MPI Standard

Performance Standards for Independent Reviews of Code Holders and Animal Ethics Committees

22 July 2022

Issued under the Animal Welfare Act 1999

New Zealand Government

TITLE

MPI Standard: Performance Standard for Independent Reviews of Code Holders and Animal Ethics Committees

COMMENCEMENT

This MPI Standard comes into force on 22 July 2022.

ISSUING AUTHORITY

This MPI Standard is issued by the Minister for Primary Industries under section 112 of the Animal Welfare Act 1999.

Contact for further information
Ministry for Primary Industries (MPI)
Agriculture & Investment Services - Tapuwae Ahuwhenua
Animal Welfare
PO Box 2526
Wellington 6140

Email: animalwelfare@mpi.govt.nz

Contents

Introduction

This introduction is not part of the Performance Standards but is intended to indicate its general effect.

Purpose

These performance standards specify requirements for accredited reviewers when independent reviews of code holders and animal ethics committees are carried out on behalf of the Director-General of MPI.

They set clear expectations for accredited reviewers and can be used for accreditation and auditing purposes.

This document may be updated from time to time. It is recommended that anyone intending to use it should contact the MPI Animal Welfare Team (animalwelfare@mpi.govt.nz).

Background

The Animal Welfare Act 1999 (the Act) provides for the welfare of animals in New Zealand. It puts obligations on people who own or are in charge of animals to provide for their welfare.

Part 6 of the Act outlines specific obligations for individuals and organisations (code holders) that use animals for research, testing and teaching (RTT) purposes. To lawfully undertake RTT activities, code holders are required to apply for and maintain a code of ethical conduct (CEC). Each CEC specifies how the code holder manages their RTT work including the establishment and process around an animal ethics committee (AEC).

Code holders are required to have their codes reviewed by an accredited reviewer every five years if they intend to continue using animals in RTT. When a code is due to expire the code holder will engage an accredited reviewer to undertake the review.

As authorised in section 112 of the Act, this document is a set of 'performance standards in relation to the exercise or performance by accredited reviewers of their functions, powers and duties under this Act'.

Who should read this MPI Standard?

This standard should be read by:

a) accredited reviewers;
b) code holders; and
c) members of animal ethics committees.

Why is this important?

The Animal Welfare Act 1999 requires that reviewers use their best endeavours to comply with, and give effect to, any relevant performance standards.

Document History

Version Date	Section Changed	Change(s) Description

Other information

The following documents are also relevant and can be referred to by the reader.

a) Animal Welfare Act 1999 (the Act), specifically;
   i) Part 6; and
   ii) Schedule 2;
b) Animal Welfare (Records and Statistics) Regulations 1999;
c) NAEAC Good Practice Guide for the Use of Animals in Research, Testing and Teaching; and
d) Animal Use Statistics.

Part 1: General Requirements

1.1 Application

(1) This performance standard applies to all independent reviews carried out under s 105 of the Animal Welfare Act 1999 (the Act).

1.2 Definitions

(1) Any term or expression that is defined in the Animal Welfare Act 1999 but is not defined in this document has the same meaning as in the Act.

(2) For the purposes of this standard:

AEC: Animal ethics committee.

Commendation: Special recognition of a matter identified by the reviewer.

Contracted Review: A review initiated by a code holder.

Critical Situation: Any situation which, in the judgement of the reviewer, places code holder, AEC or the Director-General's credibility at risk (this could potentially lead to the suspension or revocation of the approval of a code of ethical conduct).

Director-General: The Director-General of the Ministry for Primary Industries.

Follow-up review: An additional review required by the Director-General as a result of a previous review.

Initiator (of review): The code holder, the Director-General, or the Minister.

Minister: The Minister of the Crown who, under the authority of any warrant or with the authority of the Prime Minister, is for the time being responsible for the administration of this Act.

MPI: Ministry for Primary Industries.

Non-compliances: A finding that, in the opinion of the reviewer, demonstrates the procedures and policies do not comply with the Act, its regulations or the relevant code of ethical conduct. It may be a specific non-compliance or a system with multiple non-compliances having a cumulative effect. Non-compliances may be created by escalation of outstanding issues from previous reviews.

Recommendation: A suggestion aimed at improving the procedures and policies, or in keeping with requirements of the terms of reference. Recommendations are non-binding (that is, they do not have to be actioned).

Reviewer: A person accredited in accordance with section 109 of the Act to undertake independent reviews of code holders and animal ethics committees.

Special Review: A review initiated by the Minister.

Terms of Reference: Specific review instructions, including goals, scope and other conditions set by the Director-General, or the Minister.

Part 2: Reviewer Responsibilities under the Act

(1) **In exercising or performing functions, powers and duties under sections 114 and 115 of the Act, a reviewer is responsible for:**

a) planning, performing and documenting the review, and for ensuring that it meets the needs of the Director-General as defined by these performance standards;
b) immediately notifying the Director-General of any critical situations that are identified during the review and advising what action will be taken;
c) preparing a draft report (where possible, within 15 working days of the completion of the review) setting out the reviewer's conclusions, including any critical situations, non-compliances, commendations, and any recommendations;
d) allowing the code holder at least 15 working days to comment on the draft report;
e) preparing a final report; and
f) sending copies of the final report to the code holder, Director-General of MPI or their delegate and the National Animal Ethics Advisory Committee within 10 working days of receipt of comments from the code holder.

