

Environmental Planning and Protection, EPA, Region 2, 290 Broadway, 22nd Floor, New York, NY 10007.

- Hand Delivery or Courier: Deliver your comments to Michael Infurna, Division of Environmental Planning and Protection, EPA, Region 2, 290 Broadway, 22nd Floor, New York, NY 10007. Such deliveries are only accepted during the Regional Office's normal hours of operation. The public is advised to call in advance to verify the business hours. Special arrangements should be made for deliveries of boxed information.

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Instructions: Direct your comments to FRL-7857-7. EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov, or e-mail. The Federal regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties, and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters or any form of encryption, and be free of any defects or viruses.

FOR FURTHER INFORMATION CONTACT: Michael Infurna, Division of

Environmental Planning and Protection, EPA Region 2, 290 Broadway, 22nd floor, New York, NY 10007; telephone number (212) 637-4177; fax number: (212) 637-4377; e-mail address: infurna.michael@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: For additional information, please see the immediate final rule published in the "Rules and Regulations" section of this **Federal Register**.

Dated: November 23, 2004.

Kathleen C. Callahan,

Acting Regional Administrator, Region 2.

[FR Doc. 05-503 Filed 1-10-05; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

42 CFR Part 9

RIN 0925-AA31

Standards of Care for Chimpanzees Held in the Federally Supported Chimpanzee Sanctuary System

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice of proposed rulemaking.

SUMMARY: The National Institutes of Health (NIH) proposes to issue standards to implement provisions of the Chimpanzee Health Improvement, Maintenance, and Protection Act (CHIMP Act) authorizing the Secretary of the Department of Health and Human Services (DHHS) to develop and publish standards of care for chimpanzees held in the Sanctuary system supported by Federal funds authorized under the CHIMP Act. These regulations will apply to only those facilities receiving Federal funds as a part of the federally funded chimpanzee Sanctuary system.

DATES: Comments must be received on or before March 14, 2005 in order to assure that NIH will be able to consider comments in preparing the final rule.

ADDRESSES: You may submit comments, identified by RIN number 0925-AA31, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- E-mail: jm40z@nih.gov. Indicate RIN number 0925-AA31 in the subject line of the message.

- Fax: 301-402-0169.

- Mail: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, National Institutes of

Health, 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, Maryland 20892.

- Hand Delivery/Courier: 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, Maryland 20892.

FOR FURTHER INFORMATION CONTACT: Jerry Moore at the address given in the **ADDRESSES** section, or telephone 301-496-4607 (not a toll-free number).

SUPPLEMENTARY INFORMATION: On December 20, 2000, the United States Congress enacted the Chimpanzee Health Improvement, Maintenance, and Protection Act of 2000 (Pub. L. 106-551). Section 1 of this law amended the Public Health Service (PHS) Act by adding a new section 481C (42 U.S.C. 287a-3a). Section 481C authorizes the Secretary to provide for the establishment and operation of a sanctuary system to provide for the lifetime care of chimpanzees that have been used, or were bred or purchased for use, in research conducted or supported by the National Institutes of Health (NIH), the Food and Drug Administration (FDA), Center for Disease Control and Prevention, or other agencies of the Federal Government, and with respect to which it has been determined by the Secretary that the chimpanzees are not needed for such research (*i.e.*, surplus chimpanzees). Section 481C (d) directs the Secretary to establish by regulation standards of care for operating the Sanctuary system to provide for the permanent retirement of surplus chimpanzees. These standards of care for chimpanzees must ensure the well-being of animals and the health and safety of the animals and the people caring for them. On April 5, 2001, the Secretary delegated to the Director, NIH, the authorities to establish and operate the sanctuary system. Subsequently, the Director, NIH, delegated the authorities to the National Center for Research Resources (NCRR). Consequently, NCRR has the lead responsibility for coordinating all efforts on behalf of the Department of Health and Human Services (DHHS) concerning the Sanctuary system for surplus chimpanzees from both Federal and non-Federal sources. Section 481C (e) authorizes the Secretary to make an award of a contract to a nonprofit private entity (*i.e.*, Sanctuary Contractor) under which the entity has the responsibility of operating (and establishing, as applicable) the Sanctuary system and awarding subcontracts to individual Sanctuary facilities that meet established standards. NCRR/NIH must approve both contractor and subcontractor awards and NCRR/NIH will verify

contractor and subcontractor (if applicable) qualifications through facility site visits, review of written documentation submitted to the contractor, and evaluating available and current resources.

NCRR/NIH will assure compliance with the Standards of Care Regulations through on site visits (at least quarterly or more often if necessary), review of quarterly and annual reports, and any other measures deemed appropriate by the NCRR/NIH Project or Contracts Officer. Noncompliance with these standards or any other federal or state regulations will result in the NCRR/NIH invoking the provisions of the contract that allows the government to terminate the contract and/or provide a management team to bring the Sanctuary back into compliance. The Sanctuary is covered by the Animal Welfare Regulations only if covered activities are performed. The CHIMP Act requires compliance with the Animal Welfare Act and the Federal Contract and these regulations require the Sanctuary Contractor to register with the USDA and agree to compliance inspections. Therefore, the USDA Inspectors responsible for enforcing the Animal Welfare Regulations will perform inspections for compliance with the Animal Welfare Regulations at a frequency and time determined by the USDA staff. Once the contractor becomes a Registered Facility the USDA will report noncompliance to NCRR/NIH as appropriate. The NCRR/NIH representative will review USDA inspection reports during on-site visits in order to monitor compliance with these proposed Standards of Care Regulations. The Sanctuary must also adhere to U.S. Public Health Service Policy on the Humane Care and Use of Laboratory Animals. If and when any noninvasive studies allowed under the CHIMP Act and these regulations are proposed for chimpanzees in the Sanctuary, the Sanctuary Contractor must obtain an Animal Welfare Assurance from the NIH Office of Laboratory Animal Welfare (OLAW) and comply with the provisions of the policy. Finally, the Sanctuary must obtain accreditation or certification by a nationally or internationally recognized body that performs such services. The Sanctuary must achieve accreditation or certification within a reasonable period of time as determined by the NCRR/NIH.

In preparing these proposed standards of care, we considered the recommendations of the Board of Directors of the Sanctuary contractor and the NCRR Chimpanzee Sanctuary Working Group, and the applicable

recommendations of the National Research Council made in its 1997 report entitled, "Chimpanzees in Research—Strategies for Their Ethical Care, Management, and Use." Individuals involved in developing recommendations from these groups represented a variety of professional areas including veterinary medicine, chimpanzee behavior, animal protection, facility management, and nonhuman primate research and care. We also consulted other publications, including: "The Guide for the Care and Use of Laboratory Animals," published by the National Research Council (NRC), "The Psychological Well-Being of Nonhuman Primates," also an NRC publication, "Public Health Service Policy on Humane Care and Use of Laboratory Animals," the accreditation guidelines used by the Association for the Assessment and Accreditation of Laboratory Animal Care, International, and the American Zoological and Aquarium Association, and the United States Department of Agriculture (USDA), Animal Welfare Regulations codified in various parts of title 9, chapter 1, Subchapter A of the Code of Federal Regulations (CFR).

We propose to amend title 42 of the CFR by adding a new part 9 to establish standards for operating the Sanctuary system to provide for the permanent retirement of surplus chimpanzees. These standards of care will apply to only the sanctuaries that are a part of the federally funded chimpanzee Sanctuary system. The proposed rule specifies the scope and specific standards that must be met by all contractors (primary or subcontractors) operating under the federally supported Chimpanzee Sanctuary system. The purpose of this notice is to invite public comment on the proposed standards of care.

The following is provided as public information.

Executive Order 12866

Executive Order 12866, "Regulatory Planning and Review," requires that all regulatory actions reflect consideration of the costs and benefits they generate, and that they meet certain standards, such as avoiding the imposition of unnecessary burdens on the affected public. Executive Order 12866 classifies a rule as a significant regulatory action if it meets any one of a number of specific conditions. We determined that this proposed rule is a "significant regulatory action," as defined under Executive Order 12866, because it raises novel legal or policy issues. Therefore, we submitted the proposed rule to the Office of Information and Regulatory

Affairs for review prior to publication in accordance with the requirements of Executive Order 12866.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. chapter 6) requires that we analyze regulatory proposals to determine whether they create a significant impact on a substantial number of small entities. Based on the analysis that follows, the Secretary certifies that this proposed rule will not have such impact when the final rule is issued.

1. Number and Type of Small Entities Affected

There are several small entities that privately fund nonhuman primate sanctuaries. However, the federally supported, contractor operated Chimpanzee Sanctuary System, established by the CHIMP Act and covered under the proposed standards of care, is the only one of its kind in existence. Congress established the Sanctuary to provide lifetime care for chimpanzees that are no longer needed in federally supported research. The proposed rule applies only to a contractor or any subcontractor operating under a contract funded by the NIH/NCRR for the Sanctuary. Only one contractor is identified in the proposed rule as the prime contractor for the Sanctuary system. The NCRR awarded this contract in September 2002. Additionally, a few subcontractors might be added in future years if the need arises. The subcontractors would be selected by the prime contractor (contingent upon NIH/NCRR approval), and report to the prime contractor. Approximately four or five biomedical research centers with chimpanzees will be responsible for the transport of animals to the Sanctuary. The entities shipping chimpanzees to the Sanctuary are required to comply with existing Animal Welfare Regulations administered by the USDA.

2. Net Cost of Compliance With the Proposed Rule

At the time NIH/NCRR awarded the contract in 2002, the contractor was aware of its role in establishing and complying with the proposed standards of care pursuant to the CHIMP Act. The costs necessary to comply with the standards of care were anticipated by the CHIMP Act and subsequent contract negotiations. The RFP and Statement of Work noted that Standards of Care would be developed in consultation with the selected contractor and that the contractor must comply with these standards. The contractor selected had

several members of their Board of Directors familiar with chimpanzee care standards and had served as consultants to some of the agencies publishing such standards. Therefore, they included resources needed to potentially comply with anticipated standards in their contract and construction grant proposals. There could be some additional unanticipated costs but they are not obvious at this time. Under the terms of the contract, the Federal Government assumes responsibility for seventy-five percent of the operational cost that includes compliance with the proposed standards of care. The net costs to the contractor are twenty-five percent of the total costs of care and maintenance of the chimpanzees, including compliance with the proposed standards of care. We estimate that this will amount to \$875,000 to \$1 million per year for the contractor. We anticipate no net increase in the costs as a result of compliance with the standards of care. We estimate that five or six research facilities might incur expenses in transporting animals to the Sanctuary, and thus will incur minor shipping costs (approximately \$10,000 to \$20,000 for 1 shipment for a total of six shipments/year.) Subcontractors will likely have existing facilities and staff though some might need to be upgraded. They would be eligible to compete for NIH Construction Grants the same as the prime contractor and thus match 10% of the construction cost. The use of subcontractors is not anticipated in the foreseeable future because of the availability of a considerable amount of unused space at the primary contractor. When the need arises for subcontractors in the operation of the Sanctuary, they will be selected by, and report to the prime

contractor, with verification of qualifications by NCRR/NIH.

