USDA Employee Survey on the Effectiveness of IACUC Regulations

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Executive Summary

USDA APHIS Animal Care conducted a brief mail survey of 40 of its field employees who are Veterinary Medical Officers (VMOs) and 9 of their supervisors to assess their opinions about the effectiveness of USDA's current approach to ensuring humane care and use of animals at research facilities through the mechanism of Institutional Animal Care and Use Committees (IACUCs) and to collect ideas about how to improve it. All VMOs and supervisors responded to the survey. Collectively, the VMOs inspect more than 1200 facilities. Seventy percent of the VMOs have 8 or more years experience inspecting research facilities and have had an opportunity to observe the effect of the IACUC regulations since their inception.

Ninety four percent of the VMOs who answered felt that the overall effect of the IACUC regulations has been to improve the welfare of research animals. Those VMOs who have the highest number of research facilities (35 or more) and spend 60% or more of their time inspecting them feel the strongest about it--that the welfare of research animals has been "Greatly Improved" by the IACUC regulations. The VMOs rate the regulations, the functioning of IACUCs, and Animal Care's enforcement of the regulations Medium to Medium High. The VMOs also rated the IACUCs' effectiveness on a range of specific functions. The pattern across these functions was relatively consistent; 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.

These findings support the conclusion that the IACUC regulations are generally effective, and that great strides have been made in improving humane care and use of animals at research facilities since the regulations were adopted, but the task is not finished yet. APHIS should not spend resources on a major overhaul of the IACUC regulations in general, but should work toward refining the system that has been established. The industry response to the system is evolving and research science is evolving. APHIS needs to stay current with these changes, needs to be consistent in what we require. The regulations were designed to allow the government to keep up as this process unfolds.

Animal Care VMOs report that some of the problem areas that need to be refined are: the search for alternatives, review of painful procedures, and monitoring the investigators' use of animals to ensure compliance with approved protocols and standard operating procedures. An estimated 600 to 800 facilities have had trouble with the search for alternatives, 450 to 600 with review of painful procedures, and 350 to 400 with monitoring for compliance. The high level of problems reported by VMOs supports the need for a review of Policy 12, "Search for alternatives." APHIS should, in conjunction with AWIC, OPRR, and industry, develop a way to appropriately encourage searching for alternatives to painful procedures.

The VMOs answering the survey identified a great number of innovations that various facilities have made that may have merit for distribution. Most of the ideas they identified for improving the regulations seem to involve clarifying the roles of the Institutional Official and the IACUC members and strengthening the IACUCs' authority. A number of VMOs advocate issuing a policy, guideline or educational materials that would close the gaps and refine the system. Animal Care needs to provide clear guidance to industry and the VMOs on what constitutes a painful or distressful procedure for AWA purposes, expectations to minimize pain and distress, and how to accurately report on them. A large number of VMOs advocated attending IACUC meetings in order to educate the members on regulation requirements and facilitate communication with them. A large number also recommended that they should be allowed to take the time

to be more thorough, review records in more detail, comprehensively evaluate sensitive protocols involving surgery, pain and distress, talk to Principal Investigators, and do occasional audits of Category D and E procedures. Downloadable forms and checklists they could share with facility personnel would be a help to them.

A list of training ideas for both IACUCs and VMOs is included in the report. Some of their needs are the same and could be met in joint sessions offered thorough the Animal Welfare Information Center and similar venues. Many of the VMOs' other training needs could be met by allowing them to join their colleagues on research facility inspections, observe types of research being conducted, and discuss ways that their colleagues resolved certain problems. Policy clarifications and guidelines, when completed, would require a more formal approach than participating with colleagues on joint inspections. Depending upon how extensive they are, they would probably entail developing training sessions focusing specifically on IACUC compliance.

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I. Introduction

The following report describes the findings of a survey of employees of the U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Animal Care (AC) concerning the effectiveness of certain regulations they enforce, under the authority of the Animal Welfare Act, that govern the care given to animals by research facilities. The regulations being evaluated are 9 CFR, Part 2, Subpart C, §2.31--2.38. The emphasis is on §2.31, "Institutional Animal Care and Use Committee (IACUC.)" A copy of the text of the regulations is shown in Appendix A.

A. Purpose of the Study

The purpose of this study is to:

- Systematically assess the opinions of Animal Care's front line employees about the effectiveness of APHIS' approach to ensuring humane care and use of animals at research facilities through the mechanism of Institutional Animal Care and Use Committees (IACUCs)
- Collect the employees' ideas about how to improve APHIS' approach to care at research facilities through IACUCs
- Make recommendations to the Animal Care Management Team about further development of APHIS' approach

This study was requested by the Animal Care Management Team in 1997 as part of a larger look at performance-based standards for animal care proposed in Animal Care's Strategic Direction of 1996. During 1997 and 1998 analytic resources were directed at other performance-based standards. Finally, in 1999, the IACUC portion of the study was accomplished.

We acknowledge there are limitations to this study. An employee survey is the most cost effective way to get an objective, balanced understanding of Animal Care's Veterinary Medical Officers' (VMOs') perceptions. Because of the pressing nature of their duties inspecting facilities, we planned a survey form that would not take them more than half an hour to complete. We did not ask them to collect information from their files or from facilities to answer the questions. They relied on the knowledge base they had acquired and could speak from with no special preparations. This study was intended to be an initial overview that would be followed up by more in-depth work in problem areas if that was found to be necessary. Follow-up study might be performed by a team of Animal Care employees, as is a standard practice in the Animal Care Program.

B. Study Team

The team for this study consisted of a combination of employees from Animal Care and Policy and Program Development:

- Betty Goldentyer, DVM, Regional Director, Eastern Region, Animal Care
- Robert Willems, DVM, Supervisory Animal Care Specialist, Eastern Region
- Natalie Roberts, PhD., Management Analyst, Policy and Program Development
- Karen Ratzow, Evaluation Specialist, Policy and Program Development

Input from Animal Care's Technical Advisory Group (TAG Team) was obtained at the initial stage, designing questions on the survey. Assistance reviewing the draft was also provided by Mike Tuck and Julie Marquis, Policy and Program Development, and Pete Schultheiss, DVM, Animal Care Staff.

II. Research Design

This chapter provides background information on some of the concepts that underlie the study and describes the methods used in the survey.

A. Underlying Concepts

1. The Regulatory Process: In order to fulfill its responsibilities under various acts passed by Congress and its mission of improving the welfare of animals, USDA, APHIS, Animal Care puts forth regulations and standards for the humane care and use of animals in certain facilities. It informs the facilities about the requirements, and the facilities comply by meeting the requirements. This regulatory development process relies heavily on publication in the *Federal Register* and is formally called "Notice and Comment Rulemaking."

Animal Care Program personnel inspect the facilities to determine if the care given to animals meets or exceeds the regulatory requirements. The inspector gives a written inspection report to the facility owners or managers at the conclusion of the inspection and, if the facility is not in compliance with the regulations, the inspector tells them what is expected and gives them an appropriate period of time to make required improvements. The inspector may also provide educational materials to the facility. Depending upon how serious the noncompliance is, the inspector returns within a certain period of time to see if the facility has made the required corrections and the animals are safe. This part of the regulatory process is usually called the "inspection process" and is labor intensive.

Animal Care inspectors also spend time educating new facilities about the requirements and informing facilities about policy developments and changes in the requirements. They also perform inspections based on complaints received from citizens concerned about particular facilities.

A regulation or standard must be legally enforceable in order to compel resistant parties to comply. There is an appeals process. If the facility disagrees with the inspector, they may write to the Regional Office and have the inspector's finding reviewed. If a facility continues in noncompliance or refuses to make corrections, the case is referred to APHIS, Investigative and Enforcement Services (IES.) IES works with Animal Care to use a variety of legal means to persuade the facility to meet the requirements, including levying fines and stipulations. In the most difficult situations, a legal case may be referred to USDA's Office of General Counsel (OGC.) A hearing is held in which OGC presents APHIS' side to an Administrative Law Judge and the facility's lawyers present the other side. The judge makes the decision. Occasionally a case may go as far as the Justice Department. This part of the regulatory process is sometimes referred to as the "enforcement process." The term "enforcement" is also used in a larger sense to refer to all of the processes referred to here, as in "APHIS' enforcement of the law."

2. IACUC Regulations: The Institutional Animal Care and Use Committee (IACUC) regulations that USDA APHIS Animal Care enforces today are the outgrowth of a legislative development including several laws that are collectively known as the Animal Welfare Act (AWA). Each time an amendment to the AWA is passed, it is incorporated into Title 7, U.S. Code, Sections 2131-2156. The laws are:

- The Laboratory Animal Welfare Act of August 24, 1966* *(Public Law 89-544)*, as amended
  -- In 1970 by P.L. 91-579 (which renamed it the Animal Welfare Act)
  -- In 1976 by P.L. 94-279
- The Food Security Act of 1985, Subtitle F, Animal Welfare (*Improved Standards for Laboratory Animals Act),* P. L. 99-198
- The Food, Agriculture, Conservation, and Trade Act of 1990 *(Pet Theft Act of 1990), Public Law 101-624*

In 1985, Congress enacted two companion laws containing provisions concerning the care and use of animals in research, testing, and education. The Food Security Act, shown above, provided USDA's mandate. The other law was the Health Research Extension Act of 1985 (P.L. 99-158), which revised the Public Health Service Act (Title 42, U.S. Code, Sections 289d) and charged the Secretary of Health and Human Services with regulating federally supported research using animals. It required "..animal care committees at each entity which conducts biomedical and behavioral research with funds provided under this Act.." [Sec. 495 (b)(1).] The Food Security Act of 1985 established "Institutional Animal Committees", defined their components and functions, and said that experimental procedures must minimize animal pain and distress and that principal investigators must consider alternatives to any procedure likely to cause pain or distress.

The Food Security Act also provided for the formation of an information service at the National Agricultural Library (the Animal Welfare Information Center), which serves as an information source and gives training programs for USDA employees and research facility personnel. Today AWIC offers a workshop giving a history of the laws and regulations, explaining the information requirements of the AWA, and providing practice in searching electronic databases for alternatives. The information AWIC provides helps facilities prevent unintended duplication of animal experimentation and improves methods of animal experimentation, including methods which could reduce or replace animal use and minimize pain and distress to animals.

On the HHS side an important role was given to the Office of Protection from Research Risks (OPRR), Division of Animal Welfare. Guidance documents were developed and updated during the 1985-86 period during the two laws were passed, including:

- "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training", *Federal Register* May 20, 1985. Interagency Research Animal Committee. Office of Science and Technology Policy, Washington, D.C. 1985
- "The Public Health Service Policy on Humane Care and Use of Laboratory Animals", U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, Office of Protection from Research Risks, Revised as of September, 1986, 28 pp. U.S. Government Printing Office: 1992--325-945
- *Guide for the Care and Use of Laboratory Animals.* Institute of Laboratory Animal Resources, Commission on Life Sciences, National Research Council, National Academy Press, Washington, D.C., 1985 (last revised in 1996)

The 1986 Public Health Service Policy defined "Institutional Animal Care and Use Committee" as a generic term for a committee whose function is to ensure that the care and use of animals in the PHS-conducted or supported activities is appropriate and humane in accordance with the policy (p. 4.) The functions of the IACUC that were published by APHIS in 1989 paralleled those identified on pages 6 and 7 of the 1986 PHS policy. Requirements for compliance with the AWA were incorporated into research projects conducted or supported by any component of the Public Health Service.

USDA APHIS published final rules for the Animal Welfare Regulations in the *Federal Register* on August 31, 1989 and February 15, 1991. The IACUC functions in 9 CRF §2.31(c) came out in the 1989 portion and may be summarized as follows:

- **Review the program:** Review, at least once every 6 months, the research facility's program, using the USDA regulations as a basis
- **Conduct inspections:** Inspect, at least once every 6 months, all of the animal facilities, including animal study areas/satellite facilities, using the USDA regulations as a basis
- **Evaluate and report:** Prepare reports of IACUC evaluations and submit the reports to the Institutional Official
- **Review complaints:** Review and investigate legitimate concerns involving the care and use of animals at the research facility resulting from public complaints and from reports of noncompliance received from facility personnel or employees
- **Report to the Institutional Official:** Make recommendations to the Institutional Official regarding any aspect of the research facility's animal program, facilities or personnel training

- **Review protocols:** Review and approve, require modifications to secure approval, or withhold approval of components of proposed activities related to the care and use of animals
- **Review protocol and SOP changes:** Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities
- **Monitor, suspend, and report:** Suspend an activity involving animals when necessary; take corrective action and report to USDA

The section on "IACUC review of activities involving animals" [9 CRF §2.31(d)] requires that the proposed activities or significant changes to ongoing activities meet certain requirements:

- **Minimization of pain and distress:** Avoidance or minimization of discomfort, distress, and pain to the animals
- **Consideration of alternatives:** Consideration by the principal investigator of alternatives to procedures that may cause more than momentary or slight pain or distress and provision of a written narrative of the methods and sources used to determine that alternatives were not available
- **No unnecessary duplication:** Written assurance by the principal investigator that the activities do not unnecessarily duplicate previous experiments
- **Alleviation of pain:** Procedures that may cause pain should be performed with analgesia or anesthesia if possible, should involve consultation with the attending veterinarian, and should not use paralytics without anesthesia
- **Others:** Several other provisions concerning unrelieved severe or chronic pain, species appropriate living conditions, medical care, personnel qualifications and training, pre-operative and post-operative care, multiple major operations, and methods of euthanasia

The other sections of the regulations contained requirements regarding the IACUC process, personnel qualifications, veterinary care, record keeping, identification of dogs and cats, annual reporting, research facilities run by the federal government, and others. (See Appendix A. for exact text of the regulation.)

Since the time USDA APHIS published its regulations and HHS PHS published its policy, a great deal has been written by both governmental and nongovernmental groups to explain the requirements to facilities.

- In 1991 the National Research Council, Commission on Life Sciences, Institute of Laboratory Animal Resources, Committee on Educational Programs in Laboratory Animal Science, published *Education and*

Training in the Care and Use of Laboratory Animals, National Academy Press, Washington, D.C.

- In 1992 the Council of the Applied Research Ethics National Association (ARENA), a national organization for members of IACUCs, Institutional Review Boards, Hospital Ethics Committees, and similar groups concerned with ethical and practical issues related to the conduct of research developed *A Guidebook for Institutional Animal Care and Use Committees.* It is posted on the World Wide Web at www.nih.gov/grants/oprr/iacuc_guidebook
- In 1994 the National Agricultural Library and the University of Illinois at Chicago jointly published *Essentials for Animal Research: A Primer for Research Personnel* (National Agricultural Library, Beltsville, MD. (Three authors are listed: B. T. Bennett, M. J. Brown, and J. C. Schofield.) The Animal Welfare Information Center at NAL has produced many articles and a newsletter and assembled a great collection of resources
- The American Association for Laboratory Animal Science formed an ad hoc committee to produce a comprehensive course to train IACUC members and develop and design a site on the World Wide Web at: www.iacuc.org
- The Scientists Center for Animal Welfare has published many documents, sponsored conferences, and designed an World Wide Web forum for members of IACUC members to provide them with a forum to discuss protocols, research animal well-being and other issues
- Many other online sources exist, including:
  -- netvet.wustl.edu
  -- nih.gov/grants/oprr/phspol.htm
  -- aphis.usda.gov/ac
  -- nal.usda.gov/awic/awic.htm
  -- clueless.ucdavis.edu
  -- omni.ucsb.edu/pro/acc-home.html
  -- ahc.umn.edu/rar/INDEX.HTML
  -- www.iacuc.org

There have been several attempts to look at the effectiveness of the IACUC regulations:

- In 1993 the Southeast Sector of Animal Care conducted an informal survey of its VMO's, but did not completely document it in a report
- In 1996, the Scientists' Center for Animal Welfare produced a preliminary report of a survey of research facilities regulated by USDA and HHS
- In Winter, 1996, Tim Allen and D'Anna Jensen, technical information specialists at the Animal Welfare Information Center, wrote an article based on their work, "IACUCs and AWIC: The Search for Alternatives", in *IACUC Special Issue of the Johns Hopkins Center for Alternatives to Animal Testing*, Vol. 12, No. 2, pp. 1-6. They reported that many people were unsure exactly what an alternative is and are confused as to what information is required to show compliance.

