Laboratory Animal Science Association

Guiding Principles on Record Keeping for Personal Licence Holders

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Note:
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This updated version takes account of Amendments to the Animals (Scientific Procedures) Act 1986 (ASPA) to transpose European Directive 2010/63/EU, which came into force 1 January 2013, as well as the associated Home Office Guidance, published in March 2014

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Guiding Principles on Record Keeping for Personal Licence Holders

Summary
This document provides personal licensees (PILh) with guidance on record keeping when carrying out regulated procedures under the Animals (Scientific Procedures) Act 1986, (ASPA). It aims to act as a reminder of what is legally required and to suggest examples of good practice.

Three types of records are legally required under ASPA:

1 Cage or enclosure labels.

2 General records.

3 Central records.

It is important to remember that the maintenance of both cage/enclosure and general records are primarily the responsibility of the personal licence holder.

In addition to these legal requirements, there are sound scientific and practical reasons to maintain good records and any other relevant information (including those kept centrally by the unit). This is because, when properly kept, records can help with the interpretation of an experimental result, the reproducibility of data, and assist in monitoring the incidence of any adverse effects.

1. Introduction

Under ASPA, a personal licence authorises an individual to apply regulated procedures within the authorised category/categories to the species of animal on the licence. Such procedures form part of a programme of work, specified in one or more project licences, to be carried out at a licensed establishment. It is the responsibility of a PILh to be familiar with ASPA, all licenced authorities and conditions attached to:

- their personal licence (PIL), (*PIL standard condition 19*);
- all relevant project licences under which the PILh works, (*PIL standard condition 19*); and
- the establishment licence(s) (PEL) at the place where they work.

The requirements for record keeping are set out in the standard conditions applied to a personal licence (PIL standard conditions 16 and 20) with further explanatory information provided in the Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (2014).

This document provides additional guidance on how records should be kept and used in accordance with good scientific and welfare practice.

2. Why keep records?

2.1 Legal requirements

There are two standard conditions attached to ALL personal licences[1] which relate to record keeping.

Standard Condition 16:

[1] Standard conditions: personal licences which are reproduced in Appendix B to the Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (2014).

"The licence holder shall ensure that all cages, pens or other enclosures are clearly labelled. The labelling must be such as to enable Inspectors, Named Veterinary Surgeons and Named Animal Care and Welfare Officers to identify the number of the project licence authorising the procedures, the project licence protocol in which the animals are being used, the date the protocol was started, and the responsible personal licence holder."

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

2.2 Good scientific and welfare practice

As well as the legal requirements, there are sound scientific reasons for maintaining good records:
First, they can help with the interpretation of the data and/or help to explain some of the unaccounted variation, including outliers (Festing *et al. 2016).*
Secondly, they enable the data to be reproduced more accurately.
Thirdly, good records of adverse effects can prove invaluable when trying to identify the cause, incidence and steps to ameliorate such effects. If unexpected adverse effects are encountered, which trigger PIL condition 13[2] and project licence (PPL) condition 18[3], the quality of the records kept will determine how easily and comprehensively the PPL condition 18 report can be completed.

3. What sorts of records?

3.1 Cage labels

The PILh must take individual responsibility for ensuring that all cages or enclosures containing animals undergoing regulated procedures carried out under the authority of their licence are clearly labelled. Failure to do so constitutes a breach of personal licence standard condition 16. The labelling should enable the inspector, Named Veterinary Surgeon (NVS) and Named Animal Care and Welfare Officer (NACWO) to identify the project licence under which the animals are being used, the responsible PILh[4], the protocol under which the procedures are undertaken and the date when the protocol started. It also enables others, who are responsible for the care and use of the animals, e.g. the animal care staff, to fulfil their responsibilities to the animals. For example, the label may include information about what procedures have been undertaken, the anticipated adverse effects of the procedure and the means of contacting the responsible PILh. The information also enables the inspector to make an informed judgement about the well-being of the animal(s), particularly with respect to their statutory duty to consider whether an animal is undergoing excessive suffering.

