Chapter

7

Research Facility Inspection–IACUC Requirements and Protocols

Contents

NOTICE

The AWA specifically prohibits Animal Care from stopping research at any research facility (registered or unregistered but requiring registration). Therefore, you (the inspector) may NOT instruct a research facility to stop conducting research under any circumstances.

IACUC Review Information for the Inspector

General Information

All IACUC responsibilities, functions, and activities **must** be completely and thoroughly reviewed.

Membership

In assessing IACUC membership, you should look for verification that:

- All required positions are filled.

NOTICE

If a required position(s) is unfilled, there is **not** a properly constituted IACUC. An improperly constituted IACUC cannot perform the required official AWA functions.

- The DVM has acceptable experience and responsibility for animal care and delegated authority for activities.
- The nonaffiliated member represents the general public, i.e., has **no** conflict of interest either personally or financially, and is **not** a laboratory animal user at any research facility.
- There are **no** more than three members from one administrative unit of the research facility, unless the facility is so small that it only has one administrative unit.
- IACUC members are qualified to assess the research facility's animal program, facilities, and procedures.
- IACUC members are properly trained and instructed in areas such as:
  - The Animal Welfare Act
  - Protocol review
  - Program review
  - Facility inspection

NOTICE

While **not** prohibited by the AWA, the inspector should strongly discourage the same person from filling multiple required positions. (Policy 15)

Meetings

In assessing meetings, you should look for verification that:

- All members are informed of all meetings.
- Meetings are held at a time when all members, especially the nonaffiliated member, can attend.
- Required members (committee chair, nonaffiliated member, and attending veterinarian) are in attendance at most meetings. (There is no requirement that all required members must be in attendance at all meetings.)

NOTICE

If any required member is absent from a substantial number of meetings, the research facility may need to find a different person to fill the position.

- All members have access to information distributed, e.g., if sent **only** over email, all members **must** have email.
- All members are sent information for an IACUC meeting in sufficient time prior to the meeting to be able to review the information.
- All members receive a list of protocols, or the actual protocols to be reviewed, in sufficient time to participate in the review or request a full committee review.
- There is a mechanism for a member to request a full IACUC review of a protocol or participation in the appointed subcommittee review.
- If a member requests a full IACUC review of a protocol, a full IACUC review is conducted.

Minutes

The IACUC meeting minutes should include:

- A list of members who attended and/or who did **not** attend
- All the activities conducted by the IACUC at the meeting
- Any dissenting opinions
- Approval of the minutes (usually of the previous meeting) by the IACUC (recommended, but **not** required)
- Substance of the deliberations of the IACUC, **not** just the decisions reached

NOTICE

For requirements for conducting meetings using telecommunications, see Telecommunications for IACUC Meetings and Electronic Communication.

Program of Humane Care and Use Review

In assessing the program review, you should look for verification that:

- The review is being conducted at least once every 6 months.
- If the IACUC adopted the AAALAC International Program Assessment report as its semiannual program review, the following requirements were met:
  - The report complied with Section 2.31(c)(1) and (3).
  - At least two members of the IACUC assisted in conducting the inspection.
  - **No** IACUC member wishing to participate in any evaluation was excluded.
  - The report was signed by a majority of the IACUC members (individual digital signatures are acceptable).
  - The report:
    - included any minority views
    - distinguished minor from significant deficiencies
    - contained a reasonable and specific plan and schedule with dates for each deficiency
    - was submitted to the Institutional Official (IO) in a timely manner
- All members are informed of the program review to be conducted by the appointed subcommittee in sufficient time to request participation.
- Any member who wants to participate in the program review is allowed to do so.
- The program of humane care and use addresses all of the required areas.
- Any identified departure from the AWA regulations and standards includes a description of and reason for the departure.
- If a departure occurred due to a program deficiency, then there is a:
  - Classification of the deficiency as a significant deficiency or a minor deficiency

NOTICE

A significant deficiency is one which is, or may be, a threat to the health or safety of the animal.

  - Description of a reasonable and specific plan for correcting the deficiency
  - Schedule with dates for correcting the deficiency
- A report of the IACUC program review:

- Is completed
- Is signed by a majority of the members (individual digital signatures are acceptable)
- Contains any minority views
- Is submitted to the Institutional Official (IO) in a timely manner

- Any uncorrected significant deficiency was properly reported to Animal Care and other appropriate Federal agencies.

Facility Inspection

In assessing the facility inspection, you should look for verification that:

- The facility inspection is being conducted at least once every 6 months.
- If the IACUC adopted the AAALAC International Program Assessment report as its semi-annual facility inspection, the following requirements were met:
  - The report complied with Section 2.31(c)(2) and (3).
  - At least two members of the IACUC assisted in conducting the inspection.
  - **No** IACUC member wishing to participate in any evaluation was excluded.
  - The report was signed by a majority of the IACUC members.
- The report:
  - included any minority views
  - distinguished minor from significant deficiencies
  - contained a reasonable and specific plan and schedule with dates for each deficiency
  - was submitted to the IO in a timely manner
- All members are informed of the date and time of the facility inspection.
- All members are informed of the facility inspection to be conducted by the appointed committee in sufficient time to request participation.
- Any member who wants to participate in the facility inspection is allowed to do so.
- All of the animal holding, housing, and use areas are inspected.
- Any identified departure from the AWA regulations and standards includes a description and reason for the departure.
- If a departure occurred due to a program deficiency, then there is a:

- ❖ Classification of the deficiency as a significant deficiency or a minor deficiency

NOTICE

A significant deficiency is one which is, or may be, a threat to the health or safety of the animal.

- ❖ Description of a reasonable and specific plan for correcting the deficiency
- ❖ Schedule with dates for correcting the deficiency

◆ A report of the IACUC facility inspection:

- ❖ Is completed
- ❖ Is signed by a majority of the members (individual digital signatures are acceptable)
- ❖ Contains minority views
- ❖ Is submitted to the IO in a timely manner

◆ Any uncorrected significant deficiency was properly reported to Animal Care and other appropriate Federal agencies.

Reports to the Institutional Official

In assessing the reports to the IO, you should look for verification that:

◆ A report(s) is submitted at least every 6 months, after each program review and facility inspection.

◆ There is a description of how and to what extent the research facility meets the AWA regulations and standards, such as:

- ❖ Facility is in total compliance and description, or
- ❖ Describes each item **not** in compliance (deficiency)

◆ Any identified departure from the AWA regulations and standards includes a description and reason for the departure.

◆ If a departure occurred due to a program deficiency, then there is a:

- ❖ Classification of the deficiency as a significant deficiency or a minor deficiency

NOTICE

A significant deficiency is one which is, or may be, a threat to the health or safety of the animal.

- ❖ Description of a reasonable and specific plan for correcting the deficiency
- ❖ Schedule with dates for correcting the deficiency

- Recommendations to the IO regarding any aspect of the facility's animal program, facilities, and personnel training are included in the report.
  - The report is signed by a majority of the members (individual digital signatures are acceptable).
- The report contains any minority views.

Other reports to the IO which should be requested and reviewed include, but are **not** limited to:

- Notice of suspension of a protocol
- Uncorrected significant deficiencies

You should review how the reports are sent to the IO.

NOTICE

If you have a concern that the Institutional Official is **not** receiving the required reports/information or acting on the required reports/information, you should visit with the IO.

Protocol Activity Suspension

In assessing the IACUC's suspension of protocol activities, you should look for verification that:

- The activity was reviewed and suspended at a convened meeting with a quorum of the IACUC present.

NOTICE

A quorum means a majority of the Committee members.

- The suspension was approved by majority vote of the quorum present.
- The IO, in conjunction with the IACUC:
  - Reviewed the reason for the suspension
  - Took appropriate corrective action
  - Instituted adequate follow-up measures and monitoring of the suspended activity
  - Informed the appropriate Animal Care Regional Office of the suspension
  - Informed other appropriate Federal funding agencies of the suspension

Complaints or Concerns

In assessing the IACUC's responsibility for addressing complaints or concerns, you should look for verification that:

- Adequate methods are in place for receiving complaints or concerns from sources outside the research facility.
- Adequate, confidential methods are in place for receiving complaints or concerns from sources inside the facility.
- Complaints or concerns were reviewed and, if appropriate, investigated for validity.

Records

In addition to the reports listed above, the following IACUC records **must** be available for review and in compliance with the AWA regulations:

- Protocols
- Proposed significant changes to protocols
- IACUC approval or non-approval of protocols or proposed significant changes to protocols
- Any other protocol-related information

Telecommunications for IACUC Meetings

Methods of telecommunications (e.g., telephone or video conferencing) are acceptable for the conduct of official IACUC business requiring a quorum, provided the following criteria are met:

- All members are given notice of the meeting.
- Documents normally provided to members during a physically-convened meeting are provided to all members in advance of the meeting.
- All members have access to the documents and the technology necessary to fully participate.
- A quorum of Committee members is convened when required.
- The forum allows for real time verbal interaction equivalent to that occurring in a physically-convened meeting (i.e., members can actively and equally participate and there is simultaneous communication).
- If a vote is called for, the vote occurs during the meeting and is taken in a manner that ensures an accurate count of the vote. A mail ballot or individual telephone polling **cannot** substitute for a convened meeting.
- Opinions of absent members that are transmitted by mail, telephone, fax, or email may be considered by the convening IACUC members, but may **not** be counted as votes or considered as part of the quorum.
- Written minutes of the meeting are maintained as required.

Information to Review

The information below represents supplemental information and materials that the facility can provide which can help verify or assess IACUC function. Documents that can be reviewed to assess IACUC function may include, but are **not** limited to:

- Audio tapes provided by the research facility
- Cage wash water temperature certification records
- Emails and email records
- IACUC facility inspection reports
- IACUC-related correspondence
- Interviews with IACUC members
- Maintenance records
- Medical/surgical records
- Memos and notes
- Program of humane care and use
- Room temperature logs
- Standard operating procedures
- Written meeting minutes

IACUC Review Information for the Registered Research Facility

Appointment of the IACUC

The Chief Executive Officer of the research facility or the Institutional Official (IO) if designated by the CEO must appoint an Institutional Animal Care and Use Committee (IACUC). [2.31]

Criteria

The IACUC **must** be qualified through the experience and expertise of its members to assess the research facility's: [2.31(a)]

- Animal program
- Facilities
- Procedures

Except as specifically authorized by law or the Animal Welfare Act regulations, the Animal Welfare Act and its regulations **do not** authorize a research facility's IACUC to dictate to a researcher how to conduct his/her research by: [2.31(a)]

- Prescribing methods for the design or performance of research or experimentation
- Setting standards for the design or performance of research or experimentation

Membership

The Institutional Animal Care and Use Committee (IACUC) **must** be composed of a Chairperson and at least two additional members. [2.31, Policy #15]

Members

The IACUC **must** be composed of: [2.31(b)(2) and (3)]

- A Chairperson
- At least one Doctor of Veterinary Medicine (DVM)
- At least one nonaffiliated member

NOTICE

To be a properly constituted IACUC, all three positions **must** be filled.

IACUC members must be qualified to assess the research facility's animal program, facilities, and procedures. The research facility is responsible for: [Policy #15]

- Ensuring the qualifications of the members
- Providing training and instruction to the members in areas such as:
  - The Animal Welfare Act
  - Facility inspection
  - Program review
  - Protocol review

Although **not** specifically prohibited by the AWA, APHIS strongly discourages one person from filling more than one of those positions, such as: [Policy #15]

- The DVM being the Chairperson
- The nonaffiliated member being the Chairperson

NOTICE

APHIS also strongly discourages the research facility's Institutional Officer from being the Chairperson or DVM.

If the IACUC consists of more than three members, **not** more than three members can be from the same administrative unit of the research facility, such as: [2.31(b)(4)]

- Biology Department
- Cardiology Department

Chairperson

The Chairperson is generally responsible for the activities of the IACUC, but the responsibility for managing the IACUC may be delegated or reside in an administrative unit.

IACUC activities may include, but are **not** limited to:

- Certifying the research facility's compliance with the AWA and its regulations and standards
- Informing the Principal Investigator of the IACUC's decisions regarding his/her protocol
- Assuring that records of activities are kept
- Leading the meetings
- Sending a list of protocols to be reviewed to members
- Sending the required reports to the Institutional Official
- Setting the agenda for meetings
- Scheduling meetings

Doctor of Veterinary Medicine

The Doctor of Veterinary Medicine **must** have: [2.31(b)(3)(i)]

- Ability to critically review a protocol for veterinary care issues, and
- Direct or delegated authority for activities involving animals at the research facility, and
- Training or experience in laboratory animal science and medicine

NOTICE

A research facility's Attending Veterinarian may fulfill the role of the DVM on the IACUC, or the position may be filled by another veterinarian.

Nonaffiliated Member

The nonaffiliated or outside member represents the interests of the general public and must **not** be: [2.31(b)(3)(ii), Policy #15]

- A laboratory animal user at any research facility
- A member of the immediate family of a person who is affiliated with the research facility
- A person with financial interest in the facility, such as an animal supplier
- Compensated to an amount which jeopardizes the member's status as a nonaffiliated member

Compensation for the nonaffiliated member may include: [Policy #15]

- Meals
- Modest monetary payment which does **not**:
  - Become an important source of income
  - Influence voting on the IACUC
- Parking
- Travel expenses

Examples of nonaffiliated members include, but are **not** limited to:

- Bioethicists
- Biologists
- Clergy
- Humane society volunteers or employees
- Non-research staff members from other institutions
- Physicians
- Practicing veterinarians
- Retirees

Alternate Members

There may be alternate members appointed to the IACUC by the IO.

Alternates may only serve as an alternate in the membership category(s) for which they are qualified. For example, the alternate for a non-affiliated IACUC member would need to also meet the non-affiliated member requirements.

If the regular member fulfills a specific membership requirement, his or her alternate must also fulfill that requirement. If the regular member fulfills more than one membership requirement, the alternate must meet the same membership requirements.

One alternate may be appointed to serve for multiple regular members provided the alternate fulfills the specific membership requirement of the members for whom he or she is substituting. However, an alternate may not represent more than one member at any one time.

Program Review

The IACUC **must** review and evaluate the research facility's program for humane care and use of animals at least once every 6 months. [2.31, Policy #17]

Method

The IACUC is responsible for determining the best method for conducting the review of the humane care and use program. [2.31(c)(3)]

The IACUC may: [2.31(c)(3)]

- Conduct the review with all IACUC members participating, or
- Appoint a subcommittee of at least two members to conduct the review.

NOTICE

No IACUC member wishing to participate in the review may be excluded.

- Invite an ad hoc consultant(s) to assist with the program review.

The IACUC may adopt the AAALAC International Program Assessment report as its semi-annual program review if:

- The report complies with Section 2.31(c)(1) and (3).
- The report is made available to the APHIS inspector upon request.
- At least two members of the IACUC assisted in conducting the inspection.
- **No** IACUC member wishing to participate in any evaluation was excluded.
- The report was signed by a majority of IACUC members (individual digital signatures are acceptable).
- The report:
  - included any minority views
  - distinguished minor from significant deficiencies
  - contained a reasonable and specific plan and schedule with dates for each deficiency
  - was submitted to the IO in a timely manner

Criteria

The review of the program of humane care and use **must** be based on the AWA regulations and standards (Title 9, Chapter I, Subchapter A–Animal Welfare). [2.31(c)(1), see Policy #17]

Additional resources which may be used include, but are **not** limited to:

- *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching*, published by the Federation of Animal Science Societies (most current edition)
- *Guide for the Care and Use of Laboratory Animals*, published by the Institute of Laboratory Animal Resources (most current edition)

Areas which should (but are **not** required) be addressed in the program of humane care and use include, but are **not** limited to:

- Animal care, such as:
  - Cleaning/sanitation
  - Environment
  - Environmental enrichment for nonhuman primates
  - Exercise for dogs
  - Food/water
  - Housing
- IACUC-approved exceptions, such as:
  - Exceptions to the cleaning or sanitation requirements
  - Exceptions to the diurnal lighting cycle requirement
  - Exceptions to the space requirement (including innovative enclosures and metabolism cages)
  - Maintaining animals at temperatures outside the ranges specified by the standards
  - Use of an animal in more than one major survival surgery (see Policy #14)
- IACUC functions, such as:
  - Attendance at meetings, especially nonaffiliated member
  - Complaint review
  - Dissemination of protocols to members
  - IACUC meeting minutes
  - IACUC records
  - Protocol review
  - Recommendations to the IO
  - Reports to the IO
  - Required meetings

- ❖ Review of humane care and use program
- ❖ Review of standard operating procedures (SOPs)

NOTICE

There is no requirement for every SOP to be reviewed every 6 months. The IACUC may determine a reasonable schedule for review of SOPs.

- ❖ Suspended activities

- ◆ Identification
- ◆ Personnel qualifications and training.
- ◆ Records
- ◆ Veterinary care, such as:
  - ❖ Anesthesia and surgery
  - ❖ Emergency, weekend, and holiday care
  - ❖ Euthanasia
  - ❖ Pain/distress management (see Policy #11)
  - ❖ Pre/post-procedural care

The findings of the program review **must** be included in a report to the IO. [2.31(c)(3)]

Facility Inspection

The IACUC **must** inspect the research facility's animal facilities at least once every 6 months. [2.31]

Facilities

Animal facilities which must be inspected include, but are not limited to:

- ◆ All sites (including remote sites) where animals are housed for more than 12 hours or used (including laboratories)
- ◆ Cage cleaning areas
- ◆ Drug storage areas, including investigators' labs and offices, if appropriate
- ◆ Food and bedding storage areas
- ◆ Holding areas
- ◆ Loading docks and transport equipment, such as:
  - ❖ Transport cages
  - ❖ Vehicles
- ◆ Study areas where animals are confined for more than 12 hours

- Surgical suites and prep areas

NOTICE

It is strongly recommended that the IACUC inspect areas where animals are housed for less than 12 hours.

In addition to inspecting the facilities, the IACUC should conduct:

- A review of management practices
- A review of the mechanism for animal users and caretakers to report animal health problems or concerns
- An assessment of animal users and caretakers ability to recognize problems of animal health and behavior
- An assessment of the care of the animals
- An assessment of the condition of the animals

Animal facilities which do **not** have to be inspected are:

- Areas containing free-living wild animals in their natural habitat

NOTICE

Field study areas are **not** required to be inspected. [2.31(c)(2)]

- Areas used exclusively for non-regulated animals
- Housing areas at another research facility if the IACUC has delegated responsibility for the animals housed in those areas to the IACUC of the other facility

NOTICE

The IACUC should document that it has delegated the facility inspection responsibility to the IACUC of the other research facility.

- Sites which are **not** in the United States or U.S. territories (foreign sites)

Method

The IACUC is responsible for determining the best method for conducting the facility inspection. [2.31(c)(3)]

The IACUC may:

- Appoint a subcommittee of at least two members to conduct the inspection, or

NOTICE

No IACUC member wishing to participate in the inspection may be excluded.

- Have all of the Committee members participate in the inspection, or

- Invite an ad hoc consultant(s) to assist with the facility inspection

The IACUC may adopt the AAALAC International Program Assessment report as its semi-annual program review if:

- The report complies with Section 2.31(c)(2) and (3).
- The report is made available to the APHIS inspector upon request.
- At least two members of the IACUC assisted in conducting the inspection,
- **No** IACUC member wishing to participate in any evaluation was excluded.
- The report was signed by a majority of IACUC members (individual digital signatures are acceptable).
- The report:
  - included any minority views
  - distinguished minor from significant deficiencies
  - contained a reasonable and specific plan and schedule with dates for each deficiency
  - was submitted to the IO in a timely manner

Criteria

The inspection **must** be based on the AWA regulations and standards (Title 9, Chapter I, subchapter A–Animal Welfare). [2.31(c)(2)]

Additional resources which may be used include, but are **not** limited to:

- *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching*, published by the Federation of Animal Science Societies (most current edition)
- *Guide for the Care and Use of Laboratory Animals*, published by the Institute of Laboratory Animal Resources (ILAR) (most current edition)

The findings of the facility inspection **must** be included in a report to the IO. [2.31(c)(3)]

IACUC Protocol Review

The IACUC must review all protocols and significant changes to approved protocols. [2.31, Policy #11, Policy #12, and Policy #14]

Criteria

In order to approve a protocol or significant change to an approved protocol, the IACUC **must**:

- Review those components of the activities related to the care and use of animals, and
- Determine that the proposed activities meet and comply with the AWA regulations and standards, unless an acceptable justification for a departure is presented in writing.

General Protocol Requirements

A protocol to conduct an activity involving animals **must** contain and comply with the requirements/assurances detailed below.

Protocols **must** meet the following requirements:

- Provide the rationale for using animals [2.31(e)(2)]
- Identify the species of animals to be used [2.31(e)(1)]
- Provide a rationale for the appropriateness of the species [2.31(e)(2)]
- Provide the approximate number of animals to be used [2.31(e)(1)]
- Provide a rationale for the number of animals to be used, such as but not limited to: [2.31(e)(2)]
  - Required for statistically significant results (tests used or statisticians consulted should be included)
  - Based on scientific literature or past experience (references should be cited)
  - Based on results of pilot study
  - Required by the Food and Drug Administration (FDA) or other Federal agency (Federal code, regulation, or standard, etc., must be cited)
  - Required by international testing requirements (code, regulation, standards, etc., must be cited)
  - Number of students/animal and procedures needed to learn

- Describe the proposed use of the animals, including final disposition of the animal [2.31(e)(3)]

NOTICE

The description should be clear enough to be easily understood by the IACUC's outside member.

