

AAALAC's Approach to Implementing the New ILAR Guide



AAALAC International - 2010



Where Science and Responsible Animal Care Connect
45 years of Excellence
1965-2010

- 2010 marks our 45th anniversary
 - 45 years of using the Guide as a standard of accreditation
- Consistent growth in the number of accredited organizations world-wide
 - 831 institutions in 34 countries

2011 Update of the Guide

- Far reaching influence
- Intensive effort to assess the impact on the accreditation process
- 2010 revisions of the Ag Guide and the European Directive also occurred
- AAALAC is forging a path forward to harmonize performance standards for the global accreditation process

- Comments from the member organizations of the AAALAC International Board of Trustees (BOT) were included in the review of the updated ILAR Guide
- The AAALAC BOT adopted a change to the Rules of Accreditation:

The *Guide for the Care and Use of Laboratory Animals (Guide)*, National Research Council 1996, or current revision thereof, shall serve as a basic guide to the establishment of specific standards for accreditation. AAALAC International may establish standards based on prevailing directives, conventions and guidelines of the country in which the accreditable unit is located.

Agenda

- Review of revised documents used in accreditation
- July 2010 Retreat of the Council on Accreditation
- Determinations of the Council
- Implementation Timeline

Council on Accreditation

2010

- **Council - Currently 51 members**
 - 9 – European section
 - 6 – Pacific Rim section
 - 36 - North American (3 sections)

2010 - A watershed year

- Three important documents were revised:
 - The FASS Ag Guide
 - European Directive
 - The ILAR Guide

Review of the Updated Ag Guide

- A committee of the Council and BOT was convened in May 2010 to review the updated FASS Ag Guide

Review of the Updated Ag Guide

- A subcommittee for each chapter was charged with conducting a detailed comparison with the previous Ag Guide and the 2011 ILAR Guide
- Topics in which there was harmony or disharmony were identified and a unified position of Council established
- After months of review and TC meetings, the recommendations of the Ag Guide Review Committee were discussed and adopted

ETS 123 and the European Directive

- ETS 123 (appendix A): performance standards
- recommendations to the Council of Europe
- European Directive: obligatory for European Union (incorporated appendix A)

Review of the European Directive

- The European Section of Council conducted a thorough review and comparison of the revised Directive and compared and the updated ILAR Guide
- During the retreat, topics in which there was harmony or disharmony were identified and a unified position of Council established

Council Retreat

- 2011 ILAR Guide - Prepublication copy released in June – Council held a 2-day Retreat in July:
 - Four subcommittees were formed and each analyzed one chapter (Chapters 2-5)
 - Analysis involved a line-by-line comparison of the 1996 Guide and the 2011 Guide
 - Analysis focused on all topics that were revised, added or deleted and their impact on the accreditation process

Council Retreat – New ILAR Guide

- Analysis also included every written comment provided to Council by:
 - BOT member organizations
 - Other scientific organizations

Council Retreat – New ILAR Guide

- Analysis of ***each topic*** also included:
 1. Comparisons with the revised European Directive and the Ag Guide
 2. Council's interpretation of meaning
 3. Council's expectations of units
 4. How the issue will be evaluated on site visits and during Council meetings

Council Retreat – New ILAR Guide

- Deliberations and analysis by each subcommittee culminated in a review by the full Council
- Summary and discussion continued at subsequent meetings
- The Council officers met to further summarize discussions
- Deliberations continued at the September meeting of the Council

Determinations of the Council

- New ILAR Guide:
 - **121** separate topics were discussed and classified according to their need for clarification.
 - 16 discussion items
 - 37 action items
 - 68 FYI items

 - 6 position statements required (so far)
 - 15 FAQ's required (so far)

 - All required interpretation by Council

Determinations of the Council

- New ILAR Guide, by Chapter (points of clarification required)
 - Chapter 2: 39 topics
 - Chapter 3: 29 topics
 - Chapter 4: 25 topics
 - Chapter 5: 28 topics

For Those Who Count

- New “must” statements – 2011 Guide
 - Chapter 1: 1
 - Chapter 2: 11
 - Chapter 3: 4
 - Chapter 4: 10
 - Chapter 5: 11

Some examples of new “musts” that Council will assess

- “*The institution **must** develop methods for reporting and investigating animal welfare concerns.*”
- “*Facilities **must** have a disaster plan.*”
- “*Procedures **must** be in place to provide for emergency veterinary care both during and outside of regularly scheduled hours. Such procedures **must** enable timely reporting of animal injury, illness, or death by animal care and research staff.*”

Determinations of the Council

2010 Ag Guide

- There is extensive harmonization between the Ag Guide and the ILAR Guide
- However, some key differences were identified:
 - IACUC composition
 - Cage/pen space
 - Some husbandry requirements (e.g. temperature)
 - Both documents indicate its standards should take precedence for Ag animals

Determinations of the Council

European Directive

- There was extensive harmonization between European guidance and the ILAR Guide
- Differences were identified:
 - Authority/ role of the AV
 - Committee functions
 - Cage/ pen space
 - Whistleblower process
 - Some facility design aspects
 - Post-approval monitoring

