



Reviewing the Reviews: An Analysis of the Process of Ensuring Regulatory Compliance in the Use of Animals in Science in New Zealand

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Summary

In New Zealand, the Animal Welfare Act 1999 requires that organisations using animals in research, testing and teaching be audited at least every five years for compliance with both the Act and the organisations' individually approved codes of ethical conduct. This paper looks at the results of this ongoing review process since the introduction of the Act at the beginning of 2000, during which time most of the organisations have been reviewed at least twice. It includes an analysis of the non-compliance issues that have arisen.

Keywords: animal use in science, regulation, New Zealand, ensuring compliance

1 Introduction

In New Zealand, the use of animals in research, testing and teaching (RTT) is governed by a self-contained set of provisions contained within Part 6 of the Animal Welfare Act 1999 (the Act). While the central focus of the Act imposes obligations on owners or those in charge of animals to ensure that the physical, health and behavioural needs of the animal are met and, where practicable, ensure that when the animal is ill or injured it receives treatment that alleviates any unreasonable or unnecessary pain or distress, Part 6 stands separate from the rest of the Act, because it provides a process that, in some circumstances, sanctions manipulations that have the potential to cause suffering, distress, or compromised care. This recognises that the manipulation of a small number of animals may result in significant benefits to a wider group of people or animals, to society generally or to the environment.

However, society has required that the legislation include adequate safeguards governing such animal use. Any individual or organisation wanting to manipulate animals is subject to a comprehensive set of requirements. Firstly, they must hold a code of ethical conduct (CEC) approved by the Director-General of Agriculture (D-G) or be employed by a person or organisation that holds an approved CEC, or be employed by a person or organisation that has an approved arrangement to use another organisation's animal ethics committee (AEC); and secondly, each individual project must first be approved by an AEC appointed by the code holder.

Currently, there are 30 code holders in New Zealand, two of which each have three AECs, giving a total of 34 such committees. An additional 78 organisations do not have their own code or AEC but are "parented" by one of the 17 code-holding organisations that have chosen to take on this responsibility. The types of organisations holding CECs are given in the following table:

Tab. 1

Institution type	Number	Number of AECs
Crown Research Institutes (CRIs)	4	6
Universities	7	9
Commercial organisations	10	10
Institutes of Technology	6	6
Government departments	1	1
Schools	1	1
Other	1	1

The review process

As a further layer of scrutiny of the animal ethics system in New Zealand, code holders and their AECs must undergo periodic reviews by independently accredited reviewers, with the aim of assessing the extent to which the code holder and the AEC are both complying with the Act and the CEC as well as implementing the policies, procedures, and requirements set out in the Act and the CEC. A satisfactory review report is a prerequisite to obtaining approval of a CEC for a second or subsequent period.

Where a code holder holds an approved CEC for the first time, or where a person did not carry out RTT in the 2 years prior to obtaining their current CEC approval, the first independent review must take place within 2 years. Subsequent reviews must be completed before the term of approval of the current CEC has expired. For example, where the CEC was approved for the maximum term of 5 years, an independent review must be carried out within the first 2 years and again 3 years later. After that, expiry reviews take place at an interval determined as part of the approval – usually every 5 years.

Reviewers are accredited by the D-G, with due regard to their competency, their character or reputation, and their ability to



maintain an appropriate degree of impartiality and independence when conducting reviews. There are currently five reviewers, although there have been up to eight. All are veterinarians except one, who is a research scientist and Chair of an AEC.

The reviewer's draft report is initially sent to the code holder for comment, with the final report, along with any code holder comments, going back to the code holder, to the D-G and to the National Animal Ethics Advisory Committee (NAEAC), an advisory committee to the Minister of Agriculture on matters relating to the use of animals in RTT.

The report may notify a critical situation, key issues, key topics and/or recommendations. A critical situation is any situation which, in the judgement of the reviewer, places the code holder's, the AEC's or the Director-General's credibility at risk. If a critical situation is identified during a review, this must be immediately notified to the Director General, and could potentially lead to the suspension or revocation of the approval of a code of ethical conduct.

A key issue is defined as a non-compliance that, in the opinion of the reviewer, demonstrates a major non-compliance of the institution's procedures and policies with the Act, its regulations or the CEC. It may be a specific non-compliance or a system with multiple non-compliances having a cumulative effect. Key issues may be created by escalation of outstanding issues from previous reviews. Any key issues found will be discussed during the review and will appear in the review report. The Director General will require these to be resolved within an agreed time frame. The effectiveness of corrective actions will be measured in subsequent reviews.

A key topic is defined as a point of interest, which is discussed in the report. It may include positive and negative findings and may give rise to key issues or recommendations.

A recommendation is a suggestion aimed at improving the procedures and policies. Recommendations are non-binding.

