

A Guide for licence holders on the Operation of the Animals (Scientific Procedures) Act 1986

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Foreword

Changes to the Animals (Scientific Procedures) Act 1986

The Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 have now been approved. The regulations 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 establishes revised measures for the protection of animals used for scientific purposes. Some of its provisions are new or go further than ASPA. Other provisions require minor changes to ASPA.

The purpose of this guide

This draft guide is intended as a 'quick start' guide to the requirements of the Animals (Scientific Procedures) Act 1986 (as amended).

What this guide 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 III to the Directive and current UK Codes of Practice.

What this guide replaces

This 'quick start' guide should be read instead of the equivalent sections of the current "Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (HC321)" published on 23 March 2000.

Detailed guidance on the operation of ASPA

More detailed draft guidance incorporating this guide and covering additional topics will be published in January 2013 for consultation.

Comments

Any comments or questions relating to this 'quick start' guide should be sent to the email address below.

Email: aspd-brp@homeoffice.gsi.gov.uk

How to contact us

All correspondence relating to applications should be sent, via your appointed Home Office contact (e.g. HOLO) if you have one, to the appropriate regional office:

Dundee Office	The Home Office PO Box 6779 Dundee DD1 9WW Aspa.dundee@homeoffice.gsi.gov.uk Tel: 01382 223189
Shrewsbury Office	The Home Office PO Box 31 Shrewsbury SY3 7WN Aspa.shrewsbury@homeoffice.gsi.gov.uk Tel: 01743 24612
Swindon Office	The Home Office PO Box 1138 Swindon SN1 2RZ Aspa.swindon@homeoffice.gsi.gov.uk Tel: 01793 514029
London Office	The Home Office, ASRU Mail Point B20, 4 TH Flr, Seacole Building 2 Marsham Street London SW1P 4DF Aspa.London@homeoffice.gsi.gov.uk Tel: 020 7035 0477

We welcome applications in electronic format in addition to the required two paper copies.

You can register with our recommended encryption system by going to: [CJSM Instructions Page](#). This enables you to automatically encrypt emails and attachments for sending to and receiving from us.

General enquiries about the new regulations and their implementation 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.

The London Office has a telephone manned by a Duty Manager from 8.30am to 5.30pm (020 7035 0477) on working days (not weekends or public holidays).

Glossary of terms

ASPA	The Animals (Scientific Procedures) Act 1986. New ASPA in this guide 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
ERP	Ethical Review Process
EU Directive	European Directive on the protection of animals used for scientific purposes (2010/63/EU)
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)
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 7
Protected animal	All living vertebrates, other than man, and any living cephalopod in addition to some immature forms – see page 6

Section 2C licence Establishment licence

Background to the Act

What the Act covers

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

In this Guide 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'.

ASPAs 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 ASPAs Schedule 2 must also hold an establishment licence. Procedures may be authorised at Places Other than Licensed Establishments (POLE), and these will be specifically identified in the relevant project licences.

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

ASPAs also regulates the breeding of animals for the use of their organs or tissues in procedures.

What is a protected animal?

ASPAs protects all living vertebrates, other than man, and any living cephalopod.

In addition:

- embryonic and foetal forms of mammals, birds and reptiles are protected during the last third of their gestation or incubation period;
- fish and amphibia once they can feed independently; and
- cephalopods at the point they hatch.

Embryonic and foetal forms will also be protected from an earlier stage of development if they are going to live beyond the stage described above; and the procedure is likely to cause them pain, suffering, distress or lasting harm after they have developed to that stage.

For example:

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.

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.

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’*. In addition, the procedure has to be for one of the purposes set out in ASPA section 5(2).

‘Pain, suffering, distress and lasting harm’ 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).

Procedures might 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 Classification in this Guide. We can also advise you about these on a case-by-case basis.

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;
- those that are carried out before the animal has developed to the stage at which it becomes a protected animal, where the animal will be allowed to live until it becomes protected and it is likely to experience pain, suffering, distress or lasting harm as a result;
- 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 Guide);
- removing organs, blood or other tissue under general anaesthesia even if the animal is not allowed to recover consciousness.

What isn't a regulated procedure?

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. The RCVS is developing guidance on this.

- *Veterinary clinical trials:* 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 Guide). A copy of Schedule 1 detailing approved methods of humane killing is available in the consolidated version of ASPA on the Home Office website.
[<http://www.homeoffice.gov.uk/science-research/animal-research/>]

The principles of the 3Rs

You can carry out a procedure only if there are no scientifically suitable alternatives available that can:

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

These principles are called the 3Rs of Replacement, Reduction and Refinement.

You will find more information about the 3Rs in the 'Project licence holders' section of this Guide.

Establishment licence holders

What is an establishment licence?

