained
- EWG Agreed Approach
- NCP Endorsement
- Modules and Learning Outcomes
- UK Course Accreditation
Training

- Flexible
- Available and accessible
- Affordable
- Of agreed quality
4 ‘functions’ to be trained

Function A - Persons performing procedures
Function B - Persons designing procedures
Function C - Persons caring for animals
Function D - Persons killing animals
Persons carrying out Function B shall have received instruction in a scientific discipline relevant to the work being undertaken and shall have species-specific knowledge.

Persons carrying out Function A, C or D shall be supervised in the performance of their tasks until they have demonstrated the requisite competence.
EWG Agreed Approach

- Sufficiently detailed learning outcomes
  - Theoretical knowledge to be gained
  - Practical skills to be obtained
- Pass / Fail Criteria
- Defined Assessment
The training modules and their associated learning outcomes provide guidance to Competent Authorities throughout Member States on the minimum training requirements under EU Directive 2010/63/EU (Article 23 & Annex V).

This is intended to enable the development of an Education and Training framework within the EU which will ensure the competence of staff and facilitate the free movement of personnel within and between Member States.
NCP Endorsement

It was agreed that the training should be on a modular structure. The modules should be:

- Compulsory to all functions as in Article 23 (2)
- Required only for (a) specific function(s)
- Of National relevance
- Additional modules facilitating learning specialised skills as well as lifelong learning
The modular structure and learning outcomes approach is not prescriptive.

The learning outcomes deal with outcome rather than processes and help to define the skills and knowledge that course participants should be able to demonstrate by the time these learning outcomes are assessed.

Learning outcomes are the specific intentions of a training programme or module, written in specific terms.

They describe what a course attendee should know, understand, or be able to do at the end of that module.
Modules

The modules do not represent a course syllabus or a list of topics to be covered.

Trainers are free to select course content, training materials and delivery methods to deliver the learning outcomes in a manner that meets their national / local / institutional and/or individual / group requirements.

The achievement of practical learning outcomes may be separate from theoretical/knowledge based learning outcomes.

Skills transfer is important in all cases.
Module delivers...

- Knowledge
- Theory of the correct techniques to be applied for practical skills (not excluding hands-on training)
- The transfer of knowledge should be tested with the appropriate pass/fail criteria
- Should provide acceptable level of knowledge and skills for working under supervision
- Modules not sufficient to achieve "competence"
NCP Agreement on Academic Qualifications for functions A,C & D

With the focus on competence, on the basis of training modules which fulfil the agreed quality criteria and are assessed in a consistent manner, passing successfully the required modules infers a level of schooling and maturity sufficient for these functions.

Functions A, C and D should not require any specific educational qualifications.
NCP Agreement on Academic Qualifications for function B

The National Contact Points consider that individuals responsible for designing procedures and projects under Article 23(2)(b) should normally hold an academic degree or equivalent in an appropriate scientific discipline. This will be important to ensure such individuals are able to apply the 3Rs effectively in the design of the procedures and projects and make appropriate ethical and scientific judgments.

There may be some individuals who are recognised as qualified to perform any of the tasks identified in Article 23 of Directive 2010/63/EU prior to its entry into force for whom recognition should be continued.

It is important to note in this context that Art 40(2)(b) describes no educational requirements for the person responsible for the overall implementation of the project.
Learning Process

In general a period of working under supervision will be necessary. This allows for:

- the **knowledge** to be turned into application
- the **skill** to be practised to gain sufficient experience

Only after this period, the person should have developed the required **competence** which should then be assessed.
Supervision

In cases where there is no risk of causing pain, distress, suffering or lasting harm to the animals, the trainee can proceed to work under supervision before achieving the Learning Outcomes.

In all other cases, learning outcomes need to be attained in line with the agreed pass criteria before proceeding to work under supervision.

