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OFFICE OF INSPECTOR GENERAL

Animal and Plant Health Inspection Service Oversight of Research Facilities

33601-0001-41

December 2014

Animal and Plant Health Inspection Service
Oversight of Research Facilities

Audit Report 33601-0001-41

What Were OIG's Objectives

Our objectives were to evaluate the adequacy of VMOs' and IACUCs' review of research facilities, determine the effectiveness of IES' role in imposing enforcement actions, assess AC's new mission critical information system—Animal Care Information System—for reliability and integrity, and follow up on APHIS' implementation of prior audit recommendations.

What OIG Reviewed

APHIS inspected an average of 1,117 registered research facilities annually. We conducted site visits at 29 of these facilities. We also reviewed monetary penalties (stipulations) issued to AWA violators in fiscal years (FY) 2010 through 2012.

What OIG Recommends

APHIS should determine if it can revise its inspection criteria for active research facilities that have not used, handled, or transported animals, so that these facilities receive more limited inspections. The agency should also formally document how it assesses penalties.

OIG audited APHIS to determine if the agency provided adequate oversight of research facilities and effectively enforced the Animal Welfare Act.

What OIG Found

Since fiscal year (FY) 2001, APHIS' Animal Care (AC) unit conducted at least 500 inspections at 107 research facilities that had not used, handled, or transported any regulated animals for more than 2 years. As a result, AC did not make the best use of its limited resources, which could have been assigned to inspect other more problematic facilities, including breeders, dealers, and exhibitors. Further, the Investigative and Enforcement Services (IES) unit worked with AC and other APHIS programs to reduce a 2,000-case agencywide backlog. However, AC did not follow its own criteria in closing at least 59 cases that involved grave (e.g., animal deaths) or repeat welfare violations.

IES issued penalties that were reduced by an average of 86 percent from Animal Welfare Act's (AWA) authorized maximum penalty per violation. Consequently, 26 of the 30 violators in our sample received penalties in 2012 totaling at least $272,298 less than what they would have received using the worksheet in effect during our 2010 audit. We also found that IES under-assessed penalties by $33,001 in four cases we reviewed by granting good faith reductions without merit or using a smaller number of violations than the actual number.

Finally, some of APHIS' veterinary medical officers (VMOs) and some Institutional Animal Care and Use Committees (IACUCs)—the oversight committees at research facilities responsible for ensuring compliance with AWA—are not always adequately monitoring experimental procedures on animals. As a result, AC has reduced assurance that protocols are properly completed, approved, and adhered to and that animals are always receiving basic humane care and treatment. We found no issues related to AC's mission critical information system. APHIS concurred with all of our recommendations.

United States Department of Agriculture
Office of Inspector General
Washington, D.C. 20250

DATE: December 9, 2014

AUDIT NUMBER: 33601-0001-41

TO: Kevin Shea
Administrator
Animal and Plant Health Inspection Services

ATTN: Marilyn Holland
Deputy Administrator
Marketing and Regulatory Programs Business Services

FROM: Gil H. Harden
Assistant Inspector General for Audit

SUBJECT: APHIS Oversight of Research Facilities

This report presents the results of the subject review. Your written response to the official draft report is included at the end of the report. Excerpts from the response and the Office of Inspector General's (OIG) position are incorporated into the relevant sections of the report. Based on your written response, we have accepted your management decision on all 15 recommendations.

In accordance with Departmental Regulation 1720-1, final action is to be taken within 1 year of each management decision to prevent being listed in the Department's annual Agency Financial Report. For agencies other than the Office of the Chief Financial Officer (OCFO), please follow your internal agency procedures in forwarding final action correspondence to OCFO.

We appreciate the courtesies and cooperation extended to us by members of your staff during our audit fieldwork and subsequent discussions. This report contains publically available information and will be posted in its entirety to our website (http://www.usda.gov/oig) in the near future.

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Background and Objectives

Background

In 1966, Congress passed Public Law 89-544, known as the Laboratory Animal Welfare Act, to regulate the humane care and handling of dogs, cats, and other laboratory animals.[1] The law was amended in 1970 (Public Law 91-579), changing the name to the Animal Welfare Act (AWA). This amendment also authorized the Secretary of Agriculture to regulate other warm-blooded animals when used in research, exhibition, or the wholesale pet trade. Additional amendments to the law were passed in 1976, 1985, 1990, 2002, and 2008—each adding new regulated activities for warm-blooded animals.[2] The Animal and Plant Health Inspection Service (APHIS), an agency of the U.S. Department of Agriculture (USDA), enforces AWA. To ensure compliance with AWA, APHIS established the Animal Care (AC) unit to inspect facilities that use, sell, or transport animals.[3]

AC is headquartered in Riverdale, Maryland, and has two regional offices located in Raleigh, North Carolina, and Fort Collins, Colorado. It employs both veterinary medical officers (VMOs) and AC inspectors, who are dispersed throughout the country to inspect licensed facilities (e.g., breeders, dealers, and exhibitors) and registered facilities (e.g., research facilities, handlers, and carriers) covered under AWA. VMOs are responsible for conducting annual inspections of all 1,117 registered research facilities, as well as a portion of the licensed facilities.[4]

Inspection and Enforcement Process

All facilities conducting or intending to conduct AWA-covered activities must be licensed or registered with APHIS, and are subject to unannounced inspections. If an inspection discovers violations of AWA standards, AC requires the facility to correct the problems within a given timeframe. Moderate repeat violations (e.g., incomplete records) may be settled with an official warning, while more serious violations (e.g., animal deaths due to negligence and lack of veterinary care) are referred to APHIS' Investigative and Enforcement Services (IES) unit for a formal investigation, which includes gathering documentary evidence, interviewing witnesses, and other actions.

After the completion of an investigation, IES national office staff review the evidence and determine, with the concurrence of AC, whether to take an enforcement action against the violator. IES can either issue an official warning or offer the violator a settlement agreement, which includes a monetary penalty (stipulation).[5] AWA authorizes a penalty of up to $10,000 per violation, but allows consideration for size of the business, gravity of the violations, good

[1] Hereafter, the term "animals" refers specifically to regulated animals covered by AWA.
[2] The term "animals" includes any live or dead dog, cat, non-human primate, guinea pig, hamster, rabbit, or other warm-blooded animal that is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes. It excludes birds, laboratory rats and mice, horses not used for research, and livestock intended as food.
[3] In fiscal year (FY) 2012, APHIS received an appropriation of $1.1 billion; AC's portion of this was $29 million.
[4] Between FYs 2009 and 2011, there was an annual average of 1,117 registered facilities.
[5] A stipulation is an agreement between APHIS and the violator, where the violator pays a reduced penalty for giving up the right to an administrative hearing.

faith, and history of previous violations. If the violator consents to a stipulation agreement, it generally pays a reduced penalty. Cases that cannot be resolved by a stipulation first undergo a review by the Office of the General Counsel (OGC) for legal sufficiency. Then, if a case is accepted by OGC, a formal administrative hearing is held before USDA's administrative law judges. If the case is appealed, a final decision is made by USDA's judicial officer. Formal actions may result in license suspensions or revocations, cease-and-desist orders, and/or monetary penalties.

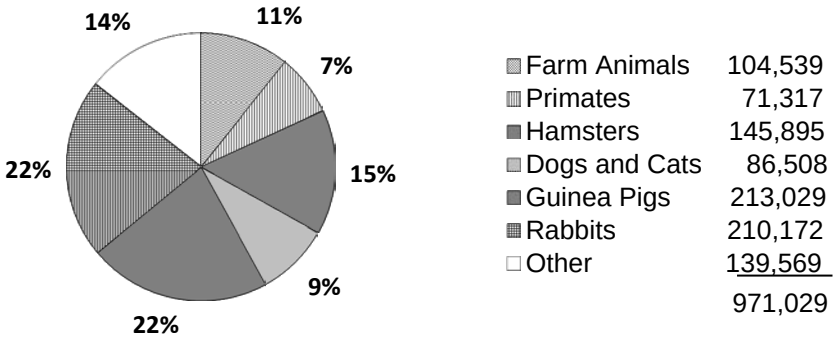
In recent years, IES had a backlog of over 2,000 cases, a volume so large that APHIS could not quickly address serious violations. According to IES, investigators often took about 20 months to complete the investigative process for a single case. To remedy the situation, APHIS' former Administrator established a taskforce in June 2011, with the goals of reducing the case backlog and drastically decreasing the time it takes to resolve investigations.

Research Facilities

Research facilities must report to APHIS the numbers of animals used each year in research. In these annual reports, facilities categorize animals according to whether they endured painful procedures and whether any relief was provided. Specifically, these categories include "with pain, no drugs," "with pain, with drugs," and "no pain, no drugs." See Exhibit C for a blank copy of an annual report.

The total number of regulated animals used in research decreased from 1,188,469 in FY 2003 to 971,029 in FY 2010. Chart 1 shows the numbers and types of animals used in research in FY 2010:[6]

Chart 1: Summary of Regulated Animals Used in Research in FY 2010



[1] We reduced the number of "Other" from APHIS' published numbers because several research facilities erroneously included field studies in their annual reports.

To comply with AWA standards, research facilities that use animals for research or instructional purposes must establish an Institutional Animal Care and Use Committee (IACUC), whose members are appointed by the research facilities. Each committee must be composed of at least

[6] AC receives animal usage information annually from research facilities; however, this was the latest information posted on APHIS' website, as of June 2013.

a chairman, a veterinarian familiar with laboratory animal medicine, and an independent member from the local community. The IACUC reviews all protocols submitted by the researchers, which provide information, such as a description of the experiments, use of animals, and type of analgesic.[7] The IACUCs are also required to inspect all animal study areas and housing facilities at least semiannually, as well as conduct "continuing reviews" of activities involving animals to ensure that researchers do not deviate from the IACUC-approved protocols and AWA regulations and standards.

Related Prior Audits

This audit is the latest in a series related to AC's administration and enforcement of AWA. Three of these audits focused on research facilities or enforcement against violators.

In 1995, an Office of Inspector General (OIG) audit of APHIS' enforcement policies found that APHIS did not fully address problems disclosed in a prior report, and that APHIS needed to take stronger enforcement actions to correct serious or repeat violations of AWA.[8] Dealers and other facilities had little incentive to comply with AWA because monetary penalties were, in some cases, arbitrarily reduced and often so low that violators regarded them as a cost of doing business.

In 2005, OIG performed an audit on animals in research facilities and found that APHIS was not aggressively pursuing enforcement actions against violators of AWA and was assessing minimal monetary penalties.[9] Inspectors believed the lack of enforcement action undermined their credibility and authority to enforce AWA. In addition to reducing the penalty by 75 percent, APHIS offered other concessions—making penalties basically meaningless. Violators continued to consider the monetary stipulation as a normal cost of business, rather than a deterrent for violating the law.

In 2010, an OIG audit of problematic dealers found that APHIS' enforcement process was ineffective, and the agency was misusing its own guidelines to lower penalties for AWA violators.[10] The agency relied on education to improve dealer compliance, but did not implement an appropriate level of enforcement. At a time when Congress tripled the authorized maximum penalty to strengthen fines for violations, actual penalties were 20 percent less than previous calculations.

[7] An analgesic is a type of medication that reduces or eliminates pain.
[8] Audit 33600-1-Ch, *APHIS Enforcement of the Animal Welfare Act* (January 1995).
[9] Audit 33002-3-SF, *APHIS Animal Care Program Inspection and Enforcement Activities* (September 2005).
[10] Audit 33002-4-SF, *APHIS Animal Care Program Inspections of Problematic Dealers* (May 2010).

Objectives

The objectives of this audit were to (1) evaluate the adequacy of VMOs' and IACUCs' review of research facilities, (2) determine the effectiveness of IES' role in imposing enforcement actions, (3) assess AC's new mission critical information system—Animal Care Information System—for reliability and integrity, and (4) follow up on implementation of prior audit recommendations. We found no issues related to AC's mission critical information system.

Section 1: AC Inspections

Finding 1: AC Performed Inspections of Research Facilities that Stopped Using Regulated Animals

Since FY 2001, Animal Care (AC) conducted at least 500 inspections at 107 research facilities that had not used, handled, or transported any regulated animals for more than 2 years.[11] Our analysis of APHIS' records found that 14 of the 107 research facilities had not used regulated animals for as long as 13 years. This occurred because AC's policy required that the agency conduct the same full inspections at all active facilities, even when no animals were present or used. As a result, AC did not make the best use of its limited resources, which could have been assigned to inspect other more problematic facilities, including breeders, dealers, and exhibitors.

