

Departures From the *Guide*

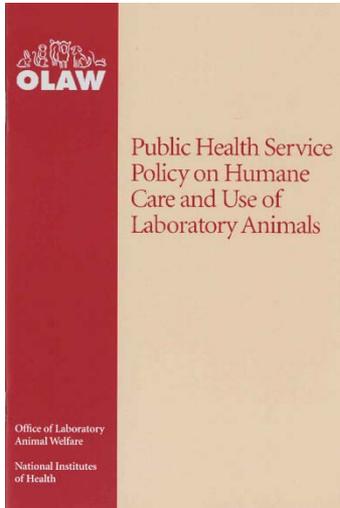
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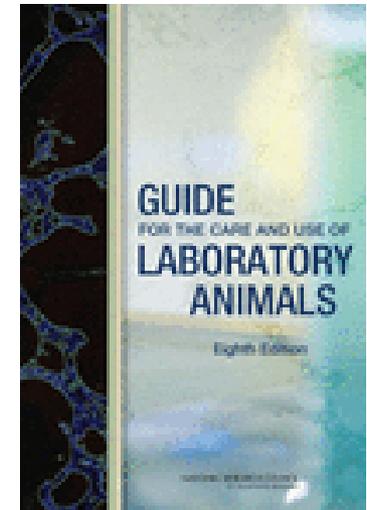


What Does the Policy Say?



PHS Policy requires that Assured institutions base their programs of animal care and use on

the *Guide for the Care and Use of Laboratory Animals (Guide)*.



What Does the Policy Expect?

IACUC shall prepare reports that “contain a description of the nature and extent of the institution’s adherence to the *Guide* and this Policy, and must **identify specifically any departures** from the provisions of the *Guide* and must **state the reasons** for each departure.”

Terms Used in this Webinar

Term	Common Meaning	Specialized Meaning
Deviation	Divergent behavior	Divergent behavior that may or may not be a departure
Departure	Variation from a previous custom	Variation from the standards of the <i>Guide</i> that must be reported Has a specialized meaning to USDA
Deficiency	Lack or insufficiency	Significant deficiency: consistent with the Policy and in the judgment of the IACUC and IO is or may be a threat to the health or safety of the animals
		Minor deficiency: a deficiency that is not significant
Exception	Case that does not conform to the general rule	Case that does not conform to the general rule (<i>Guide</i>) Has a specialized meaning to USDA
Exemption	Privilege that dispenses with the general rule	Has a specialized meaning to USDA

Guide Emphasizes Performance

A performance standard is a standard or guideline that, while describing the desired outcome, provides flexibility in achieving that outcome.

- Performance standards are emphasized by the *Guide*.
- Throughout the *Guide* are definitions of desired outcomes and guidance on how to achieve outcomes.
- Performance standards are not prescriptive and require a sophisticated approach vs. engineering standards.
- They empower institutions to make decisions specific to their program needs.

Guide Notice NOT-OD-12-148

Guidance on Departures from the Provisions of the *Guide for the Care and Use of Laboratory Animals*

- Read the Eighth Edition of the *Guide* carefully.
- *Guide* establishes exceptions in specific situations.
- These exceptions are not departures from the *Guide*.
- These exceptions are not required to be reported to the IO in the semiannual report.
- Notice describes types of departures based on “must” and “should” statements in the *Guide*.



- Guide Notice NOT-OD-12-148
- <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-148.html>

OLAW on *Guide* Must, Should, May

Must: A minimum standard required of all Assured institutions.

Should: Should statements often involve performance standards.

- Established performance standards are not departures.
- An institution may depart from a should statement if their action results in an equivalent outcome and is reviewed and approved by IACUC.

May: A suggestion that an institution can choose to implement if it is suitable for their program.



New OLAW FAQ C7

What are PHS Policy reporting requirements for departures from the *Guide*?

- The IACUC must review and approve departures from the *Guide*.
 - IACUC approval of departures must be based on scientific, veterinary medical, or animal welfare issues.
 - Semiannual reports from the IACUC to the IO must identify specifically any departures.
- Read the *Guide* closely; it establishes exceptions in specific situations. Exceptions are not departures from the *Guide* and do not have to be reported.



Deviations from the *Guide*

A. Specifically described exception

B. Must

1. IACUC-approved scientific justification, veterinary medical, or animal welfare issue
2. Noncompliance

C. Should

1. Locally established performance standard
2. IACUC-approved scientific justification, veterinary medical, or animal welfare issue
3. Noncompliance

<http://grants.nih.gov/grants/olaw/departures.htm>



Specifically Described Exception

A. Conduct of an activity according to a specifically described exception listed in the *Guide*.

- Status: **Not a departure**
- Report to IO: **No**
- Report to OLAW: **No**
- Guidance: **8th Edition *Guide***



Specifically Described Exception Scenario 1

- ✓ In an animal study protocol, the PI requests single housing for her mice so that she can measure individual fluid consumption.
- ✓ After considering the proposed experiment, the IACUC approves the protocol.