In 1997 APHIS Animal Care collected together its policies and issued them in a manual, "Animal Care Policies". These included several of relevance to IACUCs:

- Policy #3, "Veterinary Care"
- Policy #11, "Painful Procedures
- Policy #12, "Written Narrative for Alternatives to Painful Procedures"
- Policy #14, "Major Survival Surgery, Single vs. Multiple Procedures"
- Policy #15, "IACUC Membership"
- Policy #16, "Dealers Selling Surgically-Altered Animals to Research"
- Policy #17, "Annual Report for Research Facilities"

In March, 1999 the National Institutes of Health undertook an initiative to reduce the regulatory burden of research facilities and proposed that several USDA requirements be reexamined, including some of the policies listed above that IACUCs are responsible for. A copy of this report can be viewed at:
http://grants.nih.gov/grants/policy/regulatoryburden/animalcare.html.

3. Employee Opinions: Animal Care Veterinary Medical Officers (VMOs) are an excellent source of information about the effectiveness of IACUC regulations in promoting the welfare of animals, because they have both a breadth and depth of understanding. Collectively, they see the entire range of facilities. All the employees who were surveyed in this study are doctors of veterinary medicine, trained in scientific method, and are familiar with the task of filling out surveys from Headquarters. They know to disqualify themselves from answering a question if they feel they don't have enough experience to make a judgment. They enter research facilities unannounced and observe the actual conditions of animals covered under the Animal Welfare Act. They have access to research protocols and minutes of IACUC meetings. They make repeated visits to the same facilities and have been able to see change or lack of it over the years. They have had to interpret the regulations and provide educational materials concerning some of them. Some of the officers have brought cases against facilities, and have met success or failure. It is critically important to know what front line employees think before any significant change in policy is made.

B. Survey Methodology

1. The survey form and cover letter: In Spring, 1999 a survey form and cover letter (shown in Appendix B.) were developed with input from Supervisory Animal Care Specialists (SACs). The form was pre-tested on only one Veterinary Medical Officer in the field, but was similar to a form administered to all employees in 1996. In June, 1999 the survey was mailed to all 40 VMOs and 9 SACs. The cover letter from Dr. DeHaven explained the purpose of the study and referred to an earlier survey they had filled out for performance-based standards on dog exercise and environmental enhancement for non-human primates. It requested employees to base their answers on their actual experience inspecting facilities and, if they did not have first hand knowledge, to circle "N/A" for that question. It explained that their answers would be collected by personnel in Policy and Program Development and would be treated confidentially and reported only as group statistics and lists of anonymous comments, but that we had to hear from every one of them. Page 3 of the survey had a Control number with the statement, "The purpose of this control number is to track who has responded and who has not. Be sure to include this page when you mail in your questionnaire. It will be torn off and discarded in PPD when your questionnaire comes in. If you do not respond, we will call until you do." After several weeks a reminder post card was sent to non-respondents. After several more weeks, calls were made to non-respondents, until they mailed theirs in.

2. The survey questions:

The survey collected four types of information:

- Facts about the respondent (Region, number of research facilities currently inspecting, year began inspecting research facilities, and approximate percentage of work year spent on research facilities)
- Respondents' opinions rating various things on five point scales:
  - -- The effect of the regulations on the welfare of animals (on a scale from "Greatly Worsened" to "Greatly Improved")
  - -- The effectiveness of the IACUC regulations (on a scale from "Very Low" to "Very High")
  - -- The effectiveness of the IACUCs (on the same scale)
  - -- Animal Care's enforcement of the regulations (on the same scale)
  - -- The effectiveness of IACUCs in fulfilling requirements in 12 areas (on the same scale.) (The areas correspond to functions mentioned in the Act, with a little more detailed breakout.)
- An estimate of the percentage of facilities they inspect that have had a problem with 9 potential trouble areas
- Narrative descriptions of their opinions about:
  - -- Specific issues that need to be addressed
  - -- Successful innovations observed
  - -- Ideas for improving performance standards and inspection methods
  - -- Ideas for training for IACUCs and themselves

3. The data analysis:

The quantitative data (Appendix C) were entered into a microcomputer database software package. Only data from VMOs were included in frequencies, percentages and average scores. Some data were exported to spreadsheets, charts were made and exported to wordprocessing packages. Tables in Appendix C were reviewed for extremes and unexpected patterns and summarized as shown in Chapter III.

The qualitative data (Appendix D) were also entered into a database. Data from both VMOs and SACs were analyzed for content, given topic codes, and arranged them in a logical flow for narrative summary. The topical category assigned to each comment is shown in the left column of the tables. Where respondents mentioned more than one topic, we divided their comments into separate entries. As one reads from the top of the listing down, one can see the range and variation of the respondents' perceptions.

III. Findings

The quantitative results of the survey are shown in Appendix C in Tables 1, 2, and 3. Table 1 gives the frequency of responses and Table 2 the corresponding percentages. Table 3 shows average ratings for questions where they are relevant.

The qualitative results are shown in Appendix D in Tables 4, 5, 6, 7, 8, and 9.

The numerical data are counted only for the 40 Veterinary Medical Officers (VMOs). The qualitative results include the ideas of 9 Supervisory Animal Care Specialists (SACs) who review the work of and supervise field staff.

A. Inspectors' Experience and Workload

All 40 VMO's responded. The first four questions ask about some characteristics of the VMO inspectors and their work.

Question 1: What Region are you in?

Problems with research facilities might differ geographically. In order to compare the responses of VMOs from different Regions and see if the Regions differ we asked what Region they are in.

The VMOs are not evenly distributed among the Regions. Of the 40 VMOs, 22 are in the Eastern Region. This is 55% of the total. Another 10 are in the Western Region. This is 25% of the total, and the Central Region has only 8, or 20% of the total.

Question 2: How many research facilities do you currently inspect each year?

Research institutions are only one kind of facility that VMOs inspect. They also inspect dealers, exhibitors, transportation facilities, and intermediate handlers. Their workloads differ. In order to get an idea of how many research facilities in total are being represented by the VMO respondents, we asked Question 2. We might want to compare the responses of VMOs with relatively more facilities with those of VMOs with fewer to see if there is a difference in their opinions.

The sum of the VMOs' estimates is 1,662 facilities. This number does not agree precisely with the count of research facilities given in the Report to Congress, but is "in the ball park." The *FY 1998 Animal Welfare Report (APHIS 41-35-059)* counts 1,267 research facilities and 2,206 research sites. The survey result is in between these two numbers. A discrepancy like this would occur if some respondents answered the survey question in terms of the number of sites they inspect, or if some of them went on joint inspections and both counted the same facility, or if different VMOs inspected different sites of the same facility and both counted the facility. The discrepancy is not significant for this study. However, we need to be

careful when giving our results about numbers of facilities and remember they are just approximate, not absolute.

Question 3: What year did you begin inspecting research facilities?

Some VMOs have more years of experience inspecting research facilities than others. We wanted to be able to compare the responses of inspectors who were hired before the IACUC regulations became effective with those who were hired after to see if their opinions differ.

Twenty eight VMOs, or 70% of them, began inspecting facilities in 1991 or earlier. They have had the opportunity to observe conditions before and after USDA's adoption of the IACUC regulations. The other 30% of the VMOs came in 1992 or later. In general, we can say that 70% of the respondents have 8 or more years of experience inspecting research facilities.

Question 4: Approximately what percentage of your work year is spent on research facilities?

Some research facilities are large and require many days to inspect. Others are small and can be inspected in less than a day. We wanted to compare the responses of VMOs with heavy research workloads with those of lighter research workloads and see if their answers differed.

One respondent marked "N/A" for this question, probably because he/she is a new employee and will not know how much of the work year will be taken up by research inspections until the first year is completed. Of the others, 7 have a heavy workload of research facilities and spend more than 75% of their time on them, and 13 have a relatively light workload and spend 25% or less of their time inspecting them. The workload of the others is between 25% and 76%.

B. Inspectors' Opinions of Overall Effectiveness

The most important questions on the survey concern the VMOs' opinions of overall effectiveness of the IACUC regulations. There are several ways to get at this. We asked four questions.[1] The questions required the inspectors to generalize about their experience. This was a difficult task for some of them, and we received unsolicited comments to that effect on several surveys: "Depends on the year;" "Depends on the individual facility;" "Varies widely." However, most of them understood the need to generalize.

Question 5: In your opinion, what has been the effect of the 1991 IACUC regulations on the welfare of research animals?

The regulations are intended to improve or safeguard the welfare of research animals. This question was intended as an overall summary judgment. The question was answered by only 32 respondents. Eight marked it "N/A" or left it blank, probably because they felt that they didn't have enough experience to judge what the effect had been. All of the non-respondents were hired in 1991 and after.

Of the 32 who did respond, 19 VMOs, or 59% indicated they thought the welfare of research animals was "Greatly Improved." Another 11 VMOs, or 34%, judged it to be "Slightly Improved." Only 2 of them, or 6% marked "No Effect" and none marked "Slightly Worsened" or "Greatly Worsened."

Another way to say this is that, rounding up, 94% of the VMOs who expressed an opinion said that the effect of the 1991 IACUC regulations has been to improve the welfare of research animals. Only 6% said there has been no effect, and none say it has worsened. This seems quite high and is good news for the Animal Care Program and IACUCs.

When the results were broken out by the inspectors' workload and experience and two patterns emerged:

- *All* (100%) of the respondents with 35 or more facilities feel the welfare of research animals has been "Greatly Improved."
- *All* (100%) of the respondents who spend 60% or more of their work year inspecting research facilities feel the welfare of research animals has been "Greatly Improved."

This finding means that the inspectors with the largest research workload appreciate the IACUC regulations the most.

[1] All percentages given in Appendix B, Table 2 are computed for the subtotals of respondents who provided ratings and exclude from the denominator those who answered "N/A" or left the question blank. The distributions add to 100% for those who answered the questions.

Question 6: How would you rate the effectiveness of the IACUC regulations in ensuring the welfare of animals?

APHIS uses the IACUC regulations as a tool to ensure the welfare of animals. Field VMOs were asked to rate the effectiveness of IACUC regulations on a scale from Very Low, to Medium Low, Medium, Medium High, or Very High.

One person disqualified them self by marking "NA" or leaving the question blank. The other 39 responses were not quite as high as the responses for Question 5 and were distributed more toward the middle of the scale. Thirteen percent of the VMOs rated the effectiveness of the regulations "Very High" and 41% rated it "Medium High." Together these two categories sum to 54%, not as high as the 94% for Question 5.

Another way to analyze this data is to compute an average score for the question. To do this we assign points from 1 to 5 for each of the rating categories, 1 being the lowest and 5 being the highest. Then we multiply the number of responses in each category by the number of points for that category, add up the points for all categories, and divide the total points by the total number of responses. The average point score resulting from this computation is shown in Table 3, on the line for Question 6. Respondents rated the effectiveness of the IACUC regulations 3.6, on average. That is between Medium and Medium High.

The inspectors think the welfare of the animals was greatly improved, but the absolute level now is only Medium to Medium High. There is still room for improvement.

Question 7: How would you rate the overall effectiveness of the IACUCs at your research facilities?

APHIS relies on IACUCs to be effective in ensuring the welfare of animals. Question 7 shifted the focus from the legal effectiveness of the regulations (which are words and concepts on paper and arguments in meeting rooms and courts) to the effectiveness of responsible committees (which are groups of actual people conducting business in facilities.)

The data were analyzed using the average points method described for Question 6. The VMOs rated the overall effectiveness of the IACUCs at their facilities 3.7, on average. This is slightly higher than they rated the regulations, but only a bit. The inspectors say, on average, that the effectiveness of the IACUCs at the facilities they inspect is Medium to Medium High.

Question 8: How would you rate Animal Care's enforcement of the IACUC regulations?

The final overall effectiveness question focused on Animal Care's enforcement process, particularly the part of the process that covers everything that happens after an inspector finds some aspect of a facility in noncompliance with the regulation. VMOs sometimes have to rely on support from their Regional Office and from Headquarters to bring a facility into compliance. The VMOs rated Animal Care's enforcement of the IACUC regulations 3.7, on average. This is consistent with their scores for the other components of the program.

Summary of Findings on Overall Effectiveness

If we look at these results as a whole, we can say that 94% of the VMOs feel that the effect of the 1991 IACUC regulations has been to improve the welfare of research animals. The VMOs that have more than 35 research facilities and spend 60% or more of their time inspecting them feel the welfare of research animals has been "Greatly Improved" by the IACUC regulations. Currently, the VMOs rate the regulations, the functioning of IACUCs, and Animal Care's enforcement as Medium to Medium High.

C. Inspectors' Opinions on How Well IACUCs Are Fulfilling Specific Functions

In addition to knowing about overall effectiveness, it was important to know what the inspectors think about specific functions that IACUCs are supposed to carry out, which things are being done well and which not so well?

Question 9. How would you rate the effectiveness of IACUCs in fulfilling their requirements in following areas?

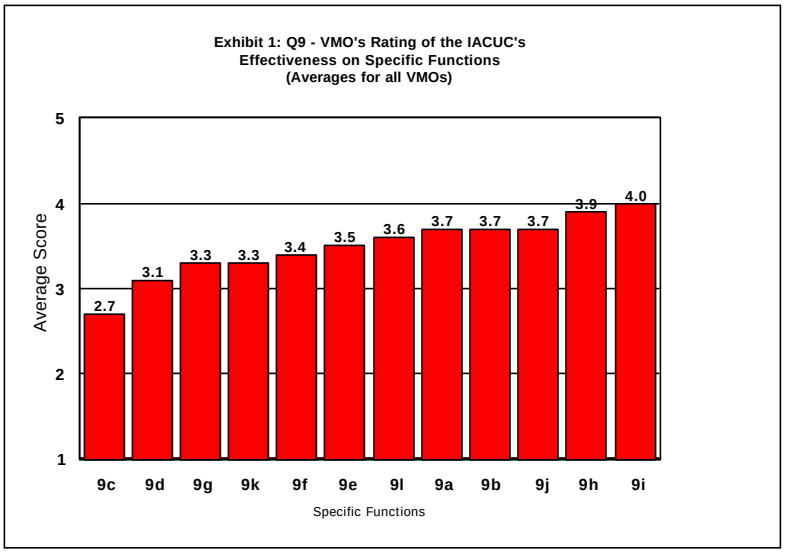
The study team was interested in learning inspectors' opinions about how IACUCs are functioning in specific areas and whether it is better in some areas than others. The areas are:

- Conducting inspections
- Reviewing protocols
- Monitoring protocols
- Monitoring and evaluating painful procedures
- Reviewing and approving SOPs
- Reviewing complaints
- Reviewing the humane care and use program
- Holding meetings
- Meeting membership requirements
- Meeting attendance requirements
- Documenting the program
- Reporting to the Institutional Official

This list includes the IACUC functions mandated by 9 CFR §2.31 but breaks them down in a slightly more concrete way and uses abbreviated language. VMOs were asked to use the rating scale again.

