

1 **Draft guidance on the Operation of the Animals**  
2 **(Scientific Procedures) Act 1986 (as amended)**  
3

1

2 **Table of contents**

3 **Table of contents**..... 2

4 **Foreword**..... 6

5 Changes to the Animals (Scientific Procedures) Act 1986.....6

6 What this guidance covers.....6

7 What this guidance replaces.....6

8 Who this guidance is for .....6

9 How the guidance is arranged .....6

10 How to submit applications .....7

11 Where to go for more information .....7

12 **Glossary of terms** ..... 8

13 **Background to the Animals (Scientific Procedures) Act 1986 (ASPA)**..... 10

14 What does ASPA cover?.....10

15 What licences are required? .....10

16 Who issues licences?.....10

17 What is a protected animal?.....11

18 Definition of 'living' .....11

19 What is a regulated procedure? .....11

20 Permissible purposes .....12

21 Procedures that may also be regulated.....12

22 What procedures are not regulated? .....13

23 **The 3Rs and choice of methods** ..... 15

24 The principles of replacement, reduction and refinement (the 3Rs).....15

25 How should the 3Rs be applied? .....15

26 Death as an end-point.....16

27 Overbreeding .....16

28 Data sharing .....16

29 Thematic reviews of the 3Rs.....16

30 **Establishment licences** ..... 18

31 What does an establishment licence cover? .....18

32 What must an establishment licence include? .....18

33 Who can hold an establishment licence? .....18

34 What training do I need to complete?.....19

35 How long will my establishment licence last? .....19

36 Death or departure of an establishment licence holder .....19

37 Before you apply for a new or amended establishment licence.....19

38 Named people.....20

39 Schedule of premises .....20

40 Installations and equipment .....21

41 How quickly will my application be decided? .....21

42 How we will assess your application for an establishment licence.....21

1	Your responsibilities as establishment licence holder.....	21
2	Amending your establishment licence .....	29
3	What happens if your establishment licence is varied, revoked or suspended? .....	30
4	Your right to make representations.....	30
5	Standard conditions for establishment licences.....	30
6	<b>Personal licences .....</b>	<b>31</b>
7	What does a personal licence cover? .....	31
8	Who can hold a personal licence? .....	31
9	What training do I need to complete?.....	31
10	How long will my personal licence last? .....	32
11	Death or departure of a personal licence holder .....	32
12	Before you apply for a personal licence .....	32
13	What information is needed in a personal licence application? .....	32
14	What is covered by the different categories of personal licence? .....	32
15	Where can I use my personal licence? .....	33
16	Which project licences can I work on? .....	33
17	How quickly will my application be decided? .....	33
18	How we will assess your application for a personal licence.....	34
19	Your responsibilities.....	34
20	Conflicts of interest.....	37
21	Amending your personal licence .....	37
22	Suspending your personal licence .....	37
23	Revoking or varying your personal licence .....	37
24	Your right to make representations.....	37
25	Standard conditions for personal licences.....	38
26	<b>Project licences.....</b>	<b>39</b>
27	What does a project licence cover?.....	39
28	Who can hold a project licence?.....	39
29	What training do I need to complete?.....	39
30	How long does a project licence last? .....	39
31	Death or departure of a project licence holder.....	39
32	Preparing your project licence application.....	40
33	What information is needed in a project licence application?.....	40
34	How quickly will my application be decided?.....	43
35	How we will assess your application for a project licence .....	43
36	Permissible purposes .....	44
37	Multiple generic projects .....	44
38	Assessing costs and benefits.....	45
39	Applying the 3Rs in your project.....	45
40	When will applications be referred to the Animals in Science Committee?.....	47
41	External assessors .....	47
42	Retrospective assessment .....	47
43	Restrictions on programmes of work .....	48
44	How we determine the severity category .....	51
45	Severity conditions on your licence .....	52
46	Use and re-use of protected animals.....	53
47	End of the procedure .....	53

1	Capturing animals from the wild .....	54
2	Release into the wild.....	54
3	Re-homing.....	54
4	Your responsibilities as project licence holder .....	55
5	Conflicts of interest.....	57
6	Amending your project licence .....	57
7	Suspending your project licence.....	58
8	Revoking or varying your project licence.....	58
9	Your right to make representations.....	58
10	Standard conditions for project licences .....	58
11	<b>Severity categories .....</b>	<b>60</b>
12	Severity classification of procedures before work starts .....	60
13	How are the severity categories defined? .....	60
14	The criteria for assigning the severity category.....	60
15	Reporting on actual severity.....	61
16	Enforcement of severity limits.....	61
17	Prohibition on severe pain, suffering or distress that cannot be ameliorated .....	62
18	<b>Humane killing of protected animals .....</b>	<b>63</b>
19	How is the killing of animals regulated? .....	63
20	When is killing an animal a regulated procedure? .....	63
21	Is the animal a “relevant protected animal”?.....	63
22	What are the requirements regarding competence?.....	63
23	What methods are permitted? .....	64
24	Can I use a method of killing specified in an establishment licence to kill animals for	
25	scientific purposes? .....	64
26	Do the regulations apply to animals killed at places other than licensed establishments	
27	(POLEs)? .....	64
28	Animals (Scientific Procedures) Act 1986 – Methods of Humane Killing .....	65
29	<b>Care and accommodation of protected animals .....</b>	<b>66</b>
30	What does ASPA require? .....	66
31	What standards apply? .....	66
32	When do the standards have to be implemented?.....	66
33	Can I apply for an exemption from the requirements?.....	67
34	Where can I get more detailed advice on the housing and care of animals? .....	67
35	<b>Named people .....</b>	<b>68</b>
36	Named Animal Care & Welfare Officer (NACWO) .....	68
37	Named Veterinary Surgeon (NVS) .....	69
38	Named Information Officer (NIO).....	71
39	Named Training and Competency Officer .....	72
40	Named Compliance Officer .....	72
41	<b>Animal Welfare and Ethical Review bodies (AWERBs) .....</b>	<b>73</b>
42	Membership.....	73
43	Role .....	73
44	Record keeping .....	74
45	<b>Non-compliance .....</b>	<b>75</b>
46	What is non-compliance? .....	75
47	Reporting non-compliance .....	75

1	Offences .....	75
2	How we will deal with non-compliance .....	76
3	Criminal sanctions .....	77
4	Administrative sanctions .....	77
5	Compliance notices .....	77
6	Revoking, suspending or varying (amending) licences .....	77
7	Severity of non-compliance .....	78
8	What can I do to avoid non-compliance? .....	78
9	Compliance advice .....	79
10	<b>About Home Office inspections .....</b>	<b>80</b>
11	What do inspectors do and why? .....	80
12	What other powers does an inspector have?.....	80
13	What qualifications do inspectors have?.....	80
14	How often do inspectors visit establishments?.....	80
15	What happens during an inspection?.....	81
16	Encouraging good practice .....	82
17	EU inspections.....	82
18	<b>The Animals in Science Committee .....</b>	<b>83</b>
19	Contact details .....	83
20	<b>Other advisers to the Secretary of State .....</b>	<b>84</b>
21	External assessors .....	84
22	People who consider representations .....	84
23	<b>Other issues.....</b>	<b>85</b>
24	Preventing public displays .....	85
25	Training .....	85
26	Annual statistics .....	86
27	Other relevant legislation .....	86
28	<b>Annex A: Standard conditions for establishment licences.....</b>	<b>87</b>
29	<b>Annex B: Standard conditions in personal licences .....</b>	<b>94</b>
30	<b>Annex C: Standard conditions in project licences.....</b>	<b>97</b>
31		
32		

1

## 2 **Foreword**

### 3 **Changes to the Animals (Scientific Procedures) Act 1986**

4 The Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 (SI  
5 2012/3039) amend the Animals (Scientific Procedures) Act 1986 to transpose  
6 European Directive 2010/63/EU on the protection of animals used for scientific  
7 purposes. Directive 2010/63/EU sets out revised measures for the protection of  
8 animals used for scientific purposes.

### 9 **What this guidance covers**

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

### 15 **What this guidance replaces**

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

### 18 **Who this guidance is for**

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

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

28

### 29 **How the guidance is arranged**

30 The first section sets out the background to the Animals (Scientific Procedures) Act  
31 1986 (ASPA).

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

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

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

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

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

## 10 **How to submit applications**

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

## 13 **Where to go for more information**

14 General enquiries about this guidance and the Animals (Scientific Procedures) Act  
15 1986 should be sent to our central email address (aspd-brp@homeoffice.gsi.gov.uk)  
16 where they will be dealt with and a response sent as soon as practicable.

