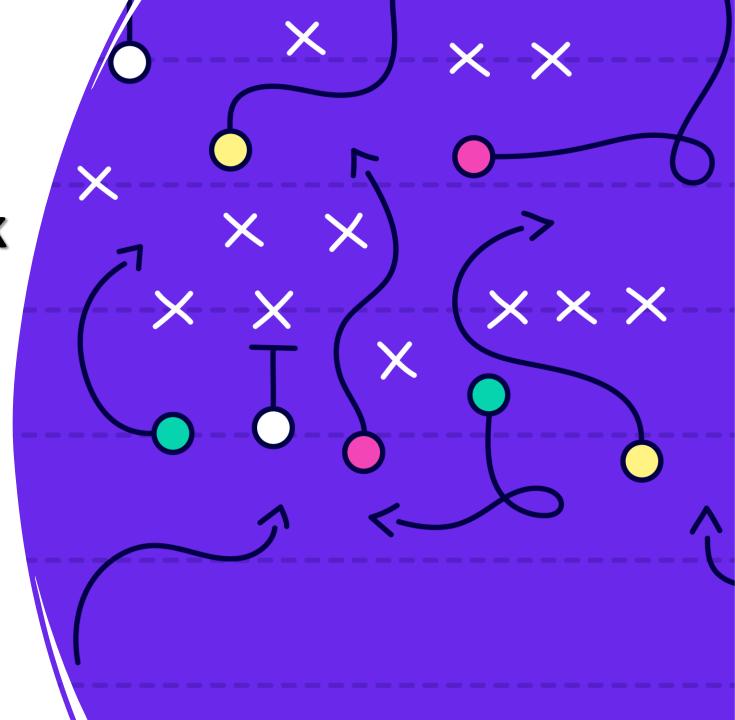
Putting the Performance Standard Playbook to Work in Your Program

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'Must' vs 'Should' vs 'May' Statements

Must: actions considered as "imperative and mandatory duty or requirement for providing humane animal care and use"

Should: strong recommendation for achieving a goal, although "individual circumstances might justify an alternative strategy"

May: a suggestion to be considered.

Must Should [Obligation, Duty, [Advice] Rule, Prohibition] May [Possibility, Polite Request]

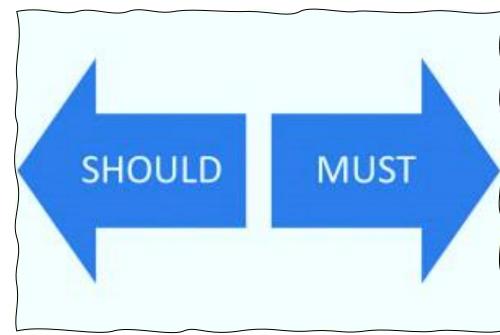
[Guide, page 8]

'Must' and 'Should' in the Guide

Expectations that programs will follow 'must' and 'should' statements unless:

- Guide-specific exception
- IACUC-approved departure based on a scientific, veterinary, or animal welfare justification
- IACUC-approved performance standard

[Guide, page 8; NIH OLAW FAQ G.10; AAALAC FAQ A.2]

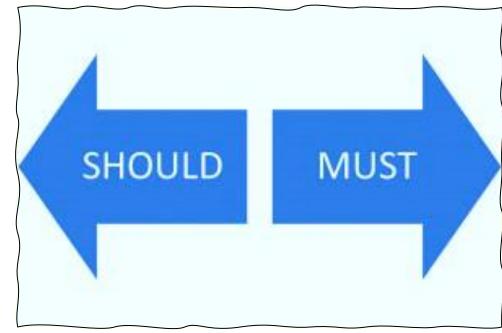


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What is a standard?

- A <u>benchmark</u> of achievement, which is based on the desired level of excellence . . . the model to be initiated and may serve, in turn, as basis of comparison [The Oxford Dictionary, 1964]
- A document or set of criteria that establishes <u>requirements</u>, <u>specifications</u>, <u>guidelines</u>, <u>or characteristics</u> to ensure materials, products, processes, and services are fit for their intended purposes [International Organization for Standardization (ISO) and the National Institute for Standards and Technology (NIST)]
- Essential <u>tools</u> that guide industries and disciplines toward consistent quality, safety, and efficiency
- <u>Parameters</u> that reflect common societal values and promote trust and reliability in various domains.



What is an engineering standard?



- A standard or guideline that <u>specifies in detail</u> a method, technology, or technique for achieving a desired outcome
- Does not provide for modification in the event that acceptable alternative methods are available or unusual circumstances arise
- Is <u>prescriptive</u> and provides <u>limited flexibility</u> for implementation
- Can be useful for establishing a baseline
- Relatively easy to use in evaluating compliance

[Guide, page 6]

What is a performance standard?

- A standard or guideline that, while describing a desired outcome, provides <u>flexibility</u> in achieving this outcome by granting discretion to those responsible for managing the animal care and use program, the researcher, and the IACUC
- Requires professional input, sound judgment, and a team approach to achieve specific goals
- Essential that the desired outcomes and/or goals be clearly defined and appropriate performance measures regularly monitored in order to verify the success of the process
- Advantageous because they accommodate the consideration of many variables (e.g., species, prior experience, facilities, staff expertise, and research goals) so <u>implementation can be best</u> <u>tailored</u> to meet recommendations in the Guide



What is a practice standard?