- Contain a written assurance from the principal investigator that the proposed activities do **not** unnecessarily duplicate previous experiments [2.31(d)(1)(iii), see]
- Medical care will be provided when necessary
- The animal's living conditions, housing, feeding, and nonmedical care will be: [2.31(d)(1)(vi)]
  - Appropriate
  - In accordance with AWA standards
  - Directed by the attending veterinarian or other qualified scientist
- All personnel who will be conducting the proposed activities on the animals are qualified and trained [2.31(d)(1)(viii)]
- Pain/distress/discomfort are minimized [2.31(d)(1)(i) and 2.31(e)(4)]
- Contain a complete description of procedures designed to assure the pain/distress/discomfort are minimized [2.31(e)(4)]
- Describe the method(s) of euthanasia to be used [2.31(e)(5)]

Painful/Distressful Procedures

Procedures that may cause more than momentary or slight pain or distress to the animal **must** contain and comply with assurances that the pain/distress is necessary and will be relieved or minimized.

Some procedures that can be expected to or may cause more than momentary pain or distress include, but are **not** limited to: (see Policy #11)

- Extensive irradiation, inhalation toxicity, or tumor growth studies
- Food or water deprivation or restriction beyond that necessary for normal pre-surgical preparation
- Forced exercise
- Noxious electrical shock or thermal stress that is not immediately escapable
- Ocular or skin irritancy testing
- Paralysis or immobility in a conscious animal
- Surgery (survival or terminal)
- Use of Freund's Complete Adjuvant

Protocols with procedures that may cause pain or distress **must** meet the following requirements:

- The principal investigator(s) (PI) has considered alternatives to the painful/distressful procedure [2.31(d)(1)(ii)]. The PI should consider:
  - Refinement alternatives that may further minimize or avoid pain and/or distress
  - Reduction alternatives that may reduce the number of animals required to attain study objectives
  - Replacement alternatives that may allow some or all of the scientific objectives to be attained without the use of live animals, or with the use of phylogenetically lower species
- If the consideration of alternatives is done by an electronic database search, then a written narrative describing the methods and sources used to determine that alternatives were **not** available should include, but is **not** limited to: [2.31(d)(1)(ii), see Policy #12]
  - Date of the search
  - Database(s) searched
  - Years covered by the search
  - Search strategy(ies) used
- If the consideration of alternatives is done by other means, then a written narrative describing the methods and sources used to determine that alternatives were **not** available should include, but is **not** limited to: [2.31(d)(1)(ii), see Policy #12]
  - Years covered by the consideration
  - Consideration strategy(ies) used
  - Sources consulted, including, if applicable:
    - Reliable unpublished research data
    - Expert consultation (list credentials)
- Painful/distressful procedures will be performed with appropriate: [2.31(d)(1)(iv)(A)]
  - Sedatives
  - Analgesics
  - Anesthetics
- If painful/distressful procedures will be performed without the appropriate sedative, analgesics, or anesthetics, then withholding such agents must: [2.31(d)(1)(iv)(A)]
  - Be in writing, and

- ❖ Detail the justification for scientific reasons for withholding these agents, and
- ❖ State the period of time (if known) that these agents will be withheld, or
- ❖ Have an assurance statement that these agents will be withheld for the shortest period of time necessary

- ◆ The research facility's attending veterinarian or his/her designee was consulted and involved in the planning of the procedure and pain/distress relief [2.31(d)(1)(iv)(B)]
- ◆ Procedures will **not** include the use of paralytics **without** anesthesia [2.31(d)(1)(iv)(C)]
- ◆ Animals experiencing severe or chronic pain/distress that **cannot** be relieved will be humanely euthanized [2.31(d)(1)(v)] See Table 7-1 on page 7-38.

Surgical Procedures

Pre- and Post-Surgical Care

Protocols that involve surgery **must** detail the provisions for pre- and post-operative care of the animals in accordance with accepted veterinary and nursing practices, such as: [2.31(d)(1)(ix)]

- ◆ Adequate monitoring of recovery
- ◆ Adequate post-procedural observation and monitoring
- ◆ Placing animal in appropriate recovery or post-recovery environment

For pain/distress-relieving drugs, the protocol should clearly specify or there should be IACUC-approved policies (e.g., guidance documents, standard operating procedures, drug formularies) for the provision of medication to minimize discomfort or pain, including but not limited to: [2.31(e)(4)]

- ◆ Anticipated signs of pain and distress
- ◆ Dosages and routes of administration
- ◆ Drugs to be used
- ◆ Frequency of administration
- ◆ Person(s) who is responsible for determining when pain-relieving drugs are needed, if appropriate
- ◆ When drugs should be administered
- ◆ When drugs should **not** be administered, if required for scientific reasons

NOTICE

A pro re nata (PRN or "as needed") frequency of administration is **not** acceptable unless there are detailed instructions and criteria for determining administration of the drug.

Survival Surgery [2.31(d)(1)(ix)]

All survival surgery **must** be performed using aseptic procedures including, but **not** limited to:

- Aseptic technique
- Masks
- Sterile instruments
- Sterile surgical gloves

NOTICE

Surgery is survival if the animal regains consciousness during or after the operative procedure.

Non-Survival Surgery

Non-survival surgery:

- Does **not** require a dedicated surgical facility
- **Must** be performed in accordance with established veterinary medical and nursing practices

Major Operative Procedure [2.31(d)(1)(ix)]

Major operative procedures on regulated non-rodent animals **must** be performed in a dedicated surgical facility which **must** be operated and maintained under aseptic procedures.

A major operative procedure means any surgical intervention that penetrates and exposes a body cavity or any procedure which produces permanent impairment of physical or physiological functions.

The IACUC has the authority to determine whether specific manipulations used in research are major operative procedures. The IACUC's determination must be based:

- on a detailed description of the procedure, and
- the anticipated or actual consequences, as characterized by the investigator.

In some cases, the classification by the IACUC of a procedure as major or minor may be readjusted post-procedurally depending on clinical outcome. If

the IACUC, after thorough review, determines that the surgical procedure only penetrates but does not expose a body cavity and that the procedure does not produce substantial impairment, the IACUC may conclude that it is not a major operative procedure.

Some major operative procedures include, but are **not** limited to:

- Amputation
- Craniotomy
- Joint replacement
- Laparotomy

NOTICE

Any laparoscopic surgery that produces substantial impairment of physical or physiological function must be considered a major operative procedure. Whether the laparoscopic procedure is classified as major or minor, the IACUC must ensure that the appropriate analgesia, sterile technique, and perioperative monitoring is employed.

- Thoracotomy
- Thyroidectomy

Non-major Operative Procedure [2.31(d)(1)(ix)]

Non-major operative procedures on regulated animals:

- Do **not** require a dedicated surgical facility
- **Must** be performed using aseptic procedures

Some minor operative procedures include, but are not limited to:

- Peripheral vessel cannulation
- Tooth extraction
- Wound suturing

Rodent Surgery [2.31(d)(1)(ix)]

Surgery on rodents:

- Does **not** require a dedicated surgical facility
- **Must** be performed using aseptic procedures

Field Site Surgery [2.31(d)(1)(ix)]

Surgeries conducted at field sites:

- Do **not** require a dedicated surgical facility

- **Must** be performed using aseptic procedures

Multiple Survival Surgeries [2.31(d)(1)(x), see Policy #14]

An animal may not be used in more than one major operative survival procedure in **one protocol** unless the multiple procedures are:

- Justified, in writing, for scientific reasons, and
- Approved by the IACUC

An animal may not be used in **two separate protocols** with major operative survival procedures unless an exemption is approved by the APHIS Administrator.

The request for approval of the exemption by the APHIS Administrator should follow the guidance in Policy 14.

NOTICE

An animal that has a veterinary procedure, such as spaying, neutering, or de-scenting, or an emergency major operative procedure for health reasons, may be used in a protocol that requires a major survival surgery.

Exceptions/Exemptions

Exceptions or exemptions to a particular AWA Regulation or Standard **approved by the IACUC** must be:

- For scientific reasons
- Justified in writing

If a regulation or standard also provides specific parameters for an exemption/exception, those parameters must be followed.

Exceptions that **should** be reported on the Annual Report:

- Exceptions approved by the IACUC under 2.38(k) that are **not** provided for under the Regulations and Standards, including but not limited to:
  - Removal of resting platforms from cat enclosures
  - Extension of interval for cleaning/sanitization of enclosures
  - Keeping animals in 24 hour dark cycle
  - Keeping animals in temperatures outside range described in Part 3—Standards for species

- Exceptions approved by Animal Care, including but not limited to:
  - Approval for use of an animal in more than one major operative procedure from which it is allowed to recover on **more than one protocol** (2.31)(d)(1)
  - Exception to the health certificate requirement (2.38)(h)
  - Temporary tethering of dogs used as the primary enclosure (3.6)(c)(4)

Exceptions that should **not** be reported on the Annual Report:

- Exceptions approved by the IACUC that are provided for under the Regulations and Standards, including but not limited to:
  - Approval for use of an animal in more than one major operative procedure from which it is allowed to recover on **one protocol** (2.31)(d)(1)
  - Short term withholding of food and water from animals (2.38)(f)(2)
  - Exemption of an individual NHP from some or all of the environmental enhancement plan (3.81)(e)(2)
  - Any deviation from the methods of euthanasia as defined in the AWA regulations which were justified for scientific reasons, in writing, by the investigator (2.31)(d)(1)(xi)
- Exceptions approved by a veterinarian as part of the provision of veterinary care, including but not limited to:
  - Animal is fasted for surgery conducted for husbandry reasons
  - Animal is housed in an enclosure that does not meet space requirements for medical reasons while recovering from husbandry or veterinary care related surgery
  - Animal develops vomiting/diarrhea (not study related) and veterinarian prescribes IV fluids and severely restricts food and water intake by mouth for several days

Significant Changes to Animal Activities

In support of the use of performance standards and professional judgment and to reduce regulatory burden, IACUC-reviewed and -approved policies (e.g., guidance documents, standard operating procedures, drug formularies) for the conduct of animal activities may be used for the administrative handling of some significant changes as outlined below.

The following significant changes must be approved by either full Committee review or designated member review:

- from nonsurvival to survival surgery
- resulting in greater pain, distress, or degree of invasiveness

- in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC
- in species
- in study objectives
- in Principal Investigator (PI)

The following significant changes may be handled administratively according to IACUC-reviewed and -approved policies in consultation with a veterinarian authorized by the IACUC:

- anesthesia, analgesia, sedation, or experimental substances
- euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals
- duration, frequency, type, or number of procedures performed on an animal

The following significant change that may be handled administratively according to an existing IACUC-reviewed and -approved policy without additional consultation or notification is:

- an increase in previously approved animal numbers

The following changes may be handled administratively without IACUC-approved policies, consultations, or notifications:

- correction of typographical errors
- correction of grammar
- contact information updates
- change in personnel, other than the PI. (There must be an administrative review to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in occupational health and safety programs, and meet other criteria as required by the IACUC.)
- Investigators may use fewer animals than approved. This does **not** require IACUC approval, notification, consultation, or administrative handling.

Protocol Review Information for the Inspector

Inspection Protocol Review Guidance

Protocols and the IACUC approval and monitoring of protocols should be completely and thoroughly reviewed during an inspection.

Sampling Guidance

You, the inspector, are responsible for conducting a thorough review of:

- The protocol approval process
- The IACUC's monitoring of protocol activity
- IACUC approved protocols and changes to protocols

Detailed below is guidance to assist you in evaluating the IACUC protocol review. However, you **must** use the regulations and your professional judgment to determine if an IACUC or protocol is in compliance.

NOTICE

If a protocol has been reviewed by an AC inspector within the last year, then the VMO should use his/her professional judgment to determine if it is necessary to conduct another review. The following guidance applies to protocols which have been initially approved, or have had significant changes approved, since the last inspection.

Prepare:

- Write down the necessary ID information for animals about which you have a concern, and
- Review the most recent annual report to identify species and numbers of animals used in columns E and D and all protocols with exemptions or exceptions, and
- Determine that you are aware of, and have access to, all protocols subject to AWA regulations, including but not limited to:
  - active protocols
  - inactive protocols from the past 1 year, and
  - protocols where no regulated species are currently present at the facility

Review:

Then always review the following protocols:

- All protocols identified during inspection as of concern
- All column E protocols

- All protocols with IACUC-approved exemptions/exceptions
- Protocols cited as noncompliant and not corrected during the last inspection

Review Additionally:

- If the facility has five or fewer remaining protocols, review all remaining protocols.
- If the facility has greater than five remaining protocols, select five additional protocols to include at least one protocol from each of the following categories, if applicable:

NOTICE

You have already reviewed the protocols of concern so this step is meant to ensure a 'random' sample of other protocols. There may be protocols in each of these categories at a particular facility totaling more than 5. Use your professional judgment to select 5 from the other species and the high risk procedures categories and do your best to mix those up in subsequent years.

  - Select one protocol for each regulated species present.
  - For the following high risk procedures, select one from each of the categories below, if applicable:
    - Potentially painful/distressful procedures (Column D)
    - Antibody production
    - Food/water restriction
    - Neuromuscular blockers
    - Surgical procedures
    - Teaching or trauma training protocols
    - Toxicity studies
    - Infectious disease studies
    - Vaccine potency/efficacy studies

Research Facility Protocol Selection Worksheet

You must complete the Protocol Selection Worksheet when you are reviewing protocols. *See Research Facility Protocol Selection Worksheet* on page 7-59. After completing the worksheet, you should:

- Submit the Worksheet (with the facility's inspection report) which will be scanned into ACIS at the RO.
- Keep a copy for your records.

- Leave a copy with the research facility if requested by the facility.

NOTICE

If you think that following these requirements will result in the expenditure of an inordinate amount of time, seek guidance from your SACS.

Verification of IACUC Activities

Ways to verify IACUC activities include, but are not limited to:

- Audio meeting minutes
- Compliance Office/Officer activities, if the facility has a Compliance Office
- Correspondence
- Email correspondence and email records
- Interviews with IACUC members
- Memos/notes
- Protocols
- Protocol submission forms
- Written meeting minutes

Protocol Approval Process

You, the inspector, should conduct a thorough review of the IACUC's protocol approval process to ensure that the IACUC is following the regulations and procedures as outlined in the "IACUC Protocol Review" subsection.

Specific Types of Protocols

Painful/Distressful Procedures (see Policy #12)

When reviewing protocols involving procedures that may cause more than momentary or slight pain/distress/discomfort (protocols in Categories D and E), some areas to pay special attention to include, but are **not** limited to:

- The principal investigator has considered alternatives to the painful/distressful procedure.
- There is a detailed narrative describing the methods and sources used to determine that **no** alternatives to the painful/distressful procedure are available.
- Measures used to alleviate the pain/distress are clearly stated and adequate, including:
  - Drugs, dosages, routes, and frequency of administration
  - Other methods, including but not limited to:

- ⇨ Acupuncture
- ⇨ Hydrotherapy
- ⇨ Hot/cold packs

❖ A pro re nata (PRN or "as needed") frequency of administration is **not** acceptable unless there are detailed instructions and criteria for determining administration of the drug

- Availability of experienced personnel, especially at night and on weekends and holidays, to assess and administer pain relief
- If pain/distress relief is **not** to be used, there is an adequate justification and endpoints are described that will be used to terminate the study and/or used as the basis for when treatment or euthanasia will be performed.
- The principal investigator has consulted and involved the attending veterinarian or his/her designee in the planning of the procedure and pain/distress relief.
- There is **not** the use of paralytics without anesthesia.
- Animals experiencing severe or chronic pain/distress that **cannot** be relieved will be humanely euthanized.
- The endpoint has been determined and identified.

NOTICE

If the research facility has written, IACUC-approved standard operating procedure(s) (SOPs) for such things as (but not limited to) surgical procedures, pain/distress relief, antibody production, routine veterinary care, housing, euthanasia, etc., and those specific procedures are not specifically described in a PI's submitted protocol, the PI's protocol **must** reference and follow the applicable SOP(s).

Antibody Production Protocols

When reviewing protocols involving antibody production, some areas to pay special attention to include, but are **not** limited to:

- The principal investigator has considered alternatives for painful/distressful procedures.
- An alternative search, if done, was properly conducted and reviewed for possible alternative procedures and a rationale provided as to why available alternatives cannot be used.
- The justification for the number of animals to be used was appropriate, such as the amount of antibody needed and the amount which can be produced by an animal.
- There is a complete description of the procedure to induce antibody production and the collection of blood/serum.

- If adjuvants likely to cause more than momentary pain/distress, such as Freund's Complete, are being used, there is at a minimum:
  - Justification for its use
  - A listing of possible adverse reactions
  - Adequate care of the animal if adverse reactions occur

Food and/or Water Deprivation or Restriction

When reviewing protocols involving food and/or water deprivation or restriction, some areas to pay special attention to include, but are **not** limited to:

- The food/water deprivation or restriction is adequately justified.
- If the animals are likely to experience distress, the principal investigator has considered alternatives to the distressful procedures.
- A search for alternatives, if done, was properly conducted and reviewed for possible alternatives to procedures that may cause more than momentary pain or distress.
- Procedures used to restrict food/water are adequately described and easily understood.
- Procedures for selection of animals and training and monitoring the animals are described in detail.
- Baseline physiological data is being collected.
- Physiological parameters are being monitored during the study, such as:
  - Body weight
  - Hydration status
  - Behavioral changes
  - Plasma osmolality
- Medical/research records are being maintained and contain information on the monitoring of the animals, if required by the protocol, Program of Veterinary Care, or Institutional policy.
- Supportive care is provided to any animal suffering dehydration or stress.
- If supportive care is **not** provided, there is an appropriate scientific justification for **not** doing so.
- How the animals' daily food and water intake was determined.
- The protocol addresses how the animal is to receive its required daily food or water intake, such as:
  - During its working sessions
  - Supplementation to the amount consumed during working sessions

- Whether small amounts of food or water provided as rewards are, or are **not** considered part of the animals' daily food or water requirement

- If the animal is **not** to receive its daily food and water requirement, procedures and parameters for monitoring the animal are detailed in the protocol.
- The endpoint has been determined and identified.

Neuromuscular Blockers

When reviewing protocols involving the use of neuromuscular blockers (NMB), some areas to pay special attention to include, but are **not** limited to:

- The use of the NMB is appropriate
- The use of the NMB is adequately described in the protocol including, but **not** limited to:
  - Name of NMB
  - Dosage
  - Timing of administration
  - Method of anesthesia
- The NMB is being used with general anesthesia
- All personnel working with the animal and NMB are properly trained in its use and possible adverse reactions
- The animal is being properly monitored, such as:
  - Heart rate and blood pressure
  - Level of anesthesia

NOTICE

Pain withdrawal response is **not** an appropriate measure of level of anesthesia as this response would be prevented by the NMB. The use of a peripheral nerve stimulator is strongly recommended as part of the monitoring procedure when NMB's are being used on an animal.

- Appropriate supportive care, such as ventilatory support, is being provided during anesthesia
- Surgical and anesthesia records are being kept and contain the appropriate information
- Recovery procedures are appropriate, i.e.:
  - The animals are reversed from the NMB when reversal agents are available before being allowed to recover from the anesthesia
  - Recovery is being monitored

Surgical Procedures

When reviewing protocols involving surgical procedures, some areas to pay special attention to include, but are **not** limited to:

- The pre-procedural care and surgical preparation of the animals are clearly stated, drugs given prior to and during the procedures, such as analgesics, tranquilizers, and anesthetics, are appropriate and at the correct dosage for the species.
- The surgical procedure is stated clearly and in detail.
- All survival surgeries are performed using aseptic technique.
- Major operative survival surgeries on non-rodents are performed in a dedicated surgical facility.
- **No** animal is being used in more than one major operative survival surgery unless appropriately approved.
- Post-surgical procedures are stated clearly and in detail, such as:
  - Observation and monitoring of recovery
  - Any special recovery environment requirements
- Pain/discomfort relief measures are stated clearly and in detail including, but **not** limited to:
  - When drugs are to be administered
  - Drug, dose, route, and frequency of administration
  - Signs of pain/distress
  - Contact person(s)
  - Other or additional methods of pain/distress relief

Teaching Protocols

When reviewing teaching protocols, some areas to pay special attention to include, but are **not** limited to:

- The rationale for the number of animals to be used was appropriate, such as the number of students per animal and procedures needed to be learned
- A consideration of alternatives for procedures that might cause more than momentary pain or distress was properly conducted and reviewed for possible alternative procedures, such as the use of:
  - Veterinary mannequins
  - Live tissue alternatives
  - Mechanical teaching devices
- There is a complete description of the procedures to be used

- The number of procedures to be performed on each animal is clearly stated, such as injections per animal
- The personnel doing the teaching are qualified and properly trained
- If the teaching procedures cause more than momentary or slight pain or distress, proper methods are used to alleviate the pain/distress

Toxicity and Vaccine Potency/Efficacy Studies

When reviewing protocols involving toxicity and vaccine potency/efficacy studies, some areas to pay special attention to include, but are not limited to:

- A consideration of alternatives (reduction, replacement, or refinement) for procedures that might cause more than momentary pain or distress was properly conducted and reviewed for possible alternative procedures, such as, but not limited to:
  - Revised up-and-down procedure (UDP) as a refinement to LD50 studies (refinement, reduction)
  - Use of cell cultures and tissue assays, such as for dermal and ocular safety testing
  - Use of sequential testing and fewer animals to identify dermal and ocular chemical hazards (reduction)

NOTICE

The Interagency Coordinating Committee on the Validation of Alternative Methods provides a list of some alternative tests.