(2) **In accordance with s 110 of the Act, the reviewer must**:

a) maintain an appropriate degree of impartiality and independence in carrying out their duties;
b) take all reasonable steps to ensure that their judgement is not impaired:
    i) by any relationship with, or interest in, the code holder or the code holder's organisation subject to review; or
    ii) by any involvement in the development of, or the process for the approval of, a code of ethical conduct; and
c) use their best endeavours to comply with, and give effect to, any relevant performance standards or other requirements issued by the Director-General under section 112; and
d) keep full and readily accessible records of each independent review for at least ten years after the review period has ended, so they can be used for subsequent reference.

(3) **In performing duties under section 110 of the Act, a reviewer must also**:

a) not have submitted a project application to any AEC established by the code holder being reviewed within the previous 5 years;
b) not have any conflicts of interest (e.g. a personal, commercial or financial interest in the code holder's organisation);
c) declare any perceived conflict of interest; and
d) not carry out more than 2 consecutive reviews of the same code holder (excluding any follow-up reviews).

Part 3: Actions Prior to the Review

3.1 Initiating the Review

(1) The code holder will contract an accredited reviewer of their choice to organise a review. The MPI Animal Welfare Team maintains a list of accredited reviewers, which code holders may consult. The list is also publicly available on the MPI website.

3.2 Review Arrangements

(1) Prior to review, the code holder and the reviewer must agree upon the matters listed below:

a) complete and full access to all relevant information, including all relevant AEC records and minutes of all AEC meetings;
b) full access to all relevant personnel and facilities;
c) full access to any information regarding any notified arrangements with the code holder and access to the sites with these arrangements as requested;
d) an opportunity to meet with all members of the AEC, individually if requested;
e) that there is enough time to carry out the review properly;
f) agreement that any intellectual property remains confidential but is still accessible to the reviewer; and
g) conditions of payment.

(2) This may be agreed either by way of formal contract or by an exchange of emails or letters with records of the contract and correspondence kept with the records referenced in 1(a) above.

3.3 Organising the Review

(1) The code holder and reviewer will agree to a time that is convenient for both parties to carry out the review.

(2) The code holder will provide the contact details for all AEC chairpersons covered by the code holder's CEC to the reviewer.

3.4 Terms of Reference

(1) The terms of reference are to review compliance by a code holder, and by each AEC appointed by the code holder, against the requirements and standards of the Act and of any regulations made under this Act and of the code of ethical conduct. The reviewer shall inform the code holder of the terms of reference of the review. The reviewer will satisfy the criteria outlined in Part 7 of this document.

3.5 Notification

(1) Before the review is scheduled to take place, the reviewer will confirm the details of the review and the names of the chairpersons of all AECs appointed in accordance with the code holder's CEC. This must be done in writing before the review commences. Formal notification may be in the form of a letter or an acknowledged email. The correspondence should request notification of any pre-entry requirements for visiting animal facilities. A suggested format for this confirmation is provided in Appendix 1.

(2) A copy of the terms of reference and any checklists for the reviewer should be included with the letter of confirmation.

(3) The reviewer will notify the MPI Animal Welfare Team that they will be undertaking the review. The team will provide the reviewer with a copy of the code holder's approved CEC and a list of any organisations or individuals which have entered into a notified arrangement to use the code holder's CEC and AEC. The reviewer will also notify the MPI Animal Welfare Team of any conflicts of interest at the time of notification of the upcoming review.

(4) The reviewer can obtain a copy of the previous review report and related correspondence from the MPI Animal Welfare Team if the review was carried out by another reviewer.

(5) Prior to the face-to-face review, the reviewer will carry out a desktop audit of the documents.

Part 4: Desktop Assessment of AEC Documentation

(1) In addition to the approved CEC and previous review report received from MPI, a comprehensive range of documentation should be requested from the code holder including:

a) evidence of AEC appointments;
b) AEC minutes since the last review;
c) a list of applications indicating the outcome of AEC consideration;
d) a selection of applications representing a range of manipulation grades, with an emphasis on those involving new staff and new manipulations;
e) reports to the AEC (approximately 15 percent of applications as a guide, but more can be viewed if the reviewer desires);
f) standard operating procedures;
g) facility plans;
h) complaints; and
i) non-compliances.

(2) The reviewer will use these documents in conjunction with a checklist (Appendix 6) to:

a) assess compliance with the code;
b) consider the appropriateness of the code;
c) prepare for the site visits, AEC observation, and personnel interviews; and
d) inform the draft report.

Part 5: Site Visit

5.1 Sign In

(1) The reviewer must adhere to any pre-entry requirements at the locations they visit.

5.2 Meeting with the Code Holder

(1) This meeting will normally be with the chief executive or other senior staff member and should cover:

a) a description of how the reviewer will approach the review;
b) reporting;
c) deadlines;
d) opportunities to comment and rights of reply on the draft reports;
e) critical situation procedure;
f) the reviewer's expectations should non-compliance be found; and
g) the distribution of the final report.

5.3 Scrutiny of Additional Documents

(1) All relevant documents, systems, programmes and records that have not already been viewed will be requested and checked (some documentation may be scrutinised in advance). This should include scrutinising the AEC application form to ensure it covers all areas required by the Animal Welfare Act:

a) the purposes of Part 6 of the Act;
b) the scientific or educational objectives of the project;
c) harm or distress caused and extent to which that can be alleviated;
d) likelihood of objectives being met given the design of the project;
e) factors involved in species selection;
f) minimum number of animals to ensure meaningful results;
g) measures to ensure general health and welfare before during and after manipulation;
h) suitability of those undertaking and supervising the project;
i) duplication (avoidance of or justification for);
j) cumulative effects of any re-use of animals;
k) commitment to ensuring findings will be adequately used, promoted or published; and
l) any other matters considered relevant to the review.