Research facilities must register with APHIS if they use, or intend to use, live animals in research or for instructional purposes. The Animal Welfare Act (AWA) states, "[AC] shall inspect each research facility at least once each year and, in the case of deficiencies . . . conduct such follow-up inspections as may be necessary. . ."[12] Although neither AWA nor the regulations define or describe an inspection or require that all inspections be the same, AC's policy—the *Animal Care Inspection Guide (AC Inspection Guide)*—requires an inspector to conduct full inspections at all active research facilities at least annually.[13]

Regulations designate every registered facility as active, unless a facility requests a change of its registration status to inactive. According to regulations, if a facility does not use animals for 2 or more years, it may request that AC change its registration status to inactive.[14] For active facilities, the *AC Inspection Guide* requires full inspections, which include physical assessments of animal holding areas and reviews of documentation, such as semi-annual reports, protocols, and meeting minutes.[15] For inactive facilities, AC conducts limited inspections, which include only physical assessments.[16]

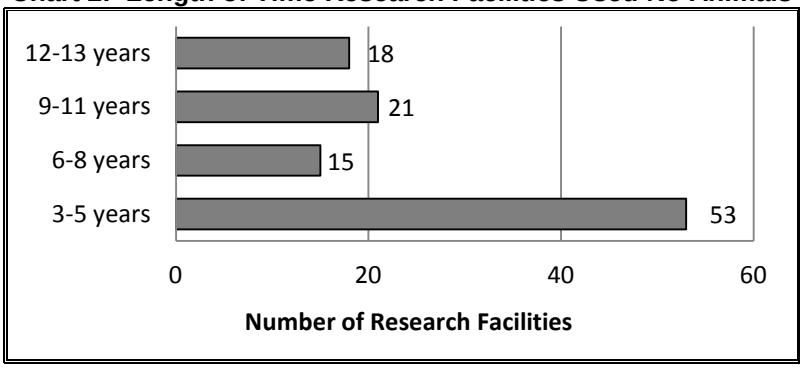
In FY 2010, AC employed 57 veterinary medical officers (VMOs) and 68 AC inspectors (trained AC technicians) to inspect a total of 8,656 registered or licensed facilities. Both VMOs and AC inspectors conduct inspections of licensed facilities (i.e., animal dealers, exhibitors, and other entities). VMOs conduct annual inspections of all registered research facilities (an average of 1,117 between FYs 2009 and 2011).[17] An inspection of a smaller research facility typically

[11] Hereafter, the term "animals" refers specifically to regulated animals covered by AWA.
[12] 7 United States Code (U.S.C.) §2146(a) (February 2010).
[13] *AC Inspection Guide*, Section 4.1(September 2010).
[14] 9 Code of Federal Regulations (CFR) 2.30(c) (January 2010).
[15] Protocols document information such as the details of animal experiments and identify the purpose of the research, the rationale for using live animals, and proof that alternatives to painful/distressful procedures were considered. Meeting minutes refer to minutes of the Institutional Animal Care and Use Committee (IACUC) meetings.
[16] *AC Inspection Guide*, Section 6.9 (September 2010).
[17] Some facilities have multiple sites, each of which needs to be inspected.

takes a day to complete, while an inspection of a larger facility may require more days, several trips, or more than one VMO.[18]

Although we identified 107 facilities that reported "no animals used" for up to 13 years, only 8 facilities opted to change their registration status to inactive, and none of them opted to cancel their registration. As a result, AC still conducted full inspections at these facilities at least annually, as was required by the *AC Inspection Guide*. An AC official told us that the facilities were concerned that the process to re-register would be burdensome if they wanted to use animals again in the future. However, AC can process a facility's registration application and send it a registration certificate within 4-5 days. Chart 2 shows the length of time that the 107 facilities did not use any animals:

Chart 2: Length of Time Research Facilities Used No Animals



We determined that AC conducted at least 500 inspections at the 107 research facilities mentioned above. Using a conservative estimate of an 8-hour day for each inspection, we calculated the total cost of these inspections to be at least $115,000 (excluding travel expenses and employee benefits).[19] Considering the fiscal challenges experienced Governmentwide, we believe that AC could more efficiently operate its inspection process.

When we spoke with the Administrator and other high level officials for AC about this issue, they agreed it would be beneficial to spend fewer resources at facilities that are not using animals. Therefore, to use its limited resources more efficiently, APHIS should consult with OGC to determine if APHIS has the administrative discretion to modify the *AC Inspection Guide* to establish inspection criteria for active research facilities that have not used, handled, or transported animals for an extended period, so that these facilities receive limited inspections, similar to those conducted at inactive facilities. Based on this determination, APHIS should take the appropriate actions to revise the inspection criteria.

[18] As some VMOs cover an entire State or more, driving to a facility could take as much as half a work day.
[19] Our estimated calculation is based on the current value of a General Schedule, Grade 12, Step 1 salary, with an 8-hour day attributed to each inspection.

Recommendation 1

In consultation with the Office of the General Counsel, determine if APHIS has the administrative discretion to revise the *AC Inspection Guide* to establish inspection criteria for active research facilities that have not used, handled, or transported animals for an extended period, so that these facilities receive limited inspections, similar to those conducted at inactive facilities. Based on this determination, take the appropriate actions to revise the inspection criteria.

Agency Response

APHIS agrees with this recommendation. In consultation with OGC, APHIS has administrative discretion to revise the *AC Inspection Guide* to establish inspection criteria for active research facilities that have not used, handled, or transported regulated species for an extended period. APHIS will revise the Inspection Guide to include criteria for inspecting facilities that have reported no regulated animal use on their Annual Reports. We will revise the *AC Inspection Guide* by June 30, 2015.

OIG Position

We accept APHIS' management decision on this recommendation.

Finding 2: VMOs Did Not Always Review Protocols and Annual Reports, as Required

Veterinary Medical Officers (VMOs) are required by AC policy to review both protocols and annual reports as part of their annual inspections of research facilities.[20] We found that 18 of the 20 VMOs in our sample did not review active protocols where no regulated species were present at the time of the inspection, inactive protocols for the past 3 years, or annual reports for accuracy and completeness. This occurred because VMOs told us they did not have sufficient time to complete all of the required reviews. In addition, VMOs are not required to document in their inspection reports the protocols they reviewed, making it difficult for supervisors to monitor their inspections. As a result, AC has reduced assurance that protocols are properly completed, approved, and adhered to for the purpose of ensuring the health and safety of the animals used in research and that the use and numbers of animals are accurately portrayed in the annual reports.

The *AC Inspection Guide* states that VMOs should determine the number of protocols to review, including "active protocols, inactive protocols from the past 3 years, and protocols where no regulated species are present at the facility." The *AC Inspection Guide* continues "if the number [of protocols] is small, review all . . . protocols for regulated animals, [or] if the number [of protocols] is large, review a representative sample of active and inactive protocols."[21]

The *AC Inspection Guide* also states "the inspector should verify that the research facility's Annual Report is accurate, that is: all animal facilities are reported, the number of animals reported is correct, animals are reported in the correct Column, [Institutional Animal Care and Use Committee]-approved exceptions are reported, [and] there are justifications for all Column E animals."[22] Column E animals are those used in experiments involving pain, without the use of pain-relieving drugs. See Exhibit C for a blank copy of an annual report.

Protocol Reviews

An important part of a research facility inspection is the review of active and inactive protocols. Active protocols are those where the facility expects to continue the ongoing experiments associated with the protocols. Inactive protocols are expired experiments that the facility does not expect to continue. AC also considers protocols to be inactive if they have not yet begun and are waiting on funding or animals to arrive.

To determine if VMOs were adequately reviewing protocols, we accompanied VMOs to 29 facilities in 11 States.[23] Based on discussions with VMOs and our observations, we found that 14 VMOs did not always review the following protocols, as required by the *AC Inspection Guide*:

[20] Annual reports summarize the number of animals used or held by the facility.
[21] *AC Inspection Guide*, Appendix 8, Section 9.8.7, p. 1 (September 2010).
[22] *AC Inspection Guide*, Section 7.3, p. 6 (September 2010).
[23] In 2011, AC had 119 inspectors nationwide—55 VMOs and 64 AC inspectors; only VMOs can inspect research facilities.

- **Active Protocols Where No Regulated Species Were Present at the Facility:** Three VMOs did not review these protocols, even though they were aware of the requirement. They stated that they selected protocols based on facility walkthroughs because those protocols applied to animals currently in use, and they could more easily determine if the animals were provided with adequate veterinary care.

  While reviewing protocols for animals present at the facility is a clear priority, VMOs must also examine protocols where animals are no longer present. One VMO told us that as a practice, she reviewed both protocols and the corresponding laboratory records for animals that were no longer present at the facility. When she compared them, she occasionally found deviations from the protocols, which she identified as violations.

- **Inactive Protocols:** Fourteen VMOs did not sample inactive protocols from the last 3 years, even though they were aware of the requirement. They stated that they did not always have time to sample these protocols, especially for the full 3-year period.

  We contend that sampling inactive protocols from the last 3 years is excessive, since VMOs conduct annual site visits to review active and inactive protocols. If inactive protocols are reviewed during annual visits, it is unnecessary to review these protocols from the prior 3 years.

If VMOs do not complete the necessary protocol reviews, there is reduced assurance that the research is conducted in accordance with AWA requirements, which could affect the health, safety, and humane treatment of the animals used in research. When we spoke with both the Deputy and Associate Deputy Administrator for AC about this issue, they agreed with our conclusions and emphasized the importance of VMOs adhering to the *AC Inspection Guide*, since it provides a detailed methodology for protocol review. They also agreed that AC's policy to review inactive protocols for a 3-year period during annual inspections is not necessary.

Further, VMOs are not required to document which protocols they reviewed and their rationale for selecting them. By requiring VMOs to document this information, supervisors can more easily confirm whether VMOs are adequately reviewing protocols.

Annual Report Reviews

Generally, VMOs are not verifying the accuracy of annual reports during their inspections (also see Finding 6). However, VMOs need to use annual reports to verify the number of animals used in experiments and confirm that animals are reported in the correct pain category.

- **Animals in Field Studies:** In reviewing the total number of regulated animals used in research (see Chart 1 in the Background section),[24] we noted unusually high

[24] This is the latest information posted on APHIS' website as of June 2013.

numbers of animals reported under "other" regulated animals. Upon further examination, we found that 3 research facilities incorrectly reported non-regulated animals in the "other" category—129,982 bats and 14,329 wild rodents that were used in field studies. The VMOs who reviewed the annual reports did not identify these evident errors, indicating that they may not be closely reviewing the reports for accuracy.

In an appendix, the *AC Inspection Guide* states "it is not necessary to include animals on the report that are . . . free living wild animals involved in research meeting the definition of a field study."[25] The appendix continues that if a facility chooses to report animals in field studies, they should be identified as non-regulated animals. This instruction should be included in the "Annual Report Checklist," an aid for the research facilities in completing their annual reports.

- **Inaccurate and Incomplete Reporting:** We found that about 45 percent of the research facilities in our sample (13 of 29) misreported the animals used in research. The facilities either reported animals in the wrong pain category or could not provide us with documentation to reconcile their annual report. Despite these errors, VMOs did not cite any of our sampled facilities for misreporting animals. Further, they cited less than 6 percent of facilities nationwide for the same violations over our 3-year scope period.

  Even when VMOs do find inaccuracies in the reports, they may not cite the facilities. During one of our visits, for example, a research facility in Texas reported most of its non-human primates in the "with pain, with drugs" category without any regard to actual pain categories involved in the experiments. Although the facility admitted to the VMO that its annual report was completed incorrectly, the VMO did not cite the facility for submitting an inaccurate annual report and did not require the facility to submit a corrected one.

In conclusion, we believe AC should reduce the sampling period for inactive protocols, and emphasize to all VMOs and supervisors their responsibility to follow the *AC Inspection Guide* in selecting and reviewing protocols and verifying the accuracy of annual reports. To better facilitate supervisory reviews, AC should also require VMOs to document the protocols they reviewed and the rationale for selecting them. Finally, AC should add instructions to the "Annual Report Checklist" that if research facilities choose to report animals in field studies, they should be identified as non-regulated animals.

[25] *AC Inspection Guide*, Appendix 4, p. 9 (September 2010). A field study is a study conducted on free-living wild animals in their habitat.