The frequencies, percentages and average ratings are shown in Tables 1, 2, and 3. All but one or two VMOs responded, except on the question about reviewing complaints. For that, three people marked "N/A" or left it blank, probably because they had no experience with complaints. From the comparison of results shown in Exhibit 1, we see that all the functions except one scored 3.0 (Medium) or above. Its relationship is flat and consistent across the board. Given that, the highest scoring functions or activities were Meeting Membership Requirements (4.0) and Holding Meetings (3.9). The lowest scoring activities were Monitoring Protocols (2.7) and Monitoring and Evaluating Painful Procedures (3.1).

The IACUCs effectiveness on a range of specific functions was relatively flat and consistent across the board. They seem to be doing well at setting up the administrative structure and developing the process, but not as well at monitoring and follow through.



9c = Monitoring protocols
9d = Monitoring and evaluating painful procedures
9g = Reviewing the humane care and use program
9k = Documenting the program
9f = Reviewing complaints
9e = Reviewing and approving SOPs
9l = Reporting to the Institutional Official
9a = Conducting inspections
9b = Reviewing protocols
9j = Meeting attendance requirements
9h = Holding meetings
9i = Meeting membership requirements

D. Inspectors' Experience with Specific IACUC Issues

It was also important to know about the VMOs' experience with various kinds of problems.

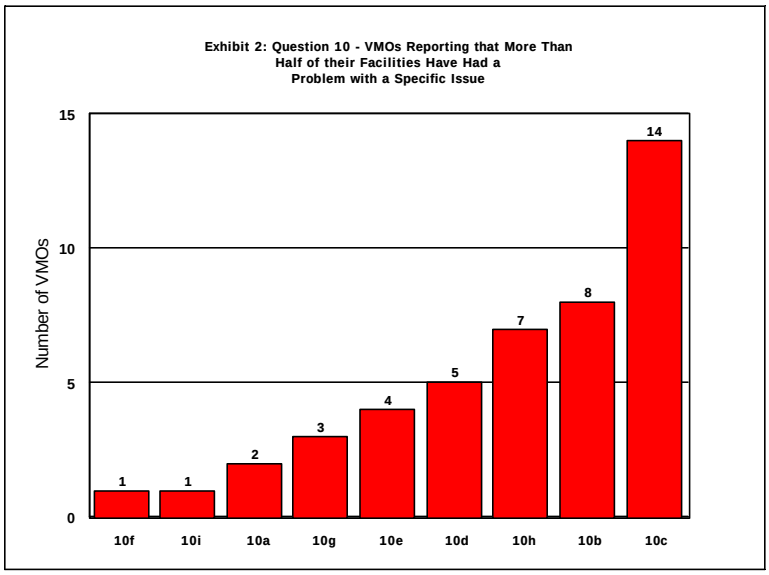
Question 10. Of the facilities you inspect, roughly what percentage have had a problem with....?

The following problem areas were of interest:

- Designated reviewer *(expedited review)* of protocols
- Review of painful procedures
- Search for alternatives
- Avoiding unnecessary duplication
- Documentation (*including SOPs and meeting minutes)*
- Facility inspection by IACUCs *(attendance at, announced vs. unannounced)*
- Balance in decision making process *(undue influence, handling difficult issues*
- Monitoring for compliance *(with approved protocols and SOPs)*
- Membership *(turnover, quality, unaffiliated member)*

Data on specific IACUC issues were analyzed two ways. First we counted how many inspectors indicated that over half their facilities have had a specific kind of problem. Second we tried to estimate the number of facilities that have had a specific kind of problem.

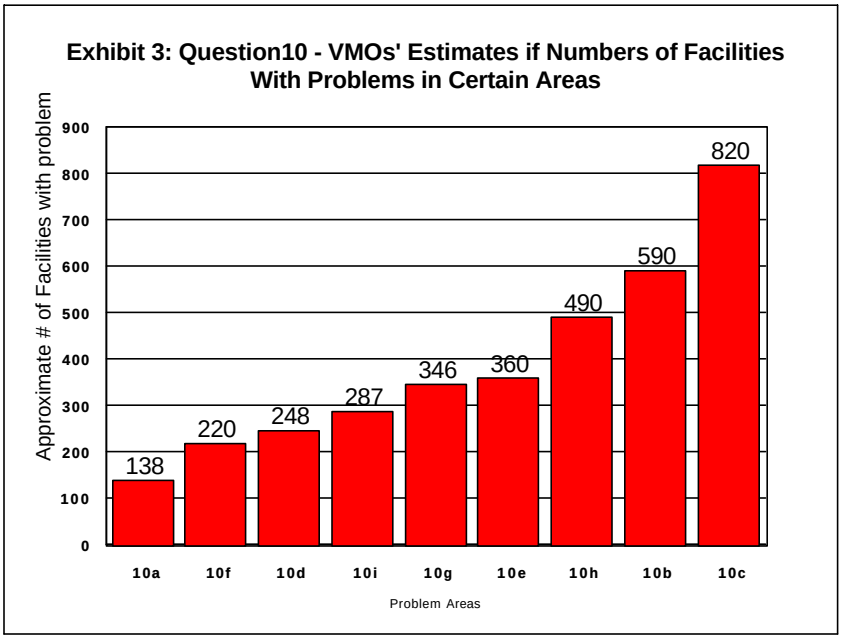
The first method grouped the VMOs' responses to Question 10 into categories and counted the number of them that reported that over half their facilities have had a problem with a specific issue. Appendix C, Table 1, Line 10 c. shows that of 38 VMOs who answered the question, 14 said that over half their facilities have had a problem with "Search for alternatives." This "Search for alternatives" is the most frequently cited problem area. The next most frequently cited problem is "Review of painful procedures." Eight of the 38 VMOs who answered the question said that over half their facilities had a problem with it. Exhibit 2 shows the data in Table 1 for all of the problem areas.



10f = Facility inspection by IACUCs
10i = Membership
10a = Designated reviewer of protocols
10g = Balance in decision making process
10e = Documentation
10d = Avoiding unnecessary duplication
10h = Monitoring for compliance
10b = Review of painful procedures
10c = Search for alternatives

Second, the approximate number of facilities likely to have a problem was computed by multiplying the percentage each VMO reported having the problem by the number of facilities he/she reported inspecting in Question 2. The results for all VMOs were summed and put into the chart. Exhibit 3 shows the relative rankings of the problems computed this way. The top three areas did not change.

- "Search for Alternatives" was the top ranking problem. An estimated 800 facilities were reported to have had trouble with it at some time. This estimate could be high because some VMOs may have counted sites as facilities. Even if we adjusted the figure down by 25%, it would still be 600 and fairly significant.
- "Review of Painful Procedures" was the second ranking problem. An estimated 600 facilities were reported to have had trouble with this element. Adjusting this estimate down by 25% to take into account some VMOs possibly counting sites as facilities, the figure would still be almost 450.
- "Monitoring for Compliance (with Approved Protocols and SOPs)" is the third problem area identified by VMOs. An estimated 500 facilities were reported to have had trouble with this function. Adjusting this estimate down by 25% to take into account some VMOs possibly counting sites as facilities, the figure would still be between 350 and 400.



10f = Facility inspection by IACUCs
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10b = Review of painful procedures
10c = Search for alternatives

E. Inspectors' Opinions on Other IACUC Issues that Need to Be Addressed

It was important to learn what issues (other than those discussed above) the VMOs feel need to be addressed.

Question 11. What other specific issues have you encountered that need to be addressed?

The question was very general and elicited a progression of concerns from VMOs. It should not be interpreted to mean that the system is not working well, but rather Animal Care needs to continue to improve and refine it so that it will be able to handle the broad types of problems identified.

There were three general categories of responses to this question:

- Structural issues
- Process issues
- Issues pertaining to the inspection process

Structural/organizational issues are listed first in Appendix D, Table 4. They include:

- The attitude of facility personnel at some institutions
- The lack of power and authority for well meaning IACUC members

- Obscured lines of responsibility on collaborative research projects with multiple registrants
- Undue influence of principle investigators
- Lack of interest or quick turnover of IACUC members resulting in lowered competence
- Failure of outside members to reflect the interests of the local community
- Failure of outside members to actively question and ask for explanations
- A limited pool from which to select internal members at small facilities
- Conflict between IACUC chair's responsibilities and his/her ownership or research interests
- Difficulty understanding IACUC functions by small facilities
- Lack of monetary incentives for achieving/maintaining excellent performance
- Ineffective training on IACUC standards
- Confusion over what activities constitute research and are regulated under the AWA

When organizational and structural problems exist, the process for ensuring humane care is more likely to be compromised. Issues VMO's raised regarding inadequate process included:

- Ineffective reporting and complaint processes
- Inadequate justification for numbers of animals used in research
- Inadequate acquisition and disposition records for animals other than dogs and cats
- Non-reporting of category E animals when there are seizures or vomiting
- Problems with alternatives to painful procedures, searches, and review of searches
- Lax monitoring whether principal investigators actually following their protocols
- Alleviation of pain inadequate during non business hours, admission, and after procedures
- Recognition of painful procedures as such and stressful procedures
- Adequate provision of post-operative analgesia
- Environment enhancement for nonhuman primates

Regarding Animal Care's inspection process:

- Two responses pertained to the frequency of inspection
- Two pertained to how inactive registrants are handled
- One raised questions regarding future inspection of rats, mice, and birds

Summary: In summary, a wide range of issues was raised by VMOs. They included both structural/organizational and process issues. No single theme emerges, except, possibly that problems are more frequent at smaller facilities. VMOs are particularly concerned about processes that are supposed to minimize pain and distress. The processes are ineffective if the organization is not set up to support it.

F. Successful Innovations Inspectors Report Having Observed

It would also be beneficial to know what innovations the VMOs have observed that might be shared with others.

Question 12: What particularly successful innovations have you observed among some of your facilities that are worthy of sharing with other facilities?

The responses to this question (see Appendix D., Table 5) fell into two main categories similar to those for Question 11 and included ideas pertaining to the following:

- Organizational innovations
- Process innovations

Structural/organizational innovations pertain to personnel, committee members, training, and internal support including:

- Voluntarily designating compliance officers from outside the research division who focus on compliance with AWA regulations and do unannounced inspections of researchers' labs
- Hiring staff or using consultants (internal or external) who are animal behaviorists, expert veterinarians, anesthesiologists, statisticians, or biostatisticians
- Rewarding caretaker level personnel who become AALAS certified
- Hiring or encouraging existing staff veterinarians to become board certified in specialty subjects other than lab animal medicine or pathology, like surgery, anesthesiology, veterinary neurology, veterinary opthamology, and veterinary internal medicine. This will help to break down mental ruts and improve their ability to adopt a perspective helpful to animal welfare
- Publishing newsletters
- Improving training programs, requirements, and courses

Process innovations relating to how the IACUCs' work is conducted. Some of them mentioned include:

- Thinking out programs of humane care and use very carefully
- Designing protocol forms and templates well
- Adopting research animal use proposal forms and outlines that break out the rationale for animal use into three separate questions: the use of animals; the use of a particular species; and the use of a given number of animals
- Doing the search for alternatives in the planning stage of research rather than as a required afterthought
- Pairing inexperienced PIs with experienced librarians to assist with searches
- Adopting new, innovative ways of performing procedures that minimize or eliminate pain and distress and sharing them with others
- Doing random, unannounced spot checking of labs and approved protocols to see if researchers are actually doing what their protocols state
- Having a reviewer select three procedures within a given time frame to review, compare them to the protocol, and submit a review sheet to the IACUC documenting the findings
- Having different members of the committee, including nonaffiliated members, screen protocols for problems prior to the IACUC meeting
- Holding seminars and creating checklists for PIs and other animal handling personnel to verify their knowledge of the protocols
- Inspecting animal vendors as a part of the program review and obtaining inspection reports on the vendors
- Calling USDA to discuss protocol changes

Summary: The VMOs identified a great number of ideas. Many good things are being done by the industry and have merit for distribution.

G. Ideas for Improving the IACUC Regulations and Inspection Process

It is also useful to collect any ideas the VMOs might have for how the IACUC regulation and inspection process might be improved.

Question 13: How can the performance standards for IACUCs be improved?

The responses to this question were coded and organized like the previous two questions were and are listed in Appendix D, Table 6. Ten respondents suggested that AC not change the regulations, just enforce the current ones already in place more strictly and inspect the research facilities more frequently.

The other VMOs mentioned a range of organizational changes. Most of these involve clarifications of the roles of the Institutional Official and the IACUC members, and strengthening the IACUC's authority. Many VMOs recommend adding a requirement for a compliance officer. Several respondents indicated that there should be some kind of an issuance giving clearer detail on what Animal Care expects, especially on painful procedures, pain management, and determination of the number of animals to be used. This issuance might include sample formats for protocols and checklists for facility inspection and program reviews. It would be the basis for educating investigators and for IACUCs, communicating what is required at meetings, workshops and in newsletters. Scheduled visits to facilitate communication about it with the IACUCs and Institutional Officials would be beneficial as well.

Question 14: How can we improve the way that we inspect IACUCs?

Appendix D, Table 7 lists the VMOs' ideas about how to improve inspections of IACUCs. Three VMOs said that Animal Care should do nothing differently. Considering the constraints the program faces, it is doing a good job and should continue. However, ten VMOs said inspectors should:

- Attend IACUC meetings and educate the IACUC members
- Make themselves available periodically to explain their responsibilities and accompany them on facility inspections
- Facilitate communication with IACUCs more actively

Ten respondents said VMOs should:

- Be more thorough, take more time, and pay attention to detail
- Review all the records the IACUC are required to keep
- Comprehensively evaluate sensitive protocols involving surgery, pain and distress and compare them with medical and study records and records kept at the lab sites
- Talk with the Principal Investigators about ongoing studies
- Do occasional audits of Category D and E procedures

In order to spend more time doing these in-depth inspections, some VMOs will need to be given fewer facilities and/or receive help from members of

a team. Animal Care will need to be given more resources or to reduce the inspection frequency of high quality research facilities to less than one per year so it can devote more inspection time to the ones that need it most.

Some VMOs said Animal Care needs to standardize, work on uniformity on how IACUCs are inspected, and develop guidelines and seminars for all research facility inspectors. The guidelines or training materials should contain:

- Checklists
- A protocol format design
- Forms for new and/or small facilities that list key points for meeting AWA regulations

These materials should be able to be downloaded from Animal Care's Home page, as is the OPRR sample format on the NIH Web page.

Though this question was about improvements in inspection, several VMOs said there should be training of VMO's by NIH, OPRR, and USDA consultants and USDA staff at least once a year. These ideas have been incorporated into the analysis of responses for Question 16.

Summary: The VMOs do not recommend a sweeping change in the IACUC regulations. Some are opposed to any significant change in them. However, a number of VMOs advocate issuing a policy, guidelines, or educational materials with a narrow focus that would close the gaps and refine the system. The topics of concern for such a policy include:

- aspects of painful procedures
- pain management
- preoperative and post-operative procedures
- determination of the numbers of animals used
- protocol content
- the search for alternatives
- protocol review
- semiannual report

A large number of VMOs advocated attending IACUC meetings in order to educate the members and facilitate communication with them. A large number also recommended they should be allowed to take the time to be more thorough, review records in more detail, comprehensively evaluate sensitive protocols involving surgery, pain and distress, talk to Principal Investigators, and do occasional audits of Category D and E procedures. Downloadable forms and checklists they could share with facility personnel would be a help.

