

Bureau of Animal Welfare, DPI Victoria

AUDIT PROTOCOL
For Part 3 of the Prevention of Cruelty to
Animals Act 1986

December 2005

Auditing and compliance activities are under continual improvement and will evolve as systems are assessed and validated. This working document is intended as a guide for auditors as directed by the Bureau of Animal Welfare under section 35 of The Act. Readers of this document should also familiarise themselves with the relevant legislation, including mandatory Codes of Practice detailed within.

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Audit Protocol

1. Introduction

The Bureau of Animal Welfare (BAW) regulates the use of animals in scientific procedures and the breeding of specified animals in Victoria. This responsibility includes administration of the relevant legislation; Part 3 of The Prevention of Cruelty to Animals Act 1986 (The Act) and Regulations 1997, policy development and implementation, support of Animal Ethics Committees and the triennial auditing of licensed institutions and inspections where indicated. The latter two roles aim to assure the public that such animal use is legally compliant, ethical and that maximal welfare protection during justified scientific procedures and specified animal breeding is provided.

The Statutory powers for auditing and inspection are described in section 35 of The Act, and further guidance on the scope and conduct for auditing or external review is provided in Appendix One of The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (7th edition, 2004) hereby referred to as The Australian Code.

Auditors nominated by the Bureau of Animal Welfare are authorised to conduct routine triennial audits of licensed institutions, the nominated AEC(s) and investigators, teachers and animal facilities according to this protocol. In addition inspectors directly authorised under section 35 of The Act have powers to conduct random or targeted inspections of licensed or alleged unlicensed institutions conducting scientific procedures.

The legal obligations and responsibilities of Institutions (license holders), nominated persons and investigators and teachers are outlined in The Act, The Regulations (whereby license conditions are stated on the license issued to the Institution) and the mandatory Codes of Practice namely:

- The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (The Australian Code)
- The Code of Practice for the Housing and Care of laboratory Mice, Rats, Guinea Pigs and Rabbits (The Laboratory Animals Code)
- The Code of Practice for the Use of Animals from Municipal Pounds for Scientific Procedures

These codes, the relevant legislation and this audit protocol can be found at www.dpi.vic.gov.au/animalwelfare/. DPI also has a general enforcement policy which outlines measures to promote and compel compliance as well as the relevant criteria and tools for addressing non-compliance issues. The latter are known as 'corrective actions' and include in order of significance; education and warnings, notices, orders by the Minister, infringements and prosecution.

As a result of the process, the audit should also enable the institution to further evaluate and modify processes to ensure it does or continues to meet its legal responsibilities. The audit report will fulfil the requirements and document the outcomes as per Appendix 1 of The Australian Code.

2. Background

Regular Government auditing provides independent regulatory oversight of an otherwise self-regulated system of AECs, animal use and specified animal breeding in Victoria. This process is to ensure that the Institution and Animal Ethics Committee (AEC) is functioning according to The Australian Code, the latter ethically assessing protocols, ensuring that the 3Rs are addressed wherever possible and monitoring approved animal use and facilities. The audit also evaluates whether the institution provides the AEC with adequate support, resources and respect within the institution as well as adequate resources and access to training for animal users.

Prior to 2006, a single consultant inspector, conducted all the audits of licensed institutions, under the direction and support of the Bureau of Animal Welfare. With expansion of the number of licensed institutions, incorporation of the auditing costs (with a 50% Government contribution for public benefit) into the institutional license fee, and further detailed requirements in the 7th edition of The Australian Code, a panel of trained auditors with considerable expertise and experience in the area of humane and ethical scientific procedures will be introduced from 2006.

3. Defining the Purpose and Scope of the Audit

The primary focus of the audit is to establish that all relevant use of animals is adequately justified, that there is adequate provision for the welfare of the animals involved and that the AEC is effective and adequately resourced, taking into account the Terms of Reference outlined in The Australian Code. The audit should also be educational and may assist to identify opportunities to promote the 3Rs and animal welfare. It may also provide an opportunity for all those responsible for animal care and use (the AEC, institutional management, scientific, educational and animal care personnel) to be involved in achieving the desired outcomes.

The ultimate purpose of the audit is to validate the ethical and humane use of animals in scientific procedures and breeding of specified animals in Victoria under the relevant license, according to the above-mentioned legislation. This is done by providing evidence according to the template in **4 parts** to demonstrate compliance or non-compliance.