17

## 1 **Glossary of terms**

2	<b>ASPA</b>	The Animals (Scientific Procedures) Act 1986. ASPA in this
3		guidance means the consolidated amended version of the Act
4		incorporating changes brought in by the European Directive
5		(2010/63/EU) on the protection of animals used for scientific
6		purposes.
7	<b>AWERB</b>	Animal welfare and ethical review body
8	<b>Breeder</b>	An establishment which breeds animals for use in procedures
9	<b>establishment</b>	
10	<b>Commission</b>	European Commission
11	<b>ERP</b>	Ethical Review Process
12	<b>EU</b>	European Union
13	<b>EU Directive</b>	European Directive on the protection of animals used for
14		scientific purposes (2010/63/EU)
15	<b>IAT</b>	Institute of Animal Technology
16	<b>Member State</b>	Member of the European Union
17	<b>NACWO</b>	Named Animal Care and Welfare Officer
18	<b>NCO</b>	Named Compliance Officer
19	<b>NIO</b>	Named Information Officer
20	<b>NTCO</b>	Named Training and Competence Officer
21	<b>NVS</b>	Named Veterinary Surgeon (or other suitably qualified expert
22		where more appropriate and agreed)
23	<b>Pain, suffering,</b>	This includes anything that affects the animal's physical, mental
24	<b>distress and</b>	and social wellbeing. It includes disease, injury and physiological
25	<b>lasting harm</b>	or psychological discomfort, whether immediately (such as at the
26		time of an injection) or in the longer term (such as the
27		consequences of applying a carcinogen).
28	<b>PEL</b>	Establishment licence (formerly PCD – Procedure Certificate of
29		Designation)
30	<b>PIL</b>	Personal licence (Procedure Individual Licence)



1	<b>PPL</b>	Project licence (Procedure Project Licence)
2	<b>POLE</b>	Place other than a licensed establishment
3	<b>Primate</b>	Non-human primate
4	<b>Procedure</b>	A procedure which is regulated under ASPA – see page 11
5	<b>Protected animal</b>	All living vertebrates, other than man, and any living cephalopod
6		in addition to some immature forms – see page 11
7	<b>RCVS</b>	Royal College of Veterinary Surgeons
8	<b>Section 2C</b>	
9	<b>licence</b>	Establishment licence
10	<b>Self-sustaining</b>	A 'self-sustaining colony' is one kept in a way that ensures the
11	<b>colony</b>	animals (primates) are accustomed to humans and which
12		consists only of animals that have been bred in captivity, either
13		within the colony or in another self-sustaining colony.
14	<b>Supplier</b>	An establishment which supplies animals for use in procedures
15	<b>establishment</b>	
16	<b>User</b>	An establishment which uses animals in procedures
17	<b>establishment</b>	
18		

## 1 **Background to the Animals (Scientific Procedures) Act 1986** 2 **(ASPA)**

### 3 **What does ASPA cover?**

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

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

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

### 13 **What licences are required?**

14 ASPA has a three-level licensing system:

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

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

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

### 25 **Who issues licences?**

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

1 **What is a protected animal?**

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

5 ***Embryonic and foetal forms of mammals, birds and reptiles***

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

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

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

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

21 **Definition of 'living'**

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

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

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

28 **What is a regulated procedure?**

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

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

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

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

### 3 **Permissible purposes**

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

5 a) basic research;

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

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

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

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

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

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

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

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

22 g) forensic inquiries.

### 23 **Procedures that may also be regulated**

24 Procedures may also be regulated under ASPA if they are:

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

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

1 Procedures which are regulated include:

- 2 • *modifying the genes of a protected animal* if this causes the animal pain,  
3 suffering, distress or lasting harm; for example, breeding animals with  
4 harmful genetic defects is a regulated procedure if you intend to keep the  
5 animals produced beyond two-thirds of the way through their gestation or  
6 incubation period;
- 7 • *those performed under general anaesthesia* if the effect on a normal  
8 conscious animal would be to cause pain, suffering distress or lasting harm;
- 9 • *administering an anaesthetic, an analgesic or other measure* to sedate or  
10 dull the perception of pain in a protected animal;
- 11 • *humane killing of a protected animal* if it is killed at a licensed establishment  
12 other than by either a method described as appropriate in Schedule 1 or a  
13 method specified on your establishment licence (see the section on Humane  
14 killing in this guidance);
- 15 • *removing organs, blood or other tissue* under general anaesthesia even if  
16 the animal is not allowed to recover consciousness.

17 **What procedures are not regulated?**

18 These are not regulated procedures.

- 19 • *Non-experimental clinical veterinary practices*: You should consult the Royal  
20 College of Veterinary Surgeons (RCVS) on what constitutes non-  
21 experimental clinical veterinary practices and the related professional  
22 standards. The clinical investigation and management of the health or  
23 welfare of animals is generally considered to be non-experimental clinical  
24 veterinary practice when it involves an intervention which is of direct benefit  
25 to the animal or its immediate peer group. See the RCVS website for further  
26 guidance.
- 27 • *Veterinary clinical trials*: Administration of substances as part of veterinary  
28 clinical trials needed for the marketing authorisation of a veterinary medicinal  
29 product are not regulated procedures. However, if you propose to carry out  
30 procedures which are likely to cross the lower threshold and go beyond the  
31 administration of a substance in accordance with an animal test certificate  
32 under the Veterinary Medical Regulations 2011, you should consult the  
33 RCVS to determine if the procedures constitute non-experimental clinical  
34 veterinary practices.
- 35 • *Non-experimental agricultural practices and practices undertaken for the*  
36 *purpose of recognised animal husbandry*: These are not regulated  
37 procedures as long as they comply with other animal welfare legislation and  
38 regulations and are being used to manage or conserve animals. *They are*  
39 *regulated if they are part of a scientific study.*

- 1       •     *Identifying animals:* Ringing, tagging or marking an animal primarily to  
2 identify it, or using any other humane way to do so, are not regulated  
3 procedures if they cause no more than momentary pain and no lasting harm.  
4 For example, micro-chipping or ear-marking a rodent is not a regulated  
5 procedure if it is being done primarily to identify the animal. *Blood sampling*  
6 *or DNA sampling using a method likely to cross the lower threshold of pain,*  
7 *suffering, distress or lasting harm are not methods used to identify an animal*  
8 *and would therefore be regulated.*
- 9       •     *Humane killing of animals:* Killing a protected animal in a licensed  
10 establishment by an appropriate humane method listed in Schedule 1, or by  
11 a method specified in that establishment's licence, is not a regulated  
12 procedure. This is still the case if the killing is to provide material for scientific  
13 use (see the section on Humane killing in this guidance). A copy of Schedule  
14 1 detailing approved methods of humane killing is available in the  
15 consolidated version of ASPA on the [Home Office website](#).
- 16

## 1 The 3Rs and choice of methods

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

3 For the purposes of ASPA [section 2A]:

- 4 • *Replacement* is the principle that, wherever possible, a scientifically  
5 satisfactory method or testing strategy not entailing the use of protected  
6 animals must be used instead of a regulated procedure;
- 7 • *Reduction* is the principle that whenever a programme of work involving the  
8 use of protected animals is carried out the number of protected animals used  
9 must be reduced to a minimum without compromising the objectives of the  
10 programme;
- 11 • *Refinement* is the principle that the breeding, accommodation and care of  
12 protected animals and the methods used in regulated procedures applied to  
13 such animals must be refined so as to eliminate or reduce to the minimum  
14 any possible pain, suffering, distress or lasting harm to those animals.

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

### 17 How should the 3Rs be applied?

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

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

- 22 • use the minimum number of animals;
- 23 • involve animals with the lowest capacity to experience pain, suffering,  
24 distress or lasting harm;
- 25 • cause the least pain, suffering, distress or lasting harm; and
- 26 • are most likely to produce satisfactory scientific results. [**Project licence**  
27 **standard condition 4**]

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

## 1 **Death as an end-point**

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

## 4 **Overbreeding**

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

7 You should minimise overbreeding as far as possible by:

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

19 Your AWERB should:

- 20 • raise awareness of overbreeding;
- 21 • devise policies and controls to minimise surpluses;
- 22 • coordinate and rationalise users' needs, animal production and breeding  
23 facilities.

## 24 **Data sharing**

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

## 28 **Thematic reviews of the 3Rs**

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



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

7

## 1 **Establishment licences**

### 2 **What does an establishment licence cover?**

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

- 6 a) applying regulated procedures to protected animals (a *user establishment*);
- 7 b) breeding protected animals listed in ASPA Schedule 2 with a view to (i) their use  
8 in regulated procedures, or (ii) the use of their tissues or organs for scientific  
9 purposes (a *breeding establishment*);
- 10 c) breeding other animals (not listed in ASPA Schedule 2) primarily for the same  
11 purposes (also a *breeding establishment*);
- 12 d) the keeping of Schedule 2 animals which have been bred elsewhere and are to  
13 be supplied with a view to (i) their use elsewhere in regulated procedures, or (ii)  
14 the use elsewhere of their tissues or organs for scientific purposes (a *supplying*  
15 *establishment*).

