AAALAC Perspectives on Implementation of the 2011 Guide

John Bradfield, DVM, PhD
Senior Director, AAALAC International
Goals

- Review of the updated ILAR Guide
- What’s new and what does it mean?
- Implementation

- Council Retreat – July 2010 – Intensive evaluation
- **121 separate topics** were discussed and classified according to their need for clarification.
  - 16 discussion items
  - 37 action items
  - 68 FYI items
- Also reviewed Ag Guide and European Directive
- Resulted in the Council developing:
  - 6 position statements required (so far)
  - 16 FAQ’s required (so far)
Determinations of the Council

- Council adopted **three** documents as primary standards of accreditation: The ILAR *Guide*, the *Ag Guide* and *ETS 123*
- See our FAQ ([www.aaalac.org](http://www.aaalac.org))
Determinations of the Council

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

- Training
- Protocol review
- Harm/ benefit
- Humane endpoints
- Unexpected outcomes
- Humidity
- Recycled air
- Social housing
- Environmental enrichment
- Special facilities

- Occupational health
- Cage and pen space
- Animals in laboratories
- Surgery in laboratories
- Temperature control/safety
- HVAC failure
- Storage
- Rack washer safety
- Environmental monitoring
Training

“All personnel involved with the care and use of animals must be adequately educated, trained and/or qualified in basic principles of laboratory animal science to help assure high-quality science and animal well-being.”
Training topics

- **Veterinary staff**
  
  “…*must* have experience, training and expertise necessary to evaluate the health and well being of the species used...”

- **Veterinary or other professional staff**
  
  Laboratory animal facility administration and management; Facility design/renovation; Human resource management; Pathology of laboratory animals; Comparative genomics; Facility and equipment maintenance; Diagnostic laboratory operations; Behavioral management

- **Animal care staff**
  
  “..*should* receive training and/or have the experience to complete the tasks for which they are responsible”
  
  Animal husbandry; Administration; Veterinary medical technology
Chapter 2: pages 15-17

Training topics

- **Research team** — *(Before the study)*
  - Animal care and use legislation
  - IACUC function; Ethics of animal use
  - Concepts of the 3-R’s; Reporting concerns; OHS
  - Handling; Aseptic technique; Anesthesia/ analgesia
  - Euthanasia

- **IACUC**
  - Formal orientation
  - Relevant legislation; Regulations, guidelines and policies
  - Animal facilities and laboratories
  - Process for protocol and program review
  - Ongoing opportunities to enhance understanding
Council’s Interpretation:

- Depending on the institution’s current training program, this training requirement may, or may not, necessitate changes.
- All training should be documented.
Chapter 2: page 22

- Personnel protection

“Personnel working in areas where they might be exposed to contaminated airborne particulate material or vapors should have suitable respiratory protection... with respirator fit testing and training in the proper use and maintenance of the respirator....”
Council’s Interpretation:

- Council expects that when personnel are required to wear respirators, respiratory fit testing and training **must** be provided.
Chapter 2: pages 25-26

Protocol Review

- This section has been revised with three additional elements of review included. There are also additional phrases which highlight specific details of important aspects of protocol review.
Council’s Interpretation:

- Rationale and purpose of the proposed use of animals.
- A clear and concise sequential description of the procedures involving the use of animals that is easily understood by all members of the committee.
- Availability or appropriateness of the use of less-invasive procedures, other species, isolated organ preparation, cell or tissue culture, or computer simulation (see Appendix A, Alternatives).
- Justification of the species and number of animals proposed; whenever possible, the number of animals and experimental group sizes should be statistically justified (e.g., provision of a power analysis, see Appendix A, Experimental Design and Statistics).
- Unnecessary duplication of experiments.
- Non-standard housing and husbandry requirements.
Council’s Interpretation:

- Impact of the proposed procedures on the animal’s well-being.
- Appropriate sedation, analgesia, and anesthesia (indices of pain or invasiveness might aid in the preparation and review of protocols; see Appendix A, Anesthesia, Pain and Surgery)
- Conduct of surgical procedures including multiple operative procedures.
- Post-procedural care and observation (e.g., inclusion of post-treatment or postsurgical animal assessment forms).
- Description and rationale for anticipated or selected endpoints.
Council’s Interpretation:

- Criteria and process for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated.
- Method of euthanasia or disposition of animal, including planning for care of long-lived species after study completion.
- Adequacy of training and experience of personnel in the procedures used, and roles and responsibilities of the personnel involved.
- Use of hazardous materials and provision of a safe working environment.
Harm-Benefit analysis

With regard to protocol review, the IACUC should consider - “Impact of the proposed procedures on the animal’s well-being.”