The place where regulated procedures are carried out, or animals are supplied or bred for use in these procedures, must have a Section 2C licence. These replaced certificates of designation on 1 January 2013.

Section 2C licences are generally known as establishment licences. This is how we refer to them in this guidance.

Certificate holders automatically became the holders of establishment licences from 1 January 2013. In addition to NVSs and NACWOs, the new licences must include details of three further named people at each establishment:

- a 'person responsible for compliance with the licence' (NCO);
- an 'information officer' (NIO); and
- a 'training and competence officer' (NTCO).

Initially, the establishment licence holder will hold all three of these new roles until you apply to us for a change to this arrangement.

What does an establishment licence cover?

An establishment licence authorises the carrying out of one or more of the following activities:

- performing procedures – these are called 'scientific procedure establishments';
- breeding protected animals listed in Schedule 2 of ASPA – these are called 'breeding establishments';
- keeping and supplying protected animals listed in Schedule 2 of ASPA – these are called 'supplying establishments'.

For example

A scientific procedure establishment may also be a breeding establishment if it breeds animals for use in procedures there or somewhere else. A breeding establishment must also be a scientific procedure establishment if any of the animals you are breeding there are genetically altered and of a potentially harmful phenotype.

Establishment licences must also contain a 'Schedule of Premises'. This gives details of the areas where animals can be used in procedures and where they can be housed.

Named persons

Establishment licences must state one or more persons who are responsible for:

- ensuring compliance with the requirements of the Act – the Named Compliance Officer (NCO) – normally this will be the holder of the establishment licence;
- overseeing the welfare and care of the animals – called the Named Animal Care and Welfare Officers (NACWOs);
- ensuring that those dealing with animals have access to any information they need –called the Named Information Officers (NIOs);
- ensuring that those dealing with animals are adequately educated, trained and supervised until they are competent and that appropriate further training continues – called the Named Training and Competence Officers (NTCOs).

The licence also identifies the Named Veterinary Surgeons (NVSs) with expertise in laboratory animal medicine who are responsible for advising on the welfare and treatment of the animals. Occasionally, and only where more appropriate, another suitably qualified expert may fill this role but you must seek our permission and explain why a veterinary surgeon is not appropriate. We may consult the RCVS over such a proposal. In this Guide, reference to NVSs includes any such agreed appointment of another suitably qualified expert.

Who can hold an establishment licence?

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

Unless you have named someone else as your 'Compliance Officer', you are the person responsible for complying with the terms and conditions of the establishment licence. You, or your named delegate, should be the best person in your establishment to do this.

In this Guide we assume that the holder of the establishment licence will also be the person responsible for ensuring compliance with all aspects of the regulations.

Note it is also permissible for the establishment licence to be held by a legal entity, such as Noname Pharmaceuticals plc or Newtown University. Where this is the case, the named person responsible for compliance will have the responsibilities described below for the establishment licence holder.

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, but at the same time take an active interest in the care and use of animals at your establishment.

This role needs certain aptitudes: proactive and effective leadership; good management and communication skills; and the commitment to nurture a 'culture of care'.

Your responsibilities

Establishment licence holders have a range of responsibilities.

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 regulated procedures.

Animal welfare and ethical review body

Every breeder, supplier and scientific procedure establishment must have an animal welfare and ethical review body (AWERB). With effect from 1 January 2013, your existing local Ethical Review Process (ERP) will automatically become your AWERB. The same people will be involved and, if necessary, its terms of reference should be amended to include all the elements of the role described below. If, in the future, you wish to make any substantial changes to your AWERB, you must first agree them with us. Any such changes may only be made with our consent.

Membership

The AWERB must comprise (as a minimum):

- at least one Named Animal Care and Welfare Officer (NACWO);
- in the case of a user establishment, a scientific member.

If you did not have at least this minimum membership on your ERP, you must immediately correct this for your AWERB from 1 January 2013.

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 reassured how you propose to ensure NVS advice is being taken.

We already encourage 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 ERP and we will expect you to continue that approach in your AWERB.

Initially the current membership of your ERP will become your AWERB (subject to including at least the minimum membership above) and it is likely that they will

continue to be the most appropriate members. You should encourage involvement of as many people as possible in the work of your AWERB, either as members or by engaging with AWERB initiatives.