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

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

### 20 **What must an establishment licence include?**

21 An establishment licence must include:

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

### 25 **Who can hold an establishment licence?**

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

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

#### 4 **What training do I need to complete?**

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

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

#### 11 **How long will my establishment licence last?**

12 An establishment licence remains in force until it is revoked.

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

#### 15 **Death or departure of an establishment licence holder**

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

#### 23 **Before you apply for a new or amended establishment licence**

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

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

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

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

## 1 **Named people**

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

- 4 • ensuring that the requirements of ASPA and conditions of the licence are  
5 complied with – *the Named Compliance Officer (NCO)*. This will usually be  
6 the holder of the establishment licence;
- 7 • overseeing the welfare and care of the animals – the *Named Animal Care  
8 and Welfare Officer (NACWO)*;
- 9 • ensuring that those dealing with animals have access to any information they  
10 need about the species they are using – the *Named Information Officer  
11 (NIO)*;
- 12 • ensuring that those dealing with animals are adequately educated, trained  
13 and supervised until they are competent and that appropriate further training  
14 continues – the *Named Training and Competence Officer (NTCO)*.
- 15 • one or more *Named Veterinary Surgeons (NVS)* with expertise in laboratory  
16 animal medicine to advise on the health, welfare and treatment of the  
17 animals. Exceptionally, you may be able to nominate other suitably qualified  
18 experts where you can show that they are more appropriate for this role.

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

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

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

## 34 **Schedule of premises**

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

1 **Installations and equipment**

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

4 **How quickly will my application be decided?**

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

7 **How we will assess your application for an establishment licence**

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

10 **Your responsibilities as establishment licence holder**

11 Establishment licence holders have a number of responsibilities:

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

23 ***Leadership***

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

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

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

### 5 ***Compliance***

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

### 11 ***Preventing unauthorised procedures***

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

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

### 22 ***The 3Rs***

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

### 26 ***Staffing***

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

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

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

### 34 ***Animal welfare and ethical review body***

35 You must ensure that your establishment has an animal welfare and ethical review  
36 body (AWERB) complying with the requirements of paragraph 6 of ASPA Schedule  
37 2C. (See the 'Animal welfare and ethical review bodies' section of this guidance.)  
38 **[Standard condition 6]**

1 ***Performance and conduct of named people***

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

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

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

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

16 ***Conflicts of interest***

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

- 21 • financial interests such as directorships and significant shareholdings;
  - 22 • significant scientific interests in the outcome of a programme of work;
  - 23 • interests of close relations and/or friends which may be relevant, for example  
24 if a partner or sibling is a director or major shareholder of the establishment;
  - 25 • any other relevant matters.
- 26

27 A Declaration Form is available on [our website](#) and must be completed for each new  
28 NVS and NACWO and sent to us with your nomination form.

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

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

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

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

2 ***Animal care and accommodation***

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

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

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

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

31 ***Countersigning project licence applications***

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



1 ***Death or departure of a project licence holder***

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

7 ***Identifying animals***

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

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

16 You must therefore make sure that:

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

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

29 ***Keeping records***

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

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

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

1 Your records should contain the following details.

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

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

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

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

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

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

### 28 ***Individual history files***

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

31 These must contain:

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

39

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

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

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

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

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

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

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

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

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

### 21 ***Sourcing animals***

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

#### 24 *Which animals cannot be used?*

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

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

34 We have limited powers to allow exemptions:

- 1 • in the case of cats and dogs, we may only grant an exemption when you  
2 cannot obtain an animal suitable for your programme of work; we cannot  
3 authorise the use of stray cats and dogs and you may only use feral animals  
4 in exceptional circumstances;
- 5 • in the case of animals taken from the wild, we may only grant an exemption  
6 where there is scientific justification for doing so;
- 7 • in the case of endangered species, you may only use these animals in  
8 projects which aim to preserve that species or for essential biomedical  
9 purposes where the endangered species is the only one suitable.

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

#### 14 ***Breeding primates***

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

#### 20 ***Humane killing of animals***

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

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

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

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

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

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

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

#### 5 ***Disposing of animals***

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

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

#### 14 ***Paying fees***

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

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

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

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

#### 26 **Amending your establishment licence**

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

- 29 • the title of your establishment;
- 30 • the class of licensed activity;
- 31 • the named people;
- 32 • the list of approved areas;
- 33 • how you are using these areas;
- 34 • the animal welfare and ethical review body.

35

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

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

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

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

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

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

10

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

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

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

19 **Your right to make representations**

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

23 **Standard conditions for establishment licences**

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

26 Sometimes we may include additional conditions, for example:

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

31

1

## 2 **Personal licences**

### 3 **What does a personal licence cover?**

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

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

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

### 14 **Who can hold a personal licence?**

15 To become a personal licence holder you must:

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

20

### 21 **What training do I need to complete?**

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

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

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

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

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

### 3 **How long will my personal licence last?**

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

### 9 **Death or departure of a personal licence holder**

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

### 13 **Before you apply for a personal licence**

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

18 Application forms are available from the [Home Office website](#).

### 19 **What information is needed in a personal licence application?**

20 Your application must include:

- 21 • your personal information for identification;
  - 22 • details of the establishment where you will primarily be working;
  - 23 • the type(s) of animal(s) on which you wish to work;
  - 24 • the category(ies) of personal licence you are requesting;
  - 25 • copies of certificates of successful completion of formal accredited module  
26 training, as appropriate.
- 27

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

### 30 **What is covered by the different categories of personal licence?**

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

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



- 1 B. Minor/minimally invasive procedures involving sedation, analgesia or brief
- 2 general anaesthesia. Plus – surgical procedures conducted under brief
- 3 terminal general anaesthesia
- 4 C. Surgical procedures involving general anaesthesia
- 5 D. Use of neuromuscular blocking agents
- 6 E. Procedures conducted in accordance with a Project Licence
- 7 F. Other

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

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

## 12 **Where can I use my personal licence?**

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

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

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

## 23 **Which project licences can I work on?**

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

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

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

## 30 **How quickly will my application be decided?**

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

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

#### 4 **How we will assess your application for a personal licence**

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

#### 11 **Your responsibilities**

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

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

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

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

#### 23 ***Animal welfare***

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

26 You should act at all times in a manner that is consistent with the principles of the  
27 3Rs – replacement, reduction and refinement. **[Standard condition 1]**

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

- 29 • being responsible for the welfare of the animals you have performed  
30 procedures on and ensuring that they are properly monitored and cared for;  
31 **[Standard condition 2]**
- 32 • knowing the techniques and species involved, what the consequences of  
33 performing procedures on them will be and the signs of pain, suffering,  
34 distress or lasting harm in that species;

- 1 • taking precautions to prevent or reduce any pain, distress, or discomfort to  
2 the animal, including using sedatives, tranquillisers, analgesics or  
3 anaesthetics; **[Standard conditions 4 and 12]**
  
- 4 • telling the project licence holder immediately if you think that the severity  
5 limit of a protocol has been, or is likely to be, exceeded; **[Standard**  
6 **condition 13]**
  
- 7 • getting and following veterinary advice and treatment, where needed;  
8 **[Standard condition 15]**
  
- 9 • arranging for the care and welfare of an animal when you are away;  
10 **[Standard condition 14]**
  
- 11 • making sure that any animal that is in severe pain or severe distress, which  
12 you cannot alleviate, is painlessly killed using an appropriate method.  
13 **[Standard condition 8]**

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

#### 16 ***Supervision***

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

#### 22 ***Record keeping and cage labelling***

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

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

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

- 32 • the project licence number;
  - 33 • the protocol;
  - 34 • the date the protocol was started;
  - 35 • the responsible personal licensee. **[Standard condition 16]**
- 36

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

1 ***Delegating tasks***

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

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

10 For example you could use an assistant to:

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

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

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

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

## 1 **Conflicts of interest**

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

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

## 7 **Amending your personal licence**

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

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

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

## 17 **Suspending your personal licence**

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

## 21 **Revoking or varying your personal licence**

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

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

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

## 31 **Your right to make representations**

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

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

4 **Standard conditions for personal licences**

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

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

9

10

1

## 2 **Project licences**

### 3 **What does a project licence cover?**

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

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

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

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

### 17 **Who can hold a project licence?**

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

### 20 **What training do I need to complete?**

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

### 24 **How long does a project licence last?**

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

### 29 **Death or departure of a project licence holder**

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

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

### 3 **Preparing your project licence application**

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

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

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

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

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

26 Application forms and details of where to send them are available on the '[Research](#)  
27 [and testing using animals](#)' pages on the Home Office website.

