6.0 Conducting the Inspection

GENERAL PROCEDURES

Each inspector should develop a consistent method of conducting inspections to ensure that his/her inspections are thorough and accurate.

Preparing for the Inspection

Prior to the inspection, you (the inspector) should review the following information:

- research facility's past inspections
- research facility's Annual Report
- variances or extensions that may have been granted
- applicable sections of the regulations and standards
- applicable sections of the Research Facility Inspection Guide
- applicable Animal Care Policies
- other relevant resource material

Conducting the Inspection

Upon arrival at the facility:

- do not enter facilities with locked gates and/or "No Trespassing" signs unless prior approval has been obtained from the registrant or designated research facility representative
- be alert for unsafe conditions, such as loose or vicious animals

Prior to conducting the actual inspection:

- contact the designated research facility representative(s) or other responsible person (see Note below)
- introduce yourself in a professional manner
- state the purpose for the visit
- show your USDA badge and ID if requested
- if appropriate, provide a business card

NOTE: Under certain circumstances, you may want to observe the facility or facility personnel prior to announcing your presence. This should be done from areas accessible to the general public. Any noncompliances noted during this observation may be cited on the inspection report.

The inspector should be accompanied by a designated research

facility representative or other responsible person (who should be at least 18 years of age), when conducting the inspection in areas not accessible to the general public.

If you do not find anyone at the research facility, follow procedure for an Attempted Inspection (see Section 8.1).

The steps detailed below are the components of an inspection and need to be performed. However, the exact order is left to the discretion of the individual inspector.

Biosafety Measures
Biosafety measures to follow in conducting an inspection include, but are not limited to:

- follow facility's biosafety procedures, or
- put on recommended protective clothing, gear and/or boots, such as:
  - dogs/cats:
    - sanitizable or disposable boots
    - coveralls (optional)
    - ear plugs (strongly recommended)
    - disposable gloves (if touch any animals)
  - macaques:
    - respirator (Level N95 or better)
      - required if within 5 feet of animals
      - recommended if further than 5 feet from animals
    - coveralls (preferably disposable)
    - full face shield and eye protection such as safety glasses or goggles
    - disposable gloves
  - other nonhuman primates:
    - respirator (Level N95 or better)

Animal Inspection
Basic steps to follow in conducting an inspection of the animals include, but are not limited to:

- observe and check the health and well-being of the animals
  - avoid handling the animals unless necessary, such as

to check for dehydration or malnutrition
  - wear disposable gloves if you must handle any animals
  - do not engage in diagnostic procedures
- approach all animals quietly and cautiously
- review husbandry practices
- review personnel experience and training
- observe handling techniques of personnel
- ask if there are any other animals that you have not been shown, such as in quarantine, isolation, holding or off-site
- review veterinary care
- inspect animal transport cages and vehicles

Facility Inspection

Basics steps to follow in conducting an inspection of the facilities include, but are not limited to:

- inspect facility premises, building(s), and equipment
- inspect all quarantine, isolation and holding areas
- inspect all food, diets, and food preparation areas
- inspect all hospital and surgical areas
- inspect researchers' labs if appropriate
- inspect all drugs for proper storage and expiration dates
- visualize problems that may occur at other times of the year
- use the Checklist for Animal Care Inspection Report (see page 5.4.7), if desired
- ask questions concerning the operation of the facility if necessary to ascertain compliance

  Examples of questions to ask include:
  - Are there any other locations, rooms, barns, sheds, etc. where:
    - animals are housed, used or held
    - food and/or bedding is stored
    - medical supplies are kept
  - Are there any collaborative studies being conducted here or at another research facility?
  - Are there any other places where cages, food bowls, water bottles, etc. are washed?
  - Where are new animals received?
  - Where are controlled drugs kept?

Records Inspection

Basic steps to follow in conducting a records inspection include, but are not limited to:

- review available records, such as:
  - IACUC records (see Section 14.4)
  - Annual Report (APHIS Form 7023)
  - acquisition/disposition records
  - health/medical records
  - non-random source dog/cat certification statements
  - random source dog/cat certification records
  - Standard Operating Procedures (SOPs)
  - investigators' logs
  - cleaning/sanitizing logs
  - temperature records
  - maintenance logs
  - any other records relating to the animals
- collect information for animals that you, the inspector, are suspicious about the source

  For example, you should question the source of dogs which are:
  - uncommon research breeds, such as:
    - small or toy breeds
    - thick coated dogs
  - tattooed with a non-USDA tattoo code or number
  - microchipped

  Note: The research facility representative may request that you traceback an animal that he/she is suspicious of the original source.

