The Use of Animals in Scientific Research
Policy… Code of Practice✓ Guidance… Procedure…
Organisation-wide✓ Local…
Approved by the University Health and Safety Committee
Chairman: Mr Paul Thomas Date: June 2017 Review Date: 2020
The purpose of presenting this document to the University Health & Safety Committee Standard 3 year review✓ Changes in practice and/or legislation… New policy document…

Contents

Glossary

3Rs	The principles of replacement, reduction and refinement
Animals Directive	European Directive on the protection of animals used for scientific purposes (2010/63/EU)
ASC	The Animals in Science Committee – the independent, non-departmental public body set up under ASPA sections 19 and 20
ASPA	The (Scientific Procedures) Act 1986 as amended by the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 incorporating changes brought in by the European Directive (2010/63/EU) on the protection of animals used for scientific purposes – also referred to as the Act
ASRU	The Animals in Science Regulation Unit. ASRU is the unit of the Home Office responsible for implementing ASPA and comprises inspectors, licensing officers and those responsible for policy
AWERB	Animal Welfare and Ethical Review Body
BioAnnex	Aquatic Facility at BUL
Codes of Practice	Codes issued under section 21 of ASPA
Commission	European Commission
Directive	Unless otherwise stated, this refers to the European Directive on the protection of animals used for scientific purposes (2010/63/EU)
Establishment	A place holding a licence which has been granted under section 2C of ASPA
Establishment licence	A licence granted under section 2C of the Act, also known as a 'section 2C licence'
EU Directive	European Directive on the protection of animals used for scientific purposes(2010/63/EU)
HOLC	Home Office liaison contact. This title is often used by establishment licence holders to denote one or several key contacts for communication with the Home Office
Inspector	An inspector in ASRU appointed under ASPA section18
Licensed breeding Establishment	An establishment which is authorised by a licence granted under ASPA section 2C to breed Schedule 2 animals for use in regulated procedures, or for their tissues, or to breed any other protected animals primarily for those purposes
Licensed supplying Establishment	An establishment which is authorised by a licence granted under ASPA section 2C to hold Schedule 2 animals bred elsewhere for supply to another establishment
Licensed user Establishment	An establishment which is authorised by a licence granted under ASPA section 2C to use animals in regulated procedures
NACWO	Named Animal Care and Welfare Officer
NC3Rs	National Centre for the Replacement, Refinement and Reduction of Animals in Research
NCO	Named Compliance Officer – a term sometimes used for the Named Person Responsible for Compliance
NIO	Named Information Officer
NPRC	Named Person Responsible for Compliance (the preferred term, also sometimes referred to as a Named Compliance Officer)
NTCO	Named Training and Competency Officer
NVS	Named Veterinary Surgeon
The Pash Centre	Mouse facility at BUL
PEL holder	The holder of a section 2C (establishment) licence under ASPA
Personal Licence	The holder of a personal licence under ASPA
PIL holder	The holder of a personal licence under ASPA
PPL holder	The holder of a project licence under ASPA
Procedure	An act of commission, deliberate omission or permission applied to, or having any effect on, an animal
Project Licence	The holder of a project licence under ASPA
Project Leader	The Principal Investigator on a research grant or supervisor of a PGR student
Protected animals	All living vertebrates, other than a human, including certain immature forms, and any living cephalopod
Protocol	A procedure or series of procedures carried out for a particular purpose as part of an authorised project
RCVS	Royal College of Veterinary Surgeons
Regulated procedure	A procedure which is regulated under ASPA
SOP	Standard Operating Procedure

Technique	A single action carried out on an animal as part of a procedure or series of procedures
The Act also referred to as ASPA	The Animals (Scientific Procedures) Act 1986 as amended by the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 incorporating changes brought in by the European Directive (2010/63/EU) on the protection of animals used for scientific purposes

1 Introduction

This document is designed to provide guidance to anyone who is responsible for leading a scientific project, which involves the use of animals, within Brunel University London (BUL). The aim of the document is help ensure that the project is within established welfare restrictions and legal responsibilities. It is required that all persons working with animals are familiar with this document and comply with its contents.
There is also guidance for those involved with scientific projects, involving animal work or products derived from this work, undertaken at other institutes both in, and outside of the UK. The aim of this code of practice is to ensure compliance with BUL's policy that all scientific work involving animals undertaken by BUL scientists complies with the highest ethical standards.