- The rationale for the number of animals to be used was appropriate.
- If the number of animals required is set by a government agency, the specific regulation or guideline is cited in the protocol.
- Appropriate methods are being used to relieve any pain or distress, unless scientifically justified.
- Animal technicians and caretakers are properly trained in identifying problems and procedures to follow.
- Humane end points for when the study can be terminated or that can be used as the basis for euthanasia or treatment have been determined and identified.

NOTICE

Non-farm animals, such as hamsters, Guinea pigs, and rabbits, used to develop and test vaccines for farm animals are covered under the AWA.

Inspection Procedures

Listed below are some additional aids to assist you in determining if the procedures outlined in the protocols are being followed.

NOTICE

Animals may be held, but **cannot** be used **without** being on a protocol.

- Ask how the research facility keeps track of the number of animals approved by the IACUC and the number of animals used by the principal investigator, such as:
  - Computer records
  - Acquisition and disposition records
  - Dead animal records
  - Inventory cards
- Ask how the facility checks the accuracy of its methods for tracking the number of animals.
- Ask for exemption/exceptions to the regulations or standards, then check the protocol to determine that the exemption/exception was approved.
- Determine if the animal care staff is familiar with the protocol procedures, especially pre- and post-painful/distressful procedure care, such as:
  - Asking the staff
  - Checking the availability of protocols
  - Checking the availability of standard operating procedures
  - Looking in medical records
- Watch the animal care staff, principal investigators, or laboratory personnel handle the animals (or ask them to handle the animals, if appropriate).
- Review medical records/investigator's logs to determine that animals with painful/distressful procedures received the proper pain/distress relieving drugs, if applicable.
- Observe animals for signs of unrelieved pain.
- Ask about weekend staffing, animal observation, and medical care.
- Determine if the medical or emergency contact numbers are readily available, such as:
  - On bulletin boards
  - In the animal rooms
  - In medical records/charts
  - In protocols
- Observe surgeries to determine that they are being conducted using aseptic technique and in dedicated surgical facilities, if required.

- Ask how the research facility tracks animals to ensure that they are **not** used for another survival surgery (unless approved by the IACUC or APHIS), such as:
  - Health records
  - Individual animal records
  - Cage cards
  - Surgery records
  - Investigator's logs
- For APHIS-approved multiple major survival surgeries, verify that the stipulations in the approval letter are being met.

Table 7-1 Species-Typical Signs of Pain

Species	Possible Signs of Pain[1 2]
Dogs	Quiet, unwilling to move, abnormal posture, lack of alertness, whimpering, groaning, howling, shivering, loss of appetite, increased respiration, growl or exhibit apprehension when approached
Cats	Ungroomed appearance, quiet, apprehensive facial expression, loss of appetite, crying, hissing, hiding, crouching or hunching
Guinea Pigs	Quiet, decreased food and water consumption, anorexia
Hamsters and Gerbils	Decreased activity, piloerection, ungroomed appearance
Rabbits	Inactivity, appear apprehensive or anxious, hunched appearance, hide, squeal or cry, possible aggressive behavior with excessive scratching and licking
Nonhuman Primates	Stops eating and/or drinking, stops grooming
Cattle	Dull, depressed appearance, heads bowed, lack of alertness, loss of appetite, rapid/shallow breathing, rigid posture
Sheep and Goats	Similar to cattle, also vocalization, teeth grinding, increased lip curling
Pigs	Changes in overall demeanor, social behavior, gait and posture, unwilling to move, hiding, excessive squealing when handled

1 Excerpted from: National Research Council: *Recognition and Alleviation of Pain in Laboratory Animals*, Washington, D.C., National Academy Press, 2009.

2 These are possible signs of pain and do not necessarily mean the animal is in pain. A lack of these signs also does not mean that the animal is not in pain.

Protocol Review Information for the Registered Research Facility

Procedure for Protocol Review

The IACUC is responsible for the review and approval of all proposed activities related to the care and use of animals. [2.31]

Procedure

A written protocol, i.e., a proposal for animals use activities, **must** be submitted to and approved by the IACUC prior to the start of any animal use activity.

The IACUC **must** review all submitted protocols and decide to: [2.31(c)(6)]

- Approve the protocol, or
- Require modifications in the protocol to secure approval, or
- Withhold approval of the protocol

The IACUC review **must** be conducted by: [2.31(d)(2)]

- Full Committee review, or
- A subcommittee of at least one member of the IACUC designated by the IACUC chair who:
  - Is qualified to conduct the review, and
  - Has the authority to:
    - Approve
    - Require modifications in the protocol to secure approval, or
    - Request a full IACUC review of the protocol

NOTICE

This person or subcommittee might be referred to as the Designated Reviewer(s) or Designated Member(s).

Prior to IACUC review, each member of the IACUC **must** be provided the following: [2.31(d)(2)]

- A list from the IACUC chair or his/her designee of the protocols to be reviewed
- A copy of any protocol, upon request

NOTICE

Any member of the IACUC may request, and **must** be granted, a full Committee review of a protocol.

No member of the IACUC or subcommittee may grant approval of a protocol until the entire IACUC has been informed that the protocol is to be reviewed, and members are given the opportunity to read the protocol.

If an IACUC member has a conflicting interest with a protocol being reviewed, e.g., is personally involved, that member may not: [2.31(d)(2)]

- Contribute to the constitution of a quorum
- Participate in the review or approval of the protocol

NOTICE

The member may provide information about the activity proposed in the protocol.

Full Committee Review

If a protocol is reviewed by the full committee: [2.31(d)(2)]

- The review **must** be conducted at a convened meeting with a quorum of the IACUC, and
- Approval **must** be by a majority vote of the quorum

Subcommittee Review (Designated Reviewer)

The Designated Reviewer(s) has the authority to:

- Approve a protocol
- Approve a significant change(s) to a protocol
- Require modifications to a protocol/significant changes
- Request a full IACUC review

A protocol or significant change approved by the Designated Reviewer does **not** need to be reviewed and approved by the full IACUC.

NOTICE

Only after all members of the IACUC have decided that a full committee review of a protocol is **not** necessary, can the protocol be reviewed by the Designated Reviewer.

Consultants

The IACUC may confer with a consultant(s) or the principal investigator(s) to aid in understanding complex areas of a protocol. [2.31(d)(3)]

Unless the consultant is a member of the IACUC, he/she must **not**: [2.31(d)(3)]

- Approve or withhold approval of a protocol
- Vote with the IACUC

Notification

The IACUC **must** notify the principal investigator(s) and the appropriate person(s) at the research facility (usually the Institutional Official or his/her designee) in writing of its decision regarding the approval of the protocol. [2.31(d)(4)]

If the IACUC decides to withhold approval or require modifications in the protocol, it **must**: [2.31(d)(4)]

- Include in its written notification the reason for the decision
- Give the principal investigator(s) an opportunity to respond in person, or in writing

The IACUC may reconsider its decision to withhold approval if the principal investigator corrects the deficiencies in the protocol to the satisfaction of the IACUC. Any change in the IACUC's decision **must** be documented in the minutes. [2.31(d)(4)]

Continuing Review

The IACUC **must** review all active protocols at least once a year, i.e., within the same month or earlier than the date of the initial approval, or more often, at the discretion of the IACUC. [2.31(d)(4) & (5)]

- The review may be conducted by the IACUC or a subcommittee.
- All IACUC members are informed of the annual reviews.
- All members are given the opportunity to participate in the annual reviews.
- The IACUC reviews and decisions are documented in writing and available for inspection.

For example, the review should consider:

- New activities
- Changes in the number and type of animal
- New exceptions to the AWA regulation and standards

Changes in Protocols

Changes in protocols may be handled either by full Committee review or designated member review, or by an administrative process as detailed in the "Significant Changes to Animal Activities" subsection.

Suspension of a Protocol Activity

The IACUC may suspend a previously-approved protocol activity. [2.31]

Criteria

The IACUC may suspend an activity that it previously approved if it determines that the activity is **not** being conducted as: [2.31(d)(6)]

- Described by the principal investigator, and
- Approved by the IACUC

The IACUC may suspend an activity **only**: [2.31(d)(6)]

- After review of the matter at a convened meeting of a quorum of the IACUC, and
- With a vote for suspension by a majority of the quorum

If the IACUC suspends an activity involving animals, the IO, in consultation with the IACUC, **must**: [2.31(d)(7)]

- Review the reasons for the suspension
- Take appropriate corrective action
- Report that action with a full explanation to the appropriate Animal Care Regional office, and any Federal agency funding that activity

Contracted Research or Projects that Involve Multiple Registrants

When registered Research Facilities (RF) contract research out to be conducted at another facility, it is the responsibility of the registrants to determine and document which party is responsible for the functions of the IACUC, animal care and handling, and reporting of the animals on the Annual Report.

No Documentation of Responsibilities

If there is no documentation of specific areas of responsibility, then:

- Both registered parties are responsible, and
- Both IACUCs should perform all required functions, and
- Only one of the RFs should report the animals on the Annual Report
- You, the inspector, should cite both RFs for any noncompliances identified.

Specific Responsibilities

If the contract designates **specific responsibilities to each partner**, the facility is a site of both registrants.

You, the inspector, should inspect only the designated institution for the specific responsibility agreed upon in the contract.

For example:

- RF A is designated to perform the semiannual program review and facility inspection, while both RF A and RF B are designated to review the protocol.
  - Both RF A and RF B are responsible for the protocol and both IACUC's must approve the protocol, **but**
  - Only RF A is responsible for the semiannual review.
  - You, the inspector, inspect:
    - the protocol review and approval at both RF A and RF B, and
    - the semiannual review only at RF A.
- The contract specifies that both RF A and RF B are responsible for the IACUC functions, but only RF B is responsible for the animal care and handling, and reporting on the Annual Report.
  - You, the inspector, inspect:
    - the IACUC functions at RF A, and
    - the IACUC functions, animal care and handling, and the AR reporting of the animals under the contract at RF B.

All Responsibilities Designated

If RF A contracts the entire project and **all responsibilities** to RF B, then:

- The location of RF B is **not** a site of RF A.
- RF A does **not** have any responsibility for the IACUC functions, animal care and handling or Annual Reporting.
- You, the inspector, inspect **only** RF B for the IACUC functions, animal care and handling, and Annual Reporting.

Individual researchers or staff frequently partner with multiple institutions. The IACUC reviewing the protocol must assure that all personnel have appropriate training and qualifications. But this does not confer any responsibility on the other RFs with which that particular individual is associated.

Records

The research facility **must** maintain records of the IACUC's activities. [2.35]

Required Research Facility Records

IACUC Records

A research facility must have the following records, if applicable, for review during inspection:

- Minutes of the IACUC meetings, including:
  - A list of members who were and were not present
  - All the activities conducted by the IACUC at the meeting
  - Any dissenting opinions
  - Approval of the minutes (usually of the previous meeting) by the IACUC (recommended, not required)
  - Substance of the deliberations of the IACUC, not just the decisions made
- Program of humane care and use
- Investigation of concerns
- Recommendations to the IO
- Records relating to animal activities, including:
  - Annual review of protocols
  - IACUC decisions on protocols and proposed changes
  - Notification of Principal Investigator of decisions on protocols and proposed changes
  - Notifications of suspension of protocol
  - Proposed significant changes to protocols
  - Protocols
- Semi-annual reports, including:
  - Review of humane care and use program
  - Facility inspection
  - Report of program and facility reviews to the Institutional Official, including minority views
  - IACUC-identified significant deficiencies
- Verification of appointment of IACUC members by the Chief Executive officer (CEO) or Institutional Official (IO)

Personnel Qualifications and Training

The research facility **must** adequately document the qualifications and training of personnel which may include, but not be limited to:

- Certificates of attendance at formal meetings
- Certificates of completion from relevant continuing education programs
- Curriculum vitae/resumes
- Diplomas or certificates from educational institutions
- Sign-up sheets from in-house training programs

Animal Records

A research facility must have the following records, if applicable, available for review during an inspection;

- Acclimation statements for transportation
- Acquisition and disposition records for dogs and cats
- Approved water and power emergency plans for marine mammals
- Attending veterinarian approved exemptions to the regulations or standards, usually part of an animal's medical records
- Record of animals on hand for dogs and cats. (Use of APHIS Form 7005 is not required.)
- Certification for acquired random source dogs and cats
- Certification for exempt sources of dogs and cats
- Documentation for all other covered animals showing that current medical problems and existing chronic conditions are:
  - being addressed, and/or
  - receiving proper veterinary care

NOTICE

Lack of this documentation may not be cited as a stand-alone noncompliance, but must be related to the regulations and the condition of the animal.

- Documentation of training of attendants or employees working with marine mammals
- Environmental enhancement plan for nonhuman primates
- Exercise plan for dogs
- Health certificates for dogs, cats, and nonhuman primates when transported across State lines
- Medical records for marine mammals
- Necropsy records for marine mammals

- Program of veterinary care, if using part-time or consulting attending veterinarian
- Water quality records for marine mammals

Annual Report

Both you and the RF should have a copy of the Annual Report.

You, the inspector, should verify that the RF's Annual Report is accurate, that is:

- All animal facilities are reported.
- Only regulated species are reported.
- Animals are reported in the correct column.
- IACUC-approved exceptions **not** provided for in Animal Welfare Act regulations and standards are reported.
- IACUC-approved exemptions provided for in the AWA regulations and standards are **not** reported.
- The number of animals reported is correct.
- There are appropriate explanations for all Column E animals.

You, the inspector, should verify that the RF's Annual Report does **not** report any animals used for the following:

- Field studies which meet the following criteria and are therefore exempt from the regulations and do **not** require a written, approved exemption. The study does **not**: [1.1, 2.31(d)(1)]
  - Harm the animals under study
  - Involve an invasive procedure
  - Materially alter the behavior of the animals under study
- Animals euthanized, killed, or trapped, and collected, such as for study or museum samples, from their natural habitat via humane euthanasia
- Agricultural research
- Food or fiber
- Wildlife management projects

NOTICE

The facility's IACUC should be involved in the above use of animals in order to review the activity that is taking place and to ensure that the method of euthanasia is humane and appropriate, if applicable.

Methods of verifying the animal numbers include, but are not limited to:

- Asking the research facility representative to demonstrate how the number of animals was determined for:
  - A particular species, or
  - A column from the annual report
- Asking for verification of animals used **by site** to obtain the total number of animals used, for example:
  - Review a particular species used by site, or
  - Review a column from the annual report by site
- Counting the animals, if appropriate or feasible
- Review of:
  - Acquisition records
  - Animal ordering information, such as invoices or computer animal tracking systems
  - Animals ordered in comparison to number of animals approved for a particular protocol
  - Facility animal census records
  - Internal billing records to PIs for animal housing/care
  - Protocol medical or animal-usage records

Animals reported in Column B of APHIS Form 7023-Annual Report, should be those animals being bred, conditioned, or held for use in teaching, experiments, research, or surgery, but not yet used for such purposes.

All animals contained on the facility's inventory on September 30 of the reporting year that were not used in a research project that year should be reported in Column B as being held for research purposes. Animals that were held but died during the year without being used for research purposes should also be reported in this column. Other animals held during the reporting year but not present at the facility on September 30 should not be reported in this column. They should be reported by the facility which possesses them on September 30.

If a research facility is licensed as a dealer:

- Breeding animals and any offspring intended for research purposes within the research facility should be reported in Column B.
- Animals intended for sale only should not be reported in Column B but should be included on the dealer license renewal.

- If the research facility is unsure of the status of an animal (research or sale only), the animal should be reported in Column B.

Animals actually used for research purposes during the reporting year must be reported in Column C, D, or E, as appropriate.

NOTICE

If methods other than anesthetics, analgesics, or tranquilizing drugs are used to relieve pain or distress, animals can still be reported in Column D if the methods are appropriate and effective.

NOTICE

The use of anesthesia does not always mean that the animal should be reported in Column D. If the animal was anesthetized for a non-invasive procedure, a blood draw, or other veterinary care procedure, the animal could be reported in Column C. The RF should determine the appropriate reporting column.

If an animal was moved to another RF during the reporting year, the animal should only be reported once by either:

- the RF with the highest pain category for the animal, or
- if the pain categories are the same, then by the last RF to possess the animal.

Refer to the following documents for additional information about the annual report:

- APHIS Form 7023–Annual Report of Research Facility
- APHIS Form 7023–Instructions for Completion of APHIS Form 7023
- Assistance with Accurate Annual Reporting for Research Facilities
- Guidelines for Reporting Animals in Column B of APHIS Form 7023
- Column E Explanation of APHIS Form 7023

Retention

All records and required reports must be maintained: [2.35(f)]

- At least 3 years, or
- Longer if:
  - Necessary to comply with any applicable Federal, State, or local law
  - The APHIS Administrator notifies the research facility, in writing, that specified records **must** be retained pending completion of an

investigation or proceeding and held until their disposition is authorized.

Records **must** be held for at least 3 years from the date of completion of the IACUC-approved protocol. [2.35(f)]

Availability

Records **must** be available for inspection and copying by: [2.35(f), 2.38(a), 2.38(b)(1)(ii) and (iii)]

- Any APHIS official
- Any funding Federal agency representative

Confidentiality and Removal of Records

APHIS inspectors **must**: [2.35(f)]

- Maintain the confidentiality of the information
- **Not** remove the records from the research facility's premises unless:
  - There has been an alleged violation.
  - The records are needed to investigate a possible violation.
  - The records are needed for other enforcement actions.

NOTICE

Release of any materials removed from the facility that contain trade secrets, or commercial or financial information that is privileged or confidential, will be governed by applicable sections of the Freedom of Information Act.

You, the inspector, should follow the guidelines below when **removing** records from a research facility:

- Only take photos or copies of records off-site if needed to support a Direct, critical or repeat citation. Do NOT remove original records.
- Make copies or scan records, instead of photographing, if possible.
- Be sure the research facility knows what records were copied, scanned, and/or photographed before leaving the facility.
- Give the research facility the opportunity to redact names, locations, and other PII before taking photos, scanning, or making copies of the record. You should allow the facility 24 to 48 hours for this redaction.
- Provide the research facility the opportunity to view your photos, if requested. If possible, delete or retake any photos that the facility states may contain potential PII, or confidential or proprietary information to remove or block the sensitive information. If the noncompliance cannot be documented without the inclusion of potentially confidential or

proprietary information, ensure that the photograph label states: "May contain confidential or proprietary information."

Electronic Communication

Some forms of electronic communication systems may be used to conduct IACUC functions.

IACUC Meetings

The IACUC meetings should allow members to be in direct communication to consider, deliberate, and vote on areas of their responsibility. This is traditionally done by face-to-face meetings.

The IACUC may conduct its activities using electronic communication systems which allow all members to be in direct communication, if **all** of the following criteria are met:

- All members are given notice of the meeting.
- Documents normally provided to members during a physically-convened meeting are provided to all members in advance of the meeting.
- All members have access to the documents and the technology necessary to fully participate.
- A quorum of Committee members is convened when required.
- The communication system allows for real time verbal interaction equivalent to that occurring in a physically-convened meeting (i.e., members can actively and equally participate and there is simultaneous communication).
- If a vote is called for, the vote occurs during the meeting and is taken in a manner that ensures an accurate count of the vote.

NOTICE

A mail ballot or individual phone polling **cannot** substitute for a convened meeting.

- Opinions of absent members that are transmitted by mail, telephone, fax, or email may be considered by the convened IACUC members, but may **not** be counted as votes or considered as part of the quorum.
- Written minutes of the meeting are maintained as required by the AWA regulations.

All activities conducted via electronic communication **must** be documented in writing and original or electronic signatures obtained, when required.

Examples of electronic communication systems include, but are **not** limited to:

- Audio-visual conferencing, including webinar-based forums
- Conference calls

Fax, email, and one-on-one communication via telephone are **not** acceptable methods for conducting IACUC functions which require a convened meeting, such as:

- Full committee review
- Suspension of an approved activity

The use of email or one-on-one communication via telephone for these activities is citable under 2.31(d)(2), 2.31(c)(3), or 2.31(d)(6).

Guidance for Veterinary Technician Programs (VTP) for the Inspector

Teaching Versus Research

The definition of activity in Part 1 of the AWA means, those elements of research, testing, or teaching procedures that involve the care and use of animals.

For the purposes of the AWA, teaching is equivalent to research. Using farm animals for teaching agricultural students is not regulated, while using farm animals for teaching veterinary/vet tech students is regulated.

Registration Requirements

Always Registered

A registration is needed if live covered animals utilized for teaching purposes are owned by the facility.

EXAMPLE

- Facility purchases or obtains donated animals from any source
- Facility uses animals that do not fall under a veterinary client patient relationship (VCPR)

A VCPR as defined by the AVMA is present when all of the following requirements are met:

- The veterinarian has assumed the responsibility for making clinical judgments regarding the health of the patient and the client has agreed to follow the veterinarians' instructions.
- The veterinarian has sufficient knowledge of the patient to initiate at least a general or preliminary diagnosis of the medical condition of the patient. This means that the veterinarian is personally acquainted with the keeping and care of the patient by virtue of a timely examination of the patient by the veterinarian or medically appropriate and timely visits by the veterinarian to the operation where the patient is managed.
- The veterinarian is readily available for follow-up evaluation or has arranged for the following: veterinary emergency coverage, and continuing care and treatment.
- The veterinarian provides oversight of treatment, compliance, and outcome.
- Patient records are maintained.