(2) Any reference to other locations should be noted. The reviewer should view approximately 15 percent of protocols approved since the previous review (or more if desired), ensuring a range of welfare impacts and including some that required significant modification.

(3) Previously recorded deficiencies in systems or records must be investigated to ensure corrective action was completed.

5.4 Additional Personnel

(1) The reviewer should request access to additional personnel to accompany them when viewing operational activities (for example, animal house technicians, animal users, tutors).

(2) The reviewer should hold discussions with as many of the AEC members as possible, including all independent members (except in extenuating circumstances). Information on the following should be discussed:

a) appointment procedures and term;

b) training;
c) adequacy of meeting processes and protocol review including the decision-making process and whether input is sought from all members;
d) adequacy of monitoring procedures; and
e) method of dealing with complaints.

(3) Where the code holder has entered into arrangements to allow external parties to use its code and AEC, interviews should be held with at least some of the external parties. Arrangements should be made for site visits (the number will be dependent on how many external parties are involved), with reference to previous reviews to ensure new sites are selected.

(4) Where possible, the reviewer should hold discussions with some users of the AEC (eg researchers/lecturers) to seek feedback on the operation of the AEC and the regulatory system generally.

5.5 Site Inspection

(1) The reviewer will review the code holder's performance by assessing selected areas, programmes, processes, records, facilities and by checking that the activities meet the requirements of the Act, regulations, the CEC and all requirements imposed by the AEC and the institution that relate to animal care and management. This will be carried out with the use of checklists that are provided in Appendix 6 (copies of the checklists can be requested from the MPI Animal Welfare Team and can be found on the MPI website).

(2) In deciding which facilities to review consideration should be given to the number of sites, their geographical location and whether facilities have been visited in previous reviews.

(3) Any defects or deficiencies will be recorded by the reviewer and discussed with the code holder.

(4) Matters requiring clarification must be resolved either during the review or at a later date, prior to submission of the draft report.

(5) Any critical situations must be immediately brought to the attention of the Director-General through the MPI Animal Welfare Team.

5.6 Exit Debrief

(1) Key review findings, particularly anything that impacts the welfare of animals, should be discussed with the code holder and the AEC chairpersons at the conclusion of the review. Where the review covers multiple AECs, this debrief should occur after each AEC has been reviewed.

Part 6: Post-Review Procedure

6.1 Draft Report

(1) The reviewer must, after conducting a review, prepare a draft report according to the criteria set out in Part 7, that outlines any critical situations, non-compliances, preliminary conclusions and any preliminary recommendations. Non-compliances should be listed in order of seriousness. The draft report should be prepared within 15 working days of the completion of the review, where possible.

(2) The reviewer will send a copy of the draft report to the code holder and ask them to provide feedback regarding any errors or inconsistencies. The reviewer can specify a reasonable time for the code holder to reply but, as specified in the Act, that timeframe must be greater than 15 days. A sample letter for dispatch alongside the draft report is provided in Appendix 2. A suggested format for the draft report is provided in Appendix 3.

6.2 Final Report

(1) Following receipt of any comments from the code holder the reviewer will prepare a final report within 10 working days, setting out their conclusions and recommendations. Responses by the reviewer to the code holder's comments should be included as a separate appendix to the final report.

(2) The final report should be clearly identified as the final report; it is recommended that this be noted in the footer.

(3) The reviewer will send copies of the final report to the code holder, MPI (technically the Director-General) and the National Animal Ethics Advisory Committee (including a copy of any responses and comments made by the code holder in relation to the draft report).

6.3 Non-compliances and Recommendations

(1) The final report must include the following explanatory note at the end of the contents page:

Important Note

a) All deficiencies identified as non-compliances are expected to be resolved by the code holder or the code holder's organisation. The effectiveness of the corrective actions will be measured in subsequent reviews. Inadequate resolution can lead to failure of the subsequent review.
b) Recommendations are non-binding, and do not affect subsequent reviews. Their implementation may provide efficiencies. The presence of recommendations to change existing specifications does not excuse the absolute requirement to conform to the existing specifications. Changes to specifications that may result from these recommendations will be promulgated officially.

6.4 Suspension or Revocation of a Code of Ethical Conduct

(1) As a result of a review the Director-General may decide to suspend or revoke the approval of a code of ethical conduct in accordance with s 96 of the Act if they believe on reasonable grounds that the code holder:

a) no longer has the skills necessary to carry out research, testing and teaching; or
b) has failed to comply with the Act or any regulation under the Act or the code of ethical conduct; or
c) has failed to rectify critical situations and non-compliances within the agreed time frame.

(2) If the Director-General decides to suspend or revoke a code of ethical conduct, the Director-General must first:

a) give the code holder the opportunity to be heard; and
b) consult with the National Animal Ethics Advisory Committee.

