(4) Any establishment wholesaling any animals (except birds, rats and mice).

(5) Any establishment exhibiting pet animals in a room that is separate from or adjacent to the retail pet store, or in an outside area, or anywhere off the retail pet store premises.

“Sanitize” means to make physically clean and to remove and destroy, to the maximum degree that is practical, agents injurious to health.

“Secretary” means the Secretary of Agriculture of the United States or his representative who shall be an employee of the Department.

“Sheltered housing facility” means a housing facility which provides the animals with shelter; protection from the elements; and protection from temperature extremes at all times. A sheltered housing facility may consist of runs or pens totally enclosed in a barn or building, or of connecting inside/outside runs or pens with the inside pens in a totally enclosed building.

“Standards” means the requirements with respect to the humane housing, exhibition, handling, care, treatment, temperature, and transportation of animals by dealers, exhibitors, research facilities, carriers, intermediate handlers, and operators of auction sales as set forth in Part of this subchapter.

“State” means a State of the United States, the District of Columbia, Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, or any other territory or possession of the United States.

“Transportation device” means an interim vehicle or device, other than man, used to transport an animal between the primary conveyance and the terminal facility or in and around the terminal facility of a carrier or intermediate handler.

“Transporting vehicle” means any truck, car, trailer, airplane, ship, or railroad car used for transporting animals.

“Weaned” means that an animal has become accustomed to take solid food regardless of compensation.

Done at Washington DC, this 7th day of March 1989.

James W. Glosser, Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 89-5011 Filed 3-9-89; 2:09 pm]

9 CFR Part 2

[Docket No. 88-014]

Animal Welfare Regulations

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: This is a request for supplemental comments on the narrow issue of the interrelationship between Part 2 of the Animal Welfare Act regulations and our proposal to amend Part 3 of the regulations. We are proposing to amend the Animal Welfare regulations, 9 CFR Part 2. As part of our revision, we are proposing to add some new sections and revise others. New sections would provide regulations on Institutional Animal Care and Use Committees, Attending Veterinarians, and Veterinary Care. These amendments are necessary to comply with the amendments to the Animal Welfare Act (7 U.S.C. 2131, et seq.) contained in Pub. L. 99-198, “The Food Security Act of 1985,” enacted December 23, 1985. We are also proposing to add new sections on Holding Facilities and Handling to improve enforcement of the Act. We are proposing to revise other portions of the regulations in content and/or format to aid the public in understanding and using the regulations for the humane care, treatment, handling, and transportation of regulated animals. Rewriting the regulations is intended to make them easier to understand, thereby increasing compliance and making them more effective.

DATE: We will consider written comments addressing only the interrelationship of Parts 1 and 2 of the regulations with the proposed standards of Part 3, as explained in greater detail in the supplementary information which follows, that are postmarked or received on or before May 15, 1989.

ADDRESS: Send an original and three copies of your comments to Helene R. Wright, Chief, Regulatory Analysis and Development Staff, PPD, APHIS, USDA, Room 1000, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 88-014. Comments received may be inspected at the APHIS Public Reading Room, Room 1141, U.S. Department of Agriculture, 14th and Independence Avenue, SW., Washington, DC, 8:00 a.m. to 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. R.L. Crawford, Animal Care Staff, REAC, APHIS, USDA, Room 268, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-7833.

SUPPLEMENTARY INFORMATION:

Background

In a document published in the Federal Register, on March 31, 1987 (52 FR 10298-10322), we proposed to revise the regulations contained in 9 CFR 2.1 through 2.130. These regulations pertain to licensing of dealers and exhibitors and registration of facilities and common carriers; recordkeeping for and identification of animals; holding periods and facilities; inspections; institutional Animal Care and Use Committees; adequate veterinary care; and other areas relating to the humane care, handling, treatment, and transportation of animals. These changes have been proposed under the authority of the Animal Welfare Act (the Act), as amended. They include some specific new requirements mandated by the 1985 amendments to the Act, contained in Pub. L. 99-198, “The Food Security Act of 1985,” enacted December 23, 1985.

The Act requires the Department to promulgate regulations and standards governing the humane handling, housing, care, treatment and transportation of certain animals by dealers, research facilities, exhibitors, carriers, and intermediate handlers. The standards and regulations must include minimum requirements with respect to handling, housing, feeding, sanitation, veterinary care, the use of pain relieving drugs, exercise for dogs, psychological well-being of nonhuman primates, recordkeeping, and other matters specified in section 13 of the Act, as amended.

We solicited comments concerning the proposal for a 60-day period ending June 1, 1987. The comment period was twice extended and ended on August 27, 1987. We did not consider comments and materials received after the closing date of August 27, 1987. We received a total of 7,857 comments addressing our proposal for Parts 1 and 2.
from the research community; 867 were from dealers and exhibitors; and 5,432 were from members of the general public. We included comments received from humane societies and groups representing the public in the areas of animal welfare and animal rights with comments received from the general public.

We received 344 comments (319 from the research community and 25 from members of the general public) stating that the Department should accord careful consideration to all of the comments received as required by the Administrative Procedure Act. We wish to assure the commenters, regulating persons, and members of the general public that the Department has carefully considered all of the comments that were received by the end of the comment period, and that we have revised the March 31, 1987 proposal on the basis of those comments where we considered it to be appropriate. These changes, discussed below, have been incorporated in this revised rule. We received much constructive input and appreciate the response.

Supplemental Request for Comments on the Interrelationship of Parts 1, 2, and 3 of the Animal Welfare Regulations

We received 334 comments (309 from members of the research community and 25 from members of the general public) suggesting that we revise the proposed rules for Parts 1 and 2, "Definition of Terms" and "Regulations," and publish a second proposal in the Federal Register for public comment. We also received 445 comments (400 from members of the research community and 45 from members of the general public) suggesting that we revise the proposals for Parts 1 and 2, publish them along with our proposal for standards for the exercise of dogs and for a physical environment to promote the psychological well-being of nonhuman primates. These specific standards are mandated by the 1985 amendments to the Act.

We have decided to respond to the comments we received addressing the proposed rules, and to publish revised rules for Parts 1 and 2 in the same issue of the Federal Register in which we publish our proposal to amend Part 3 of the regulations, entitled "Standards." The revised rules reflect our consideration of the nearly 6,000 comments we received, our experience in administering and enforcing the regulations, and our ongoing consultation with the U.S. Department of Health and Human Services and other interested agencies. It is our present determination that upon their adoption as final rules, the revised provisions of Parts 1 and 2 conform with the requirements of the Animal Welfare Act, as amended.

Accordingly, we are publishing Parts 1 and 2 at this time, revised from our initial proposal, as explained in detail below. The revised rule for Part 2 contains specific regulations required by the 1985 amendments to the Act. These include regulations setting forth the responsibilities of Institutional Animal Care and Use Committees (IACUCs); requirements for Committee approval of animal care and use procedures in research involving animals; training by research facilities; use of pain relieving drugs; and inspection of animal use areas by the Committee. We believe that publication of the revised proposal for Part 2 concerning the administrative and institutional responsibilities of persons subject to the Act will assist the public in reviewing the proposed standards in Part 3 by placing the proposed standards in context. Also, many of the terms used in Part 3 are defined in Part 1, and a revised proposed rule containing definitions of those terms will aid the public in understanding the terms. The Department has decided upon this approach in the hope that it will answer many of the issues that would otherwise be raised in considering the standards contained in Part 3.

By way of example, we received 3 comments in response to proposed Part 2 (2 from dealers and 1 from a member of the general public) endorsing exercise for dogs and 12 comments (10 from dealers and 2 from a member of the general public) opposing mandatory exercise for dogs. One member of the general public commented in opposition to allowing dogs to be kept on leashes.

The requirements for exercise of dogs are directed by the Act (7 U.S.C. 2143(a)(2)(B)). They are contained in Subpart A of our proposed revision of Part 3, published elsewhere in this issue. (See companion document no. 87-404.) We invite public comment in response to the proposed rule to amend Part 3.

At the urging of many commenters, we are publishing the revised rules for Parts 1 and 2 for the sole purpose of soliciting comments on the narrow issue of the interrelationship of the definitions and regulations in Parts 1 and 2 with the standards we are proposing in Part 3. The public is therefore invited to comment exclusively on this issue. We will not consider comments going beyond this issue.

Comments raising objections or suggesting changes to the March 31, 1987 proposal are discussed below in this supplementary information. Due to the length of this document and the scope of the issues addressed, subheadings are provided in the supplementary information to guide the reader through the material. Section numbers are used in the subheadings wherever possible to further assist the reader. We have provided the number of comments received and their source (e.g., research community, members of the general public) pertaining to each section because this information may be of interest to some readers. Except as explained in this supplementary information, the provisions of the March 31, 1987 proposal have been included in this revised rule for the reasons set forth in that proposal.

In our discussion of the comments we received, we refer to both the proposed rule published March 31, 1987 and to this revised proposed rule. In order to assist the reader in distinguishing between these two documents, we use the terms "proposed" or "proposition" when referring to the March 31, 1987 proposed rule. We use the terms "revised" or "revision" when referring to this revised rule.

In the supplementary information to proposed Parts 1 and 2, we stated that, based upon the information available to the Department, the proposed rules were issued in conformance with Executive Order 12291 and Secretary's Memorandum No. 1512-1, and that they had been determined not to be "major rules" (52 FR 10295 and 10307). We also stated that the information collection provisions included in proposed Part 2 had been submitted for approval to the Office of Management and Budget (OMB) (52 FR 10307) and that proposed Part 1 contained no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501, et seq.). We further stated that the proposed rules would not have a significant economic impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act (52 FR 10295 and 10307-10308).

We received 851 comments (625 from the research community, 25 from members of the general public, and 1 from a dealer) stating that the Department should perform the regulatory analyses required for: (1) A "major rule" under Executive Order 12291; (2) determining the impact on small entities in accordance with the Regulatory Flexibility Act; and (3) the Paperwork Reduction Act. Commenters demanded that we consider in our analysis the burden of administrative requirements required of the attending veterinarian and the Institutional
Animal Care and Use Committee under the proposal. We received 881 comments (834 from the research community, 1 from an exhibitor, and 26 from members of the general public) stating their disagreement with our statement that the proposed regulations are not a “major rule” under Executive Order 12291 and that the regulations would not impose significant financial burdens on registrants and licensees.

In conducting the regulatory analyses referenced above, we considered Parts 1 and 2 separately. The determinations we made were preliminary ones. Now, with more information available to us, including the comments we received, we have determined to consider the combined impact of Parts 1, 2, and 3. We have determined that, considered together, the rules for Parts 1, 2, and 3 are a major rule. A discussion of the regulatory analyses performed appears under the headings, “Executive Order 12291,” “Regulatory Flexibility Act,” and “Paperwork Reduction Act.”

General Comments

We received 839 comments (910 from members of the general public, 25 from the research community, 3 from exhibitors, and 1 from a dealer) expressing general support for the proposed regulations. We also received 296 comments (285 from members of the general public and 1 from the research community) in support of the proposed regulations and stating that the Department should not lessen them due to pressure from associations for biomedical research. We received 256 comments (189 from members of the general public, 44 from the research community, 16 from dealers, and 1 from an exhibitor) expressing general opposition to stronger regulations. We also received many comments expressing specific objections to the proposed regulations.

We received 1,050 comments (1,034 from the research community and 26 from members of the general public) stating that the proposed rules exceed our statutory authority under the Act and are not consistent with the intent of Congress. We disagree with these comments and believe that ample statutory authority exists for these regulations. In the supplementary information which follows, we respond to those comments challenging our statutory authority for specific provisions of the regulations and our carrying out of congressional intent.

We received 613 comments (588 from the research community and 25 from members of the general public) stating that the Department did not coordinate with the Secretary of Health and Human Services (HHS) in issuing the proposed regulations, as required by the Act. Section 15 of the Act directs that:

[(t)he Secretary shall consult and cooperate with other Federal departments, agencies, or instrumentalities concerned with the welfare of animals used for research, experimentation or exhibition, or administration of statutes regulating the transportation in commerce or handling in connection therewith of any animals when establishing standards pursuant to section 13 and in carrying out the purposes of this Act. The Secretary shall consult with the Secretary of Health and Human Services prior to issuance of regulations. (7 U.S.C. 2146(a)).]

The Department did consult extensively with HHS. On numerous occasions before issuing the proposed regulations, we discussed the issues with HHS representatives and provided HHS with copies of each draft of our proposal for review and comment. HHS indicated its concurrence with the proposed regulations. In evaluating the comments received in response to the proposal and in preparing this revised rule, we have consulted extensively and on an ongoing basis with HHS. A representative from The National Institutes of Health was detailed to work with APHIS and to provide the HHS position on all issues affecting the research community that were raised by the commenters. We also convened a meeting with representatives of HHS to discuss and resolve outstanding differences between HHS and the Department. Through this give and take we achieved what we understand to be a mutually satisfactory resolution of many of our outstanding differences. We believe that this revised rule is reasonable and, based upon our ongoing communication with HHS, that it could be readily implemented in the research community.

We received 106 comments (105 from the research community and 1 from a member of the general public) stating that the regulations as proposed would be inconsistent with other federal regulations. We disagree with the import of this characterization. We believe that any remaining differences between Parts 1 and 2 of the Animal Welfare regulations, as revised, and those related regulations of other agencies, particularly those of HHS, are necessitated by requirements contained in the Act. As stated in the preceding paragraph, we have attempted to reconcile differences between HHS and the Department. Our regulations must, however, fulfill the mandate of Congress and must be authorized by the Act, as amended.

We received 1,004 comments (979 from the research community and 25 from members of the general public) objecting to the proposed regulations on the grounds that they would interfere with or impede research. The Department has remained especially sensitive throughout the rule-making process to this issue. Congress stated in the 1985 amendments that “[n]othing in [the] Act (i) except as provided in paragraph (7) of [subsection (a)] shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to the design, outlines, or guidelines of actual research or experimentation by a research facility as determined by such facility; (ii) as provided * * * shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to the performance of actual research or experimentation by a research facility as determined by such research facility; * * * (7 U.S.C. 2143(a)(6)(A) (i) and (ii)). Paragraph (7) of subsection (a) provides that the Secretary will require each research facility to show upon inspection and to report at least annually that it is in compliance with the Act and that professionally acceptable standards governing the care, treatment, and use of animals are being followed during research or experimentation. It also requires the research facilities to provide information and assurances concerning painful procedures, and an explanation for any deviation from the standards promulgated under section 13(a) of the Act (7 U.S.C. 2143(a)(7)). Nevertheless, the Act imposes new responsibilities upon research facilities, as well as others subject to the Act, which necessarily impact upon the internal workings of research facilities. There are some costs necessarily associated with changes of this kind. Regulated persons who must alter their internal procedures and structure and their lines of reporting and responsibility to accommodate the 1985 amendments to the Act may feel that the regulations impose an undue burden.

We believe, however, that the burdens imposed on research facilities are statutorily required and are reasonable in order to effectuate the purposes of the Act and the 1985 amendments to the Act, and that they are the minimum necessary to accomplish those goals.

We received 315 comments (290 from the research community and 25 from members of the general public) stating that APHIS has failed to show a rational connection between the proposed rules and the agency record. We have been charged with the responsibility of administering and enforcing the Animal Welfare Act since it was enacted in 1966. Our experience has revealed areas
in which more stringent regulations are necessary. The supplementary information contained in the March 31, 1987 proposed rule and in this revised rule highlight areas where additional regulatory efforts have proven necessary. These revised regulations provide mechanisms designed to prevent circumvention of the Act and the regulations and to assist the Department in its enforcement efforts. They are based either on the 1985 amendment to the Act or on the Department's experience in enforcing the regulations. We believe these revisions would better effectuate the intent of Congress to promote animal welfare.

We received 622 comments (597 from the research community and 25 from members of the general public) stating that the proposed regulations improperly enlist Institutional Animal Care and Use Committees and attending veterinarians as enforcement agents of the federal government, and 1 comment from a member of the research community in support of their use as Department agents. The duties of the Committee and the attending veterinarian at research facilities are more fully described in this supplementary information under the discussion of Subparts C and D, "Institutional Animal Care and Use Committee and Other Requirements for Research Facilities" and "Attending Veterinarian and Adequate Veterinary Care." We note that responsibility for compliance with the Act and the regulations and for providing necessary assurances has always rested with the institutions and with the legally responsible institutional officials. Many of their duties can most effectively be carried out through the Committee and the attending veterinarian acting as agents of the facility and its officials, since the Committee and attending veterinarian are usually in the best position to determine whether the research facility is in compliance. For this reason, the Act imposes many oversight and supervisory responsibilities on them. We believe that the reassignment of responsibilities to the research facility from the Committee and attending veterinarian in Subparts C and D of this revised rule clarifies our intent that institutions act through them while remaining ultimately responsible.

We received comments from 105 members of the general public opposing the use of animals for research altogether. We have made no changes based on these comments. It would be beyond our authority to ban the use of animals in research. Our regulations are authorized by the Act, and the Act specifically states that "the use of animals is instrumental in certain research and education for advancing knowledge of cures and treatment for diseases and injuries which afflict both humans and animals; * * * " (7 U.S.C. 2131(b)).

Seventy-four commenters (72 from the research community and 2 dealers) stated that the proposed regulations are poorly organized and written, and that clarification is needed. We believe that this supplementary information and the revised proposed rule that follows provides the necessary reorganization and clarification.

Two commenters from the research community stated that APHIS will be unable to enforce the regulations. We disagree with the commenters based upon the Department's enforcement record. Congress has entrusted the Department with enforcement and promulgation of the Animal Welfare Act and with the promulgation and enforcement of regulations under the Act since the Act's enactment in 1966. We will continue our best efforts to meet this responsibility and to perform in accordance with the mandate of Congress.

Subpart A—Licensing

We received 255 comments (270 from the research community and 25 from members of the general public) generally endorsing the proposal regarding Subpart A.

Section 2.1 Requirements and application

Proposed § 2.1 sets forth who must obtain a license under the Animal Welfare regulations and provides the application procedure for obtaining a license. It details the information which an applicant must provide and where an applicant must file to become licensed. This section also provides the application fee and renewal application fee. (Annual license fees are provided in proposed § 2.6.) Exemptions from the requirement to be licensed are included in this section along with a provision for obtaining a voluntary license in very limited circumstances. Renewal procedures are provided and grounds for denial, suspension, or revocation of a license are included in this section as well. Grounds for denial of an initial license application are addressed in detail in proposed § 2.11.

Before addressing the comments received concerning proposed § 2.1, we note the following clarifications we are making in this revised rule. First, proposed § 2.1(a)(1) would require that:

Any person, 18 years of age or older, operating or desiring to operate as a dealer, exhibitor, or operator of an auction sale except persons who are exempted from the licensing requirement under paragraph 3 of this subsection must have a license.

We are concerned that this provision could be misconstrued as allowing a person under 18 years of age to operate as a dealer, exhibitor, or operator of an auction sale without having to obtain a license. We believe that most readers will understand that persons must be at least 18 years of age to be eligible to obtain a license to operate as a dealer, exhibitor, or operator of an auction sale, and that a license is required to operate in those capacities. The intent underlying the minimum age requirement was stated in the supplementary information to the proposed rule. We have revised the final rule to reflect our intent more accurately.

Second, under § 2.5. as revised in this rule, licenses are valid and effective unless they are terminated, suspended, or revoked, or expire at the end of the 1-year term. The proposed rule provided that licenses would be valid and effective for 1 year, and did not distinguish between initial license applications and applications for additional 1-year terms. We have made conforming changes throughout Subpart A to differentiate between new license applications and license renewals. Accordingly, proposed § 2.1(a)(2) is revised to require an applicant for renewal of a license to indicate all premises, facilities, or sites where animals are kept or the licensee operates on the application for renewal. We are also replacing "termination date" with "expiration date," wherever it is used to mean the calendar end of the 1-year license term, as in § 2.1(e).

Section 2.1 of the current regulations provides that persons who are exempt from the licensing requirement under section 3 of the Act do not have to apply for a license to operate as a dealer, exhibitor, or operator of an auction sale where dogs or cats are sold affecting commerce. We proposed to revise § 2.1 by identifying those persons exempt from the licensing requirements under section 2 or section 3 of the Act.

We received 35 comments pertaining to § 2.1, as proposed. Four commenters from the general public stated that proposed § 2.1 would allow too many exemptions from the requirement to obtain a license. Section 2 of the Act (7 U.S.C. 2132(f)) defines the term "dealer" as:

any person who, in commerce, for compensation or profit, delivers for transportation, or transports, except as a
carrier, buys, or sells, or negotiates the purchase or sale of, (1) any dog or other animal whether alive or dead for research, teaching, exhibition, or use as a pet, or (2) any dog for hunting, security, or breeding purposes, except that this term does not include—(i) a retail pet store except such store which also acts as a research facility, an exhibitor, or a dealer; or (ii) any person who does not sell, or negotiate the purchase or sale of any wild animal, dog, or cat and who derives no more than $500 gross income from the sale of other animals during any calendar year.

The regulatory exemptions proposed are either statutorily mandated or are in accordance with the intent of the Act, which is to regulate the commercial use of animals, other than their use as food or fiber.

Twelve dealers stated that the proposed exemptions from the licensing requirement for retail pet stores and for persons who maintain three or fewer breeding female dogs or cats and who sell the offspring born and raised on their premises for pets or exhibition would be improper. The Act requires that dealers and exhibitors must be licensed, and specifically provides that "any retail pet store or other person who derives less than a substantial portion of his income (as determined by the Secretary) from the breeding and raising of dogs or cats on his own premises and sells any such dog or cat to a dealer or research facility shall not be required to obtain a license as a dealer or exhibitor under this Act." (7 U.S.C. 2133). As defined in the Act, the term "dealer" does not include retail pet stores, except those which sell any animals to a research facility, exhibitor, or a dealer (7 U.S.C. 2132(f)). Accordingly, the proposed exemptions are statutorily required and will continue to be included in the regulations.

We are making a change in proposed § 2.1(a)(3)(i) to delete mink from the listing of pet-type animals which retail pet stores can sell and still be exempt from the licensing requirement. This change is in accordance with the revised definition of "retail pet store" in the revised rule for Part 1—"Definition of Terms," published elsewhere in this issue. (See companion docket no. 88-013.)

We are also correcting proposed § 2.1(a)(3)(iii) to read "Any person who maintains a total of three (3) or fewer breeding female dogs and/or cats * * *

* * * *

This section is intended to exempt the hobby breeders who derive less than a substantial portion of their income from the breeding and sale of dogs or cats, in accordance with section 3 of the Act (7 U.S.C. 2133). The correction would clarify that a person having a combined total of three or fewer breeding female dogs, or three or fewer breeding female cats, or three or fewer breeding female dogs and cats qualifies for exemption from the licensing requirement, not a person having three or fewer breeding female dogs and three or fewer breeding female cats.

We are similarly correcting proposed § 2.1(a)(3)(iv) to read "Any person who sells fewer than 25 dogs and/or cats per year * * *

* * * *

This section is intended to exempt persons who derive less than a substantial portion of their income from the breeding and raising of dogs and cats, and we have determined that the sale of a combined total of fewer than 25 of these animals would qualify a person for this exemption. The correction clarifies that a person selling fewer than 25 dogs, or 25 cats, or 25 dogs and cats qualifies for exemption from the licensing requirement, not a person selling fewer than 25 dogs and fewer than 25 cats.

We are making an additional change in proposed § 2.1(a)(3)(iv) to include terms which were inadvertently omitted from the proposal. The words "teaching, or testing" are added between "research" and "purposes" in the revised rule to make clear that the exemption for sales of fewer than 25 dogs and/or cats applies to sales for research, teaching, and testing purposes, in accordance with the purposes of the Act.

Five commenters (2 dealers, 1 exhibitor, and 2 members of the general public) stated that an additional exemption from the requirement to obtain a license for federal, state, and local parks with free roaming herds of animals native to the area which utilize auctions as part of a herd size control program should be added to the regulations. The legislative history of the Act indicates that the term "dealers" as used in the Act is limited to private persons and entities and nonprofit or charitable institutions, and does not include federal agencies or political subdivisions of state or local governments. (See Conference Report No. 1948, at p. 9, August 11, 1990.) There is no authority under the Act to license federal, state, and local governments as dealers, and accordingly no exemptions for them have been provided.

One dealer commented that the licensing requirements should be less stringent and should allow more exemptions, such as for brokers and for sales through classified ads and publications. The Act includes brokers in the definition of "dealer" by referring to any person who "negotiates the purchase or sale" of any of the covered animals and we are statutorily required to license these persons. Furthermore, the Act does not provide an exemption from the licensing requirements for sales accomplished through classified ads and publications. These sales are "in commerce" and are subject to the Act and regulations. The medium through which a sale is accomplished is irrelevant so long as it is in commerce. We do not regulate classified ads or publications; however, we can and do use them to find persons who should be licensed in accordance with the regulations.

One commenter from the research community sought clarification of the licensing requirements applicable to research facilities selling animals. Research facilities acting as dealers are subject to the same regulations as any other dealer and must be licensed in accordance with § 2.1, unless they are a department, agency, or instrumentality of the United States, or of a state or local government, in which case they need not obtain a license.

Three dealers commented that the Department should require anyone selling animals at auction sales to obtain a license. We have found that many individuals sell a number of animals at auctions during the course of a year. We believe that the proposed exemptions are consistent with the Act and provide appropriate threshold points for the imposition of the requirement to obtain a license. Moreover, budgetary and personnel restrictions would prevent us from being able to regulate effectively all of these persons.

Similarly, we disagree with the 3 commenters from the general public who stated that the Department should require licensing of all persons who sell or trade animals at flea market operations. The legislative history of the Act makes clear that the licensing requirement was intended to regulate the commercial sale or use of animals as part of a business concern. Some animal sellers at flea markets sell animals as part of a commercial operation, but many others sell them for use as pets or for personal enjoyment. The proposed licensing requirements and exemptions will still require large volume or commercial sellers to obtain a license.

Three commenters from the research community stated that the Department should delete the requirement that persons who sell exotic or wild animals be licensed as dealers. Licensing of these persons is statutorily mandated (7 U.S.C. 2132(f)).

One research facility objected to the imposition of dealer licensing requirements on sellers of small
quantities of wild animals since research facilities would not be able to purchase small quantities of non-domesticated species from an unlicensed source. The definition of "dealer" in the Act permits an exemption based on dollar amount of sales only for those persons who do not sell wild animals (or dogs or cats) and therefore persons who sell wild animals must be licensed, regardless of the number of animals they sell (7 U.S.C. 2132(f)(ii)). We require research facilities to purchase these animals from licensed sources, in accordance with the Act.

Proposed § 2.1(b) would eliminate voluntary licenses, except for persons who sell fewer than 25 dogs or cats per year for research or teaching purposes. This will prevent people from trying to circumvent certain state and local community laws concerning keeping dangerous animals. We received 2 comments from dealers objecting to the restricted grounds for issuance of voluntary licenses, and suggesting that people who buy only 1 or 2 animals as pets or for breeding purposes would have to buy their animals from a licensed dealer, possibly at higher prices. One commenter from the general public commended us for this provision. We believe the dealers' concern is misplaced. It is not the intent of the Act or of the Department to regulate the acquisition of private pets or animals for personal use and enjoyment.

Broader use of voluntary licenses requires greater use of the Agency's limited resources and personnel, which could be utilized more effectively by focusing on animals used in commercial or research operations. The regulation for voluntary licenses remains as proposed, except that reference to the $10 application fee and a provision for annual license fees is included in paragraph (b) for clarification.

Reference to the renewal fee for voluntary licenses is also included in § 2.1(e)(1) of the revised rule. Annual license fees are provided in § 2.6 of the regulations for Class "A," Class "B," and Class "C" licensees. However, the proposed regulations inadvertently did not require license fees for voluntary licensees, who, by definition, do not qualify for licensing under any of the Classes. Voluntary licensees operate most like Class "A" licensees, except that they are exempt from the licensing requirements. Accordingly, the annual license fee for a voluntary license would be that of a Class "A" license (breeder) under this revised rule.

Five commenters (4 exhibitors and 1 dealer) commented that we should eliminate the $10 application fee for license renewals required by proposed § 2.1(e) and 1 exhibitor suggested having a one-time application fee for the initial license application required by proposed § 2.1(d), instead of the annual $10 application fee. We believe that it is more equitable to charge licensees on a yearly basis to cover annual processing costs, since a one-time fee could overcharge some and undercharge others.

The $10 application fee is also required when a licensee applies for a change in the class of license from that issued to him or her, such as a change from a Class "A" to a Class "B" license. This is necessary because a change in class requires administrative processing that is similar to processing a new application or a renewal application. We have redesigned proposed paragraph (e) as (e)(1) in the revised rule. We have added a new paragraph (e)(2) to the revised rule and revised § 2.6(a) ("Annual licensee fees") to clarify this requirement.

We have revised § 2.1(e)(1) to require licensees to submit a completed application form with their $10 application fee. We believe that it is necessary specifically to require submittal of this form along with the fee since many licensees overlook it.

Section 2.2 Acknowledgement of regulations and standards

We are revising § 2.2 so that it applies to applications for license renewals, as well as to initial license applications. This change is necessary to conform with § 2.5, as revised in this rule, which provides that licensees are valid and effective if renewed, unless terminated, suspended, or revoked.

Section 2.3 Demonstration of compliance with standards and regulations

For the reasons outlined above under the discussion of § 2.1, we are revising proposed § 2.3 in this rule so that it includes applications for license renewals, as well as initial license applications. Accordingly, we have revised paragraph (a) to require that each applicant for a license or renewal of a license must demonstrate compliance with the regulations and standards in Parts 2 and 3 of Subchapter A. We have removed the words, "before a license will be issued" from the requirement because it applies to both initial licenses and license renewals. We have revised paragraph (b) to clarify that it only applies to initial license applications.

We are revising § 2.3(a) to require each applicant to make his or her animals, premises, facilities, vehicles, equipment, other premises, and records available for inspection by APHIS officials during business hours, and at other times mutually agreeable to the applicant and APHIS, rather than "and/ or at other times" as proposed. We believe this revision is necessary to prevent licensees from avoiding inspections by being unable to agree to a time with APHIS officials.

We received three comments (2 from the general public and 1 from the research community) expressing support for this section as proposed. Two dealers commented that we should limit the number of opportunities an applicant has for inspection to demonstrate their compliance with the regulations and standards and 1 also commented that applicants should be required to pay the cost of re-inspection. (Demonstration of compliance is a prerequisite to issuance of a license.) We believe this suggestion has merit and that a limit on inspections should be incorporated in the regulations. This section is revised to impose a limit of three pre-licensing inspections. If the applicant is unable to pass inspection after 3 attempts he or she will forfeit the application fee, to help cover the administrative cost of processing their application and the cost of the inspections, and will be ineligible to reapply for a license for a period of 6 months following their last inspection.

As is the case for the prior inspections, the applicant will be advised of deficiencies and the necessary corrective measures that must be taken to comply with the regulations and standards, and accordingly to pass inspection. We believe that allowing an applicant 3 opportunities to pass inspection is reasonable, since it would give the applicant notice of any deficiencies found by an inspector and a second chance to rectify any remaining deficiencies found after re-inspection. We also believe that if an applicant is unable to pass inspection after 3 attempts, 6 months provides sufficient time to enable him or her to take the necessary corrective measures which he or she has been unable to provide between the 3 failed inspections.

We are not incorporating the suggestion that licensees pay the cost of re-inspections. The initial application fees and annual fees are intended to help the federal government defray the cost of program operations. We believe that the fees we have assessed are reasonable and equitable for the nature of the operations being licensed, and have determined at this time that additional fees are not appropriate.
Section 2.4 Non-interference with APHIS officials

Under proposed § 2.11(a), APHIS would deny a license to any applicant who "(6) has interfered with, threatened, abused (including verbal abuse), or harassed any [APHIS official] in the course of carrying out his or her duties." As explained below under the subheading "§ 2.11 Denial of license," and in the supplementary information to the proposal of March 31, 1987, at 52 FR 10300, we explain that we have determined the need to include in the regulations a prohibition against interference with APHIS officials. Also, as explained in greater detail below under that subheading, § 2.11 applies to denial of initial license applications only in this revised rule, and not to renewals. Based on our experience in enforcement efforts, we have determined that it is necessary to require licensees to comply with the prohibition against interference and harassment of APHIS personnel, as well as new applicants. We are therefore removing paragraph (a)(6) from § 2.11 in the final rule and are including its provisions as § 2.4 in the revised rule so that it is applicable to both initial license applicants and licensees.

Section 2.5 Duration of license and termination of license

We did not receive any comments regarding this section as proposed. We are revising § 2.5, however, to clarify that licenses are valid and effective if renewed each year and have not been terminated, suspended, or revoked. Similarly, we are revising proposed paragraph (b) to refer to an application for license renewal. These amendments are necessary to avoid any misconception that every license automatically terminates at the end of its 1-year term and that each year an applicant must follow the procedure applicable to obtaining an initial license. For this reason, and as previously stated, we are replacing the word "termination" with "expiration" in § 2.5 and all of Subpart A wherever it refers to the calendar end of the 1-year license term.

We are making one correction to § 2.5(b) to specify that a license will be notified by "certified" mail, rather than first class mail, of the expiration date of a license, to ensure that all licensees have notice that they must renew their license or it will automatically terminate because it has expired. Except for nonsubstantive changes made for clarification, the remaining provisions of this section remain as initially proposed.

Section 2.6 Annual license fees

We received a number of comments addressing the proposal to increase license fees. Thirty-seven dealers expressed opposition to yearly license fees in general. Charging license fees is statutorily mandated. Section 23 of the Act directs the Secretary to charge and collect reasonable license fees "adjusted on an equitable basis taking into consideration the type and nature of the operations to be licensed * * *" (7 U.S.C. 2153).

Nine comments from the general public and 6 dealers indicated their general support for the increased license fees. One member of the general public stated that the increases were too low. We received 49 comments [32 dealers, 12 exhibitors, and 4 members of the general public] stating that some fee increase is justified, but that the increases we proposed are too high or too drastic a change from the current fee tables. We received 298 comments (273 from the research community and 25 from members of the general public) stating concern that the fee increases could discourage some small dealers from becoming licensed. We have reconsidered the proposed fee structure in light of those comments and are revising them downward as follows: (For ease of comparison, the proposed fees are indicated in parentheses, and the revised fees are indicated without parentheses.)

| TABLE 1.—DEALERS, BROKERS, AND OPERATORS OF AN AUCTION SALE—CLASS “A” AND “B” LICENSES |
|-------------------------------------------------|----------------|----------------|
| Over                                           | But not over   | (Fee) Fee      |
| $0                                             | $500           | $(50) $30      |
| 500                                            | 2,000          | (100) 60       |
| 2,000                                          | 10,000         | (200) 120      |
| 10,000                                         | 25,000         | (400) 225      |
| 25,000                                         | 50,000         | (600) 350      |
| 50,000                                         | 100,000        | (800) 475      |
| 100,000                                        | 1,000,000      | (1,000) 750    |

| TABLE 2.—EXHIBITORS—CLASS “C” LICENSE |
|---------------------------------------|----------------|----------------|
| Number of animals                     | (Fee) Fee      |
| 1 to 5                                | $(50) $30      |
| 6 to 25                               | (125) 75       |
| 26 to 50                              | (225) 175      |
| 51 to 500                             | (375) 225      |
| 501 and up                            | (500) 300      |

We believe these fees are a reasonable increase over the existing fees, and that they are equitably adjusted for the different classes of licensees and for the ranges in dollar volume of business derived from transactions involving animals.

We have removed proposed paragraph (b)(4) from § 2.6 in the revised rule because it could be construed as implying that a dealer can operate without a license. This is not the case. Only persons exempt from the licensing requirements may operate without a license, as provided in § 2.1(a)(3). Proposed paragraphs (b)(5) and (6) are redesignated as paragraphs (b)(4) and (5) in this revised rule.

We are revising paragraphs (b)(1) through (5) to clarify that paragraphs (b)(1) through (3) are applicable to license renewals, paragraph (b)(4) is applicable to initial licenses, and paragraph (b)(5) is applicable to both initial licenses and license renewals.

We received 8 comments (4 from exhibitors, 3 from members of the general public, and 1 from a dealer) regarding the division of fees between the lessor and lessee of animals, as provided by proposed § 2.6(b)(5). Paragraphs (1), (2), and (5), stating that either the lessor or lessee should be responsible for including the revenue from a leased animal in determining their annual fee, but not both. We disagree with these comments since both the lessor and lessee derive income from the leased animals. There are two income streams resulting from use of a leased animal, and both business operations are required to pay a fee which is equitable for the nature and type of operation it is. Also, both the lessor and lessee are licensed, and thereby impose costs on the Department to ensure compliance with the regulations and standards. We believe it is proper to require both the lessor and lessee to include their respective income from an animal in determining their annual fee.

We also received 4 comments from the research community and 2 from members of the public suggesting the need to code animals leased to research facilities as a tracing mechanism to ensure that the animals are not used for more than one major operative procedure from which they are allowed to recover. We consider this requirement to be unwarranted since, to the best of our knowledge, animals are rarely, if ever, leased for research purposes. We are not making any changes in § 2.6 based upon this comment.

We are making one change in paragraph (d) for clarification. Paragraph (d) provides that if a person meets the licensing requirements for more than one class of license, he must pay the fee for his predominant type of
business, as determined by the Secretary. The clarification will add that in addition to the fee paid, the class of license that person must obtain will be determined by his or her predominant type of business. As a result of this change, a person cannot have more than one license in accordance with § 2.11(c). The words "obtain a license and" are added following "he shall be required to." We are revising the rule to refer to both masculine and feminine genders. Accordingly, "he" is replaced with "he or she" in § 2.6(d) and throughout the revised rule. Similarly, "his" is replaced with "his or her" wherever it appears.

Section 2.7 Annual report by licensees

We are revising proposed § 2.7 to clarify that it applies to license renewals only, and not to initial license applications.

Proposed § 2.7(a) would provide as follows:

Each year, within 30 days prior to the termination of his/her license, a licensee shall file with the Area Veterinarian in Charge an application for license and annual report upon a form which will be furnished to him upon request to the Area Veterinarian in Charge. When the requirements of §§ 2.21, 2.25, 2.3, and 2.6 have been met, the license will be issued subject to the exceptions in §§ 2.5, 2.10, and 2.11.

We are revising proposed § 2.7(a) to refer only to license renewals and the requirement that licensees submit an annual report in order to renew their license. In this revised rule, we refer to the expiration date of the license and have replaced "license" with "license renewal." We are also removing the last sentence of proposed § 2.7(a) because it refers to requirements applicable to issuance of an initial license, and these are set forth in § 2.21(d).