NOTICE

If a registered VTP is conducting non-regulated activity at a clinic, shelter, or farm, these locations should not be added as sites of the VTP.

Usually Not Registered

A registration may not be needed if the facility does not own any of the regulated animals utilized for teaching and all animals used are either:

- Patients (which could include work performed for a shelter), or
- Pets whose owners are always present. This would include animals at clinics, shelters or farms where a staff person is onsite and available to observe the activities.

Special Circumstances That May Require Registration

These and other special circumstances must be evaluated with the SACS on a case-by-case basis.

- A "pet", including animals belonging to a student, staff or faculty, is housed at the facility and used in different teaching situations without the owner being present.
- Animals not owned by the facility are housed at the facility for an extended period of time.

AVMA Accreditation

The AVMA does **not** require that a VTP be registered with the USDA.

The AVMA does require that the VTP apply AWA guidelines to all animal use. All animal activities conducted by a program must be approved by an animal care and use committee whose structure and function are in accordance with AWA requirements.

Licensing Requirements for Providing Animals to VTP

No License Required

The following sources of animals do **not** require a license:

- Persons donating animals to the vet tech program
- Exempt persons who have certified that the dogs and/or cats being sold were born and raised on the persons' premises and that they have sold fewer than 25 dogs and/or cats that year for research
- Municipal pounds or shelters

NOTICE

If a veterinary technician program is obtaining animals from municipal (city/county/state) pounds or contract pounds, then a five day hold is required per 2.38 (j). See Holding Period Regulations Summary Chart.

Dealer's License Required

The following sources of animals require a license:

- Private shelters, unlike municipal and contract pounds, are not exempt from the licensing requirements if animals are being sold (as opposed to being donated). Rescue groups fall into the category of private shelters.
- Dealers who breed and raise regulated animals for covered activities.

Inspection Procedures

You (the inspector) should only inspect the animals and animal facilities for animals owned by the facility.

Do not inspect animals or housing areas for animals owned by other entities such as vet clinics, hospitals, shelters, or animals that fall under a veterinary client patient relationship.

If the facility asks you to inspect or look at non-regulated animals or facilities, you may go through these areas with the facility representative but do not document any findings on an inspection report. Consult your SACS if further guidance is necessary.

Records Requirements

For regulated animals used in regulated teaching activities, the records requirements are the same as for any other research facility.

The following records must be available for review during the inspection, if applicable:

- Acquisition/disposition records
  - Must be kept for any dogs or cats acquired by the facility that do not fall under a veterinary client patient relationship
- Annual Reports

Records are **not** required for:

- Dogs/cats used in the context of a veterinary client patient relationship, However the ownership of these animals should be clear in other facility records maintained as part of the veterinary client patient relationship.
- All regulated animals other than dogs and cats

All regulated species of animals used for regulated purposes must be included on the annual report.

The following animals should **not** be included on the annual report:

- Client, staff, or student-owned animals utilized in the presence of the owner
- Animals utilized for teaching purposes at working farms, ranches, veterinary hospitals or shelters if used in the context of a veterinary client patient relationship.
- Animals used in the context of a veterinary-client-patient relationship.

Records must be held for at least three years (beyond the final disposition of the animal). [2.35(f)]

Identification Requirements

For **regulated** animals used in **regulated** teaching activities, the animal identification requirements are the same as for any other research facility.

Research facilities are only required to individually identify dogs and cats.[2.38(g)]

There are no individual identification requirements for other regulated species.

Protocols

For protocols involving regulated animals used in regulated teaching activities, protocol and IACUC oversight requirements are the same as for any other research facility.

For animals that are not regulated by the AWA (i.e. pets or patients) no protocols or IACUC oversight is required.

Special Considerations

Contact your SACS if any of these circumstances come to your attention via inspection or another method:

- Complaints are received regarding the welfare of the animals
- Inspector becomes aware of animal injury or death as the result of non-regulated teaching procedures
- The owner of an animal expresses concern about its care or use
- It is unclear if a veterinary client patient relationship actually exits

Holding Period Regulations Summary Chart

Reg	Applies To	Holding Period	Species	Comments:
2.38(j)	Research Facilities acquiring dogs and cats from sources OTHER than licensees and exempt* persons	5 full days (not including day of acquisition and time in transit)	Applies to live dogs and cats	The hold is performed by the research facility The hold only applies when the vet tech program permanently obtains the animals
2.101 (a)**	Dealers/Exhibitors	5 days (not including day of acquisition and time in transit)	Applies to live dogs and cats	The hold is performed by the licensee acquiring the animal
2.101 (a)1**	Dealers/Exhibitors who acquire from a private or contract pound/shelter	10 days (not including day of acquisition and time in transit)	Applies to live dogs and cats	The hold is performed by the licensee acquiring the animal
2.101 (a)2**	Dealers/Exhibitors who acquire animals from another licensee	24 hours (not including time in transit). SEE COMMENTS	Applies to live dogs and cats	The live dogs or cats MUST have completed an initial 5 day holding period with the first licensee to acquire the animal OR The live dogs or cats MUST have completed a 10 day holding period with the first licensee, if this licensee acquired the animal from a private or contract shelter/pound. Once the initial 5 or 10 day period is completed, each subsequent dealer/exhibitor need only hold for 24 hours (not including transit time).
2.133 (a)	Municipal, contract and private pounds and shelters, Research facilities also licensed as dealers**, WHEN THESE FACILITIES SELL/PROVIDE LIVE DOGS/CATS TO LICENSED DEALERS	5 full days, to include a Saturday (not including day of acquisition and time in transit)	Applies to live dogs and cats	This is the hold performed by the pound or shelter. For random source animals: dealers must provide to recipients a certification that includes: -Information about themselves (the dealer (name/address/cert#) -Recipient info (name/address/cert# if applicable, signature) -Name/address of person/pound/shelter the animal was originally acquired from, with an assurance that the person/pound/shelter was notified the animal might be used for research. -Signed statement from pound or shelter that animal met holding requirement (must include a USDA ID #) -Date animal was acquired by dealer -Description of animal (USDA approved ID, species/breed/sex/age/color/markings) Dealers must keep certifications at least 1 yr following disposition (research facilities must keep for 3 yrs).
2.132	Random Source B Dealers (allowable sources)	See Section 2.101	Applies to live dogs and cats	Allowable Sources of dogs/cats 1. Other licensed dealers 2.State/county/city owned and operated pounds/shelters 3.private or contract shelter/ pound 4. If to be sold by B dealer for research: persons who certify that animals were bred and raised on their premises AND who have sold fewer than 25 dogs and/or cats that year 5. If to be sold by B dealer for pets: persons who certify that animals were bred/raised on premises AND maintain 3 or fewer breeding female dogs and/or cats.

*Municipal (city/county/state) pounds shelters cannot be licensed as dealers, and so are considered exempt sources for licensing requirements. HOWEVER, they are NOT considered exempt for the purposes of 2.38(j).
**Exceptions to holding periods required by dealers/exhibitors:
2.101 (3): Animals may be euthanized at any time for disease/injury/emaciation
2.101 (4): Live dogs/cats 120 days old or less if obtained from the person who bred/raised the animal, are only subject to a 24 hour hold (excluding transit time). The same 24 hour hold applies to any subsequent dealer/exhibitor who acquires the animal.

Figure 7-1 Holding Period Regulations Summary Chart

Research Facility Protocol Selection Worksheet

Research Facility Protocol Selection Worksheet*

Inspection Date:_____

Facility Name: _____

Registration Number: _____

Reason Protocols Were Selected for Review:	How Many Protocols Were Selected
1. Protocols identified during inspection of concern (select all)	
2. Column E protocols (select all)	
3. Protocols with IACUC-approved exemptions/exceptions (select all)	
4. Protocols cited as noncompliant and not corrected during the last inspection (select all)	
5. Additional Protocols Selected: a. If <5 remaining protocols, select all remaining: b. If >5 remaining protocols, select 5 additional protocols: 1) Protocol for each regulated species and/or, 2) Protocols involving high risk procedures (see Chapter 7, Animal Welfare Inspection Guide for guidance):	
Total Protocols Selected and Reviewed	

*Note: Protocol selection guidance applies to protocols which have been initially approved, or have had significant changes approved, since the last inspection. For protocols reviewed by an Animal Care Veterinary Medical Officer within the last year, professional judgment should be used in determining whether another review is necessary.

Figure 7-2 Research Facility Protocol Selection Worksheet

Chapter 4. Specific Types of Inspections

Contents

DISCLAIMER

The Animal Welfare Inspection Guide is intended to be a reference document to assist the inspector. The Inspection Guide does **not** supersede the Animal Welfare Act (AWA), the AWA Regulations and Standards, AC policies and other guidance, the Required Inspection Procedures, standard procedures, or the inspector's professional judgment. All inspection decisions **must** be justified by applicable sections of the AWA and/or the AWA Regulations and Standards.

4.1. Airport Inspection

Registered Transporters or Intermediate Handlers operating at an airport **must** meet all applicable transportation Regulations and Standards.

4.1.1. Badging Credentials

Some airports, especially large airports, may require that you obtain a badge to access the airport property and facilities. Prior to conducting your first inspection, you should check with the airport authorities to determine if a badge is needed.

If there is a fee for the badge, the fee may be charged to your Purchase MasterCard.

4.1.2. Conducting an Airport Inspection

When conducting an inspection, some additional procedures include, but are not limited to:

- Follow all the safety rules
- Be accompanied by an airline representative unless you are approved by the airport authorities to be unaccompanied
- Inspect all areas where animals may be housed or transported, including but not limited to
  - Ticket counter
  - Cargo area
  - Baggage area
  - Any other areas where animals are held before travel, such as offices and live animal rooms
  - Planes on the tarmac if necessary
  - Transport vehicles and conveyances used to transport animals to and from the planes
- Check for applicable required records, such as:
  - Health Certificates [2.78]
  - Consignor information such as from Waybills or other records
  - Certifications required for the different species
  - COD payment guarantee [2.77]
- If you find an unlicensed dealer, broker, or unregistered transporter:
  - Make a copy of the Waybill and any other supportive documentation

showing regulated activity, and

- Follow the procedure for a "Search Inspection"

4.1.2.1. Commercial Dog Importations

If an inspector identifies an import shipment that is out of compliance with Section 2.150/2.151/2.152, he/she **must** confirm whether there is documentation in ACIS that the importer has been notified previously of the need for a permit:

- If the importer has been notified previously, the inspector will cite the appropriate section on the Inspection Report and forward all information to the CS staff
- If the importer has **not** been notified, or the inspector cannot confirm that the importer has been notified, do **not** write an Inspection Report. The inspector should collect the information as requested below on the importer and forward to the CS staff.

For information to be sent to the CS staff:

- Make a copy of the Waybill. Be sure that the Waybill has the name and contact information for the importer.
- Send the copy of the Waybill to: ac.dogimport.mailbox@aphis.usda.gov

4.1.3. Inspection Reports

4.1.3.1. No NCIs Reports

For an Inspection Report with no noncompliances, the inspector may:

- Complete the IR **at the airport**, have it signed by the facility representative and leave a copy with that facility representative, **OR**
- Send the IR (unsigned by the facility representative that you conducted the inspection with) to the Ft. Collins AWO office by email or mail (Note: Put Facility Representative in the "Received By" signature line and the title of the facility representative that you conducted the inspection with in the Title line) and indicate in your email or by a note attached to the IR that the AWO office should send a copy to the airline corporate office

4.1.3.2. Inspection Reports with NCIs

For NCIs cited on an airline Inspection Report:

- Do **not** give a correction date for any NCIs
- Designate an NCI meeting the criteria for a Direct or Critical as a "Direct" or "Critical"
- Do **not** designate a Repeat NCI as a "Repeat"

- If applicable, obtain a copy of the appropriate Waybill for each NCI, reference the Waybill number in the NCI narrative, and submit with the Inspection Report to the AWO Field Office

For delivery of an Inspection Report with noncompliances, the inspector may:

- Complete the IR at the airport, have it signed by the facility representative and leave a copy with the facility representative (preferred), OR
- Send the IR directly to the airline corporate office using an acceptable method of delivery

4.1.4. Photographs

Take photographs of all NCIs cited at commercial airline carrier inspections.

4.2. Animal Rides

An exhibitor who uses regulated animals to give rides to the public must meet all applicable Animal Welfare Act Regulations and Standards.

4.2.1. Criteria

Examples of regulated animals are:

- Camels
- Elephants
- Llamas

4.2.2. Conducting the Inspection

When inspecting animals used for rides, make sure that the exhibitor meets all the applicable Regulations [9 CFR Sections 2.40, 2.50, 2.75, 2.78, 2.80, 2.125, 2.126, 2.130, 2.131], and all the Standards, including the transportation Standards, for the animals being used.

When conducting your inspection, some suggested areas to pay attention to include, but are **not** limited to:

- Animal's locomotion, gait, and uniformity of stride
- Animal's physical condition and behavior
- Appropriateness of the weight load for the animal
- Attentiveness of the handler during the ride, i.e., is the handler distracted in some manner and not paying attention to his/her duties
- Availability and frequency of access to drinking water
- Availability of shade or shelter
- Condition of the equipment, i.e., **no** sharp edges, **no** broken straps, buckles, or fasteners, padding **not** thin or excessively worn
- Plan to provide veterinary care if an animal is injured away from the home facility
- Foot care, especially elephants
- Number of personnel, i.e., are there enough personnel to watch for dangerous behaviors from the animals, the riders, and the viewing public
- Perimeter fence and/or barriers between the animals and the general viewing public
- Rest for animals between rides and overnight

NOTICE

Animals must be allowed a rest period equal to the amount of time that they were giving rides. [2.131(c)(2)]

- Proper fit of saddles, riding equipment, halters, or restraint devises. Some signs of improper fit include:
  - Abrasions
  - Hair loss
  - Irritated skin
  - Redness
  - Sores
- Training and handling experience of the handlers and employees
- Reluctance of the animal to lead or work

NOTICE

Put the name of the elephant(s) on the Inspection Report.

4.2.3. Inspection Reports

For a TRA inspection, follow the guidance in Traveling Exhibitor Inspection – Inspection Reports.

4.3. Auction Market Inspection

The auction market operator **and** the consigner of the animal, if the consigner is licensed or required to be licensed, are responsible for compliance with all applicable Regulations and Standards

4.3.1. Criteria

At the time of the Prelicensing Inspection(s) of the auction facility and during Routine Inspections, the inspector should ensure that the applicant/auction operator understands all the applicable Regulations and Standards emphasizing the following:

- All animals must be handled so there is minimal risk of harm to the animals and the public. Operators of auctions during public exhibition should use sufficient barriers and/or distance so as to ensure the safety of the animals and public. A sufficient number of readily identifiable attendants should be present at all periods of public contact with the animals
- Incompatible animals must **not** be held in the same enclosure
- Requirements for record keeping, transportation, cleaning, sanitation, and general animal health and well-being are monitored and met during the auction
- The animal enclosures meet the space requirements:
    - Animals are considered to be "in transit" and may remain in the enclosures while at the auction as long as all requirements for transport enclosures (from the Transportation Standards for the appropriate species) are met or exceeded
- The auction operator is responsible for compliance with all Regulations and Standards, including applicable Transportation Standards, once the animal is accepted by the auction market. The auction's responsibility does not extend to animals kept in transport vehicles in auction parking lots.

At the time of the auction, you (the inspector) should:

1. Contact the licensee or his/her representative at the facility
2. Introduce yourself
3. Show official ID, if requested
4. Ask the licensee or representative if:

    A. He/she or a designated person should accompany you around the auction grounds, or

    B. If it is permissible for you to inspect the grounds and the sellers/buyers on your own
5. Check for regulated animals

6. If a USDA licensee brings in a regulated animal, conduct an inspection of the animal in transit
7. If an unlicensed person brings in a regulated animal:
   A. Inform the person of the Animal Welfare Act licensing requirement and that regulated activities may **not** be conducted without a license
   B. Explain the Regulations and Standards for his/her animals
   C. Give the person an application packet, if appropriate
8. Answer any applicable questions
9. Check the animals for any visible signs of illness or distress (see Animals Requiring Veterinary Care).
10. If a licensee purchases and transports a regulated animal, conduct an inspection of the animal in transit prior to the licensee leaving the auction facility, if possible

NOTICE

If a noncompliant item is noted at the time of consignment, inform the auction operator or auction representative of this noncompliance.

4.3.2. Animals Requiring Veterinary Care

The auction operator is responsible for obtaining veterinary care for sick animals in his/her custody being sold for regulated purposes.

If a licensee has transported a sick or injured animal, the inspector should ask if the attending veterinarian or a veterinarian at the auction has been contacted. If **not**, the licensee should be cited for this noncompliance.

4.3.3. Records

4.3.3.1. Sale Day

Ensure that licensees who have transported dogs, cats, and nonhuman primates across a state line have health certificates. The auction operator is not required to maintain a copy of these records.

4.3.3.2. After the Sale Day

Conduct an inspection of the records containing all the information for the animals consigned to and sold by the auction operator on a different day than the sale day.

4.3.3.3. Acquisition Records Follow-Up

A person consigning a regulated animal to an auction market may or may not

require a USDA dealer's license.

Consignment of regulated animals to an auction is not sufficient cause alone for requiring a license, since the consignor may be exempt from licensing under Section 2.1(a)(3) of the Regulations or excluded.

The inspector should:

1. Collect the names/addresses of unlicensed persons consigning regulated animals to the auction

NOTICE

The auction catalog is a good source for this information and should be obtained, if available.

2. As time permits, conduct a search of any unlicensed person in your area selling regulated animals to determine if he/she is conducting any regulated activities
3. Send sales information for unlicensed persons not in your area to the appropriate SACS or inspector to conduct a search if deemed necessary

4.4. Barrier Facility Inspection

Animals housed in a barrier facility **must** be maintained in accordance with all Animal Welfare Act Regulations and Standards. Barrier facilities can include but are **not** limited to quarantine/isolation areas, areas conducting research with infectious agents, areas housing animals that are Specific Pathogen Free (SPF) or gnotobiotic.

4.4.1. Criteria

The inspector **must** be able to inspect all regulated animals and all animal-related areas at a licensed barrier facility to ensure compliance.

If it is not possible for the inspector to enter the animal rooms in the barrier facility due to the possibility of disease exposure and/or contamination of the inspector or the animals, the inspection may be conducted by:

- Analyzing environmental records.
- Selecting random animals to be visually inspected
- Video viewing from outside the barrier room
- Visual inspection through an adequate viewing window

The inspector should follow the entry procedures normally used by the facility's personnel.

NOTICE
The facility should supply a copy of its barrier entry procedures upon request.

The facility should:

- **Not** require more stringent entry Standards for the inspector
- Provide the protective clothing and supplies needed to complete the inspection, such as pen, paper, flashlight, etc., if the facility will not allow you to take your own supplies into the barrier area
- Provide a means of taking photographs, such as taking the photos for you or providing a disposable camera, if the facility will not allow you to take your camera into the barrier area or you are conducting the inspection from outside the barrier area

The facility may ask the inspector to verify that he/she has **not** been in contact with, or exposed to, certain animals for a specified period of time, generally 72 hours. This verification is acceptable.

NOTICE

Do **not** sign any statement which places you responsible for the health of the animals in the barrier facility.

All supplies required to maintain compliance should be available within the barrier facility. For example, veterinary equipment required for the procedures should be present in a surgery room behind a barrier when surgical activities are conducted.

4.4.2. Alternative Methods of Inspection

4.4.2.1. Video Camera Inspection

If a video camera is to be used for inspecting the barrier facility, the facility should meet the following minimum guidelines:

- If possible, record the inspection so the inspector and licensee or designated person can refer back to the recording to review an area if any questions arise after the facility inspection
- Have sufficient or supplemental lighting in the room to allow for good visibility
- Have a color monitor so that color differences can be seen. For example: to distinguish blood from other fluids, or to see algae/scum growth in water.
- Have a communication system between the person operating the camera and the inspector so that the inspector can direct the person to view different areas, or zoom in on an area
- A high resolution video camera should be used so that the inspector can clearly see the animals in the enclosures and see subtle differences, such as being able to distinguish between bedding and feces in or beneath the enclosures
- Use a portable video camera with the ability to video all parts of all the rooms that will require inspection, such as the animals rooms, food and bedding storage areas, medication storage areas, and enclosure washing/sanitizing areas

4.4.2.2. Through a Viewing Window

If the inspection is to be conducted through a viewing window(s), the facility should meet the following minimum guidelines:

- All parts of all the rooms that will require inspection, such as the animal rooms, food and bedding storage areas, medication storage areas, and enclosure washing/sanitizing areas, must be visible through the window(s)
- The lighting in the room must be sufficient to allow for good visibility or the

facility must have supplemental lighting available

- There must be a communication system between the person inside the room and the inspector, so that the inspector can direct the person to bring enclosures or animals to the window, or to open cabinets or containers

4.5. Change in Class of License Inspection

A licensee **must** complete the pre-license process to change his/her class of license. Refer to Chapter 2, Required Inspection Procedures, for information regarding the pre-license process.

If during an inspection, you determine that the licensee has the wrong class of license for the regulated activity that he/she is conducting:

- You may **not** start the pre-license process to change the license. The licensee **must** follow the procedures for applying for a new license, i.e., submit an application, pay the application fee, etc.