The learning outcome approach should allow the achievement of an acceptable level of understanding of the subject to ensure that no unnecessary pain, suffering, distress or lasting harm is inflicted when working under supervision.
Education and training framework

Acquisition of knowledge - theory for practical skills
Practice/experience - how to apply the knowledge - practise on skills
Development of deeper learning - critical thinking

Competence

Tasks without likelihood of causing pain, suffering, distress or lasting harm

Training / Working under supervision Pass assessment Evaluation of deeper learning Competence to perform tasks Maintenance of skills

Tasks with likelihood of causing pain, suffering, distress or lasting harm

Training Pass assessment Working under supervision Evaluation of deeper learning Competence to perform tasks Maintenance of skills

Enlargement of skills
Competency

- The attainment of the learning outcomes does not mean that the trainee has achieved competence.

- Competence and competencies are achieved through practical application of the acquired knowledge and experience gained through working.

- Competencies are assessed separately from learning outcomes.
Core, Pre-requisite & Additional

- The modules are split into three types: Core, Pre-requisite and Additional.

- Completion of all Core modules is compulsory and provides the basic training for all personnel performing any of the functions A-D of Article 23.

- A Pre-requisite module is a module which is required in addition to the Core modules to meet the minimum training needs for a specific function.
Core, Pre-requisite & Additional

The exception is for those persons performing only function D (killing animals) where a simplified single module was developed combining the necessary learning outcomes from the respective Core and Pre-requisite modules and may be completed as an alternative.
Modules

- After **successful** completion of the initial training module for a species/group of species, skills expansion to **further** species will require demonstration of attainment of learning outcomes for the **new** species within the same module.

- However, it may not be necessary to repeat all elements of the initial training module for the new species.
Home Office Licence Categories

There will be six licence categories available to apply for and licensing staff should be able to assess and grant Category A, B, C and E. Category types D (NMBA) and F (Other) will be a small subset requiring referral to an Inspector.

- **Category A**  Minor/minimally invasive procedures not requiring sedation, analgesia or general anaesthesia

  - **Category B**  Minor/minimally invasive procedures involving sedation, analgesia or brief general anaesthesia. Plus – surgical procedures conducted under brief terminal general anaesthesia

  - **Category C**  Surgical procedures involving general anaesthesia

  - **Category D**  Use of neuromuscular blocking agents

  - **Category E**  Procedures conducted in accordance with a project licence for education and training

  - **Category F**  Other
Named Persons

- **Person for ensuring access to information (Information Officer)**

- **Person responsible for ensuring adequate education, training, appropriate supervision and competence (Training & Competence Officer - TCO)**

- **Person responsible for ensuring conditions of establishment licence are complied with (Compliance / Certificate Holder)**

- **Veterinary Surgeon with expertise in lab animal medicine, or other suitably qualified person, to provide advice on welfare and treatment (NVS)**

- **Person responsible for overseeing care and welfare (NACWO)**
Eligibility for PIL A, B and C Home Office Licences

- Eligibility for PIL A, B and C licences will be based upon modules completed together with a declaration by the TCO that supervision will be provided until competence is demonstrated.

- Authorisation will be done by ASRU Licensing staff (referring to Inspectors when necessary) in most cases.

- The Home Office expect the entry point for most applicants to be at PIL B but they are proposing to allow for a PIL A for those few licensees who may never need to use anaesthetics (eg, some summer students; licensees who only perform dosing and sampling, etc).

- Home Office recognise that the boundary between PIL B and PIL C will need to be explained in the Guidance Notes.
Elegibility for PIL D Home Office Licences

- Eligibility for licence PIL D will be based upon assurances that the applicant has extensive experience of anaesthesia making them competent to use NMBAs safely - Inspectors will normally be consulted to advise on these applications.

