Draft guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (as amended)

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Foreword

Changes to the Animals (Scientific Procedures) Act 1986

The Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 (SI 2012/3039) amend the Animals (Scientific Procedures) Act 1986 to transpose European Directive 2010/63/EU on the protection of animals used for scientific purposes. Directive 2010/63/EU sets out revised measures for the protection of animals used for scientific purposes.

What this guidance covers

It provides advice on what revised ASPA covers and guidance to holders of establishment licences, project licences and personal licences and new licence applicants. It also provides guidance on severity classification, humane killing and the accommodation and care of animals, including the status of Annex 3 to the Directive and current UK Codes of Practice.

What this guidance replaces

This guidance replaces the “Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (HC321)” published on 23 March 2000.

Who this guidance is for

This guidance is for everyone involved with animals that are bred for, supplied for, or used in scientific procedures. This includes:

- holders of establishment licences, project licences and personal licences;
- new licence applicants;
- other named people such as Named Veterinary Surgeons;
- others working in user, breeder and supplier establishments;
- Home Office inspectors;
- members of the Animals in Science Committee;
- others with an interest in this area.

How the guidance is arranged

The first section sets out the background to the Animals (Scientific Procedures) Act 1986 (ASPA).

We follow this with a section describing the principles of replacement, reduction and refinement (the 3Rs) and choice of methods.

The next sections tell you what you need to know about establishment licences, personal licences and project licences.

We then give information about severity categories, humane killing of protected animals and the care and accommodation of animals.

We next describe the duties and training of named people, including Named Animal & Welfare Officers and Named Veterinary Surgeons.

The remaining sections cover Animal Welfare and Ethical Review Bodies, non-compliance, Home Office inspections, the Animals in Science Committee, other advisers to the Secretary of State, and other miscellaneous issues.

How to submit applications

Application forms and details of where to send them are available on the 'Research and testing using animals' pages on the Home Office website.

Where to go for more information

General enquiries about this guidance and the Animals (Scientific Procedures) Act 1986 should be sent to our central email address (aspd-brp@homeoffice.gsi.gov.uk) where they will be dealt with and a response sent as soon as practicable.

Glossary of terms

ASPA	The Animals (Scientific Procedures) Act 1986. ASPA in this guidance means the consolidated amended version of the Act incorporating changes brought in by the European Directive (2010/63/EU) on the protection of animals used for scientific purposes.
AWERB	Animal welfare and ethical review body
Breeder establishment	An establishment which breeds animals for use in procedures
Commission	European Commission
ERP	Ethical Review Process
EU	European Union
EU Directive	European Directive on the protection of animals used for scientific purposes (2010/63/EU)
IAT	Institute of Animal Technology
Member State	Member of the European Union
NACWO	Named Animal Care and Welfare Officer
NCO	Named Compliance Officer
NIO	Named Information Officer
NTCO	Named Training and Competence Officer
NVS	Named Veterinary Surgeon (or other suitably qualified expert where more appropriate and agreed)
Pain, suffering, distress and lasting harm	This includes anything that affects the animal's physical, mental and social wellbeing. It includes disease, injury and physiological or psychological discomfort, whether immediately (such as at the time of an injection) or in the longer term (such as the consequences of applying a carcinogen).
PEL	Establishment licence (formerly PCD – Procedure Certificate of Designation)
PIL	Personal licence (Procedure Individual Licence)

PPL	Project licence (Procedure Project Licence)
POLE	Place other than a licensed establishment
Primate	Non-human primate
Procedure	A procedure which is regulated under ASPA – see page 11
Protected animal	All living vertebrates, other than man, and any living cephalopod in addition to some immature forms – see page 11
RCVS	Royal College of Veterinary Surgeons
Section 2C licence	Establishment licence
Self-sustaining colony	A 'self-sustaining colony' is one kept in a way that ensures the animals (primates) are accustomed to humans and which consists only of animals that have been bred in captivity, either within the colony or in another self-sustaining colony.
Supplier establishment	An establishment which supplies animals for use in procedures
User establishment	An establishment which uses animals in procedures

Background to the Animals (Scientific Procedures) Act 1986 (ASPA)

What does ASPA cover?

The Animals (Scientific Procedures) Act 1986 (ASPA) regulates procedures that are carried out on 'protected animals' for scientific research and testing that may cause pain, suffering, distress or lasting harm.

ASPA also regulates the breeding and supply of certain species of animals for use in regulated procedures and the breeding of animals for the use of their organs or tissues in procedures.

In this guidance regulated procedures are called 'procedures' to avoid repetition. If we are referring to procedures which are non-regulated, we make that clear by using the term 'non-regulated procedures'.

What licences are required?

ASPA has a three-level licensing system:

- those carrying out procedures must hold a '*personal licence*', which ensures that they are qualified and suitable;
- the programme of work in which the procedures are carried out must be authorised in a '*project licence*';
- the place at which the work is carried out must hold an '*establishment licence*'.

Places breeding and/or supplying the species of animal listed in ASPA Schedule 2 must also hold an establishment licence.

Procedures may be authorised at Places Other than Licensed Establishments (POLEs), and these will be specifically identified in the relevant project licences.

Who issues licences?

ASPA licences are issued by the Home Office in England, Scotland and Wales and by the Department of Health, Social Services and Public Safety (DHSSPSNI) in Northern Ireland.

What is a protected animal?

ASPA protects *all living vertebrates, other than man, and any living cephalopod*. Fish and amphibia are protected once they can feed independently and cephalopods at the point when they hatch.

Embryonic and foetal forms of mammals, birds and reptiles

Embryonic and foetal forms of mammals, birds and reptiles are protected during the last third of their gestation or incubation period.

Embryonic and foetal forms are protected from an earlier stage of development if they are going to live beyond the last third of their gestation or incubation period and the procedure is likely to cause them pain, suffering, distress or lasting harm after they have developed to that stage.

NB. Before you plan or perform procedures on foetal, larval or embryonic forms, you must have a thorough knowledge of the gestation and incubation periods of the animals you are using and the stage of development they will reach during the course of your work.

You will need a licence to carry out procedures on an embryonated bird egg if you manipulate the egg during the first two-thirds of the incubation period and then allow the embryo to survive into the final third of the incubation period. If, on the other hand, you kill the embryo before the start of the final third of the incubation period, you will not need a licence for this procedure.

Definition of 'living'

A protected animal is living until its circulation stops permanently or its brain is destroyed.

ASPA considers *decerebrate animals* to be living, and therefore protected, because their brains are not completely destroyed.

You will need a licence to decerebrate an animal and to use these animals in procedures.

What is a regulated procedure?

A procedure is regulated if it is carried out on a protected animal and may cause that animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by inserting a hypodermic needle according to good veterinary practice. We call this the 'lower threshold'.

Procedures may be regulated if they involve doing something, such as dosing or sampling, or not doing something, such as withholding food or water.

We have also established thresholds for regulating these and other procedures such as psychological stress, changes to diet and environmental changes. Please refer to

the section on Severity categories in this guidance. We can also advise you about these on a case-by-case basis.

Permissible purposes

Procedures have to be for one of the following permissible purposes:

a) basic research;

b) translational or applied research with one of the following aims:

(i) the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality, or their effects, in man, animals or plants;

(ii) the assessment, detection, regulation or modification of physiological conditions in man, animals or plants; or

(iii) the improvement of the welfare of animals or of the production conditions for animals reared for agricultural purposes;

c) the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs or any other substances or products, with one of the aims mentioned in paragraph (b);

d) the protection of the natural environment in the interests of the health or welfare of man or animals;

e) research aimed at preserving the species of animal subjected to regulated procedures as part of the programme of work;

f) higher education or training for the acquisition, maintenance or improvement of vocational skills;

g) forensic inquiries.

Procedures that may also be regulated

Procedures may also be regulated under ASPA if they are:

- *part of a series or a combination of non-regulated procedures* which together may cause the animal pain, suffering, distress or lasting harm – for example, multiple or cumulative minor changes to the environment may disturb the animal sufficiently to be regulated, even if the individual changes do not warrant regulation;

- anything that is done *intending, or resulting in, the birth or hatching of a protected animal* that may as a result of the procedure experience pain, suffering, distress or lasting harm.

Procedures which are regulated include:

- *modifying the genes of a protected animal* if this causes the animal pain, suffering, distress or lasting harm; for example, breeding animals with harmful genetic defects is a regulated procedure if you intend to keep the animals produced beyond two-thirds of the way through their gestation or incubation period;

- *those performed under general anaesthesia* if the effect on a normal conscious animal would be to cause pain, suffering distress or lasting harm;

- *administering an anaesthetic, an analgesic or other measure* to sedate or dull the perception of pain in a protected animal;

- *humane killing of a protected animal* if it is killed at a licensed establishment other than by either a method described as appropriate in Schedule 1 or a method specified on your establishment licence (see the section on Humane killing in this guidance);

- *removing organs, blood or other tissue* under general anaesthesia even if the animal is not allowed to recover consciousness.

What procedures are not regulated?

These are not regulated procedures.

- *Non-experimental clinical veterinary practices*: You should consult the Royal College of Veterinary Surgeons (RCVS) on what constitutes non-experimental clinical veterinary practices and the related professional standards. The clinical investigation and management of the health or welfare of animals is generally considered to be non-experimental clinical veterinary practice when it involves an intervention which is of direct benefit to the animal or its immediate peer group. See the RCVS website for further guidance.

- *Veterinary clinical trials*: Administration of substances as part of veterinary clinical trials needed for the marketing authorisation of a veterinary medicinal product are not regulated procedures. However, if you propose to carry out procedures which are likely to cross the lower threshold and go beyond the administration of a substance in accordance with an animal test certificate under the Veterinary Medical Regulations 2011, you should consult the RCVS to determine if the procedures constitute non-experimental clinical veterinary practices.

- *Non-experimental agricultural practices and practices undertaken for the purpose of recognised animal husbandry*: These are not regulated procedures as long as they comply with other animal welfare legislation and regulations and are being used to manage or conserve animals. *They are regulated if they are part of a scientific study*.

- *Identifying animals*: Ringing, tagging or marking an animal primarily to identify it, or using any other humane way to do so, are not regulated procedures if they cause no more than momentary pain and no lasting harm. For example, micro-chipping or ear-marking a rodent is not a regulated procedure if it is being done primarily to identify the animal. *Blood sampling or DNA sampling using a method likely to cross the lower threshold of pain, suffering, distress or lasting harm are not methods used to identify an animal and would therefore be regulated*.

- *Humane killing of animals*: Killing a protected animal in a licensed establishment by an appropriate humane method listed in Schedule 1, or by a method specified in that establishment's licence, is not a regulated procedure. This is still the case if the killing is to provide material for scientific use (see the section on Humane killing in this guidance). A copy of Schedule 1 detailing approved methods of humane killing is available in the consolidated version of ASPA on the Home Office website.

The 3Rs and choice of methods

The principles of replacement, reduction and refinement (the 3Rs)

For the purposes of ASPA [section 2A]:

- *Replacement* is the principle that, wherever possible, a scientifically satisfactory method or testing strategy not entailing the use of protected animals must be used instead of a regulated procedure;

- *Reduction* is the principle that whenever a programme of work involving the use of protected animals is carried out the number of protected animals used must be reduced to a minimum without compromising the objectives of the programme;

- *Refinement* is the principle that the breeding, accommodation and care of protected animals and the methods used in regulated procedures applied to such animals must be refined so as to eliminate or reduce to the minimum any possible pain, suffering, distress or lasting harm to those animals.

These principles are called the 3Rs. You will find more information about the 3Rs in the 'Project licence' section of this guidance.

How should the 3Rs be applied?

Project licence holders must ensure their programme of work does not involve any regulated procedures for which there is a scientifically satisfactory alternative method or testing strategy that does not entail the use of a protected animal.

In addition, the programme of work must as far as possible:

- use the minimum number of animals;

- involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm;

- cause the least pain, suffering, distress or lasting harm; and

- are most likely to produce satisfactory scientific results. **[Project licence standard condition 4]**

Personal licence holders must take steps to prevent or reduce to a minimum any pain, suffering distress or discomfort that may be caused to the animals in any procedure they apply.

Death as an end-point

Death as an end-point must be avoided as far as possible and replaced with an early and humane end-point.

Overbreeding

Overbreeding happens when the animals bred prove unsuitable for procedures or are surplus to requirements.

You should minimise overbreeding as far as possible by:

- planning projects carefully and with sufficient time built in to breed animals for specific requirements;
- applying proper experimental and statistical designs that minimise the number of animals you need;
- justifying your requirements for particular characteristics (for example, sex, weight or age) within a properly designed study;
- collaborating with other users at your establishment and other places;
- questioning the need for small, in-house breeding colonies of common strains;
- sharing or cryopreserving ‘tick over’ strains;
- keeping records of surplus animals and reviewing the reasons for this.

Your AWERB should:

- raise awareness of overbreeding;
- devise policies and controls to minimise surpluses;
- coordinate and rationalise users’ needs, animal production and breeding facilities.

Data sharing

Procedures must not be applied to an animal if the data is already available in another Member State and has been obtained by procedures which satisfy any relevant regulatory requirements of the EU.

Thematic reviews of the 3Rs

Article 58 of the EU Directive requires the Commission to carry out periodic, thematic reviews of the three Rs in consultation with Member States. Although the obligation

to carry out reviews is on the Commission, and does not require transposition, we believe that similar reviews can play an important part in ensuring the effective operation of ASPA. We therefore propose to carry out our own thematic reviews and to consult the Animals in Science Committee, practitioners and other interest groups on suitable topics. We will also encourage the Commission to ensure that Europe-wide thematic reviews are carried out.

Establishment licences

What does an establishment licence cover?

Under ASPA section 2B, you may not carry on an undertaking involving any of the following activities unless you are authorised to do so in an 'establishment licence' issued under ASPA section 2C:

a) applying regulated procedures to protected animals (a *user establishment*);

b) breeding protected animals listed in ASPA Schedule 2 with a view to (i) their use in regulated procedures, or (ii) the use of their tissues or organs for scientific purposes (a *breeding establishment*);

c) breeding other animals (not listed in ASPA Schedule 2) primarily for the same purposes (also a *breeding establishment);*

d) the keeping of Schedule 2 animals which have been bred elsewhere and are to be supplied with a view to (i) their use elsewhere in regulated procedures, or (ii) the use elsewhere of their tissues or organs for scientific purposes (a *supplying establishment*).

A user establishment may also be authorised as a breeding establishment if it breeds animals for use in procedures there or somewhere else.

A breeding establishment must also be a user establishment if any of the animals bred there are genetically altered *and* of a potentially harmful phenotype.

What must an establishment licence include?

An establishment licence must include:

- details of the holder of the licence;
- details of the 'named persons' required by ASPA section 2C(5);
- a schedule of premises.

Who can hold an establishment licence?

Establishment licences may be held by a natural or legal person, i.e. by an individual or by a corporate entity, such as Noname Pharmaceuticals plc or the University of Nowhere.

Where the holder is a corporate entity, we will expect the responsibilities of the establishment licence holder, set out below, to be carried out by the *Named Compliance Officer* (see below and the 'Named people' section of this guidance).

What training do I need to complete?

You are expected to have completed module 1 of an accredited training course or to have equivalent knowledge and experience.

If you are a new establishment licence holder we recommend that you take additional training relevant to your role. Courses aimed at establishment licence holders are arranged by the Laboratory Animal Science Association through their forum.

How long will my establishment licence last?

An establishment licence remains in force until it is revoked.

For further information, see the 'What happens if your establishment licence is varied, revoked or suspended?' section of this guidance.

Death or departure of an establishment licence holder

An establishment licence ends if the licence holder dies or leaves the establishment. However, the licence may continue for a further 28 days if we are informed within seven days. This allows time for a new licence to be authorised with a new establishment licence holder. If the departed establishment licence holder is also the Named Compliance Officer, an individual must be nominated by the establishment management to be responsible during this time for ensuring compliance with the requirements of ASPA and the conditions of the establishment licence.

Before you apply for a new or amended establishment licence

Before you fill in your application form you should collect all the necessary details including those of all the named people at your establishment and of the area/s where animals are going to be held and/or used in procedures.

You will also need to request authorisations for any methods of killing you intend to use that are not specified in Schedule 1 and for setting free or re-homing animals once procedures are complete.