A 'Class A' licensee is anyone meeting the definition of "dealer" whose business consists only of animals acquired for the sole purpose of maintaining or enhancing the breeding colony and animals that are bred and raised on the premises.

A 'Class B' licensee is anyone meeting the definition of "dealer" whose business includes the purchase and/or resale of any animal. Class B licensees include brokers and operators of auction sales, as such individuals who negotiate or arrange for the purchase, sale, or transport of animals in commerce. A Class B dealer may also exhibit animals as a minor part of the business.

A 'Class C' licensee is anyone meeting the definition of "exhibitor" whose business involves showing or displaying animals to the public. A Class C exhibitor may buy and sell animals as a minor part of the business to maintain or add to the animal collection.

4.5.1. Criteria

To change his/her class of license, a licensee **must**:

- Complete an Application for License–New License (APHIS Form 7003A–Application for New License)
- Complete an **announced** Pre-license Inspection with **no** noncompliant items cited
- Send the appropriate license fee and a cancellation form for the old license to the AWO Field Office

If the inspector finds that a licensee has changed or plans to change his/her regulated activity, notify the licensee that he/she needs a different class of license and:

- **Must** complete an Application for License–New License (APHIS Form 7003A–Application for New License), complete the TIN form, and pay the application fee
- Must **not** conduct the unlicensed activity until the new license is issued, but may conduct the regulated activities covered under the current license

The licensee should request an application packet from the Ft. Collins Animal Welfare Operations Field Office, if necessary.

4.5.2. Conducting the Inspection

4.5.2.1. Noncompliant Items Identified

If noncompliant items are identified during the inspection:

1. Enter the Inspection Report into ACIS under the Pre-license site.
   A. Make sure no license number is visible in the certificate box in the ACIS screen for that new site
   B. If the licensee does not have a new Pre-license site, contact the AWO Field Office to add a new site
2. Classify the inspection as "Pre-license #1"
3. Inform the licensee that he/she **cannot** conduct the new activity if it is **not** allowed under his/her current license. For example, a Class A dealer wants to exhibit animals
4. Add the statement to the report "NO CLASS (enter class of license) ACTIVITIES MAY BE CONDUCTED UNTIL A VALID USDA CLASS (enter class of license) LICENSE IS OBTAINED."
5. Schedule another inspection, if possible

4.5.2.2. No Noncompliant Items Identified

If no noncompliant items are identified on the inspection:

1. Enter the Inspection Report into ACIS under the new Pre-license site.
   A. Make sure no license number is visible in the certificate box in the ACIS screen for that new site
   B. If the licensee does **not** have a new Pre-license site, contact the AWO Office to add a new site
2. Classify the inspection as "Pre-license Inspection #1"
3. Follow the procedure for a Pre-license Inspection as detailed in Chapter 2-Required Inspection Procedures.
4. Add the statement to the report "NO CLASS (enter class of license) ACTIVITIES MAY BE CONDUCTED UNTIL A VALID USDA CLASS (enter class of license) LICENSE IS OBTAINED."
5. Have the licensee send the new license fee, and the voluntary cancellation form for the old license to the AWO Field Office.

NOTICE

If the licensee changes his/her class of license prior to the expiration date of the previous license, no refund of the previous license fee is given.

4.6. Complaint Inspection

A complaint inspection is conducted in response to an animal welfare concern received by Animal Care.

4.6.1. Sources of Information

Sources of information include, but are **not** limited to:

- General public
- Non-government organization
- Other Federal agency
- City, county, or State agency
- APHIS personnel
- Whistle blower

Methods of obtaining information include, but are **not** limited to:

- Email
- Fax
- Letter
- Personal contact
- Phone call

NOTICE

An inspector can never reveal, or confirm, the source of any complaint.
The complainant does NOT have to give his/her name to file a complaint.
If the complainant does provide his/her name, it may be subject to a Freedom of Information Act (FOIA) request.

4.6.2. Receipt of the Complaint Information

If the inspector receives a complaint directly from the public, State or local official, humane society, etc., discuss the issue with the complainant to determine if the complaint information applies to the AWA and/or the Animal Care Program.

If the complaint information is a possible noncompliance, instruct the complainant how to file an animal welfare complaint, either by contacting the appropriate AWO Field Office or through the Animal Care Website.

If the complainant does not want to file the complaint, collect all the information and contact your SACS.

The AWO Field Office will complete the Animal Welfare Complaint Sheet and

send the Complaint Sheet and the complaint information to the home inspector and the SACS.

If the complaint information does **not** apply to the AWA or Animal Care, explain the AWA Regulations and Standards to the complainant and refer the complainant to another agency (e.g., U.S. Fish and Wildlife, State wildlife or animal welfare agency, local animal control, or humane society) if appropriate.

4.6.3. Responding to the Complaint

The usual time frame for responding to a complaint is 30 days if an inspection is required. However, the response time may depend on the severity of the situation. The response time may be:

- Within 24 hours when:
  - The animal's health and well-being is threatened, e.g., an elephant is locked up in a truck on a hot day; or an extremely ill tiger is **not** being cared for properly
  - The public's safety is threatened, e.g., unsafe enclosures for dangerous animals, or unsafe handling of non-caged dangerous animals.
- As directed by your SACS or other program official for a situation with high public attention or Headquarters /Administration involvement.

NOTICE

For **elephant complaints**, the SACS must discuss the plan to address the complaint with the AWO Director before assigning an inspector and/or addressing the complaint.

4.6.4. Information Follow-Up

After you have followed up on the complaint, you should:

- Complete an Inspection Report, if appropriate
- Complete the Animal Welfare Complaint Sheet
- Send the completed Complaint Sheet to your SACS for review

The SACS should send the reviewed Complaint Sheet to the Ft. Collins AWO Field Office.

4.7. Courtesy Visits

Courtesy Visits are opportunities for Animal Care to provide learning opportunities and build relationships with facilities. A Courtesy Call may be conducted as opposed to a face-to-face visit as appropriate.

4.7.1. General Information

Courtesy Visits are appropriate for:

- Facilities that are considering seeking licensure or registration under the AWA
- Facilities seeking guidance or suggestions regarding how to ensure that they meet compliance Standards
- Facilities seeking to improve their understanding of the AWA requirements, and to verify that improvements they are making meet compliance Standards

Courtesy Visits are scheduled and announced in advance.

If an inspector goes to a facility for an unannounced inspection:

- An inspection **must** be conducted
- A Courtesy Visit may be scheduled for another time but you **cannot** perform a Courtesy Visit in lieu of an inspection

Courtesy Visits should not influence or change the inspection or enforcement process at a facility.

A Courtesy Visit is not a Compliance Visit. Compliance Visits, which are conducted by Compliance Specialists (or SACS for research facilities), are visits to follow-up with the licensee/registrant on the noncompliant items and provide personalized assistance for the compliance challenges. If you think a Compliance Visit is more appropriate, you should discuss this with your SACS.

If you are unsure if it is appropriate to conduct a Courtesy Visit at a facility or if a facility requests more than one Courtesy Visit, contact your supervisor for guidance.

If you get a request for a Courtesy Visit but are unable to fit it into your schedule, contact your supervisor to see if coverage can be obtained.

4.7.2. Documenting a Courtesy Visit

All Courtesy Visits, whether at regulated or non-regulated facilities, **must** be documented in ACIS:

- If two or more employees are involved in the activity, only one employee will make the entry into ACIS
- If the visit is not a follow up to a noncompliant item(s), the home or lead inspector will make the entry

- If the customer does not have a CID, contact Program Support to have one created and then enter the activity
- The specific activity should be entered into the Customer Activity tab in ACIS, selecting the 'add new activity' button, entering the date of activity, and selecting the specific corresponding activity type that most appropriately describes the visit, using the following definitions:

1. **Courtesy visit with applicant:** These visits are to ensure an applicant understands the Regulations and Standards, and is prepared for the first Pre-license Inspection. These visits are done prior to the first Pre-license Inspection.
2. **Courtesy call to applicant:** Same as "courtesy visit with applicant," except done via telephone as opposed to face-to-face. In addition to calls made before the first Pre-license Inspection, these calls can also be made between the first and second, and/or between the second and third Pre-license Inspection. This includes emails and texts for the same purpose.

NOTICE

"Courtesy call to applicant" is **not** the standard call made to all applicants as part of the pre-license process. It is in addition to that call.

Courtesy visits and calls to applicants also include visits and calls to 'potential' applicants who are seeking guidance about whether their facility would be in compliance.

3. **Courtesy visit to follow up on compliance concerns:** Face-to-face visit with the licensee/registrant (L/R) to ensure that the L/R understands how to correct a noncompliance of the Regulations or Standards, including teachable moments.
4. **Courtesy call to follow up on compliance concerns:** Same as "courtesy visit to follow up on compliance concerns," except done via telephone as opposed to face-to-face. This includes emails and texts for the same purpose.
5. **Courtesy visit due to change in circumstance (new building, species, etc.):** Face-to-face visit with a L/R to review a new, or "in-the-works," project to determine if it would be in compliance with the applicable Regulations or Standards. Examples include but are not limited to: new construction, new research proposal, acquisition of a new species, new site, new handling methods, etc.
6. **Courtesy call due to change in circumstance (new building, species, etc.):** Same as "courtesy visit due to change in circumstance," except done via telephone as opposed to face-to-face. This includes emails and texts for the same purpose.
7. **Courtesy visit with the attending veterinarian (AV):** These visits are to establish and/or maintain and/or develop a relationship with a facility's AV.

Visits with the AV to discuss a potential non-compliant item or a specific veterinary care issue identified during an inspection are not considered courtesy visits; they are part of the inspection process.

8. **Courtesy calls to the attending veterinarian:** Same as "courtesy visit with the attending veterinarian," except done via telephone as opposed to face-to-face. This includes emails and texts for the same purpose.

4.7.3. Conducting the Courtesy Visit

UNLICENSED/UNREGISTERED FACILITY

For a facility that is NOT licensed or registered:

- Discuss AWA requirements for the type of facility being visited and ensure the representative understands the expectations
- Offer to walk through the facilities and animal areas, and provide feedback regarding the facility's level of compliance

NOTICE

If a "Direct" animal welfare problem(s) is identified during a Courtesy Visit at a facility that is not licensed or registered, write a memo describing the areas of concern and contact your supervisor or the SOTW for guidance.

LICENSED/REGISTERED FACILITY

For a current licensee or registrant:

- Offer to look at areas they are concerned with, and offer suggestions for short and long term compliance and/or where they can obtain helpful information.
- If a Direct noncompliance is identified during the courtesy visit, the L/R should be instructed to address the cause of the noncompliance immediately, and promptly notify your supervisor

NOTICE

If a Direct NCI(s) is identified during a Courtesy Visit at a licensed/ registered facility, the Courtesy Visit does **not** become an inspection and an Inspection Report is not completed. Instruct the licensee/registrant to correct the NCI(s), and promptly notify your supervisor to discuss how to follow up on the Direct. For example:

- Return and conduct an unannounced inspection in 1 or 2 days
- Return and conduct an unannounced inspection with a VMO in 1 or 2 days
- Call the licensee/registrant to determine what action has been taken
- Call and discuss with the Attending Veterinarian

Courtesy Visits, when used appropriately, can be a valuable tool to improve compliance, and can promote animal welfare at some facilities.

4.8. Dead Animal/Parts or Serum/Blood Dealer Inspection

A dealer who sells dead animals, unborn animals, organs, limbs, blood, serum, or other body parts of regulated animals **must** meet all applicable Regulations and Standards.

4.8.1. Dead Animal/Parts

4.8.1.1. General Information

4.8.1.1.1 Dogs and Cats

If the animals arrive at the premises dead, specific areas to inspect include, but are **not** limited to:

- Records of acquisition
- Records of disposition

If the dogs/cats arrive at the premises alive and are held prior to euthanasia, the facility must meet all the applicable Standards, including official USDA identification. A complete inspection should be conducted.

4.8.1.1.2 All Animals Other Than Dogs and Cats

If the licensee does not acquire nor take control of the animals prior to the animals' deaths, **no** records are required.

If the animals arrive at the premises alive and are euthanized upon arrival, specific areas to inspect include, but are **not** limited to:

- Animal holding/euthanasia area
- Euthanasia procedures
- Acquisition and Disposition Records

If the animals arrive at the premises alive and are held prior to euthanasia, conduct a complete inspection.

4.8.2. Blood and Serum Collection

A dealer's procedure for collection of blood and serum should be evaluated carefully to ensure the welfare of the animals. Removal of excessive amounts of blood may have negative effects on the animal.

4.8.2.1. General Guidelines

If an animal is held long-term for collection of blood and/or serum, the inspector procedure should review:

- Volume per collection
    - Normally, the maximum amount of blood that should be withdrawn in one bleeding is 15% of the total blood volume (TBV)

- TBV is usually estimated to be 5 – 10% of total body weight (TBW) for most species, with one gram equal to one milliliter

- Frequency of collection
- An animals has to recover from the previous blood draw before another blood draw
  - Recovery times usually range from 1 – 4 weeks depending on the species and volume of blood drawn
- Long-term care

If the inspector has concerns about the amount of blood being drawn or the frequency of collection, he/she should discuss with the attending veterinarian and/or his/her SACS.

References which may be useful to determine appropriate collection volumes and methods include, but are not limited to:

Diehl et al. (pp. 17 – 19): https://www.aaalac.org/accreditation/RefResources/BloodRemoval.pdf

Hawk et al.: https://research.wustl.edu/wp-content/uploads/2017/10/Formulary-for-Laboratory-Animals.pdf

Parasuraman et al.: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3043327/

4.9. Dogs and Cats in Residence Inspection

Inspecting dogs and/or cats that are being kept and/or bred inside the licensee or applicant's home can be challenging. Many of the Standards used during routine kennel inspections are **not** applicable. It is important that the inspector take the overall conditions into account in making a determination and always contact a supervisor if there are questions.

- All regulated dogs and cats **must** be officially identified and listed on the appropriate animal inventory form
- Do **not** enter or stay in a residence unless you are sure you are safe
- Do **not** intrude into areas of the home which are not critical to evaluating the conditions for the regulated dogs or cats
- Do **not** open cabinets, refrigerators, drawers, or doors unless you have the expressed permission of the owner and the contents are directly related to the care of the dogs or cats
- Do **not** refer to the facility as a "house", "home", or "residence" on an Inspection Report. Use the term "facility", or some other mutually agreeable term such as "small dog area" or "retired breeder housing area."
- Do **not** use the impervious surfaces Standards under sections 3.2(d), 3.26(d), or 3.51(d), unless there is a designated housing or whelping area inside the home. For example, a bathroom used for whelping should have surfaces that can be sanitized but that applies to the bathroom area only. A living room where dogs hang out and watch television cannot be required to have surfaces that are impervious to moisture.
- Focus on the health of the animals and any direct hazards to their health or safety, particularly in areas **not** dedicated to housing animals. For example, in the living room, you would be looking at the health of the animals and such potential hazards as access to electric wires, bleach, choking or ingestion hazards, or significant waste disposal issues.
- Occasionally, a mudroom, laundry room, enclosed porch, or bathroom is used as a designated whelping or housing area. When animals are present, these areas **must** provide adequate temperature and ventilation and be easily cleaned and sanitized for the health of the animals.
- Wear clean boots or shoe covers to enter the premises. Do **not** use the same boots or shoe covers in which you inspected any other kennel buildings.
- When photographs are required, be extremely careful to only photograph what is necessary to document the noncompliance. Be sensitive to the fact that taking a large number of photographs in someone's house or photographing personal belongings may add stress to the inspection process. Take the minimum number of photographs needed.

It is important to be sensitive to the fact that this is the licensee's or applicant's

home and act accordingly. There is no limit under the AWA on the number of pets that a person can have in their house. We know from experience that a large number of dogs or cats housed in a residence can create unhealthy conditions. If you encounter an unusually large number of dogs or cats in a residence, or have concerns about general conditions in a residence, postpone the completion of the inspection and contact your supervisor.

4.10. Domestic Hoofstock Inspection

A dealer, exhibitor or research facility using domestic hoofstock who does not meet the AWA exclusions or exemptions **must** meet all applicable Regulations and Standards, including the transportation Standards.

Domestic hoofstock are:

- Alpacas
- Cows
- Goats
- Llamas
- Pigs and mini-pigs
- Sheep
- Hybrid crosses of the above animals

4.10.1. Domestic Hoofstock Housed in an Agricultural Setting

Agricultural settings include, but are not limited to:

- Pastures or ranges
- Outdoor pens with shelters and/or barns
- Production housing

When inspecting an agricultural setting, the inspector should use Subpart F of the AWA Standards. The inspector may also refer to the Guide for the Care and Use of Agricultural Animals in Teaching and Research, Third Edition, January 2010.

4.10.2. Domestic Hoofstock Housed in a Non-Agricultural Setting

Non-agricultural settings include, but are not limited to:

- Zoos
- Indoor displays such as nature centers or sportsman shows
- Research facilities

When inspecting a non-agricultural setting, the inspector should use Subpart F of the AWA Standards.

4.11. Drive-through Zoo/Park Inspection

A zoo or animal park which allows people to drive through, either in their own vehicles or a zoo/park vehicle, **must** meet all applicable Regulations and Standards.

Consider a team inspection for drive-through parks.

In addition to the regular equipment, inspectors should bring:

- Binoculars for each inspector to facilitate viewing of animals
- Cameras with adequate zoom to photograph animals at a distance

4.11.1. Conducting the Inspection

4.11.1.1. Driving through the Zoo/Park

Driving through the facility for inspection can be done in a facility–owned vehicle or in a GOV:

- Due to restrictions on the use of GOVs, the facility representative cannot accompany the inspectors in a government vehicle
- During the inspection, it is acceptable to ride in a vehicle provided and driven by the facility representative

Safety while driving through the zoo/park:

- Pay particular attention to safety while moving
- Watch for animals and other vehicles in the roadways
- Driver's attention should be focused on driving safely
- Passenger should be taking notes, photographs, and observing animals

Regardless of whose vehicle is used, it is important to:

- Drive slowly
- Stop frequently to observe the animals and their behavior
- Stop in locations where you can view animals congregating
- Pay particular attention to animals that may be isolated from the groups
- Observe the other vehicles driving through the zoo/park
- Watch for public interactions with the animals
- If public feeding is allowed, observe how it is accomplished

NOTICE

When inspectors are conducting the inspection from a GOV, the facility representative can accompany the inspectors by driving behind the inspectors' vehicle. In this case, cell phones or a radio may be used to point out any potential noncompliance or to ask questions that may arise.

4.11.2. Animal Inspection

Inspectors should evaluate the licensee's methods for providing both routine herd-wide preventative health care (as required by the facility's attending veterinarian) as well as care to individual animals that may become sick or injured. These methods may include:

- Annual or semi-annual animal 'round ups' where preventative care such as vaccination and deworming can be administered to all animals
- Moving individual animals into smaller areas to facilitate treatment using training or chutes
- Chemical immobilization administered by a remote delivery system

To help evaluate the handling methods, ask or look at:

- The equipment in use, such as:
  - Chutes
  - Drugs
  - Remote drug delivery systems
- Ensure that the equipment and drugs are appropriate for:
  - The species
  - Setting/terrain

Expansive habitats may necessitate the use of chemical capture and restraint drugs. To be considered adequate veterinary care the facility staff must be trained in their use and have the appropriate facilities and equipment to respond to adverse events if they occur.

4.11.3. Handling

When inspecting for compliance with the Handling Regulations at a drive-through zoo/park, some recommended items to evaluate include, but are not limited to:

- Compatibility of the animals in an area
- Caution signs, such as:
  - Do not get out of car

  - Do not put fingers in cages
  - Feeding only allowed when facility attendants are present
- Posting or distribution of the safety rules
- Monitoring of the zoo/park by employees during their regular duties
- Number of employees/attendants to patrol the zoo/park
- Monitoring of areas not readily visible to attendants
- Procedure in the event of an animal escape or attack

4.11.4. Public Feeding

The public may not bring outside food into the facility for public feeding. Food must be provided by the facility [2.131(d)(4)]. Remember to ask questions about measures that the facility has in place to prevent this practice and what actions are taken if this situation is found by the facility.

Food offered to the animals **must** be:

- Wholesome
- Palatable
- Presented in an appropriate manner

There are many methods for public feeding at drive-through zoos/parks which may be compliant. For example:

- Facilities use designated areas for feeding so that attendants can be present at those areas. Feeding in other areas is not permitted and the facilities have methods in place to discourage this practice.
- Facilities only permit feeding from facility operated vehicles that have sufficient attendants accompanying the public group
- Regular patrolling by facility staff of the feeding area
- Video surveillance of the feeding area with radio dispatch
- Distribution of written policies on feeding, such as handouts given to the public stating feeding rules such as, windows must be closed unless a facility attendant is present, and no feeding of animals unless an attendant is present
- Posted Caution Signs

When public feeding occurs from facility-owned vehicles, inspectors should evaluate how many attendants are present and whether they can intervene in the event of a problem. When the vehicle driver is the only attendant it may be difficult to ensure both animal and visitor safety. This is particularly true for large vehicles, those with driver separation from the public, or horse drawn vehicles.

4.11.5. Facility Inspection

When inspecting drive-through zoos, remember to evaluate all aspects of the facilities.

