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USDA Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Updates from USDA Animal Care

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Supervisory Animal Care Specialist
February 8-9, 2024

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USDA Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Purpose
Animal Care

Excellent Customer Service

Learning Opportunities to Support

Quality Inspections and Guidance

Assistance for Regulated Facilities

Ensure the humane treatment of animals covered by the Animal Welfare Act, eliminate soring and promote fair competition at events covered by the Horse Protection Act, and provide national leadership on the safety and well-being of pets and other animals during disasters.

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USDA Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Noncompliance Statistics
FY 2023

Class R Registrant Inspections
1,267

519 NCIs cited
80 critical NCIs

2.31 Institutional Animal Care and Use Committee — 36%

2.38 Miscellaneous — 17%

2.33 Attending Veterinarian and Adequate Veterinary Care — 10%

92% of Class R Inspections Substantially Compliant

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USDA Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Regulatory Changes

21st Century Cures Act | Dog Standards | Contingency Plan | Inspections/Semi-annual Reviews | Regulating Birds

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USDA Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

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USDA

21st Century
Cures Act

Section 2034(d) directed USDA in collaboration with NIH and FDA to reduce administrative burden

- §2.30: Registration
- 2.31(d)(5): Continuous review
- §2.36(a): Annual report signatures

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Modification to §2.30
Registration

Removes the requirement to update registration every 3-years	• APHIS Form 7023 (Annual Report Form) • APHIS Form 7033 (Change in Business Operations Form)
Removes Inactive Status	• A facility will either be registered or unregistered • A facility can no longer request inactive status

Cancellation	• Conditions for Cancellation
	  • Submission of change in status as research facility
	  • Submission of a written request to Deputy Administrator
	  • Cancellation by Deputy Administrator if sufficient evidence exists of no regulated activity
	• Requirements for registration after cancellation
	  • Notify Animal Care 10 days prior to initiating regulated activity

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Modification to §2.31(d)(5)
Continuous Review

Complete Annual Review	• Eliminated the requirement for the IACUC to conduct continuing review of activities not less than annually • IACUC shall complete review of activities no less than every 3 years

Modification to §2.36(a)
Annual Report Signatures

CEO or IO Signatures	• Eliminated the requirement for Chief Executive Officer or Institutional Official to sign the annual report • Reporting facility shall submit annual report to Deputy Administrator on or before December 1 of each calendar year

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Online Annual Report Submission

Animal Use Activities from 1 OCT 2022 to 30 SEP 2023 due on 1 DEC 2023
Online portal:
https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/SA_Obtain_Research_Facility_Annual_Report

ONLINE ANNUAL REPORTING
JUST. GOT. EASIER.

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Veterinary Care Standards
For Dogs

Section §3.13 requires facilities to develop a **Program of Veterinary Care** for dogs.

• November 2020

• Program of Veterinary Care – APHIS Form 7002
  • Scheduled visit by Attending Veterinarian no less than once every 12m
  • Annual physical exam
  • Vaccinations
  • Treatment for parasites and pests
  • Preventative care plans
  • Medical records
• Continuous access to potable water

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BE PREPARED

Slide 13

Contingency
Plan

The **contingency planning rule** took effect on January 3, 2022.

- Stay from July 31, 2013 lifted
- Required for all licensees and registrants
  - Identify emergency situations common to facility's local area
  - Outline specific tasks in response to identified emergencies/disasters
  - Identify chain of command
  - Address recovery
- Reviewed no less than annually
- Employee training
- APHIS form 7093 (optional)

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Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

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Inspection Guidance / Semiannual Reviews

- Unannounced and in-person inspections following county and CDC COVID-19 guidelines
- As of 1 OCT 2022, discontinued delay of semi-annual reviews
  - Flexibilities for conducting semi-annual program review maintained

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Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

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AWA Standards
Birds

2002 Definition of Animal

2020 US Court of Appeals

2022 Published Federal Register

2022 Comment Period

Publication Final Rule February 2023

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Registration:
Research

Birds that are bred for use in research are <u>not covered</u> by the Animal Welfare Act.