Role

The AWERB:

- promotes awareness of animal welfare;
- provides 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;
- considers standards of animal care and accommodation, including breeding stock, and the humane killing of animals;
- sets up and regularly reviews procedures and protocols, including management systems, for monitoring, reporting and following up on the acquisition, welfare and proper use of animals at your establishment;
- supports named people, and other staff dealing with animals, on animal welfare and ethical issues;
- promotes the development and uptake of the 3Rs and advises staff how to apply them;
- reviews all applications for new project licences and amendments to existing licences from a local perspective, considering how the 3Rs are being applied and advising you of the acceptability of proposals, bringing local knowledge and local expertise to bear;
- throughout the lifetime of projects, follows their development and outcome, including those requiring retrospective review, so that lessons learnt can be used to further apply the 3Rs;
- advises on re-homing animals including appropriate socialisation;
- responds to enquiries and considers advice received from the national Animals in Science Committee.

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.

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.

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, personal licences and project licences.

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.

Humane killing

Only people listed on your register of competent persons should be allowed to kill an animal humanely, using a method detailed in Schedule 1. We recommend that you display a copy of Schedule 1 and the relevant section of this Guide (see page 56) in all areas used for killing animals.

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.

Animal care and accommodation

You are responsible for making sure that all protected animals at your establishment have appropriate care and accommodation.

Unless your establishment licence or a specific project licence exempts you, 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 Annex III of the EU Directive (2010/63/EU) or any higher or additional standard set out in a UK code of practice in force on 9 November 2010 (see the Code of Practice section in this Guide);
- 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.

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.

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.

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 Guide 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. 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.

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.

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 rehomed 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. 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 scientific procedure 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.

We will give more information in the 'sourcing, using and disposing of animals' section of the detailed guidance.

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.

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.

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 this Guide 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 Guide 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.

[<http://www.homeoffice.gov.uk/science-research/animal-research/>]

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 Guide).

Conduct of named people

When applying for an establishment licence you must nominate someone to ensure that the requirements of ASPA and conditions of the licence are complied with – the Named Compliance Officer (NCO). This will normally be you as the holder of the establishment licence. In addition you must nominate:

- one or more people to oversee the welfare and care of the animals – this person is called the Named Animal Care and Welfare Officer (NACWO);
- 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;
- one or more people to ensure that those dealing with animals have access to any information they need about the species – this person is called the Named Information Officer (NIO);
- one or more people to ensure that those dealing with animals are adequately educated, trained and supervised until they are competent – this person is called the Named Training and Competence Officer (NTCO).

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 and the 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).

All these named people should help you fulfil your 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).

You are accountable to us for a named person's performance and conduct. 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 normally their advice on the health, welfare and use of animals,

both at the planning stage and when work is in progress. They should take 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.

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.

Conflicts of interest

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.

An example of a Declaration Form you may use is available on our website [<http://www.homeoffice.gov.uk/science-research/animal-research/>]. The form must be completed for each new NVS and NACWO. You should review these declarations regularly, at least annually, and they should be available for inspectors to check. You should require these named persons 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 a 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.

Paying fees

You need to pay us fees to recover the costs of operating ASPA. This includes the costs of inspecting, licensing and 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.

Your training

You are expected to have completed UK 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.

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;
- serious or persistent non-compliance with conditions;
- 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.

You have the right to make representations to us if we are intending to vary, suspend or revoke your 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 from 1 January 2013.

Standard conditions for establishment licences

We grant establishment licences subject to standard conditions. These are set out below.

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
- permitting you to use a method of humane killing which is not included in Schedule 1.

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.

Personal licence holders

What is a personal licence?

A personal licence shows that you are qualified and suitable to carry out regulated procedures, under supervision if necessary. The licence authorises you to carry out procedures of specified descriptions (categories) on specific descriptions of animal. This must be as part of a programme of work detailed in a project licence.

Your primary place of work will be included on your licence. The licence is not restricted to working only at your primary place of work. Revised standard conditions apply as a result of the 2012 amendments to the Act.

You have primary responsibility for the welfare of the animals on which you perform regulated procedures.

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;
- have appropriate experience of handling protected animals and looking after the animals' welfare.

What changes are there to personal licences from 1 January 2013?

The following applies to all existing and new personal licences from 1 January 2013:

- you are no longer restricted to working at the place(s) specified on your licence (section 14 of the schedule);
- new applications for a personal licence must be endorsed by the Named Training and Competency Officer (NTCO), not sponsored by a personal licensee as at present;
- revised standard conditions will apply.

The description of the techniques that you are authorised to undertake has also been simplified for new licences, but will be restricted to the detail in the current section 15 of old licences until those licences are amended.

Will you be amending my current licence?

We will be amending all current personal licences in a managed way, establishment by establishment, during 2013. Unless you have an essential change to process, please wait until we contact your establishment licence holder. Please do not ask us to amend or review your licence where no real change is required.

New applications

We have a new application form for personal licences available on the Home Office website (see 'How to contact us' section of this Guide). If you are already preparing an application we will accept the existing form and signatories until 31 January 2013 and you will receive a 'new style' licence. From 1 February 2013 all applications for personal licences must be made on the new form.

