

<p>DOCUMENTING INSPECTION FINDINGS</p>	<p>Inspection findings must be documented in the narrative section of the inspection report.</p>
<p><i>No noncompliant items identified</i></p>	<p>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.”</p>
<p><i>New noncompliant item identified</i></p>	<p>If a noncompliant item(s) is identified, then it should be cited in the inspection report narrative.</p> <p>The citation should include the following:</p> <ol style="list-style-type: none"> 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: <ul style="list-style-type: none"> ▶ 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;
<i>Noncompliance</i>	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.
<i>Why a noncompliance</i>	There may be an alternative procedure which will cause less pain or distress to the animals and affect their health and well-being.
<i>How to comply</i>	A search for alternatives must be conducted and reviewed and approved by the IACUC.
<i>Correction date</i>	Correct by <i>(date)</i> . 5 adult cats are affected.
EXAMPLE 2:	
<i>Standard (paraphrase)</i>	SECTION 3.83 WATERING Potable water must be available to the nonhuman primates and water receptacles must be kept clean and sanitary.
<i>Noncompliance</i>	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.
<i>Why a noncompliance</i>	The presence of debris, scum and algae in an indicator of contamination of the water which can cause illness in the animals.
<i>How to comply</i>	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.
<i>Correction date</i>	To be corrected by <i>(date)</i> .
EXAMPLE 3:	
<i>Standard (applicable portion only)</i>	SECTION 3.105 (a) FEEDING The food for marine mammals must be wholesome, palatable, and free from contamination...
<i>Noncompliance</i>	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.
<i>Why a noncompliance</i>	The feeding of unwholesome, unpalatable and rancid food does not provide adequate nutrition to the animals and may affect their health and well-being.
<i>How to comply</i>	Appropriate, good quality food must be fed to the marine mammals.
<i>Correction date</i>	Correct by <i>(date)</i>

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:

<i>Standard</i>	SECTION 3.6(a)(2)(ix) REPEAT
<i>Noncompliance</i>	PRIMARY ENCLOSURES - GENERAL REQUIREMENTS Of the 10 pens previously cited, the wooden side walls and floors of 7 pens (<i>if pens are numbered, include the numbers</i>) on west side of Room 12 in Bldg G are still chewed and scratched and are not impervious to moisture.
<i>Partial correction</i>	Three pens (<i>if pens are numbered, include the numbers</i>) have been repaired and repainted.
<i>Why a noncompliance</i>	The wood surfaces cannot be properly cleaned and sanitized which could affect the health and well-being of the dogs.
<i>Why a repeat noncompliance</i>	On the previous inspection (1/14/06), these wooden surfaces were chewed and scratched and not impervious to moisture.
<i>How to comply</i>	The wooden surfaces in the remaining 7 pens must be repaired and made impervious to moisture.
<i>Optional</i>	This is a repeat violation - original correction date was (<i>date</i>).

***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.