7.0 Completion of the Inspection Report

GENERAL INFORMATION

The inspector must complete an official inspection report at the end of the inspection. The inspection report should follow the format of the Inspection Report Template in the laptop computer.

The inspection report must contain the following general information entered automatically by LARIS:

- research facility's name as listed on Application For Registration (APHIS Form 7011)
- mailing address as listed on Application For Registration (APHIS Form 7011)
- customer ID
- USDA registration number
- site number as assigned by LARIS (**Make sure that you are in the correct site. DO NOT** enter an inspection into an inactivated site.)
- site name, if applicable
- date of inspection

If any of the above information is incorrect in LARIS, you should contact the Regional Office to have the database corrected after you have completed the inspection report.

Type of Inspection

The inspection report must specify the type of inspection conducted. You must enter the type of inspection into the LARIS Inspection Report template.

Types of Inspections are:

- *Routine* - normal periodic, unannounced inspection including:
  - partial or focused inspection
  - re-inspection for direct noncompliant items
  - complaint inspection
  - search inspection
- *Attempted* - situation where an authorized person was not available to accompany the inspector. No inspection was conducted.

Finalizing the Inspection Report	You should finalize the inspection report in LARIS at the end of each inspection, after you have checked it for accuracy and completeness, and reviewed it with the registrant. If you do not finalize the inspection report at the end of an inspection, BE SURE to finalize the inspection report before replicating. NOTE: You do not have to finalize an inspection report to do an inspection report for another site of the same registrant or a different registrant.
Adding a person, facility or site to the LARIS database	If the person, facility, or site is **not** in the LARIS database, you should: • complete the inspection report using the word-processing Inspection Report Template • after the inspection, contact an ILA or the Program Specialist at the Regional Office • provide the ILA or Program Specialist the following information: ▸ research facility's full name, if applicable ▸ complete mailing or business address ▸ complete site address ▸ county, if known ▸ business telephone number, including area code • obtain the customer number, if available • replicate the LARIS database • enter the information from the Inspection Report into the LARIS database exactly as it is on the word-processing Inspection Report • attach a copy of the LARIS Inspection Report to the word-processing Inspection Report

INSPECTION REPORT NARRATIVE

The narrative section of the inspection report must be accurate, precise and descriptive enough to clearly identify any noncompliant item (NCI).

Inspection notes

Prior to writing the narrative section:

- organize your inspection notes
- look up Section and subsection numbers/letters
- group observations under Section numbers

Check off each item as you cite it in the inspection report.

NOTE: The following may be used as inspection aids:

- Checklist for Animal Care Inspection Report (page 7.2.5)
- Canine Care Checklist (page 7.2.6)

These sheets should be discarded after the official inspection report has been completed.

Narrative appearance

The narrative section should be neat and orderly. You may want to:

- start each part of the four-part citation on a new line
- skip a line between citations and other information
- capitalize a heading or important information to make it stand out
- type it into Microsoft WORD first by typing:
  - directly into MS Word and copying and pasting into the inspection report, OR
  - into MS Word using the LARIS "narrative" screen bridge by following these directions:
    1. Click the cursor into the large white "NCI Narrative" block in LARIS
    2. Press CTRL + E to activate MS WORD
    3. Type and spell/grammar check your text
    4. Upon completion of the narrative, close MS WORD
    5. Select "save" for all exit questions. Note: The text will not be saved as a separate Word document.
    6. Text will be inserted into the "Narrative" block. Note: Formatting, such as bolding,

	italics, bullets, will not be transferred. NOTE: You may want to save an electronic copy of the inspection report or noncompliance citations to copy and paste into the next inspection report, if necessary. If the inspection report/citations were typed into MS Word, save as a Word document. If the citations were typed into the inspection report using the LARIS-Word bridge, save the inspection report as a PDF file.
Narrative content	The narrative section **should** contain: (see pages 7.2.7) • names of locations inspected, if applicable ▸ you and the registrant/representative should decide on names or designations, such as Bldg A or Bldg 1, for the different locations ▸ only the names of the locations, i.e., no addresses ▸ be consistent when using names of locations • a detailed description, using complete sentences, of any noncompliant items identified on the inspection using the four-part citation (See "Documenting Inspection Findings" - Section 7.3) • documentation of information, either verbal or written, given to a registrant or facility representative, such as: ▸ new regulations or changes in regulations/standards ▸ proposed changes in regulations/standards ▸ specific topics discussed • other information pertinent to the inspection • document as a "Note" any discussion about a problem(s) that is not currently a noncompliance but may become a noncompliance in the future • a statement that the inspection and exit interview was conducted with the registrant or his/her representative. No specific name(s) should be used (except yours), only the person's title or position. For example: ▸ "Inspection and exit interview conducted by (*your name*) with registrant." ▸ "Inspection and exit interview conducted by this inspector with facility manager." ▸ "Inspection conducted by (*your name*) with facility manager; exit interview conducted by this inspector with IACUC Chair."

NOTE: On the first inspection after the implementation of a new or change in a regulation/standard, the registrant should be informed of the change. Do not cite as an NCI unless it is a "direct" NCI. Note on the inspection report that the regulation/standard was discussed with the registrant/representative. If not in compliance on the next inspection, cite the NCI using the appropriate regulation or standard. **An Animal Care Policy should never be referred to on an inspection report.**

You **may** choose to include the following information in the narrative section, if the registrant does not object:

- corrected noncompliant items (NCIs) from the previous inspection, if the registrant/representative wants them listed. This should be done as a "Note" at the end of the inspection report and:
  - each corrected NCI may be listed individually, or
  - if all NCIs are corrected, the statement, "All NCIs identified on the previous inspection are corrected." or a similar statement may be used

The narrative section should **NOT** contain:

- date of last inspection
- animal inventory
- references to Animal Care Policies
- personal or proprietary information, such as:
  - name(s) of person(s) accompanying you on the inspection
  - names of principal investigators or research facility personnel
  - names of sellers of animals
  - sources of animals
  - names of buyers of animals
  - addresses, other than the research facility's mailing and/or business address
  - telephone numbers, other than your contact information if applicable
  - social security numbers
  - driver's license numbers
- personal comments about the facility
- comments on public complaints

	• recommended enforcement action • administrative messages to the Regional Office NOTE: Remember that the inspection report is a legal and a public document. It may be requested by the public or used in a court proceeding.

