The **A P C**
Animal Procedures Committee

ANIMAL PROCEDURES COMMITTEE

December 2010

MODULE 5 AND THE TRAINING OF PROJECT LICENCE HOLDERS

Module 5 and the training of project licence holders

Contents

1. Introduction

This report presents the second part of the APC Education and Training sub committee[1] (ETSC) overview of modular training under the Animals (Scientific Procedures) Act 1986 (ASPA). Part 1[2], completed in January 2006, reviewed training for personal licensees (APC 2006). This Part 2 addresses module 5 training for project licence applicants and reflects the work that was progressed through three workshops held in February 2006, May 2007 and September 2009. These brought together course organisers, trainers, the accrediting bodies[3] and others with an interest in, or responsibility for, training and the Home Office Inspectorate.

This report is aimed at certificate holders, ERPs, course providers and accrediting bodies whose collective responsibility is to provide training which satisfies the needs of project licence holders, develop module 5 training where required, and to contribute ideas for continuing professional development (CPD) and in-house training for existing project licence holders and their contacts. This report should clarify the aims of module 5 training, identifies issues of concern and offers a set of core competencies for 'an ideal project licence holder'. However, the report does not attempt to define a set of learning outcomes for module 5, this requiring much more consultation with course organisers, trainers, accrediting bodies and the Home Office Inspectorate. In the latter stages of preparing this the revised European Directive 86/609[4] has become a factor likely to affect the training of project licence holders in addition to ongoing efficient regulation initiatives and the development of a new project licence application form.

The core competencies do, however, provide a basis from which a more detailed syllabus and set of learning outcomes for module 5 may be developed. The core competencies described also constitute an aide-mémoire that will we believe help project licence holders understand what is expected of them. Since the competencies provide a profile of the knowledge and skills that a project licence holder requires, they can also be used to help identify the most appropriate people to take on this responsibility.

The report focuses on training under the UK ASPA 1986, but the competencies described are also relevant to training for personnel in other countries who direct and/or manage projects that involve the use of animals. Together with elements of modules 1 – 4, they encompass the FELASA recommendations for equivalent staff (FELASA Category C) in Europe (see FELASA (2000) and Appendix 2)[5]. The report may therefore be of wider international interest particularly in light of the harmonisation aims of revised Directive 86/609..

It is important to state at the outset that this report is not a review of the delivery of module 5 courses nor is it a review of individual courses and no implications are made accordingly.

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[1] The Sub-Committee includes the same co-opted members as for the review of modules 1-4, (see Appendix 3). All members had direct experience of organising, running, or teaching on, module 5 courses.

[2] http://apc.homeoffice.gov.uk/reference/apc-education-modular-training.pdf

[3] The Society of Biology (formerly the Institute of Biology (IOB)), the Universities Accrediting Group (UAG) and the Scottish Accreditation Board (SAB)

[4] lex.europa.eu/LexUriserv/LexUriServe.do?uri=COM:2008:0543:FIN:EN:PDF

[5] http://www.felasa.eu/document-library/cat_view/17-guidelines-a-recommendations/18-education-a-training

1.1 Module 5 current status

There are currently approximately a dozen module 5 training course providers in the UK, with courses lasting between 1 and 2 days (see appendix 1 and the LASA directory 2007-2009 for details).

1.2 The aim of module 5 training

Section 5(2) of the ASPA that states:

> "*A project licence shall not be granted except to a person who undertakes overall responsibility for the programme to be specified in the licence*".

The main purpose of module 5 training is to ensure that prospective project licence holders are aware of their responsibilities and liabilities under ASPA. They need an understanding of what is meant by '*overall responsibility*' and their duties in this respect. Training should also provide them with the tools necessary to prepare and manage a programme of scientific work involving the use of living animals. Thus, it should:

(i) impart knowledge and help develop skills;
(ii) raise awareness and increase understanding of the duties, responsibilities and competencies required of project licence holders; and
(iii) influence practice i.e. engender attitudes and behaviours appropriate to the level of responsibility (such as an understanding of the need to take appropriate advice and actively keep up to date with, and implement, the 3R's).

Module 5 training can only provide *an introduction* to the many issues that a project licence holder has to deal with. It is intended to provide a framework within which individuals can develop the competencies required to be effective in their role. It needs to be seen in the context of continuing professional development (CPD) and individual personal development plans. This is already recognised in industry as good practice.

It is therefore essential that attending a module 5 course is not seen merely as a means of obtaining a project licence. In many respects it should help licence holders to manage project licences so as to comply with the legal and ethical obligations.

1.3 Training requirements

The Home Office training requirements are summarised in Table1. Attendance on a module 5 course has been mandatory for prospective project licence holders since 1995 and is also strongly recommended for those whose role equates to that of a 'project licence contact' Existing project licence holders who wish to renew their licences may also be required by their establishment to attend.

Table 1: Summary of current HO requirements re module 5 training

Category of Staff	Module 5 training
New project licence applicants	Mandatory
Project contacts	Strongly recommended
Existing project licence holders (from pre-1994) who have never done module 5	Strongly recommended
Project licence holders applying to renew a licence	Recommended as an update

Recommendation 1*. The ETSC believes that module 5 training should be mandatory for those who are contacted by the Project Licence to perform major duties on either a long term or regular basis, and recommends to the Home Office that this is strongly encouraged.*

2. Issues of concern

Discussions with training course organisers, trainers, representatives of the accrediting bodies and project licence holders at the workshops highlighted the following concerns.