(3) If the Director-General decides to approve the suspension or revocation of a code of ethical conduct, the Director-General must publish a notice of the decision in the *Gazette.*

Part 7: Summary of Required Report Content

(1) The review report outlining the code holder's performance shall include the expected content as outlined below and in Appendix 6.

a) Background information on the activities of the code holder, in particular the nature and extent of the research, testing or teaching; and the code holder's philosophy towards research, testing and teaching and the 3 Rs.
b) The functions, duties, powers and membership of the animal ethics committee.
c) The animal ethics committee's procedures for meetings, the decision process, documentation of conflict of interest and effective input of committee members.
d) The animal ethics committee's consideration of projects and outcomes.
e) Evidence that projects comply with the animal ethics committee approval including involvement of appropriately qualified personnel, appropriate transportation, housing and treatment of animals and conduct of experiments.
f) Animal facilities have appropriate policies and procedures approved by the animal ethics committee.
g) People manipulating animals are trained and competent and monitoring of projects is undertaken at frequencies set out by the code of ethical conduct.
h) Where incidences of non-compliance have been observed, the escalation process was appropriate, consideration by the full animal ethics committee occurred and adequate documentation was available.
i) Applications from parented organisations comply with the requirements of the code of ethical conduct and animal ethics committee procedures, and a sample of parented organisations have been interviewed and visited.
j) Complaint procedures are in place and appropriate, and any animal welfare complaints have been appropriately escalated.
k) Where applicable, any requests to amend, suspend or revoke the code of ethical conduct are included and documented.

Appendix 1: Sample covering letter – Formal confirmation of review

[date]

Tēnā koe *[name]*

As discussed by [phone/email] on *[date]*, you as code holder have asked me to conduct a review of your code of ethical conduct and all animal ethics committees appointed by you as the code holder.

The purpose of the review is a requirement of the Animal Welfare Act 1999 to verify compliance by a code holder, and by each AEC appointed by the code holder, against the requirements and standards of this Act and of any regulations made under this Act and of the code of ethical conduct.

The terms of reference are attached for your information. This letter is to confirm dates for the review as follows:

[date, day, month, year, code holder, location(s)]

You have advised that the names of the chairpersons of the animal ethics committees are: *[list names].* I understand that they and the members of the AEC will be available to take part in the review on the above date(s).

Please advise of any pre-entry requirements for visiting your animal facilities.

Nāku noa, nā,

[Name]

[Address and Phone Number]

[email]

Appendix 2: Sample covering letter – For dispatch with draft report

[date]

Tēnā koe *[name]*

You now have the opportunity to comment on the attached draft report. Your comments will be considered and if appropriate the draft report will be modified. These comments, and my response, will be included in an appendix in the final report. A copy of the final report will be sent to you, the Director-General of the Ministry for Primary Industries, and to the National Animal Ethics Advisory Committee.

The Animal Welfare Act 1999 requires that code holders are allowed at least 15 working days within which to respond to and comment on the contents of the draft report. However, please ensure that your comments are forwarded to me within 15 working days of receipt of the draft report if possible. If you do not wish to comment, please reply to confirm that the draft was received.

Nāku noa, nā,

[Name]

Appendix 3: Suggested Format for Review Reports

Title page

Important note

Table of contents

1 Terms of reference

2 Date of review

3 Locations reviewed

4 Reviewer

5 Name of code holder and AEC chairpersons

6 Additional personnel present (optional)

7 Type of review (contracted/follow-up/special)

8 Background

9 Summary (including feedback from AEC users (internal and external))

10 Non-compliances, commendations and recommendations

11 Assurances/actions

12 Summary of non-compliances

13 Summary of recommendations

14 Distribution of report

15 Signature of reviewer

Appendices

- Appendix 1 Code holder feedback
- Appendix 2 Interview comments
- Appendix 3 Document control
- Appendix 4 Checklist(s)
- Appendix 5 Any other documentation

Appendix 4: Document Control Sheet

Type of Review: (Contracted / Follow-up / Special Review)

Reviewer Name:

	D	M	Y
1. Date when the review was requested			
2. Date when the code holder was notified in writing confirming the review date and when the terms of reference were sent			
3. Date of the review			
4. Date of completion			
5. Date when the DG was notified of any critical situation(s)			
6. Date when the draft report was sent to code holder			
7. Date when responses were received from the code holder			
8. Date when the final report was sent to MPI (DG), NAEAC and the code holder			

This document control sheet is to be appended to review reports.

Appendix 5: Terms of Reference

(1) The terms of reference shall include:

a) goal;
b) scope;
c) initiator and AEC Chairperson's name/Chairpersons' names;
d) type of review (contracted/follow-up/special);
e) standards/legislation (including regulations);
f) checklists;
g) additional personnel;
h) response to critical situation;
i) mechanism for resolving non-compliances;
j) draft report response process; and
k) final report distribution.

Example Terms of Reference Template

Goal(s)

To verify that [name of code holder or AEC] meets the performance criteria specified by the Director-General, Ministry for Primary Industries (MPI) for reviewers accredited to undertake reviews of code holders and Animal Ethics Committees.

Where appropriate, to report on the effect of the content and application of MPI's standards, guidelines and criteria on the review of code holders and animal ethics committees.

Scope

Shall include an interview with [name of code holder or AEC] and examination of [name of code holder or AEC]'s records and procedures at their office and elsewhere, if required.

Shall include examination of MPI's records associated with [name of code holder or AEC]'s accreditation and performance as an accredited reviewer.

Initiators

The initiators of this review are [names and positions of MPI team member and manager and AEC Chairperson's name].