U.S. Department of Agriculture Animal and Plant Health Inspection Service ANIMAL CARE	Checklist for Animal Care Inspection Report

Name of Licensee/Registrant _____ Site No. _____ Li c./Reg./No. _____

Site Name _____ Date of Inspection _____

	FACILITIES (permanent and transport)
	Structure & Construction
	Condition & Site
	Surfaces & Cleaning
	Utilities/Washrooms/Storage
	Drainage & Waste Disposal
	Temperature/Ventilation/Lighting
	Shelter from elements
	Capacity/Perimeter fence/Barrier

	PRIMARY ENCLOSURE
	General Requirements
	Space & Additional Requirements
	Protection from Predators

	ANIMAL HEALTH AND HUSBANDRY
	Exercise & Socialization
	Environment Enhancement
	Feeding
	Watering
	Cleaning Sanitation
	Housekeeping & Pest Control

	OTHER
	Identification
	Records & Holding Period
	Handling
	Veterinary Care
	IACUC
	Personnel Qualifications

CANINE CARE REMINDERS

____ Daily observation of all dogs within kennel.
____ All dogs requiring veterinary care have been attended.
____ Veterinary records have been updated.
____ Outdated medications have been disposed of properly.
____ Attending veterinarian has made a kennel inspection within 12 months.
____ All dogs have convenient access to feed and water.
____ All feed and water bowls have been cleaned and sanitized within last 2 weeks.
____ All open bags of feed and bedding are in tightly lidded containers.
____ All unopened bags of feed stored off of floor and away from walls.
____ All enclosures spot cleaned daily.
____ Areas behind and below enclosures have been cleaned as necessary.
____ All enclosures have been cleaned and sanitized within last 2 weeks.
____ All surfaces in contact with dogs are impervious to moisture.
____ Surfaces within enclosures are free of sharp points and edges.
____ Mesh floors of sufficient size to prevent feet falling through.
____ Adequate floor space is provided for all dogs.
____ All dogs have a minimum of 6 inches headroom in enclosure.
____ Nursing bitches have additional space required for litter.
____ All dogs in outside kennels have necessary shelters.
____ All outside shelters have wind and rain breaks in place.
____ All outside kennels have sufficient shade structures.
____ Temperature controlled areas are between 45-85 degrees F.
__ __ All animal areas within kennel are well ventilated.
____ Doors, flaps, gates, etc. are in good repair and operate properly.
____ All drains are functioning properly.
____ Pest control measures are in place as necessary.
____ Items not necessary for animal husbandry are not kept within kennel area.
____ Animal husbandry items are stored in proper areas within kennel.
____ All dogs and weaned puppies have an approved means of identification.
____ Records of dogs on hand have been updated and are accurate.

USDA

United States Department of Agriculture
Animal and Plant Health Inspection Service

cust_id

insp_id

site_id

INSPECTION REPORT

JOHN DOE UNIVERSITY
100 INVESTIGATOR LANE
RESEARCH, MN 55555

Customer ID: 9999
Certificate: 41-R-9999

Site: 001
MAIN BUILDING

Inspection
Type: Routine
Date: Mar-01-2006

The following locations were inspected: Main Building, Research Bldg A, & Swine Barn

2.31 (c)(2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

c) IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall: (2) Inspect, at least once every six months, all of the research facility's animal facilities, including animal study areas, using title 9, chapter I, subchapter A-Animal Welfare, as a basis for evaluation;

The IACUC has not conducted an inspection of the research facility's animal facilities since April 15, 2005.

The animal facilities must be inspected to assess compliance with the Animal Welfare Act standards and to ensure the health and well-being of the animals.

`n IACUC inspection of all regulated animal facilities must be conducted and documented and then conducted at least every 6 months ereafter.

Correct by April 1, 2006

3.83

WATERING

Potable water must be available to the nonhuman primates and water receptacles must be kept clean and sanitary.

The water receptacles in the macaques enclosures in Bldg A have a layer of debris and scum floating on the top.

The presence of debris and scum is an indicator of contamination of the water which can cause illness in the animals.

The water receptacle must be cleaned more frequently and thoroughly, or other appropriate measures taken to prevent a build up of dirt, debris, and scum in the water.

Correct by 3/2/06 10 chimps affected.

Inspection and exit interview conducted by this inspector with facility's attending veterinarian.

Prepared By: _____ **Date:**

Title: Animal Care Inspector **Inspector ID:** 9999 MAR-1-2006

Received By: _____ **Date:**

Title: ATTENDING VETERINARIAN MAR-1-2006

DOCUMENTING INSPECTION FINDINGS	Inspection findings must be documented in the narrative section of the inspection report.
No noncompliant items identified	If all items are in compliance, then the following statement or a similar statement should be typed on the inspection report: **"No noncompliances identified on this inspection."**
New noncompliant item identified	If a noncompliant item(s) is identified, then it should be cited in the inspection report narrative. The citation should include the following: 1. Section number and subsection letter/number of the noncompliance, if applicable **NOTE:** If more than one NCI is being cited under that Section, the Section number and subsection letter/number, if applicable, and title should be typed at the beginning of the narrative. NOTE: If a noncompliant item can fall into more than one section or subsection, cite the noncompliance in the most specific section or subsection. 2. Title and subtitle, if applicable, of the regulation or standard (See Example 3) 3. Text of the regulation or standard being violated by the noncompliance. NOTE: The regulation/standard may be quoted, paraphrased, or copied and pasted from the electronic version of the regulations & standards. For long regulations or standards, put only the applicable portion on the Inspection Report. 4. Clear, detailed description of the noncompliance. This description should include, but is not limited to: ▸ your actual observations, i.e., specifically what you see, hear, touch or smell ▸ location of the problem, e.g., building, barn, farm ▸ specific place or area of the problem, e.g., room, pen, location within pen. Note: A predetermined designation may be used as agreed upon by you and the registrant or facility representative.