Matters involving the use of animals in scientific research, compliance with Home Office Regulations and the Animals (Scientific Procedures) Act 1986 are the remit of the Animals Research Ethics Sub-Committee. As a research-led institution, BUL is committed to the policy provided by the National Centre for the Replacement, Refinement and Reduction of Animals in Research. Animals are only used in research where no suitable non-animal alternative exists.

BUL supports and endorses the ARRIVE Guidelines (Animal Research: Reporting in Vivo Experiments), which are intended to improve the quality of reporting of animal research in order to maximise valuable information published and minimise unnecessary studies.

BUL is a signatory to the Concordat on Openness in Animal Research, which helps us continue to take practical steps towards openness and transparency in our animal research.

2 Scope

This code of practice applies to the Uxbridge campus as a whole, and to scientific projects, involving animal work or products derived from this work, undertaken at other institutes both in, and outside of the UK.

3 Overview

This Code of Practice identifies the following areas that must be considered when planning an animal-based project.

- Home Office Requirements
- Local Ethical Review Process and Animals (Scientific Procedures) Act, 1986
- 3 Rs (Replacement, Reduction, and Refinement)

- Animal projects conducted outside of BUL campus
- Quality Management
- Early project planning, pre-start and wash-up meetings
- Health and Safety policies and practices
- BioAnnex and The Pash Centre administration

All work requiring animals, animal accommodation, or use of post-mortem facilities at BUL (Uxbridge Campus) **MUST** be discussed with the Facility Manager and before applications for funding are made.

It is an important principle that the Project Leader takes responsibility for ensuring that all staff, including those from the animal facility, who are involved in studies, are properly briefed and have read and are aware of the relevant SOPs, risk assessments, and protocols before commencing the study.

4 Roles and Responsibilities

4.1 Access

Access to the facility is granted by the Facility Manager and/or the Establishment Licence holder.

4.2 Supervision

All visiting students, researchers, and new staff must be supervised by a named responsible individual until such time as they are deemed competent by the Named Training and Competence Officer (NTCO) to work unsupervised. It is the responsibility of the Project Leader to ensure that supervision is available and that the Facility Manager or deputy is informed, in advance, of any visitors.

4.3 Lone Working

Please refer to local guidelines on Lone Working in the Animal Facility guidelines and also to the BUL Lone Working Policy.

4.4 Working with Pathogens – Safety Responsibilities

All staff wishing to make use of the BioAnnex or The Pash Centre facilities to carry out work with biological pathogens must consult with the University Health, Safety and Environment Officer, and also have been approved by the Biological and Genetic Modification Safety Committee (BGMSC) and the Animal Welfare Ethics Review Board (AWERB) before any pathogen work is commenced, and before any new pathogens are brought onto the campus.

It is also required that individuals must be familiar with, and trained to work with any pathogens intended for use in *in-vivo* work. Prior to commencing any *in-vivo* work with any pathogens staff must also familiarise themselves with the relevant risk assessments.

Project Leaders shall conduct a full risk assessment, as required under the University Health and Safety regulations. The responsibility for carrying out this risk assessment, where it impinges on work being carried out in BioAnnex or The Pash Centre facilities will primarily be with the Project Leader. Where necessary, BioAnnex and The Pash Centre facility staff will advise on the areas in which it can give specific guidance, e.g. matters of animal husbandry.

The risk assessment(s) associated with the proposed work will be discussed with Facilities Manager or a designated named Deputy responsible for the area in which the work will be conducted, as well as with the University Health, Safety and Environment officer. Once all relevant parties have agreed the assessments, copies must be sent to the Facilities Manager or Deputy before work is started.

The Facilities Manager reserves the right to refuse permission for work to be performed if the correct procedure is not followed.

