U.S. Department of Agriculture

Office of Inspector General
Western Region

Audit Report

APHIS Animal Care Program
Inspection and Enforcement Activities

Report No. 33002-3-SF
September 2005

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

September 30, 2005

REPLY TO
ATTN OF: 33002-3-SF

TO: W. Ron DeHaven
Administrator
Animal and Plant Health Inspection Service

ATTN: William J. Hudnall
Deputy Administrator
Marketing and Regulatory Programs

FROM: Robert W. Young /s/
Assistant Inspector General
for Audit

SUBJECT: APHIS Animal Care Program – Inspection and Enforcement Activities

This report presents the results of our audit of the subject program. Your September 28, 2005, response to the draft report, excluding attachments, is included as exhibit E of the report. Excerpts from your response and the Office of Inspector General's positions have been incorporated into the relevant sections of the report.

We agree with your management decision for Recommendations 2, 3, 6, 7, 9, 12, 14 through 18, and 20. The actions needed to reach management decision on Recommendations 1, 4, 5, 8, 10, 11, 13, and 19 are identified in the Findings and Recommendations section of the report. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer.

In accordance with Department Regulation 1720-1, please furnish a reply within 60 days describing the corrective action taken or planned and the timeframes for implementation of those recommendations for which management decision has not yet been reached. Please note that the regulation requires a management decision to be reached on all recommendations within a maximum of 6 months from report issuance.

We appreciate the cooperation and assistance provided by your staff during our audit.

Executive Summary

Results In Brief

Animal care and use in the United States is a controversial topic with varying points of view from the public, animal rights groups, breeders, research laboratories, and others. In 1966, the Secretary of Agriculture was given the statutory authority to enforce the Animal Welfare Act (AWA), which set minimum standards of care and treatment for certain warm-blooded animals[1] bred for commercial sale, used in research, transported commercially, or exhibited to the public.

This report presents the results of our audit of the Animal and Plant Health Inspection Service's (APHIS) Animal Care (AC) unit, which has the responsibility of inspecting all facilities covered under the AWA and following up on complaints of abuse and noncompliance. We also reviewed AC's coordination with the Investigative and Enforcement Services (IES) staff, which provides support to AC in cases where serious violations have been found. In addition, we evaluated the effectiveness of the Institutional Animal Care and Use Committees (IACUCs)—the self-monitoring committees at the research facilities responsible for ensuring compliance with the AWA.

We found that most AC employees are highly committed to enforcing the AWA through their inspections and are making significant efforts to educate research facilities and others on the humane handling of regulated animals. However, we identified several ways in which AC should improve its inspection and enforcement practices to ensure that animals receive humane care and treatment and that public safety is not compromised.

- *Due to a lack of clear National guidance, AC's Eastern Region is not aggressively pursuing enforcement actions against violators of the AWA.*[2] We found that regional management significantly reduced its referrals of suspected violators to IES from an average of 209 cases in fiscal years (FYs) 2002-2003 to 82 cases in FY 2004. During this same period, regional management declined to take action against 126 of 475 violators that had been referred to IES.[3] In contrast, the Western Region declined action against 18 of 439 violators.

[1] Regulated animals are any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warmblooded animal. It excludes birds, rats of the genus *Rattus*, mice of the genus *Mus*, bred for use in research; horses not used for research; and other farm animals such as livestock and poultry under certain circumstances.
[2] The data in this section, which we compiled from IES records, may include some Horse Protection Act cases, for which AC is also responsible.
[3] IES estimates that these cases cost APHIS at least $291,000 to investigate.

We found cases where the Eastern Region declined to take enforcement action against violators who compromised public safety or animal health. For example, one AC inspector requested an investigation of a licensee whose primate had severely bitten a 4-year-old boy on the head and face. The wounds required over 100 stitches. Although this licensee had a history of past violations, IES has no record of a referral from AC. In another case, the Eastern Region did not take enforcement action when an unlicensed exhibitor's monkey bit two pre-school children on separate occasions. The exhibitor failed to provide a sufficient public barrier and failed to handle the animal to ensure minimal risk to the public.

As a result, the two regions are inconsistent in their treatment of violators; the percentage of repeat violators (those with 3 or more consecutive years with violations) is twice as high in the Eastern Region than in the Western Region. Eastern Region inspectors believe the lack of enforcement action undermines their credibility and authority to enforce the AWA.

- *Discounted stipulated fines assessed against violators of the AWA are usually minimal.* Under current APHIS policy, AC offers a 75-percent discount on stipulated fines[4] as an incentive for violators to settle out of court to avoid attorney and court costs. In addition to giving the discount, we found that APHIS offered other concessions to violators, lowering the actual amount paid to a fraction of the original assessment. An IES official told us that as a result, violators consider the monetary stipulation as a normal cost of conducting business rather than a deterrent for violating the law.[5]

- *Some VMOs did not verify the number of animals used in medical research or adequately review the facilities' protocols and other records.*[6] We found that 13 of 16 research facilities we visited misreported the number of animals used in research. In reviewing the protocols, some Veterinary Medical Officers (VMOs) did not ensure that the facilities provided them with a complete universe of protocols from which to select their sample. These VMOs told us that the selection process was based on "good faith" and that they relied on the facilities to provide them with accurate records. In addition, a VMO did not review readily available disposition records that disclosed unexpected animal deaths at a research facility.

- *Some IACUCs are not effectively monitoring animal care activities or reviewing protocols.* During FYs 2002 through 2004, the number of research facilities cited for violations of the AWA has steadily increased

[4] These fines are not mandatory but agreed to by the violator.
[5] This was also discussed in OIG Audit No. 33600-1-Ch issued in January 1995.
[6] Protocols are the researchers' proposals for the use of animals in research.

from 463 to 600 facilities. Most VMOs believe there are still problems with the search for alternative research, veterinary care, review of painful procedures, and the researchers' use of animals.

- *AC's Licensing and Registration Information System (LARIS) does not effectively track violations and prioritize inspection activities.* The LARIS database records AC inspections and archives violation histories for all breeders, exhibitors, research facilities, and others. We determined that the system generates unreliable and inaccurate information, limiting its usefulness to AC inspectors and supervisors.

- *FMD and IES did not follow the law and internal control procedures in their processing and collection of penalties.* APHIS' Financial Management Division (FMD) did not transfer 81 of 121 delinquent AC receivables totaling $398,354 to the U.S. Department of Treasury for collection as required by the Debt Collection Improvement Act of 1996 (see exhibit A). In addition, IES did not comply with APHIS' internal cash controls to secure the collection of fines.

Recommendations In Brief

To ensure consistent treatment of violators, we recommend that AC incorporate specific guidance in AC's operating manual that addresses referrals and enforcement actions. We also recommend that AC review all cases where the regions decline to take enforcement actions against violators.

To increase the effectiveness of stipulated fines, we recommend that APHIS eliminate the automatic 75-percent discount for repeat violators or direct violations,[7] calculate fines based on the number of animals affected per violation, and seek legislative change to increase fines up to $10,000 for research facilities.

AC needs to emphasize the need for more detailed reviews of protocols, including those where animals are not present at the facility during the inspection. AC also needs to require research facilities to identify annually the number of protocols in their annual reports, and require the VMOs to verify the number of animals used in research.

To reduce the number of violations, AC needs to modify regulations to require IACUCs to conduct more frequent reviews of facilities identified as repeat violators (3 or more consecutive years with violations). We also recommend that AC require IACUCs to implement policies to fully train committee members on protocol review, facility inspections, and the AWA.

[7] Direct violations have a high potential to adversely affect the health and well-being of the animal.

For LARIS, AC needs to implement temporary measures to address system deficiencies until the new system is operational. Finally, IES and FMD need to follow APHIS policies for internal controls over cash collection, and FMD must timely process receivables for collection.

Agency Response

In its September 28, 2005, written response to the draft report, the APHIS National Office concurred with the report findings and recommendations, except for Recommendation 13. APHIS' response is included in exhibit E of this report.

OIG Position

We accept APHIS' management decision for Recommendations 2, 3, 6, 7, 9, 12, 14 through 18, and 20. The actions needed to reach management decision on Recommendations 1, 4, 5, 8, 10, 11, 13, and 19 are identified in the Findings and Recommendations section of the report. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer.

Abbreviations Used in This Report

AC	Animal Care
ACL	Audit Command Language (software)
APHIS	Animal and Plant Health Inspection Service
AWA	Animal Welfare Act
OCFO	Office of the Chief Financial Officer
ER	Eastern Region
FMD	Financial Management Division
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IES	Investigative and Enforcement Services
LARIS	Licensing and Registration Information System
OGC	Office of the General Counsel
OIG	Office of Inspector General
RBIS	Risk-Based Inspection System
USC	United States Code
USDA	United States Department of Agriculture
VMO	Veterinary Medical Officer
WR	Western Region

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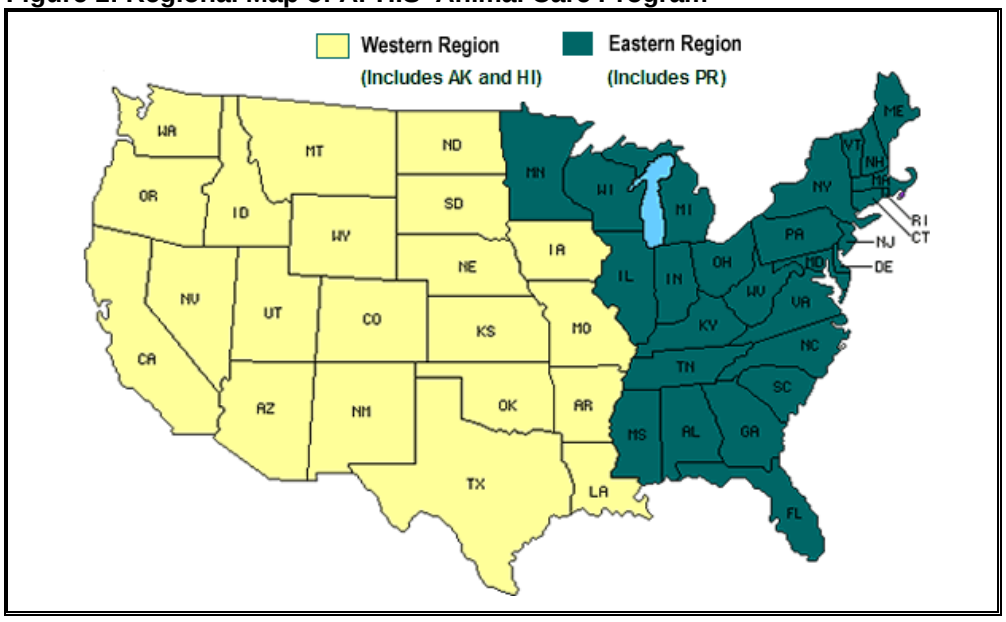
Background and Objectives

Background

In 1966, Congress passed the Animal Welfare Act (AWA), Public Law 89-544, which sets the minimum standards of care and treatment for certain warm-blooded animals bred for commercial sale, used in research, transported commercially, or exhibited to the public. The Animal and Plant Health Inspection Service (APHIS), an agency of the U.S. Department of Agriculture (USDA), has the statutory authority to enforce the AWA. APHIS' Animal Care (AC) unit is responsible for inspecting all facilities covered under the AWA and following up on complaints of abuse and noncompliance. In fiscal year (FY) 2004, the annual appropriations were approximately $16 million.

AC is headquartered in Riverdale, Maryland, and has two regional offices located in Raleigh, North Carolina, and Fort Collins, Colorado. Figure 1 below shows the geographical coverage for AC's Eastern and Western Regions.

Figure 1: Regional Map of APHIS' Animal Care Program



In FY 2004, the Eastern Region employed 17 inspectors (highly trained AC technicians), 29 Veterinary Medical Officers (VMOs), and 5 supervisors/ managers; the Western Region employed 29 inspectors, 25 VMOs, and 6 supervisors/managers. VMOs are licensed veterinarians and conduct inspections of all registered research facilities. Both VMOs and inspectors conduct inspections of licensed facilities (i.e., animal dealers, exhibitors, and other entities). At larger research facilities, more than one VMO may conduct the annual inspection.

In FY 2004, the 100 VMOs/inspectors nationwide were responsible for inspecting over 8,800 facilities. In addition, some inspectors travel hundreds of miles from one facility to the next. Given the limited number of inspectors and the large number of facilities, AC created a risk-based inspection system (RBIS) in February 1998 to better focus AC's inspection strategy. Under this system, not all facilities are inspected annually. Some facilities meeting the criteria for low frequency intervals are subject to inspection once every 2 years, while others determined to require high frequency inspections are inspected at least 3 times annually.