- species and number of animals or specific animal affected, if appropriate

5. Explanation of why the item is a noncompliance
6. Options or a general description of how the research facility can meet the regulation or standard
7. Correction date (see Section 7.4)
   Note: If an NCI is corrected during the inspection, the inspector may use his/her discretion whether or not to cite the NCI. If cited, put "Corrected during the inspection."
8. "Direct" NCI designation, if appropriate (see Indirect & Direct Noncompliant Items - Section 7.6)
9. "Repeat" designation if appropriate (see "Repeat noncompliant items identified" on page 7.3.5)

For Inspection Reports done in the word processing system, type or write in "Direct" and/or "Repeat" next to the Section number of the citation.

NOTE: If a noncompliance is identified in an area of the facility, such as a pen, room, or building, where there are no regulated animals on the day of your inspection, the noncompliance should be cited **only if**:

- a regulated animal(s) is being affected by the noncompliance, for example, an empty pen is dirty and is attracting flies and pests which are affecting the animals in the adjoining pens, OR
- the area is currently in use, even though there may be no animals on the day of your inspection, or
- the area is ready for use

EXAMPLE 1:
Standard
(direct quote)

SECTION 2.31(d)(ii) IACUC
The IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: (ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e.g., the Animal

	Welfare Information Center, used to determine that alternatives were not available;
Noncompliance	Protocol #06-85 involves a surgical procedure that will cause more than momentary pain and there is no documentation in the protocol that a search for alternatives was conducted.
Why a noncompliance	There may be an alternative procedure which will cause less pain or distress to the animals and affect their health and well-being.
How to comply	A search for alternatives must be conducted and reviewed and approved by the IACUC.
Correction date	Correct by (*date*). 5 adult cats are affected.
EXAMPLE 2:	
Standard (paraphrase)	SECTION 3.83 WATERING Potable water must be available to the nonhuman primates and water receptacles must be kept clean and sanitary.
Noncompliance	The water receptacle in the outdoor adult macaque enclosure with 10 macaques has a layer of debris and scum floating on the top of the water and a thick layer of algae along the sides.
Why a noncompliance	The presence of debris, scum and algae in an indicator of contamination of the water which can cause illness in the animals.
How to comply	The water receptacles must be cleaned more frequently and thoroughly or other measures taken to prevent a build-up of dirt, debris, scum, or algae in the water.
Correction date	To be corrected by (*date*).
EXAMPLE 3:	
Standard (applicable portion only)	SECTION 3.105 (a) FEEDING The food for marine mammals must be wholesome, palatable, and free from contamination...
Noncompliance	The fish being fed to the two marine mammals is soft, spongy, and covered with mold. It also has a strong rancid smell indicating that it is not wholesome.
Why a noncompliance	The feeding of unwholesome, unpalatable and rancid food does not provide adequate nutrition to the animals and may affect their health and well-being.
How to comply	Appropriate, good quality food must be fed to the marine mammals.
Correction date	Correct by (*date*)

If an NCI involves multiple sections of regulations/standards OR multiple species, each section of the regulation/standard must be cited separately.

For example, a food storage room used to store food for guinea pigs, rabbits, nonhuman primates, and wild/exotic animals is cluttered, dirty and has broken bags with food spilling on the floor, and the unopened bags of nonhuman primate food are stored directly on the floor and up against the walls.
Sections 3.25(c), 3.50(c), 3.75(e) and 3.125(c) - STORAGE OF FOOD would be in noncompliance. Each of these sections should be cited for the species affected.

If multiple noncompliances involve one section and subsection of the regulations/standards, these NCIs may be grouped together.

For example, for farm animals:

-the roof of the barn has an opening which allows rain and snow to fall into the pens
-the partition between the sheep pen and the food storage area has numerous holes
-the front gate of the calf pen has a broken hinge and does not close properly

Section 3.125(a) STRUCTURAL STRENGTH would be in noncompliance and all three items could be cited together.

If multiple noncompliances involve the same section but different subsections, each NCI must be cited separately.

For example, for nonhuman primates, there are multiple NCIs of SECTION 3.80 PRIMARY ENCLOSURES - General Requirements

SECTION 3.80(a)(2)(i) - A pen housing 4 spider monkeys has broken wire mesh flooring in the right rear corner with sharp wire ends sticking up into the pen
SECTION 3.80(a)(2)(vii) - There is no shade area in the outdoor nonhuman primate enclosure and it is summer with ambient temperatures over 100°F
SECTION 3.80(a)(2)(ix) - A pen housing 4 baboons has wooden walls with all the paint scratched off so that the walls can no longer be properly cleaned and sanitized

Each of these should be a separate citation.

Repeat noncompliant item identified

A repeat noncompliant item is:

- a noncompliance cited on the last inspection report which has not been corrected, and/or
- a new noncompliance of the same section & subsection cited on the previous inspection
  For example, inadequate lighting cited in one building on the previous inspection has been corrected, but on the current inspection, there is inadequate lighting in another building, and/or
- a noncompliance for a different species which is the same or similar to a noncompliance cited on the previous inspection
  For example, on the previous inspection, open bags of dog food were not stored in a leakproof container with a tightly fitting lid. On the current inspection, this has been corrected but the open bags of nonhuman primate food are not in proper containers.

