



Animal Care

Tech Note



United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service



www.aphis.usda.gov/animal_welfare/

November 2014

The Reporting of Adverse Events at Research Facilities on USDA Inspection Reports

USDA's Animal and Plant Health Inspection Service (APHIS) enforces the Animal Welfare Act, which regulates the use of certain animals in certain activities – including using covered animals for medical research, testing and education. Facilities that conduct these activities are inspected by APHIS to ensure compliance with the Animal Welfare Act and its associated regulations.

Serious adverse events are incidents that led to significant injury or illness, unrelieved pain or distress, or death of a regulated animal. Inspection reports will reflect self-corrections made by a facility of a serious adverse event to accurately portray the compliance status of the facility.

Inspection procedures regarding self-corrected serious adverse events are currently outlined in the Animal Welfare Inspection Guide¹ and the 2012 stakeholder announcement². A citation will be written if the incident resulted in significant injury or illness, unrelieved pain or distress, or death of the animal as a result of a non-compliance with a regulation or standard. In accordance with the memorandum of understanding³ which permits information sharing between the National Institutes of Health's Office of Laboratory Animal Welfare (OLAW) and APHIS, an inspector may choose to indicate OLAW's decision regarding the incident on the inspection report when there is documentation.

APHIS will not cite a facility for an incident if it caused no serious adverse effects, had no history of repeat noncompliance, was corrected in a timely manner, or led to effective preventative measures. A citation will be issued if any one of these criteria is not met.

Complaints from third parties involving previously reviewed non-compliances or events that are three years old or older will not be revisited by APHIS unless new information has been provided. OLAW agrees with this approach, which is in accordance with the memorandum of understanding which is designed to foster continual improvements in animal welfare, reduce duplicative oversight, and lessen regulatory burden.

Cited references:

1. https://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Inspection%20Guide.pdf

2. http://www.aphis.usda.gov/publications/animal_welfare/2012/inspection_incident_response_sa.pdf
3. <http://grants.nih.gov/grants/olaw/references/finalmou.htm>

Frequently Asked Questions

Question: What is APHIS's policy regarding the review of past incidences of non-compliance?

Answer: An inspector may choose to review past incidences of non-compliance when it is determined by professional judgment to be warranted. Unless new information has been provided, past incidents of non-compliance which were previously reviewed or occurred three years in the past will not be revisited at the request of a third party.

Question: Can APHIS cite for a serious adverse incident that was already investigated and completed by OLAW?

Answer: Yes. APHIS can cite if the incident: resulted in serious adverse effects; was not corrected timely manner; resulted in no effective preventative measures; or involved a history of repeated noncompliance.

Question: Will self-reporting an adverse event prevent the issuance of a citation?

Answer: No. Self-reporting has no bearing on whether a citation will be issued but may be taken into consideration as evidence of "good faith" during an enforcement action.

Question: Is it a requirement to report serious adverse events and incidents to APHIS?

Answer: No. The following are required by the Animal Welfare Act regulations to be reported:

- Change of operations: 9 CFR §2.30 (c) (1)
- Protocol suspension: 9 CFR §2.31 (d) (7)
- Uncorrected significant deficiencies from a semi-annual inspection: 9 CFR §2.31 (c) (3)
- The Annual Report: 9 CFR §2.36

Additional Information

For more information, please contact:

USDA - APHIS - Animal Care
4700 River Road, Unit 84
Riverdale, MD 20737
301-851-3751
E-mail: ace@aphis.usda.gov