Inspection and Enforcement Process

All facilities that use, sell, or transport animals covered by the AWA for regulated activities must be licensed or registered with APHIS. The VMOs and inspectors conduct unannounced inspections of these facilities. If an inspection reveals deficiencies in meeting the AWA standards, the inspector instructs the facility to correct the problems within a given timeframe.

Minor violations (e.g., incomplete records or lost identification tags) may be settled with an official notice of warning, while more serious cases (e.g., animal deaths due to negligence and lack of veterinary care) may be referred to APHIS' Investigative and Enforcement Services (IES) staff, which provides support to all APHIS programs. IES field personnel conduct comprehensive investigations, track unresolved cases, and coordinate investigative efforts within APHIS and with other Federal and State agencies. IES National Office staff reviews the completed investigative reports and recommends an appropriate action to the AC regional office, which determines the enforcement action based on the gravity of the violation, the violator's prior history, and the size of the business.

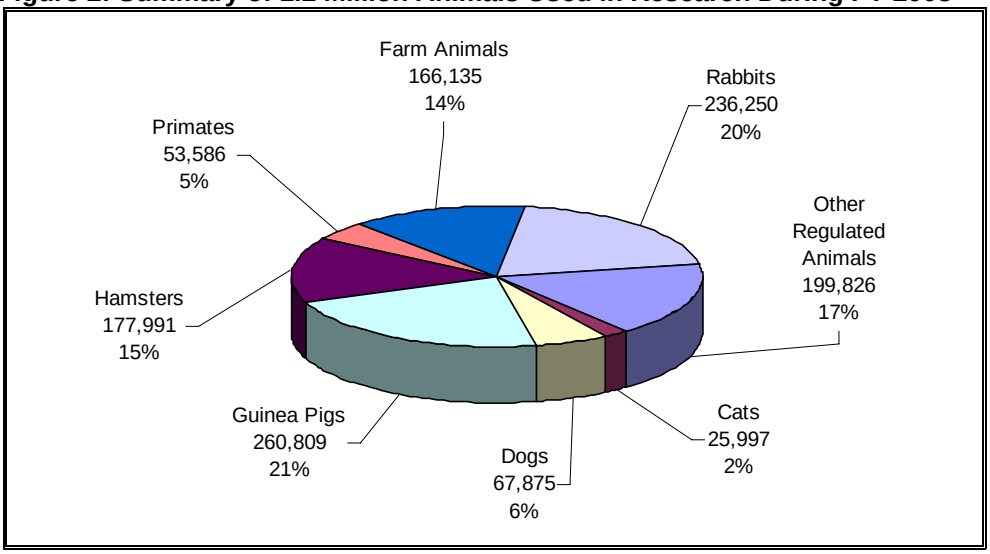
Some cases may be resolved at the agency level through agreements (stipulations) with the violator or through formal administrative action before an administrative law judge. Stipulated agreements allow alleged violators to pay a discounted fine, have their license suspended, or both. Cases that warrant formal prosecution undergo Office of the General Counsel (OGC) review for legal sufficiency prior to issuance of a formal administrative complaint. Formal action may result in license suspensions or revocations, cease-and-desist orders, civil penalties, or combinations of these penalties through administrative proceedings.

Institutional Animal Care and Use Committees

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

at least a chairman, a veterinarian familiar with laboratory animal medicine, and an independent member from the local community. The IACUC reviews all requests to use animals in research and the protocols that dictate the experiments. The committees are also required to inspect at least semiannually all animal study areas and housing facilities. Figure 2 shows the numbers of regulated animals used in research during FY 2003.

Figure 2: Summary of 1.2 Million Animals Used in Research During FY 2003



Research facilities are required to report the numbers of animals used each year to AC. In their annual reports, the facilities categorize the types of animals according to whether they endured painful procedures and whether any relief was provided. These categories include "with pain, no drugs for relief," "with pain, with drugs," and "no pain, no drugs."

Objectives

Our objectives were to: (1) evaluate AC inspection and IES investigative activities, (2) determine the effectiveness of the IACUCs in monitoring research facilities, (3) evaluate the penalty assessment and collection process, and (4) assess the integrity of the information systems used to collect AC data.

The Scope and Methodology section can be found at the end of this report.

While most Animal Care (AC) employees are committed to enforcing the Animal Welfare Act (AWA) and educating research facilities and businesses on the humane handling of animals, improved inspection and enforcement procedures would enhance public confidence that regulated animals receive humane care and treatment.

Of particular concern, AC management in the Eastern Region is not aggressively pursuing enforcement actions against violators of the AWA. The Eastern Region significantly reduced its referrals of suspected violators to the Investigative and Enforcement Services (IES) unit—from an average of 209 cases in fiscal years (FYs) 2002-2003 to 82 cases in FY 2004. When the region did refer cases to IES, management declined to take enforcement action against 126 of 475 violators (27 percent).

When violators are assessed stipulated fines, the fines are usually minimal and not always effective in preventing subsequent violations. Under current APHIS policy, AC gives an automatic 75-percent discount to almost all violators as a means of amicably reaching an agreement on the amount of the fines and avoiding court.

Finally, we noted that some VMOs when inspecting research facilities do not verify the number of animals used in medical research or adequately review the facilities' protocols and other records.

Finding 1 The Eastern Region Is Not Aggressively Pursuing Enforcement Actions Against Violators of the AWA

During FYs 2002-2004, AC's Eastern Region significantly reduced its referrals to the IES unit and declined to take enforcement action in 27 percent[8] of the cases where violations were cited. This occurred because the National Office did not provide clear direction concerning referrals and enforcement actions. Without established procedures that demonstrate how to apply general AC policy to specific cases, regional managers are left to implement AC guidelines as they deem appropriate. As a result, the regions are inconsistent in their treatment of violators; the percentage of repeat violators is higher in the Eastern Region than in the Western Region; and

[8] These numbers do not include cases where IES found no violations or had insufficient evidence to pursue enforcement action; however, the data may include some Horse Protection Act cases, which fall under AC's jurisdiction.

Eastern Region inspectors believe the lack of enforcement undermines their credibility and authority to enforce the AWA.

APHIS has not established national guidelines that specifically address when AC should refer cases to investigations. However, if a case is referred and IES determines that violations have occurred, the AWA[9] authorizes APHIS to impose civil penalties up to $2,750 per violation. APHIS may also suspend, for up to 21 days, the license of any facility[10] that violates provisions of the AWA. According to the AWA, the agency should give "due consideration to the appropriateness of the penalty with respect to the size of the business of the person involved, the gravity of the violation, the person's good faith, and the history of previous violations."[11]

Violations of the AWA are disclosed and confirmed through two separate processes: AC inspections and IES investigations. If AC inspectors identify serious violations during an inspection or if deficiencies remain uncorrected at a follow-up inspection, AC can refer the case to the IES staff. After IES conducts a comprehensive investigation, the case is returned to the appropriate AC region for enforcement action.

Minor infractions may be settled with an enforcement action such as an official notice of warning, while more serious cases may be resolved at the agency level through stipulated fines against the violator or through formal administrative action before an administrative law judge. Stipulated agreements allow alleged violators to pay a greatly discounted fine, have their license suspended, or both.

Decrease in the Number of Referrals to IES

Based on IES data, we determined that AC's Eastern Region significantly reduced the number of referrals to IES. Between FYs 2002-2003, the Eastern Region referred an average of 209 cases; in FY 2004, the region referred 82. In response, regional management told us that the best way to achieve compliance is through education, and enforcement actions such as fines and stipulations can at times promote hostility. The Assistant Regional Director for AC told us, "We do not want to punish violators for their past history…enforcement is a tool of last resort; it is better to get compliance first, if you can."

According to the IES Eastern Regional Director, AC advised him at the beginning of FY 2004 that he would not be receiving as many referrals as he had in the past. As a result, he told us that many suspected violators have not been investigated. A National Office official agreed that "the inspector and

[9] 7 U.S.C. 2149(a) dated March 25, 2004. The penalty was adjusted for inflation to $2,750 in June 2000.
[10] This excludes research facilities because they are not required to obtain licenses; they only register with AC.
[11] 7 U.S.C. 2149(b) dated March 25, 2004.

supervisor are in the best position to know whether a case should be referred to investigations."

The Eastern Region's decision to reduce the number of referrals appears to be arbitrary, even though cases should be reviewed based on their own merits. For example, in March 2004 a VMO recommended that AC management refer to IES a licensee whose primate had severely bitten a 4-year-old boy on the head and face. The wounds required over 100 stitches. Although this licensee had a history of past violations, IES has no record of a referral from AC.

The IES Eastern Regional Director also said, "The excessive focus on education has been very de-motivating to both inspectors and investigators who want the suspects investigated." One VMO told us, "Education is only part of compliance. Those willing to get educated are not usually the problem facilities. Too much emphasis is placed on education at the expense of enforcement." Due to regional management's position on referrals and enforcement, the VMOs believe they are now losing credibility with the facilities, and their morale is low. Over 53 percent of the Eastern Region VMOs—licensed veterinarians—we interviewed believe that the region does not support their work or does not enforce the AWA as aggressively as it should.[12]

The Western Regional Director for AC stated, "AC's mission is to achieve compliance through inspections and education. However, if education does not have the desired impact on the violators' activities, then enforcement is the best way to achieve compliance. It punishes the violator and is a deterrent to others. In the Western Region, we do not decline any cases if there is evidence of violations in the investigation report. At a minimum, we would issue a formal warning."

Failure To Take Enforcement Actions

To determine how the AC regions enforced the AWA, we reviewed IES' Final Action Report for FYs 2002-2004. Eastern Region enforcement guidelines state that sanctions are necessary to dissuade violators from committing the same violations. However, we noted that during this period the Eastern Region issued only 38 stipulated fines to violators for a total of $88,001, while the Western Region issued 143 stipulated fines for $187,060.

In addition, the Eastern Region declined to pursue action against 126 of 475 violators (27 percent). In contrast, the Western Region declined action on 18 of 439 violators (4 percent). We reviewed the cases for 45 of the 126 violators to determine if the Eastern Region declined to take action for

[12] In comparison, 100 percent of the VMOs in the Western Region believed the region supported their work (although one expressed some concerns about occasional differences of opinion concerning enforcement actions against research facilities).

valid reasons. We agree that management had valid reasons, such as the case number was a duplicate, for declining action against five violators. However, no action was taken against 22 violators even after an IES investigation had confirmed violations of the AWA.[13] For example, no enforcement action was taken against an unlicensed exhibitor whose monkey bit two pre-school children on separate occasions. The exhibitor failed to provide a sufficient public barrier to ensure minimal risk to the public.

The IES Eastern Region Director stated, "IES has been frustrated when we send investigators to review a referral, and then AC decides to drop the case without taking action." IES estimates that these cases (related to the 126 violators) cost APHIS at least $291,000 to conduct. In view of APHIS' limited manpower, this is a wasteful use of valuable resources.

Considering the difference in philosophies between the regions on how to achieve compliance with the AWA, we concluded that AC was not treating violators consistently nationwide. We found no National guidelines addressing when AC should decline enforcement action after an IES investigation has documented violations of the AWA.

Higher Number of Repeat Violators in the Eastern Region

Some VMOs stated that because facilities are realizing there is no consequence for violating the AWA, the number of repeat violators in the Eastern Region is increasing. We reviewed several cases where regional management declined to take action against repeat violators and found several examples where public safety or animal health was compromised.

In one case in FY 2002, AC declined to take action against a zoo with a history of violations. Later in the year, a child scaled a barrier fence around the zoo's jaguar exhibit and was injured by a jaguar. Although the zoo replaced the fence with a taller one, the fence was still too low. In September 2002, after two jaguars escaped, AC requested another investigation. A subsequent inspection identified another fence-related problem—this time with the zoo's perimeter fence. An intruder was able to gain access through the perimeter fence and cut the jaguars' fence, allowing them to escape. Although one jaguar was recaptured, another was killed. After three separate investigations, the zoo paid a $3,000 settlement in December 2002. Since then, regional management has declined to take additional enforcement action, even though AC has reported serious violations at the zoo.