DO NOT list a noncompliance as corrected if you are going to be citing an NCI in the same Section and subsection or a similar NCI for a different species on the current Inspection Report.

Note: See "Recurring/Chronic noncompliant item" on page 7.3.7.

CHECK THE "REPEAT NCI INDICATOR" ON THE LARIS INSPECTION SCREEN, then cite the NCI in the narrative as follows:

- section number and subsection letter/number of the noncompliance, if applicable
  NOTE: If more than one NCI is being cited under that Section, the Section number and subsection letter/number, if applicable, and title should be typed at the beginning of the narrative.
- title and subtitle, if applicable, of the regulation or standard
- the regulation or standard quote may be omitted
- clear, detailed description of the noncompliance. This description should include, but is not limited to:
  - your actual observations, i.e., specifically what you see, hear, touch or smell

- location of the problem, e.g., building, barn, farm
- specific place or area of the problem, e.g., room, pen, location within pen
- species and number of animals or specific animal affected

- description of any partial corrections
- explanation of why the item is a noncompliance
- explanation of why the item is a repeat noncompliance
- options or a general description of how the research facility can meet the regulation or standard
- DO NOT ASSIGN A NEW CORRECTION DATE, but you may reference the previously assigned correction date
- "Direct" NCI designation, if appropriate (see Indirect & Direct Noncompliant Items - Section 7.6)

For a repeat NCI, an enforcement action must be recommended (see Section 9.3 - Enforcement Actions) on an Enforcement Action sheet.

EXAMPLE 4:

Standard — SECTION 3.6(a)(2)(ix) **REPEAT**
PRIMARY ENCLOSURES - GENERAL REQUIREMENTS

Noncompliance — Of the 10 pens previously cited, the wooden side walls and floors of 7 pens *(if pens are numbered, include the numbers)* on west side of Room 12 in Bldg G are still chewed and scratched and are not impervious to moisture.

Partial correction — Three pens *(if pens are numbered, include the numbers)* have been repaired and repainted.

Why a noncompliance — The wood surfaces cannot be properly cleaned and sanitized which could affect the health and well-being of the dogs.

Why a repeat noncompliance — On the previous inspection (1/14/06), these wooden surfaces were chewed and scratched and not impervious to moisture.

How to comply — The wooden surfaces in the remaining 7 pens must be repaired and made impervious to moisture.

Optional — This is a repeat violation - original correction date was (*date*).

Recurring/Chronic noncompliant item

A recurring or chronic noncompliant item is the same or a similar noncompliance which is not found on consecutive inspections, i.e., it is cited on one inspection, corrected by the next inspection, then re-occurs on the 3rd and/or a subsequent inspection(s).

The recurring noncompliance can be:

- the same or a similar noncompliance as cited previously
- the same noncompliance but identified for different species
- a noncompliance of the same Section of the regulations or standards

Some factors to consider when deciding if the NCI is recurring or chronic include, but are not limited to:

- have you noticed a pattern
- have you discussed the NCI with a person of higher authority at the facility
- have you discussed the development of an active program or system of maintenance with the licensee
- how far back was the last time the NCI was cited
- what is the severity of the NCI
- how many inspections have been conducted between the recurrence

You should use your professional judgment in deciding what action to take, such as:

- citing the NCI as a new noncompliant item (see page 7.3.1)
- citing the NCI as a REPEAT NCI (see page 7.3.5)
  Note: Include in the description other inspection dates that this NCI has occurred.
- discussing the NCI with your SACS

Corrected noncompliant item

If there was a noncompliant item(s) cited on the previous inspection which has been corrected, this may be noted on the inspection report.

At the end of the inspection, ask the registrant/representative if he/she wants the corrected noncompliances listed on the inspection report.

If the registrant/representative wants the NCI(s) listed, type this in as a "Note" at the end of the inspection report narrative. DO NOT enter the corrected NCI(s) Section number(s) into the LARIS NCI fields.

NOTE: If you are going to be citing an NCI in the same Section and subsection or a similar NCI for a different species, do not cite the NCI from the previous inspection as corrected. This is a repeat noncompliances and should be cited as such. (see "Repeat noncompliant item" on page 7.3.5).
For example:

- Section 3.83 - Watering (NHPs) was cited on the previous inspection. This noncompliance was corrected but on this inspection, Section 3.130-Watering (Other Animals) is in noncompliance.
- Section 3.131(a) - The ferret cages were cited on the previous inspection for an excessive accumulation of feces. On this inspection, the ferret cages were clean but the chinchilla cages had an excessive accumulation of feces.

EXAMPLE 5:

NOTE: Noncompliant items identified on the previous inspection(s) that are corrected:
SECTION 3.1(e) Storage of Food
SECTION 2.40(b)(2) Veterinary Care
OR
NOTE: All NCIs identified on the previous inspection(s) are corrected.

Noncompliant item with correction time remaining

If an NCI was cited on a previous inspection and it remains uncorrected but the correction date has not passed or the facility has received an extension for correction from the Regional Office, cite the NCI in the narrative as follows:

- section number and subsection letter/number of the noncompliance as cited on the previous inspection
  NOTE: If more than one NCI is being cited under that Section, the Section number and subsection letter/number, if applicable, and title should be typed at the beginning of the narrative.

- title and subtitle, if applicable, of the regulation or standard as cited on the previous inspection
- a basic description of the noncompliance
- the date the NCI was originally identified
- the original correction date or extension correction date

NOTE: This is not a repeat NCI.

EXAMPLE 6:

SECTION. 3.78(d) PERIMETER FENCE-NONHUMAN PRIMATES -
The nonhuman primate outdoor housing facility containing 14 spider monkeys does not have a perimeter fence around it.
This noncompliance was originally cited on 2/5/06.
Correction time remains until 8/31/06, **OR** Extension granted until 8/31/06.