Three dealers and 1 exhibitor commented that clarification is needed concerning requirements to include statements about young animals in their annual reports and in other reports. The requirement to identify all dogs and cats when obtained or when weaned is set forth in proposed § 2.50. All animals must be identified in the licensee's records at his or her facility when born or obtained from outside the premises, in accordance with proposed §§ 2.75 and 2.77. Proposed § 2.7(d) would require exhibitors (Class "C" licensees) to include in their annual report the number of animals owned, held, or exhibited by the licensee either during the previous year or at the time of signing the annual report, whichever is greater. The figure used must include all animals regardless of age, and is the basis for determining the Class "C" license fee. We do not believe this requirement needs further elaboration in the regulations.

We received 8 comments (4 exhibitors, 3 dealers, 1 from the research community) objecting to the requirement provided in proposed § 2.7(e) for licensees to have the attending veterinarian certify in the licensee's annual report that the attending veterinarian understands the regulations and standards under the Act, and that he or she has visited the premises and carried out the responsibilities indicated in the regulations and in the written program of adequate veterinary care. The commenters stated that the requirement to have a written program of veterinary care as provided in proposed § 2.40 is sufficient. We agree that the attending veterinarian should not be required to sign the licensee's annual report in light of the requirements in proposed § 2.40 that licensees maintain a written program of adequate veterinary care which is subject to inspection at the licensee's facility and is sent to the Area Veterinarian in Charge each year. We have therefore deleted this requirement from the revised rule.

Section 2.8 Notification of change of name, address, control, or ownership of business

We have made one correction in this section. The phrase "or by any additional sites" should read "or of any additional sites...." We received no comments addressing this section and have made no other substantive changes.

Section 2.10 Licensees whose licenses have been suspended or revoked

Two dealers commented in opposition to our proposal to make license revocations permanent. We were urged to allow the facts and circumstances surrounding the offense leading to revocation to be taken into consideration in determining the appropriate amount of time a former licensee must wait before he or she could apply for a new license, instead of being permanently ineligible. We disagree with these comments. Whether a license should be suspended or revoked is determined after notice and a hearing. Testimony as to the facts and circumstances surrounding the offense would be brought out at the hearing. In such an administrative proceeding conducted in accordance with the Department's Rules of Practice, revocation would be ordered for serious offenses which are determined to warrant this sanction, as compared to suspension, which could be ordered for a stated period of time for less serious offenses. We believe that the commenters' concerns that the facts and circumstances be considered would be amply addressed in the required hearing. Accordingly, revocation of a license will remain a permanent sanction. As discussed below under the next subheading, we are adding to § 2.10(a) the provision from proposed § 2.11(b) stating that any person whose license has been suspended may reapply for a license after the period of suspension is ended. We are revising it, however, to provide that any person whose license has been suspended may apply to the Area Veterinarian in writing for reinstatement of his or her license, rather than having to reapply for a new license. No other substantive changes are made in this section.

Section 2.11 Denial of license

The comments we received addressing proposed § 2.11 deal principally with existing licenses, convincing us of the need to separate the provisions concerning denial of initial license applications from provisions concerning suspended or revoked licenses. We are discussing those comments in this discussion of "§ 2.11, Denial of license," since readers who are more interested in the substance of proposed § 2.11 than that of § 2.10, and who may have commented specifically with regard to § 2.11, may look to this heading for our response instead of the heading, "§ 2.10 Licensees whose licenses have been suspended or revoked."

Many of the comments we received concerning proposed § 2.11 addressed due process issues which would be raised if we suspended or revoked a license. As should be clear from the supplementary information, paragraph (a) and most of paragraph (b) of this section are concerned with denial of initial license applications, and do not have any bearing on suspension or revocation of existing licenses. We have renamed this section "Denial of initial license applications" to avoid any further confusion.

Paragraphs (b) and (c) refer to both suspended licenses and denials of license applications. For purposes of clarity, we are removing the reference to suspended licenses from § 2.11.

Accordingly, paragraphs (b) and (c) will address denial of initial license applications. The content of proposed § 2.11(b) with regard to suspended licenses has been added to § 2.10(a) in the revised rule, and that of § 2.11(c) is already contained in § 2.10(a) so there is no need for further revision.
We received several comments objecting to the proposed reasons for which we would deny a license application, and to this section in general. Thirty-three commentators from the research community stated that a plea of nolo contendere (no contest) under state or local cruelty to animals laws within 1 year of application for a license should not be an automatic basis for denial of a license, since a licensee may elect to enter this plea rather than a plea of not guilty, to avoid the time and expense of a full hearing on the charge.

In light of this comment, we are revising the rule to provide that if no penalty is imposed as a result of a plea of nolo contendere, the applicant may reapply immediately without having to wait a year. We believe this will accommodate those persons who exercise their rights to enter this plea, while allowing the Administrator to deny a license to persons involved in violations of the cruelty to animals laws.

We received 368 comments (321 from the research community, 11 from dealers, 7 from exhibitors, and 27 from members of the general public) opposing subparagraph (6) as a basis for denial of a license. A similar prohibition against interfering with, threatening, abusing, or harassing any APHIS official in the course of carrying out his or her duties is provided in § 2.4 in the revised rule. Accordingly, we have added § 2.4 to § 2.11(a)(1) in the revised rule so that it remains a basis for denial of a license.

As proposed, subparagraph (6) would provide that a license will not be issued to any applicant who “[i]nterferes with, threatens, abuses, or harasses any Veterinary Services inspector in the course of carrying out his/her duties.” The comments stated that this is too ambiguous and subjective a basis for denying or revoking a license. We are retaining this basis for denial of a license because we have determined a genuine need for it, based upon our experience in enforcing the regulations. First, adequate safeguards against subjective determinations are contained in § 2.11(b) as proposed, which provides that an applicant whose application is denied may request a hearing in accordance with the applicable rules of practice. At a hearing, the Department would have to support its denial of an application in accordance with the rules of practice and would have to show that it is reasonable and not arbitrary and capricious. We believe this is sufficient to avoid subjectivity or arbitrariness from entering into the determination. Second, § 2.11 applies to denial of an application for a license, not suspension or revocation of an issued license. Suspension and revocation procedures include notice and hearing and must satisfy the requirements of due process of law.

We received 318 comments (282 from the research community, 10 dealers, and 26 members of the general public) objecting to proposed paragraph (b) of § 2.11 which provides that the denial of a license would remain in effect until a final legal decision is made following a hearing, on the basis that this could deprive a person of their livelihood for years before they receive the benefit of due process of law.

As explained above, this section applies to initial license applications, not to renewals of existing licenses. Suspension and revocation of an issued license would be in accordance with the requirements of the applicable Departmental rules of practice. Except as previously noted, paragraph (b) remains as initially proposed.

We received 303 comments (278 from the research community and 25 from members of the general public) opposing subparagraph (6), which provides that a legal entity in which a person whose license application has been [suspended or] denied has a substantial interest, financial or otherwise, will not be licensed within 1 year of the denial [or until completion of the suspension period]. (The bracketed provisions refer to suspended licenses and are contained in § 2.16(a) in the final rule).

One commenter was concerned that the regulation as proposed could prevent a facility from being licensed for a year simply because one of its shareholders had been denied a license. We do not believe this concern is well-founded, as the regulation is limited to legal entities in which a person whose application has been denied has a “substantial” interest. This may or may not apply to a shareholder, depending upon that person’s interest. We do not agree with the commenter that the proposed restriction should apply only if that person has a “substantial interest, financial or otherwise, and responsibility for the operation or management of the applicant.” Licenses can be issued at the lowest level of legal entity, that is, to individuals. Any person who was engaged in activity serious enough to warrant denial of a license application should not be allowed to continue in operation under the umbrella of another legal entity in which they can exercise any measure of control and can influence operations. This is what the proposed regulation is intended to prevent. A similar provision has been included in the regulations since 1970 without problems or objections, and it remains in this revised rule. Except for deletion of references to suspension of licenses which are covered by § 2.10, paragraph (c) remains as initially proposed.

We received 7 comments from the general public stating that the proposed regulations concerning denial and revocation of licenses are too lenient on facilities and on individuals and should be more stringent. We have attempted to strengthen the regulations in areas where we believe will enhance our enforcement efforts. We believe that the regulations as proposed and as revised in this rule provide sufficient bases upon which to deny, suspend, or revoke licenses, and will assist us in handling noncompliance and other problematic situations we have encountered in regulating licensees.

Except for the changes described above, Subpart A—Licensing remains in the revised rule as originally proposed. Subpart B—Registration

Proposed § 2.28, "Annual report of research facilities," is redesignated § 2.31 in this revised rule. Comments received addressing proposed § 2.28 are discussed under the heading, "Subpart C—Institutional Animal Care and Use Committee and Other Requirements for Research Facilities," subheading, "Proposed § 2.28 Annual report of research facilities."

Section 2.25 Requirements and procedures

We received 299 comments (274 from the research community and 25 from members of the general public) stating that § 2.25 as proposed is generally acceptable. Commenters who addressed the proposed registration requirements and procedures were concerned with the requirement that registrants update their registration form every 3 years. As explained in the supplementary information to the proposed rule, this requirement is new to the Animal Welfare regulations. We received 122 comments from the research community and 1 from a member of the general public stating that renewal of registration should be required every 5 years to coincide with the U.S. Public Health Service current requirement for the submission of assurance statements covered by the Health Research Extension Act of 1985. Five commenters from the research community stated more generally that the proposed requirements should coincide with those of the PHS. The proposed 3-year time period corresponds with other federal recordkeeping requirements, most
notably the USDA records retention and disposition policy, making it the most practical interval for us to administer. The PHS requirement for submission of assurances up to every 5 years is not inconsistent with the 3-year period we proposed. We have consulted with representatives from HHS specifically on this point, and they have indicated their willingness to abide by the 3-year registration renewal period as proposed. Accordingly, we are retaining the requirement for renewal of registration every 3 years.

We received one comment from a member of the research community requesting clarification regarding the requirement for registration by federal research facilities. We received another comment from a member of the research community requesting clarification of proposed § 2.25, generally. In response to the first comment, we are clarifying the section to state that federal research facilities are not required to register with the Secretary under the regulations. In response to the second comment, we note that except for provisions requiring research facilities to update their registration every 3 years, § 2.25 as proposed is substantially the same as it has been since 1987. We have experienced few problems in applying its requirements since that time, and we do not believe clarification is necessary.

Except for the clarification regarding federal research facilities, no changes are made in § 2.25 in the revised rule.

Section 2.26 Acknowledgement of regulations and standards

Proposed § 2.26 provides as follows:

A copy of the regulations and standards in this Subchapter will be supplied with each registration form. The registrant shall acknowledge receipt of such regulations and standards and agree to comply with them by signing a form provided for such purpose by Veterinary Services. Such form shall be filed with the Area Veterinarian in Charge.

We received 298 comments (274 from the research community and 25 from members of the general public) stating that this section as proposed is generally acceptable. One commenter stated that it should be deleted from the regulations. The required acknowledgement is necessary to ensure that registrants have knowledge of the regulations and standards with which they must comply. A similar provision is contained in Subpart A—"Licensing" for the same reason. We believe that the acknowledgement should remain in the regulations.

One commenter requested general publication and distribution of the Animal Welfare Manual and applicable Veterinary Services Memoranda. These are internal USDA, APHIS documents intended to assist APHIS inspectors. They do not contain "rules of general applicability" and accordingly, there is no need to publish them in the Federal Register as part of the regulations.

The proposed section is substantially the same as current § 2.26. It remains as proposed.

Section 2.27 Notification of change of operation

Proposed paragraph (a) of § 2.27 requires that:

(a) registrant shall notify the Area Veterinarian in Charge by certified mail of any change in the name or address, or any change in the operations or business, which would affect the research facility, exhibitor, carrier, or intermediate handler, within 10 days after making such change.

We received 422 comments (397 from the research community and 25 from members of the general public) objecting that proposed § 2.27(a) is too broad. We received 295 comments (270 from the research community and 25 from members of the general public) expressing concern that the supplementary information is inconsistent with the proposed regulation because it is broader than the proposed regulation. The supplementary information accompanying Subpart B "Registration" states that notification is required "of any change in address, operations or management." The commenters expressed concern that the preamble language would encompass personnel or management changes which do not affect the information required by the registration form.

Another commenter was concerned that the preamble implied that failure to report minor management or operations changes would be a violation of the regulations, and that clarification to avoid difficulties in interpreting this requirement is necessary. We are in agreement with these comments and are adopting the clarification suggested by a commenter, to read as follows:

A registrant shall notify the Area Veterinarian in Charge by certified mail of any change in the name, address, or ownership, or other change in operations affecting its status as a research facility, exhibitor, carrier, or intermediate handler, **

This revision should clarify that notification is required for operational changes which affect this registrant's status as a registered entity, in addition to name and address changes. This requirement will assist us in keeping accurate records on current registrants, and avoid wasting Agency resources when a registrant has gone out of business or has changed its operations.

We received 302 comments (277 from the research community and 25 from members of the general public) stating that notification should be required within 30 days instead of the 10 days proposed. The 10-day period is in the current regulations and has been in the regulations since they were first issued. It has caused no problems or difficulties and is a sufficient amount of time within which affected facilities can report. We are therefore retaining it in the regulations.

Except for the change in paragraph (a) set forth above, § 2.27 remains in the revised rule as initially proposed.

Subpart C—Institutional Animal Care and Use Committee and Other Requirements for Research Facilities

Introduction

Proposed Subpart C elicited numerous and varied comments addressing the proper role, duties, and structure of Institutional Animal Care and Use Committees ("Committees") and research institutions in promoting animal welfare. Many of the commenters expressed particular concern that the proposed regulations placed responsibilities on the Committee and on the attending veterinarian (Subpart D) that they believed should lie with the institution. There was also concern that APHIS improperly placing the Committee and the attending veterinarian in the position of whistleblower and enforcer of the Animal Welfare regulations.

Research facilities have been required, through their animal care committee and/or attending veterinarian, to provide guidelines and consultation to their research personnel regarding the use of pain relieving drugs since the regulations were revised in accordance with the 1970 amendments to the Act. They have also been required to have a program of adequate veterinary care established and maintained under the supervision and guidance of a veterinarian. The 1985 amendments to the Act placed special significance on these institutional personnel as a means of assuring animal welfare, and represented a significant departure from the then-existing Act. The clear message from Congress was that additional regulatory efforts are needed to enhance animal welfare, to minimize animal pain and distress in research, and to restrict the multiple use of animals in major operative experiments. For the first time, Congress legislated that all research facilities must have an "Institutional Animal Care Committee" of a statutorily prescribed...
composition with inspection and reporting duties (7 U.S.C. 2143(b)). Similar committees are already in place at research facilities receiving grant monies and awards from the U.S. Public Health Service under the Health Research Extension Act of 1985, Pub. L. 99–158, for research, training, and biological testing activities involving animals. Congress also mandated in the 1985 amendments to the Act that research facilities provide training to scientists, animal technicians, and other personnel involved with animal care and treatment. The Act retained the requirement that the facilities provide assurances they are adhering to the standards promulgated under the Act, and requires that they provide an explanation for any deviation from those standards. The 1985 amendments to the Act continue the Secretary’s authority “to promulgate such rules, regulations, and orders as he may deem necessary in order to effectuate the purposes of this Act.” (7 U.S.C. 2151).

The legislative history of the 1985 amendments to the Act demonstrates that at least one significant proponent in the Senate was of the view that “[v]eterinary inspectors from the U.S. Department of Agriculture cannot be present on a daily basis. However, their enforcement capability can and should be enhanced by the Institutional Animal Committee...”. Senate Majority Leader Dole’s statement, Congressional Record, December 18, 1985, at p. S17943.

As part of our response to the mandate from Congress, we proposed three new sections, §§ 2.30, 2.35, and 2.40, to implement the 1985 amendments to the Act. Section 2.30 sets forth responsibilities and requirements specifically imposed upon research facilities. Section 2.35 details the responsibilities and duties of the Institutional Animal Care and Use Committee which each research facility must establish. Section 2.40 details the requirement imposed upon all registrants and licensees to provide and maintain a program of adequate veterinary care and the requirements imposed upon attending veterinarians. This section consolidates the veterinary care regulations currently contained in each subpart of Part 3 and imposes additional requirements based upon the 1985 amendments to the Act.

Reorganization of §§ 2.30 and 2.35

Many comments we received were critical of the allocation of certain duties and responsibilities to the Committee and attending veterinarian rather than to the facility. Most of the comments we received were from members of the research community, the group most affected by the regulations proposed in Subpart C. Unless otherwise indicated, the comments addressed below were received from members of the research community.

Sixty-one commenters stated that too much authority would be given to the attending veterinarian and the Committee under the proposed regulations. We also received 400 comments (375 from the research community and 25 from members of the general public) objecting that the proposed regulations would place too much responsibility on the attending veterinarian and the Committee. Particular duties and areas of responsibility proposed in the regulations were singled out by the commenters as being improper and inappropriate.

The statutory language and the legislative history of the 1985 amendments to the Act support our proposal to impose various duties and responsibilities on the Committee and on the attending veterinarian. We agree, however, with the commenters that the ultimate responsibility for animal welfare at research facilities rests with the institutions themselves. We have carefully considered the comments we received, and have determined to reorganize and restructure portions of Subpart C in this revised rule to place responsibility on the research facilities, except where it is expressly reserved by the Act to the Committee. Similarly, we have revised portions of Subpart D concerning the requirement for a program of adequate veterinary care at research facilities to reflect that many of its aspects are the responsibility of the research facility, unless otherwise required by the Act.

Those areas of responsibility that are reassigned to the research facilities in the revised rule are described below under subject headings for ease of reference. We address the comments we received concerning the substance of the proposed provisions, as opposed to the allocation of responsibility for them, following this discussion.

The following chart provides the derivation of the paragraphs contained in § 2.30 in the final rule, as an additional aid to the reader. The paragraphs listed under the heading, “Revised rule” were derived from the corresponding paragraphs listed under the heading, “Proposed rule.”

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1. Training. Section 13(d) of the Act requires the research facility to train personnel involved with animal care and treatment (7 U.S.C. 2143(d)). We had proposed in § 2.35(f) that each research facility provide training for personnel in animal use, care, and treatment and that this training be provided through the Committee and the attending veterinarian. The Committee would review the training and designate those personnel requiring additional training, and the training program would include instruction in certain prescribed areas as well as in other areas the Committee may feel is necessary. We received 467 comments (462 from the research community and 25 from members of the general public) stating that these training requirements should not be included in § 2.35 since they are the facility’s responsibility, not the Committee’s. We agree that training is ultimately the responsibility of the facility. The Act does not require the training requirement to the Committee. Accordingly, in the revised rule we have removed training from § 2.35 and have included it in § 2.30(f) as a requirement for research facilities.

2. Procedures for personnel to report violations. Thirty-two commenters from the research community objected to the requirement contained in proposed § 2.35(b)(2)(iii) that the Committee establish procedures for personnel to report violations of the regulations or standards, including problems, deviations, or deficiencies with animal housing, care, or use. As proposed, the
Committee would also review and investigate reports, if warranted, and file a report. The commenters stated that the duty to establish these procedures should be imposed upon the research institution, and not the Committee. We agree that this requirement is not imposed upon the Committee by the Act and we therefore are including it in § 2.30(j) of the revised rule as the facility's responsibility. We continue to believe, however, that the Committee is the appropriate body to review and investigate any reports received because it is established to assess animal care and use and because it has inspection authority under the Act and the regulations. We are retaining that allocation of authority as proposed. The report prepared as a result of the Committee's review would be filed at the same central location as those prepared as part of the Committee's semiannual inspections.

3. Response to Agency requests for information. We received two comments objecting to proposed § 2.35(b)(3)(i) which would require the Committee to respond to requests from the Deputy Administrator [Administrator] to make research protocols [ACUPs] involving animals and assurance statements available to the Agency. The commenters stated that this should be the responsibility of the research facility, not the Committee. We agree that the research facility is ultimately accountable for responding to official Department requests, and we are including responsibility for doing so in § 2.30(f) of the revised rule as an additional requirement for research facilities. As explained in the revised rule for Part 1 published elsewhere in this issue, research protocol is changed to ACUP and Deputy Administrator is changed to Administrator. (See companion docket no. 88-013.)

4. Use of pain relieving drugs. Similarly, although we did not receive any comments regarding proposed § 2.35(b)(3)(iv), which requires the Committee to explain how pain relieving drugs are used whenever an animal is involved in a painful procedure, the ultimate responsibility for this assurance lies with the facility and we are therefore including this requirement in § 2.30(e) in the revised rule.

5. Painful procedures. Ninety-four commenters from the research community objected to Committee responsibility for requiring certain assurances and conduct when painful procedures will be performed, as proposed in § 2.35(b)(3)(v) through (vii). Paragraph (v) of proposed § 2.35(b)(3) provides that the Committee shall require written assurances from the principal investigator that alternative procedures were considered for a procedure likely to cause pain or distress, that there are no other suitable procedures, and that the experiment is not unnecessarily duplicative. Paragraph (vi) of proposed § 2.35(b)(3) provides that the Committee must require that certain conditions are followed in any practice which could be expected to cause pain to animals. Paragraph (vii) of proposed § 2.35(b)(3) would require the Committee to assure that no animal is used in more than one major operative experiment from which it is allowed to recover, except in certain circumstances. Again, research facilities are ultimately responsible for these assurances and for compliance with the requirements set forth in § 2.35(b)(3)(v) through (vii) as part of its operations. Because the Act does not specifically impose these duties on the Committee, we are placing them in paragraphs (e) and (f) of § 2.30 in the revised rule, as additional requirements for research facilities.

6. Exceptions. We did not receive any comments specifically addressing proposed § 2.35(c), which provides that exceptions to compliance with the Animal Welfare regulations and standards shall be made by the Committee only when necessary for the research design and they are specified in the protocol [ACUP]. A similar provision is contained in proposed § 2.30(g) with regard to painful procedures and major operative experiments from which an animal is allowed to recover. Under both sections, the principal investigator would be required to file a report with the Committee explaining any areas of noncompliance. A copy of the report must be kept on file by the facility and made available for Agency inspection or to officials of granting agencies. These provisions are set out in paragraphs (f) and (g) of § 2.30 in the revised rule, as the research facility is ultimately responsible for any exceptions to the Act and regulations, although exceptions must be approved by the Committee.

7. Written procedures for exercise for dogs and for the psychological well-being of nonhuman primates. We received 301 comments (276 from the research community and 25 from members of the general public) stating that the responsibility for carrying out the requirements of proposed § 2.35(d) should be imposed on the research facilities, and not the Committee. Thirty-five commenters similarly stated that the responsibility should be imposed on the research facility, which can then delegate authority to the Committee to carry out the requirements.

Proposed § 2.35(d) provides as follows:

The Committee shall establish, in consultation with the attending veterinarian, written procedures and systems for the exercise of dogs and for the psychological well-being of primates in accordance with the regulations and standards, and a record system indicating that such a procedure or system is being carried out.

Again, the Committee is not required by the Act to establish these procedures, although it is required to inspect for compliance with the Act. Therefore, we are including the substance of proposed § 2.35(d) in § 2.30(h) as a requirement for research facilities in the revised rule.

8. Federal research facilities. The requirements contained in proposed § 2.35(e) “Federal research facilities,” have also been moved to § 2.30 in the revised rule since they are a responsibility of a research facility, albeit a federal research facility, and not the Committee.

9. Proposed § 2.35(g) “Annual report of research facility” requires the Committee Chairman to sign an assurance statement on the Annual Report (VS Form 18-23) certifying that the Committee has carried out the responsibilities and requirements of § 2.35, that the facility is in compliance with the Animal Welfare standards, that the Committee has required a detailed explanation to be provided by the principal investigator when pain relieving drugs are withheld, that all explanations are attached to the annual report, and that the committee has required that all other exceptions to the standards be required by research protocol [ACUP] and approved by the Committee. We received 49 comments stating that the responsible institutional official with authority to bind the facility should be required to sign the statement, not the Committee Chairman, since the provision of an adequate animal care and use program is the facility’s responsibility. Twenty-nine commenters cited the assurance required in § 2.28(b)(9) “Annual report of research facilities,” and objected that the additional assurance of the Committee Chairman required in proposed § 2.35(g) is redundant and outside the authority of the Act.

As discussed under the heading “Subpart B—Registration,” in this final rule, only the responsible institutional official with authority to bind the facility will be required to sign the annual report. That official may in turn require assurances from the Committee of the kind proposed in § 2.35(g), however, we
are not requiring them in the facility's annual report. The substance of the assurances that were required of the Committee Chairman in proposed § 2.35(g) will be deleted from that section and required instead in § 2.35(b)(2)(D) of the revised rule, as part of the Committee's report.

Subpart C of the revised rule has been rewritten to reflect that the areas of responsibility described above have been reassigned and are part of the requirements imposed upon research facilities. Comments we received addressing the substance of the proposed provisions of Subpart C, as opposed to comments addressing responsibility for those areas, are discussed below in the order in which those provisions appear in the revised rule. We believe that discussing the comments in this manner will help guide the reader through the substance of the revised rule.

General

We received 301 comments (276 from the research community and 25 from members of the general public) stating that this subpart should include standards which apply only to research facilities. Subpart C as proposed does not require them in the facility's annual report. The substance of the requirements imposed upon research facilities, Comments we received addressing the substance of the proposed provisions of Subpart C, as opposed to comments addressing responsibility for those areas, are discussed below in the order in which those provisions appear in the revised rule. We believe that discussing the comments in this manner will help guide the reader through the substance of the revised rule.

Section 2.30 Additional requirements for research facilities

Section 2.30(a). Thirty commenters suggested that paragraph (a) of § 2.30 should specifically reference research facilities using or holding animals for experimentation, in addition to those using or holding animals for "research, testing, or teaching" as proposed. We did not propose to include separately "experimentation" since it is generally considered to be covered by the term "research." Section 2 of the Act defines "research facility" as one which, among other things, uses live animals in "research, tests, or experiments * * *" (7 U.S.C. 2132). Since the Act enumerates these functions, we agree that the regulations should as well. Section 2.30(a) is therefore revised by adding "experimentation" following "research."

We received 131 comments objecting to the requirement contained in proposed § 2.30(a)(2) that research facilities ensure that adequate veterinary care, including the appropriate use of drugs or euthanasia, is provided for at all times. We disagree with these commenters. We believe this requirement is necessary in order to fulfill the requirement of the Act that adequate veterinary care be provided at all times by research facilities (7 U.S.C. 2143(a)(3)(A)). Section 2.30(a)(2) remains in the revised rule as initially proposed.

The requirements for adequate veterinary care are provided in Subpart D—"Attending Veterinarian and Adequate Veterinary Care." We are also adding a new paragraph (a)(3) to § 2.30 to state that research facilities are required to establish and maintain a written program of adequate veterinary care, in accordance with § 2.40. Proposed paragraph (a)(3) is redesignated (a)(4) in the revised rule.

Section 2.30(b). We received 322 comments (297 from the research community and 25 from members of the general public) stating that the Institutional Animal Care and Use Committee which § 2.30(b) requires to be established and maintained should be renamed the "Institutional Animal Committee" to be consistent with the Act. For the reasons explained under the heading, "Committee," in the supplementary information to the revised rule for Part I—"Definition of Terms," published elsewhere in this issue of the Federal Register (companion docket no. 88-013), we have determined that "Institutional Animal Care and Use Committee" is more appropriate since it is descriptive of the areas of concern to the Committee and is consistent with the terminology used by the Public Health Service, National Institutes of Health, which utilizes similar committees. No change is made to the name of the Committee in the revised rule.

Section 2.30(c). As proposed, § 2.30(c) would require research facilities to "provide the Committee and the attending veterinarian with the authority to enter all animal areas at any reasonable time in order to carry out their responsibilities." We received 535 comments (510 from the research community and 25 from members of the general public) objecting to this requirement on the grounds that it exceeds our statutory authority, could interfere with research, and could lead to unauthorized release of proprietary information. We believe these concerns are unwarranted.

First, statutory authority exists: the Act directs the Secretary to promulgate standards with respect to animals in research facilities, to include requirements for animal care, treatment, and practices to ensure pain and distress are minimized, for adequate veterinary care with appropriate use of drugs, for consideration of alternatives to any painful procedure, for consultation with a doctor of veterinary medicine in the planning of painful procedures, and for ensuring that an animal is not used in more than one major operative experiment from which it is allowed to recover except if scientifically necessary (7 U.S.C. 2145(a)(8)). The Act specifically authorizes the Committee, of which the
attending veterinarian is a member, to conduct inspections of research facilities, to review practices involving animals and the condition of animals, and to ensure compliance with the provisions of the Act to minimize pain and distress to animals (7 U.S.C. 2143(b)(3)). Section 21 of the Act authorizes the Secretary to "promulgate such rules, regulations, and orders as he may deem necessary in order to effectuate the purposes of the Act." (7 U.S.C. 2151).

Second, concerns that inspections at any time could interfere with ongoing research and with research results by disturbing the animals or upsetting the controlled environment could be allayed by providing guidelines for conducting inspections in the facility's written policies and procedures. In this manner, facility personnel, including Committee members and the attending veterinarian, will be informed of any necessary and reasonable restrictions on the timing of inspections before any are performed under these regulations. The establishment of guidelines would help reassure research personnel that the inspection regulations are implemented in good faith. We caution, however, that they must not be used as a means of preventing inspections during research, surgery, or other procedures.

Third, regarding release of trade secret or proprietary information, the scientific or proprietary portion of ongoing research is not the subject of inspection. Moreover, even if trade secrets or proprietary information were apparent on physical inspection, Section 27 of the Act makes it unlawful for any member of the Committee to release any confidential information of the research facility, including trade secrets, and provides sanctions for violations (7 U.S.C. 2157). This statutory deterrent should allay concerns about the unauthorized release of proprietary information.

It is necessary that the Committee be assured free access to all animal areas to perform its responsibilities and duties properly. Access to all animal areas at any reasonable time to conduct inspections as the Committee deems appropriate must be assured in order to effectuate the purposes of the Act and as a means of promoting compliance with the Act and the regulations between Committee inspections. Reports are not a substitute for first-hand observation of animal care to ensure compliance.

We are revising § 2.30(c) in the revised rule to require that each research facility must also provide the attending veterinarian with the authority to enter all animal areas at any time, to ensure compliance with the facility's program of adequate care. As explained in greater detail below under the heading, "Subpart D—Attending Veterinarian and Adequate Veterinary Care," this access is necessary to enable attending veterinarians to perform their duties as intended by the Act. Section 2.30(c) is revised to reflect this change.

Section 2.30(d). Proposed § 2.30(d) would require Committee approval only for research protocols [ACUPs] falling under Categories 3 and 4 of the "Categories of Animal Use in Research and Teaching" in proposed § 2.35(b)(3)(ii), which categorize procedures according to the degree of animal pain or distress involved. Procedures that involve "significant but unavoidable pain or distress to the animals" are in Category 3. Procedures that involve "the inflicting of severe pain or distress or chronic, unrelieved pain or distress, or death" are in Category 4. Procedures that involve no pain or minor pain are in Category 1 and 2, respectively.

Nineteen commenters (16 from the general public and 3 from the research community) suggested that the Committee review and approve all research protocols [ACUPs] instead of only those classified in the third and fourth categories of pain. One commenter suggested that the Categories of Animal Use could result in researchers classifying their procedures in Categories 1 and 2 to avoid closer scrutiny.

We initially proposed Committee review of protocols [ACUPs] involving more significant amounts of pain or distress as a means of fulfilling the intent of Congress to minimize animal pain and distress. The Committee would approve of those ACUPs only if they were shown to be justified and scientifically necessary and if alternatives were considered and determined to be unsatisfactory. Closer scrutiny of procedures falling in Categories 3 and 4 was considered appropriate to focus attention on these concerns.

Upon reconsideration of the utility of the "Categories of Animal Use" and the difficulty of designing or selecting a practical and appropriate categorization system, we have decided to adopt the suggestion of these commenters and require approval of all ACUPs by the Committee. This practice is currently required by the U.S. Public Health Service (PHS) and therefore all research facilities receiving grants or awards under the Health Research Extension Act of 1988, Pub. L. 100-688, are already doing so. Accordingly, this requirement should not be a burdensome addition to the requirements already imposed upon research facilities.

For these reasons and as more fully explained below in the discussion of comments addressing proposed § 2.35, we are eliminating the "Categories of Animal Use in Research and Teaching" from the regulations.

We understand that the requirement for Committee review and approval of all ACUPs will impose a greater burden on the Committee's human resources and we have therefore provided a mechanism to enable the Committee to accomplish its tasks. As is more fully explained below in the discussion of § 2.35, approval by a quorum of the Committee will be required for all ACUPs. However, the Committee can assign individual members to review designated ACUPs and then present them to the Committee for approval or disapproval. In this manner, the Committee should not become overburdened or a bottleneck in the research approval process.

We received 596 comments (571 from the research community and 25 from members of the general public) stating that the requirement in proposed § 2.30(d) that the Committee review research protocols [ACUPs] exceeds our statutory authority. We received 382 comments (357 from the research community and 25 from members of the general public) stating that the requirement for protocol [ACUP] review by the Committee should be deleted. The Act provides ample authority for requiring Committee review of "protocols" [ACUPs] and that Committee review is necessary to fulfill the intent of Congress.

Section 13 of the Act (7 U.S.C. 2143) directs the Secretary to promulgate standards to govern the humane handling, care, treatment, and transportation of animals by research facilities and other regulated entities. In addition to the requirements for exercise of dogs and for a physical environment adequate to promote the psychological well-being of nonhuman primates, the Secretary is directed to include requirements for animal care, treatment, and practices in experimental procedures to minimize animal pain and distress; for requiring the principal investigator to consider alternatives to any painful procedure; for requiring consultation with a doctor of veterinary medicine; for use of pain relieving drugs; for pre- and post-surgical care by laboratory workers; and for ensuring that no animal is used in more than one major operative experiment from which it is allowed to recover except in certain circumstances. The Act states that
except to those standards may be made "only when specified by research protocol and that any such exception shall be detailed and explained in a report outlined under paragraph (7) and filed with the Institutional Animal Committee." (7 U.S.C. 2143(a)(3)(E)). Paragraph (7) of Section 13 of the Act (7 U.S.C. 2143(a)(7)) directs the Secretary to require each research facility to show upon inspection and through reports that it is complying with the Act and that professionally acceptable standards of care are being followed. In order to do so, each facility must provide information on painful procedures used, assurances that alternatives were considered, assurances that the facility is adhering to the regulations promulgated under section 13 of the Act, and an explanation for any deviation from those regulations (7 U.S.C. 2143(a)(7)).

The Committee is directed by the Act to require the establishment of a Committee at every research facility, in order to assess animal care, treatment, and practices (7 U.S.C. 2143(b)(1)). The Committee is statutorily directed to:

Inspect at least semiannually all animal study areas and animal facilities of such research facility and review as part of the inspection—(A) practices involving pain to animals, and (B) the condition of animals to ensure compliance with the provisions of the Act to minimize pain and distress to animals. (7 U.S.C. 2143(b)(3)).

The Committee is also directed to file an inspection certification report which includes:

Reports of any violation of the standards promulgated, for any deviations, required by the Secretary, including any deficient conditions of animal care or treatment, any deviations of research practices from originally approved proposals that adversely affect animal welfare, any notification to the facility regarding such conditions, and any corrections made thereafter; * * * (7 U.S.C. 2143(b)(4)).

In order for research facilities to provide the assurances required, they must be cognizant of all procedures at the facility involving animals and they must make a determination that the procedures are in compliance with the Act and the regulations. This can best be accomplished through the Committee. Research facilities will necessarily rely upon Committee inspection reports in order for them to provide the assurances required in their annual report in good faith. The responsible institutional official with authority to bind the facility will need to rely upon the Committee's reports in certifying compliance with the Act and the regulations, as required in § 2.31 of the final rule. Without this mechanism, the assurances and certifications might be successfully challenged as not based on actual knowledge.

We have determined that it is necessary that the Committee review all ACUPs, referred to as "research protocols" in our proposed regulations, in order to fulfill the intent of the Act and to effectuate the express purposes of the Act. We received 120 comments stating that review of protocols [ACUPs] should be limited to conform with the U.S. Public Health Service policy which requires Committee review of only those components of research protocols related to animal care and use. We believe that much of the resistance to the proposed requirement that the Committee review "research protocols" arises out of a misconception that the Committee would be involved in evaluating the design, outlines, guidelines, and scientific merit of proposed research. As stated in the supplementary information accompanying the revised rule for Part 1—"Definition of Terms," published elsewhere in this issue (see companion docket no. 86-013), this is not the case. The Committee will be involved with reviewing how the research will treat or affect an animal, the condition of an animal, and the circumstances under which an animal will be maintained. It will not be involved in evaluating the design, outlines, guidelines, and scientific merit of proposed research. The requirement that the Committee review what is now termed the ACUP remains in the revised rule as proposed, except that the Committee will review all ACUPs, and not just those involving significant or severe degrees of pain or distress.

Two commenters stated that, under proposed § 2.30(d), the Committee should review and approve not just painful procedures, but also the species of animals to be used for proposed research, the number to be used, the type of housing to be used, any experimental methods to be employed, and the training of investigators. As stated above, we proposed the requirement for review of the procedures classified in Categories 3 and 4 because the stated intent of Congress in amending the Act was to minimize animal pain and distress, multiple major surgeries, and unnecessary duplication of animal research. The Committee is required and authorized to assess animal care, treatment, and practices in experimental research. There is no indication in the Act or in the legislative history of the Act that Congress intended the Committee to consider the species and number of animals used, the housing to be used, experimental methods, or training of investigators, other than as they affect animal care, treatment, and procedures. Requirements for training are imposed by the Act upon the facilities (7 U.S.C. 2143(d)). All exceptions to the regulations and standards must be explained and justified by the ACUP and approved by the Committee. Accordingly, we do not agree that additional reference to Committee review of these areas is needed.

Except for the change explained above to require review of all ACUPs by the Committee, § 2.30(d) remains in the revised rule as originally proposed.

Section 2.30(e). As described above, areas of responsibility have been reassigned from the Committee to the research facility and accordingly are added to § 2.30. Comments concerning the substance of those provisions will now be addressed in the order in which they appear in the revised rule, beginning with § 2.30(e). We will discuss the material under subject headings. The section designations used in the proposed rule have been changed and are not used. However, we have included the former section designations as they appeared in the proposed rule so that the reader can cross-reference the proposal.

