

# INSPECTION REQUIREMENTS

April 19, 2010

## GENERAL REQUIREMENTS

When conducting an inspection, the inspector must be accompanied by the licensee, registrant, or the facility's designated representative (who must be at least 18 years of age). **IMPORTANT:**

- Do not enter facilities with locked gates and/or No Trespassing signs unless prior approval has been obtained from the facility.
- If you do not find anyone at the facility, follow the procedure to complete an attempted inspection.
- Prior to notifying the facility of your presence, inspectors may observe and record findings without being accompanied by a facility representative at facilities that are open to the public. Before documenting findings on an inspection report, the inspector must discuss the findings with a facility representative.
- A complete exit briefing must be conducted.

The following inspection aids are available to assist with inspections:

- Checklist for Animal Care Inspection sheet
- Canine Care Checklist
- Traceback SOP for random source B dealers
- Inspector Safety and Etiquette When Inspecting Non-Domestic Animals
- Guidance for identifying Direct NCIs
- Enforcement Actions (EA) Guidance for Inspection Reports, which includes guidance for the appropriate action to recommend
- Current RBIS

In all situations, follow the facility's biosafety procedures that they have in place for visitors, and/or put on recommended protective clothing, gear and/or boots. During dog kennel inspections, inspectors should wear disposable shoe covers. Inspectors should wear disposable gloves if it is necessary to touch an animal (at all facilities).

**NOTE:** The licensee is responsible for ensuring the safety of the inspector from the animals. If you feel unsafe, ask the licensee to correct the situation. If the licensee does anything you feel is unsafe you should state that you will leave the facility immediately unless the situation is corrected. If you feel you are in imminent danger, safely leave the area.

## INSPECTION STEPS

Basic steps to follow in conducting an inspection of a facility include, but are not limited to:

- Inspect the animals, premises, building(s), enclosures, equipment, and transportation vehicles/equipment for all pertinent requirements of the regulations and standards.
- Consider problems that may occur at other times of the year.

- Review the facility's program of veterinary care, husbandry practices, required records, and when appropriate, the "Exercise Plan" for dogs and "Plan for Environmental Enrichment" for nonhuman primates
- For big cats, review the feeding plan to assure adequate nutrition
- When possible, observe the animal handling techniques of facility personnel.

## **DOCUMENTING INSPECTION FINDINGS**

Inspection findings must be documented in the narrative section of the inspection report. Do not type any personal identifiable information (PII) in the narrative of any inspection report, including addresses and phone numbers.

**No NCIs identified** - - If all items are in compliance, then the following statement should be typed on the inspection report: No noncompliance identified on this inspection.

For inspections in response to an incident or complaint, often further review (and/or an IES investigation) is needed to determine compliance. If you are not certain whether noncompliance was involved, do not cite "no noncompliance" under those circumstances. The following stand-alone statement should be typed on the inspection report: "The (incident) is under review."

**New NCIs identified** - - If a new NCI(s) is identified, it should be cited in the inspection report narrative. The citation should include the following:

1. The section number and most specific subsection letter/number of each noncompliance, and the text of the regulation or standard being cited.  
NOTE: The regulation/standard may be quoted or paraphrased
2. A clear, detailed description of the noncompliance, including when appropriate, the number of animals affected
3. An explanation of why the item is a noncompliance and/or the impact it is having on the animals
4. A correction deadline and a "general" description of what the licensee/registrant needs to do to correct the problem, and assure that it doesn't continue/recur. This description should not be worded in such a way that it could be interpreted that AC is mandating how an NCI is going to be corrected. A correction deadline should be appropriate to the severity of the NCI, and unless animal welfare will be put in jeopardy, be realistic as to what the facility can accomplish.

Use "Direct" NCI designation, if appropriate.

If a noncompliant item falls into more than one section or subsection, cite the noncompliance only in the most applicable section or subsection for each species affected.

**Repeat NCI identified** - - A repeat noncompliant item must be designated on the inspection report whenever an NCI of the same section & subsection was cited on the last inspection. This applies even if different animals and/or different portions of the facility are involved.

NOTE: An NCI *may* be designated as a “repeat” if the same section, subsection, and/or issue were cited on a prior inspection report, even if it was not the most recent inspection. For these NCIs, inspectors should use their professional judgment in deciding whether to cite the NCI as a new or repeat NCI. Your SACS can provide guidance in these situations.

NOTE: When determining whether to cite an IACUC NCI as a repeat, it is critically important that you drill down to the most specific subsection.

NOTE: In the narrative for a repeat NCI, the regulation/standard quote may be omitted, but components 2 and 3 of an NCI narrative (listed above) must be included. Also, do not assign a new correction date for repeat NCIs.

Use “Direct” NCI designation, if appropriate.