5. Home Office Requirements

The requirements of the Animals (Scientific Procedures) Act 1986 (ASPA) should be adhered to at all times and the full list of requirements can be found at
https://www.gov.uk/government/publications/consolidated-version-of-aspa-1986

5.1 The Animals (Scientific Procedures) Act 1986 (ASPA)

ASPA regulates procedures that are carried out on "protected animals'" for scientific research and testing that may cause pain, suffering, distress or lasting harm.
ASPA has a three-level licensing system:

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

5.2 Establishment Licence (see Section 3 Guidance on ASPA)

Under ASPA section 2B, to carry on an undertaking involving any of the activities listed below must be authorised in an 'establishment licence' granted under ASPA section 2C. In this context 'undertaking' means 'enterprise, venture, business or operation'. A licence granted under section 2C is called an 'establishment licence'. The activities referred to above are:

a) applying regulated procedures to protected animals (a 'licensed user establishment');
b) breeding protected animals listed in ASPA Schedule 2 with a view to
   (i) their use in regulated procedures, or
   (ii) the use of their tissues or organs for scientific purposes (a 'licensed breeding establishment');
c) breeding other protected animals (not listed in ASPA Schedule 2) primarily for the same purposes (also a licensed breeding establishment);
d) the keeping of Schedule 2 animals which have been bred elsewhere and are to be supplied with a view to
   (iii) their use elsewhere in regulated procedures, or
   (iv) the use elsewhere of their tissues or organs for scientific purposes (a 'licensed supplying establishment').

An establishment engaging in any of the activities listed above must be authorised for each of the activities accordingly. Similarly, a breeding establishment must also be authorised as a user establishment if, for example, any of the animals bred there are genetically altered and of a potentially harmful phenotype.

Authorisation as a supplying establishment is required only for establishments holding Schedule 2 animals that have been bred elsewhere, including outside of the UK, and are to be supplied to another establishment for use in regulated procedures or for scientific use of their tissues or organs.

A breeding establishment does not require authorisation as a supplier to hold and supply animals that have been bred on its premises for scientific use elsewhere.
The place where regulated procedures are carried out, or animals are supplied or bred for use in these procedures, must have a Section 2C licence.

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

- ensuring compliance with the requirements of the Act – the Named Compliance Officer (NCO) – normally this will be the holder of the establishment licence;
- overseeing the welfare and care of the animals – called the Named Animal Care and Welfare Officers (NACWOs);

- ensuring that those dealing with animals have access to any information they need –called the Named Information Officers (NIOs); and
- ensuring that those dealing with animals are adequately educated, trained and supervised until they are competent and that appropriate further training continues – called the Named Training and Competence Officers (NTCOs).
- The licence also identifies the Named Veterinary Surgeons (NVSs) with expertise in laboratory animal medicine who are responsible for advising on the welfare and treatment of the animals.

The Establishment Licence also directs that:

5.2.1 The 3Rs

All research and activities at BUL must follow the principles of the 3Rs – replacement, reduction, and refinement. This applies to breeding protected animals, keeping them for supply, and using them in regulated procedures.

5.2.2 Animal Welfare and Ethical Review Body (AWERB)

Every breeder, supplier and scientific procedure establishment must have an Animal Welfare and Ethical Review Body (AWERB). The Terms of Reference should include all the elements of the role described below. If, in the future, any substantial changes to the role of the AWERB, the PEL must first agree them the Home Office.

Membership
The AWERB must comprise (as a minimum):

- at least one NACWO; and
- a scientific member.

The AWERB must also take advice from a Named Veterinary Surgeon (NVS). The AWERB will therefore normally include an NVS as a member.

5.2.3 Keeping records

- The PEL and the Facilities staff are jointly and individually responsible for keeping records of the source, use and disposal of all protected animals used in procedures, bred or obtained for use, or supplied for use.
- These records should account for each protected animal, except for immature forms (at foetal, larval or embryonic stages) which can be recorded in batches until they are issued for use.
- The NVS should supervise health records and make sure these are kept to a proper professional standard.

5.2.4 It is the responsibility of the PEL to ensure that "all reasonable steps to prevent the performance of unauthorised procedures in the establishment" are taken.

5.2.5 The PEL requires that the Facilities Manager hold the originals of the Certificate of Designation, and all Project and Personal licences.

5.2.6 All communications regarding records and licensing with the Home Office must be via the Facilities manager and/or the designated deputy.

5.2.7 The Home Office require a single point of contact between BUL and themselves and shall not enter into negotiation or correspondence with individuals regarding their licence application without the awareness and authorisation of the Home Office Liaison Contact (HOLC). At BUL the HOLC is the Facilities Manager.

5.2.8 The responsibilities of the Establishment Licence Holder are explained in detail in Section 3.13 of the Guidance to ASPA document.