Painful procedures. In enacting the 1985 amendments to the Act, Congress
was particularly and expressly concerned with minimizing animal pain and distress. Toward this end, proposed § 2.30(e) would require research facilities to establish a written policy applicable to any practice which may be painful to an animal. The policy must require various measures to be taken when painful procedures are performed and must be designed to ensure that these measures are adequately followed. Proposed § 2.35 contains similar requirements although it places the responsibility for ensuring compliance with those measures on the Committee. It is rather lengthy. Each discussion begins with the requirement that the experiment does not unnecessarily duplicate previous experiments. The use of pain relieving drugs, anesthetics, analgesics, and tranquilizers does not mean that a procedure is not painful. This section applies to all procedures that involve pain or that might be expected to involve pain, whether or not the pain is relieved.

Each paragraph of § 2.30(e) is discussed individually below in numbered sections because the section is rather lengthy. Each discussion begins with the requirement of the revised rule and then explains its derivation from the proposal. Comments concerning the different provisions are then addressed. We believe this approach will assist the reader in understanding the requirements and rationale of this revised rule.

1. Section 2.30(e)(1) of the revised rule directs the research facility to require written assurance from the principal investigator to the Committee that alternative procedures were considered but were not suitable, and that the experiment does not unnecessarily duplicate previous experiments. The assurance must be given before a painful procedure can be undertaken. The assurance must also indicate what information sources were consulted, what alternative procedures were considered, and what techniques are planned to minimize pain and discomfort to the animals. This requirement was originally imposed upon the Committee in proposed § 2.35(b)(3)(v) and on the research facility in proposed § 2.30(d).

We received a number of comments concerning this assurance. We received 402 comments (377 from the research community and 25 from members of the general public) objecting to the assurance required of the principal investigator as either duplicative or not authorized by the statute. We have, by reorganizing §§ 2.30 and 2.35, eliminated duplicative assurances. In the revised rule, the assurance is only required of the research facility. The assurance is not only authorized by the statute, but is in fact mandated by it. Section 13(a)(3)(B) of the Act requires that the principal investigator consider alternatives to painful procedures and section 13(a)(7)(B)(i) of the Act requires research facilities to provide an assurance demonstrating that this has been done (7 U.S.C. 2143(a)). The assurance is therefore necessary to enable the research facility to comply with the Act.

We received 138 comments (136 from members of the general public and 2 from the research community) expressing their belief that there is a need for greater proof that alternative methods were sought or considered and that the experiment is not unnecessarily duplicative. One member of the general public commented that the requirement for an assurance that a painful procedure is not unnecessarily duplicative needs clarification.

Our consultation with HHS included consideration of this provision. Representatives from HHS were concerned that the phrase "unnecessarily duplicative" could be misconstrued. They pointed out that intentional replication of research is often an essential component of research, either for validation of the findings of others or to establish an in-house model of research that was developed elsewhere. They also pointed out that section 13(e) of the Act requires the Secretary to establish an information service at the National Agricultural Library to provide information which "could prevent unintended duplication of animal experimentation * * *" (7 U.S.C. 2143(e)). Section 1(b)(3) of the Act, however, includes a finding of the Congress that "measures which eliminate or minimize the unnecessary duplication of experiments on animals can result in more productive use of Federal funds: * * *" (7 U.S.C. 2131(b)(3)). Deliberate duplication of research can be deemed necessary if approved by the Committee. We do not agree that additional clarification of the regulation is needed.

Eight commenters suggested rewording the assurance required in proposed § 2.35(b)(3)(v)(B) from "[t]he assurance is to indicate what information sources were consulted, * * *" to "[t]he assurance is to indicate to the satisfaction of the Committee * * *". For the following reasons, we do not agree that this change is necessary. The requirements of § 2.30, including the requirement that the Committee approve the ACUP, must be satisfied before a painful procedure can commence. Sections 2.30(d) and (e) of the final rule require the principal investigator to provide a written statement to the Committee stating that alternative procedures were considered and that the procedure is not unnecessarily duplicative, as part of the Committee’s ACUP review and approval process. The ACUP would not be approved by the Committee unless it is satisfied with the assurance. Moreover, it is the responsibility of the research facility to require the assurance and they in turn must certify that they have in fact done so as part of their annual report. These provisions taken together should be sufficient to prevent unnecessary duplication of research.

2. Section 2.30(e)(2) of the revised rule provides that the research facility must require the principal investigator to consult with the attending veterinarian in the planning of a painful procedure, and that the principal investigator must consult with the attending veterinarian during the procedure under certain circumstances. The attending veterinarian must be allowed to observe the procedure at any time to ensure compliance with the regulations. In proposed § 2.35(b)(3)(vi)(A), the Committee was directed to require the principal investigator to consult with the attending veterinarian. In proposed § 2.30(e)(1) the research facility was required to establish a written policy ensuring that this consultation is conducted.

We received 148 comments stating that the phrase "and during the procedure" should be deleted from proposed § 2.30(e)(1). The commenters expressed concern that consultation during the conduct of an approved procedure would be prohibitively costly and would place the attending veterinarian in the position of policing the institution for compliance with the Animal Welfare regulations. We had intended that the attending veterinarian must be readily available during the course of a painful procedure to consult in the event of special, unanticipated, or unusual situations, and have therefore rephrased the requirement in the revised rule to make clear our intent. We also believe that the attending veterinarian should be allowed to make random checks of procedures to assure that the
regulations and standards are being followed. We have found that on occasion the attending veterinarian has become aware of a noncompliance situation in a classroom or laboratory and has been prevented from remedying it. We have also learned of instances where the attending veterinarian has been prevented from entering an animal area once a procedure has begun. To ensure that these situations do not occur, and that the attending veterinarian is not obstructed in performing his or her duties, the attending veterinarian must have the authority to conduct random oversight inspections of procedures in progress. We have clarified § 2.30(e)(2) in the revised rule to reflect that the attending veterinarian must be available for consultation during a painful procedure as well as during ACUP planning and development. It also requires that the research facility ensure that the attending veterinarian is allowed access to all animal and research areas to observe the procedure at any time during the course of the procedure, in order to fulfill the requirements of paragraph (e)(2).

3. Section 2.30(e)(3) of the revised rule requires research facilities to ensure the use of pain relieving drugs, anesthetics, analgesics, and tranquillizers to minimize pain unless they are withheld in accordance with the provisions of § 2.30(e)(4), and that they be administered in accordance with the directions and recommendations of the attending veterinarian and in accordance with the accepted or established use of the drugs. Proposed § 2.35(b)(3)(iv) would have required the Committee to ensure that pain relieving drugs are used in any painful procedure unless an exemption is approved by the Committee and the attending veterinarian. Proposed § 2.30(e)(2) would have required the research facility to establish a written policy ensuring the proper use of pain relieving drugs. For the reasons stated above under the heading, “Reorganization of §§ 2.30 and 2.35,” in this revised rule the research facility, not the Committee, is responsible for requiring that pain relieving drugs are used unless an exemption is approved by the Committee and the attending veterinarian. Proposed § 2.30(e)(2) would have required each research facility to establish a written policy providing for the proper use of pain relieving drugs. Proposed § 2.35(b)(3)(iv) would place responsibility for ensuring the proper use of pain relieving drugs on the Committee and would provide that pain relieving drugs could only be minimized or withheld if fully explained and justified in the research protocol [ACUP] and agreed to by the Committee and the attending veterinarian. Proposed § 2.35(b)(3)(vii)(F) would place specific responsibility on the Committee for prohibiting the withholding of pain relieving drugs except when scientifically necessary and approved by the Committee and the attending veterinarian.

We received 138 comments (136 from members of the general public and 2 from the research community) stating that stronger regulations requiring pain relieving drug use are necessary. We disagree that stronger regulations are needed. Responsibility for requiring proper use of pain relieving drugs is placed on the research facility in this revised rule in response to the comments suggesting that the facility and not the Committee is ultimately responsible for this assurance. The responsible institutional official will be required to certify in the annual report that the research facility has complied with the regulations concerning use of pain relieving drugs. Accordingly, we believe that additional regulations are not necessary.

One commenter objected in general to the requirement that pain relieving drugs be used in any procedure that would reasonably be expected to cause pain or distress in a human subject. The commenter stated that this is not always consistent with current veterinary practice. We believe that the exemption provision in § 2.30(e)(4) adequately addresses those instances when use of pain relieving drugs is not consistent with current veterinary practice, and that the presumption should remain in favor of providing pain relieving drugs, in order to carry out the purposes of the 1985 amendments to the Act.

4. Section 2.30(e)(4) of the revised rule provides that research facilities must require that pain relieving drugs, anesthetics, analgesics, and tranquillizers be reduced in amount or withheld only if scientifically necessary, fully explained in the ACUP, and approved by the attending veterinarian and the Committee. The drugs can then be reduced in amount or withheld only for as long as necessary, as specified in the ACUP. Proposed § 2.30(e)(2) would require each research facility to establish a written policy providing for the proper use of pain relieving drugs. Proposed § 2.35(b)(3)(iv) would place responsibility for ensuring the proper use of pain relieving drugs on the Committee and would provide that pain relieving drugs could only be minimized or withheld if fully explained and justified in the research protocol [ACUP] and agreed to by the Committee and the attending veterinarian. Proposed § 2.35(b)(3)(vii)(F) would place specific responsibility on the Committee for prohibiting the withholding of pain relieving drugs except when scientifically necessary and approved by the Committee and the attending veterinarian.

The Act requires that pain and distress be minimized or eliminated. We believe that the attending veterinarian, by virtue of his or her training, duties, and responsibility, is qualified to make this assessment on behalf of the animals. It is the responsibility of the principal investigator to convince the Committee and the attending veterinarian that scientific necessity justifies withholding drugs. If the Committee is convinced of the scientific necessity, it too can attempt to convince the attending veterinarian. We believe that full concurrence by the Committee and the attending veterinarian is necessary in this area, due to the stated intent of Congress.

5. Section 2.30(e)(5) of the final rule directs research facilities to require that the attending veterinarian provide training of laboratory personnel in the proper use of pain relieving drugs so as to minimize pain and distress to animals. Proposed § 2.35(b)(3)(vii)(B) would have required the Committee to require that the principal investigator provide for the proper use of pain relieving drugs in accordance with established or accepted veterinary procedures, and provide for training of laboratory personnel to carry out those procedures. We did not receive any comments addressing the substance of the requirement as proposed. However, as part of the reassignment of responsibilities and the reorganization of §§ 2.30 and 2.35, responsibility for training of laboratory personnel in those procedures is placed on the research facility in the revised rule.

We also believe that the attending veterinarian is in the best position and is most qualified to provide training of laboratory personnel in the proper use of pain relieving drugs because of his or her expertise in medicine and in established or accepted veterinary procedures. Accordingly, while research facilities are ultimately responsible for ensuring that this training is provided, we believe that it is most appropriately carried out through the attending veterinarian.

6. Section 2.30(e)(8) of the revised rule directs research facilities to require that all pre-procedural, procedural, and post-procedural care be provided by laboratory workers or surgical personnel, in accordance with the attending veterinarian’s instructions and established veterinary medical and nursing procedures. It also directs research facilities to require that this care and the qualifications of those personnel be evaluated and approved by the attending veterinarian. Proposed
§ 2.30(e)(3) would have required each research facility to establish a written policy ensuring all pre-surgical, surgical, and post-surgical care by laboratory workers is in accordance with established veterinary medical and nursing procedures, and ensuring that the care, surgical rooms, and qualifications of personnel have been evaluated and approved by the attending veterinarian. Proposed § 2.35(b)(3)(vi)(C) would have required the Committee to require that pre-surgical and post-surgical care be provided by laboratory workers, in accordance with the instructions of the attending veterinarian and established veterinary medical and nursing procedures. In the revised rule, this responsibility is placed on the research facility because, as discussed under the heading, "Reorganization of §§ 2.30 and 2.35," the facility is ultimately responsible for proper care. Also, because the facility is responsible for the acts of its employees, it is ultimately responsible for ensuring their qualifications. Evaluation of the qualifications of personnel is carried out through the attending veterinarian because he or she is most qualified to evaluate those qualifications.

In the revised rule, the requirements imposed on research facilities encompass pre-procedural, procedural, and post-procedural care, and are not limited to surgical procedures. This revision is necessary because painful procedures, as defined in the revised rule for Part 1 (see companion docket no. 88-013), published elsewhere in this issue, include any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied. Therefore, practices or procedures that might reasonably be expected to be painful procedures, are not limited to surgical procedures. The Act directs the Secretary to promulgate requirements "for animal care, treatment, and practices in experimental procedures to ensure that animal pain and distress are minimized, including adequate veterinary care.* * * *(7 U.S.C. 2143(a)(3)(A)). All procedures must be covered by the required program of adequate veterinary care in accordance with the Act. Accordingly, it is necessary to direct that research facilities require that personnel rendering pre-procedural, procedural, and post-procedural care perform in accordance with the instructions of the attending veterinarian, and that the care and the qualifications of personnel be evaluated and approved by the attending veterinarian, in order to ensure adequate veterinary care and to effectuate the mandate of the Act.

Six commenters stated that the word "veterinary" preceding "medical and nursing procedures" should be deleted from proposed § 2.35(b)(3)(vi)(C). We believe that it is more precise to specify veterinary medical and nursing procedures when we are referring to care and procedures involving animals. Therefore, the word "veterinary" is retained in § 2.30(e)(6) in the revised rule.

7. Section 2.30(e)(7) of the revised rule provides that research facilities must require that all survival surgeries be conducted only in facilities intended for that purpose, that they be operated and maintained under aseptic conditions, and that surgery be evaluated and approved by the attending veterinarian. Proposed § 2.30(e)(3) would have required each research facility to establish a written policy ensuring, among other things, that surgical rooms be evaluated and approved by the attending veterinarian. Proposed § 2.35(b)(3)(vi)(D) would have required the Committee to require that all aseptic survival surgeries be conducted in facilities intended for that purpose, that such facilities be operated and maintained under aseptic conditions, and that any surgery be performed or directly supervised by trained, experienced personnel. This responsibility has been placed on the research facility in the revised rule since the facility is ultimately responsible for the proper conduct of surgeries.

We received 12 comments suggesting that we restrict the requirements for "all aseptic survival surgeries" to non-roent species. The regulations do not apply to laboratory bred rats and mice and therefore no such restriction is necessary.

We also received 387 comments (362 from the research community and 25 from members of the general public) objecting to the requirement that all aseptic survival surgeries be conducted in facilities intended for that purpose as too restrictive. One commenter suggested that we distinguish between major and minor surgical procedures. We disagree with these comments. The suggested major/minor distinction would likely lead to disputes over what should be considered major and what minor. By its terms, the requirements provided in § 2.30(e) are limited to painful procedures. We believe that this is the appropriate distinction upon which we are referring to the requirements contained in paragraph (e)(7). We are therefore retaining the requirements stated above for all survival surgeries which are painful procedures.

8. Section 2.30(e)(8) of the revised rule provides that research facilities must require that any surgery be performed or directly supervised by trained, experienced personnel. Proposed § 2.35(b)(3)(vi)(D) would have required the Committee to require that all aseptic survival surgeries be performed or directly supervised by trained, experienced personnel. For the reasons provided under the heading, "Reorganization of §§ 2.30 and 2.35," and because responsibility for the proper conduct of surgical procedures ultimately belongs to the facility, this responsibility is placed on the research facility in the revised rule.

9. Section 2.30(e)(9) of the revised rule requires research facilities to prohibit the use of paralytic drugs without anesthesia. Proposed § 2.30(e)(4) would require each research facility to establish a written policy prohibiting the use of paralytic drugs without anesthesia and proposed § 2.35(b)(3)(vi)(E) would require the Committee to do so as well. For the reasons provided under the heading, "Reorganization of §§ 2.30 and 2.35," this responsibility is placed on the research facility in the revised rule, since it is ultimately responsible for rendering proper care.

Thirty-one commenters stated that "paralytic drug" should be defined in the regulations. We agree and are including a definition of "paralytic drug" in revised Part 1—"Definition of Terms," published elsewhere in this issue of the Federal Register (See companion docket no. 88-013.)

One commenter suggested strengthening the proposed regulations by stating the level of surgical anesthesia that should be required in order to use a paralytic drug. We believe that this is a matter that should be left to the research facility's program for providing adequate veterinary care. Also, consultation with the attending veterinarian should include matters such as the proper level of surgical anesthesia.

10. Section 2.30(e)(10) of the revised rule requires research facilities to establish a written policy to ensure compliance with the provisions of §§ 2.30(e)(1) through (9). Proposed § 2.30(e) would have required research facilities to establish a written policy limited to ensuring the various aspects of veterinary care and procedures provided in proposed § 2.30(e). Due to the reassignment of responsibilities in Subpart C, the written policy must be extended to cover additional areas of
animal care and treatment. For this reason, the requirement to establish a written policy is revised to cover the provisions of paragraphs (e) (1) through (9). We received 123 comments stating that establishing a written policy for the veterinary consultation required by proposed § 2.30(f)(1) (§ 2.30(e)(2) in the revised rule) is unnecessary. Since facilities are responsible for requiring this consultation and for maintaining a program of adequate veterinary care, and must certify that the required care is being provided in accordance with the Animal Welfare regulations and standards, it is necessary that each research facility have a written policy so that the rules all personnel must follow are clear. The written policy must be provided to all principal investigators so that they can comply with its provisions. Distribution of the policy will ensure that all personnel have knowledge of the required consultations and procedures for minimizing and reducing animal pain, and can be held responsible by facilities for compliance with it. A written policy will also reduce any confusion over what is required before a painful procedure can be performed, and will standardize procedures within a research facility. Without a written policy the research facility would not be able to adequately monitor compliance by its personnel and could not assure that the requirements of the law were being followed. We have retained the requirement that a written policy be established requiring veterinary consultation and the other provisions of § 2.30(e) in this revised rule. Section 2.30(f) Multiple major operative experiments. Section 2.30(f)(1) of the revised rule states that research facilities using or holding animals for research, testing, or teaching must establish and follow written procedures which assure that no animal is used in more than one major operative experiment from which it is allowed to recover except under the circumstances provided in the regulation. Proposed § 2.30(f) would have required research facilities to establish procedures which assure that no animal is used in more than one major operative experiment from which it is allowed to recover except as provided in proposed § 2.35. Proposed § 2.35(b)(3)(vii) would have required the Committee to assure that no animal is so used except in certain circumstances provided in proposed § 2.35(b)(3)(vii) (A) through (G) of the section. Because the research facility is ultimately responsible for assuring the proper use of animals, the requirements to assure that no animal is used in more than one major operative experiment from which it is allowed to recover except in certain circumstances and to establish procedures which assure this are placed on the facility. We are requiring, in this revised rule, that the procedures be in writing so that all personnel will have knowledge of them. We received 39 comments objecting to the limitation on major operative experiments using the same animal. The commenters stated that this would interfere with research involving extensive behavior training or other research. We understand that this requirement may interfere with some research which involves animals used in multiple surgeries which are unrelated, or which are not part of the same procedure, or which do not fall under any of the exceptions provided in the regulations. This is precisely what the Act intended. Section 13(a)(2)(D) of the Act requires the Secretary to promulgate standards including requirements that "no animal is used in more than one major operative experiment from which it is allowed to recover except in cases of—(i) scientific necessity; or (ii) other special circumstances as determined by the Secretary. 7 U.S.C. § 2143(a)(2)(D)). The regulations prevent multiple use of animals only when there is no scientific necessity or other special circumstances justifying it. The regulations include a mechanism for obtaining permission from the Secretary if special circumstances exist which are not included in the regulations. We believe that this regulation will not interfere with the justified use of an animal in multiple surgeries.

Four commentors stated that the general public stated that the regulation provides too many exceptions from the prohibition against multiple surgeries, and that the exceptions are too broad. One commenter stated that the terms "major operative experiment" and "scientific necessity" should be defined and that the exceptions should not apply to animals used in teaching and demonstration exercises. We believe that the exceptions provided in the regulation are all necessary exceptions to the prohibition of the Act. We also believe the exceptions are stated narrowly. The exception for scientific necessity requires approval by the Committee and is not subject to unilateral interpretation by the investigator. The Committee is the appropriate body to evaluate whether or not a proposed procedure is scientifically necessary, and we do not believe it is necessary to define this term. The term "major operative experiment" is defined in Part 1—"Definition of Terms." (See companion docket no. 68-013, published elsewhere in this issue.) Whether exceptions should be made for animals used in research, testing, teaching and demonstration exercises is left to the research facilities, however, the exceptions granted must still fall within one of the circumstances provided in the regulation in order to use an animal in multiple major operative experiments. No changes have been made based upon this comment.

Section 2.30(g) Exceptions. Section 2.30(g) of the revised rule provides the limited circumstances under which exceptions to the Animal Welfare standards and regulations can be made. It also provides the reporting procedure which must be followed if an exception is made by a research facility.

Responsibility for granting exceptions is placed on the research facility in the revised rule, since it is the research facility's responsibility under the Act to certify compliance with the standards and regulations and to explain any deviation from the standards (7 U.S.C. § 2143(a)(7)(B)). The Committee must first approve the ACUP since its duty is to assess animal care, treatment, and practices, and since the Act requires that any exceptions to the standards be made only when specified by research protocol and when detailed and explained in a report filed with the Committee (7 U.S.C. § 2143(a)(3)(E)). The research facility can grant exceptions to the standards and regulations only when necessary for the accomplishment of the research design, and only if the exception: (1) is specified in the ACUP; (2) is explained in detail; and (3) is approved by the Committee. The principal investigator must file a report with the Committee before it reviews the ACUP, detailing the areas of noncompliance. The facility must keep a copy of the report on file and make it available to APHIS inspectors and officials of funding Federal agencies. The facility must attach a copy of all reports detailing and explaining exceptions to compliance to its annual report.

As revised, § 2.30(g) consolidates the provisions of proposed §§ 2.30(g) and 2.35(c). Proposed § 2.30(g) would have allowed exceptions to the requirements of proposed § 2.30 (e) and (f) (animal care assurances and procedures assuring against multiple use of animals in major operative experiments, respectively) to be made only when specified by the "research protocol" (ACUP) and approved by the Committee. The principal investigator would be required to detail and explain
the exception in a written report to be filed with the Committee and attached to the facility's annual report to the Department. It would also provide for withholding of pain relieving drugs when scientifically necessary. (This provision has been included in § 2.30(a)(4) of the revised rule.) Proposed § 2.35(f) would have allowed the Committee to grant exceptions only when necessary for the accomplishment of the research design, specified in the "research protocol" [ACUP], and explained in detail. The principal investigator would be required to file a report with the Committee explaining the exception in detail. A copy of the report would be required to be kept on file by the facility and to be available for inspection by USDA inspectors or officials of granting agencies.

Under the revised rule, only the Committee is authorized to approve exceptions to compliance with the regulations and standards, however it is made clear that the research facility is ultimately responsible for any exceptions granted.

We received 335 comments objecting to the proposed requirement that the principal investigator first file a written report, and suggesting that an oral report to the Committee is sufficient. We cannot make any changes based upon this comment since the Act specifically requires that exceptions to the standards be detailed and explained in a report and filed with the Committee (7 U.S.C. 2143(a)(6)(E)). The Act also requires a written explanation from research facilities for any deviation from the standards. Because of these specific requirements in the Act, we do not have the authority to require only an oral report instead of a written report.

Six commenters stated that the procedure provided in proposed § 2.30(g) for approval of exceptions to the requirements of proposed § 2.30(e) and (f) should also be available for exceptions from other requirements in the regulations. We believe that the revised rule is broad enough to cover exceptions from any of the Animal Welfare regulations and will allay the commenters concerns that exceptions to regulations other than § 2.30(e) and (f) be possible.

Section 2.30(f) Exercise for dogs and psychological well-being of primates. As stated in the discussion of the reassignment of responsibilities from the Committee to the research facility under the heading, "Reorganization of §§ 2.30 and 2.35," the research facility is responsible in this revised rule for establishing written procedures and systems for the exercise of dogs and for the psychological well-being of primates in accordance with the regulations and standards, and for establishing a record system indicating that such a procedure or system is being carried out. This must be done in consultation with the attending veterinarian. (These procedures may be included in the facility's standard operating procedure, although this is not mandatory.) The proposed standards for exercise of dogs and to promote the psychological well-being of nonhuman primates are provided in a related document published elsewhere in this issue. (See companion docket no. 87-004.)

We received 357 comments (332 from the research community and 25 from members of the general public) stating that the requirement for establishing these procedures and systems should be implemented by the attending veterinarian. As originally proposed, to avoid conflicts between the attending veterinarian and the other Committee members. The reassignment of responsibility for these procedures to the research facility removes the possibility of conflict between the Committee and the attending veterinarian. The Committee will still be responsible for inspecting animal areas to ensure that pain and distress are minimized and it is also required to approve of any ACUPs which deviate from the standards of Part 3. These functions should not conflict with the attending veterinarian's consultative role in developing written procedures and systems. No change is made as a result of these comments.

We received 505 comments (460 from the research community and 25 from members of the general public) objecting to the requirement for a separate record system to document that these procedures are being carried out. The requirements for exercise of dogs and for promoting the psychological well-being of nonhuman primates are two of the primary directives of the 1985 amendments to the Act. We believe that a separate record system provides a vital mechanism to ensure compliance with the regulations and to give our inspectors a means of checking for compliance. This is particularly so with regard to exercise for dogs and promoting the psychological well-being of nonhuman primates. Unlike tangible requirements, such as cage sizes and cleanliness which can be observed at all times, there must be written verification that the procedures concerning exercise for dogs and psychological well-being of nonhuman primates are being followed in order to ensure compliance. We believe that the required recordkeeping is reasonable and will ensure compliance. No change is made in the regulations based upon this comment.

Section 2.30(j) Training. The requirement to provide for the training and continuing education of personnel was imposed upon the research facilities in the proposed rule. However, the task of reviewing the status of the training and the qualifications of researchers, and of designating those personnel needing additional training was imposed on the Committee in proposed § 2.35(f). This requirement is also imposed on research facilities in § 2.30(j) of the revised rule, because the Act makes the facilities responsible for training (7 U.S.C. 2143(d)). We have determined, however, that this responsibility should be carried out through the attending veterinarian, since the training will be in areas in which the attending veterinarian has expertise such as proper drug usage and pre- and post-procedural care. (The proposed rule would require training in proper pre-surgical and post-surgical care of animals. For the reasons set forth in our discussion of § 2.30(e)(6) under the subheading, "Painful procedures," this requirement applies to all procedures in order to ensure adequate veterinary care, and is not limited to surgical procedures.)

Nineteen commenters stated that the proposed training requirements are beyond the scope of the Act. We have considered this comment, but are making no changes based upon it. The training requirements are either specifically stated in the Act or are necessary adjuncts of the areas of animal care in which instruction is required by the Act (7 U.S.C. 2143(d)). For example, the requirement in § 2.30(i)(4)(ix) to provide training in the proper use of pain relieving drugs is a necessary adjunct of "[includ[ing]" instruction on research or testing methods that minimize or eliminate the use of animals or limit animal pain or distress; * * * " (7 U.S.C. 2143(d)(2)).

We are making some changes in the requirements for annual review of the status and qualifications of personnel who use animals, because other institutional mechanisms exist for discovering deficiencies in the level of training and qualification. We have also eliminated the requirement for training in the area of animal ethics. These modifications are discussed below in this section.

Two commenters noted their support for the proposed training requirements and suggested more stringent training requirements. We believe the training requirements contained in § 2.30(j) are within the scope of the Act and satisfy
the intent of the Act. If, after the regulations are in effect, it appears that more stringent regulations are necessary, we will consider proposing additional or revised regulations.

Seventy-nine commenters suggested that training should be made available to individuals based upon the species of animal they use or some other specific need. Proposed § 2.35(f)(2) would have required that the training "be made available annually or as appropriate to the individuals and their responsibilities" and a similar provision is maintained in this revised rule. We are concerned that the proposed language could be misconstrued as requiring that only the frequency and not the substance of training be appropriate to the individuals and their responsibilities. Section 2.30(i)(2) is clarified in the revised rule to reflect that both the substance of the training must be appropriate to the individuals and their responsibilities, as well as the frequency of the training that is made available to them. Under the rule, the research facilities can determine whether training should be based upon the species of animal used, or whether other criteria should be used, in accordance with their determination of what is appropriate, so long as the areas listed in § 2.30(i)(4) are covered.

We received 560 comments (535 from the research community and 25 from members of the general public) objecting to the requirement of proposed § 2.35(f)(3) that the Committee annually review the status of training and qualifications of researchers who use animals. The commenters stated that this would be costly and impractical. Although responsibility for this review is placed on the research facility in this revised rule, we anticipate that the same objection will be raised, as the facility must bear the cost of the review.

Representatives of HHS have pointed out that internal mechanisms exist in research facilities, such as performance appraisals, which would highlight the need for additional training, and that facilities should be afforded an opportunity to satisfy the requirements of the Act by developing monitoring procedures which utilize these existing mechanisms. We agree that some facilities may have adequate means of reviewing the status of training and the qualifications of personnel, and we are revising the requirement for annual review at research facilities. Research facilities could avoid a separate annual review as required by § 2.30(i)(3) in the revised rule, if they have a written policy requiring that they annually review their personnel in the areas of training and qualifications.

We received 434 comments (409 from the research community and 25 from members of the general public) suggesting that the areas of instruction required in paragraph (4) be listed in two groups: one for all employees and one for employees involved with animal care, use, and treatment. By its terms, the training required by § 2.30(i) in the revised rule is limited to those persons involved with animal use, care, and treatment. Those persons who do not have this contact with animals would not be required to undergo the requisite training. Accordingly there is no need to divide the areas identified in § 2.30(i)(4) into two parts as the commenters suggested. Training of personnel who are not involved with animal care, use, and treatment is left to the determination of the research facilities, because it is beyond the scope of the Act.

Proposed § 2.35(f)(4)(i) would require instruction in "[h]umane methods of animal maintenance and experimentation and animal ethics; * * *". Eight commenters suggested that the requirement for instruction in animal ethics be deleted and another 37 commenters suggested substituting "research ethics" for "animal ethics." We agree that the term "animal ethics" invites differing philosophical views over what the substance and content of the instruction should be, making regulation difficult. Therefore, we are deleting the reference to "animal ethics." The remaining required areas of instruction fulfill the intent of the Act.

We received 299 comments (274 from the research community and 25 from members of the general public) objecting to paragraph (4)(xi) of proposed § 2.35(f). As proposed, it would have required instruction in "[o]ther training, techniques, or procedures the Committee, or the Secretary, may feel is necessary." Responsibility for this determination is reassigned to the research facility as part of the reorganization of §§ 2.30 and 2.35. The commenters stated that paragraph (xi) is meaningless for compliance purposes and should be deleted. We disagree. The Secretary must have the flexibility to require training in additional areas if it is determined to be necessary. Also, as scientific knowledge evolves, it could become apparent that additional or different training in new technologies is needed, and the Secretary must have the authority under the regulations to require this training in order to fulfill the intent of the Act.

Except for those changes discussed above, the substance of proposed § 2.35(f) remains as originally proposed. However, responsibility for compliance with the requirement to provide training is placed on the research facility in § 2.30(i) of the revised rule.

Section 2.30(j) Reporting. Proposed § 2.35(b)(2)(iii) would require the Committee to establish a reporting procedure for personnel or employees to report violations of the Animal Welfare regulations, including problems, deviations, or deficiencies with animal housing, care, or use. The Committee would review and investigate reports of violations and would then prepare and file a report at a central location. It would also protect Committee members and personnel from discrimination or reprisal for reporting violations. The Act requires that the Committee file an inspection certification report, including reports of any violations or deficient conditions of animal care or treatment, any deviations of research practices from originally approved proposals that adversely affect animal welfare, any notification to the facility regarding such conditions, and any corrections made (7 U.S.C. 2143(b)(4)(A)). The Act does not specifically mandate that the Committee devise a reporting procedure for personnel to report violations. Accordingly, this responsibility is reassigned to the research facilities in § 2.30(j) of the revised rule. The Committee, however, is still required to review and investigate reports, under the revised rule. The Committee is in the best position to do so because it is established to assess animal care and use, and has inspection authority under the Act. Research facilities are also required to establish the central location for filing reports under the revised rule. This requirement is set forth in § 2.30(m).

We received 367 comments (342 from the research community and 25 from members of the general public) stating that the proposal to require a reporting procedure to report violations or deficiencies to the Committee exceeds the authority of the Act, as the Act refers to training for these procedures only. Section 33(d) of the Act requires each research facility to provide training including instruction on "methods whereby deficiencies in animal care and treatment should be reported." (7 U.S.C. 2143(d)). This directive presumes the establishment of a reporting procedure. The legislative history of the 1985 amendments to the Act which require this training makes this point eminently clear. In the Congressional Record of
December 18, 1985, at page S17943, Senator Dole stated:

"It is intended that all personnel be acquainted with the provisions of this Act and instructed to report deficiencies promptly to ensure that the facility is in compliance at all times. No one should be discriminated against for reporting violations of the Act. Veterinary inspectors from the U.S. Department of Agriculture cannot be present on a daily basis. However, their enforcement capability can and should be enhanced by the institutional Animal Care and Use Committee and personnel in laboratories must be protected against any reprisal for reporting mistreatment of animals.

The Conference Report included in the Congressional Record of December 17, 1985 at page H12421 states, "[a]ll personnel are intended to be acquainted with the provisions of this Act and instructed to report deficiencies promptly to ensure that the institution is in compliance at all times. No employee shall be discriminated against for reporting violations." We believe the Act intended that a mechanism for reporting violations and deficiencies be implemented at research facilities as a vital means of ensuring compliance with the Act and the regulations. The Secretary is authorized to promulgate regulations deemed necessary to effectuate the purposes of the Act, including the reporting of violations and deficiencies. The requirement for a reporting procedure therefore does not exceed the statutory authority.

Two members of the general public and 1 commenter from the research community stated that the reporting provisions should include protection for the employer as well as for employees and Committee members. The legislative history cited above addresses protection against reprisal or discrimination for employees who report violations. It is silent on employers and facilities that report personnel as being in violation of the Act or regulations. The Act intends that facility personnel function as checks on each other and on the facility as a whole, and relies on the facility to monitor its own house. The facilities have the resources to safeguard themselves and their supervisory officials and we do not believe that regulations providing this protection are warranted.

Section 2.30(k) Federal research facilities. Proposed § 2.35(e) would have required federal research facilities to establish an Institutional Animal Care and Use Committee (Committee) having the same duties and functions as nonfederal research facilities except that the Committee would report deficiencies to the head of the federal agency conducting the research instead of toAPHIS, and the head of the federal agency would be responsible for all corrective action and for granting of all exceptions to inspection protocol. As stated in the initial paragraphs of the supplementary information to Subpart C, we have determined that it is more appropriate to include this provision in § 2.30 since it is directed to the research entity and not the Committee. It is § 2.30(k) in the revised rule.

We received two comments concerning proposed § 2.35(e) "Federal research facilities," both from members of the research community. The comments stated that "institutional official responsible for animal care and use" should be substituted for "head" of the federal agency, because authority to administer animal care may be delegated to another official in the agency. We disagree and have used the language appearing in the Act. The Department is not involved in a determination by an agency "head" to delegate authority in accordance with agency internal procedure. We cannot by regulation place this authority at a lower level than that legislated by Congress. No change is made in the revised rule.

Section 2.30(l) Reviews. Proposed § 2.35(b)(3)(i) would require the Committee to make all research protocols [ACUPs] and assurance statements required by PHS or other funding Federal agencies available for review upon the request of the Administrator, to assure compliance with the Act. Department inspectors would be required to maintain the confidentiality of the requested material. Under the reorganization described above, the responsibility for responding to a Departmental request ultimately rests with the research facility or responsible institutional official acting on behalf of the research facility, and is included in § 2.30 in the revised rule as subsection (1).

We received 529 comments (504 from the research community and 25 from members of the general public) objecting to the requirement to make all protocols [ACUPs] and assurance statements available to APHIS. Some of the concerns focused on public release of the materials. Others were that the requirement exceeds statutory authority. As to the latter concern, the Secretary has authority under the Act to require production of all ACUPs and assurance statements as part of the authority to require each research facility to show, upon inspection, that the provisions of the Act are being followed (7 U.S.C. 2143(a)(7)). Section 16 of the Act authorizes the Secretary to make investigations or inspections as he or she deems necessary to determine whether any provision of the Act or the regulations and standards have been or are being violated (7 U.S.C. 2146(a)). Review of ACUPs and assurance statements would provide important information and would be key indicators as to whether any of the provisions of the Act or regulations are being violated or have been violated.

We understand the research facilities' concern with public release of these documents, particularly before a violation of the Act or the regulations has been established. We agree in part with commenters who stated that this material should not be retained by USDA and possibly subject to release to the public in response to Freedom of Information Act requests to USDA.

Section 2.30(1) is revised to reflect that these materials will not be removed from the research facilities' premises unless there has been an alleged violation or the material is needed for an investigation or other enforcement purposes.

Thirty-eight commenters requested clarification as to when the Administrator could request that "protocols" and assurance statements be made available for review by the Department. These documents would be requested whenever there is reason to believe there may be noncompliance with the Act or the regulations, when needed to investigate possible or alleged violations, and when needed for other enforcement purposes.

Section 2.30(m) Reports. Proposed § 2.35(b)(3)(iv) would require that any reports required by proposed § 2.35 be kept on file at the research facility for at least 3 years and be made available for inspection and review by APHIS inspectors and any funding Federal agency. We did not receive any comments addressing this proposed requirement. We have revised the requirement in this rule, however, to provide that, upon notification from the Administrator, research facilities must retain records for more than 3 years pending completion of an investigation or proceeding, as required by § 2.81. This is a nonsubstantive change because research facilities are subject to the provisions of § 2.81.

Proposed § 2.35(b)(2)(i) would require that the Committee file its inspection certification report at a central location at the research facility. We are including the requirement that research facilities maintain a central location for filing reports.

The proposed rule referred to inspection and review of reports by APHIS inspectors. We have revised
these provisions to provide for inspection and review of reports by APHIS officials as a result of the change in terms used for APHIS personnel, as described in a related document published elsewhere in this issue of the Federal Register, docket no. 88-031, Part 1—"Definition of Terms." The term "APHIS official" as defined in Part 1 would include an APHIS inspector.

The research facility is ultimately responsible for retaining the Committee’s reports and assurance statements. Accordingly, this provision has been placed in § 2.30 in the revised rule as paragraph (m). We have also revised it to refer to any reports required by Part 2, instead of § 2.35 as originally proposed, due to the reorganization of §§ 2.30 and 2.35.

Section 2.31 Annual report of research facilities. Proposed § 2.28 requires each research facility to submit an annual report to the Area Veterinarian in Charge. This was proposed under Subpart B—"Registration." We believe it is more appropriate to include this requirement under Subpart C—"Institutional Animal Care and Use Committees and Other Requirements for Research Facilities," since it applies only to research facilities. Accordingly, it is redesignated as § 2.31 in the revised rule. The comments we received concerning the annual report refer to proposed § 2.28 and we will refer to the proposed section and paragraph designations in addressing the substance of those comments.