Identification of Noncompliant Items

If noncompliant items are noted during the inspection, you should:

- identify the noncompliant items
- make notes on the noncompliant items
- point out each noncompliance to the designated research facility representative or responsible person
- explain why an item is noncompliant
- discuss possible solutions if asked
- discuss any problem that is not currently a noncompliance but may become an NCI in the future

	NOTE: If **no** animals are present in an area with a noncompliance, the NCI should be cited only if the area is: • currently in use but no animals are there at the time of your inspection, or • ready for use
Identification of Unsafe Conditions	Be alert for unsafe facility conditions: • if the conditions affect the animals, note or cite on the inspection report • if the conditions are not a violation of the AWA, report these items to the designated research facility representative or other responsible person at the facility Examples would be: ▸ unlocked controlled substances ▸ locked emergency exits ▸ absence of smoke detectors • if the conditions adversely affect you, leave the area

IACUC REVIEW	All IACUC responsibilities, functions, and activities must be completely and thoroughly reviewed.
	You (the inspector) are responsible for conducting a complete and thorough inspection of a research facility's IACUC. Detailed below are some aids to assist you in evaluating the IACUC. However, you must use the regulations and your professional judgment to determine if an IACUC is in compliance. Ways to assess that the IACUC is functioning properly include, but are not limited to: • written meeting minutes • audio tapes • Program of Humane Care and Use • IACUC facility inspection reports • IACUC-related correspondence • memos/notes • e-mails and e-mail records • interviews with IACUC members • approved protocols • standard operating procedures • medical/surgical records • room temperature logs • maintenance records • cage wash water temperature certification records
Membership	In assessing IACUC membership, you should look for verification that: [2.31(a) & (b), Policy #15] • all required positions are filled NOTE: If a required position(s) is unfilled, there is not a properly constituted IACUC and decisions made by this IACUC are invalid. • there is documentation of appointment of members by the Chief Executive Officer (CEO) • the same person does not fill more than one required position NOTE: This is not prohibited by the AWA but you should strongly recommend that different people fill each required

position. [Policy #15]

- the DVM has acceptable experience and responsibility for animal care and activities
- the nonaffiliated member represents the general public, i.e., has no conflict of interest either personally or financially (see page 17.2.2)
- there are no more than 3 members from one administrative unit of the research facility
- 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
  - facility inspection

Meetings

In assessing meetings, you should look for verification that: [2.31(c)]

- meetings are held at least every 6 months for the program review and/or facility inspection
- all members are informed of all meetings, such as:
  - full IACUC meetings
  - subcommittee meetings
  - executive committee meetings
- meetings are held at a time when all members, especially the nonaffiliated member, can attend
- required members, especially the nonaffiliated member and the attending veterinarian, are in attendance at most meetings
  NOTE: 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 e-mail, all members must have e-mail
- 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 • substance of the deliberations of the IACUC, not just the decisions reached • any minority views • approval of the minutes (usually of the previous meeting) by the IACUC
Program of Humane Care & Use Review	In assessing the program review, you should look for verification that: [2.31(c)(1) & (c)(3)] • the review is being conducted at least once every 6 months • if the IACUC adopted the AAALAC International Program Assessment report as its semi-annual program review, the following requirements were met: ▸ the report complied with Section 2.31(c) ▸ at least 2 members of the IACUC participated in the evaluation ▸ no IACUC member wishing to participate was excluded ▸ the report was signed by a majority of the IACUC members ▸ the report included any minority views • all members are informed of the date and time of the program review • 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 (see Section 18.1)

- departures from the AWA are identified on the program review with:
  - a detailed description of the departure
  - the reason for the departure
  - classification of the departure as a significant deficiency or a minor deficiency
  - a plan and date(s) for correction of the deficiency
- IACUC-approved exemptions and variances are specifically identified, including:
  - a description of the exemption/variance
  - reason for the exemption/variance
- a report of the IACUC program review:
  - is completed
  - is signed by a majority of the members
  - contains any minority views
  - is sent to the Institutional Official
- any uncorrected significant deficiency was properly reported to Animal Care and other appropriate Federal agencies (see page 18.3.2)

Facility Inspection

In assessing the facility inspection, you should look for verification that: [2.31(c)(2) & (c)(3)]