You may find it helpful, at an early stage, to discuss your proposed application or amendment with the inspector assigned to your establishment.

Application forms and details of where to send them are available from the Home Office website.

Named people

Establishment licences must name one or more people who are responsible for the following activities:

- ensuring that the requirements of ASPA and conditions of the licence are complied with – *the Named Compliance Officer* (NCO). This will usually be the holder of the establishment licence;

- overseeing the welfare and care of the animals – the *Named Animal Care and Welfare Officer* (NACWO);

- ensuring that those dealing with animals have access to any information they need about the species they are using – the *Named Information Officer* (NIO);

- ensuring that those dealing with animals are adequately educated, trained and supervised until they are competent and that appropriate further training continues – the *Named Training and Competence Officer* (NTCO).

- one or more *Named Veterinary Surgeons* (NVS) with expertise in laboratory animal medicine to advise on the health, welfare and treatment of the animals. Exceptionally, you may be able to nominate other suitably qualified experts where you can show that they are more appropriate for this role.

All these named people should help the holder of the establishment licence fulfil his/her responsibilities. They should all play a central role and be actively involved on a daily basis in the local animal welfare and ethical review body (AWERB).

Named people should be promptly replaced if they leave, or their responsibilities change meaning they cannot continue in their role. Your establishment licence will need to be amended accordingly.

We recommend that you refer to the *Register of Laboratory Animal Technologists* when identifying individuals to fill the NACWO post(s). The Register promotes professionalism in laboratory animal care, high ethical standards and qualification of career animal technologists. To be included in the Register applicants must hold the Membership or Fellowship Diploma of the Institute of Animal Technology or equivalent. They must also have at least five years' relevant experience, including two years post qualification. Members comply with the Guide to Professional Conduct and are subject to a disciplinary code. Further details are available from the Institute of Animal Technology (www.iat.org.uk).

Schedule of premises

Establishment licences must contain a 'Schedule of Premises' detailing the areas of the establishment's premises where animals are used in procedures and where they are housed.

Installations and equipment

You can find details of required installations and equipment in our guide for the care and accommodation (which can be found on the Home Office website).

How quickly will my application be decided?

We will inform you of our decision within 40 days of receiving your complete and correct application.

How we will assess your application for an establishment licence

An inspector will check your application and visit your establishment to verify that all of the requirements set out above have been met.

Your responsibilities as establishment licence holder

Establishment licence holders have a number of responsibilities:

- providing leadership;
- ensuring compliance;
- preventing unauthorised procedures;
- applying the 3Rs;
- ensuring your establishment has enough staff;
- setting up and running an animal welfare and ethical review body;
- the performance and conduct of named persons;
- avoidance of conflicts of interest;
- ensuring animals have appropriate care and accommodation;
- countersigning project licence applications;
- record keeping and identification of animals.

Leadership

You will need to be proactive and provide effective leadership. You will need good management and communication skills and the commitment to nurture a ‘culture of care’ in your establishment.

You must represent the governing authority of the establishment. For example, you may be the director of a research institute, a university registrar or the chief executive officer of a company.

You must know the main provisions of ASPA and what your responsibilities are under it. You must have sufficient seniority and authority to fulfil these responsibilities and at the same time take an active interest in the care and use of animals at your establishment.

Compliance

Unless you have named someone else as your 'Compliance Officer' (see 'Named Persons', above), we assume that you will also be the person responsible for ensuring compliance with all aspects of ASPA and the terms and conditions of the establishment licence. You, or your Named Compliance Officer, should be the best person in your establishment to do this.

Preventing unauthorised procedures

You are responsible for preventing unauthorised procedures at your establishment. You must put in place robust systems for complying with ASPA and the terms and conditions of your establishment licence and any personal licences and project licences held there.

The appropriate personal and project licences must be in place before any animals are issued for use in procedures. We strongly recommend that your management systems ensure no one carries out procedures until you have copies of the relevant licence authorities. You should also check that individual personal and project licence holders know they have the appropriate authority before performing procedures.

The 3Rs

You must ensure that activities at your establishment follow the principles of the 3Rs – replacement, reduction and refinement. This applies to breeding protected animals, keeping them for supply and using them in procedures. **[Standard condition 1]**

Staffing

You must have enough staff to maintain a high standard of husbandry and care.

You are responsible, through your NTCO, for making sure that all staff are adequately educated and trained before they work with any protected animals or that they are supervised until they are competent. **[Standard condition 5]**

You must also see that licensees, those applying for licences and anyone else who comes into contact with animals can access the education and training they need to do their job competently.

Animal welfare and ethical review body

You must ensure that your establishment has an animal welfare and ethical review body (AWERB) complying with the requirements of paragraph 6 of ASPA Schedule 2C. (See the 'Animal welfare and ethical review bodies' section of this guidance.) **[Standard condition 6]**

Performance and conduct of named people

You are accountable to us for the performance and conduct of your named people. **[Standard condition 15]** If we think that a named person is unsuitable, or not doing their job properly, we may vary or revoke your licence unless you can resolve the problem immediately or can nominate someone else to take over their role.

You should ensure that named people have the necessary authority to carry out their roles. All project and personal licence holders and other staff dealing with animals should seek and follow their advice on the health, welfare and use of animals, both at the planning stage and when work is in progress. They should also follow their advice on how to gain and maintain competence.

Named people must be able to access licences and other documents about the production, care and use of animals at your establishment. They must be given the necessary training and resources.

You should ensure arrangements are made for the care and welfare of animals when the NVS and NACWO are unavailable. **[Standard condition 16]**

Conflicts of interest

Given their role in providing independent advice on animal welfare, you must avoid any scientific, financial or other conflicts of interest among those carrying out the role of NVS or NACWO. The people nominated for these roles must sign a declaration detailing any relevant potential conflicts of interest including:

- financial interests such as directorships and significant shareholdings;
- significant scientific interests in the outcome of a programme of work;
- interests of close relations and/or friends which may be relevant, for example if a partner or sibling is a director or major shareholder of the establishment;
- any other relevant matters.

A Declaration Form is available on our website and must be completed for each new NVS and NACWO and sent to us with your nomination form.

You should review these declarations regularly, at least annually. You do not need to send the updated declarations to us but they should be available for inspectors to check. You should also require these named people to inform you promptly about any significant changes to their declarations and you must inform us of such changes without delay.

In addition, for any group of protected animals you should have at least three people filling the five key roles of: establishment licence holder, project licence holder, personal licence holder, NACWO and NVS.

Also when an NVS or NACWO has a substantial interest in the scientific outcome of a programme of work, you should arrange alternative provision for the veterinary or welfare oversight of the animals in question.

Please ask us for advice if you are in any doubt about a potential conflict of interest.

Animal care and accommodation

You are responsible for making sure that all protected animals at your establishment have appropriate care and accommodation. **[Standard condition 4]**

Unless your establishment licence or any relevant project licence provides a specific exemption, you must ensure that:

- the environment, housing, freedom of movement, food, water and care you provide for each animal are appropriate for its health and wellbeing;
- the fabric, installations, equipment and environment of the approved areas meet, or are better than, the minimum standards set out in our guide on care and accommodation, 2013 (see the 'Guide for the care and accommodation' section of this guidance);
- conditions for transporting an animal are appropriate for its health and wellbeing;
- any restrictions on an animal's physiological and ethological needs are kept to an absolute minimum;
- the animal's care, accommodation and physical environment are checked daily by a competent person;
- a suitably qualified person monitors the animal's wellbeing and health at least daily;
- any avoidable pain, suffering, distress or lasting harm is prevented in a timely way and, if this is discovered, is eliminated as quickly as possible;
- quarantine and acclimatisation facilities are provided and used when needed;
- there are adequate fire precautions and security measures to prevent animals escaping and unauthorised intrusions;
- the use of rooms or other areas is as described in the licence and all those with responsibilities under ASPA have details of these approved areas.

Any significant changes to your establishment which may have a negative effect on animal welfare must first be approved by us by amending your licence.

Countersigning project licence applications

You, or someone you have designated, must countersign each request for a project licence or amendment involving work at your establishment confirming that the application has completed local review by your AWERB.

Death or departure of a project licence holder

You must tell us about the death or departure of a project licence holder within seven days of finding out about it if you wish to continue work under that project licence at your establishment. The project licence can continue for a further 28 days to allow you to complete work in progress or obtain a new licence. During this time you are responsible for conducting the project. **[Standard condition 22]**

Identifying animals

You should ensure that personal licence holders have properly labelled each cage and confinement area holding animals for which they are responsible (see the 'Personal Licence' section of this guidance for details). Cages or confinement areas containing animals that are not undergoing a regulated procedure must be labelled with a cage reference/area reference which identifies the animals held, by individual or batch.

Dogs, cats and primates housed at your establishment must be easily identifiable with a permanent form of identification. **[Standard condition 10]**

You must therefore make sure that:

- before any unmarked dog, cat or primate is weaned, it is given a permanent individual identification mark in the least painful way;
- before any unmarked dog, cat or primate that has not been weaned is transferred to another establishment, it is given a permanent individual identification mark unless it is impractical to do so;
- in the above case, a record of its mother is kept until the animal has been given a permanent individual identification mark;
- where an unmarked dog, cat or primate is transferred to your establishment after being weaned, it is given a permanent individual identification mark as soon as possible.

If asked, you must provide a sound reason why any cat, dog or primate has not been marked.

Keeping records

You are responsible for keeping records of the source, use and disposal of all protected animals used in procedures, bred or obtained for use, or supplied for use. **[Standard condition 8]**

These records should account for each protected animal, except for immature forms (at foetal, larval or embryonic stages) which you can record in batches until they are issued for use.

The NVS should supervise health records and make sure these are kept to a proper professional standard. **[Standard condition 14]**

Your records should contain the following details.

Animal – number, species and breed or strain; type of harmful mutant, genetic modification, or surgical preparation, where applicable; approximate age on arrival; sex; if female, whether pregnant; identification number or code, by individual or group number; microbiological status (e.g. gnotobiotic, qualified pathogen free, or conventional); and dates in and out of quarantine, if applicable.

Source – the name and address of the breeder or supplier; if it is a Schedule 2 animal, whether it has been bred for use in procedures; for harmful mutants, genetically modified animals or surgically prepared animals, the name and address of the source, and if bred or prepared in the UK, the authorising project licence number; date of arrival, or date of birth if born at that breeding establishment; the name and address of the person for whom the animal has been acquired.

Use – the numbers and types of animals allocated as breeding stock or held for supply or use in procedures; at a user establishment, the project licence to which the animal was issued; in the case of continued use between projects, re-use and reissue without previous use, each project to which the animal was issued.

Disposal – the number and species of animals that were killed by an appropriate Schedule 1 method or a method authorised in the establishment or project licence for scientific use of tissues and organs at the end of procedures or as surplus to requirement; those that died of other causes and the cause of death, where known; those that were supplied to another licensed establishment; those that were re-homed as a pet, discharged to a farm, to a slaughter house, to the wild, or supplied for export.

You must also keep a daily record of the environmental conditions in enclosed holding areas.

You should keep all these records for at least five years after the animal's death, or from the date of its release where relevant.

Individual history files

You must also keep individual history files for cats, dogs and primates. **[Standard condition 9]**

These must contain:

- the animal's identity;
- its place and date of birth, if known;
- a statement saying whether the animal was bred for use in procedures;
- any relevant reproductive, veterinary and social information;
- a record of the programmes of work involving the animal's use in procedures;
- for primates, whether it was the offspring of primates bred in captivity.

At breeding establishments you must start an individual history file as soon as possible after the animal is born.

At supplying and user establishments, where the animal has been obtained from an establishment in the UK or from an authorised breeder, supplier or user in another EU member state, the individual history file should accompany the animal.

Where the animal comes from a source outside the EU, or where the individual history file is not available, you should start one as soon as possible.

When animals are moved from one establishment to another you should provide the individual history file to the next establishment licence holder.

If the animal is re-homed, you must provide a copy of any veterinary or social information to the person with whom the animal is re-homed.

If the animal dies, is set free or re-homed, you should keep its individual history file for at least five years.

You must retain details of all project and personal licences currently authorised at your establishment. The personal licence records should cover at least the current and previous fee period (April to March).

You must make all records available to us when asked to do so. Sometimes we may ask for a summary of some or all of your records.

You should use the information in the records as tools to monitor and improve standards and practices at your establishment.

Sourcing animals

There are restrictions on using certain types of animal in procedures which you must comply with.

Which animals cannot be used?

You cannot use the following animals, unless we have granted a specific authorisation:

- any cat or dog unless it has been bred at and obtained from a breeding establishment;
- a protected animal described in ASPA Schedule 2, unless it has been bred at a breeding establishment and obtained from that breeding establishment or a supplying establishment;
- any vertebrate of an endangered species;
- a protected animal taken from the wild.

We have limited powers to allow exemptions:

- in the case of cats and dogs, we may only grant an exemption when you cannot obtain an animal suitable for your programme of work; we cannot authorise the use of stray cats and dogs and you may only use feral animals in exceptional circumstances;

- in the case of animals taken from the wild, we may only grant an exemption where there is scientific justification for doing so;

- in the case of endangered species, you may only use these animals in projects which aim to preserve that species or for essential biomedical purposes where the endangered species is the only one suitable.

Breeding and supplying establishments can only obtain animals listed in Schedule 2 from other designated sources, unless we authorise otherwise. If you want to obtain an animal from a non-designated source you must show us that there are no animals suitable for your programme of work available from a designated source.

Breeding primates

If your establishment breeds primates which are not already second generation captive bred (F2), you must have a strategy, acceptable to us, for increasing the numbers bred from animals that were bred in captivity. You may not breed or use marmosets (*Callithrix jacchus*) which are not at least second generation captive bred. **[Standard condition 7]**

Humane killing of animals

You must keep a register of people at your establishment who are competent to kill protected animals and ensure that only those people carry out this task. You must also check that before anyone is added to this register they have been educated and trained to kill animals, and once registered, they are supervised until they are competent. **[Standard condition 2]**

The people on your register who only use methods listed in Schedule 1 of ASPA do not need to have a personal or project licence for such killing. You should refer to the section of guidance on humane killing to ensure people at your establishment have any necessary authorisations for other methods.

You must make sure that you have enough registered people available at all times so that someone is there to kill an animal if necessary. You should check that any equipment needed is to hand and well maintained.

We recommend that you display a copy of Schedule 1 and the relevant section of this guidance in all areas used for killing animals.

At times it may be necessary to kill animals that have not been used in procedures, for example those that are surplus to stock. You must make sure this is done competently. They must be culled by an appropriate Schedule 1 method or another method authorised in your licence. At breeding and supplying establishments this only applies to animals listed in Schedule 2.

You are responsible for complying with the relevant provisions and keeping records of the disposal of the animals.

A copy of Schedule 1 detailing approved methods of humane killing is available in the consolidated version of ASPA on the Home Office website.

Disposing of animals

You must ensure that any animal still living after undergoing a series of procedures is kept at your establishment under the supervision of a veterinary surgeon. This is the case unless we have authorised the animal's transfer to another establishment and a veterinary surgeon has certified that it will not suffer if it is no longer kept at your establishment.

Our permission is needed if you propose to release animals from the controls of ASPA, for example for re-homing. This will usually need to be specified in the relevant project licence (see the 'Project Licence' section of this guidance).

Paying fees

You need to pay us fees to cover the costs of operating ASPA. This includes the costs of inspecting, licensing and of the Animals in Science Committee.

We charge annual fees for the establishment licence and for each personal licensee working at your establishment with 'primary availability'. If the 'primary availability' changes, we will charge the establishment licence holder at each establishment holding 'primary availability' for that personal licensee during that year (April to March). We do not currently charge for project licences.

We issue an invoice each year for fees payable for the previous year. This must be paid within 28 days. If unpaid, we may revoke your establishment licence, subject to your right to make representations.

We can vary these fees and will give you notice of any increases.

Amending your establishment licence

You can ask us to amend your establishment licence at any time. You must request an amendment if there are changes to:

- the title of your establishment;
- the class of licensed activity;
- the named people;
- the list of approved areas;
- how you are using these areas;
- the animal welfare and ethical review body.

The new authorities will not come into force until we have granted an amended licence.

You can find an application form for amendments to your licence on our website.

What happens if your establishment licence is varied, revoked or suspended?

An establishment licence may be revoked at any time at your request.