Specifically Described Exception Scenario 1

- **Guide:** *Social animals **should** be housed in stable pairs or groups of compatible individuals unless they must be housed alone for **experimental reasons** or because of social incompatibility.* page 51.
- **Discussion:** This is a deviation from a should statement according to a specifically established exception in the *Guide* (experimental reasons). Exceptions are not departures from the *Guide*. It need not be reported to the IO in the semiannual report.

Specifically Described Exception Scenario 2

- ✓ Prior to implementing the 8th Edition *Guide*, an institution singly housed all rabbits.
- ✓ After attempts at social housing, the veterinarian determines that a group of older male rabbits cannot be successfully socially housed.
- ✓ The facility manager and veterinarian prepare an SOP describing appropriate social housing of newly acquired rabbits that includes pairing of sibling does or neutered bucks.
- ✓ The IACUC approves an institution-wide SOP for social housing rabbits.

Specifically Described Exception Scenario 2

- **Guide:** *Social animals **should** be housed in stable pairs or groups of compatible individuals unless they must be housed alone for experimental reasons or because of **social incompatibility**.* page 51.
- **Discussion:** The institution fulfilled the intent of the *Guide* should statement regarding social housing. Singly housing the older bucks is a deviation from a should statement according to a specifically established exception in the *Guide* (social incompatibility) and is not a departure from the *Guide*. It need not be reported to the IO in the semiannual report.

Specifically Described Exception Scenario 3

- ✓ The institution has previously housed all dogs in pairs.
- ✓ The veterinarian determines that one older dog can no longer be socially housed because of arthritis that requires specialized care and padded flooring.
- ✓ The vet informs the IACUC of the circumstances for singly housing the dog based on veterinary-related concerns.

Specifically Described Exception Scenario 3

- **Guide:** *Social animals **should** be housed in stable pairs or groups of compatible individuals unless they must be housed alone for experimental reasons or because of social incompatibility. page 51. Single housing of social species should be the exception and justified based on experimental requirements or **veterinary-related** concerns about animal well-being. page 64.*
- **Discussion:** This is a deviation from a should statement according to a specifically established exception in the *Guide* (veterinary-related concern) and is not a departure from the *Guide*. It need not be reported to the IO in the semiannual report.

Deviating From a Must

B.1. According to IACUC-approved scientific justification, veterinary medical, or animal welfare reason.

- Status: **Approved departure**
- Report to IO: **Semiannual report**
- Report to OLAW: **No**
- Guidance: **Policy IV.C.1.**



Deviating From a Must

Scenario B.1.

- ✓ The PI proposes to confine dogs for 3 days post surgery in small cages to limit the dogs' ability to stand.
- ✓ The dogs will be observed hourly by a veterinary technician who will remove each dog from the cage no less frequently than every 4 hours for stretching and supervised walking.
- ✓ IACUC reviews & approves the protocol.

Deviating From a Must Scenario B.1.

- **Guide:** *At a minimum, animals **must** have enough space to express their natural postures...* page 56.
- **Discussion:** This is a deviation from a must statement of the *Guide* that has been scientifically justified by the PI & reviewed & approved by the IACUC. It is an approved departure and must be reported in the semiannual report to the IO.

Deviating From a Must

B.2 .Without IACUC approval.

- Status: **Noncompliance**
- Report to IO: **Promptly**
- Report to OLAW: **Promptly**
- Guidance: **Policy IV.F.3., NOT-OD-05-034**



Deviating From a Must Scenario B.2.

- ✓ The IACUC learns that one of the satellite facilities has inadvertently been omitted from the disaster plan.

Deviating From a Must Scenario B.2.

- **Guide:** *Facilities must therefore have a disaster plan. page 35.*
- **Discussion:** This is a noncompliance. The IACUC must develop a plan & schedule to correct this unapproved deviation from a must statement in the *Guide*.

Deviating From a Should

C.1. Deviation from *Guide should* statement according to a locally established performance standard.

- Status: **Not a departure**
- Report to IO: **No**
- Report to OLAW: **No**
- Guidance: **OLAW Position Statements**

What's a Performance Standard?

A well-established performance standard meets the following criteria:

- ✓ supports scientific objectives;
- ✓ supports the health and welfare of the animal;
- ✓ includes a justified performance index; and
- ✓ has associated outcome criteria.

We've "always done it this way" does not meet these criteria. See *Guide* page 6.

Deviating From a Should Scenario C.1.