General. We received numerous comments addressing the annual report required of research facilities, the information we are requiring to be included in the report, and the proposed certifications of the report.

We received 434 comments (417 from the research community and 26 from members of the general public) stating that the proposed regulation exceeds the Department’s statutory authority. We believe that the annual report and its contents are not only authorized, but are mandated by the Act. Section 13(a)(7)(A) of the Act states that the Secretary "shall require each research facility to show upon inspection, and to report at least annually, that the provisions of this Act are being followed * * " (7 U.S.C. 2143(a)(7)(A)). The Act goes on to specify information that the research facilities must provide in their report. We believe that the information we are requiring in the report is either specifically required by the Act or is necessary to enable the Department to determine if the facility is in compliance with the Act and the regulations.

We also received 168 comments from the research community objecting that the information required to be provided on the annual report would involve extensive record-keeping and reporting beyond the requirements of the Act. The assurances and information required of research facilities by § 2.28 are required by section 13 of the Act. This information enables the Department to inspect for compliance with the regulations and standards under the Act, and enables the Secretary to submit the comprehensive and detailed annual written report to Congress required by section 25 of the Act (7 U.S.C. 2155).

We received 456 comments (431 from the research community and 25 from members of the general public) requesting that the annual report be revised and simplified. They also stated that § 2.28 as proposed would require redundant assurances. We agree that simplification of the report is desirable, and we have modified the report requirements in the revised rule.

One commenter from the research community stated that the annual report should be revised to include all pertinent information. We are currently reviewing the annual report form, Form VS 18-28. The form will be updated and revised as necessary to include all information that will now be required by the regulations.

Two commenters from the research community suggested that we incorporate the registration update required by § 2.25 in the annual report. These two reporting requirements serve very different purposes. We believe that combining them would create problems rather than simplify matters. The registration update is required of all registrants every 3 years so that the Department can maintain accurate records of the identity and location of registrants. The annual report is, as its name indicates, a yearly report required only from research facilities. Not all registrants are research facilities. If the two different reporting requirements were combined for the research facilities, yet another reporting system would have to be devised for those registrants who are not research facilities, to avoid unnecessary or inapplicable information collection. We believe it prudent to keep these two reporting requirements distinct.

Proposed § 2.28(a). As proposed, § 2.28(a) would require the Chief Executive Officer (CEO) of the facility, the attending veterinarian, and the chairman of the Institutional Animal Care and Use Committee (Committee) to sign the annual report. Proposed § 2.28(b)(9) would require a statement by the CEO that the attending veterinarian and the Committee have the authority to enter any animal area to carry out their responsibilities, that the Committee has satisfactorily carried out its responsibilities, and that the facility is in compliance with the Act, regulations, and standards. Section 2.26(c) would require the attending veterinarian and the Committee chairman to certify the annual report, in accordance with § 2.24(f)(2)(iii) and 2.35(g) of the proposed rule.

Fifty-five commenters from the research community stated that only the CEO should be required to sign the report. Ninety-six commenters from the research community stated that reference to the "CEO" in proposed § 2.28(b)(9) should be changed to "institutional official" to coincide with the PHS Policy. Four commenters from the research community stated that the report and assurances are the responsibility of the facility and should not require other certification. We agree that the assurances of compliance required in the report are the responsibility of the institution, not the Committee Chairman or the attending veterinarian, because it is the ultimate responsibility of the facility to ensure compliance with the Act and the regulations. Therefore, we are revising the rule to require that the annual report be signed only by the CEO or a "responsible institutional official with authority to bind the facility." This revision means that it needn't be the CEO who signs the report, however the institutional official who does sign the report must be authorized to bind the facility. We are also amending proposed § 2.28(a) to require the signature of all three individuals as a means of detecting noncompliance at facilities. For example, if an attending veterinarian refused to sign the report, we would suspect that he or she was, in some way, not satisfied with the facility's administration of the program of veterinary care. In order to satisfy this concern, which we still have, we are also amending proposed § 2.28(a) to include a mechanism for including all dissenting views in the annual report. This is described in greater detail below under the discussion of proposed § 2.28(c).

Proposed § 2.28(b). As proposed, § 2.28(b)(1) states that the annual report shall "*show that professionally acceptable standards governing the care, treatment, and use of animals, * * were followed by the research facility; * * *. We received 411 comments (386 from the research community and 25 from members of the
pain, distress, or use of pain relieving drugs (anesthetics, analgesics, or tranquilizers) which pain relieving drugs were administered. The assurance required in § 2.28(b)(2) would apply to the procedures in the succeeding paragraphs. If the requirement for assurance that alternatives to painful procedures have been considered were combined with proposed paragraph (b)(7) it could be construed as pertaining only to those procedures for which pain relieving drugs are withheld, contrary to the requirements of the Act. For this reason, no changes will be made to paragraph (b)(2) in the revised rule, or to its placement within the section.

Although we did not receive any comments concerning the specific provisions of proposed § 2.28(b)(3) which requires assurance that the facility is adhering to the standards and regulations under the Act and that an explanation for any deviation from them be attached to the annual report, we are revising it to include assurance that the facility required that exceptions to the standards and regulations be specified and explained in an ACUP and approved by the Committee. We believe that these changes are consistent with the requirements of section 13(a)(7) of the Act (7 U.S.C. 2143(a)(7)) and with §§ 2.30 and 2.35 of this revised rule.

We received 391 comments (386 from the research community and 25 from members of the general public) objecting to the requirement of proposed paragraph (b)(4) that the annual report state the location of facilities where animals are housed or used in actual research, testing, teaching, or experimentation. One commenter stated a concern that if facilities must provide the location of the facility or facilities where animals are housed or used in actual research, testing, teaching, or experimentation, one commenter stated a concern that if facilities must provide the specific sites within the facilities where animals are housed or used, the information would be accessible to the public through the Freedom of Information Act and could compromise their security.

It is necessary for APHIS to know the location of animals at research facilities in order to inspect all animal sites, as required by the Act. This information is essential for enforcement purposes, as evidenced by the case of a research facility at a major university which maintained nonhuman primates for years, hidden from APHIS inspectors, by failing to disclose the animal site to APHIS.

We believe the commenters' concerns about revealing the location of animal areas are unwarranted. This information has been required in the annual report since the regulations were revised in 1972 to incorporate the 1970 amendments to the Act, and there is no indication that a facility's security was compromised because third persons learned the whereabouts of laboratory animals through Freedom of Information Act requests. Furthermore, once APHIS has inspected a facility, an inspection form is completed which details the location of animals at each site. This form is filed with the Agency and may potentially be disclosed through Freedom of Information Act requests. Therefore, leaving this information out of the annual report may not prevent third persons from obtaining the information.

We are clarifying proposed paragraph (b)(4)(ii)(A) in the revised rule to also require the location of the facility or facilities where animals are housed for future use in research, testing, teaching, or experimentation, to avoid any confusion that we are only requiring this information for animals in actual use.

Since deletion of this requirement would not have the effect intended by the commenters, and since the information is necessary for the Department to comply with the Act, paragraph (b)(4)(ii)(A) will remain as proposed except for the above clarification.

Thirty-five commenters from the research community stated that facilities should be required to identify animals by their common scientific names on the annual report, rather than by their common names, in order to obtain factual information and for accuracy in the collection and utilization of the information. One commenter stated that this information is necessary for the public and the legislators, so that policy regarding the use of animals in research can be appropriately established.

Proposed paragraphs (b) (5) through (8) of § 2.28(b) would require facilities to "state the common names and the numbers of animals" maintained or used for the various purposes described in those paragraphs. The requirement to identify animals by their common names has been part of the annual report since the report was first established under the 1970 amendments to the Act.

Common names are likewise used in the Department's annual report to Congress. No problems or difficulties arising from the reporting system for facilities or the use of common names of animals have become apparent to us. Based upon our experience, we do not believe that it is necessary to require use of scientific names on annual reports. We received 92 comments from the research community stating that the requirement of proposed § 2.28(b)(6) to report the number of animals "upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the..."
animals" with the use of pain relieving drugs, and of proposed § 2.28(b)(7) to report the number of animals similarly used but for which the use of pain relieving drugs would adversely affect the procedures and are withheld, exceeds the Department's statutory authority. Proposed paragraph (b)(7) also provides that "[a] detailed statement on the procedures producing pain or distress in these animals and explaining the reasons such drugs were not used shall be attached to the annual report." Thirty commenters from the research community objected to this requirement as exceeding the statutory authority, and 389 commenters (944 from the research community and 25 members of the general public) objected to this requirement and suggested that we change it to conform with the statutory language which requires "information on procedures likely to produce pain or distress in any animal * * *" (7 U.S.C. 2143(a)(7)(B)).

We disagree with these commenters; we have the statutory authority to require the information in the form proposed.

One of the stated purposes of the Act is to "insure that animals intended for use in research facilities * * * are provided humane care and treatment; * * *" (7 U.S.C. 2131). Another is to provide requirements to "ensure that animal pain and distress are minimized * * with the appropriate use of anesthetical, analgesic, tranquilizing drugs, or euthanasia; * * *" (7 U.S.C. 2143(a)(3)(A)). Accordingly, section 13(a)(3)(A) of the Act allows "exception to such standards * * only when specified by research protocol and that any such exception shall be detailed and explained in a report outlined under paragraph (7) and filed with the Institutional Animal Committee" (7 U.S.C. 2143(a)(3)(A)). Paragraph (7)(A) of section 13(a) of the Act mandates that the Secretary "shall require each research facility to show upon inspection, and to report at least annually, that the provisions of this Act are being followed and that professionally acceptable standards governing the care, treatment, and use of animals are being followed by the research facility during actual research or experimentation," (7 U.S.C. 2143(a)(7)(A)). Paragraph (7)(B) of section 13(a) requires research facilities to provide:

(i) Information on procedures likely to produce pain or distress in any animal and assurances demonstrating that the principal investigator considered alternatives to those procedures;

(ii) assurances satisfactory to the Secretary that such facility is adhering to the standards described in this section; and

(iii) an explanation, or any deviation from the standards promulgated under this section. (7 U.S.C. 2143(a)(7)(B)).

We believe that these provisions of the Act authorize the Secretary to require the common names and the numbers of all animals upon which painful procedures were conducted. The required information is necessary to enable us to determine, upon inspection and through annual reports of facilities, that the Act is being complied with, and that the intent of Congress—to ensure that research animal pain and distress are minimized—is being advanced. The Agency must be able to make this determination in order to fulfill our annual reporting obligation to Congress, in accordance with section 25 of the Act (7 U.S.C. 2135).

The additional requirement in proposed § 2.28(b)(7) for a detailed statement explaining the reasons why pain relieving drugs, which are required by the Act unless it is scientifically necessary to withhold them, were not used, is mandated by section 13 of the Act, as set forth above. The statement is a necessary component of a facility's assurance that the provisions of the Act are being followed, "that professionally acceptable standards governing the care, treatment, and use of animals are being followed by the research facility during actual research or experimentation," and that the "facility is adhering to the standards * * *" (7 U.S.C. 2143(a)(7)(A) and (B)). Current § 2.26(a)(4) contains a similar requirement for a "brief statement" explaining why pain relieving drugs have been withheld. We believe the proposal to require a detailed statement of reasons for not using pain relieving drugs reflects the intent of Congress in amending the Act and that this requirement is mandated by section 13 of the Act (7 U.S.C. 2143(a)). For these reasons, paragraphs (b)(6) and (7) remain as proposed in § 2.31 of the revised rule.

Six commenters from the research community stated that the requirement of proposed § 2.28(b)(8) to report the number of animals being bred, conditioned or held for use, teaching, testing, experiments, research, or surgery, but not yet used, should be revised to reflect more accurately the number of animals held for use but not used. One commenter expressed concern that the number of unused animals at a facility is highly variable and changes daily so that the annual report would not provide an accurate figure. It would also not be an accurate means of determining the number of animals held by all facilities since animals are transferred between facilities and would be counted multiple times. In addition, some animals may be used in a procedure, and then held for another use, and would be counted at least twice: once as an animal used for teaching, testing, experiments, research, or surgery under paragraphs (b)(5), (6), or (7), and a second time as an animal being bred, conditioned, or held for use, teaching, testing, an experiment, research, or surgery under paragraph (b)(8).

We do not believe that it is necessary to revise paragraph (b)(8). That paragraph requires an accounting of all animals that have not yet been used and are being bred, conditioned, or held for use by a facility, not the number of transferred animals would be included in the annual report of each facility in which it is placed since it would be "new" to that facility. It is also true that an animal that was used in a procedure that is completed and is being held for use in another procedure would be included under paragraph (b)(8).

We received 314 comments (289 from the research community and 25 from members of the general public) suggesting that the substance of paragraph (b)(8) should be combined with paragraph (b)(4) so that there is a single requirement for reporting the number of animals at a facility. We disagree. Proposed paragraph (b)(4) of § 2.26 pertains to location of animals at a facility, not the number of animals. These are two distinct reporting requirements which the Department uses separately in the Department's annual report to Congress. Combining these requirements would complicate our reports and would not reduce the effort required of reporting facilities to present this data. Since there would be no beneficial effect gained from adopting the commenters' suggestion, both requirements remain in the revised rule.

Proposed paragraph (b)(9) of § 2.28 would require a statement by the CEO in the annual report stating: (1) That the attending veterinarian and the Committee members have authority to enter any animal area in the facility at any reasonable time to carry out their responsibilities under the regulations; (2) that the Committee has satisfactorily carried out its responsibilities; and (3) that the facility is in compliance with the Act, regulations, and standards. We received 365 comments (280 from the research community and 25 from members of the general public) stating that the statement concerning access by
the attending veterinarian and the Committee members to animal areas is redundant and unnecessary because it would be included within the assurances of compliance required in proposed paragraphs (b)(1) and (3). The commenters also objected to requiring the CEO's signature. We believe it is appropriate to require a separate statement by the CEO addressing these three concerns. Although paragraphs (b)(1) and (3) of proposed § 2.28 generally address compliance with the standards and regulations, we feel it is important that the CEO or responsible institutional official with authority to bind the facility bear responsibility for assuring that the statements made in the annual report are accurate and that the facility is in compliance. We believe that this accountability is necessary to ensure that the annual reports are meaningful and reliable.

For the reasons provided above in connection with proposed § 2.26(a), either the Chief Executive Officer or the "responsible institutional official with authority to bind the facility" may make the required statement in the annual report, and § 2.31(b)(9) is revised accordingly, in response to the comments received.

Thirty-seven commenters from the research community stated that the term "reasonable time" in proposed § 2.28(b)(9) should be defined, and 344 commenters (319 from the research community and 25 members of the general public) stated that the Committee members should not be allowed unrestricted entry to animal areas at any time if they believe the facility would interfere with ongoing research or the protection of proprietary information. Thirty commenters suggested that the Committee members and the attending veterinarian should have "reasonable access" to animal areas instead of "authority to enter any animal area, at any reasonable time" as proposed. The commenters stated that allowing reasonable access would prevent undue disruption of the animal or controlled environmental conditions, prevent interference with research, and protect proprietary information. The commenters suggested that "reasonable access" would require consultation with the principal investigator before entry into an animal area if research is being conducted, unless the Committee has reason to believe there is a problem related to animal welfare.

We do not believe that "reasonable time" requires additional clarification in the regulations. Research facilities can clarify what is a reasonable time through their written procedures or through guidelines issued by the CEO or responsible institutional official with authority to bind the facility. As previously explained in the discussion of Subpart C under the subheading, "§ 2.30(c)," it is not our intent to interfere with ongoing research, but we feel strongly that the Committee must have authority to enter all animal and research areas at any reasonable time without having to fulfill formal procedures as a prerequisite, and that the attending veterinarian must have authority to enter all animal or research areas at any time in order to ensure compliance with the program of adequate veterinary care. Section 2.31(b)(9) is revised to reflect this change. We do not intend that the Committee and attending veterinarian make a practice of barging into animal areas, and in this respect we agree that the principal investigator should be consulted as the commenter suggests. We do not believe it is appropriate to include a requirement for this in the regulations, however. Each facility is free to establish guidelines or a policy regarding consultation and to establish its own written procedures. We will retain the requirement that the annual report contain a statement, signed by the CEO or responsible institutional official, certifying that the Committee members have authority to enter any animal or research area at any reasonable time in order to carry out their responsibilities, and that the attending veterinarian is permitted access to all animal or research areas at any time.

Proposed § 2.28(c). We proposed in § 2.28(c) that the annual report be certified by the attending veterinarian and the Committee Chairman, in addition to being signed by the CEO under paragraph (a). We also proposed in § 2.28(c) that the annual report indicate the concurrence or nonconcurrence of the nonaffiliated member of the Committee.

Four commenters from the research community stated that the report and its assurances should be the responsibility of the CEO and should not require any other certifications. We received 370 comments (345 from the research community and 25 from members of the general public) stating that the entire paragraph should be deleted since the signature of the CEO required in paragraph (a) would be sufficient. One commenter was concerned that the proposed certification requirements improperly placed the burden of responsibility for the facility's compliance on the attending veterinarian and the Committee Chairman, and that at most they should be required certify to performance of their duties and fulfillment of their responsibilities. Others were concerned with the veto power given the attending veterinarian and the Committee Chairman, and the potential for abuse. One commenter noted that requiring the attending veterinarian to certify the annual report could place members of the Committee at odds with each other by giving one member the power that the Committee as a whole should have, and that this would undermine the ability of the Committee to perform its intended role.

Having considered the comments, we have determined that only the CEO or responsible institutional official with authority to bind the facility need sign and certify the annual report. Therefore, we are deleting the requirement from proposed § 2.28(c) that the attending veterinarian and Committee Chairman certify the annual report. The requirement that the CEO or responsible institutional official sign the annual report is already contained in paragraph (a) of § 2.31 in the revised rule, and we are adding a requirement that this official must also certify the report.

We received 179 comments from the research community stating that the requirement contained in proposed § 2.28(c) that the nonaffiliated member of the Committee indicate concurrence or nonconcurrence with the annual report should be deleted. Three members of the general public and one member of the research community stated that the annual report should reflect all dissenting opinions, and not single out the nonaffiliated member of the Committee. Some of the commenters pointed out that the Act, in Section 13, provides a mechanism for filing a minority view in connection with the inspection certification report prepared by the Committee (7 U.S.C. 2143(b)(4)(A)). The commenters further point out that the Committee report is separate from the annual report of the facility, and that the nonaffiliated member's view would appear to be irrelevant for purposes of submitting the facility's annual report.

Upon reconsideration of the requirement, we agree with the commenters that the emphasis on the concurrence or nonconcurrence of the nonaffiliated member of the Committee should be broadened to provide for the concurrence or nonconcurrence of any member of the Committee. We have revised this requirement to give all members of the Committee an equal opportunity to express a minority or nonconcurring view. To assure that the
members are afforded this opportunity, the CEO or responsible institutional official with authority to bind the facility will be required to certify that he or she circulated the report to the Committee members and that each was advised that they could add a minority report or indicate their nonconcurrence. We intend that the report would be circulated to each member with an attached routing slip containing a blank space in which the member could indicate that he or she read the report and concurred or did not concur, and that he or she was attaching a minority report to be included with the annual report. The slip would be replaced with a new blank slip for each Committee member’s review. In this manner, confidentiality between the responsible institutional official and between each member of the Committee would be maintained. The annual report must contain a space in which the CEO or responsible institutional official states that all Committee members had an opportunity to indicate nonconcurrence, and to state whether any minority reports are attached. As stated above, the CEO or responsible institutional official would be required to certify these statements.

We believe that this requirement will allow each member an opportunity to express dissent from the annual report and that his or her opinion will be forwarded to the Department. This is particularly important for ensuring that the nonaffiliated member is not excluded from Committee functions. The nonaffiliated member’s purpose is to provide representation for general community interests, and this may or may not result in that member being at odds with the other members of the Committee. We are aware of circumstances where the nonaffiliated member of the Committee has been prevented from meaningful participation in Committee functions or shut out of Committee meetings altogether because he or she presents a contrary or unpopular view. This mechanism should alert the Department to the need for further inspections or investigations of the facility. Accordingly, §2.28(c) is revised to provide for the concurrence or nonconcurrence of all members of the Committee with the annual report.

Section 2.35 Institutional Animal Care and Use Committee

The remaining provisions of §2.35 in the revised rule are those areas either specifically assigned by the Act to the Committee or necessary to implement the provisions of the Act which mandate Committee action. Many of the comments we received concerning §2.35 as proposed have been addressed under the headings, “Introduction,” “General,” and “Reorganization of §§2.30 and 2.35.” The comments we received addressing the remaining provisions are discussed below. Nevertheless, noted, the comments were received from members of the research community.

General. We received a number of comments addressing proposed §2.35 and the role of the Committee in general. Some comments were made concerning use of the Committee as an instrumentality of the facility, both for enforcing the regulations and for performing tasks assigned to the facilities by the Act. The reassignment of responsibilities is fully detailed in a preceding section of this supplementary information, under the heading, “Reorganization of §§2.30 and 2.35.”

Two commenters from the general public stated that the Committees were not given adequate authority in the proposed regulations. The Act prescribes the areas of authority delegated to the Committee and the revised rule is in accordance with the Act. The research facilities remain free to delegate authority to the Committee to perform additional duties on behalf of the facility. We believe it is best to leave this determination to the research facilities.

Fourteen members of the general public commented that the Department should promulgate national standards, instead of delegating responsibility to the Committees. We are proposing to do so in the proposed rule for Part 3—“Standards,” published elsewhere in this issue. (See companion docket no. 87-004.) Part 3 provides the standards for the humane handling, care, treatment, and transportation of different animals covered by the Act. The Act requires that the Committees inspect the facilities for compliance with the Act and regulations and assess and report on animal care at the facility. The Committee is necessarily responsible for approving deviations from the standards as part of its duties under the Act; however it does not set the standards. We believe the concern of the commenters has been addressed in proposed Part 3.

We received 168 comments objecting to proposed §2.35, on the basis that it would require extensive recordkeeping and reporting requirements beyond those required by the Act. We acknowledge that §2.35 will add new recordkeeping and reporting requirements, however, these are all mandated by the Act and are necessary in order to assure compliance with the Act, regulations, and standards.

Membership. We received 2 comments from members of the general public suggesting that the regulations provide protection for Committee members from possible reprisals. Similar committees have existed in accordance with the PHS Policy at institutions receiving grants or awards under the Health Research Extension Act of 1985, without incident, to our knowledge. We do not feel it necessary to include regulations to protect Committee members at this time.

Two commenters stated that having the chief executive officer (CEO) of the research facility select the Committee members, as proposed in §2.35(a)(2), in lieu of the Committee, is not in accordance with the Act. Delegation of authority is a matter left to the facilities in accordance with their charter and by-laws.

Delegation should only be to an administrative official who is not involved in the actual conduct of research, however, in order to comply with the intent of the Act that the Committee members are selected by a legally responsible official who is in a position to select a suitable Committee as described by the Act. No change is required in the regulations since this is an internal institutional matter.

Paragraph (a)(4) of proposed §2.35 states that Committee members “shall possess sufficient ability to assess animal care, treatment, and practices in experimental research as determined by the needs of the research facility.” One commenter expressed concern that the paragraph seems to state that each individual Committee member must possess “expertise” in animal care, treatment, and practices in experimental research. The commenter recommended that the paragraph be clarified to state that the Committee as a whole must have this expertise, but not each and every single member. We disagree with the commenter. The plain language of paragraph (a)(4) is sufficiently clear and is taken from the Act which provides that Committee members must have sufficient ability to assess animal care, and related matters. Committee members must possess some knowledge of animals, but “expertise” in these
areas is not required. This ability is required for each of the Committee members, not just for the Committee as a whole. Another commenter stated that "special" ability to assess animal care should not be required. It is not. Paragraph (4) requires "sufficient" ability to assess animal care, not "special" ability. Section 2.35(a)(4) remains as originally proposed.

Paragraph (a)(5)(i) of proposed § 2.35 states that of the Committee members, "at least one shall be a Doctor of Veterinary Medicine who is the attending veterinarian for the research facility and who is accredited by the U.S. Department of Agriculture in accordance with regulations passed by the Secretary under the Animal Welfare Act." As explained in a related document published elsewhere in this issue of the Federal Register, docket no. 88-013, Part 1—"Definition of Terms," we are removing references to "accreditation" from these regulations pending the promulgation of regulations required by the Act and the development of standards for the Animal Welfare "accreditation" program.

We received 398 comments (373 from the research community and 25 from members of the general public) stating that research facilities should be given the flexibility of assigning another staff veterinarian to the Committee in place of the attending veterinarian. There is nothing in the Act or the regulations to prevent research facilities from delegating the duties of the attending veterinarian on the Committee to another veterinarian; however, final responsibility for those duties rests with the attending veterinarian. Section 2.35(a)(5) is revised to clarify that the duties of the attending veterinarian may be delegated to a staff veterinarian.

Proposed paragraph (a)(5)(ii) of proposed § 2.35 would require that of the Committee members, "at least one shall not be affiliated in any way with such facility other than as a member of the Committee consisting of more than three members not more than three members shall be from the same administrative unit of such facility." We received 465 comments (440 from the research community and 25 from members of the general public) requesting that the term "administrative unit" be defined. We have done so in a related document, docket no. 86-013, Part 1—"Definition of Terms," published elsewhere in this issue. The term "administrative unit" would mean the following:
The organizational or management unit at the departmental level of a research facility.

Paragraph (7) of proposed § 2.35(a) requires that the Committee maintain a current list of Committee members containing their names, degrees, positions, qualifications, addresses, and telephone numbers. The attending veterinarian must maintain a copy of the current list and it must be available for inspection by APHIS officials. We received 492 comments (407 from the research community and 25 from members of the general public) stating that home addresses and telephone numbers of the Committee members should not be a part of records accessible to the public and 108 comments stating that only the Committee Chairman's business address should be required rather than the home addresses of all the Committee members. We agree that the list need not contain the home addresses and telephone numbers of the Committee members and that only the Committee Chairman's business address and phone number should be required. Paragraph (7) is revised to reflect this change.

Duties and responsibilities—

General. Proposed § 2.35(b) specifies the duties and responsibilities that the Committee must perform in accordance with the Act. A number of the duties that were contained in this proposed section were not imposed on the Committee by the Act, and have been reassigned to the research facility. A more complete explanation of the reassignment of duties and responsibilities, and precise section references are contained under the heading, "Reorganization of §§ 2.30 and 2.35."

2. Inspections. In the supplementary information to the proposed rule, we invited comments addressing how inspections could be carried out at research facilities having a large number of animal sites and study areas. We received 289 comments stating that the Committee should be allowed to delegate inspection and/or review responsibilities to a subcommittee or to other personnel, and that their inspection reports could then be evaluated by a quorum of the Committee. We also received 485 comments (460 from the research community and 25 from members of the general public) urging APHIS to consult with officials of the U.S. Public Health Service on requirements for Committee inspection before promulgating a final rule. The commenters felt that this would be both helpful for the research facilities, which would have to comply with both the Animal Welfare regulations and the PHS Policy on Committee inspections if they receive grants or awards under the Health Research Extension Act of 1985, and for APHIS since the Policy provides guidelines for the accomplishment of inspections and evaluations. As pointed out by some commenters, at most facilities the same Committee will be responsible for complying with the Animal Welfare regulations and the PHS Policy. Representatives from HHS advised the Department that the PHS Policy...
allows the Committee to determine at its discretion "the specific means to accomplish the semiannual evaluation of institutional programs and facilities, however, the IACUC remains responsible for the accuracy and adequacy of the evaluation and report." Facilities can work within their existing organizational structures to accomplish the requisite inspections and evaluations. Under the PHS Policy, the IACUC can appoint a subcommittee or designate personnel to perform the inspections, as 289 commenters suggested.

Having consulted with HHS and having considered the comments we received, we agree that the Committee should be able to appoint subcommittees composed of at least 2 Committee members to perform inspections. We are revising § 2.35(b) in this rule to allow each Committee at a research facility to designate a subcommittee to perform inspections, however, no Committee member who wishes to participate in an inspection may be excluded from participation in that inspection. The right of each Committee member to participate in any inspection conducted under Subpart C is set forth in § 2.35(b)(1)(v) of the revised rule. Section 13 of the Act requires that all formal actions of the Committee must be performed by a quorum of the Committee, and inspections are specifically included as formal actions (7 U.S.C. 2143(b)(2)). In order to satisfy the Act, § 2.35 is further revised to require the subcommittees to present their findings and recommendations, including inspection certification reports, and Committee recommendations, inspections, and subcommittee inspections, to a quorum of the Committee for formal action.

One commenter stated that the Committee should have the authority to suspend activities as it does under the PHS Policy. We agree with the commenter that painful procedures that are not in compliance with the Act and regulations should be suspended and that this can be accomplished through the Committee. Under the PHS Policy, the Institutional Animal Care and Use Committee may suspend an activity that it previously approved, if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the NIH Guide for the Care and Use of Laboratory Animals, the institution's Assurance, or the requirements of the PHS Policy which must be met in order for a proposed research project or a significant change in a research project to be approved.

We believe that authority to suspend approval of ACUPs is necessary for the Committee to function effectively and to act on behalf of the research facility in monitoring compliance. For this reason, we propose to include in the assurance statement required from the Committee as part of its inspection report, a statement that all painful procedures are in accordance with the "research protocols" [ACUPs] approved by the Committee and any approved changes to the "research protocols" [ACUPS], and that if the procedures "are not in accordance with the approved 'protocol' [ACUP] that the investigator[s] has been instructed to cease such methods and procedures immediately and to comply with the 'protocols' [ACUPs], procedures, and practices that were approved by the Committee." (Proposed § 2.35(b)(2)(ii)(D)). We have added paragraph (iv) to § 2.35(b)(1) in this revised rule to clarify that the Committee has authority to withdraw its approval. The effect of Committee withdrawal of approval is provided in § 2.35(b)(3) in the revised rule.

The research facility is responsible for directing that the research, testing, or teaching cease, otherwise the facility would not be in compliance with the regulations. We are requiring in § 2.35(b)(1)(iv) that the Committee direct the CEO to instruct the principal investigator to cease immediately any research, testing, or teaching involving pain to animals that is not in compliance with the approved ACUP, because it is the research facility's responsibility to direct cessation of activities that are not in accordance with the approved ACUP. In order to ensure that there is no added delay in ordering cessation of such activities, we are requiring that the Committee notify the CEO or responsible institutional official of noncompliance with an approved ACUP involving a painful procedure in its deficiency notification report, as provided in § 2.35(b)(2)(ii).

Forty-four commenters objected to the proposed requirement of § 2.35(b)(1)(i) that the Committee inspect all animal study areas and animal facilities at least twice a year, no more than 6 months apart, stating that it is too specific. Section 13(b)(3) of the Act requires that the Committee conduct inspections "at least semiannually" (7 U.S.C. 2143(b)(3)). We proposed that the inspections be conducted no more than 6 months apart to ensure that the underlying purpose for requiring semiannual inspections is carried out, that is, to ensure that throughout the course of the year each animal area is in compliance with the Act and the regulations. The utility of the inspections is maximized if neither too much nor too little time elapses between inspections. The PHS Policy requires the Institutional Animal Care and Use Committee to inspect the institution's animal facilities at least once every 6 months. This too seems designed to ensure that the twice yearly inspections are effectively spaced out over the course of the year, and is consistent with the proposed rule.

We are revising the requirement for twice yearly inspections to provide that inspections must be performed "at least twice a year, 6 months apart" rather than "no more than 6 months apart" as proposed. We are not requiring that inspections be performed at precise 6-month intervals to the day, but rather that they be performed at some time during the month or 30-day period in which the Committee performs its inspections. We believe that this requirement, as revised, allows facilities sufficient flexibility and time to conduct inspections. We are also revising the regulations to require that at research facilities maintaining multiple animal sites, Committee inspections of all animal sites and animal facilities must be completed within 30 days of commencing the first site inspection so that the Committee can complete and file a comprehensive inspection report. This requirement is necessary for APHIS officials and inspectors to have complete and current inspection reports to review when inspecting research facilities. This requirement is contained in § 2.35(b)(1)(vi) of the revised rule.

We received 307 comments (282 from the research community and 25 from members of the general public) suggesting that first priority for inspections should be given to areas for which exception requests have been submitted in accordance with proposed § 2.35(b)(1)(iii). We appreciate the concern that those animal study areas may require additional attention to ensure that they are in compliance with the Act and the regulations; however, the Act requires at least semiannual inspection of all animal study areas. There is no provision in the Act for assigning priorities to the order of inspections of the different animal study areas—they must all be inspected. The research facility may decide the order of inspections.

3. Reports. Under proposed § 2.35(b)(2), the Committee is directed to file an inspection certification report after each inspection which contains the following: (1) The date the inspection was made; (2) the signature of a majority of the Committee members and any minority views of the Committee; (3)
reports of violations of the regulations, standards, or assurances; (4) deficiencies in animal care or treatment; (5) Committee findings and recommendations; (6) any deviations from originally approved "protocols" [ACUPs] that adversely affect animal welfare; (7) notification to the facility of conditions, deviations, or deficiencies; (8) corrections made by the facility; and (9) any other information pertinent to the activities of the Committee and to the animal facilities. The report must also include an assurance statement by the Committee that its members have reviewed all painful procedures using animals and that the procedures are in accordance with approved ACUPs or approved changes to the ACUPs, and, if the procedures are not in accordance with approved ACUPs, that the investigator has been instructed to cease those practices immediately and to comply with the approved ACUPs.

We have revised the proposed rule to require that all inspection certification reports may be rejected and filed by the Committee in a timely fashion. We believe that 10 business days from completion of the site inspections required under § 2.35(b)(1) is a reasonable timeframe to impose on the Committee and that it is necessary to ensure that the required information is on file and is current.

We have also revised the rule to reflect the fact that subcommittees of at least 2 Committee members may perform inspections. This is provided in § 2.35(b)(1)(i) of the revised rule. The subcommittee must present its findings to a quorum of Committee members for formal action, as required under § 2.35(b)(2)(i) of the revised rule. Under proposed § 2.35(b)(2)(i), the Committee must notify the research facility of deficiencies found during an inspection. If the deficiencies remain uncorrected 30 days after notification and opportunity for correction, the Committee must notify the Administrator and any funding Federal agency and provide them with a copy of the report and the notification given to the facility. The Committee must also provide any APHIS inspector and any funding Federal agency of the project with a copy of any report showing deficiencies in complying with the regulations and standards which remain uncorrected.

We received 471 comments (446 from the research community and 25 from members of the general public) objecting to the requirement of proposed § 2.35(b)(2)(i) that the Committee's inspection certification reports be available to APHIS officials and to officials of funding Federal agencies for copying. Under section 13 of the Act, the Committee reports must be kept on file for at least 3 years at the facility and must be available for inspection by APHIS and any funding Federal agency (7 U.S.C. 2143(b)(4)(B)). It is necessary for APHIS inspectors to be able to copy reports to obtain documentation of noncompliance and to conduct investigations of possible noncompliance. These are the occasions when inspectors would need to copy the Committee reports. The requirement remains as initially proposed.

We received 307 comments (282 from the research community and 25 from members of the general public) stating that the Committee should not be required to monitor projects on an ongoing basis to assess deviations from originally approved protocols [ACUPs], as required by the assurance statement that is part of the Committee's report under proposed § 2.35(b)(2)(i)(D). This requirement is mandated by section 13(b)(4)(A) of the Act. It requires that the Committee's report include "any deficient conditions of animal care or treatment, any deviations of research practices from originally approved proposals that adversely affect animal welfare." (7 U.S.C. 2143(b)(4)(A)). Ongoing practices and procedures must necessarily be monitored in order to comply with this requirement. No change is made in the revised rule based upon this comment.

We received 321 comments (296 from the research community and 25 from members of the general public) objecting to the assurance statement required in proposed § 2.35(b)(2)(ii) for reporting deficiencies to the Deputy Administrator. As previously explained, the reference to the Deputy Administrator is changed to the Administrator. We have revised the notification procedure to reflect the fact that the facility is ultimately responsible for compliance with the Act and regulations, and that the CEO or responsible institutional official must certify the facility's compliance in the annual report. Accordingly, § 2.35(b)(2)(ii) is revised to require that the Committee notify the CEO of the research facility or the official responsible for animal care if the CEO has delegated authority to that official, as well as the administrative unit representative, of any deficiencies found, including noncompliance with an approved ACUP involving a painful procedure. This notification must be done, in writing, within one business day of discovery. The Committee must also provide a copy of its inspection certification report citing a deficiency to the CEO or the institutional official responsible for animal care, and to the administrative unit representative. The facility then has 30 days to correct the deficiency. If it remains uncorrected 30 days after notification of the CEO or other responsible institutional official, the Committee must notify the Administrator and any funding Federal agency of the uncorrected deficiency in accordance with section 13(b)(4)(C) of the Act (7 U.S.C. 2143(b)(4)(C)). We are requiring that this must be done within 5 days of completion of the 30-day correction period to avoid further delay. The Committee must provide a copy of
its inspection certification report and a copy of its written notification of deficiency to the Administrator. The Committee must also file a copy of its inspection certification report and written notification of deficiencies at the central repository maintained by the facility in accordance with § 2.30(m) for all reports required in this Subchapter so that they are available to APHIS officials and inspector(s), and to any funding Federal agency. The proposed rule erroneously referred to the “administrative representative” and not to the “administrative unit representative” as intended. Section 2.35(b)(2)(ii) of the revised rule reflects these changes.

We did not receive any comments addressing proposed § 2.35(b)(3)(iv), which requires that reports remain on file for at least 3 years at the research facility and be available for inspection and review by APHIS inspectors and any funding Federal agency. This requirement is set forth in § 2.30(m) of this rule, and it is revised to require that, upon notification from the Administrator, research facilities must also retain records pending completion of an investigation or proceeding under the Act, and until their disposition is authorized by the Administrator.

4. Reviews. Following the reorganization of §§ 2.30 and 2.35, and the realignment of duties and responsibilities so that only statutorily mandated duties are imposed on the Committee, and the revisions to Subpart C described above, the remaining reviewing functions of the Committee under the proposed rule would be as follows:

(f) No research, testing, or teaching involving [ACUPs] falling under Categories 3 and 4 in this paragraph performed by a facility’s personnel at any location shall commence prior to approval by the Committee (of the ACUP). Prior to granting approval, the Committee shall ensure that [ACUPs] in any of the categories listed in the Categories of Animal Use in Research and Teaching contain provisions for acceptable and proper animal care, treatment, practices, methods, and use of pain-relieving drugs. [(Proposed § 2.35(b)(3)(ii)).]