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

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

4 The responsible licensee may be the licensee who applied the most recent procedure, or a nominated licensee who takes primary responsibility for the study. In the latter case, a record of all procedures undertaken on each animal and by whom must be maintained and be readily available.

The requisite information may, with the agreement of the inspector, be in coded or electronic form, provided that there is easy access to all such information when required, especially when the PILh is not available.

Record keeping systems are evolving rapidly. In some establishments, records are now kept either in central data bases and/or on an electronic card, which is associated with a microchip implanted in the individual animal or cage card. Therefore, in future, cage labels may record only the cage number and bar code(s) or embedded RFID chip. These enable access to all the information, which formerly would have appeared on the cage label. Electronic access means this information can be easily read using a hand-held electronic device. However, the essential information must be available to the inspector, on the cage card, in the event that access to the electronic database is not possible.

Whatever system is used, **all records must be up-dated regularly**, to ensure accuracy at all times and to reflect what has happened to the animal (including the last procedure). When **electronic records** are maintained, these **need to be both up-dated and backed up regularly**.

The cage label should not be used as the only record of procedures because they can be lost or damaged. The information on cage labels must be supported by the PILh's own paper or electronic records which may be supplemented by other records required by the facility manager and/or establishment licence holder (PELh). When an experiment has ended and the animals have been killed, the cage labels may be kept and used as part of the general record of the work (which is another reason why good labels are so useful).

Box 1: **An example of the way a cage label might be formatted to capture both legal and good practice information:**

<table>
<tr><td colspan="3">Project Licence Identification:
Protocol Number:</td></tr>
<tr><td>Species/Strain/GA/stage of development</td><td>Sex</td><td>No of Animals</td></tr>
<tr><td colspan="3">Experiment Start Date
Experiment End Date</td></tr>
<tr><td colspan="3">Severity category
For each procedure:
Date
Type of procedure
Responsible PILh
When substances are administered:
a) the route of administration
b) name/code or nature of the substance
(Optional) Daily weights</td></tr>
</table>

3.2 General records

PIL standard condition 20 stipulates that the maintenance of records of **all** regulated procedures carried out on **each** protected animal must be kept for at least 5 years. Most licensees currently keep paper records using one or more of the following: a laboratory book, a day book, or a record of procedures book. However, as newer electronic systems are introduced, the way records are kept is likely to change. Whatever the format of the records, any recorded information kept by a licensee, which relates to the use of animals in regulated procedures, may be requested by the Secretary of State and Home Office inspector at any time and should therefore be up to date. Also, some of this information will be required by the project licence holder (PPLh) when they complete the Home Office Annual Return of Procedures.

Standard condition 20 also covers supervision and competence. PILhs are advised to read the LASA Guiding Principles for Supervision and Assessment of Competence as required under EU and UK legislation[5] for advice on the types of records that are required to satisfy this aspect of standard condition 20.

PILhs are encouraged to keep clear, detailed records of all their work. To help licensees achieve this, LASA has provided two boxes of prompts (below). These should elicit the appropriate level of detail and help PILhs to produce records that would meet both legal and good practice standards.

[5] LASA Guiding Principles for Supervision and Assessment of Competence as required under EU and UK legislation (2016)

Box 2. LASA recommendation for the general records:
(Note that some of this information will have been captured on the cage labels)

- project licence number under which the work is performed;[6]
- protocol number;
- animal species[6]/strain;
- animal identification code/chip number;
- genetic status of the animal[6];
- source of the animal[6];
- sex of the animal;
- age/stage of development of the animal[6];
- where appropriate the weight of the animal at the start of the experiment and subsequently if animals are weighed at intervals during the experiment;
- date when the experiment began and is expected to end;
- brief description of the procedure(s) and dates when all procedures were carried out;
- details of test material if used (e.g. the compound, drug name or code - in blinded studies);
- the maximum actual severity experienced by each animal[6] and whether a project licence Condition 18 report was necessary;
- details of morbidity, mortality and/or any adverse effects observed and what steps were taken to alleviate effects;
- details of special care requirements (i.e. what was needed and what was done);
- actual date the procedure ended;
- details of the disposal of the animal (e.g. method of killing) or release from the controls of the ASPA and discharge from the establishment licence (note additional records are required for animals discharged from the controls of the ASPA i.e. those animals that are rehomed or set free);[6]
- re-use if appropriate;[6]
- details of supervision, competence and Continued Professional Development (CPD). See LASA Guiding Principles on the Supervision Requirements for Personal Licensees[5];
- copies of any veterinary (or other) reports, certificates and/or advice.

