

## 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 animal care and use programs to conduct semiannual program evaluations that incorporate 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, which is or may be a threat to the health and safety of the animals as judged by the IC Animal Care and Use Committee (IC ACUC) in consultation with the Office of Animal Care and Use (OACU) and Institutional Official/Deputy Director for Intramural Research (IO/DDIR).

As this status must be a consensus by the IC ACUC, OACU, and the IO/DDIR, consultation must occur between these groups prior to assigning this status and finalizing the semiannual report. Examples of significant deficiencies that the Office of Laboratory Animal Welfare (OLAW) provides include failure or malfunction of HVAC, electrical or watering systems sufficient to affect critical housing and/or operational areas, and broad circumstances, such as natural disaster, 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 ACUC in consultation with the OACU, and IC Scientific Director, and then reported through the OACU to the IO/DDIR. 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/DDIR.

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*. The reportable nature of the significant deficiency will be determined in consultation with the OACU Director and forwarded to the IO/DDIR and OLAW if warranted.

[AAALAC International](#) requires prompt reporting of adverse events relating to the animal care and use program as well as other serious incidents or concerns that negatively impact animal well-being. Significant deficiencies will be reported to AAALAC by OACU.

### **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 are variances that require correction, but which are not serious breaches of policy or conditions endangering the health and safety of the animals. Minor deficiencies in animal facilities include infrequent 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 institution-at-large 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/DDIR to achieve resolution. In those circumstances, OACU will work with the IC ACUC and Scientific Director, in consultation with the IO/DDIR, to establish a plan for resolution.

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