- 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)
  - at least 2 members of the IACUC participated in the evaluation
  - no IACUC member wishing to participate was excluded
  - the report was signed by a majority of the IACUC members
  - the report included any minority views
- 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 subcommittee 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 (see Section 18.2) • departures from the AWA are identified on the facility inspection with: ▸ a detailed description of the departure ▸ the reason for the departure ▸ classification of the departure as a significant deficiency or a minor deficiency ▸ a plan and date(s) for correction of the deficiency • a report of the IACUC facility inspection: ▸ is completed ▸ is signed by a majority of the members ▸ contains any minority views ▸ is sent to the Institutional Official • any uncorrected significant deficiency was properly reported to Animal Care and other appropriate Federal agencies (see page 18.3.2)
Reports to the Institutional Official	In assessing the reports to the Institutional Official (IO), you should look for verification that: [2.31(c)(3) & (c)(5)] • 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) • departures from the AWA are contained in the report with: ▸ a detailed description of the departure ▸ the reason for the departure ▸ classification of the departure as a significant deficiency or a minor deficiency ▸ a reasonable and specific plan for correction of the deficiency ▸ dates for correcting the deficiency

- IACUC-approved exemptions and variances are specifically identified, including:
  - a description of the exemption/variance
  - reason for the exemption/variance
- 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
- the report contains any minority views

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

- uncorrected significant deficiencies
- notice of suspension of a protocol

You should review:

- how the reports are sent to the Institutional Official, and
- if there is any confirmation from the IO that the reports were received

NOTE: If you have a concern that the Institutional Official is not receiving the required reports/information, you should visit with the IO.

Protocol Activity Suspension

In assessing the IACUC's suspensions of protocol activities, you should look for verification that: [2.31(c)(8), (d)(6) & (d)(7)]

- the activity was reviewed and suspended at a convened meeting with a quorum of the IACUC present
- the suspension was approved by majority vote of the quorum present
- the Institutional Official, 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

	NOTE: If the reason for the protocol suspension was a noncompliance, then you should cite the noncompliance whether it has been corrected or not. If the noncompliance was corrected, you should state this in the citation. If not, follow the standard procedure for citing a noncompliance.
Complaints/Concerns	In assessing the IACUC's responsibility for addressing complaints or concerns, you should look for verification that: [2.31(c)(4)] • adequate methods are in place for receiving complaints/ concerns from sources outside the research facility • adequate, confidential methods are in place for receiving complaints/concerns from sources inside the research facility • complaints or concerns were reviewed and, if appropriate, investigated for validity • appropriate action was taken on valid complaints/concerns • any allegation of reprisal was investigated • apparent valid allegations of reprisal were reported to the appropriate research facility official and Federal agency, if appropriate **NOTE:** If the issue in the complaint or concern was a noncompliance, then you should cite the noncompliance whether it has been corrected or not. If the noncompliance was corrected, you should state this in the citation. If not, follow the standard procedure for citing a noncompliance.
Records	In addition to the reports listed above, the following IACUC records must be available for review and in compliance with the AWA regulations: [2.35(a)(2)] • protocols (see Sections 6.3 and 14.4) • proposed significant changes to protocols • IACUC approval or non-approval of protocols or proposed significant changes to protocols • any other protocol-related information

PROTOCOL REVIEW

Protocols and the IACUC's approval and monitoring of protocols must be completely and thoroughly reviewed.

You (the inspector) are responsible for conducting a thorough inspection of:

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

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

For the protocol review, you should:

1. determine the number of protocols subject to your (the inspector) review including:
   - active protocols, AND
   - inactive protocols from the past 3 years, and
   - protocols where no regulated species are present at the facility
2. if the number is small, review all of the research facility's protocols for regulated animals, OR
3. if the number is large, review a representative sample of active and inactive protocols. such as:
   - for each regulated species
   - for high profile species, such as dogs, cats, or nonhuman primates
   - for high profile procedures, such as "Specific Types of Protocols" starting on page 6.3.5
   - for different PIs
   - for each Category with animals listed on the past 3 years Annual Reports
   - protocols involving invasive procedures, e.g., skull cap placement, laparotomy, or thoracotomy
   - food and/or water restriction protocols
   - antibody production protocols
4. review all Category E protocols from the past 3 years

NOTE: The list of protocols reviewed by the IACUC may be used to determine the number of protocols and the specific protocols to be reviewed by you. Note: You may need to ask for a list of inactive protocols.

