

Inspection Procedures in Response to an Incident or Adverse Event in Regulated Facilities

With this announcement, the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) seeks to provide clear direction to research facilities, exhibitors, dealers, carriers, and intermediate handlers on procedures for reporting incidents and adverse events and to clarify how the agency responds to such notifications in accordance with the Animal Welfare Act (AWA) and the Animal Welfare Regulations (AWR).

An incident or adverse event is an occurrence that includes but is not limited to:

- Facility disasters, such as floods or fires;
- Mishandling or escapes;
- Attacks and fighting between animals as a result of incompatibility;
- Human injury as a result of an animal attack;
- Injury or death related to cage washers, environmental enrichment devices, and squeeze or guillotine mechanisms; and
- Failures in HVAC systems, automatic feeders, or watering systems.

There is no regulatory requirement that AWA licensees or registrants report incidents or adverse events to APHIS Animal Care, with the exception of an event that results in the suspension of a protocol at a research facility (in accordance with AWR § 2.31 [d][7]). 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, or demonstrate their good faith intention to comply with the AWA and regulations.

Animal Care may conduct an inspection in response to a facility reporting an incident or adverse event. However, a citation will not be indicated on the inspection report if the following factors are evident:

- The licensee/registrant found the problem in a timely manner,
- The incident or adverse event was not reasonably foreseeable,
- Timely and appropriate corrective action was taken to prevent a recurrence,
- There is no ongoing pattern of violations at the facility, and
- There were no serious animal welfare impacts.

A noncompliance item (NCI) will be placed in the report if the incident had a severe impact on animal health and well-being, 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. If the problem is not corrected by the date assigned by the inspector, it will be listed as a Repeat NCI on the next inspection report.

Some incidents or adverse events will be followed by an announced visit from Animal Care as an effort to ensure that the facility has appropriate personnel and documentation available. These post-incident visits will not, however, take the place of Animal Care's regular, unannounced compliance inspections.

Note to Stakeholders: Stakeholders announcements and other APHIS information are available on the Internet at www.aphis.usda.gov. For additional information on this topic, contact Dave Sacks at (301) 851-4079 or email david.sacks@aphis.usda.gov.

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