What information is needed in a personal licence application?

Your application needs to include:

- personal information for identification;
- details of the establishment from which your application is made;
- the 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. If English is not your first language, your NTCO will check that you understand the provisions of ASPA.

What does a personal licence cover?

- the species or types of animals which you may use;
- the description of the regulated procedures which you may carry out.

What is covered by the different categories of personal licence?

The following categories of personal licence, A to F, permit you to carry out procedures which fall within 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 Project Licence (<i>number</i>) |
| F. | Other (a free text field) |

Category E is for education and training work under a specific project licence and category F is to cover anything that doesn't fit properly elsewhere. If you are unsure if a particular regulated procedure falls within a category you should consult your Home Office Inspector.

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; and
- to qualify for the categories of procedures you will need to complete the relevant formal modular training (with current exemptions): current UK modules 1–3 will qualify for categories A and B; UK modules 1–4 qualify for categories A, B and C.

You may be exempt from this if you can supply evidence of equivalent relevant education, training and experience. The numbering of modules is likely to change during 2013 to comply with EU modules. We will provide further guidance.

New personal licence holders will have to undertake further training and be supervised until competent at their place(s) of work. This training and supervision should be periodically reviewed with your NTCO.

Where is my personal licence valid?

The named place will be the licensed establishment where you are based – called the 'primary availability'. This organisation is responsible for paying a fee for your licence and will maintain your training and competence record.

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 commencing any work there.

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

Which project licences may I work under?

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

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.

We may add additional conditions that restrict your work.

How long will my personal licence be valid for?

Although personal licences continue in force until revoked, we are required to review each personal licence at least every five years. For this review, you must provide any information that is reasonably required. 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.

Your responsibilities

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

You should be familiar with the details of the licences for projects you are working on, including objectives, plans of work and protocols. You must only perform regulated procedures with the permission and in full knowledge of the project licence holder. You should also understand the tasks the project licence holder asks you to perform, including any endpoints you need to apply.

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.

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.

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

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;
- 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;
- telling the project licence holder immediately if you think that the severity limit of a protocol has been, or is likely to be, exceeded;
- getting and following veterinary advice and treatment, where needed;

- arranging for the care and welfare of an animal when you are away;
- making sure that any animal that is in severe pain or severe distress, which you cannot alleviate, is painlessly killed using an appropriate method.

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

To ensure that regulated procedures are performed competently, you should 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 or her, until the project licence holder and NTCO where you are working are satisfied you have achieved competence.

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.

Your records should be retained for at least five years and should be available to the NCTO and project licence holder(s) where you work and, on request, to our inspectors.

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.

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 authorities

You can delegate to assistants, who do not themselves possess the requisite personal licence authority but are under your control, the delegable tasks which form an integral part of the regulated procedures that you are authorised to perform. The tasks must not require technical knowledge or skill. Any delegation must be in accordance with any relevant guidance we have published under section 21 of the Act.

Any assistant must be trained, instructed and supervised.

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 if 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.

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

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.

We have to reissue your licence before any amendments can come into force.

We can suspend your licence if this seems necessary urgently 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.

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

We may revoke 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;
- 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; or
- at your request.

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 below.

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

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.

Project licence holders

What is a project licence?

A project licence authorises you, the holder, to perform specific regulated procedures on specific animals at a specific place or places.

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

Only one person may hold a project licence. We do not grant project licences to numbers of individuals, to organisations or research groups.

How to apply for a project licence

You may find it helpful, at an early stage, to discuss your proposed application or amendment with the inspector assigned to your establishment. You must also consult the NVS and the NACWO. You should be aware that it may take you some time to prepare your complete application, especially if it describes a novel or complex programme 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 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 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 which may relate to your proposal and will consider, amongst other things, how 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.

We will not commence assessment until a complete and correct application 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.

Application forms are available from the Home Office website. You should send your completed application to the relevant ASRU regional office dealing with the main establishment where you will be working (see the 'How to contact us' section of this Guide). We currently offer the CJSM system to enable you to also submit your application in encrypted electronic format.

How we notify you about your application

We will acknowledge receipt of your application when we receive it. If your application is incomplete or incorrect, we will tell you as soon as we can with advice as to what you should do to complete and correct it.

Within 40 days of receiving your complete and correct application we will either grant your project licence or let you know that your application has been refused. For complex programmes of work we may extend this period by up to 15 working days. If we are extending the period, we will let you know.

What does a project licence cover?