We can also vary, suspend or revoke your licence if its conditions are breached or for another reason, such as:

- failure to comply with a compliance notice;
- failure to pay fees;
- where named people are no longer able to meet their responsibilities and you have not sought appropriate replacements.

Suspending or revoking a licence immediately invalidates all personal and project licences at your establishment and means you may no longer breed, keep or use animals.

We can suspend your establishment licence urgently to safeguard animal welfare. In this case, all procedures must stop immediately. We may require you to take action to safeguard the welfare of your animals or we may take that action.

We can vary the terms and conditions of your licence, for example if parts of your establishment no longer meet the required standards.

Your right to make representations

Under ASPA section 12, you have the right to make representations if we intend to vary or revoke your licence other than at your request. If we notify you of such an intention, we will provide you with guidance on your right to appeal.

Standard conditions for establishment licences

We grant establishment licences subject to standard conditions. These are set out at Annex A.

Sometimes we may include additional conditions, for example:

- to further restrict the use of animals;
- to set specific requirements at your establishment for managing the work; or
- authorising you to use a method of humane killing which is not included in Schedule 1.

Personal licences

What does a personal licence cover?

Your personal licence shows that you are qualified and suitable to carry out specified regulated procedures, under supervision if necessary.

Under ASPA, you are not allowed to apply a regulated procedure to an animal unless all three of the following requirements are met:

- you hold a *personal licence* authorising you to apply a procedure of that description to an animal of that type;
- the procedure is applied as part of a programme of work authorised in a project licence; *and*
- the place where the procedure is carried out is specified in that project licence.

Who can hold a personal licence?

To become a personal licence holder you must:

- be at least 18 years old;
- have satisfactorily completed the appropriate training modules; and
- have appropriate experience of handling protected animals and looking after their welfare.

What training do I need to complete?

As a personal licence holder we expect you to have at least five GCSEs or Standard Grade passes (including a biological science) or equivalent vocational qualifications.

You must also complete the relevant formal modular training to qualify for the specific categories of procedure you require. See the Home Office website for details. You may be exempt from these requirements if you can supply evidence of equivalent relevant education, training and experience.

If you are a new personal licence holder you will have to undertake further training and be supervised until competent at your place(s) of work.

You should review your training and supervision needs periodically with your NTCO.

If English is not your first language, your NTCO will check that you understand the provisions of ASPA.

How long will my personal licence last?

Although your personal licence will remain in force indefinitely or until revoked, we will review it at least every five years. You may be asked for information to assist this review. This may include similar details to those you provided for your initial application, and confirmation that this information is still correct. You may also be asked to provide your records of animal use.

Death or departure of a personal licence holder

Your personal licence will end on your death or if you leave your establishment. In that event, the establishment licence holder will assume responsibility for animals on which you have performed procedures.

Before you apply for a personal licence

Before you apply for a personal licence you must complete all the training relevant to the licence category or categories you want us to authorise. In particular, as a personal licensee you have primary responsibility for the welfare of animals and it is important that you have acquired the competence to assume that responsibility.

Application forms are available from the Home Office website.

What information is needed in a personal licence application?

Your application must include:

- your personal information for identification;
- details of the establishment where you will primarily be working;
- the type(s) of animal(s) on which you wish to work;
- the category(ies) of personal licence you are requesting;
- copies of certificates of successful completion of formal accredited module training, as appropriate.

Your application must be endorsed by the Named Training and Competency Officer (NTCO) at the establishment where you will primarily be working.

What is covered by the different categories of personal licence?

The categories of personal licence are as follows. These permit you to carry out procedures of the descriptions specified.

A. Minor/minimally invasive procedures not requiring sedation, analgesia or general anaesthesia

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

C. Surgical procedures involving general anaesthesia

D. Use of neuromuscular blocking agents

E. Procedures conducted in accordance with a Project Licence

F. Other

Category E is for education and training work under a specific project licence and category F is to cover anything that does not fit readily elsewhere.

You should consult your Home Office inspector if you are unsure whether a particular regulated procedure falls within a particular category.

Where can I use my personal licence?

Your licence must specify your primary place of work. This will be the establishment where you are based – called the 'primary availability'. This establishment is responsible for paying a fee for your licence and will maintain your training and competence record.

Your licence is not restricted to working only at your primary place of work. You may work under your personal licence at any licensed establishment in the UK but you should contact the NTCO at any additional establishments before starting any work there.

You may also work at places which are not included in an establishment licence (POLEs) but this should be as part of an authorised programme of work.

Which project licences can I work on?

For categories A, B, C and D, you can work on any projects as long as the classes of techniques and species you are using are authorised in your licence and on the project licence and the project licence holder and establishment are aware of your work.

Category E or F licences may limit you to working on a specific project licence.

We may add additional conditions to your personal licence that restrict your work.

How quickly will my application be decided?

We aim to process all applications for personal licences within 20 working days.

We provide a fast-track service for personal licence applications for overseas students and others planning short-term work or studies in the UK and aim to process these applications within five days of receipt.

How we will assess your application for a personal licence

We will check that you are old enough to hold a licence and that you satisfy the educational requirements and have satisfactorily completed training appropriate to the category of licence you have requested. We will also check that your application has been endorsed by the NTCO for the establishment in which you will be working. In some cases, you might be asked for further information and your application may be referred to an inspector for advice.

Your responsibilities

You must comply with the terms and conditions of your licence.

Before you carry out a regulated procedure you must check that it is authorised by a project licence and is being carried out at a place named in that project licence. You should also check that the required categories or descriptions of techniques and animals are listed in your personal licence. **[Standard condition 19]**

You should be familiar with the details of the licences for projects you are working on, including their objectives, plans of work and protocols.

You must only perform regulated procedures with the permission and in the full knowledge of the project licence holder. You should also understand the tasks the project licence holder asks you to perform, including any end-points you need to apply.

Animal welfare

You must not allow an animal to experience severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated. **[Standard condition 3]**

You should act at all times in a manner that is consistent with the principles of the 3Rs – replacement, reduction and refinement. **[Standard condition 1]**

You are responsible for the welfare of the animals you work on. This involves:

- being responsible for the welfare of the animals you have performed procedures on and ensuring that they are properly monitored and cared for; **[Standard condition 2]**

- knowing the techniques and species involved, what the consequences of performing procedures on them will be and the signs of pain, suffering, distress or lasting harm in that species;

- taking precautions to prevent or reduce any pain, distress, or discomfort to the animal, including using sedatives, tranquillisers, analgesics or anaesthetics; **[Standard conditions 4 and 12]**

- telling the project licence holder immediately if you think that the severity limit of a protocol has been, or is likely to be, exceeded; **[Standard condition 13]**

- getting and following veterinary advice and treatment, where needed; **[Standard condition 15]**

- arranging for the care and welfare of an animal when you are away; **[Standard condition 14]**

- making sure that any animal that is in severe pain or severe distress, which you cannot alleviate, is painlessly killed using an appropriate method. **[Standard condition 8]**

If two or more personal licence holders are working with the same animal, you must be clear who is primarily responsible for that animal.

Supervision

Until the project licence holder and NTCO where you are working are satisfied that you have achieved competence, you should not apply regulated procedures unless given the appropriate level of supervision by the project licence holder, or an experienced personal licence holder assigned by him or her. This is to ensure that regulated procedures are performed competently. **[Standard condition 17]**

Record keeping and cage labelling

You must keep records of all the regulated procedures you perform and note whether you were supervised. You should record any resulting morbidity or mortality to enable your supervisors to decide if you need further training or supervision. **[Standard condition 20]**

Your records should be retained for at least five years and should be available to the NTCO and project licence holder(s) where you work and, on request, to our inspectors. **[Standard condition 20]**

You must clearly label cages, pens and other enclosures. The label should include details of:

- the project licence number;
- the protocol;
- the date the protocol was started;
- the responsible personal licensee. **[Standard condition 16]**

You can use a coding system as long as this can be easily decoded by others caring for the animals or with responsibilities under ASPA, including our inspectors.

Delegating tasks

You can delegate tasks which form an integral part of the regulated procedures that you are authorised to perform to assistants under your control who do not themselves possess the requisite personal licence authority. The tasks must not require technical knowledge or skill. Any such assistant must be trained, instructed and supervised.

Any delegation must be in accordance with any relevant guidance we have published under section 21 of ASPA, including relevant sections of this guidance. **[Standard condition 18]**

For example you could use an assistant to:

- fill food hoppers and water bottles with previously mixed diets or liquids of altered constitution or to which test substances have already been added;
- put an animal in a predefined altered environment such as a pressure chamber;
- press the exposure button to deliver predetermined doses of irradiation to an animal;
- pair animals for breeding animals with harmful genetic defects;
- withdraw contents from an established ruminal fistula;
- operate automated machinery for inoculating eggs;
- place animals in restraining devices, as defined by the project licence;
- withdraw food or water, as defined by the project licence;
- place avian eggs into pre-set chillers at the end of a procedure.

We may consider giving you authority to delegate other tasks, but only when you are present and the animal has been rendered insentient by decerebration or general anaesthesia that will continue until it dies. This might include administering substances through a catheter, or administering electrical stimuli through electrodes that you have implanted.

During surgery unlicensed assistants can only perform simple duties under your instruction. This may include cutting of sutures or ligatures. They may not make or close surgical incisions or perform any other intervention that requires knowledge or technical skill.

You should consult us if you are unsure whether or not a task can be delegated.

Conflicts of interest

Conflicts of interest must be avoided. For any group of protected animals there should be at least three people filling the five key roles of: establishment licence holder, project licence holder, personal licence holder, NACWO and NVS. (See the 'Establishment licence' section of this guidance.)

Please ask us for advice if you are in any doubt about a potential conflict of interest.

Amending your personal licence

You can ask us at any time to add new categories of techniques, new species or change the primary availability on your licence. You will need to supply, where relevant:

- evidence of additional training;
- a declaration from the NTCO at the new primary availability that supports your request.

Do not start using any new techniques etc. until you have received your amended licence. We have to reissue your licence before any amendments can come into force.

Suspending your personal licence

Where necessary, we can suspend your licence to safeguard an animal's welfare. If this happens, you must immediately stop all procedures. We may require you to take action to safeguard the welfare of your animals or we may take that action.

Revoking or varying your personal licence

You can return your licence to us at any time for it to be revoked, for example if you are leaving your job.

In addition, we may revoke, suspend or vary personal licences:

- as a result of a breach of a condition – for example if you can no longer be entrusted with the responsibilities of a licensee; or we might vary a licence to add new conditions; or
- where it is appropriate to do so – for example, if the establishment licence holder named on your licence asks us to revoke the availability at that establishment.

Your right to make representations

Under ASPA section 12, you have the right to make representations to us if we intend to vary or revoke your licence other than at your request or at the request of

the establishment licence holder should that establishment cease to be your sole or primary place of work. If we notify you of such an intention, we will provide you with guidance on your right to appeal.

Standard conditions for personal licences

We grant personal licences subject to standard conditions. These are set out at Annex B.

Sometimes we may include additional conditions, for example to restrict the authorities on your licence.

Project licences

What does a project licence cover?

Under ASPA, you are not allowed to apply a regulated procedure to an animal unless the procedure is applied as part of a programme of work authorised in a project licence and the place where the procedure is carried out is specified in that project licence.

A project licence is a licence granted by the Secretary of State which specifies a programme of work and authorises the application, as part of that programme, of specified regulated procedures to animals of specified descriptions at a specified place or specified places.

A place may not be specified in a project licence unless it is a place where a person is authorised by an establishment licence to apply regulated procedures to protected animals.

You must have a project licence before carrying out any regulated procedures on animals.

Who can hold a project licence?

Each project licence is granted to a single, named individual. We do not grant project licences to organisations or research groups.

What training do I need to complete?

You must have completed the relevant training for project licence holders before applying for your licence. Your establishment NTCO will be able to advise you. Details are also provided on the Home Office website.

How long does a project licence last?

A project licence may last for up to five years. You must apply for a new licence when the licence expires if you wish to continue the work. If your project licence was granted for less than five years you may be able to extend it to five years from the original date of issue, if we agree.

Death or departure of a project licence holder

A project licence ends if the licence holder dies or leaves the establishment. However, the licence may continue for a further 28 days if the establishment licence holder (or a personal licence holder working on the project if it is at a POLE) lets us

know within seven days. This will allow work in progress to be completed or a new licence to be obtained.

Preparing your project licence application

It may take you some time to prepare your complete application, especially if it describes a novel or complex programme of work or involves using specially protected species (cats, dogs, primates or the horse family, endangered species or feral animals) or raises matters of significant public interest.

You may find it helpful, at an early stage, to discuss your proposed application, or amendment to an existing licence, with the inspector assigned to your establishment as well as with other, experienced project licence holders. You must also consult your NVS and NACWO.

You may need to make revisions to your original draft before it is a complete and correct proposal. We will try to be as clear and prompt as possible in advising you of this.

All applications, whether for a new project licence, or amendments to an existing licence, must also be reviewed by the local animal welfare and ethical review body (AWERB) at the establishment where the work is going to take place. If you plan to work at more than one establishment, you will need to arrange for this review at each establishment.

The AWERB will advise you of any local issues or policies relevant to your proposal and will consider, amongst other things, how effectively you are applying the 3Rs in your work. Their conclusions will assist the decision by the establishment licence holder whether to support your application to work at their establishment. Your complete application needs to be signed by all the relevant establishment licence holders before you send it to us.

Application forms and details of where to send them are available on the 'Research and testing using animals' pages on the Home Office website.

What information is needed in a project licence application?

Your application must:

- describe the programme of work, the regulated procedures, the descriptions of animals and the place or places you want to be specified in the project licence;
- include information on the matters set out in Annex 6 of the EU Directive;
- include such other information as we may reasonably require; and
- be accompanied by a project summary written in non-technical terms.

Incomplete or incorrect applications

We will acknowledge receipt of your application when we receive it. If your application contains any errors or lacks essential information necessary for us to evaluate it, we will tell you as soon as we can and explain what you should do to complete and correct it.

Programme of work

A project licence covers a single programme of work. It must describe the programme, state its objectives, describe the predicted benefits of the programme and identify the adverse effects (harms) likely to be experienced by the animals and how you will avoid, recognise and alleviate them.

A project licence might cover the entire process of researching a new medicinal drug, involving lots of animals of various species, numerous protocols and a large team of personal licence holders. Or it might cover the work of one scientist researching just one part of a process, using a few animals of a single species.

Regulated procedures to be applied

Your application must describe the experimental or other scientific protocols you propose to follow and specify the regulated procedures you may apply within each protocol. You must assign a severity class to each protocol (see the 'Severity categories' section of this guidance).

Description of the animals to be used

Your application must specify the number and species of animals you plan to use.

Place or places you want to be specified in the project licence

You must specify the place where the work will be carried out. In most cases this will be a licensed establishment. We call this the 'primary availability'. The licence may also name other licensed establishments where the work can take place. These are called 'secondary availabilities'.

Exceptionally, you may be authorised to carry out procedures at a place other than a licensed establishment (known as a POLE) – for example, at a field site. In this case you must notify us when the work is to be carried out so that an inspector can choose whether to be there. We may also put extra safeguards in place to protect the welfare of any animals that are to be left unattended or released into the wild (set free) once you have completed the procedures.

Information on the matters set out in Annex 6 of the EU Directive

Your application must explain, or provide details of:

- the relevance and justification of (a) the use of animals including their origin, estimated numbers, species and life stages; and (b) procedures;
- the application of the 3Rs;
- the planned use of anaesthesia, analgesia and other pain-relieving methods;

- measures proposed to reduce, avoid and alleviate any animal suffering, from birth to death where appropriate;
- use of humane end-points;
- the experimental or observational strategy and statistical design to minimise animal numbers, pain, suffering, distress and environmental impact;
- proposed re-use of animals and the accumulative effect on the animals;
- the proposed severity classification of procedures;
- measures proposed to avoid unjustified duplication of procedures;
- the housing, husbandry and care conditions for the animals;
- proposed methods of killing; and
- the competence of the persons involved in the project.

Other information

There may be other information that you will need to include in your application. We will advise you of this on a case-by-case basis.