Recommendation 2

Revise the *AC Inspection Guide* to reduce the sampling period for inactive protocols from 3 years to 1 year to align with agency inspection requirements.

Agency Response

APHIS agrees with this recommendation. We will revise the *AC Inspection Guide* by June 30, 2015.

OIG Position

We accept APHIS' management decision on this recommendation.

Recommendation 3

Emphasize to all veterinary medical officers and supervisors their responsibility to follow the *AC Inspection Guide* in selecting and reviewing protocols, and to review annual reports for accuracy.

Agency Response

APHIS agrees with this recommendation. We will emphasize to Animal Care staff their responsibility to follow the *AC Inspection Guide* in selecting and reviewing protocols and to review Annual Reports for accuracy. We will inform staff and revise the *AC Inspection Guide* by June 30, 2015.

OIG Position

We accept APHIS' management decision on this recommendation.

Recommendation 4

Require VMOs to document and maintain a record of the protocols they reviewed and the rationale for selecting them.

Agency Response

APHIS agrees with the intent of this recommendation. APHIS has determined that the development and distribution of protocol selection and review guidance is the most effective method to ensure that VMOs are appropriately selecting animal use protocols for review. The guidance for use during inspections will include a standardized protocol selection list and instructions to include the reason each protocol was selected for review. The guidance will also include instructions to the VMOs to retain the completed lists so that supervisors can review those lists during supervisory "ride-alongs" and/or reviews. APHIS will revise the *AC Inspection Guide* regarding the inspector's process for reviewing research protocols by June 30, 2015.

OIG Position

We accept APHIS' management decision on this recommendation.

Recommendation 5

Add instructions to the "Annual Report Checklist" that if research facilities choose to report animals in field studies, they should be identified as non-regulated animals.

Agency Response

APHIS agrees with this recommendation. We will provide written guidance to the research facilities on the updated requirements for completion of the "Annual Report of Research Facility" form. We will develop and distribute this guidance by June 30, 2015.

OIG Position

We accept APHIS' management decision on this recommendation.

Section 2: Enforcement

Finding 3: APHIS Closed Cases Involving Animal Deaths

When APHIS' former administrator charged Investigative and Enforcement Services (IES) with reducing its agencywide backlog of over 2,000 open investigations, IES worked with AC and other APHIS programs to close old or unviable cases without completing the investigations. IES' goal was for AC to close 646 cases—75 percent of its inventory—but AC did not fully achieve this. AC identified 392 AWA and non-AWA cases for closure;[26] 211 cases were closed through the issuance of an official warning and 181 cases were closed with no action. We found that AC did not follow its own criteria for at least 59 cases that involved grave (e.g., animal deaths) or repeat welfare violations.[27] This occurred because AC officials believed they had to meet the goal established by IES, although IES later told us that this goal was not mandated. As a result, some violators that committed grave violations only received official warning letters, while other violators with similar violations received monetary penalties. Such inconsistent enforcement could risk weakening the agency's enforcement authority.

According to AC's criteria, a case would not be closed if animals were in imminent danger or suffered serious neglect, or the case involved a confiscation, animal attacks, or other grave animal welfare occurrences—depending on the circumstances, history of compliance, and adequacy of documentation. Also, a case would not be closed if violators had a previous stipulation, judgment, or repeated welfare-related violations, depending on their gravity.[28]

In January 2012, the former APHIS Administrator sent a letter to stakeholders regarding the case backlog. The letter stated, "In recent years, APHIS' backlog of open investigations has increased to well over 2,000 . . . Such a large backlog in open investigations has greatly impacted our enforcement process—primarily, the number of open investigations does not enable APHIS to swiftly address serious violations . . . we are taking two interdependent actions: reducing the number of open investigations in the backlog and drastically decreasing the time it takes to resolve investigations."[29] The administrator emphasized, "I understand that this new approach may lead some to believe we are assuming a weaker stance on enforcement than in the past. Nothing could be further from the truth."[30]

To reduce the backlog of open investigations, IES charged four programs—AC, Customs and Border Protection, Plant Protection and Quarantine, and Veterinary Services—to identify their oldest and least viable cases for closure. For AC, these included cases that (1) were older than

[26] Initially, AC and IES closed 432 cases; subsequently, IES elected to re-open 40 cases.
[27] Grave violations include those that undermine the purposes of the Act (i.e., refusing to allow inspection, intimidating APHIS officials, falsifying documents) or that directly harm animals (i.e., animal escape or handling resulting in trauma or death, physically abusing animals, lack of attending veterinarian with sick, dead, and dying animals).
[28] An AC document entitled, "AWA Criteria for Case Backlog" (September 2011 through January 2012).
[29] "Open Letter to Stakeholders on Investigation and Enforcement Process Streamlining" (January 11, 2012).
[30] "Prioritizing Investigations and Enforcement Actions," emailed to APHIS staff (November 16, 2011).

4 years (near the statute of limitations[31]) with non-grave welfare violations, (2) involved non-critical repeat violations, or (3) involved regulated activity without a license (unless the severity of the situation necessitated pursuing a formal investigation). IES estimated that it could process about 1,000 cases annually and, therefore, set an inventory goal of 600 to 800 cases for the 4 programs. With a total of 1,305 cases to be closed, AC was charged with closing 646 cases (75 percent of its inventory), almost as many as the other three programs combined. We discussed these goals with IES' former Director, who told us that the goals were not mandated and could have been discussed at any point.

AC did not achieve this goal and actually closed 392 cases.[32] The Associate Deputy Administrator stated that she told IES the remaining cases were too serious to close. While APHIS needed to take action to reduce its case backlog to manageable levels, we identified 59 cases that were closed, even though they involved grave (e.g., animal deaths) or repeat welfare violations. In lieu of IES completing an investigation, these violators received an official warning letter. The following are examples of cases that AC should not have closed, according to its criteria:

- During FYs 2007 to 2011, IES opened 22 cases involving the same airline carrier. Ten of these cases included grave violations where a total of 13 animals died. As a result of the backlog reduction, the cases resulted in only one official warning letter.

- A research facility in Oregon found two rabbits with broken legs after allowing the animals exercise time. One rabbit was deemed to be healthy and allowed to heal on its own, while the facility's veterinarian decided that the other rabbit should be euthanized. However, the facility brought in the wrong rabbit to be euthanized and, therefore, killed a healthy animal.

- An exhibitor in Texas did not adequately maintain the zoo premises that housed certain animals, allowing a pack of dogs to enter the deer enclosure and kill four deer.

For the 59 cases we identified, the violators who committed grave violations, such as animal deaths resulting from violations, received official warning letters. However, in our review of the IES stipulations, we found other violators who received a monetary penalty for similar violations. Such inconsistent enforcement could risk weakening the agency's enforcement authority.

In addition, AC did not document its rationale for closing backlog cases. Officials told us that they expedited the process by closing groups of cases that fit a particular profile. Under typical circumstances, if a case is closed by IES, the file contains rationale or documentation to support their action.

[31] The statute of limitations sets out the maximum time that parties have to initiate legal proceedings from the date of an alleged offense.
[32] Among the 392 cases closed, 211 were closed with an official warning letter and 181 were closed without any enforcement action.

When we discussed this issue with AC, the Associate Deputy Administrator agreed that the decision making process should have been documented. She also expressed concerns that without changes to the enforcement process, IES could accumulate another case backlog in the future. We agree that changes must be made to IES' process to expedite enforcement actions against violators. During the audit, IES provided us with documentation of the Lean Six Sigma assessment of its enforcement process, along with continuing updates on its implementation of business process improvements.[33] In a January 2012 factsheet, IES announced that it expects to reduce the average time it takes to resolve an investigation from 600 to 365 days. We did not review or verify the result of this time reduction effort.

Recommendation 6

Require the Animal Care unit to document its rationale for closing any case that is not closed by the Investigative and Enforcement Services.

Agency Response

APHIS agrees with this recommendation. APHIS will issue a memorandum to require AC staff to document the rationale for closing any investigative case that is not closed by IES. This memorandum will be issued by December 31, 2014.

We would like to take this opportunity to provide some information pertinent to OIG's reference to IES' "time reduction effort" in the paragraph preceding Recommendation 6. On September 4, 2014, APHIS provided its stakeholders with an update detailing the successful 80 percent reduction in IES' open cases between 2011 and 2014. This reduction was the result of the agency's first Business Process Improvement project focused on reviewing steps taken in the enforcement process. In addition, IES reduced the average time it takes to investigate and take action on alleged violations from 632 days to 328 days (about 48 percent) during the three year period.

OIG Position

We accept APHIS' management decision on this recommendation.

[33] Lean Six Sigma is a process to critically assess and evaluate the current enforcement review process.

Finding 4: IES Offered Reduced Penalties to Some Violators

In an ongoing effort to refine its enforcement process, APHIS revised its penalty worksheet at least 4 times from October 2010 to February 2012 to better assess penalties for AWA violators. However, our review of 30 recent stipulations disclosed that total monetary penalties were lower than those calculated by prior worksheets.[34] In 2012, IES issued penalties to violators that were reduced by an average of 86 percent from AWA's authorized maximum penalty, even though these cases involved animal deaths and other egregious violations. This occurred because IES (1) increased its "settlement reduction" from 50 to 75 percent to be consistent with other APHIS programs[35] and (2) stated that USDA's administrative law judges (ALJs) were assessing lower penalties than those proposed by APHIS. As a result, violators in 26 of the 30 cases received penalties totaling at least $272,298 less than what they would have received using the worksheet in effect during our 2010 audit. OIG adjusted the worksheet to account for the Congressional increase in the statutory maximum penalty to $10,000 for violations that predate the enactment of the legislative change.

AWA authorizes APHIS to impose civil penalties of up to $10,000 per violation. However, it also states that APHIS will give due consideration to certain factors when calculating penalties, such as the size of business, prior history of violations, gravity of violations, and good faith.[36] Penalty guidelines state, "In most instances, APHIS will issue monetary stipulations seeking the 'stipulation' amount generated by the penalty worksheet. However, there are occasions where APHIS may deem it appropriate to issue a monetary stipulation for the 'OGC amount' generated by the penalty worksheet."[37]

If AC discovers serious violations during its inspections, the cases are referred to IES for a formal investigation, which includes gathering documentary evidence, interviewing witnesses, and other actions. After the completion of an investigation, IES national office staff review the evidence and determine, with the concurrence of AC, whether to take enforcement action. Using the penalty worksheet and guidelines, IES can either issue an official warning or offer the violator a settlement agreement, which includes a monetary stipulation. If the violator agrees to the stipulation, it generally pays a reduced penalty. Cases that cannot be resolved by a stipulation go through a formal administrative hearing before USDA's ALJs. Formal actions may result in license suspensions or revocations, cease-and-desist orders, or monetary penalties.

Within 1 ½ years from October 2010 to February 2012, APHIS revised the penalty worksheet and guidelines four times in its on-going effort to refine the penalties so that they are more "appropriate and fulfill the purposes of AWA." See Table 1 for a simplified version of the IES' 2012 worksheet, which shows the effect if the highest reductions are applied to the maximum

[34] A stipulation is an agreement between APHIS and the violator, where the violator pays a reduced penalty for giving up the right to an administrative hearing.
[35] APHIS' penalty worksheet calculates two penalty amounts: the "OGC amount" and the "stipulation amount." The OGC amount is the penalty amount that would be sought by OGC at an administrative hearing. However, as an incentive for violators to forgo a hearing, IES offers violators an additional 75-percent discount to settle (settlement discount) to arrive at the stipulation amount.
[36] 7 U.S.C. §2149(b) (February 2010).
[37] "Determining Penalties Under the AWA," p. 18 (February 14, 2012).

penalty. This hypothetical example is for one violation only, involving a person who operates a small business with no prior history of violations under AWA, who committed a minor violation that did not impact the health and well-being of animals and who demonstrated a good faith effort to comply with AWA, and for which APHIS applied the maximum discretionary reduction in the penalty. Stipulations usually include penalties for multiple violations, which would increase the total penalty amount.