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

- protocols
- protocol submission forms
- written meeting minutes
- audio meeting minutes
- correspondence
- memos/notes
- e-mail correspondence and e-mail records
- interviews with IACUC members
- Compliance Office/Officer activities, if the facility has a Compliance Office

PROTOCOL APPROVAL

Process

In assessing the protocol approval process, you should look for verification that:

- all protocols involving regulated animal use are submitted to the IACUC
- NO animal activity is started before the protocol has been properly approved
  NOTE: No IACUC member can approve a protocol or give permission for an animal activity to start before the protocol has gone through the proper approval process.
- the IACUC has a mechanism for distributing protocols and other pertinent information to IACUC members which is accessible to all members, i.e., if distributed by e-mail, all members have e-mail or an alternate method of distribution is used for members without e-mail
- all members are sent a list of protocols to be reviewed prior to the review in sufficient time to request a copy of the protocol or participate in the review

	• if the protocol was reviewed by the full IACUC: ▸ there was a quorum present ▸ approval was by a majority vote of the quorum • no IACUC member voting on the protocol had a conflicting interest • any **significant changes to protocols** were approved using the same procedures as for a protocol review • any IACUC requested additions or changes to protocols were made before final approval was given • all IACUC decisions regarding protocols, or significant changes to protocols are documented in writing and available for inspection • no official, department, or committee of the research facility overrides IACUC denials of protocols or significant changes to protocols. NOTE: Implementation of an IACUC approved protocol may be delayed or prohibited by another official, department or committee, for example, the Radiation Safety Committee if the protocol does not meet its requirements.
Notification	In assessing the protocol notification requirement, you should look for verification that: [2.31(d)(4)] • the Principal Investigator is notified in writing of the IACUC's decision on his/her protocol • the Research Facility (usually the Institutional Official or his/her designee) is notified in writing of all protocol review decisions • if protocol approval was denied, the IACUC: ▸ notified the Principal Investigator of the reason for the denial ▸ gave the Principal Investigator the opportunity to respond
Annual Review	In assessing the annual review of protocols, you should look for verification that: • all active protocols are reviewed by the IACUC or a subcommittee annually • 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
PROTOCOL REVIEW	
General Requirements	In assessing an IACUC's review of a protocol, you should look for verification that: • the rationale for using animals is clearly stated, acceptable, and scientifically justified • the species of animal(s) to be used is clearly stated • the appropriateness of the species is adequately and scientifically justified • the number of animals to be used is clearly stated • how the approximate number of animals to be used was determined is clearly stated or shown, such as: ▸ 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 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 • the proposed use of the animals is clearly and adequately detailed • the principal investigator has provided a written assurance that the proposed activity is not an unnecessary duplication of previous experiments • medical care is provided for the animals when needed • the animals' living conditions and care are adequate and appropriate • personnel conducting the research or handling the animals are

properly trained and qualified
- there is a description of how pain/distress/discomfort are minimized, if applicable
- disposition of animals at termination of study is stated, including harvesting of tissues or body parts
- the method of euthanasia is:
  - clearly stated, including drug(s) and dosages, and
  - consistent with the current *Report of the AVMA Panel on Euthanasia,* **or**
  - an alternative method justified in the protocol and approved by the IACUC
- any exemption/exception to the AWA regulations or standards is adequately justified

NOTE: Routine veterinary care, housing, euthanasia, etc., may be detailed in standard operating procedures (SOPs), but the protocol must refer specifically to that SOP(s).

Specific Types of Protocols

Painful/Distressful Procedures

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

- the procedure is properly classified
- 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 (see page 18.5.2 for electronic and non-electronic search requirements)
- measures used to alleviate the pain/distress are clearly stated, including:
  - drugs, dosages, and frequency of administration

  NOTE: A "PRN" or "as needed" frequency of administration is not acceptable unless there are detailed instructions and criteria for determining administration of the drug.
  - other methods, such as:
    - hydrotherapy
    - hot/cold packs

- measures used to relieve pain/distress are adequate, i.e., correct drug, dose, frequency, etc.
- availability of experienced personnel, especially at night and on weekends, to assess and administer pain relief
- if pain/distress relief is not to be used, there is an adequate justification (see page 18.5.3)
- the principal investigator has consulted and involved the attending veterinarian or his/her designee in the planning of the procedure and pain/distress relief
- if a paralytic is used, it is used with anesthesia
- animals experiencing severe or chronic pain/distress that cannot be relieved will be humanely euthanized
- the endpoint has been determined and identified

NOTE: If the research facility has a standard operating procedure(s) (SOP) for pain/distress relief, the protocol must reference that SOP.