3. The Percentage Cost of Compliance With the Proposed Rule

We estimate that the percentage cost for complying with the proposed rule is less than three percent of the total operational cost of the Sanctuary. We anticipate that no additional staff is needed to comply with the proposed standards of care. The staffing under the terms of the contract is based upon the requirement to provide quality care and maintenance for the chimpanzees as required by the CHIMP Act and the contract.

Executive Order 13132

Executive Order 13132, "Federalism," requires that Federal agencies consult with State and local government officials in the development of regulatory policies with federalism implications. The Secretary reviewed this proposed rule as required under the Order and determined that it will not have federalism implications. The Secretary certifies that the proposed rule will not have an effect on the States or on the distribution of power and responsibilities among various levels of government when the final rule is issued.

Paperwork Reduction Act

Sections 9.3(a)(7)(v)(C), 9.6(c)(6), 9.6(d), 9.8(a)(4), 9.11(a), 9.11(b)(1)(ii), and 9.12(b) of this proposed rule contain reporting information collection requirements that are subject to OMB approval under the Paperwork Reduction Act of 1995, as amended (44 U.S.C. chapter 35). Sections 9.3(a)(11), 9.4(c)(1), 9.4(c)(3), 9.5(c)(4), 9.5(e), 9.6(c)(8), 9.6(c)(10), 9.8(a)(1-4), 9.8(b), 9.9(c), 9.10(a)(1), 9.10(a)(2), 9.10(b)(1),

9.11(a), 9.12(b), contain record keeping requirements which also are subject to OMB approval under the Paperwork Reduction Act. In addition, elements of disclosure are found in sections 9.3(a)(13), 9.4(c)(2), 9.5(c), 9.5(e), 9.5(f)(2), 9.6(c)(10), 9.9(a)(3), 9.10(a)(1), 9.10(b)(1), and 9.11(a). The title, description, and respondent description of the information collection and record keeping requirements contained in the proposed rule have been submitted to OMB for review. Other organizations and individuals desiring to submit comments on the information collection and record keeping requirements should send their comments to (1) Dr. Charles MacKay, Project Clearance Officer, National Institutes of Health, Rockledge Centre 1, 6705 Rockledge Drive, Room 3509 Bethesda, Maryland 20817, telephone 301-435-0978 (not a toll-free number); and (2) the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, Room 10235, 725 17th Street, NW., Washington, DC 20503. Attention: Desk Officer for the National Institutes of Health, Department of Health and Human Services. After we obtain OMB approval, we will publish the OMB control number in the **Federal Register**.

Title: Standards of Care for Chimpanzees Held in the Federally-supported Chimpanzee Sanctuary System.

Description: The information collections and record keeping will be used by NIH and the Sanctuary contractor and subcontractors to document proper and adequate care, identification, accountability, billing, regulatory compliance, and adherence to contract specifications and terms.

Respondent Description: Private nonprofit entities or institutions

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

	Annual number of respondents*	Annual frequency	Average burden (hours)	Annual burden hours per response
Reporting:				
§ 9.3(a)(7)(v)(C)	1-3	2	6	12
§ 9.6(c)(6)	1-3	3	2	6
§ 9.6(d)	1-3	2	0.5	1
§ 9.8(a)(4)	1-3	4	5	20
§ 9.11(a)	**1-3	1	1	12
§ 9.11(b)(1)(ii)	**1-3	6	2	12
§ 9.12(b)	1-3	1	6	6
Subtotal		19	22.5	69
Recordkeeping:				
§ 9.3(a)(7)(v)(c)	1-3	2	2	4
§ 9.3(a)(10)	**1-3	1	8	8
§ 9.3(a)(11)	**1-3	1	8	8
§ 9.4(c)(1)	1-3	1	1	1
§ 9.4(c)(3)	1-3	1	6	6

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN—Continued

	Annual number of respondents*	Annual frequency	Average burden (hours)	Annual burden hours per response
§ 9.5(c)(4)	1-3	1	2	2
§ 9.5 (e)	1-3	1	4	4
§ 9.6(c)(8)	1-3	5	0.05	0.25
Subtotal		13.00	31.05	33.25
§ 9.6(c)(10)	1-3	4	0.1	0.4
§ 9.8(a)(1-4)	1-3	1	0.5	5
§ 9.8(b)	1-3	5	2	10
§ 9.9(c)	1-3	12	0.2	2.4
§ 9.10(a)(1)	1-3	12	0.2	2.4
§ 9.10(a)(2)	1-3	4	3	12
§ 9.10(b)(1)	1-3	3	1.5	4.5
§ 9.11(a)	***1-3	6	1	6
§ 9.12(b)	***1-3	1	3	3
Subtotal		48	11.50	43.30
Disclosure:				
§ 9.3(a)(10)**	1-3	6	0.5	3
§ 9.3(a)(11)**	1-3	1	0.5	1
§ 9.3(a)(13)	1-3	1	1	1
§ 9.4(c)(2)	1-3	1	0.1	0.1
§ 9.5 (c)	1-3	1	8	8
§ 9.5(e)	1-3	****1	2	2
§ 9.5(f)(2)	1-3	0.2	8	1.6
§ 9.6(c)(10)	1-3	4	0.1	0.4
§ 9.9(c)	1-3	10	0.2	2
§ 9.10(a)(1)	1-3	10	0.2	2
§ 9.10(b)(1)	1-3	1	0.2	0.2
§ 9.11(a)***	1-3	2	1	2
Subtotal		38.2	21.8	23.3
Total	1-3	118.2	.85	168.25

* Presently, there is only one (1) respondent, the Contractor for the federally supported Chimpanzee Sanctuary System. The estimates are based upon a maximum of three (3) respondents in the future.

** See also §§ 9.5(c) & 9.5(e).

*** The reporting requirements for these sections vary because it is estimated that chimpanzees will be shipped six (6) times per year. This requires 6 notifications of shipment notices to the Project Officer. While not anticipated, it is possible that approximately one (1) of these shipments might require reporting because of undesirable conditions, a death, failure to provide adequate food or water, or other conditions affecting animal welfare. Such incidents must be reported immediately to the NCRR Project Officer who will in turn work with the USDA representatives in investigating the matter.

**** 1 × event.

List of Subjects in 42 CFR Part 9

Animal welfare, Humane care and treatment of chimpanzees.

Dated: April 28, 2004.

Elias A. Zerhouni,

Director, National Institutes of Health.

Approved: September 29, 2004.

Tommy G. Thompson,

Secretary.

Accordingly, NIH proposes to amend title 42 of the Code of Federal Regulations by adding part 9 to read as follows:

PART 9—STANDARDS OF CARE FOR CHIMPANZEES HELD IN THE FEDERALLY SUPPORTED SANCTUARY SYSTEM

Sec.

- 9.1 Applicability and purpose.
- 9.2 Definitions.
- 9.3 Sanctuary policies and responsibilities.
- 9.4 Physical facility policies and design.
- 9.5 Chimpanzee ownership, fees, and studies.
- 9.6 Animal care, well-being, husbandry, veterinary care, and euthanasia.
- 9.7 Reproduction.
- 9.8 Animal records.
- 9.9 Facility staffing.
- 9.10 Occupational Health and Safety Program and biosafety requirements.
- 9.11 Animal transport.
- 9.12 Compliance with the Standards of Care, USDA and PHS policies and regulations.
- 9.13 Other Federal laws, regulations, and policies that apply to this part.
- 9.14 Authority of the Secretary of Health and Human Services to amend or issue additional standards of care regulations.

Authority: 42 U.S.C. 216, 287a–3a.

§ 9.1 Applicability and purpose.

(a) *General.* The standards of care set forth in this part apply to the chimpanzee sanctuaries that are contracted (or subcontracted) to the Federal Government to operate the federally supported chimpanzee Sanctuary system authorized by section 481C of the Public Health Service (PHS) Act, as amended (42 U.S.C. 287a–3a).

(b) *What is the purpose of the federally supported chimpanzee Sanctuary system and the authority for establishing these standards of care regulations?* The Chimpanzee Health Improvement, Maintenance, and Protection Act (Public Law 106–551, referred to as the “CHIMP Act” or “Chimpanzee Retirement Act”) was enacted by Congress to provide for the establishment and operation of a

Sanctuary system to provide lifetime care for chimpanzees that have been used, or were bred or purchased for use, in research conducted or supported by the agencies of the Federal Government, and that are determined to be no longer needed for such research. The CHIMP Act also mandates that standards of care for chimpanzees in the Sanctuary shall be developed to ensure the well-being of chimpanzees and the health and safety of the chimpanzees.

(c) *To what chimpanzee sanctuaries do the standards of care in this part apply?* The standards of care set forth in this part apply to only those sanctuaries that are contracted or subcontracted to the Federal Government to operate the federally supported chimpanzee Sanctuary system.

§9.2 Definitions.

As used in this part:

Adequate veterinary care means a program directed by a veterinarian qualified through training and/or experience to provide professional medical care to the chimpanzees within the Sanctuary and with the appropriate authority to provide this care. The program also provides guidance to all caregivers on all matters relating to the health and well-being of the chimpanzees.

American Zoo and Aquarium Association (AZA) means the professional society comprised of individuals with various backgrounds and interests that is devoted to advancing the knowledge and understanding of zoo animals and the management of zoos in the United States.

American Zoo and Aquarium Association (AZA) Accreditation Standards are those standards developed by the AZA that are used to review, evaluate, and accredit zoos or zoological gardens. These standards cover a variety of areas including facilities, policies and procedures, training, staff qualifications, medical and animal care, husbandry and well-being procedures, and conservation, along with other specific areas.

Animal Care and Use Committee means the Institutional Animal Care and Use Committee established under section 13(b) of the Animal Welfare Act of 1985 and the Health Research Extension Act of 1985. For the purpose of these Standards of Care, it shall consist of at least five (5) members including the Chairperson, a Doctor of Veterinary Medicine (D.V.M. or V.M.D.) knowledgeable in nonhuman primate care and diseases and with delegated program responsibility, a member not affiliated with the Sanctuary, a scientist,

and a member of the animal protection community. This Committee is required if research as defined by the Animal Welfare Act Regulations and the Public Health Service Policy (research, teaching, testing, exhibition) is to be conducted at the Sanctuary.

Animal protection organization means a nonprofit organization whose primary mission is protection of animals through positive advocacy and action.

Animal Resource Manager (or Animal Resource Supervisor) means the individual employee responsible for managing the non-professional staff providing care for the chimpanzees at the Sanctuary. This individual may perform other duties as assigned by the Sanctuary contractor.