Type of Review

Contracted/follow-up/special

Standards / Legislation

Shall include consideration of relevant legislation, standards and requirements, including but not limited to:

a) Animal Welfare Act 1999
b) Performance Standard for Independent Reviews of Code Holders and Animal Ethics Committees (this document, current version and additional information on the MPI website).
c) National Animal Ethics Advisory Committee: Good Practice Guide for the Use of Animals in Research, Testing and Teaching (current version).

Checklists

The reviewer's checklist can be found in Appendix 6.

It can also be found on the MPI website (current version on the MPI website).

Additional Personnel

The reviewer may call upon the services of other parties as deemed appropriate to facilitate the review. The initiator or reviewer may determine if observers will attend any part of the review.

Response to Critical Situation

The reviewer will raise critical situations with MPI. Additionally, the code holder can also raise matters with the Animal Welfare Team (animalwelfare@mpi.govt.nz or 0800 83 33 33).

Mechanism for resolving non-compliances

The mechanism for resolving any identified serious non-compliances will be recorded in the Serious Non-Compliances, Corrective Action Requirements section of the review report.

Closure of any non-compliances raised will be as agreed with, and to the satisfaction of, the initiator.

Draft report response process

A draft report will be provided to the code holder for comment, and correction where appropriate, following the field visit(s).

Upon completion of the review, and after the code holder has had their chance to comment, the reviewer will finalise the report.

Final report distribution

The final report will be distributed to the code holder, and MPI and NAEAC via the Animal Welfare Science Team.

Other Terms of Reference

The review will be conducted according to the *Performance Standards for Independent Reviews of Code Holders and Animal Ethics Committees* under Part 6 of the Animal Welfare Act 1999.

The reviewer will provide the code holder with a copy of these Terms of Reference prior to or at the outset of review visits.

All costs associated with the review will be arranged and managed between the reviewer and the code holder.

Appendix 6: Reviewer Checklists

Introduction

The following checklist provides templates for questions that reviewers are encouraged to ask when carrying out reviews to aid NAEAC and MPI in their decision making. The checklists are based on questions from the previous *Template for Checklists for the Review of Code Holders and Animal Ethics Committees* and NAEAC's *Code of Ethical Conduct Template*. The recording of metrics also provides a quantifiable measure that can be used to track and assess code holder and AEC compliance with their code and the Act.

This revised checklist has been developed in collaboration between MPI, NAEAC and accredited reviewers.

1. Introduction/Background on the Activities of the Applicant

Scope of Activity	
Is the description of the general nature and extent of the RTT activities in which the applicant is engaged, or proposes to be engaged, appropriate?	☐
RTT and 3 Rs	
Is the organisation's philosophy towards RTT and the 3 Rs explicit and adequate?	☐
Responsible Persons	
Describe the individuals in the organisation who will be responsible for administering the CEC.	☐
Persons/Organisations under the CEC	
Describe the person(s) and/or organisation(s) to whom the CEC applies.	☐
Do all AEC members and researchers/investigators have access to a copy of the CEC?	☐

2. Establishment, Functions, Powers and Membership of the Animal Ethics Committee

Functions, Duties and Powers of the Committee	
Is the AEC clear on its functions, duties and powers under the Act?	☐
Membership of the AEC	
Is the code holder a member of the AEC? If not: – Is the senior representative of the company/organisation appointed by the chief executive? and; – Does that representative have the capability of evaluating the scientific or teaching value of every proposal? and; – Is the senior representative endorsed by the AEC?	☐
Have the statutory external members been nominated appropriately by the respective organisations (Royal New Zealand Society for the Prevention of Cruelty to Animals (RNZSPCA), a territorial authority or regional council and the New Zealand Veterinary Association (NZVA)) and do they meet the requirements of the Act (Section 101)?	☐
Are statutory external members remunerated fairly?	☐
Additional Members	
Are there any additional members/organisational members?	☐
Is the actual membership of the AEC in accordance with the CEC?	☐
Vacancies	

Have there been any unexpected/prolonged absences during the current period of the CEC?	☐
Induction and Training of New Members	
Do AEC members appointed during the current CEC approval period consider that the induction and training was adequate?	☐
Terms of Appointment	
Do the terms and conditions for appointed members of the AEC align with the CEC?	☐
Is the appointment of the Deputy Chair in accordance with the CEC?	☐

3. AEC Procedures

AEC Meetings	
Has the AEC determined its own procedures?	☐
Frequency of Meetings	
How many times has the AEC met during the current CEC approval period?	☐
How many of the meetings were face to face?	☐
Use of Tele/Video Conferencing	
Did the AEC use video/teleconferencing during the current CEC approval period? If so: - How many times and how does this compare to face-to-face meetings? - Did the tele/videoconferencing adhere to the policy and procedures described in the CEC?	☐
Timing for Circulation of Agenda Items	
How much notice was given to AEC members of meeting time and place?	☐
Do AEC members consider that meeting documents were circulated with sufficient time and in a manner to allow adequate preparation and consideration?	☐
Were adequate records of meetings kept?	☐
Quorum	
Was every meeting (including tele/video) quorate? If not: - How often was the meeting inquorate and what practices were put in place to deal with AEC business?	☐
Decision Process	
Were all decisions made by the AEC in accordance with the CEC?	☐
Conflicts of Interest	
Have conflicts of interest been sought and documented?	☐
How were perceived or real conflicts of interest handled by the AEC?	☐
Effective Input of Committee Members	
Do all AEC members consider that they were sufficiently supported/resourced to ensure they could provide effective input into the performance of the AEC during the current CEC approval period?	☐
Confidentiality	
How did the AEC manage the confidentiality and protection of confidential information?	☐
Consideration between Meetings	