Ask about alternate housing. Many drive-through zoos/parks:

- Move a portion of the animals to alternate housing
- Rotate pastures
- May close for a portion of the year and move the animals

4.11.5.1. Separation of Businesses

Some drive-through zoos/parks also have other animal-related activities that are not considered by the park's owner to be part of the regulated enterprise, such as production farms or hunting preserves. It is important to determine what is regulated and what is exempt:

- Generally regulated if:
  - The animals are all comingled throughout the facility pastures or enclosures
  - The animals are viewed by the public during their visit to the facility
  - The animals from an off-site area are brought to and from the exhibit site

4.11.5.2. Animal Compatibility

Drive-through zoos/parks often have large multi-species enclosures. This can lead to compatibility issues if care is not taken in selecting the species and individual animals.

During inspection:

- Pay attention to animal interactions particularly around resources such as feeders, water sources, shelter, etc.
- Assess body condition. This can also be helpful in determining whether animals are getting adequate feed or if competition is negatively impacting them.
- Remember, not all compatibility issues are constant. Seasonal hormonal fluctuations associated with breeding season/rutting season can impact both intra-species and inter-species compatibility, so vary inspections by time of year.
- Evaluate animal records closely to help identify injuries or deaths which may be due to compatibility issues

4.11.5.3. Access to Shelter

Adequate shelter is essential for all animals at all facility types. The large

enclosures provide opportunity for naturalistic habitat, but also present unique challenges.

Natural shelter such as trees may not be sufficient in all circumstances.

When natural shelter is not adequate to protect animals from discomfort, artificial shelter must be available.

When evaluating artificial shelter, the inspector should ensure that:

- There is sufficient space for all animals
- There are enough shelters for all animals to fit into comfortably
- Shelters are strong enough for all species

NOTICE

Remember to assess the shelter in combination with compatibility as dominant animals may prevent submissive animals from using shelters if there is insufficient space.

4.11.5.4. Access to Potable Water

Ponds and/or streams used as the sole water source may be considered adequate potable water. However, the following items must be evaluated:

- Natural stream, river, pond or lake water should appear clear and there should be no indication of animal impacts caused by the water
- When covered by algae, water beneath should appear clear. Presence of algae does not mean the water is not potable.
- Ponds may freeze during the winter presenting a hazard for animals when the only water source
- Ask the facility representatives to point out potable water sources during inspection as additional water sources may be concealed to provide a natural looking environment.

4.11.5.5. Environmental Hazards

These natural environmental features may be hazards for some species but be appropriate habitat for others. You will need to make determinations about safety for the animals. Therefore when inspecting, remember to:

- Evaluate the physical terrain
- Know the natural history of the animals
- Be aware that some of these hazards change seasonally or between inspections
- Evaluate the facility's program for self-identifying/correcting issues before adverse animal impacts occur

- Review the facility records for injuries, deaths, and animals provided veterinary care to help evaluate the impact of physical hazards

4.11.5.6. Records

Exhibitors are required to make, keep, and maintain records of:

- Acquisition (including births)
- Disposition (including deaths and euthanasia)
- Animals on hand [for animals other than cats and dogs, see Section 2.75(b)(1)].

Increased mortality or decreased births can be indicators of both animal health and/or welfare problems. Therefore, accurate record keeping is essential for:

- Facilitating communication between the licensee and the attending veterinarian
- AC Personnel to evaluate compliance with the AWA Regulations and Standards.
- Evaluating effects of natural hazards
- Evaluating compatibility issues

When reviewing records of animal deaths/euthanasia, inspectors should remember to ask questions. For example, ~~W~~what were the circumstances surrounding the death or serious injury **and** was appropriate veterinary care provided?

For possible noncompliances already addressed by the facility, see "Incentives for Identifying, Reporting, Correcting and Preventing Noncompliances" in Chapter 2.

4.11.5.7. Necropsy Records

In some circumstances, necropsy examinations may be appropriate as part of the provision of adequate veterinary care. For example, if there are:

- Abnormally high death losses
- Significant unexplained mortality
- Other conditions indicative of an undiagnosed infectious disease

Inspectors should request to see documentation of necropsy examinations. If such records exist, they must be made available for inspection pursuant to section 2.125.

4.11.5.8. Animal Inventory

In large drive-through zoos/parks, there may be instances where it is not possible to ensure accuracy when counting a particular species during the

inspection. For example:

- A large group of fallow deer in expansive multi-acre exhibit
- Pot-bellied pigs allowed to roam the entire facility
- Small number of shy animals that are easily hidden in the natural environment
- Prairie dogs in a confined space that has only overhead viewing

In these cases, the inspector must assess the accuracy of the records. Examples of methods that may be used include, but are not limited to:

- Facilities may record births or deaths as they occur and then confirm total numbers of animals on hand at annual or semi-annual 'round-ups' where routine health procedures are also conducted
- Although individual animal identification is not specifically required by the AWA (for animals other than dogs & cats), licensees may ear-tag or otherwise identify individual animals as a best practice
- Some states may require ear-tag or other type of permanent identification for cervids

If the facility's method for maintaining records of animals on hand appears adequate, inspectors may use the facility's animal count for the purposes of the inspection inventory.

4.11.5.9. Training and Qualifications

During the evaluation of records is a good time to ask about the qualifications and training of the employees. Employees may be involved in activities that require specialized training, such as:

- Immobilization of animals
- Movement of large dangerous hoof stock
- Movement of very flighty hoof stock
- Determining compatibility among varied species
- Distinguishing between normal and abnormal behavior for a variety of species
- Observing illness/injury among a variety of species

It is important to check that employees are adequately trained and supervised by someone who has the necessary knowledge to instruct them.

4.12. Lion and Tiger Enclosure Inspection

This document provides **guidance** for assessing lion, tiger, and lion-tiger hybrid enclosures under commonly found circumstances at stationary facilities for purposes of primary containment.

Enclosures that clearly do not meet performance Standards for containment as per 9 CFR section 3.125(a) must be cited. All citations must refer back to the language of the Regulations; **there are no engineering Standards**.

4.12.1. Evaluating Enclosures

- Factors to consider when evaluating enclosures include:
- Height. Acceptable fencing for lions, tigers, and lion-tiger hybrids is typically a minimum of 12 feet in height, plus an additional method of preventing escape, such as, but not limited to:
  - A kick-in at the top
  - Hotwire attached to the fencing around the entire enclosure with sufficient joule rating to prevent the big cat from climbing to the top
  - A 2.5 - 3 foot-wide section of non-climbable material such as sheet metal attached to the fencing below the top of the entire enclosure fence to prevent climbing
  - An enclosure with a completely covered top (Note: Enclosures with a complete covered top must be high enough to allow for normal and typical behaviors and postures.)
- A wet or dry moat can be used to contain lions, tigers, and lion-tiger hybrids. Moats are typically 25 feet wide or greater and 16 feet deep or filled with 5 feet of water. Remember that if the animal enclosure is higher than where the public is standing, additional distance is needed as animals can jump farther when going from high to low ground.
- Trees and cage furnishings should be far enough away from the enclosure fence to prevent the big cats from climbing out

Note that this guidance is for enclosure design for compliance 9 CFR 3.125(a), and does not address handling requirements such as public barriers, which may need to be assessed as a separate issue.

NOTICE

If the inspector has any concerns about an enclosure's ability to contain lions, tigers and/or lion tiger hybrids, the inspector should contact his/her supervisor and Animal Care's Big Cat Specialist for guidance.

Compliant big cat fencing

The inspector should consult with the licensee on an appropriate identifier for each enclosure. The identifier may be the name of the animal in the enclosure, the location of the enclosure on the premises, an enclosure number, or any other agreed upon identifier.

4.13. Marine Mammal Facility Inspections

A licensee who conducts regulated activity with marine mammals **must** meet all applicable Regulations and Standards, including the transportation Standards.

4.13.1. Conducting the Inspection

Prior to inspecting a marine mammal facility, you should review the Marine Mammal Standards, Subpart E and the facility's recent inspection history.

When inspecting a facility with marine mammals, some items to evaluate are listed below.

4.13.2. Veterinary Care

Marine mammals must be provided adequate veterinary care, including but not limited to:

- All marine mammals must be visually examined by the attending veterinarian at least semiannually. Also, all cetacean or sirenian must be physically examined by the attending veterinarian annually, unless APHIS grants an exception based on considerations related to the health and safety of the cetacean or sirenian.
- Each marine mammal must have medical records that include physical examination information
- Review records for each animal with medical concerns or under treatment first. Verify that animals with inappetence over 24 hours are documented and the attending veterinarian has been notified.
- Ask about any births or deaths
- Ask how the facility cleans, disinfects and stores equipment used for medical/husbandry behavior training (e.g., gastric tubes, toothbrush, sample collection containers)
- Ask if any marine mammals are in quarantine or isolation and why
- Ensure that quarantine or isolation pools/areas for marine mammals held for **nonmedical** purposes meet the minimum space requirements
- Review the medical records and attending veterinarian justification for any marine mammals held for **medical** purposes for more than 2 weeks in quarantine or isolation pools/areas that **do not** meet the minimum space requirements
- Evaluate and inspect holding areas (for isolation, separation and treatment):
    - If a marine mammal is kept separated or isolated, there should be veterinary justification and provisions for periodic review of the plan by the attending veterinarian

- Review necropsy/histopathology reports
- Review any incident, husbandry, daily feeding and supplement logs and training logs

4.13.3. Space

Marine mammal primary enclosures must meet the space requirements in section 3.104.

4.13.3.1. Space requirements for marine mammals housed in unusual circumstances

Situations that may require further evaluation of space to assess compliance for marine mammal pools may include:

- Irregularly shaped pools
- Pools with islands or obstructions within the swimming area of the animals
- Pools with varying depths, where the shallow areas of the pool do not meet the minimum depth requirement for the species housed
- Pools with gates or channels that must be included in the minimum horizontal dimension (MHD) calculation for the pool to meet the required minimum horizontal dimension

Gather clear documentation necessary to submit to your SACS to thoroughly assess the situation. This documentation should include photographs and measurements.

Photographic documentation should include, but not be limited to:

- Document the pool(s) using photographs taken from at least two different angles, with photos taken across the width and length of the pool, or two different views of a round or irregular pool
- Include two-view photographs of obstructions, such as islands or pool outcroppings that may impede an animal's ability to swim within the pool
- Include close-up and distance photographs of channels, gates, and/or narrow areas that may require animals to adjust their swimming patterns. Include photographs taken looking down from the side of the pool, documenting the depth of the channel, gate design, or shallow areas.
- Include photographs of channels, outcroppings, or islands taken from underwater viewing windows, when possible
- Try to obtain video footage of the animals swimming in the pool, optimally when they are passing through gates, narrow channels, or swimming in a pattern around an island, to determine the animals' ability to navigate the narrow or irregular areas or to document the animals' ability to swim through shallow sections that do not meet the depth requirement

Measurements should include, but not be limited to:

- Measurements of the depth, width and length or circumference of shallow areas of the pool that are noncompliant and that require further assessment
- For pools with a sloping bottom, determine from either architectural plans, or from your own measurements, the approximate point at which the pool is a compliant depth for the largest species housed
- Create a map of the pool indicating the areas meeting the minimum depth requirements
- Measure the length, width, and depth of all channels that are necessary for the animals to use
- Determine from written records, facility personnel or SOP the amount of time gates are left open for the animals to access separate areas of the pool
- Measure the width, length, and depth of irregular areas of the pool if there is a question about calculating the MHD of the pool

4.13.4. Feeding

Food for marine mammals must be wholesome, palatable and free from contamination and must be of sufficient quantity and nutritive value to maintain marine mammals in good health.

- To minimize nutrient loss and bacterial contamination, frozen or thawed food must be stored, thawed and prepared properly. At a minimum, you should:
- Inquire about the source(s) of the food
- Inquire about types of food being fed and their nutrient analysis. Diets must be prepared with consideration for factors such as age, species, condition, and size of the marine mammal being fed
- Be aware that fatty fish, such as mackerel and tuna, have a shorter shelf life (4-6 months)
- Check freezers and refrigerators to verify proper temperatures. Freezers/cold storage **must** be maintained at a maximum temperature of 0 degrees F
- Examine the stored food and ask how food is stored and rotated to ensure that it maintains optimal nutritive value by minimizing freezer storage time and does not become freezer burned
- Check the catch date on boxes - old food loses nutritive value over time
- Verify frozen food has not thawed and refrozen or boxes damaged indicating possible contamination:
    - Check for water, blood, or ice pooling beneath or frozen to boxes, and
    - Check for freezer burn which could affect palatability and moisture content of the food. Signs of freezer burn include white or desiccated

flesh.

- Ask how food is thawed. Thawing **must** be conducted in a manner that minimizes contamination and will assure that the food retains nutritive value and wholesome quality until the time of feeding. When food is thawed in standing or running water, cold water **must** be used.
- Ask to see and examine a representative sample of thawed food to verify wholesomeness. Attention should be given to skin appearance, gill color, eye clarity, elasticity of the flesh, odor, and condition of viscera.
- Review the diet and amounts fed for each animal and ask how it is determined
- Review how calories/needs are calculated
- Review the feeding schedule/frequency
- Ask about supplementation and how it was determined. For example, cetaceans should have a multi-vitamin with B1 (Thiamine) at a minimum.
- Review daily food consumption records for each marine mammal
- All food **must** be fed to marine mammals within 24 hours once removed from freezers for thawing

4.13.5. Water Quality

The water in the primary enclosures must **not** be detrimental to the health of the marine mammals. When inspecting pools, at a minimum, you should:

- Ensure that each pool is being monitored and tested
- Look at SOPs for water testing
- Ask about frequency of testing
- Who does testing/where performed? Is it In house or sent out to the lab?
- Review water quality data for preceding year for ALL pools
- Keep in mind that pools that are rectangular in shape or have a narrow passage into another pool should be monitored carefully because dead spaces may affect water quality
- If water is tested at an intake valve, the facility may also consider testing water taken from another area of the pool
- Daily testing:
    - pH must be tested daily:
        - A pH between 7.6 and 8.0 is ideal for marine mammal life support systems
        - Facilities with natural saltwater do **not** have to test for pH
    - Water samples shall be taken and tested at least daily for chemical

additives (e.g., chlorine and copper) added to the water to maintain water quality standards

- Weekly testing:
  - Coliforms must be tested at least weekly
  - Coliforms with a consistent value of zero each week may be of concern
  - if coliforms exceeds 1000MPN/100 ml, action **must** be taken:
    - Two subsequent samples may be taken within 48 hours intervals and averaged with the first sample to obtain new count
    - If number still exceeds 1000MPN/100 ml then water is unacceptable **and** must be immediately corrected
    - Many facilities will do a partial to full water change to correct the problem

Check Salinity levels:

- Salinity should range from 15 - 36 PPT (parts per thousand):
  - Natural seawater salinity is 32 – 35 PPT
  - Salinity less than 20 PPT is likely to cause skin and eye pathology in cetaceans
  - Eye problems may be observed in pinnipeds housed in fresh or brackish water

4.13.6. Shelter and Shade

All marine mammals kept outside **must** be provided with shelter to afford them protection from the weather and direct sunlight.

When inspecting the shelter provided, at a minimum, you should:

- Look carefully at each animal for eye damage which can be caused by inadequate shelter from direct sunlight and is a serious, painful health concern for both pinnipeds and cetaceans
- Look at supplements being given (Eye-Sea is a common supplement given to marine mammals with eye damage and/or to prevent damage)
- Check if any animals have zinc oxide on heads or back. If yes, they may be ill and may need additional shelter.
- Observe a training session. Ensure animals are **not** being asked to look into sun during feeding.
- If public feeding is allowed, then observe the activity to ensure that the animals are not forced to look directly into the sun while getting their food reward
- Shelters can be natural or artificial so long as they are appropriate for the species concerned, when local climatic conditions are taken into

consideration. For example, facilities may use moveable umbrellas to protect animals' eyes during training.

Polar bears: The dry resting and social activity area for polar bears **must** be provided with **enough shade** to accommodate all polar bears housed in the primary enclosure at the same time.

4.13.7. Public Barriers

The requirements for public barriers are contained within section 3.101 (a)(2) under General Facilities and section 2.131(c)(1) under Handling:

- All marine mammals **must** be provided with protection from abuse and harassment by the viewing public by:
  - The use of a sufficient number of readily identifiable employees or attendants to supervise the viewing public, or
  - The use of physical barriers, or
  - A combination of these [3.101(a)(2)]
- During public exhibition, any animal must be handled so there is minimal risk of harm to the animal and to the public, **with sufficient distance and/or barriers** between the animals and the general viewing public so as to assure the safety of the animals and public [2.131 (c)(1)]

You should routinely observe public viewing areas to verify:

- If employees or attendants are used to protect marine mammals from abuse or harassment, then:
  - There are a sufficient number of uniformed or readily identifiable employees or attendants to supervise the viewing public, **and**
  - The attendants are adequately trained and attentive to the actions of the public
- The attendants are able to quickly respond to situations where the public potentially could have unsupervised contact with the animals:
  - Ask how the attendants would respond to any unsafe behaviors by the public. A common problem seen at marine mammal facilities involves the accidental or deliberate dropping of inedible items in the pool which can pose a serious health hazard if ingested.
- If physical barriers such as fences, walls, or glass partitions, are used, then they must be sufficient to protect the marine mammals from abuse and harassment by the viewing public and to assure the safety of the animals and the public
- If a combination of attendants and physical barriers are used, then they must effectively provide protection from abuse and harassment and assure the safety of both the marine mammals and the public

4.13.8. Separation

Marine mammals known to be social in the wild **must** be housed with at least one compatible animal of same or biologically related species, except when the attending veterinarian, in consultation with the husbandry/training staff, determines that such housing is **not** in the best interest of the marine mammal's health or well-being.

When inspecting, at a minimum, you should:

- Check that social needs of the marine mammals are being addressed. If unsure, contact your SACS for guidance.
- Marine mammals housed together **must** be compatible and other animals housed near the marine mammals **must not** cause them unreasonable stress or discomfort or interfere with their good health
- For marine mammals housed separately, check for a written plan approved by attending veterinarian, and developed in consultation with husbandry/ training staff, justifying the length of time of the separation and outlining the type and frequency of enrichment and interaction to be provided to the marine mammal

4.13.9. Employees

A facility must have a sufficient number of adequately trained employees or attendants working in concert with the attending veterinarian to maintain the husbandry practices as required in the AWA Standards. Such practices **must** be under the supervision of a marine mammal caretaker with **demonstrable experience** in marine mammal husbandry and care.

When inspecting, at a minimum, you should:

- Review written documentation that the employees/attendants have successfully completed a facility training course which includes, but is not limited to:
    - Species appropriate husbandry techniques
    - Animal handling techniques
    - Proper reporting protocols on recordkeeping
    - Notifying veterinary staff of medical concerns
- Check that any training of marine mammals is being done by or under the direct supervision of experienced trainers
- Ensure that trainers or handlers meet professionally recognized standards for experience and training. If you are unsure, contact your SACS.
- Ask if they have an ongoing or periodic training program which incorporates industry standards and best practices

4.13.10. Recordkeeping

Marine mammal facilities **must** maintain all records required under Subpart G-Records and any specific records required for marine mammals, such as:

- Medical records for individual animals
- Necropsy records
- Feeding records
- Water quality records

When inspecting records, at a minimum, you should:

- Review all of the required records and ensure they are being kept for 1 year (or 3 years for necropsy records)
- Contact National Policy Staff (NPS) if you need to obtain National Oceanic and Atmospheric Administration (NOAA) inventory data
- Verify the facility's inventory and cross reference with NOAA inventory

4.13.11. Swim-with-the-dolphin (SWTD)/Interactive Programs

Section 3.111 Standards have been suspended.

4.14. New Site Approval Inspection

Animal Care designates housing areas that are roughly 35 miles or further from the main address of the licensed or registered facility as separate sites. Site designations are used for tracking and inspection management purposes.

If the use of a single site designation causes a major problem at a facility, discuss the situation with your SACS.

The amount of time necessary to inspect all housing/exhibition facilities at a site is not a rationale for designating a separate site.

The licensee must list all sites and their addresses on the Application for License (APHIS Form 7003 or 7003-A).

New buildings or enclosures at an existing or nearby site do **not** require pre-approval. It is often helpful to perform a courtesy visit of new or proposed construction at currently licensed or registered sites but it is not a requirement. All buildings and enclosures in use should be inspected during the routine unannounced inspection of the existing site.

4.14.1. Addition of a Site

A site may be added to an existing license as follows:

- Licensee must notify, preferably by certified mail, the Ft. Collins AWO Field Office of the address of the new site
- AWO Field Office will inform the field inspector
- Inspector should schedule an inspection with the licensee as soon as possible

No application fee or additional license fee is required to be paid for the addition of a new site.

No regulated activities may take place at the new site until it has passed inspection.

4.14.2. Site Inspection

When conducting a Site Approval inspection, the following guidelines should be followed:

- The inspection is scheduled and announced. The Inspection Report should note that "The inspection was an announced site approval inspection."
- Inspection type is Routine
- Conduct a complete inspection of the new site
- No Teachable Moments may be given; the site must be in full compliance
- No correction date is given if an NCI is identified except for Directs as noted below

- If a Direct NCI is identified:
  - Designate the NCI as a "Direct" and assign an appropriate correction date, and
  - Inform the licensee that an "unannounced" inspection will be conducted on or after the correction date to see if the Direct NCI was corrected
  - If the licensee contacts the inspector for another Site Approval inspection prior to the Direct NCI correction date, document that the Direct NCI is corrected on the Inspection Report for that inspection
- No NCI should be designated as a Repeat
- If the facility is in compliance, type the following statement on the
- Inspection Report: "No noncompliant items identified during this inspection.