### 28 **What information is needed in a project licence application?**

29 Your application must:

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



1 ***Incomplete or incorrect applications***

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

6 ***Programme of work***

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

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

15 ***Regulated procedures to be applied***

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

20 ***Description of the animals to be used***

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

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

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

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

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

34 Your application must explain, or provide details of:

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

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

12 ***Other information***

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

15 ***Project summary***

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

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

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

1 **How quickly will my application be decided?**

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

9 **How we will assess your application for a project licence**

10 The purpose of our evaluation is to verify that:

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

18 In carrying out the evaluation we must:

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

- 1           • use of other endangered species (ASPA Schedule 2B, para 3(3));
- 2           • use of feral animals (ASPA Schedule 2C, para 25 (2));
- 3           • use of wild-caught and purpose-bred animals (ASPA Schedule 2C para
- 4           25(3));
- 5           • assess whether carrying out the programme of work would give rise to any
- 6           scientific reason for an exemption under paragraph 11(5) of Schedule 2C
- 7           relating to the care and accommodation of animals;
  
- 8           • on the assumption that a project licence is granted in respect of the
- 9           programme of work, whether and (if so) when the programme should be
- 10          retrospectively assessed under section 5F.

## 11 **Permissible purposes**

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

- 14 a) basic research;
- 15 b) translational or applied research with one of the following aims:
  - 16           (i) the avoidance, prevention, diagnosis or treatment of disease, ill-health or
  - 17           other abnormality, or their effects, in man, animals or plants;
  - 18           (ii) the assessment, detection, regulation or modification of physiological
  - 19           conditions in man, animals or plants; or
  - 20           (iii) the improvement of the welfare of animals or of the production
  - 21           conditions for animals reared for agricultural purposes;
- 22 c) the development, manufacture or testing of the quality, effectiveness and safety
- 23       of drugs, foodstuffs and feed-stuffs or any other substances or products, with one
- 24       of the aims mentioned in paragraph (b);
- 25 d) the protection of the natural environment in the interests of the health or welfare
- 26       of man or animals;
- 27 e) research aimed at preserving the species of animal subjected to regulated
- 28       procedures as part of the programme of work;
- 29 f) higher education or training for the acquisition, maintenance or improvement of
- 30       vocational skills;
- 31 g) forensic inquiries.

## 32 **Multiple generic projects**

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

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

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

## 10 **Assessing costs and benefits**

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

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

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

## 22 **Applying the 3Rs in your project**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## 11 **External assessors**

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

17 For more information, see the 'Other advisers to the Secretary of State' section of  
18 this guidance.

## 19 **Retrospective assessment**

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

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

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

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

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

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

## 12 **Restrictions on programmes of work**

13 Additional restrictions apply to programmes of work involving the following:

- 14 • animals containing human material;
- 15 • neuromuscular blocking agents;
- 16 • primates (including endangered primates);
- 17 • endangered species (other than primates);
- 18 • cats, dogs and the horse family (equidae);
- 19 • feral domestic animals;
- 20 • Great apes (chimpanzees, pygmy chimpanzees, gorillas and orang-utans);
- 21 • testing cosmetics or household products;
- 22 • developing or testing alcohol or tobacco products;
- 23 • developing or testing offensive weapons;
- 24 • education and training.

### 25 ***Animals containing human material***

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



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

4 ***Neuromuscular blocking agents***

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

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

11 ***Project licences authorising the use of non-endangered primates***

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

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

17

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

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

24 ***Project licences authorising the use of endangered primates***

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

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

29

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

34 You must also provide scientific justification showing that the purpose of the  
35 programme of work cannot be achieved by the use of animals which are not  
36 primates; and are not of a species listed in Annex A to Council Regulation (EC) No  
37 338/97 on the protection of species of wild fauna and flora by regulating trade  
38 therein.

1 ***Use of purpose-bred primates***

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

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

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

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

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

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

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

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

26 You must also provide scientific justification showing that the purpose of the  
27 programme of work to be specified in the licence cannot be achieved by the use of  
28 animals which are not of a species listed in Annex A to Council Regulation (EC) No  
29 338/97 on the protection of species of wild fauna and flora by regulating trade  
30 therein.

31 ***Project licences authorising the use of cats, dogs and equidae***

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

36 ***Other restrictions***

37 We will not grant project licences for work using:

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

1 or using any animals for:

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

### 9 ***Licences for education and training***

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

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

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

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

### 25 **How we determine the severity category**

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

29 You can find more details in the ‘Severity categories’ section of this guidance.

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

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

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

- 35 • the type of manipulation and handling;

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

11 Besides looking at the procedures involved, we also consider:

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

### 17 **Severity conditions on your licence**

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

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

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

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

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

### 3 **Use and re-use of protected animals**

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

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

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

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

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

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

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

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

### 34 **End of the procedure**

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

38 **[Standard condition 9]**

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

- 3 • we authorise you to move it to another establishment [**Standard condition**  
4 **24**]; and
- 5 • the Named Veterinary Surgeon certifies that it will not suffer if it is no longer  
6 kept at your establishment.

### 7 **Capturing animals from the wild**

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

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

### 18 **Release into the wild**

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

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

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

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

### 31 **Re-homing**

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

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

## 1 **Your responsibilities as project licence holder**

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

8 As the project licence holder you must ensure that:

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

### 20 ***Deputies to project licence holders***

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

24 Deputies may be useful to you when:

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

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

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

2 ***Keeping records***

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

5 **[Standard condition 19]**

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

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

20 ***Retrospective assessment of severity***

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

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

30 ***Avoiding duplication in projects***

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



1 **Annual statistical returns**

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

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

10 **Conflicts of interest**

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

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

16 **Amending your project licence**

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

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

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

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

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

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

#### 4 **Suspending your project licence**

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

#### 9 **Revoking or varying your project licence**

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

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

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

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

#### 24 **Your right to make representations**

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

#### 30 **Standard conditions for project licences**

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

33 Sometimes we may include additional conditions, for example:

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

- 1      •      to allow you to obtain and use animals listed in Schedule 2 but that come
- 2                      from a non-designated source.
- 3

1

## 2 **Severity categories**

### 3 **Severity classification of procedures before work starts**

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

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

### 13 **How are the severity categories defined?**

#### 14 ***Non-recovery***

15 These are procedures that are performed entirely under general anaesthesia from  
16 which the animal will not recover consciousness.

#### 17 ***Mild***

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

#### 21 ***Moderate***

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

#### 26 ***Severe***

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

### 31 **The criteria for assigning the severity category**

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

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

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

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

### 13 **Reporting on actual severity**

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

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

### 23 **Enforcement of severity limits**

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

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

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

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

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

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

8 There is useful information and examples of severity assessment on the [EU website](#).

9

1

## 2 **Humane killing of protected animals**

### 3 **How is the killing of animals regulated?**

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

### 7 **When is killing an animal a regulated procedure?**

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

### 12 **Is the animal a “relevant protected animal”?**

13 A relevant protected animal is a protected animal which:

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

20

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

### 23 **What are the requirements regarding competence?**

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

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

1 **What methods are permitted?**

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

4 a) a Schedule 1 method;

5 b) a method specified in the establishment licence;

6 c) a method specified in a project licence;