(ii) The Committee shall approve any [ACUP] only when animal pain, distress, and functional or sensory impairment are minimized; all survival surgery is performed using aseptic procedures; adequate veterinary care is planned for and provided; multiple use of such animal(s) is justified for the purpose of conserving an endangered species or marine mammals or as an essential related component of a particular project or [ACUP]; and the appropriate use of anesthetics, analgesics, tranquillizing drugs, or euthanasia, when necessary, and that the use of such drugs is in accordance with instruction of the attending veterinarian. [(Proposed § 2.35(b)(3)(iii)).]

As previously discussed under the heading “§ 2.30(d),” we have determined that the Committee must review and approve all ACUPs before any research, testing, or teaching involving animals can commence, and § 2.35(b)(3)(i) of this revised rule (formerly proposed § 2.35(b)(3)(i)) is revised accordingly. Requiring review of all ACUPs, not just those involving painful procedures, is consistent with PHS Policy and avoids the need for determining the degree of pain or distress that can reasonably be anticipated to result from a proposed procedure.

We had originally proposed that “no research, testing, or teaching involving protocols falling under Categories 3 and 4 of the Categories of Animal Use in Research and Teaching performed by a facility’s personnel at any location shall commence prior to approval by the Committee.” [(Proposed § 2.35(b)(3)(iii)).]

Using the “Categories of Animal Use in Research and Testing” was proposed as a means of classifying animal procedures into 4 categories, ranging from those involving little or no pain or distress to those involving severe or unrelied pain or distress. The Committee would be required to review the ACUPs for procedures falling in the categories involving higher degrees of pain, Categories 3 and 4, to ensure that they contained provisions for acceptable and proper animal care, treatment, practices, methods, and use of pain-relieving drugs. Examples of the types of procedures typically falling into the different categories were provided in the proposed Categories of Animal Use.

We received numerous and varied comments regarding the proposed Categories, ranging from general approval and suggestions that the proposed categories be incorporated into the Annual Report (VS Form 19–23) (12 commenters) to disapproval and suggestions that they be deleted because the commenters found them confusing and/or inappropriate (27 commenters).

Four commenters recommended that the proposed categories be revised to include additional detail, including further categorization and definition. The Committee has adopted these recommendations in this final rule.

It became clear from our review of the comments that a fair number of the commenters were misconstruing the proposed examples as fixed categorizations of procedures into the 4 proposed categories. This was certainly not our intent in providing the examples. As stated in the supplementary information accompanying the proposed rule at 52 FR 10302, “[t]hese [Categories of Animal Use in Research and Teaching] are for the guidance of the investigator in planning the research protocol [ACUP] and for the Committee in determining the degree of pain or distress to be allowed and the necessity of such pain or distress when approving the protocol [ACUP] * * * * * . The list of examples is not all inclusive but is provided as guidance for where a particular protocol [ACUP] might be classified in relation to the pain or distress involved.”

Despite this explanation of the examples provided for each category, we received 72 comments objections to all toxicity studies being classified as Category 3. Toxicity studies were included as an example of the type of procedure which would typically but not necessarily fall under Category 3 as involving “significant but unavoidable pain or distress to the animals.” A toxicity study which did not involve this level of pain or distress would not be in Category 3 under the proposed rule.

Other commenters addressing the proposed Categories of Animal Use included one from a member of the general public suggesting that a fifth category for “severe pain” be included, and one from a member of the research community generally approving of the proposed categories.

The proposed Categories of Animal Use was selected from among several like categorizations and was developed by the Scientists Center for Animal Welfare. This categorization was the result of many conferences and seminars addressing the issue of how to classify procedures involving differing levels of pain and is currently in use in 20 or more research facilities. As a result of the comments received, we have considered a number of alternatives for addressing the concerns raised by the commenters. One alternative considered was using a different categorization system. It is likely, however, that similar issues would be raised in response to any proposed categorization of types of procedures. We also considered proposing additional examples of the types of procedures that would typically fall into the different categories, in response to the comments requesting additional definition and categorization, however these too could be misconstrued as fixed categorizations rather than as examples provided for guidance. We next considered removing the examples from the rule to avoid any misconception as to whether they were actually fixed categorizations. This would likely raise concerns that the
One member of the general public commented that unanimous approval by the Committee should be required for all protocols [ACUPs]. This is contrary to the Act, which requires a quorum for all formal actions of the Committee (7 U.S.C. 2143(b)(2)]. "Quorum" is defined by the Act as a majority of the Committee members (7 U.S.C. 2132[m]). No change is made in the revised rule based upon this comment.

Also, in accordance with PHS Policy, we are providing a mechanism to enable the Committee to require that an approved practice or procedure be suspended, in accordance with proposed and revised § 2.35(b)(3)(i)(D), if it determines that a procedure or practice is not being performed in accordance with the approved ACUP. We are providing that the Committee can do so by withdrawing or suspending its approval of an ACUP. Section 2.30(d) requires Committee approval for all ACUPs before they commence, and section 13(a)(3)(E) of the Act requires that any exceptions to the standards be specified in the ACUP and explained in a report filed with the Committee (7 U.S.C. 2143[a](0)[E]). Accordingly, once Committee approval is withdrawn, the procedure or practice must cease or the research facility is in violation of the regulations. Section 2.35(b)(3)(i) of the revised rule is changed to provide that no research, testing, or teaching involving warm-blooded animals covered by the Act shall continue if the Committee suspends its approval.

Eight commenters from the general public urged that painful experiments should not be allowed at all. One of the stated purposes of the provisions to the Act is to minimize animal pain and distress (7 U.S.C. 2143[b](3)]. The Act is clear, however, in its direction that except as provided in section 13[a][6] of the Act, it does not authorize the Secretary to promulgate regulations "with regard to the design, outlines, or guidelines of actual research or experimentation by a research facility as determined by such facility." (7 U.S.C. 2143[a][6]). Therefore, the Department therefore does not have the authority to prohibit all painful experiments.

Three commenters from the general public suggested that in determining whether to approve a proposed ACUP, the Committee should compare the public gain which would result from the research versus the pain inflicted on the animal. Although the Act does not direct the Committee to make this judgment, it does direct the Committee to ensure compliance with the Act to "minimize pain and distress to animals" and to inspect research facilities for compliance with the Act, regulations, and standards (7 U.S.C. 2143[b][3]). One of the stated findings of Congress set forth in the Act is that "measures which eliminate or minimize the unnecessary duplication of experiments on animals can result in more productive use of federal funds" and "measures which help meet the public concern for laboratory animal care and treatment are important in assuring that research will continue to progress." (7 U.S.C. 2131). Proposed § 2.35(b)(3)(iii) provides the bases upon which the Committee will approve or disapprove a proposed ACUP. The bases enumerated include provision for the commenters' concerns. We further believe that the provision for a nonaffiliated member of the Committee who is "intended to provide representation for general community interests in proper care and treatment of animals" (7 U.S.C. 2143[b][1][B][iii]) will bring these considerations to bear in Committee deliberations, and that the Committee as a whole will keep the purposes of the Act in mind in performing its duties. No change is made based upon this comment and it is redesignated as § 2.35(b)(3)(ii) in the revised rule.

Two commenters stated that the language in proposed § 2.35(b)(3)(ii) should be changed from "The Committee shall approve such protocols only when * * * " to "The Committee shall approve procedures only when * * * ". We have revised this paragraph by replacing the term "protocol" with "ACUP."

We are also revising the conditions listed in proposed § 2.35[b][3][iii] in the revised rule which must be satisfied for the Committee to approve an ACUP, and are correcting the typographical and grammatical errors that appeared in it.

We received 478 comments from members of the general public in regard to proposed § 2.35[b][3][ii] concerning the need for stronger and stricter requirements for reporting painful procedures and use of pain relieving drugs, and for better identifying those procedures not involving pain, procedures involving unrelieved pain, and procedures involving pain relieved with drugs. We have addressed these comments separately from those concerning the proposed Categories of Animal Use because they more properly concern the research facility's annual report, VS Form 18-23 than proposed § 2.35(b)(3)[ii]. The annual report requires an accounting of the number of animals utilized in procedures involving no pain, unrelieved pain, and relieved pain. We are aware of instances where
animals are reported under Column "C", "no pain" because the pain is relieved with drugs. This is improper because the relief of pain does not make the procedure does not involve pain. As noted previously, 12 commenters felt that the proposed Categories of Animal Use should be used on VS Form 18-23, instead of the current designations.

We believe that the combination of Committee review of all ACUPs, requiring Committee approval of all proposed ACUPs before they can commence, Committee inspections, and the research facility's responsibility to assure that pain and distress are minimized will result in more accurate reporting of painful procedures. The annual report, VS Form 18-23 will also be clarified to require that painful procedures be reported as such, regardless of whether or not pain is relieved.

We received 40 comments stating that "Committee" should appear in § 2.35(b)(3) of the final rule in place of "attending veterinarian" wherever the phrase "in accordance with the instructions of the attending veterinarian" appears. The phrase appears in proposed § 2.35(b)(3)(ii) only in regard to the use of pain relieving drugs. The requirements in the remaining paragraphs of proposed § 2.35(b)(3) are incorporated in § 2.20 of the revised rule because they are the responsibility of the research facility. Procedures and practices which must be done in accordance with the instructions of the attending veterinarian, as provided in proposed § 2.35(b)(3), are those which pertain to providing proper veterinary care, and providing for animal health and well-being, such as the proper use of drugs and pre- and post-procedural care. As explained previously, adequate veterinary care must be provided in all research procedures and is not limited to those involving surgery. Section 2.35(b)(3) of this rule is revised accordingly. These areas within the expertise of the attending veterinarian, as opposed to the Committee, and remain subject to the instructions of the attending veterinarian in the revised rule.

Subpart D—Attending Veterinarian and Adequate Veterinary Care Introduction

As explained above under the heading "Subpart C—Institutional Animal Care and Use Committee and Other Requirements for Research Facilities" and under the subheading, "Reorganization of §§ 2.30 and 2.35," in this revised rule we are reassigning responsibility to the research facilities for certain duties that had been placed upon the attending veterinarian in the proposed rule. These changes are made in response to the concerns raised by 480 commenters (455 from the research community and 25 from members of the general public) who stated that as proposed, § 2.40(e) would place the attending veterinarian in the position of enforcement agent for the Department. These changes should also allay the concerns of the four commenters from the research community who stated that the Committee was improperly given veterinary responsibilities in § 2.35 of the proposed rule.

With this reorganization of §§ 2.30, 2.35, and 2.40, and the reassignment of responsibilities, we believe that the research facility, the Committee, and the attending veterinarian will serve as an effective built-in institutional quality assurance mechanism. The Act requires standards for adequate veterinary care, and consultation with a veterinarian in the planning of any painful procedure. The regulations in this revised rule are intended to ensure proper planning and conduct of research procedures and adequate veterinary care.

Although ultimate responsibility for many of the responsibilities originally placed on the Committee and the attending veterinarian in the proposed rule is placed on the research facility in the revised rule, many of these responsibilities must still be performed under the guidance or supervision of the attending veterinarian or in consultation with the attending veterinarian because they fall within his or her expertise. Accordingly, § 2.30 of this rule has been revised to require each research facility using or holding animals for research, testing, or teaching to establish, maintain, and abide by a written program of adequate veterinary care in accordance with § 2.40. (A research facility may or may not include the written program of adequate veterinary care in its standard operating procedure (SOP) if it employs a full-time attending veterinarian.)

In Subpart D, paragraph (e) of proposed § 2.40, "Research facilities," is most affected by the reassignment of responsibility. For example, proposed § 2.40(e)(2) would have required the attending veterinarian to provide consultation and guidance in areas of veterinary care. In the revised rule, it is the research facility's responsibility to require and ensure that the attending veterinarian performs those functions. General. Proposed § 2.40 would require a written program of adequate veterinary care between a dealer, exhibitor, or research facility, and its attending veterinarian, which includes a program for disease control and prevention, pest and parasite control, pre- and post-procedural or surgical care, nutrition, euthanasia, proper and appropriate use of anesthetics, analgesics, tranquilizers, and any other pain relieving drugs.

We received comments addressing the nature of the program of adequate veterinary care generally, and the frequency of program review by the Area Veterinarian in Charge that should be required when there is a part-time as opposed to a full-time attending veterinarian. These areas of commenters' concern are clarified in the revised rule and are discussed below.

We received 10 comments (8 from the research community and 2 from dealers) generally in favor of strengthening the current regulations concerning veterinary care and 35 comments (27 from dealers and 8 from exhibitors) generally opposed to strengthening the requirements. We have determined, based upon our experience, and for the reasons provided in the supplementary information to the proposed rule, published in the Federal Register, March 31, 1987, (see 52 FR at 10303), that enhanced requirements for adequate veterinary care are necessary to promote the health and well-being of animals.

We received 329 comments (304 from the research community and 25 from the general public) expressing concern that the tone of proposed Subpart D is negative and will create a confrontational relationship between attending veterinarians and research personnel and/or Committee members, rather than a cooperative relationship. We believe that the reorganization of §§ 2.30, 2.35, and 2.40 in the revised rule should allay this concern, because it resolves any disputes over areas of expertise and responsibility. With the reassignment of the areas of responsibility of the research facilities, Committee members, and attending veterinarians in this revised rule, we believe the regulations will result in a synergistic relationship which fosters animal welfare.

Attending veterinarian. Proposed § 2.40(a) would require each licensee or registrant to have an attending veterinarian who is "accredited" by the U.S. Department of Agriculture in accordance with regulations issued by the Secretary under the Act. The attending veterinarian would be responsible for providing adequate veterinary care to the animals in accordance with the written program of adequate veterinary care required in
proposed paragraphs (b) and (c) of § 2.40.

We received numerous comments from the research community addressing "accreditation" of the attending veterinarian. Forty-six commenters from the research community objected that proposed § 2.40(e) is unacceptable without the details of "accreditation" being included; 907 commenters (492 from the research community and 25 members of the general public) stated a more general concern that the process for "accrediting" veterinarians was not explained in the proposed rule. One hundred commenters from the research community stated that APHIS is not in a position to establish professional qualifications for "accreditation" of attending veterinarians.

As previously explained in this supplementary information, and under the heading, "Attending veterinarian," in a related document, Part 1 — "Definition of Terms," published elsewhere in this issue of the Federal Register, docket no. 88-013, we are removing references to "accreditation" from the regulations pending the Department's renaming and development of standards for the "accreditation" program. Proposed standards will be published separately at a later date in a proposed rule. We believe that this action will satisfy the commenters' concerns.

**Program of adequate veterinary care.**

Proposed § 2.40(b) would require the attending veterinarian to establish, maintain, and supervise programs of disease control and prevention, pest and parasite control, pre- and post-procedural care, nutrition, euthanasia, and adequate veterinary care for all animals on the premises of the dealer, exhibitor, and research facility. The programs must also include the proper and appropriate use of anesthetics, analgesics, tranquilizers, and euthanasia, when indicated. The reader should note that the requirement for a program of pre- and post-procedural care in proposed § 2.40(b) applies to all research procedures and processes involving animals and is not limited to surgical procedures. Accordingly, we have revised all of the provisions of § 2.40 in this rule to refer to pre- and post-procedural care in place of pre- and post-surgical care wherever it appears.

In addition to the comments objecting to the allocation of responsibilities among the facilities, the Committee, and the attending veterinarian, we also received 84 comments from members of the research community stating that the establishment, maintenance, and supervision of a program of adequate veterinary care in research facilities should be the responsibility of the Committee, and not the attending veterinarian. We do not agree that this responsibility should be imposed on the Committee. The Act does not require the Committee to develop a program of adequate veterinary care. Moreover, only one member of the Committee, the attending veterinarian, would be certain to have the requisite expertise to do so. As previously explained under the discussion of Subpart C, we have determined that responsibilities not imposed by the Act on the Committee should be placed on the facility.

Establishment and maintenance of the program of adequate veterinary care is the responsibility of the facility, as provided in § 2.30 of the revised rule. Accordingly, proposed § 2.40(b) is revised to state that responsibility for establishing and maintaining a program for adequate veterinary care is on the dealer, exhibitor, and research facility, instead of the attending veterinarian. The program would remain under the supervision and control of the attending veterinarian, however, because of the attending veterinarian's expertise. We have also clarified paragraph (b), to provide that programs for disease control and prevention, pest and parasite control, pre- and post-procedural care, nutrition, the proper and appropriate use of anesthetics, analgesics, tranquilizers, and euthanasia when indicated, are all elements of a program of adequate veterinary care and must be included by a dealer, exhibitor, and research facility in order to have a comprehensive program as intended by the Act.

Two commenters from the research community stated that the Department should promulgate regulations on what constitutes an adequate program of veterinary care. The elements that must be included in a program of adequate veterinary care are provided in § 2.40(b) of the revised rule. They are programs for disease control and prevention, pest and parasite control, pre- and post-procedural care, nutrition, euthanasia, and the appropriate use of pain relieving drugs. It is the responsibility of the dealer, exhibitor, or research facility to ensure that its program of veterinary care adequately covers those areas. We are also revising § 2.40(c) to require that these areas be included in the written program for adequate veterinary care. In addition, § 2.40(d) of this revised rule requires, that the attending veterinarian provide anesthesia and analgesics to provide. Additional review of determinations regarding the use of drugs is provided under § 2.35. Under that section, the ACUP must be reviewed and approved by the Committee, and the principal investigator must explain why an exception to the requirement to provide for the use of pain relieving drugs is justified. We do not believe that the attending veterinarian will be in the position of deciding critical experimental issues that are outside the scope of his or her expertise or duties.

We received 25 comments from members of the research community stating that veterinarians are not trained for the role of determining what anesthesia and analgesics to provide. We believe the attending veterinarian has this expertise and is best suited to provide guidance concerning the proper use of pain relieving drugs and the need for them. One commenter stated that requiring the principal investigator to provide anesthesia and analgesics in accordance with the attending veterinarian's recommendation places the attending veterinarian in the position of deciding critical experimental issues, and this is not the role for which the attending veterinarian is trained. We disagree with the commenters. Under proposed § 2.40(o)(2)(i), the attending veterinarian is required to provide consultation and guidance to the principal investigator and to laboratory personnel during both planning and development of the ACUP and during the performance of the actual research. The principal investigator can consult with the attending veterinarian regarding the special needs and requirements of the research and experimental design, and together they can resolve outstanding matters concerning the use of pain relieving drugs. Additional review of determinations regarding the use of drugs is provided under § 2.35. Under that section, the ACUP must be reviewed and approved by the Committee, and the principal investigator must explain why an exception to the requirement to provide for the use of pain relieving drugs is justified. We do not believe that the attending veterinarian will be in the position of deciding critical experimental issues that are outside the scope of his or her expertise or duties.

We received 10 comments (3 from dealers and 7 from exhibitors) stating veterinary care should satisfy the commenters' concern.

Three exhibitors commented that a responsible official of the dealer, exhibitor, and research facility should coordinate with the attending veterinarian in developing a program of adequate veterinary care. We believe that the concerns raised by this comment have been addressed in the revised rule, which requires dealers, exhibitors, and research facilities to establish and maintain the program of veterinary care and requires the program to be under the control and supervision of the attending veterinarian. The suggested coordination will result from this requirement, if properly implemented.

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We received 10 comments (3 from dealers and 7 from exhibitors) stating veterinary care should satisfy the commenters' concern.
that the attending veterinarian should not have to be present for routine health care procedures, such as vaccinations and worming. We agree with the commenters. For this reason, there was no proposed requirement that the attending veterinarian be present at all times for those procedures, nor is there one in the revised rule. The requirement is that the program of adequate veterinary care, including the procedures involved in administering a program of adequate veterinary care, be conducted under the supervision and control of the attending veterinarian. This does not require the attending veterinarian's presence at all times. No change is made in the revised rule based upon this comment.

Proposed § 2.40(c) would require that a written program of adequate veterinary care between the dealer, exhibitor, or research facility and the “Doctor of Veterinary Medicine” be drawn up and reviewed annually by APHIS. It would also require that the program provide for regularly scheduled visits by the veterinarian as appropriate to the facility's needs, if a part-time or consulting veterinarian is the attending veterinarian. Each dealer, exhibitor, and research facility would be required to keep a copy of the program on file on the premises and to provide a copy to the Area Veterinarian in Charge annually. Proposed paragraph (c) would also provide minimum requirements that must be included in the written program of adequate veterinary care, in addition to the areas of care provided in paragraph (b).

Six commenters from the research community stated that the term “attending veterinarian” should appear in place of “Doctor of Veterinary Medicine.” We agree and have made this change in the revised rule. We intended specifically that the attending veterinarian, not any “Doctor of Veterinary Medicine,” be involved in the development of the program of veterinary care. We have revised paragraph (c) accordingly.

We received 315 comments (200 from members of the research community and 25 members of the general public) stating that the written program of adequate veterinary care required in proposed § 2.40(c) reads like a contract between the facility and a part-time or consulting attending veterinarian and therefore would not be appropriate for full-time or staff attending veterinarians. Representatives of HHFS suggested that institutions with a full-time attending veterinarian on staff should not be required to prepare and submit annually for review a separate program document, since they would have a program of adequate veterinary care in place through established positions, lines of authority, and standard operating procedures. We agree in part with the HHFS suggestion. We believe that if a dealer, exhibitor, or research facility has established a written program of adequate veterinary care, separately or as part of its standard operating procedure, and has a full-time attending veterinarian on staff, it need not annually prepare and submit to APHIS a separate document for the program of adequate veterinary care. This is because the written program or SOP, coupled with the established lines of authority and responsibility, would address the requirement for maintaining a program of adequate veterinary care.

We also agree that if a dealer, exhibitor, or research facility has a written program of adequate veterinary care and a full-time attending veterinarian on staff, it is sufficient if the written program of adequate veterinary care is reviewed by APHIS inspectors in the course of their regular duties, on the premises, rather than requiring the dealer, exhibitor, or research facility to redraft and submit a copy of their program annually to the Area Veterinarian in Charge. Dealers, exhibitors, and research facilities that have a full-time attending veterinarian on staff generally are less likely to change their attending veterinarian than those with a part-time or consulting attending veterinarian, and therefore changes to the program of adequate veterinary care due to changes in personnel are less likely. Additionally, full-time staff attending veterinarians can make daily personal observations or receive reports on animal conditions and care from employees under their supervision, and are in a position to respond promptly to veterinary care needs with trained personnel. Part-time or consulting attending veterinarians would not have the same opportunity to observe and to act.

We are requiring in the revised rule that if a dealer, exhibitor, or research facility utilizes the services of a part-time or consulting attending veterinarian, it must provide the Area Veterinarian in Charge with its written program of adequate veterinary care, prepared and signed by its attending veterinarian, on an annual basis. We are requiring that a part-time or consulting attending veterinarian prepare and sign the written program of adequate veterinary care annually in order to verify that it is the current program of veterinary care being implemented by the attending veterinarian and the dealer, exhibitor, or research facility. The dealer, exhibitor, or research facility must also keep a copy of the program on file at its premises at all times.

We are revising § 2.40(c) in this rule to clarify these differences for dealers, exhibitors, or research facilities that have a full-time attending veterinarian on staff and those that utilize the services of a part-time or consulting attending veterinarian. They appear in paragraphs (c)(1) and (2) of § 2.40 in the revised rule.

Thirty-seven commenters (36 from the research community and 1 exhibitor) stated that the program of veterinary care should be reviewed every 3 years, instead of annually, to coincide with registration renewal. We are retaining the requirement for annual review. The need for adequate veterinary care has nothing to do with registration renewal every 3 years. Rather, it is concerned with the daily health needs of the animals. The commenters do not mention the fact that the requirement for annual review of the program of veterinary care also applies to dealers and exhibitors. We believe that annual review is desirable in any event, because of changes in the technology of veterinary care delivery, and changes in accepted procedures.

Four dealers commented that visits by a part-time or consulting attending veterinarian should not be required to be by appointment, but should only be required to be made on a routine basis. Proposed § 2.40(c) requires “regularly scheduled visits appropriate to the facility’s needs.” There is no requirement for visits by appointment. Our concern is that visits be sufficiently frequent to provide adequate veterinary care, as “appropriate to the facility's needs.” No change is made to this provision in the revised rule.

We have made one additional change to proposed paragraph (c). In providing the minimum requirements that must be included in the written program of adequate veterinary care, we omitted reference to the areas of veterinary care that must be included. These are the areas of veterinary care identified in § 2.40(b) of both the proposed and the revised rules. This reference is added as new paragraph (c)(3) and proposed paragraphs (c)(1) through (6) are redesignated as (c)(3)(i), (ii), and (iv) through (viii) in the revised rule. This change also responds to the 2 comments we received from members of the research community who stated that regulations should be provided on what determines adequate veterinary care. Observation of animals and care for sick, diseased, injured, lame, or blind
animals. Proposed § 2.40(d) would require daily observation of animals by the dealer, exhibitor, veterinarian, animal caretaker in charge, or someone under their direct supervision. In drafting proposed § 2.40(d), we inadvertently omitted research facilities from the entities required to observe each animal daily. We believe this subsection was understood to apply to research facilities since the second sentence refers to animals obtained for research purposes. Also, proposed § 2.40(e)(2) imposes requirements on the attending veterinarian of a research facility in addition to those contained in paragraphs (a) through (d). The term "research facility" is added following "exhibitor" in the revised rule. The term "veterinarian" was intended to refer to an attending veterinarian, and is modified in the revised rule accordingly.

We received two comments from the research community stating that provision should also be included for observation of the animals by the principal investigator. We agree with this comment since the investigator is qualified to perform the required observation. The revised rule is changed to include observation by the investigator.

One exhibitor and 1 member of the research community commented that the requirement for daily observation of the animals is excessive. One commenter noted that it is impractical to require the veterinarian of a large facility, such as large exhibition facilities or game farms, to observe each animal daily, and that observation might actually be detrimental to the proper management of some species such as bears isolated for cubbing. We disagree with the commenter. The requirement for daily observation of most species has been part of the regulations since 1967 without resultant problems. It is also consistent with the NIH Guide for the Care and Use of Laboratory Animals, which states that "[a]nimals should be observed and cared for by qualified personnel every day, including weekends and holidays. * * * *" (p. 28).

Daily observation is a necessary part of good husbandry practices. It is extremely important that this requirement be retained in order to detect possible problems, including detection of disease and abnormal behavior. Also, it is not necessary that one individual observe all the animals. The proposed regulation would require daily observation by "the dealer, exhibitor, research facility, [attending] veterinarian, [principal investigator], or animal caretaker in charge, or someone under their direct supervision."

The requirements imposed on the attending veterinarian of a research facility in the proposed rule include providing consultation and guidance to principal investigators and laboratory personnel during planning and development of an ACUP, and during actual research, whenever a procedure is likely to produce pain or distress in an animal. Proposed paragraphs (A) through (D) of § 2.40(e)(2)(i) identify specific areas in which the attending veterinarian must provide consultation and guidance. Proposed § 2.40(e)(2)(ii) would require the attending veterinarian to establish a recordkeeping system and a standard operating procedure which indicates and assures the proper use of drugs and proper pre- and post-surgical care on a daily basis. Proposed § 2.40(e)(2)(iii) would require the attending veterinarian to sign an assurance statement on the research facility’s annual report, VS Form 18-23, certifying that he or she has authority to enter all animal areas, that he or she has carried out the requirements of § 2.40, and that he or she has read and understands the regulations and standards contained in Parts 2 and 3 of the Animal Welfare regulations.

In the revised rule, § 2.40(e)(1), the research facility is directed to require that the attending veterinarian be a member of the Committee. Similarly, it is the research facility’s responsibility, under § 2.40(e)(2)(i), to require the attending veterinarian to provide the requisite consultation and guidance. Also, as discussed in this supplementary information under the heading, "Subpart B—Registration," only the chief executive officer or the institutional official with responsibility for animal care will be required to sign the facility’s annual report. This is consistent with the PHS Policy. Accordingly, paragraph (iii) is deleted from § 2.40(e)(2) in the revised rule.

Many of the comments we received addressing proposed § 2.40(e) were from members of the research community. Therefore, unless otherwise indicated, the source of the comments discussed in this section is the research community.

Ten commenters stated that the word "all" should be deleted from paragraphs (e)(1) ("The attending veterinarian shall have * * * authority to enter all animals rooms, sites, facilities, and animal use areas, at any time"), (e)(2)(i)(D) (the attending veterinarian shall provide consultation and guidance in "[e]valuation and approval of all animal surgical areas"), and (e)(5)(iii)(A) (attending veterinarian shall sign an assurance statement on the facility’s annual report certifying that he or she has "authority to enter all animal rooms, sites, facilities, and animal use areas, at any time."
has "authority to enter all animal areas". Proposed § 2.40(e)(2)(iii) is removed from the revised rule since the attending veterinarian is not required to sign the annual report. The other references to "all" remain as proposed, because we believe it is essential that all animal rooms and animal areas be accessible to the attending veterinarian to assure proper and adequate veterinary care and to carry out the intent of the Act. The requirements that the attending veterinarian provide consultation and guidance in the areas of evaluation and approval of all animal surgical areas and qualifications of personnel involved with animal surgery are ultimately the responsibility of the facility and are included in § 2.30 in the revised rule. The facility must assure, however, that evaluation and approval of all animal surgical areas and qualifications of personnel are done in accordance with instructions of the attending veterinarian. Accordingly, § 2.40(e)(2)(ii)(D) of the revised rule retains the requirement that the research facility require the attending veterinarian to provide consultation and guidance with respect to evaluation and approval of all animal surgical areas and qualifications of personnel involved with animal surgery.

Fifteen commenters stated that the attending veterinarian should be allowed access to enter animal rooms, sites, facilities, and animal use areas only "at any reasonable time," rather than "at any time" as proposed in § 2.40(e)(1). The commentators expressed concern that entry by the attending veterinarian in an animal study area during a procedure could be disruptive. We have determined that access "at any time" is imperative to prevent obstruction by those principal investigators for whom there is never a "reasonable" time to allow entry by the attending veterinarian. It is desirable that the attending veterinarian consult with the investigator to determine what would be a reasonable time and that the attending veterinarian be able to examine the ACUP in making this determination so as not to disrupt procedures or a controlled research environment. This may be done as part of the consultation and guidance provided during ACUP planning and development, and during actual research. Moreover, as previously discussed in the discussion of § 2.30(b) under the heading, "§ 2.30 Additional requirements for research facilities," research facilities could establish guidelines in the facility's written policies and procedures to help reassure personnel that this right of access would be exercised in good faith. It is important, however, that the attending veterinarian retain the right to have access at any time to ensure compliance with the program of adequate veterinary care, for the benefit of the animal.

Forty-four commenters stated that the requirements imposed on the attending veterinarian in proposed § 2.40(e)(2) properly belong to the Committee. We do not agree. The Act requires that the principal investigator consult with a doctor of veterinary medicine in the planning of any procedure likely to produce pain or distress in an experimental animal (7 U.S.C. 2134(a)(3)(C)). The areas listed in proposed paragraphs (A) through (D) of § 2.40(e)(2)(i) are necessary components of research planning and development and of veterinary care.

Proposed § 2.40(e)(2) states that:

In addition to the requirements set forth in paragraphs (a) through (d) of this section, the attending veterinarian of a research facility shall:

(i) provide consultation and guidance to principal investigators and other laboratory personnel during protocol [ACUP] planning and development, and during actual research, whenever any procedure is likely to produce pain or distress in an animal. Such consultation and guidance shall include at least the following areas:

(A) the proper use of tranquillizers, analgesics, anaesthetics, and euthanasia according to the accepted, or common veterinary practice procedures;
(B) provision for adequate pre-surgical and post-surgical care by laboratory workers in accordance with current established veterinary medical and nursing procedures;
(C) agreement to the withholding of tranquillizers, anaesthesia, analgesia, or euthanasia only when scientifically necessary and only for the necessary period of time; and
(D) evaluation and approval of all animal surgical areas and qualifications of personnel involved with animal surgery.

(ii) establish a recordkeeping system and of veterinary care.

We received 506 comments (481 from the research community and 25 from members of the general public) stating that proposed paragraph (e) of § 2.40 implied that the attending veterinarian would be required to be present during all actual research and that this is impractical and unnecessary. It is not our intent that the attending veterinarian must be present at all times during all actual research or during all actual research that might produce pain or distress in an animal. Rather our intent is that the attending veterinarian must be available for consultation and to provide guidance, and must have free access to all animal areas if he or she determines it is necessary to be present during the conduct of research procedures. During our consultations with representatives from HHS, they stated that many institutions interpreted proposed § 2.40(e) as requiring the attending veterinarian's presence. They suggested the following clarifying modification to paragraph (e)(2)(i):

"Provide consultation and guidance to principal investigators and other laboratory personnel during [ACUP] planning and development, and if deemed necessary by the IACUC [Committee] during actual research, whenever any procedure is likely to produce pain or distress in an animal."

We agree that the attending veterinarian should be present during actual research that is likely to produce pain or distress in animals if requested by the Committee. We also believe the attending veterinarian should be present if requested by the investigator, if complaints from personnel or humane groups are received, or to observe the research for compliance with the approved ACUP. The facility's written policy under § 2.30(e)(10), and the facility's program of adequate veterinary care. The revised rule is modified to clarify that the attending veterinarian's care. The revised rule is modified to clarify that the attending veterinarian's presence during actual research that is likely to produce pain or distress is required only under these circumstances.

\[\text{Paragraph (iii) is not repeated here since the requirement for the attending veterinarian to sign the annual report is removed from the revised rule.}\]
One commenter objected to the requirement in proposed § 2.40(e)(2)(i) that the principal investigator consult with and receive guidance from the attending veterinarian during ACUP planning and development and during actual research whenever those procedures would be likely to produce pain or distress. Section 13(a)(3)(C)(i) of the Act specifically mandates this consultation in the planning of "any practice which could cause pain to animals." \(7\text{ U.S.C. 2143(a)(3)(C)(i)}\). For this reason and for the reasons stated above in our discussion of required consultation and guidance, no change is made in the revised rule based upon this comment.

We received 40 comments stating that the requirement of proposed § 2.40(e)(2)(ii), that the attending veterinarian establish a recordkeeping system to assure proper drug usage and proper pre- and post-surgical care, be deleted. Twenty-nine commenters noted that procedures for proper drug use and pre- and post-surgical care would be provided in the ACUP, making a separate recordkeeping system unwarranted. We agree with the commenters insofar as requiring assurance of proper care is the institution's responsibility. We believe that the research facility should have some means of verifying the elements of proper veterinary care and that their written program of adequate veterinary care should provide for a recording system which indicates compliance with proper veterinary care procedures. We have revised paragraph (ii) in this rule to reflect that research facilities are required to have their attending veterinarian establish, as part of the facility's program of adequate veterinary care, procedures and a recording system in the program of adequate veterinary care which indicate and assure proper drug usage and proper pre- and post-procedural care.

Four commenters stated that only the institutional official responsible for animal care should be required to sign the annual report, Form VS 18-23. We agree for the reasons set forth under the heading, "Subpart B—Registration" and have removed paragraph (iii) from the revised rule.

No other changes are made to § 2.40 in the revised rule.

Subpart E—Identification of Animals, Time and method of identification

In proposed § 2.50, we proposed animal identification requirements intended to strengthen those of the existing regulations. We received 5 comments (2 from dealers and 3 from the general public) generally endorsing the stricter identification requirements and in favor of use of tags, tattoos, or both as the most reliable means of identification. One commenter urged that the type of marking provided in the regulations be by a humane method.

Another commenter noted the need for requiring adequate recordkeeping as a means of verification of the animals' identity.

We have reconsidered the proposed requirements in light of the commenters' concern for stricter identification requirements in general. We believe that the requirements contained in proposed § 2.50 will result in more animals held by all classes of dealers and by research facilities being properly identified by tagging or by an approved tattoo. In this regard, we have reconsidered allowing class "A" dealers to identify live dogs or cats on the premises by "an accurate and distinctive description," a tattoo marking, or a formal tag, and have determined that all animals on the premises should be identified by tattoo or official tag. We are eliminating the option to identify animals by description from proposed § 2.50(e)(3) since it could result in inaccuracies or improper substitution of animals. With this method of identification removed from the regulations, we believe that the requirements in paragraph (n)(3) can be combined with those of (n)(1). Accordingly, § 2.50(e)(1) is revised to require identification by tag or tattoo of all live dogs and cats held on the premises, purchased, or otherwise acquired, sold, or otherwise disposed of or removed from the premises.

The commenter noting concern about humane methods of identification was most concerned that the method used not be unreasonably painful or distressful, such as a piercing or tagging could be. The regulations are sufficiently clear in their requirement that tags must be attached "by means of a collar made of material generally considered acceptable to pet owners" and provides guidelines as to what would be considered acceptable and what would be unacceptable. Unacceptable materials are those such as wire, elastic, or sharp metal, that might cause discomfort or injury to the animals. Ear tagging is not an acceptable means of identification. We do not believe that additional regulations concerning the means of tagging are needed at this time.

Although we did not receive any comments addressing proposed § 2.50(b), we wish to clarify that it requires identification of all live dogs or cats under a Class "B" dealer's control, or on his premises, and not just those that are purchased or otherwise acquired. The word, "or," was inadvertently omitted from paragraph (b) in the proposal. To correct any misconception we are revising paragraph (b)(1) to read as follows:

"When live dogs or cats are held, purchased, or otherwise acquired, they shall be immediately identified—"

We are making a conforming change in paragraph (c) for the same reason.

We did not receive any other comments concerning the remaining sections of proposed Subpart E, however we have determined that some revision is necessary.

We have clarified proposed § 2.50(e) by revising paragraph (e)(1) to include animals from any exempt source. Proposed paragraph (e)(2) is therefore removed from the revised rule because it is subsumed in paragraph (e)(1). We have revised proposed paragraph (e)(1) by redesignating its provisions as paragraphs (e)(1)(i), (ii), and (e)(2) in the revised rule to make it easier to follow. Paragraph (e)(1) of the proposed rule would provide that all live dogs or cats delivered for transportation, transported, purchased or otherwise acquired, sold, or disposed of by a research facility be identified at the time of delivery, purchase, sale, disposal, or acquisition by either: (1) An official tag or tattoo that was affixed to the animal at the time it was acquired by the research facility, or (2) A tag, tattoo, or collar applied to the dog or cat by the research facility which individually identifies the dog or cat by description or number. The latter alternative is redesignated as paragraph (e)(1)(ii) in the revised rule. We have determined that a tag, tattoo, or collar would identify the dog or cat by number only, and not by description, due to space and other practical limitations. We are removing identification by description from this provision in the revised rule.

