Report of the Animal Procedures Committee for 2010

Presented to Parliament pursuant to Section 20(5) of the Animals (Scientific Procedures) Act 1986.

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ANIMAL PROCEDURES COMMITTEE

Membership as at 31 December 2010

Sara NATHAN OBE (Chairman) – Freelance journalist and former editor of Channel 4 News. Has a portfolio of public appointments including as a member of the Judicial Appointments Commission, a consultant editorial adviser to the BBC Trust and a member of the Solicitors Regulation Authority. She has previously served on the boards of Ofcom and the Human Fertilisation and Embryology Authority.

Hannah BUCHANAN-SMITH BSc PhD – Professor of Psychology, the University of Stirling.

Michael DENNIS BSc – Head of Primate Programme, Health Protection Agency.

John DOE MIBiol PhD – Head of Product Safety, Syngenta.

Simon GLENDINNING BA BPhil DPhil – Reader in European Philosophy in the European Institute at the London School of Economics and Political Science.

Penny HAWKINS BSc PhD – Deputy Head of Research Animals Department, Royal Society for the Prevention of Cruelty to Animals.

Peter HUNT MPhil PhD MSB FIAT RAnTech – Biological Standards Officer, Cardiff University.

Robert KEMP FIAT (Hon), RAnTech – AstraZeneca (retired).

Keith KENDRICK BA PhD CBiol FSB – Gresham Professor and Head of Cognitive and Systems Neuroscience, Babraham Institute.

Dawn OLIVER BA MA PhD Barrister – Professor of Constitutional Law, University College, London.

Ian PEERS BSc (Hons) PGCE M.ed. Psych PhD FRSS – Director of Statistics, AstraZeneca.

John PICKARD BA MA MB BChir FRCS MChir F Med Sci – Professor of Neurosurgery, University of Cambridge.

Mark PRESCOTT BSc (Hons) PhD – Head of Research Management and Communications, National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs).

Ken SIMPSON BMSc (Hons) MBChB (Hons) MSc MD PhD FRCP (Edin) – Medical practitioner at the Edinburgh liver transplantation programme.

David SMITH MPhil CBiol MSB PhD Reg. Tox (IOB) EUROTOX FBTS – A senior director of toxicology for AstraZeneca.

Sarah WOLFENSOHN BSc MA VetMB Cert LAS FSB Dip ECLAM MRCVS RCVS – Independent Veterinary Consultant.

CHAIR'S LETTER TO THE SECRETARY OF STATE FOR THE HOME DEPARTMENT AND TO THE NORTHERN IRELAND MINISTER OF HEALTH, SOCIAL SERVICES AND PUBLIC SAFETY

I am pleased to submit the Animal Procedures Committees Report for 2010.

The Committee has provided advice on a number of specific issues as well as core work around project licence applications and consideration of infringements.

In particular, I note the provision of advice on guidance for Module 5; the training of project licence holders; and guidance on the roles and responsibilities of those involved in the delivery and accreditation of those working under the Animals (Scientific Procedures) Act.

The Committee has published guidance to the Home Office on the consultation on Directive 2010/63/EU which set out the views of the Committee and has been prepared in advance of the Home Office consultation on the Directive. This document seeks to provide guidance on the consultation itself as well as to set out the Committee's current views on both the spirit and letter of UK legislation.

My grateful thanks to all those who have contributed to the Animal Procedures Committee's work over the year.

SARA NATHAN

INTRODUCTION

This report describes the work carried out during 2010 by the Animal Procedures Committee (APC).

The Committee is established by the Animals (Scientific Procedures) Act 1986 to give advice to the Secretary of State on the use of animals in scientific procedures. Two important requirements of the 1986 Act are as follows:

- It shall be the duty of the Animal Procedures Committee to advise the Secretary of State on such matters concerned with the Act and her functions under it as the Committee may determine, or as may be referred to the Committee by the Secretary of State.

- In its consideration of any matter the Committee shall have regard for the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use in scientific procedures.

Annex A to this report sets out some information about the Committee, including its legislative background, the Ministers to whom it reports and its membership. On joining the Committee, members agree to be bound by its Code of Conduct (see Annex B). Annex C details the membership of the Committee's Sub-Committees and Working Groups. A register of members' interests is available on the APC website[1].

In taking forward its work across the year, the Committee met five times. In addition there were eight Sub-Committee and Working Group meetings (Annex C details the membership of the Committee's Sub-Committees and Working Groups). As in previous years, the Committee held an annual conference that provided a forum for learning, discussion and debate.

[1] The APC website:http://webarchive.nationalarchives.gov.uk/20130222193641/http://homeoffice.gov.uk/agencies-public-bodies/apc/

THE MAIN OUTPUTS AND EVENTS FROM THE COMMITTEE'S WORK IN 2010

- Published considerations for the Home Office on the guidance on the roles and responsibilities of those involved in the delivery and accreditation of those working under the Animals (Scientific Procedures) Act.

- Published considerations for the Home Office on Module 5 and the training of project licence holders. The purpose of Module 5 training is to ensure that prospective licence holders are aware of their responsibilities under the Animals (Scientific Procedures) Act.

- Prior to publication of the Home Office's consultation on the implementation of Directive 2010/63/EU, provided (published) considerations as to potential content of the consultation.

- Held a joint conference with the Home Office Animals Inspectorate.

THE WORK OF THE COMMITTEE DURING 2010

1. The Animal Procedures Committee has four Sub-Committees that advise the main Committee on issues of continuing interest and engagement. These are the Applications Sub-Committee; Education and Training Sub-Committee, Housing and Husbandry Sub-Committee; and the Primate Sub-Committee. As well as the four Sub-Committees, there were two Working Groups during this year. The first was concerned with the revision of Directive 86/609/EEC and its implementation. The revised Directive 2010/63/EU came into force in November 2010 and the Working Group changed its name to reflect this. The second Working Group responded to the Academy of Medical Sciences consultation on animals containing human material.

Committee representation and visits

2. The Committee made regular visits to establishments licensed under the Act to inform its work, build up contacts and discuss relevant issues with those involved in animal research and testing. The visits are by invitation and are not inspections or visits to ensure compliance with the Animals (Scientific Procedures) Act, which is the responsibility of the Home Office Inspectorate. It is agreed that the Committee makes no public comment about visits. The Committee is very grateful to all establishments for those invitations.

3. In September the Committee welcomed the Minister Lynne Featherstone MP to its meeting. The Minister highlighted the Department's aims which were the ending of the testing of household products on animals and the work to reduce the overall use of animals in scientific procedures, together with overseeing the transposition of the new EU Directive 2010/63/EU. The Minister said she appreciated the value of the independent advice the Committee provided on the use of animals in scientific procedures.

4. Members of the Committee attend the annual Certificate Holders' Forum which brings together those responsible for designated establishments where research under the Animals (Scientific Procedures) Act is permitted to take place. These fora provide an opportunity for the APC to gain further knowledge of, and share, best practice with other Certificate Holders, and for new Certificate Holders to gain training and continuous professional development and form links with other experienced Certificate Holders and the Home Office Inspectorate.[2]

5. The Chair attended the annual NC3Rs science review meeting in order to engage with stakeholders.

The Committee's work following BUAV allegations

6. In the 2009 report we reported that the then Home Office Minister, Meg Hillier MP had asked the Chief Inspector to look into alleged issues arising out of a report by the British Union for the Abolition of Vivisection (BUAV) issued in November 2009. The report made a series of allegations concerning animal care and use at Wickham Laboratories. Additionally, the Minister also asked for independent oversight of the Inspectorate's investigation – this was provided by the Committee. The Inspectorate report was published in November 2010 and discussed at the December meeting of the Committee.

7. The Committee was concerned that while the establishment had been carrying out regulatory testing of Botulinum toxin using the prescribed assay, it had not been encouraged to refine or reduce the use of the LD50 test in view of the body of research available that identifies non-animal alternatives and less lethal assays.

[2] Holders of Certificates of Designation have responsibility not only for ensuring that the fabric and staffing of designated places are maintained to appropriate standards but also for ensuring that reasonable steps are taken to prevent unauthorised procedures and adequate training is available for all animal users. Statement of Home Office policy 1 February 1993.

8. The Committee was also concerned at the lack of mechanisms that existed to review the competence of the Named Veterinary Surgeon and recommended that the Home Office draft guidance on the separate roles of the Certificate Holder, Named Veterinary Surgeon and Owner and on how an establishment could develop and encourage a culture of care. In response, the Home Office advised that this was an area that it would be looking into shortly.

9. The Committee requested that the Home Office provide regular updates so that the Committee could keep under review the establishment's progress.

Applications Sub-Committee

10. The Home Office refers a small number of project licence applications each year to the Applications Sub-Committee for advice. Categories of licence referred to the Sub-Committee include:

- any involving the proposed use of wild-caught non-human primates;
- any involving the proposed use of cats, dogs, Equidae[3] or non-human primates in protocols of substantial severity;
- any projects with a substantial severity banding, or major animal welfare or ethical implications, involving (a) xenotransplantation[4] of whole organs, or (b) chronic pain models, or (c) study of the central nervous system; and
- applications of any kind raising novel or contentious issues or giving rise to serious societal concerns.

11. Any such applications referred to the Sub-Committee are initially discussed through open dialogue between members, the applicant and the Animals Inspectorate. Following those deliberations, and after a private discussion, the Committee submits its considerations to the Minister.

12. To assist applicants meeting the Committee to discuss a referral, applicants can refer to the APC's published guidance[5]. This guidance provides background to the Committee review process and sets out some of the questions commonly asked of project licence applicants. It is the aim of the Committee to consider the total suffering experienced by the animals on the project, during their whole lifetimes, and to rationalise this against the expected benefits. The Committee will also seek the applicant's approach to the 3Rs[6], individual study and programme design, standards of housing and husbandry and the extent to which pain, suffering, distress and lasting harm can be avoided, recognised, alleviated and managed. All of this information is used in the harm/benefit assessment when deciding whether a project is justified.

13. In 2010 three licence applications were referred by the Home Office to the Committee for advice.

Project Licence Applications

14. A project licence application was referred to the APC for advice as the proposed work involved studies on non-human primates in procedures of substantial severity into the understanding of neurogenerative diseases, including Parkinson's disease. The ASC met the licence holder for clarification and sought further explanations of the proposal. In its discussion, the Committee asked questions about several issues including housing and husbandry and study design. The ASC considered that the applicants satisfactorily addressed the issues raised.

[3] **Equidae** – the *Equidae* family of mammals which includes horses, asses and zebras.

[4] **Xenotransplantation** – the transplantation of cells, tissues or organs from an animal of one species to an animal of a different species.

[5] http://webarchive.nationalarchives.gov.uk/20090804143651/http://www.apc.gov.uk/reference/guidance_to_project_licence_applicants_update.pdf

[6] 3Rs: the Replacement, Reduction and Refinement of animal experiments.

15. The second referred application sought authority to breed a transgenic pig strain for the provision of tissues for research on the immune responses to bioprosthetic devices used, in particular, for heart replacement surgery for humans. Following a meeting with the applicant, the Committee was satisfied that that the applicant had fully addressed the issues.

16. The third referral concerned a programme of work involving non-human primates in neuroscience research. The project had been granted for six months with a severity limit of moderate. However, the Committee had been asked to review the licence and confirm whether or not the licence should be reclassified as substantial. In its considerations the Committee met the licence holder and sought clarification on several issues. This included the lifetime experience of the animals involved, where and how the 3Rs had been adopted in the proposal, the frequency of surgical interventions, the duration of the study and the housing and husbandry. Following consideration, the Committee recommended that the project licence be reclassified to a substantial banding.

Work of the Primates Sub-Committee (PSC)

17. The role of the Primates Sub-Committee (PSC) is to advise the wider Committee on issues relating to the acquisition, housing, care and use of non-human primates in scientific procedures. Under the Animals (Scientific Procedures) Act, unless an exception is agreed, animals listed in Schedule 2 to the Act, including non-human primates, may not be used unless they have been bred at a designated breeding establishment or obtained from a designated supplying establishment. As the demand within the United Kingdom for non-human primates exceeds domestic supply, the Home Office has, for a number of years, agreed that UK designated establishments can import such animals from specified overseas breeding and supplying centres which are deemed acceptable. As part of the acceptance process, Home Office Inspectors appraise the suitability of such centres through meticulous visits to determine standards of animal care and accommodation. Acceptance is additionally based on APC considerations and further information supplied by UK users.

18. In 2010 the PSC was updated on the revised process for the acquisition of non-human primates from non-designated sources which had been agreed with the APC in 2006. A number of the agreed steps had been implemented since then, and the final steps were to be implemented. In particular, as there is now greater confidence in the health status of the animals being received from approved centres, it was proposed that the form and information required from the Named Veterinary Surgeon would be simplified so that only one health report was normally submitted, four to six weeks after receipt of the batch. However, if there were any health issues with any batch upon receipt or during those last few weeks, the Inspectorate would be immediately informed. Additionally, the Home Office confirmed that any health problems would be reported to the Committee; the PSC welcomed these changes.

19. Members asked about requests from establishments which had not previously imported animals and the Home Office confirmed that, as there were only a small number of users, requests from new users or breeders were infrequent. They were carefully considered on a case-by-case basis. The Inspectorate would normally visit any new sources and routinely performed an audit on the lifetime records to provide confidence that the animals were purpose bred and to review their history and treatment.

20. The PSC supported a proposal from the Home Office to set up a joint working group with the Home Office Animal (Scientific Procedures) Inspectorate to consider how best to set out guidance on how to apply cumulative severity analysis in neuroscience research applications. It was agreed that it was important, however, to maintain a clear separation in the advice provided to the Secretary of State by the Committee and that provided by the Inspectorate regarding such work. Accordingly, it was agreed to jointly draft the terms of reference of such a study.

Education and Training Sub-Committee (ETSC)

21. The Education and Training Sub-Committee (ETSC) continued work on drafting a report on the role of module 5 training for project licensees, which defines core competencies, and on advice regarding the learning outcomes appropriate for personal licence applicants. This work was completed by the end of the year, with the reports submitted to the Home Office (Annex E).

22. The ETSC also provided advice to the Home Office on questions the department might consider when drafting its consultation on the new Directive 2010/63/EU. Particularly, the Committee provided advice on Article 23 Competence of personnel and Article 24 Specific requirements for personnel.