No Regulated Animals Present

Even though there may be no regulated animals present at a facility, an inspection may still be conducted.

Factors to consider when deciding whether to inspect a facility include, but are not limited to:

- is the facility due for an inspection
- are there active protocols
- are there records to inspect
- are there areas of the facility which you have never inspected before, e.g., new building
- is this a new facility added to your territory
- does this facility have a history of noncompliance
- even though there are no animals currently at facility, do regulated animals go in and out of the facility
- are there transportation vehicles to inspect

If in your best judgment there is nothing to inspect, you may choose not to conduct an inspection.

If you conduct an inspection:

- classify the inspection as "Routine"
- under inventory state "No regulated animals present at this time."

- if a partial inspection, state which areas were inspected, such as records and/or specific buildings
- NCIs found during the inspection should only be cited if the area with the noncompliance:
  - is currently in use but no animals are there on the day of your inspection, or
  - is ready for use
- for the correction date, use the following or a similar statement: "Correct before being used for animals regulated by the Animal Welfare Act."

If you do **not** conduct an inspection,

- do not complete an inspection report
- send a memo to your SACS explaining why an inspection was not conducted

Reminder: If you do not enter an inspection report into LARIS, it will not count as an inspection for RBIS.

CORRECTION DATE	A correction date is the time period in which a noncompliant item must be corrected.

A correction date should be:

- realistic as to what the research facility can accomplish, and
- appropriate to the severity of the NCI
- determined with the concurrence of the research facility representative, if appropriate

NOTE: If the inspection report is being sent by certified mail, be sure to allow for the mailing time when setting the correction date.

A correction date is given for :

- newly identified "Direct" NCIs (see Direct/Indirect NCIs - Topic 7.6) - These should be given a short correction period, e.g., immediately, by close of business on *(date)*, within 72 hours, within 10 days. The correction date should **never** exceed 30 days.
  NOTE: Reinspection for correction of a "D" noncompliant item must occur no more than 45 days after the correction date.
- newly identified "Indirect" NCIs - Field inspectors may allow up to 1 year for a correction.

A correction date is **NOT** given for:

- an NCI corrected during the inspection - The inspector may decide, using his/her own discretion, whether or not to cite the NCI. If cited, put "Corrected during the inspection." Documenting this NCI may be necessary to show the facility's history of compliance.
- repeat noncompliant items
- transportation violations identified while the animal is in transit

For an NCI previously identified for which time remains for correction, the correction date should be transferred from the previous inspection report or the extension approval letter. For example, "Pending correction date is *(month/day/year)*" or "Extension granted until *(month/day/year)*".

EXTENSION OF CORRECTION DATE

An extension is an additional amount of time granted through the Regional Office for the correction of a noncompliant item.

A research facility may request an extension if it will not be able to correct the NCI by the correction date.

If at the time of the inspection, the research facility representative anticipates that an extension will be needed:

- explain to him/her how to request an extension (see below)
- document on the inspection report that the procedure for requesting an extension was explained to the representative

NOTE: Extensions are for special circumstances and should not be suggested to the research facility representative for correction of routine noncompliant items.

An extension request, whether anticipated or unexpected, must be:

- in writing
- appropriate, i.e., for indirect NCI related to facility maintenance or construction
- specific as to the reason/justification for the request. For example:
  - unexpected delays during the correction process, such as budget or severe weather delays
  - unforeseen special circumstances that prevent completion , such as equipment back orders
- sent to the appropriate Animal Care (AC) Regional Office
- received by the AC Regional Office **on or before** the original correction date

The Regional Office will notify, in writing, the research facility as to whether or not the extension was granted.

INDIRECT & DIRECT NONCOMPLIANT ITEMS

A noncompliant item documented on the inspection report must be determined by the inspector to be either "Indirect" or "Direct".

Indirect Noncompliance

An "Indirect" noncompliant item does NOT have a high potential to adversely affect the health and well-being of the animal. This NCI should be followed up as part of the next routine complete inspection.

No special designation for an indirect NCI is required on the inspection report.

Examples of "Indirect" NCIs include, but are not limited to:

- surfaces not impervious to moisture
- inadequate records
- minor veterinary care issues
- semi-annual IACUC program review overdue
- number of animals not adequately justified
- training records of personnel incomplete

For more examples and a comparison of direct vs indirect noncompliances, see Chart on pages 7.6.4 - 7.6.5.

Direct Noncompliance

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

Required Reinspection

A **complete or partial reinspection** of a research facility with a "Direct" NCI **must** be completed no more than 45 days after the correction date. NOTE: The correction date for a direct noncompliance should be short and **never** exceed 30 days (See Section 7.4 - Correction Dates).

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

For a "Direct" NCI, **in the LARIS database**, you should:

1. highlight "DIRECT" in the NCI Severity Category field
2. assign a "HIGH DEGREE OF RISK" in the NCI Significance field
3. check that the word "DIRECT" prints next to the regulation/standard Section number and title on the Inspection Report

NOTE: If you enter an NCI into LARIS as a "Direct", you must reinspect the research facility within 45 days of the correction date, even if the NCI was corrected at the time of the inspection.