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

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

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

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

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

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

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

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

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

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

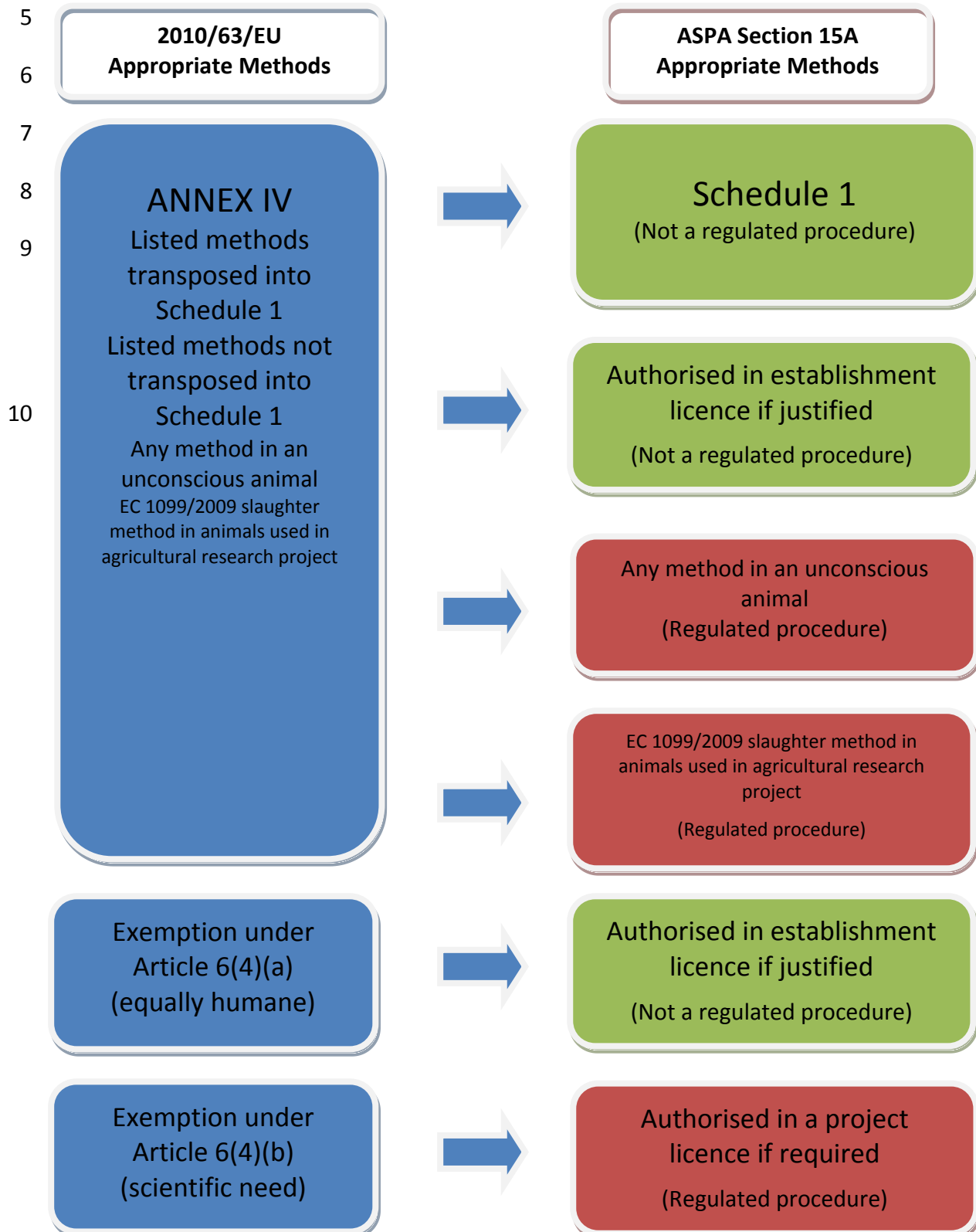
36



1

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

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



## 1 **Care and accommodation of protected animals**

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

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

### 8 **What does ASPA require?**

9 Licensed establishments must ensure that:

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

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

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

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

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

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

### 25 **What standards apply?**

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

31

### 32 **When do the standards have to be implemented?**

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

1 **Can I apply for an exemption from the requirements?**

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

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

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

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

15

1

## 2 **Named people**

### 3 **Named Animal Care & Welfare Officer (NACWO)**

#### 4 ***Your role and responsibilities***

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

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

9 You should:

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

- 1       • help the establishment licence holder to keep suitable records, under the  
2 supervision of the veterinary surgeon, of the health of the animals; of the  
3 environmental conditions in the approved areas in which animals are held;  
4 and of the source and disposal of animals; and
  
- 5       • be an active member of the AWERB at your establishment, and advise  
6 applicants for licences and licence holders on practical opportunities for  
7 implementing the 3Rs.

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

### 15 ***Your training***

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

### 23 **Named Veterinary Surgeon (NVS)**

#### 24 ***Your role and responsibilities***

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

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

30 You should:

- 31       • be familiar with the main provisions of ASPA;
  
- 32       • ensure that adequate veterinary cover and services are available at all times  
33 at your establishment and that those caring for animals have your contact  
34 details;
  
- 35       • monitor the health and welfare of the animals under your care by regularly  
36 visiting all parts of your establishment specified in the establishment licence;

- 1       •     notify the personal licence holder in charge of an animal if its health or  
2       welfare is giving cause for concern; if the licence holder is unavailable, you  
3       must make sure the animal is cared for and, if necessary, killed humanely  
4       using a Schedule 1 method, or another method approved in the  
5       establishment licence;
  
- 6       •     be familiar with relevant methods of humane killing listed in Schedule 1,  
7       together with any additional approved methods specified on the  
8       establishment licence;
  
- 9       •     have a thorough knowledge of the husbandry and welfare needs of the  
10      species kept at your establishment, including the prevention, diagnosis and  
11      treatment of disease; and be able to advise on quarantine requirements and  
12      health screening, and the impact of housing and husbandry systems on the  
13      welfare and needs of an animal;
  
- 14      •     control, supply and direct the use of controlled drugs, prescription-only  
15      medicines and other therapeutic substances used on animals at your  
16      establishment;
  
- 17      •     keep animal health records for all the animals at your establishment,  
18      including advice or treatment given; and ensure that these records are  
19      available to the Named Animal Care & Welfare Officer, the establishment  
20      licence holder and the Home Office;
  
- 21      •     certify that an animal is fit to travel to a specified place;
  
- 22      •     have regular contact with the establishment licence holder and the other  
23      Named People; and
  
- 24      •     be an active member of the AWERB at your establishment.

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

- 27      •     the impact of procedures on animals;
  
- 28      •     recognising pain, suffering, distress or lasting harm;
  
- 29      •     general and experimental surgical techniques, and post-operative care;
  
- 30      •     appropriate methods of general anaesthesia, analgesia and euthanasia;
  
- 31      •     strategies for minimising the severity of protocols, including recognising and  
32      implementing suitable end-points.

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

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

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

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

### 9 ***Your training***

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

### 12 ***Other suitably qualified person***

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

### 19 **Named Information Officer (NIO)**

#### 20 ***Your role and responsibilities***

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

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

26 You should:

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

## 1 **Named Training and Competency Officer**

### 2 ***Your role and responsibilities***

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

6 You should:

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

## 28 **Named Compliance Officer**

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

34



1

## 2 **Animal Welfare and Ethical Review bodies (AWERBs)**

### 3 **Membership**

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

#### 8 ***Named Veterinary Surgeon***

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

#### 14 ***Independent members***

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

### 18 **Role**

19 The role of the AWERB is to:

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

- 1 • review all proposals for project licences from a local perspective, consider  
2 how the 3Rs are being applied and advise the establishment licence holder  
3 on their acceptability, bringing local knowledge and local expertise to bear;
- 4 • throughout the lifetime of projects, follow their development and outcome,  
5 including those requiring retrospective review, so that lessons learnt can be  
6 used to further apply the 3Rs;
- 7 • advise on re-homing animals including appropriate socialisation;
- 8 • respond to enquiries and consider advice received from the national Animals  
9 in Science Committee.

#### 10 **Record keeping**

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

14

1

## 2 **Non-compliance**

### 3 **What is non-compliance?**

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

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

### 7 **Reporting non-compliance**

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

### 11 **Offences**

12 The following are offences under ASPA sections 22 and 23:

- 13 a) operating a user, breeding or supplying establishment without a section 2C  
14 establishment licence;
- 15 b) applying regulated procedures to protected animals without a person licence<sup>1</sup>;
- 16 c) applying regulated procedures to protected animals that are not authorised in a  
17 project licence<sup>1</sup>;
- 18 d) failing to provide information required to assist the retrospective assessment of a  
19 project;
- 20 e) failing to comply with the ASPA provisions relating to:
  - 21 • re-use (ASPA s14);
  - 22 • the action to be taken at the end of a series of regulated procedures  
23 (ASPA s15);
  - 24 • the prohibition of public exhibitions (ASPA s16);
  - 25 • the use of neuromuscular blocking agents (ASPA s17)<sup>1</sup>;
  - 26 • setting free and re-homing (ASPA s17A);
  - 27 • humane killing (ASPA s15A)<sup>2</sup>;

---

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

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

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

5 In addition:

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

## 10 **How we will deal with non-compliance**

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

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

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

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

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

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

---

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

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

#### 4 **Criminal sanctions**

5 The criminal sanctions applicable to the offences listed above are set out in sections  
6 22 and 23 of ASPA.

#### 7 **Administrative sanctions**

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

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

#### 16 **Compliance notices**

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

- 19 a) specifies the licence condition or ASPA provision with which you have failed to  
20 comply;
- 21 b) specifies the action you should take to ensure that the failure is not continued or  
22 repeated;
- 23 c) specifies any action you should take to eliminate or reduce any consequences of  
24 the failure;
- 25 d) requires you to take that action within a specified time; and
- 26 e) explains what will happen if you fail to comply with the notice, including possible  
27 revocation of your licence.  
28