A project licence covers a single programme of work. It:

- describes the programme;
- states the objectives;
- specifies where the work will take place;
- details the experimental or other scientific protocols you must follow;
- specifies the regulated procedures you may apply within each protocol;
- describes the number and species of animals you may use;
- describes the predicted benefits of the programme;
- identifies the likely adverse effects (harms) and how you can avoid, recognise and alleviate them;
- assigns a severity class to each protocol;
- is accompanied by a project summary written in non-technical terms.

For example

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.

Note that you will be in breach of the Act if you carry out the regulated procedures in the licence for something outside your programme of work.

Where the work takes place

Most of the work will be carried out at a licensed establishment. In the licence this is called 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 non-designated place, for example at a field site. These are called POLEs (places other than licensed establishments). 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.

How long does a project licence last?

A project licence lasts for up to five years. You must apply for a new licence if the work continues longer than this.

If your project licence was granted for less than five years you can extend it to five years from the original date of issue, if we agree.

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 allows work in progress to be completed or a new licence to be obtained.

Your responsibilities

As the project licence holder you are responsible for complying with the conditions of the licence and conducting the programme of work it specifies.

You direct and manage all the personal licensees working on the project.

You must ensure that:

- the programme of work is strictly followed;
- the severity controls of each protocol are implemented effectively;
- severity conditions are met;
- 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.

Keeping records

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

They should include:

- the names of the personal licence holders performing procedures authorised by the licence;
- details of the procedures and protocols you 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;
- from 1 January 2014, the actual severity of the series of procedures applied to the animal or, in the case of animals that are re-used, the severity of each procedure or series of procedures;
- copies of any veterinary or other certification and advice you have received.

Annual statistical returns

You are responsible for supplying data to the Home Office on the procedures you start during the year (from 1 January 2014, this will apply to procedures you complete during the year).

This information must be provided by 31 January each year on the 'return of procedures' form.

We issue code lists and explanatory notes annually to help you complete the form. These code lists will change significantly for reporting procedures completed after 1 January 2014 – we will be providing further guidance in early 2013.

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.

Your training

You must have completed the relevant training for project licence holders before applying for your licence. At present this means UK modules 1, 2 and 5. However, the numbering of modules is likely to change during 2013 to comply with EU modules. We will provide further guidance.

You must also have completed UK modules 3 and 4 if you need the particular skills included in these modules to carry out the procedures specified in your project licence.

In most cases you will already be a personal licence holder and so you will only need to complete UK module 5 before applying for a project licence. You should also have relevant knowledge of the species you propose to use in your project licence. Your establishment NTCO will be able to advise you.

What are ‘permissible purposes’?

Permissible purposes are:

- basic research;
- translational or applied research which aims to:
 - avoid, prevent, diagnose or treat disease, ill-health or an abnormality, or their effects, in man, animals or plants;
 - assess, detect, regulate or modify physiological conditions in man, animals or plants; or
 - improve the welfare of animals or the production conditions of animals reared for agriculture;
- the development, manufacture or testing of the quality, effectiveness and safety of drugs, food, animal feed, or any other substances or products with one of the above aims;
- the protection of the natural environment in the interests of the health or welfare of man or animals;
- research aiming to preserve the species of animal subjected to regulated procedures as part of the programme of work;
- higher education or training to gain, maintain or improve vocational skills;
- forensic enquiries.

We will only grant a project licence if we are satisfied that your programme of work is for one or more of these permissible purposes.

Assessing costs and benefits

Before granting a project licence, we have to weigh up 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.

Even if the benefits outweigh the costs we may not grant a project licence.

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

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 taken every reasonable effort to incorporate 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.

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 (see the section on Severity classification in this Guide for examples of procedures which might be considered *severe*).

We must be satisfied that you are using best practice 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.

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.

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.

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

Restrictions on programmes of work

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.

Use of primates (including endangered primates)

We will grant a project licence for a programme of work using primates only if:

- the work is to be carried out for:
 - a) basic research (only if the primate species is non-endangered);
 - b) avoiding, preventing, diagnosing or treating debilitating or potentially life-threatening clinical conditions in man; or
 - c) any of the aims in b) during the development, manufacture or testing of substances such as drugs;
 - d) research aimed at preserving the species of primate being used.

You must be able to justify why the purpose of the work cannot be achieved by using any other species, and if the work involves an endangered species, why the purpose cannot be achieved using a non-endangered species.

Endangered species (other than primates)

We impose more stringent controls for using any endangered species, all of which cannot be used in basic research. Hence we will grant a project licence for such work only if:

- the work is to be carried out for:
 - a) avoiding, preventing, diagnosing or treating disease, ill-health or an abnormality, or their effects, in man; or
 - b) any of the aims in a) during the development, manufacture or testing of substances such as drugs;
 - c) research aimed at preserving the endangered species being used.

You must be able to justify why the purpose of the work cannot be achieved by using a non-endangered species.