2.1 Interpretation of the syllabus

The course syllabus is set out in the Home Office policy on Education and Training[6] and is reproduced as Table 2. However, as presented, the syllabus is brief and there is little guidance on its interpretation, or on what it is expected to achieve over the short duration of the module 5 taught course. Understandably, course organisers have developed diverse approaches to delivering the module. People teach as well as learn in different ways so this is not necessarily a negative point. However, trainers and accrediting bodies have reported that it would be useful to have more guidance on the breadth and depth of subject matter that should be covered for each syllabus topic. This would help ensure that courses do not diverge too far and would enable the best use to be made of the limited time available. The development of core competencies and accompanying guidance notes within this document (see section 4) are intended to help with this. As an aid to learning and teaching the module 5 course, a proposed taught elements framework has been drafted following discussion with trainers and accrediting bodies (see Appendix 9: Taught Elements)

[6] (see Appendix F) The Guidelines on the Operation of the ASPA 1986 (Home Office 2000)

Table 2: The syllabus

1. Ethical aspects of the use of live animals

2. Analysis of the literature
   - Critical appraisal
   - Literature searches

3. Alternatives
   - Refinement
   - Reduction
   - Replacement

4. Project design
   - Plan of work
   - Good laboratory practice
   - Appropriate laboratory methods
   - Selection of appropriate animal models
   - Appropriate statistical methods

5. Project licence management
   - Responsibilities
   - Supervision of personnel and programme of work
   - Record keeping requirements
   - Annual return of procedures

6. Legal aspects – the European and wider international context

2.2. Time available

The time available for the course was highlighted as a particular issue; some topics such as experimental design, literature review, statistical methods and selection of animal models, ideally to be covered in depth would take longer than the entire duration of the course. Nevertheless, these are essential skills that project licence holders need to acquire in their scientific training. The Committee accept that there would normally only be enough time in module 5 to try to make sure that applicants fully appreciate the importance of such skills, understand the main principles involved, and are aware of the need to seek further information and advice. This is particularly important where applicants have no previous experience of animal work.

2.3 Pre-course experience of trainees

The Home Office expects those applying for project licences to be experienced Personal Licensees and to have attended *at least* module 1 and 2 unless there are exceptional circumstances[7]. (Possible exemptions should always be discussed with

[7] An example of a circumstance where exemption might be allowed would be a small remote establishment working on a single species with excellent in-house, though non-accredited, training

the local Home Office Inspector.) However, in practice, participants come to the courses with diverse scientific backgrounds and different levels of knowledge and skills and this can make it difficult to deliver training appropriate to each individual on a course.

Typically, new project licence applicants are experienced scientists with a good knowledge of some of the scientific topics addressed by the syllabus. They are usually well advanced in their career and may have completed other modules at some time.

The variation in background and experience is one of the most difficult problems that trainers face. Decisions regarding the level of detail for course topics, and harmonisation of training between courses, would be easier if course delegates had to come up with a defined minimum knowledge and skills base. Course providers could consider whether there are pre-course materials, or delegate selection criteria, that could help in this respect. The key issue is to get all attendees at least to the same minimum standard as a course output. This harmonisation issue ties in with the current thinking of the proposed revisions to EC 89/609.

Recommendation 2: *Accrediting bodies in collaboration with related groups and organisations should devise some exemption criteria for the different parts of the module 5 taught course. These should be reviewed by the ETSC.*

2.4 Course materials

There could be scope for course providers to produce shared course materials (e.g. core text, PowerPoint presentations, reference material, case studies) this would help build on the strengths of existing courses and prevent too great a divergence between them. IP and commercial constraints will of course have to be respected.

2.5 Assessment

Bodies that accredit module 5 courses require some form of assessment. Assessment indicates whether the course is achieving its objectives and help trainees reflect on what they do or do not know. However, different course organisers use different methods of teaching and there are acknowledged difficulties with assessment of some aspects of the course.

Committee suggestions for methods of assessment in relation to the core competencies are given in appendix 5-8 of this document.

Recommendation 3: *Accrediting bodies together with Training Providers should discuss the issue of assessment using Appendixes 5 - 8 as a guide.*

3. Additional training workshops provided by the Home Office Inspectorate

The Home Office Inspectorate offer training workshops which act as an adjunct to the module 5 course. These workshops aim to:

- Identify what information Animals (Scientific Procedures) Inspectorate (ASPI) needs in order to assess an application according to ASPA requirements
- Explain how best to provide this information on the application form and how the questions on the form relate to these required assessments
- Provide guidance on the level of information required to allow the assessment to occur

- Allow consideration of the applicants own proposed work, help them clarify their objectives, and assist in applying the principles to their own work
- Provide a forum for project licensees to meet with their Home Office Inspector and other licensees and stimulate an ongoing working dialogue.

Such workshops aim to assist applicants in achieving the goal of 'right first time' applications. Workshops are intended to supplement, not replace, the Notes for Applicants attached to the Project Licence Application Form. Some applicants, and in some cases with help of their local ERPs, write applications of sufficient quality that such workshops are superfluous. Some require just a 1:1 meeting with their inspector to discuss specific issues.

The workshops do not cover much of the material which should be covered in module 5, although there is likely to be overlap when discussing ASPA section 5 (Project Licences). Sections 10 (Conditions: Licences and designation certificates), 14 (Re-use of protected animals) and 17 (Neuromuscular blocking agents) of ASPA also need to be considered and appropriately presented by the applicant, and reinforcement of learning acquired in module 5 is often needed for these issues.

The workshops have been attended by new and previous applicants and by ERP members to allow updating of knowledge to current thinking within the Home Office.