- ✓ The PI proposes to trio breed transgenic and inbred mice in solid bottom cages with 71 in² of floor space according to an SOP developed by the animal facility.
- ✓ The strains proposed are difficult to breed and generate small numbers of pups.
- ✓ The SOP addresses parameters of wellbeing and requires prompt weaning and separation of animals to avoid overcrowding. The SOP is based on local performance measures including growth rate, cage dimensions, and husbandry practices.
- ✓ The SOP has been reviewed and approved by IACUC.

Deviating From a Should

Scenario C.1.

- **Guide:** *The space recommendations presented here are based on professional judgment and experience. They **should** be considered the minimum for animals housed under conditions commonly found in laboratory animal housing facilities. Recommended Minimum Space for Commonly Used Laboratory Rodents Housed in Groups. Female + litter, Floor Area/Animal in² = 51 in² Table 3.2. pages 56-57.*
- **Discussion:** This is a deviation from a should statement that follows a well-established performance standard, is not a departure from the *Guide* & not reported in the semiannual report to IO.

Deviating From a Should

C.2. Deviation from *Guide should* statement according to IACUC-approved scientific justification, veterinary medical, or animal welfare issues.

- Status: **Approved departure**
- Report to IO: **Semiannual report**
- Report to OLAW: **No**
- Guidance: **Policy IV.C.1.**

Deviating From a Should Scenario C.2.

- ✓ In describing a food-restricted animal study, the PI stated that animals have to be anesthetized before weighing & cited data demonstrating the adverse effect of anesthesia on the animal's performance of behavioral tasks required in the proposed study.
- ✓ He cited other parameters of animal well-being that the research team will monitor and requested permission to weigh the animals monthly rather than weekly.
- ✓ IACUC reviewed & approved the request.

Deviating From a Should

Scenario C.2.

- **Guide:** Regarding food-restricted diets, the *Guide* says, *body weights **should** be recorded at least weekly.* page 31.
- **Discussion:** This is a deviation from a should statement based on a scientific justification that has been reviewed & approved by the IACUC. It is an approved departure from the *Guide* and must be reported in the semiannual report to the IO.

Deviating From a Should

C.3. Deviation from *Guide* **should** statement without IACUC approval.

- Status: **Noncompliance**
- Report to IO: **Promptly**
- Report to OLAW: **Promptly**
- Guidance: **Policy IV.F.3., NOT-OD-05-034.**



Deviating From a Should Scenario C.3.

- ✓ The PI's approved protocol includes having the research team sanitize solid bottom rodent cages in a satellite facility.
- ✓ The PI goes on sabbatical and the research team decides that sanitation every three weeks is sufficient.
- ✓ A post-approval monitor discovers the discrepancy and informs the IACUC.

Deviating From a Should

Scenario C.3.

- **Guide:** *In general, enclosures & accessories...**should** be sanitized at least once every two weeks. Solid-bottom caging...usually require[s] sanitation at least once a week. (page 70)*
- **Discussion:** This is a noncompliance. The IACUC must develop a plan & schedule to correct this unapproved deviation from a should statement in the *Guide*.

Summary on Deviations

- A. Conduct of an activity according to a specific exception described in the *Guide* (Not report)
- B. Must
 1. IACUC-approved scientific justification, veterinary medical, or animal welfare issue (Report in semiannual)
 2. Noncompliance (Report to OLAW through IO)
- C. Should
 1. Locally established performance standard (Not report)
 2. IACUC-approved scientific justification, veterinary medical, or animal welfare issue (Report in semiannual)
 3. Noncompliance (Report to OLAW through IO)

Reporting Departures

How does OLAW expect IACUCs to report and track approved departures?

- The first time IACUC approves a departure, it must be reported in the next semiannual report to the IO.
- A record of the departure must be maintained for as long as the departure is active and approved.
- The IACUC may determine how best to maintain and update records of approved departures. This may involve electronic records such as a spreadsheet, database, or another recordkeeping method.
- PHS Policy IV. B.3. requires that the departures record is updated at a minimum every 6 months.

Question 1

Does the IACUC have the authority to approve a departure from any provision of the *Guide*?

Question 2

Is a departure protocol-specific
or program-specific?

Question 3

If a departure is approved by the IACUC at a prime grantee institution, but the work is being performed at a collaborating institution (performance site), does the prime grantee's approved departure apply to the work at the performance site?

Or, is the IACUC at the performance site required to also approve the departure from the *Guide*?

Question 4

How should the IACUC respond to an investigator who says, “We’ve been doing it that way for 10 years and the animals have never experienced welfare issues, so it’s a well established performance standard.”

Question 5

Will the IACUC's ongoing reconsideration of approved departures really make a difference in the welfare of the animals?

Question 6

Will these changes in the *Guide* increase the workload of IACUC members and staff?

Question 7

Is there an expectation that the institution maintain a list of “shoulds” based on locally established performance standards?

Question 8

Does the IACUC need to review and approve performance standards since they are not considered departures from the *Guide*?