Animal Welfare Act/Regulations means the Act of August 24, 1966 (Pub. L. 89-544), (commonly known as the Laboratory Animal Welfare Act) as amended by the Act of December 24, 1970 (Pub. L. 91-579), (the Animal Welfare Act of 1970), the Act of April 22, 1976 (Pub. L. 94-279), (the Animal Welfare Act of 1976), and the Act of December 23, 1985 (Pub. L. 99-198), (the Food Security Act of 1985), and as may be subsequently amended, and the United States Department of Agriculture (USDA) regulations implementing the Animal Welfare Act in title 9, chapter 1, subchapter A of the CFR.

Animal Welfare Assurance means the documentation from an institution assuring compliance with the PHS Policy on Humane Care and Use of Laboratory Animals. This policy is administered by the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health.

Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) means the nonprofit organization that is recognized in the United States and abroad as being the body responsible for the accreditation of laboratory animal programs.

Behaviorist means a person hired by the Sanctuary to administer or oversee the enrichment and behavioral program for the chimpanzees at the Sanctuary. This individual must be qualified through training or experience.

Biosafety Officer means the individual responsible for establishing and monitoring workplace safety procedures designed to minimize or prevent injury or loss due to biohazards in accordance with policies established by the Sanctuary administration.

Board of Directors (BOD) means the individuals selected by the Contractor to govern the nonprofit institution responsible for operating the federally supported chimpanzee Sanctuary

system. The board members must meet the qualifications and criteria stated in the CHIMP Act.

Chair of the Board of Directors means the individual chosen by the BOD or other legally empowered entity to carry out such action, who is responsible for chairing meetings and acting on behalf of the board. This individual reports directly to the board.

Chief Executive Officer (CEO) means the principal person responsible for overall accomplishment of the mission of the chimpanzee Sanctuary.

CHIMP Act means the Chimpanzee Health Improvement, Maintenance, and Protection Act of December 20, 2000 (Pub. L. 106-551) commonly known as the "CHIMP Act" or "Chimpanzee Retirement Act," and any future amendments.

Chimpanzee means a member of *Pan troglodytes*. It excludes the pygmy chimpanzee (*Pan paniscus* or bonobo).

Chimpanzee caregivers (caregivers) means all Sanctuary technical and husbandry staff providing long term care and services for the chimpanzees.

Contractor/Primary Contractor/Sanctuary Contractor means the nonprofit entity awarded a contract by the Federal Government to establish and operate the chimpanzee Sanctuary system.

Euthanasia means the humane death of a chimpanzee accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress. The method must be consistent with the recommendations of the American Veterinary Medical Association Panel on Euthanasia.

Exhibition means exhibiting chimpanzees to the public for compensation. It specifically excludes limited viewing for educational purposes.

Facility director means the individual responsible for directing the overall activities at the Sanctuary site.

Facility Veterinarian means a person who has graduated from a veterinary school accredited by the American Veterinary Medical Association (AVMA) Council on Education, or who has a certificate issued by the AVMA's Education Commission for Foreign Veterinary Graduates; has training and/or experience in the care and management of nonhuman primates; and has direct or delegated authority for activities involving chimpanzees at the federally funded chimpanzee Sanctuary.

Federal agency means an executive agency as such term is defined in section 105 of title 5, United States Code, and refers to the agency from which the research facility receives a

Federal award for projects involving animals.

Federal Acquisition Regulations (FAR) means the codified rules applicable to contracts, specifically those sections of the FAR (48 CFR chapter 1, part 52) that are applicable to contracts between the Federal Government and a contractor (in this case a private, nonprofit entity under contract to operate the chimpanzee sanctuary system).

Federally-owned chimpanzees mean chimpanzees that have been purchased by, bred by, or donated to a Federal agency for use in biomedical/behavioral research. Chimpanzees whose ownership was subsequently transferred from Federal ownership via written transfer agreements are no longer federally-owned. Newborn chimpanzees generally belong to the same entity that owned the mother at the time of the baby's birth.

Guide means the "Guide for the Care and Use of Laboratory Animals" published by the National Academy of Sciences, Institute for Laboratory Animal Research of the National Research Council.

Housing facility means any land, premises, shed, barn, building, trailer, or other structure or area housing intended to house chimpanzees.

Indoor housing facility refers to any structure or enclosure (e.g., cages, pens, rooms) for maintaining animals in a controlled environment that provides for normal physiological and behavioral needs.

International Species Information System (ISIS) means the organization that provides the chimpanzees in zoos, research facilities, exhibitors, etc., with a unique identification number that can be used to track and account for chimpanzees around the world.

Interstate air transport live animals (IATA) regulations means those regulations and standards covering the air transportation of nonhuman primates developed and implemented by the International Air Transportation Association.

Invasive research (studies) utilizes those procedures that cause more than momentary pain, distress, fear, discomfort, injury, or other negative modalities to a chimpanzee. Any procedure that enters or exposes a body cavity is considered to be invasive. Except as outlined in the CHIMP Act, Sanctuary chimpanzees may not be used in invasive research. Some examples of invasive studies are:

(1) Experimental exposure to a substance that may be detrimental to a chimpanzee's health (e.g., infectious disease, radiation). This does not

include accidental exposures to infectious diseases transmitted from cage mates, or from radiation or other exposures at the time of regularly scheduled or necessary veterinary examinations and treatments;

(2) Any invasion of a body cavity;

(3) Surgery and surgical implantation of devices. Procedures of this nature performed for non research or study purposes are allowable when the Sanctuary staff determine they are needed for veterinary medical or colony management purposes and is in the best interest of the chimpanzee or the chimpanzee colony;

(4) Behavioral studies that cause distress or discomfort, such as induction of a fear response;

(5) Testing of any drug;

(6) Purposeful manipulation of social groups or the removal or addition of individuals in order to conduct behavioral research (e.g., on aggression). Creation and refinement of social groups will be necessary when the animals arrive at the Sanctuary and this should take place only when necessary in regards to colony management and should not be driven by independently initiated research studies;

(7) Restraint unless it is in conjunction with the annual exam or clinical care; and

(8) Darting or anesthesia induction other than at annual exam or in the case of an emergency in which the chimpanzee's well-being is at stake.

National Primate Research Center (NPRC) means those centers supported by the National Center for Research Resources, National Institutes of Health, Department of Health and Human Services, as national resources for providing high-quality nonhuman primate research resources and facilities. As of November 2003, there were 8 such centers.

National Research Council means the committee of the National Academy of Sciences that advises the Federal Government on matters related to science, research, and research resources.

Non-invasive research (studies) means the use of procedures that depend upon close observation of chimpanzee behavior or on medical information collected during the course of normal veterinary care. These procedures do not require removal of the chimpanzees from their social group or environment, or require a separate anesthetic or sedation event to collect data or record observations. Some examples of non-invasive studies are:

(1) Visual observation;

(2) Behavioral studies designed to improve the establishment and

maintenance of social groups. These activities may cause stress as a result of novel interactions between chimpanzees and between chimpanzees and caregivers, but they are not considered invasive as long as they are intended to maximize the well-being of the chimpanzees;

(3) Medical examinations as deemed necessary to oversee the health of the chimpanzees, in the least invasive manner possible. Collection of samples routinely obtained during a physical examination for processing during this time is also considered noninvasive since a separate event is not required;

(4) Administration and evaluation of environmental enrichment used to promote the psychological well-being of the chimpanzees; and

(5) Actions taken to provide essential medical treatment to an individual chimpanzee exhibiting symptoms of illness. This applies only to serious illness that cannot be treated while the chimpanzee remains within the colony.

Non-federally owned chimpanzees mean chimpanzees that have not been purchased by, bred by, or donated to the Federal Government for use in federally supported research projects. In accordance with the CHIMP Act, chimpanzees owned on the date of passage of the CHIMP Act by a National Primate Research Center may enter the Sanctuary system without requiring the NPRC to pay a fee.

Outdoor housing facility (area) means corrals, Primadomes (a prefabricated outdoor housing unit), fenced open areas, or similar structures or areas, for maintaining chimpanzees with access to adequate protection from the extremes of environmental elements and harsh weather conditions.

Outdoor ranging area means an area that allows chimpanzees greater ranging space than corrals or other outdoor housing area, and includes a variety of vegetation, shrubbery, grasses and trees, thereby providing for a fairly unrestricted natural setting for the chimpanzees to engage in species appropriate activities. The area is secured by an outer perimeter barrier.

Project Officer means the individual designated by the Federal Government to represent the contracting officer and interests of the Federal agency, within defined areas, in monitoring and overseeing the chimpanzee Sanctuary system contract.

Sanctuary or federally supported chimpanzee Sanctuary system means the Sanctuary or Sanctuary system established by the Federal Government through contracting with a private, nonprofit entity, for the purpose of carrying out the provisions of the

CHIMP Act of 2000. The system includes a primary Contractor and may include additional subcontractors as required. This Sanctuary system is supported primarily from funds allocated by the NCRR/NIH/DHHS with some matching funds from the nonprofit contractor.

Sanctuary Chimpanzee Care Committee (SCCC) or similar designated committee means the group of individuals designated by the CEO of the Sanctuary that reviews and monitors adherence to the policies, procedures, and regulations at the Sanctuary.

Sanctuary Contractor means the nonprofit, private entities selected by the NCRR/NIH to develop and operate the chimpanzee Sanctuary system. This Contractor is also known as the "primary contractor" for the Sanctuary system.

Sanctuary Director means the individual who provides day to day direction and oversight to the employees responsible for performing the daily tasks at the facility.

Secretary means the Secretary of Health and Human Services or his/her designee.

Subcontractor means a private, nonprofit entity selected by the primary contractor to provide additional Sanctuary services.

Surplus chimpanzees means chimpanzees that are no longer needed in research, and that were used, or were bred or purchased for use in research conducted or supported by the Federal Government.

USDA licensed intermediate handler/carrier means any person, including a department, agency, or instrumentality of the United States or of any State or local government, who is engaged in any business in which it receives custody of animals in connection with their transportation in commerce and who is licensed by the USDA.

Zoonotic disease(s) means diseases that are transmissible from chimpanzees to humans.

§9.3 Sanctuary policies and responsibilities.