The Inspectorate acknowledges that they do not, and should not have the monopoly on assisting applicants and ERP members in these ways. They do not have the resources to provide such workshops to all on demand. Resource to assist individual applicants on request has always been found to date. The Inspectorate welcome opportunities to interact with ERPs, course providers and accrediting bodies in order to optimize delivery of the information given in the workshops. The Inspectorate is uniquely placed in being able to update the stakeholders on changes within the Home Office. It is expected that updating seminars will continue to be given on request, or as required.

4. Core competencies for an ideal project licence holder and how module 5 training can contribute to developing these

The responsibilities of project licence holders are defined in the ASPA standard conditions and accompanying Guidance Notes (HO 2000). These were used within the ETSC workshops and subsequently to develop a set of core competencies which cover the knowledge, skills and attitudes required of an 'ideal' project licence holder. They can be assigned to four main headings:

- legislation;
- ethics and welfare;
- good scientific practice and the 3Rs;
- operational management.

See table 3, appendix 4 which together encompass the topics in the module 5 syllabus. Each of the four core competencies can then be broken down further as shown in the boxes in section 4.2. There is no absolute distinction between the four competency areas. For example, there is overlap between the ethics and welfare competency, good scientific practice and the 3Rs, and legal issues, and many of the operational management aspects are closely related to points in the other three areas. Nevertheless, it is helpful to define them separately in order to go on to define training objectives and learning outcomes for module 5 itself and to provide guidance to new licencees of what is expected of them.

4.1 Developing training objectives and learning outcomes for module 5 from the core competencies

Definitions of terms;

Core competency: This defines the knowledge, skills and attitudes required to carry out a task effectively.
Training objectives: These are specific goals for a learning experience; as such they identify what the trainer intends to achieve.
Learning outcomes: These are specific goals for a learning experience, and thus identify the hoped for changes in the learner.
Training objectives and learning outcomes: are closely linked; generally these will mirror each other and the terms are often used interchangeably.
Taught Elements: The individual components of the syllabus that may be presented in the classroom as part of a Module 5 introductory course.
Teaching Tools: The various ways that are used to achieve the learning outcomes.

As stated earlier, the responsibilities, and hence core competencies, required of project licence holders are much broader than for personal licencees, and module 5 training alone cannot be expected to ensure that licensees are immediately competent in each area. For example, some of the individual competencies listed under 4.2.3 'Good Scientific Practice and the 3Rs' and 4.2.4 'Operational management' are likely to be developed through candidates' scientific training and experience in managing staff and projects. They cannot really be 'taught' in a short course, although the need for these skills can be emphasised.

The Committee recognises difficulty in specifying the breadth and level of detail that a course should go in to for any subject area but maintain the proviso that the course needs to educate to the minimum standard of essential knowledge. This critically should depend on the knowledge and experience of the prospective licensees, the scope and nature of the projects they are to manage, and the type of establishment they come from. There needs to be flexibility in how a course is constructed to take account of these differences since some topics will be more, or less, relevant depending on specific circumstances (e.g. animal species involved in research). However, in the spirit of EU harmonisation and the aims of the proposed revisions to Directive 86/609, courses will need to be transferable between different research environments.

Some issues should however be routinely explored in more depth during the course. These include:

- the specific ASPA requirements and responsibilities of the project licence holder (competency 1 and supporting notes in appendix 5)
- the ongoing requirement under ASPA to minimise welfare costs during the lifetime of the project licence (competency 2 and supporting notes in appendix 6)
- the need to maximise the likelihood of success and minimise animal numbers through good experimental design and clear experimental strategy (competency 3 and supporting notes in appendix 7)
- the need for and mechanism of ensuring appropriate supervision of personal licence holders to make sure technical competence is developed (competency 4 and supporting notes in appendix 8)

4.2 The Core Competencies

4.2.1 Competency 1 - Legislation

A project licence holder must have a comprehensive understanding of the national and international legal and regulatory framework within which project licences are constructed and managed, and of the legal responsibilities of themselves as project licence holders. They must:

(i) Understand the legal framework of the Animals (Scientific Procedures) Act 1986 (ASPA) and associated codes of practice and guidance, to at least the level expected in the APC review of modular training module 1 – this depends on acceptance of the proposed revision) for personal licence holders; and be aware of relevant EU and international legislation such as Directive 86/609 and Convention ETS 123 that are likely to impact on UK legislation.

(ii) Understand the legal responsibilities of the project licence holder as set out in the Guidance Notes on the Operation of the ASPA 1986 (Home Office 2000). In particular, the individual must know that standard, and possibly special, conditions are attached to each project licence and certificate of designation, and be able to relate the scope of these.

(iii) Understand the difference between delegation of duties (which is acceptable) and delegation of responsibilities (which is not acceptable).

(iv) Understand that the ASPA requires that the justification for programmes of work is assessed by weighing potential adverse effects on the animals against the likely benefits; that harms to animals must be minimised, and benefits maximised; and be able to prepare a project licence accordingly.

(v) Understand and recognise the legal responsibilities of other named persons with statutory responsibilities under the ASPA.

(vi) Be aware of other legislation and regulations which impact on the welfare and use of animals, including those relating to veterinary care, animal health, transport, quarantine controls and human health and safety.

4.2.2 Competency 2 - Ethics and welfare

A project licence holder must be able to identify, understand and respond appropriately to the ethical and welfare issues raised by the use of animals in scientific procedures generally, and specifically within their own programme of work. They must:

(i) Understand that there is a broad range of ethical, welfare and scientific perspectives on the use of animals in scientific procedures, and that thinking on all of these matters evolves over time and is influenced by context. Understand that this means there is need for *on-going* critical evaluation of the justification for using animals and of implementation of the Three Rs at all stages of the life of a project.