Question 9

What if a program discovers that it has not been reporting departures that should have been reported?

Question 10

What should institutions do if previously approved departures are no longer identified in the *Guide* Eighth Edition?

Question 11

Is feeding animals on the floor, if outlined in the protocol, considered a departure from the *Guide*?

Question 12

The IACUC has approved an SOP that stipulates that individuals entering our rodent facility must use PPE. Prior to leaving the facility, which has no shower, all PPE are discarded. Is this an IACUC approved departure from a should statement that must be reported in the semiannual report? How would we measure equivalent outcomes between showering out and removal of PPE?

Question 13

Specific for the deviation from "should" with regard to trio breeding, if the PI conducts the breeding and it is not done by a central facility, does each PI have to have a separate SOP for this deviation using performance standards?

Question 14

Do we have to include departures from social housing for veterinary medical reasons?

Question 15

Is it appropriate to adopt the 1996 *Guide* standards rather than the 2011 *Guide*? For example, the 2011 *Guide* states: *Food should be stored at less than 70°F and less than 50% humidity.* If an institution is not able to meet the less than 50% humidity at all times of the year, is it appropriate to continue to use the 1996 *Guide* recommendations for food storage?

Question 16

Is it the expectation of OLAW that performance standards be formally defined, provide justification, and then be reviewed and approved by the IACUC?

Question 17

For experimental animals, on arrival, animals may be singly housed for a few days until allocation to the study by body weight occurs. The animals are socially housed when they are on study. Is this considered a departure?

Question 18

If the departure is described in an approved protocol, does that meet record keeping requirements?

Question 19

Would you clarify what you mean by maintenance of a departures list as a spreadsheet every six months? Is it OK to add departures as the protocols are approved and then refer to this list in the semiannual report to the IO?

Question 20

If we collect data and use it to develop a performance standard and the IACUC approves the performance standard, do we need to continue collecting data on an ongoing basis for subsequent review by the IACUC?

Question 21

How frequently does the IACUC need to reconsider ongoing departures?
Every six months? Annually? Every three years?

Question 22

Are excursions outside prescribed temperature and humidity levels considered departures from the *Guide*?

Question 23

I thought OLAW did not require dual review. You stated that the performance site IACUC has to approve a departure approved by the grant recipient IACUC. Does that mean that OLAW expects both IACUCs to review and approve the departure or at least a review and approval by the performance site IACUC.

Question 24

We are currently testing ammonia levels in our cages to see if we can change cages every two weeks. After we develop a performance standard based on these metrics and it is reviewed and approved by the IACUC, do we need to report this to OLAW? If yes, do we continue to test and report this as we continue from year to year?

Question 25

If a departure is described in a non-PHS-funded study, should it be reported?

Question 26

We understand the need for the IACUC to review a veterinary prescribed departure but do not understand this statement that the IACUC needs to approve the departure. This statement implies that the IACUC could choose to not approve the departure and thus override the veterinary decision. Please clarify.

Question 27

Does the IACUC have to approve a departure that is driven by veterinary medical need and the requirement that this needs to be reported? The USDA does not require exemptions from the AWA/AWR if the exemptions are driven by veterinary care needs that are not due to the potential side-effects of research.

Question 28

Our rabbit care SOP says “single housing” which is a departure based off a *Guide* approved exception for "experimental reasons". Does this exception need to be made into a policy or can the IACUC just review and approve the current SOP?

Question 29

What is expected for housing of social species when the housing unit is not adequate for pair or group housing?
E.g., rabbit cages, horse barn stalls.

Question 30

Are facilities that house rabbits expected to purchase caging that would accommodate pair housing or are we expected to find a way to provide social contact?

Question 31

How should an institution deal with the potential conflict between statement that social animals should be housed in pairs vs. the recommended space allocation for animals (e.g., rabbits)?

Question 32

A pharmaceutical grade alternative to a drug being administered to mice is available, but only available from a foreign company and is of unknown (suspect) quality. The PI has been using the non-pharmaceutical drug of reliable quality for several years. Can the IACUC approve this deviation from a must and how is it reported?

Question 33

Do you have suggestions for getting departures practiced by PIs in the animals facility communicated to the IACUC?

Question 34

Facilities need to implement the 2011 changes to the guide by 2012. Aside from the checklist provided by OLAW, how else can we provide "proof" of the changes?

Question 35

What is OLAW's position on recommendations that are not must or should statements? Our facility cannot adjust storage room temp below 70°F. We order small amounts of feed weekly so our food does not sit in the room long. May we store feed short term in conditions outside *Guide* recommendations? (p. 66 in the Guide states, "Storage of natural-ingredient diets at less than 21°C (70°F) and below 50% relative humidity is recommended.")

OLAW Online Seminar Series Upcoming Schedule



December 13, 2012 – Topic: TBD