Housing and Husbandry[7] Sub-Committee (H&HSC)

23. The Housing and Husbandry Sub-Committee (H&HSC) met three times in 2010 to provide (as with the ETSC) advice on potential questions the Home Office might consider when drafting their consultation on the new Directive. The H&HSC recommended that the Home Office should invoke Article 2 of the Directive, which allows Member States to retain more stringent measures than they had in place on the date when the new Directive came into force, in order to avoid the use of some techniques of concern for euthanasia.

Academy of Medical Sciences Working Group

24. This Group was established to respond to the Academy of Medical Sciences consultation on animals containing human material. Professor Martin Bobrow from the Academy of Medical Sciences was invited to the Committee's December meeting to update members on progress of the report. Members were pleased to learn of the progress and looked forward to learning of the recommendations when the report was published. The APC responded to the consultation on 24 March 2010 – see Annex I.

Revision of Directive 86/609/EEC (latterly Directive 2010/63/EU) Working Group

25. A considerable amount of the work of the APC in 2010 was devoted to considering and commenting on the revision of European Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes. The purpose of the Working Group was to actively contribute to the development of policy thinking around the implications of the Directive.

26. In July 2010 the Working Group met Home Office officials to discuss updates on the progress of the revision of the Directive and associated topics. Following that meeting, the Working Group produced a comprehensive paper that provided recommendations to the Home Office on some of the proposed content of the consultation document which the Home Office was to produce on the new Directive once the revision process was complete. The revised Directive 2010/63/EU came into force in November 2010 and the APC's recommendations[8] were submitted to the Home Office in December 2010. These were welcomed and taken into consideration in the drafting of the consultation document.

Liaison Group of Animal Welfare Advisory Bodies

27. To facilitate liaison between the separate advisory bodies for farm, companion, research and zoo animals the Committee is part of a liaison group together with the Companion Animal Welfare Council (CAWC), the Farm Animal Welfare Council (FAWC) and the Zoos Forum of the Liaison Group of Animal Welfare Advisory Bodies. The role of the liaison group is to consider any matter relating to animal welfare, and in particular, to share information on and discuss matters relevant to all sectors and, where appropriate, to organise meetings on these subjects and or provide reviews, opinion and or advice on them. It also addresses matters from government, where appropriate, relating to animal welfare across the sectors and provides advice to the Government, other bodies and the public as appropriate.

[7] **Husbandry** (animal) – the practice of breeding, raising and caring for animals.

[8] http://webarchive.nationalarchives.gov.uk/20130222193641/http://www.homeoffice.gov.uk/publications/agencies-public-bodies/apc/directive-consultation-guidance?view=Binary

Infringements

28. The Home Office report on infringements under the Act to the Committee. Infringements are separately reported by the Home Office at Annex E.

The Committee's work programme for 2011

29. The Committee's work programme for 2011 was discussed at the APC Annual Conference in November 2010. It was considered that the advisory work associated with implementing Directive 2010/63/EU, and its future transposition into UK legislation regulating animal care and use, would remain a priority. The Committee's work programme for 2011 is detailed in Annex K.

ANNEX A

BACKGROUND INFORMATION ABOUT THE COMMITTEE

This annex sets out some basic information about what the Animal Procedures Committee is and what it does.

The Legislation

1. The Committee was first appointed in 1987 and was set up by sections 19 and 20 of the Animals (Scientific Procedures) Act 1986 ("the Act"). The Act replaced the Cruelty to Animals Act 1876. The Act requires the licensing of any experiment or other scientific procedure carried out on living, protected animals which may cause them pain, suffering, distress or lasting harm. The Act regulates scientific procedures carried out on all vertebrate species except humankind – that is mammals, reptiles, birds, amphibians and fish – and one invertebrate species, *Octopus vulgaris*.

2. The Act also requires the licensing of places where certain species of animal are bred for use in regulated procedures. The species whose breeding is regulated in this way are genetically modified sheep and pigs, all primates, dogs, cats, all of the most common types of rodent used in scientific procedures, rabbits, ferrets, and quail.

3. The Act applies throughout the United Kingdom. For work taking place in England, Scotland and Wales the Home Office issues licences under the Act on behalf of the Home Secretary. In Northern Ireland, licences are issued by the Department of Health, Social Services and Public Safety. In each department there is an Inspectorate consisting of professional staff with medical or veterinary qualifications which examines and advises on all applications for authorities under the Act. The inspectors also inspect establishments and the licensed work being carried out there.

The Committee

4. The function of the Animal Procedures Committee is to provide the Home Secretary and the Northern Ireland Minister of Health, Social Services and Public Safety with independent advice about the Act and their functions under it. The two Ministers are responsible for appointing members of the Committee. Members are experts from a wide variety of backgrounds, and the list at the beginning of this report sets out the membership as at the end of.2010.

5. The Animals (Scientific Procedures) Act 1986 requires:

- that there must be at least 12 people on the Committee (in addition to the Chair); and
- that at least two-thirds of the members must have full registration as medical practitioners or veterinary surgeons, or be qualified in a biological subject relevant to the work of the Committee;
- at least one member must be a barrister, solicitor or advocate;
- at least half of the members must not have held a licence under the Act during the last six years; and
- the interests of animal welfare should be adequately represented (this has tended to mean, in practice, the appointment of members associated with animal welfare organisations, but all members pay high regard to animal welfare).
- By convention there is normally a philosopher on the Committee, although this is not a statutory requirement.

6. Members are appointed for terms of up to four years and can be re-appointed once. The 1986 Act specifies that payments may be made to the Chairman by way of remuneration, and that other members can receive reimbursement for any reasonable expenses incurred by them in the performance of their duties. During the financial year 2010-11, the APC spent £18,266 in such payments.

7. Under section 20 of the 1986 Act, the Committee can devise its own agenda and can offer advice on any issue which it thinks relevant. But it must also deal with any question which Ministers refer to it.

8. Whatever issue the Committee is looking at, the law requires it to take account both of the legitimate requirements of science and industry and of the protection of animals against avoidable suffering and unnecessary use in scientific procedures.

Ministers

9. The Home Secretary can delegate her responsibilities under the Act to another Minister in the Home Office, who administers the Act in England, Scotland and Wales. From May 2010, Lynne Featherstone MP took responsibility for research using animals. In Northern Ireland the administration of the 1986 Act is the responsibility of the Department of Health, Social Services and Public Safety (DHSSPSNI) for whom Michael McGimpsey MLA has been the responsible Minister during 2010.

ANNEX B

THE ANIMAL PROCEDURES COMMITTEE'S CODE OF CONDUCT

1. The Animal Procedures Committee is an advisory non-executive Non-Departmental Public Body (NDPB) established under section 19 of the Animals (Scientific Procedures) Act 1986.

2. Members of the Committee are responsible for ensuring that the Committee fulfils its statutory duty as set out in section 20 of the 1986 Act:

"To advise the Secretary of State on such matters concerned with this Act and his functions under it as the Committee may determine or as may be referred to the Committee by the Secretary of State".

3. The 1986 Act adds that:

(i) in its consideration of any matter the Committee shall have regard both to the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use in scientific procedures;

(ii) the Committee may perform any of its functions by means of Sub-Committees and may co-opt as members of any Sub-Committee any persons considered by the Committee to be able to assist that Sub-Committee in its work;

(iii) the Committee may promote research relevant to its functions and may obtain advice or assistance from other persons with knowledge or experience appearing to the Committee to be relevant to those functions;

(iv) the Committee shall in each year make a report on its activities to the Secretary of State who shall lay copies of the report before Parliament; and

(v) members of the Committee shall be appointed for such periods as the Secretary of State may determine but no such period shall exceed four years and no person shall be re-appointed more than once.

4. The Secretary of State for the Home Department (or, in Northern Ireland, the Minister of the Department of Health, Social Services and Public Safety) is answerable to Parliament for the performance of the Committee, including the policy framework within which it operates.

5. To ensure its accountability in carrying out its duties, the Committee will seek to work as openly as possible, complying with the Code of Practice on Access to Government Information.

6. Members are required to observe the Seven Principles of Public Life endorsed by the Nolan Committee on Standards in Public Life and to comply with this Code.

7. Each member must at all times act in good faith and observe the highest standards of impartiality, integrity and objectivity in relation to the conduct of the Committee's business. In particular, members should:

(i) familiarise themselves with the terms of reference of the Committee;

(ii) undergo any required induction training;

(iii) declare any personal or business interest which may, or may be perceived (by a reasonable member of the public), to influence their judgement. This should include, as a minimum, personal direct and indirect pecuniary interests, and should normally also include such interests of close family members and of people living in the same household. A register of interests will be kept up to date and will be open to the public;

(iv) not participate in the discussion or determination of matters in which they have a personal or business interest, and should normally withdraw from the meeting (even if held in public) if their interest is direct and pecuniary;

(v) make a declaration of interest at any Committee meeting if it relates specifically to a particular issue under consideration, for recording in the minutes (whether or not a Committee member withdraws from the meeting);

(vi) not misuse information gained in the course of their public service for personal gain or for political purpose, nor seek to use the opportunity of public service to promote their private interests or those of connected persons, firms, businesses or other organisations;

(vii) not hold any paid, or high profile unpaid, posts in a political party, and not engage in specific party political activities on matters directly affecting the work of the Committee. When engaging in other political activities, members should be conscious of their public role and exercise proper discretion; and

(viii) understand and accept that they are appointed as individuals and not as representatives of organisations by which they are employed or with which they have significant contacts.

8. The Chair has particular responsibility for providing effective leadership to the Committee and for:

(i) ensuring that the Committee meets at appropriate intervals, and that the minutes of meetings and any reports to the Secretary of State accurately record the decisions taken, and where appropriate, the views of individual members;

(ii) representing the views of the Committee to Ministers;

(iii) representing, where appropriate, the views of the Committee to the general public;

(iv) ensuring that new members are briefed on appointment;

(v) sitting on the panel which advises Ministers on new appointments and re-appointments.

9. Notwithstanding 8(ii) above, any Committee member has the right of access to Ministers on any matter which he or she believes raises important issues relating to his or her duties as a Committee member. In such cases, the agreement of the rest of the Committee should normally be sought.

10. Committee members may be personally liable if, in the performance of their Committee duties, they make a fraudulent or negligent statement which results in a loss to a third party. They may also commit:

(i) an offence under section 24 of the Animals (Scientific Procedures) Act 1986;

(ii) a breach of confidence under common law; or

(iii) a criminal offence under insider dealing legislation

if they misuse information gained through their position on the Committee. Individual members who have acted honestly, reasonably, in good faith and without negligence will not, however, have to meet out of their own personal resources any personal civil liability which is incurred in execution or purported execution of their duties.

11. In accepting this Code of Conduct members accept that they will not disclose any information or documents if they are marked “Restricted” and not disclose any subsequent comments about material which has been marked “Restricted”. Members also undertake not to make copies of any such documents, and to follow the advice provided by the Chairman and Secretariat about the handling of such documents.

ANNEX C

MEMBERSHIP OF APC SUB-COMMITTEES AND WORKING GROUPS AS AT 31 DECEMBER 2010

Membership of current Sub-Committees and Working Groups are listed below.

Education and Training Sub-Committee

Mr Robert Kemp **(Chair)**
Dr Peter Hunt
Dr David Smith
Mrs Sarah Wolfensohn

Primates Sub-Committee

Professor John Pickard **(Chair)**
Professor Hannah Buchanan-Smith
Mr Michael Dennis
Dr Mark Prescott
Mrs Sarah Wolfensohn

Housing and Husbandry Sub-Committee

Professor Keith Kendrick **(Chair)**
Professor Hannah Buchanan-Smith
Mr Michael Dennis
Dr Penny Hawkins
Dr Mark Prescott

Applications Sub-Committee

Ms Sara Nathan **(Chair)**
Dr John Doe
Professor Dawn Oliver or Dr Simon Glendinning
Dr Ian Peers
Professor John Pickard
Dr Mark Prescott
Mrs Sarah Wolfensohn

Academy of Medical Sciences Call for Evidence Working Group

Professor Keith Kendrick **(Chair)**
Dr Simon Glendinning
Dr Ken Simpson

Revision of Directive 86/609/EEC (latterly Directive 2010/63/EU) Working Group

Dr Penny Hawkins **(Chair)**
Dr Peter Hunt
Professor Dawn Oliver
Dr Ian Peers
Dr Ken Simpson
Dr David Smith

ANNEX D

APPLICATIONS SUB-COMMITTEE

1. The Applications Sub-Committee met on three occasions during this period. The aim of the Sub-Committee will be to complete consideration of any issues that affect an application within 30 calendar days. This will partly depend on the Home Office at an early stage identifying cases to be referred to the Sub-Committee.

2. The Sub-Committee will comment on the broader issues raised by applications and on specific details where appropriate. Where necessary it may seek to interview the licence applicant(s).

3. When an application is received from the Home Office, it is copied to the Secretariat for secure distribution to the Applications Sub-Committee. The Sub-Committee will meet, interview the applicant if necessary, and formulate draft recommendations.

4. The Sub-Committee will consider whether to amend its recommendations in the light of those comments, and then forward its definitive advice to the Home Office. At the next meeting of the APC, the Sub-Committee's advice will be reported retrospectively, and it will be open to any APC member to raise any issue of concern.

Rolling membership

5. The APC Chairman is an *ex officio* member of the Sub-Committee, and chairs such meetings.

6. Other members of the APC may be brought into the Sub-Committee depending on their expertise and the subject of the licence application.

ANNEX E

INFRINGEMENT PROCESS

1. The Home Office provided the APC with an annual summary of infringements – these are breaches of the 1986 Act, or of licence or designated establishment conditions. Once Home Office action on the infringement has been completed a report is forwarded to the Committee for information. Under the current Home Office framework infringements are reported in four categories, A–D[9].

Category A Infringement

The characteristics of a category A infringement may include the following:

- no evidence of intent to subvert the ASPA 1986 controls;
- no significant refinement or reduction consequences;
- resolved or remedy in place within days of discovery;
- no disputed facts and no likelihood of representations being made; and
- no prospect of prosecution.