(ii) Be able to identify ethical and animal welfare issues arising from the proposed work; be prepared to provide the information necessary to enable a robust harm/benefit assessment to be performed; and explain why they personally consider that the potential benefits outweigh the likely adverse effects.

(iii) Recognise that there are ethical limits to what it is considered permissible to do under the ASPA, (i.e. via administrative 'bans' imposed by the Secretary of State) and that even within these legal constraints, there are also likely to be national, institutional and temporal differences in this respect.

(iv) Understand the role and function of the local ethical review process (ERP) within the establishment, and the importance of active and positive engagement with the process.

(v) Understand the need to communicate appropriate information to lay persons, including members of the local ERP and a wider public audience, and be able to prepare a satisfactory lay summary to facilitate this.

(vi) Recognise that they have a duty of care to the animals used under their licence; understand that in constructing and managing a project licence they must be able to identify, assess and minimise all of the welfare costs to animals throughout their lifetime (including adverse effects relating to sourcing, transport, housing, husbandry, handling and procedures);

(vii) Be able to formulate and apply appropriate humane (in addition to scientific) end-points and establish criteria suitable for identifying when each has been reached.

(viii) Understand the importance of disseminating information that will promote understanding of ethical issues, good animal welfare and application of the Three Rs.

4.2.3 Competency 3 –Good scientific practice and the 3Rs

A project licence holder should be able to develop, direct and control a programme of work in order to achieve its stated objectives, while ensuring compliance with the terms and conditions of the project licence. This includes implementation of the three R's throughout the programme of work. They must:

(i) Be able to develop a scientific strategy that will achieve robust results, and prepare a project licence application accordingly.

(ii) Be aware of the availability and potential contribution of methods within the overall research programme that complement the use of living animals; recognise that technological advances continually produce potential refinements and replacements and appreciate the need to continually assess opportunities to identify and implement these.

(iii) Be able to identify opportunities for reduction, refinement or replacement and contemporary good practice through, for example, literature searches, discussion with colleagues and from professional bodies.

(iv) Be able to formulate clear and unambiguous hypotheses and select the most appropriate animal or non-animal models, taking into account scientific, ethical and welfare aspects.

(v) Recognise the need for good experimental design and understand the principles involved including the need to: design experiments and analyse numerical data using appropriate statistical methods; recognise causes of biological variability; and ensure consistency between experiments.

(vi) Appreciate the need to be up to date with developments in laboratory animal science and technology so as to ensure good science and animal welfare.

(vii) Be able to balance the potential conflict between adopting new techniques and maintaining the integrity of existing scientific data.

(viii) Understand the importance of project management, strategic planning and setting realistic milestones and appropriate decision points.

(ix) Appreciate the importance of rigorous scientific technique and the requirements of assured quality standards such as GLP.

4.2.4 Competency 4 – Operational management

Have sufficient knowledge, communication and management skills to ensure effective and efficient operational management of a project licence, and that all personnel working under the licence comply with their legal and ethical responsibilities.

(i) Appreciate the ways in which activities of the named persons with statutory responsibilities under the ASPA contribute to effective project licence management.

(ii) 'Recognise the breadth of authorities contained within the Certificate of Designation and the limitations imposed thereof'.
'Understand the relevance of PODES, (Places Other Than Designated Establishments), and the possible implications for the plan of work'.

(iii) Recognise the limitations of their own experience, and know when specialist expertise (for example in animal health, welfare, statistics) is needed. Know how and where to gather advice and who to go to.

(iv) Understand how the local ERP addresses research proposals and its role in mid-term and/or retrospective review.

(v) Be aware of local arrangements relating to project licence management, e.g. procedures for ordering animals, species and strains available, safe working practices, security, accommodation standards, disposal, etc. (see learning outcomes for module 1-3).

(vi) Be able to ensure there are effective communication processes in place for all team members, including personal licensees, named persons, line managers and others, and that they all receive the information that they need.

(vii) Understand that it is the responsibility of the project licence holder 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. d) ensure personal licensees are familiar with the project licence

(viii) Know what records are required by the establishment, by the ASPA, and by the standard conditions of the project licence, and who is responsible for these.

(ix) Understand the importance of instilling a sense of responsibility in all those working within the project. Recognise the need for: regular review of progress with the scientific and animal welfare team; early identification of potential problems; and the importance of planning for contingencies (e.g. when the project licence holder is absent).

(x) Be able to manage resources (money, staff, consumables, time) to achieve valid scientific results.

(xi) Know what actions to take in the event of unexpected problems arising.

(xi) Know what actions should be taken in the event of any suspected infringements occurring.

5. Continuous Professional Development

The ETSC believe that records need to be kept by all project licensees which detail the training received or credited. If these were to be recorded against each competency the record would also highlight which competencies were still to be addressed.

Achieving the four competencies outlined in 4.2 may be acquired in three ways:

a. approved prior learning
b. Module 5 training
c. Continuing professional development

Recommendation 4*: The ETSC believes that the Home Office Inspectorate should consider implementing a standard system to record project licence training and further continuous professional development.*

6. The impact of the amended EC Directive 86/609

Once the amendments to the Directive have been finalised and adopted the ETSC would like to review this document in light of any unforeseen requirements within it or practices developed and implemented by other Member States.

7. Acknowledgements

The ETSC is grateful for the continued co-operation and enthusiasm of all those who participated in all stages of developing this report.