Project summary

Your application must be accompanied by a project summary written in non-technical terms. You should complete the project summary template which is available on our website. We expect that, for all but the most complex of projects, you will be able to provide a satisfactory project summary using between 500 and 1,000 words. The project summary must:

- explain objectives of the programme of work specified in your application;
- describe the types of animal and estimate the number of each type that you will use;
- predict the harm to the animals that will be caused and benefits that will be gained by carrying out the programme of work; and
- demonstrate how you will comply with the principles of replacement, reduction and refinement throughout the project.

Your project summary must not contain any information of a confidential nature; nor any information the publication of which may lead to the infringement of any person's intellectual property rights; nor your name or address nor that of any other person.

How quickly will my application be decided?

We will not start assessment until a complete and correct application, including a satisfactory non-technical project summary, is received. We will normally assess well-drafted applications for a straightforward programme, or to continue an on-going programme, within 40 working days of receiving your complete and correct application. For applications describing a complex or novel programme, especially those involving special species, we may need to extend this period by up to 15 working days.

How we will assess your application for a project licence

The purpose of our evaluation is to verify that:

- carrying out the programme of work is justified from a scientific or educational point of view or is required by law;
- the purposes of the programme of work justify the use of protected animals; and
- the programme of work is designed so as to enable the regulated procedures applied as part of it to be applied in the most humane and environmentally sensitive manner possible.

In carrying out the evaluation we must:

- evaluate the objectives of the programme of work and its predicted scientific benefits or educational value;
- assess the compliance of the programme of work with the principles of replacement, reduction and refinement;
- classify as ‘non-recovery’, ‘mild’, ‘moderate’ or ‘severe’ the likely severity of each regulated procedure that would be applied as part of the programme of work;
- carry out a harm–benefit analysis of the programme of work to assess whether the harm that would be caused to protected animals in terms of suffering, pain and distress is justified by the expected outcome, taking into account ethical considerations and the expected benefit to human beings, animals or the environment;
- assess any scientific justification relating to the following:
    - use of animals at a POLE (ASPA 5(3));
    - methods of killing (ASPA 15A(7)); or
    - use of neuromuscular blocking agents (ASPA 17(2));
    - use of endangered primates (ASPA Schedule 2B, para 1(4));
    - use of non-endangered primates (ASPA Schedule 2B, para 2(4)); or

- use of other endangered species (ASPA Schedule 2B, para 3(3));
- use of feral animals (ASPA Schedule 2C, para 25 (2));
- use of wild-caught and purpose-bred animals (ASPA Schedule 2C para 25(3));

- assess whether carrying out the programme of work would give rise to any scientific reason for an exemption under paragraph 11(5) of Schedule 2C relating to the care and accommodation of animals;

- on the assumption that a project licence is granted in respect of the programme of work, whether and (if so) when the programme should be retrospectively assessed under section 5F.

Permissible purposes

We cannot grant a project licence unless the programme of work is to be carried out for one of the following purposes:

a) basic research;

b) translational or applied research with one of the following aims:

(i) the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality, or their effects, in man, animals or plants;
(ii) the assessment, detection, regulation or modification of physiological conditions in man, animals or plants; or
(iii) the improvement of the welfare of animals or of the production conditions for animals reared for agricultural purposes;

c) the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs or any other substances or products, with one of the aims mentioned in paragraph (b);

d) the protection of the natural environment in the interests of the health or welfare of man or animals;

e) research aimed at preserving the species of animal subjected to regulated procedures as part of the programme of work;

f) higher education or training for the acquisition, maintenance or improvement of vocational skills;

g) forensic inquiries.

Multiple generic projects

Article 40(4) of the EU Directive provides that Member States may authorise multiple generic projects if they are to satisfy regulatory requirements or are using animals for production or diagnostic purposes with established methods.

"Generic" is best understood by reference to the breeding of genetically altered mice, the production of antibodies or the conduct of a safety evaluation test – within each of which the particular experiment, study or production process is the same irrespective of the actual genotype, specific antibody or substance concerned.

In multiple generic projects, as in any project, it is the responsibility of the project licence holder to ensure that the 3Rs are applied effectively throughout the life of the project, taking into consideration any scientific or technical developments which may permit greater replacement, reduction or refinement than was possible at the time the project was authorised (see 'Applying the 3Rs in your project' below).

Assessing costs and benefits

Before granting a project licence, we have to weigh the likely cost (harm) to the animals against the benefits that are likely to be gained from the work. We have to ensure that the costs are minimised and the benefits are maximised.

By 'likely cost' we mean the adverse effects that the animals are likely to experience – pain, suffering, distress or lasting harm. By 'likely benefit' we mean how far man, animals, plants or the environment may benefit if the project meets its objectives. It relates to the value that may be placed directly on the outcomes of the programme of work, rather than on more general long-term benefits.

We assess the costs and benefits at the start of a programme of work but you should continue this throughout the life of the licence to make sure that the original assumptions and assessment are still sound.

Applying the 3Rs in your project

Your licence will require you to ensure, to the greatest extent, that the specified regulated procedures:

- use the minimum number of animals;
- involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm;
- cause the least pain, suffering, distress or lasting harm; and
- are most likely to produce satisfactory scientific results. **[Standard condition 4]**

We may review your project licence, and may recall and revise it, if suitable replacement, reduction or refinement alternatives become available during its lifetime.

In assessing the costs and benefits of a programme of work and its individual protocols we follow the principles of the 3Rs. These are to: replace the use of

animals; reduce the number of animals needed; or refine the procedures to cause less suffering.

In your application you should set out how you have incorporated the 3Rs into your plan of the work. You should also consult 'named people' at your establishment, especially the NVSs and NACWOs.

We must be satisfied that the work is justified from a scientific or educational point of view or is required by law, and that the objectives justify using animals.

You must also show us that you will apply the regulated procedures in the most humane and environmentally sensitive way.

If you wish to use endangered species, primates, cats, dogs or equidae (e.g. horses) you will have to make the case as to why other species cannot be used instead. You may not use great apes or stray animals of domestic species.

We recognise that sometimes it is possible to reduce the number of animals used by causing more suffering to fewer animals. We will judge this on a case-by-case basis to reflect the most appropriate balance between reduction and refinement. However, in most cases, reducing the suffering of each individual animal will be the priority.

All procedures must be carried out under general or local anaesthesia unless we feel that administering the anaesthetic would cause more suffering for the animal than the procedure itself.

If you are not using anaesthesia, you must use analgesics or another appropriate way of minimising any pain, suffering, distress or harm caused. You must make sure that no animal is subjected to severe pain, distress or suffering that is likely to be long-lasting and cannot be ameliorated. **[Standard condition 7]**

We must be satisfied that you are using good practices and that the work will be carried out competently. In your application you must describe how you intend to prevent or minimise the extent, duration and incidence of adverse effects. This includes specifying humane end-points and control measures such as observation schedules.

Once granted, your licence will require you to ensure, throughout the life of the licence, that the purpose of the programme of work cannot be achieved by using a scientifically satisfactory method or testing strategy which does not involve protected animals and which, where appropriate, satisfies the relevant EU regulatory requirement. **[Standard condition 2]**

You will also have to ensure that you do not perform procedures for which the results are already available in a Member State using procedures which satisfy the relevant EU regulatory requirement. **[Standard condition 3]**

When will applications be referred to the Animals in Science Committee?

We will refer some project licence applications to the Animals in Science Committee for advice. In particular, we may refer applications involving:

- the use of wild-caught non-human primates;
- the use of cats, dogs, equidae or non-human primates in severe procedures;
- projects with major animal welfare or ethical implications, for example involving the use of human material; xenotransplantation of whole organs; chronic pain models; or study of the central nervous system;
- applications of any kind raising novel or contentious issues, or giving rise to serious societal concerns.

External assessors

Where we need additional expert advice on a particular project licence application we may appoint an independent external assessor to evaluate that application. If we intend to do this, we will let you know and also take account of your views in selecting the assessor. Usually you will be told who they are and the questions we have asked them to address.

For more information, see the ‘Other advisers to the Secretary of State’ section of this guidance.

Retrospective assessment

All projects using non-human primates, and all projects involving procedures classified as severe, must be retrospectively assessed.

We will consider whether other projects should be retrospectively assessed on a case-by-case basis when we assess their project applications. We will inform you of our decision. In considering whether to require a retrospective assessment we will take account of:

- the number and type of procedures to be used;
- the number and species of animals to be used;
- the nature of the programme of work and its objectives; and
- whether the project raises any important animal welfare or ethical concerns, novel or contentious issues, or societal concerns.

We may require you to provide information for the retrospective assessment when it is carried out. The retrospective assessment will consider:

- whether the programme of work has been carried out;
- whether the objectives of the programme of work have been achieved;
- the amount of harm caused to animals by the carrying out of the programme of work (including the number of animals subjected to regulated procedures as part of the programme of work, the species of animals subjected to those procedures and the severity of those procedures); and
- whether any lessons can be learnt from the programme of work which may contribute to the further implementation of the principles of replacement, reduction and refinement.

When it is complete, we will update the non-technical summary for the project to include the findings of the retrospective assessment.

Restrictions on programmes of work

Additional restrictions apply to programmes of work involving the following:

- animals containing human material;
- neuromuscular blocking agents;
- primates (including endangered primates);
- endangered species (other than primates);
- cats, dogs and the horse family (equidae);
- feral domestic animals;
- Great apes (chimpanzees, pygmy chimpanzees, gorillas and orang-utans);
- testing cosmetics or household products;
- developing or testing alcohol or tobacco products;
- developing or testing offensive weapons;
- education and training.

Animals containing human material

Projects involving the use of human material may raise significant ethical issues and societal concerns. In addition to regulation under ASPA, they may also require regulation under other legislation, for example, the Human Fertilisation and Embryology Act 1990 and the Human Tissue Act 2004. You should, therefore, seek the earliest possible advice from us and the other regulators to confirm the authorities you will require.

As part of their evaluation, we may refer project applications made under ASPA for work involving the use of human material to the Animals in Science Committee for independent advice.

Neuromuscular blocking agents

We must specifically authorise you to use neuromuscular blocking agents (NMBAs). We will not allow you to use them without appropriate anaesthesia or analgesia. You must ensure that personal licensees using NMBAs on your project licence have the necessary personal licence authority.

You must comply with our guidance on the use of neuromuscular blocking agents which you can find on the Home Office website.

Project licences authorising the use of non-endangered primates

We will grant a project licence for a programme of work using primates of non-endangered species only if the work is to be carried out for:

- basic research;
- translational or applied research;
- research aimed at preserving the species of primate being used.

Translational or applied research must be for the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions or their effects in man, or the development, manufacture or testing of the quality, effectiveness and safety of drugs for the same purposes.

You must also provide scientific justification showing that the purpose of the programme of work cannot be achieved by the use of animals that are not primates.

Project licences authorising the use of endangered primates

We will grant a project licence for a programme of work using primates of endangered species only if the work is to be carried out for:

- translational or applied research;
- research aimed at preserving the species of primate being used.

Translational or applied research must be for the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions or their effects in man, or the development, manufacture or testing of the quality, effectiveness and safety of drugs for the same purposes.

You must also provide scientific justification showing that the purpose of the programme of work cannot be achieved by the use of animals which are not primates; and are not of a species listed in Annex A to Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein.

Use of purpose-bred primates

Non-human primates, like other species listed in Schedule 2, may only be used in procedures where they have been bred for use in procedures. In addition, unless an exemption has been granted, marmosets may only be used in procedures if they are the offspring of marmosets bred in captivity or have been obtained from a self-sustaining colony of marmosets.

Other species of primate may, in due course, be subject to the same additional restrictions as marmosets.

You will need to provide scientific justification showing that the purpose of the programme of work cannot be achieved using such animals to obtain an exemption to these requirements.

A 'self-sustaining colony' is one kept in a way that ensures the animals are accustomed to humans and which consists only of animals that have been bred in captivity, either within the colony or in another self-sustaining colony.

Project licences authorising the use of endangered animals that are not primates

We will grant a project licence for a programme of work using other endangered species only if the work is to be carried out for:

- translational or applied research; or
- research aimed at preserving the species of animal being used.

Translational or applied research must be for the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality, or their effects, in man, animals or plants; or the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs or any other substances or products, for the same purposes.

You must also provide scientific justification showing that the purpose of the programme of work to be specified in the licence cannot be achieved by the use of animals which are not of a species listed in Annex A to Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein.

Project licences authorising the use of cats, dogs and equidae

We will grant a project licence for a programme of work using cats, dogs and equidae only where the purpose of the programme of work to be specified in the licence can be achieved only by their use; or where it is not practicable to obtain other suitable animals.

Other restrictions

We will not grant project licences for work using:

- Great apes (chimpanzees, pygmy chimpanzees, gorillas and orang-utans);

or using any animals for:

- testing cosmetics or household products;
- developing or testing alcohol or tobacco products (however, we may consider the use of alcohol or tobacco as research tools for investigating disease or novel treatments);
- developing or testing offensive weapons (but we may grant licences for developing and testing ways of protecting or treating UK service men and women, or the population as a whole).

Licences for education and training

We will not issue project licences for education or training in primary or secondary schools. We will consider applications for higher education or for training to acquire, maintain or improve vocational skills.

Projects will normally be limited to training individuals who will eventually be carrying out scientific work using living animals and those who need an understanding of *in vivo* biological phenomena. We currently issue licences for training of practising surgeons in micro-vascular techniques.

We will rigorously apply the principles of the 3Rs – replacement, reduction and refinement – and the harm–benefit analysis in assessing applications for such work. The severity of any protocols in such projects should be either non-recovery or mild. We will also require you to review your project's objectives regularly (at least once a year) to consider the latest alternatives for replacing, reducing and refining the use of animals.

You should not combine your application for an educational or training project licence with an application for other permissible purposes.

How we determine the severity category

Before we grant a project licence we have to classify how severe the series of procedures specified in each protocol is likely to be. These are the severity categories. **[Standard condition 10]**

You can find more details in the 'Severity categories' section of this guidance.

We determine the severity of a procedure, or series of procedures, by the degree of pain, suffering, distress or lasting harm that the animal is likely to experience.

Our decision will be based on the most severe effects that the animal is likely to suffer after applying all the appropriate refinement techniques.

We look at the types of procedure you are going to use considering particularly:

- the type of manipulation and handling;

- the nature of the pain, suffering, distress or lasting harm likely to be caused by the procedure;
- its intensity, duration, frequency and the number of techniques being used in each animal;
- cumulative suffering within a procedure;
- if the animals are prevented from behaving naturally by restricting their housing, husbandry and standards of care;
- methods used to eliminate pain, suffering and distress, including refining housing, husbandry and care;
- humane end-points and how they will be applied.

Besides looking at the procedures involved, we also consider:

- the type of species and genotype;
- the maturity, age and gender of the animal;
- whether animals will experience training to make them more amenable to the procedure;
- if the animal is to be reused, the actual severity of the previous procedures.

Severity conditions on your licence

Your project licence requires you to ensure that no unnecessary pain, suffering, distress or lasting harm is caused. **[Standard condition 7]** You should approach the severity limit authorised in your project licence only when absolutely necessary to meet the project's objectives.

If it looks as if the severity limit is going to be exceeded, you must contact us. We may authorise a temporary higher severity limit or vary other controls on the project licence, if you can justify this, for up to 14 days. This gives us time to review the likely costs and benefits and consider amending your project licence. **[Standard condition 18]**

The conditions of your licence will be breached if you do not notify us promptly when an animal suffers, or is likely to suffer, more than is authorised. This will also be the case if the end-points you apply result in more suffering than is necessary to achieve the project's objectives.

If an animal suffers for an unforeseen reason unrelated to regulated procedures, such as intercurrent disease, you may not be in breach of your licence if you have taken steps to alleviate that suffering.

However, on no account may you allow an animal to experience severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.

Use and re-use of protected animals

The 'use' of an animal lasts from the time you carry out the first procedure on that animal up until you have completed any observations or collection of data for your experiment or test.

For the purposes of this section, a series of regulated procedures applied to an animal for a *particular purpose* will be treated as constituting a single regulated procedure.

Re-use means using an animal again in the same or a different procedure or series of procedures for a particular purpose where you could equally have used a previously unused animal.

We must give our consent to the re-use of an animal and specifically authorise it in your project licence(s). For us to do so the following conditions must be met.

Firstly, the actual severity of the regulated procedure, or each of the regulated procedures, previously applied to the animal must have been classified, and in a case where more than one regulated procedure has previously been applied to the animal, the actual severity of no more than one of those procedures must have been classified as "severe".

