

Self-Assessment Checklist

For use in audits of Scientific Procedures Premises License (SPPL) and Specified Animals Breeding License (SABL).

License details

License details	Details required
License name and number	
License nominees	
AEC name/s	
Executive officer/s	
Due date for return to licensing and audit unit	
Name and role of person/s completing this form	

Guidance for completing this form

The purpose of collecting the following information is to allow the audit to be tailored to the licence, and to make the most efficient use of auditing time. Please complete and return, with attachments, to sp.licensing@agriculture.vic.gov.au by the due date.

Parts A and B require only an indication of whether the document or action required by the *Australian code for the care and use of animals for scientific purposes*, 2013 (the Australian code) has been developed for the licence or not. Comments may be made to explain how, for example, other documents fulfil the requirement.

Parts C, D, and E include checklists for the content of each document. The checklists are intended to assist you to ensure these documents comply with the Australian code's specific requirements.

PART A: PROCEDURES AND GUIDELINES

Australian code reference	Procedure/guideline	Complete (C) Under development (D)	Comments
2.2.32	AEC procedures:		
	Application for AEC approval to commence a project or activity.		
	Annual report form for approved projects.		
	Proposed amendment to an approved project or activity.		
	Unexpected adverse events reporting.		
	Reporting on an approved project that has been completed or discontinued.		
2.1.5(v)	Guidelines for animal care and use:		
	How competency is assessed and ensured.		
	Strategies to ensure maintenance of health status of animals.		
	Monitoring and assessment of animals.		
	Actions required for unexpected events and emergencies.		
	Approval, in advance, for the immediate use of animals, if required, for the diagnosis of unexplained and severe disease outbreaks (if applicable).		
2.2.36	Procedure to ensure all approved standard operating procedures		

	(SOPs) are made available to all relevant people, including AEC members. (mandatory if SOPs are referenced by applicants to the AEC)		
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PART B: RECORD KEEPING AND REPORTING

Australian code reference	Record keeping and reporting	Complete (C) Under development (D)	Comment
2.2.37; 2.3.28	Institution annual review of the operation of the AEC and assessment of AEC annual report.		
2.2.37	Provide the date of the most recent meeting between the institution and the AEC Chair.		
2.1.9	Institution annual review of the effectiveness of the processes regarding complaints and non-compliance.		
2.5.15	Facility manager(s) annual report of activities to the AEC.		

PART C: AEC TERMS OF REFERENCE AND PROCEDURES

Australian code reference	Record keeping and reporting	Complete (C) Under development (D)	Comment
2.1.6 (ii)	TOR publicly available.		
2.2.18 (i)	TOR define the scope of AEC responsibilities for: • ethical review • approval • monitoring of animal care and use.		
2.2.18 (ii)	TOR includes a provision for the AEC's institutional accountability.		

2.2.18 (iii)	TOR includes a provision for AEC mechanisms of reporting.		
2.2.18 (iv)	TOR includes provisions for the way in which the AEC meets the requirements for categories of minimum membership.		
2.2.20 Mandatory to establish procedures Non-mandatory list	*Procedures for animal ethics committee governance and operation: • management of confidentiality • administrative processes • meeting procedures • communication • complaints and non-compliance • records and documentation.		
2.2.21	*Procedures for declaration of interests and management of perceived or actual conflicts of interest involving AEC members, and experts whose advice is sought by the AEC, which require people with a conflict of interest to remove themselves from the AEC's decision making on matters that relate to the conflict of interest.		
2.2.23	*Procedures to ensure the AEC executive (if established): • includes the chairperson and at least one member from Category C or D • may be delegated to approve minor amendments to approved projects or activities, for ratification at the next AEC meeting		

	• must not approve new applications.		
2.2.23	*AEC procedures include a definition of a minor amendment that may include a change to an approved project or activity where the proposed change is not likely to cause harm to the animals, including pain and distress.		
2.2.13	*AEC procedures define responsibilities of the chairperson: • for impartially guiding the operation of the AEC resolving conflicts of interest related to the business of the AEC • representing the AEC in any negotiations with the institution's management.		
2.2.9	*Procedures for the appointment, re-appointment and retirement of AEC members.		