4. Overview of the Auditing System

Following professional auditing training of the panel and independent consultation with the Bureau during 2005, audit and report documents have been revised. These will be used as templates by the panel, with a single auditor assigned to an audit as scheduled. This approach will standardise the conduct of audits plus the provision for further consultation amongst peers and with the BAW, to ensure consistency of process.

An audit is a wide ranging examination of an institution and nominated AEC's procedures, records, facilities, animals and other relevant information to assess whether there is an adequate system in place to facilitate and demonstrate compliance with the legislation. This process is essentially a retrospective determination of compliance or non-compliance and evaluation of whether improvements or corrective actions are required, and in what form these should take.

The actual audit will involve three aspects:

1. A systematic desk top examination of relevant information, records and standard operating procedures (SOPs); and
2. A comprehensive on-site inspection of facilities, animals and records to verify that the relevant Minimum Standards, information, records and animal welfare have been achieved; and
3. Pre-arranged face-to-face meetings.

The audit process involves the following steps.

Planning the audit	
(i)	Identifying when an audit will be undertaken and notifying the relevant auditor and institution accordingly.
(ii)	Arrangements by the auditor
(iii)	Auditor preparation prior to conducting an audit

↓ 2 weeks

Conducting the audit	
(iv)	Conducting the audit, commencing with an opening meeting, then use of the template in 4 parts.

↓ 1 week (approx)

Assessment of audit findings	
(v)	Based on audit findings, assessing the level of compliance with license conditions.
(vi)	Referring any non-compliance issues to the BAW for consideration and potential investigation (and possibly to the panel, as needed)
(vii)	Conducting a final brief meeting with the institution

↓ 3 weeks

Reporting on audit findings	
(viii)	Auditor preparation of the audit report as per the established proforma and sending to BAW
(ix)	BAW review, finalise, distribute and file the report and any corrective action notice(s)

↓ as required

Follow-up as required	
(x)	Conducting any follow-up visits deemed necessary by the auditor or panel and BAW. Any follow up correspondence.

The BAW and panel of auditors will attempt to work cooperatively with the institution, its personnel and nominated AEC to facilitate the auditing process. A cordial and professional approach to an audit ensures a high level of communication and permits the objectives of the audit to be more readily achieved. An institution will be requested by the auditor to provide information, records, SOPs and access to facilities and personnel as required to fulfil the process of a routine audit.

5. The audit process in detail:

Planning the audit.

(i) Identifying when an audit will be undertaken, allocating auditors and notifying the institution.

The Bureau of Animal Welfare will identify when an audit will be undertaken, considering the following:

- Time since last audit considering a triennial rotation
- History of non-compliance of the institution and its AEC
- Reporting to BAW of any alleged non-compliance
- System or management faults that the BAW has been made aware of
- Culture and attitude of the institution and its AEC

An audit may also be initiated as a result of an investigation into a separately alleged non-compliance. If, for example, a non-compliance is unsubstantiated during an investigation, an audit may be recommended for a broader assessment of the institution's conduct or to ensure recommendations are implemented to ensure demonstration of compliance in the future.

The Bureau will allocate a single member of the panel for each audit according to the general activities of the institution, specific expertise and time availability of the auditor and to ensure objective conduct, free from bias and conflict of interest. Attempts will be made to allocate a single auditor for two sequential audits of an institution, to enable some familiarity and to ensure that any out-standing concerns or non-compliance are consistently assessed and appropriated addressed. All auditors are required to disclose any conflict of interest (financial or otherwise) and to sign a confidentiality agreement preventing disclosure of information, used or obtained in the auditing process, beyond its intended use.

The Bureau of Animal Welfare will notify the institution accordingly (usually fax), defining the purpose, scope, approximate time frame and scheduled auditor for the audit plus the availability of this protocol at the DPI website.

