The New *Guide*: Diving into the Details of Chapters 1 & 2

B. Taylor Bennett DVM, PHD, DACLAM
Senior Scientific Advisor
National Association for Biomedical Research
The Purpose of the *Guide*

- To assist your institution in laying the foundation for a comprehensive animal care and use program that relies on the use of **performance standards and professional judgment** to assure that such use is in accordance with the highest scientific, humane and ethical principles.

- Tailor the animal care and use program to the unique needs of your institution.
• Consideration of Public Comments on Proposed Adoption and Implementation of the *Guide for the Care and Use of Laboratory Animals: Eighth Edition*

• ... OLAW will issue position statement(s) that will be posted on the OLAW website and a 60 day public comment period will commence to permit the public to provide feedback regarding their understanding of the position statement(s).

• If OLAW decides to adopt the eighth edition of the Guide, an updated implementation plan will be posted on the OLAW website.
Chapter 1

• Key Concepts
  – Applicability and Goals of the Guide
  – Intended Audiences and Uses
  – Ethics and Animal Use
  – The Three Rs
  – Key Terms
  – Policies, Principles and Procedures
  – Must, Should and May

07/12/2011
Chapter 1

• Page 1 –

  – “…all who care for, use, or produce animals for research, testing, or teaching must assume responsibility for their well-being.”

  – “…establishes the minimum ethical, practice, and care standards for researchers and their institutions.”

  – Incorporating humane care into all aspects of laboratory animal care and use.
Chapter 1

• Page 2 - Applicability and Goals – 1 should
  – “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.”
• Page 3 - Intended Audiences and Use - 3 shoulds

  – “In all instances where Guide recommendations are different from applicable legal or policy requirements, the higher standard should apply.”
Chapter 1

• Page 4 - Ethics and Animal Use
  – The U. S. Government Principles
  – PHS Policy is intended to implement and supplement those principles
Chapter 1

• Page 4 - The Three Rs - 1 must & 5 shoulds (1/5)
  – Page 5 - Veterinary consultation **must** occur when pain and distress is beyond the level anticipated in the protocol description or when interventional control is not possible.
  – Reuse to reduce animal usage
  – End point justification
  – The need to balance the goals of refinement and reduction on a case-by-case basis
• Page 5 - Key Terms
  – Engineering and performance standards
  – Practice standards
  – Strong case for the use of professional judgment in establishing processes within your institution

• Page 7 – Policies, Principles and Procedures
• Page 8 - Must, Should and May

  – *Should* indicates a strong recommendation for achieving a goal; however, the Committee recognizes that individual circumstances might justify an alternative strategy.

  – “Because the *Guide* is written in general terms, IACUCs have a key role in interpretation, implementation, oversight, and evaluation of institutional animal care and use programs.”
Chapter 2

- Animal Care and Use Program

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Chapter 2

• Animal Care and Use Program
  – Regulations, Policies and Principles
  – Program Management
    • Program Management Responsibility
    • Personnel Management
  – Program Oversight
    • The Role of the IACUC
    • Postapproval Monitoring
  – Disaster Planning and Emergency Preparedness
Chapter 2

• Page 11 – Introduction – 1 should
  – Program definition
  – Establish and provide sufficient resources for a Program that is managed in accordance with the Guide and in compliance with applicable regulations, policies, and guidelines.
  – Defines the overall Program and key oversight responsibilities and provides guidelines to aid in developing an effective Program
  – If one looks at the total musts and shoulds in the major topics and subtopics
Chapter 2

Regulations, Policies, and Principles – 0/1
Program Management – 9/90
  Program Management Responsibility – 2/7
  Personnel Management – 7/83
Program Oversight – 6/53
  The Role of the IACUC – 6/51
  Postapproval Monitoring – 0/2
Disaster Planning and Emergency Preparedness – 2/8
Chapter 2

• Page 12 - Regulations, Policies and Principles – (0/1)
  – “Programs should be operated in accord with the Guide and relevant regulations, policies, and principles.”
  – “The use of laboratory animals is governed by an interrelated, dynamic system of regulations, policies, guidelines, and procedures.”
Chapter 2

• Program Management (9/90)
  – Program Management Responsibility
    • Attending Veterinarian (2/7)
  – Personnel Management (7/83)
    • Occupational Health and Safety of Personnel (4/60)

• Program Oversight (6/53)
  – The Role of IACUC (6/51)
The institutional official (IO) bears ultimate responsibility for the Program, although overall Program direction should be a shared responsibility among the IO, AV, and IACUC.

