



Guiding Principles on Record Keeping for Personal Licence Holders

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Updates:

Guidelines may be updated from time to time to reflect changes in practice. If you have received a hard copy of this report, please check on the website that this is the latest version.

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Summary

This document provides personal licensees 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 as well as suggest examples of good practice.

Three types of records are legally required under ASPA:

- 1 Cage or enclosure labels.
- 2 General 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.

- 3 Central records

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

1. Introduction

Under the Animals (Scientific Procedures) Act 1986 (ASPA), a personal licence authorises an individual to apply regulated procedures (specified both in the personal and project licences) to animals, as part of a programme of work specified in a project licence and carried out at a designated establishment. It is the responsibility of a personal licensee to be familiar with all conditions attached to:

- his/her personal licence;
- all relevant project licences under which the personal licensee works; and
- the Certificate of Designation for the establishment(s) at which s/he works.

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

This document also 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 licences¹ which relate to record keeping.

Standard Condition 11:

“It is the responsibility of a personal licensee to 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 & Welfare Officers to identify the project in which the animals are being used, the regulated procedures which have been performed, and the responsible personal licensee.”

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

Standard Condition 21:

“The personal licensee 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 maintained 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. Adequate records can help with the interpretation of the data and/or the control of some of the unaccounted variation, including outliers (Festing *et al.* 2002) as well as enable the data to be reproduced more accurately.

In addition, good records of adverse effects can prove invaluable when trying to identify the cause, incidence and steps to ameliorate such effects.

3. What sorts of records?

3.1 Cage labels

Personal licensees must take individual responsibility for ensuring that all cages or enclosures containing animals undergoing regulated procedures under the authority of their licence are clearly labelled. Failure to do so constitutes a breach of personal licence standard condition 11. The labelling should enable the Named Veterinary Surgeon (NVS) and Named Animal Care and Welfare Officer (NACWO) to identify the project on which the animals are being used, the responsible personal licensee², the procedures undertaken and when the procedure(s) occurred. It also enables others responsible for the care and use of the animals, e.g. the animal care staff, to fulfil their responsibilities towards the animals concerned. For example, the label may include information about the anticipated adverse effects of the procedure and the means of contacting the responsible personal licensee. 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.

Some information (e.g. details about the personal and project licence, or specific procedures) may, with the agreement of the Home Office Inspector, be in coded or electronic form, provided that there is easy access to all such information when required, especially when the personal licensee 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 the microchip implanted in the individual animal. Therefore, in future, cage labels may only record the cage number and bar code(s) from which all the information that would have appeared on the label will be accessed and read using a hand-held electronic reader.

Whatever system is used, **all records must be up-dated regularly** to ensure accuracy at all times and must reflect what has happened to the animal including the last procedure. When **electronic records** are maintained these not only **need to be regularly up-dated but also backed up**.

² The responsible licensee may be the licensee who applied the last regulated 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 cage label should not be used as the only record of procedures. Cage labels can be lost or damaged. The information on cage labels must be supported by the personal licensee's own paper or electronic records. 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 valuable).

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

Project Licence Identification Procedure Code (19b)		
Species/Strain/GA	Sex	No of Animals
Experiment Start Date Experiment End Date		
Severity Date(s) when the procedure(s) is/are undertaken Type of procedure(s) Responsible licensee (Optional) If substances are administered: a) the route of administration b) name or nature of the substance (Optional) Daily weights		

3.2 General records

Standard condition 21 requires that the maintenance of records of **all** regulated procedures carried out on **each** protected animal be kept for at least a 5 year period. Most licensees currently keep records in a paper format, e.g. in 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. Regardless of how the records are kept any recorded information kept by a licensee which relates to the use of animals in regulated procedures may be requested by the Home Office Inspector at any time and should therefore be kept up to date. Also some of this information will be required by the project licence holder when s/he completes the Home Office Annual Return of Procedures.