Did the AEC consider any matters that arose between scheduled meetings?	☐
How many items were considered between scheduled meetings?	☐
What proportion of AEC decisions were made between scheduled meetings?	☐
Did the decision processes adhere to the policy and procedures described in the CEC?	☐
Did the AEC utilise sub-committees to consider matters between scheduled meetings? If so, were the processes in accordance with the CEC?	☐
Use of Subcommittees	
Does the AEC make use of subcommittees?	☐
Public Presence at Meetings	
Was there any public presence at AEC meetings?	☐
Applicant Presence at Meetings	
Were applicants allowed to be present at AEC meetings?	☐
Secretariat Support	
Do members of the AEC consider that the AEC has had adequate secretarial support during the current CEC approval period?	☐
Record Keeping and Information Management	
Has the AEC maintained documentation in order to meet the requirements of the CEC and the Act?	☐
Reporting of Statistics to MPI	
Has the code holder forwarded statistics on animal use and impact of use to MPI each year as required?	☐
Process to Amend the CEC	
Has the AEC recommended to the code holder that the CEC be amended during the current CEC approval period?	☐

4. Consideration of Projects by the AEC

Criteria for Consideration	
The AEC must ensure that approved proposals meet the following criteria as set out in the Act (Section 100).	
Does the proposal meet the purposes of Part 6, including the 3 Rs?	☐
Were the scientific or educational objectives clearly identified?	☐
What harm and distress will the animals experience and how will this be alleviated?	☐
Will the experimental design or demonstration meet the objectives?	☐
What factors have been considered regarding the choice of species?	☐
What statistical justification was provided for the proposed number of animals?	☐
What measures were in place to ensure the health and welfare of the animals?	☐
Will suitably qualified persons be involved in this project?	☐
Does the application provide information on the multiple use of animals and the effects on the welfare of those animals?	☐
Is there a commitment to ensure the findings will be adequately used, promoted or published?	☐
If any additional criteria were imposed, were they considered by the AEC?	☐

Outcomes for Consideration	
Did the AEC utilise all potential outcomes as described in the CEC?	☐
What were the numbers for each outcome?	☐
Maximum Approval Period	
How did the AEC manage projects that spanned longer than the maximum approval period described in the CEC?	☐
Changes to Approved Applications	
Has the AEC made changes to approved projects, including minor modifications during the current CEC approval period? If so: - Were the processes in accordance with the CEC?	☐
Use of non-human hominids	
Did the Director-General give approval for use of non-human hominids?	☐
Power to Suspend, Revoke and Vary Approvals	
Has the AEC exercised the power to suspend or revoke approvals or set, vary or revoke conditions of project approval during the current CEC approval period? If so: - Was there adequate documentation? - Is there evidence that a documented process has been followed?	☐

5. AEC Post-Approval Responsibilities

Compliance	
Have all manipulations performed during the current approval period adhered to the AEC approval conditions? If not: - Has the non-compliance been documented adequately? - Have referral procedures been followed for follow-up action?	☐
Appropriate Qualifications	
Have all manipulations been undertaken by appropriately qualified personnel, or under the direct supervision of appropriately qualified personnel?	☐
Adverse Events	
Is there adequate documentation for adverse events?	☐
Were adverse events dealt with promptly and appropriately in accordance with the Act?	☐
Were adverse events reported to the AEC, and how were the outcomes of these events managed by the AEC to prevent any other such incidents?	☐
Grading	
Does the AEC have a clear understanding of impact grading of proposed and approved projects?	☐
Euthanasia for tissue collection/dissection	
Does the AEC have adequate policies and procedures in place regarding euthanasia for the purposes of tissue collection/dissection?	☐

6. Conduct of Experiments

The AEC should consider these as part of the project approval process. Application forms that guide applicants by asking the appropriate questions will be of assistance to both the applicant and the AEC.	
Limiting pain and distress	
Did the investigator consider any potentially adverse effects of a manipulation, and have a plan for managing these?	☐
Were pilot studies carried out (for example, where the manipulation was to be carried out for the first time, or to confirm new techniques, or to refine humane endpoints)?	☐
Is there evidence that animals were adequately monitored during the experiment for evidence of pain and distress? - Were score sheets used to documents these observations? - Were appropriate indicators used? (for example, abnormalities in behaviour, movement, sound, heart and respiration rate, appetite, body weight, temperature, defaecation and urination, reproduction etc.) - Were unexpected outcomes of manipulation reported to the AEC?	☐
Were the anaesthetics/analgesics and or tranquillising agents used appropriate to the species? (Refer to "Analgesic Best Practice for the Use of Animals in Research and Teaching")	☐
Were study endpoints developed that minimised pain or distress? (See section 7.4.3 of the Good Practice Guide for suggestions.)	☐
Was the method of euthanasia appropriate?	☐
Surgery	
Was there evidence of careful planning for surgical procedures? - Was there pre-operative examination? - Was there pre-operative fasting? - Was administration of pre-operative antibiotic or analgesic considered? - Was three evidence of use of experienced surgeons? - Was there evidence of aseptic technique for recovery surgery? - Was there appropriate post-operative care, with duties of staff clearly defined, emergency procedures established and records maintained?	☐
More severe or controversial manipulations	
If the AEC approved the use of neuromuscular blocking agents or electroimmobilisation, was special care taken to prevent pain or distress?	☐
If animal models of human diseases are used was the most appropriate species selected, and was care taken to minimise pain and distress?	☐
If procedures have been approved that involve modifying an animal's behaviour, was positive reinforcement used? If noxious stimuli were used were these as mild as possible and used for the minimum time necessary?	☐
For toxicological testing proposals were *in vitro* methods used for initial screening tests, and did the procedures involving animals follow internationally accepted methods?	☐
For work involving hazards, was the advice of the organisation's biohazards committee sought, and were appropriate procedures for containment, disposal and decontamination established?	☐