(a) *What are the policies and responsibilities governing the Sanctuary system?* It will be the policies and responsibilities of the Sanctuary system to:

(1) Create a safe and species-appropriate physical and social environment for the lifetime care of chimpanzees;

(2) Comply with all applicable provisions of the animal welfare regulations and other Federal, State and local laws, regulations and policies;

(3) Achieve accreditation from appropriate accrediting bodies within a

reasonable time frame mutually agreed upon by the contractor and NCRR;

(4) Prohibit any invasive research on the resident chimpanzees but permit non-invasive studies (as authorized in 42 U.S.C. 287a-3a) that do not compromise the well-being of the chimpanzees and that are approved by an appropriate Sanctuary Chimpanzee Care Committee. Definitions for the terms "invasive" and "non-invasive" are set forth in § 9.2 of this part;

(5) Prohibit exhibition of chimpanzees in the Sanctuary. This policy does not prohibit educational activities that may involve limited viewing of chimpanzees in their environment and that are designed to promote an understanding of chimpanzee behavior, well-being, or importance to the ecological system;

(6) Staff the organization with people with appropriate training and experience; and

(7) Establish a Sanctuary Chimpanzee Care Committee (SCCC) responsible for oversight of the facility programs and operations to ensure the health and well-being of the chimpanzees and the occupational safety of the staff. The Committee must consist of no fewer than five people who should include the sets of experiences or qualifications in the following paragraphs (a)(7)(i) through (v):

(i) A chair (person) knowledgeable of the needs of chimpanzees;

(ii) A veterinarian with chimpanzee care experience;

(iii) A behaviorist with experience in chimpanzee behavior;

(iv) A member of the chimpanzee care staff; and

(v) Member or members from the community, including at least one with affiliation or employment with an animal protection organization as defined in section 9.2 of this part.

(vi) The Sanctuary Chimpanzee Care Committee will:

(A) Oversee and evaluate the chimpanzee care and socialization program;

(B) Review and approve proposed education programs that might interfere with the chimpanzees' well-being or routine activities;

(C) Conduct a formal review of the program on a semiannual basis and submit reports to the Sanctuary director and Board of Directors. The reports must be available for review by the USDA and NIH representatives during site visits;

(D) Establish a mechanism for receipt and review of concerns involving the care of chimpanzees and resolving such concerns; and

(E) Review all study proposals and all euthanasia events. The SCCC

membership may require additional qualified individuals to perform the functions of an Animal Care and Use Committee (ACUC) if and when the need arises. The contractor may establish a separate ACUC. The ACUC must be established in accordance with the applicable provisions of the Animal Welfare Act regulations. Euthanasia events performed for medical or humane reasons will be based upon sound professional veterinary judgment that conforms to current veterinary medical practices and must be in the best interest of the chimpanzee. Euthanasia performed for emergency reasons without an advance review by the SCCC shall be reviewed by the SCCC as soon as possible after the event to assure compliance with established policy.

(8) Establish procedures to prevent any reproduction in the colony through appropriate permanent birth control, preferably by vasectomy of all sexually mature male chimpanzees in the Sanctuary;

(9) Assure that chimpanzees accepted into the Sanctuary are not discharged for any reason, except as provided for in section 481C(d)(3) of the Public Health Service Act as added by section 2 of the CHIMP Act;

(10) Develop procedures for chimpanzees that are seropositive for or harboring infectious agents, or have been previously exposed to infectious agents (whether experimentally-induced or naturally-occurring), that will allow them to be accepted by the Sanctuary and properly housed; the procedures must be submitted to the NCRR for approval;

(11) Develop guidelines for accepting chimpanzees not owned by the Federal Government into the Sanctuary if the conditions are met as outlined in 42 U.S.C. 287;

(12) Assure that the Board of Directors of the primary contractor consist of no more than thirteen (13) individuals and that the conditions governing the terms of the board members comply with the CHIMP Act. The Board of Directors must include individuals with the following expertise and experience as set forth in the CHIMP Act. Subcontractors, if applicable, shall be governed by the policies developed by the Board of Directors of the primary contractor:

(i) At least one veterinarian that is qualified in veterinary care of nonhuman primates. These qualifications may be met through postdoctoral training, experience, or both;

(ii) Individuals with expertise and experience in zoological science and

with knowledge in behavioral primatology;

(iii) Individuals with experience in the animal protection field;

(iv) Individuals with experience and expertise in the field of business and management of nonprofit organizations;

(v) Individuals knowledgeable and experienced in accrediting programs of animal care;

(vi) Individuals with experience and expertise in containing biohazards;

(vii) A member who serves as the Chair of the Board of Directors. This member may be elected or appointed by the Board from individuals identified in paragraphs (a)(12)(i) through (vi) of this section; and

(viii) No member of the board shall have been fined for, or signed a consent decree, for any violation of the Animal Welfare Act.

(13) Assure that a chimpanzee may be removed from the Sanctuary for research purposes only if the Secretary determines that the provisions of the CHIMP Act are met. In accordance with the provisions of the CHIMP Act, the removal of a chimpanzee from the Sanctuary for research requires a recommendation from the contractor's Board of Directors, and publication in the **Federal Register** of a notice of intent for public comment for a period not less than 60 days. The final decision rests with the Secretary. Ownership of chimpanzees removed for that purpose remains with the Sanctuary (or the Federal Government) and all chimpanzees removed for research must be returned to the Sanctuary when the studies are completed.

(b) *Who is responsible for developing or revising Sanctuary policies?* (1) The Sanctuary contractor is responsible for developing, revising, and implementing policies affecting the Sanctuary.

(2) The Federal agency (NCRR/NIH) designated by the Secretary must concur with any changes that substantially change existing policies. The Secretary, or designee, will determine if a policy change will have a substantial impact upon current policy after consultation with the Sanctuary contractor.

§ 9.4 Physical facility policies and design.

(a) *What standards apply to the facility design and physical plant?* (1) The chimpanzee Sanctuary facility must be designed to provide sufficient space and variety of natural or artificial objects to accommodate natural activities of chimpanzees while restricting their movement and range to the defined area. Cages, compounds, and all housing areas shall be designed to withstand the continuous and harsh assaults common when chimpanzees are

confined. It is highly recommended that the Sanctuary administrators engage a design firm that is experienced in designing chimpanzee facilities or demonstrates the capability to involve individuals possessing such experience. Housing areas appropriate for the complex social behavior of chimpanzees should allow them to express a full range of species typical behavior. The facility design and physical plant consists of the following components: indoor design features; outdoor design features; construction and construction materials; physical barriers; shelter; service support space, including storage areas for food, supplies, and equipment; personnel and administrative support space; quarantine and isolation facilities; treatment area; heating, ventilation, and air conditioning (HVAC); food preparation area; and animal waste treatment.

(2) Primary enclosures must promote chimpanzee well-being and provide a safe and sanitary environment for both the chimpanzees and their human caregivers and attendants, safe and sanitary environment for both the chimpanzees and their human caregivers and attendants, and allow for behavioral needs of the species. Daily observation of chimpanzees within the enclosures is required and shall be accomplished with minimal disturbance to the chimpanzees. A housing system shall include indoor and outdoor enclosures that must be kept in good repair to prevent escape and injury to the chimpanzees, promote physical comfort, and facilitate sanitation and servicing:

(i) Indoor areas shall have special areas for social introductions and medical treatment. Indoor design features will generally include rooms, units, gates and passage corridors to allow for transferring and isolating chimpanzees for medical procedures, protection from aggression, etc. The floor surfaces must not be slippery; and the floors and walls should be sealed to facilitate proper sanitation. Doors to the chimpanzee housing areas shall not open directly to the outside, unless they open into enclosed outdoor housing or free-ranging areas. Indoor containment materials must be well anchored, durable, and free of sharp or jagged edges to prevent escape or injury to the chimpanzees. Light fixtures must be sealed to prevent the introduction of moisture. Lighting must be adequate for appropriate animal care and observation, but not disruptive or harmful to the chimpanzees. Furnishings for climbing, resting, swinging, and sleeping must be durable,

nontoxic, comfortable and easily sanitized or replaceable when soiled;

(ii) Primary housing in a Sanctuary must include large outdoor compounds, corrals, or other ranging areas. The Sanctuary should be in an area with a climate suitable for chimpanzees to reduce the need for long-term, indoor housing. Outdoor ranging areas must provide enough space for the formation of social groups of varying sizes, ages and sexes. Chimpanzee facilities must have areas for social introductions and medical treatment. During the design and construction of the facility, special consideration must be given to plans for removing chimpanzees from the ranging area for emergency and routine procedures. Primary barriers must be constructed to prevent escape of chimpanzees and secondary or perimeter barriers should prevent entry of unauthorized persons into the facility. Grasses, hay, bamboo, or other material suitable for nest building should be available in the ranging area and artificial objects that simulate or enhance the natural environment may be used to further promote chimpanzee well being;

(iii) Primary enclosures must be constructed with materials that balance the needs of the chimpanzees with the ability to provide for sanitation. They must have smooth impervious surfaces with minimal ledges, angles, corners, and overlapping surfaces so that accumulation of dirt, debris, and moisture is reduced and satisfactory cleaning and disinfecting are possible. Less durable material, such as non pressure treated wood, can provide a more appropriate environment in some situations (such as runs, pens, and outdoor corrals) and can be used to construct perches, climbing structures, resting areas, and perimeter fences for primary enclosures. Wooden items must be replaced when they become damaged or difficult to sanitize. All primary enclosures must be kept in good repair to prevent escape of and injury to chimpanzees, promote physical comfort, and facilitate sanitation and servicing. Damaged, rusting or oxidized equipment that threatens the health or safety of the chimpanzees must be repaired or replaced;

(iv) Physical barriers must be designed to contain the chimpanzees within the Sanctuary grounds and to prevent the intrusion of unauthorized persons. Some examples of barrier structures include properly and safely designed water moats, strong chain link fencing with curved or "V" shaped barbed wire topping, solid concrete, brick, or pre-cast concrete walls, and electrical fences. Each Sanctuary site

may choose the type of barrier that is suitable for that location;

(v) Outdoor facilities must provide either natural or artificial structures that chimpanzees can use for shelter to escape rain, direct sun, wind, and extreme temperatures. Indoor and outdoor housing units can serve this purpose when chimpanzees are confined to smaller outdoor facilities;

(vi) Personnel and administrative support space must be appropriately designed and provided to adequately accommodate the technical, managerial, professional, and administrative staff;

(vii) Quarantine and isolation facilities are required for the Sanctuary. These facilities must be designed to prevent the spread of undesirable agents from quarantine and isolation rooms to other parts of the facility. These facilities may also be used to isolate incoming chimpanzees to evaluate and to assess their behavior before assimilation into the resident population. Sufficient space must be designed in the area to accommodate a station that provides protective equipment for the staff and others to be worn when entering areas housing the chimpanzees. Shower, toilet and locker facilities must be located within or near the quarantine and isolation areas for preventative health and sanitation reasons. Provisions for enrichment in quarantine areas must also be made;

(viii) An area for treatment of and performing veterinary clinical procedures on chimpanzees must be provided at each Sanctuary site. This area must be constructed and provisioned to perform emergency procedures, including minor surgery and emergency surgical procedures if needed, and complete physical examinations. The Sanctuary must provide facilities for extended care of medical conditions as the need arises. Emergency treatment carts must be available for emergency situations when a chimpanzee requires on-site treatment. Aging chimpanzees present special medical challenges that should be addressed in the preventative medicine and animal health plan; and

(ix) Heating, ventilation, and air-conditioning (HVAC) must comply with the standards of the Guide when chimpanzees must be confined to closed, indoor quarters for isolation, treatment or other situations on a short-term basis. It is critical to provide ventilation that allows chimpanzees to seek a thermo-neutral zone that fits their needs. In general, the design of the Sanctuary facility can be such that the mechanical systems may not be required, except in tightly closed areas. The use of shelters, nesting materials,

circulating fans, and space heaters are examples of means that address the comfort needs of the chimpanzees.