[6] This information will be required by the PPLh for the annual return of procedures in accordance with project licence standard condition 20.

Box 3. LASA recommendation for additional records that should be kept when animals undergo regulated surgical procedures

- weight of the animal before surgery and daily weights and/or food/water consumption for at least the first 5 days after surgery;
- health status of the animal (e.g. conventional health, Specific Pathogen Free);
- details of anaesthetic regime used[7]
- analgesia used;
- peri-operative care required and administered (including analgesia and other medication if required);
- progress of surgery (e.g. complications if encountered);
- adverse effects, observed (e.g. infection, wound dehiscence) and action taken;
- actual severity.

Increasingly, researchers are developing and using score sheets as part of the experimental protocol. Score sheets can be used to standardise the type of information recorded (e.g. behaviour and/or health of an animal undergoing regulated procedures); to highlight deviations from the norm; and to ensure that end points are not exceeded. Therefore, score sheets constitute a record and should be retained in the same way as other records.

3.3 Centrally recorded data

Central records of the source, use (e.g. project licence number, wild-type stock, breeding efficiency), health and disposal of animals must be kept in all animal facilities on behalf of the PELh[8].

In addition, PELhs are required to ensure that facilities comply with the Home Office Code of Practice for the Housing and Care of Animals Bred, Supplied and Used for Scientific Purposes[9]. To demonstrate such compliance, animal unit staff should normally record such parameters as temperature, humidity, noise, light cycle, air change rates. The unit NACWO (or facility manager) is normally the person tasked with keeping these records on behalf of the PELh.

The PELh is required to keep a register of everyone competent to kill animals at the establishment; this should include both the species and the methods that they are competent to use[10].

A PILh, requiring any of this additional information because, for example, it could affect the outcome of the experiment, should contact the unit NACWO (or the appropriate person). While these records should be kept for 5 years, PILhs are advised to request this type of information either during, or as soon as possible after, the experiment has

7 This should include the type of anaesthetic used, the route of administration, the duration of anaesthesia, whether the animal has previously been anaesthetised and whether the animal will recover.
8 In accordance with standard conditions 8, 9 and 14 applied to all 2C establishment licences.
9 In accordance with standard condition 4 applied to all 2C establishment licences.
10 In accordance with standard condition 2 applied to all 2C establishment licences.

been completed. This will ensure that all records that contain information, which might have to be considered, are available when the experimental data are analysed.

For those licensees working at places other than 2C licence establishments (POLEs[11]), additional records may be required. Due to the diversity of work carried out at POLEs, PILhs are recommended to discuss record keeping with their local Home Office inspector before beginning work.

4. References

Home Office (2014), Guidance on the Operation of the Animals (Scientific Procedures) Act 1986. London: Her Majesty's Stationary Office.
https://www.gov.uk/government/publications/operation-of-aspa

Code of Practice for the Housing and Care of Animals Bred, Supplied and Used for Scientific Procedures (2014) London: Her Majesty's Stationary Office.
https://www.gov.uk/government/publications/code-of-practice-for-the-housing-and-care-of-animals-bred-supplied-or-used-for-scientific-purposes

Festing, M, Overend, P, Cortina Borja, M, Berdoy, M (2016). The design of Animal Experiments: Reducing the Use of Animals in Research through Better Experimental Design. SAGE Publications Ltd

LASA 2016 Guiding Principles for Supervision and Assessment of Competence as required under EU and UK legislation 2nd Edition. A report by the LASA Education, Training and Ethics Section. (M. Jennings and M. Berdoy eds.)

5. Additional reading

Guidelines for Keeping a Laboratory Record, Rice University, Houston, Texas
www.ruf.rice.edu/~bioslabs/tools/notebook/notebook.html

[11] Place other than a licensed establishment (formally known as a "PODE").

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