Focusing only on research facilities, we found that the number of Eastern Region facilities with violations in FY 2003 and 2004 was more than twice as many as those in the Western Region, 264 versus 106 respectively. We

[13] For the 18 remaining violators, we were unable to determine the reasons for AC's declinations since IES retains its investigative reports for only 1 year.

reviewed the top 50 repeat violators in the nation and found that despite the Eastern Region's emphasis on education to achieve compliance, 88 percent of the violators were located in the Eastern Region. (See exhibit C for a complete list of the top 50 violators. Table 1 shows that the Eastern Region has a proportionately higher rate of repeat violators than the Western Region.)

Table 1: Research Facilities – Top 50 Violators in FYs 2002-2004

Region	Average No. of Research Facilities	% Research Facilities	No. of Repeat Violators	% Repeat Violators
Eastern	650	60%	44	88%
Western	450	40%	6	12%
Total	1,100	100%	50	100%

Although AC can temporarily revoke licenses for breeders and exhibitors, this is not the case with research facilities. The AWA[14] does not authorize "the Secretary, during inspection, to interrupt the conduct of actual research or experimentation…" Therefore, it is more critical for AC to take enforcement actions against research facilities that are repeat violators. If facilities believe there is no consequence for violating the AWA, then credibility becomes an issue. Considering the number of repeat violators—those that continue to violate year after year—enforcement should be used as a deterrent.

Clearer National Direction Needed

The problems described above occurred because the National Office delegated enforcement responsibility to the regions but failed to provide them with clearly defined direction concerning investigative referrals and enforcement actions. The regions rely on the policy manuals[15] to conduct inspections. However, the manuals do not establish detailed procedures for enforcement. Without established procedures that demonstrate how to effectively and consistently apply general AC policy to specific cases, regional managers are left to implement AC guidelines as they deem appropriate.

The former Assistant Deputy Administrator told us, "In the past, the AC National Office was much more involved with enforcement and investigations. Now, all responsibility has been turned over to the regions, which opens the door for inconsistency. Cases can be dropped at the regional level and never receive National Office attention. When we had more oversight at the National Office, we had more consistency."

[14] 7 U.S.C. 2143(a)(6)(A)(iii) dated March 25, 2004.
[15] AC's Policy Manual, Dealer Inspection Guide, and Research Facility Inspection Guide.

To promote consistency between the regions, reinforce the credibility and authority of VMOs/inspectors, and reduce the percentage of repeat violators, the National Office should incorporate specific guidance in AC's operational manuals that addresses referrals and enforcement actions.

Recommendation 1

Incorporate specific guidance in AC's operating manual that addresses referrals and enforcement actions in order to ensure consistent treatment of violators.

Agency Response. To ensure AC's consistency in the treatment of violators, AC will incorporate into all the Inspection Guides a flow chart that provides enforcement action guidelines for inspection reports. AC's Eastern and Western Regional Directors have collaborated to create one flow chart that will be used nationally. The Manual Team will be responsible for inserting the enforcement action flow chart into the inspection guides by November 30, 2005.

OIG Position. We agree with APHIS' corrective action. To achieve management decision, APHIS needs to provide us with a copy of the flowchart.

Recommendation 2

Review all cases where the regions decline to take enforcement actions against violators.

Agency Response. If there is evidence of a violation, but AC's Regional Director recommends that prosecution be "denied/declined," the AC Deputy Administrator or Assistant Deputy Administrator and the Investigative Enforcement Services (IES) Director or Assistant Director will review and approve the "denied/declined" final action prior to closing the case. Also, if AC or IES propose different final actions, the AC Deputy Administrator or Assistant Deputy Administrator and the IES Director or Assistant Director will review the aggravating and mitigating factors and, together, will determine the appropriate final action. The policy is now in place. IES will maintain in its tracking system the reason for "denied/declined."

OIG Position. We accept APHIS' management decision on this recommendation. For final action, APHIS needs to provide a copy of the new policy to the Office of the Chief Financial Officer (OCFO).

Finding 2 — Amount of Stipulated Fines Was Not Always a Deterrent to Violators

APHIS' stipulated fines assessed against violators of the AWA are usually minimal. Under current policy, APHIS gives an automatic 75-percent discount to almost all violators—including research facilities—as a means of amicably reaching an agreement on the amount of the fines and avoiding court. As a result, violators now consider the monetary stipulation as a normal cost of conducting business rather than as a deterrent for violating the AWA.

The AWA[16] authorizes APHIS to impose civil penalties of up to $2,750 per violation. Although these stipulated fines are one of the few tools APHIS can use against violators, the AWA authorizes APHIS to reduce the fines depending upon the circumstances (e.g., the person's good faith or history of previous violations).

APHIS officials told us that they offer an automatic 75-percent discount on stipulated fines as an incentive for violators to settle the cases to avoid attorney and court costs. However, for repeat violators or direct violations,[17] APHIS should offer no discount because of the serious nature of the offenses. For example, in FY 2002, a zoo in Texas was offered a discounted stipulation totaling $5,600 (the original fine was $22,500) for violations that led to the death of a rhinoceros and a separate incident that resulted in the death of five gorillas from chlorine gas.

In addition, an OGC official told us that discounted fines can be problematic if the violator declines the stipulation and the case is forwarded to OGC for processing. If there is a significant difference between APHIS' stipulation offer and OGC's recommended fine, it may be difficult to justify the higher amount.

In addition to giving the discount, we found that APHIS offered other concessions, making the fines basically meaningless.

- *Using Part of Fine to Improve Facility*. An exhibitor failed to construct an adequate bear pen, which resulted in a bear biting a volunteer worker. In addition, the exhibitor was cited for 2 other serious violations, 13 moderate violations, and 1 minor violation.

[16] 7 U.S.C. 2149(a) and 2149(b) dated March 25, 2004. The penalty was adjusted for inflation to $2,750 in June 2000.
[17] Direct violations have a high potential to adversely affect the health and well-being of the animal.

APHIS calculated the total fine at $13,200. After the 75-percent discount, the exhibitor agreed to pay $3,300—$1,650 in cash and $1,650 to repair the facility. The exhibitor benefited by the transaction because he could have been required to pay the $3,300 plus the cost of replacing his perimeter fence. His stipulated fine was actually discounted by 87.5 percent (75 percent discount plus 12.5 percent for repairs).

- *Waiving Portion of Discounted Fine*. An exhibitor who failed to provide veterinary care for his animals was cited for 5 serious violations, 15 moderate violations, and 3 minor violations.

  APHIS calculated the total fine at $17,325. After the 75-percent discount, the exhibitor agreed to pay $4,300—$1,000 in cash and $3,300 to be suspended provided that the exhibitor remain in compliance for 2 years. In effect, the exhibitor paid 6 percent of the original fine.

For FYs 2002-2004, we reviewed 76 of 181 cases in which violators agreed to a stipulated fine. We found that 45 of 59[18] (76 percent) continued to commit violations of the AWA, while 28 of the 45 (62 percent) committed similar or the same violations.

Larger Fines Needed for Research Facilities

APHIS uses a stipulation table to calculate fines for a wide variety of entities, from a small farmer that breeds dogs to a research facility with billions in assets (see exhibit D). The table categorizes the violations into three levels: minor, moderate, and serious. The fines are then calculated based on the level of the violation and on business assets. However, for businesses with assets above $100,000, the fines for violations do not increase, making the penalties negligible for research facilities with assets in the billions of dollars.

In reviewing the table, we noted that a very small breeder with no previous history of violations is assessed $110 for a minor infraction. In comparison, a research facility or university with a history of serious violations and court cases is assessed $550 for the same offense. With the 75-percent discount, this is an insignificant fine for research facilities. For example:

- In FY 2002, a university in Illinois with assets totaling $6.2 billion[19] was cited for 12 serious violations related to veterinary care issues and the death of a monkey and a pig. The facility agreed to a discounted fine of $9,400 (the original fine was $37,675). Later in FY 2002, and again in FY 2004, the facility came under investigation for violating the AWA.

[18] For 14 of the 76 cases, we were unable to determine if follow-up inspections were conducted because these facilities were unlicensed.
[19] 2004 Consolidated Financial Statements.

- In FY 2003, at a university in New York, researchers experimented on a female dog without realizing the animal was pregnant. The dog then gave birth to eight puppies, which the researchers improperly euthanized with expired medication and without any sedative to relieve the pain. Although the facility had $6.7 billion[20] in assets, APHIS offered it a discounted stipulation totaling $2,000 (the original fine was $7,150).

The Western Regional Director for AC agreed that the difference in fines between a small exhibitor and a research facility is negligible. Also, an OGC official agreed that the maximum fine set by the AWA may be low for research facilities. For exhibitors and breeders, AC can revoke licenses in addition to issuing fines. However, because research facilities only register with AC (i.e., there are no licenses to revoke), there is a definite need for higher fines to enforce the AWA.

During FYs 2002 through 2004, 2 of the top 50 research facility violators paid monetary fines totaling $11,400 combined. These same facilities were later cited for violations during AC inspections. APHIS needs to reconsider its stipulation policy by assessing larger fines against research facilities with significant assets. To accomplish this, APHIS needs to seek legislative change to increase fines for these facilities.

APHIS should also calculate fines by taking into account the number of animals affected by each violation. Currently, APHIS bases fines solely on the number of violations. According to IES, most investigations involve violations that affect multiple animals. In addition, an OGC official told us that the AWA does not preclude APHIS from charging fines on a violation per animal basis. For example, if two animals are affected under one violation, APHIS could fine the facility on two counts.

Recommendation 3

Eliminate the automatic 75-percent discount when calculating fines for repeat violators or direct violations.

Agency Response. The automatic 75 percent reduction in civil penalties has been eliminated when it involves repeat violators or direct violations. The Penalty Assessment Work Group, formed in August 2004 by the AC/IES Management Teams, met in August 2005 to determine new guidelines for assessing penalties. Penalties assessed are based on such factors as history of violations, severity of violations, and willingness to work toward compliance once a violation has been noted.

[20] 2000 Consolidated Financial Statements.

OIG Position. We accept APHIS' management decision on this recommendation. For final action, APHIS needs to provide a copy of the new penalty guidelines to OCFO.

Recommendation 4

Seek legislative change to increase fines up to $10,000 for research facilities.

Agency Response. A legislative change will need to be initiated by the Secretary of Agriculture.

OIG Position. We are unable to accept APHIS' management decision on this recommendation. The agency needs to provide us with its plans, including timeframes, to draft the recommended legislation for the Secretary.

Recommendation 5

Calculate fines based on the number of animals affected per violation, when appropriate.

Agency Response. The Penalty Assessment Work Group, which met in August 2005 to review and update penalty assessments, developed new internal guidelines that IES will use to determine when calculating fines on a per animal basis.

OIG Position. We agree with APHIS' corrective action. To achieve management decision, APHIS needs to provide us with a copy of the new penalty guidelines.

Finding 3 AC Needs To Improve Its Monitoring of Research Facilities

In monitoring research facilities, some VMOs did not verify the number of animals used in medical research, adequately sample the facilities' protocols, or review other available records. This occurred because the inspection manual is too general, and the VMOs relied on the facilities to provide accurate and pertinent records. As a result, APHIS is misinformed on the number of regulated animals used in research, and has less assurance that protocols are properly completed, approved, and adhered to for the purpose of ensuring the health and safety of the animals.

Regulations[21] require research facilities to report annually "the common names and the numbers of animals upon which research, teaching, testing, or experimentation was conducted…."

In addition, AC's Research Facility Inspection Guide[22] (inspection guide) states that VMOs "are responsible for conducting a thorough inspection of IACUC-approved protocols and changes to protocols, the IACUC's monitoring of protocol activity, and the protocol approval process." VMOs may decide to review all protocols or select a representative sample. To determine if the procedures outlined in the protocols are being followed, VMOs can ask the IACUCs,[23] the self-monitoring oversight committees at each facility, how they track the number of animals approved versus the number actually used by the principal researcher. The VMOs can then verify this by reviewing computer files, acquisition and disposition records, dead animal records, and inventory cards.[24]

We accompanied 11 VMOs and their supervisors to 16 research facilities in California, Maryland, and New York. At each facility, we (1) reviewed the IACUC's activities by reading the meeting minutes, (2) observed some VMOs selecting sample protocols for inspection, (3) verified the number of animals used in research and reported by the facility, and (4) with assistance from the VMOs, reviewed some protocols to determine if the facilities provided complete explanations for using animals in the "with pain, no drugs" experiments.