- Licences under category PIL E will fall into special categories. For example, the Home Office currently have a special licensing arrangement for microsurgery training courses.
# Proposed Module Training for E&T Under the new ASPA – PIL A, B and C

## Modules and Pre-Requisite Modules

<table>
<thead>
<tr>
<th>Module</th>
<th>Function A - Carrying out procedures (PIL A)</th>
<th>Function A - Carrying out procedures (PIL B)</th>
<th>Function A - Carrying out procedures (PIL C)</th>
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</thead>
<tbody>
<tr>
<td>1 National and International laws and guidance</td>
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<tr>
<td>2 Ethics, animal welfare and the Three Rs - Level 1</td>
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<tr>
<td>3 Ethics, animal welfare and the Three Rs - Level 2</td>
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<td>4 Basic and appropriate species specific biology (note 1)</td>
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<td>5 Minimally invasive procedures, generally not requiring anaesthesia - species specific - theory</td>
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<td>6 Procedures generally not requiring anaesthesia - species specific - skills</td>
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<td>7 Animal care, health and management - species specific</td>
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<td>8 Recognition of species specific pain, suffering and distress (including humane end-points)</td>
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<td>9.1 Human methods of killing - Theory</td>
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<td>9.2 Human methods of killing - Skills</td>
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<tr>
<td>9.3 Human methods of killing - Stand-alone module for function D</td>
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<tr>
<td>10 Anaesthesia for minor procedures</td>
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<td>11 Anaesthesia for surgical procedures</td>
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<tr>
<td>12 Design of Procedures and projects - Level 1 (note 2)</td>
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<tr>
<td>13 Design of Procedures and projects - Level 2</td>
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<tr>
<td>14 Occupational health and safety (note 3)</td>
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<tr>
<td>15 Animal husbandry, care and enrichment practices - level 2</td>
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<td>16 ???</td>
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<td>17 Principles of surgery</td>
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<td>18 ?</td>
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<td>19 ?</td>
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<td>20 ?</td>
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</table>

**Key**
- Core module for all functions
- Pre-requisite module for anyone who will be carrying out a specific function
- Commitment from ECO to ensure provided under supervision after licence granted

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Paul Vallender & Bernie Godson
UK Modular Courses

- Home Office have agreed that it would be unreasonable to require the new EU modules to be introduced from 1st January 2013.

- The new structure has not yet been approved by the National Contact Points (NCP) nor information provided to all stakeholders.

- EWG is still a work in progress

- The existing modules will be compatible with the new modules.
UK Modular Courses

- Home Office will continue to accept the current UK modules until such time as trainers have been able to realign their courses to fit with the EU modular structure.

- It is envisaged that this will take most of 2013.
UK Modular Courses

- The overall content of modular courses is unlikely to change dramatically, but there is likely to be an impact on context.

- Training will be broken down into a greater number of modules.
UK Modular Courses

- Some will have to be tailored to the needs of the individual according to function.
- Some will have to be delivered at different levels according to function/role.
- New assessment criteria will need to be developed for theoretical and practical teaching.
Course Organisers are preparing new Modules for courses held after 1st January 2013.

These will include revised information on the transposed UK legislative framework.

Modules will evolve as more information becomes available from the EWG.

Number of meetings arranged between UK Accrediting Bodies and Course Organisers throughout 2013.
Education and training framework

Accrediting bodies working to agreed principles on how to approve modules:
- mutual recognition

Structure for overseeing standards and principles

- Approved modules with agreed learning outcomes
- Agreed principles for pass/fail criteria
- Agreed principles for assessing competence

Tasks without likelihood of causing pain, suffering, distress or lasting harm

Tasks with likelihood of causing pain, suffering, distress or lasting harm

- Training / Working under supervision
- Pass assessment
- Evaluation of deeper learning
- Competence to perform tasks
- Maintenance of skills

Acquisition of knowledge → Practice - experience → Development of deeper learning - critical thinking

- Competence to perform tasks
- Maintenance of skills

Enlargement of skills
Stages of Supervision

EXAMPLE FROM LASA GUIDING PRINCIPLES ON THE SUPERVISION REQUIREMENTS FOR PERSONAL LICENSEES (2010)

A. Direct - supervisor present (for new trainees).
B. Supervisor aware and available locally to provide assistance.
C. Supervisor aware and available to attend if needed at short notice.
D. Supervisor aware and available by telephone.
Assessment of Competence

- **Separate supervision and competence assessment** where possible.