Cats, dogs and the horse family (equidae)

We will not generally grant licences for work using cats, dogs and members of the horse family (horses, donkeys, mules etc.). We will only do so if we are satisfied that the aim of the work cannot be achieved without doing so, or that it is not practicable to obtain animals of another suitable species.

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 only 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.

You can find more details in the ‘Severity Categories’ section of this Guide.

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:

- type of species and genotype;
- 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. 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.

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.

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

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.

A licence is revoked on its expiry date. We may 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.

You have the right to make representations to us, unless your licence is being varied or revoked at your own request.

Standard conditions for project licences

We grant project licences subject to standard conditions. These are set out below.

Sometimes we may include additional conditions, for example:

- to ask you for a report after introducing a novel procedure;
- to allow you to use animals listed in Schedule 2 but that come from a non-designated source.

Conditions in project licences

1. The licence holder is responsible for the overall implementation of the programme 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:
 - (a) any feral animal of a domestic species;
 - (b) any animal taken from the wild;

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

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

14. If the application of regulated procedures to animals taken from the wild is authorised in this licence the holder shall ensure:
 - (a) 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
 - (b) 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.
15. 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.
16. 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.
17. All authorised procedures shall be carried out under general or local anaesthesia unless:
 - (a) anaesthesia would be more traumatic to the animal concerned than the procedures themselves; or
 - (b) anaesthesia would be incompatible with the purposes of the procedures.
18. 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.
19. 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.

20. 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.
21. 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.
22. The project licence holder shall submit such other reports as the Secretary of State may from time to time require.
23. 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:
 - (a) all personal licensees performing those procedures;
 - (b) the named person responsible for compliance;
 - (c) the named animal care and welfare officers responsible for the day to day care of the animals;
 - (d) the named veterinary surgeon, on request; and
 - (e) the named information officer and named training and competency officer, on request.
24. The licence holder must obtain the permission of the Secretary of State before:
 - (a) 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
 - (b) any animal is released for slaughter, unless this is already explicitly authorised by the project licence.
25. The licence remains the property of the Secretary of State, and shall be surrendered to him on request.

Severity categories

This section describes the severity categories. It gives examples of various procedures under each category.

You can find details of how we apply the severity categories in the section for project licence holders.

Non-recovery

All procedures are performed under general anaesthesia and the animal will not recover consciousness.

Mild

Procedures cause an animal to experience short-term mild pain, suffering or distress. This category also includes procedures which cause no significant impairment to the animal's wellbeing or general condition.

Procedures that could produce greater suffering may be classified as mild if there are effective safeguards in place to treat the animal or stop the procedure before the animal shows more than adverse minor effects.

Examples of different types of procedure that would be classified as mild are:

- administering anesthesia except for the sole purpose of killing;
- pharmacokinetic study where a single dose is administered and a limited number of blood samples are taken (totaling < 10 % of circulating volume) and the substance is not expected to cause any detectable adverse effect;
- non-invasive imaging of animals (e.g. MRI) with appropriate sedation or anaesthesia;
- superficial procedures, e.g. ear and tail biopsies, non-surgical subcutaneous implantation of mini-pumps and transponders;
- applying external telemetry devices that cause only minor impairment to the animals or minor interference with normal activity and behaviour;
- administering substances by subcutaneous, intramuscular, intraperitoneal routes, gavage and intravenously via superficial blood vessels, where the substance has no more than a mild impact on the animal, and the volumes are within appropriate limits for the size and species of the animal;
- inducing tumours, or spontaneous tumours, that cause no detectable clinical adverse effects (e.g. small, subcutaneous, non-invasive nodules);
- breeding of genetically altered animals, which is expected to result in a phenotype with mild effects;
- feeding of modified diets, that do not meet all of the animal's nutritional needs and are expected to cause mild clinical abnormality within the timescale of the study;
- short-term (<24h) restraint in metabolic cages;
- studies involving short-term deprivation of social partners, short-term solitary caging of adult rats or mice of sociable strains;

- models which expose animals to noxious stimuli which are briefly associated with mild pain, suffering or distress, and which the animals can successfully avoid;
- a combination or accumulation of the following examples may result in a 'mild' classification:
 - assessing body composition by non-invasive measures and with minimal restraint;
 - monitoring ECG with non-invasive techniques with minimal or no restraint of habituated animals;
 - applying external telemetry devices that are expected to cause no impairment to socially adapted animals and do not interfere with normal activity and behaviour;
 - breeding genetically altered animals which are expected to have no clinically detectable adverse phenotype;
 - adding inert markers in the diet to follow passage of digesta;
 - withdrawal of food for <24h in adult rats;
 - open field testing.