Determinations of the Council

- Adopted the ILAR Guide, the Ag Guide and ETS 123 as the **three primary standards** of accreditation

Determinations of the Council

- **Position statements:**
 - The use of the Ag Guide, ILAR Guide and ETS 123 for Ag species
 - Performance based criteria for cage/pen space
 - Social housing
 - Role of the AV/ Veterinary Care
 - Rack washer safety
 - Revised definition of “laboratory animals”

Determinations of the Council

FAQ's:

- Frequency of program reviews and facilities inspections
- Environmental enrichment
- Aseptic surgery and alcohol as a sterilant
- Intraoperative monitoring
- Harm-Benefit analysis
- Surgery performed in Investigator laboratories
- Vibration detection and suppression
- Windows in animal rooms (and the facility)
- Allergy prevention (engineering controls supersede PPE)
- Doors and Frames – hospital stops
- Recycled air
- Humidity control
- Reporting animal welfare concerns
- PAM
- Ownership and client owned animals (veterinary schools)

Determinations of the Council

- Revise the Program Description Outline
 - Streamline
 - Eliminate redundancy
 - Prompt for new information relative to the updated Guide

New ILAR Guide – Selected Topics

■ Chapter 2: Animal Care and Use Program

- Attending Veterinarian¹⁴ – roles and responsibilities
- “....there should be clear and regular communication between the AV and the IACUC.”
- “....the primary oversight responsibilities within the Program rest with the IO, the AV and the IACUC.”
- “Program needs should be clearly and regularly communicated to the IO by the AV...”
- “The Institution must provide the AV sufficient authority”
- “The IACUC along with the AV, has the responsibility for determining that personnel performing surgical procedures are appropriately qualified and trained..”

New ILAR Guide – Selected Topics

- **Chapter 2: Animal Care and Use Program**
 - Agricultural animals³⁵ (which standard?)
 - ILAR Guide: *“The Guide applies to agricultural animals used in biomedical research, including those maintained in typical farm settings.”*
 - FASS Guide: *“Therefore, regardless of the teaching or research objective, the FASS Ag Guide should serve as a primary reference document for the needs and requirements of agricultural animals.”*

New ILAR Guide – Selected Topics

- **Chapter 2: Animal Care and Use Program**
 - Lab animal allergy²⁴: early detection, engineering controls before PPE
 - *“The medical surveillance program should promote early diagnosis of allergies... PPE should be used to supplement, not replace, engineering or process controls...”*

New ILAR Guide – Selected Topics

- **Chapter 2: Animal Care and Use Program**
 - Frequency of Program Review/ Inspections²⁶
 - *“Program review and facilities inspections should occur at least annually or more often as required.”*

New ILAR Guide – Selected Topics

■ Chapter 2: Animal Care and Use Program

■ Humane Endpoints^{28,29} – 4 criteria

- *“The humane endpoint should be relevant and reliable...”*

“...and should be carefully considered during protocol review...”

“...defined when possible prior to the start of the study.”

“...precisely defining the humane endpoint (critical 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.”

New ILAR Guide – Selected Topics

- **Chapter 2: Animal Care and Use Program**
 - Harm – Benefit analysis²⁸
 - *“....the IACUC is obliged to weigh the objectives of the study against potential animal welfare concerns.”*

New ILAR Guide – Selected Topics

- **Chapter 2: Animal Care and Use Program**
 - New protocol review criteria²⁷
 - *“A clear and concise sequential description of procedures...” “Impact of the procedures on the animals’ well-being” “Description and rationale for anticipated or selected endpoints.” “...the IACUC should evaluate scientific elements of the protocol....”*

New ILAR Guide – Selected Topics

- **Chapter 2: Animal Care and Use Program**
 - Monitoring for unexpected outcomes^{29,30}
 - *“...newly generated GMA lines should be carefully observed from birth to early adulthood...” “When the initial characterization of a GMA reveals a condition that negatively impacts animal well-being, this should be reported to the IACUC.”*

New ILAR Guide – Selected Topics

■ Chapter 2: Animal Care and Use Program

- Physical restraint^{30,31}: vet assessment, + reinforcement, conditions for removal
- *“Animals that do not adapt to necessary restraint systems should be removed from the study.” “....animals can be trained, through use of positive reinforcement techniques, to cooperate with research procedures...”*
“Alternatives to physical restraint should be considered”

New ILAR Guide – Selected Topics

■ Chapter 2: Animal Care and Use Program

- Disaster plan³⁷ – more detail
- *“Facilities **must** have a disaster plan”*
 - “...prevent animal pain, distress and deaths...”*
 - “...essential personnel who should be trained...”*
 - “...assure personnel safety...”*
 - “...plans should be approved by the institution...”*
 - “...must be humanely euthanized”*

New ILAR Guide – Selected Topics

Examples of performance criteria that may be used:

“When socially housed, animals should be provided sufficient space and structural complexity to allow them to escape aggression or hide from other animals in the pair or group.”