***For all repeat NCIs, you must communicate with your SACS to recommend an enforcement option.***

**“Direct” NCI identified** - - A “Direct” noncompliance is a noncompliance that is currently adversely affecting the health and well-being of the animal, or has the high potential to adversely affect the health and well-being of the animal in the near or immediate future. The correction deadline for a “Direct” noncompliance should be short and never exceed 30 days, and a complete or partial reinspection of a facility with a “Direct” NCI must be completed no more than 45 days after the date of the inspection. The reinspection must be conducted at the facility even if the “Direct” NCI was corrected during the inspection. For a serious direct noncompliance, such as a severe veterinary care problem, the correction date should be very short, e.g., 1 day, and the reinspection should occur the next day and/or whenever needed to verify the correction and ensure animal welfare. Examples of “Direct” versus indirect NCIs are provided in the Direct NCI Guidance handout.

***For all “Direct” NCIs, you must communicate with your SACS to recommend an enforcement option.***

**Exit Briefing** - - An exit briefing is required for all inspections, unless your personal safety is at risk, or harassment, verbal abuse, or other factors are interfering with the inspection process. Take as much time as necessary during the exit briefing to:

- summarize everything that occurred during the inspection,
- discuss the noncompliant items in detail with the licensee or facility representative,
- discuss what he/she may do to correct the problem (if asked),
- make sure that facility representative understands what is expected of him/her,
- educate him/her about animal welfare and the AWA regulations and standards,
- obtain a signature and/or explain to the facility representative how the inspection report will be delivered.

Unless an exit briefing could not be completed, a statement must be included on all

inspection reports stating “An exit briefing was conducted with the licensee (or registrant or facility representative).” NOTE: do not use names.

NOTE: If the inspection report is to be delivered by email or certified mail, you must still conduct a detailed and thorough exit briefing. Any item that you will be citing on the inspection report must be discussed during the exit briefing.

**Signature on the Inspection Report** - - The inspector and the licensee or his/her representative should sign all pages of the inspection report. The signature of the licensee or his/her representative certifies that the person received a copy of the inspection. It does not necessarily mean that the person agrees with the findings of the inspection. If the facility representative refuses to sign the inspection report, you should:

- a) leave a copy of the inspection report with the representative after noting on the inspection report that you are doing so, or,
- b) leave a copy of the inspection report with the representative and send a copy via certified mail.

Any facility with a disagreement about the inspection findings may follow the inspection appeals process; the process is described on AC’s website. If the licensee or registrant refuses to sign the inspection report, explain the circumstances in the narrative, and leave the signature block blank.

**Delivery of the Inspection Report** - - Unless you obtain supervisory approval to do otherwise, hand delivery is required for inspection reports with Direct NCIs. Although hand delivery is preferred for other inspections as well, they may be delivered via email or certified mail. For all delivery methods, the inspection report must arrive at the facility before the earliest correction deadline or within 5 days post inspection, whichever is earlier. If you cannot meet this deadline, you must obtain supervisory approval.

If sent by email, the inspector must request an email reply verifying receipt of the inspection report by the facility. The email receipt must accompany the original inspection report into the regional office. If an email reply is not received, the inspector must deliver the report by another method so that receipt can be verified.

*Note: A reinspection conducted to evaluate a particular direct or repeat NCI only, should be identified as a “focused reinspection” in the inspection report narrative. A focused reinspection must include an exit briefing.*

## **INSPECTION PHOTOGRAPHS**

Photographs must be taken to document photographable noncompliant item(s) in all of the following situations.

- Direct NCIs and all NCIs on an inspection with a Direct
- Repeat NCIs and all NCIs on an inspection with a Repeat
- All NCIs cited at a facility with an ongoing case
- NCIs that are likely to be appealed
- Transportation (airline) NCIs
- 3<sup>rd</sup> prelicense inspections to document NCIs, or to show that the facility was actually in full compliance (include photos showing NCIs that were documented

- on prior prelicense inspections were corrected)
- If there are repeat, direct, or transportation records noncompliances, the records must be photocopied or photographed.

All photographs that are to be retained must be labeled and uploaded into ACIS no later than 2 weeks after the inspection. Photos that do not need to be retained should be deleted by the inspector.

## **POST INSPECTION PROCEDURES**

For all inspection interference and refusal occurrences, and for all inspection reports that document a repeat or “Direct” NCIs, or, result in an “unsatisfactory” RBIS rating (based on the ratio of animals inspected and points assigned), you must discuss the finding(s) with your SACS to recommend an enforcement option.

## **RBIS**

You must inspect the facilities below on or before the deadline given in ACIS; if you cannot, you must contact your SACS prior to the deadline so that another inspector can be assigned to conduct the inspection.