Is work involving the manipulation of animals' genetic material carried out in accordance with MPI requirements?	☐
Is there evidence that where tumours were induced, the site was chosen carefully, animals monitored carefully, and the endpoint was appropriately observed?	☐
Where lesions of the CNS are a feature of a project, have special caging and animal care been provided as specified?	☐
For work involving the withholding of food or water, was the monitoring and care provided within those limits specified and approved by the AEC?	☐
For work in which a foetus is affected, was cognisance taken of the requirements, pain and distress of both the mother and foetus? Where new-born or newly hatched animals are used, were appropriate care and facilities provided?	☐
For research work on pain and its relief, was the use of painful stimuli limited to levels which do not distress humans, limited to the minimum time necessary, and were the animals given pain relief, or able to escape from the painful stimuli?	☐

7. Animal Facilities

Management of Animal Facilities	
Does every facility (including those of parented organisations) have appropriate policies and procedures approved by the AEC to ensure that all animal facilities and practices are in accordance with good practice and scientific knowledge (as recommended by NAEAC in its Good Practice Guide for the Use of Animals in Research, Testing and Teaching) and to the relevant codes of welfare issued under section 75 of the Act? The following should be considered for each animal facility.	☐
Person-in-charge	
Name of Supervisor/Manager: Qualifications and experience: Is a veterinary consultant used? Name:	☐
Does the person-in-charge have responsibilities for the management of the day-to-day animal care, including weekend coverage?	☐
Do they contribute to the development and maintenance of the organisation's animal care policies and procedures?	☐
Do they ensure that there is reliable monitoring of the well-being of all animals?	☐
Do they ensure that all ill or injured animals are treated promptly, that the cause of death is investigated for animals that die unexpectedly, and that unexpected death or illness is documented?	☐
Do they ensure that staff wear protective clothing and maintain high standards of personal hygiene in animal areas?	☐
Do they receive information from the AEC regarding project work? (for example, copies of applications and approvals)	☐
Do they maintain liaison with investigators regarding all issues relating to animals involved in project work?	☐
Staff	
What are the number and qualifications/experience of animal care staff?	☐

Are the staff numbers sufficient for the numbers and types of animals?	☐
Are these staff: - Trained? - Competent?	☐
Development of SOPs	
Is every facility and its standard operating procedures fit for purpose?	☐
Small Colony Procedures	
Are there documented procedures for the management of holding and breeding facilities?	☐
Is there a regular schedule of cage, equipment and facility sanitisation?	☐
Are there adequate records for the source, care, allocation, movement between locations, use and disposal of all animals?	☐
Are there adequate records of the genetic constitution, fertility, fecundity, morbidity and mortality of animal breeding groups?	☐
Are there adequate records of the health status and disease diagnosis (that is, frequency of testing/observation, and comprehensiveness)?	☐
Immediate Environment of Animals	
Are cages/pens or containers suitable for the animals housed in them?	☐
Do cages/pens or containers allow for species-specific behavioural and environmental requirements?	☐
Are animals kept in single housing, and if so, for what reasons?	☐
Is food and water readily available?	☐
Is there protection from spread of disease and pests?	☐
Can animals be observed easily?	☐
Are nesting materials provided, and are these appropriate?	☐
Are the cages of smooth durable construction?	☐
Are the cages clean and easily cleaned?	☐
Are the cages well maintained?	☐
Are the cages escape-proof?	☐
Do the cages protect from climatic extremes?	☐
Are the cages designed to prevent injury to animals?	☐
Are the cages large enough for the animals to turn, lie down, stand up etc.?	☐
Is the population density appropriate for the species, age, environment etc.?	☐
Are wire-floored cages in use? If so: - Are these used only when essential to the project? - Is a solid resting area available?	☐
Enrichment	
Are animals provided with opportunities/stimuli to promote expression of normal behaviour (for example, is recompense made for unnatural environments)?	☐