8. References

FELASA (2000). FELASA recommendations for the education and training of persons carrying out animal experiments (Category A-D). Report of the Federation of European Laboratory Animal Science Associations Working Group on Education of Persons Carrying out Animal Experiments (Category B) accepted by the FELASA Board of Management. *Laboratory Animals 34:229-235. 2000)*

Home Office (1993). *Report of the Animal Procedures Committee for 1992.* London: HMSO

Home Office (1994). *Report of the Animal Procedures Committee for 1993.* London: HMSO

Home Office (2000). *Guidance on the Operation of the Animals (Scientific Procedures) Act 1986.* London: HMSO

Home office (2006) Animal Procedures Committee Education and Training sub committee: Review of Modular Training. Published on the APC website at http://www.apc.gov.uk

Appendix 1. Organisations currently offering module 5 courses (from Directory of Animal Research Training courses 2007-2009, published by LASA)

1. B&K Universal Ltd
2. Bioscientific Events Ltd.
3. DSTL Ltd.
4. Imperial College
5. Medical School, University of Newcastle
6. NI Licensee Training Group, Belfast
7. The Royal Veterinary College.
8. UBSS Cambridge
9. University of Edinburgh
10. Universities of Liverpool and Manchester, (Joint Module 5 Training Course)
11. University of Oxford
12. University of Sheffield

Appendix 2: FELASA recommendations for Category C staff

Minimum requirement: BSc, MSc in a biomedical discipline, plus 80-hr or equivalent course in laboratory animal science.

Eight main topics in this basic study:

- Biology and husbandry
- Microbiology and disease
- Health hazards and safe practices in the animal house
- Design and conduct of animal experiments
- Anaesthesia, analgesia and experimental procedures
- Alternatives to animal use
- Ethical aspects and legislation
- Analysis of scientific literature

The course should be concluded by an examination or other form of assessment.

Appendix 3: Membership of the APC ETSC and co-opted members

ETSC members:
Graham Moore (chair from January 2006-January 2008)
Maggy Jennings (chair until January 2006)
Michael Festing (until August 2009)
Peter Hunt
Bob Kemp
David Smith (from June 2009)
Sarah Wolfensohn (from June 2009)
Observer from the Home Office Inspectorate:
Maggie Lloyd (until August 2008)
Kathy Ryder (from September 2008)
Co-opted members:
Manuel Berdoy
Bryan Howard
Jane Smith

Janet Watson (until August 2009)
Maggy Jennings (from April 2006)

Appendix 4

Table 3: The relationship between the module 5 syllabus and core competencies for project licence holders

Current module 5 syllabus	Core Competency
• Legal aspects – the European and wider international context	Legislation
• Ethical aspects of the use of live animals	Ethics and Welfare
• Project design - Plan of work - Good laboratory practice - Appropriate laboratory methods - Selection of appropriate animal models - Appropriate statistical methods • Alternatives - Refinement - Reduction - Replacement • Analysis of the literature - Critical appraisal - Literature searches	Good scientific practice and the 3Rs
• Project licence management - Responsibilities - Supervision of personnel and programme of work - Record keeping requirements - Annual return of procedures	Operational Management

Appendix 5 Supporting notes on Competency 1 – Legislation.

All the suggested competencies relate to acquiring factual information and can therefore be taught using lectures or a combination of lectures and case studies. Assuming applicants are Personal Licence Holders, they will already have covered some, e.g. 1(i), 1(iv), 1(v), in module 1 training, but delegates will need reminding of them, especially if they have not done module 1 recently. However, the emphasis in module 5 needs to be on section 5 of ASPA and the legal responsibilities of a project licence holder.

Competency 1(iv) on the harm/benefit assessment is covered in more detail under competency 2 Ethics and Welfare. The principles can be taught but group work, exploring what constitutes a harm and a benefit and how individuals weigh these, can be particularly useful.

For competency 1(vi) – be aware of legislation and regulations that impact animal welfare, it would be helpful to develop a standard list of legislation and regulations that project licence holders need to be aware of.

Assessment

The first two competencies may be assessed using MCQs or by asking candidates to identify the 'tests' that ASPA poses. Competencies 1(iii) to 1(vi) could be assessed by asking for short answers to a posed scenario, or by combining MCQs with a case study. For example candidates could be asked:

- Competency 1(iii) - What is meant by the harm/benefit analysis, or what requirements do you, as a project licence holder, have in regard to the harm/benefit assessment.
- Competency 1(iv) - You are project licence holder, and have a 4-month sabbatical in the USA starting at the end of the month. You write to the Home Office stating that you delegate responsibility to your contact (*formerly known as deputy*) in your absence. What is the Home Office Inspector likely to say in reply?
- Competency 1(v) – List three responsibilities of, or write a paragraph each on, the role and responsibilities of a) NACWO; b) NVS; c) certificate holder.
- Competency 1(vi) - as project licence holder, you want to move animals abroad to a collaborator. What issues must you consider? Include legislative requirements where possible.

Appendix 6 Supporting notes on Competency 2 – Ethics and Welfare.

These competencies are encompassed by all three aims of module 5 training (imparting knowledge, raising awareness and engendering appropriate attitudes and behaviour). The development of most of the competencies in this section would benefit from an interactive session with plenty of time for discussion perhaps involving group debate on specific subjects. Some points can be taught, for example, it is easy to provide information about the different types of ethical framework and assess candidates by asking them to identify which are utilised under ASPA 1986.