Subpart F—Stolen Animals

Proposed § 2.60 would provide that "(e)any person subject to the Act shall not buy, sell, exhibit, use for research, transport, or offer for transportation, any stolen animal." One of the findings of Congress on which the Act is premised is that "regulation of animals and activities as provided in [the] Act is necessary ** ** in order (3) to protect the owners of animals from the theft of their animals by preventing the sale or use of animals which have been stolen." \(7\text{ U.S.C. 2151(b)}\). Section 2.60 was proposed in order to prevent the buying and selling of stolen animals and those obtained under questionable circumstances, since the requirements of marking for identification and
recordkeeping have proven insufficient to stop these practices. We received 377 comments (352 from the research community and 25 from members of the general public) stating that proposed § 2.60 should either be deleted from the regulation entirely or that it should be limited to persons "knowingly or willfully" engaging in activities using stolen animals. Fourteen commenters (2 from the research community and 12 from members of the general public) stated that they are in favor of the proposed regulation.

As stated above, we have determined that this section is necessary and it remains in the rule, as revised. We have considered the comments stating that the regulations should prohibit only willful or knowing use of stolen animals and have determined that the resultant regulation would be ineffective and virtually unenforceable. We are concerned that persons seeking to use the animals as provided in the regulation would choose to remain ignorant of the circumstances under which the animal was obtained. We have also considered adding an exception for circumstances in which the person holding the animal has made reasonable, good faith efforts to determine whether the animal was stolen or its origin. We have determined that the proposed regulation would be most effective in preventing theft of animals if the various activities involving stolen animals listed in the regulation constitute per se violation of the regulations. Only in this manner can we be certain that persons subject to the Act will use best efforts in endeavoring to avoid using stolen animals. We are hopeful that the incidence of stolen animals will subside if the market for them is eliminated.

Section 2.50 remains in the revised rule as originally proposed.

Subpart G—Records

Dealers and exhibitors

We received 5 comments (1 from the research community, 1 from an exhibitor, and 3 from the general public) noting the need for stricter recordkeeping requirements in general. We believe that the additional recordkeeping requirements proposed in Subpart G will assist the Department by enhancing traceability of the animals, which is one of the prime objectives of the recordkeeping requirements, and will be a valuable tool in combating the sale of animals obtained unlawfully.

We are amending § 2.75 in this revised rule to reflect that it applies to dealers other than operators of auction sales and brokers, and to exhibitors. This clarification is necessary because operators of auction sales and brokers are dealers under the Act (7 U.S.C. 2131(f)) and under the definition of "dealer" contained in Part 1—"Definition of Terms" (see companion docket no. 88-013, published elsewhere in this issue), because they negotiate the purchase or sale of animals, in commerce, for compensation or profit. Section 2.77 provides the recordkeeping requirements applicable to operators of auction sales and brokers to whom animals are consigned.

Proposed § 2.75 would impose recordkeeping requirements upon dealers and exhibitors that are substantially similar to those required under current § 2.75, except that dealers and exhibitors would also be required to maintain in their records the vehicle license number and state, and the driver's license number and state of anyone not licensed or registered under the Act from whom a dog or cat is acquired. This requirement was not included in proposed § 2.75(b) and we have determined that it is equally appropriate to include it for animals other than dogs and cats. This requirement was proposed to facilitate tracing the seller and the source of the animals, particularly when the source or origin of the animals is in question. Five commenters from the general public stated their approval of this requirement.

One member of the general public suggested that we require owner release statements which acknowledge ownership of the animals whenever they are acquired in an adoption or an otherwise transferred. We are concerned that anyone who contrives to sell or transfer stolen animals would likely be willing to provide a fraudulent owner release statement. Secondly, a person subject to the Act might attempt to defend against a charge of violating § 2.60 by pleading good faith reliance on the owner release statement and could argue that it is not reasonable to require a person to go beyond obtaining the statement to satisfy themselves that the animals were not stolen. This would affect the Department's efforts to enforce § 2.60 of the regulations effectively under those circumstances or to prosecute persons charged for activities involving stolen animals. Because of these concerns with the commenter's suggestion, we are not requiring an owner release statement at this time. If we determine that it should be included in the regulations, we will publish a notice of proposed rulemaking and solicit public comments on the proposal.

One exhibitor commented that APHIS, and not licensees, should maintain dealer records, such as the Record of Disposition of Dogs and Cats (VS Form 18-4). The Department is authorized under sections 10 and 12 of the Act to require that dealers and exhibitors maintain records with respect to the purchase, sale, transportation, identification, and previous ownership of animals (7 U.S.C. 2140, 2142). The Department is also authorized under sections 10 and 12 of the Act to inspect and copy those records (7 U.S.C. 2140, 2142). No change is made in the revised rule based upon this comment.

Section 2.75 remains as originally proposed.

Proposed § 2.78 would similarly require research facilities to maintain in their records the vehicle license number and state, and the driver's license number and state of the person from whom a dog or cat was purchased or otherwise acquired if that person is not licensed or registered under the Act. Proposed § 2.78 would also require research facilities to maintain in their records the USDA license or registration number of that person if that person is licensed or registered under the Act. Current § 2.78 is more general in its requirement that research facilities maintain a license number if that person is licensed under the Act.

The requirement to maintain the vehicle license number and state, and the driver's license number and state of the person who owned or consigned the animal(s) for sale was omitted from proposed § 2.77(a). We have determined that it is equally appropriate to impose this requirement on dealers who are operators of auction sales and brokers, for the reasons stated above. Accordingly, § 2.77(a) is revised to include this requirement. We are also revising § 2.77(a) in this rule to include the date of birth or approximate age of the animal in the description required, because this requirement was inadvertently omitted from the proposed rule.

We received 303 comments (278 from members of the research community and 25 from members of the general public) stating that the requirement to maintain a record of the USDA license or registration number is not in the Act and that APHIS has failed to demonstrate how requiring it would benefit animal welfare. Section 10 of the Act requires research facilities to make and retain records with respect to the purchase, sale, transportation, identification, and previous ownership of live dogs and cats, as the Secretary may prescribe (7 U.S.C. 2140). Section 12 of the Act
authorizes the Secretary to promulgate recordkeeping requirements governing the purchase, handling, or sale of animals, in commerce, by research facilities (7 U.S.C. 2142). The regulations at this time No change additional provisions need be included under the heading, "Requirements and Act. obtaining such license under section exhibitor issued holding a valid license as a dealer or subject to section licensed sellers only. We believe that be revised to state that research requirements for maintaining a record of facilities animals, in commerce, is made in the revised rule as a result of this comment.

Health certification and identification

Proposed § 2.79 would continue the requirement of current § 2.79 that a health certificate, executed and issued by a licensed veterinarian, must accompany any dog, cat, or nonhuman primate delivered by a dealer, research facility, exhibitor, operator of an auction sale, broker, or department, agency, or instrumentality of the United States or of any State or local government, to an intermediate handler or carrier for transportation in commerce. It further provides that VS Form 16-1 may be used for health certification by a licensed veterinarian. VS Form 16-1 is the "U.S. Interstate and International Certificate of Health Examination for Small Animals."

One commenter from the research community stated that federal institutions that are dealers are not required to sign Form 18-1. Nevertheless, the Act does require any "department, agency, or instrumentality of the United States having laboratory animal facilities," to provide health certificates (7 U.S.C. 2144). Section 14 of the Act requires that they comply with paragraphs (a), (f), (g), and (h) of section 13 (7 U.S.C. 2143), and section 13(f) provides the requirements for a health certificate to accompany dogs, cats, and "additional kinds or classes of animals designated by regulation of the Secretary." (7 U.S.C. 2144.)

We intended to impose these prohibitions on persons who transport animals in commerce themselves, rather than limiting the prohibitions to persons who deliver the animals to carriers or intermediate handlers, but inadvertently did not do so in the proposed rule. Imposing these prohibitions on persons who transport animals in commerce themselves is necessary because increasing numbers of dealers, research facilities, and other persons are transporting animals themselves, rather than using carriers and intermediate handlers to do so. The health and safety concerns underlying the minimum age requirement and health certification requirement apply equally to the animals in transport, regardless of the legal status of the person transporting the animal, and it is inconsistent with these concerns to place the prohibitions on carriers and intermediate handlers only.

Therefore, § 2.79 is revised in this rule by extending its prohibitions to any dealer, research facility, operator of an auction sale, broker, or department, agency, or instrumentality of the United States or of any State or local government transporting any dog, cat, or nonhuman primate in commerce. This would apply to federal agencies as well. We are similarly extending the prohibition of § 2.130 to any person transporting dogs or cats in commerce.

We also note that in our proposal to amend Part 3—"Standards" (see companion docket no. 87-004, published elsewhere in this issue), we are proposing to make the transportation standards included in Subparts A-D applicable to any person subject to the Act who transports the regulated animals in commerce, rather than restricting the standards to carriers and intermediate handlers as in the current regulations.

Subpart H—Compliance with Standards and Holding Period

Compliance with standards

Proposed § 2.100(a) would require the following:

Each dealer, exhibitor, operator of an auction sale and research facility shall comply in all respects with the regulations set forth in Part 2 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 may be made for research facilities only when such exceptions are specified in the research protocol; are explained in detail in a report filed with the Institutional Animal Care and Use Committee; and are approved by the Committee.

Seven commenters objected to the wording of proposed § 2.100(a). Four commenters from the research community objected to use of the term "research protocol" in the proposed regulation. Three of those commenters and 2 additional commenters from the research community stated that the statutory language should be used instead. A seventh commenter, also from the research community, stated that the phrase "are explained in detail in a report filed with the Institutional Animal Care and Use Committee; and are approved by the Committee" should be removed from the regulation.

We consider these comments to be unjustified. The proposed language is taken from the statute. Section 13(a)(3)(E) of the Act plainly states "that exception to such standards may be made only when specified by research protocol and that any such exception shall be detailed and explained in a report outlined under paragraph (7) and filed with the Institutional Animal Care and Use Committee." (7 U.S.C. 2143(a)(3)(E). The term "research protocol" is taken directly from the statute. However, as explained in Part 1—"Definition of
Terms,” docket no. 88–013, published elsewhere in this issue of the Federal Register, we have replaced it with “animal care and use procedure” (ACUP) everywhere it appears in proposed Parts 1 and 2. This change is to satisfy concerns voiced by members of the research community and HSIS that the Department would be interfering in research design. The requirement that exceptions to the standards be detailed and explained in a report to the Committee is also directly from the statute and remains in the revised rule. We are revising § 2.100 to also require that exceptions from the provisions of § 2.131, “Handling,” may be made by research facilities when specified in the ACUP, explained in detail in a report filed with the Committee, and are approved by the Committee. This change is necessary because § 2.131 pertains to the humane handling of all animals covered by the Act and is derived from the standards in Part 3. We have included § 2.100 in Part 2 because all persons subject to the Act must comply with it when handling all animals covered by the Act.

Proposed § 2.100(b) would apply to carriers and intermediate handlers, and would require that they comply with the regulations in Part 2 and the standards in Part 3 pertaining only to the humane transportation of animals in commerce. Proposed § 2.100(a) would apply to dealers, exhibitors, operators of auctions sales, and research facilities, and would require that they comply with the regulations in Parts 2 and 3 in their entirety. We have determined that because intermediate handlers hold animals for several days while awaiting transportation in commerce, they should be required to comply with all of the standards in Part 3 for the humane handling, care, treatment, and housing of animals during these holding periods, and not just those pertaining to transportation. We are therefore revising § 2.100(a) in the final rule to include intermediate handlers and we are removing them from § 2.100(b) in the revised rule.

Except for these three changes, § 2.100 remains as proposed.

Holding period

Proposed § 2.101(a) would require a 5-day holding period for dogs and cats by dealers and exhibitors following their acquisition of the animal. One dealer objected to the 5-day holding period. Section 5 of the Act provides as follows:

No dealer or exhibitor shall sell or otherwise dispose of any dog or cat within a period of five business days after the acquisition of such animal or within such other period as may be specified by the Secretary * * *(7U.S.C. 2133).

Five days is considered to be the appropriate holding period under most circumstances. We consider that this is a reasonable period of time to allow persons to locate missing animals, and to enable a dealer or exhibitor to determine whether a dog or cat is fit for further transfer. Accordingly, the 5-day holding period remains in the revised rule. We are revising the rule, however, to ensure that animals are held 5 full days. We are concerned that if a dealer or exhibitor obtains an animal late in the day on a Monday, for example, that it could count that Monday as one business day, and disposes of the animal early on Friday by counting Friday as one business day as well. This would not allow owners sufficient time to locate their missing animals. This problem would be compounded if the dealer or exhibitor is open for business over the weekend and counts Saturday and Sunday as business days. Using the time of acquisition in the example set forth above, an animal obtained late Thursday night might be disposed of first thing Monday morning, without allowing its owner a reasonable period of time to locate the missing animal. To prevent this occurrence, we are revising § 2.101(a) to provide that, except as otherwise provided in paragraph (a), any live dog or cat acquired by a dealer or exhibitor must be held for 5 full days, not including the day the animal was acquired. We are also providing that the 10-day holding period applicable to live dogs or cats acquired by a dealer or exhibitor from any private or contract pound or shelter excludes the day the animal was acquired.

We intended that all time periods provided in § 2.101 would exclude time in transit. This exclusion was inadvertently omitted from the initial requirement of paragraph (a) that “[a]ny live dog or cat acquired by a dealer * or exhibitor shall be held by him, under his supervision and control, for a period of not less than 5 business days after acquisition of such animal.” Reference to excluding time in transit has been included in this revised rule, as well.

We proposed certain exceptions to the 5-day holding period in § 2.101(a). The second exception stated in the proposed regulation would allow dealers or exhibitors who obtained dogs or cats obtained from governmentally owned and operated pounds or shelters to hold the animals for only 24 hours, instead of the 5-day period otherwise required, if the animals completed a 5-day holding period at the governmentally owned and operated pound or shelter.

We received 5 comments from members of the general public objecting to the proposed exception for dealers and exhibitors who obtain dogs or cats from governmentally owned and operated pounds or shelters which would excuse them from the 5-day holding period. We agree with the commenters that this exception should be removed from the regulations. Based upon our review of the comments, we have determined that a 1-day holding period would not provide owners with a reasonable period of time to recover lost animals that have been placed in the pound or shelter, and that eliminating the 5-day holding period for dogs and cats obtained from governmentally owned and operated pounds or shelters would not be in the best interests of the animals or their owners and would not be in keeping with the intent of the Act. Therefore, we are retaining the 5-day holding period in the final rule for all dogs and cats obtained by a dealer or exhibitor, except as follows:

(1) In the revised rule we are requiring a 10-day holding period, not including the day of acquisition, for dogs and cats acquired or obtained by a dealer or exhibitor from a private or contract animal shelter or pound. A holding period for animals obtained from a private or contract shelter or pound was not included in the proposal because proposed § 2.132 would have prohibited class “B” dealers from obtaining random source dogs or cats from those sources. Accordingly, it was not necessary to provide a holding period. As explained below under the heading, “§ 2.132 Procurement of random source dogs and cats, dealers,” the revised rule provides that class “B” dealers may obtain random source dogs and cats from private or contract pounds or shelters, and must comply with the holding period required under § 2.101 and § 2.132. We believe that a 10-day holding period for dogs and cats obtained from a private or contract pound is appropriate and reasonable because holding periods for these animals are determined by local laws and vary greatly. Holding periods may not even be required under some local laws. Moreover, animals held in private or contract pounds often are from several different towns or counties, depending upon the contract arrangement, and the 10-day period will allow owners additional time to locate lost or stolen animals.

(2) Dogs and cats that have completed a 5-day holding period with another dealer or exhibitor, or a 10-day holding period with another dealer or exhibitor if obtained from a private or contract shelter or pound, may be sold or
otherwise disposed of by subsequent dealers or exhibitors after a 24-hour holding period;

(3) Any dogs and cats suffering from disease, emaciation, or injury may be destroyed by euthanasia before completing the requisite holding period; and

(4) Any dogs and cats that are 120 days of age or less and that have been obtained from the person that bred and raised them, or the person may be disposed of by dealers or exhibitors after a 24-hour holding period.

The comments we received expressed concern that lost or stolen animals could be sold to research facilities before their owners are able to locate them. Proposed § 2.101 provides holding periods for dogs and cats that are applicable to dealers and exhibitors. One of the reasons for requiring holding periods is to allow owners of lost or stolen animals a reasonable time to locate their animals before they are sold or otherwise disposed of by the dealer or exhibitor.

We have determined that research facilities obtain dogs and cats from sources other than dealers and exhibitors which must comply with § 2.101, and exempt sources. Some of these dogs and cats may be lost or stolen animals. We believe that an effective way to protect owners of lost or stolen animals would be to impose a similar holding requirement on research facilities that obtain dogs and cats from those other sources. Accordingly, we are requiring in this revised rule that research facilities that obtain dogs and cats from sources other than dealers, exhibitors, and exempt persons must hold the animals for 5 full days, not including the day of acquisition, after acquiring the animal, excluding time in transit. Research facilities would still be subject to the identification of animals requirements in § 2.50. We believe that this measure is necessary to effectuate the purpose of the Act and that it is authorized under Section 21 of the Act (7 U.S.C. 2151).

We are revising paragraph (b) of § 2.101 to include reference to § 2.131, "Handling," for the reasons set forth above in this supplementary information, under the heading, "Holding period."

Holding facility

We are correcting a typographical error in proposed § 2.102[a][3]. That paragraph incorrectly references § 2.4. We have changed it in the revised rule to refer to § 2.1, as we intended.

Subpart I—Miscellaneous

Section 2.125 Information as to business

Proposed § 2.125 would require persons subject to the Act to provide to any Veterinary Services representative information concerning any business of theirs which may be requested in connection with enforcement of the Act and the Animal Welfare regulations. The proposal differs from the current regulation only in that carriers and intermediate handlers would also be required to furnish business information upon the request of a Veterinary Services representative. (Reference to "Veterinary Services representative" is changed to "APHIS official" in the revised rule.) The current regulation only applies to dealers, exhibitors, operators of auction sales, and research facilities.

We received 16 comments from the research community stating that the proposal would exceed our authority under the Act and that we have gone beyond the intent of the 1985 amendments to the Act. Another 4 comments from the research community stated that proposed § 2.125 should be deleted for this reason. We believe these comments are unjustified, because the requirements contained in proposed § 2.125 have been in effect since 1967 with respect to dealers, exhibitors, and research facilities, and have not been subject to challenge. Nor have we encountered difficulty in obtaining compliance from the research community. Section 10 of the Act provides authority for requiring recordkeeping by dealers, exhibitors, and research facilities in respect to the "purchase, sale, transportation, identification, and previous ownership" of animals. Research facilities must make and retain required records with respect to live dogs and cats only. Authority to include carriers and intermediate handlers is specifically provided in Section 10 of the Act which further expressly requires that "[s]uch records shall be made available at all reasonable times for inspection and copying by the Secretary." (7 U.S.C. 2140.) Section 12 of the Act authorizes the Secretary to promulgate "recordkeeping requirements governing the purchase, handling, or sale of animals, in commerce, by dealers, research facilities, and exhibitors at auction sales and by the operators of such auction sales." (7 U.S.C. 2142.) Section 21 authorizes the Secretary to promulgate regulations in order to effectuate the purposes of the Act (7 U.S.C. 2151). The Department has determined that it is necessary to expand the scope of current § 2.125 to include carriers and intermediate handlers because of their increased involvement in handling animals in commerce. Expanding the scope of this regulation is also necessary to enhance enforcement efforts. We believe that such authority is provided in the Act for requiring this information.

We received 302 comments (277 from the research community and 25 from members of the general public) objecting to proposed § 2.125. We believe that the Act states that only those records required by the Act to be kept need to be made available to APHIS. Current and proposed § 2.125 would require the furnishing of any information concerning the business of the [persons subject to the act] which may be requested by such representative [of APHIS] in connection with the enforcement of the provisions of the Act, the regulations and the standards in this subchapter. In order to carry out the Department's enforcement authority, Congress expressly authorized the Secretary to "promulgate such rules, regulations, and orders as he may deem necessary in order to effectuate the purposes of this Act." (7 U.S.C. 2151.) Authority to require that business information that is pertinent to enforcing the provisions of the Act and the Animal Welfare regulations be provided to the Department upon request is necessary in order to carry out the intent of Congress. This authority must apply equally to all information which may assist efforts to enforce the provisions of the Act and the regulations, but which is not specifically required to be kept by the Act, in order for the Department to be able to effectively enforce the regulations.

We received 48 comments (46 from the research community, 1 from an exhibitor, 1 from a member of the general public) suggesting we define "proprietary and business information" and clarify proposed § 2.125 to indicate that APHIS cannot use it to obtain proprietary information. We do not agree that these modifications are necessary. Current § 2.125 has been part of the Animal Welfare regulations since 1967. There have been no complaints that it has been wrongfully used to obtain proprietary information. The information required to be provided under the regulation is that which pertains to the conduct of business by persons subject to the Act. The information is necessary for the Department to effectively carry out its regulatory and enforcement authority under the Act.

For the above reasons no change is made to proposed § 2.125 in the revised rule.
One commenter from the research community stated that we should clarify the requirements for compliance by federal research facilities under proposed § 2.125. Federal research facilities are not required to be registered under the Act; however, they are directed to comply with "the standards and other requirements promulgated by the Secretary for a research facility under section 13 (a), (f), (g), and (h)." (7 U.S.C. 2144.) Except for the information required in the annual report of research facilities, they would not be required to furnish information to APHIS under § 2.125.

Section 2.126 Access and inspection of records and property

Proposed § 2.126 would require dealers, exhibitors, research facilities, intermediate handlers, and carriers to provide access to Department representatives for inspection of their premises, animals, and records, to copy records, and to take photographs to document times of noncompliance. We received 193 comments from the research community stating that reference to access to records and to taking photographs should either be deleted from the section or that the proposal should be revised to limit access to records and photographing of the premises. We received 139 comments from the research community stating that the entire section should be deleted or revised within the limits of the Department’s statutory authority under the Act. One commenter from the research community expressed concern that photographs could become available to the public through loss, theft, or FOIA requests. Statutory authority for Departmental access to conduct inspections of premises and records and to copy records is provided in Sections 10 and 18 of the Act (7 U.S.C. 2140, 2148). Section 10 of the Act requires persons subject to the Act to make and retain records as prescribed by the Secretary and provides that:

[Such records shall be made available at all reasonable times for inspection and copying by the Secretary.]" (7 U.S.C. 2140).

Section 16 provides that:

[The Secretary shall make such investigations or inspections as he deems necessary to determine whether [any person subject to the Act] has violated or is violating any provision of this Act or any regulation or standards issued thereunder, and for such purposes, the Secretary shall, at all reasonable times, have access to the places of business and the facilities, animals, and those records required to be kept pursuant to section 10 of any such person.]"

It further requires that these inspections be conducted at least once each year and that follow-up inspections be conducted until all deficiencies or deviations are corrected (7 U.S.C. 2146(a)).

The Department’s authority to take photographs to document deficiencies has been upheld in an unpublished decision by a United States Court of Appeals following the Department's Judicial Officer’s decision in In re: Donald Stumbo, d.b.a. Stumbo Farms, 43 Agric. Dec. 1079 (1984). We believe that § 2.126 as proposed is within the Department’s authority under the Act and that no revision is necessary.

Two dealers commented that Department representatives should make appointments before conducting inspections. We disagree with the commenters. The Act provides that the Secretary shall have access “at all reasonable times” (7 U.S.C. 2146(a)) and that persons subject to the Act must make their records available “at all reasonable times for inspection and copying by the Secretary.” (7 U.S.C. 2140). We have found that the ability to conduct unannounced inspections enhances our enforcement efforts and is vital to encouraging actual and ongoing compliance with the Act. It is also necessary for determining whether inspection findings are reliable indicators of the actual conduct of business by the inspected entity. We are concerned that setting appointments would allow noncomplying persons to prepare for inspection, while operating at other times in noncompliance, because they feel secure they will not be inspected by the Department without warning. For this reason, no change is made in the revised rule based upon this comment.

We received 6 comments (4 dealers and 2 exhibitors) stating that the property surrounding an animal facility should either not be subject to inspection or that there should be a limit, such as 100 feet, on the surrounding area subject to inspection. Department representatives will continue to inspect surrounding land areas in order to detect problems with pests, odors, drainage, and trash or abandoned material, all of which can affect animal welfare. We agree that at some distance from a regulated person’s premises, the condition of the area no longer has any bearing on the welfare of animals on the premises. However, the distance would vary in every situation, depending on the type of housing facility used, the area under the control of the regulated person, and other factors. Because these factors vary so widely and so unpredictably, it is not practical for us to specify a limit in the regulations.

We received 6 comments (5 from members of the research community and 1 dealer) stating that specific criteria should be established for the conduct of inspections by APHIS inspectors. As stated in proposed § 2.126, Department representatives will inspect facilities, property, records, and animals as considered necessary to enforce the provisions of the Act and the regulations and standards contained in Subchapter A—“Animal Welfare.” The standards contained in Part 3—“Standards,” provide specific site requirements which must be satisfied by persons subject to the Act holding animals. In a related document published elsewhere in this issue we are proposing standards applicable to dogs, cats, guinea pigs, hamsters, rabbits, and nonhuman primates. (See companion docket no. 87-004.) We believe that further specification of criteria is not necessary at this time. We encourage comments concerning the proposed standards, because they also contain criteria that will be used in conducting inspections.

One member of the general public commented that the regulations should include inspection of humane societies, animal shelters, pounds, and the like. These types of shelters are subject to regulation and inspection if they sell animals for a regulated purpose, such as to research facilities or dealers.

Eleven commenters from the research community stated that federal facilities should be subject to inspection by the Department. We do not have authority under the Act to inspect facilities operated by federal agencies; however, they must comply with section 13 (a), (f), (g), and (h) of the Act, and must submit an annual report to APHIS each year. Accordingly, government owned and operated pounds are exempt from inspection by APHIS.

Section 2.128 Inspection for missing animals

Proposed § 2.128 would require dealers, exhibitors, research facilities, carriers, and intermediate handlers to allow access by “police or other officers of law enforcement agencies with general law enforcement authority (not those agencies whose duties are limited to enforcement of local animal regulations)” to enter the premises to inspect animals and records for the purpose of locating animals that are missing. Ten commenters from the research community stated that the section should be deleted from the regulations. One commenter stated that it violates the requirements of due
process of law and the Fourth Amendment protection against unreasonable searches and seizures. The commenter stated that searches for missing animals should be conducted under the existing procedures of local, state, and/or federal law enforcement agencies.

The Department is required by the Act to promulgate rules and regulations requiring persons subject to the Act to allow inspections to search for missing animals. Section 17 of the Act directs the Secretary to “promulgate rules and regulations requiring persons subject to the Act to permit inspection of their animals and records at reasonable hours upon request by legally constituted law enforcement agencies in search of lost animals.” (7 U.S.C. 2147). Under the proposed rule, the searches must be conducted in accordance with the conditions and limitations provided in paragraphs (a) and (b) of §2.128. Paragraph (a)(1) would require the law officer to furnish a written description of the missing animal, and the name and address of its owner before making the search. Accordingly, there must be a reasonable basis to believe that the animal is on the premises. We believe that §2.128 does not violate any Constitutional rights. Cooperation to conduct these searches is required because the person holding a missing or stolen animal may not have any intent to do so and may not be aware that the animal has been stolen due to falsified shipping or purchase records. The regulations have required cooperation in searching for missing animals since 1967 without incident or challenge and remains in the revised rule.

Six commenters from the research community stated that the section should be clarified to include local animal regulations enforcement officers, humane association officers, and APHIS inspectors, and to extend the searches to animals undergoing experimentation or research procedures. We are unwilling to make these changes because the Act and the legislative history are clear that humane association and animal control officers are not authorized to conduct searches for missing animals. The officers conducting the searches must have general law enforcement authority, as required by the Act. Furthermore, both the Act and the legislative history underlying it are clear that Congress did not intend for the Department to interfere with the conduct of actual research (See H.R Report No. 1848 (August 11, 1966)). Nor did Congress intend for private persons or groups to use this provision as a means of interfering with research facilities by using it to gain entry.

Concern that APHIS is not authorized to search for missing animals is inappropriate. APHIS inspectors are authorized to inspect animals and animal records in the course of a regular inspection or an inspection to determine if there is a violation of the Act or any of the regulations, including §2.60. The searches identified in §2.128 are limited to those conducted by law enforcement agencies and so there is no need for mention of APHIS inspectors.

Accordingly, proposed §2.128 remains as initially proposed.

Section 2.129 Confiscation and destruction of animals

We received 1 comment from the research community objecting to the reference to the International Union for the Conservation of Nature and Natural Resources (IUCN) in proposed §2.129(c) as inappropriate because the U.S. Department of Interior, Fish and Wildlife Service (FWS) is statutorily authorized to identify and list threatened and endangered species. The commenter also suggested identifying nonhuman primates as an endangered species along with marine mammals. The commenter suggested that the Department should consult with the appropriate government agency having statutory authority regarding importation or use of an endangered species. Once a confiscated animal has been identified as an endangered species, Proposed 2.129(c) would direct the Administrator to consult with certain agencies and the IUCN, when possible, before making any decision regarding destruction of a confiscated animal that is designated an endangered species.

Proposed §2.129(c) concerns internal Agency procedure only and is not directed to any person subject to the Act and the regulations. Accordingly, we are removing it from the revised rule. Before making any decision regarding the destruction of a confiscated animal that is an endangered species, however, the Administrator will, when possible, consult with representatives of FWS, the National Marine Fisheries Service, Department of Commerce, or other appropriate government agencies, and the IUCN.

We did not receive any other comments concerning proposed §2.129. However, we are revising this section to clarify that any animal confiscated under this section, not just certain ones, may be placed with other licensees or registrants which comply with the standards and regulations, and that the costs for this will be borne by the dealer, exhibitor, intermediate handler, carrier, or research facility from whom the animals were confiscated. In order to make this clear, we are breaking proposed §2.129(b) into two portions, now designated as (b) and (c), and are making editorial changes to the proposed requirements. We are also removing the separate reference to operators of auction sales from paragraph (a) because they are dealers.

Section 2.130 Minimum age requirements

We did not receive any comments concerning proposed §2.130. Proposed §2.130 would prohibit any person from delivering a dog or cat to a carrier or intermediate handler for transportation in commerce unless the animal is at least 8 weeks of age and has been weaned. The only exception is for transportation in commerce to a registered research facility. We inadvertently failed to include a prohibition which would prevent any person subject to the Act from transporting a dog or cat in commerce by themselves, that is, without using a carrier or intermediate handler, unless the animal is at least 8 weeks of age and is weaned, except for transport in commerce to a research facility. We have included this prohibition in the revised rule.

Section 2.131 Handling

Sections 3.111 and 3.135 of Part 3—"Standards," Subparts E and F provide handling requirements for marine mammals and warmblooded animals other than dogs, cats, rabbits, hamsters, guinea pigs, and nonhuman primates respectively. Section 3.135 was included as part of Part 3, Subpart F, which was added when Congress amended the Act in 1970 to include all warmblooded animals used for research or exhibition purposes, or sold as pets. Section 3.111 was added in 1979 when standards covering marine mammals were added to Part 3. Subparts A through D do not contain comparable provisions. As stated in the supplementary information accompanying the proposed rule for Part 2, published March 31, 1987, 52 FR 10306, our experience has demonstrated the necessity for handling regulations to protect the welfare of all animals covered by the Act, and to enable the Department to better prosecute cases of inhumane handling and treatment. Accordingly, proposed §2.131 would provide handling regulations applicable to all animals covered by the Act. In this revised rule, §§3.111 and 3.135 are removed from Part 3 and replaced with §2.131.
Proposed § 2.131(a) would require that:

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

(a)(2) Care shall be exercised to avoid harm to the handlers of such animals and to avoid unnecessary harm to the animals.

(a)(3) Physical abuse or deprivation of food or water shall not be used to train, work, or otherwise handle animals.

Two commenters from the research community stated that proposed § 2.131 should be deleted from the final rule. One of the commenters objected that the requirement to protect animals from "unnecessary discomfort, trauma, overheating, excessive cooling, behavioral stress, or physical harm" is vague and that as proposed, a person subject to the Act would not understand their responsibilities under the regulations. Another 108 commenters from the research community objected to use of the term "behavioral stress" in proposed § 2.131(a)(1).

Proposed § 2.131 contains language, including that which the commenters objected to, that is substantially similar to the provisions of current §§ 3.111 and 3.135. Sections 3.111 and 3.135 have proven effective in enforcement efforts. They provide in part as follows:

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

We have not been presented with any legal challenges to this language.

Our experience in enforcing these handling regulations has demonstrated the need for similar regulations for all animals covered by the Act. The Act requires that the Secretary promulgate minimum requirements to govern the humane handling of animals (7 U.S.C. 2143(a)(1)), Section 2.131 therefore remains in the revised rule. It should be noted that in accordance with §§ 2.30(g) and 2.35(b)(3) of the revised rule, exceptions to compliance with this regulation by a research facility in order to accomplish a research design must be explained in detail and justified by the ACUP, and must be approved by the Committee. However, our experience has demonstrated the necessity to maintain this regulation prohibiting physical abuse or deprivation of food or water to train, work, or otherwise handle animals. These have been common methods of training animals in the past, as they are fast and simple and effective. But they can also be cruel and inhumane, and they are often unnecessary as other methods can accomplish the same ends in time. Paragraph (a)(3) therefore remains in the revised rule as proposed, except for one clarifying change. We have added the words "of animals" following "Physical abuse".

Proposed § 2.131 would require as follows:

(b)(1) Animals shall be exhibited only for periods of time and under conditions consistent with their good health and well-being.

(b)(2) A responsible and knowledgeable uniformed employee or attendant must be present at all times during periods of public contact.

(b)(3) At a minimum, when dangerous animals such as lions, tigers, wolves, bears, or elephants are allowed to have contact with the public, the animals must be under the direct control and supervision of a knowledgeable and experienced animal handler.

(c)(1) During public exhibition, any animal must be handled so there is minimal risk of harm to the animal and to the public, with sufficient distance and/or barriers between the animal and the general viewing public so as to assure safety to the animals and to the public.

(c)(2) Performing animals shall be allowed a rest period between performances at least equal to the time for one performance.

(c)(3) Young or immature animals shall not be exposed to rough or excessive handling or exhibited for periods of time which would be detrimental to their health or well-being.

(c)(4) Drugs, such as tranquilizers, shall not be used to facilitate, allow, or provide for public handling of the animals.

One member of the general public commented that the rest period that would be required under proposed paragraph (c)(2) should be extended to 3 times the performance time rather than a period of time equal to the performance time. Current §§ 3.111 and 3.135 require a rest period equal to the performance time. Experience with this requirement has demonstrated that it provides an adequate rest period. We are not aware of any negative behavior by performing animals or problems with the animals as a result of this length rest period. No change is made in proposed paragraph (c)(2) in the revised rule.
One member of the general public commented that dangerous animals should not be allowed contact with the public. The regulations in proposed paragraphs (b) and (c) of § 2.131 do not create a right of exhibitors to allow contact between wild or dangerous animals and the public. Proposed § 2.131(c) would require that in order to publicly exhibit an animal, an exhibitor must handle animals so that there is minimal risk of harm to the public. Proposed § 2.131(b) sets forth the conditions that apply to public exhibition of an animal if, and only if, handling an animal so that there is minimal risk of harm to the public would allow public exhibition. We are reversing the order of proposed paragraphs (b) and (c) in the revised rule in order to make clear that exhibitors do not have a right to allow contact between the public and dangerous animals.

Section 2.132 Procurement of random source dogs and cats, dealers

In order to carry out the intent of Congress and to "protect the owners of animals from the theft of their animals which have been stolen" (7 U.S.C. 2131(b)(3)), we proposed to limit the sources from which class "B" dealers can acquire live random source dogs and cats. We proposed to limit those sources to State, county, or city owned and operated pounds or shelters. Under the proposed regulation, class "B" dealers would not be able to obtain random source dogs and cats from nongovernment pounds or shelters or from individuals who did not breed and raise the dogs and cats on their own premises. Nonrandom source dogs and cats could be obtained from persons who bred and raised the dogs and cats on their own premises. One intended effect of the proposed regulation was to prevent the sale of random source dogs and cats to dealers at flea markets, auctions, and trade-day type sales. Our objective was to prevent the theft of animals for purposes of selling them to dealers who in turn would sell the stolen animals to research facilities.

Another intended effect of the proposed regulation was to eliminate the indiscriminate impoundment of "lost" animals by contract pound operators who are also licensed dealers. In the past several years, we have learned of increasing numbers of complaints and allegations that contract private animal pounds that are also licensed dealers under the Act have been overzealous in impounding dogs and cats. There are allegations that the impounded dogs and cats are not always stray or lost animals. In addition, the Agency has become aware of several instances where licensed dealers obtained stolen dogs and cats, or obtained dogs and cats under false pretenses or misrepresentation.

We proposed in § 2.132, to prohibit dealers from obtaining live random source dogs and cats from private or contract pounds or shelters, or from individuals who did not breed and raise the dogs and cats on their own premises. The proposed regulation would prevent operators of contract or private pounds or shelters from operating as class "B" dealers and selling their animals to research facilities. Our objective again was to prevent pound operators from obtaining dogs and cats from questionable sources, holding them for a short period, and then selling them to research facilities. We also intended to prevent pound operator-dealers from intermingling the animals and selling those dogs and cats that must be held by the pound operator for the requisite holding period pending identification and return to their owner, with those that have completed the requisite holding period and may be sold to research facilities or otherwise disposed of. The proposed regulation would also have the effect of preventing class "B" dealers from obtaining random source dogs and cats from other dealers for resale.

We received 2,665 comments from members of the general public supporting the proposed limitation of sources from which class "B" dealers can obtain random source dogs and cats. We also received 21 comments from members of the research community and 3 comments from dealers expressing support for proposed § 2.132.

We also received 167 comments from members of the research community objecting to the proposed regulation on the grounds that it extaxes our statutory authority, would limit the availability of animals for use by research facilities, and/or would increase the cost of animals to research facilities.

We believe that objections to the proposed regulation stating that it extaxes our statutory authority are incorrect. As expressed above and in the supplementary information to the proposal, preventing the theft of dogs and cats for the purpose of selling them to research facilities was one of the principal concerns prompting enactment of the Animal Welfare Act. To effectuate this purpose, the revised rule provides a number of measures, such as the records required by §§ 2.75 and 2.76 and the prohibition contained in § 2.60 against buying, selling, or using stolen animals, which were designed to prevent the sale of stolen animals and accordingly discourage the practice of stealing animals for sale to research facilities. Section 21 of the Act authorizes the Secretary to "promulgate such rules, regulations, and orders as he may deem necessary in order to effectuate the purposes of [the Act]." (7 U.S.C. 2151). The statutory authority for proposed § 2.132 is clear.