Secondly, a veterinary surgeon with knowledge of the lifetime experience of the animal or animals must have advised that their general state of health and wellbeing is likely to have been fully restored following the application of the previous procedure or procedures.

Thirdly, the further (re-use) procedure must be part of a programme of work specified in a project licence; and must be classified as "non-recovery", "mild" or "moderate".

Our consent may relate to the specific animal concerned or to animals used in specified procedures or specified circumstances. But in the case of an animal that has been subjected to a regulated procedure the *actual severity* of which has been classified as "severe", our consent must relate to the specific animal concerned and we will give consent only after we have consulted a veterinary surgeon who has examined the animal to advise whether consent should be given. Furthermore, we must be satisfied that there are exceptional circumstances that justify the animal being used for the further regulated procedure.

End of the procedure

At the end of procedures you must humanely kill any animal that is suffering, or likely to suffer, adverse effects as a result of the procedures you have applied. (See the 'Humane killing of protected animals' section of this guidance for more information.) **[Standard condition 9]**

In other cases, the Named Veterinary Surgeon must decide whether the animal can be kept alive. You must continue to keep the animal at your establishment unless:

- we authorise you to move it to another establishment **[Standard condition 24]**; and

- the Named Veterinary Surgeon certifies that it will not suffer if it is no longer kept at your establishment.

Capturing animals from the wild

Capture of animals in the wild is to be carried out only by competent persons using methods that do not cause the animals avoidable pain, suffering, distress or lasting harm.

You must not carry out procedures on an animal taken from the wild that is found to be injured or in poor health unless and until it has been examined by a veterinary surgeon or other competent person and action has been taken to minimise the suffering of the animal. We may waive the requirement to take action to minimise the suffering of the animal where such action would prevent the purposes of the programme of work specified in the licence being achieved – for example, if the purpose is to study disease, such as a parasitic infection, in animals in the wild.

Release into the wild

You must have our prior consent to release an animal into the wild either during the course of, or at the end of, a series of procedures. Such consent will usually be incorporated in your project licence.

We must be satisfied that you have taken the maximum possible care to safeguard the animal's wellbeing. You will have to show us that the animal is fit to be set free and that it will be at no biological disadvantage because of the procedures it has undergone or because of its time in captivity.

We must also be satisfied that the release of the animal does not pose a danger to public health or the environment. You must also ensure that you have met the requirements of other relevant legislation.

We may ask you to obtain certificates of fitness for release signed by a Named Veterinary Surgeon.

Re-homing

You must not re-home an animal without our prior consent. Such consent will usually be incorporated in your project licence.

We must be satisfied that the animal's health allows it to be re-homed, you have taken measures to safeguard its wellbeing and ensure its socialisation in its new home, and it poses no danger to public health or the environment.

Your responsibilities as project licence holder

As the project licence holder you are responsible for complying with the conditions of the project licence and conducting the programme of work it specifies. **[Standard condition 1]** You will be in breach of the Act if you carry out the regulated procedures in the licence for a purpose not related to your programme of work. You also direct and manage all of the personal licensees working on the project. **[Standard condition 6]**

As the project licence holder you must ensure that:

- the programme of work is strictly followed;
- the severity controls of each protocol are implemented effectively;
- severity conditions are met; **[Standard condition 18]**
- only the animals authorised are used;
- others working on the project have a personal licence and are trained and supervised until they have demonstrated the requisite competence;
- procedures are only carried out at the place or places specified in your licence;
- the required records are maintained; **[Standard condition 19]**
- annual statistical returns are provided when requested. **[Standard condition 20]**

Deputies to project licence holders

Only one person can hold a project licence. You may, however, have one or more people who can deputise for you in your absence. You can delegate some of your authority to them.

Deputies may be useful to you when:

- control of the project is best exercised through one of more deputies because of its nature or scope;
- work needs to be done in more than one place;
- you are likely to be absent from time to time;
- you do not hold a personal licence.

Deputies to project licence holders should hold a personal licence and ideally have completed appropriate project licence holder training – see the Home Office website for more details.

You are responsible for the performance and conduct of your deputies.

Keeping records

You are also responsible for keeping full and accurate records of the procedures carried out under the project licence. We may ask to look at these at any time. **[Standard condition 19]**

Your records should include the names of the personal licence holders performing procedures authorised by the licence. They should record details of the procedures and protocols you and they apply, including:

- the species of protected animals used;
- a running tally of the numbers of each species used in each protocol;
- the sex and approximate age of the animals at the start of the protocols;
- the identification of the animals used (where appropriate);
- the start and end dates of the protocols;
- a brief description of the procedures you apply;
- the morbidity or mortality produced;
- the fate of the animals at the end of procedures (e.g. killed in the establishment released to private care);
- details of any continued use or re-use;
- copies of any veterinary or other certification and advice you have received.

Retrospective assessment of severity

On completion, a suitably qualified person must classify the actual severity of each procedure carried out as ‘non-recovery’, ‘mild’, ‘moderate’, or ‘severe’ using the criteria set out in Annex 8 to the Directive and the EU Guidance agreed between Mmeber States. For the purposes of this requirement, a series of regulated procedures applied to an animal for *a particular purpose* is to be treated as constituting a single regulated procedure.

The requirement to classify actual severity in this way applies from 1 January 2013, although the data will not need to be submitted for publication in our annual statistics until January 2015.

Avoiding duplication in projects

You must ensure that you do not carry out procedures on an animal if the data you want to obtain is already available. You may be justified in replicating work in order to validate the study under your own conditions or if you have reasonable doubts as to the veracity of the data. **[Standard condition 3]**

Annual statistical returns

You are responsible for supplying data to the Home Office on the procedures you carry out for publication in the *Statistics of Scientific Procedures using Living Animals*. This information must be provided by 31 January each year on the 'return of procedures' form. If your project licence expires or is revoked during the year, you must make the return within 28 days of the date of expiry or revocation. If you fail to submit the data by the required date, or supply inaccurate data, we may revoke your licence. **[Standard condition 20]**

We issue code lists and explanatory notes annually to help you complete the form.

Conflicts of interest

Conflicts of interest must be avoided. For any group of protected animals there should be at least three people filling the five key roles of: establishment licence holder, project licence holder, personal licence holder, NACWO and NVS. (See the Establishment licence section of this guidance.)

Please ask us for advice if you are in any doubt about a potential conflict of interest.

Amending your project licence

You might need to amend your project licence as the work evolves. This may be because:

- there are material discrepancies between the predicted and actual adverse effects;
- you want to add new objectives;
- you want to introduce new or revised protocols to help meet your objectives or incorporate new reduction, refinement or replacement strategies;
- you need to revise the estimated numbers of animals to be used;
- your details need to be updated;
- availabilities need to be added or deleted.

Your amendment request should be approved by your AWERB before it is sent to us.

Our inspectors will advise us whether and on what terms we should grant the amended authorities. We may refer your request to an external assessor or the Animals in Science Committee.

Amendments only take effect once we have issued your revised licence. You should wait until you have your amended licence document before you carry out any work under the revised authorities.

You must make sure that personal licence holders are familiar with the amended terms and conditions. You must also supply a copy of the revised authorities to the establishment licence holder.

Suspending your project licence

We may suspend a project licence if there is an urgent need to safeguard the welfare of a protected animal. If this happens all procedures authorised by that licence must stop immediately. We may require you to take action to safeguard the welfare of your animals or we may take that action.

Revoking or varying your project licence

A licence is revoked on its expiry date. We may also revoke or vary project licences at other times. These include:

- as a result of a breach of a condition – for example if the holder can no longer be entrusted to manage the programme of work; or we might vary a licence to add new conditions;
- where it is appropriate to do so – for example, where advances in science alter the balance between the likely costs and the likely benefits;
- at your request.

If you want to relinquish responsibility for the programme of work, or can no longer comply with the terms and conditions of your licence, we will need a fresh application from the new applicant if the programme of work is to continue.

Exceptionally, for example if we have issued the licence very recently, we may issue a licence to the new applicant with the same conditions, expiry date, licence number and conditions.

Your right to make representations

Under ASPA section 12, you have the right to make representations if we intend to vary or revoke your licence other than at your request or at the request of the establishment licence holder should that establishment cease to be your sole or primary place of work. If we notify you of such an intention, we will provide you with guidance on your right to appeal.

Standard conditions for project licences

We grant project licences subject to standard conditions. These are set out in Annex C.

Sometimes we may include additional conditions, for example:

- to ask you for a report after introducing a novel procedure;

- to allow you to obtain and use animals listed in Schedule 2 but that come from a non-designated source.

Severity categories

Severity classification of procedures before work starts

When a project licence is granted the likely severity of each regulated procedure to be applied as part of the programme of work must be classified as either 'non-recovery', 'mild', 'moderate' or 'severe' using the criteria set out in Annex 8 to the Directive and the EU Guidance agreed between Member States. This classification will be confirmed in the project authorisation. You can find details of how we apply the severity categories in the section for project licence holders.

The severity of a procedure is to be determined by the degree of pain, suffering, distress or lasting harm expected to be experienced by an individual animal during the course of the procedure.

How are the severity categories defined?

Non-recovery
These are procedures that are performed entirely under general anaesthesia from which the animal will not recover consciousness.

Mild
Procedures as a result of which the animals are likely to experience short-term mild pain, suffering or distress, as well as procedures with no significant impairment of the well-being or general condition of the animals.

Moderate
Procedures as a result of which the animals are likely to experience short-term moderate pain, suffering or distress, or long-lasting mild pain, suffering or distress as well as procedures that are likely to cause moderate impairment of the well-being or general condition of the animals.

Severe
Procedures as a result of which the animals are likely to experience severe pain, suffering or distress, or long-lasting moderate pain, suffering or distress as well as procedures that are likely to cause severe impairment of the well-being or general condition of the animals.

The criteria for assigning the severity category

The assignment of the severity category must take into account any intervention or manipulation of an animal within a defined procedure. It is to be based on the most severe effects likely to be experienced by an individual animal after applying all appropriate refinement techniques.

When assigning a procedure to a particular category, the type of procedure and a number of other factors are to be taken into account. All of these factors are to be considered on a case-by-case basis:

- type of manipulation, handling;
- nature of pain, suffering, distress or lasting harm caused by (all elements of) the procedure, and its intensity, the duration, frequency and multiplicity of techniques employed;
- cumulative suffering within a procedure; and
- prevention from expressing natural behaviour, including restrictions on the housing, husbandry and care standards.

Examples of procedures assigned to each of the severity categories are provided in section III of Annex 8 to the EU Directive.

Reporting on actual severity

On completion, a suitably qualified person must classify the actual severity of each procedure as 'non-recovery', 'mild', 'moderate', or 'severe' using the criteria set out in Annex 8 to the Directive and the EU Guidance agreed between Member States. For the purposes of this requirement, a series of regulated procedures applied to an animal for a particular purpose is to be treated as constituting a single regulated procedure.

The requirement to classify actual severity in this way applies from 1 January 2013, although the data will not need to be submitted for publication in our annual statistics until January 2015.

Enforcement of severity limits

The severity classification should be treated as a 'severity limit'. You should approach the limit of severity which has been authorised only when absolutely necessary to meet the specified objective of the procedure.

The project licence holder, or deputy project licence holder, must contact us if it seems likely that the severity limit of a procedure has or may be exceeded. If you can show sufficient justification, we may temporarily authorise a higher severity limit for a period of up to 14 days to allow the balance of likely benefit and likely cost to be reviewed and amendment to the project licence to be considered.

These requirements will be regarded as breached if we are not notified promptly when a protected animal has suffered (or is likely to suffer) more than is authorised by the severity limit. They will also be breached if the end-points applied resulted in more suffering than was necessary to achieve the specific objectives of the procedure.

We will not consider it a breach if the suffering arose for an unforeseeable, extraneous reason (that is, a problem unrelated to the regulated procedures) providing adequate and effective steps have been taken promptly to alleviate the suffering.

Prohibition on severe pain, suffering or distress that cannot be ameliorated

You must make sure that no animal is subjected to severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.

There is useful information and examples of severity asessement on the EU website.

Humane killing of protected animals

How is the killing of animals regulated?

ASPA requires that “relevant protected animals” are killed by a competent person using a method that is defined as “appropriate”. Note that killing a relevant protected animal in breach of this requirement could be a criminal offence.

When is killing an animal a regulated procedure?

Killing a ‘relevant protected animal’ by an appropriate Schedule 1 method or a method specified in the establishment licence is not a regulated procedure. In all other cases the method of killing is a regulated procedure and you will need project and personal licence authorities.

Is the animal a “relevant protected animal”?

A relevant protected animal is a protected animal which:

- is being or has been used in a regulated procedure; or
- has been bred for use in a regulated procedure; or
- is being or has been kept for use in a regulated procedure; or
- is kept so that it can be supplied for use in a regulated procedure; or
- is killed in a licensed establishment for the scientific use of its tissues or organs.

If the animal to be killed is not a “relevant protected animal” then killing the animal is outside the scope of the Act.

What are the requirements regarding competence?

Before you kill a relevant protected animal you must be registered by your establishment licence holder to kill the type of animal in question by the proposed method.

You will need to have been adequately educated and trained in the killing of animals before your name can be entered in the register and you must be supervised when killing animals until you have demonstrated that you are competent to kill animals of those descriptions by the methods used.

What methods are permitted?

You may only kill a relevant protected animal using a method "appropriate" for that type of animal. These are either:

a) a Schedule 1 method;

b) a method specified in the establishment licence;

c) a method specified in a project licence;

d) a method complying with Article 4 of Council Regulation (EC) No 1099/2009 when used to kill an animal used in an agricultural research project requiring animals to be kept under commercial farm conditions; or

e) any method if an animal is already unconscious in the course of a series of regulated procedures and will not regain consciousness.

Can I use a method of killing specified in an establishment licence to kill animals for scientific purposes?

A method of killing may be specified in the establishment licence only if, *on the basis of scientific evidence*, it is at least as humane as a Schedule 1 method appropriate for the same type of animal.

A method specified in the establishment licence may be used to kill animals for a scientific purpose as well as for non-scientific reasons, whether or not they have undergone or are undergoing regulated procedures.

Where a method of killing specified in an establishment licence is used to kill animals undergoing regulated procedures, the method of killing will not be a regulated procedure so it will not need to be specified as such in the project licence, neither will you need to hold a personal licence.

Do the regulations apply to animals killed at places other than licensed establishments (POLEs)?