PART D: COMPLAINTS AND PROCEDURES

Australian code reference	Record keeping and reporting	Complete (C) Under development (D)	Comment
2.2.29 Section 5	Procedures for dealing with: • complaints of non-compliance with the Australian code • complaints related to the AEC process • irreconcilable differences between the AEC and an investigator.		

5.1	Procedures for complaints concerning: • the care and use of animals by the institution • conscientious objection in the case of teaching activities • the AEC process of review of an application or report, including resolution of disagreements between AEC members, between the AEC and investigators, and between the AEC and the institution • the process for independent external review.		
5.2	Complaints procedures: • give priority consideration to the wellbeing of the animals, and ensure that activities with the potential to adversely affect animal wellbeing cease immediately • clearly define the mechanisms for receiving, investigating and addressing complaints • clearly define the responsibilities of all parties • ensure fair, prompt, timely, effective, confidential processes that		

	accord with procedural fairness, the principles of natural justice and protection of whistleblowers • identify and ensure appropriate reporting to the institution, AEC, state or territory government authorities, and any other relevant bodies are made available to all relevant people.		
5.3	For projects involving more than one institution and/or AEC, procedures include mechanisms for reporting between the relevant institutions and AECs on complaints. (if applicable)		
5.4	Complaints procedures ensure that where complaints concern the care and use of animals that: • relate to activities that have the potential to adversely affect animal wellbeing, the activities cease immediately • relate to activities that would normally require AEC approval, the complaints are referred to the AEC to investigate whether such activities are conducted in accordance with AEC approval • raise the possibility of 'research misconduct', as described in the Australian code for the responsible conduct of research, the complaint		

	is handled in accordance with procedures specified in that document allege misconduct, that falls outside the range of 'research misconduct', as described in the Australian code for the responsible conduct of research, the complaint is handled in accordance with institutional processes for dealing with other forms of misconduct.		
5.5	Procedures for the AEC's investigation of complaints referred to it by the institution: - ensure that, where activities are conducted in accordance with an AEC approval, the activities are reviewed in consultation with all relevant people to ensure that the reason for the complaint is addressed. The AEC may decide that modification to a project or activity is required, or an approval for a project or activity is suspended or withdrawn - ensure that, where activities are not conducted in accordance with AEC approval, the matter is referred back to the institution for action (non-mandatory).		
5.6	Procedure for complaints concerning the AEC process		

	of review of an application or report that cannot be resolved by communication between the complainant and the AEC that is the subject of the complaint.		
5.6	Procedures ensure the ultimate decision regarding the ethical acceptability of an activity lies with the AEC and must not be overridden.		
5.8	Procedures for unresolved complaints.		

Part E: Non-compliance procedure

Australian code reference	Record keeping and reporting	Complete (C) Under development (D)	Comment
2.2.29 5.1 (iv)	Procedures cover dealing with non-compliance with the Australian code by any party or person involved in the care and use of animals including: - investigators - animal carers - the AEC - governance officials - external parties subject to agreements.		
5.2	Non-compliance procedures: - give priority consideration to the wellbeing of the animals, and ensure that activities with the potential to adversely affect animal wellbeing cease immediately - clearly define the mechanisms for receiving, investigating and addressing complaints		

	• clearly define the responsibilities of all parties • ensure fair, prompt, timely, effective, confidential processes that accord with procedural fairness, the principles of natural justice and protection of whistleblowers • identify and ensure appropriate reporting to the institution, AEC, state or territory government authorities, and any other relevant bodies are made available to all relevant people.		
5.3	For projects involving more than one institution and/or AEC, procedures include mechanisms for reporting between the relevant institutions and AECs on non-compliance. <i>(if applicable)</i>		

Required documents

Provide the following documents as attachments:

- a) Register of all applications to the AEC, including the outcomes of deliberations for the previous three years (Australian code reference 2.2.30).
- b) Records of breaches of the Australian code since October 2014 (Australian code reference 5.10).
- c) Register of standard operating procedures (SOPs), if applicable, including approval date by AEC (Australian code reference 2.2.33) *Note: this register must be provided if SOPs are referenced in applications to the AEC.*

Provision of other relevant information

Provide a list of any other relevant policies, procedures or guidelines developed by the institution for the purpose of ensuring compliance with the Australian code.