



## GUIDELINES FOR CORRECTION OF VIOLATIONS AND DEVIATIONS

*Institutional Animal Care and Use Committee (IACUC)*

Office of the Vice Chancellor for Research

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These guidelines for corrections are based on advice from the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) and the U.S. Public Health Service's Office of Laboratory Animal Welfare (OLAW). Principal Investigators (PI) are responsible for compliant animal care and use in their research, teaching and outreach programs. Self-monitoring and self-reporting are expected. Therefore, the correction process begins with the PI. The correction process generally entails a three-stage response by the IACUC to protocol deviations, dependent upon intent, severity, and repetition.

1. When the violation is unintentional and is not programmatic;
  - The Chair of the IACUC sends a letter to the PI notifying him/her of the violation and the expectations for corrective action.
  - The PI is required to respond to the Chair of the IACUC indicating procedures that have been established to help prevent future violations.
  - The IACUC membership is informed and may provide advice on corrective action.
2. When the violation is more serious in nature or is repeated;
  - The matter is discussed at a convened meeting of the IACUC and a decision is made by the full committee regarding the appropriate action. The committee consults *The Guide for the Care and Use of Laboratory Animals (The Guide)*, and determines institutional responsibilities for reporting the violation to OLAW, the USDA, or any other agency or funding source.
  - The committee reports the violation to the Institutional Official (IO; the Vice Chancellor for Research) along with suggestions for additional actions to be taken by that office.
  - Retraining of the PI and staff is likely to be required, along with additional requirements established by the IO.
3. When a violation is repeated a third time, if it is intentional, or if it is programmatic;
  - The IO is contacted by the Chair of the IACUC.
  - The matter is discussed at a convened meeting of the IACUC and recommendations are submitted to the IO. The recommendations may include suspension of a protocol or suspension of all activities using animals.
  - OLAW, the USDA, or other agencies are notified as appropriate.

The goal for all corrections is to ensure appropriate and compliant animal care and use at the University of Illinois. The IACUC uses its collective judgment to achieve this goal and circumstances may warrant a response that differs from these guidelines.

Approved: 11/3/2009, 12/3/2013

## Questions and Answers: Inspection Procedures in Response to an Incident or Adverse Event

### **Q. What is an incident or adverse event?**

**A.** Incidents and adverse events at facilities regulated under the Animal Welfare Act (AWA) include but are not limited to: floods, fires, or other facility disasters; animal mishandling or escapes; attacks and fighting between animals as a result of incompatibility; human injury as a result of an animal attack; failures in HVAC systems, automatic feeders, or watering systems; and injury or death related to cage washers, environmental enrichment devices, and squeeze or guillotine mechanisms.

### **Q. Should incidents and adverse events be reported to Animal Care by the licensee/registrant?**

**A.** There is no regulatory requirement that licensees or registrants report incidents or adverse events to Animal Care (a division of the U.S. Department of Agriculture [USDA], Animal and Plant Health Inspection Service [APHIS]), with the exception of an event that results in the suspension of a protocol at a research facility. Licensees and registrants may choose to report incidents or adverse events in order to advise Animal Care of the situation, provide documentation of their corrective actions, and demonstrate their good faith intention to comply with the AWA and regulations.

### **Q. Will incidents and adverse events be cited as noncompliance items (NCIs) on an Animal Care inspection report?**

**A.** These types of events will not be cited as NCIs if (1) the licensee/registrant found the problem in a timely manner, (2) the incident or adverse event was not reasonably foreseeable, (3) the licensee/registrant took timely and appropriate corrective action to prevent a recurrence, (4) there is not an ongoing pattern of violations at the facility, and (5) there were no serious animal welfare impacts as a result of the event. However, if there were serious animal welfare impacts, the problem was not identified and/or corrected in a timely manner, the incident was reasonably foreseeable, or there is an ongoing pattern of violations, Animal Care will cite the event as an NCI.

### **Q. Will incidents and adverse events that are cited get a correction date?**

**A.** An NCI that resulted in serious animal welfare impacts will be assigned a correction date. If applicable, the inspector may document on the inspection report that the NCI was corrected during the inspection. If the citation is a repeat of a previous citation, the NCI will be listed as a Repeat NCI on the report, and no correction date will be given.

### **Q. Will Animal Care inspections in response to incidents or adverse events be announced?**

**A.** Routinely, Animal Care conducts unannounced inspections to determine if facilities are in compliance with the AWA regulations and standards. In an effort to ensure that a facility has appropriate personnel and documentation available, Animal Care may conduct an announced visit to evaluate an incident or adverse event. These post-incident visits do not, however, take the place of regular, unannounced compliance inspections.

### **Additional Information**

For more information about the AWA and its regulations and standards, visit the APHIS Animal Care Web site at [www.aphis.usda.gov/animal\\_welfare](http://www.aphis.usda.gov/animal_welfare). You can also contact the program's headquarters office at:

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