

Iowa State University Institutional Animal Care and Use Committee (IACUC)	
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Institutional Animal Care and Use Committee (IACUC) Policy DOCUMENTATION OF PERFORMANCE STANDARDS POLICY

1. Background

The Animal Welfare Regulations¹ (AWR) and Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals⁴ and other applicable federal⁵, state, and local laws delineate the requirements for the humane handling, care, treatment, housing, and transportation of animals. Similarly, the *Guide for the Care and Use of Laboratory Animals*² (*Guide*) and the *Guide for the Care and Use of Agricultural Animals in Research and Teaching*³ (*Ag Guide*) were designed to assist institutions in caring for and using animals in ways judged to be scientifically, technically, and humanely appropriate. These publications cover major components of the animal care and use program, such as institutional policies and responsibilities; animal environment, housing, and management; veterinary medical care; and physical plant.

The *Guide* and *Ag Guide* outline specific outcomes for each of the components and allow institutional discretion in using facility-appropriate methods to achieve the goals, referred to in the *Guide* as a “performance” approach (Part 3, AWR). The Office of Laboratory Animal Welfare (OLAW) supports the use of engineering standards as a baseline and has indicated that the “performance approach is desirable because many variables (such as the species and previous history of the animals, facilities, expertise of the people, and research goals) often make prescriptive (“engineering”) approaches impractical and unwarranted. Optimally, engineering and performance standards are balanced, thereby providing standards while allowing flexibility and judgment based on individual situations.” OLAW further specifies that “IACUC approved deviations from the *Guide* must be clearly documented and reflect the scientific or veterinary justification relevant to the action and approved by the IACUC.” The requirement to justify exceptions is also found in the AWR which specifically states that exceptions to the standards must be specified, adequately justified, and approved by the IACUC.

A performance standard is a standard or guideline that, while describing a desired outcome, provides flexibility in achieving this outcome by granting discretion to those responsible for managing the animal care and use program, the researcher, and the IACUC. The performance approach requires professional input, sound judgment, and a team approach to achieve specific goals. It is essential that the desired outcomes and/or goals be clearly defined and that appropriate performance measures are regularly monitored in order to verify the success of the process. Performance standards can be advantageous because they accommodate the consideration of many variables (such as the species and previous history of the animals, facilities, staff expertise, and research goals) so that implementation can be best tailored to meet the recommendations in the *Guide*.

OLAW states that a well-established performance standard supports scientific objectives, supports the health and welfare of the animal, includes a justified performance index, and has associated outcome criteria.

An engineering standard differs from a performance standard. An engineering standard or guideline specifies in detail a method, technology, or technique for achieving a desired outcome; it does not provide for modification in the event that acceptable alternative methods are available or unusual circumstances arise. Engineering standards are prescriptive and provide limited flexibility for implementation. However,

an engineering standard can be useful to establish a baseline and is relatively easy to use in evaluating compliance.

2. Policy

PIs must be familiar with *Guide* and *Ag Guide* standards and request approval from the IACUC for any deviations desired for scientific, veterinary, or other reasons.

IACUC members and/or the Attending Veterinarian must review requests for deviations to the standards submitted by PIs and assess the request.

Deviations from the *Guide* and *Ag Guide* must be clearly documented and approved by the IACUC and/or the Attending Veterinarian as appropriate (e.g., veterinary care standards). Requests to deviate from an IACUC-approved standard operating procedure, from a specific standard in the IACUC protocol submitted for approval, or from standards set forth in the *Guide* or *Ag Guide* should include the following information:

1. The specific standard should be specified.
2. The desired outcome should be defined in detail.
3. The scientific rationale, veterinary justification, previous history working with the animals, expertise of the people involved, etc., for the deviation must be clearly documented.
4. The criteria for assessing the outcome and the time frame for evaluation of expected outcomes must be clearly delineated.

3. References and Regulations

1. Animal Welfare Regulations, 9 CFR 2.38(k)(1).
2. *Guide for the Care and Use of Laboratory Animals*, Eighth Edition. Institute of Laboratory Animal Resources, Commission on Life Sciences, National Research Council, National Academy Press, Washington, D.C., 2011.
3. *Guide for the Care and Use of Agricultural Animals in Research and Teaching*, Third Edition. Federation of Animal Science Societies, Champaign, IL, 2010.
4. U.S. Department of Health and Human Services, Office of Laboratory Animal Welfare, “PHS Policy on Humane Care and Use of Laboratory Animals Frequently Asked Questions,” <http://grants.nih.gov/grants/olaw/faqs.htm>, last revised November 28, 2017.
5. The US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training of the IRAC (1985).

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