We also surveyed 30 of the 65 VMOs to obtain their views about the effectiveness of the AC program and to determine if the IACUCs adequately reviewed the protocols, avoided unnecessary duplication of experimentation, conducted an adequate search for alternative methods,[25] etc. Based on these interviews and our site visits, we believe that the VMOs are highly committed to enforcing the AWA through their inspections and are making significant efforts to educate the facilities on the humane handling of animals. However, we found that some improvements are needed in two areas:

Verification of the Number of Animals Reported by Facilities

We found that 13 of 16 research facilities that we visited misreported the number of animals used in research. We selected these 16 facilities because they were cited for violations of the AWA in the past 3 years; 15 conducted research involving pain or distress to the animals without drugs for relief. Although the AWA requires research facilities to report annually the number

[21] 9 CFR 2.36 (b)(5-8), dated January 1, 2002.
[22] Dated April 2001.
[23] Institutional Animal Care and Use Committee.
[24] Research Facility Inspection Guide, Chapter 6.3, page 6, dated April 2001.
[25] Alternative methods that incorporate the replacement, reduction, or refinement of animals used in research and that minimize animal pain and distress.

of animals used in research, AC's inspection guide does not specifically require the VMOs to verify the reported numbers. As a result, APHIS is being misinformed about the actual number of regulated animals used in research. Examples are:

- A research facility in New York reported only three nonhuman primates—the number of animals purchased during that current fiscal year. During our site visit, we found that the facility's census records showed there were 42 additional nonhuman primates that underwent research at this facility. The facility agreed to resubmit an amended report.

- Another research facility in New York reported only nine rabbits in its most current annual report. However, during our site visit we saw one dog in a cage and records indicated 15 rabbits were used during the reporting period.

- A major research facility in California was unable to provide us support for the 24,000 animals it reported. Staff at the facility informed us that they compiled data on the number of animals used through an electronic survey of its researchers. However, the response rate was estimated to be from 75 to 90 percent, meaning that no one knows how many animals were actually used in research.

Although facilities are responsible for reporting the number of animals used in research, members of the IACUCs were usually responsible for compiling the number for the institution (see finding 4).

Review of Protocols and Other Records

In FY 2000, APHIS conducted a survey of its 49 VMOs to solicit their opinions on how to improve inspections of IACUCs. Ten of 49 respondents thought that VMOs should focus more on (1) comprehensively evaluating protocols involving surgery, pain, and distress and comparing them to medical and study records and (2) reviewing all of the required IACUC records.

After interviewing the VMOs and accompanying them on site visits, we noted weaknesses in related areas. Examples are:

- *Universe of Protocols.* The inspection guide allows VMOs the choice of reviewing all the protocols for regulated animals or reviewing a representative sample, such as category E protocols (those involving invasive procedures without drugs). We noted that some VMOs did not ensure that the facilities provided them with the total number of protocols (universe) from which to select their sample. These VMOs told

us that the selection process was based on "good faith" and that they relied on the facilities to provide them with accurate records.

Other VMOs were more thorough in assessing the IACUCs' protocol approval process. These VMOs reviewed all of the IACUC's written meeting minutes, which document discussions of each protocol and the basis for approving them. They also reviewed the researchers' notes and medical records to ensure that they were provided all pertinent protocols.

- *Limited Sampling of Protocols.* Two VMOs informed us that they only review protocols for animals that are present at the facility during their inspections. Because of this limited sampling, they may not uncover problems with the other protocols, such as failure to conduct an adequate search for alternatives or to document that the experiment did not duplicate previous research. Without reviewing a representative sample of protocols, it is unclear how these inspectors could assess an IACUC's protocol approval process.

- *Review of Other Records.* One of the VMOs mentioned above also did not review guinea pig disposition records that disclosed unexpected animal deaths—some due to drug overdose, others with no explanation. According to facility staff, the overdoses were caused by the miscalibration of the device used to inject a drug. By not reviewing the records, the inspector did not know there was a problem with the equipment or whether the problem was fixed.

  Regulations currently require the maintenance of acquisition and disposition records for dogs and cats; those records are not required for other regulated species. However, if records are available for the other species, we believe that inspectors should review them, at least on a sample basis, to determine if there have been any unusual animal deaths.

To ensure that inspectors verify the number of animals used in medical research, adequately sample the facilities' protocols, and review other available records, AC should revise its inspection guide. The guide should require the verification of the number of animals reported in the annual reports and emphasize the need for more detailed reviews of protocols and other available animal records. APHIS should also require the research facilities to identify annually the number of protocols under each of the pain/no pain categories in their annual reports.

Recommendation 6

Revise the Research Facility Inspection Guide to require VMOs to verify the number of animals reported in the research facilities' annual reports.

Agency Response. We agree this is important information. The appropriate sections of the RFIG will be updated by November 30, 2005. We will also revise Policy #17 to further assist research facilities in completing reports properly. The draft revision to Policy #17 will be completed by October 1, 2005.

OIG Position. We accept APHIS' management decision on this recommendation. For final action, APHIS needs to forward the revised Research Facility Inspection Guide to OCFO.

Recommendation 7

Emphasize the need to adequately sample protocols, including those where animals are not present at the facility during the inspection. Also, emphasize the need to review disposition records, if available, for regulated animals other than dogs or cats.

Agency Response. We agree with the need to do complete inspections of research facilities. The RFIG contains instructions for the VMOs to sample protocols where animals are not present and to review other available records. However, we will add additional emphasis on using the RFIG for these reviews by November 30, 2005.

OIG Position. We accept APHIS' management decision on this recommendation. For final action, APHIS needs to forward a copy of the additional emphasis to OCFO.

Recommendation 8

Require the research facilities to identify annually the number of protocols under each of the pain/no pain categories in their annual reports.

Agency Response. AC will propose a change to the regulations in order to require that research facilities include this information in their annual reports. AC has a proposed rule workplan on the annual reports, which is presently being reviewed by APHIS' Regulatory and Analysis Branch. It will be modified to include this proposed amendment. APHIS cannot predict the timing, nor the final outcome, of notice and comment rulemaking.

We agree it is important for VMOs to review a representative sample of protocols during their inspections. Currently, research facilities are required to provide a list of proposed activities to be reviewed to each Institutional Animal Care and Use Committee (IACUC) member. VMOs will use these lists as the universe from which to select sample protocols while these regulatory changes are pending. VMOs will begin using this approach by October 1, 2005.

OIG Position. We agree with APHIS' corrective action. To achieve management decision, APHIS needs to revise the Research Facility Inspection Guide to require the VMOs/inspectors to use the list of proposed activities as the universe from which to select their sample protocols, in the event the proposed regulatory changes are not incorporated in the rules.

Finding 4 Some IACUCs Are Not Effectively Monitoring Research Facilities

Some IACUCs are not effectively monitoring animal care activities, protocols, or alternative research methods. This situation exists because (1) the IACUCs are only required to conduct facility reviews on a semiannual basis, (2) IACUCs experience a high turnover rate, and (3) some members are not properly trained. In very few cases, the facilities are resistant to change, showing a general disregard for APHIS regulations. As a result, the facilities are not conducting research in compliance with the AWA or, in some cases, not providing humane conditions for research animals.

The AWA[26] requires research facilities to establish an IACUC. The committee members are generally employees of the facilities and consider their activities as collateral duties. The committees must be composed of at least a chairman, a veterinarian familiar with laboratory animal medicine,[27] and an independent member from the community. Committee members must "possess sufficient ability to assess animal care, treatment, and practices in experimental research." The committees are required to inspect at least semiannually all animal study areas and housing facilities, focusing on practices involving pain to animals and the condition of the animals.

OIG's previous audit[28] of APHIS' enforcement of the AWA found that the activities of the IACUCs did not always meet the standards of the AWA. Some IACUCs did not ensure that unnecessary or repetitive experiments would not be performed on laboratory animals. In addition, the audit found numerous problems with protocols and reporting.

To assist the IACUCs in accomplishing their responsibilities, APHIS and the National Institutes of Health issued detailed laboratory guidelines on animal care. Nonetheless, we noted some IACUCs are still having problems in such areas as adequately monitoring researchers for compliance with their protocols (e.g., the search for alternatives, review of painful procedures, and unnecessary duplication of research) and following up on the correction of deficiencies. During FYs 2002 through 2004, the number of research facilities cited for violations of the AWA has steadily increased. In FY 2002, 463 of the 1,030 facilities were in violation. In FY 2004, that number increased to 600 of 1,176 facilities.

[26] 7 U.S.C. Ch.54 §2143 (b).
[27] At smaller facilities, this individual is sometimes a contractor.
[28] Audit No. 33600-01-Ch issued in January 1995.

IACUC Monitoring of Research Facilities

In FY 2000, APHIS conducted a survey of 40 VMOs and their 9 supervisors to assess their opinions on the effectiveness of the IACUCs. In general, VMOs concurred that IACUCs need to improve the search for alternatives, the review of painful procedures, and monitoring the researchers' use of animals to ensure compliance with approved protocols and standard operating procedures. 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."

In FY 2004, we re-surveyed 30 VMOs and their supervisors to determine if the IACUCs improved their performance. Although most VMOs believed that the IACUCs improved in certain areas, VMOs still found a total of 6,801 violations at these facilities from FYs 2002-2004. The VMOs believe there are still problems with the search for alternatives, veterinary care, review of painful procedures, and the researchers' use of animals. Using AC's database, we compiled and analyzed the data for all inspections conducted at research facilities from FYs 2002-2004. Table 2 shows the most frequent violations cited by the VMOs.

Table 2: The Most Frequent Violations at Research Facilities – FYs 2002-2004

Regulation Violated by Research Facility	No. of Violators (A)	No. of Violations (B)	% Facilities With Violations (A)/1,100*
Search for Alternatives. Researchers considered alternatives to painful procedures and documented the availability of the alternatives (9 CFR 2.31(d)(1)(ii)).	322	391	29%
Reporting. IACUC submitted reports of its evaluations of animal facilities to the institutional official (9 CFR 2.31(c)(3)).	281	329	26%
Veterinary Care. Research facility maintained adequate veterinary care that includes appropriate methods and availability (9 CFR 2.33(b)(2)).	202	277	18%
Protocols. Protocols contained a complete description of the proposed use of animals (9 CFR 2.31(e)(3)).	188	256	17%
Housekeeping. Research facilities met standards of care regarding housekeeping for rabbits (9 CFR 3.56(c)).	102	157	9%
* The average number of research facilities during FYs 2002-2004 was 1,100.			

We reviewed AC files for 58 research facilities; some of the violations we noted were:

- An IACUC in California approved a protocol for the production of antibodies using approximately 80 rabbits. Instead, 1,024 rabbits were used under this protocol. IES is currently investigating this case.

- Another research facility in California failed to give a post-surgical nonhuman primate analgesic to relieve unnecessary discomfort and pain after a craniotomy in which four burr holes were made into the cranium. It also failed to provide post-surgery veterinary care.

  At the same facility, a post-surgical lamb was observed to have difficulty breathing and was frothing from the mouth. The lamb was not monitored until an AC inspection identified it to be in distress. A second post-surgical lamb was found dead. This facility was referred to OGC for legal action.

- A research facility in Illinois failed to provide adequate veterinary care, which resulted in the death of a primate and a pig. The IACUC also failed to approve protocols or to review significant changes to protocols. The fine was $9,400.

- At a research facility in Indiana, AC inspectors found proof that a summer intern was improperly trained to perform operations on animals. Evidence indicated that the trainer left the area during another intern's first surgery. The fine was $4,000.

According to our analysis, 33 of the top 50 (66 percent) research facility violators in the nation were educational institutions suggesting that IACUCs at universities are less effective (see exhibit C). The VMOs explained that universities usually have more protocols, the protocols are more varied, and students are less experienced in good laboratory practices. Even though the top 50 facilities were cited for numerous violations over a 3-year period, records indicate that only nine were referred to IES for investigation.

In FY 2003, AC received a petition from the Association of Veterinarians for Animal Rights, which cited frequent violations concerning the search for alternatives. AC responded to the petition by conducting inspections at all veterinary schools in the nation. The inspections focused on teaching protocols and cited numerous violations in the search for alternatives, unnecessary duplication of research, and justification for the number of animals used.

We also learned that in a very few cases, the facilities were resistant to change, showing a general disregard for APHIS regulations. VMOs

informed us that some institutional officials were not supportive of IACUC activities and APHIS regulations, resulting in significant issues with animal care at the facilities. In one example, the research facility ignored the VMO's reports of violations and did not take corrective action for several years. In cases of negligence of fiduciary duty, APHIS should seek an OGC opinion to determine if institutional officials can be held personally liable.