5.3 Personal Licence (see Section 4 Guidance on ASPA)

5.3.1 A personal licence shows that the holder is qualified and suitable to carry out regulated procedures, under supervision if necessary. Under ASPA the holder is not allowed to apply a regulated procedure to an animal unless all three of the following conditions are met:

- a Personal Licence authorising the holder to apply a procedure of that description to an animal of that type;
- the procedure is applied as part of an authorised programme of work specified in a Project Licence; and
- the place where the procedure is carried out is specified in that Project Licence.

5.3.2 The primary place of work for a Personal Licence Holder (PIL) will be included on the licence. The licence is not normally restricted to working only at the Holder's primary place of work.

5.3.3 The PIL has primary responsibility for the welfare of the animals on which they perform regulated procedures.

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

- you are no longer restricted to working at the place(s) specified on your licence (section 14 of the schedule);

- new applications for a personal licence must be endorsed by the NTCO, not sponsored by a Personal Licensee as previously; and
- revised standard conditions apply.

5.3.4 The following categories of personal licence, A to F, permit you to carry out procedures which fall within the descriptions specified:

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

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

C. Surgical procedures involving general anaesthesia

D. Use of neuromuscular blocking agents

E. Procedures conducted in accordance with Project Licence (number)

F. Other (a free text field)

5.3.6 Your responsibilities as a Personal Licence Holder are explained in detail in Section 4.13 of the Guidance to ASPA document, and outlined in Appendix 1 below.

5.4 Project Licence Holders (PPL) (see Section 5 in Guidance on ASPA)

5.4.1 A Project Licence (PPL) is a licence granted by the Secretary of State which specifies a programme of work and authorises the application, as part of that programme, of specified regulated procedures to animals of specified descriptions at a specified place or places. The place or places must be either:

- A licenced user establishment; or
- A place other than a licenced establishment.

You must have a Project Licence before regulated procedures are carried out on animals.
Only one person may hold a project licence.

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

- describes the programme;
- states the objectives;
- specifies where the work will take place;
- details the experimental or other scientific protocols you must follow;
- specifies the regulated procedures you may apply within each protocol;
- describes the number and species of animals you may use;
- describes the predicted benefits of the programme;
- identifies the likely adverse effects (harms) and how you can avoid, recognise and alleviate them;

- assigns a severity class to each protocol; and
- is accompanied by a project summary written in non-technical terms.

Most of the work will be carried out at a Licenced establishment. In the licence this is called the ‘primary availability‘. The licence may also name other Licenced establishments where the work can take place. These are called ‘secondary availabilities‘.

5.4.3 Your responsibilities as a PPL holder are set out in detail in Section 5.23 of the Guidance on ASPA, and outlined below in Appendix 2.

6 Local ethical review process undertaken by the AWERB

BUL requires that all scientific work involving animals, whether carried out under ASPA or not, to be approved by its ethical review process. Advice on the application of the law to proposed studies can be obtained from the Facilities Manager or the University Health, Safety and Environment team.

There are various situations in which BUL staff may be involved with scientific projects using animals that are conducted outside of BUL. These may or may not be studies regulated by the ASPA.
Examples of those which are not might include;

- Studies carried out under the auspices of the Medicines Act,1968;
- Work being carried out in another country as part of a BUL London project.

Alternatively, studies may be initiated or funded by BUL but conducted under ASPA, by approved third parties under the authority of their own Project Licences.
The Animal Welfare Ethics Review Board (AWERB) through the ethical review process will scrutinise all scientific work involving animals in which BUL staff are involved.

Work undertaken by BUL scientists under ASPA outside the BUL (Uxbridge Campus), but in the UK, has blanket approval as this will have undergone the same ethical review process as if it were it to be undertaken at BUL Campus.

However, copies of any scientific papers resulting from this type of work should be sent to the AWERB committee secretary for the committee’s information. The AWERB is a subcommittee of the University Research Ethics Committee (UREC), and reports directly to this committee.

7 Publications

Where a publication describes work involving animal experimentation which has not been subject to scrutiny by BUL London's ethical review process, the opinion on the publication of the AWERB members should be sought.

If the committee or the chairperson, acting on behalf of the committee, advises against publication on ethical grounds, the author **must** withdraw from authorship of the paper and ensure that the publication makes no direct or indirect attribution to BUL. In cases of dispute between the committee and the scientist concerned it will forward its recommendations to the Establishment Licence Holder for consideration.

It should be noted that if the animal work is not described in the paper the committee does not need to see it.