"Bred for use in research" means an animal that is bred in captivity and used for research, teaching, testing, or experimentation purposes.

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Excluded

- Field studies that do not materially alter the birds, such as observational studies.
- Studies for the purpose of supporting agriculture (intended to improve the quality of food or feathers).
- Animal, pest, and population management studies for the purposes of limiting wildlife damage and human interaction.
- Studies involving avian patients in clinical trials under a veterinary-client-patient relationship.
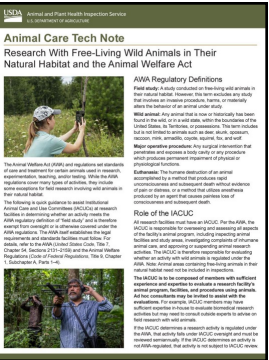- Use of only dead biologic specimens—no live animals.

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Field Studies

Field study: A study conducted on free-living wild animals in their natural habitat. However, this term excludes any study that involves an invasive procedure, harms, or materially alters the behavior of an animal under study.

Please refer to our Tech Note on our website: *"Research With Free-Living Wild Animals in Their Natural Habitat and the Animal Welfare Act "*

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Dates

- **Already** registered research facilities must become compliant with the avian regulations by August 22nd, 2023
- **Newly** registered research facilities must become compliant with the avian regulations by February 22nd, 2024
- Covered birds must be included on the Annual Report by Dec. 1st 2024

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Avian Noncompliance Data*

- **274 Noncompliances cited**

Top 5 Avian Noncompliances Cited	
§3.154 Missing environment enhancement plan	84
§2.40(a)(1) Missing program of veterinary care	18
§3.153(a)(1)(i) Having sharp points or edges	14
§3.158(d) Lack in pest control	11
§3.152(b) Lack of outdoor shelter	10

*Data as of 10/12/2023

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Reporting Exceptions to the Standards and Regulations

- Some regulations and standards include provisions for exceptions or exemptions.
  - Euthanasia methods [2.31(d)(1)(xi)]
  - Exemption of individual NHP or bird from some or all of the environmental enhancement plan [3.81(e)(2); 3.154(e)]
  - Primary enclosure floor size requirements for "innovative housing"
  - Withholding of water from an NHP if required by the research protocol approved by the IACUC [3.83]
- All the provisions or conditions of the exception or exemption must be met.
- These exceptions and exemptions must be included in semiannual program review reports to the IO, but not on the annual report.

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Reporting Exceptions to the Standards and Regulations

- The IACUC may approve exceptions to the regulations or standards when specified and justified in the animal use proposal [2.38(k)(1)].
  - Removal of resting platforms from cat enclosures
  - Extension of interval for cleaning/sanitization of enclosures
  - Keeping animals in 24-hour dark cycle
  - Keeping animals in temperatures outside range described in Part 3 – Standards for Species
  - Not performing daily observations of all animals
  - Altered diets that are not wholesome to induce a disease condition
- These exceptions must be included in semiannual program review reports and the annual report.

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Reporting Exceptions to the Standards and Regulations: Summary

USDA

Semiannual Program Review Report
- All exceptions and exemptions to the standards and regulations
- Reasons for each departure

Annual Report
- IACUC-approved exceptions not provided for in the regulations and standards
- Explanation, species and number of animals affected

Do Not Report
- Exceptions to other documents (e.g. *The Guide for the Care and Use of Laboratory Animals*)

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Reporting Pain and Distress Categories on the Annual Report

USDA

Reporting can be prospective or retrospective.

Animals on long-term studies that cross multiple reporting period periods may be reported in different columns.

Column E is for animals that experienced unrelieved pain or distress as part of the research protocol.
- Does not include breakthrough or unanticipated pain or distress that is treated when recognized

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LOCAL INSPECTOR

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