H. Inspectors' Opinions on Training Needed

The Animal Care training program for Fiscal Year 2000 must be planned in advance. Therefore it is important to know VMOs' opinions about what types of training are needed--both for the IACUCs and for inspectors themselves. The last two questions of the survey addressed this.

Question 15: What training do you feel would be useful for IACUCs?

Training for IACUC members would provide them with knowledge, skills, and ability to better perform their oversight functions in the facility and, over time, would affect the principal investigators in the facility. While Animal Care can not necessarily provide the training, describing what is needed from the VMOs' points of view might be helpful to others who can. Responses to this question are shown in Appendix D, Table 8. VMOs support training for IACUCs in the following subject areas:

- Basic requirements and mandates of USDA, including standards, regulations, a model program and protocols and how to develop and review it
- The IACUC's role and responsibilities and practical information about how to conduct meetings, hire outside reviewers and report problems
- Using the "3-R's" (replacement, refinement, reduction) for minimization of pain and distress
- Pain relief philosophy; ethics of pain and distress issues
- How to conduct a proper literature search for and consider alternatives to painful procedures and duplicative efforts
- A list of procedures that cause pain and distress; how to recognize pain and distress in animals; and information on current practices and methods of analgesic delivery
- How to properly justify numbers of animals used; criteria to address in describing rationale for appropriate number of animals
- How to conduct a protocol review and random spot checks of approved protocols to see if the researchers are actually doing what the protocols state

The VMOs' also offered various ideas about who should be trained and how:

- Some advised that workshops be mandated for all Institutional Official and IACUC members
- Others said training should be held for new registrants. They should send their chairperson to meetings of established IACUCs at other facilities
- Still others believed it should cover Principal Investigators

- Some VMOs mentioned that there should be a mandated method to keep track of training, trainees would benefit from going outside the facility to obtain it, and training should cover all employees, even "floor sweepers"
- Some respondents reminded us that a refresher course is needed every 2 or 3 years
- A few inspectors believed that the training would be most effective if it would cover a discussion of issues, a comparison of problems in different IACUCs, and provide answers to questions posed by members

Some VMOs felt training should be presented by APHIS/VMOs, include discussion of the facility's own issues, and provide references and contacts to IACUCs that have performed with excellence. Other VMOs felt a USDA seminar should be held around the country on a regular basis, include personnel from OPRR and NIH as well as from APHIS, and have extensive training materials.

Question 16: What training do you feel you need?

The answers given by VMOs about the training they felt they need are shown in Appendix D, Table 9. Material from Question 14 has been incorporated into the analysis below.

Some of the training VMOs feel they need is similar to that they recommended for IACUCs. Other training needed is unique to their role as inspectors. Both IACUCs and APHIS Animal Care inspectors need to know:

- Alternatives to painful procedures
- Proper methods for recognizing, evaluating, alleviating, and reporting about pain
- Proper methods for reviewing protocols
- Acceptable methods for holding meetings and reviewing records

Training videos might be helpful for this technical material. In addition, both IACUCs and VMOs would benefit from:

- A discussion of IACUC issues with consultants from NIH, OPRR, and USDA
- A practical session comparing different IACUCs in which trainees evaluate case studies

VMOs also need to be generally knowledgeable about research and they need exact guidance on an inspection. This includes:

- A background overview of types of research currently being conducted on animals
- Common laboratory testing methods being used and their objectives

- Xenotransplantation antibody production and transgenics
- SPF production
- Virology and bacteriology colony screening, husbandry and housing constraints for it
- A list of painful/distressful procedures commonly used
- Changes in accepted procedures
- What's new in post-procedural care
- Practical, and technical information related to animals (especially rats, mice, and birds)
- A general review and refresher with an emphasis on uniformity and consistency of inspection methods
- Statistics for adequacy of numbers of animals used

Many of the VMOs indicated that their training could be accomplished by working with other APHIS VMOs experienced with research facilities (riding along with them and discussing what they find in the way of problems and how it is resolved). They also mentioned working more closely and receiving training from personnel from the Office of Prevention of Research Risks, and getting an update on FDA and EPA and what is accepted in when doing drug submissions, for example, and when alleviating pain and distress. One person also mentioned attending meetings such as PRIM&R.

Much of the exact guidance could be provided through the "Inspection Guide" manual used by VMOs.

IV. Summary and Recommendations

USDA APHIS Animal Care conducted a brief mail survey of 40 of its field employees who are Veterinary Medical Officers (VMOs) and 9 of their supervisors to assess their opinions about the effectiveness of USDA's current approach to ensuring humane care and use of animals at research facilities through the mechanism of Institutional Animal Care and Use Committees (IACUCs) and to collect ideas about how to improve it. All VMOs and supervisors responded to the survey. Collectively, the VMOs inspect more than 1200 facilities. Seventy percent of the VMOs have 8 or more years experience inspecting research facilities and have had an opportunity to observe the effect of the IACUC regulations since their inception.

Ninety four percent of the VMOs who answered felt that the overall effect of the IACUC regulations has been to improve the welfare of research animals. Those VMOs who have the highest number of research facilities (35 or more) and spend 60% or more of their time inspecting them feel the strongest about it--that the welfare of research animals has been "Greatly Improved" by the IACUC regulations. The VMOs rate the regulations, the functioning of IACUCs, and Animal Care's enforcement of the regulations Medium to Medium High. The VMOs also rated the IACUCs' effectiveness on a range of specific functions. The pattern across these functions was relatively consistent; 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.

These findings support the conclusion that the IACUC regulations are generally effective, and that great strides have been made in improving humane care and use of animals at research facilities since the regulations were adopted, but the task is not finished yet. APHIS should not spend resources on a major overhaul of the IACUC regulations in general, but should work toward refining the system that has been established. The industry response to the system is evolving and research science is evolving. APHIS needs to stay current with these changes, needs to be consistent in what we require. The regulations were designed to allow the government to keep up as this process unfolds.

Animal Care VMOs report that some of the problem areas that need to be refined are: the search for alternatives; review of painful procedures, and monitoring for compliance with approved protocols and standard operating procedures. An estimated 600 to 800 facilities have had trouble with the search for alternatives, 450 to 600 with review of painful procedures, and 350 to 400 with monitoring for compliance. The high level of problems reported by VMOs supports the need for a review of Policy 12, "Search for alternatives." APHIS should, in conjunction with AWIC, OPRR, and

industry, develop a way to appropriately encourage searching for alternatives to painful procedures.

The VMOs answering the survey identified a great number of innovations that various facilities have made may that have merit for distribution. Most of the ideas they identified for improving the regulations seem to involve clarifying the roles of the Institutional Official and the IACUC members and strengthening the IACUCs' authority. A number of VMOs advocate issuing a policy, guideline or educational materials that would close the gaps and refine the system. Animal Care needs to provide clear guidance to industry and the VMOs on what painful procedures are, how to minimize pain and distress, how to alleviate them when they are necessary for the research, and how to accurately report on them. A large number of VMOs advocated attending IACUC meetings in order to educate the members and facilitate communication with them. A large number also recommended that they should be allowed to take the time to be more thorough, review records in more detail, comprehensively evaluate sensitive protocols involving surgery, pain and distress, talk to Principal Investigators, and do occasional audits of Category D and E procedures. Downloadable forms and checklists they could share with facility personnel would be a help to them.

A list of training ideas for both IACUCs and VMOs is included in the report. Some of their needs are the same and could be met in joint sessions offered thorough the Animal Welfare Information Center and similar venues. Many of the VMOs' other training needs could be met by allowing them to join their colleagues on research facility inspections, observe types of research being conducted, and discuss ways that their colleagues resolved certain problems. Policy clarifications and guidelines, when completed, would require a more formal approach than participating with colleagues on joint inspections. Depending upon how extensive they are they would probably entail developing training sessions focusing specifically on IACUC compliance.

Appendix A

[Code of Federal Regulations]
[Title 9, Volume 1, Parts 1 to 199]
[Revised as of January 1, 1999]
From the U.S. Government Printing Office via GPO Access
[CITE: 9CFR2.31]

TITLE 9-- ANIMALS AND ANIMAL PRODUCTS

CHAPTER I--ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

PART 2--REGULATIONS--Table of Contents

Subpart C--Research Facilities

Sec. 2.31 Institutional Animal Care and Use Committee (IACUC).

(a) The Chief Executive Officer of the research facility shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to assess the research facility's animal program, facilities, and procedures. Except as specifically authorized by law or these regulations, nothing in this part shall be deemed to permit the Committee or IACUC to prescribe methods or set standards for the design, performance, or conduct of actual research or experimentation by a research facility.

(b) IACUC Membership. (1) The members of each Committee shall be appointed by the Chief Executive Officer of the research facility;

(2) The Committee shall be composed of a Chairman and at least two additional members;

(3) Of the members of the Committee:

(i) At least one shall be a Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the research facility;

(ii) At least one shall not be affiliated in any way with the facility other than as a member of the Committee, and shall not be a member of the immediate family of a person who is affiliated with the facility. The Secretary intends that such person will provide representation for general community interests in the proper care and treatment of animals;

(4) If the Committee consists of more than three members, not more than three members shall be from the same administrative unit of the facility.

(c) IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall:

(1) Review, at least once every six months, the research facility's program for humane care and use of animals, using title 9, chapter I, subchapter A--Animal Welfare, as a basis for evaluation;

(2) Inspect, at least once every six months, all of the research facility's animal facilities, including animal study areas, using title 9, chapter I, subchapter A-Animal Welfare, as a basis for evaluation; *Provided, however,* That animal areas containing free-living wild animals in their natural habitat need not be included in such inspection;

(3) Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Official of the research facility; *Provided, however,* That the IACUC may determine the best means of conducting evaluations of the research facility's programs and facilities; and *Provided, further,* That no Committee member wishing to participate in any evaluation conducted under this subpart may be excluded. The IACUC may use subcommittees composed of at least two Committee members and may invite ad hoc consultants to assist in conducting the evaluations, however, the IACUC remains responsible for the evaluations and reports as required by the Act and regulations. The reports shall be reviewed and signed by a majority of the IACUC members and must include any minority views. The reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the research facility and made available to APHIS and to officials of funding Federal agencies for inspection and copying upon request. The reports must contain a description of the nature and extent of the research facility's adherence to this subchapter, must identify specifically any departures from the provisions of title 9, chapter I, subchapter A--Animal Welfare, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding that activity;

(4) Review, and, if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees;

(5) Make recommendations to the Institutional Official regarding any aspect of the research facility's animal program, facilities, or personnel training;

(6) Review and approve, require modifications in (to secure approval), or withhold approval of those components of proposed activities related to the care and use of animals, as specified in paragraph (d) of this section;

(7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities; and

(8) Be authorized to suspend an activity involving animals in accordance with the specifications set forth in paragraph (d)(6) of this section.

(d) IACUC review of activities involving animals. (1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing; *Provided, however,* that field studies as defined in part 1 of this subchapter are exempt from this requirement. Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements:

(i) Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals;

(ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e. g., the Animal Welfare Information Center, used to determine that alternatives were not available;

(iii) The principal investigator has provided written assurance that the activities do not unnecessarily duplicate previous experiments;

(iv) Procedures that may cause more than momentary or slight pain or distress to the animals will:

(A) Be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time;

(B) Involve, in their planning, consultation with the attending veterinarian or his or her designee;

(C) Not include the use of paralytics without anesthesia;

(v) Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure;

(vi) The animals' living conditions will be appropriate for their species in accordance with part 3 of this subchapter, and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by the attending veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied;

(vii) Medical care for animals will be available and provided as necessary by a qualified veterinarian;

(viii) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures;

(ix) Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices. All survival surgery will be performed using aseptic procedures, including surgical gloves, masks, sterile instruments, and aseptic techniques. Major operative procedures on non-rodents will be conducted only in facilities intended for that purpose which shall be operated and maintained under aseptic conditions. Non-major operative procedures and all surgery on rodents do not require a dedicated facility, but must be performed using aseptic procedures. Operative procedures conducted at field sites need not be performed in dedicated facilities, but must be performed using aseptic procedures;

(x) No animal will be used in more than one major operative procedure from which it is allowed to recover, unless:

(A) Justified for scientific reasons by the principal investigator, in writing;

(B) Required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the attending veterinarian; or

(C) In other special circumstances as determined by the Administrator on an individual basis. Written requests and supporting data should be sent to the Animal and Plant Health Inspection Service, Animal Care, 4700 River Road, Unit 84, Riverdale, Maryland 20737-1234;

(xi) Methods of euthanasia used must be in accordance with the definition of the term set forth in 9 CFR part 1, Sec. 1.1 of this subchapter, unless a deviation is justified for scientific reasons, in writing, by the investigator.

(2) Prior to IACUC review, each member of the Committee shall be provided with a list of proposed activities to be reviewed. Written descriptions of all proposed activities that involve the care and use of animals shall be available to all IACUC members, and any member of the IACUC may obtain, upon request, full Committee review of those activities. If full Committee review is not requested, at least one member of the IACUC, designated by the chairman and qualified to conduct the review, shall review those activities, and shall have the authority to approve, require modifications in (to secure approval), or request full Committee review of any of those activities. If full Committee review is requested for a proposed activity, approval of that activity may be granted only after review, at a convened meeting of a quorum of the IACUC, and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity), except to provide information requested by the IACUC, nor may a member who has a conflicting interest contribute to the constitution of a quorum;

(3) The IACUC may invite consultants to assist in the review of complex issues arising out of its review of proposed activities. Consultants may not approve or withhold approval of an activity, and may not vote with the IACUC unless they are also members of the IACUC;

(4) The IACUC shall notify principal investigators and the research facility in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the principal investigator an opportunity to respond in person or in writing. The IACUC may reconsider its decision, with documentation in Committee minutes, in light of the information provided by the principal investigator;

(5) The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than annually;

(6) The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the Committee. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present;

(7) If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any Federal agency funding that activity; and

(8) Proposed activities and proposed significant changes in ongoing activities that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the research facility. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.

(e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following:

(1) Identification of the species and the approximate number of animals to be used;

(2) A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used;

(3) A complete description of the proposed use of the animals;

(4) A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals; and

(5) A description of any euthanasia method to be used.

[54 FR 36147, August 31, 1989, as amended by 59 FR 67611, Dec. 30, 1994;
63 FR 62926, Nov. 10, 1998]

Sec. 2.32 Personnel qualifications.

(a) It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel.

(b) Training and instruction shall be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility's responsibilities under this section and Sec. 2.31.

(c) Training and instruction of personnel must include guidance in at least the following areas:

(1) Humane methods of animal maintenance and experimentation, including:

(i) The basic needs of each species of animal;

(ii) Proper handling and care for the various species of animals used by the facility;

(iii) Proper pre-procedural and post-procedural care of animals; and

(iv) Aseptic surgical methods and procedures;

(2) The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress;

(3) Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;

(4) Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act;

(5) Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:

(i) On appropriate methods of animal care and use;

(ii) On alternatives to the use of live animals in research;

(iii) That could prevent unintended and unnecessary duplication of research involving animals; and

(iv) Regarding the intent and requirements of the Act.

Sec. 2.33 Attending veterinarian and adequate veterinary care.