- **Objective** assessment - expectations known to trainee; **Pass / Fail parameters**.
Guiding Principles on the Supervision Requirements for Personal Licensees
EXAMPLE TAKEN FROM LASA GUIDING PRINCIPLES ON THE SUPERVISION REQUIREMENTS FOR PERSONAL LICENSEES (2010)

Two Examples of Personal Licensee Supervision and Competency Records

Example 1

<table>
<thead>
<tr>
<th>PL 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 cured 0 - 4</th>
<th>Level of supervision future 0 - 4</th>
<th>PL (signature)</th>
<th>Supervisor's signature confirming competence to proceed unsupervised</th>
<th>Date competency confirmed</th>
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<tbody>
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</table>

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
(ii) Basic in vivo Procedures (examples)

<table>
<thead>
<tr>
<th>Technique</th>
<th>Species</th>
<th>Level 1 Working under supervision</th>
<th>Level 2 Competency Assessed</th>
<th>Level 3 Competency as Trainer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Date</td>
<td>Signature of Trainer</td>
<td>Date</td>
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<tr>
<td>Animal handling and restraint</td>
<td>Mouse</td>
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<td></td>
<td>Rat</td>
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<tr>
<td>Oral administration of substances</td>
<td>Mouse</td>
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<td>Rat</td>
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<tr>
<td>Intraperitoneal administration of</td>
<td>Mouse</td>
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<td>substances – small animals</td>
<td>Rat</td>
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<tr>
<td>Subcutaneous administration of</td>
<td>Mouse</td>
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<tr>
<td>substances</td>
<td>Rat</td>
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<tr>
<td>Withdrawal of blood from superficial blood vessels</td>
<td>Mouse</td>
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<td>Rat</td>
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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 she 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.
### EXAMPLE TAKEN FROM LASA GUIDING PRINCIPLES ON THE SUPERVISION REQUIREMENTS FOR PERSONAL LICENSEES (2010)

#### (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>
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<tbody>
<tr>
<td>e.g. pharmacological preparation under terminal anaesthesia</td>
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<td>e.g. implantation of ICU cannula</td>
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#### Assessment of Competence

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- **Level 3:** Records the date when a level of competence has been achieved that allows the personal licensee to supervise and teach other licensees.
EWG Summer 2013

- Role of Training & Competency Officer (TCO)
- Training for other roles (Veterinarians, Project Evaluators)
- Use of live animals for training
- Exemptions / exceptions from training
Objectives of EWG

- Reach common understanding of the issues

- Acknowledge necessity for expert judgement

- Agree common format and approach

- Promote good practice and optimum processes

- Provide practical, demonstrative examples to facilitate understanding
EU FRAMEWORK FOR A MODULAR TRAINING COURSE ACCREDITATION FOR DIRECTIVE 2010/63/EU

EU L.A.S. E&T PLATFORM
(independent of the EC)
composed of an elected, limited number of representatives of MSs, Acc.Bodies, Course/Module Providers (e.g. 5+3+2) to
- establish criteria for accrediting bodies
- recognise and maintain list of accrediting bodies
- maintain criteria for modules
- rotating/permanent Chairmanship/Secretariat

Accrediting body Nat'l/role of MS authorities
Accrediting body Int'l
Accrediting body Public
Accrediting body Private

Course/module provider
Course/module provider
Course/module provider
Course/module provider
Course/module provider
Course/module provider
Course/module provider

The Commission can facilitate by providing

1. Information portal containing
   Links for
   • accrediting bodies
   • course/module providers
   • space for course/module providers to catalogue courses/modules
   Information on
   • criteria for modules
   • standards for supervision
   • standards for assessment
   • standards and templates for recording training and assessment
   • contact details for the EU Platform

2. Ad-hoc meeting facilities, Expert Working Groups for specific topics
Level playing field?
Work in progress...
But then acting is all about faking. We're all very good at faking things that we have no competence with.

John Cleese