Standard condition 21 also covers supervision and competence. Personal licensees are referred to the LASA Guiding Principles on the Supervision Requirements for Personal Licensees³ for advice on the types of records that are required to satisfy this part of standard condition 21.

Personal licensees are encouraged to keep clear, detailed records of all their work. To help licensees achieve this, LASA has provided two boxes of prompts which should elicit the level of detail which would result in records which would meet both legal and good practice standards.

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;⁴
- protocol code (i.e. 19b reference number);
- animal species⁴/strain;
- animal identification code/chip number;
- genetic status of the animal⁴;
- source of the animal⁴;
- sex of the animal;
- age and/or weight of the animal at the start of the experiment and subsequently if animals are weighed at intervals throughout the experiment;
- date when the procedure(s) began and are expected to end;
- brief description of the procedure(s)⁴ and dates when all procedures were carried out;
- details of test material if used (e.g. the compound or drug name);
- 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);
- 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 Certificate of Designation (note additional records are required for animals discharged from the controls of the ASPA);
- re-use⁴ or continued use if appropriate;
- details of supervision and compliance. See LASA Guiding Principles on the Supervision Requirements for Personal Licensees³;
- copies of any veterinary (or other) certificates and/or advice.

³ [LASA Guiding Principles on the Supervision Requirements for Personal Licensees](#)

⁴ This information will be required by the project licence holder for the annual return of procedures.

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, SPF);
- anaesthetic code (e.g. AB, AB L, AB G, AB R and AD and for terminal work: AC)⁴;
- anaesthetic (regime) used;
- analgesia used;
- progress of surgery (e.g. complications if encountered);
- peri-operative care required and administered (including medication if required);
- adverse effects, observed (e.g. infection, wound dehiscence).

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 form of record and should be retained in the same way that other records are maintained.

3.3 Centrally recorded data

Central records of the source, use (e.g. project licence number, wild type stock, breeding), health and disposal of animals must be kept in all animal facilities on behalf of the Certificate holder⁵.

In addition, Certificate holders are required to provide facilities which comply with Home Office codes of practice⁶. To demonstrate such compliance, animal unit records (e.g. temperature, humidity, noise, light cycle, air change rates) are required. The unit NACWO (or facility manager) is normally the person tasked with keeping these records on behalf of the Certificate holder.

A personal licensee, requiring any of this additional information because, for example, it may have an impact on the outcome of the experiment, should contact the unit NACWO (or the appropriate person). While these records should be kept for 5 years, personal licensees are advised to request this type of information either during, or as soon as possible after, the experiment has 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 designated establishments (PODEs), additional records may be required. Due to the diversity of work carried out at PODEs, personal licensees are recommended to discuss record keeping with their local Home Office Inspector before beginning work.

⁵ In accordance with [standard conditions 6 and 7 applied to Certificates of Designation for Designated Scientific Procedure Establishments](#) and [standard conditions 5 and 6 applied to the Certificates of Designation for Designated Breeding and Supplying Establishments](#).

⁶ [Standard conditions 1 and 9 on Certificates of Designation for Designated Scientific Procedure Establishments](#) and [standard conditions 2 and 9 for Designated Breeding and Supplying Establishments](#).

4. References

Home Office (2000), [Guidance on the Operation of the Animals \(Scientific Procedures\) Act 1986](#). London: Her Majesty's Stationary Office.

[Code of Practice for the Housing and Care of Animals in Designated Breeding and Supplying Establishments](#). (1995) London: Her Majesty's Stationary Office

[Code of Practice for the Housing and Care of Animals used in Scientific Procedures](#). (1989) London: Her Majesty's Stationary Office

[Festing, M, Overend, P, Gaines Das, R, Cortina Borja, M, Berdoy, M \(2002\)](#). The design of Animal Experiments: Reducing the Use of Animals in Research through Better Experimental Design. [Royal Society of Medicine Press Ltd](#).

LASA 2007 [Guiding Principles on the Supervision of Requirements for Personal Licensees](#). 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

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