If you have to use the **word-processing or hand-written Inspection Report**:

- type or write the word "DIRECT" next to the regulation/standard Section number and title
- follow the above procedure when you enter the Inspection Report into the LARIS database

Examples of "Direct" NCIs include, but are not limited to:

- animals in need of urgent veterinary care, e.g.
  - serious illness or injury
  - excessive (frequent and voluminous) diarrhea and/or vomiting
  - bloody (red, dark, and/or tarry) diarrhea and/or vomiting
  - excessively thin/debilitated animals with no care provided
  - moribund - recumbent, labored breathing, little response to stimuli, etc.
- matted dog with underlying lesions and/or other health issues caused by the mats
- inadequate, spoiled or contaminated food and water

- lack of drinkable water, i.e., no water or extremely contaminated water
- grossly inadequate enclosure space where animal **cannot**:
  - make normal postural adjustments
  - hold its head up
  - lie in full recumbency
- lack of shade or shelter for current weather or temperature extremes that threaten the animal's health and well-being
- sharp wire, nails or other objects which are likely to cause injury and are in an area where the animal will come into contact with them
- live unprotected electrical cord or heat lamp in an enclosure where an animal can reach it
- feet falling through flooring which is impacting the animal's ability to walk and/or function normally
- excessive accumulation of feces, urine, mud or other debris that the animal cannot get away from or avoid lying in
- lack of ventilation which has resulted in noxious fumes (e.g. your eyes burn) at the level of the animal's eyes or nose
- inappropriate handling that clearly causes pain or distress, such as, the use of:
  - electrical shock or starvation to train animals
  - a power hose to make animals shift
- IACUC-related problems, such as:
  - nonfunctional IACUC
  - inadequate analgesia
  - inappropriate procedures to alleviate pain
  - lack of adequate medical care for animals

For a comparison of direct vs indirect noncompliances, see Chart on pages 7.6.4 - 7.6.5.

EXAMPLES OF DIRECT vs INDIRECT NONCOMPLIANCES

DIRECT NONCOMPLIANCE	INDIRECT NONCOMPLIANCE
Lack of veterinary care for a serious condition, such as: • serious illness or injury • emaciated or debilitated animals with no care provided • generalized dermatitis or severe otitis externa with no care provided • large, infected lick granuloma with no care provided	Lack of veterinary care for a minor condition, such as: • cherry eye • mild or localized dermatitis • mild otitis externa • small lick granuloma • accumulation of tarter on teeth with no related impact on the animal
Inadequate enclosure space where animal **cannot**: • make normal postural adjustments • hold its head up • lie in full recumbency	Minor space deficiency with no apparent impact on the animal
Lack of shade or shelter in extreme conditions for all species; or lack of shade or shelter in uncertain conditions for less hardy species	Lack of shade or shelter in minor or uncertain conditions for animals that do not normally seek shelter in those conditions (i.e., bison)
Food that is clearly spoiled or contaminated	Pest control problem but no food contamination
Structural violation where: • sharp wire, nail or other object is likely to cause injury, AND • it is in an area where the animal will come into contact with it (e.g., floor or near a food bowl)	Structural violation where: • sharp wire, nail or other object is not in an area where the animal will come into contact with it (e.g., ceiling)
Matted dog with underlying lesions and/or other health impacts caused by the mats	Matted dog with no lesions or only minor lesions, and no other health impacts
Live unprotected electrical cord or heat lamp in an enclosure where an animal can reach the cord or lamp	Cords or lamps in enclosures that are not live and the animal is unlikely to get entangled in them

DIRECT NONCOMPLIANCE	INDIRECT NONCOMPLIANCE
Feet falling through flooring to a degree that it is impacting the animal's ability to walk and/or function normally	Feet can fall through the flooring but there is no significant threat of injury to the animal and no visible impact on the animal's ability to function
Lack of drinkable water, i.e., no water or extremely contaminated water Note: In such a situation, ask the registrant to offer fresh water to the animal. If the animal drinks voraciously, this would be considered a direct NCI.	Lack of drinkable water, but the animal appears normal and does not drink voraciously when offered fresh water
Excessive accumulation of feces, urine, mud, water and/or other debris that the animal cannot get away from	Accumulation of feces, urine, mud, water and/or other debris but the animal can avoid the areas of accumulation while still having adequate freedom of movement
Handling of animals that clearly causes pain or distress, such as, the use of: • electrical shock or starvation to train animals • a power hose to make animals shift	Handling violation with no apparent (serious) negative impacts on the animal
Lack of ventilation which has resulted in noxious fumes (e.g., your eyes burn): • in the entire room/building • in the area surrounding the animal • at the level of the animal's eyes or nose, such as: ▸ floor level ▸ in closed cages (hamsters, gerbils, etc.)	Lack of ventilation without noxious fumes: • in the entire room/building • in the area surrounding the animal • at the level of the animal's eyes or nose, such as: ▸ floor level ▸ in closed cages (hamsters, gerbils, etc.)
Incompatible animals housed in the same enclosure	Animals housed together that occasionally fight but without serious physical or psychological harm

SIGNATURES	The inspector and a research facility representative should sign all pages of the inspection report.
	The signature of the 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. Any disagreements about the inspection findings should be referred to the appropriate Animal Care Regional Office. **Date:** The signature date on the inspection report (lower right hand corner) should be: • for the inspector - the date the inspection report was written and signed • for the research facility - the date a copy of the inspection report was received NOTE: The inspection date on the inspection report (upper right hand corner) should be the date that the inspection was conducted OR the date the inspection was started if the inspection took multiple days to complete. The inspection date and the signature date may be different dates. **Refusal to sign:** If a representative of the research facility refuses to sign the inspection report: • do **not** put on the inspection report (narrative or signature block) that the person refused to sign the inspection report • type in the signature block "Hand-delivered" • leave a copy of the inspection report with the representative, if possible, and • send the research facility a copy of the inspection report, even if a copy was left with the representative at the time of the inspection, by: ▸ certified, return receipt mail, OR ▸ email with a return acknowledgment or receipt requested

INSPECTION APPEALS PROCESS

If the registrant has a concern about any findings on the inspection report, the inspection appeals process should be used to resolve the dispute.

Procedure

A registrant/facility representative may **not** make written comments about the inspection findings on the inspection report.