(a) Each research facility shall have an attending veterinarian who shall provide adequate veterinary care to its animals in compliance with this section:

(1) Each research facility shall employ an attending veterinarian under formal arrangements. In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility;

(2) Each research facility shall assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use; and

(3) The attending veterinarian shall be a voting member of the IACUC; *Provided, however,* That a research facility with more than one Doctor of Veterinary Medicine (DVM) may appoint to the IACUC another DVM with delegated program responsibility for activities involving animals at the research facility.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:

(1) The availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter;

(2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care;

(3) Daily observation of all animals to assess their health and well-being; *Provided, however,* That daily observation of animals may be accomplished by someone other than the attending veterinarian; and *Provided, further,* That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian;

(4) Guidance to principal investigators and other personnel involved in the care and use of animals regarding handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia; and

(5) Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures.

Sec. 2.34 [Reserved]

Sec. 2.35 Record keeping requirements.

(a) The research facility shall maintain the following IACUC records:

(1) Minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee deliberations;

(2) Records of proposed activities involving animals and proposed significant changes in activities involving animals, and whether IACUC approval was given or withheld; and

(3) Records of semiannual IACUC reports and recommendations (including minority views), prepared in accordance with the requirements of Sec. 2.31(c)(3) of this subpart, and forwarded to the Institutional Official.

(b) Every research facility shall make, keep, and maintain records or forms which fully and correctly disclose the following information concerning each live dog or cat purchased or otherwise acquired, owned, held, or otherwise in their possession or under their control, transported, euthanized, sold, or otherwise disposed of by the research facility. The records shall include any offspring born of any animal while in the research facility's possession or under its control:

(1) The name and address of the person from whom a dog or cat was purchased or otherwise acquired, whether or not the person is required to be licensed or registered under the Act;

(2) The USDA license or registration number of the person if he or she is licensed or registered under the Act;

(3) The vehicle license number and state, and the driver's license number and state of the person, if he or she is not licensed or registered under the Act;

(4) The date of acquisition of each dog or cat;

(5) The official USDA tag number or tattoo assigned to each dog or cat under Sec. 2.38(g) of this subpart;

(6) A description of each dog or cat which shall include:

(i) The species and breed or type of animal;

(ii) The sex;

(iii) The date of birth or approximate age; and

(iv) The color and any distinctive markings;

(7) Any identification number or mark assigned to each dog or cat by the research facility.

(c) In addition to the information required to be kept and maintained by every research facility concerning each live dog or cat under paragraph (a) of this section, every research facility transporting, selling, or otherwise disposing of any live dog or cat to another person, shall make and maintain records or forms which fully and correctly disclose the following information:

(1) The name and address of the person to whom a live dog or cat is transported, sold, or otherwise disposed of;

(2) The date of transportation, sale, euthanasia, or other disposition of the animal; and

(3) The method of transportation, including the name of the initial carrier or intermediate handler, or if a privately owned vehicle is used to transport the dog or cat, the name of the owner of the privately owned vehicle.

(d)(1) The USDA Interstate and International Certificate of Health Examination for Small Animals (APHIS Form 7001/VS Form 18-1) and Record of Acquisition and Dogs and Cats on Hand (APHIS Form

7005/VS Form 18-5) are forms which may be used by research facilities to keep and maintain the information required by paragraph (b) of this section.

(2) The USDA Interstate and International Certificate of Health Examination for Small Animals (APHIS Form 7001/VS Form 18-1) and Record of Disposition of Dogs and Cats (APHIS Form 7006/VS Form 18-6) are forms which may be used by research facilities to keep and maintain the information required by paragraph (c) of this section.

(e) One copy of the record containing the information required by paragraphs (b) and (c) of this section shall accompany each shipment of any live dog or cat sold or otherwise disposed of by a research facility; *Provided, however,* That, except as provided in Sec. 2.133 of this part, information that indicates the source and date of acquisition of any dog or cat need not appear on the copy of the record accompanying the shipment. One copy of the record containing the information required by paragraphs (b) and (c) of this section shall be retained by the research facility.

(f) All records and reports shall be maintained for at least three years. Records that relate directly to proposed activities and proposed significant changes in ongoing activities reviewed and approved by the IACUC shall be maintained for the duration of the activity and for an additional three years after completion of the activity. All records shall be available for inspection and copying by authorized APHIS or funding Federal agency representatives at reasonable times. APHIS inspectors will maintain the confidentiality of the information and will not remove the materials from the research facilities' premises unless there has been an alleged violation, they are needed to investigate a possible violation, or for other enforcement purposes. Release of any such materials, including reports, summaries, and photographs that contain trade secrets or commercial or financial information that is privileged or confidential will be governed by applicable sections of the Freedom of Information Act. Whenever the Administrator notifies a research facility in writing that specified records shall be retained pending completion of an investigation or proceeding under the Act, the research facility shall hold those records until their disposition is authorized in writing by the Administrator.

[54 FR 36147, Aug. 31, 1989, as amended at 58 FR 39129, July 22, 1993;
60 FR 13895, Mar. 15, 1995]

Sec. 2.36 Annual report.

(a) The reporting facility shall be that segment of the research facility, or that department, agency, or instrumentality of the United States, that uses or intends to use live animals in research, tests, experiments, or for teaching. Each reporting facility shall submit an annual report to the AC Regional Director for the State where the facility is located on or before December 1 of each calendar year. The report shall be signed and certified by the CEO or Institutional Official, and shall cover the previous Federal fiscal year.

(b) The annual report shall:

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

(2) Assure that each principal investigator has considered alternatives to painful procedures;

(3) Assure that the facility is adhering to the standards and regulations under the Act, and that it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report. In addition to identifying the IACUC-approved exceptions, this summary must include a brief explanation of the exceptions, as well as the species and number of animals affected;

(4) State the location of all facilities where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes;

(5) State the common names and the numbers of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. Routine procedures (e.g., injections, tattooing, blood sampling) should be reported with this group;

(6) State the common names and the numbers of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used;

(7) State the common names and the numbers of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used shall be attached to the annual report;

(8) State the common names and the numbers of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.

[54 FR 36147, Aug. 31, 1989, as amended at 63 FR 62926, Nov. 10, 1998]

Sec. 2.37 Federal research facilities.

Each Federal research facility shall establish an Institutional Animal Care and Use Committee which shall have the same composition, duties, and responsibilities required of nonfederal research facilities by Sec. 2.31 with the following exceptions:

(a) The Committee shall report deficiencies to the head of the Federal agency conducting the research rather than to APHIS; and

(b) The head of the Federal agency conducting the research shall be responsible for all corrective action to be taken at the facility and for the granting of all exceptions to inspection protocol.

Sec. 2.38 Miscellaneous.

(a) *Information as to business: furnishing of same by research facilities.* Each research facility shall furnish to any APHIS official any information concerning the business of the research facility which the APHIS official may request in connection with the enforcement of the provisions of the Act, the regulations, and the standards in this subchapter. The information shall be furnished within a reasonable time and as may be specified in the request for information.

(b) *Access and inspection of records and property.* (1) Each research facility shall, during business hours, allow APHIS officials:

(i) To enter its place of business;

(ii) To examine records required to be kept by the Act and the regulations in this part;

(iii) To make copies of the records;

(iv) To inspect the facilities, property, and animals, as the APHIS officials consider necessary to enforce the provisions of the Act, the regulations, and the standards in this subchapter; and

(v) To document, by the taking of photographs and other means, conditions and areas of noncompliance.

(2) The use of a room, table or other facilities necessary for the proper examination of the records and for inspection of the property or animals shall be extended to APHIS officials by the research facility.

(c) *Publication of names of research facilities subject to the provisions of this part.* APHIS will publish lists of research facilities registered in accordance with the provisions of this subpart in the Federal Register. The lists may be obtained upon request from the AC Regional Director.

(d) *Inspection for missing animals.* Each research facility shall allow, upon request and during business hours, police or officers of other law enforcement agencies with general law enforcement authority (not those agencies whose duties are limited to enforcement of local animal regulations) to enter its place of business to inspect animals and records for the purpose of seeking animals that are missing, under the following conditions:

(1) The police or other law officer shall furnish to the research facility a written description of the missing animal and the name and address of its owner before making a search;

(2) The police or other law officer shall abide by all security measures required by the research facility to prevent the spread of disease, including the use of sterile clothing, footwear, and masks where required, or to prevent the escape of an animal.

(e) *Confiscation and destruction of animals.* (1) If an animal being held by a research facility is not being used to carry out research, testing, or experimentation, and is found by an APHIS official to be suffering as a result of the failure of the research facility to comply with any provision of the regulations or the standards set forth in this subchapter, the APHIS official shall make a reasonable effort to notify the research facility of the condition of the animal(s) and request that the condition be corrected and that adequate care be given to alleviate the animal's suffering or distress, or that the animal(s) be destroyed by euthanasia. In the event that the research facility refuses to comply with this request, the APHIS official may confiscate the animal(s) for care, treatment, or disposal as indicated in paragraph (e)(2) of this section, if, in the opinion of the Administrator, the circumstances indicate the animal's health is in danger.

(2) In the event that the APHIS official is unable to locate or notify the research facility as required in this section, the APHIS official shall contact a local police or other law officer to accompany him or her to the premises and shall provide for adequate care when necessary to alleviate the animal's suffering. If, in the opinion of the Administrator, the condition of the animal(s) cannot be corrected by this temporary care, the APHIS official shall confiscate the animal(s).

(3) Confiscated animals may be placed, by sale or donation, with other registrants or licensees that comply with the standards and regulations and can provide proper care, or they may be euthanized. The research facility from which the animals were confiscated shall bear all costs incurred in performing the placement or euthanasia activities authorized by this section.

(f) *Handling.* (1) Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.

(2)(i) Physical abuse shall not be used to train, work, or otherwise handle animals.

(ii) Deprivation of food or water shall not be used to train, work, or otherwise handle animals; *Provided, however:* That the short-term withholding of food or water from animals, when specified in an IACUC-approved activity that includes a description of monitoring procedures, is allowed by these regulations.

(g) *Identification of dogs and cats.* (1) All live dogs or cats, including those from any exempt source, delivered for transportation, transported, purchased or otherwise acquired. sold, or disposed of by a research facility, shall be identified at the time of such delivery for transportation, purchase, sale, disposal, or acquisition in one of the following ways:

(i) By the official tag or tattoo which was affixed to the animal at the time it was acquired by the research facility, as required by this section; or

(ii) By a tag, tattoo, or collar, applied to the live dog or cat by the research facility and which individually identifies the dog or cat by number.

(2) All official tag or tattoo numbers shall be correctly listed in the records of purchase, acquisition, disposal, or sale which shall be maintained in accordance with Sec. 2.35.

(3) Unweaned puppies or kittens need not be individually identified while they are maintained as a litter with their dam in the same primary enclosure, provided the dam has been individually identified.

(4) The official tag shall be made of a durable alloy such as brass, bronze, or steel, or of a durable plastic. Aluminum of a sufficient thickness to assure the tag is durable and legible may also be used. The tag may be circular in shape and not less than 1 1/4 inches in diameter, or oblong and flat in shape and not less than 2 inches by 3/4 inch, and riveted to an acceptable collar.

(5) Each tag shall have the following information embossed or stamped on so that it is easily readable:

(i) The letters ``USDA";

(ii) Numbers identifying the State and dealer, exhibitor, or research facility (e.g., 39-AB); and

(iii) Numbers identifying the animal (e.g., 82488).

(6) Official tags shall be serially numbered and shall be applied to dogs or cats in the manner set forth in this section in as close to consecutive numerical order as possible. No tag number shall be used to identify more than one animal or shall be reused within a 5-year period.

(7) Research facilities may obtain, at their own expense, official tags from commercial tag manufacturers.[2] At the time the research facility is registered, the Department will assign identification letters and numbers to be used on the official tags.

(8) Each research facility shall be held accountable for all official tags acquired. In the event an official tag is lost from a dog or cat while in the possession of a research facility, the facility shall make a diligent effort to locate and reapply the tag to the proper animal. If the lost tag is not located, the research facility shall affix another official tag to the animal in the manner prescribed in this section and record the tag number on the official records.

(9) When a dog or cat wearing or identified by an official tag arrives at a research facility, the facility may continue to use that tag to identify the dog or cat or the tag may be replaced as indicated in paragraph (g)(1) of this section. All tags removed by a research facility shall be retained and disposed of as indicated in this section.

(10) Where a dog or cat to which is affixed or which is identified by an official tag is euthanized, or dies from other causes, the research facility shall remove and retain the tag for the required period, as set forth in paragraph (g)(11) of this section.

(11) All official tags removed and retained by a research facility shall be held until called for by an APHIS official or for a period of 1 year.

(12) When official tags are removed from animals for disposal, the tags must be disposed of so as to preclude their reuse for animal identification. No animal identification number shall be used within any 5-year period following its previous use.

(h) *Health certification.* (1) No research facility, including a Federal research facility, shall deliver to any intermediate handler or carrier for transportation, in commerce, or shall transport in commerce any dog, cat, or nonhuman primate unless the dog, cat, or nonhuman primate is accompanied by a health certificate executed and issued by a licensed veterinarian. The health certificate shall state that:

(i) The licensed veterinarian inspected the dog, cat, or nonhuman primate on a specified date which shall not be more than 10 days prior to the delivery of the dog, cat, or nonhuman primate for transportation; and

(ii) When so inspected, the dog, cat, or nonhuman primate appeared to the licensed veterinarian to be free of any infectious disease or physical abnormality which would endanger the animal(s) or other animals or endanger public health.

[2] A list of the commercial manufacturers who produce these tags and are known to the Department may be obtained from the AC Regional Director. Any manufacturer who desires to be included in the list should notify the Administrator.

(2) The Secretary may provide exceptions to the health certification requirement on an individual basis for animals shipped to a research facility for purposes of research, testing, or experimentation when the research facility requires animals not eligible for certification. Requests should be addressed to the Animal and Plant Health Inspection Service, Animal Care, 4700 River Road, Unit 84, Riverdale, Maryland 20737-1234.

(3) The U.S. Interstate and International Certificate of Health Examination for Small Animals (APHIS Form 7001/VS Form 18-1) may be used for health certification by a licensed veterinarian as required by this section.

(i) *Holding of animals.* If any research facility obtains prior approval of the AC Regional Director, it may arrange to have another person hold animals: *Provided,* That:

(1) The other person agrees, in writing, to comply with the regulations in this part and the standards in part 3 of this subchapter, and to allow inspection of the premises by an APHIS official during business hours;

(2) The animals remain under the total control and responsibility of the research facility; and

(3) The Institutional Official agrees, in writing, that the other person or premises is a recognized animal site under its research facility registration. APHIS Form 7009/VS Form 18-9 shall be used for approval.

(j) *Holding period.* Research facilities that obtain dogs and cats from sources other than dealers, exhibitors, and exempt persons shall hold the animals for 5 full days, not including the day of acquisition, after acquiring the animal, excluding time in transit, before they may be used by the facility. Research facilities shall comply with the identification of animals requirements set forth in Sec. 2.38(g) during this period.

(k) *Compliance with standards and prohibitions.* (1) Each research facility shall comply in all respects with the regulations set forth in subpart C of this part and the standards set forth in part 3 of this subchapter for the humane handling, care, treatment, housing, and transportation of animals; *Provided, however,* That exceptions to the standards in part 3 and the provisions of subpart C of this part may be made only when such exceptions are specified and justified in the proposal to conduct the activity and are approved by the IACUC.

(2) No person shall obtain live random source dogs or cats by use of false pretenses, misrepresentation, or deception.

(3) No person shall acquire, buy, sell, exhibit, use for research, transport, or offer for transportation, any stolen animal.

(4) Each research facility shall comply with the regulations set forth in Sec. 2.133 of subpart I of this part.