“....the IACUC is obliged to weigh the objectives of the study against potential animal welfare concerns.”
Council’s interpretation: (FAQ)

- Although the term may be new, the concept is not
- AAALAC International expects that IACUC’s (ACC, EC or other oversight body) as part of the protocol review process, will weigh the potential adverse effects of the study against the potential benefits
Chapter 2: pages 27-28

- Humane endpoints

“Determination of humane endpoints should involve the PI, the veterinarian, and the IACUC, and should be defined when possible prior to the start of the study”

“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.”
Humane endpoints

Council’s Interpretation:

- Experimental and humane endpoints should be clearly defined in the animal care & use protocol, and be reviewed and approved by the IACUC. Humane endpoint determination should involve PI, veterinarian and IACUC prior to start of the study.

- When establishing humane endpoints, 4 critical criteria are essential for consideration:
  1) a precise definition
  2) frequency of observations
  3) training of personnel
  4) required response when the endpoint is reached.
Chapter 2: pages 28-29 (&77)

- Unexpected outcomes

“Because of the potential for unexpected outcomes that may affect animal well-being when highly novel variables are introduced, more frequent monitoring of animals may be required. With their inherent potential for unanticipated phenotypes, GMAs are an example of when increased monitoring for unexpected outcomes could be implemented.”

“Regardless of whether genetic manipulation is targeted or random, the phenotype that initially results is often unpredictable and may lead to expected or unexpected outcomes that impact the animal’s wellbeing or survival at any stage of life.”

“When the initial characterization of a GMA reveals a condition that negatively impacts animal well-being, this should be reported to the IACUC, and more extensive analysis may be required to better define the phenotype...”
Chapter 2: pages 28-29 (&77)
Unexpected outcomes

Council’s Interpretation:

- Develop a program to increase awareness of the need to report, and a mechanism for reporting back to IACUC
- Important for unexpected outcomes in pilot studies & other special experimental considerations (e.g., GMAs)
Relative Humidity

“Relative humidity should also be controlled, but not nearly as narrowly as temperature for many mammals; the acceptable range of relative humidity is considered to be 30 to 70% for most mammalian species.”

“Ideally relative humidity should be maintained within +/- 10% of set point; however, this may not be achievable under some circumstances.”
Council’s Interpretation: (FAQ)

- The Guide recommends that humidity be maintained between 30-70% throughout the year.
- AAALAC International will assess the variation around the set point using a performance approach.
- If no issues had been identified that would compromise the health and well-being of the animals or jeopardize the integrity of animal studies, then it is not likely that the Council would consider this variation a problem.
Recycled air

“The use of recycled air to ventilate animal rooms may save energy but entails risks. Because many animal pathogens can be airborne or travel on fomites (e.g., dust), exhaust air recycled into heating, ventilation, and air conditioning (HVAC) systems that serve multiple rooms presents a risk of cross contamination. Recycling air from non-animal use areas (e.g., some human occupancy areas and food, bedding, and supply storage areas) may require less intensive filtration or conditioning and pose less risk of infection.”
Council Interpretation: continue to expect the guidelines outlined in the 1996 Guide (FAQ)

- “...however, the use of nonrecycled air is preferred for ventilation of animal use holding areas.”
- “Room air is mixed with at least 50% fresh air (that is, the supply air does not exceed 50% recycled air).”
- “Recycled air is returned only to the room or area from which it was generated, except if it comes from other than animal-housing areas.”
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.”

“An appropriate housing space or enclosure should also account for the animal’s social needs.”