We have considered those comments which stated that preventing the sale of dogs and cats obtained from private or contract pounds or shelters would cut off a legitimate and valuable source of research animals and would drastically increase the cost of available animals. We understand that research facilities need a continuing source of dogs and cats for research. It was not our intent to reduce the available supply of dogs and cats for research purposes, but instead to exert better control over the source of dogs and cats for dealers.

To accommodate the need for a supply of research animals and to ensure that those animals are legally acquired by dealers for sale to research facilities, we are revising § 2.132 as follows: We are removing the prohibition against the purchase and sale of random source dogs and cats by dealers. We will allow dogs and cats from private or contract animal pounds to be obtained and sold by dealers and registrants, but with certain restrictions in order to better ascertain how, where, from whom, and when the dogs and cats were obtained by the pound, and when they were sold to the dealer. Any licensee or registrant who also operates a private or contract pound or shelter must maintain two physically separate and distinct animal facilities, one for the pound or shelter and one for the dealer or registered facility. The dealer or registrant must also maintain separate and accurate records at each facility.

Dealers must comply with the 10-day holding period required in § 2.101, regardless of whether the dog or cat was obtained from a contract pound or shelter operated by the dealer or registrant, or from another contract pound or shelter.

Any licensee or registrant under the Act who also operates a private or contract pound or shelter must maintain records in accordance with §§ 2.75 and 2.76 for live nonrandom source dogs and cats. Because the information required by §§ 2.75 and 2.76 is not available for lost or stray animals, the following information is required to be maintained by the pound or shelter for lost or stray animals.

...
dogs and cats: (1) An accurate description of the dog or cat; (2) how, where, from whom, and when the dog or cat was obtained; (3) how long the dog or cat was held by the pound or shelter before being transferred to the dealer operation; and (4) the date the dog or cat was transferred to the dealer operation. The information must be maintained in separate records, at both the pound or shelter and at the licensed or registered operation.

We believe that these restrictions and recordkeeping requirements will result in reducing the ease and temptation of transferring impounded animals to the dealer operation before any required holding period has been completed at the pound or shelter. They should also make it easier to trace the source of an animal in order to locate a missing dog or cat. We also believe that they will assist the Agency in its efforts to protect the owners of lost or stolen animals. These restrictions and recordkeeping requirements will provide us with adequate controls on the sale and movement of dogs and cats and will allow this resource to continue to be utilized as a source of research animals.

We are also revising § 2.132 to clarify that live nonrandom source dogs and cats may be obtained from hobby breeders, because the animals would have been bred and raised on the individual's premises.

We are including an express prohibition against any person subject to the Act obtaining random source dogs or cats by use of false pretenses, misrepresentation, or deception, as an additional safeguard against dealers using their other status as a pound or shelter to obtain dogs and cats and immediately transferring the animal to the dealer operation for sale to a research facility. This is also intended to prevent them from obtaining animals by claiming they will give it a "good home" and then selling it for research purposes.

We received 1 comment from a member of the research community stating that the regulations should allow dogs and cats held in government operated shelters to be available if they have been held for a 7-day period and there is public notice. This was not addressed in the regulations as the holding period at government pounds and the sale of animals held there is governed by local law. No change is made based upon this comment.

Statutory Authority

This rule is issued pursuant to the Animal Welfare Act (Act), as amended, 7 U.S.C. 2131–2157. Congress recently added significantly to the Secretary’s responsibilities under the Act, particularly with regard to the use of animals by research facilities, in the Food Security Act of 1985, Pub. L. No. 99-198, approved December 23, 1985. The declared policy of the Act is to ensure that animals intended for use in research facilities, as pets, or for exhibition purposes, are provided humane care and treatment; to assure the humane treatment of animals during transportation; and to prevent the sale of stolen animals.

The Act requires that animal dealers and exhibitors obtain a license from the Secretary, and that research facilities, carriers, and intermediate handlers register with the Secretary. The Act directs the Secretary to issue specific regulations concerning, inter alia, recordkeeping, veterinary care, handling, transportation, identification of animals, and holding period requirements. In addition, the 1985 amendments require the Secretary to issue expanded regulations governing the use of animals in research facilities. Section 21 of the Act continues to authorize the Secretary to issue such regulations as he deems necessary to effectuate the purposes of the Act.

The recent amendments mandate that these regulations include standards for care, treatment, and practices in experimental procedures which will minimize pain and distress. The Secretary is to require that researchers consider alternatives to painful procedures and that, with regard to painful procedures, researchers must consult a veterinarian; use adequate tranquilizers, anesthetics, and analgesics; and provide for adequate pre- and post-surgical care. Moreover, exceptions to these standards may be made only when specified by research protocol and explained in a report mandated in the Act.

The Act also mandates that the Secretary issue regulations requiring research facilities to show and report that they are complying with the Act and that they are following professionally acceptable standards in the care and treatment of animals during research. The Act directs the Secretary to require each research facility to establish a committee to assess the facility’s use and treatment of animals. The Act specifies the composition of the committee, including the requirement that each committee must be composed of at least three members and that each committee must have at least one member who is a veterinarian and at least one who represents the community interest in proper animal care. The Act mandates many of the committee’s responsibilities, including that it inspect and report at least semi-annually on the condition and use of animals and report any violations of the standards. The Secretary is also to require each research facility to provide training for all personnel involved in animal care.

This rule contains regulations required by the 1985 amendments as well as modifications to existing regulations based on the Department's experience in administering the Act.

Executive Order 12291

On March 31, 1987, the Department published proposed rules to amend Part 1—"Definition of Terms" and Part 2—"Regulations," of the Animal Welfare Act regulations (52 FR 10292, 10298) in order to implement the 1985 amendments to the Animal Welfare Act, Pub. L. 99-198, the "Food Security Act." The proposed action was reviewed pursuant to Executive Order 12291 and it was determined that it did not constitute a "major rule." We solicited comments with regard to the proposed rules, and have made modifications to those rules as explained in the "Supplementary Information." At this time, we are also publishing a proposal to revise the standards contained in 9 CFR Part 3—"Standards," published elsewhere in this issue of the Federal Register.

In revising Parts 1 and 2, and in preparing the proposed rule for Part 3, we assessed the economic effects of the regulations in accordance with the requirements of Executive Order 12291. We considered alternative approaches to carrying out our statutory mandate, many of which we adopted. A regulatory impact analysis of revised Parts 1 and 2, and the proposal for Part 3 was prepared. Based on that analysis, which included consideration of both quantifiable and nonquantifiable effects of the rules, the Administrator has determined that Parts 1 and 2 would have an impact on the economy in excess of $10 million annually, and would constitute a "major rule."

The following requirements under Parts 1 and 2 represent some of the major costs to the regulated industries: (1) The establishment and responsibilities of the animal care and use committees; (2) aseptic surgical facilities and adequate pre- and post-procedural care; (3) increased responsibilities for attending veterinarians; (4) additional administrative responsibilities; (5) increases in license fees; and (6) identification for dogs and cats less than 16 weeks of age.

The economic impacts of these rules are discussed in more detail in a regulatory impact analysis, which is available for public inspection in Room
Regulated research facilities will be required to spend approximately $142 million to renovate, equip, replace, or construct aseptic surgical facilities, and provide for adequate pre- and post-surgical care. Capital expenditures attributable to Part 3 include costs for renovation, equipment replacement, and new construction of animal housing facility space. Capital expenditures to improve animal housing facilities would result from the new minimum standards for general environmental conditions, space or primary enclosure size requirements, exercise of dogs, and enrichment of nonhuman primate enclosures.

In addition to capital expenditures, total annual operating expenditures estimated at $207 million will also be required. Approximately 60 percent of this total ($123 million) is accounted for by Parts 1 and 2, primarily the requirements for the establishment and operations of the institutional animal care and use committees, additional responsibilities for attending veterinarians, and record-keeping requirements. Annual expenditures attributable to Part 3 would result from the need for additional personnel (animal handlers) to exercise dogs, and the daily maintenance of animal housing facilities.

An important result of this regulatory analysis is that policy decisions must consider other direct and indirect effects associated with the promulgation and enforcement of federal rules. Increased federal legislation causes important economic benefits and costs which are unevenly distributed among registrants and licensees. Direct benefits accrue to society by knowing that animals may be better cared for and treated humanely. The value of these social benefits are subject to personal preferences and concerns. Improvements in the well-being of regulated animals may also provide gains in productivity to the industry. On the other hand, increased costs of compliance will be passed from the regulated industry to consumers who purchase their goods and services. For example, the field of biomedical research and education depends heavily on the use of animals to conduct tests and experiments. Increased costs for animal uses have broader economic and health implications for all of us. Study results do not suggest that these regulations would cause establishments to abandon the use of animals since current biomedical research outlays are in excess of $12.8 billion per year. Nonetheless, there could be important effects associated with allocating additional funds or expenditures to comply with the amended animal welfare regulations.

### Regulatory Flexibility Act

As part of the regulatory impact analysis performed by the Department we have analyzed the potential impact on small entities of Parts 1 and 2, as revised, and the proposal to amend Part 3 of the Animal Welfare regulations, as required by the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). Based upon our analysis, we have determined that Parts 1 and 2 of the regulations would affect all regulated small entities, primarily by increases in annual license fees and identification requirements for dogs and cats. However, these economic impacts would not be significant. It is anticipated that the largest impact on small entities would result from Part 3—"Standards", if it is implemented as proposed. Under these circumstances the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

### Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with state and local officials. (See 7 CFR 3015, Subpart V.)

### Paperwork Reduction Act

In accordance with section 3507 of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), the information collection provisions that are included in this proposed rule will be submitted for approval to the Office of Management and Budget (OMB). Your written comments will be considered if you submit them to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20535. You should submit a duplicate copy of your comments to Helene R. Wright, Chief, Regulatory Analysis and Development Staff, PPD, APHIS, USDA, Room 866, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

### List of Subjects

9 CFR Part 2

Licensing, registration, identification of animals, records, Institutional Animal Care and Use Committees and Adequate Veterinary Care, Miscellaneous.

9 CFR Part 3

Animal welfare, Humane animal handling, Pets, Transportation.

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**Summary of Regulatory Impact Analysis**

<table>
<thead>
<tr>
<th>Costs</th>
<th>Benefits</th>
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<tbody>
<tr>
<td>Direct</td>
<td>Direct</td>
</tr>
<tr>
<td>Regulated industry.</td>
<td>Increased public satisfaction from improved animal welfare*</td>
</tr>
<tr>
<td>Capital expenditure:</td>
<td>Imposed research</td>
</tr>
<tr>
<td>(All parts) $576 million.</td>
<td>Information*</td>
</tr>
<tr>
<td>(Parts 1-2) $142 million.</td>
<td>Productivity gains for regulated industries*</td>
</tr>
<tr>
<td>Annual costs:</td>
<td>Indirect</td>
</tr>
<tr>
<td>(All parts) $207 million.</td>
<td>Market effects for users of biomedical research</td>
</tr>
<tr>
<td>(Parts 1-2) $126 million.</td>
<td>(goods and service), pet industry, and animal exhib-</td>
</tr>
<tr>
<td>APHIS program costs $2 million.</td>
<td>its*</td>
</tr>
<tr>
<td>Impact on Federal sites*</td>
<td>Increased Federal financial support for biomedical community*</td>
</tr>
<tr>
<td>Indirect</td>
<td>Non-market effects*</td>
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</tbody>
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* Not quantified.

Compliance with more stringent federal regulations on the humane care and treatment of animals used for research, testing, teaching, exhibition, and business ventures would result in major direct and indirect effects imposed on the regulated industries and the general economy. An examination of the estimated cost impacts indicates that the amended regulations constitute a "major rule" based on annual effects in excess of $100 million on the economy and large cost increases on regulated industries for animal uses and maintenance, in particular to the biomedical research community. However, this study could not properly assess the relative significance of these cost increases on the regulated industry or the presence of adverse effects on competition innovation, and the ability of domestic enterprises to compete with foreign enterprises in international markets.

Regulated persons or establishments will be required to spend approximately $876 million in capital expenditures over the next two or three years. Of this amount approximately 18 percent is attributable to Parts 1 and 2. If Parts 1 and 2 were enforced separately, regulated research facilities will be
Accordingly, we are proposing to amend 9 CFR Part 2 as follows:

1. Part 2 is revised to read as follows:

PART 2—REGULATIONS

Subpart A—Licensing

Sec.
2.1 Requirements and application.
2.2 Acknowledgment of regulations and standards.
2.3 Demonstration of compliance with regulations and standards.
2.4 Non-interference withAPHIS officials.
2.5 Duration of license and termination of license.
2.6 Annual license fees.
2.7 Annual report by licensees.
2.8 Notification of change of name, address, control, or ownership of business.
2.9 Officers, agents, and employees of licensees whose licenses have been suspended or revoked.
2.10 Licensees whose licenses have been suspended or revoked.
2.11 Denial of initial license application.

Subpart B—Registration

2.25 Records and procedures.
2.26 Acknowledgment of regulations and standards.
2.27 Notification of change of operation.

Subpart C—Institutional Animal Care and Use Committee and Other Requirements for Research Facilities

2.30 Additional requirements for research facilities.
2.31 Annual report of research facilities.
2.32 Institutional Animal Care and Use Committee.

Subpart D—Attending Veterinarian and Adequate Veterinary Care

2.40 Attending veterinarian and veterinary care.

Subpart E—Identification of Animals

2.50 Time and method of identification.
2.51 Form of official tag.
2.52 How to obtain tags.
2.53 Use of tags.
2.54 Lost tags.
2.55 Removal and disposal of tags.

Subpart F—Stolen Animals

2.60 Prohibition on the purchase, sale, or transportation of stolen animals.

Subpart G—Records

2.75 Records: Dealers and exhibitors.
2.76 Records: Research facilities.
2.77 Records: Operators of auction sales.
2.78 Records: Carriers and intermediate handlers.
2.79 Health certification and identification.
2.80 C.O.D. shipments.
2.81 Records, disposition.

Subpart H—Compliance with Standards and Holding Period

2.100 Compliance with standards.
2.101 Holding period.
2.102 Holding facility.

Subpart I—Miscellaneous

2.125 Information as to business: furnishing of by dealers, exhibitors, operators of auction sales, research facilities, intermediate handlers, and carriers.
2.126 Access and inspection of records and property.
2.127 Publication of names of persons subject to the provisions of this part.
2.128 Inspection for missing animals.
2.129 Confiscation and destruction of animals.
2.130 Minimum age requirements.
2.131 Handling of animals.
2.132 Procurement of random source dogs and cats, dealers.

Authority: 7 U.S.C. 2133, 2135, 2136, 2140, 2144, 2146, 2147, 2151; 7 CFR 2.17, 2.51, and 371.2(d).

Subpart A—Licensing

§ 2.1 Requirements and application.

(a)(1) Any person operating or desiring to operate as a dealer, exhibitor, or operator of an auction sale, except persons who are exempt from the licensing requirements under paragraph (f)(2) of this section, must have a valid license. A person must be 16 years of age or older to obtain a license. A person seeking a license shall apply on a form which will be furnished by the Area Veterinarian in Charge in the State in which that person operates or intends to operate. The applicant shall provide the information requested on the application form, including a valid mailing address through which the licensee or applicant can be reached at all times, and a valid premises address where animals, animal facilities, equipment, and records may be inspected for compliance. The applicant shall file the completed application form with the Area Veterinarian in Charge.

(2) If an applicant for a license or license renewal operates in more than one State, he or she shall apply in the State in which he or she has his or her principal place of business. All premises, facilities, or sites where such person operates or keeps animals shall be indicated on the application form or on a separate sheet attached to it. The completed application form, along with the application fee indicated in paragraph (d) of this section, and the annual license fee indicated in table 1 or 2 of § 2.6 shall be filed with the Area Veterinarian in Charge.

Subpart D—Attending Veterinarian and Adequate Veterinary Care

2.40 Attending veterinarian and veterinary care.

Subpart E—Identification of Animals

2.50 Time and method of identification.
2.51 Form of official tag.
2.52 How to obtain tags.
2.53 Use of tags.
2.54 Lost tags.
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2.60 Prohibition on the purchase, sale, or transportation of stolen animals.

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2.132 Procurement of random source dogs and cats, dealers.

Authority: 7 U.S.C. 2133, 2135, 2136, 2140, 2144, 2146, 2147, 2151; 7 CFR 2.17, 2.51, and 371.2(d).
Dogs and Cats set forth in Part 3 and shall agree in writing on a form furnished by APHIS to comply with all the requirements of the Act and this subchapter. Voluntary licenses will not be issued to any other persons. To obtain a voluntary license the applicant shall submit to the Area Veterinarian in Charge the application fee of $10 plus an annual license fee. The class of license issued and the fee for a voluntary license shall be that of a Class "A" licensee (breeder). Voluntary licenses will not be issued to any other persons or for any other class of license.

(c) No person shall have more than one license.

(d) A license will be issued to any applicant, except as provided in §§ 2.10 and 2.11, when the applicant:
   (1) Has met the requirements of this section and of § 2.2 and 2.3, and
   (2) Has paid the application fee of $10 and the annual license fee indicated in § 2.8 to the Area Veterinarian in Charge and the payment has cleared normal banking procedures.

(e) On or before the expiration date of a license, a licensee who wishes a renewal shall submit to the Area Veterinarian in Charge a completed application form and the application fee of $10, plus the annual license fee indicated in § 2.8 by certified check, cashier's check, personal check, or money order. A voluntary licensee who wishes a renewal shall also submit the $10 application fee plus an annual license fee. An applicant whose check is returned by the bank will be charged a fee of $15 for each returned check. One returned check will be deemed nonpayment of fees and will result in denial of license. Payment of fees must then be made by certified check, cashier's check, or money order. An applicant delayed until his or her payment has cleared normal banking procedures.

(2) The $10 application fee must also be paid if an applicant is applying for a changed class of license. The applicant may pay such fees by certified check, cashier's check, personal check, or money order. An applicant whose check is returned by a bank will be charged a fee of $15 for each returned check and will be required to pay all subsequent fees by certified check, money order, or cashier's check. A license will not be issued until payment has cleared normal banking procedures.

(f) The failure of any person to comply with any provision of the Act, or any of the provisions of the regulations or standards in this subchapter, shall constitute grounds for denial of a license, or for its suspension or revocation by the Secretary, as provided in the Animal Welfare Act.

§ 2.2 Acknowledgment of regulations and standards.

APHIS will supply a copy of the applicable regulations and standards to the applicant with each request for a license application or renewal. The applicant shall acknowledge receipt of the regulations and standards and agree to comply with them by signing the application form before a license will be issued or renewed.

§ 2.3 Demonstration of compliance with regulations and standards.

(a) Each applicant must demonstrate that his or her premises and any animals, facilities, vehicles, equipment, or other premises used or intended for use in the business comply with the regulations and standards set forth in Parts 2 and 3 of this subchapter. Each applicant for an initial license or license renewal must make his or her animals, premises, facilities, vehicles, equipment, other premises, and records available for inspection during business hours and at other times mutually agreeable to the applicant and APHIS, to ascertain the applicant's compliance with the regulations and standards.

(b) In the case of an application for an initial license, the applicant must demonstrate compliance with the regulations and standards, as required in paragraph (a) of this section, before APHIS will issue a license. If the applicant's animals, premises, facilities, vehicles, equipment, other premises, or records do not meet the requirements of this subchapter, APHIS will advise the applicant of existing deficiencies and the corrective measures that must be completed to come into compliance with the regulations and standards. The applicant will have two more chances to demonstrate his or her compliance with the regulations and standards through re-inspection by APHIS. If the applicant fails the third inspection he or she will forfeit the application fee and cannot reapply for a license for a period of 6 months following the third inspection. Issuance of the license will be denied until the applicant demonstrates upon inspection that the animals, premises, facilities, vehicles, equipment, other premises and records are in compliance with all regulations and standards in this Subchapter.

§ 2.4 Non-Interference with APHIS officials.

A licensee or applicant for an initial license shall not interfere with, threaten, abuse (including verbal abuse), or harass any APHIS official in the course of carrying out his or her duties.

§ 2.5 Duration of license and termination of license.

(a) A license issued under this part shall be valid and effective unless:
   1) The license has been revoked or suspended pursuant to section 19 of the Act.
   2) The license is voluntarily terminated upon request of the licensee, in writing, to the Veterinarian in Charge.
   3) The license has expired or been terminated under this part.

(b) The applicant has failed to pay the application fee and the annual license fee as required in §§ 2.10 and 2.11. There will be no refund of fees if a license is terminated prior to its expiration date.

(c) Any person who is licensed must file an application for a license renewal and an annual report form (VS Form 18-3) as required by § 2.7, and pay the required fees, on or before the expiration date of the present license or the license shall expire and automatically terminate on its anniversary date. The licensee will be notified by certified mail at least 60 days prior to the expiration date of the license. Failure to comply with the annual reporting requirements, or to pay the required license fees prior to the expiration date of the license, shall result in automatic termination of such license on the anniversary date of the license.

(d) Licensees must accept delivery of registered mail or certified mail notice and provide the Area Veterinarian in Charge notice of their address in conformity with the requirements in § 2.1.

(e) Any person who seeks the reinstatement of a license that has been automatically terminated must follow the procedure applicable to licensees set forth in § 2.1.

(f) Licenses are issued to persons for specific premises and do not transfer upon change of ownership, nor are they valid at a different location.

(g) A license which is invalid under this part shall be surrendered to the Area Veterinarian in Charge. If the license cannot be found, the licensee shall provide a written statement so stating to the Area Veterinarian in Charge.

§ 2.6 Annual license fees.

(a) In addition to the application fee of $10 required to be paid upon the application for a license, license renewal, or changed class of license under § 2.1, each licensee shall submit to the Area Veterinarian in Charge the
annual license fee prescribed in this section. Paragraph (b), of this section indicates the method used to calculate the appropriate fee. The amount of the fee is determined from Table 1 or 2 of this section.

(b)(1) Class “A” license. The annual license renewal fee for a Class “A” dealer shall be based on 50 percent of the total gross amount, expressed in dollars, derived from the sale of animals to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, directly or through an auction sale, by the dealer or applicant during his or her preceding business year (calendar or fiscal) in the case of a person who operated during such a year. If animals are leased, the lessor shall pay a fee based on 50 percent of any compensation received from the leased animals and the lessee shall pay a fee based upon the net compensation received from the leased animals, as indicated for dealers in Table 1 of this section.

(2) Class “B” license. The annual license renewal fee for a Class “B” dealer shall be established by calculating the total amount received from the sale of animals to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, directly or through an auction sale, during the preceding business year (calendar or fiscal) less the amount paid for the animals by the lessee. This net difference, exclusive of other costs, shall be the figure used to determine the license fee of a Class “B” dealer. If animals are leased, the lessor and lessee shall each pay a fee based on the net compensation received from the leased animals calculated from Table 1 of this section.

(3) The annual license renewal fee for a broker or operator of an auction sale shall be that of a class “B” dealer and shall be based on the total gross amount, expressed in dollars, derived from commissions or fees charged for the sale of animals, or for negotiating the sale of animals, by brokers or by the operator of an auction sale, to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, during the preceding business year (calendar or fiscal).

(4) In the case of a new applicant for a license as a dealer, broker or operator of an auction sale who did not operate during a preceding business year, the annual license fee will be based on the anticipated yearly dollar amount of business, as provided in paragraphs (b)(1), (2), and (3) of this section, derived from the sale of animals to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, directly or through an auction sale.

(5) The amount of the annual fee to be paid upon application for a Class “C” license as an exhibitor under this section shall be based on the number of animals which the exhibitor owned, held, or exhibited at the time the application is signed and dated or during the previous year, whichever is greater, and will be the amount listed in Table 2. Animals which are leased shall be included in the number of animals being held by both the lessor and the lessee when calculating the annual fee. An exhibitor shall pay his or her annual license fee on or before the expiration date of the license and the fee shall be based on the number of animals which the exhibitor is holding or has held during the year (both owned and leased).

(c) The license fee shall be computed in accordance with the following tables:

### Table 1.—Dealers, Brokers, and Operators of an Auction Sale—Class “A” and “B” License

<table>
<thead>
<tr>
<th>Fee</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>$ 0</td>
<td>$ 500</td>
<td>$ 30</td>
</tr>
<tr>
<td>250</td>
<td>500</td>
<td>60</td>
</tr>
<tr>
<td>2,000</td>
<td></td>
<td>120</td>
</tr>
<tr>
<td>10,000</td>
<td>25,000</td>
<td>225</td>
</tr>
<tr>
<td>25,000</td>
<td>50,000</td>
<td>350</td>
</tr>
<tr>
<td>50,000</td>
<td>100,000</td>
<td>475</td>
</tr>
</tbody>
</table>

### Table 2.—Exhibitors—Class “C” License

<table>
<thead>
<tr>
<th>Number of Animals</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 5</td>
<td>$ 30</td>
</tr>
<tr>
<td>6 to 29</td>
<td>75</td>
</tr>
<tr>
<td>30 to 59</td>
<td>175</td>
</tr>
<tr>
<td>51 to 500</td>
<td>225</td>
</tr>
<tr>
<td>501 and up</td>
<td>300</td>
</tr>
</tbody>
</table>

(d) If a person meets the licensing requirements for more than one class of license, he shall be required to obtain a license and pay the fee for the type business which is predominant for his operation, as determined by the Secretary.

(e) In any situation in which a licensee shall have demonstrated in writing to the satisfaction of the Secretary that he or she has good reason to believe that the dollar amount of his or her business for the forthcoming business year will be less than the previous business year, then his or her estimated dollar amount of business shall be used for computing the license fee for the forthcoming business year: Provided, however: That if the dollar amount upon which the license fee is based for that year does in fact exceed the amount estimated, the difference in amount of the fee paid and that which was due under paragraphs (b) and (c) of this section based upon the actual dollar business upon which the license fee is based, shall be payable in addition to the required annual license fee for the next subsequent year, on the anniversary date of his or her license as prescribed in this section.

§ 2.7 Annual report by licensees.

(a) Each year, within 30 days prior to the expiration date of his or her license, a licensee shall file with the Area Veterinarian in Charge an application for license renewal and annual report upon a form which the Area Veterinarian in Charge will furnish to him or her upon request.

(b) A person licensed as a dealer shall set forth in his or her license renewal application and annual report the dollar amount of business, upon which the license fee is based, from the sale of animals, directly or through an auction sale, to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, by the licensee during the preceding business year (calendar or fiscal), and any other information as may be required thereon.

(c) A licensed dealer who operates as a broker or an operator of an auction sale shall set forth in his or her license renewal application and annual report the total gross amount, expressed in dollars, derived from commissions or fees charged for the sale of animals by the licensee to research facilities, dealers, exhibitors, retail pet stores, and persons for use as pets, during the preceding business year (calendar or fiscal), and any other information as may be required thereon.

(d) A person licensed as an exhibitor shall set forth in his or her license renewal application and annual report the number of animals owned, held, or exhibited by him or her, including those which are leased, during the previous year or at the time he signs and dates the report, whichever is greater.

§ 2.8 Notification of change of name, address, control, or ownership of business.

A license shall promptly notify the Area Veterinarian in Charge by certified mail of any change in the name, address, management, or substantial control or ownership of his business or operation, or of any additional sites, within 10 days of any change.
§ 2.9 Officers, agents, and employees of licensees whose licenses have been suspended or revoked.

Any person who has been or is an officer, agent, or employee of a licensee whose license has been suspended or revoked and who was responsible for or participated in the violation upon which the order of suspension or revocation was based will not be licensed within the period during which the order of suspension or revocation is in effect.

§ 2.10 Licensees whose licenses have been suspended or revoked.

(a) Any person whose license has been suspended for any reason shall not be licensed in his or her own name or in any other manner within the period during which the order of suspension is in effect. No partnership, firm, corporation, or other legal entity in which any such person has a substantial interest, financial or otherwise, will be licensed during that period. Any person whose license has been suspended for any reason may apply to the Area Veterinarian in Charge, in writing, for reinstatement of his or her license.

(b) Any person whose license has been revoked shall not be licensed in his or her own name or in any other manner nor will any partnership, firm, corporation, or other legal entity in which any such person has a substantial interest, financial or otherwise, be licensed.

(c) Any person whose license has been suspended or revoked shall not buy, sell, transport, exhibit, or deliver for transportation, any animal during the period of suspension or revocation.

§ 2.11 Denial of initial license application.

(a) A license will not be issued to any applicant who:

(1) Has not complied with the requirements of §§ 2.1, 2.2, 2.3, and 2.4 and has not paid the fees indicated in § 2.5;

(2) Is not in compliance with any of the regulations or standards in this subchapter;

(3) Has a license revoked or whose license is suspended, as set forth in § 2.10;

(4) Has been fined, sentenced to jail, or pled no contest (no contest) under State or local cruelty to animal laws within 1 year of application, except that if no penalty is imposed as a result of the plea of no contest the applicant may reapply immediately; or

(5) Has made any false or fraudulent statements, or provided any false or fraudulent records to the Department.

(b) An applicant whose license application has been denied may request a hearing in accordance with the applicable rules of practice for the purpose of showing why the application for license should not be denied. The license denial shall remain in effect until the final legal decision has been rendered. Should the license denial be upheld, the applicant may again apply for a license 1 year from the date of the final order denying the application.

(c) No partnership, firm, corporation, or other legal entity in which a person whose license application has been denied has a substantial interest, financial or otherwise, will be licensed within 1 year of the license denial.

Subpart B—Registration

§ 2.25 Requirements and procedures.

(a) Each research facility other than a federal research facility, carrier, and intermediate handler, and each exhibitor not required to be licensed under section 3 of the Act and the regulations of this subchapter, shall register with the Secretary by completing and filing a properly executed form which will be furnished, upon request, by the Area Veterinarian in Charge. The registration form shall be filed with the Area Veterinarian in Charge for the State in which the registrant has his or her principal place of business, and shall be updated every 3 years by the completion and filing of a new registration form which will be provided by the Area Veterinarian in Charge. Where a school or department of a university or college uses or intends to use animals for research, tests, experiments, or teaching, the university or college rather than the school or department will be considered the research facility and will be required to register with the Secretary. An official who has the legal authority to bind the parent organization shall sign the registration form.

(b) In any situation in which a school or department of a university or college demonstrates to the Secretary that it is a separate legal entity and its operations and administration are independent of those of the university or college, the school or department will be registered rather than the university or college.

(c) A subsidiary of a business corporation, rather than the parent corporation, will be registered as a research facility or exhibitor unless the subsidiary is under such direct control of the parent corporation that the Secretary determines that it is necessary that the parent corporation be registered to effectuate the purposes of the Act.

§ 2.26 Acknowledgment of regulations and standards.

APHIS will supply a copy of the regulations and standards in this subchapter with each registration form. The registrant shall acknowledge receipt of and shall agree to comply with the regulations and standards by signing a form provided for this purpose by APHIS and by filing it with the Area Veterinarian in Charge.

§ 2.27 Notification of change of operation.

(a) A registrant shall notify the Area Veterinarian in Charge by certified mail of any change in the name, address, or ownership, or other change in operations affecting its status as a research facility, exhibitor, carrier, or intermediate handler, within 10 days after making such change.

(b) [1] A registrant which has not used, handled, or transported animals for a period of at least 2 years may be placed in an inactive status by making a written request to the Area Veterinarian in Charge. A registrant shall file an annual report of its status (active or inactive). A registrant shall notify the Area Veterinarian in Charge in writing at least 10 days before using, handling, or transporting animals again after being in an inactive status.

(2) A registrant which goes out of business or which ceases to function as a research facility, carrier, intermediate handler, or exhibitor, or which changes its method of operation so that it no longer uses, handles, or transports animals, and which does not plan to use, handle, or transport animals again at any time in the future, may have its registration cancelled by making a written request to the Area Veterinarian in charge. The former registrant is responsible for reregistering and demonstrating its compliance with the Act and regulations should it start using, handling, or transporting animals at any time after its registration is canceled.

Subpart C—Institutional Animal Care and Use Committee and Other Requirements for Research Facilities

§ 2.30 Additional requirements for research facilities.

(a) Each research facility using or holding animals for research, experimentation, testing, or teaching shall ensure:

(1) That animal pain and distress are minimized;

(2) That adequate veterinary care including the appropriate use of anesthetics, analgesics, tranquilizing drugs, or euthanasia, is provided at all times;
(3) That a written program of adequate veterinary care is established and maintained in accordance with §2.40; and

(4) That animals are housed and cared for according to this subchapter and that any deviations are fully explained by the principal investigator and are approved by the Institutional Animal Care and Use Committee.

(b) Each research facility shall establish and maintain an Institutional Animal Care and Use Committee (Committee).

(c) Each research facility shall provide the Committee with the authority to enter all animal areas at any reasonable time and shall provide the attending veterinarian with the authority to enter all animal areas at any time, in order to carry out their responsibilities.

(d) Each research facility must require that the animal care and use procedure (ACUP) for any procedures and practices involving live warmblooded animals be approved by the Committee, prior to the start of research, testing, or teaching involving an animal; that the principal investigator consider alternatives to any procedure likely to produce pain or distress in an experimental animal; and that the principal investigator document such considerations in a written statement to the Committee as required by §2.30(e).

(e) Each research facility that engages in any practice or procedure using an animal that might reasonably be expected to be a painful procedure must:

(1) Prior to the beginning of such practice or procedure, require that the principal investigator for each such practice or procedure provide written assurance to the Committee that:
   (i) Alternatives by procedures have been considered and that no other procedures are suitable; and
   (ii) The experiment does not unnecessarily duplicate previous experiments. The assurance must indicate what information sources were consulted, what other procedures were considered, and what techniques will be used to minimize pain and discomfort to the animals;
   (2) Require that the principal investigator consult with the attending veterinarian during ACUP planning and development and during actual research, and ensure that the attending veterinarian is allowed access to all animal and research areas at any time during actual research:
      (i) If deemed necessary by the Committee;
      (ii) If requested by the investigator;
      (iii) If in response to complaints regarding the research or procedures; or
      (iv) If the attending veterinarian is observing the research for compliance with an approved ACUP, the facility's program of adequate veterinary care, or the facility's written policy established in accordance with this section;
   (3) Require that pain relieving drugs, anesthetics, analgesics, and tranquilizers are used to minimize pain unless they are withheld in accordance with the provisions of paragraph (4), and that they are administered in accordance with the directions and recommendations of the attending veterinarian and in accordance with the accepted or established use of the drugs;
   (4) Require that pain relieving drugs, anesthetics, analgesics, and tranquilizers be reduced in amount or withheld only if scientifically necessary, and fully explained and justified in the ACUP and approved by the attending veterinarian and the Committee.
   The research facility must require that these drugs be reduced in amount or withheld only for as long as necessary as specified in the ACUP and approved by the Committee;
   (5) That the attending veterinarian provide training of laboratory personnel in the proper use of pain relieving drugs, anesthetics, analgesics, and tranquilizers so as to minimize pain and distress;
   (6) That all pre-procedural, procedural, and post-procedural care be provided by laboratory workers or surgical personnel in accordance with the instructions of the attending veterinarian and established veterinary medical and nursing procedures, and that this care and the qualifications of the personnel be evaluated and approved by the attending veterinarian;
   (7) That all survival surgeries be conducted only in facilities intended for that purpose, that the facilities be operated and maintained under aseptic conditions, and that surgical rooms be evaluated and approved by the attending veterinarian;
   (8) That any surgery be performed or directly supervised by trained, experienced personnel;
   (9) Prohibit the use of paralytic drugs without anesthesia; and
   (10) Establish a written policy to ensure compliance with paragraphs (e)(1) through (9) of this section.

(f)(1) Each research facility using or holding animals for research, testing or teaching shall establish and follow written procedures which assure that no animal is used in more than one major operative experiment from which it is allowed to recover except:

   (i) When scientifically necessary and approved by the Committee;
   (ii) When required by or related to other surgical procedures and approved by the Committee;
   (iii) When required to reduce or conserve the number of marine mammals or endangered species of animals used and approved by the Committee;
   (iv) When required to protect the health and well-being of the animal as determined by the attending veterinarian;
   (v) When the procedure is a routine, elective veterinary surgical, or diagnostic procedure; or
   (vi) In other special circumstances as determined by the Secretary on an individual basis. Written requests and supporting data should be sent to the Administrator, APHIS, USDA, 6505 Belcrest Road, Federal Building, Room 756, Hyattsville, MD 20782.

(2) Cost savings alone is not adequate reason for performing multiple survival surgical procedures.

(g) Exceptions. Exceptions to compliance with the standards and regulations set forth under Title 9 CFR, Chapter 1, Subchapter A—Animal Welfare, may be made by the research facility only when necessary in order to accomplish the research design, and when specified in the ACUP, explained in detail, and approved by the Committee. The principal investigator must file a report with the Committee prior to ACUP review explaining the areas of noncompliance in detail. A copy of the report must be kept on file by the facility and must be available for inspection by APHIS inspectors or officials of granting agencies. A copy of all written reports detailing and explaining exceptions to compliance with the standards and regulations must be attached to the facility's annual report.

(h) Exercise for dogs and psychological well-being of primates. The research facility shall establish, in consultation with the attending veterinarian, written procedures and systems for the exercise of dogs and for the psychological well-being of primates in accordance with the regulations and standards, and a record system documenting that such a procedure or system is being carried out.

(i) Training. (1) Each research facility shall provide for the training and continuing education of scientists, research technicians, animal technicians, and other personnel involved with animal use, care, and treatment at the facility.

   (2) This training shall be reviewed by the Committee and the attending veterinarian, shall be appropriate to the
individuals and their responsibilities, and shall be made available annually or as appropriate to the individuals and their responsibilities.

(3) The research facility shall review the status of the training and qualifications of researchers to use animals at least once a year, and shall review the list of research personnel and shall designate those who require additional training. The review may be part of another review of personnel as long as the research facility has a written policy ensuring that all personnel are reviewed annually in these areas.

(4) This training shall be available for review by Department inspectors. Training shall include instruction in at least the following areas:

(i) Humane methods of animal maintenance and experimentation;
(ii) Research or testing methods that minimize or eliminate the use of animals or limit animal pain or distress;
(iii) Utilization of the information service at the National Agricultural Library;
(iv) Methods whereby deficiencies in animal care and treatment should be reported;
(v) The basic needs of each species of animal;
(vi) Familiarization with the intent and requirements of the Animal Welfare Act;
(vii) How to handle and care properly for the various species of animals used by the facility;
(viii) Proper pre-procedural and post-procedural care of animals;
(ix) Proper use of anesthetics, analgesics, and tranquilizers in the species of animals used by the facility, including the common or accepted use of these drugs in those species for which the drug is not licensed;
(x) Acceptable aseptic surgical methods and procedures;
(xi) Other training, techniques, or procedures the research facility or the Secretary, may feel is necessary.