This site is now approved for regulated activity."

If the licensee conducts regulated activities at the new site before it has been approved, this should be cited on the Inspection Report under Section 2.5(d) – Conducting regulated activity without a valid license at the new site.

4.15. Pet Store Inspection

A pet store licensed as a dealer or exhibitor must meet all applicable Regulations and Standards for all the regulated animals in the store except for the exceptions detailed below.

4.15.1. Criteria

If a pet store is licensed, all regulated animals in the pet store or under the control of the licensee **must** be inspected and included in the inventory.

Regulated animals commonly encountered in a pet store include, but are not limited to:

- Traditional pet types, such as:
  - Cat
  - Chinchilla
  - Dog
  - Ferret
  - Gerbil
  - Guinea pig
  - Hamster
  - Rabbit
- Wild/exotic animals or pocket pets, such as:
  - Chipmunk
  - Degu
  - Duprasi
  - Flying squirrel
  - Hedgehog
  - Jerboa
  - Naked mole rat
  - Nonhuman Primate (usually for exhibit)
  - Opossum
  - Skunk
  - Spiny mice
  - Sugar glider

4.15.2. Record Requirements

A pet store must have all the records required of a B-Dealer, such as:

- Program of Veterinary Care
- Acquisition Records except as outlined below
- Disposition Records except as outlined below
- Exercise Plan for Dogs if applicable
- Environmental Enhancement Plan for NHPs if applicable
- Health Certificates if applicable

4.15.2.1. Acquisition Records

A "Record of Acquisition" is required for **all** regulated animals acquired by the pet store.

- Information in 2.75(a) is required, but use of APHIS Form 7005–Record of Acquisition of Dogs and Cats on Hand is optional
- Information in 2.75(b) is required, but use of APHIS Form 7020–Record of Acquisition, Disposition or Transport of Animals (Other Than Dogs and Cats) or APHIS Form 7020A-Continuation Sheet for Record of Acquisition, Disposition, or Transport of Animals (Other than Dogs and Cats) is optional
- If animals are found to have been "dropped off" by unknown person(s) at a licensed pet store, the licensed pet store has the option of taking the animals in and selling them retail. In such cases, the licensed pet store would be required to document the available acquisition information.

4.15.2.2. Disposition Records

A "Record of Disposition" is required **only** for the animals that were the basis for licensing, such as wild/exotic pocket pets, raccoons, primates, etc.

- Use of APHIS Form 7020–Record of Acquisition, Disposition or Transport of Animals (Other Than Dogs and Cats) or APHIS Form 7020A-Continuation Sheet for Record of Acquisition, Disposition, or Transport of Animals (Other than Dogs and Cats) is optional

4.15.3. Identification

Cage cards are an acceptable form of identification for dogs and cats at pet stores.

4.16. Petting Zoo Inspection

4.16.1. Inspection Procedures

4.16.1.1. Handling

Closely observe the handling of the animals when inspecting a petting zoo.

Proper handling of the animals includes, but is **not** limited to:

- Animals are exhibited **only** for a period of time and under conditions consistent with their good health and well-being
- During periods of public contact, an adequate number of employees or attendants are present at all times. These employees/attendants **must** be:
  - Knowledgeable
  - Readily identifiable
  - Responsible
  - Able to monitor all public interaction with the animals
- If public feeding is allowed, food **must** be:
  - Appropriate for the animal's nutritional needs and diet
  - Appropriate to the type of animal
  - Provided by the animal facility
  - Properly stored to minimize contamination or loss of nutritional value
- There are adequate public barriers, when appropriate
- There is minimal risk of harm to the animals and the public
- Dangerous animals, such as, but not limited to, lions, tigers, or bears must be:
  - Separated from the public by a barrier, and/or
  - Under the direct control and supervision of a knowledgeable and experienced handler

NOTICE

Nondomestic cats 4 weeks (28 days) of age or younger may not be handled by the public. [2.131(c)(3)]

4.16.1.2. Public Contact

If young or immature animals are being exhibited, they may **not** be:

- Exhibited for periods of time that would be detrimental to their health and well-being

- Exposed to rough or excessive public handling

Drugs may **not** be used to facilitate, allow, or provide for public handling of the animals.

NOTICE

At approximately 12 – 16 weeks of age **dangerous animals**, such as, tigers, lions, bears, and wolves, become too big, too fast and too strong to be used for public contact. If you encounter a licensee allowing public contact with a dangerous animal over 12 weeks of age, contact your SACS.

4.16.1.3. Miscellaneous

Other items to evaluate include, but are **not** limited to:

- Animal areas where the public is **not** allowed
- Cleanliness and sanitation of the enclosures
- Compatibility of the animals in an enclosure
- Condition of the animals
- Enclosure fencing to protect the animals

NOTICE

You should recommend that the licensee follow the CDC Guidelines for protecting the public against enteric pathogens, if he/she is **not** already doing so.

- Method(s) for allowing animals time away from public contact, such as:
  - Large enclosures
  - Solid walls on the outside of enclosures
  - Limited or controlled access to the animals
- Method(s) for allowing animals time away from view of the public, such as:
  - Barns
  - Burrows or dens
  - Curtained off areas
- Inspect public feed dispensers for:
  - Appropriateness of food items for the species
  - Cleanliness
  - Accumulation of old food or feed debris, especially at the bottom of the dispenser

- Security measures if animals left overnight
- Shelter, shade, cooling and heating appropriate for the environmental conditions the animals may experience
- Vehicles used to transport the animals
- Water availability for the environmental conditions

Remember the following housing restrictions:

- Guinea pigs may **not** be housed in outdoor facilities, unless located in the appropriate climate and with prior approval from the AWO Field Office
- Hamsters may **not** be housed in outdoor facilities
- Rabbits, guinea pigs, and hamsters may **not** be housed in the same primary enclosure with any other species

4.16.2. Traveling Petting Zoo Itinerary

No fewer than 2 days prior to overnight travel, AWO Field Office must receive a document identifying the information required below. This means, that if USPS is used, the document must be mailed sufficiently far in advance to arrive at the AWO Field Office by the deadline.

Itinerary information is required for all regulated animals that are away from the home site at least overnight for the purpose of exhibition. This does **not** include animals:

- Transported to a veterinary facility for treatment or evaluation
- Relocated for breeding loan
- Relocated during renovations
- Taken home overnight for extensive husbandry care (such as attendants taking very young animals home for overnight feedings and monitoring)

The following information must be included in the itinerary document submitted to the AWO Field Office:

4.16.3. Exhibitor information:

1. Name of licensee (person exhibiting and transporting the animals)

   A. Business name of licensee, if applicable

   B. USDA AWA license/registration number

2. Name of owner of animal (for leased, borrowed, loaned, etc. animal)

4.16.4. Animal information:

1. Name of animal
2. Identification number of animal or identifying characteristics

3. Species of animal (scientific name or common name)
4. Sex and age of animal

4.16.5. Exhibition and transport information:

1. Name of exhibition location
2. Address of the exhibition location
3. Dates at the exhibition location
4. Name, date, location (address, directions, GPS location, etc.) of all stops and layovers where animals are removed from transport enclosures

If the exhibitor's travel plans change:

- He/she should contact the AWO Field Office to amend the itinerary
- If the change in itinerary is reported verbally (by telephone for example) and not in writing, such as by email or fax, the change in plans must be followed by written notification as soon as possible
- If there is an emergency change after USDA business hours (weekdays, 8:00am to 5:00pm Central Time), the exhibitor must notify the AWO Field Office by the next business day

4.16.5.1. No Itinerary Submitted

If you encounter a traveling petting zoo exhibitor:

1. Check ACIS for a current itinerary
2. If there is not a current itinerary in ACIS, check with Program Support at the Ft. Collins AWO Field Office to determine if there is a current itinerary that has not yet been entered into ACIS
3. If the AWO Field Office confirms that a current itinerary has not been submitted, cite the exhibitor under 2.126(c)

4.17. Photo Shoot Inspection

Anyone providing or using regulated animals for photo shoots may need to be licensed and meet all the applicable Regulations and Standards.

4.17.1. Types of Photo Shoots

4.17.1.1. Regulated Photo Shoots

The following types of animal photo shoots require a license, except as exempted under the DeMinimus rule, including, but **not** limited to:

- Photos of people petting or sitting with wild/exotic animals such as:
  - Tiger, lion or bear cub, and other baby animals

NOTICE

Nondomestic cats 4 weeks (28 days) of age or younger may not be handled by the public.
At approximately 12 - 16 weeks of age **dangerous animals**, such as, tigers, lions, bears, and wolves, become too big, too fast and too strong to be used for public contact.
If you encounter either of these situations, contact your SACS.

  - Marine mammals
  - Nonhuman primates
  - Camels or reindeer in nonagricultural or nontraditional settings
- Animal actors/movie animals
- Animals released into a natural setting for the photo
- Photos for advertising or calendars and magazines

4.17.1.2. Exempt Photo Shoots

The following types of photo shoots do **not** require a license:

- Photos of free-living wild animals
- Pictures of people with their pets
- Photo shoots with only domesticated farm animals
- Photos shoots at exhibits of traditional farming and agricultural practices (such as displays of working animals, such as reindeer pulling a sled or working on a farm)
- Photo shoots at exhibits of art portraying traditional farming and agricultural settings (such as nativity scenes with a camel or domesticated farm-type animals displayed in a barn or other traditional farm-type setting)

- Photo shoots at exhibits with **eight or fewer** of any combination of the following types of animals:
  - Pet animals
  - Small exotic or wild mammals
  - Domesticated farm type animals

4.17.2. Conducting the Inspection

When inspecting a photo shoot, you should observe the photo shoot before introducing yourself. In addition, time how long the animal is displayed with people before being given a rest break.

Recommended items to observe or evaluate include, but are **not** limited to:

- Observe the animal(s) for behavioral stress, such as:
  - Struggling
  - Vocalization
  - Pulling at leash or straining
  - Panting/increased respiration
  - Sleeping
  - Limpness
- Age of dangerous animals being used for public contact photos
  - Minimum age – 4 weeks; maximum age depends on the animal but for dangerous animals generally 12 weeks (See guidance in Chapter 3 Conducting the Inspection)
- Availability of potable water
- Observe food and food storage and check feeding schedule
- Availability of veterinary care, if needed
- Housing of the animal(s) when **not** being used for the photo shoot including, but not limited to the ability of the animal to exhibit species typical behaviors
- Measures to protect the safety of the public and the animal(s) such as:
  - Adequate attendants
  - Plexiglas
  - Tethering of animals to secure structures
  - Leashing of animals
  - Handler(s) located between the dangerous animal and public at all times
- Number of employees available to control the animal(s)
- Off-exhibit area, if any

- Procedure in the event of an animal escape or attack
- Public barriers, especially for animals **not** currently being used for photos
- Rest periods for the animals. Observe and time how long rest periods are in addition to **asking** how much rest is provided
- Restraint methods for the age and size of the animal(s)
- Safety measures for the movement of the animal from the enclosure to the photo shoot and back

NOTICE
Drugs and alcohol may **not** be used to control the animals.

- Safety measures if **no** perimeter fence
- Training and handling experience of the employees
- Transport of the animal to and from the photo shoot. Inspect:
  - trailer or vehicle used for transport
  - primary container used to house the animal during transport
- Review paperwork such as Program of Veterinary Care, health certificate if required, and acquisition records

4.18. Pre-license Inspection Process

All Pre-license Inspections should be conducted using the Enhanced Pre-license Process (EPLP) based on the guidance provided to all inspectors and the guidelines in this section.

Do **not** conduct a Pre-license Inspection until all of the applicant's paperwork has been processed by the Program Section and the inspector has been informed that the applicant may be inspected.

There must be regulated animals at the facility at the time of the inspection. If this a problem due to State laws/regulations or local ordinances, contact your SACS.

4.18.1. Initial Contact with the Applicant

Prior to conducting the first Pre-license Inspection:

- Contact the applicant within ten days of receiving application notification letter from the AWO Field Office
- Schedule and conduct a Pre-license phone discussion
  - The discussion can be done in person but not at the same time as the Pre-license inspection
  - The discussion should be scheduled since it can take 45-90 minutes, and
  - The applicant will need time to gather paperwork and prepare questions for the discussion
  - In order for this call to be effective, the applicant and the inspector must be focused and prepared for the discussion
- Have a phone discussion with the applicant to determine if the facility is ready for the 1st Pre-license Inspection
- Schedule the 1st Pre-license Inspection
  - Let the applicant know this could take 4-6 hours and will involve discussion and review of the AWA requirements and an inspection
  - Contact a Compliance Specialist or second inspector to accompany you if you feel that you may need assistance

4.18.2. First Pre-license Inspection

4.18.2.1. Conducting the Inspection

Prior to starting the physical inspection:

- Go through informational materials with the applicant
- Use the following Commercial Breeder PowerPoint file found on the Center for Animal Welfare (CAW) website as appropriate to the species

(https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/caw)

- Program of Veterinary Care
- Exercise Plan for Dogs
- Additional PowerPoint files and educational material can also be used as needed

- Focus on using informational materials that are applicable to all facilities
- Remind the applicant that they are legally responsible for being familiar with and compliant with the AWA (9 CFR)
- Remind the applicant that interference during the inspection and/or refusal to allow an inspection are serious issues

During the inspection of **animals and the facility**:

- Be sure to inspect all animals used for regulated purposes
- **For dealers with dogs**, you must:
  - Have the applicant pull all dogs showing signs of medical issues so that you can evaluate whether veterinary attention is needed and/or is already being provided, **and**
  - Also select **ten percent** of the remaining dogs for the applicant to pull so that you can look for medical issues associated with their mouths, teeth, ears, eyes, skin, general condition, etc. Do **not** just focus on one area; take the opportunity to look at the entire dog for medical issues. **Remember**, wear a new pair of gloves after touching each dog or after each enclosure.
- If you identify a veterinary care issue that would normally be cited during a Routine Inspection, it **must** be cited on the Inspection Report for the Pre-license Inspection
- Inspect the entire facility thoroughly:
  - This includes equipment and vehicles intended for use with animals
  - Be certain to verify the locations of all animals on site and off site that are used or intended for regulated use
- Inspect all housing areas thoroughly:
  - This includes all housing for all regulated animals – even if the applicant states it is temporary housing
  - If you have a concern about the primary enclosure, especially for large carnivores, elephants, great apes, and/or marine mammals, you should contact your SACS to discuss
  - NOTE: If the applicant was previously licensed, he/she must re-apply for any variance (e.g., perimeter fence) granted under the cancelled license
- Inspect all storage areas thoroughly:

- Including vaccine and medication storage
- All food and bedding storage

4.18.2.2. Handling and Qualifications

For an applicant with **large carnivores, elephants, great apes, and/or marine mammals**, the applicant's (and employee's, if applicable) knowledge and qualifications and handling practices should be evaluated carefully. If the inspector cannot determine if the applicant has adequate experience and knowledge of the species being handled, contact the appropriate AC personnel, i.e., SACS and species specialist or AC Specialist.

If the experience and qualifications cannot be determined at the 1st Pre-license Inspection, an appropriate statement similar to the following statement should be included on the Inspection Report:

"The handling practices, and/or applicant/employee qualifications are under review."

If the handling practices or qualifications require further review, it is the responsibility of the inspector to contact his/her SACS to determine how to proceed.

4.18.2.3. Records

During the inspection of records:

- Discuss the required documents for a compliant Pre-license Inspection:
  - Record of Acquisition of Dogs and Cats on Hand (APHIS Form 7005) or Record of Animals on Hand (APHIS Form 7019 or equivalent):
    - For a new applicant (not Failure To Renew), there should be as much detail as possible, such as name and address, phone number, directions to seller's facility, some way to contact seller
    - For a previously licensed applicant (Failure To Renew), the records must be complete including all acquisition information
  - Exercise Plan for Dogs:
    - Must be in writing and accurately reflect the conditions at the facility
    - Must be approved by the attending veterinarian
  - Plan for Environmental Enhancement (for nonhuman primates)
    - Must be in writing and accurately reflect the conditions at the facility
    - Must be approved by the attending veterinarian
  - Written Program of Veterinary Care, if a part-time attending veterinarian is used
    - The APHIS Form 7002 is not a required form—other methods/forms

may be used to document the PVC

4.18.2.4. Post Inspection Procedure

After the physical inspection:

- Discuss all NCIs identified with the applicant
- If there are any NCIs – leave the facility and write the Inspection Report
  - This allows you time to write a detailed and thorough report
  - This is the first Inspection Report this applicant has ever received and it must help them understand what is expected of them
- **Hand deliver the Inspection Report and conduct a thorough exit briefing**
- Do **not** send the Inspection Report by email or certified mail. If you cannot hand deliver the Inspection Report, contact your SACS
- Review with the applicant again any areas you believe necessary
  - Use PowerPoint files that apply to the situations seen at the Pre-license Inspection
  - Provide the applicant ONLY agency-approved educational materials, such as:
    - Dog Breeder Resource Guide
    - Copies of the Power Points
    - Animal Care Aids
  - Tech notes

4.18.3. Second Pre-license Inspection

The 2nd PL Inspection, if required, may be scheduled at the time of the 1st

Pre-license Inspection or you should instruct the applicant to contact you when he/she is ready (but within 90 days following the 1st PL inspection).

During the 2nd PL Inspection:

- Refer to the 1st Pre-license Inspection criteria for guidance
- Conduct a full and complete inspection. Inspect all records, animals, facilities and storage. There are **no** focused Pre-license Inspections.
- Review with the applicant additional presentations on Husbandry, Housing, and Transport as applicable

4.18.4. Third Pre-license Inspection

If a 3rd PL Inspection is needed:

- There **must** be at least 2 AC personnel on the inspection. This could be the

home inspector and another ACI/VMO, a Compliance Specialist, or a Supervisor.

- Work with the applicant to prepare for the inspection and achieve full compliance
- Be sure the applicant understands this is the last inspection available for compliance and if the applicant does not pass this inspection, he/she must wait 6 months to re-apply for a license

During the 3rd PL Inspection:

- Refer to the 1st Pre-license Inspection criteria for guidance
- Conduct a full and complete inspection. Inspect all records, animals, facilities and storage. There are **no** focused Pre-license Inspections.
- Review with the applicant additional presentations on Husbandry, Housing, and Transport as applicable

4.18.5. Completing the Inspection Report

4.18.5.1. No NCIs – Applicant Passes PL Process

If the applicant has a no NCI Inspection Report, he/she passes the PL process.

You should:

- Complete an Inspection Report which must include the following statements:
- Exit briefing statement
- "No non-compliant items identified during this inspection."
- *"This (1st/2nd/3rd) Pre-license Inspection for a Class ("A"/ "B" /"C") license and exit briefing were conducted with the applicant."*
- *"Licensing fee must be mailed to: (Add address of Ft. Collins AWO Field Office)"*
- *"Conducting regulated activities without a valid USDA license is a violation of the Animal Welfare Act."*
- Hand deliver the Inspection Report (required)
- Verify accuracy of application with applicant
- Stress the importance of continued compliance and discuss "Repeat", "Direct" and "Critical" noncompliances
- Finish with the following CAW Commercial Breeder PowerPoint files:
- Identifying Animals and Keeping Records
- Maintaining Your License
- Discuss optimal hours with the applicant and record the days/times in the comments section of ACIS

4.18.5.2. NCIs Identified – Applicant Does NOT Pass PL Process

If the facility is **not** in full compliance, cite all noncompliant items using the first three components of the four-part citation description found in New NCIs Cited but do **not** give correction dates.

NOTICE
Do not designate any noncompliance as a Direct, Critical, or Repeat.

If the applicant does not pass on the 1st or 2nd Pre-license Inspection:

- Make sure that the applicant knows of the 90 day limit and plan accordingly
- Complete an Inspection Report which must include the following statements:
  - Exit briefing statement
  - "This (1st/2nd) Pre-license Inspection for a Class ("A"/ "B" /"C") license and exit briefing were conducted with the applicant."
  - "All items must be in compliance within (2 /1) more inspection(s) or by (date-90 days counted from 1st PL Inspection) or the applicant will forfeit the application fee and must wait 6 months to reapply."
  - "Please contact (Inspector Name) to schedule your next Pre-license Inspection."
  - "Conducting regulated activities without a valid USDA license is a violation of the Animal Welfare Act."
- Hand deliver the Inspection Report (required)
- Remind applicant it is his/her responsibility to contact the inspector when ready for the next Pre-license Inspection

If the applicant does not pass on the **3rd Pre-license Inspection**:

- Complete the Inspection Report citing all NCIs **and** cite 2.3(b) to indicate failure to come into compliance on the third Pre-license Inspection
- Include the following statements on the Inspection Report:
  - Exit briefing statement
  - "This 3rd Pre-license Inspection for Class ("A"/ "B" /"C") license and exit briefing were conducted with the applicant."
  - "The applicant will forfeit the application fee and must wait 6 months from (insert date of failed 3rd PL Inspection) to reapply."
  - "Conducting regulated activities without a valid USDA license is a violation of the Animal Welfare Act"

4.18.6. PL Inspection Process Reminders

- All Pre-license Inspections must be thorough and complete. There are no focused Pre-license Inspections.
- All Pre-license Inspections should be completed using the Enhanced Pre-license Process (EPLP) Guidance. If guidance is not available for the specific species being inspected, existing guidance should be adapted and used as needed.
- All Pre-license Inspection Reports must be hand delivered. If hand delivery is not possible, discuss extenuating circumstances with your SACS
- Pre-license presentations should be done prior to conducting the inspection of facility and whenever deemed appropriate during the pre-license process to help clarify any issues found during the inspection
- This is where the bar of compliance can be set and future problems can be avoided
- Discuss optimal hours with the applicant and record the days/times in the comments section of ACIS

4.19. Search Inspection

A search is an inquiry relating to possible unlicensed activity.