Inaccuracies in Annual Reports

We also found that the majority of research facilities we reviewed misreported the numbers of animals used in research. Some facilities did not follow APHIS guidelines for completing their annual reports, while other facilities are not using the numbers of animals supported by their records. As a result, APHIS is misinformed about the true number of animals used annually in research facilities throughout the nation (as noted in finding 3).

Regulations[29] state, "The annual report shall state the common names and the numbers of animals upon which teaching, research, experiments or tests were conducted…" AC Policy[30] as well as the instructions attached to the template annual report state that animals used in multi-year studies will be counted once each year.

We visited 16 registered research facilities that were cited for violations in the past 3 years.[31] After comparing the most current annual report submitted by each facility to the supporting documents on hand, we found that 13 of the 16 research facilities misreported the numbers of animals used in their research. Of these facilities, nine had underreported, three had overreported, and we could not determine the actual number of animals used in the remaining facility. Some facilities agreed to resubmit an amended annual report.

Although research facilities must be registered, APHIS has no authority to revoke the registration of a noncompliant research facility. Even administrative law judges may find it difficult to terminate or refuse to renew registrations in cases where serious or repeat violations occur because USDA does not have the authority to interrupt the conduct of research.

We concluded that IACUCs need to improve their monitoring of researchers for compliance with the protocols (e.g., the search for alternatives, review of painful procedures, unnecessary duplication of research), in following up on the correction of deficiencies, veterinary care, and in reporting accurate annual reports to APHIS. This is imperative because although AC can temporarily revoke licenses for breeders and exhibitors, this is not the case

[29] 9 CFR 2.36 (b) (5-8), dated January 1, 2002.
[30] Animal Care Policy 17, dated March 17, 1999.
[31] Fifteen facilities conducted research involving pain or distress to animals without the use of drugs for relief.

with research facilities. The AWA[32] does not authorize "the Secretary, during inspection, to interrupt the conduct of actual research or experimentation…" Therefore, it is more critical for AC to take enforcement actions against research facilities that violate the AWA (refer to finding 1).

Recommendation 9

Modify regulations to require the IACUCs at research facilities identified as repeat violators (those with 3 or more consecutive years with violations) to conduct more frequent reviews.

Agency Response. Facilities with 3 or more consecutive years with violations will necessarily be subject to more frequent inspections, which is currently AC's standard procedure. AC Risk-Based Inspection System (RBIS) will flag all such facilities and ensure that they are inspected more frequently and to provide more support for enforcement.

OIG Position. We accept APHIS' management decision on this recommendation. No final action is needed. Although we recommended that IACUCs identified as repeat violators conduct more frequent reviews, this may not improve compliance given that the current IACUC reviews are ineffective. However, with APHIS' limited resources, it is paramount that the IACUCs' self-monitoring function operates as intended, enabling AC's VMOs to broaden their coverage of other entities such as breeders and exhibitors.

Recommendation 10

Require IACUCs to implement policies that fully train committee members on protocol review, facility inspections, and the AWA.

Agency Response. We agree that educating the IACUCs is an important component of the self-monitoring system. This may also assist with Recommendation #9. AC will modify Policy #15 to indicate it is our interpretation that this regulation also applies to IACUC members. The draft will be done by October 1, 2005.

OIG Position. We are unable to accept APHIS' management decision on this recommendation. The agency needs to clarify which regulation it is referring to, and it needs to provide us with a copy of the modified Policy #15.

[32] 7 U.S.C. 2143(a)(6)(A)(iii), dated March 25, 2004.

Recommendation 11

Instruct research facilities to ensure that the numbers of animals reported in the annual report are accurate.

Agency Response. As noted in our reply to Recommendation #6, we agree this is important information. The RFIG will be amended to instruct inspectors to verify the accuracy of the numbers of animals reported. The Manual Team will be responsible for updating the Research Facility Inspection Guides and inserting the three clarifications listed in the response to Recommendations 6, 7, 8, and 11. The Guide can be updated, printed, and distributed by May 1, 2006. In the interim, the Animal Care Management Team will distribute an instruction memo to the VMOs with the clarifications they need to use immediately. Policy #17 will be amended to further assist research facilities in this endeavor.

OIG Position. We agree with APHIS' corrective action. To achieve management decision, APHIS needs to provide us with a copy of the revised Policy #17.

Recommendation 12

Seek an OGC opinion to determine if institutional officials can be held personally liable in cases of negligence of fiduciary duty.

Agency Response. The following verbatim response was obtained from the Office of General Counsel on September 6, 2005:

"Under section 2139 of the Animal Welfare Act (AWA), 'the act, omission, or failure of any person acting for or employed by a research facility…within the scope of his employment or office, shall be deemed the act, omission, or failure of such research facility,…as well as of such person.' Section 2139 applies to alleged violations of the AWA or regulations by any person that is engaging in AWA regulated activities. Under the AWA, APHIS only has jurisdiction over persons who are engaging in regulated activities as dealers, research facilities, exhibitors, carriers, and intermediate handlers. Employees of dealers, research facilities, exhibitors, carriers, and intermediate handlers are not liable for any violations committed by their employers, unless the employee is also engaging in AWA regulated activities. Accordingly, section 2139 does not apply to institutional officials who oversee regulated activities of a research facility, but are not engaged in AWA regulated activities themselves. In cases where an institutional official is charged by the research facility with oversight of regulated activities and does not fulfill that duty adequately, the research facility, and not the individual, is responsible for any violations of the AWA or the regulations that may occur."

OIG Position. We accept APHIS' management decision on this recommendation. For final action, APHIS needs to forward the OGC opinion to OCFO.

Finding 5 Information From LARIS Is Not Always Accurate

AC's Licensing and Registration Information System (LARIS) lacks certain key features that prevent it from effectively tracking violations and prioritizing inspection activities. According to the former Assistant Deputy Administrator, who was responsible for the implementation of LARIS, the system was never fully tested when it was first implemented in 1994 and it has not undergone continued computer maintenance. As a result, the system generates unreliable and inaccurate information, limiting its usefulness to AC inspectors and supervisors.

Departmental Manual 3200-001[33] states that, "agencies will…provide for maintenance in the operation phase [of an application system]" which includes running, changing, or repairing the system as necessary to ensure that the system still meets user and security requirements.

APHIS acknowledges LARIS as one of its mission-critical systems and has continued to use and support the system for the past 10 years; however, OIG's 1995 audit of APHIS' enforcement of the AWA found that information contained in LARIS was generally unreliable and inaccurate. LARIS did not effectively track violations and prioritize inspections. It also did not correctly show the extent of the violations disclosed by the inspections.

LARIS is a database used by AC personnel to record licensing and registration of all breeders, exhibitors, and other facilities and to document their inspection and violation histories. A subsystem of LARIS, the Risk-Based Inspection System (RBIS), calculates the minimum number of inspections that are needed annually based on a continual risk assessment of each facility's violation history. After reviewing several reports, we determined that LARIS does not always track inspections correctly and contains inaccurate data.

- *Misclassifies Attempted Inspections.*[34] RBIS erroneously treats "attempted" inspections as "completed" inspections. To compensate for this, most inspectors use their own *ad hoc* systems (e.g., spreadsheets, notes, calendars) to track inspections.

- *Unable to Track Re-inspections.* RBIS does not track the dates for upcoming "re-inspections," the required inspections that follow-up on

[33] "Management Application Systems Life Cycle Management," Chapters 2.4(A) and 2.6(C)(2), dated March 3, 1988.
[34] An attempted inspection occurs when an authorized person from the facility is not available to accompany the inspector and no inspection is conducted.

the facilities' corrective action for direct violations. Again, inspectors use their *ad hoc* systems to schedule re-inspections, which may not always be a fail-proof alternative.

AC's guidelines[35] state, "a complete or partial re-inspection of a facility with a direct [violation] **must** be completed no more than 45 days after the correction date." For FYs 2003 and 2004, we identified 43 inspection reports that cited direct violations and found that 13 re-inspections were not conducted within the required 45-day re-inspection period.[36]

- *Missing Edit Checks*. LARIS does not have basic edit checks—parameters programmed into the system so that it does not accept illogical data. For example, the system lacks the ability to screen out meaningless dates in its inspection reports. Figure 5, which is a facsimile of a LARIS report, highlights this problem (note the dates of the inspections).

Figure 5: LARIS – Missing Edit Checks

INSPECTION FREQUENCY by NEXT INSPECTION DATE
01-NOV-2004

Site	Last Inspection	Type of Inspection	Next Inspection	Inspection Frequency
X	30-MAY-2030	ROUTINE	30-MAY-2031	One Time Per Year
X	18-AUG-2994	ROUTINE	18-AUG-2995	Two Times Per Year

- *Outdated Information*. Two facilities that had cancelled their licenses and were no longer listed on LARIS' Current Licensees Report in June 2004 still appeared on the Inspection Frequency Report 5 months later. Figure 6 is a facsimile of the Inspection Frequency Report dated November 2004, which shows the former licensees as requiring inspections.

Figure 6: LARIS – Outdated Information

INSPECTION FREQUENCY by NEXT INSPECTION DATE
14-NOV-2004

Site	Last Inspection	Type of Inspection	Next Inspection	Inspection Frequency
X	13-FEB-2001	ROUTINE	13-FEB-2004	One Time Per 3 Years
X	31-JUL-2003	ROUTINE	31-JUL-2004	One Time Per Year

[35] Research Facility Inspection Guide, Chapter 7.6, page 1, dated April 2001.
[36] Although 11 of these re-inspections were eventually conducted, we could find no evidence that the remaining 2 were conducted.

- *Discrepancies Between LARIS Reports*. When the VMOs and inspectors conduct site visits, they prepare inspection reports and enter them directly into LARIS. However, the number of violations recorded in the inspection reports does not always match the information listed in LARIS' Violation History Report, which should summarize all violations. For example, one facility was cited for 11 AWA code violations in the inspection report, while 88 violations were recorded in the history report. AC was unable to provide us with a definitive explanation for the difference.

We interviewed 30 of the 65 VMOs[37] to determine if the LARIS and RBIS systems served their needs in performing their duties. Of these, 29 VMOs expressed dissatisfaction with the systems. VMOs commented that the systems are slow, cumbersome, and not user friendly and that the information is inaccurate. In response, AC's computer specialist explained that "some of the 'bugs' [in LARIS] are technical, and some are just code that is not working as intended."

We learned that AC contracted a computer programmer and formed a task force of inspectors and staff to create a new database by September 2005. In addition to addressing the flaws we identified with LARIS, plans for the new system include being more user friendly when querying inspection reports, correcting inaccurate data in reports, improving the users' ability to retrieve information, and complying with the electronic Freedom of Information Act requirements. However, to avoid the problems we identified with LARIS, AC needs to ensure that the new system is properly tested and maintained.

Recommendation 13

Implement temporary measures to address attempted inspections and re-inspections until the new system is operational.

Agency Response. We understand the basis for this recommendation and agree with its intent; however, the new system, OACIS (On-line Animal Care Information System) is scheduled to be operational in March 2006. We do not believe the implementation of temporary measures that would take some weeks to develop and implement and would then be in place for 6 months or less is either cost effective or an efficient use of scarce resources.

OIG Position. We are unable to accept APHIS' management decision on this recommendation. Although many inspectors may be aware of LARIS' limitation in tracking re-inspections and attempted inspections, there may be others (especially new inspectors) who are not aware of the limitation. The agency should send a memorandum or e-mail to its VMOs/inspectors,

[37] The 65 VMOs include AC supervisors from both regions.

warning them of the limitation of LARIS in tracking re-inspections and attempted inspections.

Recommendation 14

Ensure that the new system is adequately tested, and that system users are able to provide feedback during development.

Agency Response. In late 2004, AC formed the OACIS integrated team, which consists of field inspectors, supervisors, AC IT support, and management personnel. Team members met in December 2004 to define and develop users' requirement for the OACIS project. They provided user input to the OACIS development contractors regarding what was needed in the new system. The system requirement was completed in February 2005 and it was reviewed and validated by the team. The system will consist of several modules. Each module will be developed and tested for functionalities according to the specifications defined in the user's requirement. The contractor will test the functional requirement of each program unit within each module as well as the integrated components for all modules for the system. The OACIS integrated team will be involved in testing similar functionalities to validate the contractor deliverables as soon as the test module(s) becomes available to ensure the user's requirement is met. Final module(s) acceptance will be based on the user testing. The project is expected to be completed by March 2006.