Program needs should be clearly and regularly communicated to the IO by the AV, the IACUC, and others associated with the Program ....
Chapter 2

• Page 14 - *The Attending Veterinarian* – (2/5)
  – “If a full-time veterinarian is not available on site, a consulting or part-time veterinarian *should* be available in visits at intervals appropriate to programmatic needs.”
Chapter 2

• Page 15 - Collaboration
  – “Interinstitutional collaboration has the potential to create ambiguities about responsibility for animal care and use. In cases of such collaboration involving animal use (beyond animal transport), the participating institutions should have a formal written understanding ...”

• Page 15 – Training and Education
  – “All Program personnel training should be documented.”
Chapter 2

• Page 18 - *Hazard Identification and Risk Assessment* – (0/5)
  
  – “Health and safety specialists with knowledge in relevant disciplines *should* be involved in risk assessment and the development of procedures to manage such risks.”
• Page 20 - Facilities, Equipment and Monitoring
  – (0/12)
  – “Safety equipment **should** be properly maintained and its function periodically validated.”
• Page 23 – *Personnel Security* – (0/2)
  
  – Contingency plans *should* also take into account the threats that criminal activities pose to laboratory animals, research personnel, equipment and facilities, and biomedical research at the institution
  
  – Considered including pre-employment screening and physical and information technology security in your contingency plan
  
  – NABR’s Crisis Management Guide
Chapter 2

• Page 23 – *Investigating and Reporting Animal Welfare Concerns* – (1/5)
  – Consistent with the requirements of the AWR and the PHS Policy
  – Response to such reports **should** include communication of findings to the concerned employee(s), unless such concerns are reported anonymously; corrective actions if deemed necessary; and a report to the IO of the issue, findings, and actions taken.
  – Reported concerns and any corrective actions taken **should** be documented.
Chapter 2

• Page 25 - IACUC Constitution and Function – (1/6)
  – “After review and inspection, a written report (including any minority views) **should** be provided to the IO …”

• Page 25 – Protocol Review – (1/4)
  – The **should** that precedes the topics which need to be addressed in the protocol
    • 15 embedded shoulds
Chapter 2

• Page 27 - *Experimental and Humane Endpoints* – (1/7)
  
  – “The PI...should **identify**, **explain**, and **include** in the animal use protocol a study endpoint that is both humane and scientifically sound.”
  
  – “Information that is critical to the IACUC’s assessment of appropriate endpoint consideration in a protocol includes **precise definition** of the humane endpoint (including assessment criteria), the **frequency of animal observation**, **training of personnel** responsible for assessment and recognition of the humane endpoint, and the **response required** upon reaching the humane endpoint.”
• Page 28 – *Unexpected Outcomes* – (0/2)

  – Genetically modified animals

  • “The first offspring of a newly generated GMA line *should* be carefully observed from birth into early adulthood for signs of disease, pain, or distress.”

  • “When the initial characterization of a GMA reveals a condition that negatively affects animal well-being, this *should* be reported to the IACUC...”
• Page 30 – *Multiple Survival Surgical Procedures*
  – *(1/6 vs 0/1)*
    – Major vs minor on case-by-case basis
    – Regardless of the classification
    – Regulated vs non-regulated species
    – Monitor animal well-being
    – Post-procedural pain or impairment
• Page 31 - *Food and Fluid Regulation* - (0/4)
  – “The development of animal protocols that involve the use of food or fluid regulation requires the evaluation of three factors: the necessary level of regulation, potential adverse consequences of regulation, and methods for assessing the health and well-being of the animals (NRC 2003b).”

• Non-Pharmaceutical Grade-Chemicals and Other Substances — (0/3)
• page 34 - Postapproval Monitoring – (0/2)

  – “The level of formality and intensity of PAM should be tailored to institutional size and complexity, and in all cases should support a culture of care focusing on the animals’ well-being (Klein and Bayne 2007).”
In Summary

• The *Guide*
  – is written in general terms
  – is to assist institutions in caring for and using animals in ways judged to be scientifically, technically, and humanely appropriate
  – intended to assist investigators in fulfilling their obligation to plan and conduct animal experiments
  – used as a foundation for the development of a comprehensive animal care and use program
  – the concept and application of performance standards is essential to this process
In Closing

• Use the Guide
  – Honest assessment of your program
  – Use your professional judgment to justify your interpretation of the recommendations
  – Carefully review OLAW’s position statements in terms of your program and your interpretation of the Guide

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Finally

• Remember
  – “The goal of the *Guide* is to promote the humane care and use of laboratory animals by providing information that will enhance animal wellbeing, the quality of research, and the advancement of scientific knowledge that is relevant to both humans and animals.”
  – I think we all share that goal everyday when we get up and go to work.
Save the Date

- November 1, 2011