Typically the outcome of a category A infringement is to note details of the infringement with no further action necessary.

Category B Infringement

The characteristics of a category B infringement may include the following:

- significant refinement or reduction concerns;
- future compliance concerns;
- not resolvable within days of discovery and further action needed;
- facts not disputed and no likelihood of dispute over the course of action proposed;
- not sufficiently serious for referral for prosecution, revocation of licences or withdrawal of a certificate to be considered; and
- may be recurrent or persistent category A infringements.

Typically the outcome of a category B infringement will be to send a letter of admonition (i.e. a warning) to those involved, although in some cases the Home Office may require further action (such as additional training or altered management practices) and might apply an additional condition to the licence or certificate.

Category C Infringement

The characteristics of a category C infringement may include the following:

- serious refinement or reduction concerns;
- future compliance concerns;

[9] http://www.homeoffice.gov.uk/publications/science-research-statistics/animals/annual-reports/animals-annual-report-2010

- disputed facts and evidence of untruthfulness or attempt to evade responsibility;
- variation, suspension or revocation of licence or certificate is merited but referral for prosecution is not merited;
- may be recurrent or persistent problems of a lower category.

Typically the outcome of a category C infringement is to amend, revoke or suspend the licence or certificate and to send a letter of admonition to the licensee or certificate holder.

Category D Infringement

The characteristics of a category D infringement may include the following:

- serous contraventions which merit referral for possible prosecution;
- the Inspectorate undertakes a preliminary investigation only, sufficient to establish whether prosecution is or is not an option; and
- if prosecution is contemplated, further investigation is then undertaken by the police and the Inspectorate.

The outcome of a category D infringement is for the Home Office to refer the case to the Crown Prosecution Service (in England and Wales) or the Procurator Fiscal (in Scotland) for them to consider prosecution.

2. The Committee recognises that publishing material in relation to infringements may be in breach of the Data Protection requirements. For further explanation of the Inspectors' Infringements process, please see the Compliance and Infringements section of the Animals Scientific Procedures Inspectorate & Division Annual Report 2010.

ANNEX F

ANIMALS PROCEDURES COMMITTEE EDUCATION AND TRAINING SUB-COMMITTEE PART 2 – MODULE 5 TRAINING

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[10] (ETSC) overview of modular training under the Animals (Scientific Procedures) Act 1986 (ASPA). Part 1[11], 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[12] 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[13] 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)[14]. 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.

1.1 Module 5 current status

There are currently approximately a dozen module 5 training course providers in the UK, with courses lasting between one and two 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".*

[10] 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.

[11] http://webarchive.nationalarchives.gov.uk/20090804143651/http://www.apc.gov.uk/reference/apc-education-modular-training.pdf

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

[13] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0543:FIN:EN:PDF

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

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 Table 1. 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 named 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[15] 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)

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

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

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* modules 1 and 2 unless there are exceptional circumstances[16]. (Possible exemptions should always be discussed with 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 helps 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 appendices 5–8 of this document.

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

[16] 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.

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 applicant's 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 optimise 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 3Rs 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 3Rs.

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 3Rs 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.

(xii) 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

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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 four-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 the 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 candidate's 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 website.

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 3Rs in the context of the need for ethical behaviour, whereas competency 3 is about how to implement the 3Rs 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 holders 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 egal 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 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 3Rs 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 end-point 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 licence 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 3Rs. Examples for discussion e.g. inviolable termination condition, legal limits on use of "special" species and 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

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ANNEX G

ANIMAL PROCEDURES COMMITTEE EDUCATION AND TRAINING SUB-COMMITTEE

Guidance on the roles and responsibilities of those involved in the delivery and accreditation of training under the Animals (Scientific Procedures) Act 1986

September 2010

Contents

1. HISTORICAL OVERVIEW AND AIMS

1.1 Overall aims

1.1.1 The aim of this document is to define what is expected from bodies accepted for accreditation of training courses for personnel working under the Animals (Scientific Procedures) Act 1986, and to offer guidance as to the expectations that these bodies should have of course providers. In the UK scientists and technicians working under the Animals (Scientific Procedures) Act 1986 are trained by the Home Office modular system. It is necessary to be confident that training standards are consistently high so as to protect animal welfare, ensure the law is implemented correctly, that ethical issues are understood and societal concerns taken into account. This advice was requested by the accrediting bodies and is meant to be considered as guidance, not instruction or compulsion.

1.2 Historical overview

1.2.1 Training for applicants for personal licences has been mandatory since 1994 and for new project licence applicants since 1995. The Home Office Policy on the Education and Training of Personnel under the Animals (Scientific Procedures) Act 1986 is set out in Appendix F of the Guidance on the Operation of the Act[17]. The Policy provides an outline syllabus for training. Inevitably, variable interpretation and implementation of the policy have occurred as issues arose in practice. Some clarifications of application of the original policy have developed over the intervening period, which are outlined in Appendix 3.

1.2.2 The Policy requires that all training programmes are accredited under schemes recognised by the Home Office. The purpose of accreditation is to achieve common and high standards for animal use which promote best practice in animal welfare and use and command public and parliamentary support. This can best be achieved by having accreditation carried out by independent bodies which are not associated either with the body providing the training or with the Home Office.

1.3 The role of the APC

1.3.1 The Animal Procedures Committee is a statutory committee which acts as an independent source of advice to the Secretary of State. In its report of 1993[18], the Committee accepted that given the range of expertise available to the Committee and its function as an independent adviser to the Secretary of State, it would be appropriate for the Committee to advise the Secretary of State on acceptance of accreditation schemes. However, it has no direct powers to implement any of its recommendations, as it works exclusively as an advisory body to the Home Secretary.

1.3.2 In the same year, an APC Working Group was set up with a remit to consider all applications for recognition of accreditation schemes by the Home Office and to offer advice to the Home Secretary via the Animal Procedures Committee. The working group agreed criteria to be used for determining the acceptability of an accreditation scheme. The following are direct quotes from the working group report:[19]

- *"Accreditation of training programmes should be carried out by independent bodies which are not directly associated with the body providing the training.*
- *The proposed scheme should have a syllabus which at least meets the requirement set by the Home Office in its policy statement of February 1993.*

[17] http://www.archive.official-documents.co.uk/document/hoc/321/321.htm

[18] http://webarchive.nationalarchives.gov.uk/20090804143651/http://www.apc.gov.uk/reference/ar93.pdf

[19] http://webarchive.nationalarchives.gov.uk/20090804143651/http://www.apc.gov.uk/reference/ar93.pdf

- *The means of assessment of trainees should be such as to "ensure that participants have adequate understanding of their responsibilities and sufficient knowledge of animal husbandry that good welfare practices will be assured".*

- *The scheme should be able to cater for a wide variety of users and species unless it is restricted to specific user groups.*

- *The scheme should set out clearly how it will be administered, how courses will be supervised and monitored, how long accreditation will last and how trainees will be notified of their performance in the course."*

1.3.3 The 1993 APC Working Group proposed the continuing oversight of the accrediting bodies, by attending joint meetings of the accrediting bodies operating the schemes as observers and attending training courses to satisfy themselves that acceptable standards are obtained.

1.3.4 In 2003, APC embarked on a review of modular training. The remit of the current Education and Training Sub-Committee that superseded the 1993 Working Group has been:

> *"To advise on the requirements for training and education of those who hold responsibilities under the Animals (Scientific Procedures) Act 1986 or who carry out duties under the controls of the Act. In doing so, to liaise with a range of bodies, including the two* bodies which accredit licensee training courses."*

In February 2006, the Education and Training Sub-Committee of the APC published its report on the first part of its review of modular training. The seven recommendations received broad agreement from the Parliamentary Under Secretary of State for the Home Office[20].

*now three accrediting bodies

1.4 Accrediting Bodies

1.4.1 Three bodies are approved for the accreditation of courses for personal and project licence applicants: The Universities' Training Group (UTG), the Society of Biology (formerly the Institute of Biology), and the Scottish Accreditation Board (SAB). Additionally, the Institute of Animal Technology (IAT) has been approved as an accrediting body for training of Named Animal Care and Welfare Officers (NACWOs). During the process of the Education and Training Sub-Committee review, the accrediting bodies indicated that they would welcome guidance on what was expected of them, and on the required learning outcomes that should be achieved from the Home Office modules.

1.4.2 It is important that efforts are made to maintain consistency across courses. It is essential that clear guidance is given to accrediting bodies as to what is expected of them and the level of achievement required from the courses they accredit. The level of achievement should be the same across all accredited courses. In July 2009 at a joint meeting of Accrediting Bodies to which representatives of the APC Education and Training Sub-Committee were invited, reached an agreement that annual reports could be submitted to the Home Office for comparative review. Appendix 6 of the guidance paper suggests categories that might be included as part of an annual report's content.

[20] http://webarchive.nationalarchives.gov.uk/20090804143651/http://www.apc.gov.uk/reference/382765_HC41_web.pdf Annex L

1.4.3 The interaction between regulators, advisory body, course providers and the Accrediting Bodies is shown in Figure 1.

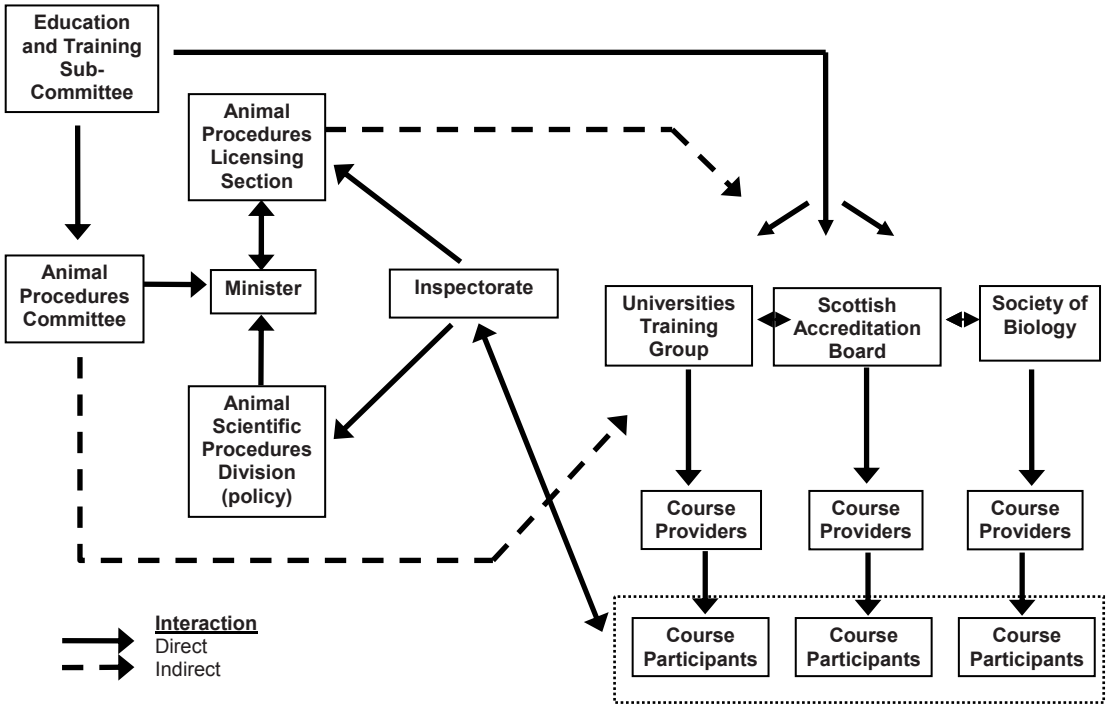

Figure 1

1.5 Points to Note

The APC is aware that accrediting bodies by their very nature are not involved in training, this being largely the responsibility of course providers. However, for the purposes of this report the Committee make the assumption that the accrediting bodies are best placed to take a guiding role in the provision of training.

This document represents the Committee's opinions of how the accreditation of modular training under Animals (Scientific Procedures) Act 1986 could evolve based on Committee members' experience, evidence gained through consultation, taught course comparisons and suggestions of best practice processes from other accredited courses.

2.1 Consistency in Level of Achievement

2.1.1 Accrediting bodies are responsible for defining the required level of achievement for accredited courses. Each accrediting body has the power to issue certificates to candidates meeting the required standard, but with this power comes the responsibility for ensuring that the defined standards are met and that courses are of an appropriate quality.

Aims, learning outcomes and assessment methods for the different modules should be described in a course framework. See Appendix 1 of this document for an example course framework.

2.2 Policy and procedures

2.2.1 Accreditation bodies should make their policies and procedures available to training providers and other interested parties. Accrediting bodies should also ensure that all aspects of this APC guidance paper are considered by themselves and by course providers.

2.2.2 Accrediting bodies should have access to up-to-date and authoritative records of courses they accredit and accrediting bodies should be prepared to provide such information if requested by the Home Office.

- The name of the course organiser;
- Contact details of the course organiser;
- The modules covered and intended audience;
- Proposed course frequency;
- Names and brief CVs of course tutors*;
- Location and physical facilities provided by the trainer or host institution*;
- Visual aids/learning materials provided*;
- Information on course materials/handouts provided*;
- Time allotted to the course;
- Methods of assessment.

*Maintenance of these records can be delegated to the course providers, but must be made available to the accrediting body on request.

An accrediting body is responsible so far as is reasonably practicable, for ensuring that any information it provides relating to a course it accredits is up to date. Accrediting bodies should satisfy themselves that course providers ensure that potential participants cannot be misled about the nature and standing of any courses offered. In addition, accrediting bodies should have provision for the Freedom of Information Act where applicable.

2.2.3 The policies and procedures of accrediting bodies should be independent and not subject to bias.

2.2.4 The accrediting body should set out what it expects from course providers. Accrediting bodies have a duty to ensure that course providers know what is expected of them and that these expectations continue to be met. Such statements should include:

- Details of any records kept by the Course Organiser and submitted to the accrediting body;
- Details of minimum learning outcomes to be addressed during training and guidance on variety of learning opportunities to be provided (group work etc.);

- Guidance on oral, written and practical assessment of candidates to be made, both within and after courses;
- Proposed frequency for accreditation visits and procedures for regular monitoring and review of quality;
- Guidance on the use of and access to candidate feedback forms;
- The responsibilities of Course Organisers towards course participants;
- Arrangements if either side wishes to terminate the accreditation agreement.