“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...”

“Appropriate social interactions among members of the same species (conspecifics) are essential to normal development and well-being...”

“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.”
Council’s Interpretation: (position statement)

- In general, social animals must be housed in stable pairs or groups of compatible individuals, and social housing will be considered by AAALAC International as the default method of housing unless otherwise justified based on scientific necessity, social incompatibility resulting from inappropriate behavior, or veterinary concerns regarding animal well-being.

- Single housing of social animals should be limited to the minimum period necessary, and where possible, visual, auditory, olfactory and tactile contact with compatible conspecifics should be provided.

- The need for single housing should be reviewed on a regular basis and approved by the IACUC (or other oversight body) 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 wellbeing and consistent with the goals of animal use.”

“They should be updated as needed to ensure that they reflect current knowledge.”

“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.”
Council’s Interpretation: (FAQ)

- Important method of improving well-being
- **Facilitate** the expression of species-appropriate behaviors.
- Should be provided in a **consistent** manner across the animal program, with due attention to personnel and animal safety.
- Personnel should be made aware of the enrichment program as one aspect of the overall **training** program
- Implementation of environmental enrichment should take into account the **scientific goals** of the study
Council’s Interpretation: (FAQ)

- AAALAC site visitors will focus their attention on the IACUC’s review of the enrichment program, documentation of the review, and implementation of the program.

- AAALAC expects that the enrichment program will be reviewed regularly by the IACUC, and that the IACUC adequately represents the research community and veterinarian(s) at the institution in the review of enrichment program.
Chapter 3: pages 55-63

- **Cage and pen space**
- There is new language in the 2011 Guide regarding the recommendations for cage/pen space
- There are new recommendations for mice and rats with litters, some categories of NHP’s and rabbits.
- There are a number of statements regarding movement and postures (able to comfortably stand erect, move without touching the sides, brachiation, etc)
Council’s Interpretation: (position statement)

- AAALAC International expects accredited institutions to comply with all national or regional regulations, policies and guidelines, as well as conditions of funding.
- AAALAC International considers performance standards paramount when evaluating cages or pens for housing animals used for research, testing or teaching.
- Performance criteria described in the ILAR Guide, Ag Guide and ETS 123 are used by AAALAC in assessing the adequacy of cage or pen space available to the animal(s).
Some examples of performance criteria: (+ many species-specific criteria)

- “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.”
- “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.”
- “Cage height should take into account 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 to the mother or the litter.”
Animals maintained in laboratories

“If animals must be maintained in a laboratory to satisfy the scientific aims of a protocol, that space should be appropriate to house and care for the animals and its use limited to the period during which it is required.”
Chapter 5: page 134
Animals maintained in laboratories

Council’s interpretation:

- Housing conditions should mimic the animal facility (ac/h, light control, temperature control, security, sanitizable surfaces, husbandry practices, management, etc.)
- Multi-use laboratories can present difficulties (HVAC, Occupational Health, etc.)
Windows

“The presence of windows in an animal facility, particularly in animal rooms, creates a potential security risk and should generally be avoided.”
Council’s Interpretation: (FAQ)

- Windows in animal rooms warrants consideration of potential security issues, as well as possible variation in the circadian rhythm of animals exposed to varying periods of daylight and room temperature fluctuations.

- Windows are required for certain species (e.g., nonhuman primates, dogs) in some countries and can, in fact, be beneficial for several laboratory animal species (e.g., nonhuman primates, dogs, cats).
Temperature control and failsafe

“Valves controlling reheat coils should fail in the closed position; steam coils should be avoided or equipped with a high-temperature cut-off system to prevent space overheating and animal loss with valve failure.”
Council’s Interpretation:

- Automated temperature fail-safes are strongly recommended for new facilities or when designing HVAC renovations.
- Other mechanisms to ensure temperatures do not reach unsafe conditions may also be acceptable.
- Dependable monitoring and alarms.
Chapter 5: page 140

- HVAC system failure – minimal 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.”
Council’s Interpretation:

