

Guidelines on Classifying Deficiencies Identified During Semiannual Evaluations

Background: The PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy)(1), the USDA Animal Welfare Act and Regulations (AWARs)(2), and NIH Policy Manual Chapter 3040-2 Animal Care and Use in the Intramural Program(3) collectively require the NIH Intramural Research Program (IRP) animal care and use programs to conduct semiannual program evaluations that include program reviews and inspections of primary animal facilities, satellite facilities (>24 hours holding), study areas (12-24 hours holding), and areas where surgical procedures are performed. These reviews and inspections utilize the *Guide for the Care and Use of Laboratory Animals (Guide)*(4), PHS Policy, and the AWARs as primary standards.

This guideline is intended to expand upon the specific language in the PHS Policy, which states that the semiannual program evaluation reports must distinguish significant deficiencies from minor deficiencies.

Significant Deficiency:

A significant deficiency is any deviation in policy, program, procedure, or facility condition from the standards described in the *Guide*, PHS Policy, or the AWARs, that in the judgement of the Institute/Center (IC) Animal Care and Use Committee (ACUC) and the Institutional Official (IO), is or may be a threat to the health or safety of the animals.

As this status must be an agreement between the IC-ACUC and the IO, consultation must occur between these groups prior to assigning this status and finalizing the semiannual report. The Office of Animal Care and Use (OACU) has delegated authority from the IO to facilitate this consultation. Examples of significant deficiencies that the Office of Laboratory Animal Welfare (OLAW) provides, include inoperable HVAC, electrical, or watering systems, failure of such systems sufficient to affect critical housing and operational areas, and situations such as natural disasters that cause injury, death, or severe distress to animals.

If program or facility deficiencies are noted, the semiannual report must contain a reasonable and specific plan and schedule for correcting each deficiency. This plan should be established by the IC-ACUC in consultation with the OACU and IC Scientific Director (SD) and then reported through the OACU to the IO. As a significant deficiency, by definition, is a threatening environment for the animals, it follows that the reasonable and specific plan and schedule for correction must indicate that management and/or policy changes will be put in place immediately to either: 1) remove the condition causing the significant deficiency until a permanent correction can be implemented; or 2) minimize the negative impact of the deficiency as much as possible and for as brief a period as possible. The IC-ACUC should follow up on the plan no later than the next semiannual program review, though more frequent monitoring may be necessary depending on the nature of the specific deficiency.

Some significant deficiencies may also be corrected on the spot or shortly after the inspection. In this situation, a report of that incident, as corrected, must be made through the OACU to the IO.

OLAW has a high level of interest in significant deficiencies and would expect an institution to expedite appropriate resources to correct the deficiency and bring the situation into compliance with applicable standards and regulations as quickly as possible. Many significant deficiencies would be viewed by OLAW as resulting from an institution's failure to fully understand or implement some aspect of its animal care and use program required by the PHS Policy, or failure to function according to commitments made in its Assurance and would require prompt reporting in accordance with PHS Policy. When required, significant deficiencies will be reported by OACU to OLAW and AAALAC International.

Minor Deficiency:

A minor deficiency is any other deviation in policy, procedure, or facility condition from the standards described in the *Guide, PHS Policy*, the AWARs, NIH Manual 3040-2, or IC policies and procedures, which is not a justified exception to those standards. In comparison to the significant deficiencies noted above, minor deficiencies refer to a problem for which an immediate solution is not necessary to protect life or prevent distress. Minor deficiencies in animal facilities include findings of moderate environmental fluctuations that are generally well tolerated, even if auxiliary equipment (i.e., heaters or chillers) may be needed to help minimize fluctuations, peeling or chipped paint, burnt-out light bulbs, missing floor drain covers, chipped floor surfaces, and similar problems.

The semiannual review process gives the IC-ACUC an opportunity to formally and specifically deal with the entire scope of the IC's policies, program, procedures, and facility conditions in support of its animal care and use program. The degree of identification and reporting of minor deficiencies is a direct reflection of the thoroughness of the IC-ACUC's oversight of its program and facilities, and a very positive indication of its responsibility to the IRP in performing effective self-regulation, while concomitantly assuring continuing compliance with applicable regulations and standards.

Unresolved Deficiencies:

The IC-ACUC is responsible for tracking and monitoring all pending deficiencies until corrective actions are fully completed.

Significant Deficiencies: If a correction deadline for a significant deficiency cannot be met, the IC-ACUC must act immediately by re-reviewing the pending deficiency, approving a new correction date, and notifying the OACU Director of the updated status.

Minor Deficiencies: If minor deficiencies remain unresolved since the last semiannual report, the IC-ACUC must review those specific items and reassess the correction timeline. The length of time a minor deficiency remains unresolved does not result in its reclassification as a significant deficiency, provided the nature of the deficiency continues to meet the definition of 'minor' as noted above.

Escalation to the IO: If any deficiency—minor or significant—proves difficult to resolve and requires direct input or support from the IO, the OACU Director must be notified. In such cases, OACU will collaborate with the IC-ACUC and the IC SD, in consultation with the IO, to develop a resolution plan.

References:

1. Office of Laboratory Animal Welfare. Public Health Service Policy on Humane Care and Use of

Laboratory Animals. In: National Institutes of Health, Office of Laboratory Animal Welfare, editor. 2015.

2. United States Department of Agriculture. USDA Blue Book: Animal Welfare Act and Animal Welfare Regulations USDA2022 [Available from: <https://www.aphis.usda.gov/media/document/17164/file>].
3. NIH Office of Animal Care and Use. 3040-2 - Animal Care and Use in the Intramural Research Program. In: Office of Management Assessment, editor. NIH Policy Manual2023.
4. Institute for Laboratory Animal Research. Guide for the Care and Use of Laboratory Animals. 8th ed. Washington (DC): National Academies Press; 2011.

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