OIG Position. We accept APHIS' management decision on this recommendation. For final action, APHIS needs to forward documentation that the new system was adequately tested to OCFO.

Recommendation 15

Provide a plan for performing system maintenance on the new system.

Agency Response. AC included a request in the fiscal year 2006 budget to have the contractors developing OACIS also to provide this service, until a new employee is hired to maintain it in-house.

OIG Position. We accept APHIS' management decision on this recommendation. For final action, APHIS needs to forward AC's request in the FY 2006 budget regarding maintenance on the new system to OCFO.

There are two types of monetary assessments for violators of the AWA—the stipulated fine and the court-ordered penalty. IES may issue a stipulation, depending on the nature of the violation. More serious cases are sent to an administrative law judge who can suspend or revoke the violator's USDA license and impose a court-ordered penalty.

During our review, the IES National Office was responsible for collecting stipulated fines. If the payments became past due, IES forwarded the fines to APHIS' Financial Management Division (FMD) in Minneapolis, which has agency-wide debt collection responsibilities. FMD also collects court-ordered penalties.

We found that IES and FMD did not follow internal controls when processing and collecting fines and penalties. Penalties that are intended to deter violations of the AWA become less effective unless APHIS correctly processes and promptly collects fines.

Finding 6 IES Did Not Follow Internal Control Procedures for Cash Collections

The IES National Office did not implement several basic controls over its cash collections, which totaled $1.8 million[38] during FYs 2003 and 2004. The Deputy Director was unfamiliar with the requirements of APHIS' Accounting and Budget Manual (Manual) and, therefore, failed to implement certain internal controls. As a result, collections were not deposited timely, increasing their risk of being lost or stolen.

In addition to its investigative responsibilities, the IES National Office collected stipulated fines for all APHIS programs. Initially, we reviewed cash collections and deposits for the AC program for FYs 2003 and 2004. After we noted some problems with internal controls, we expanded our review to include IES collections for all APHIS programs to determine if the problems were systemic. We found the following:

- IES Did Not Log Collections Upon Receipt. Although the collection clerk opened the mail and made deposits, she did not maintain collection logs. A complete accounting of all collections cannot be assured without proper controls.

[38] This amount consists of fines from all APHIS programs as of July 2004.

The manual[39] states, "A log of collections and deposits should be maintained at each office and should include a sequential number; the name and address of the payee; the purpose, amount and date of the collection; the check or money order number; information to cross-reference the collection…and the date the collection was transmitted to the lockbox."

- *IES Did Not Reconcile Collections*. Since IES did not maintain a collection log, it could not reconcile collections to deposits. Reconciliations are needed to ensure that no collections were lost or omitted prior to deposit.

  The manual[40] states, "A third employee, preferably an office manager should daily reconcile collections to amounts transmitted and initial the log indicating no deviations."

- *IES Did Not Promptly Deposit Collections.* IES accumulated stipulated fines and deposited them at intervals ranging from once a week to as long as 6 weeks. On average, checks were held about 16 to 20 days. Even though the collection clerk stated that she deposited checks two to three times a week, we could find no evidence to support her claim. When collections are not deposited promptly, the potential for loss, misplacement, or misuse is increased.

  The manual[41] states, "Employees must deposit collections or transmit collection for deposit within 24 hours, if practical, but no later than the second workday from the date of receiving the collection."

- *IES Had No Separation of Duties Over Cash Collections.* The collection clerk responsible for receiving and recording collections also prepared and mailed all deposits. A basic principle of internal controls is dividing critical functions between two or more persons, a technique often referred to as separation of duties. Errors are more likely to be detected when duties are separated, and fraud is less likely to occur when its success depends upon collusion.

  The manual[42] states, "A separate employee should enter the collections into the accounting system and transmit the collections."

We discussed these internal control weaknesses with the IES Director and Deputy Director. The Deputy Director explained that she was unaware of the separation of duties for cash collections as well as other requirements in the

[39] Chapter 10, page 46, dated October 1, 2002.
[40] Chapter 10, page 46, dated October 1, 2002.
[41] Chapter 10, page 44, dated October 1, 2002.
[42] Chapter 10, page 46, dated October 1, 2002.

manual. The IES Director told us he plans to transfer the collection function to FMD, which has agency-wide debt collection responsibilities.

Recommendation 16

Instruct IES to provide a plan and timeframe for transferring collections to FMD.

Agency Response. Beginning in October 2004, IES transferred the collection activity for APHIS issued civil penalty stipulations to FMD. IES' stipulation letter to the alleged violator requests that he or she send payment directly to the APHIS Lockbox in St. Louis, Missouri. FMD processes the payments and updates the IES case management tracking system with the collection data.

OIG Position. We accept APHIS' management decision on this recommendation. For final action, APHIS needs to forward to OCFO a sample copy of IES' stipulation letter showing that payments are now sent to the APHIS lockbox in St. Louis, Missouri.

Recommendation 17

Until collections are delegated to FMD, instruct IES to implement internal controls over its cash collections in accordance with APHIS' Budget and Accounting Manual.

Agency Response. Beginning in October 2004, IES instituted a number of internal controls to ensure integrity in the civil penalty collection process. While over 90 percent of the civil penalty payments go directly to FMD, IES still receives a small number of checks for civil penalties assessed at the ports of entry and mailed in after the traveler has left the port, as well as checks received by the Office of General Counsel for cases resolved by the USDA administrative law judges. IES has instituted controls in accordance with the APHIS Budget and Accounting Manual.

OIG Position. We accept APHIS' management decision on this recommendation. For final action, APHIS needs to provide a copy of IES' new internal controls to OCFO.

Finding 7 IES and FMD Delayed Processing Court Orders for AC

The IES National Office held court-ordered penalties on average 3 months in FY 2003 and 7½ months in FY 2004 before sending them to FMD for collection. FMD also compounded the delays by not establishing the receivables timely. This occurred because IES and FMD did not prioritize the activity. As a result, court-ordered fines were delayed in accruing interest, and penalty assessments were more difficult to collect due to the age of the receivables.

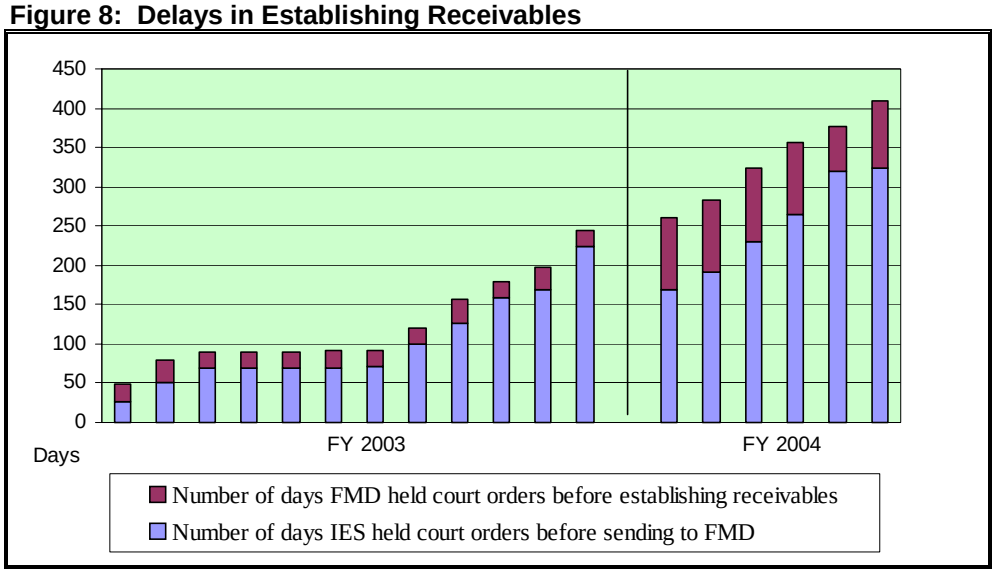
APHIS' Budget and Accounting Manual[43] defines the key factors necessary to successfully manage debts owed to APHIS: "(1) promptly record, in a centralized book (system) of record, all amounts due to us after we have performed services or provided goods; (2) quickly collect all the money due to us; (3) follow up quickly, forcefully, and persistently when debts become delinquent."

Before FMD can legally establish a receivable against a violator, it must receive a court order. We reviewed FMD's process for establishing receivables and found that IES accumulated court orders before sending them to FMD in batches once or twice a year. In FY 2003, the average time was 3 months from when a court order was issued to when it was received by FMD. In FY 2004, the average time was about 7½ months. When we questioned IES about these significant delays, the IES Deputy Director told us she was unaware that the court orders were not sent to FMD on a monthly basis. Although IES did not have a specific policy about timeliness in forwarding court orders, management had an unofficial policy to deliver the files on a monthly basis.

Once the court orders were received from IES, FMD took an additional 3 months to establish receivables. FMD management did not prioritize the timely establishment of receivables, and the debt management specialist responsible for establishing receivables was assigned to work on other tasks. Figure 8 shows the delays in establishing receivables. The average time to establish a receivable for FYs 2003 and 2004 was about 123 days and 335 days, respectively.

[43] Chapter 12, page 1, dated October 1, 2002.

Figure 8: Delays in Establishing Receivables



Penalties are intended to deter unlawful practices of the AWA. If APHIS takes up to 10 months to process court-ordered penalties, the probability of collection is reduced and the penalties become less effective. To prevent this, APHIS needs to streamline the process for establishing receivables.

Recommendation 18

Implement a plan that would expedite the process for establishing receivables of court-ordered fines.

Agency Response. As of December 2004, IES instituted procedures to expedite the processing of Administrative Law Judge (ALJ) orders to FMD for processing as follows:

IES sends all ALJ orders (Consent Decisions, Decision and Orders) to FMD every Friday. A cover sheet is attached to each docket showing: docket number, case number, violator, civil penalty, person sending, phone number, and date. This specifies the amount to be collected and alleviates the need for FMD to interpret the court order. A copy of the order and cover sheet are filed with the case. IES maintains a spreadsheet with the information from the cover sheet as well as a copy of the cover sheet for tracking purposes.

OIG Position. We accept APHIS' management decision on this recommendation. For final action, APHIS needs to provide its new procedures to OCFO.

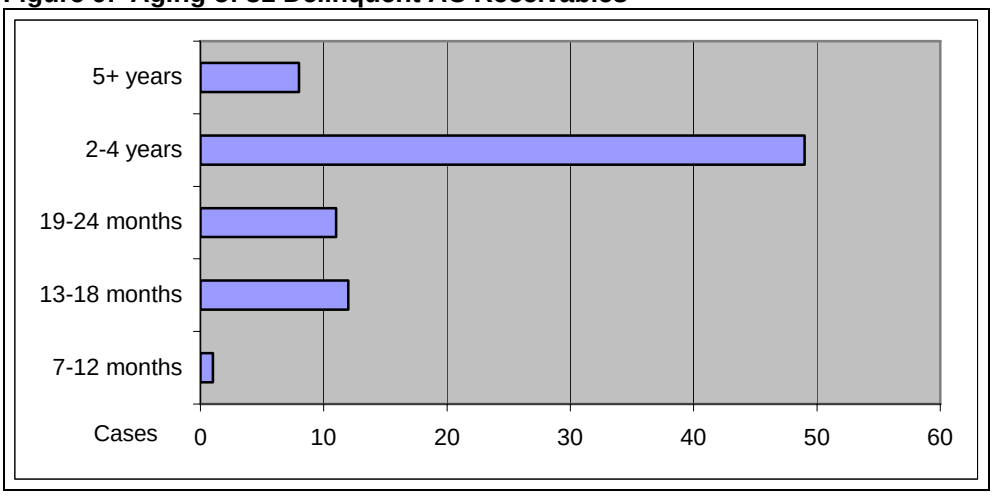
Finding 8 FMD Did Not Transfer Delinquent Receivables for Collection

FMD did not transfer 81 of 121 delinquent AC receivables totaling $398,354 to the U.S. Department of Treasury for collection. This occurred because FMD officials did not consider the collection of receivables to be a priority. As a result, FMD may be forced to write off some receivables, and it will become increasingly difficult to collect the others unless immediate action is taken.

The Debt Collection Improvement Act of 1996 requires agencies, "to transfer a debt or claim that has been delinquent 180 days or more to Treasury for collection."