2.3 Resources

Accrediting bodies should satisfy themselves about the standing of the course provider and that the provider can fulfil the requirements. There should be sufficient appropriately trained and qualified staff, and adequate facilities to ensure that training of an appropriate standard can be delivered.

2.4 Quality and standards of training

2.4.1 Although planning and delivery of material is delegated to course providers, the accrediting body is responsible for monitoring the quality and standard of training generally and should be able to satisfy itself that any delegated responsibility is being properly discharged. It should therefore be able to verify and make judgements on the range and suitability of the learning opportunities being provided, and that the learning outcomes covered at least meet the minimum requirement in the APC Module 1–4 report.

2.4.2 It may be appropriate on occasion for course providers to draft in individual experts to cover training in handling of unusual species. In these cases the accrediting body is still responsible for monitoring to ensure that the quality and standard of training is acceptable. The accrediting body should therefore issue guidelines for course providers on what is expected from external expert trainers, and check that these have been appropriately applied.

2.4.3 The accrediting body should ensure course providers supply prospective candidates with a course framework for each module and that reference is made to the minimum qualifications required.

The course framework should give clear information on the nature of the course and its relationship to the licensing requirements. It should also provide information about the appropriate contact for more details. The aims and learning outcomes should be set out, together with the proposed methods of teaching, appropriate reference material, approximate time required to complete the module and the proposed method of assessment. Potential participants must be able to identify that courses run by different providers are of equivalent standard, even if the teaching methods are different. Aims and learning outcomes should be periodically reviewed for continuing validity and relevance.

Note

Applicants for personal licences are currently required to possess 5 GCSEs at grades A-C or equivalent including in a biological science. Exemptions to this requirement may be considered, for example if there is evidence of relevant comparable education or experience. There is clear guidance in Section 6.5 of the Guidance on the Operation of the Animals (Scientific Procedures) Act 1986. Such cases should also be discussed with the local HO Inspector. Where there are participants for whom English is not the first language, an assessment should be made before the course, of their competence in English. Participants who are unable to understand the course will be at a disadvantage and may not grasp fully their responsibilities under the Act. Certificate Holders are reminded that they should ensure that all candidates going through a Licensee Training Course at a Designated Establishment must have sufficient grasp of English to ensure they can understand the materials presented.

2.4.4 Accrediting bodies should ensure that assessment methods are sufficiently robust.

Assessments should be consistent within and across institutions and between courses accredited by different bodies, and should be at a level appropriate to the stated learning outcomes (see example in Appendix 4 Level of Learning Outcome). Accrediting bodies should liaise with each other to ensure that standards of assessment are equivalent and to maintain the quality of the output. Standards should be set for the conduct of written and practical assessments, and procedures put in place to ensure that they are adhered to (see Part 4 for more information on assessment).

2.5 Accreditation visits

2.5.1 Assessment and auditing of courses is essential to maintaining their suitability and the credibility of teaching staff. Accreditation visits are a key feature of this process and should be used to determine whether the quality and standard of training provided are appropriate. Course assessments should identify if the intended learning outcomes are covered by the teaching and associated handout material, and whether the assessment covers a suitable sample of the desired learning outcomes. The outcomes-based approach to assessment has an emphasis on transparency, and to establish the relationship between learning outcomes, teaching materials and other modes of training. Accreditation visits should be carried out at appropriate intervals and must include feedback from course participants on the quality/suitability of the course.

An accrediting body must ensure that their appointed assessors are independent, adequately prepared/briefed and are fully aware of the relevant factors.

2.5.2 As an example, the content of an accrediting body's course assessment might include:

Initial report to the accrediting body

- the overall conception of the course; its structure, conceptual framework, balance, coverage, workload and level;
- the design of the teaching skills and assessment; the effectiveness of the course materials as teaching aids in the context of their own experience;
- the likely effectiveness of the course materials in terms of meeting the needs of a diverse body of participants;
- evaluation of the extent to which the proposed course meets the defined standard (are required learning outcomes addressed);
- the effectiveness of multi-media materials and software (if used);
- in courses with an animal handling component, the effectiveness of the arrangements for teaching practical elements;
- robustness of proposed methods of assessment during and at the end of the course and relationship to the intended learning outcomes.

In the event that the quality of a course was found to be unsatisfactory, following any remedial action an accrediting body should carry out a further follow-up report. Ideally this should be carried out in line with existing plans for re-accreditation.

Courses will normally be re-accredited after an interval of no greater than five years.

Re-accreditation Report

- detailed comment on all the matters identified in the *Initial Report* that should have been addressed;
- overall achievement of the course aims;
- the effectiveness of the teaching material;
- the final outcome of the course; and
- areas for further improvement (if appropriate).

2.6 Certificates

2.6.1 The accrediting body should have sole authority to issue training certificates and must ensure and emphasise the importance of security in relation to the possession of such certificates. Certificates should record the name and location of the course provider, and all information that is necessary for a full understanding of the participant's achievement.

3. THE ROLE OF THE COURSE ORGANISER

3.1 Information provided to participants

3.1.1 The course organiser should provide participants with a course framework setting out the roles of the course organiser, descriptions of the units and modules to show the intended learning outcomes and the teaching, learning and assessment methods, the timing of the course and a clear schedule for delivery of the course and the assessment. Where practical, details of the course should be circulated to prospective participants before the course is delivered and/or course descriptions could be made available on a suitable secure website.

3.1.2 Information should be provided about assessment; participants should have clear information on the ways in which their achievements will be judged. Course providers should consider providing informal feedback and guidance to participants during the course, to aid their learning and to illustrate likely standards for the formal assessment. Information on assessment methods should be included in the course framework.

3.1.3 Participants should be given clear and realistic guidance setting out their responsibilities as learners. This should include guidance on what is expected to be gained through self-directed learning, collaborative learning such as discussions with other participants, and through supported learning. Guidance should identify whether an activity is compulsory or not, and the ground rules for communication with tutors and/or other course participants. **It should also be made clear that the course is an introduction to being a licensee and that further supervision and development will be required.**

3.2 Learner support and feedback

3.2.1 Course participants should be provided with support material and assistance, such as tutorials or web-based conferences, and clear up-to-date information about the support available, including likely response times. Support can be provided face to face, locally or online for the duration of the course or until the assessment and feedback have been completed.

3.2.2 Where there are participants for whom English is not their first language an assessment should be made before the course of their competence in English. Participants who are unable to understand the course will be at a disadvantage and may not fully grasp their responsibilities. The course provider should be encouraged to discover from the sponsoring institution that people have sufficient command of English to understand the material presented.

Pre-course preparation can be used to encourage candidates to undertake essential background reading or viewing of audiovisual programmes, and provide an introduction to the ethical issues surrounding animal use. If a participant enrolling on a course does not fulfil the minimum educational requirement for personal licensees, course providers may wish to refer them to the Home Office for advice before enrolling them on a course. It may be appropriate to identify a suitable contact at the participant's home institution that is responsible for ensuring that induction and preparation have been successful before a participant is allowed to enrol on the course.

3.2.3 It is good educational practice to obtain feedback from participants either immediately after a course or upon completion of the assessment, to determine whether the course met expectations and has been sufficient for their subsequent needs. It is a measure of success of the course if the knowledge and skills acquired influence what the participant does subsequently, and this can only be determined by obtaining feedback ideally at a later stage. Course providers should instigate an active review process of the effectiveness of the course based on feedback from a sample of course participants. The review process should also be open to scrutiny by the accrediting body.

3.3 Structure of courses

3.3.1 Courses may use a combination of formal and informal teaching, being intensive over one or two days or part time over several days. The modular system is designed to be flexible so it can be tailored to individual needs. However, it is important to maintain standards and ensure that sufficient time and resources are allocated to training. It is consistency of output that is required, rather than uniformity in the process of training.

3.3.2 People learn in a variety of different ways (See Appendix 2 of this document for an overview of learning styles), and it is essential that courses provide a variety of learning opportunities appropriate to different learning styles. A course utilising exclusively a lecture format may be able to convey a large quantity of information in a short time, but interaction is very limited and retention of the information can be poor. Experiential learning where participants take a more active role is often a more effective method of learning. Suitable learning activities include interactive group discussions, practical sessions, role playing or problem-solving exercises. Such activities are most effective with small groups of 6–8 participants, and consideration should be given to including such small group activities in training programmes if not currently being used. This is of particular concern with flexible and distance learning programmes, where interaction with the tutor and other participants is limited. Consideration should be given to the innovative uses of interactive learning tools for taught parts of the courses.

3.4 Resources

3.4.1 Staff engaged in training should be experienced both in their subject matter, and ideally, as trainers. Where possible, they should have been trained in educational principles and practice.

Suitable personnel might include veterinary surgeons, senior technicians, ethicists and scientists. In all cases the trainer with overall responsibility for the course should be clearly identified to the participants, and should be the point of contact for enquiries and appeals.

3.4.2 Upto-date, relevant course material is a very useful resource that participants can refer to after the course has finished. It should be utilised during the training, so that participants can identify readily where specific information can be found, how it fits in to the course and for use in interactive teaching activities. Course material can be provided as bound or loose notes, handbooks, or in electronic form. There should be easy access to key documentation such as the Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 and the Codes of Practice. Continued access to online facilities should be encouraged after the training has ended.

3.4.3 The time needed to deliver the learning outcomes to the required standard will depend on the needs of the individual participants and their institution, thus it is not appropriate to specify minimum times to be spent on each module. Time should be allocated to allow for the provision of different sorts of learning opportunity, including practical and interactive elements. As a guide, it is likely that formal tuition for each core module will take 4–8 hours, with a variable period of private study and practical experience, depending on the background and experience of the participants.

3.4.4 Where e-learning is used or a need for remote access to assessment is required, it is necessary to ensure that suitable systems are in place to verify the origin of any assessed work. Participants need to be confident that their work will not be lost or misidentified. Administrative and electronic systems used for assessment purposes must be sufficiently robust and reliable and free from the possibility of external interference. Where online records are used there should be adequate provision for storage and backup of records.

4. ASSESSMENT OF COURSE PARTICIPANTS

4.1 Responsibilities of Accrediting Bodies and Course providers

4.1.1 Accrediting bodies are responsible for the standard and format for assessments. Course providers are responsible for the conduct of assessments. The accrediting body should determine the selection criteria for those who will carry out oral or practical assessments. Course providers should then identify suitable personnel based on these criteria. The accrediting body should check the suitability of assessors as part of the accreditation process.

4.2 Assessors

4.2.1 Assessors should themselves be able to carry out assessable tasks or demonstrate knowledge to the required standard. They should be familiar with the standards required, and be able to make judgements about the course participants based on these standards. The expertise of trainers and assessors is the key factor underpinning valid and reliable assessment.

4.3 Assessment

4.3.1 Learning outcomes fall into at least three areas:

- Knowledge and understanding
- Practical skills and attributes
- Transferable skills and attitudes

An explanation of learning outcomes and their assessment is detailed in Appendix 4 of this document. Any method of assessment used should be appropriate to the type of learning outcome, for example, animal handling is generally best examined by a practical examination using live animals, attitudes may be assessed through group discussions or role play, and factual knowledge can be examined by using written or verbal questions. Examples of a learning assessment tools can be found in tables 1 and 2 of this report.

4.3.2 Written examination questions should be suitably robust, and moderated to ensure validity and reliability.

4.3.3 An assessment of participants' knowledge and understanding requires very careful consideration particularly as some learning outcomes are not suited to question and answer validation.

Where multiple choice type questions are used for assessment the APC is of the opinion that they should ideally be of the 'single best answer' type. Further explanation on the application and use of MCQs is outlined in Appendix 5 of this document.

4.3.4 Assessment of practical skills can be subjective and open to challenge. However, it can be made more objective by identifying relevant criteria to be assessed, and assigning a mark for the participant's abilities in each area with the aid of descriptors. This can be facilitated by the use of assessment grids, such as illustrated in the tables below. The use of such grids may reduce the potential for variability between assessors.

Table 1. An Example Practical Assessment Sheet

	Fail	Refer	Pass	Good pass	Excellent
Element Assessed	Criteria	Criteria	Criteria	Criteria	Criteria
Observation	Participant fails to notice obvious indicators of health and well-being in environment	Participant notices some obvious indicators of health and well-being	Participant notices some obvious and subtle indicators of health and well-being, and can discuss at a superficial level	Participant notices obvious and subtle indicators of well-being, and can discuss in some detail	Participant notices obvious and subtle indices of health and well-being, and can discuss at length
Approach to animals	Participant is anxious and tentative and has difficulty approaching the animal	Participant is anxious but can approach the animal with some coaxing	Participant is not obviously anxious but approaches the animal tentatively	Participant is not anxious and is able to approach the animal with a degree of confidence	Participant is confident and approaches the animal immediately and in a relaxed manner
Theoretical knowledge	Participant demonstrates little or no theoretical knowledge of biology and husbandry for the species	Participant demonstrates superficial knowledge of biology and husbandry	Participant demonstrates knowledge of key aspects of biology and husbandry	Participant demonstrates detailed knowledge of biology and husbandry	Participant demonstrates detailed understanding of biology and husbandry and can discuss at length
Animal stress	Animal makes obvious signs of distress at being handled, such as vocalisation and struggling	Animal makes some signs of distress with significant struggling	Animal is mostly calm but with some struggling	Animal is calm with some struggling but settles	Animal is calm and relaxed and does not struggle
Handling ability	Participant is unable to demonstrate correct ways to hold the animal	Participant can demonstrate one way to hold the animal but cannot control it and cannot age and sex accurately	Participant can demonstrate one or more ways to hold the animal but not always securely	Participant can restrain the animal securely and can age and sex accurately on some occasions	Participant can restrain the animal securely in a variety of ways and can age and sex accurately

Notes

The above table could be used to provide feedback to candidates, particularly those in the 'refer' or 'fail' categories.