(x) Support facilities must be appropriate for the goals of the facility. In accordance with the Guide and the Animal Welfare Regulations, and currently available data, several types of functional support areas are required, including veterinary treatment and surgery, quarantine, food storage, bedding storage (if used), dry storage, administrative space, and equipment.

(xi) Animal waste from the Sanctuary must be properly treated to remove known hazardous agents before discharging it into the environment in accordance with currently acceptable and effective waste treatment procedures including current industry standards and Federal, State, and Local governmental guidelines and regulations.

(b) *What security measures are required for the Sanctuary?* The Sanctuary must provide adequate security against unauthorized entry, sabotage, malicious damage, theft of chimpanzees and property, and minimize any chance of escape by a chimpanzee. The security staff must have training and/or experience in methods and equipment designed to detect possible security breaches and the ability to respond to security events in a timely and effective manner. Perimeter containment shall be used to protect the compound housing the chimpanzees consistent with the recommendations of the Guide.

(c) *Is the Sanctuary required to develop disaster and escaped animal contingency plans?* (1) The Sanctuary facility must prepare contingency plans outlining simple and easy to follow plans for dealing with natural and manmade disasters and steps to be taken in case a chimpanzee escapes from the compound. Separate plans will be developed for disasters and recovery of escaped chimpanzees. These plans must be prepared prior to the arrival of chimpanzees at the facility. All employees with responsibilities under the plans must be familiar with the contents of each plan and able to execute the plans when a situation occurs. Incidents and actions taken must be documented for future reference.

(2) As a minimum, the disaster plan must identify disasters likely to occur in the area, including severe rainstorms, crippling snowstorms, forest fires, sabotage and hurricanes, that may endanger the lives of the chimpanzees or staff, the names and telephone numbers of persons to contact in the event of an emergency, procedures to be

followed in collecting and securing chimpanzees, local or state services that may be required, and the person or persons responsible for determining final action. Personnel required to respond to a disaster must obtain any special identification cards needed to report to duty. Other elements considered appropriate to addressing disasters should be added by the Sanctuary contractor if necessary.

(3) The design of the perimeter security must be such that chance for escape of a chimpanzee is minimized. A well-prepared, properly crafted plan can lead to decisive actions being taken to recapture the chimpanzee in a timely fashion. The plan must be designed to minimize or eliminate injury to the chimpanzee and the persons attempting to gain control of the escaped chimpanzee. Details must include step-by-step procedure options for capture, person(s) to contact, person(s) or organizational unit(s) required to respond to an alert due to an escape, transportation back to the Sanctuary facility, and how corrective actions will be implemented to prevent future incidents.

(d) *Incorporation by reference.* The Guide for the Care and Use of Laboratory Animals published by the National Research Council (Guide), 1996, International Standard Book Number 0-309-05377-3, is incorporated by reference in this section. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the publication from the National Academy Press, 2101 Constitution Avenue, NW., Lockbox 285, Washington, DC 20055; or you may order it electronically via the Internet at <http://www.nap.edu>; or view it online at <http://oacu.od.nih.gov/regs/guide/guidex.htm>. You may inspect a copy at NIH, NCR, 1 Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20817-4874, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

§ 9.5 Chimpanzees ownership, fees, and studies.

(a) *Who owns the chimpanzees in the federally supported Sanctuary?* The Federal government retains ownership of chimpanzees owned by the Federal government at the time they enter the Sanctuary system. Non-federally owned or supported chimpanzees will be

owned by the Sanctuary. The chimpanzees shall continue to be maintained in the Sanctuary throughout their lifetime and shall not be discharged from the Sanctuary except as specifically indicated in the CHIMP Act.

(b) *Is there a charge for placing chimpanzees in the Sanctuary?* No fees shall be charged for federally owned or supported chimpanzees entering the Sanctuary. Chimpanzees that were owned by a NPRC when the CHIMP Act became effective are also admitted without payment of fees. Fees for maintenance of the chimpanzees alluded to above are provided for in the contract between the Federal Government and the Sanctuary contractor.

(c) *May the Sanctuary agree to accept chimpanzees that are not owned by the Federal Government?* The Sanctuary may accept chimpanzees that are not owned by the Federal Government subject to the following conditions:

(1) Ownership of the chimpanzee must be transferred to the Sanctuary;

(2) Fees for these chimpanzees may be levied based on a range of considerations that include most importantly, the well-being of the chimpanzee, and secondarily factors that include (but are not limited to) the resources available to support the chimpanzee, the health, age and social history of the chimpanzee, and other relevant factors affecting the cost of caring for the chimpanzee;

(3) Available space exists in the Sanctuary; and

(4) An agreement exists between the Sanctuary system and the NCRR/NIH documenting that the chimpanzee may be brought into the Sanctuary.

(d) *What additional conditions apply when non-governmentally-owned chimpanzees transfer to the chimpanzee Sanctuary?* The following additional conditions apply when non-governmentally-owned chimpanzees transfer to the chimpanzee Sanctuary:

(1) Chimpanzees transferred to the Sanctuary sites must be permanently incapable of reproduction, for example, by vasectomy or tubal ligation;

(2) Complete histories must accompany each chimpanzee. Any chimpanzee missing documentation for any period of research or other use may not be transferred to the Sanctuary without the concurrent authorization of the Sanctuary contractor's Board of Directors and the NCRR; the records may be created and retained in electronic form; and

(3) Appropriate screening of each chimpanzee must be performed to assess the likelihood of the chimpanzee

being a health or safety threat to the care staff, and/or other chimpanzees.

(e) *What are the criteria for acceptance and the fees for admission into the Sanctuary for non-governmentally-owned chimpanzees?* The chimpanzee Sanctuary contractor, in conjunction with the NCRR, must establish criteria and a fee system for acceptance of non-governmentally-owned chimpanzees. Funds collected for this purpose must be accounted for and used to help defray the expenses incurred in operating the Sanctuary.

(f) *Under what circumstances might a chimpanzee from the Sanctuary be returned to research at a United States research facility?* (1) The CHIMP Act provides details for the return of chimpanzees to research for a specific need as determined by the Secretary. While the likelihood of a chimpanzee from the Sanctuary being returned to research is remote based upon current consensus, the CHIMP Act does provide for such event. The Act lists several conditions that must be met prior to initiating any research on a chimpanzee in the Sanctuary and before the Secretary can grant approval. These conditions are:

(i) The chimpanzee in question possesses unique characteristics (based upon prior use or medical history) that are not found in other chimpanzees outside of the Sanctuary;

(ii) Technological or medical advances have occurred that were not available at the time the chimpanzee was accepted into the Sanctuary and that such advancement can and will be used in the research;

(iii) The research is essential to an important public health need;

(iv) The research design involves minimal pain, physical or psychological harm, distress, and disturbance to the chimpanzee or social group.

(2) The evaluation by the Board of Directors of the Sanctuary of whether the proposed research satisfies the criteria above will be forwarded to the Secretary for a final determination. Prior to rendering a final decision, the Secretary will publish in the **Federal Register** the proposed findings of the Secretary, the findings of the Board of Directors, and the evaluation by the Secretary. The Secretary will solicit public comment on the proposal for not less than 60 days before making a final decision. This process is designed to ensure a thorough review of the proposal, including input from the public, and to reduce or eliminate arbitrary findings by the Board of Directors. An additional condition for approved use is that the applicant for such use has not been fined or signed

a consent decree for any violation of the Animal Welfare Act.

§9.6 Animal care, well-being, husbandry, veterinary care, and euthanasia.

(a) *What are the requirements for promoting the well-being of Sanctuary chimpanzees?* The goal of chimpanzee housing and management in the Sanctuary is to promote the chimpanzees' well-being. Long-term care staff shall have the expertise and the commitment to plan, administer, and evaluate the effectiveness of the well-being program. The staff behaviorist will evaluate the well-being of individual chimpanzees and develop programs to improve the life of Sanctuary chimpanzees in general.

(b) *What are the provisions for daily chimpanzee husbandry and care?* Adequate and proper care for chimpanzees in the Sanctuary must be provided with respect to physical environment, housing and husbandry, behavioral management, and population management and control. Specific requirements include the following:

(1) Physical Environment/Husbandry/Housing. (i) *Husbandry.* Chimpanzees must have access to food, water, and bedding (if appropriate) at all times, unless medical or behavioral conditions dictate otherwise. Husbandry procedures shall represent current policies and practices and conform to standards set by a nationally recognized accrediting association. Indoor primary enclosures must be cleaned at least once daily or as often as required to maintain a clean and healthful environment. Outdoor enclosures must be monitored and, if necessary, a plan to handle excessive waste accumulation must be established and implemented as needed. Outdoor ranging areas as a rule will not require a routine cleaning schedule, but must be monitored and maintained if there is an excessive accumulation of waste that is unsanitary, or when other potentially unhealthy conditions exist. Feeding and watering implements must be sanitized at intervals required to maintain them in a sanitary condition. The minimum interval shall be as stated in the "Guide;"

(ii) *Indoor housing.* Indoor housing areas shall provide sufficient space for chimpanzees to perform species-typical behavior and expression. Examples of such activities include but are not limited to natural movements, climbing, swinging, resting, group interactions, sleeping, etc. At a minimum, chimpanzees confined to cages, runs, or similar enclosures shall be housed in pairs or larger groups unless contraindicated for medical, behavioral or other justifiable reasons. These

enclosures must be designed to allow any member of the group to disengage from aggression by other chimpanzees through the provision of climbing devices, resting boards, sufficient space, or accessibility to adjoining cages or outdoor cages. Visual, tactile, and auditory contact should be maintained where possible. Primary enclosures must be constructed of sturdy materials that will properly contain chimpanzees. Cages and holding rooms, or similar units, must be capable of being readily sanitized. Primary enclosures will be cleaned as often as required to provide a clean and healthful environment. The Sanctuary must have special areas for social introductions and medical treatment. The design of primary enclosures must be such to allow for shifting of chimpanzees during cleaning procedures to prevent them from being injured during the sanitation process;

(iii) *Outdoor housing.* Primary housing in the Sanctuary must include outdoor compounds or other ranging areas. Enclosures must minimize the potential for escape of chimpanzees and entry of unauthorized persons into the facility. The design must include an area for staff persons to separate themselves from chimpanzee enclosures and the outer perimeter. Outdoor spaces in the Sanctuary must include some element of their natural habitat such as trees, shrubs, grasses, hills, water for drinking, and natural or artificial shelter for retreat from inclement weather. Outdoor ranging areas should provide enough space for the formation of groups or families of varying sizes, ages, and sexes; and

(iv) *Housing conditions.* All indoor and outdoor enclosures must be kept in good repair to prevent escape or injury to the chimpanzees, promote physical comfort, and facilitate sanitation and servicing. Damaged, rusting or oxidized equipment that threatens the health or safety of the chimpanzees must be repaired or replaced promptly.