Moderate

Procedures where animals are likely to experience short-term moderate pain, suffering or distress, or long-lasting mild pain, suffering or distress. This category also includes procedures that are likely to cause moderate impairment of the animal's wellbeing or general condition.

Examples of different types of procedure that would be classified as moderate are:

- frequent application of test substances which produce moderate clinical effects, and withdrawal of blood samples (>10 % of circulating volume) in a conscious animal within a few days without volume replacement;
- acute dose-range finding studies, chronic toxicity/carcinogenicity tests, with non-lethal end-points;
- surgery under general anaesthesia and appropriate analgesia, associated with post-surgical pain, suffering or impairment of general condition. Some examples are: thoracotomy, craniotomy, laparotomy, orchidectomy, lymphadenectomy, thyroidectomy, orthopaedic surgery with effective stabilisation and wound management, organ transplantation with effective management of rejection, surgical implantation of catheters, or biomedical devices (e.g. telemetry transmitters, minipumps etc.);
- models of induction of tumours, or spontaneous tumours, that are expected to cause moderate pain or distress or moderate interference with normal behaviour;
- irradiation or chemotherapy with a sub-lethal dose, or with an otherwise lethal dose but with reconstitution of the immune system. Adverse effects would be expected to be mild or moderate and would be short-lived (<5 days);
- breeding of genetically altered animals which are expected to result in a phenotype with moderate effects;
- creation of genetically altered animals through surgical procedures;

- use of metabolic cages involving moderate restriction of movement over a prolonged period (up to 5 days);
- studies with modified diets that do not meet all of the animal's nutritional needs and are expected to cause moderate clinical abnormality within the time-scale of the study;
- withdrawal of food for 48 hours in adult rats;
- evoking escape and avoidance reactions where the animal is unable to escape or avoid the stimulus, and are expected to result in moderate distress.

Severe

Procedures where the animal is likely to experience severe pain, suffering or distress, or long-lasting moderate pain, suffering or distress. This category also includes procedures that are likely to cause severe impairment of the animal's wellbeing or general condition.

Examples of different types of procedure that would be classified as severe are:

- toxicity testing where death is the end-point, or fatalities are to be expected and severe pathophysiological states are induced – e.g. single dose acute toxicity testing (see OECD testing guidelines);
- testing of a device where failure may cause severe pain, distress or death of the animal (e.g. cardiac assist devices);
- vaccine potency testing characterised by persistent impairment of the animal's condition, progressive disease leading to death, associated with long-lasting moderate pain, distress or suffering;
- irradiation or chemotherapy with a lethal dose without reconstitution of the immune system, or reconstitution with production of graft versus host disease;
- models with induction of tumours, or with spontaneous tumours, that are expected to cause progressive lethal disease associated with long-lasting moderate pain, distress or suffering – for example tumours causing cachexia, invasive bone tumours, tumours resulting in metastatic spread, and tumours that are allowed to ulcerate;
- surgical and other interventions in animals under general anaesthesia which are expected to result in severe or persistent moderate postoperative pain, suffering or distress or severe and persistent impairment of the general condition of the animals. Production of unstable fractures, thoracotomy without adequate analgesia, or trauma to produce multiple organ failure;
- organ transplantation where organ rejection is likely to lead to severe distress or impairment of the general condition of the animals (e.g. xenotransplantation);
- breeding animals with genetic disorders that are expected to experience severe and persistent impairment of general condition, e.g. Huntington's disease, muscular dystrophy, chronic relapsing neuritis models;
- use of metabolic cages involving severe restriction of movement over a prolonged period;
- inescapable electric shock (e.g. to produce learned helplessness);

- complete isolation for prolonged periods of social species e.g. dogs and non-human primates;
- immobilisation stress to induce gastric ulcers or cardiac failure in rats;
- forced swim or exercise tests with exhaustion as the end-point.

Humane killing of protected animals

From 1 January 2013 there will be additional controls on the killing of protected animals. This section of the guide is intended to help you to identify the controls that apply and to determine whether killing an animal is a regulated procedure. You should familiarise yourself with section 15A and section 2(7) of new ASPA.

How does new ASPA regulate the killing of animals?

New section 15A 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.

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 on the register, kept 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 defined in section 15A as “appropriate” for the 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.

When is killing an animal a regulated procedure?

Under section 2(7) killing a relevant protected animal by an appropriate Schedule 1 method or a method specified in the establishment licence is not a regulated procedure (a and b above).

In all other cases the method of killing is a regulated procedure and you will need project and personal licence authorities (c, d and e above).

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)?

