

Guidelines on Classifying Deficiencies Identified during Semiannual Reviews

The PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy), the Animal Welfare Regulations, the Guide for the Care and Use of Laboratory Animals (Guide) and NIH Policy Manual 3040-2, [Animal Care and Use in the Intramural Program](#) collectively require our animal care and use programs to conduct semiannual program reviews that incorporate inspections of primary animal facilities, satellite facilities (>24 hours holding), study areas (12-24 hours holding) and areas where survival surgeries are conducted. Additionally PHS Policy and the Guide require that all other animal activity areas be reviewed at least annually.

This guideline is intended to expand upon the specific language in the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy), which states: “The [semiannual program review] reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, consistent with this Policy, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency.”

SIGNIFICANT DEFICIENCY

A significant deficiency is any deviation(s) in policy, procedure or facility condition from the standards enunciated in the Guide for the Care and Use of Laboratory Animals (Guide), PHS Policy, or the Animal Welfare Regulations (AWRs), which is/are or may be a threat to the health and safety of the animals. Such a finding is one which the Institute or Center (IC) Animal Care and Use Committee (ACUC) collectively judges to be (or to have been) a major problem impacting negatively upon the health or safety of the animals and should be reported through the Scientific Director to the Deputy Director for Intramural Research (DDIR) who serves as the Institutional Official for NIH. If the finding was corrected on the spot or shortly thereafter, a report of that incident, as corrected, should be reported through the Office of Animal Care and Use (OACU) to the DDIR. In the event the correction of the underlying deficiency requires the execution of a planned modification or improvement over a period of time, then a reasonable and specific plan and schedule for correction must be established as quickly as possible and reported through the OACU to the DDIR. Those findings should again be addressed within the body of the next IC semiannual report and include a specific date for correction. 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 put in place; 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 the ‘pending’ deficiencies until the plan for correction is executed. If the date for correction will be exceeded, the pending deficiency must be re-reviewed by the IC ACUC and a new date for correction approved.

The Office of Laboratory Animal Welfare (OLAW) has a high level of interest in significant deficiencies and would undoubtedly 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. Normally, significant deficiencies would be viewed by OLAW as synonymous with "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 Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) Council would probably view significant deficiencies as mandatory deficiencies, whether self-declared or noted during a site visit. A mandatory deficiency places an institution's accreditation status at risk and corrective actions for that deficiency must be accomplished within the time limit granted by Council.

MINOR DEFICIENCY

Any other deviation(s) in policy, procedure or facility condition from the standards enunciated in the Guide, PHS Policy, the AWRs, NIH Manual 3040-2, or IC policies and procedures, which are/were not justified exceptions to those standards. In comparison to the significant deficiencies noted above, minor deficiencies are variances which 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 peeling or chipped paint, burnt-out light bulbs, missing floor drain covers, and similar problems.

The semiannual review process gives the ACUC an opportunity to formally and specifically deal with the entire scope of its IC's policies, 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 ACUC's oversight of its ACU program and facilities, and a very positive indication of their responsibility to the institution-at-large for performing effective self-regulation and concomitantly assuring continuing compliance with applicable regulations and standards.

UNRESOLVED DEFICIENCY(IES)

In the event that an ACUC is dealing with a deficiency that remains uncorrected that deficiency should be listed in section E. of the semiannual report and be highlighted in the recommendations made to the Institutional Official via the Scientific Director in the IC's semiannual report. In OACU's semiannual summary report to the Institutional Official, ongoing significant deficiencies will be briefly described and recommendations provided for corrections.

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