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

#### 32 **Revoking, suspending or varying (amending) licences**

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

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

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

### 8 **Severity of non-compliance**

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

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

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

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

### 16 **What can I do to avoid non-compliance?**

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

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

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

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

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

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

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

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

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

6 **Compliance advice**

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

10

1

## 2 **About Home Office inspections**

### 3 **What do inspectors do and why?**

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

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

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

### 16 **What other powers does an inspector have?**

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

### 20 **What qualifications do inspectors have?**

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

### 24 **How often do inspectors visit establishments?**

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

27 We use the following factors to make the risk assessment:

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



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

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

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

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

## 16 **What happens during an inspection?**

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

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

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

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

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

1 We will keep inspection reports for at least five years.

2 **Encouraging good practice**

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

6 **EU inspections**

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

12

1

## 2 **The Animals in Science Committee**

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

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

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

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

### 17 **Contact details**

18 You can contact the committee through its secretariat by:

19 emailing [asc.secretariat@homeoffice.gsi.gov.uk](mailto:asc.secretariat@homeoffice.gsi.gov.uk)

1

## 2 **Other advisers to the Secretary of State**

### 3 **External assessors**

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

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

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

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

16 The assessor's advice is not binding.

### 17 **People who consider representations**

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

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

24

1 **Other issues**

2 **Preventing public displays**

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

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

6 **Training**

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

9 a) carrying out procedures on animals;

10 b) designing procedures and projects;

11 c) taking care of animals; or

12 d) killing animals.

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

15 • Module 1: Historical background, Ethics, ASPA and other relevant  
16 legislation;

17 • Module 2: Recognition of wellbeing, handling, humane killing;

18 • Module 3: Biology and husbandry, common diseases and monitoring, basic  
19 anaesthesia and analgesia, and minor procedures;

20 • Module 4: Surgical anaesthesia and analgesia and surgical procedures;

21 • Module 5: Ethics, alternatives, project design and management.

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

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

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

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

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

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

#### 15 **Annual statistics**

16 We are required to publish annually information about the use of animals in  
17 procedures. We do this in *Statistics of Scientific Procedures on Living Animals*. From  
18 2015 we must publish this report by 10 November each year.

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

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

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

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

#### 29 **Other relevant legislation**

30 A list will be compiled in due course.

1

## 2 **Annex A: Standard conditions for establishment licences**

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

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

8 2. (1) The licence holder shall ensure that a register is maintained of those who  
9 are competent to kill protected animals. A person's name shall not be  
10 included in the register unless the person has been adequately educated  
11 and trained in the killing of animals.

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

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

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

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

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

26 (a) the full name of the holder; or

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

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

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

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

- 1 (f) the full name and qualifications of the named training and competency  
2 officer; or
- 3 (g) the areas appearing on the schedule of premises for the establishment or  
4 the class of use within those areas; or
- 5 (h) the types of protected animals to be held and/or used in regulated  
6 activities at the establishment.
- 7 4. (1) All protected animals must at all times be provided with adequate care  
8 and accommodation appropriate to their type or species.
- 9 (2) Any restrictions on the extent to which such an animal can satisfy its  
10 physiological and ethological needs shall be kept to the absolute minimum.
- 11 (3) Unless otherwise authorised by the Secretary of State an environment,  
12 housing, freedom of movement, food and water appropriate for the health  
13 and wellbeing of each protected animal shall be provided.
- 14 (4) The licence holder shall ensure that the installations and equipment at  
15 the establishment are suitable for the species of protected animals kept at  
16 the establishment and for the regulated procedures, if any, carried out at the  
17 establishment. The design, construction and method of functioning of the  
18 installations and equipment must be such as to enable regulated procedures  
19 to be performed in a manner that provides reliable results, uses the minimum  
20 number of animals and causes the minimum degree of pain, suffering,  
21 distress and lasting harm to the animals used.
- 22 (5) The health and wellbeing of protected animals, and the environmental  
23 conditions in all parts of the establishment where protected animals are kept,  
24 shall be checked at least once daily by competent persons. Arrangements  
25 shall be made to ensure that any defect discovered and any avoidable pain,  
26 suffering, distress or lasting harm discovered is eliminated as quickly as  
27 possible.
- 28 (6) The holder shall ensure that the conditions under which any protected  
29 animal is transported are appropriate for the animal's health and well-being.
- 30 (7) Unless otherwise authorised by the Secretary of State the licence holder  
31 shall ensure that at least the following standards are met:
- 32 (a) any applicable standard concerning the care and accommodation of  
33 animals or installations and equipment, which is set out in Annex 3 of the  
34 Animals Directive;
- 35 (b) any additional or higher standard concerning the care and  
36 accommodation of animals which is set out in any code of practice issued or  
37 approved under section 21 that was in force on 9 November 2010.



- 1 (8) For the purposes of subparagraph (7)(a) a standard set out in Annex 3 of  
2 the Animals Directive is not to be treated as being an “applicable standard” if  
3 the Annex specifies a date from which the standard is to have effect and that  
4 date has not been reached.
- 5 5. The licence holder shall ensure that the establishment shall be appropriately  
6 staffed at all times to ensure the well-being of the protected animals. Staff  
7 shall be adequately educated and trained before they perform any function  
8 relating to the care of the protected animals and shall be supervised when  
9 performing any such function until they have demonstrated the requisite  
10 competence.
- 11 6. (1) The licence holder is required to have established, and to maintain, an  
12 Animal Welfare and Ethical Review Body.
- 13 (2) The Animal Welfare and Ethical Review Body must consist at least of:
- 14 (a) the named animal welfare officer and named veterinary surgeon,
- 15 (b) if this licence authorises the application of regulated procedures to  
16 protected animals at the establishment, the holder of a project licence which  
17 specifies the establishment as a place where regulated procedures may be  
18 carried out, or another person with suitable scientific credentials acceptable  
19 to the Secretary of State, and
- 20 (c) such other persons as may be specified in guidance issued by the  
21 Secretary of State.
- 22 (3) The Animal Welfare and Ethical Review Body must carry out the tasks  
23 mentioned in Article 27.1 of the Animals Directive and any other advisory  
24 and reviewing tasks specified in this licence or in guidance issued by the  
25 Secretary of State.
- 26 (4) The licence holder shall ensure that whenever the Animal Welfare and  
27 Ethical Review Body provides advice a record is made of the advice and of  
28 any decisions taken in response to the advice. Such records shall be kept for  
29 a minimum period of three years and shall, on request, be submitted to the  
30 Secretary of State or made available to an Inspector.
- 31 7. If this licence authorises the breeding of protected animals, the holder is not  
32 authorised to breed, at the establishment, non-human primates from any  
33 animal not bred in captivity unless the holder has in place a strategy  
34 acceptable to the Secretary of State for increasing the proportion of primates  
35 bred from animals bred in captivity. Any substantial changes to the strategy  
36 that are proposed shall be submitted to the Secretary of State for approval.
- 37 8. (1) Records shall be maintained, in a format acceptable to the Secretary of  
38 State, of the source, use and final disposal of all protected animals bred,  
39 kept or used at the establishment for any regulated activities.

- 1 (2) Such records shall include at least the following information:
- 2 (a) the number and the species of animals bred, acquired, supplied, used in  
3 procedures, or discharged from the control of the Act;
- 4 (b) the origin of the animals, including whether they are bred for use in  
5 procedures;
- 6 (c) the dates on which the animals are acquired, supplied, or discharged  
7 from the control of the Act;
- 8 (d) from whom the animals are acquired;
- 9 (e) the name and address of the recipient of animals;
- 10 (f) the number and species of animals which died or were killed in each  
11 establishment. For animals that have died, the cause of death shall, when  
12 known, be noted; and
- 13 (g) where this licence authorises the applying of regulated procedures to  
14 protected animals, the projects in which animals are used.
- 15 (3) Such records shall be kept for a minimum of five years from the date of  
16 final disposal of the animal and, on request, be submitted to the Secretary of  
17 State or made available to an Inspector.
- 18 (4) The licence holder shall, on request, submit to the Secretary of State a  
19 summary report, in a form specified by the Secretary of State, of the source,  
20 use and final disposal of all protected animals bred, kept, or used at the  
21 establishment for any regulated activities.
- 22 9. (1) For the purposes of this condition, an “individual history file” is a file kept  
23 in relation to a dog, cat or non-human primate which contains particulars of  
24 the animal’s identity; particulars of the animal’s date and place of birth (if  
25 known); a statement as to whether the animal was bred for use in regulated  
26 procedures; any relevant reproductive, veterinary and social information  
27 about the animal; a record of the programmes of work, if any, which have  
28 involved the use of the animal in regulated procedures; and in the case of a  
29 primate, a statement as to whether the animal is the offspring of primates  
30 bred in captivity.