Husbandry Procedures	
Do animals receive appropriate, uncontaminated and nutritionally adequate food in sufficient quantities?	☐
If animals are fed in groups, are there sufficient feeding points to avoid undue competition for food?	☐
Is suitable drinking water constantly available?	☐
Are husbandry procedures, which are not part of project work, such as immunisations, carried out by competent personnel?	☐
Animal Identification	
Are all animals identified?	☐
Is the identification method reliable?	☐
Does the identification method cause minimal stress?	☐
Disposal of Animal Carcasses and Waste	
Is appropriate provision made for the prompt and sanitary disposal of animal carcasses and waste material?	☐
Environmental Factors	
For either indoor or outdoor facilities, consider the following environmental factors for the species housed there.	
Is the ventilation appropriate for the species?	☐
Are the temperature and humidity appropriate for the species?	☐
Is the odour control appropriate for the species?	☐
Is the noise level appropriate for the species?	☐
Is the light intensity and/or light cycles appropriate for the species?	☐
Outdoor Holding Facilities	
For each outdoor holding facility, consider the following aspects and their compatibility with the needs of the species housed there.	
Is the facility the appropriate size for the species?	☐
Is there shelter provided?	☐
Is there water provided?	☐
Does the facility meet species-specific needs?	☐
Is the facility compliant with established best practice for the species (that is, does it conform to the code of welfare for that species)?	☐
Indoor Housing	
For each indoor housing facility, consider the following aspects and their compatibility with the needs of the species housed there.	
Is the building maintained in good repair?	☐
Is the building kept clean and tidy?	☐
Is the building compatible with the needs of the animals to be housed there?	☐
Is the building compatible with the projects to be undertaken?	☐
Is the building designed and operated to control environmental factors appropriately?	☐
Is the building designed and operated to limit contamination associated with the keeping of animals, delivery of food, water and bedding, and the entry of people and other animals?	☐

Is there a pest control programme to exclude vermin?	☐
Are there adequate storage areas for food, bedding and equipment?	☐
Is the choice of detergents, disinfectants and pesticides appropriate?	☐
Are cleaning practices monitored to ensure effective sanitation? Explain: - what parameters are monitored? - what records are kept?	☐
Is there a reticulated water supply?	☐
Is there adequate waste-water control and drainage?	☐
Are there contingency plans for emergencies such as flooding, fire, or a breakdown in lighting, heating, cooling or ventilation?	☐
Monitoring Animal Facilities	
Does the AEC undertake annual monitoring of all animal facilities for approved projects, including the monitoring the approved projects of parented organisations?	☐
Acquisition of Animals	
Are any animals collected from their natural habitats? If so: - Have measures consistent with s.6.7 of the NAEAC Good Practice Guide been followed?	☐
Are any animals obtained from other countries? If so: - Have the measures consistent with s.6.8 of the Guide been followed?	☐
Are any of the animals transported? If so: - Have the measures consistent with in s.6.9 of the Guide been followed?	☐
On admission of new animals, are quarantine provisions undertaken consistent with s.6.16 of the Guide? - Are animals quarantined? - Is animal health evaluated and treatment provided if necessary? - Are animals acclimatised to the new facility? - Is commencement of experiments delayed until the completion of quarantine?	☐
Transportation of Animals	
Have animals been transported under species appropriate, humane and hygienic conditions at all times?	☐
Has the code of welfare for Transport within New Zealand been followed?	☐
Housing of Animals	
Have the policies and procedures that ensure that where animals are housed, their health is safeguarded and that undue stress is avoided been followed? If not: - Has the non-compliance been documented adequately?	☐
Standard Operating Procedures (SOPs)	
Has the AEC approved SOPs relating to procedures, care and use of animals? If so: - Does the AEC undertake a scheduled review of SOPs?	☐

Sick and Injured Animals	
Have any animals become sick or injured during the current CEC approval period? If so: - Has the non-compliance been documented adequately?	☐

8. Monitoring of AEC Approvals

Appropriate Training	
Has the AEC ensured that all people manipulating animals are trained and competent to carry out the procedures?	☐
Is there an appropriate training programme for the types of manipulation that are used?	☐
Frequency of Monitoring	
Has the AEC kept adequate records detailing the frequency of monitoring visits by the AEC or its nominee during the current CEC approval period?	☐
Are these records in accordance with the CEC?	☐
Monitoring of Manipulations Grade C-E	
Has the AEC kept adequate records detailing the frequency of monitoring visits by the AEC or its nominee during the current CEC approval period?	☐
Are these records in accordance with the CEC?	☐
Monitoring by Nominated Veterinarians	
Did the AEC utilise the expertise of a veterinarian nominated as representing the AEC during the current CEC approval period?	☐
Are these monitoring visits documented and outcomes recorded following the visit?	☐
End of Approval Reporting	
Is the AEC informed of the outcome of approved projects at the completion of the project?	☐
Was an appropriate End of Approval report received for every approved project during the current CEC approval period?	☐
End of Approval Grading	
Was it necessary for the AEC to reassess the impact gradings of approved projects at the completion of the project?	☐
End of Approval Statistics	
Did the AEC receive animal use statistics at the completion of every project during the current CEC approval period?	☐
Non-Compliance	
Were any incidences of non-compliance detected/reported during the current CEC approval period? If so: - Was there adequate documentation, consideration by the whole AEC and appropriate escalation processes?	☐

9. Arrangements for External Parties to Use the CEC and AEC

Parenting Arrangements	
Did the AEC undertake any parenting agreements during the current CEC approval period? If so: - Is this in accordance with the CEC and was MPI notified?	☐

Were all processes for the parented organisations with regard to approval, monitoring and compliance equal to the processes applied to other projects?	☐

10. Complaints Procedures

Reporting of Complaints	
Were any complaints made during the current CEC approval period? If so: - Were the procedures for dealing with the complaints appropriate?	☐
Animal Welfare Complaints	
Were any animal welfare complaints made during the current CEC approval period? If so: - Was there appropriate escalation to MPI and/or RNZSPCA?	☐

11. Process to Amend, Suspend or Revoke the CEC

CEC Amendments, Suspension or Revocation	
Were any requests made during the current CEC approval period for amendment, suspension or revocation of the CEC?	☐