[54 FR 36147, Aug. 31, 1989, as amended at 58 FR 39129, July 22, 1993;
59 FR 67612, Dec. 30, 1994; 60 FR 13895, Mar. 15, 1995; 63 FR 62926,
Nov. 10, 1998]

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

4700 River Road
Riverdale, MD 20737

SUBJECT: Performance-Based Standards for IACUC's

TO: Veterinary Medical Officers
Animal Care

In August, 1996, as part of Animal Care's Strategic Direction, we asked your opinions about two performance-based standards; opportunity for exercise for dogs and environmental enrichment for nonhuman primates. As you know, the response from the latter resulted in the formation of a team that has develop policy guidelines for primate enrichment that will soon be published in the *Federal Register* for comment. These were presented to you in draft form for comment at the National Work Conference.

Now it's time to address the third area of performance-based standards -- IACUC regulations. Please give us your opinions about IACUCs on the attached questionnaire. The information you provide will help determine how we can improve the IACUC regulations, policies, and inspection procedures.

Try to base your answers on your experience inspecting research facilities. If you don't have first hand knowledge of the regulations or a part of the process mentioned, or have no opinion, just circle "N/A" for that question. ***We must hear from every VMO for purposes of statistical reliability and to get the total national picture.*** Your answers will be treated confidentially and reported only as group statistics and lists of anonymous comments.

Return the form in the envelope provided by **July 19, 1999**, to Natalie Roberts, APHIS, Policy and Program Development, 4700 River Road, Unit 120, Riverdale, MD 20737. If you have any questions about the survey or would like to help interpret the results, you may call Bob Willems at (919) 856-4577 or Natalie Roberts at (301) 734-8937, or e-mail either of them on Lotus Notes.

W. Ron DeHaven
Deputy Administrator
Animal Care

Enclosure

APHIS:AC:WRDeHaven:rf:734-4980-6-24-99:c:\ac\iacuc memo.lwp

APHIS - Protecting American Agriculture

An Equal Opportunity Employer

This survey's purpose is to evaluate the effectiveness of the performance-based regulations for Institutional Animal Care and Use Committees (IACUCs) in research facilities (9CFR 2.30--2.38). Please return the completed form in the envelope provided to Natalie Roberts, APHIS, PPD, 4700 River Road, Unit 120, Riverdale, MD 20737 by July 19, 1999. If you have questions, call her at (301) 734-8937 or Bob Willems at (919) 856-4577.

A. Your Experience and Workload

1. What Region are you in? *(Circle one)* **East** **Central** **West**
2. How many research facilities do you currently inspect each year? _____
3. What year did you begin inspecting research facilities? _____
4. Approximately what percentage of your work year is spent on research facilities? _____ %

B. Your Opinion of Overall Effectiveness

	Greatly Worsened	Slightly Worsened	No Effect	Slightly Improved	Greatly Improved	N/A
5. In your opinion, what has been the effect of the 1991 IACUC regulations on the welfare of research animals? *(Circle one)*	1	2	3	4	5	

	Very Low	Medium Low	Medium	Medium High	Very High	
6. How would you rate the effectiveness of the IACUC regulations in ensuring the welfare of animals?	1	2	3	4	5	N/A
7. How would you rate the overall effectiveness of the IACUCs at your research facilities?	1	2	3	4	5	N/A
8. How would you rate Animal Care's enforcement of the IACUC regulations?	1	2	3	4	5	N/A

C. Your Opinion on Specific IACUC Functions

	Very Low	Medium Low	Medium	Medium High	Very High	
9. How would you rate the effectiveness of IACUCs in fulfilling their requirements in the following areas?						
a. Conducting inspections.	1	2	3	4	5	N/A
b. Reviewing protocols.	1	2	3	4	5	N/A
c. Monitoring protocols.	1	2	3	4	5	N/A
d. Monitoring and evaluating painful procedures.	1	2	3	4	5	N/A
e. Reviewing and approving SOPs.	1	2	3	4	5	N/A
f. Reviewing complaints.	1	2	3	4	5	N/A
g. Reviewing the humane care and use program.	1	2	3	4	5	N/A
h. Holding meetings.	1	2	3	4	5	N/A
i. Meeting membership requirements.	1	2	3	4	5	N/A
j. Meeting attendance requirements.	1	2	3	4	5	N/A
k. Documenting the program.	1	2	3	4	5	N/A
l. Reporting to the Institutional Official.	1	2	3	4	5	N/A

D. Your Experience and Opinions on Specific IACUC Issues

10. Of the facilities you inspect, roughly what percentage have had a problem with:

a. Designated reviewer (Expedited review) of protocols.	**%**	N/A
b. Review of painful procedures.	**%**	N/A
c. Search for alternatives.	**%**	N/A
d. Avoiding unnecessary duplication.	**%**	N/A
e. Documentation (*including SOPs and meeting minutes)*.	**%**	N/A
f. Facility inspection by IACUCs *(attendance at, announced vs. unannounced)*.	**%**	N/A
g. Balance in decision making process *(undue influence, handling difficult issues)*.	**%**	N/A
h. Monitoring for compliance *(with approved protocols and SOPs)*.	**%**	N/A
i. Membership *(turnover, quality, unaffiliated member)*.	**%**	N/A

11. What other specific issues have you encountered that need to be addressed?
(Please explain. Use the back on any of these if you need more space.)

12. What particularly successful innovations have you observed among some of your facilities that are worthy of sharing with other facilities?

13. How can the performance standards for IACUCs be improved?

14. How can we improve the way that we inspect IACUCs?

15. What training do you feel would be useful for IACUCs?

16. What training do you feel you need?

CONTROL NUMBER: _____

The purpose of this control number is to track who has responded and who has not. Be sure to include this page when you mail in your questionnaire. It will be torn off and discarded in PPD when your questionnaire comes in. If you do not respond, we will call until you do.

Table 1: Survey on Effectiveness of IACUC Regulations — Number of Responses (Frequencies)

A. Your Experience and Workload

		East	Central	West	Total
1. What Region are you in?		22	8	10	40
2. How many research facilities do you currently inspect each year?		1,056	226	380	1,662
3. What year did you begin inspecting research facilities?	≤ 1991	16	6	6	28
	m 1992	6	2	4	12
4. Approximately what percentage of your work year is spent on research facilities?	Light 0-25%	8	4	1	13
	Medium 26-75%	9	3	7	19
	Heavy 76-100%	4	1	2	7
	N/A or blank	1	0	0	1

B. Your Opinion of Overall Effectiveness

	Greatly Worsened	Slightly Worsened	No Effect	Slightly Improved	Greatly Improved	Sub Total	N/A or blank	Total
5. In your opinion, what has been the effect of the 1991 IACUC regulations on the welfare of research animals?	0	0	2	11	19	32	8	40

	Very Low	Medium Low	Medium	Medium High	Very High	Sub Total	N/A or blank	Total
6. How would you rate the effectiveness of the IACUC regulations in ensuring the welfare of animals?	0	2	16	16	5	39	1	40
7. How would you rate the overall effectiveness of the IACUCs at your research facilities?	0	3	12	18	6	39	1	40
8. How would you rate Animal Care's enforcement of the IACUC regulations?	2	2	10	16	8	38	2	40

C. Your Opinion on Specific IACUC Functions

9. How would you rate the effectiveness of IACUCs in fulfilling their requirements in the following areas?

	Very Low	Medium Low	Medium	Medium High	Very High	Sub Total	N/A or blank	Total
a. Conducting inspections.	0	5	9	18	6	38	2	40
b. Reviewing protocols.	1	1	13	17	7	39	1	40
c. Monitoring protocols.	4	11	16	7	1	39	1	40
d. Monitoring and evaluating painful procedures.	2	8	18	8	3	39	1	40

Table 1: Survey on Effectiveness of IACUC Regulations Number of Responses (Frequencies)

C. Your Opinion on Specific IACUC Functions (CONT'D)

9. How would you rate the effectiveness of IACUCs in fulfilling their requirements in the following areas?

	Very Low	Medium Low	Medium	Medium High	Very High	Sub Total	N/A or blank	Total
e. Reviewing and approving SOPs.	1	1	20	11	6	39	1	40
f. Reviewing complaints.	1	3	17	12	4	37	3	40
g. Reviewing the humane care and use program.	0	6	17	14	2	39	1	40
h. Holding meetings.	0	0	9	24	6	39	1	40
i. Meeting membership requirements.	0	0	10	19	10	39	1	40
j. Meeting attendance requirements.	1	0	16	13	9	39	1	40
k. Documenting the program.	0	3	22	12	2	39	1	40
l. Reporting to the Institutional Official.	0	1	15	19	3	38	2	40

D. Your Experience and Opinions on Specific IACUC Issues

10. Of the facilities you inspect, roughly what percentage have had a problem with:

	0-20%	21-50%	51-100%	Sub Total	N/A or blank	Total
a. Designated reviewer (Expedited review) of protocols.	32	3	2	37	3	40
b. Review of painful procedures.	19	11	8	38	2	40
c. Search for alternatives.	13	11	14	38	2	40
d. Avoiding unnecessary duplication.	28	4	5	37	3	40
e. Documentation (*including SOPs and meeting minutes)*.	24	10	4	38	2	40
f. Facility inspection by IACUCs *(attendance at, announced vs. unannounced)*.	26	10	1	37	3	40
g. Balance in decision making process *(undue influence, handling difficult issues)*.	26	8	3	37	3	40
h. Monitoring for compliance *(with approved protocols and SOPs)*.	15	16	7	38	2	40
i. Membership *(turnover, quality, unaffiliated member)*.	26	11	1	38	2	40

Table 2: Survey on Effectiveness of IACUC Regulations

Percentage of Responses

A. Your Experience and Workload

		East	Central	West	Total*
1. What Region are you in?		55%	20%	25%	100%
2. How many research facilities do you currently inspect each year?		64%	14%	23%	100%
3. What year did you begin inspecting research facilities?	**≤ 1991**				70%
	≥ 1992				30%
4. Approximately what percentage of your work year is spent on research facilities?	**Light 0-25%**				33%
	Medium 26-75%				49%
	Heavy 76-100%				18%

B. Your Opinion of Overall Effectiveness

	Greatly Worsened	Slightly Worsened	No Effect	Slightly Improved	Greatly Improved	Total
5. In your opinion, what has been the effect of the 1991 IACUC regulations on the welfare of research animals?	0%	0%	6%	34%	59%	100%

	Very Low	Medium Low	Medium	Medium High	Very High	Total
6. How would you rate the effectiveness of the IACUC regulations in ensuring the welfare of animals?	0%	5%	41%	41%	13%	100%
7. How would you rate the overall effectiveness of the IACUCs at your research facilities?	0%	8%	31%	46%	15%	100%
8. How would you rate Animal Care's enforcement of the IACUC regulations?	5%	5%	26%	42%	21%	100%

C. Your Opinion on Specific IACUC Functions

9. How would you rate the effectiveness of IACUCs in fulfilling their requirements in the following areas?

	Very Low	Medium Low	Medium	Medium High	Very High	Total
a. Conducting inspections.	0%	13%	24%	47%	16%	100%
b. Reviewing protocols.	3%	3%	33%	44%	18%	100%
c. Monitoring protocols.	10%	28%	41%	18%	3%	100%
d. Monitoring and evaluating painful procedures.	5%	21%	46%	21%	8%	100%
e. Reviewing and approving SOPs.	3%	3%	51%	28%	15%	100%
f. Reviewing complaints.	3%	8%	46%	32%	11%	100%
g. Reviewing the humane care and use program.	0%	15%	44%	36%	5%	100%
h. Holding meetings.	0%	0%	23%	62%	15%	100%
i. Meeting membership requirements.	0%	0%	26%	49%	26%	100%

Table 2: Survey on Effectiveness of IACUC Regulations — Percentage of Responses

C. Your Opinion on Specific IACUC Functions

9. How would you rate the effectiveness of IACUCs in fulfilling their requirements in the following areas?

j. Meeting attendance requirements.	3%	0%	41%	33%	23%	100%
k. Documenting the program.	0%	8%	56%	31%	5%	100%
l. Reporting to the Institutional Official.	0%	3%	39%	50%	8%	100%

D. Your Experience and Opinions on Specific IACUC Issues

10. Of the facilities you inspect, roughly what percentage have had a problem with:

	0-20%	21-50%	51-100%	Total
a. Designated reviewer (Expedited review) of protocols.	86%	8%	5%	100%
b. Review of painful procedures.	50%	29%	21%	100%
c. Search for alternatives.	34%	29%	37%	100%
d. Avoiding unnecessary duplication.	76%	11%	14%	100%
e. Documentation (*including SOPs and meeting minutes)*.	63%	26%	11%	100%
f. Facility inspection by IACUCs *(attendance at, announced vs. unannounced)*.	70%	27%	3%	100%
g. Balance in decision making process *(undue influence, handling difficult issues)*.	70%	22%	8%	100%
h. Monitoring for compliance *(with approved protocols and SOPs)*.	39%	42%	18%	100%
i. Membership *(turnover, quality, unaffiliated member)*.	68%	29%	3%	100%

Table 3: Survey on Effectiveness of IACUC Regulations — Average Scores

B. Your Opinion of Overall Effectiveness

	Very Low (1 point)	Medium Low (2 points)	Medium (3 points)	Medium High (4 points)	Very High (5 points)	Total Responses	Total points	Avg. Score
6. How would you rate the effectiveness of the IACUC regulations in ensuring the welfare of animals?	0	4	48	64	25	39	141	3.6
7. How would you rate the overall effectiveness of the IACUCs at your research facilities?	0	6	36	72	30	39	144	3.7
8. How would you rate Animal Care's enforcement of the IACUC regulations?	2	4	30	64	40	38	140	3.7

C. Your Opinion on Specific IACUC Functions

9. How would you rate the effectiveness of IACUCs in fulfilling their requirements in the following areas?

	Very Low (1 point)	Medium Low (2 points)	Medium (3 points)	Medium High (4 points)	Very High (5 points)	Total Responses	Total points	Avg. Score
a. Conducting inspections.	0	10	27	72	30	38	139	3.7
b. Reviewing protocols.	1	2	39	68	35	39	145	3.7
c. Monitoring protocols.	4	22	48	28	5	39	107	2.7
d. Monitoring and evaluating painful procedures.	2	16	54	32	15	39	119	3.1
e. Reviewing and approving SOPs.	1	2	60	44	30	39	137	3.5
f. Reviewing complaints.	1	6	51	48	20	37	126	3.4
g. Reviewing the humane care and use program.	0	12	51	56	10	39	129	3.3
h. Holding meetings.	0	0	27	96	30	39	153	3.9
i. Meeting membership requirements.	0	0	30	76	50	39	156	4.0
j. Meeting attendance requirements.	1	0	48	52	45	39	146	3.7
k. Documenting the program.	0	6	66	48	10	39	130	3.3
l. Reporting to the Institutional Official.	0	2	45	76	15	38	138	3.6

Appendix D

Table 4: Responses to Q11. What other specific issues have you encountered that need to be addressed?