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, such as, www.nal.usda.gov/awic/pubs/antibody/overview.htm
- an alternatives search, if done, was properly conducted and reviewed for possible alternative procedures
- 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
- an alternatives search, if done, was properly conducted and reviewed for possible alternative procedures
- 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
- 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 or 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. NOTE: Pain withdrawal response is **NOT** an appropriate measure of level of anesthesia.
- 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 animal is recovered from the NMB 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 procedure, such as analgesics, tranquilizers or 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 that one major operative survival surgery UNLESS appropriately approved (see page 18.5.6 for requirements)
- 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: (see page 18.5.4)
  - when drugs are to be administered
  - when or which drugs are **not** to be administered, if applicable, with an explanation
  - drug, dose, route, and frequency of administration
  - signs of pain/distress
  - contact person(s)
  - other or additional methods of pain/distress relief

NOTE: If the research facility has a standard operating procedure(s) (SOP) for surgical procedures or pain/distress relief, the protocol must reference that SOP(s).

Teaching Protocols

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

- the justification 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 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 Studies

When reviewing protocols involving toxicity studies, some areas to pay special attention to include, but are not limited to:

- a consideration of alternatives was properly conducted and reviewed for possible alternative procedures, such as:
  - Local Lymph Node Assay
  - Up-and-Down Procedure

  (See http://iccvam.niehs.nih.gov/about/overview/htm)
- the justification 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
- the end point has been determined and identified

INSPECTION PROCEDURES

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

- if protocol numbers are not listed on the cages, ask for the protocol numbers of random animals.
  NOTE: Animals may be held but cannot be used without being on a protocol.
- choose random protocol numbers from cage cards or animal charts/records and check in IACUC records that these protocols were approved
- 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)
- 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 (see page 6.3.13)
- ask about weekend staffing, animal observation and medical care
- determine if the medical or emergency contact people's 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, such as:
  - approved species of animal is being used
  - surgeries performed during approved time period
  - only approved number of animals have been used
  - identification of the major operative procedure
  - only maximum number of approved survival surgeries have been conducted on the animals
  - animals have not undergone any other major survival surgery
  - all animals under the protocol are permanently identified
  - medical/surgical records accompany animals to other protocols
  - medical records include the name, dose, route, and time of administration of any medication given
  - appropriate peri-operative medication is given to the animals as directed by the attending veterinarian
  - copies of medical records are provided to any subsequent owners of the animals or any person to whom the animals are assigned
  - surgical exemption is reported on the USDA Annual Report
  - IACUC is evaluating exemption annually, including:
    - an assessment of the animals
    - effectiveness and soundness of the methods used on the animals
    - effectiveness and soundness of the procedures used on the animals
    - procedures used to minimize pain and distress
  - evaluation must be included in the IACUC reports

SPECIES-TYPICAL SIGNS OF PAIN*

SPECIES	POSSIBLE SIGNS OF PAIN**
DOGS	quiet, unwilling to move, lack of alertness, whimpering or howling, loss of appetite, increased respiration, growl or exhibit apprehension when approached, *groaning*
CATS	quiet, apprehensive facial expression, loss of appetite, crying, hissing, hiding, crouching or hunching, ungroomed appearance
GUINEA PIGS & HAMSTERS	decreased activity, piloerection, ungroomed appearance, excessive licking and scratching, rapid/shallow respiration, loss of appetite, grunting or chattering, do not try to escape when handled
RABBITS	inactive, appear apprehensive or anxious, hunched appearance, hide, squeal or cry, possible aggressive behavior with excessive scratching and licking, grinding of teeth, excessive salivation
NONHUMAN PRIMATES	huddling or crouching in corner, stops eating/drinking, sad expression, moaning, screaming, stops grooming, clenching of teeth
CATTLE, SHEEP, GOATS	dull, depressed appearance, heads bowed, lack of alertness, loss of appetite, rapid/shallow breathing, rigid posture, vocalization, *droopy ears, rough hair coat, hunched appearance*
PIGS	changes in social behavior, gait and posture, *excessive* squealing when handled, unwilling to move, hiding

**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.
Italics - added by Manual Team

*excerpted from: National Research Council: Recognition and Alleviation of Pain and Distress in Laboratory Animals, Washington, D.C., National Academy Press, 1992.

EXIT BRIEFING	The exit briefing is the time to summarize everything that occurred during the inspection.