The D-G, having received the final report, must then inform the code holder in writing whether the review indicates that a satisfactory level of compliance has been achieved. If compli-

ance is unsatisfactory, the D-G must inform the code holder of the actions that must be taken in order to achieve a satisfactory level of compliance. If the code holder does not subsequently comply, or if the response is unsatisfactory, the D-G can decline approval of a new CEC or can revoke the existing CEC.

2 Method

This study analysed all reviews carried out since the introduction of the Act at the beginning of 2000 until the end of 2008, with emphasis on the results of such reviews, on the resultant actions required where non-compliance was identified and on the main areas of non-compliance.

3 Results

Sixty reviews of 34 AECs were undertaken during the assessment period. Of these, 45 were expiry reviews, including 16 second term expiry reviews. Six reviews were undertaken of institutions with new CECs and AECs, and nine follow-up reviews were required as the result of unsatisfactory levels of compliance. The results are given in Table 2.

The compliance of twenty-one out of 29 institutions (72%) was judged satisfactory at their first expiry review, and of 13 out of 16 (81%) at their second expiry review. Five out of six institutions (83%) with new codes of ethical conduct and CECs had satisfactory reviews, while all reviews that were required following identification of areas of non-compliance were satisfactory.

During the period surveyed, there were 10 institutions whose level of compliance was found to be unsatisfactory, one of these on two occasions. Of these, three institutions were not required to undergo re-review, one because it was amalgamating with another institution, one because it chose not to renew its CEC but to be parented by another organisation, and the third because

Tab. 2

Year	1 st expiry	Result		2 nd expiry	Result		New	Result		Follow-up	Result	
		✓ ¹⁾	✗ ²⁾		✓	✗		✓	✗		✓	✗
2002	8	6	2									
2003	10	7	3			2	2		2	2		
2004	9	6	3			1		1	3	3		
2005									2	2		
2006									2	2		
2007	1	1		7	5	2	2	2				
2008	1	1		9	8	1	1	1				
Totals	29	21	8	16	13	3	6	5	1	9	9	

1) Satisfactory

2) Unsatisfactory



the key issue, although serious enough to warrant mention, had already been resolved by the time of the review. One institution was required to be reviewed annually for three years.

Of the institutions with an unsatisfactory level of compliance, two were universities (one twice), four were Institutes of Technology, three were commercial organisations and one was a CRI.

Two institutions that were found satisfactory on their first expiry review were found unsatisfactory on their second expiry review.

Critical situations identified

There were no critical situations identified during the survey period.

Key issues identified

Key issues were identified in 12 of the 60 reviews and fell into three main groups – AEC procedures, monitoring and animal facilities.

1. AEC procedures
 - a. AEC not appointed in accordance with the code
 - b. Lack of documented AEC procedures and approvals
 - c. Lack of adherence to maximum approval periods
 - d. Projects proceeding without AEC approval
 - e. Lack of compliance with CEC and AWA in criteria for approval
 - f. Lack of compliance for stated standards for meeting frequency, quorum, minute taking
2. Monitoring of compliance
 - a. Failure to monitor compliance with approved protocols
3. Facilities
 - a. Inadequate ventilation
 - b. Temperature controls inadequate resulting in higher than acceptable temperatures.

Key topics identified

Forty six of the 60 reviews identified key topics. In 28 reviews, positive key topics were identified. For nine of these, only positive topics were raised, with five of the nine being assessments at follow-up reviews. Examples of positive key topics include:

- Commendation of animal care and enrichment;
- Commendation of the focus on animal welfare;
- Commendation of excellent recording and quality control systems;
- Commendation for inclusion of a biometrician on the AEC.

Negative key topics fell into seven categories:

1. AEC processes complying with some but not all CEC requirements (noted in 26 reviews). Examples:
 - a. Procedures for dealing with complaints not included;
 - b. Endpoints not well defined.
2. Lack of documentation of AEC processes (noted in 14 reviews). Examples:
 - a. No formal detailing of AEC processes;
 - b. No clear process for managing records.
3. Inadequacy of the monitoring process (noted in 15 reviews). Examples:
 - a. Lack of a formal monitoring process;
 - b. Lack of visits to view procedures by external members.

4. Inadequate documentation of monitoring by the AEC (noted in three reviews). Examples:
 - a. Applicants not required to report back at the end of their study;
 - b. Monitoring reports not written or filed.
5. Inadequate facilities (noted in five reviews). Examples:
 - a. Rodent cages inappropriate;
 - b. Lack of hygiene on panels round ventilation vents;
 - c. Inadequate cage washer resulting in an unacceptable hygiene risk.
6. A lack of facility and animal care documentation in the form of standard operating procedures (noted in four reviews).
7. 11 Miscellaneous issues (noted in 11 reviews). Examples:
 - a. A lack of staff familiarity with the CEC;
 - b. Inadequate attendance at AEC meetings of some members.

