

## Guidelines on Classifying Deficiencies Identified During Semiannual Evaluations

The [PHS Policy on Humane Care and Use of Laboratory Animals](#) (PHS Policy), the [USDA Animal Welfare Act Regulations](#) (AWARs), and NIH [Policy Manual 3040-2 Animal Care and Use in the Intramural Program](#) 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)*, PHS Policy, and 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 IC ACUC and the Institutional Official (IO), is or may be a threat to the health and 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. 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 a finding is determined to be a significant deficiency, the semiannual report must contain a reasonable and specific plan and schedule for correcting the problem. 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 finding.

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, "serious or continuing non-compliances with PHS Policy," or "serious deviations from the

provisions of the *Guide*," and would require prompt reporting, in accordance with PHS Policy. When required, significant deficiencies will be reported 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 policies, program, procedures, and facility conditions in support of its Animal Care and Use (ACU) 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 animal care and use program and facilities, and a very positive indication of their responsibility to the IRP for performing effective self-regulation, while concomitantly assuring continuing compliance with applicable regulations and standards.

**Unresolved Deficiencies**

The IC ACUC should track and monitor any pending deficiencies until the plan for correction is fully executed. If the date for correction of a major deficiency will be exceeded, the pending deficiency should be re-reviewed by the IC ACUC immediately, a new date for correction approved, and the OACU Director notified of the changed status.

If minor deficiencies have not been resolved since the last semiannual report, the ACUC must review those specific items, and reassess the timeline for correction. In addition, the OACU Director must be informed of any ongoing issue that is not easily resolvable and requires input and support directly from the IO to achieve resolution. In those circumstances, OACU will work with the IC ACUC and IC SD, in consultation with the IO, to establish a plan for resolution.

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