The exit briefing should be conducted with the designated research facility representative(s), such as:

- Attending Veterinarian
- IACUC Chairperson
- Institutional Official
- Quality Assurance Officer
- Government Liaison
- Compliance Officer
- Facility Director

Take as much time as necessary during this opportunity to:

- discuss the noncompliant items in detail with the research facility representative(s)
- assess his/her understanding of the problem(s)
- discuss what the research facility may do to correct the problem, if asked
- make sure that research facility representative understands what is expected
- educate him/her about animal welfare and the AWA regulations and standards

The exit briefing includes, but is not limited to:

- presenting the research facility representative with a copy of the inspection report
- reading the inspection report with the research facility representative
- reviewing the details of the inspection report
- answering questions
- obtaining signatures

INSPECTION PHOTOGRAPHS

Photographs may be taken to document a noncompliant item(s) and/or facility conditions.

Digital photos are the photographs of choice.

Film photographs should only be taken when it is impossible to take digital photos, such as:

- the digital camera is broken, or
- batteries are dead

Photographs **should** be taken of:

- direct noncompliant items (NCIs)
- repeat NCIs
- NCIs which may result in an enforcement action or case
- NCIs which are additional information for an ongoing investigation or case
- transportation violations

NOTE: In all of the above situations, take photos of **all** noncompliant items identified on that inspection.

You may choose to take photographs of:

- indirect NCIs if:
  - there are a number of NCIs
  - the NCIs may become repeats
- NCIs to help you write the inspection report narrative
- NCIs to support your inspection report narrative
- items requiring further interpretation
- an NCI for clarification for the registrant. For example, to show the registrant at the exit interview, if he/she was not the person accompanying you on the facility inspection.
- items in compliance for future reference

You (the inspector) should use your discretion and professional judgment in deciding when to take photographs and take photographs whenever you feel it is necessary.

If the registrant or representative refuses to allow you to take photos of noncompliances, cite under 2.38(b)(v).

For **records violations**, where applicable make photocopies of the records rather than photographs.

Submit photographs to the Regional Office:

- with every applicable REPEAT violation
- with the request for an enforcement action or investigation
- as additional information for ongoing investigations or cases
- for further interpretation

NOTE: Photographs taken for clarification for the registrant or reference purposes do not have to be sent to the Regional Office. You should hold these photographs for as long as necessary.

When submitting photos:

- use a separate CD for each registrant/licensee's photos
- submit two sets of photos, one labeled and one unlabeled
  Note: These may be submitted on the same CD.

When submitting photos for an **enforcement action or investigation**:

- submit digital photos on a CD (do not print pictures)
  Note: Use a separate disk for each registrant/licensee's photos.
- submit film photographs on paper
- photos should be 4"x 6" in size
- submit 2 sets of photos: one set labeled and one set unlabeled
- each labeled photo should contain: (see pages 6.5.7 & 6.5.8):
  - inspector's name
  - date and time photo was taken
  - licensee or research facility name
  - license/registration number, if applicable
  - CFR section violated
  - very brief description of the violation including location within the facility
  - include the waybill number on transportation violations
- **all** photos related to the inspection and/or investigation should be submitted, even if some of the photos are of poor quality or are irrelevant. NOTE: IES will determine which pictures will be used as supporting evidence.

Processing photographs

Digital Photographs

Digital photographs should be handled as follows:

- transfer all digital photos to your laptop computer (Do NOT delete any photos)
  NOTE: The memory card with the original photographs should be kept by you as it may be needed for an investigation or case.
- size the photographs to approximately 4" x 6". Note: The picture itself should be approximately 4" x 6". Increase the canvas size to add labeling (see page 6.5.5) - do not decrease the picture size.
- label the photographs
  NOTE: There are many ways to do this. A sample procedure is on pages 6.5.5 - 6.5.6.
- include the waybill number on transportation-related pictures, if applicable
- save the photographs on a CD
  Note: Use a separate CD for each registrant/licensee.
- when applicable, send the disk or CD to the Regional Office
  Note: Digital photographs should be sent to the Regional Office by e-mail only when:
  - requested by the SACS or Regional Office
  - for informational purposes

Photographs from Film

Photographs from film should be handled as follows:

- prints should be 4" x 6"
- label the back of the photographs using:
  - pre-printed label (see page 6.5.8), or
  - computer template label
- include the waybill number on transportation-related pictures, if applicable
- attach the label upside down in relation to the picture

Remember to submit two sets of photograph: ons set labeled and one set unlabeled.