4.19.1. Subjects of Searches

Subjects of searches include, but are **not** limited to:

- Persons breeding and selling dogs, cats or pet-type animals wholesale or retail sight unseen
- Persons selling wild or exotic animals retail or wholesale
- A non-registered research facility purchasing regulated animals
- Persons exhibiting regulated animals
- Persons using regulated animals for rides
- Involuntarily terminated licensees or registrants (e.g., canceled due to non-renewal, suspended due to consent decisions and orders)

NOTICE

If you have reason to suspect that an involuntarily terminated license/ registrant is continuing to operate without a license or registration, conduct a search within 60 days of the termination of the license, if possible.

- Previously identified violators

Use good judgment to decide when you have made a reasonable effort to verify unlicensed activities.

Examples of possible ways to verify unlicensed activity are:

- Checking dealer, broker, carrier/handler records
- Checking newspaper advertisements
- Checking the internet
- Communicating with other inspectors
- Making phone calls
- Visiting the facility

4.19.2. Sources of Information

Sources of information include, but are **not** limited to:

- Advertisements
- Animal protection groups
- Anonymous tips

- APHIS personnel
- City, county, or State agency
- Dog or exotic animal auction records
- General public
- Internet sites
- Newspaper/journal articles
- Other Federal agency
- State health certificates
- Whistle blower

Sources may provide information by the following methods:

- Email
- Letters
- Personal contact
- Phone calls

NOTICE

The informant does not have to give his/her name. However, if the informant does give his/her name, do not give out the person's name in order to maintain confidentiality.

4.19.3. Information Follow-Up

Decide if the information supplied to the Animal Care program involves a regulated activity or animal.

If the information does **not** involve a regulated activity or animal:

- Discuss with the informant AWA regulated activities/animals
- Thank the informant for his/her interest in the welfare of animals
- Refer the informant to the appropriate office/agency, if known. Possible referral agencies include:
  - U.S. Fish and Wildlife Service
  - NIH-OLAW
  - State wildlife agency
  - Local animal control
  - State or local humane society
  - State animal welfare agency

- Take no further action

If the information does involve a regulated activity or animal:

- Thank the informant for his/her interest in the welfare of animals
- Complete the top portion of a Search sheet. (See *USDA, APHIS, Animal Care Search for Unlicensed Activity Worksheet*)
- Determine if the information applies to a person in your territory

If the information applies to a person, business, or research facility not in your territory:

- Tell the informant that the facility is **not** in your area, but that you will forward the information to the AWO Field Office for distribution to the appropriate inspector
- Give the informant the AWO Field Office phone number for follow-up
- Forward the information (e.g., copies of records, invoices, sale bills) to your SACS for referral to the appropriate SACS

If the information applies to a person in your territory, conduct a search.

4.19.4. Preparing for the Search

Confirm whether the individual/business is already entered into ACIS:

- If the person does not already have a customer identification number (CID), request an ILA to assign one. You will need to provide all the relevant information to the ILA.
- If the person already has a CID, review the relevant facility information including: inspection history, previous licenses, prior search results, or other activity (included being sent an application or unlicensed facility letter). Remember to check both inspection history, activity tab, and the files tabs for this information.

4.19.5. Conducting the Search

Searches may be conducted:

- By phone
- By internet
- In person – If you have any concerns, contact the person by another method

Verify the information received by:

- Contacting the authorized representative
- Gathering additional information, such as:
  - Newspaper or journal articles
  - Classified ads

- Information off the internet
- Internet web site addresses

If regulated activities are not being conducted, then complete a Search sheet and submit your findings to your SACS and AWO Field Office.

If regulated activities are being conducted, then:

- Explain to the owner or authorized representative that the activity requires a USDA license or registration
- Discuss with the owner or authorized representative all the pertinent portions of the AWA and Regulations and Standards
- Request a decision about the continuation of the regulated activity
- Give or have the AWO Field Office send an application packet to the authorized representative
- If you give the person an application packet, let the AWO Field Office know
- Take photographs documenting the regulated activity **if you can do so safely**. This may include supporting documentation, such as, billboards or other public advertising, waybills, or broker records that you obtained from other sources.
- If the owner or authorized representative has **not** previously been contacted by Animal Care or licensed, offer to conduct a Courtesy Visit (See Courtesy Visits):
  - Go through the facility thoroughly, and
  - Explain all NCIs and potential NCIs to the owner/authorized representative
- If the owner or business has **previously** been licensed/registered or received a letter or Application/Registration Packet:
  - Advise the owner that he/she will be receiving an Inspection Report citing the conducting of regulated activity
  - Complete an Inspection Report:
  - Classify the inspection as “Routine”
  - In the narrative, cite Section 2.1(a)(1) for conducting regulated activities without a license or Section 2.30(a) for conducting regulated activities without a registration for a research facility or Section 2.25(a) for conducting regulated activities without a registration for a transporter/intermediate handler, and describe the regulated activity
    - State the following at the end of the Inspection Report: “No regulated activities may be conducted until USDA license/registration is obtained.”
    - Send the Inspection Report to him/her by regular and certified, return

receipt mail

4.19.5.1. No Courtesy Visit Conducted

If the owner or authorized representative does not want a Courtesy Visit OR you decide **not** to conduct a Courtesy Visit for safety concerns:

1. Inform the owner or authorized representative that he/she or the business is noncompliant with the Animal Welfare Act by conducting a regulated activity **without** a license/registration
2. Take photographs documenting the regulated activity, if you can do so safely
3. Give or have the AWO Field Office send an application or registration packet, if applicable, to the owner or authorized representative
4. Discuss how to proceed with your SACS

4.19.6. Post Search Procedures

After conducting a search, ALWAYS:

1. Complete a Search sheet
2. Enter the Courtesy Visit into ACIS
3. Enter the Inspection Report into ACIS, if applicable
4. Enter any photos taken of the regulated activity or supporting documentation into ACIS
5. Submit the Search sheet with Inspection Report if applicable to your SACS for review
6. After approved by your SACS, email a copy of the Search sheet and Inspection Report if applicable to the AWO Field Office
7. If conducting regulated activity was cited on an Inspection Report, discuss with your SACS if an enforcement action would be appropriate

4.19.7. Follow-Up Procedure

If an owner/business/research facility you contacted on a search was conducting a regulated activity and the owner or business has **not** applied for a license/ registration within 3-4 months, discuss with your SACS if you should revisit the facility to determine if a regulated activity is still being conducted.

If the person is **no** longer conducting a regulated activity:

- Complete a Search sheet documenting this fact
- Submit the Search sheet following the standard procedure

If the person/business/research facility is still conducting a regulated activity:

- If safe and appropriate, remind the authorized representative that a USDA

license/registration is required to conduct this activity

- Document the regulated activity by either:
  - Conducting an inspection, if possible, or

NOTICE

The noncompliance cited for conducting regulated activities without a license/registration, should be designated as a "Repeat" noncompliance.

  - Completing another Search sheet
- Take photographs, if possible
- Discuss how to proceed with your SACS

4.19.8. On the Road Inspection

If you find an unlicensed exhibitor on-the-road, inform the exhibitor that:

- A USDA license is required for the activity he/she is conducting
- All applicable AWA Regulations and Standards **must** be met at all sites
- He/she **cannot legally** exhibit until licensed

Obtain the following information from the exhibitor:

1. Location of the home base or permanent facility which he/she returns to between tours
2. Animals currently housed at the home base or permanent site
3. Name of any other Animal Care inspectors that the exhibitor has been in contact with and the results of that contact
4. Ways to contact the exhibitor while on-the-road
5. An itinerary

If the exhibitor refuses to give you any information:

- Get vehicle license tag number, if possible, to obtain follow-up information
- Try to get contact information and itinerary from the manager, if applicable
- Discuss how to proceed with your SACS

4.20. Traveling Exhibitor Inspection

Each inspector should develop a consistent method of conducting inspections of traveling exhibitors that ensures a thorough and accurate inspection.

4.20.1. Home Site Inspection

A Traveling Exhibitor **must** have a home site (001). If animals are housed at the home site, the facility must meet all the applicable AWA Regulations and Standards for a permanent location.

If no one is home and/or available for an inspection at the home site, there is no itinerary showing all animals were traveling and it is during the exhibitor's optimal hours if applicable, then an Attempted Inspection Report should be written.

If animals are not housed at the home site, i.e., it is a business or mailing address:

- An inspection must still be conducted at this site
- If the licensee is not at the home site, an authorized person should be designated by the licensee and available to conduct an inspection
- At a minimum, records, such as the program of veterinary care and acquisition/disposition/animals on hand, should be available at the home site
- Note on the Inspection Report that no animals are housed at this facility and that it is a business/mailing address. For example: "No animals present at facility. This site serves as a mailing address."

4.20.2. General Information

Inspections of traveling exhibitors are different from inspections at the home facility. However, all of the applicable AWA Regulations and Standards must be met.

If you become aware that a traveling exhibitor is, or will be, performing in your territory:

- Check ACIS for the date and results of the last TRA inspection.
- Do not conduct an inspection if:
  - An inspection has been conducted within 90 days, and
  - The inspection had no noncompliances, and
  - There is no open complaint on the exhibitor
- If the traveling exhibitor was not inspected within 90 days and/or had a noncompliance on the last TRA inspection, or there is an open complaint on the exhibitor, contact your SACS to determine if an inspection is needed
- Contact the home inspector or home SACS to see if there are any ongoing

concerns or active complaints

4.20.3. Admission to the Venue

If the venue, e.g., theme park, State/county fair, Renaissance festival, or craft show has an admission gate:

1. Go to the admission gate/ticket window
2. Identify yourself in a professional manner
3. State the purpose of your visit
4. Show your USDA badge and ID

At most venues, you will **not** be required to pay admission. However, if an admission fee is requested, ask to speak to someone in management.

If you need to pay admission, contact your SACS for approval, then charge the admission fee on your Purchase MasterCard (preferable), or pay cash/personal credit card (you will be reimbursed).

NOTICE

Under certain circumstances, you may want to observe the exhibition, facility, or facility personnel prior to announcing your presence. If necessary, pay the entrance fee and you will be reimbursed. The observation should be done from areas accessible to the general public. Immediately after observing the exhibition/ facility/personnel, you **must** announce yourself to the licensee/registrant or facility representative and arrange to complete the inspection and address any findings that you observed prior to announcing yourself.

Prior to conducting the actual inspection or immediately after your unannounced observation:

1. Contact the licensee/registrant or authorized representative
2. Introduce yourself in a professional manner
3. State the purpose for the visit
4. Show your USDA badge and ID
5. Provide a business card if appropriate

If you do not find anyone at the facility, follow procedures for an Attempted Inspection (see Attempted Inspection in Chapter 2).

4.20.4. Conducting the Inspection

- Prior to conducting the inspection:
- Contact the home inspector or the inspector who conducted the last TRA inspection if you have questions

- Review prior inventories
- In ACIS, review past inspections, including photos if available, teachable moments, current enforcement actions, and contact information

4.20.4.1. General Inspection Requirements

When inspecting a traveling exhibitor, some recommended items to evaluate/ observe include, but are not limited to:

- A performance/act
- Adequate shelter and shade for animals housed outdoors
- Availability and use of exercise areas
- Chained or tethered animals
- Enclosures for adequate space during travel and at the temporary location
- Feeding schedules

NOTICE

Food deprivation may not be used for training.

- Food preparation and storage areas
- Fresh meat if required. Ask about:
  - Sources of the meat while on the road
  - Storage
  - Method(s) of thawing
- Handling of the animals – observe:
  - Handling before contacting the authorized representative if needed
  - Any direct contact activity allowed with the public, such as feeding or photos
- Health and well-being of all the animals, such as:
  - Alertness and activity level
  - Behavior
  - Foot and hoof care
  - Normal appearance
  - Presence of wounds
- If you have concerns about an animal, ask to see the animal up close, if you can do so safely
- Loading and unloading of animals
- Qualifications and training of the animal handlers

- Records (see Records)
- Security measures to protect the animals and the public, such as:
  - Barrier fences or electric fences
  - Night security
  - Uniformed attendants
- Source and quality of the drinking water to make sure it is potable
- Sufficient number of employees to provide for the animal's care
- Transport vehicles (see Transport Vehicles)
- Veterinary care and vet records (see Veterinary Care)

For animals in transit, see Animals in Transit.

CAUTION

Be alert and cautious around the animals. Remember that big cats spray, nonhuman primates spit and throw feces, and animals may be able to get their legs, paws/feet, trunk, etc. through the bars of their enclosures.

4.20.4.2. Dogs and Cats

If the dogs or cats live loose in the licensee's traveling home, such as a house trailer or camper:

- Ask how the dogs/cats are transported in the conveyance to ensure that the travel Standards are being met.
- Check the room(s) that the dogs/cats live in to ensure that it meets all primary enclosure Standards.
- Check for required records and ID

4.20.4.3. Wild and Exotic Animals

- When inspecting wild and exotic animals, ensure that:
- All animals in the enclosure are able to make normal postural adjustments (stand in an upright position, turn around, and lie down with limbs extended in a normal manner **without** obstruction from enclosure sides or having to extend feet through bars or feeder doors)
- Animals that normally engage in occasional vertical postures, such as bears and many felines, have sufficient vertical space available to accommodate these postures
- The primary enclosures for other animals should have adequate space for each animal to express all non-injurious species-typical:
  - Behaviors

- Postures/movement (such as grooming)
- Social adjustments

Some information to remember when inspecting certain species:

- **Baboons and chimps** have sexual swellings that may resemble tumors.
- **Camels**:
  - When males become excited, they may blow up a sac-like extension of the soft palate into a red "balloon" which hangs out from the corner of their mouth.
  - Males in a "musth/rut" may:
    - Dribble urine
    - Drool, slobber, and froth at the mouth
    - Have rough/scaly hair coats
    - Lose a significant amount of weight
    - Make gurgling sounds
- **Large cats**–females in heat:
  - Become very vocal
  - Roll around
  - Urine spraying behavior (all big cats)
- **Tethered hoof stock** should have tethers of sufficient length and arrangement to be able to comfortably lie down, get up, self-groom, and move about within a reasonable distance.

4.20.4.4. Veterinary Care

When inspecting traveling exhibitors, check for the following:

- The exhibitor has an attending veterinarian
- If the attending veterinarian is part-time, there is a formal arrangement
- Environmental enhancement plan for nonhuman primates, which may need to be different than the plan at the home facility
- Exercise plan for dogs while in travel status, which may need to be different than the exercise plan at the home facility
- Health and well-being of the animals
- Health certificates, if required
- Required medical records for marine mammals

4.20.4.5. Records

A traveling exhibitor should have the applicable required records with him/her on the road. However, if the records are at another site or location, it is acceptable for the records to be emailed or faxed to the site of the inspection during the inspection if possible. Otherwise, the exhibitor can email or fax the records to the inspector within 48 hours to be in compliance.

If the required records are not available and not received by the inspector within 48 hours, cite as a noncompliance under the appropriate Section.

A traveling exhibitor must have all the appropriate records for the regulated animals for up to 1 year from the disposal or euthanasia of the animals.

The following records, when applicable, **must** be available for review during an inspection on the road, as required by the Regulations and Standards:

- Acquisition records or a record of animals on hand for all regulated animals present
- Disposition records for all regulated animals that have left the current tour since it began, or died or been euthanized while on the road
- Exercise plan for dogs
- Health certificates for dogs, cats, nonhuman primates and marine mammals, if required
- Individual medical records for marine mammals
- Necropsy records for marine mammals
- Nonhuman primate environmental enhancement plan
- Program of veterinary care appropriate for the animals being exhibited
- Water quality records for marine mammals

NOTICE

Copies of the original records are acceptable.

4.20.4.6. Transport Vehicles

Inspect transport vehicles for:

- Cleanliness
- Condition of the floor, i.e., rotting areas which could give way and/or allow entry of exhaust fumes
- Food storage areas
- Separation of species while in transit
- Space and height for the species transported

- Structural strength, such as:
  - Bent or warped surfaces
  - Loose fittings or grates
  - Protruding edges
- Vehicle safety features, such as:
  - Door latches and locks
  - Good tires
  - Proper hitches
  - Tires rated for the weight load carrying
  - Vehicle rated for the weight load carrying
- Ventilation and temperature when doors are closed
- Working temperature control systems, such as heaters, fans, and air conditioners
- Accessibility to the animals as needed
- Adequate barriers, protection and security of the transport vehicle/trailer to keep the public from getting close to the animals while the vehicle is stopped, such as at a motel or restaurant. This is especially important for trailers with large openings, such as stock trailers.

4.20.5. Animals in Transit

When in transit, all regulated animals must be housed in enclosures that meet the transportation requirements for that species.

An animal is considered “in transit” when it is moving in a conveyance from:

- The home facility to a temporary location
- A temporary location (exhibition venue) to another temporary location
- A temporary location to the home facility

Stopping overnight, such as at a hotel/motel, or stopping for short rest periods and food breaks for the drivers, handlers, and other people accompanying the animals is still considered “in transit.”

4.20.6. Animal Races

Examples of animals used for staged animal races include, but are not limited to:

- Camels
- Gerbils
- Hamsters

NOTICE

Professional dog races, such as greyhound races, field trials, and tracking events and races with farm animals such as pigs are exempt.

While conducting your inspection, areas to pay special attention to include, but are not limited to:

- Individual tolerances of the animals
- Length of race for species being raced
- Methods used to encourage the animals to run
- Number of races per day for each animal
- Rest periods for animals between races
- Species and age of animals being raced

NOTICE

If you have questions, or are unsure about a situation, use your professional judgment and/or call your SACS.

4.20.7. Animal Rides

See Animal Rides in this Chapter.

4.20.8. Circus and Performing Animal Inspections

Some areas to pay special attention to include, but are not limited to:

- Amount of time animals perform and are rested
- Handling of the animals
- Housing for animals between shows
- Methods or types of restraints used to control the animals

NOTICE

Drugs may **not** be used to control the animals.

- Procedure for moving animals from housing to the performance area
- Procedure in the event of an animal escape or attack
- Public barriers
- Training and handling experience of the handlers and employees
- Transport enclosures and transportation vehicles
- Type and safety of public contact with dangerous animals

NOTICE

If you have questions or are unsure about a situation, use your professional judgment and/or call your SACS.

Circuses may be:

- Covered under one exhibitor's license
- Composed completely of individually licensed exhibitors who work for the circus. In this case, a separate Inspection Report must be completed for each licensee.
- Composed of a combination of a licensed circus and individually licensed exhibitors. In this case:
  - Complete one Inspection Report for the licensed circus itself and include all the regulated animals covered under the circus's license, and
  - Complete separate Inspection Reports for each individually licensed exhibitor

NOTICE

It is important to know which exhibitor's license covers the particular animal you are inspecting. It is common for exhibitors/animal acts to travel with more than one circus in a touring season. If you have questions or are unsure about a situation, call your SACS.

4.20.8.1. Observing the Circus or Performing Animal Show

Prior to announcing your presence, you may want to watch an actual performance to observe the handling of the animals and the types of acts/tricks the animals are performing.

Make a notation on the Inspection Report, whether you watched the performance or not.

NOTICE

Drugs may **not** be used to control the animals.

- Pre-performance activities involving the public
- Procedure for moving animals in and out of the rings
- Space requirements for the animals, i.e., are animals housed in their transport enclosures? If so, do these enclosures meet the space requirements when not in actual transit?
- Vertical space for animals that require it, such as bears, large cats, and nonhuman primates

- Check substrate where animals are housed (dirt, concrete, asphalt) for:
  - Temperature as concrete and asphalt may get very hot
  - Sufficient amount of bedding

NOTICE

Never enter a pen or enclosure unless absolutely necessary and the animal(s) are secured.

4.20.9. Petting Zoos

See Petting Zoo Inspection.

4.20.10. Photo Shoots

See Photo Shoot Inspection.

4.20.11. Inspection Reports

When entering an Inspection Report for a traveling exhibitor not at his/her home site, ensure that:

- You use the "traveling-on-the-road" (TRA) site designation in ACIS
- If the licensee does **not** have a TRA site already in ACIS or the TRA site is not active, follow the procedures for Action to Take When a Person, Facility, or Site is Not in the ACIS Database
- If the licensee has more than one TRA site, use the correct TRA site if it is in ACIS, such as the "Blue Unit" or the "Red Unit"
- In the narrative section, include:
  - Name of the venue, e.g., Douglas County Fair, and
  - Location of the inspection, i.e., city and State, and
  - Name of the circus, unit, or group, if applicable, and
  - If there was a show/performance, if you did or did not watch the show/performance
  - Names of the elephants inspected if applicable
- Email a copy of the Inspection Report to the home inspector or inform the home inspector that you conducted a TRA inspection

4.20.12. Itinerary

All traveling exhibitors must submit an itinerary. For details, see Traveling Petting Zoo Itinerary.

Check to see if the facility has submitted an itinerary for future exhibitions, especially if there were NCIs on the Inspection Report.