Prior to Finalizing the Inspection Report

If a registrant/facility representative has questions or concerns about a noncompliant item(s) cited on the inspection report, you, the inspector, should:

- at the exit briefing, take time to adequately explain why the noncompliance was cited
- if you and the registrant/facility representative resolve the disagreement, amend the citation
- if the dispute cannot be resolved:
  - inform the registrant/facility representative of the next step in the appeals process
  - give the registrant/facility representative a copy of the appeals process letter (see page 7.8.4)

If there was an unresolved disputed noncompliance:

- finalize the inspection report
- inform your SACS that there may be an appeal of a noncompliance(s) cited on the inspection report

After Finalizing the Inspection Report

If a registrant/facility representative has questions or concerns about a noncompliant item(s) cited on the inspection report, you, the inspector, should:

- if requested, meet with the registrant/facility representative again to discuss the noncompliance
- if you and the registrant/facility representative resolve the disagreement on the noncompliance, you should:
  - generate an amended inspection report (see page 7.8.2)
  - inform your SACS of the resolution

- give or send (by certified mail) a copy of the amended inspection report to the registrant/ facility representative
- send a copy of the amended inspection report to the Regional Office

- if the dispute cannot be resolved:
  - inform the registrant/facility representative of the next step in the appeals process
  - give the registrant/facility representative a copy of the appeals process letter (see page 7.8.4)
  - inform your SACS that there may be an appeal of a noncompliance(s) cited on the inspection report

If the registrant/facility representative's appeal of a noncompliance is determined to be valid, i.e., a citation is to be modified or deleted, a new, amended inspection report will be generated in LARIS either by the original inspector or the SACS, as determined by the SACS.

If the registrant/facility representative's appeal of a noncompliance is determined to be invalid, a letter will be written by the SACS to the registrant/facility representative informing him/her of the decision. The inspector will receive a copy of the letter.

NOTE: Inspection appeals should **NOT**:
- delay reinspection of direct noncompliances
- interfere with efforts to ensure that the immediate welfare needs of the animals are met

Amended Inspection Report

The amended inspection report should:
- be dated the date that the actual inspection was conducted in "Inspection Date"
- be dated the date that the amended inspection report was signed or sent to the registrant/facility representative/registrant in the "signature block"
- cite any noncompliances that were modified on appeal

- cite the noncompliances that were not appealed or overturned on appeal. NOTE: The citation on the amended inspection report must be identical to the citation on the original inspection report.
- contain the statement: "This is an amended report of inspection report (*LARIS inspection "id" codes of original inspection report*)."

If the inspector generates the amended inspection report, he/she should send a copy of the inspection report:

- to the registrant/facility representative by certified, return receipt mail
- to the SACS or Regional Office

If the SACS generates the amended inspection report, he/she should send a copy of the inspection report:

- to the registrant/facility representative by certified, return receipt mail
- to the inspector
- to the Regional Office

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Services

Animal Care

4700 River Rd.
Riverdale, MD 20737

Dear Licensee or Registrant:

Animal Care (AC) understands that at times there may be concerns about findings noted on inspection reports. It is in the best interest of you (the facility), AC, and, above all, the welfare of the animals to resolve disputes quickly and cooperatively. AC hopes the following process will achieve that goal.

If you have questions or concerns regarding the findings on an AC inspection report, you should:

1. Discuss the area in question with the inspector. You may have this discussion during the inspection or call your inspector later. Take sufficient time to clarify the areas of disagreement and, if necessary, your inspector can set up an appointment to meet with you again to discuss issues. Most concerns and questions can be resolved in this first step.

2. If questions or concerns persist, send a written description of the areas of concern to the Supervisory Animal Care Specialist (SACS) in your regional office. The SACS will review your concerns and determine if errors or misinterpretations were made by the inspector that need correction. If appropriate, an amended inspection report will be issued. As noted above, AC realizes that disagreements are a natural part of regulatory oversight, and inspectors understand that regulated facilities have the right to appeal inspection findings. An appeal of inspection findings will never result in reprisal against the facility by any AC employee.

3. If areas of disagreement persist, contact your regional director. He or she will consider the issues and seek review from the AC headquarters staff, if appropriate.

4. If the matter is still unresolved to your satisfaction, send your concerns to me, AC Deputy Administrator, at the Headquarters address below.

For more information about this process or compliance inspections, please contact your AC regional office. Other information about AC is available from our website and you may send questions or comments to our e-mail address, both shown below.

Chester Gipson
Deputy Administrator
Animal Care

Headquarters
USDA/APHIS/AC
4700 River Road, Unit 84
Riverdale, MD 20737
Phone: (301) 734-7833
Fax: (301) 734-4978

Eastern Region
USDA/APHIS/AC
920 Main Campus Drive
Suite 200, Unit 3040
Raleigh, NC 27606
Phone: (919) 855-7100
Fax: (919) 855-7123

Western Region
USDA/APHIS/AC
2150 Centre Ave.
Building B, Mailstop 3W11
Fort Collins, CO 80526
Phone: (970) 494-7478
Fax: (970) 494-7460

E-mail
ace@usda.gov

Internet Homepage
www.aphis.usda.gov/ac

7.8.4

MISTAKES ON THE INSPECTION REPORT

The inspection report must be read carefully before printing and finalizing to determine that all information and spelling are correct.

Prior to printing the final inspection report

To make the inspection report as error free as possible:

- **make sure that you are entering the inspection:**
  - **under the correct registrant**
  - **under the correct certificate number**
  - **in the correct site**
- check that all information is entered into the database correctly, such as:
  - animal inventory
  - name and title of person signing the inspection report
- check that all information in the narrative is correct, such as:
  - citation Section and subsections
  - regulation or standard correctly paraphrased, if applicable
  - buildings inspected
  - date of last inspection, if on inspection report
  - inventory of animals, if on inspection report
- for repeat NCIs or NCIs with correction time remaining, check that the section/subsection is the same cited on the previous inspection(s). If the incorrect section or subsection was cited on the previous inspection, cite the correct section and subsection and add: "Cited incorrectly under (*section/subsection #)* on (*date*) inspection."
- reread the narrative section to ensure that appropriate wording has been used to describe the problem
- check spelling and grammar
  Note: You can type the narrative in MS Word first by following the instructions at the bottom of page 7.2.1.
- review a DRAFT copy of the inspection report with the registrant/facility representative
- make the appropriate changes, if necessary
- print the DRAFT copy (original or corrected) of the inspection report for a signature

Be sure to finalize the inspection report.