We reviewed all outstanding receivables[44] and found that FMD did not transfer 81 delinquent receivables—most between 2 and 5 years old—to Treasury for collection (see figure 9 for an aging summary). We learned that FMD planned to write off two receivables totaling $14,192 because they were nearly 10 years old. The probability of collecting the remaining balance of $384,162 ($398,354 less $14,192) is significantly reduced as the receivables age.

Figure 9: Aging of 81 Delinquent AC Receivables



The debt collection manager stated that in FYs 2001 and 2002, FMD's focus was implementing a new accounting information system, the Foundation Financial Information System. While this reason may explain the delays for FYs 2001 and 2002, it does not explain the 57 cases that were 3 to 10 years delinquent before FFIS was implemented.

[44] This includes all outstanding receivables as of June 3, 2004.

In addition, FMD management told us that it did not have access to pertinent information such as the violators' tax identification numbers, which are needed in order to transfer the delinquent receivables. However, the LARIS database contains tax identification numbers for licensees and registrants, and FMD should have been able to obtain this information from AC.

Recommendation 19

Establish a timeframe to transfer the $398,354 in receivables over 180 days to Treasury for collection.

Agency Response. FMD was not required to transfer 14 of the 81 delinquent AC receivables totaling $134,192.82 to Treasury for collection. The remaining 67 receivables, totaling $264,161.18, have been reviewed and appropriate steps have been taken including referring debts to Treasury Cross Servicing (CS), writing off the debts, or collections on payment plans with many leading to debts paid in full.

Debts that had been previously referred to Treasury Offset Program (TOP) have been forwarded to CS and will be removed from TOP as soon as CS submits the debt to TOP.

OIG Position. We agree with APHIS' corrective action. To achieve management decision, the agency needs to provide us with a list of the 14 receivables and explain the reasons why it did not transfer them to Treasury.

Recommendation 20

Establish a formal system to share pertinent information such as tax identification numbers between AC and APHIS' debt collection unit.

Agency Response. FMD has developed a process for obtaining tax identification numbers for stipulations and dockets, which are received without this information from IES. Modifications have been made to the IES tracking system to allow FMD more access to violator data including the tax identification numbers. An IES staff member has been designated as a contact person to assist FMD with questions on documents received and its tracking system. FMD also extended its research abilities by using Choicepoint AutotrackXP data beginning in May 2005 to research tax identification numbers.

OIG Position. We accept APHIS' management decision on this recommendation. For final action, APHIS needs to provide a copy of its new procedure to OCFO.

Scope and Methodology

We conducted a nationwide review of AC's inspection activities and enforcement of the AWA during FYs 2003 through 2004. We expanded our scope to include FY 2002 data because we wanted to further evaluate the pattern of enforcement between the AC regions. As part of our audit, we reviewed the pertinent laws and regulations governing the AC program and the current policies and procedures AC had established as guidance for inspections and enforcement.

We performed fieldwork at the AC and IES National Offices in Riverdale, Maryland; the AC and IES regional offices in Fort Collins, Colorado, and Raleigh, North Carolina; the FMD Financial Services Branch located in Minneapolis, Minnesota; and a total of 16 research facilities in California, Maryland, and New York (see exhibit B for a complete listing of audit sites). We performed audit fieldwork from May 2004 through January 2005.

We used Audit Command Language (ACL) software to select our samples and to analyze research facility violations. Using ACL and data imported from the LARIS database, we determined the States with the most research facilities, research facilities with the largest number of violations cited during our scope period for each region, and the most common types of violations at research facilities.

To accomplish our audit, we:

- *Interviewed AC Personnel*. We interviewed AC National Office officials and 30[45] of 65 VMOs (15 from each region) to obtain information about the AC program and IACUCs.

- *Reviewed AC Inspection Reports and Files*. At each AC regional office, we judgmentally reviewed files of research facilities that were cited for the largest number of violations, as of the date of fieldwork. We sampled inspection reports for 28 facilities in the Western Region and 30 facilities in the Eastern Region to determine if annual inspections and re-inspections were conducted timely.

- *Reviewed Enforcement Actions*. At IES' National Office, we obtained the final action data for all AC investigations closed from FYs 2002-2004.

[45] We intended to interview all 49 VMOs and their supervisors who participated in AC's 2000 survey regarding the effectiveness of the IACUCs; however, only 30 of the 49 VMOs still worked in the same capacity.

In the Eastern Region, the data identified 809 individuals with completed or closed investigations. Of these, IES determined that 475 violated the AWA, which required the region to decide whether to take enforcement action. AC declined to take action against 126. At IES, we reviewed 45 of these to determine the Eastern Region's reasons for closing the cases without taking enforcement action.[46]

In the Western Region, the data identified 572 individuals with completed or closed investigations. Of these, IES determined that 439 violated the AWA, which required the region to decide whether to take enforcement action. AC declined to take action against 18.

- *Reviewed Files for Discounts Offered by AC.* Also at IES, we reviewed the files for 76 of 181 registrants and licensees that agreed to pay stipulated fines to determine the amount of the discounts offered by AC. We then used ACL to identify violations or repeat violations subsequent to the issuance of the stipulation.

- *Visited 16 Research Facilities*. The States of California and New York have the most registered research facilities in the Nation.[47] For these States, we judgmentally selected research facilities that were cited for violations during each FY between 2002 and 2004, and that conducted research "with pain, no drugs for relief." In addition, we selected one facility in Maryland due to its proximity to the APHIS National Office and because it had been a repeat violator of the AWA. We visited these facilities to assess the IACUCs' protocol processes and to validate the number of animals reported on their most current annual report.

- *Analyzed Reports From LARIS*. During our initial fieldwork, we learned that AC was developing a new database to replace LARIS. Because of this, we limited our review of LARIS to issues that came to our attention through interviews with AC employees and through our own review of the LARIS reports that we obtained from the AC's National and regional offices.

- *Reviewed the Cash Collection Process for Fines Levied Against Violators*. We reviewed internal controls at both IES and FMD, which collect court penalties and stipulated fines. At IES, we reviewed all deposit logs for AC-related collections. Because IES did not have adequate internal controls in place, we expanded our scope to include cash deposits for Plant Protection and Quarantine and Veterinary Services to determine the impact of the problem. Also at IES, we reviewed files for all 18 court decisions and orders requiring collections

[46] We were only able to review 20 IES investigation files and 25 correspondence records because of its 1-year file retention policy. Only files that were investigated and declined with no action in FY 2004 were available.
[47] For FY 2002-2004, the number of active research facilities averaged 1,100.

to determine when they were forwarded to FMD. We selected all available decisions and orders for which penalties had been issued.

At FMD, we initially reviewed outstanding AC receivables over $10,000 for FYs 2003-2004. However, because FMD did not comply with the Debt Collection Act of 1996, we expanded our scope to include all outstanding receivables for AC fines.

This audit was conducted in accordance with generally accepted government auditing standards.

Exhibit A – Summary of Monetary Results

FINDING NUMBER	RECOMMENDATION NUMBER	DESCRIPTION	AMOUNT	CATEGORY
1	1	AC declined to take enforcement action against violators after IES had conducted an investigation.	$291,000	FTBPTBU-Management or Operating Improvement/Savings
8	19	FMD did not transfer delinquent AC receivables to Treasury for collection.	$398,354	FTBPTBU-Management or Operating Improvement/Savings
TOTAL MONETARY RESULTS			**$ 689,354**	

Exhibit B – Sites Visited

ORGANIZATION	LOCATION
APHIS National Offices	
Animal Care	Riverdale, MD
Investigative and Enforcement Services	Riverdale, MD
APHIS Western Regional Office	
Animal Care	Fort Collins, CO
Investigative and Enforcement Services	Fort Collins, CO
Research Facility No. 670	Palo Alto, CA
Research Facility No. 193	La Jolla, CA
Research Facility No. 303	Menlo Park, CA
Research Facility No. 677	Sunnyvale, CA
Research Facility No. 691	San Diego, CA
Research Facility No. 699	San Diego, CA
Research Facility No. 898	Pomona, CA
Research Facility No. 110	Davis, CA
Research Facility No. 71	San Francisco, CA
APHIS Eastern Regional Office	
Animal Care	Raleigh, NC
Investigative and Enforcement Services	Raleigh, NC
Research Facility No. 47	Baltimore, MD
Research Facility No. 208	Brooklyn, NY
Research Facility No. 255	New York, NY
Research Facility No. 142	Staten Island, NY
Research Facility No. 245	Buffalo, NY
Research Facility No. 88	Brooklyn, NY
Research Facility No. 318	Albany, NY
APHIS Financial Management Division	Minneapolis, MN

Exhibit C – Research Facilities – Top 50 Violators

Research Facility No.[48]	Violations in FY			Total Violations[49]	State	Region
	2002	2003	2004			
1	80	88	88	256	RI	ER
2	75	145	20	240+	IL	ER
3	105	88	24	217+	FL	ER
4*	36	44	93	173	MA	ER
5	72	63	36	171	TN	ER
6	0	57	42	99	NY	ER
7	17	25	48	90+	MA	ER
8*	5	64	11	80+	MO	WR
9	16	40	12	68	MA	ER
10	14	12	30	56	CT	ER
11*	18	30	6	54	MA	ER
12	11	23	20	54	PA	ER
13*	8	20	16	44	MA	ER
14*	7	18	19	44	MA	ER
15	2	12	29	43	GA	ER
16*	9	18	15	42	PA	ER
17	6	17	18	41	OK	WR
18	4	18	17	39	MA	ER
19*	0	21	18	39	PA	ER
20	12	15	9	36	PA	ER
21*	4	25	6	35	CA	WR
22*	8	16	10	34	GA	ER
23	5	11	17	33	WI	ER
24	11	10	12	33	PR	ER
25	18	11	3	32	CA	WR
26	4	10	18	32+	MA	ER
27	16	4	11	31	WY	WR
28	18	3	9	30+	CT	ER
29	3	3	23	29+	NY	ER
30	6	16	7	29+	PA	ER

[48] This information, obtained from LARIS, identifies the facilities with the highest number of violations for the 3-year period; it may not necessarily reflect those facilities with the most direct violations. All facilities are universities except those noted with asterisks.
[49] Only 9 of the top 50 (indicated with a "+" sign) were referred to IES.

Exhibit C – Research Facilities – Top 50 Violators

Research Facility No.	Violations in FY			Total Violations	State	Region
	2002	2003	2004			
31*	2	6	20	28	CT	ER
32	5	8	15	28	PA	ER
33*	2	14	10	26	MA	ER
34*	17	4	5	26	CT	ER
35	3	12	11	26	IL	ER
36	4	18	3	25	MA	ER
37	5	5	15	25	CT	ER
38*	8	11	6	25	PA	ER
39*	6	8	10	24	MA	ER
40	14	7	3	24	MA	ER
41	4	7	13	24	CT	ER
42	7	10	7	24	GA	ER
43*	3	9	11	23+	NY	ER
44*	3	6	14	23	CA	WR
45	6	9	7	22	NJ	ER
46	6	11	5	22	PA	ER
47	10	11	1	22	MD	ER
48*	19	1	1	21	ME	ER
49	5	9	7	21	MA	ER
50	4	14	3	21	RI	ER

Exhibit D – Stipulation Worksheet

ANIMAL CARE PENALTY WORKSHEET

If the violator has:	And the Business assets are:	And the level of violation is:	The fine for one count is:	Times the number of counts:	The total is:
No previous history	Less than $25,000	Minor	$110x___		
		Moderate	$275x___		
		Serious	$1100x__		
	$25,000 - $100,000	Minor	$275x___		
		Moderate	$550x___		
		Serious	$1650- 2750x___		
	More than $100,000	Minor	$275x___		
		Moderate	$825x___		
		Serious	$1650-2750x___		
Previous history of a Stipulation or multiple APHIS 7060s in last five years	Less than $25,000	Minor	$275x___		
		Moderate	$550x___		
		Serious	$1650-2750x___		
	$25,000 - $100,000	Minor	$275x___		
		Moderate	$825x___		
		Serious	$1650-2750x___		
	More than $100,000	Minor	$550x___		
		Moderate	$1100x__		
		Serious	$2750x__		
Previous history of a Consent Decision or Decision and Order in last five years	Less than $25,000	Minor	$275x___		
		Moderate	$1100x__		
		Serious	$1650x__		
	$25,000 - $100,000	Minor	$550x___		
		Moderate	$1650x__		
		Serious	$2750x__		
	More than $100,000	Minor	$550x___		
		Moderate	$1650x__		
		Serious	$2750x__		
STIPULATION (TOTAL X 25%)			TOTAL FORMAL PENALTY		

Revised: 6/16/00

USDA

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

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TO: Robert W. Young
Assistant Inspector General for Audit
Office of Inspector General

FROM: W. Ron DeHaven
Administrator
Kevin Shea /sv
SEP 2 8 2005

SUBJECT: APHIS Response to OIG Report, Animal Care Program: Inspection and Enforcement Activities (33002-0003-SF)

Thank you again for the opportunity for the Animal and Plant Health Inspection Service to comment on the above OIG report. This correspondence incorporates responses from Animal Care, Financial Management Division, and Investigative and Enforcement Services.