8 Project Planning and Management

8.1 Early project Planning

When planning a project which may require the use of animals, the Project Licence Holder (PPL) shall, by carrying out appropriate literature and database searches and by communication with their peers, ensure that the scientific objectives of the proposed project can only be achieved by the use of live animals and that there are no experimentally viable non-animal alternatives available.

Once it has been established that the use of animals is necessary, and before a bid for funding is made or a contract is signed, the project leader (PL) must ensure that the necessary project and personal licences are in place and discuss their outline requirements for animals and accommodation with the Facilities Manager or their deputy, to ensure that the basic requirements can be met from within the BioAnnex or The Pash Centre facilities.

For large projects, once the concept note or draft protocol has been written, PLs must ensure that the Facilities Manager has seen it and signed it off. This signature, together with that of the PEL, is required before the document is submitted to ensure that if funding is forthcoming, the BioAnnex and or The Pash Centre facilities will be able provide the facilities to service the project. Without this assurance, animal facilities staff cannot guarantee that the requirements of the project for animal services will be met.

8.2 Pre-start meetings

Pre-start meetings must be held for all projects involving the use of animals. The Facilities Manager needs to know that the PL for each project involving the use of animals has ensured that all the requirements necessary for the proper conduct of the study are in place and have been communicated to all relevant staff, via a pre-start

meeting, prior to the study commencing. (One month for projects involving genetically modified organisms, or pathogens and two weeks for general projects not using pathogenic or GM material).
It is advisable that applications for GM work are planned well in advance of this application process as permissions and licensing requirements can take 30 days or more to process, please consult directly with the University Health, Safety and Environment Officer.

A proper briefing must include, as a minimum, actions by the Project Leader to ensure that;

- All relevant SOPs are in place in the animal unit(s) before the study starts.
- All staff that will be involved in the study have read and discussed all of the relevant SOPs before the start of each study and signed that they have done so.
- All relevant log books are in place in the animal unit(s) before the study starts and that BioAnnex or The Pash Centre facilities staff have been made aware of their duties in regard of these logs.
- A copy of the study protocol is available in each of the units and all staff involved have read and discussed this with the PL.
- Copies of all Risk Assessments have been issued to the Facilities manager for the units involved and have been discussed with the relevant staff where necessary.

The staff required to attend these meetings are:

- Named Animal Care and Welfare Officer (NACWO)
- Named Information Officer (NIO)
- Named Training and Competence Officer (NTCO)
- Any other relevant staff

8.2 On-going studies – progress meetings

Regular reviews must be added to the project plan, depending on the condition of the study. If amended study protocols are required at any stage these must be submitted to the Facilities Manager and where necessary, to the AWERB committee prior to them being used.

8.3 Wash up meetings

At the end of a study, the PL must organise a ‘wash-up’ meeting involving all staff who have contributed to the study, in order that the study be reviewed and any deficiencies or positive aspects identified.
These should be identified by the PL and a copy circulated to the PEL and the Facilities Manager for discussion at the AWERB. The same personnel who attended the pre-start meeting are to attend the wash up meeting. This will also be applicable to the renewal of Project Licences.

All data recorded by animal facilities staff as part of its own operating requirements, or to comply with Home Office regulations will be kept and archived by the Facilities manager or the deputy facilities manager.

Any study-specific data is the responsibility of the Project Leader and the animal facilities staff are not responsible for its archiving.

9 CONTINGENCIES

9.1 Accidents in Animal facilities

Refer to BUL Health and Safety Policy, and also to the Accident, Incident or Dangerous Occurrence section of the Health and Safety Website (https://intra.brunel.ac.uk/safety/accidents/Pages/Reporting-Accidents.aspx)

9.2 Contamination of Animal facilities

Before commencing work with any agent or pathogen in BUL animal facilities, the project leader initiating the work must familiarise themselves and associated staff with relevant risk assessments, procedures and emergency response plans. If a specific procedure needs to be written, this will be done in conjunction with relevant animal facilities staff.

In the event of a spillage in an animal facility the animal facility staff responsible for biosecurity and/or safety in the area will take charge of immediate containment.

It is the job of the Facilities Manager to ensure that animal facilities staff responsible for biosecurity/safety are appropriately trained and are present to organise immediate decontamination procedures. The Facilities Manager or a delegated deputy will be contacted to provide assistance such as additional personnel and materials as required.