Major Errors

If a **major error** is noted on the inspection report after the final copy has been printed or the inspection report has been finalized, it must be corrected.

Major errors include, but are not limited to:

- wrong site
- incorrect inspection type
- incorrect citation
- direct or significant noncompliance omitted
- failure to specify a noncompliance as "direct" or "repeat"
- correction date(s) omitted
- correction date given for a repeat noncompliance

NOTE: Spelling or grammatical errors are not considered major errors.

Correcting or Amending the Inspection Report

No pen and ink changes may be made to the Inspection Report.

If a major error(s) is noted after the **final** copy has been printed or the inspection report has been **finalized AND a copy of the inspection report HAS NOT BEEN SIGNED BY the registrant/facility representative**:

- contact your SACS and the Regional Office to have the inspection report reactivated (Note: You must replicate in order for the RO to reactivate the inspection report.)
- correct the reactivated inspection report
- provide a copy of the corrected inspection report to the registrant/facility representative through the usual delivery methods

If a major error(s) is noted after the **final** copy has been printed or the inspection report has been **finalized AND a copy of the inspection report HAS BEEN SIGNED BY and GIVEN TO the registrant/facility representative**:

- notify your SACS
- enter a new inspection report into LARIS (see below)
- provide a copy of the corrected inspection report to the registrant/representative through the usual delivery methods

	The new inspection report should • be dated the date that the actual inspection was conducted in "Inspection Date" • be dated at the bottom the date that the amended inspection report was: ▸ "Prepared" by you, and ▸ signed by or sent to the registrant Note: These dates do not have to be the same. • correct the major mistake for which the amended inspection report is being generated • cite the noncompliances that were correct on the incorrect report. NOTE: These citations must be identical to the citation on the incorrect report. • contain the statement at the end of the narrative: "This is an amended report correcting inspection report (*cust id, insp id, site id*) by (*insert correction)*." Examples of corrections are: ▸ correcting the site number from 001 to 002 ▸ correcting date of the inspection ▸ changing the Section of the Veterinary Care citation from 2.40 to 2.33
Mistakes Noted by the Regional Office	If the Regional Office discovers a mistake on an inspection report: 1. the inspection report will be emailed to the inspector and the SACS 2. the inspector must correct the inspection report following the procedure outlined above 3. the inspector must deliver the amended inspection report to the licensee in person or send by certified, return receipt mail **within 2 weeks**

HANDWRITTEN INSPECTION REPORTS

There are certain situations where the inspector may choose to or have to hand write the inspection report.

If you hand write an inspection report, you must use the blank pre-printed inspection report form (see page 7.10.3).

You should always have a supply of blank pre-printed inspection reports either with you or in the government vehicle.

When using the pre-printed inspection report:

- hand write all information in a legible and neat manner
- use black or blue ink

Situations where the inspection report may be handwritten include, but are not limited to:

- computer failure
- printer failure
- airports where it is difficult to get a computer through security
- unique situations which may arise where the use of the computer is not feasible

If you want to give the registrant/facility representative a copy of the handwritten inspection report at the time of the inspection, you can:

- make a carbon copy of the inspection report
- make a photocopy of the inspection report
- complete two original inspection report forms and sign both copies

If you do not give the registrant/facility representative a copy of the handwritten inspection report at the time of the inspection, you should send a copy to hem/her by certified, return receipt mail.

REMEMBER:

1. You must enter the handwritten inspection report into the LARIS database as soon as possible
2. The narrative entered into the LARIS database must be identical to the handwritten inspection report
   NOTE: Dates of the actual inspection, Prepared, and Received should be the same as on the handwritten inspection report.
3. The following statement must be placed in the narrative section: "**This is an electronic version of the report dated *xx/xx/xx.***"
4. A copy of the LARIS inspection report should be sent to the registrant by regular mail or email
5. A copy of the LARIS inspection report should be attached to the handwritten inspection report
6. The handwritten inspection report and LARIS copy should be sent following your standard procedure, i.e. SACS or the Regional Office, after it is entered into LARIS

For a ***printer failure***, you may do a handwritten report or use the following procedure:

- enter the inspection report into the LARIS database
- review the inspection report with the registrant/facility representative on the computer screen
- when the printer is repaired, send a copy of the inspection report to:
  - the registrant by certified, return receipt mail, and
  - to the SACS or Regional Office

United States Department of Agriculture
Animal and Plant Health Inspection Service
Animal Care

INSPECTION REPORT

Name of Licensee/Registrant	Site No.	Lic. / Reg. Number
Business Name (DBA)	Site Name	Date of Inspection
Facility Mailing Address	Site Address	Inspection Time
City, State, Zip (for facility)	Site City, State, Zip (for site)	Inspection Type

NARRATIVE

Prepared By: _____ Date: _____

Title: _____, USDA, APHIS, Animal Care LARIS ID NO. _____

Copy Received By: _____ Date: _____

Title: _____

NON-REGULATED ANIMALS	Non-regulated animals should not be inspected or mentioned on the inspection report unless there is the potential for a negative effect on the health or well-being of the regulated animal(s).
	Examples of a potential negative effect are: • rats with an infectious disease being housed in the same room with rabbits • the number of non-regulated animals is so large that the current staffing is inadequate to properly care for the regulated animals