Performance Standards

Janet C. Garber, DVM, PhD
Garber Consulting

Susan Silk, MS
Director, Division of Policy and Education, OLAW, NIH

Jerry Collins, PhD, Division of Policy and Education, OLAW, and Yale University

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Questions?

We are not answering questions in real time during this webinar. However, you may submit questions about this topic to OLAW at olawdpe@od.nih.gov. The questions and answers will be posted on the OLAW website in the Education Resources Section associated with this webinar.

Performance Standard

- Not a new concept
- “Introduced” in the 1985 *Guide*
- Further defined and emphasized in the 1996 *Guide*
- Expanded discussion throughout the 2011 *Guide*, emphasizing flexibility and professional judgment.

Guide for the Care and Use of Laboratory Animals
ILAR, National Research Council of the National Academies

Statement of Task

Update the ‘96 version of the *Guide*:

- Reflect new scientific information
- Add discussion and guidance on new topics
- Consider all materials and information provided
- Maintain performance standards
- Consistent with PHS Policy, AWRs, and AVMA Euthanasia Guidelines

Engineering Standard

- A standard or guideline that 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.
- Prescriptive and provides limited flexibility for implementation.

Performance Standard

- A standard or guideline that, while describing a desired outcome, provides flexibility in achieving this outcome.
- It is essential that the desired outcome be clearly defined and appropriate performance measure(s) regularly monitored in order to verify the success of the process.

Performance Standards

- The key to evaluation and oversight of all aspects of the program.
- “Ideally, engineering and performance standards are balanced, setting a target for optimal practices, management and operations, while encouraging flexibility and judgment, if appropriate, based on individual situations.”

Performance Standards

- Remain a key concept in application of the *Guide*
- Overwhelming support for this approach
- Better definition of desired outcomes
- More guidance on how to achieve the outcomes
- Does require a high level of sophistication, empowering institutions to leverage their expertise in making decisions specific to their program needs

Key Concepts to Remember

- “Institutions should use the recommendations in the *Guide* as a foundation for the development of a comprehensive animal care and use program and a process for continually improving this program.”
- “It is intended that the *Guide* be read by the user in its entirety…”

“Must”, “Should”, & “May”

- “Must” indicates actions that the Committee considers to be imperative and are a mandatory duty or requirement.

- “Should” indicates a strong recommendation for achieving a goal, however, the Committee recognizes that individual circumstances might justify an alternative strategy.

- “May” indicates a suggestion to be considered.

OLAW on “Must”

- OLAW considers a “must” statement in the *Guide* to be a minimum standard required of Assured institutions.
- IACUC must review and approve departures from the minimum standards of the *Guide*.
- IACUC approval must be based on scientific, veterinary medical, or animal welfare issues.
- PHS Policy directs that institutions must identify specifically any departures from the provisions of the *Guide* and state the reasons for each departure.
- Departures must be included in semiannual reports to the IO.

OLAW on “Should”

- “Should” statements often involve performance standards. OLAW does not consider established performance standards to be a departure from the *Guide*.
- An institution may elect to follow a different course of action, if that action results in an equivalent outcome and is reviewed and approved by the IACUC.
- Institutions are not required to comply with “should” statements that do not apply to their program.

OLAW on “May”

- A “may” statement is a suggestion that a program can implement, if suitable.

- *Guide* “may” statements are compliant with PHS Policy.

“Must” & “Should” on Checklist

- OLAW Semiannual Program Review and Facility Inspection Checklist has been updated; now includes all “shoulds” and “musts” in the *Guide*.

- NA (not applicable) column has been added to the Checklist. Appropriate selection of NA is sufficient documentation that IACUC has considered a standard and determined that it is not applicable to their program.

- Use of the Checklist is not required.

http://grants.nih.gov/grants/olaw/sampledoc/cheklist.htm

Practice Standards

"The application of professional judgment to a task or process over time, which has been demonstrated to benefit or enhance animal care and use."