Table 1: Simplified Penalty Worksheet

AWA Maximum Penalty for One Violation		$10,000
Factors to Consider	**Range of Reduction**	**Scenario**
Size of Business	0 to 50%[1]	($5,000)
Prior History	0 to 30%	($3,000)
Gravity	0 to 17%	($1,700)
Penalty Subtotal		$300
Good Faith	0 or 25% of Penalty Subtotal	($75)
OGC Amount[2]		$225
Settlement	0 or 75% of OGC Amount	($169)[3]
Initial Stipulation		$56
Discretionary	Up to ± 30% of Initial Stipulation	($17)
Final Stipulation[4]		$39
Highest Reduction Possible[5]		99.6%

[1] This reduction is up to 50 percent for dealers. For all others, the reduction is up to 43 percent.

[2] The OGC amount may also be affected by the use of the discretionary reduction.

[3] The actual effect of this reduction in most of the cases we reviewed was significantly higher than all other reductions on the worksheet.

[4] This hypothetical example is for one violation only; stipulations usually include fines for multiple violations, which would increase the stipulation accordingly.

[5] This is the highest reduction possible; the highest reduction in the cases we reviewed was 97 percent.

When assessing penalties, AWA authorizes APHIS to give consideration to size of business, prior history of violations, gravity of violations, and good faith.[38] IES established a range of reductions for each of these factors to account for the different circumstances of each case.

After applying the AWA-authorized reduction, IES established two additional reductions in its guidelines. A settlement adjustment reduces penalties by 75 percent as an incentive for violators to forgo their right to a hearing, thereby saving the agency the associated costs. The discretionary reduction allows IES to recommend an upward or downward change in the penalty

[38] 7 U.S.C. §2149(b) (February 2010). Good faith includes a person who has animals that are in good health and do not suffer as a result of the violations, and cooperates with IES and AC.

up to 30 percent, if IES or AC believes that the monetary penalty calculated by the penalty worksheet is not appropriate.[39]

For example, a transporter in Texas did not remove 14 dogs from a truck that was left running overnight, allowing engine exhaust to enter the cargo space where the animals were housed. All 14 dogs inside the truck died of asphyxiation. The deaths arose from a single decision to house the dogs in a running truck overnight, and the transporter believed the ventilation system was functioning properly. APHIS determined that the stipulated penalty amount generated by the penalty guidelines and worksheet was too high in light of case-specific factors, and elected to adjust the stipulated penalty amount by 30 percent—the maximum discretionary reduction—to $17,150.[40]

To determine the extent of the reductions and penalties generated by the 2012 worksheet, we reviewed 30 stipulations that were issued between February and September 2012. The violations in these cases were mostly either serious (e.g., compromise the health and well-being of animals) or grave (e.g., result in animal deaths). Even in these circumstances, violators were offered penalties reduced to between 57 and 97 percent of AWA's authorized maximum penalty per violation, or 86 percent on average. While we are not advocating that APHIS assess the maximum penalty, we contend that reductions to this degree are too lenient and may not serve as an adequate deterrent for violators, especially in cases involving egregious violations.

IES officials told us that they increased the settlement reduction from 50 to 75 percent to be consistent with other APHIS programs and USDA's ALJs are assessing lower penalties than those proposed by APHIS. The following sections discuss these issues in detail.

IES Increased the Settlement Reduction from 50 to 75 Percent

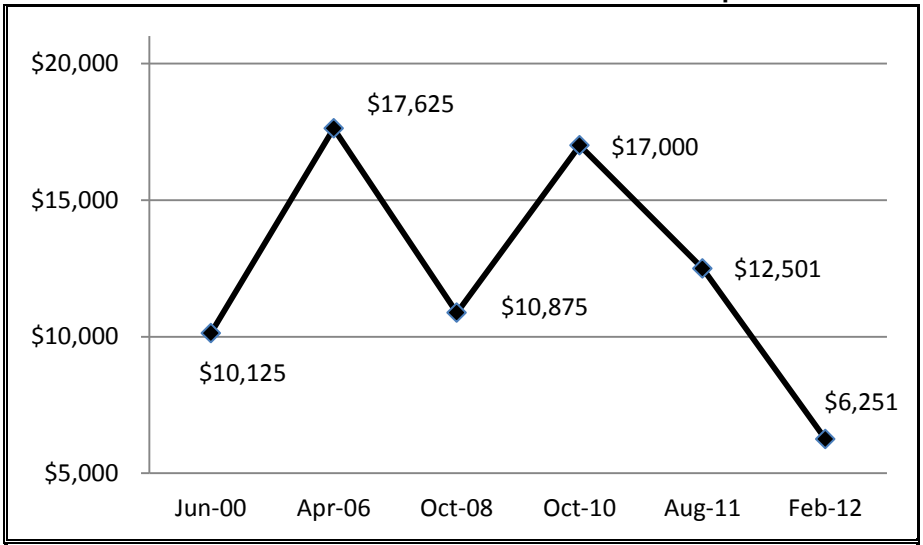
In three prior OIG audits, we reported that IES' enforcement of AWA was ineffective and the penalty worksheet calculated minimal penalties that did not deter violators.[41] We recommended that APHIS eliminate the 75-percent settlement reduction for repeat violators or ones with direct violations.[42] The agency agreed and reduced this adjustment to 50 percent for violations that occurred after June 1, 2005. Also, after a recommendation in a prior audit, Congress increased the maximum penalty per violation from $3,750 to $10,000 in June 2008 to "strengthen fines for violations of AWA."

However, in February 2012, IES reinstated the 75-percent settlement reduction on penalties to be consistent with other APHIS programs. To analyze the effect of this action, we compared the average penalties generated by each of the six penalty worksheets used between June 2000 and February 2012 for the 30 stipulations we

[39] The discretionary reduction was effective since August 2011.
[40] Even so, the violator requested a hearing rather than accepting the proposed settlement.
[41] Audit 33600-1-Ch, *APHIS Enforcement of the Animal Welfare Act* (January 1995); Audit 33002-3-SF, *APHIS Animal Care Program Inspection and Enforcement Activities* (September 2005); and Audit 33002-4-SF, *APHIS Animal Care Program Inspections of Problematic Dealers* (May 2010).
[42] A direct violation is one that has a high potential to adversely affect the health and well-being of the animal.

reviewed.[43] We noted that APHIS' current penalty worksheet generated the lowest constructed penalties, compared to the previous versions. To construct penalties, we adjusted prior worksheets to reflect the Congressional increase.[44] Chart 3 illustrates these penalties.

Chart 3: Constructed Penalties for 30 Reviewed Stipulations*



* The points represent the median (middle) amount of the constructed penalties.

The median penalty dropped 50 percent from August 2011 to February 2012 because IES increased its settlement reduction from 50 to 75 percent. This action, combined with the other reductions, had the effect of offsetting Congress' increase of the maximum penalty. It is the primary reason the violators in the 30 stipulations we reviewed received total reductions ranging between 57 and 97 percent—penalties in 26 of these cases totaled at least $272,298 less than those calculated using the worksheet in effect during our 2010 audit.[45]

ALJs Generally Did Not Lower Penalties for Violators

IES officials were concerned that the penalty worksheet and guidelines generated penalties higher than those assessed by Administrative Law Judges (ALJs), subjecting APHIS to claims of excessive penalty demands under the Equal Access to Justice Act (EAJA).[46]

[43] The worksheets were revised in June 2000, April 2006, October 2008, October 2010, January 2011, August 2011, and February 2012 to reflect changes in IES' penalty guidelines as well as Congressional increases to the maximum penalty. We did not include the January 2011 worksheet in our analysis because the only change related to matching older cases with the appropriate maximum.
[44] For comparative purposes, we used the current maximum penalty of $10,000 on all six worksheets.
[45] During our 2010 audit, APHIS used the October 2008 worksheet.
[46] 28 U.S.C. §2412 (January 2012). One of the purposes of EAJA is to discourage marginal or abusive Federal enforcement actions directed at small parties.

To determine if the worksheets generated higher penalties, we analyzed 94 decisions made by ALJs between January 2009 and March 2013.[47] See Table 2 for a summary of the decisions we reviewed:

Table 2: ALJ Decisions (January 2009 – March 2013)

Result	No. of Cases
License Suspended, Revoked, Cancelled, Denied, or Permanently/temporarily Disqualified[1]	71
Case Dismissed	3
Equal or Higher Penalty than the OGC Amount	9
Lower penalty than the OGC Amount	11
Total Cases	**94**

[1] In 13 cases, licenses were suspended; in 58 cases, licenses were revoked, cancelled, denied, or permanently/temporarily disqualified.

Based on Table 2, we determined that ALJs did in many cases lower the penalties below the OGC amounts; however, they generally incorporated other non-monetary sanctions into their decisions. For the 94 decisions we reviewed:

- 71 violators either had their license suspended, revoked, cancelled, or denied, or were permanently/temporarily disqualified from the program—often these violators also received a monetary penalty. APHIS stated license suspension or revocation may be an effective punishment for violating AWA.

- 3 cases were dismissed by the ALJs due to APHIS' insufficient evidence or procedural deficiencies.

- 9 violators were assessed a penalty equal to or higher than the OGC amount. For 2 of the violators, a portion of the penalties was held in abeyance, contingent on future compliance with AWA. If the violators do not comply, they will have to pay the full amount that was equal to or higher than the OGC amount.

- 11 violators were assessed a lower penalty than the OGC amount. However, for 7 of the violators, the penalties were still equal to or higher than IES' stipulation offer. Only the 4 remaining cases might merit IES' concerns about being subject to EAJA claims.

To illustrate their concern about ALJs assessing penalties lower than those calculated by the worksheet, IES told us about one case where an unlicensed dealer sold 956 dogs. However, we found that IES used a supplemental table to calculate penalties specifically for unlicensed animal sales. Using the table, IES calculated a penalty of $449,109 for

[47] We reviewed 108 decisions overall; however, 14 of the decisions did not contain enough information for us to make a relevant conclusion. We excluded these decisions from our analysis.

this case; ultimately, the violator was assessed a penalty of $191,200. If this table generates excessive penalties, IES should revise it to make penalties more appropriate.

In conclusion, we recognize that it is APHIS' responsibility to make decisions about how to administer its programs and that the reductions provide APHIS the flexibility to adjust penalties for widely varying case-specific circumstances. However, we believe that the reductions taken as a whole are excessive, given the circumstances of the 30 stipulations we reviewed. The violators in these cases received penalties totaling at least $272,298 less than they would have received using the worksheet in effect during our 2010 audit.

APHIS should review the adjustments allowed on the penalty worksheet. This review should consider such options as lowering the settlement reduction (e.g., from 75 to 65 percent) across all programs, decreasing the range of AWA-authorized reductions, or decreasing the discretionary reduction. APHIS should then document in a formal policy the reasons for the decisions made (i.e., points and ranges of reductions for each factor) to provide reductions in the penalty worksheet. Additionally, APHIS should revise the supplemental penalty table for unlicensed animal sales to ensure the penalties it generates are not excessive.

Recommendation 7

Review the adjustments given on the penalty worksheet and consider such options as lowering the settlement reduction (e.g., from 75 to 65 percent) across all programs, decreasing the range of AWA-authorized reductions, or decreasing the discretionary reduction.

Agency Response

APHIS agrees with this recommendation. By September 30, 2015, we will convene a meeting of the Civil Penalty Action Team for the AWA to review the penalty guidelines and worksheet and consider whether APHIS should revise any of the adjustments noted above. APHIS will consult with OGC, in an advisory capacity, as necessary.

OIG Position

We accept APHIS' management decision on this recommendation.

Recommendation 8

Document in a formal policy the reasons for the decisions made (i.e., points and ranges of reductions for each factor) to provide reductions in the penalty worksheet.

Agency Response

APHIS agrees with this recommendation. We will convene a meeting of the Civil Penalty Action Team for the AWA. APHIS will consult with OGC, in an advisory capacity, as necessary. APHIS will document the reasons for the decisions made regarding each of the adjustments in a formal policy by September 30, 2015.

OIG Position

We accept APHIS' management decision on this recommendation.

Recommendation 9

Revise the supplemental penalty table for unlicensed animal sales to ensure the penalties it generates are not excessive.

Agency Response

APHIS agrees with this recommendation. We will revise the penalty table for unlicensed animal sales to ensure the penalties it generates are not excessive, by September 30, 2015. In the interim, APHIS will continue to carefully review penalties associated with unlicensed animal sales until the revisions are in place to ensure the penalties are fair, equitable, and consistent with the statutory factors outlined in the AWA for determining appropriate penalties.

OIG Position

We accept APHIS' management decision on this recommendation.