Table 2. Example Assessment Grid for participants in training for group discussion

	Fail	Refer	Pass	Good pass	Excellent
Element Assessed	Criteria	Criteria	Criteria	Criteria	Criteria
Interaction	Participant fails to participate in group discussions	Participant interacts infrequently and demonstrates some understanding of key areas with some errors	Participant interacts adequately and demonstrates understanding of key areas	Participant interacts frequently, demonstrates understanding of key areas and can discuss in some detail	Participant interacts freely, is active in discussions and can discuss issues at length
Theoretical knowledge	Participant demonstrates little or no theoretical knowledge	Participant demonstrates superficial knowledge	Participant demonstrates knowledge of key aspects	Participant demonstrates detailed knowledge	Participant demonstrates detailed understanding and can discuss at length
Attitude and ethical awareness	Participant is unwilling to engage with issues	Participant participates to a limited extent but appears not to be aware of major issues	Participant engages to a limited extent but demonstrates some understanding of key issues	Participant is willing to engage and demonstrates some understanding of the issues	Participant engages freely and demonstrates sensitivity and awareness of issues

Notes

The above table could be used to provide feedback to candidates, particularly those in the 'refer' or 'fail' categories. Where candidate's contributions are being assessed as part of a discussion group, the group should ideally comprise no more than six individuals.

APPENDIX 1

Example course framework

This is intended to be an example of how a course framework might be constructed. It is based on the proposed Module A, as described in the APC review of Modules 1–4[21].

Module A: Legislation, ethics and local rules

The aim of this module is to provide participants with a basic understanding of the legislative framework in which regulated procedures may be conducted in protected animals, and give them an opportunity to consider the ethical issues surrounding animal use for this purpose.

Teaching and learning strategy

This module will consist of:

(i) Lectures;

(ii) Group discussion of ethical issues;

(iii) A practical demonstration of appropriate, and applicable health and safety equipment;

(iv) Self directed study of course material; and

(v) Self directed study of problem sheets (where available).

It is anticipated that completion of this module would take approximately 18 hours, to include 10 hours of self directed study.

Assessment strategy

This module will be assessed by:

- Multiple choice questions;
- Tutors assessment of performance during group discussions, according to assessment grid (Table 2); and
- Assessment by tutor of completed problem sheets.

Learning outcomes for this module:

Learning outcomes fall into three areas:

- Knowledge and understanding;
- Specific skills and attributes; and
- Transferable skills and attributes.

This module covers a) legislation, b) ethics and c) local rules. On completion of the module it is expected that you will be able to:

[21] http://webarchive.nationalarchives.gov.uk/20090804143651/http://www.apc.gov.uk/reference/apc-education-modular-training.pdf

a) Legislation

- Relate which legislation; codes of practice and guidance pertain to the conduct of scientific procedures on animals, including Codes of Practice, Council of Europe Convention ETS 123, and EC Directive 86/609/EEC;
- Relate the purpose of ASPA as in the first line of the Act;
- Define protected animal, including respective stages of development;
- Define regulated procedure;
- Indicate that programmes of work fall into permissible purposes (as defined by ASPA 5.3);
- Describe the three levels at which control is exercised under the Act as stated in ASPA section 3 (Person, Project and Place);
- Indicate that the controls are exercised through assessment of applications for licences and certificates, inspection of work in progress, and reporting of non-compliance;
- Indicate that assessment of applications and monitoring of compliance is done by the Home Office Inspector and know how to contact him/her;
- Indicate that the PCDh is responsible for compliance at an establishment and that this responsibility may be exercised through the local ERP;
- State that the PILh bears primary responsibility for the animals they have applied regulated procedures to, and that they must make suitable arrangements for periods when they are absent;
- Indicate that if permission to delegate non-technical procedures to non-licence holders has been granted, the personal licence holder still bears responsibility;
- Outline scope of PILh responsibilities as defined by the PIL standard conditions, including record keeping and cage labelling, and appreciate how to apply themselves in this respect;
- Recognise what a personal licence is and what it looks like;
- Indicate that regulated procedures may only be carried out if part of a series of regulated procedures authorised by a project licence;
- State that it is the responsibility of the personal licence holder to check that appropriate authorities exist in personal and project licences before performing regulated procedure;
- Indicate which sections of a project licence describe what is authorised and why;
- Appreciate that key personnel (NVS, NACWO, PCDh, PPLh) have statutory duties and other responsibilities under ASPA;
- Define death as in ASPA;
- Indicate the circumstances in which protected animals should be killed;
- Relate that restrictions on the re-use of animals exist and state that re-use is strictly controlled;
- Relate that Schedule 1 exists for humane killing, that it is precise and that a CoP exists;

- Indicate that Schedule 2 exists, and identify implications for supply of animals;
- Indicate that Schedule 2A exists and outline its provisions;
- Indicate what an infringement is and that there are penalties attached;
- Indicate that other legislation may be relevant, and where to find further information.

b) Ethics

- Appreciate that the ethical framework which underpins ASPA requires that programmes of work are justified by weighing likely adverse effects on the animals against the likely benefits;
- Appreciate that there are limits on what it is considered permissible to do within a research establishment and that there are cultural, national, temporal and institutional differences in this respect;
- Be able to identify ethical and animal welfare issues in their own work;
- State that when considering welfare issues, pain, suffering, distress and lasting harm should be interpreted in their widest sense and include the whole life experience of the animal;
- Define the 3Rs, indicate what they are for, and how these relate to the ethical principles;
- Appreciate the need for, and be prepared to contribute to, a culture of care and appreciate the importance of having an appropriate attitude;
- Be responsible and willing and able to reflect on the consequences of their actions;
- Indicate the purpose of the local ERP;
- Identify relevant sources of information relating to ethics and the 3Rs.

c) General rules

- Identify the project licence(s) they will be working under and the holder(s);
- Identify their supervisor if applicable, and state that responsibility for supervision lies with the project licence holder;
- Indicate whom to contact in the event of unexpected events;
- Indicate who their local HOLO (if applicable) is;
- Be able to identify Named Persons and appreciate that they are sources of information and advice;
- Be aware of the importance of excluding non-authorised persons from areas where protected animals are held and used, and action to be taken if such entry occurs.

Health, safety and security

- Indicate that health and safety at work is controlled by legislation;
- Indicate different hazards associated with the use of laboratory animals (allergy, injury, infection);
- Describe signs commonly associated with allergy to laboratory animals, and steps to be taken to avoid this developing and required in the event of such signs developing;

- Define what is meant by zoonoses;
- Indicate procedures to be followed in the event of accidents;
- Indicate steps to be taken to ensure personal safety and security and the safety of colleagues;
- Explain action to be taken if accosted by animal rights protesters, or if followed when leaving the workplace.

Supply and disposal of animals

- Describe in general terms local procedures for the acquisition and disposal of animals, and disposal of waste;
- Indicate that acclimatisation and habituation are important and that they may affect the outcome of experiments;
- Indicate action to be taken in the event of unexpected adverse outcomes;
- Indicate that working in animal facilities requires compliance with relevant SOPs/GLP if appropriate.

Local issues

- Indicate relevant contact person(s) (e.g. Unit manager);
- Identify the project licence(s) they will be working under and the holder(s);
- Identify their supervisor if applicable, and state that responsibility for supervision lies with the project licence holder;
- Indicate whom to contact in the event of unexpected events;
- Indicate who their local HOLO (if applicable) is;
- Be able to identify Named Persons and appreciate that they are sources of information and advice;
- Be aware of the importance of excluding non-authorised persons from areas where protected animals are held and used, and action to be taken if such entry occurs.

APPENDIX 2

Different ways of learning

Education is the acquisition of knowledge, skills and attitudes, or the ability to formulate and test hypotheses. There are many theories surrounding the process of learning, but some common themes emerge. Many writers believe that knowledge cannot be transferred from expert to ignorant; rather it has to be constructed by the learner. This means that learning is a process of problem solving and self searching: Others suggest that some learning can take place by uncritically receiving information given by someone else, but other learning takes place only by testing and experimenting on the basis of experience (Dudley, 1993)[22].

Experiential learning and the learning cycle

Experience is increasingly believed to form the basis of all learning. It has been suggested that learning is accomplished by critical reflection on experience (Freire, 1972)23. Learning psychology indicates that in the adult, learning is mainly problem-centred (Knowles, 198424; Andragogy – see later in this section). Personal experience is increasingly believed to form the basis of all learning, and action is a fundamental aspect of such experience. Experiential learning based on the Kolb Learning Cycle requires learning to be achieved through cycles of concrete experience, reflective observation, abstract conceptualisation and active experimentation. This then becomes the concrete experience for further reflection thus completing the cycle (Kolb, 198425). Action then can be argued to be an essential part of the learning process, not an add-on at the end. Without action, learning may not taken place effectively. As a continuation of this cycle, Kolb points out that critical reflection may lead to the drawing of conclusions, and the formation of hypotheses, which can then be tested in new situations. This of course forms the basis for research. His highly influential book entitled 'Experiential Learning: Experience as the source of learning and development' was first published in 1984 and since then his ideas have had a dramatic impact on the design and development of lifelong learning models. David Kolb's work can be traced back to that famous dictum of Confucius:

> "Tell me, and I will forget. Show me, and I may remember. Involve me, and I will understand."

An 'experiential learning cycle' is a means of representing sequences in experiential learning. It is often assumed that the stages of a 'learning cycle' are managed by a facilitator, but they can also be self-managed or even 'unmanaged' in the sense that learning from experience is a normal everyday process for most people. From a trainer's perspective, an experiential learning cycle is a 2, 3, 4 or 5 stage learning sequence which encourages continuity from one experience to another. It is sometimes referred to as a 'training cycle', which can be misleading, especially if the theory underpinning it is about learners and learning. The learning cycle could, for example, involve online activities or set tasks before a course starts. In this way candidates come prepared with questions based on the difficulty or understanding of the task set.

Learning styles

Individuals develop one or more preferred learning styles. Individuals can learn through more than one of these; however, people tend to learn better using one or more styles than through others. In any group of learners, there will be a range of preferred learning styles, thus it is necessary for a wide range of teaching and learning activities to be used in order to provide learning opportunities suitable for all participants (Rogers, 1996[26]).

[22] Dudley, E. (1993). The critical villager. London: Routledge.

[23] Friere, P. (1972). Pedagogy of the oppressed. Harmondsworth: Penguin.

[24] Knowles, M. and associates (1984) Andragogy in Action, Gulf Publishing Co, Houston.

[25] Kolb, D. A. (1984). Experiential learning: experience as the source of learning and development. Englewood Cliffs, NJ: Prentice-Hall.

[26] Rogers, A. (1996). Teaching adults. Buckingham: Open University Press.

Active learners prefer to learn by doing immediately, without theoretical background, and prefer to find things out for themselves. They want to try as many things as possible.

Reflective learners prefer to wait and see; they watch and listen to others first before trying for themselves. They collect different opinions before making up their minds.

Theorising learners like to understand basic principles thoroughly, thinking things through step by step and dealing with general principles rather than specific cases.

Experimental or pragmatic learners like to experiment to apply new insights. They do not believe what they are told until they have seen it for themselves. They like solving problems and become impatient with too much talk.

Thus different types of learning activity will suit different types of learner. Traditional methods of teaching by information transfer followed by practical application of the information would seem to fit with these theories, providing different types of learning opportunity for different types of learner.

Andragogy – Adult Learning, assumptions, practicalities and the role of the tutor

M. Knowles' theory of andragogy is an attempt to develop a theory specifically for adult learning. Knowles emphasises that adults are self-directed learners, and expect to take responsibility for decisions. Adult learning programmes must accommodate this fundamental aspect. However, andragogy makes the following assumptions about the design of learning:

(1) Adults need to know why they need to learn something; they are relevancy-oriented;

(2) Adults need to learn experientially;

(3) Adults approach learning as problem-solving;

(4) Adults learn best when the topic is of immediate value.

In practical terms, andragogy means that instruction for adults needs to focus more on the process and less on the content being taught. Strategies such as the following are most useful in the context of module courses:

- the use of case studies;
- role playing;
- simulations;
- self-evaluation.

In these circumstances the tutor has two main roles, as a facilitator and a knowledgeable resource, not only lecturer or an assessor.

Moving from Pedagogy to Andragogy

There is little doubt that the most dominant form of instruction is pedagogy, or what some people refer to as didactic, traditional, or teacher-directed approaches. In the pedagogical model, the teacher has full responsibility for making decisions about what will be learned, how it will be learned, when it will be learned, and if the material has been learned. Pedagogy, or teacher-directed instruction as it is commonly known, places the participant in a submissive role requiring obedience to the teacher's instructions. It is based on the assumption that learners need to know only what the teacher teaches them. The result is a teaching and learning situation that actively promotes

dependency on the instructor (Knowles, 1984[27]). Up until very recently, this model has been applied equally to the teaching of children and adults, and in a sense, is a contradiction in terms. The reason is that as adults mature, they become increasingly independent and responsible for their own actions. They are often motivated to learn by a sincere desire to solve immediate problems in their lives. Additionally, they have an increasing need to be self-directing. In many ways the pedagogical model does not account for such developmental changes on the part of adults, and thus produces tension, resentment, and resistance in individuals (Knowles, 1984[28]). The growth and development of andragogy as an alternative model of instruction has helped to remedy this situation and improve the teaching of adults.

[27] Knowles, M. and associates (1984) Andragogy in Action, Gulf Publishing Co, Houston.

[28] ibid.

Flexible and distributed learning (e.g. e-learning):

Some sections of the modular training programmes may be delivered by e-learning. In particular the Legislation section of module 1 lends itself to an e-learning environment whereas the others generally require participants to take an active role in the learning experience. Careful design of an e-learning package can ensure it is suitably interactive and provides an appropriate range of learning opportunities.

Systems should be thoroughly tested and piloted prior to use, and should be free from viruses. The reliability of the delivery system used for web-based or interactive learning should be tested, and suitable contingency plans developed in case of failure of the designated delivery system.

Any delivery system used for remote access learning must be tailored to the environment in which the participant is working, but must be at the lowest level of technology available to participants. The delivery system should be fit for purpose, and be fully available with a suitable life expectancy.

Delivery of course materials should be secure and reliable, and some method put in place for acknowledgement of receipt. Password protected access or access authentication mechanisms should be provided.

Study materials used should meet the expectations of the accrediting body with respect to the quality of teaching and learning support.