- Information in peer-reviewed literature
- Time-proven experience in the field
- Modification of practices and procedures with changing conditions and new information

Practice Standards, or… Developing Standards of Practice

- Evolve over time
- Begin locally (at your institution)
- Implement performance standards for your situation
- Monitor, evaluate & validate the success of your approach
- Share → present / publish
- May not fit all situations, but may illustrate an approach useful for other institutions

Applying Performance Standards

- Define outcomes; what are the objectives?
- How will the objectives be achieved?
  - There are many ways to achieve defined goals.
- How will success be measured?
  - Modification of practices and procedures with changing conditions and new information.

Flexibility

Applying Performance Standards

- Use of Non-Pharmaceutical-Grade Chemicals
- Environment
- Social Housing
- Environmental Enrichment
- Cage / Pen Space

Use of Non-Pharmaceutical-Grade Chemicals

- Investigators must use pharmaceutical-grade substances for both investigational and clinical purposes in their PHS-funded studies with animals, unless there is a reason to use non-pharmaceutical-grade substances.

- Use of non-pharmaceutical-grade substances must be justified and that justification must be reviewed and approved by the IACUC.

- The use of non-pharmaceutical-grade substances has been, and will continue to be, a necessary and acceptable component of biomedical research.

Use of Non-Pharmaceutical-Grade Chemicals

- A pharmaceutical-grade compound is any active or inactive drug, biologic, reagent, et cetera, that is approved by the FDA for which a chemical purity standard has been written or established by any recognized pharmacopeia (e.g., USP, NF, BP, EP).

- The FDA publishes the Green Book (veterinary) and Orange Book (human) databases of approved drugs. Substances listed in these databases are recognized as pharmaceutical-grade.

http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm

http://www.fda.gov/Drugs/InformationOnDrugs/default.htm

Additional Information on the Use of Non-Pharmaceutical-Grade Chemicals

- Examples for use of non-pharmaceutical-grade substances
- Recorded webinar
- Slides and transcripts PDF

http://grants.nih.gov/grants/olaw/educational_resources.htm

Environment - Temperature

- Macroenvironmental temperature
  - Table 3.1 – rodents 20-26°C
- Generally reflect tolerable limits…provided they are housed with adequate resources for behavioral thermoregulation
- Should normally be selected and maintained with minimal fluctuation near the middle of these ranges

Environment - Temperature

- “The ambient temperature in which thermoregulation occurs without the need to increase metabolic heat production or activate evaporative heat loss mechanisms is called the thermoneutral zone (TNZ) and is bounded by the lower (LCT) and upper critical temperatures (UCT).”
- “In general, dry bulb temperatures in animal rooms should be set below the animal’s LCT to avoid heat stress. This, in turn, means that animals should be provided with adequate resources for thermoregulation (nesting material, shelter) to avoid cold stress.”
- TNZ for mice is 26-34°C, LCT is 26°C.

Temperature

Implications:

- When animal room temperatures are set lower, as recommended in the table, nesting material should be provided.
- Nesting material is not just enrichment.
- Variation around a set point should be minimized.

Social Housing

- “All animals should be housed under conditions that provide sufficient space as well as supplementary structures and resources required to meet physical, physiologic, and behavioral needs.”
- “Single housing of social species should be the exception and should be justified based on experimental requirements or veterinary-related concerns regarding animal well-being.”
- “Social animals should be housed in pairs or groups of compatible individuals unless they must be housed alone for experimental reasons or because of social incompatibility.”

Social Housing

Implications:

- Requires understanding of species-typical social behavior.
- Cage complexities and important resources provided in a way that they cannot be monopolized by dominant animals or elicit aggression between animals.
- The need for single housing should be reviewed on a regular basis and approved by the IACUC and / or veterinarian.