Finding 5: IES Needs to Further Refine its Guidelines for Penalty Calculation

Although we reported this issue in a prior audit,[48] OIG believes that IES needs to continue to refine its guidelines when calculating penalties. For 4 of the 29 cases we reviewed, IES granted good faith reductions without merit or used a smaller number of violations than the actual number.[49] This occurred because IES (1) did not place sufficient emphasis on animal health and safety when determining good faith reductions and (2) incorrectly believed it did not have enough evidence to pursue some violations. As a result, four violators were under-assessed penalties totaling $33,001.

Penalty guidelines state that, while IES and AC collectively agree on penalties, IES is ultimately "responsible for ensuring that AWA penalty calculations are consistent" and in accordance with the guidelines.[50] Also, AWA states that "[APHIS] shall give due consideration to the appropriateness of the penalty with respect to the size of the business . . . the gravity of the violation, the person's good faith, and the history of previous violations."[51]

In a prior audit, we found that APHIS misused guidelines in 32 of the 94 cases we reviewed to lower the penalties for AWA violators.[52] To follow up on our prior audit recommendations, we reviewed all 29 AC cases that were closed with a stipulation agreement between October 2010 and June 2011. This also included a review of four versions of the guidelines and three versions of the penalty worksheet.[53]

As stated in Finding 4, APHIS revised the penalty worksheet and guidelines four times in its on-going effort to refine the penalties so that they are more "appropriate and fulfill the purposes of AWA." Compared to the results in our prior audit, APHIS has improved how it applied the guidelines. However, we noted that when applying its guidelines, IES under-assessed penalties in 4 of the 29 cases. Table 3 summarizes IES' under-assessments:

Table 3: Penalty Under-assessments

Case	APHIS Calculation	OIG Calculation	Under-assessment	Reason
1	$3,000	$4,000	($1,000)	Good Faith
2	$6,857	$9,143	($2,286)	Good Faith
3	$37,893	$60,179	($22,286)	Number of Violations
4	$18,107	$25,536	($7,429)	Number of Violations
Total			**($33,001)**	

[48] Audit 33002-4-SF, *APHIS Animal Care Program Inspections of Problematic Dealers* (May 2010).
[49] The 29 cases in this finding were a separate sample of cases than those in Finding 4.
[50] "Determining Penalties Under the AWA," p. 2 (September 2010).
[51] 7 U.S.C. §2149(b) (February 2010).
[52] Audit 33002-4-SF, *APHIS Animal Care Program Inspections of Problematic Dealers* (May 2010).
[53] Prior audit recommendations were to be implemented by September 30, 2010; fieldwork for this audit began in July 2011.

Good Faith

Good faith is defined by penalty guidelines as "compliance with standards of decency and honesty" and "sincere integrity in profession and performance." Criteria that constitute good faith include complying with AWA and correcting violations, having animals that are in good health and do not suffer as a result of the violations, and cooperating with APHIS. Good faith may reduce the total penalty by 25 percent. In contrast, a violator that lacks good faith may have a prior history, repeat violations, refuse to cooperate with IES or take responsibility for their animals, or engage in regulated activity without a license after being notified of AWA licensing requirements. A violator lacking good faith should receive no reduction.[54]

In 2 of the 29 cases we reviewed, IES applied the good faith reduction when it was not warranted, as detailed below:

- **Case 1:** A research facility in Missouri was assessed a $3,000 penalty because a lab technician left a chinchilla (a squirrel-sized animal with a bushy tail and large round ears) in a cage that was processed through a cage wash.[55] Although penalty guidelines state that a violator who demonstrates good faith has animals that do not suffer as a result of any violation, the chinchilla in this case was subjected to at least 180-degree water, which caused its death. IES gave the facility a good faith reduction because it had no prior history,[56] self-reported the violation, and took corrective action by modifying its standard operating procedures to provide additional safeguards.

  While we agree that a person who lacks good faith may have a prior history, having no prior history does not necessarily substantiate good faith, especially when animals die or suffer because of the violation. Further, while self-reporting violations and taking corrective actions may be circumstances that warrant a good faith reduction, we do not believe these considerations should be controlling when violations involve serious animal injury or animal deaths. Since self-reporting is considered by the agency in its good faith determinations, it should be expressly added to its guideline for future cases.

  As noted above, guidelines state that a person who shows good faith may have animals that are in good health and do not suffer from the violations. OIG believes the facility should not have received a good faith reduction because the chinchilla suffered before its death as a result of the violation, and the facility was especially negligent in causing the death. We calculated this facility's penalty without a good faith reduction, resulting in a $1,000 higher penalty.

[54] "Determining Penalties Under the AWA," p. 7 (September 2010). The penalty guideline related to good faith was not changed in the subsequent versions of the guideline.
[55] This was one of the multiple violations cited for this facility within a 3-year period.
[56] According to IES guidelines, violations cited in a previous inspection report or Official Warnings issued for violations are not considered as prior history.

- **Case 2:** An exhibitor in North Carolina received an official warning for failure to eliminate a safety hazard in a bear enclosure. The exhibitor ignored the warning and did not correct the violation for the next two annual inspections. According to penalty guidelines, a person who shows good faith must be willing to comply with AWA and correct violations. Even so, IES gave the exhibitor a good faith reduction when it assessed a $6,857 penalty.

  Guidelines also state that a good faith reduction must not be applied if the violator received a warning within the past 3 years. Since IES calculated the penalty 3^{+} years after the warning letter was issued, officials believed that the good faith prohibition did not apply.

  However, the bear enclosure violation was not remedied and continued to be cited during the 3-year period. We calculated this facility's penalty without a good faith reduction, resulting in a $2,286 higher penalty. When we discussed this case with IES, officials told us they recognized the deficiency in their penalty guidelines and subsequently revised them to mitigate the occurrence of a similar situation.

Number of Violations

IES must ensure that it uses the correct number of violations when calculating penalties. AWA states, "Each violation and each day during which a violation continues shall be a separate offense."[57] APHIS further defined how to count violations in its penalty guidelines. For example, for violations resulting in animal deaths, each animal is counted as a separate violation.[58] In 2 of the 29 cases, IES penalized violators for a smaller number of violations than the actual number, as detailed below:

- **Case 3:** During our prior audit, we visited a breeder's facility in Oklahoma, where we saw one dog in need of immediate veterinary care for a serious hind leg injury.[59] The breeder admitted to two OIG auditors and an inspector that the dog had been in this condition for at least 7 days. The inspector's report stated "[Dog] has left hind leg with bones exposed . . . old dead hair has wrapped around the leg below where the bones are exposed . . . red raw flesh is exposed above the bones and below the bones on the lower portion of the foot. Dog has been in this condition for the past 7 days."

  IES did not count seven violations, one for each day, as required by AWA. Instead, IES counted this instance as one violation of inadequate veterinary care, along with 15 other unrelated violations. In total, this resulted in a $37,893 penalty. The IES branch chief told us that because IES did not have sufficient evidence, e.g., pictures, for each of the 7 days the dog was in its condition, IES did not count each day as a separate violation.

[57] 7 U.S.C. §2149(b) (February 1, 2010).
[58] "Determining Penalties Under the AWA," pp. 6-7 (September 2010).
[59] Audit 33002-4-SF, *APHIS Animal Care Program Inspections of Problematic Dealers* (May 2010).

However, we determined IES had sufficient evidence because the investigator's report stated that "in his affidavit, [the violator] responded to each of the violations . . . He did not contest any of the violations listed on the inspection reports." In addition, there were three on-site witnesses to the violator's admission statement. The picture of the dog also showed that the injury must have occurred days ago, in that the wound was rotting and turning black—the condition of the dog was so severe that it was euthanized immediately by a veterinarian. When we calculated the breeder's penalty, we added six violations—one for each additional day the dog remained in its condition—resulting in a $22,286 higher penalty.

- **Case 4:** An exhibitor in Texas was assessed an $18,107 penalty because animals were killed or injured at the facility on multiple occasions. The first time, stray dogs entered the exhibitor's facility through a poorly constructed perimeter fence and killed five animals; the second time, a Malayan Tapir escaped from its cage because a staff member left it open, resulting in the death of one animal and injuries to two others; the third time, a stray dog killed two animals and injured four others.

  While IES penalized the exhibitor for the animal deaths, it did not penalize the exhibitor for the injured animals. IES' branch chief believed that she accounted for the injuries under grave violations, although the penalty worksheet showed otherwise. When we calculated the exhibitor's penalty, we included violations for the injured animals, resulting in a $7,429 higher penalty. When we discussed this case with IES, officials told us that they recognized the deficiency in their penalty guidelines and subsequently revised them to mitigate the occurrence of a similar situation.

Based on the above cases, APHIS should revise its guidelines to expressly include self-reported violations for potential good faith reductions and give greater consideration for violations resulting in serious animal injury or animal deaths when determining good faith reductions to penalties. APHIS should also require that justifications for good faith decisions be documented in case files. Finally, APHIS should emphasize to IES that the use of testimony and inspectors' reports can be sufficient, appropriate evidence to determine the number of violations.

Recommendation 10

Revise *Determining Penalties Under the Animal Welfare Act* guidelines to expressly include self-reported violations for potential good faith reductions and give greater consideration for violations resulting in serious animal injury or animal deaths when determining good faith reductions to penalties. Require that justifications for good faith decisions be documented in case files.

Agency Response

APHIS generally agrees with this recommendation, with one exception. APHIS already considers self-reported violations in its good faith assessment. APHIS will revise "Determining Penalties Under the Animal Welfare Act" guidelines to expressly include self-reported violations for potential good faith reductions, and to require that justifications for good faith decisions be documented in case files, by September 30, 2015.

With respect to the recommendation to give greater consideration for violations resulting in serious animal injury or death when determining whether an alleged violator has demonstrated good faith, under the current penalty guidelines, the determination of good faith is a balancing test, in which APHIS weighs a variety of factors, as outlined in the guidelines. Allegations involving serious animal injury or animal death are given greater weight, but do not automatically preclude a finding of good faith. The standard as set forth in the guidelines was developed, in part, based on language from administrative decisions issued by the Secretary of Agriculture. APHIS will convene a meeting of the Civil Penalty Action Team for the AWA that will review the penalty guidelines regarding good faith and consider whether it should be adjusted to give greater consideration for violations resulting in serious animal injury or animal deaths. APHIS will consult with OGC, in an advisory capacity, as necessary.

OIG Position

We accept APHIS' management decision on this recommendation.

Recommendation 11

Emphasize in IES guidelines that the use of testimony and inspectors' reports can be sufficient, appropriate evidence to determine the number of violations

Agency Response

APHIS agrees with this recommendation. APHIS will revise its existing guidelines for AWA cases to note that the use of testimony and inspection reports can be sufficient, appropriate evidence to determine the number of violations, depending on the circumstances. However, APHIS will continue to be guided by OGC and the administrative decisions by the Secretary of Agriculture when determining what constitutes sufficient evidence to pursue an alleged violation. To the extent that each "count" for penalty calculation purposes must be supported by a preponderance of the evidence to prevail at a hearing, APHIS will only count alleged violations that meet this evidentiary standard. APHIS will complete these revisions by September 30, 2015.

OIG Position

We accept APHIS' management decision on this recommendation.

Section 3: Research Facilities

Finding 6: Some Institutional Animal Care and Use Committees Are Not Adequately Monitoring Research Facilities

Some Institutional Animal Care and Use Committees (IACUCs), the oversight committees at research facilities responsible for ensuring compliance with AWA, did not adequately approve, monitor, or report on experimental procedures on animals. During FYs 2009 – 2011, VMOs cited 531 of 1,117 research facilities for 1,379 IACUC-related violations regarding their lack of oversight.[60] This occurred because some IACUCs (1) were not judicious or adequately trained in reviewing and approving protocols, (2) did not make monitoring activities a priority, or (3) did not recognize the importance of submitting an accurate annual report.[61] As a result, animals are not always receiving basic humane care and treatment and, in some cases, pain and distress are not minimized during and after experimental procedures.