(j) Procedures for personnel to report violations. The research facility shall establish a reporting procedure whereby laboratory or research facility personnel or employees can report violations of any regulation or standard established under the Act including problems, deviations, or deficiencies with animal housing, care, or use. The Committee shall review and, if warranted, investigate any such reports, in addition to the twice yearly inspections, and shall prepare and file a report at the central location specified in §2.30(m), indicating the nature of the problem or complaint, the Committee's findings, and any corrective actions taken. 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 standard under the Act.

(k) 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 this section and by §2.35 with the following exceptions:

(1) The Committee shall report deficiencies to the head of the federal agency conducting the research rather than to APHIS;
(2) 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.

(1) Reviews. Upon the request of the Administrator, the research facility shall make available for review all ACUPS involving animals and all assurance statements required by the U.S. Public Health Service (PHS) or any other funding Federal agency. 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, or unless they are needed to investigate a possible violation or for other enforcement purposes.

(m) Reports. Any reports required by this part shall remain on file at a central location maintained by the research facility for at least 3 years and shall be available for inspection and review by APHIS officials and inspectors and any funding Federal agency. Upon notification from the Administrator, research facilities must retain specified records for more than 3 years pending completion of an investigation or proceeding under the Act, as required by §2.81.

§2.31 Annual report of research facilities.

(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 Area Veterinarian in Charge 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 a responsible institutional official with authority to bind the facility, and shall cover the previous federal fiscal year.

(b) Such 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, during pre- and post-procedural care, and during actual research, teaching, testing, surgery, or experimentation were followed by the research facility;
(2) Assure that the principal investigator has considered alternatives to painful procedures;
(3) Assure that the facility is adhering to the standards and regulations under the Animal Welfare Act, and that it has required that exceptions to the standards and regulations be specified and explained by the ACUP and approved by the Committee. An explanation for any deviation from the standards and regulations shall be attached to the report;
(4) State the location of the facility or 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 adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. A detailed statement on the procedures producing pain or distress in these animals and explaining 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; and
(9) Include a statement by the CEO or responsible institutional official with
authority to bind the facility that the Institutional Animal Care and Use Committee has authority to enter any animal or research area at any reasonable time, and that the attending veterinarian has authority to enter any animal or research area at any time, in order to carry out their responsibilities as set forth under §§ 2.35 and 2.40 and that the Committee has satisfactorily carried out its responsibilities; and that the facility complies with the Act, regulations, and standards.

(c) The CEO or responsible institutional official with authority to bind the facility shall certify on the annual report that the annual report was circulated to each member of the Committee and that each member of the Committee was given the opportunity to express concurrence or nonconcurrence with the report, and to attach a minority report to the annual report. The certification must indicate whether any member of the Committee indicated nonconcurrence. All minority reports provided to the CEO or responsible institutional official under this paragraph must be attached to the annual report. Each member's concurrence or nonconcurrence will be held confidential by the CEO and responsible institutional official.

§ 2.35 Institutional Animal Care and Use Committee.

(a) Membership.

(1) Each research facility shall establish and maintain an Institutional Animal Care and Use Committee (Committee);

(2) The members of each Committee shall be appointed by the Chief Executive Officer of the research facility;

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

(4) Committee members shall possess sufficient ability to assess animal care, treatment, and practices in experimental research as determined by the needs of the research facility;

(5) Of the members of the Committee:

(i) At least one shall be a Doctor of Veterinary Medicine who is the attending veterinarian for the research facility. The Committee-related duties of the attending veterinarian may be delegated to a staff veterinarian in accordance with the written policy and procedures of 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;

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

(7) The research facility shall maintain an up-to-date list of Committee members and shall indicate for each member his or her name, degrees, position, and qualifications. The business address and telephone number of the Chairman must also be included on the list. A copy of the current list of Committee members shall be maintained by the attending veterinarian for the facility and shall be made available for inspection by APHIS officials.

(b) Duties and Responsibilities.

(1) Inspections. (i) The Committee or a subcommittee composed of at least 2 Committee members shall inspect at least twice a year, 6 months apart, all animal study areas and animal facilities of the research facility and shall review as part of the inspection:

(A) All practices and procedures involving pain to animals; and

(B) The condition of all animals, in order to ensure compliance with the provisions of the Act to minimize pain and distress to the animals.

(ii) The Committee or subcommittee shall use Title 9, Chapter 1, Subchapter A—Animal Welfare, as a basis of its inspection of animal areas and facilities.

(iii) Exceptions to the requirement of inspection of animal study areas may be made by the Secretary if the animals are studied in their natural environment and the study area prohibits easy access.

Requests for such exemption shall be addressed to the Administrator, APHIS, USDA, Room 758, 8505 Belcrest Road, Hyattsville, MD 20792, and shall clearly set forth the reasons why such inspections cannot be made.

(iv) The Committee may suspend or withdraw its approval of ACUPs for research, testing, or teaching involving pain to animals that it previously approved if it determines upon inspection that the practice or procedure is not being conducted in accordance with the previously approved ACUP or in accordance with the Animal Welfare Act, regulations, or standards. The Committee must direct the CEO or responsible institutional official to instruct the principal investigator to cease noncomplying activities immediately.

(v) The Committee may suspend or withdraw its approval of ACUPs for research, testing, or teaching involving pain to animals that it previously approved if it determines upon inspection that the practice or procedure is not being conducted in accordance with the previously approved ACUP or in accordance with the Animal Welfare Act, regulations, or standards. The Committee must direct the CEO or responsible institutional official to instruct the principal investigator to cease noncomplying activities immediately.

(vi) If the research facility maintains multiple animal sites, the Committee must complete its inspection of all animal study areas or animal facilities within 30 days of commencing the first inspection.

(2) Reports. (i) Committee inspection certification report. After each inspection performed by a subcommittee, the subcommittee must present its findings to a quorum of the Committee for approval and formal action. After each inspection is completed, or upon the approval of the presentation of findings if the inspection is performed by a subcommittee, the Committee must file an inspection certification report at a central location at the research facility established in accordance with § 2.35(m). The Committee must file its inspection certification report within 10 business days of completing its inspection of all animal study areas or animal facilities. The reports shall be available to APHIS officials and to officials of funding Federal agencies for inspection and copying. Inspection certification reports shall contain at least the following:

(A) The date the inspection was made;

(B) The signature of a majority of the Committee members and any minority views of the Committee;

(C) Reports of:

(1) Any violations of the regulations, standards, or assurances required by the Secretary, including any deficient conditions of animal care or treatment and any findings and recommendations of the Committee;

(2) Any deviations of research practices from originally approved ACUPs that adversely affect animal welfare;

(3) Any notification to the facility regarding such conditions, deviations, or deficiencies;

(4) Any corrections made by the facility; and

(5) Any other information pertinent to the activities of the Committee and the status or condition of the animal facilities; and

(D) An assurance statement by the Committee that its members have reviewed all painful procedures using animals and that the procedures:

(1) Are in accordance with the ACUPs approved by the Committee; or

(2) Are in accordance with any changes or special procedures approved by the Committee; or

(3) Are not in accordance with the approved ACUPs and that the Committee has notified the CEO or institutional official responsible for animal care to instruct the investigator(s) to cease such methods and procedures immediately and to comply with the ACUPs approved by
the Committee under paragraph (b)(3) of this section.

(ii) Deficiency notification reports.

(A) The Committee shall notify the CEO or institutional official responsible for animal care and the administrative unit representative, in writing, of any deficiencies in compliance with the Act, regulations, or standards found during an inspection, and of any noncompliance with an approved ACUP involving a painful procedure, within 1 business day of discovery of the deficiency. The Committee shall file a copy of the deficiency notification in the central location established at the research facility in accordance with § 423.3(m).

(B) The Committee shall provide the CEO or other institutional official responsible for animal care and the administrative unit representative with a copy of the report required under paragraph (b)(3)(i) of this section.

(C) If 30 days after notification of the deficiency any deficiency remains uncorrected, the Committee shall notify the Administrator and any funding Federal agency of the deficiency, in writing, within 5 business days of the expiration of the 30-day correction period. The Committee shall also provide a copy of its report and its notification of the deficiency to the Administrator and to any funding Federal agency.

(3) Reviews.

(i) No research, testing, or teaching involving warm-blooded animals covered by the Act performed by a facility’s personnel at any location shall commence prior to approval of the ACUP by the research, testing, or teaching by the Committee, nor shall it continue if the Committee withdraws or suspends its approval. An individual member of the Committee may be assigned to review an ACUP and to suggest needed modification of the ACUP to the principal investigator. The Committee member must present his or her recommendation for approval or disapproval to a quorum of the Committee for formal action. Prior to granting approval, the Committee shall ensure that the ACUP contains provisions for acceptable and proper animal care, treatment, practices, methods, and use of pain-relieving drugs. A quorum of the Committee must review a proposed ACUP upon the request of any member of the Committee.

(ii) The Committee shall approve an ACUP only when:

(A) Animal pain, distress, and functional or sensory impairment are minimized;

(B) All survival surgery is performed using aseptic procedures;

(C) Adequate veterinary care is planned for and provided;

(D) Proposed multiple use of animal(s) which undergo surgery is justified for the purpose of conserving an endangered species or marine mammals or as an essential related component of a particular project or ACUP;

(E) Provision is made for the appropriate use of analgesics, anesthetics, tranquilizers, and euthanasia when necessary, and that the use of these drugs is in accordance with established or accepted veterinary medical procedures and usage. The use of these drugs shall be in accordance with the instructions of the attending veterinarian.

Subpart D—Attending Veterinarian and Adequate Veterinary Care

§ 2.40 Attending veterinarian and veterinary care.

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

(b) Each research facility, dealer, or exhibitor shall establish and maintain programs of adequate veterinary care, including programs for disease control and prevention, pest and parasite control, pre- and post-procedural care, nutrition, euthanasia, and the proper and appropriate use of anesthetics, analgesics, tranquilizers, and euthanasia agents.

(c) Written program of adequate veterinary care.

(1) If a part-time or consulting attending veterinarian is utilized, the dealer, exhibitor, or research facility shall submit annually to the Area Veterinarian in Charge a written program of adequate veterinary care, prepared and signed by its attending veterinarian. The program shall include regularly scheduled visits by the attending veterinarian appropriate to the needs of the dealer, exhibitor, or research facility. The dealer, exhibitor, or research facility must keep a copy of the written program on file at the premises.

(2) If a full-time attending veterinarian is utilized, the dealer, exhibitor, or research facility shall have a written program of adequate veterinary care which will be reviewed by APHIS inspectors on the premises during inspections.

(3) The written program of adequate veterinary care shall include at least the following:

(i) The facility's name and address;

(ii) The veterinarian's name and address;

(iii) Provision for programs of disease control and prevention, pest and parasite control, pre- and post-procedural care, nutrition, euthanasia, and the proper and appropriate use of anesthetics, analgesics, and tranquilizers;

(iv) How the programs are to be established and reviewed;

(v) The frequency of visits to be made to the premises by the veterinarian to assure adequate veterinary care and supervision of required programs;

(vi) The method or system of euthanasia to be utilized, by species, and who shall be authorized to perform it and

(vii) The dated signature of the attending veterinarian and of a legally responsible official of the research facility, dealer, or exhibitor.

(d) Each animal shall be observed daily by the dealer, exhibitor, attending veterinarian, research facility, principal investigator, the animal caretaker in charge, or someone under the direct supervision of the attending veterinarian, principal investigator, or the animal caretaker in charge, who is required to report promptly his or her findings to trained personnel. Any necessary veterinary care shall be promptly provided. All research facilities, dealers, or exhibitors shall provide veterinary care to or humanely dispose of sick, diseased, injured, lame, or blind animals unless such action is inconsistent with the research purposes for which the animal was obtained and is being held: Provided, however: That this provision shall not affect compliance with any State or local law requiring the holding, for a specified period, of animals suspected of being diseased.

(e) Research facilities. Each research facility shall require that the attending veterinarian be a member of the Committee and that he or she shall have the authority to enter all animal rooms, sites, facilities, animal use areas, and animal research areas at any time.

(f) In addition to the requirements set forth in paragraphs (a) through (d) of this section, the research facility shall require the attending veterinarian:

(i) To provide consultation and guidance to principal investigators and other laboratory personnel during ACUP planning and development, and during actual research, whenever any procedure is likely to produce pain or distress in an animal, if the attending veterinarian's presence and consultation is deemed necessary by the Committee,
is requested by the investigator, is in response to complaints regarding the research or procedures, or if the attending veterinarian is observing the research for compliance with the facility's written policy established in accordance with §2.30(e)(10), an approved ACUP, or the written program of adequate veterinary care. Such consultation and guidance shall include at least the following:

(A) The proper use of tranquilizers, analgesics, anesthetics, and euthanasia according to the accepted, or common veterinary practice procedures;

(B) Provision for adequate pre- and post-procedural care by laboratory workers in accordance with current established veterinary medical and nursing procedures;

(C) Agreement to the withholding of tranquilizers, anesthetics, analesics, or euthanasia only when scientifically necessary and only for the necessary period of time; and

(D) Evaluation and approval of all animal surgical areas and qualifications of personnel involved with animal surgery.

(ii) To establish, as part of the program of adequate veterinary care, procedures and a recording system which indicate and assure that the proper drugs are being used and that proper pre- and post-procedural care is being carried out on a daily basis.

Subpart E—Identification of Animals

§ 2.50 Time and method of identification.

(a) A class "A" dealer (breeder) shall identify all live dogs and cats on the premises as follows:

(1) All live dogs and cats held on the premises, purchased, or otherwise acquired, sold or otherwise disposed of, or removed from the premises for delivery to a research facility or exhibitor to another dealer, or for sale, through an auction sale or to any person for use as a pet, shall be identified by an official tag of the type described in §2.51 affixed to the animal's neck by means of a collar made of material generally acceptable to pet owners as a means of identifying their pet dogs or cats;

or

shall be identified by a distinctive and legible tattoo marking acceptable to and approved by the Administrator.

(2) Live puppies or kittens, less than 16 weeks of age, shall be identified by:

(i) An official tag as described in §2.51;

(ii) A distinctive and legible tattoo marking approved by the Administrator; or

(iii) A plastic-type collar acceptable to the Administrator which has legally placed thereon the information required for an official tag pursuant to §2.51.

(b) A class "B" dealer shall identify all live dogs and cats under his or her control or on his or her premises as follows:

(i) When live dogs or cats are held, purchased, or otherwise acquired, they shall be immediately identified:

(ii) By affixing to the animal's neck an official tag as set forth in §2.51 by means of a collar made of material generally acceptable to pet owners as a means of identifying their pet dogs or cats;

or

(iii) By a distinctive and legible tattoo marking approved by the Administrator.

(c) If any live dog or cat is already identified by an official tag or tattoo which has been applied by another dealer or exhibitor, the dealer or exhibitor who purchases or otherwise acquires the animal shall continue identifying the dog or cat by the previous identification number, or may replace the previous tag with his own official tag or approved tattoo. In either case, the class B dealer or class C exhibitor shall correctly list both official tag numbers or tattoos in his or her records of purchase which shall be maintained in accordance with §§2.75 and 2.77. Any new official tag or tattoo number shall be used on all records of any subsequent sales by the dealer or exhibitor, of any dog or cat.

(3) Live puppies or kittens, less than 16 weeks of age, shall be identified by:

(i) An official tag as described in §2.51;

(ii) A distinctive and legible tattoo marking approved by the Administrator; or

(iii) A plastic-type collar acceptable to the Administrator which has legally placed thereon the information required for an official tag pursuant to §2.51.

(4) When any dealer has made a reasonable effort to affix an official tag to a cat, as set forth in paragraphs (a) and (b) of this section, and has been unable to do so, or when the cat exhibits serious distress from the attachment of a collar and tag, the dealer shall place the collar and tag to the door of the primary enclosure containing the cat and take measures adequate to maintain the identity of the cat in relation to the tag. Each primary enclosure shall contain no more than one weaned cat without an affixed collar and official tag, unless the cats are identified by a distinctive and legible tattoo or plastic-type collar approved by the Administrator:

(c) A class "C" exhibitor shall identify all live dogs and cats under his or her control or on his or her premises, whether held, purchased, or otherwise acquired:

(1) As set forth in (b)(1) or (b)(3) of this section, or

(2) By identifying each dog or cat with:

(i) An official USDA sequentially numbered tag that is kept on the door of the animal's cage or run;

(ii) A record book containing each animal's tag number, a written description of each animal, the data required by §2.76(a), and a clear photograph of each animal; and

(iii) A duplicate tag that accompanies each dog or cat whenever it leaves the compound or premises.

(d) Unweaned puppies or kittens need not be individually identified as required by paragraphs (a) and (b) of this section while they are maintained as a litter with their dam in the same primary enclosure, provided the dam has been individually identified.

(e)(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 at the research facility and which individually identifies the dog or cat by number.

(2) Both 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 §2.76.

(f)(1) All animals, except dogs and cats, delivered for transportation, transported, purchased, sold, or otherwise acquired or disposed of by any dealer or exhibitor shall be identified by the dealer or exhibitor at the time of delivery for transportation, purchase, sale, acquisition or disposal, as provided for in this paragraph and in records maintained as required in §§2.75 and 2.77.

1 In general, well fitted collars made of leather or plastic will be acceptable under this provision. The use of certain types of chains presently used by some dealers may also be deemed acceptable. APHIS will determine the acceptability of a material proposed for usage as collars from the standpoint of humane considerations on an individual basis in consultation with the dealer or exhibitor involved. The use of materials such as wire, elastic, or sharp metal that might cause discomfort or injury to the dogs or cats is not acceptable.
(2) When one or more animals, other than dogs or cats, are confined in a container, the animal(s) shall be identified by:

(i) A label attached to the container which shall bear a description of the animals in the container, including:

(A) The number of animals;
(B) The species of the animals;
(C) Any distinctive physical features of the animals; and
(D) Any identifying marks, tattoos, or tags attached to the animals:

(ii) Marking the container with a painted or stenciled number which shall be recorded in the records of the dealer or exhibitor together with:

(A) A description of the animal(s);
(B) The species of the animal(s); and
(C) Any distinctive physical features of the animal(s); or

(iii) A tag or tattoo applied to each animal in the container by the dealer or exhibitor which individually identifies each animal by description or number.

(3) When any animal, other than a dog or cat, is not confined in a container, it shall be identified on a record, as required by §2.75, which shall accompany the animal at the time it is delivered for transportation, transported, purchased, or sold, and shall be kept and maintained by the dealer or exhibitor as part of his or her records.

§ 2.51 Form of official tag.

(a) 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 shall be one of the following shapes:

(i) Circular in shape and not less than 11/4 inches in diameter, or
(ii) Oblong and flat in shape, not less than 2 inches by 1/2 inch and riveted to an acceptable collar.

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

(1) The letters "USDA";
(2) Numbers identifying the State and dealer, exhibitor, or research facility (e.g., 39-AB); and
(3) Numbers identifying the animal (e.g., 82488).

(c) Official tags shall be serially numbered. No individual dealer, exhibitor, or research facility shall use any identification tag number more than once within any 5-year period.

§ 2.52 How to obtain tags.

Dealers, exhibitors, or research facilities may obtain, at their own expense, official tags from commercial tag manufacturers*. At the time the dealer, exhibitor, or research facility is issued a license or is registered, the Department will assign identification letters and numbers and inform them of the identification letters and numbers to be used on the official tags.

§ 2.53 Use of tags.

Official tags obtained by a dealer, exhibitor, or research facility shall be applied to dogs or cats in the manner set forth in §2.50 and in as close to consecutive numerical order as possible. No tag number shall be used to identify more than one animal. No number shall be repeated within a 5-year period.

§ 2.54 Lost tags.

Each research facility, dealer, or exhibitor 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, dealer, or exhibitor, the research facility, dealer, or exhibitor shall make a diligent effort to locate and replace the tag to the proper animal. If the lost tag is not located, the research facility, dealer, or exhibitor shall affix another official tag to the animal in the manner prescribed in §2.50, and record the tag number on the official records.

§ 2.55 Removal and disposal of tags.

(a) 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 research facility may replace the tag as indicated in §2.50(e). All tags removed by a research facility shall be retained and disposed of as indicated in this section.

(b) If a dealer, exhibitor, or research facility finds it necessary to euthanize a live dog or cat to which is affixed or which is identified by an official tag, or upon the death of a dog or cat from other causes, the dealer, exhibitor, or research facility shall remove and retain the tag for the required period, as set forth in paragraph (c) of this section.

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

(d) 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.

Subpart F—Stolen Animals

§ 2.60 Prohibition on the purchase, sale, use, or transportation of stolen animals.

Any person subject to the Act shall not buy, sell, exhibit, use for research, transport, or offer for transportation, any stolen animal.

Subpart G—Records

§ 2.75 Records: Dealers and exhibitors.

(a)(1) Every dealer other than operators of auction sales and brokers to whom animals are consigned, and exhibitor shall keep, and maintain records or forms which fully and correctly disclose the following information concerning each dog or cat purchased or otherwise acquired, owned, held, or otherwise in his or her possession or under his or her control, or which is transported, euthanized, or otherwise disposed of by that dealer or exhibitor. The records shall include any offspring born of any animal while in his or her possession or under his or her control.

(i) 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;

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

(iii) 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;

(iv) The name and address of the person to whom a dog or cat was sold or given and that person's license or registration number if he or she is licensed or registered under the Act;

(v) The date a dog or cat was acquired or disposed of, including by euthanasia;

(vi) The official USDA tag number or tattoo assigned to a dog or cat under §§ 2.50 and 2.54;

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

(A) The species and breed or type;
(B) The sex;
(C) The date of birth or approximate age; and
(D) The color and any distinctive markings;

(viii) The method of transportation including the name of the initial carrier or intermediate handler or, if a privately owned vehicle is used to transport a dog or cat, the name of the owner of the privately owned vehicle;
(ix) The date and method of disposition of a dog or cat, e.g., sale, death, euthanasia, or donation.
(2) Record of Dogs and Cats on Hand (VS Form 18-5) and Record of Disposition of Dogs and Cats (VS Form 18-6) are forms which may be used by dealers and exhibitors to make, keep, and maintain the information required by paragraph (a)(1) of this section.
(3) The USDA Interstate and International Certificate of Health Examination for Small Animals (VS Form 18-1) may be used by dealers and exhibitors to make, keep, and maintain the information required by paragraph (a)(1) of this section and § 2.79.
(4) One copy of the record containing the information required by paragraph (a)(1) of this section shall accompany each shipment of any dog or cat purchased or otherwise acquired by a dealer or exhibitor. One copy of the record containing the information required by paragraph (a)(1) of this section shall accompany each shipment of any dog or cat purchased or otherwise acquired by a dealer or exhibitor. Provided, however: That information which indicates the source and date of acquisition of a 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 (a)(1) of this section shall be retained by the dealer or exhibitor. Every dealer other than operators of auction sales and brokers to whom animals are consigned, and exhibitor shall make, keep, and maintain records or forms which fully and correctly disclose the following information concerning animals other than dogs and cats, purchased or otherwise acquired, owned, held, leased, or otherwise in his or her possession or under his or her control, or which is transported, sold, euthanized, or otherwise disposed of by a dealer or exhibitor. The records shall include any offspring born of any animal while in the care of the person from whom the animal was purchased or otherwise acquired; and the name and address of the person from whom the animals were purchased or otherwise acquired.
(5) The USDA license or registration number of the person if he or she is licensed or registered under the Act; and 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.
(6) The name and address of the person to whom an animal was sold or given.
(7) The date of purchase, acquisition, sale, or disposal of the animal(s); and (vii) The number of animals in the shipment. (2) Record of Animals on Hand (other than dogs and cats) (VS Form 18.19) and Record of Acquisition, Disposition, or Transport of Animals (other than dogs and cats) (VS Form 18.20) are forms which may be used by dealers and exhibitors to keep and maintain the information required by paragraph (b)(1) of this section.
(3) One copy of the record containing the information required by paragraph (b)(1) of this section shall accompany each shipment of any animal other than a dog or cat purchased or otherwise acquired by a dealer or exhibitor. One copy of the record containing the information required by paragraph (b)(1) of this section shall accompany each shipment of any animal other than a dog or cat purchased or otherwise acquired by a dealer or exhibitor. Provided, however: That information which indicates the source and date of acquisition of any animal other than a dog or cat need not appear on the copy of the record accompanying the shipment. The dealer or exhibitor shall retain one copy of the record containing the information required by paragraph (b)(1) of this section.

§ 2.79 Records: Research facilities.
(a) 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 such research facility. The records shall include any offspring born of any animal while in the research facility’s possession or under its control.
(i) 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;
(ii) The USDA license or registration number of the person if he or she is licensed or registered under the Act;
(iii) 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;
(iv) The date of acquisition of each dog or cat;
(v) The color and any distinctive markings;
(vi) The date and method of disposition of any dog or cat sold or otherwise disposed of.
(b) 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.
(c) The USDA Interstate and International Certificate of Health Examination for Small Animals (VS Form 18-1), and Record of Disposition of Dogs and Cats (VS Form 18-6) are forms which may be used by research facilities to keep and maintain the information required by paragraph (a) of this section.
(d) One copy of the record containing the information required by paragraphs (a) and (b) 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 information which 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 (a) and (b) of this section shall be retained by the research facility.
§ 2.77 Records: Operators of auction sales and brokers.

(a) Every operator of an auction sale or broker shall make, keep, and maintain records or forms which fully and correctly disclose the following information concerning each animal consigned for auction or sold, whether or not a fee or commission is charged:

(1) The name and address of the person who owned or consigned the animal(s) for sale;

(2) The name and address of the buyer or consignee who received the animal;

(3) The USDA license or registration number of the person(s) selling, consigning, buying, or receiving the animals if he or she is licensed or registered under the Act;

(4) 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;

(5) The date of the consignment;

(6) The official USDA tag number or tattoo assigned to the animal under §§ 2.50 and 2.54;

(7) A description of the animal which shall include:

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

(ii) The sex of the animal; and

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

(iv) The color and any distinctive markings;

(b) The auction sales number or records number assigned to the animal.

(b) One copy of the record containing the information required by paragraph (a) of this section shall be given to the consignee, and one copy of the record shall be given to the purchaser of each animal: Provided, however: That information which indicates the source and date of consignment of any animal need not appear on the copy of the record given the purchaser of any animal. One copy of the record containing the information required by paragraph (a) of this section shall be retained by the operator of such auction sale, or broker, for each animal sold by the auction sale or broker.

§ 2.78 Records: Carriers and intermediate handlers.

(a) In connection with all live dogs, cats, or nonhuman primates delivered for transportation, in commerce, to any carrier or intermediate handler, by any dealer, research facility, exhibitor, operator of an auction sale, broker, or department, agency, or instrumentality of the United States or of any State or local government, the accepting carrier or intermediate handler shall keep and maintain a copy of the health certification completed as required by § 2.79, tendered with each live dog, cat, or nonhuman primate.

§ 2.79 Health certification and identification.

(a) No dealer, research facility, exhibitor, operator of an auction sale, broker, or department, agency, or instrumentality of the United States or of any State or local government 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:

(1) 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

(2) 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.

(b) 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 Administrator, APHIS, USDA, Room 758, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

(c) No intermediate handler or carrier to whom any live dog, cat, or nonhuman primate is delivered for transportation by any dealer, research facility, exhibitor, broker, operator of an auction sale, or department, agency, or instrumentality of the United States or any State or local government shall receive a live dog, cat, or nonhuman primate for transportation, in commerce, unless and until it is accompanied by a health certificate issued by a licensed veterinarian in accordance with paragraph (a) of this section, or an exemption issued by the Secretary in accordance with paragraph (b) of this section.

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

§ 2.80 C.O.D. shipments.

(a) No carrier or intermediate handler shall accept any animal for transportation, in commerce, upon any C.O.D. or other basis where the cost of the animal or the cost for any transportation or any other incidental or out-of-pocket expense is to be paid and collected upon delivery of the animal to the consignee, unless the consignor guarantees in writing that the payment of all transportation, including any return transportation, if the shipment is unclaimed or the consignee cannot be notified in accordance with paragraphs (b) and (c) of this section, including reimbursing the carrier or intermediate handler for all out-of-pocket expenses incurred for the care, feeding, and storage or housing of the animal.

(b)(1) Any carrier or intermediate handler receiving an animal at a destination on a C.O.D. or other basis where the cost of the animal or the cost for any transportation or other incidental or out-of-pocket expense is to be paid and collected upon delivery of the animal to the consignee shall attempt to notify the consignee at least once every 6 hours for a period of 24 hours after arrival of the animal at the animal holding area of the terminal cargo facility. The carrier or intermediate handler shall record the time, date, and method of each attempted notification and the final notification to the consignee, and the name of the person notifying the consignee, on the shipping document and on the copy of the shipping document accompanying the C.O.D. shipment. If the consignee cannot be
the consignee, which is not claimed upon delivery of the animal to the consignor. Any carrier or intermediate handler which has notified a consignee of the arrival of a C.O.D. or other shipment of an animal, where the cost of the animal, or the cost for any transportation, or other incidental or out-of-pocket expense is to be paid and collected upon delivery of the animal to the consignee, which is not claimed by the consignee within 48 hours from the time of notification, shall return the animal to the consignor, or to whomever the consignor has designated, on the next practical available transportation, in accordance with the written agreement required in paragraph (a) of this section and shall notify the consignor.

(c) It is the responsibility of any carrier or intermediate handler to provide care, feed, and hold properly any animal accepted for transportation, in accordance with the written agreement required in paragraph (a) of this section and shall notify the consignor.

The other person agrees in writing to have another person hold animals for the required period provided for in paragraph (a) of this section for the payment of the cost of any transportation or out-of-pocket or other incidental expenses incurred in the transportation of any animal.

**§ 2.101** Holding period.

(a) Any live dog or cat acquired by a dealer or exhibitor shall be held by him or her, under his or her supervision and control, for a period of not less than 5 full days, not including the day of acquisition, after acquiring the animal, excluding time in transit: Provided, however:

1. That any live dog or cat acquired by a dealer or exhibitor from any private or contract animal pound or shelter shall be held by that dealer or exhibitor under his or her supervision and control for a period of not less than 10 full days, not including the day of acquisition, after acquiring the animal, excluding time in transit;
2. Live dogs or cats which have completed a 5-day holding period with another dealer or exhibitor, or a 10-day holding period with another dealer or exhibitor if obtained from a private or contract shelter or pound, may be sold or otherwise disposed of by subsequent dealers or exhibitors after a minimum holding period of 24 hours by each subsequent dealer or exhibitor, excluding time in transit;
3. Any dog or cat suffering from disease, emaciation, or injury may be destroyed by euthanasia prior to the completion of the holding period required by this section; and
4. Any live dog or cat, 120 days of age or less, that was obtained from the person that bred and raised such dog or cat, may be exempted from the 5-day holding requirement and may be disposed of by dealers or exhibitors after a minimum holding period of 24 hours, excluding time in transit. Each subsequent dealer or exhibitor must also hold each such dog or cat for a 24-hour period excluding time in transit.

(b) During the period in which any dog or cat is being held as required by this section, the dog or cat shall be unloaded from any means of conveyance in which it was received, for feed, water, and rest, and shall be handled, cared for, and treated in accordance with the standards set forth in Part 3, Subpart A, of this subchapter and § 2.131 of this part.

(c) 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 § 2.50 during this period.

**§ 2.102** Holding facility.

(a) If any dealer or exhibitor obtains the prior approval of the Area Veterinarian in Charge, he may arrange to have another person hold animals for the required period provided for in paragraph (a) of § 2.101: Provided that:

1. The other person agrees in writing to comply with the regulations in Part 2 and the standards in Part 3 of this subchapter and to allow inspection of his premises by an APHIS official during business hours; and
2. The animals remain under the total control and responsibility of the dealer or exhibitor.

(3) Approval will not be given for a dealer or exhibitor holding a license as set forth in § 2.1 to have animals held for purposes of this section by another licensed dealer or exhibitor.

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An operator of an auction sale is not considered to have acquired a dog or cat which is sold through the auction sale.
Services Form 18.9 shall be used for approval.

(b) If any research facility or intermediate handler obtains prior approval of the Area Veterinarian in Charge, it may arrange to have another intermediate handler obtain prior approval.

§ 2.127 Publication of names of persons subject to the provisions of this part.

APHIS will publish lists of persons licensed or registered in accordance with the provisions of this part in the Federal Register. The lists may be obtained upon request from the Area Veterinarian in Charge.

§ 2.128 Inspection for missing animals.

(a) Each dealer, exhibitor, research facility, intermediate handler and carrier shall, upon request, during business hours, allow, under the following conditions, 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 his or her place of business to inspect animals and records for the purpose of seeking missing animals that are missing:

(1) The police or other law officer shall furnish to the dealer, exhibitor, research facility, intermediate handler or carrier 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 dealer, exhibitor, research facility, intermediate handler or carrier 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.

(b) An inspection for missing animals by law enforcement officers shall not extend to animals that are undergoing actual research or experimentation by a research facility as determined by the research facility.

§ 2.130 Minimum age requirements.

No dog or cat shall be delivered by any person to any carrier or intermediate handler for transportation, in commerce, or shall be transported in commerce by any person, except to a registered research facility, unless such dog or cat is at least eight (8) weeks of age and has been weaned.

§ 2.131 Handling.

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

(a)(2) Physical abuse of animals or deprivation of food or water shall not be used to train, work, or otherwise handle animals.

(b)(1) During public exhibition, any animal must be handled so there is minimal risk of harm to the animal and
to the public, with sufficient distance and/or barriers between the animal and the general viewing public so as to assure the safety of animals and the public.

(2) Performing animals shall be allowed a rest period between performances at least equal to the time for one performance.

(3) Young or immature animals shall not be exposed to rough or excessive public handling or exhibited for periods of time which would be detrimental to their health or well-being.

(4) Drugs, such as tranquilizers, shall not be used to facilitate, allow, or provide for public handling of the animals.

(c)(1) Animals shall be exhibited only for periods of time and under conditions consistent with their good health and well-being.

(2) A responsible, knowledgeable, and readily identifiable employee or attendant must be present at all times during periods of public contact.

(3) At a minimum, when dangerous animals such as lions, tigers, wolves, bears, or elephants are allowed to have contact with the public, the animals must be under the direct control and supervision of a knowledgeable and experienced animal handler.

(4) If public feeding of animals is allowed, the food must be provided by the animal facility and shall be appropriate to the type of animal and its nutritional needs and diet.

§ 2.132 Procurement of random source dogs and cats, dealers.

(a) A class "B" dealer may obtain live random source dogs and cats only from:

(1) Other dealers who are licensed under the Animal Welfare Act and in accordance with the regulations in Part 2;

(2) State, county, or city owned and operated animal pounds or shelters; and

(3) A legal entity organized and operated under the laws of the State in which it is located as an animal pound or shelter, such as a humane shelter or contract pound.

(b) A class "B" dealer shall not obtain live random source dogs and cats from individuals who have not bred and raised the dogs and cats on their own premises.

(c) Live random source dogs and cats may be obtained from persons who have bred and raised the dogs and cats on their own premises, such as hobby breeders.

(d) Any person subject to the Act shall not obtain live random source dogs or cats by use of false pretenses, misrepresentation, or deception.

(e) Any licensee or registrant under the Act who also operates a private or contract animal pound or shelter shall comply with the following:

(1) The animal pound or shelter shall be located on premises that are physically separated from the licensed or registered facility. The animal housing facility of the pound or shelter shall not be adjacent to the licensed or registers facility.

(2) Accurate and complete records shall be separately maintained by the licensee or registrant and by the pound or shelter. The records shall be in accordance with §§ 2.75 and 2.76, unless the animals are lost or stray. If the animals are lost or stray, the pound or shelter records shall provide:

(i) An accurate description of the animal;

(ii) How, where, from whom, and when the dog or cat was obtained;

(iii) How long the dog or cat was held by the pound or shelter before being transferred to the dealer; and

(iv) The date the dog or cat was transferred to the dealer.

(3) Any dealer who obtains or acquires a live random source dog or cat from a private or contract pound or shelter, including a pound or shelter they operate, shall hold the dog or cat for a period of at least 10 full days, not including the day of acquisition, excluding time in transit, after acquiring the animal, and otherwise in accordance with § 2.101.

Done at Washington, D.C., this 7th day of March 1986.

James W. Glosser,
Administrator, Animal and Plant Health Inspection Service.
[FR Doc. 85-5612 Filed 3-8-86; 2:15 p.m.]
BILLING CODE 3410-34-M

9 CFR Part 3
[Docket No. 87-004]

Animal Welfare—Standards

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations for the humane handling, care, treatment, and transportation of dogs and cats, guinea pigs and hamsters, rabbits, and nonhuman primates. The regulations for dogs, cats, and nonhuman primates would be completely revised and rewritten. The regulations for guinea pigs, hamsters, and rabbits would be amended to revise the space requirements for primary enclosures; to amend the temperature requirements in cargo spaces in primary conveyances; and to reinstate various transportation requirements. These actions are necessary to update the regulations, to make them more consistent with other Federal regulations concerning the handling, care, treatment, and transportation of these animals, and to comply with the recent amendments to the Animal Welfare Act (7 U.S.C. 2131, et seq.), enacted December 23, 1985. Rewriting the regulations is also intended to make them easier to understand, thereby increasing compliance and making them more effective.

DATES: We will consider written comments postmarked or received on or before August 14, 1986.

ADDRESS: Send an original and three copies of your comments to Helene R. Wright, Chief, Regulatory Analysis and Development Staff, PPD,APHIS, USDA, Room 1000, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 87-004. Comments received may be inspected at the APHIS Public Reading Room, Room 1141, U.S. Department of Agriculture, 14th Street and Independence Avenue, SW., Washington, DC, 8:00 a.m. to 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT:
Dr. R.L. Crawford, Director, Animal Care Staff, REAC, APHIS, USDA, Room 208, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. (301) 436-7833.

SUPPLEMENTARY INFORMATION:

General Background and Statutory Information

Regulations on the humane handling, care, treatment, and transportation of (1) dogs and cats, (2) guinea pigs and hamsters, (3) rabbits, and (4) nonhuman primates, are contained in 9 CFR Part 3. Subpart A contains the regulations concerning dogs and cats; Subpart B contains the regulations concerning guinea pigs and hamsters; Subpart C contains the regulations concerning rabbits; and Subpart D contains the regulations concerning nonhuman primates. The regulations in each of these Subparts include minimum standards for handling, housing, feeding, watering, sanitation, ventilation, shelter, and veterinary care. The regulations are issued and enforced by the Animal and Plant Health Inspection Service (APHIS), of the United States Department of Agriculture (USDA), under authority of the Animal Welfare