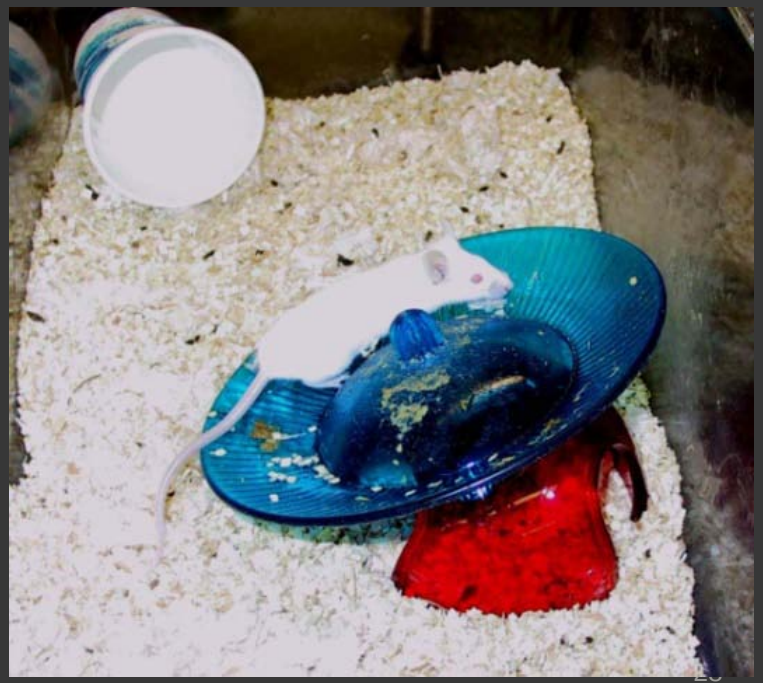
Environmental Enrichment

- "Enrichment programs should be reviewed by the IACUC, researchers and veterinarian on a regular basis to ensure that they are beneficial to animal well-being and consistent with the goals of animal use."
- "Personnel responsible for animal care and husbandry should receive training in the behavioral biology of the species they work with to appropriately monitor the effects of enrichment, as well as identify the development of adverse or abnormal behaviors."

Environmental Enrichment

Implications:

- Enrichment strategies should take into account the scientific goals of the study.
- Enrichment should be considered an independent variable and suitably controlled.
- Training - Personnel responsible for daily care should be adequately familiar with normal animal behavior such that abnormal behavior may recognized and reported.



Cage & Pen Space

- New recommendations for mice and rats with litters, some categories of nonhuman primates, and rabbits
- Expanded discussion of considerations for housing → performance standards
- Tables include specific comments
- Recommendations stress pair or group housing

Performance Criteria for Cage & Pen Space

- “At a minimum, animals must have enough space to express their natural postures and postural adjustments without touching enclosure walls or ceiling, be able to turn around, and have ready access to food and water. In addition, there must be sufficient space to comfortably rest away from soiled areas.”