Retain negatives, as they may be requested by for an investigation

	or case. Hold photographs, negatives and copies of the photographs which were not sent to the Regional Office, until requested or needed, or files are purged.

INSTRUCTIONS FOR LABELING AND PROCESSING DIGITAL PHOTOGRAPHS USING ADOBE PHOTODELUXE

RETRIEVE THE PHOTOGRAPH FROM THE CAMERA OR THE COMPUTER FILE WHERE IT IS STORED.

SIZE

The picture should be sized to approximately 4 x 6 inches

1. Click on **Advanced** on the left side tool bar
2. Click on **Size** tab
3. Click on **Photo Size**
4. Change the size of the picture to approximately 4 x 6 inches, if necessary
5. Click on **Canvas Size**
6. Increase the height by 1 inch
7. Click on OK - There should now be white space around the photo
8. Place your cursor in the middle of the photo
9. Single left click, hold, and drag the photo to the top of the frame
10. A box will appear around your photograph - place your cursor outside of the photo and single left click to remove the box and complete the sizing process

TEXT

1. Click on the "**T**" on the toolbar at the top of the picture - a Text Tool window will open
2. Change the font size to 12
3. Type your text in the text box, including:
   - licensee, registrant or facility name
   - license/registration number, if applicable
   - CFR section violated, if applicable
   - a very brief description of the non-compliant item, photo subject, or item you want to point out
   - photographer's name
   - date and time photo was taken

   NOTE: Proof read the text carefully for content and spelling.
4. Click on OK. The text should appear in a box in the middle of the picture.
5. Move the cursor into the box
6. When the cursor changes to a **single-headed** black arrow - single left click, hold, and drag the text box into the white area below the picture
7. Click and drag the text box lines to fit under the picture
8. Place your cursor outside of the photo and single left click to remove the box and complete the labeling process

NOTE: If you notice an error in your text after placing it in the picture:

- single left click in the text area - a box should appear around the text
- single right click in the box
- select "Cut" from the drop-down menu
- start at Step #1

SAVING YOUR PICTURE

Photographs should be saved in the JPEG format

1. Click on File
2. Click on Save As
3. Click on JPEG File
4. In the "Save in:" window, using the drop down menu, select where you want to save the picture (disk or CD)
5. In the "File name" window, type in the name you want to give the photo
6. Click on Save
7. A prompt will appear asking if you want to continue converting to JPEG format or want JPEG conversion to begin - click on OK
8. After the conversion has been completed, close the photo by clicking on the "X" at the top right hand corner of the photo

NOTE: You may be prompted to save the photo multiple times, you should click on **NO**. This is very important - only save the photo once.

SENDING PICTURES BY E-MAIL

1. Go to LotusNotes
2. Send the picture(s) as you would any other attachment to an E-mail letter or memo

PRINTING YOUR PICTURE

1. Click on **Send & Save** on the left side tool bar
2. Click on **To Printer**
3. Click on **Print**
4. Click on OK

PHOTOGRAPH LABEL - Computer Generated

SUBJECT NAME:	
LICENSE/REGISTRATION #:	
9 CFR SECTION #:	
DESCRIPTION:	
DATE:	
TIME:	
PHOTOGRAPHER:	

PHOTOGRAPH LABEL - Non-Computer Generated

SUBJECT NAME _____
LIC/REG/CASE NO._____
SECTION NO. _____TIME_____
DESCRIPTION OF PHOTOGRAPH

PHOTOGRAPHER: DATE:

ACCESS AND INSPECTION OF PROPERTY AND RECORDS

A registered research facility must permit an inspection of the facility and/or records by APHIS officials and provide a responsible person to accompany the APHIS officials. [2.38(b), 2.25(c), 2.30(d)]

Criteria

Access to conduct an inspection includes:

- entry into place(s) of business
- entry into all areas where regulated animals are housed, used, or held
- entry into all animal areas to search for missing animals
- examination or copying of required records
- documentation of conditions and areas of noncompliance by the taking of photographs or other means
- use of a room, table, or other facilities necessary for the examination of the records and inspection of the property and animals and for completion of the inspection report

If an official of the research facility denies you, the inspector, entry into the place(s) of business or any animal housing, use, or holding area, this should be documented as a refusal of inspection (see Refusal of Inspection - Section 8.6).

If an official of the research facility refuses to allow any of the other criteria for access, such as taking of photographs or copying of records, this should be documented as a noncompliance on the inspection report.