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

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

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

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

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

28 10. (1) The licence holder shall ensure that before any unmarked dog, cat or  
29 non-human primate is weaned at the place specified in the licence the  
30 animal is marked. The licence holder shall ensure that before any unmarked  
31 dog, cat or non-human primate that has not been weaned is transferred from  
32 the establishment to a place specified in another section 2C licence, the  
33 animal is marked unless it would not be reasonably practicable to do so.  
34 Where an unmarked dog, cat or non-human primate that has not been  
35 weaned is transferred to the establishment, the establishment shall maintain  
36 records attesting the identity and origin of the animal's mother until the  
37 animal is marked.

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

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

- 1 (4) The holder shall comply with any request made by the Secretary of State  
2 for an explanation of why any dog, cat or primate at the establishment has  
3 not been marked.
- 4 (5) For the purpose of this condition, “marked” means provided with a  
5 permanent means of individual identification and “unmarked” refers to an  
6 animal that has not been provided with a permanent individual identification  
7 mark.
- 8 11. (1) Inspectors shall be provided with access at all reasonable times to all  
9 parts of the establishment which are concerned with the use, holding,  
10 breeding or care of protected animals.
- 11 (2) The licence holder must give any necessary assistance to inspectors  
12 carrying out visits by virtue of section 18(2A)(b); and to experts of the  
13 European Commission carrying out duties under Article 35 of the Animals  
14 Directive.
- 15 12. Unless authorised by the Secretary of State, there shall be no variation of  
16 the use of the approved areas of the establishment in the licence that may  
17 have adverse consequences for the welfare of the protected animals held.
- 18 13. Unless otherwise authorised by the Secretary of State:
- 19 (a) only the types of protected animals specified in the licence may be kept  
20 in the place or places specified in the licence for the purpose of the regulated  
21 activities specified in the licence; and
- 22 (b) for the purpose of the regulated activities specified in the licence, these  
23 animals may only be kept, bred and used in the areas listed in the schedule  
24 to the licence.
- 25 14. Records shall be maintained, in a format acceptable to the Secretary of  
26 State and under the supervision of the named veterinary surgeon, relating to  
27 the health of all protected animals bred, kept or used at the establishment for  
28 any regulated activities. Records shall, on request, be submitted to the  
29 Secretary of State or made available to an Inspector.
- 30 15. The licence holder shall nominate and be responsible for the performance of  
31 named persons, acceptable to the Secretary of State, as required by section  
32 2C(5) .
- 33 16. Arrangements to ensure that animals are given adequate care must be  
34 made in the event that the named persons referred to in condition 15 above  
35 are not available for any reason.
- 36 17. Adequate security measures shall be maintained to prevent the escape of  
37 protected animals and to prevent intrusions by unauthorised persons.

- 1 18. Quarantine and acclimatisation facilities shall be provided and used as  
2 necessary.
- 3 19. Adequate precautions against fire shall be maintained at all times.
- 4 20. If this licence authorises the applying of regulated procedures to protected  
5 animals, the holder shall take all reasonable steps to prevent the  
6 performance of unauthorised procedures in the establishment.
- 7 21. The licence holder shall make adequate and effective provision for regular  
8 and effective liaison with and between those entrusted with responsibilities  
9 under the Act and with others who have responsibility for the welfare of the  
10 protected animals kept at the establishment.
- 11 22. Where this licence authorises the applying of regulated procedures to  
12 protected animals, the licence holder shall notify the Secretary of State of the  
13 death of a project licence holder within seven days of its coming to his or her  
14 knowledge when, unless the Secretary of State directs otherwise, the project  
15 licence shall continue in force for 28 days from the date of notification. The  
16 section 2C licence holder will, during that period, assume responsibility for  
17 ensuring compliance with the terms and conditions of the project licence.
- 18 23. (1) This condition applies where this licence authorises the applying of  
19 regulated procedures to protected animals.
- 20 (2) A protected animal which, having been subjected to a completed series  
21 of regulated procedures, is kept alive shall continue to be kept at the  
22 establishment under the supervision of a veterinary surgeon or other suitably  
23 qualified person unless:
- 24 (a) it is moved, with the authority of the Secretary of State, to another  
25 establishment;
- 26 (b) the Secretary of State consents under section 17A to the animal no  
27 longer being kept at the establishment; or
- 28 (c) its re-use in another procedure is authorised by the Secretary of State.
- 29 24. A copy of these conditions shall be readily available for consultation by all  
30 licence holders and named persons in the establishment.
- 31 25. The licence remains the property of the Secretary of State, and shall be  
32 surrendered to him on request.
- 33

1

## 2 **Annex B: Standard conditions in personal licences**

- 3 1. In exercising his or her responsibilities, the licence holder shall act at all  
4 times in a manner that is consistent with the principles of replacement,  
5 reduction and refinement.
- 6 2. The licence holder is entrusted with primary responsibility for the welfare of  
7 the animals on which he or she has performed regulated procedures; the  
8 licence holder must ensure that animals are properly monitored and cared  
9 for.
- 10 3. The licence holder must not apply a regulated procedure to an animal if the  
11 procedure may cause the animal severe pain, suffering or distress that is  
12 likely to be long-lasting and cannot be ameliorated.
- 13 4. The licence holder must not apply a regulated procedure to an animal unless  
14 the holder has taken precautions to prevent or reduce to the minimum  
15 consistent with the purposes of the procedure any pain, suffering, distress or  
16 discomfort that may be caused to the animal.
- 17 5. Where the licence holder is applying a regulated procedure to an animal the  
18 holder must ensure that any unnecessary pain, suffering, distress or lasting  
19 harm that is being caused to the animal is stopped.
- 20 6. Where the licence holder is applying or has applied a regulated procedure  
21 which is causing the animal severe pain, suffering or distress the holder  
22 must take steps to ameliorate that pain, suffering or distress.
- 23 7. The licence holder shall ensure that where the holder applies a regulated  
24 procedure death as the end-point of the procedure is avoided as far as  
25 possible and is replaced by an early and humane end-point.
- 26 8. In all circumstances where an animal which is being, or has been, subjected  
27 to a regulated procedure is in severe pain, suffering or distress which is likely  
28 to be long-lasting and cannot be ameliorated, the licence holder must ensure  
29 that the animal is immediately killed in accordance with section 15A.
- 30 9. The licence holder may apply a regulated procedure without the use of  
31 general or local anaesthesia only if the holder is satisfied that:
- 32 (a) the procedure will not inflict serious injuries capable of causing severe  
33 pain; and

- 1 (b) the use of general or local anaesthesia would be more traumatic to the  
2 animal than the procedure itself or would frustrate the purposes of the  
3 procedure.
- 4 10. When anaesthesia (whether general or local) is used, it shall be of sufficient  
5 depth to prevent the animal from being aware of pain arising during the  
6 procedure.
- 7 11. If the licence holder applies a regulated procedure to an animal with the use  
8 of general or local anaesthesia the holder must, unless it would frustrate the  
9 purpose of the procedure, use such analgesics or other pain-relieving  
10 methods as may be necessary to reduce any pain that the animal may  
11 experience once the anaesthesia wears off.
- 12 12. The licence holder must use analgesia or another appropriate method to  
13 ensure that the pain, suffering and distress caused by regulated procedures  
14 are kept to a minimum.
- 15 13. It is the responsibility of the personal licence holder to notify the project  
16 licence holder as soon as possible when it appears either that the severity  
17 limit of any procedure listed in the project licence or that the constraints upon  
18 adverse effects described in the project licence have been or are likely to be  
19 exceeded.
- 20 14. The licence holder shall ensure that suitable arrangements exist for the care  
21 and welfare of animals during any period when the personal licence holder is  
22 not in attendance.
- 23 15. The licence holder shall ensure that, whenever necessary, veterinary advice  
24 and treatment are obtained for the animals in his or her care.
- 25 16. The licence holder shall ensure that all cages, pens or other enclosures are  
26 clearly labelled. The labelling must be such as to enable Inspectors, named  
27 veterinary surgeons and named animal care and welfare officers to identify  
28 the number of the project licence authorising the procedures, the project  
29 licence protocol in which the animals are being used, the date the protocol  
30 was started, and the responsible personal licence holder.
- 31 17. In order to ensure that regulated procedures are performed competently, the  
32 licence holder shall not apply regulated procedures unless given the  
33 appropriate level of supervision by the project licence holder or an  
34 experienced personal licence holder deputed by him/her for such time as  
35 may be needed to achieve competence.