AWA requires IACUCs to inspect all animal study areas and housing facilities at least semiannually, focusing on practices involving pain to animals and monitoring the condition of the animals.[62] Regulations state, "The IACUC shall conduct continuing reviews of activities . . . at appropriate intervals as determined by the IACUC, but not less than annually."[63]

AWA also requires research facilities to establish an IACUC. The committee members are generally employees of the facilities and consider their activities as collateral duties. Members are appointed by the research facilities and must include at least a chairman, a veterinarian familiar with laboratory animal medicine, and an independent member from the local community. Its members must "possess sufficient ability to assess animal care, treatment, and practices in experimental research."[64]

In FY 2000, APHIS conducted a survey of its VMOs and their supervisors to assess their opinions on the effectiveness of the IACUCs. The survey concluded that "IACUCs seem to be doing well at functions related to setting up the administrative structure and developing the process, but not as well at monitoring and follow through."[65] In our 2005 audit, we also reported that IACUCs were not effectively monitoring animal care activities, protocols, or alternative research methods.[66]

To determine if IACUCs improved their monitoring activities and "follow through," we analyzed violations cited by VMOs in their inspection reports, interviewed IACUC officials, and reviewed IACUC files. We found that nearly half of all research facilities continued to be cited by the

[60] There was an annual average of 1,117 research facilities registered with AC during FYs 2009 to 2011.
[61] Although Institutional Officials sign and submit the annual reports, IACUCs are agents of the research facilities. They should know how many animals are used by or under the control of the facility, and identify inaccuracies accordingly.
[62] 7 U.S.C. §2143(b) (February 2010).
[63] 9 Code of Federal Regulations (CFR) 2.31(d)(5) (January 2010).
[64] 7 U.S.C. §2143(b) (February 2010).
[65] *USDA Employee Survey on the Effectiveness of IACUC Regulations* (April 2000).
[66] Audit 33002-3-SF, *APHIS Animal Care Program Inspection and Enforcement Activities* (September 2005).

VMOs for inadequate protocol reviews and monitoring. See Table 4 for the most frequent areas of IACUC violations—protocol reviews, monitoring, and annual reports:

Table 4: IACUC Violations in FYs 2009-2011

Area of Violations	No. of Violators	No. of Violations
Protocol Reviews	288	566
Monitoring:		
Veterinary Care	277	456
Semiannual Inspections	118	173
Protocol Deviations	46	57
Continuing Reviews	31	41
Annual Reports	67	86
Total	**531**[1]	**1,379**

[1] Some research facilities' IACUCs were cited in multiple areas of violations.

Protocol Reviews

Regulations require that protocols document the consideration of alternatives to painful procedures, provide a rationale for the use of live animals, and that the researcher will obtain IACUC approval prior to making significant changes to the protocol.[67] Regulations also require that protocols contain an assurance that the procedures do not unnecessarily duplicate previous experiments.[68] IACUCs are responsible for ensuring that all protocols meet these requirements before approval. Researchers must then follow the IACUC-approved protocols or seek approval for an amendment, if there is a significant deviation.

During FYs 2009 – 2011, VMOs cited 566 violations related to inadequate protocol review and approval at 288 research facilities. These violations included (1) incomplete descriptions of the proposed use of animals, (2) inadequate searches for alternatives to painful procedures, (3) no descriptions of euthanasia method to be used in the experiment, and (4) no descriptions of procedures designed to assure that pain to animals would be limited to that which is unavoidable.

We concluded that some IACUC members were not judicious in reviewing protocols. Also, some VMOs stated that IACUC members could benefit from additional training for protocol review and approval. We agree that APHIS should provide training or best practice guidelines to the facilities.

[67] CFR 2.31 (c)(7) and 2.31 (d)(1) (January 2010).
[68] CFR 2.31 (d)(1)(iii) (January 2010).

Monitoring

Regulations require that IACUCs, as agents of the research facilities, "review, at least once every six months, the research facility's program for humane care and use of animals . . . [and] inspect, at least once every six months, all of the research facility's animal facilities, including animal study areas." Regulations also require that IACUCs conduct continuing reviews of activities at appropriate intervals, but not less than annually.[69]

Continuing IACUC oversight and monitoring helps ensure the health and well-being of animals. Methods include continuing protocol reviews, laboratory inspections, veterinary or IACUC observations of selected procedures, and observations of animals. During FYs 2009 – 2011, VMOs found 727 violations related to IACUC monitoring. While some VMOs attributed these violations to a lack of IACUC training, some IACUCs did not make monitoring a priority. Four areas with frequent violations were veterinary care, semiannual inspections, protocol deviations, and continuing reviews of activities:

- **Veterinary Care:** Each research facility is required to establish and maintain programs of adequate veterinary care and to employ an attending veterinarian, who provides veterinary care to the animals in compliance with regulations. However, VMOs cited 277 research facilities for not providing adequate veterinary care. Violations included a lack of (1) appropriate methods to prevent, control, diagnose, and treat diseases and injuries; (2) adequate pre-procedural and post-procedural care in accordance with current established veterinary medical nursing procedures; (3) a written program of veterinary care; and (4) daily observation of animals to assess their health and well-being.

- **Semiannual Inspections:** Semiannual program and facility inspections are an assessment of a facility's humane care and use program, and are central to monitoring efforts. These inspections were either not conducted, incomplete, or untimely at 118 facilities.

- **Protocol Deviations:** IACUCs are required to ensure that researchers' use of animals complies with approved protocols. However, even though VMOs inspect facilities once a year and experiments may not be conducted at that time, they still cited 46 facilities with 57 violations for protocol deviations. Deviations ranged from doubling the number of implants in an animal to using more animals than authorized by the protocol.

  We observed one protocol deviation at a facility in Maryland where researchers dropped chili pepper flakes into the eyes of an animal to induce tearing; the protocol called for carefully placing a few flakes on the cheek below the animal's eyes. In another example, a facility in North Carolina did not obtain IACUC approval before implementing significant changes, including those regarding the number of animals

[69] 9 CFR 2.31(d)(5) (January 2010).

used, glucose monitoring, and the insulin dose and route. Although the protocol approved the induction of diabetes in 10 rabbits, the researcher used 46 rabbits, 21 of which died.

- **Continuing Reviews of Activities:** VMOs cited 31 IACUCs for not conducting their continuing review of protocols. Regulations and the *AC Inspection Guide* require that IACUCs conduct continuing reviews of activities at appropriate intervals, but not less than annually.[70] APHIS generally referred to these continuing reviews as "annual reviews," and AC officials interpreted the activities to mean a review of all protocols.

  However, the *AC Inspection Guide* elaborates in another section—"Other IACUC Functions, Animal Use Activity Monitoring"—that IACUCs are also responsible for detecting deviations from AWA regulations and standards, ensuring proper use and care of animals, ensuring investigator compliance with the IACUC-approved protocol, detecting changes not approved by the IACUC in protocol animal use activities, and detecting any non-IACUC-approved use of animals.[71] These activities should be ongoing and are found in most post approval (of protocols) monitoring programs, which had already been implemented by 19 of the 29 facilities we visited to ensure that researchers comply with approved protocols.

  Instead of being listed in the "Other" section of the *AC Inspection Guide*, AC should incorporate these required activities in the "continuing reviews of activities" section of the regulations and in the "Annual Review" section of the Guide. This will emphasize to the regions, as well as the facilities, that annual reviews are more than a review of protocols and should include all of the activities listed above to detect deviations from protocols and ensure proper use and care of animals.

In conclusion, IACUCs should routinely monitor research activities to ensure the facilities comply with both AWA and the IACUC-approved protocols. Considering that VMOs cited 727 violations related to monitoring, we believe IACUCs (especially those with numerous violations) should increase the number of continuing reviews of activities and document their reviews, conducting as many as necessary to decrease the number of violations.

Inaccurate Annual Reports

APHIS requires research facilities to submit annual reports, which identify the numbers and types of animals used during the previous fiscal year. The reports also indicate if pain-relieving drugs were administered during the experiments or if the animals experienced pain without the benefit of any drugs. Pain categories include "with pain, no drugs," "with pain, with drugs," and "no pain, no drugs." See Exhibit C for a blank copy of an annual report.

[70] 9 CFR 2.31(d)(5) (January 2010).
[71] *AC Inspection Guide*, Appendix 8, Section 9.8.12 (September 2010), which cites 9 CFR 2.31(d)(5).

Regulations state, "The reporting facility shall be that segment of the research facility . . . that uses or intends to use live animals in research, tests, experiments, or for teaching. Each reporting facility shall submit an annual report to the AC Regional Director for the State where the facility is located . . ."[72] Policy states, "Consolidate the numbers to be reported from the various sites operated by your registered facility on a single submitted form. Do not send in a separate form for each site at which the facility used animals in the previous year. Instead, attach to the report a statement listing the location of all facilities or sites at which animals were used . . ."[73]

In our 2005 audit, we found that over 80 percent of the research facilities we visited (13 of 16) misreported the numbers of animals they used in research.[74] We recommended that APHIS "instruct research facilities to ensure that the numbers of animals reported in the annual report are accurate." In response, APHIS amended the *AC Inspection Guide* and distributed an instructional memo to VMOs concerning the changes to ensure the VMOs verify the accuracy of the numbers of animals reported.

In this audit, almost 45 percent of the research facilities we visited (13 of 29) misreported the numbers of animals used in research, reported animals in the wrong pain category, or could not provide us with documentation to reconcile their annual report. The facilities need to recognize the importance of the reports and take greater care in preparing them; the VMOs need to be more diligent in confirming their accuracy (also see Finding 2).

Also, APHIS requires multi-State facilities (usually large corporations) to submit consolidated annual reports because the agency uses only one registration number per facility. Many of these facilities have sites that are located in both APHIS regions; the facilities' headquarters consolidate the annual reports and submit them to the region, where they are incorporated. Eight of the 29 facilities we visited were multi-State facilities. When we conducted our review at these facilities, we asked for site-specific annual report data to confirm their accuracy. Two facilities told us that they were unable to provide this information.

We believe that consolidated annual reports impede the inspection process because VMOs are unable to properly prepare for their inspections if they do not have a general idea of the number and types of animals they may encounter at each site. One large facility without a site-specific annual report told us that "for the species reported, the numbers represent a summary of numbers from between three to seven sites depending on the species. Therefore, it is not possible [for the VMO] to reconcile any given site's animal inventory to the number listed in the annual report, regardless of the documents provided."

We discussed this with APHIS officials, who agreed that registration numbers could be modified to add a unique identifier to each site, such as an "a" or "b" at the end of each

[72] 9 CFR 2.36(a) (January 2010).
[73] Appendix 4, Annual Report Guidance, p. 6 (September 2010).
[74] Audit 33002-3-SF, *APHIS Animal Care Program Inspection and Enforcement Activities* (September 2005).

registration number. The Associate Deputy Administrator for AC agreed that research facilities should maintain site-specific annual report data.

In conclusion, APHIS should emphasize to the research facilities the importance of submitting an accurate annual report and require facilities to submit site-specific annual report data.

Recommendation 12

Provide training or best practice guidelines for protocol review and approval to research facilities.

Agency Response

APHIS agrees with this recommendation. We will develop and distribute guidance to the research facilities on protocol review and approval, by June 30, 2015.

OIG Position

We accept APHIS' management decision on this recommendation.

Recommendation 13

Incorporate the activities from the "Other [Institutional Animal Care and Use Committee] IACUC Functions, Animal Use Activity Monitoring" section of the *AC Inspection Guide* in the "Continuing Reviews of Activities" section of the regulations and in the "Annual Review" section of the *AC Inspection Guide*.

Agency Response

APHIS agrees with the intent of this recommendation. APHIS could engage in the rulemaking process to propose incorporation of some language from the *AC Inspection Guide* into the 9 CFR regulations. However, the length of time necessary for such changes to the regulations is significant and the anticipated benefits are not soon realized during this process. APHIS will undertake non-regulatory actions to implement this recommendation by ensuring that IACUCs appropriately monitor the animal use activities to further comply with the AWA.

APHIS will develop and distribute guidance to research facilities on conducting continuing reviews of their animal use activities by June 30, 2015.

OIG Position

We accept APHIS' management decision on this recommendation.

Recommendation 14

Develop guidance and training for the research facilities that includes the activities in the "Other IACUC Functions, Animal Use Activity Monitoring" section of the *AC Inspection Guide*. Require IACUCs (especially those with numerous violations) to increase their number of continuing reviews of activities and document their reviews by providing a description of their activities.

Agency Response

APHIS agrees with the intent of this recommendation. Based on a review of 9 CFR Section 2.31 (d)(5) by OGC, an IACUC is compliant in terms of their minimum responsibility to have continuing reviews as long as the IACUC is conducting the reviews of the activities involving animals at least yearly. The IACUC can certainly have it more often than that, but 2.31 (d)(5) reserves that judgment completely to the IACUC itself. Requiring IACUCs to increase their number of continuing reviews will require a regulatory change. APHIS could engage in the rulemaking process to require IACUCs to increase their number of continuing reviews. However, the length of time necessary for changes to the regulations is significant and the anticipated benefits are not soon realized during this process.

