

ICARE



Interagency Collaborative Animal Research Education

OLAW CONVERSATIONS

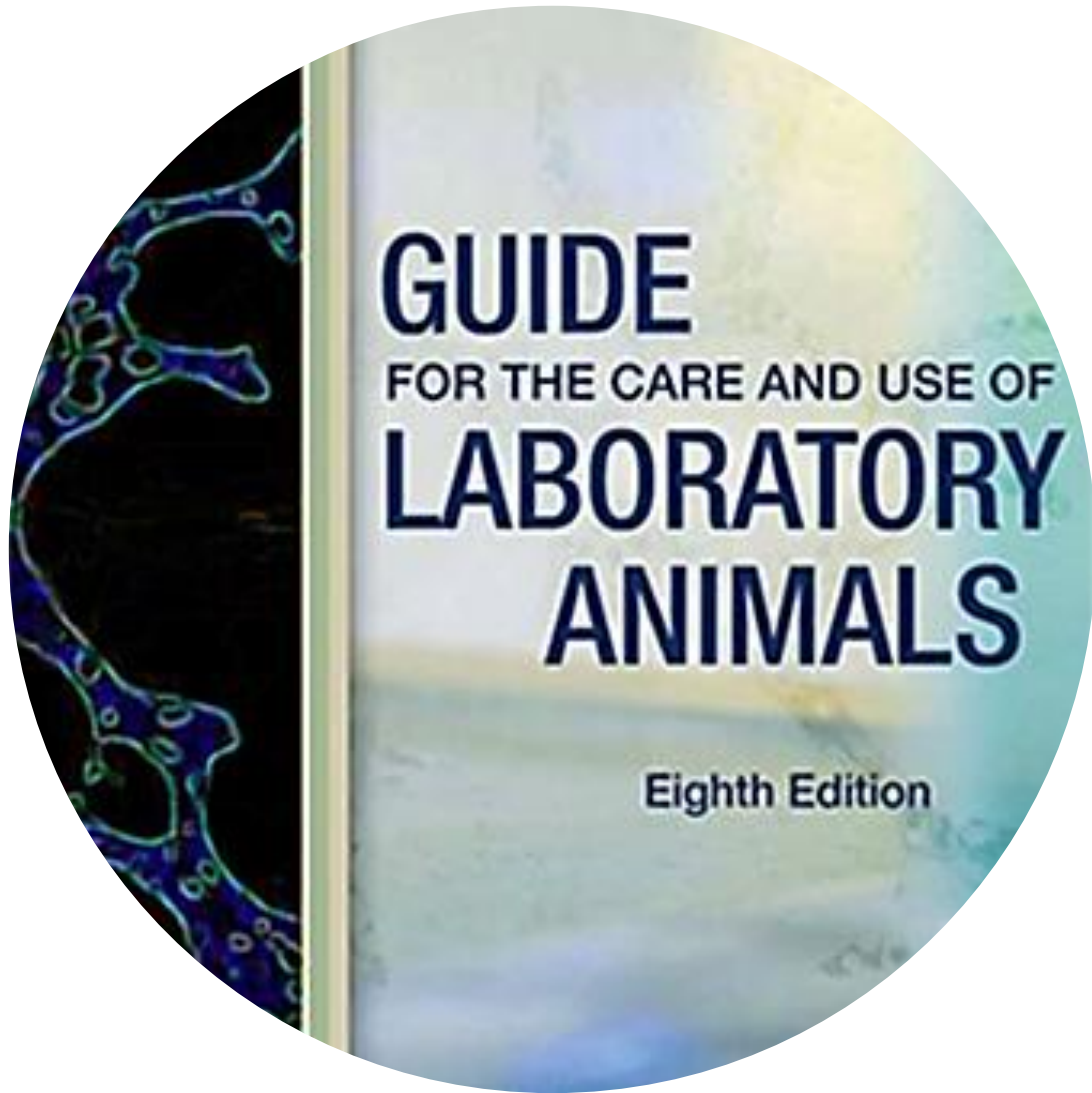
Practical Approaches to Performance Standards

December 19, 2023



National Institutes of Health
Office of Laboratory Animal Welfare

OLAW Guidance on Performance Standards



Recommendations in the Guide are based on published data, scientific principles, expert opinion, and experience with methods and practices that have proved to be consistent with both high-quality research and humane animal care and use. These recommendations should be used as a foundation for the development of a comprehensive animal care and use program, **recognizing that the concept and application of performance standards**, in accordance with goals, outcomes, and considerations defined in the Guide, **is essential to this process.**

Guide, p. xiii

OLAW FAQs

OLAW FAQ G.10

What is OLAW's position on performance standards?