- Expect automated fail-safe mechanisms to be in place for areas where minimal function is critical (certain ABSL containment areas).
- Back-up systems for providing appropriate HVAC system function during outages are appropriate (but management of facilities during outages may also be an adequate way to address temporary HVAC concerns/limitations).
- Monitoring mechanical systems is critical.
Corridors as storage

“Corridors are not appropriate storage areas.”
Chapter 5: page 141
Corridors as storage

Council’s interpretation:
- Storage in corridors should be limited, but may be acceptable in some circumstances
- Management plan
- Consideration of safety/egress, biosecurity, contamination control, occupational health and safety
- Feed and bedding should not be stored in corridors
Rack washer safety

“Consideration should be given to such factors as the following:

- Personnel safety by ensuring that safety showers, eyewash stations, and other equipment are provided as required by code; exposed hot water and steam lines are properly insulated; procedures with a propensity to generate aerosols are appropriately contained; and equipment, such as cage/rack washers, and bulk sterilizers, which personnel enter, are equipped with functioning safety devices that prevent staff from becoming trapped inside.”
Chapter 5: page 143
Rack washer safety

Council’s Interpretation: (position statement)
- Rack washer safety must entail 3 critical components
  - Egress
  - De-energizing device
  - Personnel training
Chapter 5: page 143

- **Environmental monitoring**

  “Automated monitoring systems, which notify personnel of excursions in environmental conditions, including temperature and photoperiod, are advisable to prevent animal loss or physiologic changes which may occur as a result of system malfunction. The function and accuracy of such systems should be regularly verified.”
Council’s Interpretation:

- Council strongly advocates regular, frequent monitoring of environmental conditions, including after hours.
- Automated monitoring systems are advisable.
- Monitoring should be able to detect excursions in animal rooms in a timely manner.
Surgery performed in laboratories

“For most survival surgery performed on rodents and other small species such as aquatics and birds, an animal procedure laboratory is recommended; the space should be 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.”
Chapter 5: page 144
Surgery conducted in laboratories

Council’s Interpretation: (FAQ)

- Minimizing contamination during surgery may be achieved by considering several factors
- Areas for surgery should be isolated and dedicated when surgery is underway
- Other activities in the lab may or may not need to be restricted depending on:
  - Location of surgical area within the lab
  - Complexity of the surgical procedure
  - Duration of surgery
  - Risk posed by other ongoing activities in the lab
Chapter 5: new sections

**Barrier Facilities (145-6)**

- No specific expectations for barrier facilities
- The Council will assess using performance criteria
- Factors mentioned in the Guide that may be important for consideration are:
  - Filtration of supply air (HEPA or 95% efficient)
  - Directional airflow (positive with respect to surrounding areas)
  - Restricted personnel entry
  - Specialized equipment (isolators, IVC’s, change stations, etc)
  - Personnel training

**Imaging (146-7)**

- No specific expectations, but factors to consider are:
  - Cross-contamination (biosecurity and OHS)
  - Transportation (biosecurity and OHS)
  - Anesthesia (support space)
  - Containment (radioisotopes, ABSL-2)
  - Holding
  - Cryogen safety*
Chapter 5: new sections

**Behavioral Studies** (149-50)
- Special considerations
  - Noise, light, vibration, odors
  - HVAC associated noise, vibration and drafts
  - Airlocks
  - Storage
  - Decontamination, cleaning and maintenance

**Aquatics** (150 + Ch-3)
- Special considerations
  - Water source and treatment
  - Impervious surfaces and equipment
  - Moisture resistance (HVAC ducts, etc)
  - GFCI
  - Inert, non-toxic plumbing and fixtures
Implementation

- Begin using the new standards for **September 2011** site visits
- Grace period” for “new” mandatory items – will be considered “temporary SFI’s” for a period of one year (until September 2012)
  - **One year:**
    - To implement new “musts” related to program management
    - To equip rooms in which cryogen is stored (MR scanners) with oxygen sensors
  - **Three years:** Significant equipment replacement, such as cages that do not meet the following performance criteria:

  “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.”
AAALAC International
Education and Outreach

Contact us anytime!

301-696-9626
www.aaalac.org
accredit@aaalac.org