Non-Interference

No one at the research facility must interfere with the inspection process. You (the inspector) do not have to tolerate abusive, threatening, or violent behavior. All threatening behavior should be taken seriously and reasonable preventive or precautionary measures should be taken. [2.25(c), 2.30(d)]

Examples of interference include, but are not limited to:

- physical abuse including:
  - pushing
  - shoving
  - hitting

- verbal abuse including:
  - yelling
  - swearing
  - belligerent language meant to:
    - demean
    - intimidate
    - coerce
    - threaten
- harassment (verbal, physical, emotional, sexual)
- assault or threat of an assault

If **anyone** (registrant, employee, researcher, etc.) at a research facility exhibits threatening behavior, follow the procedures delineated in Section 6.7 - *Workplace Violence*

DO NOT return to a research facility where you have been threatened, assaulted, or abused:

- without appropriate resolution of the incident
- without being accompanied by another APHIS official or law enforcement agent, if appropriate

WORKPLACE VIOLENCE

A registrant, person required to be registered or research facility must **NOT** interfere with, threaten, abuse, or harass any APHIS official in the course of carrying out his/her duties. [2.4, 2.25(c), 2.30(d)]

Interference

No one at a research facility is allowed to interfere with the inspection process. You (the inspector) do not have to tolerate abusive, threatening, or violent behavior. All threatening behavior should be taken seriously and reasonable preventive or precautionary measures should be taken.

The following are definitions of possible acts of violence or threatening behavior:

- ABUSE (Physical) - An act which includes pushing, shoving, or hitting
- ABUSE (Verbal) - An act which includes yelling, swearing, or belligerent language meant to demean, intimidate, coerce, or threaten
- ASSAULT - Any willful attempt or threat to inflict injury upon another person, when coupled with an apparent present ability to do so, and/or intentional display of force such as would give the victim reason to fear or expect immediate bodily harm
- HARASS - Any repeated action or attempted action which is intended to impede, fatigue, or exhaust another person
- THREAT - Any oral or written expression or physical movement that is interpreted by a reasonable person as conveying an intent to place that person in fear of bodily injury to him/herself or to a third party
- VIOLENCE - Any act (verbal, written, chemical or physical aggression) or attempted act which is intended to control or cause, or is capable of causing, death or serious bodily injury to oneself or others or damage to property

DO NOT return to a research facility where you have been threatened, assaulted, or abused:

- without appropriate resolution of the incident
- without being accompanied by another APHIS official or law enforcement agent, if appropriate

Reporting Interference

Imminent Danger

If you, the inspector/APHIS official, determine that there is imminent danger due to a person's behavior (registrant, authorized representative, employee, researcher, etc.), you should:

1. Leave the premises immediately and carefully, **in a manner that is not likely to inflame the situation further**
2. Call local law enforcement, if appropriate
3. Call your SACS as soon as possible
4. Complete an inspection report within 24 hours containing the following information:
   - any noncompliances identified prior to stopping the inspection
   - a statement that the inspection was stopped because the person(s) (give his/her name) was interfering with the inspection process
5. Complete a separate memo within 24 hours containing the following information, if applicable:
   - the names of any witnesses
   - a detailed, factual description of the person's behavior
   - any quotes or threatening statements made
   - the target of the violent or threatening behavior
   - the time and date the incident occurred
6. Send a copy of the inspection report to the research facility's Institutional Official by certified mail

Non-Imminent Danger

If you, the inspector/APHIS official, determine that a person's behavior (registrant, authorized representative, employee, researcher, etc.) is interfering with the inspection process, but imminent danger does not exist, you should:

1. Notify the registrant/authorized representative that you consider this behavior as interference
2. Warn the registrant/authorized representative that if the behavior continues, you will stop the inspection
3. Leave the premises immediately and carefully, **in a manner that is not likely to inflame the situation further,** if the behavior does not stop

4. Call your SACS within 12 hours of the incident
5. Complete an inspection report within 24 hours containing the following information:
   - any noncompliances identified prior to stopping the inspection
   - a statement that the inspection was stopped because the person(s) (give his/her name) was interfering with the inspection process
6. Complete a separate memo within 24 hours containing the following information, if applicable:
   - the names of any witnesses
   - a detailed, factual description of the person's behavior
   - any quotes or threatening statements made
   - the target of the violent or threatening behavior
   - the time and date the incident occurred
7. Send a copy of the inspection report to the research facility's Institutional Official by certified mail