(ii) Arrangements by the auditor for an audit

Once an audit is scheduled and an auditor is allocated, the auditor must make the following arrangements of dates/times (by phone/email) approximately two weeks before visiting the institution:

- Introduction and overview of the audit in 4 main parts
- To access to AEC paperwork- ie. minutes for the last 3 years, project records, annual, progress and final reports, terms of reference, operating procedures (If Interstate license holders/AECs see ** in iii)
- Explain that at least 3 protocols will be examined in detail- from assessment of application to recording of animal use, annual reports
- To attend at least part of an AEC meeting (if scheduling permits) or meet with the independent AEC members (ie. category C and D members)
- Establish any quarantine requirements (* below) or fieldwork site details.
- To inspect the animal facilities with the relevant staff
- To review access to and records of training of AEC members and investigators/teachers (staff/ students)

- Advise that further arrangements will be made to meet with selected investigators/teachers (after review of AEC records)
- To meet with the license nominated person and chair of AEC at the end of the audit

***Quarantine:** the time lapse required between entering animal facilities must be established prior to visiting. Protective clothing should be provided by the institution's animal facility as appropriate for the existing level of biosecurity. Auditors must not enter non-human primate facilities if known risk of incubation exists or they are suffering from the common cold, influenza, mumps, herpes simplex or any other relevant transmissible diseases. Auditors must observe the quarantine and biosecurity protocols of the institution (eg. protective clothing, footbathing, delineated barriers, clean to dirty priority order of visit, showering). As appropriate auditors must observe any exit requirements and clean and disinfect shoes/boots before leaving premises.

(iii) Auditor preparation prior to conducting an audit

The auditor will liaise with the BAW licensing officer to obtain and become familiar with the following details (in confidence) prior to an audit:

- License type and details (nominated person, nominated AEC(s), premises (if applicable))
- Any logistical details regarding fieldwork or breeding licenses
- AEC details (names of members and contacts for the chair and executive officer- phone/email contact, if exists)
- Previous inspection/audit reports (**), outstanding issues or complaints
- Last year's annual returns, noting any death as an end point procedures (see regulation 12 (2)) and 'particular procedures' of interest.
- Any other information/ requests specified by the BAW

** **Interstate license holders and/or AECs** are requested to make recent audit /review reports from their home jurisdiction available (in confidence) to the BAW prior to the scheduled audit, as a condition of license.

The auditor must be familiar with this protocol and obtain the relevant auditing template, have copies of the legislation and mandatory codes, plus any other appropriate species codes, guidelines or policies. The auditor may wish to use a laptop or clipboard to complete the audit template.

(iv) Conducting the audit

Opening meeting with the organisation

A brief meeting should be convened on day one of the audit with the auditor and a representative from the institution (eg. the executive officer or ethics administrator or other as applicable). The purpose of the meeting is to:

- Introduce the auditor
- Confirm the agreed scope, audit plan and timetable for activities
- Confirm availability of pre-arranged resources, staff etc
- Advise the use of a standard audit template
- Establish line of communication and promote involvement of the institution in the audit.

Collection, examination and analysis of information, records, procedures/evidence for the audit :

The auditor will proceed with the actual audit activities using a standard template* in 4 parts:

- Audit of the AEC (documentation and meeting/interview)
- Audit of project information provided to the AEC
- Audit of project animal use (purposive sampling of projects)
- Audit of any animal facilities and current animal use

This process may involve varying means of collecting evidence to document compliance/non-compliance. These means may involve direct examination of records, animals and facilities, use of instantaneous ammonia and light meters (particularly for housed mice, rats, guinea pigs and rabbits), digital cameras and face-to-face discussions. For further details the audit template is also available on the BAW website.

Assessment of audit findings

(v) Assessing compliance with the license conditions

Based on audit findings (with reference to BAW or the audit panel if required), the auditor will assess the general level of compliance with license conditions, identifying any issues of concern or lack of required management systems to ensure compliance.

(vi) Findings of non-compliance

It is important to note that an audit is not an investigation. The purpose of an audit is to find deficiencies in an institution's system of operation, suggest improvements and report evidence to determine if an institution is compliant or non-compliant.

All incidents of non-compliance must be reported to BAW by the auditor.

Where there is identification of non-compliance that relates to animal use in excess of AEC approval or compromised animal welfare (beyond that approved by the relevant AEC), immediate referral to BAW is required for consideration and potential investigation by an authorised officer. If directed by BAW, the auditor may be required to stop the audit to enable an authorised officer to attend and collect evidence and information appropriate for a potential prosecution*. This action is not often required but continuing an audit in light of a serious non-compliance finding may jeopardise an investigation.