Recommendations

As recommendations are non-binding, they tend to be suggestions from the reviewer for increasing quality and efficiency in the AEC process. Examples include:

1. The animal programme manager should be a member of the AEC;
2. Acclimatisation of indoor sheep is recommended;
3. A review of meeting frequency is recommended;
4. An internal audit process is suggested;
5. The formalisation of monitoring procedures as an SOP is suggested;
6. An improvement in the clarity of the application form is suggested.

Rereviews

The terms of reference for follow-up reviews are set by the MAF Director of Animal Welfare and vary depending on the initial review result. Outstanding issues are required to be remedied within a given timeframe, with time limits set for follow-up reviews. Follow-up reviews are required to be performed by the same reviewer who did the initial non-compliant review. In all but one case, a single follow-up review was required within at most a year of the unsatisfactory review, with the focus being on those areas of non-compliance. In one case,

Tab. 3

Reviewer	No. of reviews (excluding follow-ups)	No. satisfactory	No. unsatisfactory
1	2	2	-
2	2	1	1
3	1	1	-
4	23	19	4
5	10	10	-
6	1	-	1
7	11	7	4
1 + 4	1	-	1



three follow-up reviews were required at yearly intervals. The first and third of these were focused only on identified non-compliant areas, while the second was a full review.

Reviewers

Reviews were carried out by seven reviewers during the sample period, with one review being conducted jointly by two of the seven.

The majority of reviews were performed by three reviewers – 23 (38% of total), 11 (18%) and 10 (17%) respectively. Two of the seven reviewers had no unsatisfactory reviews – one had done only one review; the other had done 10.

4 Discussion

With the first round of expiry reviews being considered an educative as well as an auditing process, given the relatively recent introduction of the Act, it would be expected that a higher proportion of second expiry reviews would show satisfactory compliance. This was the case: 13 from 16 (81%) compared to the 21 from 29 (72%) at the first expiry review. However, three reviews are singled out for comment: in two cases (A & B) organisations were found satisfactory at the first review but not the second, and in another case (C), neither the first nor the second was deemed satisfactory.

A. A small organisation covering a limited number of animal-based activities, mainly in the training area. This organisation was reviewed by the same reviewer at first and second expiry reviews, with the cumulative effect of key topics from both reviews leading to the unsatisfactory result. As a result of the unsatisfactory review, this organisation has given up its CEC and is now parented by another institution.

B. An Institute of Technology training veterinary nurses, where once again the care of animals was commended. However, due to changing personnel combined with an inadequate transfer of knowledge of the animal ethics system, the current approval for use of animals had expired. This was rectified when identified and no further action was required.

C. In this case once again, attention to the welfare of the animals and to AEC processes was commended, but the non-compliances on both occasions related to structural problems with older buildings, with a relatively long timeframe allowed for rectifying the problems because of the considerable financial outlay required.

A point arising from B above is the relatively high proportion of Institutes of Technology where compliance has been unsatisfactory. Four from six (67%) have had unsatisfactory reviews compared to universities (27%), commercial organisations (33%)

and CRIs (25%). There are several reasons that might account for the higher rate of unsatisfactory reviews:

1. The animal manipulations covered by these institutions are mainly concerned with the handling of animals by students in animal care or veterinary nursing. Such manipulations are regarded as having a relatively low impact on the welfare of animals, and for this reason, may be seen as less important to tutors who, from the very nature of their jobs, would see themselves as having a focus on animal welfare.
2. There is often a high turnover of staff in such institutions, with inadequate transfer of information, resulting in a poor understanding of the system.

MAF is currently reviewing the situation in relation to Institutes of Technology to find ways of circumventing these problems.

With a small number of reviewers, some of whom have performed very few reviews, an emphasis is placed on ensuring consistency of the review process. Procedures to improve consistency include:

- Provision of performance standards for reviews;
- Provision of a template for a checklist based on information provided to code holders in two documents: *the Guide to the Preparation of Codes of Ethical Conduct and the Good Practice Guide for the Use of Animals in Research, Testing and Teaching*;
- An annual teleconference where reviewers “meet” with MAF staff and members of the National Animal Ethics Advisory Committee to discuss the previous year’s reviews including any new issues raised as a result of those reviews;
- Regular update of reviewer documents as a result of the annual meetings as well as any other issues that have arisen;
- Three-yearly audit of the performance of the reviewers themselves.

In conclusion, the analysis of reviews between 2002 and 2008 shows that in the majority of cases (24 from 34 organisations) a satisfactory level of compliance with the Act and CEC was achieved. For those where compliance was adjudged unsatisfactory, subsequent follow-up reviews showed that a satisfactory level of compliance had been achieved. Given these results, the review system would appear to be working well and should add confidence to the overall regulatory system for the use of animals in RTT in New Zealand.

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