- Application of professional judgment by qualified, experienced individuals to a task or process over time, an approach that has been demonstrated to benefit or enhance animal care and use
- Professional judgment comes from information in peerreviewed scientific literature and textbooks and, as in many other disciplines, from time-proven experiences in the field
- In the absence of published scientific literature or other definitive sources, where experience has demonstrated a particular practice improves animal care and use, practice standards have been used in determining appropriate recommendations in the Guide.
- In most situations, the Guide is intended to provide flexibility so institutions can modify practices and procedures with changing conditions and new information.

[Guide, page 7]

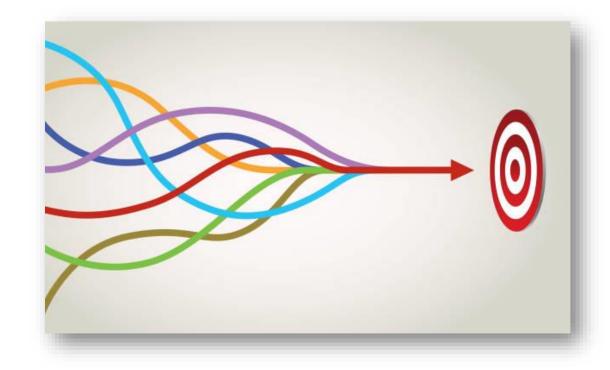
Performance Standards . . .

- Not a new concept
- Introduced in the 1985 Guide
- Defined and emphasized more extensively in the 1996 Guide
- Emphasis expanded in the 2011 Guide, promoting flexibility and professional judgment
- Can be implemented at the institutional or program or individual protocol level



Why use performance standards?

- Provides significant flexibility for institutions to modify and update practices and procedures as new information becomes available and as program needs change (responsiveness)
- Permits program-specific changes within the legal framework, without the need to revise legislation (timeliness)
- Promotes changes that advance animal health and welfare, without hindering scientific progress (effectiveness)



Performance standards:

Support scientific objectives

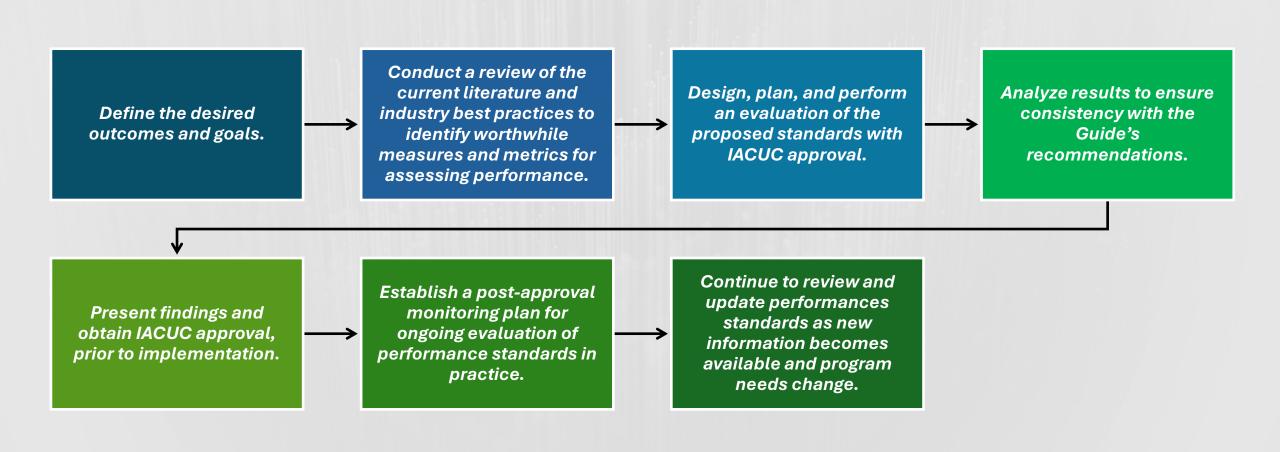
Support the health and welfare of the animal

Include a justified performance index

Have associated outcome criteria

Are approved and regularly re-evaluated by the IACUC

Developing performance standards:



"Extending cage-changing intervals for rodents" [Guide page 70]

- Define outcomes. What are the objectives?
- How will the objectives be achieved?
- How will success be measured?





"Increasing housing density for rodents" [Guide pages 56-58]

- Define outcomes. What are the objectives?
- How will the objectives be achieved?
- How will success be measured?

"Housing a new species not included in the Guide's recommendations"

- Define outcomes. What are the objectives?
- How will the objectives be achieved?
- How will success be measured?





"Storing animal diets where temperature and humidity cannot be maintained within the Guide's recommended ranges" [Guide page 66]

- Define outcomes. What are the objectives?
- How will the objectives be achieved?
- How will success be measured?

"Using a non-pharmaceutical grade compound in lieu of the commercial product" [Guide page 31]

- Define outcomes. What are the objectives?
- How will the objectives be achieved?
- How will success be measured?





"Housing different species within the same housing area" [Guide page 111]

- Define outcomes. What are the objectives?
- How will the objectives be achieved?
- How will success be measured?



ANY THOUGHTS OR QUESTIONS?