The more subjective aspects (e.g. in competencies 2(i), 2(ii)) may be more difficult to teach and assess, but are nonetheless important. There is likely to be insufficient time to go into the practical detail of the harms and benefits that may occur in all of the delegates' projects, yet this is important information that course participants need to know. Participants will need to understand the underlying principles with regard to what constitutes a harm and a benefit - the course needs to give them the 'tools' to identify harms and benefits in their own work, perhaps using illustrative worked examples. Depending on how the course is run, trainees could develop a greater level of detail on these issues for their own projects within the module 5 course itself, during Inspectorate workshops (described in Section 3.1 of this report) or with the assistance (if required) of local staff and / or local Home Office Inspector.

For those competencies that relate to local activities such as establishment 'limits' and the ERP, participants will need to be informed (rather than 'taught') of the need for them to ask about this in-house. Trainers should be aware of and if required, inform trainee, of a local contact for each trainee. The standard functions of the ERP as set out in the Guidance on the Operation of the ASPA (Home office 2000) 1986 can be explained first.

Assessment
For most of these competencies assessment will need to demonstrate the candidates understanding of the principles that have been covered. For some (e.g. competencies 2(iii) or 2(iv) it should be possible to ask for short answers to questions (e.g. on the 'administrative bans, or functions of the ERP), or to pose scenarios such as asking participants to formulate and apply appropriate humane end-points and

establish criteria suitable for identifying when each has been reached. They could also be asked to prepare a statement to justify work in a particular area or on a particular species perhaps.

Competency 2(viii) can be tested by asking candidates to write a lay summary of a given project or to critique examples published on the Home Office web-site.

For the more local aspects, candidates could be asked to prepare a list of action points for when they return to their respective establishments.

Appendix 7 Supporting Notes on Competency 3 –Good scientific practice and the 3Rs

There is some overlap between competency 3 and competencies 1,2 and 4, but 3 has a more practical element. Interestingly, competency 2 requires an understanding of the three Rs in the context of the need for ethical behaviour, whereas competency 3 is about how to implement the three Rs in practice.

This set of core competencies is also the one where it is most difficult to define the level of information that needs to be got across in a module 5 course, and where there is probably most overlap with the HO Inspectorate workshops. This is because the competencies all relate to the scientific, professional and management capabilities, training and experience of the prospective licensee. Most of the skills required should already have been acquired as part of scientific training and professional experience, and only personnel who are likely to be able to deliver such skills should be put forward as prospective project licence holders.

For some of the topics covered in each competency, the most that module 5 can hope to deliver is an overview of the skills required. It can therefore only provide information on the *principles and strategies* employed to deal with the issues, for example to develop a good hypothesis, determine the availability of alternative methods or select the appropriate model.

Participants are likely to come with varying levels of expertise and it may be difficult to design a course that is a satisfactory level for all the delegates. At the very least it is important to give an overview of the principles of experimental design and raise awareness of common pitfalls where people go wrong, with worked examples for reinforcement and assessment.

Assessment
Since it is difficult to define the level of information that needs to be imparted in this part of the course, it is likewise difficult to prescribe methods of assessment.

The main output is to make candidates aware of the need to plan carefully, with decision points and clear criteria for success at each stage. A way to assess part of the module might therefore be to ask delegates to read a case study, draft an appropriately phrased objective, and prepare a decision tree for achievement of the objective. This would help reinforce the need to have a clear scientific strategy.

Assessment of experimental design could be tested using scenarios appropriate to the trainees' research areas.

Candidates could also be asked to prepare a list of action points of, for example, resources to be explored when they return to their establishments, or questions they

should ask themselves, such as 'how will I make sure I am using the least number of animals', or 'who can advise me about refinements?'

Appendix 8 Supporting Notes on Competency 4 – Operational Management.

Few of these competencies (with the exception of 4(vi) and 4(vii)) can be achieved by straightforward delivery of facts on an individual training course. Some, (4(ii) – 4(v)) are about arrangements or management practices at local establishments, so delegates need to be informed of the importance of seeking out relevant information on their return. Others are about developing personal qualities and experience required of good managers, such as communication and leadership skills. These may best be addressed with roles and responsibilities exercises, or case studies in groups. For example, delegates could consider who is best qualified to advise on, or deal with, various issues and potential problems, or how to ensure effective communication with people in various roles and on different sites.

A key point to get across is the project licence holder's responsibilities regarding supervision, so most of the time should be spent on exploring how this can best be managed. Some project licence holder's will not themselves be proficient in the procedures under the licence, and it is important to ensure that they understand that they retain overall responsibility for all work under the licence even when an action or activity is delegated.

Assessment
The knowledge-based competencies can be assessed by MCQs or short answers and this is particularly important with respect to supervision. For example, candidates could be asked how they would manage supervision and assessment of competence for a Personal Licensee working under their project licence.

For the rest of the skills, training involves raising awareness of the need for the skill, and the candidate's limits in this respect, so assessment may need to be based on a self assessment, either during the course or on their return to their establishment. Examples could include setting a task to identify how the requisite skills could be acquired, or the people/resources necessary to fill any gaps in the project licence holder's knowledge. Where topics relate to local arrangements, candidates could be asked to make a list of points to enquire about on their return to their establishment, such as how the local ERP works, and what the procedure is for submitting a licence amendment.

Appendix 9 Module 5 Taught Elements

This suggestion is based on the original syllabus for the module 5 course (see Appendix F Guidance on the operation of the Animals (Scientific Procedures) Act 1986. One should note however, that:-

- This appendix is intended as an aid to learning and teaching of the module 5 course. Although entitled "Taught Elements" it is recognised that the delivery time available in a module 5 course may only allow an introduction to the topics.