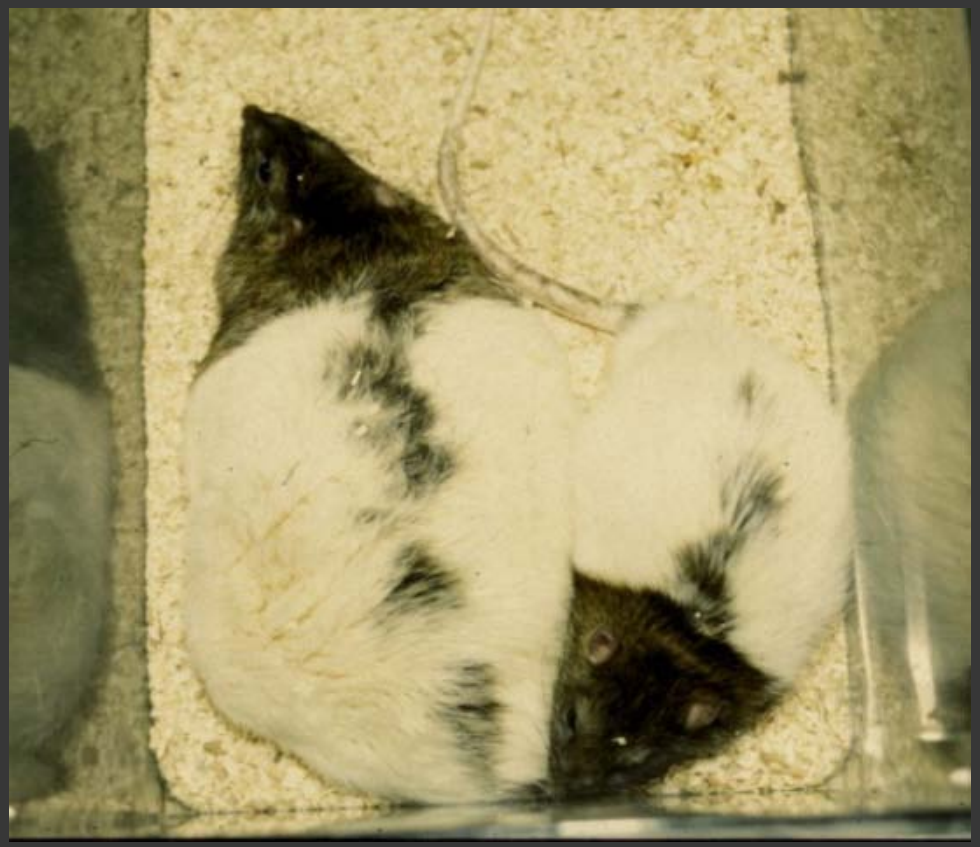
- “Cage height should take into account the animal’s typical posture and provide adequate clearance for the animal from cage structures, such as feeders and water devices.”

- “Sufficient space should be allocated for mothers with litters to allow the pups to develop to weaning without detrimental effects for the mother or the litter.”

Space Recommendations & Performance Standards

Implications

- An animal's space needs are complex.
- Tables contain recommended minimums.
- Consideration of only the animal's body weight or surface area may be inadequate.
- Considerations for determining space needs:
  - Age & sex of animals,
  - Number & duration of housing,
  - Intended use (production vs. experimentation),
  - Special needs.



Space Recommendations & Performance Standards

Implications

- Space allocations should be assessed, reviewed, and modified as necessary by the IACUC considering the performance indices such as:
  - health,
  - reproduction,
  - growth,
  - behavior,
  - activity,
  - use of space,

  - …and special needs determined by the characteristics of the animal strain or species and use.

Space Recommendations & Performance Standards

Rodent Breeding

- Previous editions lacked guidance.
- Recommended space for female + litter reflects current standard of practice in some breeding operations using commercially available “high density” housing racks.
- Intended to be a starting point for addressing space needs of breeding groups.

Space Recommendations & Performance Standards

Rodent Breeding

The *Guide* intentionally does not indicate specific space needs of “other breeding configurations” to allow institutions to determine appropriate housing conditions for their own situation based on performance indices discussed throughout the document.

Space Recommendations & Performance Standards

Rodent Breeding

The *Guide* does not suggest that the minimum space recommendations for other breeding groups are additive, or that the recommendations for like-sized, group housed rodents be used in determining the space needed for other breeding configurations.

OLAW supports this guidance.

Space Recommendations & Performance Standards

Rodent Breeding Groups

- Comment in the Table states that, “Other breeding configurations may require more space and will depend on considerations such as number of adults and litters, and size and age of litters.”
- That is…other breeding configurations (pairs, trios, etc.) may require more space than the recommended minimum for a female + litter.

Table is on page 57, 8th Edition of the Guide.