APHIS will pursue a non-regulatory solution to implement this recommendation. APHIS will distribute guidance to ensure that IACUCs appropriately monitor the animal use activities and further comply with the AWA. This guidance for research facilities will include information from the *AC Inspection Guide* on conducting continuing reviews of their animal use activities, by June 30, 2015.

OIG Position

We accept APHIS' management decision on this recommendation.

Recommendation 15

Provide research facilities with guidance on how to prepare annual reports accurately and require the facilities to submit site-specific annual report data.

Agency Response

APHIS agrees with this recommendation and agrees that the inspector should verify that the research facility's Annual Report is accurate and that the availability of site-specific data on Annual Reports will facilitate the inspection process of research facilities with multiple animal research sites. Based on a review by OGC, 9 CFR Section 2.36(a) requires only that the reporting facility be "that segment of the research facility . . . that uses . . . live animals in research. . ."

APHIS will undertake non-regulatory actions to implement this recommendation. APHIS will develop and distribute guidance for the research facilities on accurate preparation of the Annual

Report. APHIS will also provide guidance for inspectors on reviewing Annual Reports. APHIS will distribute the guidance documents by June 30, 2015.

APHIS will consult with OGC to determine if APHIS has administrative discretion to revise the Annual Report form to include site-specific animal use data. Based on this determination, we will take appropriate action to revise the form. APHIS will seek advice from OGC by October 31, 2014.

On November 7, 2014, APHIS clarified its written response dated October 29, 2014. The email provided to us stated the following: "Based on consultation with OGC, APHIS has administrative discretion to revise the Research Facility Animal Use Annual Report form (APHIS Form 7023 and 7023a) to include sections for site-specific animal use data. The form changes require Office of Management and Budget (OMB) approval. On January 30, 2015 APHIS will initiate appropriate action to revise the form. APHIS will also develop guidance for the research facilities on accurate preparation of the revised Annual Report form. APHIS will distribute the revised form and guidance after approved by OMB."

OIG Position

We accept APHIS' management decision on this recommendation.

Scope and Methodology

We conducted a nationwide audit of AC's inspections of research facilities and its enforcement of AWA during FYs 2009 through 2011.[75] For research facilities that did not use animals, we expanded the audit's scope to FY 1999. We performed fieldwork at the AC and IES national offices in Riverdale, Maryland; the two regional offices in Raleigh, North Carolina, and Fort Collins, Colorado; and 29 research facility sites in 11 States (see Exhibit B for a list of audit sites). We performed audit fieldwork from July 2011 through April 2013.

We judgmentally selected 29 of 1,117 research facilities for site visits based on (1) research experiments categorized as "with pain, no drugs," (2) the number of prior violations, (3) the total number of animals used in research, (4) public complaints, and (5) the prior OIG research facilities audit.[76]

To accomplish our audit, we:

- **Reviewed Criteria:** We reviewed the pertinent laws and regulations governing the AC program and the current policies and procedures AC and IES established as guidance for inspections and enforcement.

- **Interviewed APHIS Personnel:** We interviewed both AC and IES national and regional office officials, and 19 VMOs to gain an understanding about the AC program, AC's inspection process, IES' investigative procedures, and the controls the units use to enforce AWA.

- **Conducted Site Visits:** We accompanied VMOs on inspections of 29 facilities to determine whether they complied with AWA, and to evaluate the effectiveness of AC's inspection and enforcement activities.

- **Interviewed Research Facility Personnel:** At the research facility sites we visited, we interviewed IACUC chairpersons and other committee members to gain an understanding of the facilities' animal care procedures and committee functions.

- **Reviewed AC Inspection Reports and Research Facility Files:** For the research facility sites we visited, we reviewed AC inspection reports, IACUC minutes, IACUC semi-annual reviews, protocols, animal usage logs, and annual reports to evaluate the effectiveness of VMOs' and IACUCs' monitoring of research facilities.

- **Analyzed Timeliness of Investigations and Closed Investigative Cases:** We reviewed AC investigations resolved in October 2008 through June 2011 to determine whether investigations were timely completed. We also reviewed all 432 cases that AC identified for closure between August 2011 and February 2012 to ensure they were closed in accordance with AC guidelines.

[75] We did not review any Federal research facilities since they are not required to be inspected by AC (7 U.S.C. §2143(c), February 2010).
[76] Audit 33002-3-SF, *APHIS Animal Care Program Inspection and Enforcement Activities* (September 2005).

- **Analyzed Stipulations:** We analyzed a total of 29 cases closed with stipulations issued between October 2010 and June 2011 to determine if IES consistently adhered to its penalty guidelines.[77] We analyzed an additional 30 stipulations issued between February 2012 to September 2012 to determine the effect on penalties due to the increased settlement reduction.[78]

- **Reviewed ALJ Decisions:** We reviewed a total of all 94 ALJ decisions on AWA cases issued from January 2009 through March 2013 to compare IES' penalty recommendations to ALJ decision amounts.[79] For this procedure, we expanded our scope to include FY 2012 and FY 2013 to analyze as broad a universe as possible and review the most recent cases.

- **Reviewed AC's Information System:** We obtained read-only access to the Animal Care Information System to verify the system's input controls, reliability, integrity, and availability of data. We reviewed registration information, inspection data, and annual report data for all research facilities registered with AC. We also verified that the Risk-Based Inspection System was appropriately scheduling upcoming inspections, based on a research facility's history of compliance with AWA and related regulations.

- **Reviewed Whistleblower Complaints:** We reviewed 28 whistleblower complaints to determine if APHIS took appropriate enforcement action in accordance with guidelines.[80] We reviewed enforcement action as a whole and our results are incorporated in Findings 3 to 5. We were unable to verify one whistleblower complaint because the complaint lacked detailed information or documentation.

- **Followed Up on Prior Audit Recommendations:** We reviewed AC's and IES' actions in response to our recommendations in the prior OIG research facilities audit to determine whether problems still persist.[81] We determined that some problems still persist, as discussed in Findings 2, 4, and 6.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[77] Prior audit recommendations were to be implemented by September 30, 2010. Therefore, we selected our sample of stipulations starting in October 1, 2010.
[78] The penalties included all facilities covered by AWA, such as dealers, breeders, research facilities, exhibitors, and intermediate handlers.
[79] We reviewed 108 decisions overall. However, 14 of the decisions did not contain enough information for us to make a relevant conclusion. We excluded these decisions from our analysis.
[80] In 13 of these complaints, the whistleblower used AC's inspection reports as the basis for the allegations. The whistleblower was concerned whether APHIS would take appropriate enforcement action.
[81] Audit 33002-3-SF, *APHIS Animal Care Program Inspection and Enforcement Activities* (September 2005).

Abbreviations

AC .....Animal Care
ALJ.....Administrative Law Judge
APHIS .....Animal and Plant Health Inspection Service
AWA .....Animal Welfare Act
CFR .....Code of Federal Regulations
EAJA.....Equal Access to Justice Act
FY .....Fiscal Year
IACUC .....Institutional Animal Care and Use Committee
IES.....Investigative and Enforcement Services
OGC .....Office of the General Counsel
OIG .....Office of Inspector General
U.S.C. .....United States Code
USDA.....United States Department of Agriculture
VMO .....Veterinary Medical Officer

Exhibit A: Summary of Monetary Results

Exhibit A lists findings and recommendations that had a monetary result, and includes the type and amount of the monetary result.

FINDING NUMBER	RECOMMENDATION NUMBER	DESCRIPTION	AMOUNT	CATEGORY
1	1	AC conducted at least 500 inspections at 107 research facilities that had not used, handled, or transported any regulated animals for more than 2 years..	$115,000	FTBPTBU[1] – Management or Operating Improvements / Savings
4	7	Monetary penalties remain low, compared to those calculated by prior worksheets. Violators in our sample received penalties totaling at least $272,298 less than what they would have received using the worksheet in effect during our 2010 audit.	$272,298	FTBPTBU[1] – Management or Operating Improvements / Savings
5	10	IES incorrectly used its guidelines for good faith and number of violations, thereby under-assessing penalties to violators.	$33,001	FTBPTBU[1] – Management or Operating Improvements / Savings
TOTAL MONETARY RESULTS			$ 420,299	

[1] Funds to be put to better use.

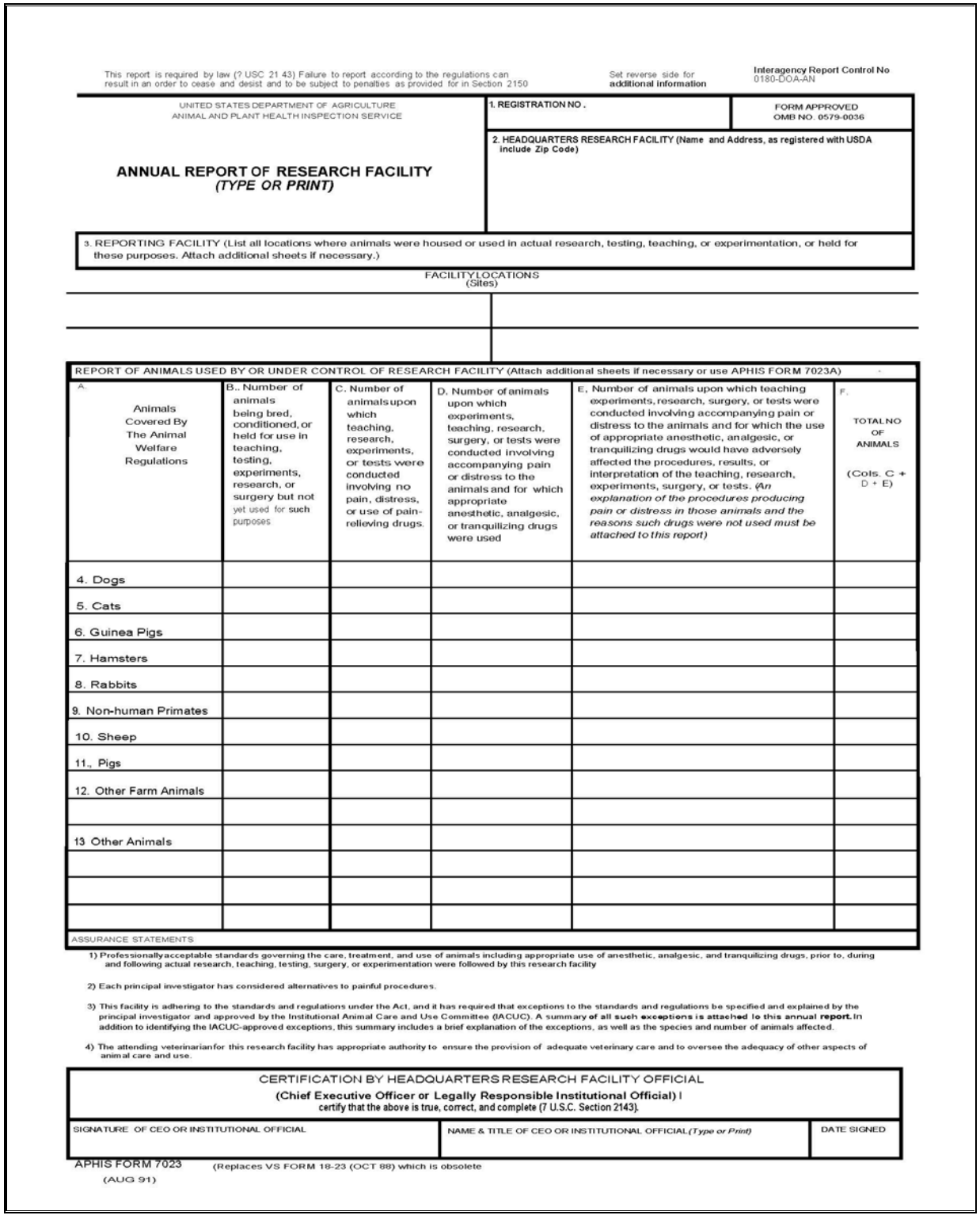
Exhibit B: Audit Sites Visited

Exhibit B shows the organization and location of all sites visited.