(2) *Behavioral management.* (i) The federally supported chimpanzee Sanctuary must employ a behavioral scientist knowledgeable in primate behavior and socialization requirements. This individual shall provide primary leadership in developing, implementing, and monitoring the chimpanzee behavioral guidelines for the Sanctuary. Each site must provide sufficient staff technician time to adequately monitor and oversee the activities of the resident chimpanzees;

(ii) *Environmental enrichment and animal well-being.* The staff behaviorist will evaluate the well-being of individual chimpanzees, and develop

programs to improve the life of Sanctuary chimpanzees in general. Enrichment of the environment for chimpanzees is required within a federally supported Sanctuary. The goal of all chimpanzee housing and management is to promote a high degree of well-being. The Sanctuary must provide for the expertise to plan, administer, and evaluate the effectiveness of the well-being program. The staff behaviorist will evaluate the well-being of individual chimpanzees, and develop programs when needed to improve the life of Sanctuary chimpanzees in general. In developing such programs the behaviorist will access individual chimpanzee experimental and housing history. An environmental enrichment program must be in place to encourage the expression of natural behavior such as social interaction, locomotion, climbing, foraging, resting, playing, manipulating objects, and nest building. Enrichment should be emphasized for chimpanzees that must be confined to smaller, indoor spaces. Chimpanzees must be able to retreat from areas where they feel threatened or agitated by close human encounters or encounters with other chimpanzees;

(iii) *Socialization.* The Sanctuary shall provide an environment that provides the opportunity for chimpanzees to live in a social setting that is compatible with their social needs. In most cases, social housing is an important means of enriching chimpanzee activities. Chimpanzees may be housed individually only if required for quarantine, medical reasons, or behavioral reasons, such as for chimpanzees that have failed several socialization attempts;

(iv) *Nesting, sleeping, and resting.* The Sanctuary must contain sufficient outdoor or ranging space and structures (natural or artificial) for the chimpanzees to build nesting areas for sleeping and resting. The site shall not be located in an area where it is noisy or frequently interrupted by human activity;

(v) *Feeding.* In the native environment, chimpanzee diets consist mainly of fruits and vegetables, insects and occasional small mammals. Chimpanzee foraging and feeding activities occupy a large portion of their waking hours, and these critical behaviors must be accommodated in the Sanctuary facilities. The Sanctuary ranging area should include some of the natural diet consumed in the wild where possible (e.g., leaves, wild fruit, and insects). The chimpanzees must be supplied with a commercially prepared diet, even when the chimpanzees are

housed in outside areas, to ensure proper nutrition. Diets shall be supplemented with natural foods when housed indoors or in indoor/outdoor enclosures. This supplementation may also be desirable for chimpanzees housed in large ranging areas. Feeding techniques that are challenging to the chimpanzees are recommended to add variety and enrichment opportunities. Aggressive behavior during feeding must be anticipated and managed to prevent serious injury to the chimpanzees. The special needs of aged chimpanzees must be considered and addressed as they may be sick, have limited movement capabilities, or have other conditions that require special considerations;

(vi) *Play activities.* The Sanctuary must provide ample space or objects for chimpanzees to engage in play activities that are considered appropriate for the species; and

(vii) *Chimpanzee training.* Many chimpanzees can be trained through positive reinforcement to cooperate with a variety of veterinary and chimpanzee care procedures. Efforts must be made to develop or maintain this capability for chimpanzees housed in the Sanctuary to the extent possible.

(3) *Population management and control.* Reproduction of chimpanzees is prohibited in the Sanctuary. Therefore, males must be sterilized by vasectomy before acceptance into the Sanctuary facility or housed apart from females until they are sterilized. Vasectomies are preferable because of their minimal invasiveness and because vasectomies can be validated through laboratory testing of semen. Seminal collection techniques must be carefully evaluated to avoid painful stimuli. Other proven methods of birth control may be used under special conditions deemed appropriate by the Facility Veterinarian and SCCC. The Facility Veterinarian will determine the appropriate test(s) to use to validate sterility. The vasectomy should be performed by a veterinarian experienced in performing vasectomies in chimpanzees. Documentation must accompany each male accepted by the Sanctuary system attesting to the fact that the male has been vasectomized and laboratory tests are negative for sperm. In instances where it is not possible to perform a vasectomy before arrival at the Sanctuary due to extenuating circumstances (such as a lack of on-site expertise), that particular male must be isolated at the Sanctuary from the females until the procedure is performed and the required tests are performed and found to be acceptable.

(c) *What are the requirements for an adequate veterinary care and animal*

health program? (1) *Veterinary care.* The Sanctuary staff must provide sufficient resources of personnel, equipment, supplies, and facilities to enable the provision of adequate veterinary care as set forth in the Guide and in the American College of Laboratory Animal Medicine document on "The Provision of Adequate Veterinary Care" available on the Internet at <http://www.aclam.com>. The Sanctuary must provide adequate veterinary care to assure the health of the chimpanzees. If the Sanctuary houses chimpanzees with infectious diseases, it must have a veterinarian knowledgeable in the infectious diseases and care of chimpanzees. The Facility Veterinarian is responsible for establishing and implementing a health monitoring system specifically designed to meet the health requirements of chimpanzees in the Sanctuary. The veterinarian must use appropriate professional judgment based upon current veterinary practices when dealing with the health and well-being of the chimpanzees in the Sanctuary.

(2) *Preventative medicine and animal health program.* The prevention of disease, metabolic conditions, and injury must be a priority focus of the Facility Veterinarian, managers, and caregivers staff. A quality preventative medicine and animal health program requires the participation of all employees having direct contact with the chimpanzees in the Sanctuary. The goal of this program shall be to maintain the chimpanzees in good health, taking into consideration each animal's age, medical history, experimental history, behavior patterns, prognosis for recovery, and current veterinary medical practices. It shall be the responsibility of the Facility Veterinarian to develop and implement the preventive medicine and animal health program. Other persons may perform some aspects of the program under the direction of the veterinarian. The veterinarian must provide guidance to all personnel involved in the care of chimpanzees to ensure appropriate handling, observation, treatment and oversight of surgery, post-surgical care, immobilization, sedation, analgesia, and anesthesia. Chimpanzees must receive an annual physical examination unless the Facility Veterinarian determines that a different interval is needed.

(3) *Quarantine and stabilization of newly arrived animals.* Newly received chimpanzees must be quarantined for a period for physiological, psychological, and nutritional stabilization before their introduction to the rest of the group. The stabilization period should be lengthened appropriately if the

chimpanzee has a significant medical problem or if abnormal medical findings are detected during the quarantine period. If the chimpanzee has not been given a complete physical examination within six months, an examination must be conducted during the stabilization period. During this period, the following additional procedures will be performed:

(i) Tuberculin tests must be negative for two (2) consecutive tests before the chimpanzee is released from quarantine. Any chimpanzee that is suspected of harboring the TB organism, or that is diagnosed with TB will be isolated and treated until determined by the Facility Veterinarian to be of no health risk to other chimpanzees or humans. The Facility Veterinarian may recommend euthanasia in those cases that do not respond to therapy and consequently the chimpanzee experiences undue pain and suffering that cannot be alleviated. The procedures noted under § 9.6(d) must be observed if euthanasia is necessary.

(ii) Fecal samples must be checked for parasites and parasitic ova.

(iii) A complete blood count and serum chemical panel must be obtained.

(iv) Additional serum for banking and/or testing shall be obtained as appropriate by the Facility Veterinarian.

(v) If the donating facility did not test for the appropriate viruses, the Sanctuary must perform a viral panel and serology for the various chronic hepatitis viruses and HIV.

(vi) Additional tests or procedures may be required if deemed necessary by the Facility Veterinarian.

(4) *Vaccination.* Chimpanzees are susceptible to many of the vaccine-preventable diseases of human childhood. Appropriate vaccines should be considered and administered if deemed necessary to protect the chimpanzees in the Sanctuary. Measles, mumps, and rubella occur predominantly as asymptomatic diseases. Vaccination protocols should be changed with the introduction of new vaccines and with the expanding knowledge of chimpanzee disease susceptibility. Additional vaccines may be warranted under specific conditions (e.g., rabies, influenza, encephalomyocarditis virus vaccine). The need for adjusting or changing the vaccines will be determined at the discretion of the Facility Veterinarian.

(5) *Parasite detection, control, and treatment.* Parasite control is an important aspect of a preventative medicine program for chimpanzees. Prophylactic de-worming must be considered and provided for newly

arrived chimpanzees if deemed appropriate by the Facility Veterinarian.

(6) *Observation, diagnosis, prevention and treatment of illness and injury.* The Sanctuary must implement appropriate methods for disease surveillance and diagnosis of diseases. Upon diagnosis of disease, treatment must be initiated unless the Facility Veterinarian determines that treatment is inappropriate for medical, ethical, or humane reasons. A person trained to recognize signs of disease must observe chimpanzees for signs of illness, injury, or abnormal behavior. The Facility Veterinarian must approve all medication or therapy plans. The staff behaviorist will develop and implement plans addressing abnormal behavior in chimpanzees. Observations must be made at least once every day including holidays and weekends. More frequent observations are warranted during postoperative recovery or when chimpanzees are ill or have an injury. Professional judgment should be used to determine the adequate frequency and quality of observations. If an entire group of chimpanzees is known or believed to be exposed to an infectious agent (e.g., *Mycobacterium tuberculosis*), the group may be kept intact during the process of diagnosis, treatment, and control. Methods of disease prevention, diagnosis, and therapy must comply with those currently accepted in veterinary medical practice. Diagnostic laboratory services facilitate veterinary medical care and can include gross and microscopic pathology, clinical pathology, hematology, microbiology, clinical chemistry, and serology. It is important that arrangements with diagnostic laboratories be established before chimpanzees arrive at the Sanctuary.