Evidence of non-compliance that relates to a retrospective error or administrative system failure must also be reported to BAW, but often the audit will be able to continue, although further detailed evidence relating to the non-compliance may need to be collected at the advice of the BAW. All evidence concerning any non-compliance must be documented in the audit template and the audit report.

Corrective Action Notices

Non-compliances will be considered as minor (eg. minor administrative record non-compliances) or major (eg. out of session or repeated inqurate AEC application

approvals, unapproved animal use, non-compliance with Minimum Standards (of Laboratory Animals Code or Regulations 16 and 23), systemic administrative non-compliances), with further examples developed and agreed by the Bureau of Animal Welfare and the panel of auditors. A major compliance or a series of related minor compliances will elicit an a 'corrective action notice', detailing the problem, what and when the corrective action is required and details of any follow- up visit as appropriate. This notice will accompany the audit report.

*Only DPI officers authorised under section 35 may administer an investigation and prosecution of Part 3 of The Act. The OMU (Offence Management Unit) acts as an independent reviewer for all DPI administered prosecutions, setting appropriate charges and carrying out prosecutions in line with the Office of Public Prosecutions.

(vii) Closing meeting with the institution

At the completion of the audit, but before the audit report is prepared, a closing meeting between the auditor and the nominated person of the license and chair of the AEC will be held. This meeting is to verbally confirm the basis of the audit findings, conveying the general findings in brief and identifying any specific immediate follow-up or corrective actions likely to be required (after discussion with BAW as appropriate). It is also essential that the institution's agreement with the audit findings is sought.

The institution may not necessarily agree with all findings of the auditor. Disagreement with the audit findings are to either be resolved by the auditor (where possible) or taken into account in the preparation of the final audit report. If necessary, further or ongoing concerns may be referred to the entire audit panel and BAW.

Report of audit findings

(viii) Preparation of the report by the auditor

The audit findings are prepared in a report by the auditor according to a proforma revised by the BAW and an independent audit trainer. The draft audit report must be provided to BAW (Principal Veterinary Officer) within 3 weeks of the completed audit. The content of the draft report includes the following:

- The name of the licensed institution, the objectives and scope of the audit with reference to the relevant legislation
- The relevant dates covering the audit activities
- Identification of the auditor and references, templates, materials used
- Audit findings, supporting evidence and advice as per the 4 parts of the audit template
 - Regarding the AEC records, terms of reference, activities and meeting
 - Regarding the written proposals scrutinised
 - Regarding specific projects and animal use audited
 - Regarding the animal facilities and records, condition and welfare of animals
- Any non-compliances and recommended actions/advice
- Any obstacles or disagreements with the institution and reasons
- Any areas of commendation, examples of best practice etc
- Overall dis/satisfaction relating to compliance with the license conditions
- Any other matters, acknowledgements of assistance

- Auditor report date

(ix) Review and finalisation of the report by the Bureau of Animal Welfare

The draft audit report is reviewed by BAW (and the audit panel if required). Reports of incidents of non-compliance and auditor recommendations are considered in detail and provide the basis for any corrective action notices to address the relevant non-compliances (see also iv). If the final audit report contains one or more corrective action notices, a written commitment is sought from the organisation to undertake the specified action in the time lines indicated. The corrective action notice will accompany the final audit report plus a summary sheet of the achieved **outcomes** articulated in Appendix 1 of the Australian Code.

As suggested in the Australian Code, the institution may consider publishing the summary page, possibly in an institutional annual report or website. The summary report can also be made available to other relevant regulatory or funding bodies.

Distribution and confidential filing of the audit report

The final audit report signed by BAW will be distributed in hard copy only to:

- The nominated person of the license
- The AEC chair and members
- The Institutional ethics officer/ executive officer

A copy is also placed on the BAW confidential license file along with any ensuing correspondence and reports of follow up visits. Relevant information is also added to the confidential BAW computer database.

(x) Follow up as required

If non-compliances are found and corrective actions are required, it may also require further consultation with the institution to ensure an achievable and practical time line is established. The auditor (or an authorised officer) would usually be required to conduct a follow-up visit. This visit is intended to monitor the institution with regard to any non-compliances or high risk of a non-compliance to ensure that the agreed corrective actions have been implemented. A final brief report to this end may also be required.

Failure by an institution to adequately justify or account for any non-action on their part may lead to an escalation of compliance strategies by the Bureau of Animal Welfare.