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

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

New ILAR Guide – Selected Topics

- **Chapter 3: Environment, Housing, and Management**
 - Ventilation and air quality⁵⁰
 - [VAV] “...systems offer considerable advantages with respect to flexibility and energy conservation, but should always provide a minimal amount of air exchange as recommended for general use laboratories”

New ILAR Guide – Selected Topics

- **Chapter 3: Environment, Housing, and Management**
 - Social housing⁵⁵
 - *“Social animals should be housed in stable pairs or groups of compatible individuals unless they must be housed alone for experimental reasons or because of social incompatibility”*

New ILAR Guide – Selected Topics

- **Chapter 3: Environment, Housing, and Management**
 - Written program of environmental enrichment⁵⁸
 - *“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”*

New ILAR Guide – Selected Topics

■ Chapter 4: Veterinary Care

- Animal procurement¹¹⁴ – breeding colonies
- *“Breeding colonies should be established based on need and managed according to principles of animal reduction such as cryopreservation for rodent stocks or strains”*

New ILAR Guide – Selected Topics

■ Chapter 4: Veterinary Care

- Emergency care¹²³ – “musts”
 - “Procedures **must** be in place to provide emergency veterinary care...” “Such procedures **must** enable timely reporting of animal injury, illness or death....” A veterinarian or veterinarian’s designee **must** be available to expeditiously assess the animals condition, treat the animal, investigate an unexpected death, or advise on euthanasia.” “...the veterinarian **must** have the authority, delegated by senior administration and the IACUC, to treat, remove from the experiment, institute appropriate measures to relieve severe pain or distress or euthanize the animal if necessary.”

New ILAR Guide – Selected Topics

■ Chapter 4: Veterinary Care

- Surgery¹²⁸ – intraoperative monitoring
- *“monitoring includes routine evaluation and recording of anesthetic depth and physiologic functions and conditions, such as body temperature, cardiac and respiratory rates and pattern, and blood pressure. Use of balanced anesthesia, including the addition of an intraoperative analgesic agent can help minimize physiologic fluctuations during surgery.”*

New ILAR Guide – Selected Topics

■ Chapter 5: Physical plant

- Windows¹⁴⁷
- *“The presence of windows in an animal facility, particularly in animal rooms, creates a potential security risk and should generally be avoided”*

New ILAR Guide – Selected Topics

■ Chapter 5: Physical plant

- Humidity control¹⁴⁹
- *“Ideally relative humidity should be maintained within +/- 10% of set point; however this may not be achievable under some circumstances”*

New ILAR Guide – Selected Topics

- **Chapter 5: Physical plant**
 - HVAC system failure¹⁵⁰ – minimum function
 - *“In the event of an HVAC system or component failure, systems should at the minimum supply facility needs at a reduced level, address the adverse effects of loss of temperature control, and where necessary, maintain critical pressurization gradients”*

New ILAR Guide – Selected Topics

■ Chapter 5: Physical plant

- Reheat coils¹⁵⁰
- *“Valves controlling reheat coils should fail closed and steam coils should be avoided or be equipped with a high temperature cut-off system to prevent space overheating and animal loss with valve failure”*

New ILAR Guide – Selected Topics

- **Chapter 5: Physical plant**
 - Corridors as storage¹⁵¹
 - *“Corridors are not appropriate storage areas.”*

New ILAR Guide – Selected Topics

■ Chapter 5: Physical plant

- Vibration¹⁵³
- *“Therefore, attempts should be made to identify all vibration sources and isolate or dampen them with vibration suppression systems”*

New ILAR Guide – Selected Topics

■ Chapter 5: Physical plant

- Rack washer safety¹⁵³
- *“...and equipment, such as cage/rack washers, and bulk sterilizers, which personnel enter, are equipped with functioning safety devices that preclude staff from becoming trapped inside.”*

New ILAR Guide – Selected Topics

■ Chapter 5: Physical plant

- Dedicated surgery in labs¹⁵⁴
- *“For most survival surgery on rodents and other small species such as aquatics and birds, an animal procedure laboratory, dedicated to surgery and related activities when used for this purpose and managed to minimize contamination from other activities conducted within the room at other times, is recommended.”*

New ILAR Guide - Implementation

- Council will continue with intense self-education efforts to clarify the 121 topics in the New ILAR Guide – in priority order
- Rewrite the Program Description Outline
- Draft Position Statements and FAQ's
- Develop and implement training programs for Emeriti, Ad hocs and the public

New ILAR Guide - Implementation

- Self-education: underway and ongoing
- Program Description Outline rewrite: underway, complete by January 2011, send to units in February 2011 for Fall trimester site visits
- Draft Position Statements/ FAQ's: underway, complete by January 2011
- Develop training programs: begin implementation immediately

Summary

- 2010 has been a seminal year for AAALAC International (revision/ development of three fundamental accreditation documents)
- Intensive review and analysis
- Harmonized disparate facets among the 3 standards
- Significant education, training and communication efforts
- Positioned AAALAC International to better harmonize and implement global performance-based standards of animal care and use.

Questions / Discussion?



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