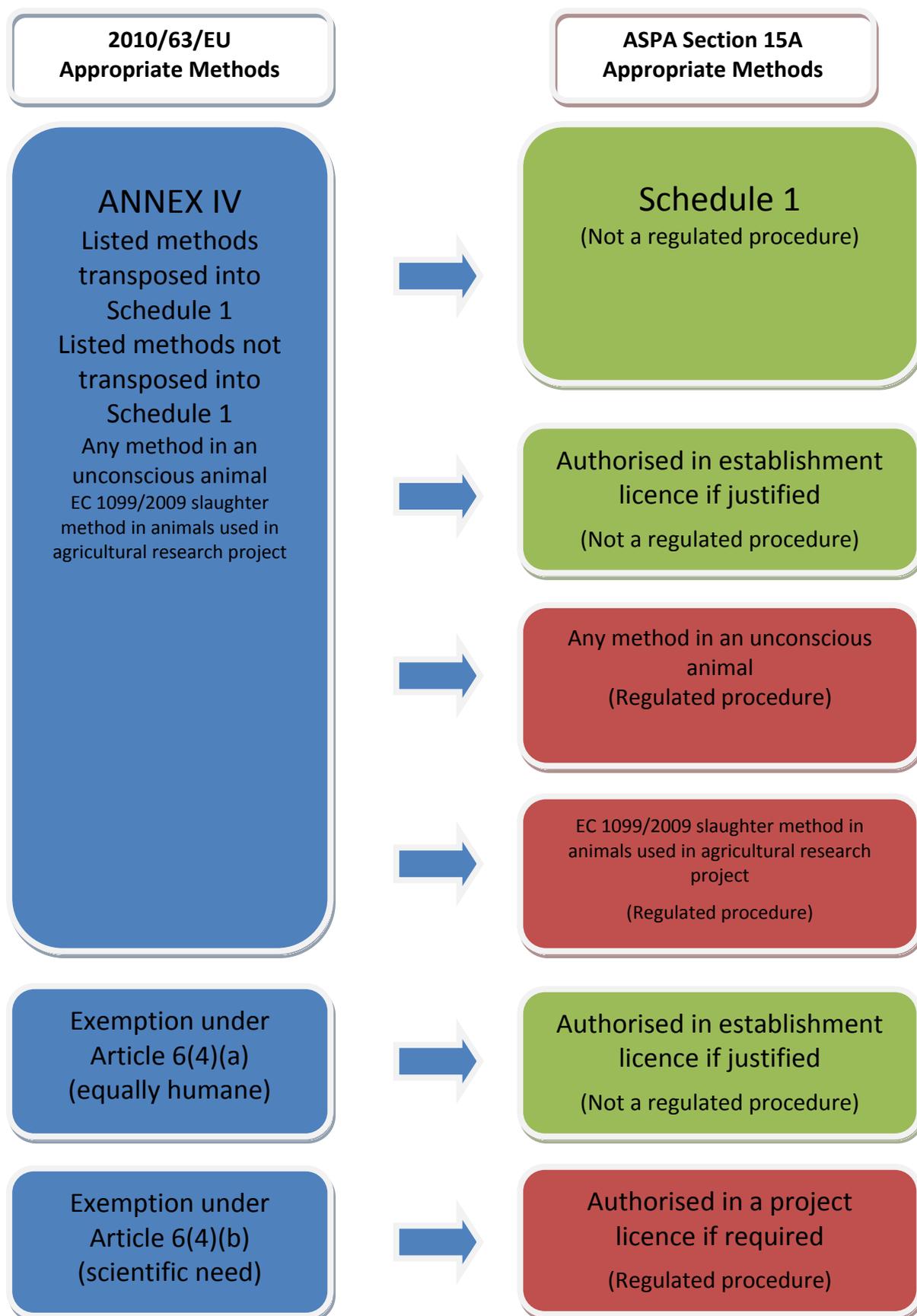
Section 15A applies equally to animals killed at POLEs except in the case where an animal is being killed for scientific use of its tissues or organs, which is outside the scope of the Act.

If you intend to kill an animal at a POLE for other scientific reasons 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).

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

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



Codes of practice on care and accommodation

During 2013 we will be consulting on, and then issuing, a single code of practice on care and accommodation covering users, breeders and suppliers.

Until that time you should familiarise yourself with Annex III of the Directive (2010/63/EU). This covers requirements for establishments and for the care and accommodation of animals.

Annex III is split into two sections:

Section A describes general requirements and is mandatory for all establishments with effect from 1 January 2013.

Section B describes the requirements for specific species of animals. The text relating to each species of this section is also mandatory from 1 January 2013.

However the tables in Section B (including their footnotes, and any text referring specifically to the tables) will not become mandatory until 1 January 2017.

Before that date the tables in the existing UK codes of practice for users, breeders and suppliers will still apply.

The text of the existing codes of practice acts as general guidance and will still apply where it does not conflict with the text in Annex III.