APPENDIX 3

Application of the modular system and personal licence applicants

Section 4(4A) of ASPA states that:

> *"The Secretary of State shall not grant a personal licence to a person unless he is satisfied that the person (a) has appropriate education and training (including instruction in a relevant scientific discipline) for the purpose of applying the regulated procedures to be specified in the licence; and (b) is competent to apply those procedures in accordance with the conditions which are to be included in the licence and to handle and take care of laboratory animals."*

Since 1 April 1994 applicants for personal licences have been required to have successfully completed an accredited training programme. This should have covered the relevant modules as indicated in the Home Office Policy on the Education and Training of Personnel under the Animals (Scientific Procedures) Act 1986 (Appendix F of the Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act 1986). Very limited exemptions from these requirements may be considered by the Home Office. Applicants seeking exemption are advised to discuss with their local Inspector at an early stage.

This section provides guidance on the training and certification requirements for different situations. Note the modules referred to in this section are defined according to the existing Home Office policy.

1. General points

1.1 Modules may be completed individually to provide flexibility.

1.2 Completion of modules 1–3 would be required for a personal licence application covering simple, non-surgical techniques, e.g. common methods of dosing and blood sampling, and procedures under brief general anaesthesia such as bleeding out or tail biopsy.

1.3 Successful completion of module 4 is necessary for all more invasive and surgical techniques and those including recovery anaesthesia, or prolonged terminal anaesthesia.

1.4 Module 1 is not species specific and though it may be done in the context of a species or species group it need not be repeated if a new technique or species are added subsequently.

1.5 Module 4 may be done in the context of a species or species group, but should be a general module in which the principles of surgery and comparative anaesthesia are taught. It need not be repeated if new species are requested after the module has been completed.

2. New licence applicants

2.1 New applicants for personal licences will be required to undertake the training modules appropriate to the skill level and the species in the application. This means that at least modules 1, 2 and 3 should be completed in all cases (except exemptions).

2.2 New applicants should generally complete training for each species (mammals) or group (other classes) that they wish to include on their licence. It may be possible if training has been completed for several species in a group to apply to add another species from that group to the personal licence without further training, but applications covering a wide range of species without an appropriate diversity of training are unlikely to be granted. Such cases should be discussed with the local Inspector. For example:

(a) an applicant providing evidence of training in rats, mice, guinea pigs and rabbits may be permitted to add

gerbils to their personal licence without further training;

(b) an applicant having completed training in mice only should be expected to complete further training before being granted authority to use rats and rabbits.

3. Existing licence applicants

3.1 A personal licensee seeking extension of authority from minor procedures to major surgical procedures (i.e. skill level of module 3 to skill level of module 4) will be expected to complete module 4.

3.2 A personal licensee seeking significant amendment to the species authorised on the licence (e.g. currently licensed and with certified training for rodents only but also seeking licence authority for dogs or a farm animal species) will be expected to undergo additional training, assessment and certification relevant to the new species on the topics covered by modules 2 and 3 before application for such amendment.

3.3 There is limited scope for exemption from training where an existing licensee is applying for an additional but closely related species.

4. Certification

4.1 Training certificates should identify the modules undertaken and the individual species (mammals) or order/family/other convenient grouping (for other classes) in which sufficient theoretical training has been provided and that have been handled in training, and certificates should not be issued for species that have not been specifically covered in the course.

4.2 It is accepted that for some species there may be no accredited training provision, for example; wild animals. In these circumstances, two approaches may be acceptable:

(a) Applicants may complete the general parts of an accredited course or a course for a similar species, and provide evidence of training with the species in question delivered by a third party prior to or after completion of the course. Accrediting bodies may issue certificates for the particular species under certain circumstances, only if the third party training has been accepted as part of the accredited course.

(b) In-house non-accredited training might be accepted by the Home Office if it was provided to existing PiLh who had undertaken module training in the principles of the new species requested, had modules 2 and 3 in a related species and if the non-accredited training in the additional species was to be provided by appropriately qualified trainers. Here the certificate would have identified the species actually handled during the accredited course, and evidence of additional in-house training should be presented to the Home Office at the application stage. In undertaking some other arrangement in place of accredited training licensees should be aware that the absence of a certificate from an accreditation body may put them at a disadvantage at some later date.

4.3 For other species, it may be inappropriate for course participants to handle the animals during training, e.g. large primates, fish. In these circumstances, demonstrations of handling or videos may be used. It is necessary for participants to provide documentary evidence of experience of handling gained in their home institutions supervised by suitably qualified trainers prior to or after modular training in order for a certificate to be issued.

5. Species Groupings

5.1 Small laboratory animals. Even closely related species such as rats, mice and gerbils are markedly different and it is not appropriate for one species to substitute for them all. For example, if someone submits a certificate covering mouse only, this would not be sufficient to cover gerbils, but if the certificate included mouse, rat, hamster, guinea pig and rabbit it may be acceptable to include gerbils on the licence application.

5.2 Farm animals. Training in either sheep or goats would normally be sufficient to allow acceptance of the other. Training in other large animals (e.g. pigs, cattle or horses) would not, although experience in cattle may be considered sufficient to cover other large ruminants.

5.3 Primates. OWM or NWM are not considered to be a substitute for the other in training.

5.4 Birds. Birds should be split into poultry, large and small wild birds, or other appropriate division. Licences for work on embryonated eggs alone could be granted following completion of modules 1 and 2, or a dedicated egg module. Training in handling of poultry is not necessary for those wishing to work only with eggs.

5.5 Reptiles, amphibia, fish. These species may be divided into convenient groups, e.g. amphibia may be divided into anurans and caudata. Fish may be treated as one group, tropical/temperate/marine/ reshwater as appropriate.

5.6 Wild and exotic species: See section 4.2.

6. Applying for licence authorities after completing accredited training

It is assumed that applicants will apply for licence authorities within a short period after completing accredited training. Where an application is made more than five years after training was completed the Home Office will require that training is repeated.

7. Summary

Training courses for new licensees are readily available and exemption from training in common laboratory species for new applicants is not often appropriate.

It is expected that applicants will have handled all species listed on the certificate; however, in the case of exotic or wild species, primates or fish this may not have taken place during the accredited training course.

Training in less common species may not be readily available, in which case certificates issued following training in a related species may suffice, if supplementary evidence of additional training and experience gained prior to or after accredited training for the species or group in question is provided.

Limited exemptions from training requirements may be considered by the Home Office, e.g. exemption from training for some species may be considered following training in several related members of a subgroup. Licence applicants should discuss requests for exemption with the Inspector. The certificate should still identify only those species/groups for which sufficient theoretical training has been completed, where handling has been completed, either as part of the course or supplementary to it.

APPENDIX 4

An explanation of Learning Outcomes and Their Assessment (LOTA)

What are learning outcomes?

Typically a learning outcome is a statement of what a participant is expected to know, understand and be able to do at the end of a course.

This definition suggests that:

- Learning is not just about knowing subject-specific details but also about the development of cognitive and key skills (for example: being questioning and analytical; being able to communicate effectively and appropriately) necessary to use the subject knowledge.
- Learning is about developing and demonstrating skills and knowledge. That is, assessment activities should be designed to give participants an opportunity to show how they are working towards the learning outcomes, and an opportunity for feedback to help them improve.
- Outcomes refer to the end of a course. Working towards the outcomes during a module or a course is a developmental process in which assessment is part of, and guides, learning.

What are learning outcomes for?

An outcomes-based approach shifts the emphasis from the tutor to the participant, from teaching to learning. The goal is to enhance learning by helping participants know what they should expect from their course, and what they are expected to be able to do if they are to be successful. The approach aims to:

- Make the curriculum, and the demands and achievements of study clear to participants, teachers and others (such as employers or professional bodies).
- Help participants develop as independent and lifelong learners, able to adapt and learn for themselves in a rapidly changing social and economic environment. Learning outcomes also:
- Enable course teams to clearly link the learning, teaching and assessment materials at the earliest stages of course production.
- Provide a framework for quality assurance.

Learning outcomes and assessment

An assessment strategy should be concerned with giving participants a range of opportunities to demonstrate their development of the intended learning outcomes, such as:

- Explicitly linking learning outcomes to assessment.
- Providing opportunities for continuous assessment as well as end-of-course assessment.
- Providing opportunities for formative as well as summative assessment.
- Using assessment criteria that are shared with, and are understood by, the participants.
- Giving opportunities for participants to gain experience of a range of appropriate assessment methods. For example, traditional examinations may not be an appropriate way to assess skills such as information management, team working, or oral communication.

- Giving associate lecturers guidance on how their feedback can support participants' achievement of relevant learning outcomes and also feed forward to future assignments to guide participants' further development, particularly of more generic skills outcomes.

Development of the learning outcomes and the assessment strategy of a course or module should take place alongside content planning. Outcomes and assessment should not be 'bolted on' to content at the end. Being explicit about the learning outcomes, and using an assessment strategy that helps participants work towards them, helps to build their confidence and support participants in becoming effective learners.

Learning outcomes should be referenced to study at a particular level so that appropriate and realistic judgements about performance and development can be made. Table 3 at the end of this appendix presents an example.

Staff involved in course production

In the course production process the learning outcomes should be used to form the basis of teaching and assessment materials and be explicitly linked to assessment. Learning outcomes must be supported by a variety of assessment methods and specifications need to be regularly reviewed and updated, particularly when changes have been made to modular content.

Tutors involved in course delivery

Tutors need to be aware of and reinforce the learning outcomes of a course, particularly those that are assessed. Learning outcomes place an increased emphasis on supporting participants' skills development, as well as on acquisition and use of subject-specific content. A tutor's concerns about course content and learning outcomes should be fed back to course developers and guidance needs to be provided by accredited bodies on appropriate methods of feedback from participants and tutors.

Participants attending course modules

Learning outcomes provide a focus for appropriate formative, as well as summative assessment activities. The proportion of summative versus formative assessment and non-examined course content will depend on the particular module. Learning outcomes provide a framework against which specific feedback can be given on a participant's progress towards the outcomes. Participants should be better able to assess their own progress, and identify where they need help particularly if several courses are taken in quick succession. Participants need to be provided with a language that helps them to recognise and articulate their own achievements.

For external assessors and the audit process

Learning outcomes form part of the quality assurance processes of any HEI and should support claims to an external assessor about what a participant is capable of doing by the end of a course. Learning outcomes should be examined by external assessors as part of the approval process for any new course.

Defining Learning Outcomes

Learning outcomes can be divided into four categories: knowledge and understanding, cognitive skills, key skills and professional/practical skills. Knowledge and understanding relate to the content and subject matter of the course; cognitive or thinking skills are associated with analysis and synthesis of the course content; key skills are more general and concern the participant's ability to communicate, use relevant ICT and information literacy skills, or work with others. Professional/practical skills are particular skills that relate to the subject area.

The following verbs are useful when writing learning outcomes for each of the four categories defined above.

Knowledge and Understanding

Describe, identify, label, show, demonstrate, organise, know, understand, be aware of, recognise, define, classify, paraphrase, give examples of, summarise, discuss, explain and clarify.

Cognitive skills

Use, select, apply, present, compare, construct, illustrate, engage with, consider, assess, evaluate, synthesise, analyse, interpret, distinguish between, differentiate, contrast, question, challenge, critique, argue, account for, justify, judge, appraise, review and defend.

Key skills and professional/practical skills

Find, identify, develop, recognise, use, manage, engage with, communicate, present, record, evaluate, compare, assess, select, choose, plan and monitor.

The table at the end of this section shows how such descriptors could be used to determine/validate a participant's knowledge following learning.

The level of learning outcomes

The learning outcomes for a course need to be written at an appropriate level. Level 1 learning outcomes for example should focus on developing understanding and skills, level 2 on using and applying knowledge and skills and level 3 on critical understanding and the application of skills. The minimum qualifications required for holding a personal licence are 5 GCSEs at A–C and proficiency in the use of English. This minimum level places restrictions on the level of learning outcomes and their assessment. Most candidates attending module 1–4 training are at or near graduate level, and most of those attending module 5 training courses are at the post-graduate/post-doctoral level. Not all candidates however are at this level. Devising learning outcomes of an appropriate depth for the subject matter that can still be learned by a candidate with the minimum qualifications is a difficult task. The balance here isn't so much between the requirements of the different participants, but between the minimum 'knowledge' required and the academic ability of candidates with minimum qualifications.

Table 3. An example of participant's levels framework

Indicator	Level 1	Level 2	Level 3
Knowledge and understanding *Knowing about and understanding your subject.*	Show that you know and understand principles, concepts and terms central to your subject.	Demonstrate knowledge and critical understanding of the principles, concepts and techniques used in your subject.	Demonstrate systematic knowledge and critical understanding of your subject, some of it in specialist areas, and informed by current thinking and developments.
Cognitive skills *Description, application, analysis and synthesis of knowledge.*	Use your knowledge and understanding to describe, analyse and interpret defined aspects of your subjects.	Apply your knowledge and understanding accurately to a range of issues, questions and problems relevant to your subject. Apply established techniques to critically evaluate and interpret your subject in a range of contexts.	Select and use accurately established techniques of analysis and enquiry outside the context in which they were first studied, and be aware of their limitations. Synthesise, critically evaluate and challenge information, arguments and assumptions from different sources, including publications informed by current issues or research developments as appropriate. Recognise the potential uncertainty, ambiguity and limits of knowledge in your subject.
Key Skills *Addressing issues and problems* *Awareness of context and environment*	Know about and begin to address issues and problems central to your subject.	Compare critically and use different approaches to issues and problems within your subject.	Identify and ask questions appropriately to explore relevant issues or problems within your subject.
Communication *Communicating clearly, effectively and appropriately with others (including interpersonal skills, collaborative and group working)*	Develop your skills in communicating information accurately and appropriately to your subject, purpose and audience.	Communicate information, arguments and ideas effectively, using the styles and language appropriate to your subject, purpose and audience.	Communicate complex information, arguments and ideas effectively and appropriately to your subject, purpose and audience.
Information Literacy *Finding, critically evaluating and using information*	Develop your skill in finding, selecting and using information or data in defined contexts.	Find, critically evaluate and use information or data accurately in a range of contexts.	Find, critically evaluate and use information or data accurately in complex of contexts.