Topic	***Respondents' comments regarding other issues encountered.*** *(Comments with multiple topics were split up and sorted separately.)*
Attitude	The source of most of the problems I have are with institutional attitude. If a facility is trying to follow the spirit of the law as well as the letter of [it, and] the IACUC is truly functional and independent, they will listen to suggestions and really try to be in compliance. If the institution doesn't take this attitude from the top down, it doesn't matter how much training or instruction they get. There is no way at this time that we can "make" a committee do a proper thorough and thoughtful review of a protocol. If a committee wants to rubber stamp protocols or leave them all to a designated reviewer and the protocols follow the regulations (i's dotted and t's crossed) there's not a whole lot we can do.
Reviews	2) rubber stamp reviews;
Attitude	I feel that the IACUC has to answer to government oversight - now they [PI's] get away with "anything" the IACUC approves;
Authority	IACUCs' feeling that they do not have the power to carry out the regulations due to political pressures of various facilities, i.e., strong administrative and research (PI) personnel.
Authority	IACUCs' authority to correct non-compliant items. In some cases the IACUC is just a "figurehead" for the institutional official and has no authority (or funding) to make corrections.
Responsibility	2) Legal separation of responsibility between collaborating facilities.
Responsibility	(3) One facility being inspected by another's IACUC - who has responsibility?
Responsibility	5) poor coordination between multiple registrants on jointly sponsored or conducted research.
Members	Most of the problems I've encountered at research facilities are a function of veterinary incompetence or "prima donna" PI's (or both.) IACUCs are generally well-meaning but sometimes led astray by above individuals.
Members	Inadequate or lack of interest on the part of attending vets to adhere to the IACUC requirements, including CEO's of biotech companies.
Members	4) too much turnover on IACUC members never get really good;
Members, outside	Outside member - not reflecting the local community.
Members	(2) "Useless" outside member - doesn't understand science, doesn't question research or ask for explanations.
Small facilities	Smaller companies have fewer members and IACUC chair may be owner/researcher. Conflict of interest exists. He/she usually will not or may not make changes if it affects business.
Small facilities	IACUC functions very well at major research facilities. Problems are at the small private companies; they don't understand IACUC and functions.
Small facilities	Conflict of interest in small facilities with a limited pool of internal members.

Table 4: Responses to Q11. What other specific issues have you encountered that need to be addressed?

Topic	***Respondents' comments regarding other issues encountered.*** *(Comments with multiple topics were split up and sorted separately.)*
Small facilities	There is also a problem with some smaller facilities with conflict of interest. Members of the IACUC are working at protocols submitted by their bosses. Pretty hard sometimes for them to vote against them. For really small facilities doing minimal research its hard for them to get a proper IACUC and to go through the process often enough to get into a pattern of doing things right.
Small facilities	Small private institutions do not function well because they do not compensate their outside members and IACUC members with monetary reward.
Small facilities	Smaller facilities do not have access to examples of proper documentation for the semiannual program review and inspection.
Small facilities	The IACUC's responsibilities are not totally understood, it's been difficult with the limited inspections to make sure issues are being addressed at the small facilities.
Training	1) Ineffective training of facility personnel in IACUC matters;
Training	Adequate documentation of training of employees (caretakers, PI's, etc.)
Activities covered	1) Confusion over what activities constitute research and are regulated under the AWA.
Reporting external	IACUCs' reporting to USDA when they find problems themselves.
Reporting internal	Problem with function of IACUC (e.g., a facility attending vet and a director of animal facility limit what information and issues reach the full committee for review, consideration, etc.
Complaint process	Notification to employees of internal complaint process.
Number of animals	Inadequate justifications for numbers.
Number of animals	Clarification of documentation/determining number of animals to be used.
Number of animals	Inadequate rationale for appropriate numbers of animals.
Acquisition, disposal	(1) We have no regulation for record-keeping requirements for the acquisition and disposition of animals other than cats and dogs. Investigators are trapping animals, buying them from pet stores. How to account for animal usage?
Pain reporting	Non-reporting of category E animals - differences of opinion on reporting seizures, vomiting, cocaine administration protocols.
Pain alternatives	Continued problems with alternatives to painful procedures, searches, review of searches.
Pain alternatives	"For profit" research institutions/companies are very lax in monitoring protocols or searching for alternatives… they have timetables for product release that rarely stand in the way of "business as usual."
Pain relief	Pain relief is 24 hours per day, not just during business hours. Admitting procedures/tests may cause pain and addressing in protocol. Do search for alternatives in planning stage, not just to have protocol approved.
Pain relief	Recognition of painful procedures as such, and administering analgesics, etc. for

	painful procedures is major problem at many facilities. Performing and documenting literature searches also a problem.
Pain relief	Adequate provision (esp. duration) of post-operative analgesia.

Table 4: Responses to Q11. What other specific issues have you encountered that need to be addressed?

Topic	***Respondents' comments regarding other issues encountered.*** *(Comments with multiple topics were split up and sorted separately.)*
Pain relief	Insuring post procedure care is adequate.
Stressful procedures	“Complete use" should always mention specifically any stressful procedure (e.g., chairing and not talk around it.)
EE of NHPs	Environmental enhancement for NHPs.
Protocols	Most common issue is compliance in regards to protocol.
Protocols	3) inability of facilities to get investigators to follow their protocol;
Protocols, how to	Some confusion for how to write protocols for veterinary technician schools (they are not doing research). I just have them present an extensive syllabus for classes.
Frequency	USDA needs to find some way to reduce frequency of inspections of high-quality research facilities to less than one per year.
Frequency	Only inspecting once a year instead of twice yearly due to insufficient number of VMOs, I have seen a lot more problems in facility compliance with AWA.
Rats, mice, & birds	Time for us to do a quality inspection. When rats, mice, and birds come on, what tests & experimental practices should we be most concerned about in protocol reviews, etc. (e.g. Ascites, what else?)
Inactives	Failure of inactive registrants to comply with IACUC requirements - if no covered animals for a period (i.e., 1 year) facility registrant should be canceled.
Inactives	How to handle facilities holding no covered animals at time of IACUC 6 month review.

Appendix D

Table 5: Responses to Q12. What particularly successful innovations have you observed among some of your facilities that are worthy of sharing with other facilities?

Topic	***Respondents' comments regarding observations worthy of sharing.*** *(Comments with multiple topics were split up and sorted separately.)*
Authority	If there is a problem that seems as through there is a reluctance to get corrected, go up the line to the Institutional Official, Provost, President. It usually gets corrected quick and you've gained compliance.
Authority	Centralized animal facility with procedures performed by personnel under the authority of the lab animal program which is directly under the IACUC.
Compliance officer	Facilities with designated compliance officers have far fewer problems!!
Compliance officer	Designating an internal compliance officer/liaison who does unannounced inspections of researcher's labs.
Compliance officer	Facility has hired their own compliance officer.
Compliance officer	Hire compliance officers with authority from outside the research division.
Compliance officer	Hiring a compliance/administrative person who is focused on compliance of AWA regulations.
Consortium efficiencies	One consortium has closely interrelated the IACUC's of their various schools/hospitals to limit paperwork required of investigators.
Employee, consultants	Strong veterinary staff.
Employee, consultant	Giving perks or raises to all employees (caretaker level) who become AALAS certified. Having an animal behaviorist on staff.
Employee, consultant	Use more ad hoc consultants, like expert veterinarians, anesthesiologists, statisticians. Hire veterinarians that are board certified in specialty subjects other than lab animal or pathology - like surgery, anesthesiology, veterinary neurology, veterinary ophthalmology, veterinary internal medicine. This helps avoid the existing rut of the ACLAM and path cliques, where everyone is dependent on the good graces of the lab research world to have a career, they all have the same old tired ideas, and none of them remember what it's like to think of the animal as "the patient."
Employee, consultant	One university is utilizing its biostatistics department to improve rationale for the numbers of animals used.
Employee, consultant	Retention of biostaticians, either as a consultant or a member.
Member	Having non-voting members in the IACUC with experience in animal research.
Member, outside	I have a facility with a local animal humane activist (advocate?) on the committee. While many institutions would never do this, it works quite well at this facility. She raises questions that others don't and she's not an impediment to getting research done.
Meetings	"Electronic IACUC meetings" by geographically remote researchers and members.
PI handling	When a problem has arisen with a principal investigator, one of my IACUCs calls that

P.I. In front of the IACUC and they "grill" the P.I. (like a trial jury). LOVE IT!

Table 5: Responses to Q12. What particularly successful innovations have you observed among some of your facilities that are worthy of sharing with other facilities?

Topic	***Respondents' comments regarding observations worthy of sharing.*** *(Comments with multiple topics were split up and sorted separately.)*
Sharing information	Newsletter. Presentation by USDA - AC inspector.
Sharing information	Note: the good facilities attend meetings and share their successes, so they tend to become universal. The bad facilities don't care and aren't looking to improve.
Training	Good training program for IACUC members and pair inexperienced and experienced librarian to assist with searches.
Training	Well thought out Program of Humane Care and Use. Training requirements and programs developed to ensure adequate training.
Protocol formats	Protocol forms.
Proposal forms	Well designed animal use proposal forms.
Proposal outline	1. Research proposal outline. 2. Dog exercise document. 3. Primate enrichment documents.
Proposal questions	Rather than asking PI's to rationalize use of animals, species, and numbers as one question, asking for their rationales as three separate questions.
Proposal questions	Many of facilities have had several evolutions of protocol formats that ask better questions and got better answers.
Pain alternatives	Documentation of searches for alternatives.
Pain alternatives	Search for alternatives done in planning stage, not required after thought.
Pain alternatives	Improved template for protocol submission requiring search for alternatives, IAW policy #12.
Pain minimization	New, innovative ways of performing procedures that minimize or eliminate pain/distress adopted at some facilities, but not always shared with or accepted by others.
Protocol changes	Calling USDA to discuss protocol changes.
Protocol monitoring	Having IACUC or representatives spot or randomly check approved protocols to see if researcher is actually doing what protocol states.
Protocol monitoring	Unannounced monitoring of protocols, seminars for PI's, facilities going to and inspecting vendors as a part of program review - facilities requesting, through freedom of information, to get inspection reports of their vendors.
Protocol monitoring	Lab inspection checklists - verify knowledge of protocol of all personnel handling animals.
Protocol review	One facility has the second reviewer for a given time frame select three procedures to review and compare to the protocol. A procedure review sheet is then submitted to the IACUC.
Protocol review	Pre-committee meeting review of protocols by different members of committee

	including non-affiliated members (note this is screening for problems prior to IACUC meeting and is not an approval step.
Protocol review	Electronic IACUC Protocol Review.

Table 5: Responses to Q12. What particularly successful innovations have you observed among some of your facilities that are worthy of sharing with other facilities?

Topic	***Respondents' comments regarding observations worthy of sharing.*** *(Comments with multiple topics were split up and sorted separately.)*
Housing NHPs	Multiple exercise cages for research primates (macaques) which allow for outside exercise - all year round. Indoor - outdoor exercise cages (primary enclosures).
Housing NHPs	Pair housing non-human primates.
Isolation areas	Video cameras in isolation areas (monitoring outside) that preclude inspector having to shower-in/shower-out and avoiding outside animal contacts.

Appendix D

Table 6: Responses to Q13. How can the performance standards for IACUCs be improved?

Topic	***Respondents' comments regarding improvements for performance standards.*** *(Comments with multiple topics were split up and sorted separately.)*
No change	I don't think they need improving.
No change in standards	Present standards are good - need to be followed more closely by some facilities.
No change in standards	The end of the sentence should read… "without increasing the regulatory burden on research facilities (particularly with new documentation requirements.")
No change	It is the IACUC's responsibility to meet the standards. We should not change the standards for their convenience.
No change	The source of most of the problems I have are with institutional attitude. If a facility is trying to follow the spirit of the law as well as the letter of the IACUC is truly functional and independent, they will listen to suggestions and really try to be in compliance. If the institution doesn't take this attitude from the top down, it doesn't matter how much training or instruction they get. There is no way at this time that we can "make" a committee do a proper thorough and thoughtful review of a protocol. If a committee wants to rubber stamp protocols or leave them all to a designated reviewer and the protocols follow the regulations (i's dotted and t's crossed) there's not a whole lot we can do.
Enforcement	Stricter enforcement - put more responsibility on IACUCs for their actions.
Enforcement	1) Take seriously and enforce them for a change. 2) Stop ignoring reprisals against whistle blowers!
Frequency	Inspect more frequently.
Frequency	Need to be inspected two times a year; VMO attend one IACUC meeting of each facility.
Frequency	USDA needs to find some way to reduce frequency of inspections of high-quality research facilities to less than one per year.
Institutional Official	We need to define the job o f the IO and enforce it - I.e., institutional correspondence with USDA should come from the IO, not the vet or a tech or an IACUC member
Authority	Strengthen authority of IACUC to correct non-compliant items.
Compliance officer	More facilities need full time "compliance" officers or coordinators.
Compliance officer	Hiring a compliance/administrative person who is focused on compliance of AWA regulations.
Member positions	Require separation of positions, such as Chairman of IACUC and Director of Lab Animal Program.

Table 6: Responses to Q13. How can the performance standards for IACUCs be improved?

Topic	***Respondents' comments regarding improvements for performance standards.*** *(Comments with multiple topics were split up and sorted separately.)*
Attending veterinarian	Giving attending vets more power and insisting they get more involved directly with evaluating competency of PI's; not treat the whistle blower clause as a joke; not be rubber stamp; also need more veterinary involvement and a vet with real power by improving the lot of the primates housed indoors with minimal enrichment; somebody needs a reality check!!
Small facilities	There is also a problem with some smaller facilities with conflict of interest. Members of the IACUC are working at protocols submitted by their bosses. Pretty hard sometimes for them to vote against them. For really small facilities doing minimal research its hard for them to get a proper IACUC and to go through the process often enough to get into a pattern of doing things right.
Policy, guidelines	Clear cut instructions on exactly what we expect.
Policy, guidelines	They will do what is required. We need to be more specific. Detailed on painful procedures.
Responsibility	1) Rewrite section 2.31 to make each component of their responsibility clear.
Section 2.31	Rewrite part 2 (esp. 2.31). After 10 years, there's a lot we could do better. We need to clarify such things as: who can be an outside member, how much reimbursement can an outside member get, what is a "significant change", what is an adequate alternatives search, what are adequate minutes, what is an adequate description of procedures, what is adequate monitoring.
Policy, guidelines	Develop a policy or guidelines on how far performance standards can be interpreted. These things to be discussed and agreed with A.C. and industry personnel.
Policy, guidelines	Maybe use policies to be more specific on requirements of regulations, I.e., pain management, determination of number of animals to be used.
Training	Education of investigators as to requirements of AWA.
Training	I think we need more training for IACUC's rather than changes in performance standards. We need to attend more IACUC meetings to provide this training and clarification if necessary (we need more time!!!)
Communication	PRIMNAR meetings and regional workshop and national meetings, USDA newsletter on performance standards.
Communication	USDA announced visits (every other inspection?) would facilitate communication with IACUCs and institutional officials.
Documentation	Documentation of discussions, correspondence, facility deficiencies, etc. at meetings must be improved - too often documentation is sketchy and vague, or not readily accessible.

Table 6: Responses to Q13. How can the performance standards for IACUCs be improved?