- This appendix, like the whole document has been developed in collaboration with accredited trainers, representatives of the accrediting bodies, the Animal Procedures Committee Education and Training sub committee and a Home

Office Inspectorate observer.

- Like the training of modules 1-4, this course provides a framework within which prospective project licence holders can be taught elements which will assist them to develop the competencies required to be effective in their role as project licence holders. Module 5 training needs to be seen in the context of continuous professional development (CPD) and realistically can only provide an introduction to the many issues that a project licence holder has to deal with.

- Based on the Core Competencies identified in the Education and Training sub committee module 5 Paper, Section 4.2, contributors to this paper have listed what, in their opinions, should be considered in a module 5 Course and have suggested how components could be delivered.

- Certificate Holders, study directors and contacts who are not Animal (Scientific Procedures) Act 1986 licence holders should be actively encouraged to attend the module 5; legal and related aspects and the ethics and welfare sections.

- There is a need to develop more training tools and encourage sharing of these between training providers. The relatively small number of module 5 providers and the accrediting organisations should take steps to facilitate this

- On the assessment of module 5, perhaps MCQs should be developed and maintained along with those for the existing module 1-4 database, together with requiring production of a lay summary and/or use of a mock PPL as additional assessment tools. Arguably trainers should exchange these tools to encourage consistency across courses.

Proposed Taught Elements

1. Legal and Related Aspects

A project licence holder must have a relevant level of understanding of the national and international legal and regulatory framework within which project licences are constructed and managed, and of the legal responsibilities of themselves as project licence holders

1.1 The main components of the legal framework of the Animals (Scientific Procedures) Act 1986, including relevant sections in the associated Codes of Practice and Guidance.

1.2 The standard and additional conditions attached to project licences and how each would apply to candidates' own projects.

1.3 "Re-use" and "continued use".

1.4 Actions to be taken in the event of an unexpected adverse event occurring, the severity limit on a protocol is exceeded, or there is a suspected infringement.

1.5 The role of the Home Office Inspector.

1.6 The purposes of the requested information in different sections of the project licence application form.

1.7 The key purposes of other relevant legislation, such as:

- European Directive 86/609 (under revision).

- Legislation relating to veterinary care (Veterinary Surgeons Act, Veterinary Medicines Regulations 2008) and The interface between the Veterinary Surgeons Act and the Animal (Scientific Procedures) Act 1986).

- Other Legislation/guidelines relating to animal health (Specific Animals Pathogen Order 2008, FELASA Recommendations on Animal Health monitoring, Diseases of Fish Act 1937, Aquaculture and Fisheries (Scotland) Act 2007).

- Legislation relating to animal welfare (Animal Welfare Act 2007, DEFRA Codes).

- Legislation relating to genetic modification of animals.

- Animal transport (IATA regulations, transport within UK, transport within establishments)

- Quarantine controls e.g. Rabies Quarantine Order and containment requirements.

- Health & Safety at Work Act 1974 - human health and safety, laboratory animal allergies, pathogens, carcinogens and radioactivity.

- Wildlife and Countryside Act – permission to use wild species and permissions for discharge.

2. Ethics and welfare aspects of the use of live animals

A project licence holder must be able to identify, understand and respond appropriately to the ethical and welfare issues raised by the use of animals in scientific procedures generally, and specifically within their own programme of work.

2.1 The range of perspectives on the use of animals in scientific procedures among the general public and informed scientists and society's views and attitudes on animals used for research since these influence both legislators, regulators and funders.

2.2 The need to empathise with those views and demonstrate recognition and acceptance of the rules set by society.

2.3 Duty based and utilitarian ethical arguments.

2.4. The concept that any harm done to the animals must be justified in terms of potential benefit to humans, other animals or the environment (the so-called harms-benefit analysis) and factors to consider when assessing both harms and benefits.

2.5 The concept of harms to the animal including direct and contingent suffering, cumulative suffering, duration of suffering and how these can impact on the severity level and the harm-benefit justification.

2.6 The importance of good animal welfare including its effect on scientific outcome as well as for social and moral reasons.

2.7 The ethics of using animals for research; welfare of animals used in research and the 3Rs as separate but related issues.

2.8 The benefits of an objective rather than a subjective assessment of welfare.

2.9 Examples of the ethical limits of permissible procedures under the Animals (Scientific Procedures) Act.

2.10 The composition and the role of the local ethical review process in helping to implement the 3Rs (teaching to include reference to Appendix J of the Guidance on the Operation of the Animals (Scientific Procedures) Act 1986).

2.11 The interaction between the project licence applicant and the ethical review process.

2.12 The use of humane end points to limit suffering.

2.13 The impact of 2.12 on the harm:benefit justification.

3. Good scientific practice and the 3Rs competency

A project licence holder should be able to develop, direct and control a programme of work in order to achieve its stated objectives, while ensuring compliance with the terms and conditions of the project licence. This includes implementation of the three R's throughout the programme of work.

3.1 The components of a good scientific strategy (hypotheses, well-defined "measures" and well designed experiments). Relate the advantages of optimal choice of design (improve the scientific quality of the work, reduction in the number of animals, time and other scientific resources).

3.2 The consequences, with appropriate examples, of a failure to implement sound scientific strategy.

3.3 Critical appraisal of scientific literature including information directly concerned with the proposed study e.g. alternatives, experimental design, refinement, animal welfare and environmental enrichment.

3.4 Sources of Information including on the 3Rs.

3.5 Situations when pilot, exploratory and confirmatory experiments may be

necessary.

Items relating to Replacement

3.6 Examples of alternative methods (methods not using animals: QSAR, *in silico*, *in vitro*).

3.7 The difference between “replacement” and “complementary methods” (alternative non-animal methods running often in parallel to inform *in vivo* experiments).