(7) *Physical and chemical restraint.* The Sanctuary should minimize the use of physical and chemical restraint. Chimpanzees in the Sanctuary should be trained to permit certain procedures with minimal or no restraint. Such procedures may include injections, dosing or other treatments, and cage-side health observations. Due to the strength of chimpanzees, consideration must always be given to the safety of the caregivers. For this reason, as well as the requirement for certain necessary interventions (e.g., complete exams, treatments, tissue collections, and transfer), chemical sedation may sometimes be necessary. A qualified individual must continuously monitor recovery from chemical restraint until the chimpanzee has regained full ambulatory capability and is alert enough to move about the cage and is alert enough to avoid injury. Padding of

the enclosure may be required if there is a danger of injury (falling) while recovering from anesthesia or heavy sedation. In most instances, chimpanzees should be isolated from their cage mates during the sedation process which is to include recovery. Physical restraint should rarely be necessary in the Sanctuary. When it is necessary to use physical restraint measures, due consideration must be given to the temporary or permanent effects upon the chimpanzee and human and animal safety concerns. Chimpanzees should be physically restrained only for the time required to complete the task at hand.

(8) *Surgery and post-surgical care.* Surgery on Sanctuary chimpanzees may be required to improve their health or repair injuries. Except for emergency situations in the following paragraph, survival surgery on Sanctuary chimpanzees must be performed under aseptic conditions and in facilities that meet the requirements of the accrediting association and must be under the direction and supervision of a veterinarian qualified to perform surgery on nonhuman primates. When emergency situations require immediate surgical intervention under less than aseptic conditions, veterinary medical judgment must be employed with the best possible technique practiced. During the post-surgical recovery period, the chimpanzee must be in a clean, dry area free from objects that might cause inadvertent harm to the chimpanzee. The chimpanzee must be constantly monitored by trained personnel until fully recovered from the anesthesia and fully ambulatory. Particular attention must be given to thermoregulation, cardiovascular and respiratory function, and postoperative pain or discomfort during recovery from anesthesia. Detailed medical and surgical records must be maintained including observations, any drugs or supportive care given, and times and dosage of medications given to the chimpanzee. The records may be created and retained in electronic forms. After anesthetic recovery, monitoring may be less intense but should include attention to basic biologic functions of intake and elimination, behavioral signs of postoperative pain, monitoring for post-surgical infections and care of the surgical incision, bandaging, and timely removal of skin sutures, clips, or staples.

(9) *Analgesia.* Relief of pain is a component of adequate veterinary care that must be provided to chimpanzees in the Sanctuary. The responsibility for assuring that pain management is current and in accordance with

acceptable veterinary medical practices rests with the Facility Veterinarian. Sanctuary caregivers must be properly trained to recognize when a chimpanzee is in pain, and provide the appropriate response to alleviate or report the condition to veterinarian or, in the absence of the veterinarian, to another individual capable of initiating the procedures necessary to reduce or eliminate the pain. Methods used to relieve the pain must be in accordance with current veterinary or medical practices, and documented in the chimpanzee medical or surgical records. These records will be available for review by USDA and NIH representatives. The records may be created and retained in electronic form.

(10) *Emergency, weekend, and holiday care.* Chimpanzees must be cared for by qualified personnel on a daily basis, including weekends and holidays, to safeguard their well-being. Emergency veterinary care must also be available during these times. In the event of an emergency, Sanctuary security should be able to reach someone that can adequately respond to such emergency. Notification procedures must be documented in the form of operating procedures and a list of persons to call. The list must include home and/or mobile telephone numbers. The operating procedure and phone numbers must be placed in a location that it is available to the appropriate individuals when needed. A copy of the disaster plan must also be available in a location that makes it readily available to the staff when needed.

(d) *Under what circumstances is euthanasia permitted?* As stated in section 481C(d)(2)(I) of the Public Health Service Act as added by section 2 of the CHIMP Act, none of the chimpanzees may be subjected to euthanasia except as in the best interest of the chimpanzee involved as determined by the SCCC and the Facility Veterinarian. Therefore, euthanasia for medical or humane reasons is permitted. Euthanasia may be permitted for reasons of health or quality of life of the individual chimpanzee, including for disease, in connection with trauma, complications of aging, or for other humane reasons. Methods of euthanasia must be consistent with the most recent report of the American Veterinary Medical Association Panel on Euthanasia (2002). When euthanasia is performed, the veterinarian will determine the appropriate agent and it will be administered only by properly trained personnel under the direction of the Facility Veterinarian. The decision to

perform euthanasia will be made by the veterinarian in consultation with the Facility Director or Deputy Director. The SCCC will participate in the decision in non-medical emergencies. All euthanasia decisions must be reviewed by the SCCC, preferably prior to euthanasia. In emergencies, where euthanasia has to be performed immediately by the Facility Veterinarian, the circumstances and the decision by the Facility Veterinarian will be presented at the next scheduled or special meeting of the SCCC. The NCRR Project Officer must be notified of the euthanasia event within 72 hours by electronic or telephonic means. Euthanasia of individual chimpanzees may negatively affect the care staff and appropriate counseling and psychological support should be considered.

(e) *Incorporation by reference.* The Guide for the Care and Use of Laboratory Animals published by the National Research Council (Guide), 1996, International Standard Book Number 0-309-05377-3, is incorporated by reference in this section. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the publication from the National Academy Press, 2101 Constitution Avenue, NW., Lockbox 285, Washington, DC 20055; or you may order it electronically via the Internet at <http://nap.edu>; or view it online at <http://oacu.od.nih.gov/regs/guide/guidex.htm>. You may inspect a copy at NIH, NCRR, 1 Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20817-4874, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

§9.7 Reproduction.

Chimpanzee reproduction is prohibited in the Sanctuary. Therefore, males must be sterilized by vasectomy before acceptance into the system, or, as a temporary measure, housed apart from females until they are sterilized. Vasectomies are advisable because they are minimally invasive and because effectiveness of the vasectomy can be validated through laboratory testing of semen. Seminal collection techniques must be carefully evaluated to avoid painful stimuli. Other proven methods of birth control may be used under special conditions deemed appropriate by the Facility Veterinarian and SCCC.

The Facility Veterinarian must determine the appropriate test(s) to use to validate sterility. A veterinarian experienced in performing vasectomies in chimpanzees should perform the operation. Documentation must accompany each male accepted to the Sanctuary system attesting to the fact that the male has been vasectomized and laboratory tests confirm that semen samples are negative for sperm.

§ 9.8 Animal records.

(a) *What records must be maintained for chimpanzees in the Sanctuary and how are they managed?* (1) Contractors and Subcontractors operating the Federal chimpanzee Sanctuary system must maintain appropriate records to allow for accountability and disposition of chimpanzees under their care as required by the USDA Animal Welfare Regulations (9 CFR 2.35). The records may be created and retained in electronic form.

(2) The animal records currently required by the USDA Animal Welfare Regulations are also required for these standards. All chimpanzees must be tracked for life by a single agency with demonstrated expertise and capability in this area. Chimpanzees must be individually and permanently identifiable.

(3) Retrievable records must be maintained for a minimum of three years beyond the disposition or death of each chimpanzee in accordance with the Animal Welfare Regulations section 2.35(f). Original records or a copy must be transferred if the chimpanzee moves to a different facility. The records must include standard information, including permanent individual identification, research use(s), reproductive status (past and present), a summary or copy of the medical and behavioral history, the sire's identification number (if available), the dam's identification number, birth date, sex, and date acquired by the Sanctuary. The disposition date must also be noted, if applicable, including whether the chimpanzee died or was transferred to another site in the Federal Sanctuary system. The records may be created and retained in electronic form.

(4) The contractor and any subcontractor(s) operating the federally supported chimpanzee Sanctuary must provide special, quarterly and annual progress reports to the designated Federal officials as identified in the contract. The annual report must also contain a statement that certifies the Sanctuary is in full compliance with these Standards of Care regulations.

(b) *What are the rules governing the disposition of necropsy records?* The

CHIMP Act requires that necropsy records from chimpanzees previously used in federally funded research projects be made available on a reasonable basis to investigators engaged in biomedical or behavioral research. In order to comply with this provision, the contractor for the Sanctuary system must devise a plan that will allow interested parties to contact the Sanctuary and receive necropsy records when they become available. Records may be provided free of charge but requesters may be required to pay for packaging and shipping costs. The records may be created and retained in electronic form.

§ 9.9 Facility staffing.

How many personnel are required to staff the chimpanzee Sanctuary and what qualifications and training must the staff possess?

(a) The professional, managerial, and support staff must be sufficient to support the scope and diversity of the activities and chimpanzee population of the Sanctuary. The level of staffing shall be adequate to ensure that the chimpanzees receive appropriate health care, are well cared for, and the administrative and fiscal operations are sound and in keeping with current practices required by NCRR, NIH;

(b) There must be a sufficient number of appropriately trained animal care and technical personnel to provide appropriate care to the chimpanzees at all times, including evenings, weekends and holidays. The number of animal care staff to chimpanzee ratio should be adjusted as experience is gained during the operation of the Sanctuary;

(c) Animal care personnel must be properly trained or experienced in providing care for the chimpanzees. Caregivers must have experience or be trained in the daily care of chimpanzees, including husbandry, enrichment techniques and observation for illness. Personnel must be familiar with regulations, guidelines and policies that relate to their duties, including basic emergency care. The Sanctuary must provide for formal or on-the-job training to facilitate the effective implementation of a high-quality and humane care program for the chimpanzees. The Sanctuary CEO is responsible for assuring that staff hired to care for the chimpanzees have a working knowledge of the physiological and behavioral needs of chimpanzees. A formal training program for new employees shall be developed and implemented. The Sanctuary shall develop a mechanism to document employee-training activities that include chimpanzee biology, husbandry,

behavior, signs of well-being vs. illness or maladaptation, zoonoses, and enrichment and socialization techniques, among other relevant subject areas. Training must be documented and available for review by regulatory, accrediting, and other agencies with a need to know;

(d) The veterinarian(s) responsible for providing veterinary medical care must be knowledgeable of nonhuman primate health care needs through training or experience and capable of providing appropriate care to the chimpanzees in the Sanctuary. Sufficient veterinarians must be available to administer the veterinary medical program;

(e) The Facility Director must be a person with experience in chimpanzee care and socialization techniques. In addition, the Director must have management and administrative experience;

(f) The Behaviorist(s) must be qualified through training and experience. The person must have formal training in one of the behavioral sciences and experience working with and observing nonhuman primates, or have developed expertise through at least four years of experience working with chimpanzees;

(g) The Biosafety Officer must have experience in developing and monitoring biohazards and dealing with biosafety issues related to captive nonhuman primates. Experience in these areas dealing specifically with chimpanzees is desirable;

(h) Animal Resource Managers or Supervisors must have experience working with nonhuman primates and demonstrate the skills and ability to supervise personnel; and

(i) The remaining support staff must possess the skills, knowledge and/or experience required to perform their duties.

§ 9.10 Occupational Health and Safety Program (OHSP) and biosafety requirements.