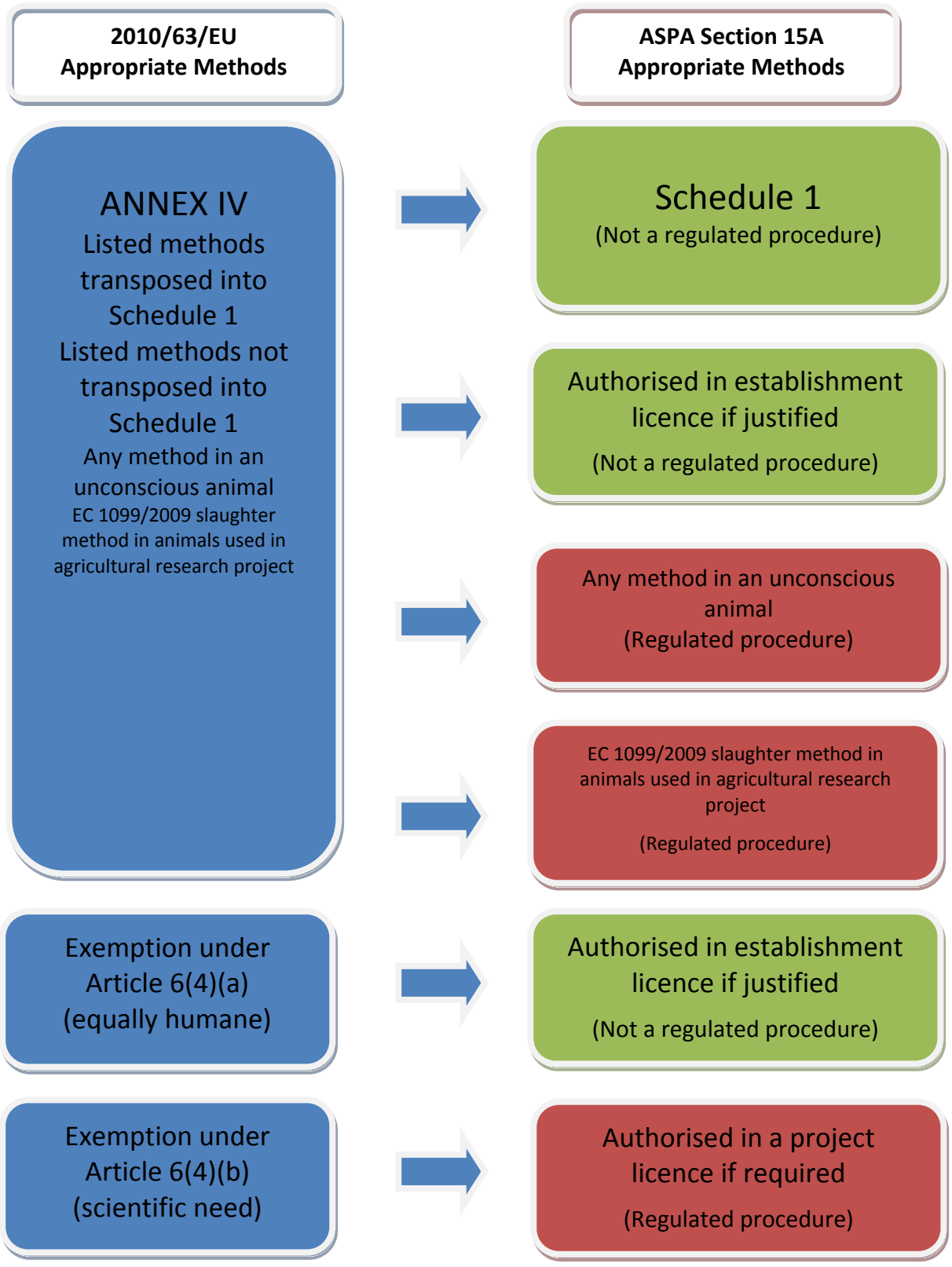
Except in the case where an animal is being killed for scientific use of its tissues or organs, which not regulated by ASPA, the requirements of ASPA section 15A apply equally to animals killed at places other than licensed establishments (POLEs).

If you intend to kill an animal at a POLE as part of a licensed project you must ensure that you are registered as competent to do so in the register kept by the establishment licence holder for the place where the project licence is primarily available.

Killing an animal at a POLE by any non-Schedule 1 method is a regulated procedure (a method authorised in an establishment licence becomes a regulated procedure if used at a POLE).

Animals (Scientific Procedures) Act 1986 – Methods of Humane Killing

The diagram below illustrates how the provisions in the new EU Directive (2010/63) translate into new ASPA.



Care and accommodation of protected animals

A guide setting out the mandatory requirements for establishments relating to the care and accommodation of animals is available on the Home Office website.

The guide is based on Annex 3 of the EU Directive. Where the UK has retained higher standards, these must be met. Details are provided in the guide. Section A of the guide describes general requirements. Section B describes the requirements for specific species of animals.

What does ASPA require?

Licensed establishments must ensure that:

(a) the environment, housing, freedom of movement, food, water and care provided for each such animal is appropriate for the animal's health and well-being;

(b) the conditions under which any such animal is transported are appropriate for the animal's health and well-being;

(c) any restrictions on the extent to which each such animal can satisfy its physiological and ethological needs are kept to the absolute minimum;

(d) the environmental conditions in which such animals are kept are checked daily;

(e) the well-being and state of health of such animals is monitored by a suitably qualified person in order to prevent pain or avoidable suffering, distress or lasting harm; and

(f) arrangements are made to ensure that any defect discovered and any avoidable pain, suffering, distress or lasting harm discovered is eliminated as quickly as possible.

What standards apply?

In most cases, establishments must, as a minimum, meet the standards concerning the care and accommodation of animals set out in Annex 3 of the EU Directive. However, where an additional or higher standard concerning the care and accommodation of animals is set out in our guide, establishments must meet those standards, as a minimum, instead. Details are provided in the guide.

When do the standards have to be implemented?

Most of the standards must be applied from 1 January 2013. Where standards apply from a different date, this is explained in the guide.

Can I apply for an exemption from the requirements?

We may allow exemptions from the requirements where compliance with them would:

- prevent a programme of work specified in a project licence being carried out; or
- prevent the objectives of a programme of work specified in a project licence from being achieved; or
- where an exemption is necessary for scientific, animal welfare or animal health reasons.

Where can I get more detailed advice on the housing and care of animals?

Questions relating to the care and accommodation of animals not covered by the guide should be referred to our central email address (aspd-brp@homeoffice.gsi.gov.uk) or to the Home Office inspector assigned to your establishment.

Named people

Named Animal Care & Welfare Officer (NACWO)

Your role and responsibilities

The Named Animal Care & Welfare Officer (NACWO) oversees the day-to-day welfare and care of animals.

You must ensure that the highest standards of husbandry and care are practised at your establishment.

You should:

- have expert up-to-date knowledge and experience of relevant animal technology;
- be familiar with the main provisions of ASPA;
- be aware of the standards of care, accommodation, husbandry and welfare set out in the relevant Codes of Practice and ensure that these are met;
- know about relevant methods of humane killing listed in Schedule 1 and any additional approved methods specified on the establishment licence, and either be competent in their use or be able to contact others, named on your establishment's register, who are;
- know which areas of your establishment are listed in the Schedule to the establishment licence and the uses they are approved for;
- ensure that a competent person sees and checks every animal kept in an approved holding area at least once daily;
- know how to contact, at any time, the Named Veterinary Surgeon or their deputy, and the establishment licence holder or their nominee. At user establishments you should also know how to contact project and personal licence holders;
- be familiar with the main provisions of project licences, particularly the adverse effects expected for each protocol, the control measures and humane end-points specified and the methods of killing specified in the licence;

- help the establishment licence holder to keep suitable records, under the supervision of the veterinary surgeon, of the health of the animals; of the environmental conditions in the approved areas in which animals are held; and of the source and disposal of animals; and

- be an active member of the AWERB at your establishment, and advise applicants for licences and licence holders on practical opportunities for implementing the 3Rs.

If the health or welfare of an animal is giving cause for concern you must tell the personal licence holder who is responsible for the welfare of that animal. If that person is unavailable, you must ensure that the animal is cared for, and, if necessary, that it is humanely killed using a Schedule 1 method, or another method approved in the establishment licence. If you have any doubt about what you should do, you should contact the Named Veterinary Surgeon or your Home Office inspector.

Your training

As a NACWO, you will be responsible for overseeing the work of those taking care of animals. Your training should give you sufficient understanding of the biology and husbandry of the relevant species as well as a thorough understanding of the regulations. In most cases, it is likely that you will have completed higher level training in animal technology. The Institute for Animal Technology manages a register of animal technicians (RAnTechs) who have shown themselves, through their qualifications, experience and an interview, to be suitable as NACWOs.

Named Veterinary Surgeon (NVS)

Your role and responsibilities

The Named Veterinary Surgeon (NVS) provides advice on the health, welfare and treatment of animals.

You must be a member of the Royal College of Veterinary Surgeons (RCVS) with expertise in the species being used in the establishment. You are accountable to the RCVS for your professional standards and conduct.

You should:

- be familiar with the main provisions of ASPA;

- ensure that adequate veterinary cover and services are available at all times at your establishment and that those caring for animals have your contact details;

- monitor the health and welfare of the animals under your care by regularly visiting all parts of your establishment specified in the establishment licence;

- notify the personal licence holder in charge of an animal if its health or welfare is giving cause for concern; if the licence holder is unavailable, you must make sure the animal is cared for and, if necessary, killed humanely using a Schedule 1 method, or another method approved in the establishment licence;

- be familiar with relevant methods of humane killing listed in Schedule 1, together with any additional approved methods specified on the establishment licence;

- have a thorough knowledge of the husbandry and welfare needs of the species kept at your establishment, including the prevention, diagnosis and treatment of disease; and be able to advise on quarantine requirements and health screening, and the impact of housing and husbandry systems on the welfare and needs of an animal;

- control, supply and direct the use of controlled drugs, prescription-only medicines and other therapeutic substances used on animals at your establishment;

- keep animal health records for all the animals at your establishment, including advice or treatment given; and ensure that these records are available to the Named Animal Care & Welfare Officer, the establishment licence holder and the Home Office;

- certify that an animal is fit to travel to a specified place;

- have regular contact with the establishment licence holder and the other Named People; and

- be an active member of the AWERB at your establishment.

At a user establishment you should advise licence holders and others on implementing the 3Rs. In particular, you should advise on:

- the impact of procedures on animals;

- recognising pain, suffering, distress or lasting harm;

- general and experimental surgical techniques, and post-operative care;

- appropriate methods of general anaesthesia, analgesia and euthanasia;

- strategies for minimising the severity of protocols, including recognising and implementing suitable end-points.

You should be familiar with the main provisions of the project licences in use at your establishment. You should be aware of the adverse effects for each protocol and

how they can be avoided, recognised and alleviated, and also of the humane end-points to be applied.

You should make sure that an appropriate clinical investigation or therapy is undertaken for the welfare of an animal being used for procedures but that data or other outputs from the work are not compromised as a result.

You need to determine whether an animal may remain alive after a series of procedures, or certify that its welfare will not be affected if it is moved from the establishment.

Your training

The RCVS approves training courses for veterinarians which they must complete during the first year after their appointment.

Other suitably qualified person

Where no suitable veterinary surgeon is available at an establishment, we may allow the appointment of another suitably qualified person to fulfil this role. You will need considerable, proven expertise in the health and welfare of the animal species held at your establishment and the range of procedures performed there. We will consult the RCVS before approving such an appointment to ensure no suitable veterinarian can be available.

Named Information Officer (NIO)

Your role and responsibilities

The Named Information Officer (NIO) ensures that everyone dealing with animals at your establishment has access to the information they need about the species concerned as well as about replacement, reduction and refinement (the 3Rs).

You must ensure that current information of appropriate quality is readily available. The information may be in hard copy format or electronically available.

You should:

- be familiar with the main provisions of ASPA;
- be familiar with the species used and the types of research performed to ensure the information available is relevant;
- have up-to-date information about accessing information sources, including sources of information on implementing replacement, reduction and refinement (the 3Rs);
- provide advice to the AWERB at your establishment on the state of information access for all those dealing with animals.

Named Training and Competency Officer

Your role and responsibilities

The Named Training and Competency Officer makes sure that everyone dealing with animals is adequately educated and trained and that they are supervised to ensure that competence is demonstrated and maintained.

You should:

- be familiar with the main provisions of ASPA;
- be familiar with training courses available either in-house or commercially;
- ensure everyone planning to work with animals under ASPA at your establishment is made known to you at an early stage in order that you can discuss their training needs with them;
- advise individuals on the training they will need to have completed in order to be issued with the licence(s) they seek;
- ensure appropriate supervision is given to support formal training as a means to achieve competence;
- ensure assessment of competence is conscientiously performed and properly recorded;
- ensure records are maintained of training provided and competence assessed for all individuals working with animals under ASPA;
- sign the declarations on licence applications to confirm the education, training, experience and character of the applicant;
- ensure that all individuals working with animals under ASPA participate in appropriate continuous training to supplement their basic training and that this is recorded to demonstrate maintenance of their competence;
- be familiar with the species used and types of research performed at the establishment to be in a position to recommend appropriate basic and continuous training courses and to identify appropriate supervisors.

Named Compliance Officer

The Named Compliance Officer ensures that the conditions of an establishment licence comply with the requirements of ASPA. Usually, this person will be the establishment licence holder. They should therefore fulfil the responsibilities of the establishment licence holder and undertake similar training. (see section on Establishment Licences).

Animal Welfare and Ethical Review bodies (AWERBs)

Membership

The AWERB must comprise (as a minimum) at least one Named Animal Care and Welfare Officer (NACWO) and, in the case of a user establishment, a scientific member. However, you should also ensure the wide involvement of people in the work of your AWERB, either as members or in AWERB initiatives.

Named Veterinary Surgeon

The AWERB must also take advice from a Named Veterinary Surgeon (NVS). We therefore strongly encourage establishment licence holders to include an NVS as a member of the AWERB. If for any reason an NVS is not a member of your AWERB, we will need to be given an assurance how you propose to ensure NVS advice is being taken.

Independent members

We will expect you to take into account the views of people who do not have responsibilities under ASPA, as well as someone who is independent of your establishment, in your AWERB.

Role

The role of the AWERB is to:

- promote awareness of animal welfare;
- provide a forum for discussion and development of ethical advice to the establishment licence holder on all matters related to animal welfare, care and use at your establishment;
- consider standards of animal care and accommodation, including breeding stock, and the humane killing of animals;
- set up and regularly review procedures and protocols, including management systems, for monitoring, reporting and following up on the acquisition, welfare and proper use of animals at your establishment;
- support named people, and other staff dealing with animals, on animal welfare and ethical issues;
- promote the development and uptake of the 3Rs and advise staff how to apply them;

- review all proposals for project licences from a local perspective, consider how the 3Rs are being applied and advise the establishment licence holder on their acceptability, bringing local knowledge and local expertise to bear;

- throughout the lifetime of projects, follow their development and outcome, including those requiring retrospective review, so that lessons learnt can be used to further apply the 3Rs;

- advise on re-homing animals including appropriate socialisation;

- respond to enquiries and consider advice received from the national Animals in Science Committee.

Record keeping

Any advice given by the AWERB, and decisions taken as a result, must be properly documented and available to inspectors. These records must be kept for at least three years.

Non-compliance

What is non-compliance?

'Non-compliance' refers to a failure to comply with:

- a condition of a licence granted under ASPA, or
- a provision of ASPA.

Reporting non-compliance

Non-compliance should be promptly reported to the inspector assigned to your establishment. If the inspector is not available, a report to our central email address (aspd-brp@homeoffice.gsi.gov.uk) should be made without delay.

Offences

The following are offences under ASPA sections 22 and 23:

a) operating a user, breeding or supplying establishment without a section 2C establishment licence;

b) applying regulated procedures to protected animals without a person licence[1];

c) applying regulated procedures to protected animals that are not authorised in a project licence[1];

d) failing to provide information required to assist the retrospective assessment of a project;

e) failing to comply with the ASPA provisions relating to:

- re-use (ASPA s14);
- the action to be taken at the end of a series of regulated procedures (ASPA s15);
- the prohibition of public exhibitions (ASPA s16);
- the use of neuromuscular blocking agents (ASPA s17)[1];
- setting free and re-homing (ASPA s17A);
- humane killing (ASPA s15A)[2];

[1] You will not be guilty of this offence if you can show that you reasonably believed, after making due enquiry, that you had the necessary authority.

f) failing to comply with a requirement imposed by an inspector under ASPA s18(3) to kill an animal immediately to alleviate excessive suffering;

g) providing false or misleading information or recklessly providing such information to obtain, or assisting another person to obtain, a licence (ASPA s23).

In addition:

h) a project licence holder is guilty of an offence who procures or knowingly permits a person under his control to carry out a regulated procedure otherwise than as part of the programme specified in the licence; or otherwise than in accordance with that person's personal licence.

How we will deal with non-compliance

It is a requirement of ASPA s18(2)(e) that inspectors report all non-compliance – however minor – to the ASRU Licensing Team acting on behalf of the Secretary of State, along with a recommendation for the action to be taken.

At an early stage in the investigation of suspected non-compliance, inspectors will take a view on whether an offence has been committed that is sufficiently serious to justify referral for prosecution. In such cases, the inspector may either suspend investigations pending referral of the matter to the prosecuting authorities, or caution the person(s) involved in line with the requirements of the Police and Criminal Evidence Act before investigating further.

Most non-compliance does not merit referral for prosecution. In these cases, inspectors will investigate the circumstances of the non-compliance to establish what happened, who was involved, and why it happened to identify what needs to be done to prevent it happening again (either within the establishment involved or, if necessary, in other establishments).

On completion of its investigation the Inspectorate will submit its report with a recommendation regarding the action to be taken.

Those involved in non-compliance, either directly or as the relevant project licensee or certificate holder, will be notified that the Inspectorate has made a report and will be informed of the nature of the non-compliance. They will then have the opportunity to provide any information they wish to be considered before a decision is made regarding the action to be taken.