Space Recommendations & Performance Standards

Rodent Breeding – Footnote “d”

- Other considerations may include:
  - Culling of litters
  - Separation of litters from the breeding group
  - More intensive management of space
- “Sufficient space should be allocated for mothers with litters to allow the pups to develop to weaning without detrimental effects for the mother or litter.”

So, How Do I Use These Guidelines (Performance Criteria)??

Breeding Groups of Mice

- Use the recommended minimum space as a starting point (51 in^2 for a female + litter)
- Pair housing?
  - Inbred strains with very small litters may not need more than 51 in^2
  - Outbred strains with very large litters will likely need more than 51 in^2

So, How Do I Use These Guidelines (Performance Criteria)??

Breeding Groups of Mice

Trios or larger groups?

- Housing other breeding groups in standard size (for example, 75-81 in^2) cages has become the standard of practice for many breeding operations.
- However, as in any housing situation, many factors (performance indices) help determine whether desired outcomes are met.

So, How Do I Use These Guidelines (Performance Criteria)??

Breeding Groups of Mice

Considerations:

- Size and age of litters
- Need for culling or separation of litters
- Sanitation frequency

Management

OLAW Implementing the *Guide*

- OLAW determined to implement the 8th Edition of the *Guide* because in our judgment, it empowers continued advancement in the humane care and use of vertebrate animals in research, research training, and biological testing.

OLAW Implementing the *Guide*

- Performance standards are the most important component of PHS oversight of animal programs at Assured institutions.
- IACUCs are able to meet their responsibility to ensure humane animal care and use while advancing quality scientific research through the use of performance standards in their oversight of institutional animal programs.
- OLAW encourages the cooperative application of diverse expertise to develop outcome-based performance standards that enhance the quality of animal care and use programs.
- OLAW expects Assured institutions to apply appropriate professional judgment and experience to the challenges inherent in developing policies and procedures to maintain a quality program that provides humane care to vertebrate animals.

OLAW Implementing the *Guide*

- Implementation of the *Guide* is expected to have a minimal impact on institutions that are currently using policies and procedures based on well-developed performance standards. These policies and procedures may not need to be revised as part of the institution's implementation of the 8th Edition of the *Guide*.
- Institutions that do not currently have performance standards are expected to use the benchmarks provided by the 8th Edition of the *Guide* to develop performance-based policies and procedures.
- Institutions must conduct at least one of their semiannual program and facility reviews using the 8th Edition of the *Guide*

OLAW Implementing the *Guide*

- As of January 1, 2012, OLAW requires Assured institutions to base their programs of animal care and use on the 8th Edition of the *Guide*.
- Assured institutions must complete at least one semiannual program review and facility evaluation using the 8th Edition of the *Guide* as the basis for evaluation by December 31, 2012.
- It is not required that all necessary changes be completed by December 31, 2012, but rather that an evaluation must be conducted and a plan and schedule for implementation of the 8th Edition of the *Guide* must be developed by December 31, 2012.

Challenges

- Short-Term: Review and assess Program components using the new *Guide*
- Read the entire *Guide*
  - Do not take statements out of context
  - Some topic areas are addressed in more than one location
- Don’t over-analyze
- Long-Term: Review and assess Program components using the new *Guide*

Challenges

- Think performance standards…….
- …much of what is reflected in the new *Guide* may not require a great deal of change for your program.

Questions

1. With all of the genetically modified animals, how can anyone know what phenotype is expected?

Questions

2. Must the IACUC review all enrichment plans or may they rely on an individual, for example a veterinarian, to assure them that the plans are OK?

Questions

3. If I hear from a colleague that a new practice standard works well, do we have to still monitor it at our institution or may we simply refer to the fact that another institution likes it?

Questions

4. If we have long standing performance standards that we know work, do we still need to review them to make sure that they are still meeting our goals?

OLAW Online Seminar Series
Upcoming Schedule

- June 7, 2012 – Grants Policy and Congruence
- September 13, 2012 – Topic: TBD
- December 13, 2012 – Topic: TBD