Topic	***Respondents' comments regarding improvements for performance standards.*** *(Comments with multiple topics were split up and sorted separately.)*
Documentation, meetings	Require more specific steps in IACUC meeting process and their documentation. Need information (e.g., questions raised, answers given regarding protocol; concerns of IACUC at present). No entry can mean no problems or an omission by content.
Protocols	Common problems seen (in "bad" facilities) include: description of pre-op procedures and post-op monitoring inadequate in protocols (I like to see post-op address 3 periods - through anes. Recovery, through first few days when monitoring should be less than once daily, and through complete recovery.) Description of drug use inadequate in protocols.
Pain alternatives	3) Go back to requiring actual narrative descriptions of alternatives, as regs actually require!
Pain relief	Stand firm - pain relief, follow up on painful procedures and search for alternatives. These are not a waste of time or too big of a burden for research facilities.
Protocol form	Have a national standard animal use protocol form.
Protocol review	Common problems seen (in "bad" facilities) include: P.I. voting on own protocol in IACUC, no notification to P.I. And facility of IACUC approval of protocol (or notification is confusing as to what was actually approved),
Protocol monitoring	Have IACUC members monitor compliance with written proposals. Could be conflicts of interest, but usually the "study" does not follow the "protocol", and there is no way for a spot inspection to prove otherwise.
Reporting, semiannual	Common problems seen (in "bad" facilities) include: semiannual report not timely, semiannual report not adequate, semiannual report deficiencies not classified as significant or minor and no plan and schedule for correction, no indication that the semiannual report has been submitted to, received by, or read by the IO, I don't think anyone is enforcing the requirements to give reasons why deficiencies occurred in SA reports.
Complaints handling	Things we could do better: have IACUCs post our phone numbers, as well as theirs, for use by complainants, have IACUCs notify us when they find a problem (e.g., suspend someone), not after it's resolved, require more than a check-off statement regarding duplication, encourage IACUCs to make more use of consultants where they lack adequate expertise (this is all I can think of off the top of my head, but it's probably enough for now, right?!)
Acquisition, disposal	Add a new regulation as stated under #11 above.

Appendix D

Table 7: Responses to Q14. How can we improve the way we inspect IACUCs?

Topic	***Respondents' comments regarding inspections of IACUCs.*** *(Comments with multiple topics were split up and sorted separately.)*
Nothing	I think we are doing a good job inspecting IACUCs.
Nothing	Just work on getting them all to comply with the current regulations.
Nothing	There's very little we can do as long as the IACUC answers to no one but itself, in reality. There's actually very little we can do except see that the "mechanics" are functioning.
Attend meetings	Attend IACUC meetings.
Attend meetings	Attend more IACUC meetings.
Attend meetings	Inspectors can attend IACUC meetings once in awhile.
Attend meetings	Attend more IACUC meetings - education.
Attend meetings	Attend their meetings regularly and accompany the IACUC on facility inspections periodically.
Attend meetings	Attend meetings of the IACUCs periodically or when there are areas of concern.
Attend meetings	Inspectors should make themselves available periodically to attend an IACUC meeting at each research facility they inspect. (I suggest once for each facility).
Attend meetings	The biggest problem I have is that no one really understands what their responsibilities are and inspecting as infrequently as we do makes it difficult for us to catch all the mistakes. When you figure out in 8 years they have only 8 different inspections, if they're okay.
Attend meetings	USDA announced visits (every other inspection?) would facilitate communication with IACUCs and institutional officials.
Attend meetings	Have all facilities pre-licensed. During this pre-license inspection, all IACUC members should be present. At this time inspectors can discuss in detail all responsibilities.
Guidelines	Standardize so we're all demanding the same quality.
Guidelines	More uniformity across the country on how IACUCs are inspected, what is required. Spend more time on paperwork review and education.
Guidelines	Develop a guideline for doing inspection for uniformity or conduct seminars solely for IACUC inspections for all inspectors doing research inspections.
Guidelines	Provide more guideline type forms for their use - new and/or small facilities sometimes have difficulty knowing how much or what to document.
Guidelines	Guide IACUCs in better protocol format design which pulls out key points for meeting AWA regulations compliance.
Guidelines	1) Require more documentation to IACUC - use a checklist as a requirement for the IACUC and a tool for inspectors 2) Require VMO attendance at IACUC meetings.

Guidelines	Have standard protocol forms.

Table 7: Responses to Q14. How can we improve the way we inspect IACUCs?

Topic	***Respondents' comments regarding inspections of IACUCs.*** *(Comments with multiple topics were split up and sorted separately.)*
More thorough	1) Be more thorough, take much more time to evaluate protocols and compare with medical and study records. 2) Make more USDA inspectors be good at it.
More thorough	Training, perseverance, attention to detail. Utilization of our Web page for sample forms, etc. (great impact seen from OPRR sample format on NIH Web page).
More thorough	Make sure we review all records we require IACUC to have. Possibly attend some IACUC meetings.
More thorough	We should make an effort to review protocols after inspection of facilities and go back to check records at lab site for comparisons as well as to check on approved procedures. Some VMO's have not done this and are missing problems.
More thorough	Inspect more labs - talk with P.I.'s (principal investigators), complete follow through of specific protocols.
More thorough	Occasional audits of all category D and E procedures.
More thorough	Somehow be present DURING studies to see if studies follow protocols.
More thorough	Focus on high profile (sensitive) types of protocols (ex., surgery, painful/distressful procedures). Communicate directly with the Institutional official and IACUC chair before problems are present.
More thorough	Fewer facilities per VMO so we can spend more time doing in depth inspections.
More thorough	USDA needs to find some way to reduce frequency of inspections of high-quality research facilities to less than one per year.
Teams	Team inspections with problem facilities - we're already doing this at some facilities. More time! More inspectors! Bigger budget would allow us the luxury of time to do more comprehensive protocol reviews at larger facilities.
Teams	Team inspection of records.
Teams	Joint inspections with OPRR.
Train VMO's	Training of VMO's by NIH and OPRR and USDA consultants and USDA staff at least once a year (training videos would be helpful).
Train VMO's	Provide training to the VMOs in pain relief methods, evaluating pain, physiology of pain, techniques of protocol evaluations.
Train VMO's	Inspectors need better understanding of research processes and procedures. Need to look closer at IACUC monitoring of ongoing studies after approval.
Train VMO's	Not so much training as maybe some way to get us all on the same page (or at best, the same book). I hear widely varying accounts of what VMOs expect and demand from their facilities. Maybe some kind of semi regular forum (e-mail) with examples of situations and discussions on who they would be handled.
Train VMO's	AC should have a training course (meeting) among all VMOs and discuss IACUC issues, how they conduct meetings, problems to compare and evaluate IACUCs across the country.
Authority	Veterinarians always need to have control over issues concerning animal care.

Table 7: Responses to Q14. How can we improve the way we inspect IACUCs?

Topic	***Respondents' comments regarding inspections of IACUCs.*** *(Comments with multiple topics were split up and sorted separately.)*
N/A	N/A
No opinion	No opinion.
No suggestions	I have no suggestions.
Unknown	Unknown.

Appendix D

Table 8: Responses to Q15. What training do you feel would be useful for IACUCs?

Topic	***Respondents' comments regarding training for IACUCs.*** *(Comments with multiple topics were split up and sorted separately.)*
Subject, basic	Basic requirements and mandates.
Subject, basic	1) Knowledge about the USDA inspection process. 2) Have a model program of humane care and use for them to use for the development of their PHCU. 3) Have a model protocol form for them to use.
Subject, basic	Familiarity with AWA, standards and regulations, particularly for established (ossified?) PI's who refuse to understand what "all the fuss is about."
Subject, basic	1) Developing/reviewing a humane animal care and use program.
Subject, function	Basic requirements and mandates.
Subject, function	IACUC responsibilities under the AWA/regs/standards.
Subject, function	Some need basic instruction or a refresher course as to what their function really is. This seems to get lost in the shuffle somehow.
Subject, function	1. What their role is - responding to political pressures. Some need to be more empowered and assertive. 2. Proper documentation and review of program.
Subject, how to	Courses which help facilities determine how to conduct a meeting, what topics to cover, what to do during the meeting, how to report problems, etc.
Subject, how to	How to utilize libraries, literature searches (for alternatives, duplicative efforts.) Have ability to hire outside reviewers (employees rarely will "tell on" their employers.)
Subject, pain alt	Alternatives searches.
Subject, pain alt	Alternatives/painful procedures.
Subject, pain alt	Information on review of searches for alternatives.
Subject, pain alt	(2) Using the "3-R's" (Replacement, refinement, reduction) and how to conduct a search for alternatives to a painful procedure.
Subject, pain alt	Painful procedures, pain relief and search for alternatives. Intent of primate enrichment and dog exercise plans and how to monitor. Good way to review program of humane care and use of animals.
Subject, pain phil	Pain relief philosophy/requirements - need a standard to point out to be followed.
Subject, pain phil	Ethics meetings concerning animal "pain and distress" issues.
Subject, pain pro	4) A list of painful/distressful procedures.
Subject, pain pro	Correct alternative searches for painful procedures. Environmental enrichment for primates.
Subject, pain pro	How to evaluate adequacy of alternatives searches.
Subject, pain recog	Recognition of pain and distress in animals. Information as to most current practices and methods of analgesic delivery.

Subject, rationale	Justification for numbers of animals. Search for alternatives.

Table 8: Responses to Q15. What training do you feel would be useful for IACUCs?

Topic	***Respondents' comments regarding training for IACUCs.*** *(Comments with multiple topics were split up and sorted separately.)*
Subject, rationale	Numbers justification. Amendments which do/ do not trigger full committee review.
Subject, rationale	Criteria to address in describing rationale for appropriate number of animals.
Subject, rationale	1) How to take the "duplication" issue seriously what it really means. 2) How to do a proper search for and consideration of alternatives. 3) How to recognize an incompetent attending veterinarian.
Subject, review	Protocol review with regards to regulations, standards for Animal Care
Subject, review	Having IACUC or representatives spot or randomly check approved protocols to see if researcher is actually doing what protocol states.
Trainee	Mandated training at workshop for IACUC's and in particular for the Institutional Official.
Trainee	1) All IACUC members must attend training such as offered at PRIM+R/Arena meeting. Lecture and group discussion, workshop. 2) Review of facility problems with VMO inspector and full committee and any questions, concerns by members - separate from regular IACUC meeting.
Trainee	I recommend new registrants to send at least their chairman to meetings of established IACUC's at other facilities.
Trainee	They're doing okay on their own, but it might be interesting to ask them this question. I think we need to be training P.I.s. The ones I talk to rarely really understand the 3 R's.
Trainee	They need a specified (by law) method to keep track of training, employees should go to outside meetings at no less than a specified interval; even the "floor sweepers" should have something on their level so they can feel like part of the team. The whole IACUC needs training in some way - they resist this.
Trainer	Presentation by USDA-AC VMOs.
Trainer	Refresher course to be sponsored by AC or the research community once a year or once every 2 or 3 years.
Trainer	At smaller facilities, offer to come and discuss IACUC issues with the members. Give them contact people with good IACUCs.
Trainer	USDA announced visits (every other inspection?) would facilitate communication with IACUCs and institutional officials.
Trainer	USDA seminar, services available around the country on a regular basis.
Trainer	Yearly seminars by OPRR and NIH on IACUC.
Training book	USDA should publish an extensive "How to" book for IACUCs
USDA employees	Training on how to conduct facility inspections and documentation of deficiencies. Training on how to write an S.O.P./protocol.
Not clear	I think most are functional IACUC's..[?] I have [?] of concern is this.

Appendix D

Table 9: Responses to Q16. What training do you feel you need?

Topic	***Respondents' comments regarding training for you.*** *(Comments with multiple topics were split up and sorted separately.)*
Animals	Animal behavior Common diseases and those related to husbandry
Animals RMB	1) Rats and mice.
Animals RMB	Rat, mice and birds.. [We] need to deal with the issues of restrictions that will be placed upon the inspectors/ barrier facilities, other areas which facility personnel are wanting no entrance if we have been in another facility within the past week.
General	Overall review and refresher. Also, cross training with other VMOs. This would help to identify any possible overlooked or forgotten areas.
General	Training to provide more consistent inspection procedures.
General	Inspectors need training to standardize all areas of IACUC inspections. We've barely scratched the surface on this one.
General	Overall discussion of IACUC issues with experienced VMOs.
General	1) IACUC training (how to discover problems not really apparent with committee); how to work at solving these problems; review of available tools (present and future) for VMO; session with AC management to review what is working and what is not working.
Pain alternatives	Alternatives searches.
Pain alternatives	Conducting searches for alternatives to: painful procedures; animal models.
Pain alternatives	How to evaluate adequacy of alternatives searches.
Pain alternatives	3) How to conduct an "excellent" literature search for alternatives, e.g., NAL/AWIC workshop for VMO's.
Pain alternatives	Need search training on alternatives for painful procedures and specific IACUC training and lab-animal medicine by video library from NIH and OPRR.
Pain alternatives	Need training in alternatives, painful procedures, and drugs used pre-op and post-op, enrichment for primates.
Pain management	Recognition of pain and distress in animals. Information as to most current practices and methods of analgesic delivery.
Pain management	Latest on anesthesia and analgesia.
Pain management	Specific anesthetic and pain management regimens for specific species.
Pain management	Besides elephant training? I'd like to know the latest methods of detecting and alleviating pain (drugs and dosages, homeopathic alternatives) and distress (handling, environment enrichment) in research animals.
Pain policy	What are our (USDA) specific requirements for policy 12. Are we to judge on adequacy of key words?
Protocol review	Protocol reviews.

Protocol review	Reviewing protocols.

Table 9: Responses to Q16. What training do you feel you need?

Topic	***Respondents' comments regarding training for you.*** *(Comments with multiple topics were split up and sorted separately.)*
Protocol review	More specifics on how to renew complicated protocols. More guidance on how to ascertain whether procedure really does not unnecessarily duplicate previous experiments - regardless of what researcher says.
Records	Records training.
Research	Research manual for inspecting - to include research jargon/description of research methods and standard tests; how specific procedures are routinely done (animal handling) start learning more about research with rats and mice (i.e., tumors, transgenics)
Research	Need a series of research training for VMO's. Need to further train inspectors on reviewing records, understanding investigator's search procedures, etc.
Research	Research training (meeting). We need a uniform method of evaluating IACUCs and how IACUCs conduct meetings, review, membership, and view pain.
Research	2) Common laboratory research procedures and alternatives.
Research	More information on the different types of research conducted, the testing methods and objectives, discussion of minimum requirements for the IACUC versus "pushing the envelope" to improve their processes. A list of painful/distress procedures.
Research	(New) Changes in accepted procedures; alternatives to procedures in research; latest in analgesics, etc.
Research	N/A - unless we start doing rats, mice, and birds - we would need training on transgenics.
Research	1) Everything relating to transgenics, in depth, not Mickey Mouse! 2) SPF production. 3) Virology and bacteriology colony screening and how it relates to husbandry and housing constraints. 4) What's new in post-procedural care: all aspects, not just analgesics. 5) Statistics for adequacy of animal numbers.
Research	More training on procedures/activities such as Xenotransplantate antibody production, transgenics.
Research OPRR	Closer working and training with OPRR.
VMOs	Cross-training with other inspectors is always useful.
VMOs	I need more expense for research related inspections by riding with other inspectors who spend a greater percentage of time at research facilities.
VMOs	Would like to see other research facilities. PRIM&R - Boston in 2000.
VMOs	Joint inspections with top rated research facility inspectors.
VMOs	VMOs sharing what they find (problems) and how it was resolved. Update on FDA/EPA on what is accepted when doing drug submissions - I.e., pain/distress relief.

Other	Spanish - some IACUC correspondence and records are in Spanish. While I can understand "most" of the written documentation I would like to have additional (advanced) Spanish course(s).

Table 9: Responses to Q16. What training do you feel you need?

Topic	***Respondents' comments regarding training for you.*** *(Comments with multiple topics were split up and sorted separately.)*
Other	Speed reading - It is foolhardy to think we are really reviewing protocols in regard to quality or quantity - it is really just a matter of chance if we find anything wrong with a specific protocol.
Other	Clear cut instructions on exactly what we expect.
Other	None, but… clinically-trained DVM's are generally NOT knowledgeable in academic/research fields (and vice versa). Remember, a PhD does not allow one to practice medicine, nor does a DVM guarantee grant-writing or research expertise. Also, remember that a DVM is an UNDERGRADUATE degree!
Other	In training now.