Once the contamination has been contained further guidance will be obtained from the University Health, Safety and Environment Team.

Any additional decontamination of the facility will be carried out by animal facility after guidance has been obtained from the University Health and Safety Team.

The animal facilities staff member responsible for biosecurity/safety of the area will ensure that the University Health, Safety and Environment Officer in the Health and Safety team is notified immediately that a spillage, or release of a Biological Agent has occurred.

10 REFERENCES

The Animals (Scientific Procedures) Act 1986.

Guidance on the Operations of the Animals (Scientific Procedures) Act 1986.

"Working safely with research animals: Management of infection risks", HSE, 1997.

BUL London:

- Health and Safety Policy
- Biological Safety Policy
- Lone Working Policy

Further policies and guidance can be found on the Health and Safety Website.

Appendix 1 - Personal Licence Holder Responsibilities

- You must comply with the terms and conditions in your licence and you must not conduct any procedure or licensable activity beyond what is covered within your Licence.
- You should be familiar with the details of the licences for projects you are working on, including objectives, plans of work, and protocols.
- You must only perform regulated procedures with the permission and in full knowledge of the project licence holder.
- You should also understand the tasks the project licence holder asks you to perform, including any endpoints you need to apply.

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

Animal welfare

- You must not allow an animal to experience severe pain, suffering, or distress that is likely to be long-lasting and cannot be ameliorated.
- You should act at all times in a manner that is consistent with the principles of the 3Rs – replacement, reduction, and refinement.
- You are responsible for the welfare of the animals you work on. This involves:
    - being responsible for the welfare of the animals you have performed procedures on and ensuring that they are properly monitored and cared for;
    - knowing the techniques and species involved, what the consequences of performing procedures on them will be and the signs of pain, suffering, distress, or lasting harm in that species;
    - taking precautions to prevent or reduce any pain, distress, or discomfort to the animal, including using sedatives, tranquillisers, analgesics, or anaesthetics;
    - telling the project licence holder immediately if you think that the severity limit of a protocol has been, or is likely to be, exceeded;
    - getting and following veterinary advice and treatment, where needed;
    - arranging for the care and welfare of an animal when you are away;

- making sure that any animal that is in severe pain or severe distress, which you cannot alleviate, is painlessly killed using an appropriate method.
- immediately informing the Facilities Manager and, if appropriate, the Establishment Licence Holder of any concerns with regard to animal welfare that are beyond those clearly covered and predicted by the relevant project Licence.

If two or more personal licence holders are working with the same animal, you must be clear who is primarily responsible for that animal. However, it is the responsibility of all individuals involved to ensure the welfare of all animals that they work with.

Supervision

To ensure that regulated procedures are performed competently, you should not apply regulated procedures unless given the appropriate level of supervision by the project licence holder, or an experienced personal licence holder deputed by him or her, until the project licence holder and NTCO where you are working are satisfied you have achieved competence.

Record keeping and cage labelling

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

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

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

- the project licence number;
- the protocol;
- the date the protocol was started;
- the responsible personal Licencee.

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

Delegating authorities

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

Any assistant must be appropriately trained, instructed, and supervised.

Appendix 2 -Project Licence Holder Responsibilities

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

- You direct and manage all the personal Licencees working on the project.
- You must ensure that:
    - the programme of work is strictly followed;
    - the severity controls of each protocol are implemented effectively;
    - severity conditions are met;
    - only the animals authorised are used;
    - others working on the project have a personal licence and are trained and supervised until they have demonstrated the requisite competence;
    - procedures are only carried out at the place or places specified in your licence

Keeping records

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

They should include:

- the names of the personal licence holders performing procedures authorised by the licence;
- details of the procedures and protocols you apply, including:
- the species of protected animals used;
- a running tally of the numbers of each species used in each protocol;
- the sex and approximate age of the animals at the start of the protocols;
- the identification of the animals used (where appropriate);
- the start and end dates of the protocols;
- a brief description of the procedures you apply;
- the morbidity or mortality produced;
- the fate of the animals at the end of procedures (e.g. killed in the establishment, released to private care);
- details of any continued use or re-use;
- from 1 January 2014, the actual severity of the series of procedures applied to the animal or, in the case of animals that are re-used, the severity of each procedure or series of procedures;
- copies of any veterinary or other certification and advice you have received.