When a decision is made those involved will be notified of the action that we propose to take. If this includes variation or revocation of licence authorities the rights to make representations under Section 12 of the Act will be explained.

[2] If you fail to comply with ASPA section 15A relating to humane killing you will not be guilty of an offence if you can show that you did not know and had no reason to believe that the animal was a relevant protected animal (within the meaning of section 15A).

Once dealt with, infringements will be reported in an anonymous form to the Animals in Science Committee. The number of infringements each year and a summary are published in the ASRU annual report.

Criminal sanctions

The criminal sanctions applicable to the offences listed above are set out in sections 22 and 23 of ASPA.

Administrative sanctions

A range of administrative sanctions is available to the Secretary of State, including measures aimed at deterring or otherwise preventing a recurrence of non-compliance. These include:

- issuing a warning letter;
- issuing a compliance notice;
- requiring additional formal training or re-training;
- applying additional, special conditions to licences; and
- revoking, suspending or varying (amending) licences.

Compliance notices

If you have breached a condition of a licence you hold, or a provision of ASPA, we may issue you with a 'compliance notice' which:

a) specifies the licence condition or ASPA provision with which you have failed to comply;

b) specifies the action you should take to ensure that the failure is not continued or repeated;

c) specifies any action you should take to eliminate or reduce any consequences of the failure;

d) requires you to take that action within a specified time; and

e) explains what will happen if you fail to comply with the notice, including possible revocation of your licence.

If remedial action needs to be taken to safeguard the welfare of protected animals and you are not willing or able to take that action, we may take that action (whether or not a compliance notice has already been issued).

Revoking, suspending or varying (amending) licences

If you have not complied with a condition of a licence you hold, or a provision of ASPA and the circumstances justify it, we may suspend, revoke or vary your licence either for a specified period or until further notice.

We may also suspend a project licence if there is an urgent need to safeguard the welfare of a protected animal. If this happens, all procedures authorised by that licence must stop immediately. We may require you to take action to safeguard the welfare of your animlas, or we may take that action oursleves.

Under ASPA section 12, you have the right to make representations to us if we intend to vary or revoke your licence other than at your request. If we notify you of such an intention, we will provide you with guidance on your right to appeal.

Severity of non-compliance

The treatment of non-compliance will depend upon how it came about, its scale and any consequential animal suffering.

Deliberate or reckless infringements will tend to be viewed more seriously than those due to other causes.

Repeated failures will generally be viewed more seriously than single incidents.

Unnecessary animal suffering or attempts to conceal the facts will tend to significantly increase the perceived gravity of non-compliance.

What can I do to avoid non-compliance?

Many breaches of licence conditions, or ASPA, occur because the detail of the authorities granted in the relevant personal and project licences have not been adequately checked.

Failure to check licence authorities will not be accepted as a mitigating circumstance.

Make sure you check your licence(s) carefully and understand what you are authorised to do. If in doubt ask your inspector.

Do not start new work until you have received and personally checked your licence(s) and conditions.

Do not assume, or accept the word of others, that authorities have been granted. You must check for yourself.

Check the detail of your licence(s) and remind yourself of the requirements of ASPA regularly, and particularly before starting any new procedure.

Ensure that your licence(s) are available to anyone with relevant responsibilities under ASPA.

Take particular care if you work under more than one project licence to ensure that the necessary authorities exist in the *relevant* project licence.

The standard conditions of issue require establishment licence holders to take all reasonable steps to prevent the performance of unauthorised procedures in their establishment. Establishment licence holders should therefore also be mindful of the common causes of non-compliance and the measures that can be taken to prevent them.

Compliance advice

Should you require it your inspector will provide advice on how to ensure compliance with licence conditions and the requirements of ASPA. They will also advise on how to avoid non-compliance.

About Home Office inspections

What do inspectors do and why?

Home Office Inspectors are appointed under ASPA section 18. Their role is to:

- advise on applications for ASPA licences, and on requests for their variation or revocation;
- advise on the periodic review of licences, including retrospective assessments;
- visit breeder, supplier and user establishments, and other places where work under ASPA is carried out (POLEs), to monitor their standards and practices and compliance with ASPA and the conditions of any licences held there;
- report all non-compliance and recommend the action to be taken; and
- encourage good practices.

Inspectors have no powers to grant, refuse, vary or revoke licences. This is done by administrative staff acting on behalf of the Secretary of State.

What other powers does an inspector have?

If an inspector considers that a protected animal is undergoing excessive suffering he/she has the power under ASPA section 18(3) to require the animal to be immediately killed using an appropriate method.

What qualifications do inspectors have?

Inspectors are all registered medical or veterinary practitioners and usually have higher scientific or clinical postgraduate qualifications and first-hand experience of biomedical research.

How often do inspectors visit establishments?

Under ASPA we are required to follow a risk-based approach when deciding how often to visit an establishment.

We use the following factors to make the risk assessment:

- the number and type of procedures, if any, you undertake;

- the severity of those procedures;
- the number and species of animals housed and used at your establishment;
- your history of compliance with ASPA and the conditions of your licence(s); and
- any information which might indicate non-compliance.

All establishments are assessed in terms of whether they are low, medium or high risk. 'High risk' does not necessarily imply poor performance or non-compliance, although compliance history is taken into account.

After a visit to your establishment your inspector will review your risk status, noting any significant changes to the relevant factors, and discuss this with key individuals, including your establishment licence holder.

In addition to the requirement for a risk-based approach, ASPA also requires that at least one-third of user establishments and all establishments keeping non-human primates are inspected every year. In practice, we aim to inspect *all establishments* at least once a year. The majority will be visited more frequently.

What happens during an inspection?

Inspectors' visits will often be unannounced. When they visit you must allow an inspector access to all parts of the establishment listed in the schedule to your establishment licence.

An inspector may also want to visit other parts of the establishment so that they can:

- inspect areas you are proposing to include in the schedule to your establishment licence;
- determine whether animals are being or have been used in procedures, or for breeding or supply, in areas not listed on the schedule;
- visit licence holders or applicants for licences;
- visit people named in the establishment licence or in the licence application.

You must provide any necessary assistance to inspectors to facilitate effective inspections, including access to records and meeting relevant personnel. You must tell us if you have any local controls or precautions in place to minimise the risks of transmitting disease as this may affect how we carry out the inspection.

After an inspection, your inspector will prepare a report on his/her findings including whether you are breaching the conditions of your licence, even if this is a minor matter (see also the section on non-compliance).

We will keep inspection reports for at least five years.

Encouraging good practice

When you apply for a project licence your inspector is likely to discuss your proposals with you in detail to ensure that you have done everything possible to follow the principles of the 3Rs.

EU inspections

Article 35 of Directive 2010/63/EU provides for the European Commission to examine the infrastructure and operation of national inspections in Member States where there is reason for concern, for example about the proportion of inspections carried out without prior warning. Should this occur, you must assist experts from the European Commission in carrying out their duties under Article 35.

The Animals in Science Committee

The Animals in Science Committee is an independent non-departmental public body. It is responsible for providing impartial, balanced and objective advice to us and to AWERBs on issues relating to ASPA and the use of animals in scientific procedures. This advice is not binding.

In carrying out its work the committee must consider both the legitimate requirements of science and industry and the protection of animals from avoidable suffering and unnecessary use in scientific procedures.

Its members are appointed according to their skills, expertise and experience and do not represent any organisation or interest group. They are expected to work in the public interest.

The committee's members have wide-ranging expertise, including in the welfare of animals, veterinary science and neuroscience research. It also includes lay members with an interest in the ethical issues of using animals in scientific research. The committee can co-opt additional expertise as appropriate.

Contact details

You can contact the committee through its secretariat by:

emailing asc.secretariat@homeoffice.gsi.gov.uk

Other advisers to the Secretary of State

External assessors

Where we need additional expert advice on licence applications we can appoint independent external assessors.

If we intend to refer your application to an external assessor, we will let you know and also take account of your views in selecting them. Usually you will be told who the assessor is and the questions we have asked them to address.

We will appoint an independent assessor if we do not have the expert knowledge required, or when there is a debate within the scientific or welfare communities, or between us and a licence applicant. This may involve, for example:

- the scientific validity of the methodology;
- the scope for further refinement of the work;
- the likely benefits arising from the programme of work; or
- the welfare costs to animals.

The assessor's advice is not binding.

People who consider representations

If we propose to refuse your application, or vary, suspend or revoke your existing authorities without your consent, you have the right to make representations against our decision.

We can appoint someone who is legally qualified to consider your representations and then report back to us. We will take their report into account when making our final decision although their advice is not binding.

Other issues

Preventing public displays

It is an offence to perform procedures as an exhibition to the general public or to be shown live on television. It is also an offence to advertise such events.

Filming of procedures for later editing or broadcast is not an offence.

Training

The Directive requires that staff are adequately educated and trained to perform any of the following functions:

a) carrying out procedures on animals;

b) designing procedures and projects;

c) taking care of animals; or

d) killing animals.

The UK has long provided such training in a modular structure which includes the following key content:

- Module 1: Historical background, Ethics, ASPA and other relevant legislation;
- Module 2: Recognition of wellbeing, handling, humane killing;
- Module 3: Biology and husbandry, common diseases and monitoring, basic anaesthesia and analgesia, and minor procedures;
- Module 4: Surgical anaesthesia and analgesia and surgical procedures;
- Module 5: Ethics, alternatives, project design and management.

Applicants for personal licences (function a) are required to complete at least modules 1, 2 and 3 for a category A and B licence. To add category C to their licence, they must also complete module 4.

Applicants for project licences (function b) are required to complete modules 1, 2 and 5. In addition, they are required to complete module 3 and/or 4 if the skills covered by these modules are required for their particular project.

Those taking care of animals are not currently required to fulfil any minimum training criteria but, at the very least, are expected to be under the supervision of a qualified and experienced animal technologist.

Those killing animals according to Schedule 1 of ASPA or by methods specifically authorised in an establishment licence are required to be included on a register held by the establishment licence holder who must ensure that the necessary training has been provided and competence demonstrated as a condition of their licence.

During 2013 we are working towards a common framework for training which will be used throughout the EU and will encourage the free movement of individuals between Member States.

We are encouraging training providers to adapt the content of their courses to the EU framework. However, this is unlikely to be completed before the end of 2013 and we therefore propose to continue to accept training according to the current modular structure until that time.

Annual statistics

We are required to publish annually information about the use of animals in procedures. We do this in *Statistics of Scientific Procedures on Living Animals*. From 2015 we must publish this report by 10 November each year.

We collate the data for this report from details that project licence holders must supply about procedures started [and completed?] during the previous year. We must receive this information by 31 January each year via a 'return of procedures' form.

If your project licence expires or is revoked during the year, you must make the return within 28 days of the date of revocation or expiry.

We issue code lists and explanatory notes annually to help you with this process.

Project licence holders are allowed to delegate completing the form but you remain responsible for submitting a timely and accurate return. If you fail to submit the data by the required date, or provide inaccurate data, we may revoke your licence.

Other relevant legislation

A list will be compiled in due course.

Annex A: Standard conditions for establishment licences

Standard conditions for establishment licences (also known as section 2C licences) are:

1. The licence holder shall ensure that the regulated activities carried on at the establishment are carried on in a manner that is consistent with the principles of replacement, reduction and refinement.

2. (1) The licence holder shall ensure that a register is maintained of those who are competent to kill protected animals. A person's name shall not be included in the register unless the person has been adequately educated and trained in the killing of animals.

(2) The register must specify, in relation to each person named, the descriptions of animals that the person is competent to kill and the methods of killing that the person is competent to use to kill each such animal.

(3) The licence holder shall ensure that each person so registered is supervised when killing animals at the establishment until he or she has demonstrated the requisite competence.

(4) The licence holder shall ensure that at all times the number of persons who are so registered and are present at the establishment is sufficient to enable any protected animal being kept at that place that needs to be killed to be killed expeditiously.

(5) The register shall, on request, be submitted to the Secretary of State or made available to an Inspector.

3. The licence holder shall notify the Secretary of State of any proposed change in:

(a) the full name of the holder; or

(b) the full name and qualifications of the named person responsible for compliance; or

(c) the full name and qualifications of the named animal care and welfare officer; or

(d) the full name and qualifications of the named veterinary surgeon; or

(e) the full name and qualifications of the named information officer; or

(f) the full name and qualifications of the named training and competency officer; or

(g) the areas appearing on the schedule of premises for the establishment or the class of use within those areas; or

(h) the types of protected animals to be held and/or used in regulated activities at the establishment.

4. (1) All protected animals must at all times be provided with adequate care and accommodation appropriate to their type or species.

(2) Any restrictions on the extent to which such an animal can satisfy its physiological and ethological needs shall be kept to the absolute minimum.

(3) Unless otherwise authorised by the Secretary of State an environment, housing, freedom of movement, food and water appropriate for the health and wellbeing of each protected animal shall be provided.

(4) The licence holder shall ensure that the installations and equipment at the establishment are suitable for the species of protected animals kept at the establishment and for the regulated procedures, if any, carried out at the establishment. The design, construction and method of functioning of the installations and equipment must be such as to enable regulated procedures to be performed in a manner that provides reliable results, uses the minimum number of animals and causes the minimum degree of pain, suffering, distress and lasting harm to the animals used.

(5) The health and wellbeing of protected animals, and the environmental conditions in all parts of the establishment where protected animals are kept, shall be checked at least once daily by competent persons. Arrangements shall be made to ensure that any defect discovered and any avoidable pain, suffering, distress or lasting harm discovered is eliminated as quickly as possible.

(6) The holder shall ensure that the conditions under which any protected animal is transported are appropriate for the animal's health and well-being.

(7) Unless otherwise authorised by the Secretary of State the licence holder shall ensure that at least the following standards are met:

(a) any applicable standard concerning the care and accommodation of animals or installations and equipment, which is set out in Annex 3 of the Animals Directive;

(b) any additional or higher standard concerning the care and accommodation of animals which is set out in any code of practice issued or approved under section 21 that was in force on 9 November 2010.

(8) For the purposes of subparagraph (7)(a) a standard set out in Annex 3 of the Animals Directive is not to be treated as being an "applicable standard" if the Annex specifies a date from which the standard is to have effect and that date has not been reached.

5. The licence holder shall ensure that the establishment shall be appropriately staffed at all times to ensure the well-being of the protected animals. Staff shall be adequately educated and trained before they perform any function relating to the care of the protected animals and shall be supervised when performing any such function until they have demonstrated the requisite competence.

6. (1) The licence holder is required to have established, and to maintain, an Animal Welfare and Ethical Review Body.

(2) The Animal Welfare and Ethical Review Body must consist at least of:

(a) the named animal welfare officer and named veterinary surgeon,

(b) if this licence authorises the application of regulated procedures to protected animals at the establishment, the holder of a project licence which specifies the establishment as a place where regulated procedures may be carried out, or another person with suitable scientific credentials acceptable to the Secretary of State, and

(c) such other persons as may be specified in guidance issued by the Secretary of State.

(3) The Animal Welfare and Ethical Review Body must carry out the tasks mentioned in Article 27.1 of the Animals Directive and any other advisory and reviewing tasks specified in this licence or in guidance issued by the Secretary of State.

(4) The licence holder shall ensure that whenever the Animal Welfare and Ethical Review Body provides advice a record is made of the advice and of any decisions taken in response to the advice. Such records shall be kept for a minimum period of three years and shall, on request, be submitted to the Secretary of State or made available to an Inspector.

7. If this licence authorises the breeding of protected animals, the holder is not authorised to breed, at the establishment, non-human primates from any animal not bred in captivity unless the holder has in place a strategy acceptable to the Secretary of State for increasing the proportion of primates bred from animals bred in captivity. Any substantial changes to the strategy that are proposed shall be submitted to the Secretary of State for approval.

8. (1) Records shall be maintained, in a format acceptable to the Secretary of State, of the source, use and final disposal of all protected animals bred, kept or used at the establishment for any regulated activities.

(2) Such records shall include at least the following information:

(a) the number and the species of animals bred, acquired, supplied, used in procedures, or discharged from the control of the Act;

(b) the origin of the animals, including whether they are bred for use in procedures;

(c) the dates on which the animals are acquired, supplied, or discharged from the control of the Act;

(d) from whom the animals are acquired;

(e) the name and address of the recipient of animals;

(f) the number and species of animals which died or were killed in each establishment. For animals that have died, the cause of death shall, when known, be noted; and

(g) where this licence authorises the applying of regulated procedures to protected animals, the projects in which animals are used.