Indicator	Level 1	Level 2	Level 3
ICT and numerical skills *Using appropriate ICT and numerical skills*	Develop your use of ICT tools and your numerical skills as appropriate to support your studies.	Use ICT tools and numerical skills, as appropriate to help you learn effectively.	Select and use ICT tools to improve your learning and extend your numerical skills, as appropriate.
Learning how to learn *Managing and improving your own learning*	Develop your understanding and use of the resources available to help you learn, and begin to develop as an independent learner.	Plan, monitor and review your progress as an independent learner.	As an independent learner, plan, monitor and evaluate your own learning and seek ways to improve your performance.
Practical and professional skills *Developing practical skills and professional awareness*	Develop as appropriate, practical and professional skills and awareness of relevant ethical issues.	Engage as appropriate, with practical and professional skills and demonstrate an awareness of relevant ethical issues.	Engage as appropriate, with practical and professional skills and relevant ethical issues.
Personal and career development *Using personal and career planning and development resources*	Plan your study pathway to link your learning with your personal and/or your career goals.	Recognise and record your skills and knowledge to support your personal and/or career goals.	Recognise, record and communicate your skills and knowledge to achieve your personal and/or career goals.

APPENDIX 5

The use of multiple choice questions (MCQs)

Current use of the MCQ

The investigation of imprecise terms used in some MB BS finals MCQ examinations, in Part 1 Membership Examination of the Royal College of Physicians and Royal College of Surgeons revealed that imprecise terms occur commonly, yet there is a wide range of opinion among the examiners themselves about their meanings. A second type of construction error – disproportionately large numbers of `true' branches – was also recorded. Exemplary practices do exist in MCQ quality assurance, but in the UK they are very much the exception rather than the rule. It is an extremely frustrating experience for someone with '*expert knowledge*' in a field being assessed, to find inaccuracies or misleading questions in MCQs [*personal communication with members and consultants on the APC ETSC and HOIs*].

Multiple choice questions (MCQs) allow a wider sampling of knowledge compared with essay questions but can be criticised for being too low level, placing too much emphasis on factual recall, and giving participants insufficient opportunities to apply their knowledge. Multiple choice questions (MCQs) are used extensively in both undergraduate and postgraduate medical education in the UK. There are two types in general use – true/false and one-best-(single-best) answer. Both types comprise a lead-in statement called the question stem and a number of branches which follow on from it. In true/false items, candidates are required to indicate whether each individual branch is true or false, whereas in the one-best-answer type they are asked to select only the single most appropriate option.

All MCQ formats are prone to construction errors. In particular, the simple true/false type appears to be highly prone to construction errors. For example, imprecise terminology and unequal numbers of `true' and `false' items are common. There are also problems concerning validity and reliability, especially where negative marking is used (i.e. when marks are deducted for incorrect answers). These drawbacks, along with the development of superior assessment methods, led institutions in the US to stop using all true/false formats in their examinations several years ago (Case & Swanson, 1996[29]). In the UK the Royal College of Surgeons no longer uses negative marking and has adopted a 'single-best-answer' approach to MCQs.

Experts on item-writing would agree on certain principles concerning the construction, marking and development of MCQs. Many would also agree that it can prove extremely difficult to convince examiners that they are of any importance in education. Where inaccuracies exist in MCQs candidates can justifiably complain that the assessment is not fit for purpose. Thus the validity of the outcome can be challenged and exposing the organisation to litigation. Whereas one-best-answer MCQs use a relative scale which allows candidates to judge the correctness of each of the options offered and indicate which they feel is the best response, true/false questions use an absolute scale (i.e. true or false) and so every branch must be unequivocally true or false in its own right. It is particularly difficult to write plausible `false' items, which is why there tend to be more `true' items than `false' ones in these MCQs. However, many developers would agree that there should be a similar number of `true' and `false' items, otherwise some candidates may be disadvantaged, depending on how they respond to items about which they are unsure (Grosse & Wright, 1985[30]). Obviously, this must also impair the reliability of the exam. Guessing is a problem in all MCQ test formats. Most high-stakes MCQ tests now use the single-best-answer format with no 'don't know' option and a number-right scoring.

[29] Case, S, Swanson, D. Extended-matching items: a practical alternative to free-response questions. *Teach Learn Med* 1993;**5** (**2**):107–15

[30] Grosse, M. E. & Wright, B. D. (1985) Validity and reliability of true–false tests. *Educational and Psychological Measurement* **45**, 1 13.

APPENDIX 6

Proposed information addressed in an Accrediting Body Annual Report

1. Introduction.
2. Current membership of the Accreditation Board.
3. Membership of the Accreditation Board over previous year – dates of membership.
4. Number of Accreditation Board meetings.
5. Number of training providers.
6. Frequency of courses per species.
7. Number of application/renewals/reaccredidation undertaken. The criteria used to determine acceptability.
8. Number of accreditation visits made and geographical range.
9. Number of spot checks/the criteria that initiate a spot check/the frequency of spot checks.
10. What modules/courses/ the timetable including species.
11. Overview of paperwork examined – both external and internal.
12. Handling – procedures where handling is not done as part of course.
13. Number of candidates taking/passing each module.
14. Assessment type e.g. can candidates use course material for reference?
15. Examples of feedback given following Accreditation visits.
16. Items noted of best practice during visits.
17. Any concerns noted from course organisers during visits.
18. Any courses not accredited/withdrawn.
19. Any notable variations between courses?
20. Meetings with course providers – agenda and outcomes.
21. Interactions with other Accrediting Boards in the UK.
22. Accreditation Board collaborations with others including Government Departments and Policy Makers.
23. Electronic learning.
24. Suggestions for change in accreditation procedure/documentation in the coming year.
25. Any other relevant items worthy of discussion.

APPENDIX 7

Membership of the APC ETSC and co-opted members

APC ETSC members

Graham Moore (*chair from January '06 – January '08*)
Michael Festing (*until Sept 2009*)
Bob Kemp
Maggy Jennings (*until March '06*)
Sarah Wolfensohn (*from June 2009*)
David Smith (*from June 2009*)
Peter Hunt (*from June 2009*)

Observer from the Home Office Inspectorate

Maggie Lloyd (*until September '08*)
Kathy Ryder

Co-opted members

Maggy Jennings (RSPCA)

Consultant

Duncan Banks (Open University)

APPENDIX H

Lynne Featherstone MP
Parliamentary Under Secretary of State
Home Office
2 Marsham Street
London, SW1P 4DF

Dear Lynne,

Guidance on the roles and responsibilities of those involved in the delivery and accreditation of training under the Animals (Scientific Procedures) Act 1986

We would like to bring to your attention a piece of work undertaken by the Animal Procedures Committee (APC) in response to a request from the UK Accrediting Bodies to define what is expected from bodies accepted for accreditation of training courses for personnel working under the Animals (Scientific Procedures) Act, and to offer guidance as to the expectations that these bodies should have of course providers.

During the preparation of the report, the former Minister Joan Ryan wrote (28th Nov 2006) to the Committee with the following questions:

1. How the effectiveness of the Accrediting Bodies can be evaluated.

There is currently no process for evaluating the effectiveness of the Accrediting Bodies. Were such a system to be developed there would need to be some clarity as to what is to be evaluated; presumably quality and efficacy of training would contribute to any evaluation/assessment or audit.

All the Accrediting Bodies have recently agreed to prepare annual reports for the Inspectorate that will outline how many courses are available, how many students taught and the proportions of pass/fail. In our report, section 1.4.2 and Appendix 6 we suggest other information that would assist in future evaluations.

2. How they can be audited and by whom.

The term audit in this case we understand to mean providing reasonable assurances as to function and performance following an independent evaluation of relevant qualitative and quantitative information. The consensus of opinion from the Accrediting Bodies (September 2009) was that the Home Office, possibly through an independent body were best placed to carry out such an audit. Looking towards the future changes in the regulation of animals used in research (revised EU Directive 86/609) that possibly, auditing of training courses should be a role of the proposed National Committee for the Protection of Animals used for Scientific Purposes.

However, will an effect of harmonising of training across the EU see an end to the need for 'national/local' accreditation bodies?

Section 2 of the Committee's report describes possible suggestions in relation to the process of evaluating quality and standards of training.

3. Whether there is any inconsistency between courses offered by the Accrediting Bodies.

The Committee understand that there is no current official guidance or general principles, the last relevant material dating back to 1993, and agree that there are differences between the courses accredited by the Accrediting Bodies. The Accrediting Bodies have acknowledged differences in approach rather than inconsistencies and explained that these are due to the diverse needs of the sectors of industry and academia accredited by them. Courses will differ according to needs specific to those sectors but the Accrediting Bodies believe the 'standards' across all courses remains equivalent.

None of these differences in the Committee's opinion should be viewed as major problems and can and are being addressed in a number of ways – regular communication between the Accrediting Bodies, meeting between training providers aligned to the three Accrediting Bodies (which is already happening), guidance to both Accrediting Bodies and Training Providers (provided in the latest Committee guidance report), annual reports (recommended in the Committee guidance report) and audits of both the Accrediting Bodies (recommended) and Training Providers (already happening).

Looking towards implementation of the new Directive and the goal of harmonised transferable skills, guidance and general principles will have to be developed as part of each Member State's commitment to Article 47 of the new Directive. The guidance outlined in this report may well become part of the new principles for training/taught courses.

4. Whether their (courses) assessment methods are sufficiently robust.

Having looked at both the training and assessment provided for modules 1–4 and that of module 5, the Committee are aware of the different approaches to assessment taken by the Accrediting Bodies. Section 4 of the Committee's report establishes the general principles but further work should be done using expertise from the Accrediting Bodies, Training Providers, Home Office Inspectorate, APC and/or National Committee to evaluate the robustness of the current system or develop a new approach that will ensure the delivery of consistent and appropriate training for all involved in the use of animals in research.

We commend this report to you. I am grateful for the efforts of the Education and Training Sub-Committee, chaired by Mr Bob Kemp and also to Dr Duncan Banks, Lecturer in Biomedical Science at the Open University who provided his expertise in open learning. I hope that you will accept our considerations in relation to the former Minister's questions and look forward to your response.

Yours sincerely

Sara Nathan

ANNEX I

Committee Response to Consultation on Code of Practice on Scientific Advisory Committees

COPSAC Consultation questions

- **Maintaining strong relationships.** It is key that Ministers, sponsoring departments and independent scientific advisers develop and sustain effective working relationships. Based on this:

  Q1a) What role should be played by and what expectations should the SAC Chair have with regard to relationships between the SAC and its sponsoring department, and the Minister or departmental Chief Scientific Adviser to whom the SAC reports?

APC Response:

The APC has a good working relationship with its Policy Group ASPD and ASPI. It is also very important that the public is reassured regarding the SAC's independence, especially in areas of societal concern, where people would want to feel that their interests are represented by an independent SAC that is not unduly influenced by the sponsoring department or any particular group of stakeholders.

The APC Chair has regular one-to-one meetings with the relevant Minister, who has attended the APC meeting but the working relationship with HO CSA is less defined – which may be a function of a change of personnel there.

Q1b) What role should be played by and what expectations should the SAC chair have with regard to relationships between the Chairs of other SACs whose interest may overlap?

APC Response:

APC meets with Defra/FAWC but there are other SACs associated with DOH and BIS where greater contact maybe beneficial. APC Chair attends HO Science Advisory Committee but there is little overlap of interest apart from all being at the Home Office.

Q1c) What steps can be taken for SACs to maintain their independence and objectivity?

APC Response:

This doesn't seem to be a problem under current arrangements; similarly the future National Committee (from January 2013) is unlikely to encounter such conflicts provided it remains separate from the competent authority (ASPI). But it is important that the public is reassured regarding the SAC's independence, especially in areas of societal concern, where people need to know their interests are represented by an independent SAC that is not unduly influenced by the sponsoring department or any particular group of stakeholders.

SAC's independence and objectivity is enhanced by ensuring that their members are properly appointed and drawn from the full range of stakeholders. It is also advisable that SACs should regularly consult external experts and bodies and ensure that members – once they have agreed to participate in an SAC – keep themselves informed of relevant progress in the field.

It is impossible for an SAC to maintain its work or objectivity without sufficient committed secretariat. The APC now only has one person, not at a high grade, and this makes it very difficult to function even if extra help is drafted in to take minutes etc. A secretariat for an SAC does much more than that and it is easy to predict the APC becoming diminished if this carries on for much longer (which it will).

Q1d) How might SACs best resolve disputes between members or with Ministers and/or sponsoring departments?

APC Response:

Current guidelines are satisfactory. And have not been deployed in the last five years at least when it comes to relationships with Ministers and the sponsoring department.

Some disagreement at least between members is to be expected especially in an SAC like the APC where members are specifically drawn from across the spectrum – this is not necessarily a disadvantage as long as different views can be expressed courteously and explained in submissions.

- **Openness and Transparency**

Question 2: It is important for SACs to operate in an open and transparent manner whilst ensuring the need to protect sensitive information.

Q2a) In some cases, for example national emergencies, publication of advice in the public domain may not be possible in advance of government decision making. How can this process be best communicated and managed?

APC Response:

Not sure this is ever likely to happen with the APC and it's difficult to envisage which other SACs have such a strategic role. However, advice on licence applications is not published until after the decision is taken by the Home Office. This is due to the need to maintain confidentiality of those involved. It might be worth broadening the 'national emergencies' to include other examples, such as to reduce the possibility of crimes being committed.

Q2b) How can SACs ensure that non-disclosure agreements (NDAs) are used appropriately? In what circumstances are NDAs appropriate?

APC Response:

The APC has not used these so far, although some of the work undertaken by the APC is classified, or uses access to classified material. In these cases the APC adheres to the Government's protocols for handling such information.

Q2c) What training could be provided to SAC Chairs and members to assist in their interactions with the media?

APC Response:

For the APC and ACMD, media training is already available through sponsor department. As the current Chair is a professional broadcast journalist, further training has not been necessary. It has been offered, however.

Q2d) What should the considerations in selecting a nominated spokesperson be, and should this be tailored to the programme of work, for example, is there a benefit in having a nominated spokesperson per project?

APC Response:

This already happens in the APC with respect to Working Groups and Sub-Committees. Note that under current guidelines, only the Chair can speak on behalf of the Committee. Generally the Chair is the public face of the Committee but may ask a Sub-Committee Chair to be a spokesperson on a particular area of expertise.