(a) *How are employee Occupational Health and Safety Program risks and concerns addressed?* (1) It is the responsibility of the Chief Executive Officer (CEO) of the Sanctuary to assure that an Occupational Health and Safety Program (OHSP) program is developed and implemented. The CEO or other responsible person may delegate responsibility for the monitoring activities associated with oversight and monitoring of the program. The Sanctuary must design and implement a plan that is consistent with current veterinary medical practices. A plan shall be considered adequate and

appropriate if it meets the guidelines and standards found in the Guide.

(2) An effective OHSP must be established at each federally supported chimpanzee sanctuary site. The program must be designed to protect all personnel, including visitors, from occupational and accidental exposure to known hazards associated with providing care or other services for chimpanzees. A health professional knowledgeable in occupational health as it relates to staff working with nonhuman primates must provide input for the OHSP. Employees in managerial and supervisory positions are obligated to provide sufficient training and oversight as necessary to minimize or eliminate exposure to occupational hazards. Employees providing day-to-day care shall follow the procedures established by the Sanctuary to avoid occupational health hazards and accidental exposures or injuries. An effective program is based upon several factors. These include knowing the hazards involved (risks), avoiding and controlling exposures (preventative measures), training and education, establishing rules and guidelines (standard operating procedures), consistency, record keeping and monitoring (documentation), and institutional and individual commitment and coordination. The Sanctuary OHSP must be reviewed with each employee at risk, and an acknowledgment of this review must be signed or initialed by the supervisor or training officer (or equivalent) and the employee.

(3) Qualified individuals with experience and training in OHSP must oversee the development of this program. The program may be directed and coordinated by the contractor's staff or consultants, or a combination of both. At a minimum, the program must address the following:

- (i) An overview of the program and the institutional commitment to the OHSP;
- (ii) OHSP training and education for employees working with or having exposure to chimpanzees;
- (iii) Facility design and operation as needed to address occupational health and safety issues;
- (iv) Hazard identification and risk assessment;
- (v) Personal protective equipment;
- (vi) Prevention and treatment procedures;
- (vii) Personal hygiene;
- (viii) Rules and guidelines for avoiding exposures;
- (ix) Record keeping and monitoring procedures; and

(x) Monitoring overall performance of these areas.

(b) *How are biosafety concerns addressed?* (1) The chimpanzees may contract natural infections of zoonotic importance that can contaminate the environment or otherwise present biohazards to humans and other chimpanzees. Certain chemicals used in the routine sanitation of facilities and equipment can be hazardous if not properly used or disposed. Other conditions may also occur where temporary or permanent hazards are present. Appropriate operating procedures and policies must be established to address these areas. The contractor for the Sanctuary system is responsible for instituting and administering an effective biosafety program that addresses the biosafety hazards at that particular site. The program should include: identifying biohazards, outlining practices and procedures to be followed, providing personal safety equipment or protective clothing and equipment, and a description of the facility requirements for working with hazardous agents or materials. Policies and procedures must be implemented to avoid exposure to environmental and animal hazards. Biosafety must be included in the training program for all Sanctuary employees. The Sanctuary must use current accepted practices and publications prepared by the CDC, NIH, and professional societies specializing in biosafety in establishing a program. The input and guidance of personnel trained or experienced in biosafety are essential.

(2) Biosafety issues in the chimpanzee Sanctuary are likely reduced compared to those encountered in a biomedical research environment since research involving toxicity testing, or radioisotopes are prohibited at the Sanctuary. For those chimpanzees that arrive in the Sanctuary that are chronically infected with viruses, blood sampling and health assessments will be needed, but no invasive research will be allowed at the Sanctuary. The major biosafety concerns relate to chimpanzees that were exposed to experimental agents prior to arriving at the Sanctuary and that still present a hazard due to chronic infection (e.g., persistent bacteremia or viremia). Complete records of both clinical and experimental agent exposure must accompany each chimpanzee sent to the Sanctuary. The donating facility must also provide recent testing, e.g., serology, virus culture, histology, so that the Sanctuary staff are fully aware of the health condition of the arriving

chimpanzee. The records may be created and retained in electronic form.

(c) *Incorporation by reference.* The Guide for the Care and Use of Laboratory Animals published by the National Research Council (Guide), 1996, International Standard Book Number 0-309-05377-3, is incorporated by reference in this section. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the publication from the National Academy Press, 2101 Constitution Avenue, NW., Lockbox 285, Washington, DC 20055; or you may order it electronically via the Internet at <http://www.nap.edu>; or view it online at <http://oacu.od.nih.gov/regs/guide/guidex.htm>. You may inspect a copy at NIH, NCRR, 1 Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20817-4874, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

§9.11 Animal transport.

(a) *What are the standards for transporting chimpanzees between other facilities and the Sanctuary?* The transportation of chimpanzees from the facility where they are housed to the Sanctuary by surface or air must be in accordance with the requirements set forth in the Animal Welfare Regulations (9 CFR part 3, subpart F) and international air transportation regulations and guidelines. Because the size of chimpanzees varies greatly, the transportation vehicle and/or primary enclosure must provide adequate space for the chimpanzee to make postural adjustments and provide adequate ventilation. Adequate ventilation is interpreted to mean the chimpanzee is able to maintain normal respiratory function and body temperature regulation. The Sanctuary Contractor must ascertain that the firm transporting the chimpanzees has the proper equipment, personnel, and experience to safely transport the chimpanzees. It is the responsibility of the donating institution in collaboration with the Sanctuary to validate this capability before releasing the chimpanzees for transport. The Sanctuary must report any undesirable problems involved with transportation to the donating institution and the transportation company. The NCRR representative will be notified telephonically and or electronically of the nature of the

incident, factors contributing to the incident, outcome, and measures taken to prevent future incidents. A record of such incident and action taken shall be available for review by representatives of the USDA and NIH. All records associated with the transportation of chimpanzees to or from the Sanctuary must be maintained for at least one year after the movement is completed in accordance with the current requirements set forth in the Animal Welfare Regulations (9 CFR 2.80).

(b) *What other transport regulations apply to the federally supported chimpanzee Sanctuary system?* (1) General requirements and regulations applicable to animal transport into and among Sanctuary sites include:

(i) The contractor will maintain contact with carrier personnel in order to ensure their compliance with proper care of chimpanzees during transit; and

(ii) The contractor must submit to the Project Officer by telephone, fax, or e-mail, the actual shipment schedule and proposed method of transport no less than 10 days prior to shipment. The Project Officer must be immediately informed of any changes or delays in this schedule in accordance with the terms of the current contract between NCRR and the Sanctuary contractor.

(2) Additional requirements and regulations applicable to ground transportation include:

(i) Transport must be provided by a USDA licensed intermediate handler; and

(ii) Transport must adhere to provisions of the Interstate Commerce Commission Authority Animal Transportation Regulations.

(3) Additional requirements and regulations applicable to air transportation include:

(i) The International Air Transport Association (IATA) Live Animal Regulations if air transportation is utilized, and

(ii) Delivery to and from the airports must be provided in an environmentally controlled truck per USDA Animal Welfare Regulations, (9 CFR part 3, subpart F).

(4) Requirements and regulations applicable to shipping units mandate that chimpanzees must be delivered in properly ventilated, escape-proof units, and each compartmentalized unit must have separate water and feed containers (9 CFR part 3, subpart F).

§ 9.12 Compliance with the Standards of Care, USDA and PHS policies and regulations.

(a) *How will compliance with the standards set forth in this part be monitored and what are the*

consequences of noncompliance with the standards? The federally supported chimpanzee Sanctuary must comply with the standards of care set forth in this part and include a statement in the Annual Progress Report certifying compliance with these standards of care in accordance with the terms of the current contract between NCRR and the Sanctuary contractor. A designated representative of the Secretary will monitor compliance. The responsibility to monitor compliance with the standards is delegated to the NCRR/NIH/DHHS. The NIH/NCRR Project Officer for this contract will conduct scheduled site visits at least one time quarterly (or more often if necessary), review monthly and quarterly reports submitted to the Project and Contracts Officer, Subcontractors are subjected to the same provisions. Failure to comply with the standards set forth in this part or to correct deficiencies noted within the allowable time period could result in termination of the contract by the Federal Government (DHHS/NIH), allowing the Secretary to correct the deficiencies according to the terms and conditions outlined in the contract. The Secretary may impose additional sanctions on the contractor up to, and including, authorizing assumption or reassignment of the management of the Sanctuary contract.

(b) *To what type of outside review or inspection will the federally supported Sanctuary be subjected?* As noted in paragraph (a) of this section, the contractor for the Sanctuary will be monitored on a regularly scheduled basis by representatives of the NCRR/NIH/DHHS. The NCRR representative will use facility site visits, reports, personal contact, and any other means as appropriate to assure compliance with these standards. The contractor and subcontractors are required to obtain and maintain an Animal Welfare Assurance from NIH's Office of Laboratory Animal Welfare (OLAW) when chimpanzees are used for non-invasive studies as authorized in the CHIMP Act. involving chimpanzees. In addition, the Sanctuary must achieve accreditation by a nationally recognized animal program accrediting body (such as the AAALAC, or the AZA) within a time frame to be determined by NCRR/NIH. The federally supported Sanctuary must comply with the requirements set forth in the Animal Welfare Regulations (9 CFR parts 1 through 3).

§ 9.13 Other Federal laws, regulations, policies, and statutes that apply to the Sanctuary.

(a) Animal Welfare Act (7 U.S.C. 2131–2159).

(b) Animal Welfare Regulations, 9 CFR, subchapter A, parts 1 and 2.

§ 9.14 Authority of the Secretary of Health and Human Services to amend or issue additional standards of care regulations.

The Secretary of the Department of Health and Human Services (or designated Federal agency) may amend, rescind, or promulgate new regulations if deemed necessary and appropriate to assure compliance with the CHIMP Act. Any such proposed changes must be published in the **Federal Register** for public comment for a minimum of 60 days.

[FR Doc. 05–394 Filed 1–10–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018—AI79

Endangered and Threatened Wildlife and Plants; Proposed Removal of the Plant *Agave arizonica* (Arizona agave) From the Federal List of Endangered and Threatened Plants

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), under the Endangered Species Act of 1973, as amended (Act), propose to remove the plant *Agave arizonica* (Arizona agave) from the Federal List of Endangered and Threatened Plants. *Agave arizonica* was listed as endangered on June 18, 1984, due to threats of habitat modification and collection. Evidence collected subsequent to the listing indicates that plants attributed to *Agave arizonica* do not constitute a distinct species but rather are individuals that have resulted from recent and sporadic instances of hybridization between two species. Current taxonomic practice is not to recognize such groups of individuals as a species. The term “species,” as defined by the Act, only includes species, subspecies, and distinct population segments. Since *Agave arizonica* is not recognized as a species, it no longer qualifies for protection under the Act.

DATES: Comments on the proposed rule must be received on or before March 14, 2005 to ensure our consideration. Public hearing requests must be received by February 25, 2005.

ADDRESSES: Comments and materials concerning this proposal should be sent