(3) Such records shall be kept for a minimum of five years from the date of final disposal of the animal and, on request, be submitted to the Secretary of State or made available to an Inspector.

(4) The licence holder shall, on request, submit to the Secretary of State a summary report, in a form specified by the Secretary of State, of the source, use and final disposal of all protected animals bred, kept, or used at the establishment for any regulated activities.

9. (1) For the purposes of this condition, an “individual history file” is a file kept in relation to a dog, cat or non-human primate which contains particulars of the animal’s identity; particulars of the animal’s date and place of birth (if known); a statement as to whether the animal was bred for use in regulated procedures; any relevant reproductive, veterinary and social information about the animal; a record of the programmes of work, if any, which have involved the use of the animal in regulated procedures; and in the case of a primate, a statement as to whether the animal is the offspring of primates bred in captivity.

(2) The licence holder shall ensure that for each dog, cat and non-human primate held at the establishment an individual history file is established and kept up to date. In the case of such an animal bred at the establishment the individual history file shall be established as soon as is reasonably practicable after the animal's birth. Where such an animal is transferred to the establishment an individual history file shall be established in relation to the animal as soon as is reasonably practicable after its transfer (unless the animal is transferred from a place specified in another section 2C licence and an individual history file previously established in relation to the animal is provided in accordance with conditions included in that other licence).

(3) The licence holder shall ensure that if a dog, cat or non-human primate kept at the establishment is transferred to a place specified in another section 2C licence, the individual history file kept in relation to the animal is provided to the holder of that other licence.

(4) The licence holder shall ensure that if a dog, cat or non-human primate kept at the establishment is transferred otherwise than to a place specified in another section 2C licence, the person to whom the animal is transferred is provided with a copy of any veterinary and social information about the animal that is included in the animal's individual history file.

(5) The licence holder shall ensure that if a dog, cat or non-human primate kept at the establishment dies at that place, is set free from that place or is transferred otherwise than to a place specified in another section 2C licence, the individual history file for the animal is kept for a period of three years following its death, setting free or transfer.

(6) A copy of any individual history file required to be kept by this condition shall, on request, be submitted to the Secretary of State or made available to an Inspector.

10. (1) The licence holder shall ensure that before any unmarked dog, cat or non-human primate is weaned at the place specified in the licence the animal is marked. The licence holder shall ensure that before any unmarked dog, cat or non-human primate that has not been weaned is transferred from the establishment to a place specified in another section 2C licence, the animal is marked unless it would not be reasonably practicable to do so. Where an unmarked dog, cat or non-human primate that has not been weaned is transferred to the establishment, the establishment shall maintain records attesting the identity and origin of the animal's mother until the animal is marked.

(2) The holder shall ensure that any unmarked cat, dog or non-human primate which is taken into the establishment after weaning shall be marked as soon as possible.

(3) The holder shall ensure that where a dog, cat or primate at the establishment is marked it is done in the least painful manner possible.

(4) The holder shall comply with any request made by the Secretary of State for an explanation of why any dog, cat or primate at the establishment has not been marked.

(5) For the purpose of this condition, “marked” means provided with a permanent means of individual identification and “unmarked” refers to an animal that has not been provided with a permanent individual identification mark.

11. (1) Inspectors shall be provided with access at all reasonable times to all parts of the establishment which are concerned with the use, holding, breeding or care of protected animals.

(2) The licence holder must give any necessary assistance to inspectors carrying out visits by virtue of section 18(2A)(b); and to experts of the European Commission carrying out duties under Article 35 of the Animals Directive.

12. Unless authorised by the Secretary of State, there shall be no variation of the use of the approved areas of the establishment in the licence that may have adverse consequences for the welfare of the protected animals held.

13. Unless otherwise authorised by the Secretary of State:

(a) only the types of protected animals specified in the licence may be kept in the place or places specified in the licence for the purpose of the regulated activities specified in the licence; and

(b) for the purpose of the regulated activities specified in the licence, these animals may only be kept, bred and used in the areas listed in the schedule to the licence.

14. Records shall be maintained, in a format acceptable to the Secretary of State and under the supervision of the named veterinary surgeon, relating to the health of all protected animals bred, kept or used at the establishment for any regulated activities. Records shall, on request, be submitted to the Secretary of State or made available to an Inspector.

15. The licence holder shall nominate and be responsible for the performance of named persons, acceptable to the Secretary of State, as required by section 2C(5) .

16. Arrangements to ensure that animals are given adequate care must be made in the event that the named persons referred to in condition 15 above are not available for any reason.

17. Adequate security measures shall be maintained to prevent the escape of protected animals and to prevent intrusions by unauthorised persons.

18. Quarantine and acclimatisation facilities shall be provided and used as necessary.

19. Adequate precautions against fire shall be maintained at all times.

20. If this licence authorises the applying of regulated procedures to protected animals, the holder shall take all reasonable steps to prevent the performance of unauthorised procedures in the establishment.

21. The licence holder shall make adequate and effective provision for regular and effective liaison with and between those entrusted with responsibilities under the Act and with others who have responsibility for the welfare of the protected animals kept at the establishment.

22. Where this licence authorises the applying of regulated procedures to protected animals, the licence holder shall notify the Secretary of State of the death of a project licence holder within seven days of its coming to his or her knowledge when, unless the Secretary of State directs otherwise, the project licence shall continue in force for 28 days from the date of notification. The section 2C licence holder will, during that period, assume responsibility for ensuring compliance with the terms and conditions of the project licence.

23. (1) This condition applies where this licence authorises the applying of regulated procedures to protected animals.

(2) A protected animal which, having been subjected to a completed series of regulated procedures, is kept alive shall continue to be kept at the establishment under the supervision of a veterinary surgeon or other suitably qualified person unless:

(a) it is moved, with the authority of the Secretary of State, to another establishment;

(b) the Secretary of State consents under section 17A to the animal no longer being kept at the establishment; or

(c) its re-use in another procedure is authorised by the Secretary of State.

24. A copy of these conditions shall be readily available for consultation by all licence holders and named persons in the establishment.

25. The licence remains the property of the Secretary of State, and shall be surrendered to him on request.

Annex B: Standard conditions in personal licences

1. In exercising his or her responsibilities, the licence holder shall act at all times in a manner that is consistent with the principles of replacement, reduction and refinement.

2. The licence holder is entrusted with primary responsibility for the welfare of the animals on which he or she has performed regulated procedures; the licence holder must ensure that animals are properly monitored and cared for.

3. The licence holder must not apply a regulated procedure to an animal if the procedure may cause the animal severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.

4. The licence holder must not apply a regulated procedure to an animal unless the holder has taken precautions to prevent or reduce to the minimum consistent with the purposes of the procedure any pain, suffering, distress or discomfort that may be caused to the animal.

5. Where the licence holder is applying a regulated procedure to an animal the holder must ensure that any unnecessary pain, suffering, distress or lasting harm that is being caused to the animal is stopped.

6. Where the licence holder is applying or has applied a regulated procedure which is causing the animal severe pain, suffering or distress the holder must take steps to ameliorate that pain, suffering or distress.

7. The licence holder shall ensure that where the holder applies a regulated procedure death as the end-point of the procedure is avoided as far as possible and is replaced by an early and humane end-point.

8. In all circumstances where an animal which is being, or has been, subjected to a regulated procedure is in severe pain, suffering or distress which is likely to be long-lasting and cannot be ameliorated, the licence holder must ensure that the animal is immediately killed in accordance with section 15A.

9. The licence holder may apply a regulated procedure without the use of general or local anaesthesia only if the holder is satisfied that:

(a) the procedure will not inflict serious injuries capable of causing severe pain; and

(b) the use of general or local anaesthesia would be more traumatic to the animal than the procedure itself or would frustrate the purposes of the procedure.

10. When anaesthesia (whether general or local) is used, it shall be of sufficient depth to prevent the animal from being aware of pain arising during the procedure.

11. If the licence holder applies a regulated procedure to an animal with the use of general or local anaesthesia the holder must, unless it would frustrate the purpose of the procedure, use such analgesics or other pain-relieving methods as may be necessary to reduce any pain that the animal may experience once the anaesthesia wears off.

12. The licence holder must use analgesia or another appropriate method to ensure that the pain, suffering and distress caused by regulated procedures are kept to a minimum.

13. It is the responsibility of the personal licence holder to notify the project licence holder as soon as possible when it appears either that the severity limit of any procedure listed in the project licence or that the constraints upon adverse effects described in the project licence have been or are likely to be exceeded.

14. The licence holder shall ensure that suitable arrangements exist for the care and welfare of animals during any period when the personal licence holder is not in attendance.

15. The licence holder shall ensure that, whenever necessary, veterinary advice and treatment are obtained for the animals in his or her care.

16. The licence holder shall ensure that all cages, pens or other enclosures are clearly labelled. The labelling must be such as to enable Inspectors, named veterinary surgeons and named animal care and welfare officers to identify the number of the project licence authorising the procedures, the project licence protocol in which the animals are being used, the date the protocol was started, and the responsible personal licence holder.

17. In order to ensure that regulated procedures are performed competently, the licence holder shall not apply regulated procedures unless given the appropriate level of supervision by the project licence holder or an experienced personal licence holder deputed by him/her for such time as may be needed to achieve competence.

18. The licence holder is authorised to delegate to assistants, who do not themselves possess the requisite personal licence authority but are under his or her control, the delegable tasks which form an integral part of the regulated procedures the licence holder is authorised to perform by this licence. The tasks must not require technical knowledge or skill, and delegation shall be in accordance with any relevant guidance published by the Secretary of State under section 21.

19. The licence holder must take all reasonable steps to ensure appropriate personal and project licence authorities exist before performing regulated procedures. The licence holder must be aware of the nature of the authorities given by this licence and the project licence, and of the conditions of issue attached to the licences.

20. The licence holder shall maintain a record of all animals on which procedures have been carried out, including details of supervision and declarations of competence by the project licence holder as appropriate. This record shall be retained for at least five years and shall, on request, be submitted to the Secretary of State or made available to an Inspector.

21. The licence holder must give any necessary assistance to inspectors carrying out visits by virtue of section 18(2A)(b); and to experts of the European Commission carrying out duties under Article 35 of the Animals Directive.

22. The licence remains the property of the Secretary of State, and shall be surrendered to him on request.

Annex C: Standard conditions in project licences

1. The licence holder is responsible for the overall implementation of the programe of work specified in this licence and for ensuring that the programme of work is carried out in compliance with the conditions of the licence.

2. The licence holder shall ensure that the specified programme of work does not involve the application of any regulated procedure to which there is a scientifically satisfactory alternative method or testing strategy not entailing the use of a protected animal.

3. The licence holder shall ensure that regulated procedures are not applied to an animal as part of the specified programme of work if the data to be obtained from the application of those procedures is already available in a Member State and has been obtained there by procedures which satisfy any relevant regulatory requirements of the EU.

4. The licence holder shall ensure that the regulated procedures applied as part of the programme of work specified in this licence are those which to the greatest extent use the minimum number of animals; involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm; cause the least pain, suffering, distress or lasting harm; and are most likely to provide satisfactory results.

5. The licence holder shall ensure that the regulated procedures applied as part of the programme of work specified in this licence are designed so as to result in the death of as few protected animals as possible; and to reduce to the minimum possible the duration and intensity of suffering caused to those animals that die and, as far as possible, ensure a painless death.

6. The licence holder shall ensure that the appropriate level of supervision is provided for all personal licensees carrying out regulated procedures under the authority of this licence.

7. The licence holder shall ensure that a regulated procedure is not applied to an animal as part of the programme of work specified in this licence if the procedure may cause the animal severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.

8. The licence holder shall ensure that where a regulated procedure is being applied to an animal as part of the programme of work specified in this licence, any unnecessary pain, suffering, distress or lasting harm that is being caused to the animal shall be stopped.

9. The licence holder shall ensure that where a regulated procedure is applied to an animal as part of the specified programme of work, death as the end-point of the procedure is avoided as far as possible and is replaced by an early and humane end-point; and as soon as the purpose of the procedure has been achieved, the procedure is stopped and appropriate action is taken to minimise the suffering of the animal.

10. The licence holder shall ensure that where a regulated procedure has been applied to an animal as part of the programme of work specified in this licence, a suitably qualified person classifies the severity of the procedure as "non-recovery", "mild", "moderate" or "severe" using the criteria in Annex 8 of the Animals Directive. For the purposes of this condition, a series of regulated procedures applied to an animal for a particular purpose is to be treated as constituting a single regulated procedure.

11. Where a series of regulated procedures are applied to an animal for a particular purpose the licence holder shall ensure that the animal is killed at the end of the series unless a veterinary surgeon or other competent person has determined that the animal is not suffering and is not likely to suffer adverse effects, as a result of the regulated procedures.

12. Regulated procedures shall not be carried out on any stray animal of a domestic species as part of the programme of work specified in this licence.

13. Except with the authorisation of the Secretary of State, regulated procedures shall not be carried out as part of the programme of work specified in this licence on any of the following type of animal:

14. any feral animal of a domestic species;

15. any animal taken from the wild;

16. a marmoset unless it is the offspring of marmosets bred in captivity or has been obtained from a self-sustaining colony of marmosets;

17. any animal of a description specified in Schedule 2 to the Act unless it has been bred for use in procedures.

18. If the application of regulated procedures to animals taken from the wild is authorised in this licence the holder shall ensure:

19. that animals taken from the wild are captured by a competent person using a method which does not cause the animal avoidable pain, suffering, distress or lasting harm; and

20. that an animal taken from the wild which is found to be injured or in poor health is not subjected to a regulated procedure unless and until it has been examined by a veterinary surgeon or other competent person; and, unless the Secretary of State has agreed otherwise, action has been taken to minimise the suffering of the animal.

21. The licence holder must give any necessary assistance to inspectors carrying out visits by virtue of section 18(2A)(b); and to experts of the European Commission carrying out duties under Article 35 of the Animals Directive.

22. If the licence holder becomes aware of a failure to comply with any conditions of the licence the holder must take appropriate steps to rectify the failure (if it is capable of being rectified); and keep a record of the steps taken.

23. All authorised procedures shall be carried out under general or local anaesthesia unless:

24. anaesthesia would be more traumatic to the animal concerned than the procedures themselves; or

25. anaesthesia would be incompatible with the purposes of the procedures.

26. The licence holder shall ensure adherence to the severity limits as specified in the project licence and observance of any other controls described in the licence. If these constraints appear to have been, or are likely to be, breached, the holder shall ensure that the Secretary of State is notified as soon as possible.

27. The licence holder shall maintain a contemporaneous record of all animals on which procedures have been carried out under the authority of the project licence. This record shall show the procedures used and the names of personal licensees who have carried out the procedures. The record shall, on request, be submitted to the Secretary of State or made available to an Inspector.

28. The licence holder shall send to the Secretary of State, before 31 January each year (and within 28 days of the licence having expired or been revoked), a report in a form specified by the Secretary of State, giving details of the number of procedures and animals used, and the nature and purpose of the procedures performed under the authority of the project licence during the calendar year.

29. The licence holder shall maintain a list of publications resulting from the licensed programme of work and a copy of any such publication shall be made available to the Secretary of State on request. The list shall, on request, be submitted to the Secretary of State or made available to an Inspector, and it shall be submitted to the Secretary of State when the licence is returned to him on expiry or for revocation.

30. The project licence holder shall submit such other reports as the Secretary of State may from time to time require.

31. The project licence holder shall ensure that details of the programme of work and regulated procedures specified in the licence, and any additional conditions imposed on those procedures, are known to:

32. all personal licensees performing those procedures;

33. the named person responsible for compliance;

34. the named animal care and welfare officers responsible for the day to day care of the animals;

35. the named veterinary surgeon, on request; and

36. the named information officer and named training and competency officer, on request.

37. The licence holder must obtain the permission of the Secretary of State before:

38. any animal undergoing regulated procedures is moved from a place specified in one section 2C licence to a place specified in another section 2C licence; or

39. any animal is released for slaughter, unless this is already explicitly authorised by the project licence.

40. The licence remains the property of the Secretary of State, and shall be surrendered to him on request.