- Direct NCIs
- HIF Facilities
- Facilities with repeats for which a 90 day re-inspection was the enforcement option selected

All research facilities must be inspected at least once every fiscal year.

## **ATTEMPTED INSPECTION**

All animal welfare inspections, with the exception of prelicense inspections, are to be conducted on an unannounced basis. An attempted inspection occurs when an authorized person is not available to accompany the inspector, and no inspection is conducted.

NOTE: The person accompanying the inspector must be an adult, i.e., 18 years of age or older.

If nobody is present at the facility, you should call the phone number(s) provided by the licensee/registant to contact him/her, and determine if an authorized person can be at the facility within 30 minutes. You should wait for 30 minutes, and if nobody shows up you should cite Section 2.126(b), and the narrative should read: “On (*date*) at (*time*), licensee failed to have a responsible person available to conduct an animal welfare inspection.”

NOTE: Use section 2.38(b) for registered research facilities.

Inspection reports citing Section 2.126(b) or Section 2.38(b) should be sent to the licensee or registant by both regular and certified mail.

## **PRELICENSE INSPECTION**

An applicant's facility must meet all applicable regulations and standards to obtain a license. Preliminary inspections are scheduled at a time agreeable to the applicant and the inspector. In addition to determining if a facility is in full compliance, preliminary inspections are the best time to educate the applicant about the AWA regulations and standards. Required written records must be completed and inspected during a preliminary inspection in order to consider the facility in compliance, including the PVC, exercise plan for dogs, environmental enhancement plan for primates. There must be a written record of animals on hand with as much of the required information completed as possible.

If the facility is not in full compliance, cite all noncompliant items using the first 3 components of the four-part citation description above (see "New NCIs Identified"), but do **not** give correction dates. The following or similar statement must be included in the narrative: All items must be in compliance within (*number of preliminary inspections left; 1 or 2*) more inspections or by (*date-90 days from 1<sup>st</sup> preliminary inspection*) or the applicant will forfeit the application fee and must wait 6 months to reapply. No regulated activities may be conducted until a USDA license is issued.

If a 3<sup>rd</sup> preliminary inspection is necessary, a 2<sup>nd</sup> inspector or supervisor must be present during the inspection, and photographs must be taken to document the condition of the facility.

For an applicant with large carnivores, elephants, great apes, and/or marine mammals, in addition to any NCIs that are cited, the inspector must include the following statement on the inspection report: "the animal enclosures, handling practices, and employee qualifications are under review." The responsible inspector must then contact his/her SACS as well as the appropriate species specialist to discuss and review the enclosures, handling practices, and qualifications.

## **REFUSAL OF INSPECTION**

If a licensee refuses to allow an inspection, be sure that you have clearly identified yourself as a USDA Animal Care inspector and that the person refusing to allow the inspection is aware of the serious nature of this violation of the AWA regulations. Unless the situation has escalated to the point at which you don't feel safe, you should ask the specific question: "Are you refusing to allow the inspection?" If the licensee still refuses to allow an inspection, leave the premises and complete an inspection report designating this as a Routine inspection. Section 2.126(a) should be cited, and you should document the specific circumstances of the refusal in the inspection report narrative; be specific as to date, time, and the identification of the person who refused to allow the inspection. Also include any pertinent statements made by the licensee or registrant. NOTE: Use Section 2.38(b) for registered research facilities. If two or more APHIS officials are present for the inspection and one is denied entry, document this as a refusal of inspection: do not conduct an inspection. Inspection reports for refusals should be sent to the licensee or registrant by both regular and certified mail.

***For any 'refusal to allow inspection', you must communicate with your SACS to recommend an enforcement option and develop a plan for follow up inspection.***

## **INTERFERENCE**

If you are being harassed, verbally abused, or interfered with in the course of carrying out inspections, you should inform the licensee or applicant that the inspection can only continue if the harassment, verbal abuse, or interference stops. If it continues, you should discontinue the inspection process and leave the premises. Write an inspection report citing Section 2.4 (NOTE: Use Section 2.30(d) for registered research facilities), and in the narrative, be specific as to date, time, and the identification of the persons involved. You should also include details of the harassment and/or verbal abuse and/or interference. The inspection report should be sent to the licensee or registrant by regular and certified mail.

***For any 'interference with the inspection' you must communicate with your SACS to recommend an enforcement action and develop a plan for follow up inspection. If you are being threatened, follow procedures to ensure your safety, including but not limited to leaving the premises and calling 911 if necessary. In that circumstance, you should consult with your supervisor after your personal safety is assured with regard to future steps.***

## **CORRECTING, RESCINDING, AND AMENDING INSPECTION REPORTS**

This should be done on a case by case basis under the direction of your SACS or Regional Office.