- 1 18. The licence holder is authorised to delegate to assistants, who do not  
2 themselves possess the requisite personal licence authority but are under  
3 his or her control, the delegable tasks which form an integral part of the  
4 regulated procedures the licence holder is authorised to perform by this  
5 licence. The tasks must not require technical knowledge or skill, and  
6 delegation shall be in accordance with any relevant guidance published by  
7 the Secretary of State under section 21.
- 8 19. The licence holder must take all reasonable steps to ensure appropriate  
9 personal and project licence authorities exist before performing regulated  
10 procedures. The licence holder must be aware of the nature of the  
11 authorities given by this licence and the project licence, and of the conditions  
12 of issue attached to the licences.
- 13 20. The licence holder shall maintain a record of all animals on which  
14 procedures have been carried out, including details of supervision and  
15 declarations of competence by the project licence holder as appropriate.  
16 This record shall be retained for at least five years and shall, on request, be  
17 submitted to the Secretary of State or made available to an Inspector.
- 18 21. The licence holder must give any necessary assistance to inspectors  
19 carrying out visits by virtue of section 18(2A)(b); and to experts of the  
20 European Commission carrying out duties under Article 35 of the Animals  
21 Directive.
- 22 22. The licence remains the property of the Secretary of State, and shall be  
23 surrendered to him on request.
- 24



1

## 2 **Annex C: Standard conditions in project licences**

- 3 1. The licence holder is responsible for the overall implementation of the  
4 programme of work specified in this licence and for ensuring that the  
5 programme of work is carried out in compliance with the conditions of the  
6 licence.
- 7 2. The licence holder shall ensure that the specified programme of work does  
8 not involve the application of any regulated procedure to which there is a  
9 scientifically satisfactory alternative method or testing strategy not entailing  
10 the use of a protected animal.
- 11 3. The licence holder shall ensure that regulated procedures are not applied to  
12 an animal as part of the specified programme of work if the data to be  
13 obtained from the application of those procedures is already available in a  
14 Member State and has been obtained there by procedures which satisfy any  
15 relevant regulatory requirements of the EU.
- 16 4. The licence holder shall ensure that the regulated procedures applied as part  
17 of the programme of work specified in this licence are those which to the  
18 greatest extent use the minimum number of animals; involve animals with  
19 the lowest capacity to experience pain, suffering, distress or lasting harm;  
20 cause the least pain, suffering, distress or lasting harm; and are most likely  
21 to provide satisfactory results.
- 22 5. The licence holder shall ensure that the regulated procedures applied as part  
23 of the programme of work specified in this licence are designed so as to  
24 result in the death of as few protected animals as possible; and to reduce to  
25 the minimum possible the duration and intensity of suffering caused to those  
26 animals that die and, as far as possible, ensure a painless death.
- 27 6. The licence holder shall ensure that the appropriate level of supervision is  
28 provided for all personal licensees carrying out regulated procedures under  
29 the authority of this licence.
- 30 7. The licence holder shall ensure that a regulated procedure is not applied to  
31 an animal as part of the programme of work specified in this licence if the  
32 procedure may cause the animal severe pain, suffering or distress that is  
33 likely to be long-lasting and cannot be ameliorated.
- 34 8. The licence holder shall ensure that where a regulated procedure is being  
35 applied to an animal as part of the programme of work specified in this  
36 licence, any unnecessary pain, suffering, distress or lasting harm that is  
37 being caused to the animal shall be stopped.

- 1 9. The licence holder shall ensure that where a regulated procedure is applied  
2 to an animal as part of the specified programme of work, death as the end-  
3 point of the procedure is avoided as far as possible and is replaced by an  
4 early and humane end-point; and as soon as the purpose of the procedure  
5 has been achieved, the procedure is stopped and appropriate action is taken  
6 to minimise the suffering of the animal.
- 7 10. The licence holder shall ensure that where a regulated procedure has been  
8 applied to an animal as part of the programme of work specified in this  
9 licence, a suitably qualified person classifies the severity of the procedure as  
10 “non-recovery”, “mild”, “moderate” or “severe” using the criteria in Annex 8 of  
11 the Animals Directive. For the purposes of this condition, a series of  
12 regulated procedures applied to an animal for a particular purpose is to be  
13 treated as constituting a single regulated procedure.
- 14 11. Where a series of regulated procedures are applied to an animal for a  
15 particular purpose the licence holder shall ensure that the animal is killed at  
16 the end of the series unless a veterinary surgeon or other competent person  
17 has determined that the animal is not suffering and is not likely to suffer  
18 adverse effects, as a result of the regulated procedures.
- 19 12. Regulated procedures shall not be carried out on any stray animal of a  
20 domestic species as part of the programme of work specified in this licence.
- 21 13. Except with the authorisation of the Secretary of State, regulated procedures  
22 shall not be carried out as part of the programme of work specified in this  
23 licence on any of the following type of animal:
- 24 14. any feral animal of a domestic species;
- 25 15. any animal taken from the wild;
- 26 16. a marmoset unless it is the offspring of marmosets bred in captivity or has  
27 been obtained from a self-sustaining colony of marmosets;
- 28 17. any animal of a description specified in Schedule 2 to the Act unless it has  
29 been bred for use in procedures.
- 30 18. If the application of regulated procedures to animals taken from the wild is  
31 authorised in this licence the holder shall ensure:
- 32 19. that animals taken from the wild are captured by a competent person using a  
33 method which does not cause the animal avoidable pain, suffering, distress  
34 or lasting harm; and

- 1 20. that an animal taken from the wild which is found to be injured or in poor  
2 health is not subjected to a regulated procedure unless and until it has been  
3 examined by a veterinary surgeon or other competent person; and, unless  
4 the Secretary of State has agreed otherwise, action has been taken to  
5 minimise the suffering of the animal.
- 6 21. The licence holder must give any necessary assistance to inspectors  
7 carrying out visits by virtue of section 18(2A)(b); and to experts of the  
8 European Commission carrying out duties under Article 35 of the Animals  
9 Directive.
- 10 22. If the licence holder becomes aware of a failure to comply with any  
11 conditions of the licence the holder must take appropriate steps to rectify the  
12 failure (if it is capable of being rectified); and keep a record of the steps  
13 taken.
- 14 23. All authorised procedures shall be carried out under general or local  
15 anaesthesia unless:
- 16 24. anaesthesia would be more traumatic to the animal concerned than the  
17 procedures themselves; or
- 18 25. anaesthesia would be incompatible with the purposes of the procedures.
- 19 26. The licence holder shall ensure adherence to the severity limits as specified  
20 in the project licence and observance of any other controls described in the  
21 licence. If these constraints appear to have been, or are likely to be,  
22 breached, the holder shall ensure that the Secretary of State is notified as  
23 soon as possible.
- 24 27. The licence holder shall maintain a contemporaneous record of all animals  
25 on which procedures have been carried out under the authority of the project  
26 licence. This record shall show the procedures used and the names of  
27 personal licensees who have carried out the procedures. The record shall,  
28 on request, be submitted to the Secretary of State or made available to an  
29 Inspector.
- 30 28. The licence holder shall send to the Secretary of State, before 31 January  
31 each year (and within 28 days of the licence having expired or been  
32 revoked), a report in a form specified by the Secretary of State, giving details  
33 of the number of procedures and animals used, and the nature and purpose  
34 of the procedures performed under the authority of the project licence during  
35 the calendar year.

- 1 29. The licence holder shall maintain a list of publications resulting from the  
2 licensed programme of work and a copy of any such publication shall be  
3 made available to the Secretary of State on request. The list shall, on  
4 request, be submitted to the Secretary of State or made available to an  
5 Inspector, and it shall be submitted to the Secretary of State when the  
6 licence is returned to him on expiry or for revocation.
- 7 30. The project licence holder shall submit such other reports as the Secretary of  
8 State may from time to time require.
- 9 31. The project licence holder shall ensure that details of the programme of work  
10 and regulated procedures specified in the licence, and any additional  
11 conditions imposed on those procedures, are known to:
- 12 32. all personal licensees performing those procedures;
- 13 33. the named person responsible for compliance;
- 14 34. the named animal care and welfare officers responsible for the day to day  
15 care of the animals;
- 16 35. the named veterinary surgeon, on request; and
- 17 36. the named information officer and named training and competency officer,  
18 on request.
- 19 37. The licence holder must obtain the permission of the Secretary of State  
20 before:
- 21 38. any animal undergoing regulated procedures is moved from a place  
22 specified in one section 2C licence to a place specified in another section 2C  
23 licence; or
- 24 39. any animal is released for slaughter, unless this is already explicitly  
25 authorised by the project licence.
- 26 40. The licence remains the property of the Secretary of State, and shall be  
27 surrendered to him on request.