Organization	Location
APHIS National Office	
Animal Care	Riverdale, MD
Investigative and Enforcement Services	Riverdale, MD
APHIS Eastern Regional Office	
Animal Care	Raleigh, NC
Investigative and Enforcement Services	Raleigh, NC
Research Facilities:	
1	Auburn, AL
2	Birmingham, AL
3	Birmingham, AL
4	Gainesville, FL
5	Jacksonville, FL
6	Tampa, FL
7	Amherst, MA
8	Boston, MA
9	Boston, MA
10	Waltham, MA
11	Baltimore, MD
12	Frederick, MD
13	Raleigh, NC
14	Research Triangle Park, NC
APHIS Western Regional Office	
Animal Care	Fort Collins, CO
Investigative and Enforcement Services	Fort Collins, CO
Research Facilities:	
1	Davis, CA
2	Irvine, CA
3	La Jolla, CA
4	Los Angeles, CA
5	Mountain View, CA
6	Palo Alto, CA
7	Denver, CO
8	Fort Collins, CO
9	De Soto, KS
10	Albuquerque, NM
11	Reno, NV
12	Alice, TX
13	Galveston, TX
14	San Antonio, TX
15	Sugar Land, TX

Exhibit C: Research Facility Annual Report

Exhibit C shows a blank copy of a research facility's annual report.



This report is required by law (7 USC 21 43) Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150

Set reverse side for additional information

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO .

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA include Zip Code)

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in those animals and the reasons such drugs were not used must be attached to this report)*	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11., Pigs					
12. Other Farm Animals					
13 Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional Official) I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF CEO OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED

APHIS FORM 7023 (AUG 91)

(Replaces VS FORM 18-23 (OCT 88) which is obsolete

USDA'S
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
RESPONSE TO AUDIT REPORT

United States Department of Agriculture

Animal and Plant Health Inspection Service

Washington, DC 20250

MEMORANDUM

TO: Gil H. Harden October 29, 2014
Assistant Inspector General
for Audit

FROM: Kevin Shea /S/
Administrator

SUBJECT: APHIS Response and Request for Management Decisions on OIG Report, "APHIS Oversight of Research Facilities" (33601-01-41)

Thank you for the opportunity for the Animal and Plant Health Inspection Service (APHIS) to comment on your October 7, 2014, Official Draft report. We have restated each Recommendation below along with our planned corrective actions and the timeframes for implementation of these actions.

Recommendation 1: In consultation with the Office of the General Counsel (OGC), determine if APHIS has the administrative discretion to revise the *AC Inspection Guide* to establish inspection criteria for active research facilities that have not used, handled, or transported animals for an extended period, so that these facilities receive limited inspections, similar to those conducted at inactive facilities. Based on this determination, take the appropriate actions to revise the inspection criteria.

APHIS Response: APHIS agrees with this Recommendation. In consultation with OGC, APHIS has administrative discretion to revise the *AC Inspection Guide* to establish inspection criteria for active research facilities that have not used, handled, or transported regulated species for an extended period. APHIS will revise the Inspection Guide to include criteria for inspecting facilities that have reported no regulated animal use on their Annual Reports. We will revise the *AC Inspection Guide* by June 30, 2015.

Recommendation 2: Revise the *AC Inspection Guide* to reduce the sampling period for inactive protocols from 3 years to 1 year to align with APHIS inspection requirements.

APHIS Response: APHIS agrees with this Recommendation. We will revise the *AC Inspection Guide* by June 30, 2015.

Recommendation 3: Emphasize to all veterinary medical officers (VMOs) and supervisors their responsibility to follow the *AC Inspection Guide* in selecting and reviewing protocols, and to review annual reports for accuracy.

APHIS Response: APHIS agrees with this Recommendation. We will emphasize to Animal Care staff their responsibility to follow the *AC Inspection Guide* in selecting and reviewing protocols and to review Annual Reports for accuracy. We will inform staff and revise the *AC Inspection Guide* by June 30, 2015.

Recommendation 4: Require VMOs to document and maintain a record of the protocols they reviewed and the rationale for selecting them.

APHIS Response: APHIS agrees with the intent of this recommendation. APHIS has determined that the development and distribution of protocol selection and review guidance is the most effective method to ensure that VMOs are appropriately selecting animal use protocols for review. The guidance for use during inspections will include a standardized protocol selection list and instructions to include the reason each protocol was selected for review. The guidance will also include instructions to the VMOs to retain the completed lists so that supervisors can review those lists during supervisory "ride-alongs" and/or reviews. APHIS will revise the *AC Inspection Guide* regarding the inspector's process for reviewing research protocols by June 30, 2015.

Recommendation 5: Add instructions to the "Annual Report Checklist" that if research facilities choose to report animals in field studies, they should be identified as non-regulated animals.

APHIS Response: APHIS agrees with this Recommendation. We will provide written guidance to the research facilities on the updated requirements for completion of the "Annual Report of Research Facility" form. We will develop and distribute this guidance by June 30, 2015.

Recommendation 6: Require Animal Care (AC) unit to document its rationale for closing any case that is not closed by the Investigative and Enforcement Services (IES).

APHIS Response: APHIS agrees with this Recommendation. APHIS will issue a memorandum to require AC staff to document the rationale for closing any investigative case that is not closed by IES. This memorandum will be issued by December 31, 2014.

We would like to take this opportunity to provide some information pertinent to OIG's reference to IES' "time reduction effort" in the paragraph preceding Recommendation 6. On September 4, 2014, APHIS provided its stakeholders with an update detailing the successful 80 percent reduction in IES' open cases between 2011 and 2014. This reduction was the result of the agency's first Business Process Improvement project focused on reviewing steps taken in the enforcement process. In addition, IES reduced the average time it takes to investigate and take action on

alleged violations from 632 days to 328 days (about 48 percent) during the three-year period.

Recommendation 7: Review the adjustments given on the penalty worksheet and consider such things as lowering the settlement reduction (e.g., from 75 to 65 percent) across all programs, decreasing the range of AWA-authorized reductions, or decreasing the discretionary reduction.

APHIS Response: APHIS agrees with this Recommendation. By September 30, 2015, we will convene a meeting of the Civil Penalty Action Team for the AWA to review the penalty guidelines and worksheet and consider whether APHIS should revise any of the adjustments noted above. APHIS will consult with OGC, in an advisory capacity, as necessary.

Recommendation 8: Document in a formal policy the reasons for decisions made (i.e., points and ranges of reductions for each factor) to provide reductions in the penalty worksheet.

APHIS Response: APHIS agrees with this Recommendation. We will convene a meeting of the Civil Penalty Action Team for the AWA. APHIS will consult with OGC, in an advisory capacity, as necessary. APHIS will document the reasons for the decisions made regarding each of the adjustments in a formal policy by September 30, 2015.

Recommendation 9: Revise the supplemental penalty table for unlicensed animal sales to ensure the penalties it generates are not excessive.

APHIS Response: APHIS agrees with this Recommendation. We will revise the penalty table for unlicensed animal sales to ensure the penalties it generates are not excessive, by September 30, 2015. In the interim, APHIS will continue to carefully review penalties associated with unlicensed animal sales until the revisions are in place to ensure the penalties are fair, equitable, and consistent with the statutory factors outlined in the AWA for determining appropriate penalties.

Recommendation 10: Revise "Determining Penalties Under the Animal Welfare Act" guidelines to expressly include self-reported violations for potential good faith reductions and give greater consideration for violations resulting in serious animal injury or animal deaths when determining good faith reductions to penalties. Require that justifications for good faith decisions be documented in case files.

APHIS Response: APHIS generally agrees with this Recommendation, with one exception. APHIS already considers self-reported violations in its good faith assessment. APHIS will revise "Determining Penalties Under the Animal Welfare Act" guidelines to expressly include self-reported violations for potential good faith reductions, and to require that justifications for good faith decisions be documented in case files, by September 30, 2015.

With respect to the recommendation to give greater consideration for violations resulting in serious animal injury or death when determining whether an alleged violator has demonstrated good faith, under the current penalty guidelines, the determination of good faith is a balancing test, in which APHIS weighs a variety of factors, as outlined in the guidelines. Allegations involving serious animal injury or animal death are given greater weight, but do not automatically preclude a finding of good faith. The standard as set forth in the guidelines was developed, in part, based on language from administrative decisions issued by the Secretary of Agriculture. APHIS will convene a meeting of the Civil Penalty Action Team for the AWA that will review the penalty guidelines regarding good faith and consider whether it should be adjusted to give greater consideration for violations resulting in serious animal injury or animal deaths. APHIS will consult with OGC, in an advisory capacity, as necessary.

Recommendation 11: Emphasize in IES guidelines that the use of testimony and inspectors' reports can be sufficient, appropriate evidence to determine the number of violations.

APHIS Response: APHIS agrees with this Recommendation. APHIS will revise its existing guidelines for AWA cases to note that the use of testimony and inspection reports can be sufficient, appropriate evidence to determine the number of violations, depending on the circumstances. However, APHIS will continue to be guided by OGC and the administrative decisions by the Secretary of Agriculture when determining what constitutes sufficient evidence to pursue an alleged violation. To the extent that each "count" for penalty calculation purposes must be supported by a preponderance of the evidence to prevail at a hearing, APHIS will only count alleged violations that meet this evidentiary standard. APHIS will complete these revisions by September 30, 2015.

Recommendation 12: Provide training or best practice guidelines for protocol review and approval to research facilities.

APHIS Response: APHIS agrees with this Recommendation. We will develop and distribute guidance to the research facilities on protocol review and approval, by June 30, 2015.

Recommendation 13: Incorporate the activities from the "Other [Institutional Animal Care and Use Committee] IACUC Functions, Animal Use Activity Monitoring" section of the *AC Inspection Guide* in the "Continuing Reviews of Activities" section of the regulations and in the "Annual Review" section of the *AC Inspection Guide*.

APHIS Response: APHIS agrees with the intent of this Recommendation. APHIS could engage in the rulemaking process to propose incorporation of some language from the *AC Inspection Guide* into the 9 CFR regulations. However, the length of time necessary for such changes to the regulations is significant and the anticipated benefits are not soon realized during this process. APHIS will undertake non-regulatory actions to implement this Recommendation by ensuring that IACUCs appropriately monitor the animal use activities to further comply with the AWA.

APHIS will develop and distribute guidance to research facilities on conducting continuing reviews of their animal use activities by June 30, 2015.

Recommendation 14: Develop guidance and training for the research facilities that includes the activities in the "Other IACUC Functions, Animal Use Activity Monitoring" section of the *AC Inspection Guide.* Require IACUCs (especially those with numerous violations) to increase their number of continuing reviews of activities and document their reviews by providing a description of their activities.

APHIS Response: APHIS agrees with the intent of this Recommendation. Based on a review of 9 CFR Section 2.31(d)(5) by OGC, an IACUC is compliant in terms of their minimum responsibility to have continuing reviews as long as the IACUC is conducting the reviews of the activities involving animals at least yearly. The IACUC can certainly have it more often than that, but 2.31(d)(5) reserves that judgment completely to the IACUC itself. Requiring IACUCs to increase their number of continuing reviews will require a regulatory change. APHIS could engage in the rulemaking process to require IACUCs to increase their number of continuing reviews. However, the length of time necessary for changes to the regulations is significant and the anticipated benefits are not soon realized during this process.

APHIS will pursue a non-regulatory solution to implement this Recommendation. APHIS will distribute guidance to ensure that IACUCs appropriately monitor the animal use activities and further comply with the AWA. This guidance for research facilities will include information from the *AC Inspection Guide* on conducting continuing reviews of their animal use activities, by June 30, 2015.

Recommendation 15: Provide research facilities with guidance on how to prepare annual reports accurately and require the facilities to submit site-specific annual report data.

APHIS Response: APHIS agrees with this recommendation and agrees that the inspector should verify that the research facility's Annual Report is accurate and that the availability of site-specific data on Annual Reports will facilitate the inspection process of research facilities with multiple animal research sites. Based on a review by OGC, 9 CFR Section 2.36(a) requires only that the reporting facility be "that segment of the research facility…that uses…live animals in research…"

APHIS will undertake non-regulatory actions to implement this recommendation. APHIS will develop and distribute guidance for the research facilities on accurate preparation of the Annual Report. APHIS will also provide guidance for inspectors on reviewing Annual Reports. APHIS will distribute the guidance documents by June 30, 2015.

APHIS will consult with OGC to determine if APHIS has administrative discretion to revise the Annual Report form to include site-specific animal use data. Based on this determination, we will take appropriate action to revise the form. APHIS will seek advice from OGC by October 31, 2014.

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