- “OLAW encourages ...outcome-based performance standards...”
- “not ...a departure from the *Guide*” (for “should” statements).
- **Meets the following criteria:**
 - **supports scientific objectives;**
 - **supports the health and welfare of the animal;**
 - **Has a justified performance index;**
 - **has associated outcome criteria.**

<https://olaw.nih.gov/faqs#/guidance/faqs>



Other OLAW FAQs

Other FAQs on performance standards

F.10. Can performance standards be used in determining rodent housing practices including management of rodent breeding colonies?

F.16. May performance standards determine housing issues?

F.17. May performance standards determine environmental enrichment issues?

F.18. Can performance standards be used in determining rabbit housing practices?

<https://olaw.nih.gov/faqs#/guidance/faqs>





Do performance standards require IACUC approval?

Yes!

All performance standards adopted by the institution must be reviewed and approved by the IACUC (E.g., institution-based performance standards, SOPs, manufacturer recommendations, etc.)



Does *development* of a performance standard require IACUC approval?

Yes, if it involves an animal activity!
The development or testing of a standard through experimentation using animals (as defined by the PHS Policy) requires a protocol approved by the IACUC!

Are Performance Standards Considered Departures?

- Yes
- No
- Unsure



Are Performance Standards Departures from the *Guide*?

	MUST	SHOULD	MAY
Description	A minimum standard required of all Assured institutions	Strong recommendations that can be achieved with an alternative method	Suggestions (optional)
Guidance on deviations	<p><u>To be followed as written</u> unless there is an IACUC-approved departure for scientific, veterinary medical or animal welfare reasons; to be reported to IO in Semiannual Report</p> <p><u>There are NO Guide exceptions and NO provisions for performance standards for must statements</u></p>	<p>NOT A DEPARTURE if conducted according to Guide specific <u>exceptions</u>, or based on a <u>locally established and IACUC-approved performance standard and not required to be included in Semiannual Report to IO.</u></p> <p>A DEPARTURE if there is a deviation in the absence of a <i>Guide</i> exception or performance standard; the deviation must be IACUC-approved and for scientific, veterinary medical or animal welfare reasons; to be reported to IO in Semiannual report</p>	Not applicable

Resources

Resource	Description	URL
OLAW FAQs on Performance Standards	F.10., 16., 17., 18. G.10.	https://olaw.nih.gov/faqs#/guidance/faqs
Summary of a workshop by the Institute for Laboratory Animal Research Roundtable on Science and Welfare in Laboratory Animal Use, published by The National Academies Press.	Downloadable pdf summary of a 2015 ILAR Workshop	https://nap.nationalacademies.org/catalog/21820/design-implementation-monitoring-and-sharing-of-performance-standards-for-laboratory-animal-use
Performance Standards	Recorded OLAW Webinar (April 19, 2012)	https://olaw.nih.gov/education/educational-resources/webinar-2012-04-19.htm
Departures Information	Departures from the <i>Guide</i> webpage	https://olaw.nih.gov/guidance/departures-from-the-guide.htm
	21st Century Cures Act – Animal Care and Use in Research webpage on Departures	https://olaw.nih.gov/policies-laws/21st-century-cures-act/Departures#resources

Questions to consider (think of specific examples at your institution, if applicable):

- How does your IACUC determine if a performance standard developed outside of your institution is suitable for use? How do you determine if modifications are needed?
- How does your IACUC codify performance standards once they are approved, and provide the new information to investigators?
- Is there post-approval monitoring to ensure appropriate application, and if so, what does that look like?





Thank you!
Next Session: TBD