3.8 The usual preference of society to use of animals of “lower neurophysiological sentience” in preference to “higher animals”.

Items relating to Refinement

3.9 Factors influencing the choice of an appropriate animal model and its justification by showing that the balance of scientific benefit outweighs animal welfare consequences.

3.10 The scientific endpoint should be set to allow required data to be obtained but this limit should be as early as possible to minimise the welfare consequences as required by Standard Condition 6 on a project licence.

3.11 The potential fate of the animals to be used and ability to sort outcome options into a hierarchy of refinement e.g. schedule 1 killing and killing under general anaesthesia.

3.12 The possible conflict between Reduction and Refinement.

Items relating to Reduction

3.13 The concepts of fidelity and discrimination as discussed by Russell and Burch and others.

3.14 The concept of variability, its causes and methods of reducing it (uses and limitations of isogenic strains, outbred stocks, genetically modified strains, sourcing, clinical or sub-clinical infections and basic biology).

3.15 Formal randomisation, blind trials and possible actions when randomisation and blinding are not possible.

3.16 Bias.

3.17 The experimental unit, (the entity which can be assigned to a treatment at random independent of all other experimental units: cage of animals, an individual animal or an animal for a period of time).

3.18 Appropriate experimental groups, “measured” variables, and methods of distinguishing between treatments.

3.19 An introduction to the determination of sample size (power analysis or the resource equation method rather than by tradition).

3.20 An introduction to the concepts of statistical power, the meaning of “p-values” and significance.

3.21 An introduction to the different types of formal experimental designs (e.g. completely randomised, randomised block, repeated measures [within subject], Latin square and factorial experimental designs).

3.22 How to access expert help in the design of an experiment and the interpretation of experimental results.

4 Project licence management

The project licensee should have sufficient knowledge, communication and management skills to ensure effective and efficient operational management of a project licence, and that all personnel working under the licence comply with their legal and ethical responsibilities.

Responsibilities

4.1 Responsibilities of the project licence holder in regard to the personal licence holders working on their licence (ensuring they do not exceed their authority, supervision and competence).

4.2 Authorised programme of work, examples and consequences of allowing procedures / techniques not meeting this work programme.

4.3 Action that needs to be taken if the project licence holder proposes to be away from the establishment.

4.4 Key legal responsibilities of the Certificate Holder, the NVS and the NACWO.

4.5 The importance of regular communication between the named people during the application and subsequent management of the project.

4.6 Persons involved in discharge of animals from controls of the Act.

4.7 The duty of care to the animals used under a project licence and the need to minimise all the welfare costs to animals throughout their lifetime, including adverse effects relating to sourcing, transport, husbandry and handling as well as procedures.

Supervision and training

4.8 The mandatory modular training system as an introduction to working under Animals (Scientific Procedures) Act 1986 including reference to HO Guidance Appendix F (A certificate of completion does not imply competence).

4.9 The need to supervise personal licensees until competence is demonstrated for each technique that they will be required to perform (including those added at a later date).

4.10 Delegable authorities and how they apply within the management of the project licence.

Record keeping requirements under the Animals (Scientific Procedures) Act.

4.11 Cage labels: who is responsible for their completion and what information should be recorded on them.

4.12 Project license holder's responsibility for the maintenance of all experimental records and what should be included.

Annual return of procedures

4.13 Information returned, why they are requested, when they need to be completed and the consequences of failure to complete them on time.

4.14 Advice on their completion (Local Home Office Inspector / specialist Home Office Inspector).

Teaching Tools.

At the APC Education and Training sub committee workshop held in September 2009 it was suggested that 'teaching tools' be outlined in the report to suggest how the taught elements of the course might be conveyed. It is hoped that these tools might be reviewed, revised and developed further by awarding bodies and the training providers.

Ethics and welfare aspects of the use of live animals

Case studies.

Case studies for harm-benefit analysis, examples of tools available to assess welfare objectively.

Debate animal use for scientific purpose. Encourage reflective behaviour on ethical issues, good animal welfare and application of the three Rs. Examples for discussion e.g. inviolable termination condition, legal limits on use of "special" species & CITES species, administrative 'bans' imposed by the Secretary of State on the testing of cosmetics and the use of great apes.

Case studies e.g. tumour scoring models, neurological assessment schemes, use of welfare assessment grid.

Good scientific practice and the 3Rs competency

Examples of 3Rs developments using new technologies e.g. imaging and robotic surgery.

Differentiate between a well designed example experiment:

- having a high power to distinguish between treatments.
- have a wide range of applicability, which is not excessively complicated and will be amenable to statistical analysis.

- and examples of the consequences of not planning the statistical analysis of an experiment at the same time as the experiment is planned (inability to disprove null hypothesis, wasted animals).

Refinements – consider the choice of route of administration: oral, intradermal injection, subcutaneous injection, intraperitoneal injection, intramuscular injection, intracerebral or intrathecal. Each produces a different outcome and in some cases one could make the argument for each and/or all, however they are presented (arguably) in the most 'refined' order, in terms of welfare consequences.

Project licence management

Reference to resources such as guidelines:

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.).
http://www.lasa.co.uk/LASA Guiding principles Supervision for PILs2010.pdf

Also there is a new guideline published on record keeping:
LASA 2009 Guiding Principles on Record Keeping for Personal Licence Holders. A report by the LASA Education, Training and Ethics section. (M. Jennings and M. Berdoy eds.).
http://www.lasa.co.uk/LASA record keeping forPILs2010.pdf