Considerations should include expertise on a subject, level of authority, confidence in performance and willingness to engage.

The APC tries to ensure its advice and conclusions are published as soon as possible and are as open as it can be given the innate sensitivities of the subject. The Committee has discussed holding open meetings but so far has considered that its subject matter would make these peculiarly difficult to arrange.

- **Engaging the Scientific Community and Succession Planning**

Question 3: In order to maintain the effective provision of scientific advice to government, SACs need to seek feedback on the advice they provide, consider the ongoing need for their advice, and consider succession planning.

Q3a) It is important to have a balance of expertise between scientific knowledge and other areas on both SACs and their secretariat.

Q3i) How can the balance of expertise on SACs between scientific experts, those from other professions and key partner organisations be determined?

APC Response:

The APC has a lay Chair and a philosopher by tradition and a lawyer by statute. The statute also says that a proportion of members must be or have been practitioners. Given that there is considerable ethical debate and the subject matter is by no means wholly scientific, there could be more ethical/lay/legal input, but certainly not less.

However rigorous the selection process, a SAC is only as good as the contribution actually made by members in meetings and to documents. The application and selection process for each SAC should emphasise the responsibilities associated with membership and set out clear expectations of potential members.

Q3ii) How can the balance of expertise required for SAC secretariats be determined?

APC Response:

Normally the sponsor department would be able to provide a secretariat with sufficient expertise. Alternative sources are available including through GO Science GSE network. A secretariat that both understands the science and can function within the civil service is critical. There needs to be some dedication. The current level of redundancy may threaten departments' ability to provide adequate secretariat and this needs to be resisted.

Q3b) What steps can SACs take to ensure that expertise is maintained and future skills needs identified? What practical steps might be taken to broaden the pool of potential candidates?

APC Response:

Difficult to see how this can be ensured in future for advisory Committees and groups following Maude's Reform particularly where SACs functions have been 're-absorbed' back into the sponsor department. For the APC, the pool is quite restricted as expertise in animal experiments is not that widespread. Also the members are unpaid. While the Committee does put the word out and advertises, most candidates are stimulated by personal contact.

Q3c) How might the broader scientific and engineering community feed into the work of SACs, the consideration of future work priorities and any potential refocusing of priorities?

APC Response:

This may be more difficult following the Maude Public Bodies Bill, but the APC uses co-option of people with specific expertise onto Sub-Committees. The Chair attends industry and stakeholder events to ensure she remains in contact and many members are also active in other organisations such as the Laboratory Animals Science Association and can get feedback and information through those.

- **General**

Question 4: Is there any other information that could be usefully included in the Code of Practice?

APC Response:

The previous Code of Practice seemed largely fit for purpose in theory but was not adhered to all the time.

An independent press officer function seems to be something that SAC chairs might on occasion find useful. Maybe the Science Media Centre could be retained to fill that function on an ad hoc basis as a source of independent media advice.

ANNEX J

Committee response to Academy of Sciences consultation on the use of animals containing human material

Dr Laura Boothman
Academy of Medical Sciences
10 Carlton House Terrace
London
SW1Y 5AH

24 March 2010

Dear Laura,

On behalf of the Animal Procedures Committee please see the enclosed opinions of the APC Biotechnology Working Group on the research use of animals containing human material within and beyond the UK. The Biotechnology Working Group limited its consideration to the suggested areas outlined in the Academy of Medical Sciences call for evidence: Animals containing human material, December 2009.

1. **Provide examples of research involving 'animals containing human material' – and indicate whether this research is taking place within, or beyond, the UK.**

1.1 Humanised mouse antibodies (mouse-human antibody chimera) production is understood to be fairly routine.

1.2 There are also a number of human Alzheimer mutation models in mice (Babraham Institute and MRC Laboratory of Molecular Biology).

1.3 Downs Syndrome mouse model developed in association with the Wellcome Trust.

1.4 In Australia a sheep model of Huntington's disease has been developed.

1.5 We understand from the Home Office Inspectorate that currently in the UK there is no interspecies work involving higher order animals such as horses, dogs, cat and non-human primates.

1.6 Additionally of the interspecies work carried out in the UK, the majority involves inserting small amounts of human DNA (single genes as opposed to total composition quantities such as 60:40 ratio).

1.7 The APC's Biotechnology Working Group believes the USA to be the most productive in producing non-human primate models of human disease: for example Huntington's disease (HD). Although rodent models of HD have been developed, these models apparently do not satisfactorily parallel the brain changes and behavioural features observed in HD patients.

2. **Provide examples of scientific advances or clinical treatments which have, or are expected to, result from research involving 'animals containing human material'.**

Regarding advances in the near future, the Biotechnology Working Group would expect further developments in:

- Human stem cell multiplication from animal cell manipulation.
- Human stem cell therapies being tested in animal models before use in humans.
- The use of mouse and/or non-human primate hybrids in the study of human infertility e.g. sperm production.
- The use of NHP hybrid cells to study neurodegenerative diseases, particularly those that affect cognitive, emotional and motoric functions.

3. **Outline specific societal, ethical, safety or welfare concerns relating to this research.**

3.1 The Biotechnology Working Group discussed societal concerns and concluded that 'lower order' animals with individual gene mutations were unlikely to raise major issues. However, the 'yuk factor' was more prominent when considering whole organ or specific cell manipulations, particularly when the public could envisage what the term 'humanised' might mean (i.e. the animals display some visible human-like features or characteristics). For example, humanising some aspect of "higher" brain function or phenotypical/morphological appearances in another species would undoubtedly raise more concerns than similar manipulations of the vascular of immune systems.

3.2 Regarding the subject of the ethics of animal/human hybrids, this is touched on in the original Academy of Medical Sciences' Interspecies embryos report of 2007[31] with reference to the concept of human dignity. It was the Biotechnology Working Group's feeling that the implicit understanding of the human/animal difference involved here should be more critically examined, and not taken for granted. Similarly the Biotechnology Working Group believe that ontological questions arising from this area of science and research would benefit from a more systematic engagement with other, non-scientific, perspectives, both from non-scientific research on human/animal questions and from public opinion in society at large.

3.3 "hybrid animals becoming so humanised that they are uncomfortable in their own skin" – these are not rational foundations of what is currently technically possible. The key argument to reaching public acceptance of this novel research must be that introducing human material into the embryo of another animal species does not make the resulting hybrid develop human-like behaviour. Furthermore, when mixing human DNA with genetic information from another species, if the proportions are only expressed quantitatively (for example 40% human genes and 60% from another species) this could be open to the serious misinterpretation that the animal has been made "40%" human. The fact that there are extensive similarities between the genomes of different species and that distinguishing features lie in the specific arrangements and organisation of genes and their resultant protein products needs to be emphasised.

3.4 The Biotechnology Working Group is also aware of the wider concerns that parts of our community have towards animal material transplants, particularly with respect to religious interpretation and boundaries such as Jehovah's Witnesses refusing transfusions and Muslim opposition towards certain uses of pig material.

The Biotechnology Working Group accepts that within the Animal Procedures Committee there are different view points and positions on the appropriateness of such research. Overall, it is believed that research involving animals containing human material is controversial and respects the view that animal use should be proportionate and appropriately challenged as part of a regulatory process. It is therefore expected that in seeking an authorisation, regulators should consider the proposer's track record in implementing the 3Rs and the ability to provide high standards of welfare and to minimise animal suffering.

4. **Submit, or provide references for, national or international regulations, guidelines, legislation, or organisational position statements which address the use of 'animals containing human material' in research.**

4.1 Following advice from the Home Office inspectorate, the Biotechnology Working Group understands that the legislative controls of hybrid embryos are currently determined by what the starting material is. Therefore, for a hypothetical animal-human embryo, provided that the nature of the starting material ('egg') was animal derived then the resulting admixed embryo would be regulated under the Animals Scientific Procedures Act (ASPA) (1986) as long as the embryo continues to be classed as a non-human (animal) vertebrate. The ASPA cannot be used to regulate an admixed embryo which is classed as human, no matter what the starting material.

4.2 With respect to the licensing of such procedures under ASPA, the Biotechnology Working Group accepts and agrees that the regulatory hurdle would be high but sees it as necessary to ensure compliance to the highest scientific and welfare standards.

[31] Inter-species embryos: A report by the Academy of Medical Sciences 2007 http://www.acmedsci.ac.uk/download.php?file=/images/project/124905166128.pdf

4.3 In relation to the global pharma industry, and the potential to manipulate weaker regulatory authorities, the Biotechnology Working Group foresees a number of potential conflicts:

(a) With the UK having one of the 'tightest' regulatory requirements such research might go to other countries with lower animal welfare standards.

(b) A number of UK institutions will now only collaborate with overseas groups if the collaborative work is carried out in accordance with UK licensing standards.

(c) Other countries' lower standards may permit controversial research which might negatively impact on the standing and acceptability of UK research in the eyes of the interested public.

(d) This novel research is entirely dependent on the moral codes of scientists and their respective organisations.

4.4 The Working Group would also like to refer the Academy of Sciences Interspecies working group to its Biotechnology report published in July 2001[32]; in particular we would ask the working group to consider the following recommendations:

Recommendation 1. In accordance with the permissible purposes set out in A(SP)A, no licences should be issued for trivial objectives, such as the creation or duplication of favourite pets, or of animals intended as toys, fashion accessories or the like, and the Home Office should consider the motives and character of would-be licensees. (paragraph 41)

Recommendation 2. In accordance with current practice, no licences should be issued for work which can be expected to produce GM animals which would suffer severe or lasting distress, including animals to be created as disease models, unless there is clear evidence that the problems could be handled humanely through specialist care and application of humane end points. (paragraph 46)

Recommendation 3. It is important that, in accordance with the current practice any proposal to modify particular genes should be accompanied by a preliminary analysis of their likely function, and the means that will be adopted to ameliorate any damaging effects of the modification. (paragraph 47)

Recommendation 4. Apart from practices of work under terminal anaesthetic and decerebrate preparation licences should not be given for the genetic modification of animals with the intention of (a) stripping animals of their biological integrity, or (b) rendering them incurably insentient. (paragraph 51)

Recommendation 5. No licences should be issued for the production of embryo aggregation chimeras especially not cross-species chimeras between humans and other animals, nor of hybrids which involve a significant degree of hybridisation between animals of very dissimilar kinds. (paragraph 57)

Recommendation 7: In accordance with current policy and practice, particular care should be taken in the case of GM animals that all the welfare costs arising from production be taken into account when a project licence application for the production of foundation stock is considered. (paragraph 73)

Recommendation 8: The APC, possibly with others, should consider the commissioning of a project to examine how to assess the welfare of transgenic animals, especially mice. (paragraph 77)

Recommendation 9: The Home Office should build on current practice to ensure that the obligation to monitor the welfare consequences of research involving either the production or the use of GM animals is included as a condition of all project licences relating to such research. (paragraph 78)

[32] APC Report on Biotechnology 2001. http://apc.homeoffice.gov.uk/reference/biorec.pdf

5. **Provide materials illustrating how the topic of 'animals containing human material' is being explored by non-specialist audiences through traditional or new media approaches (e.g. magazine articles, programme downloads, social networking sites).**

Unlike the scientific community where ethical review bodies are common, non-specialist interest groups are believed to be not so prolific although clearly ***the emerging discipline of embryology research and development is likely to have a significant social, political and personal impact in the 21st century***. The Biotechnology Working Group understands that BIOS at the London School of Economics and the British Animal Studies Network may offer useful contributions to the debate on Interspecies embryology.

6. **Outline any other issues which are considered of relevance to the study (except those listed above as falling outside the remit of the call for evidence).**

UK Transposition of the Revision of Directive 86/609/EEC – the protection of animals used for experimental and other scientific purposes – is not expected to compromise current and future advances in animal embryology technology. Transposition and implementation of the directive is likely to involve two further rounds of formal consultation. If the revised directive is completed in 2010 this would require that revised UK legislation take effect 1 January 2013.

ANNEX K

APC WORK PROGRAMME FOR 2011 onwards

OBJECTIVE	TARGET DATE
Applications Sub-Committee	
Consider and advise on applications for project licences referred to the Committee by the Home Office.	As required
Education and Training Sub-Committee	
Advise on issues relating to Education and Training.	As required
Housing and Husbandry Sub-committee	
Advise on issues relating to housing, husbandry and care.	As required
Primates Sub-Committee	
Develop a mechanism for horizon scanning of current situations/trends in the use of primates in medical research and the understanding of diseases, excluding regulatory toxicology.	2011
Consideration of overseas centres supplying non-human primates to UK laboratories.	As required
Cumulative Severity Working Group	
Draft the terms of reference	On going
86/609 Working Group	
Advise on and evaluate revisions to the European Directive and their transcription into UK legislation, guidance and Codes of Practice.	On going
Infringements	
Trend analysis of recent infringement data.	2011

ANNEX L

GLOSSARY

Embryo aggregation chimaera – an embryo containing genetically distinct types of cells.

Embryonated egg – an egg which contains an embryo.

Equidae – the family of mammals that have a single functional digit although the second and third digits persist as splint bones. *Equids* include horses, asses and zebras.

Ethology – the scientific study of animal behaviour.

Husbandry (animal) – the practice of breeding, raising and caring for animals.

In vitro – literally "in glass", i.e. experiments conducted using cells, tissues or organs in an artificial environment, outside a living organism.

In vivo – refers to experimentation done in a whole, living organism.

Retrospective reporting – the reporting of data already collected; a study of past events, in contrast to a *prospective study* which attempts to predict what will happen in the future.

3R's – the *replacement, refinement* and *reduction* of animals in research.

Xenotransplantation – the transplantation of cells, tissues or organs from an animal of one species to an animal of a different species.

List of Acronyms

APC – Animal Procedures Committee

ASC – Applications Sub Committee

ASPA – Animals (Scientific Procedures) Act 1986

CRO – Contract Research Organisation

LASA – Laboratory Animal Science Association

LAVA – Laboratory Animal Veterinary Association

NACWO – Named Animal Care and Welfare Officer

NC3Rs – the National Centre for the Replacement, Refinement and Reduction of Animals in Research

NDPB – Non Departmental Public Body

NVS – Named Veterinary Surgeon

PSC – Primate Sub-Committee

SAC – Scientific Advisory Committee