Recommendation #1: Incorporate specific guidance in Animal Care's (AC) operation manual that addresses referrals and enforcement actions in order to ensure consistent treatment of violators.

APHIS Response: To ensure AC's consistency in the treatment of violators, AC will incorporate into all the Inspection Guides a flow chart that provides enforcement action guidelines for inspection reports. AC's Eastern and Western Regional Directors have collaborated to create one flow chart that will be used nationally. The Manual Team will be responsible for inserting the enforcement action flow chart into the inspection guides by November 30, 2005.

Recommendation #2: Review all cases where the regions decline to take enforcement actions against violators.

APHIS Response: If there is evidence of a violation, but AC's Regional Director recommends that prosecution be "denied/declined," the AC Deputy Administrator or Assistant Deputy Administrator and the Investigative Enforcement Services (IES) Director or Assistant Director will review and approve the "denied/declined" final action prior to closing the case. Also, if AC or IES propose different final actions, the AC Deputy Administrator or Assistant Deputy Administrator and the IES Director or Assistant Director will review the aggravating and mitigating factors and, together, will determine the appropriate final action. The policy is now in place.

IES will maintain in its tracking system the reason for "denied/declined."

Recommendation #3: Eliminate the automatic 75 percent discount when calculating fines for repeat violators or direct violations.

APHIS Response: The automatic 75 percent reduction in civil penalties has been eliminated when it involves repeat violators or direct violations. The Penalty Assessment Work Group, formed in August 2004 by the AC/IES Management Teams, met in August 2005 to determine new guidelines for assessing penalties. Penalties assessed are based on such factors as history of violations, severity of violations, and willingness to work toward compliance once a violation has been noted.

Recommendation #4: Seek legislative change to increase fines up to $10,000 for research facilities.

APHIS Response: A legislative change will need to be initiated by the Secretary of Agriculture.

Recommendation #5: Calculate fines based on the number of animals affected per violation, as appropriate.

APHIS Response: The Penalty Assessment Work Group, which met in August 2005 to review and update penalty assessments, developed new internal guidelines that IES will use to determine when calculating fines on a per animal basis.

Recommendation #6: Revise the Research Facility Inspection Guide (RFIG) to require VMOs to verify the number of animals reported in the research facilities' annual reports.

APHIS Response: We agree this is important information. The appropriate sections of the RFIG will be updated by November 30, 2005. We will also revise Policy #17 to further assist research facilities in completing reports properly. The draft revision to Policy #17 will be completed by October 1, 2005.

Recommendation #7: Emphasize the need to adequately sample protocols, including those where animals are not present at the facility during the inspection. Also, emphasize the need to review disposition records, if available, for regulated animals other than dogs or cats.

APHIS Response: We agree with the need to do complete inspections of research facilities. The RFIG contains instructions for the VMOs to sample protocols where animals are not present and to review other available records. However, we will add additional emphasis on using the RFIG for these reviews by November 30, 2005.

Recommendation #8: Require the research facilities to identify annually the number of protocols under each of the pain/no pain categories in their annual reports.

APHIS Response: AC will propose a change to the regulations in order to require that research facilities include this information in their annual reports. AC has a proposed rule workplan on the annual reports, which is presently being reviewed by APHIS' Regulatory and Analysis Branch. It will be modified to include this proposed amendment. APHIS cannot predict the timing, nor the final outcome, of notice and comment rulemaking.

We agree it is important for VMOs to review a representative sample of protocols during their inspections. Currently, research facilities are required to provide a list of proposed activities to be reviewed to each Institutional Animal Care and Use Committee (IACUC) member. VMOs will use these lists as the universe from which to select sample protocols while these regulatory changes are pending. VMOs will begin using this approach by October 1, 2005.

Recommendation #9: Modify regulations to require IACUCs at research facilities identified as repeat violators (those with 3 or more consecutive years with violations) to conduct more frequent reviews.

APHIS Response: Facilities with 3 or more consecutive years with violations will necessarily be subject to more frequent inspections, which is currently AC's standard procedure. AC Risk-Based Inspection System (RBIS) will flag all such facilities and ensure that they are inspected more frequently and to provide more support for enforcement.

Recommendation #10: Require IACUCs to implement policies that fully train committee members on protocol review, facility inspections, and the AWA.

APHIS Response: We agree that educating the IACUCs is an important component of the self-monitoring system. This may also assist with Recommendation #9. AC will modify Policy #15 to indicate it is our interpretation that this regulation also applies to IACUC members. The draft will be done by October 1, 2005.

Recommendation #11: Instruct research facilities to implement controls to ensure that the number of animals reported in the annual report is accurate.

APHIS Response: As noted in our reply to Recommendation #6, we agree this is important information. The RFIG will be amended to instruct inspectors to verify the accuracy of the numbers of animals reported. The Manual Team will be responsible for updating the Research Facility Inspection Guides and inserting the three clarifications listed in the response to Recommendations 6,7,8, and 11. The Guide can be updated, printed, and distributed by May 1, 2006. In the interim, the Animal Care Management Team will distribute an instruction memo to the VMOs with the clarifications they need to use immediately. Policy #17 will be amended to further assist research facilities in this endeavor.

Recommendation #12: Seek an OGC opinion to determine if institutional officials can be held personally liable in cases of negligence of fiduciary duty.

APHIS Response: The following verbatim response was obtained from the Office of General Counsel on September 6, 2005: Under section 2139 of the Animal Welfare Act (AWA), "the act, omission, or failure of any person acting for or employed by a research facility ... within the scope of his employment or office, shall be deemed the act, omission, or failure of such research facility, ... as well as of such person." Section 2139 applies to alleged violations of the AWA or regulations by any person that is engaging in AWA regulated activities. Under the AWA, APHIS only has jurisdiction over persons who are engaging in regulated activities as dealers, research facilities, exhibitors, carriers, and intermediate handlers. Employees of dealers, research facilities, exhibitors, carriers, and intermediate handlers are not liable for any violations committed by their employers, unless the employee is also engaging in AWA regulated activities. Accordingly, section 2139 does not apply to institutional officials who oversee regulated activities of a research facility, but are not engaged in AWA regulated activities themselves. In cases where an institutional official is charged by the research facility with oversight of regulated activities and does not fulfill that duty adequately, the research facility, and not the individual, is responsible for any violations of the AWA or the regulations that may occur.

Recommendation #13: Implement temporary measures to address attempted inspections and re-inspections until the new system (OACIS) is operational.

APHIS Response: We understand the basis for this recommendation and agree with its intent; however, the new system, OACIS (On-line Animal Care Information System) is scheduled to be operational in March 2006. We do not believe the implementation of temporary measures that would take some weeks to develop and implement and would then be in place for 6 months or less is either cost effective or an efficient use of scarce resources.

Recommendation #14: Ensure that the new system is adequately tested, and that system users are able to provide feedback during the development.

APHIS Response: In late 2004, AC formed the OACIS integrated team, which consists of field inspectors, supervisors, AC IT support, and management personnel. Team members met in December 2004 to define and develop users' requirement for the OACIS project. They provided user input to the OACIS development contractors regarding what was needed in the new system. The system requirement was completed in February 2005 and it was reviewed and validated by the team. The system will consist of several modules. Each module will be developed and tested for functionalities according to the specifications defined in the user's requirement. The contractor will test the functional requirement of each program unit within each module as well as the integrated components for all modules for the system. The OACIS integrated team will be involved in testing similar functionalities to validate the contractor deliverables as soon as the test module(s) becomes available to ensure the user's requirement is met. Final module(s) acceptance will be based on the user testing. The project is expected to be completed by March 2006.

Recommendation #15: Provide a plan for performing system maintenance on the new system (OACIS).

APHIS Response: AC included a request in the fiscal year 2006 budget to have the contractors developing OACIS also to provide this service, until a new employee is hired to maintain it in-house.

Recommendation #16: Instruct IES to provide a plan and timeframe for transferring collections to FMD.

APHIS Response: Beginning in October 2004, IES transferred the collection activity for APHIS issued civil penalty stipulations to the Financial Management Division (FMD). IES' stipulation letter to the alleged violator requests that he or she send payment directly to the APHIS Lockbox in St Louis, Missouri. FMD processes the payments and updates the IES case management tracking system with the collection data.

Recommendation #17: Until collections are delegated to the FMD, instruct IES to implement internal controls over its cash collections in accordance with the APHIS' Budget and Accounting Manual.

APHIS Response: Beginning in October 2004, IES instituted a number of internal controls to ensure integrity in the civil penalty collection process. While over 90 percent of the civil penalty payments go directly to FMD, IES still receives a small

number of checks for civil penalties assessed at the ports of entry and mailed in after the traveler has left the port, as well as checks received by the Office of General Counsel for cases resolved by the USDA administrative law judges. IES has instituted the following controls in accordance with the APHIS Budget and Accounting Manual:

The IES Program Support Assistant (PSA) responsible for opening the mail enters all checks into an electronic Check Log. Checks are entered into a log with the case number or serial number, violator, check number, amount, date received, and who received it. The PSA gives the checks to the IES Document Control Team (DCT) for processing and submission on a daily basis.

The DCT processes the checks and forwards them to the APHIS Lockbox in St. Louis. DCT enters the check data (case number or serial number, violator, check number, amount, date received, date sent to St Louis, initials of person processing, and date check was returned to violator (if necessary). A copy of the check and any supporting documentation (i.e., settlement agreement, PPQ 591, or processing form from port) is made and filed in the case file. A cover sheet is attached to each check that shows case and/or docket number, violator name, check number, check amount, and tax identification number. It is also signed and dated by the sender. A copy of the cover sheet is also made for the case file. All checks are mailed by certified mail. All checks are processed within 24 hours of receipt. If IES cannot process the check in 24 hours, the reason is annotated on the log.

FMD processes the checks received at the APHIS Lockbox and updates the IES Tracking System with the amount received. Once FMD records the full payment as collected, DCT closes the case in the tracking system.

IES has instituted a system where three different groups (PSA, DCT, and FMD) record the payment information at three different points in the process (upon receipt in the mail, upon submission to the lockbox and after deposit and entry into the tracking system). Any discrepancies between these three records are traced and resolved immediately.

Recommendation #18: Implement a plan that would expedite the process for establishing receivables of court-ordered fines.

APHIS Response: As of December 2004, IES instituted procedures to expedite the processing of Administrative Law Judge (ALJ) orders to FMD for processing as follows:

IES sends all ALJ orders (Consent Decisions, Decision and Orders) to FMD every Friday. A cover sheet is attached to each docket showing: docket number, case number, violator, civil penalty, person sending, phone number, and date. This

specifies the amount to be collected and alleviates the need for FMD to interpret the court order. A copy of the order and cover sheet are filed with the case. IES maintains a spreadsheet with the information from the cover sheet as well as a copy of the cover sheet for tracking purposes.

Recommendation #19: Establish a timeframe to transfer the $398,354 in receivables over 180 days to Treasury for collection.

APHIS Response: FMD was not required to transfer 14 of the 81 delinquent AC receivables totaling $134,192.82 to Treasury for collection. The remaining 67 receivables, totaling $264,161.18, have been reviewed and appropriate steps have been taken including referring debts to Treasury Cross Servicing (CS), writing off the debts, or collections on payment plans with many leading to debts paid in full.

Debts that had been previously referred to Treasury Offset Program (TOP) have been forwarded to CS and will be removed from TOP as soon as CS submits the debt to TOP.

Recommendation #20: Establish a formal system to share pertinent information such as tax identification numbers between AC and APHIS' debt collection unit.

APHIS Response: FMD has developed a process for obtaining tax identification numbers for stipulations and dockets, which are received without this information from IES. Modifications have been made to the IES tracking system to allow FMD more access to violator data including the tax identification numbers. An IES staff member has been designated as a contact person to assist FMD with questions on documents received and its tracking system. FMD also extended its research abilities by using Choicepoint AutotrackXP data beginning in May 2005 to research tax identification numbers.