 **The New *Guide***

Are you ready?

The fourth installment of the IACUC training series is not a scenario, but a summary of the 8th edition of the *Guide for the Care and Use of Laboratory Animals (Guide).*  As with the previous IACUC training offerings, the goal is to facilitate discussion. Please consider reviewing this information (see below) at your next IACUC meeting; more detailed information regarding the new *Guide* is available at <http://www.research.va.gov/programs/animal_research/>. The IACUC Training Scenario 2012 series will provide additional guidance on specific topics included in the new *Guide*.

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| **Chapter #** | **New and Expanded Topics** |
| 1 | Ethics of Animal Use  Three R’s |
| 2 | Responsibilities of Key Personnel (IO, AV, IACUC)  Institutional Collaborations  Training and Education  Program Oversight   * IACUC * PAM   Special Considerations for Protocol Review   * Experimental and Humane Endpoints * Unintended Consequences * Physical Restraint * Multiple Survival Surgical Procedures * Food and Fluid Regulation * Use of Non-Pharmaceutical Grade Chemicals and other Substances * Field Studies * Agricultural Animals   Disaster Planning and Emergency Preparedness |
| 3 | Terrestrial Animals  Aquatic Animals   * Water quality * Life Support System   HVAC  Vibration  Environment Enrichment  Housing and Space Recommendations  Procedural Habituation and Training of Animals |
| 4 | Transportation of Animals  Preventative Medicine - Animal Biosecurity  Clinical Care and Management  Surgery - Intraoperative Monitoring |
| 5 | Centralization and Decentralization  HVAC  Vibration Control  Environmental Monitoring  Special Facilities  Security and Access Control |

On November 3, 2011, AAALAC International announced their intention to implement a one-year (i.e. until September 1, 2012) phase-in period of categorizing new “must statements” as “Temporary Suggestions for Improvement” (TSI). Should your institution receive TSI, they must be addressed in post site visit communication, by independent correspondence or in your annual report (if submitted prior to September 1, 2012). Initially, your accreditation will not be effected by TSI; however, Council will determine whether the institution’s responses are appropriate or if additional corrective action is required. After September 1, 2012, uncorrected TSI will be considered mandatory correction items and may affect an institution’s accreditation status.

The following are “must” statements that are new additions to the 8th edition of the *Guide.*

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| **Chapter #** | **Pg. #** | **“Must” statements** |
| 1 | 1 | This edition of the *Guide for the Care and Use of Laboratory Animals* (the *Guide*) strongly affirms the principle that all who care for, use, or produce animals for research, testing, or teaching **must** assume responsibility for their well-being. |
| 1 | 5 | Veterinary consultation **must** occur when pain or distress is beyond the level anticipated in the protocol descrip­tion or when interventional control is not possible. |
| 2 | 14 | The institution **must** provide the AV with sufficient authority, including access to all animals, and resources to manage the program of veterinary care. |
| 2 | 15 | Veterinarians providing clinical and/or Program oversight and support **must** have the experience, training, and expertise necessary to appropriately evaluate the health and well-being of the species used in the context of the animal use at the institu­tion.  In such instances [consulting veterinarian available on part-time basis], there **must** be an individual with assigned responsibility for daily animal care and use and facility management. |
| 2 | 23 | The institution **must** develop methods for reporting and investigating animal welfare concerns, and employees **s**hould be aware of the importance of and mechanisms for reporting animal wel­fare concerns. In the United States, responsibility for review and investi­gation of these concerns rests with the IO and the IACUC. |
| 2 | 26 | IACUC members named in protocols or who have other conflicts **must** recuse themselves from decisions concerning these protocols. |
| 2 | 27 | The identification of humane endpoints is often challenging, however, because multiple factors **must** be weighed, including the model, species (and sometimes strain or stock), animal health status, study objectives, institutional policy, regulatory requirements, and occasionally conflicting scientific literature. |
| 2 | 29 | Restraint devices **s**hould not be considered a normal method of housing, and **must** be justified in the animal use protocol.  Veterinary care **must** be provided if lesions or illnesses associated with restraint are observed. The presence of lesions, illness, or severe behavioral change often necessitates the temporary or per­manent removal of the animal from restraint. |
| 2 | 30 | When applicable, the IO **must** submit a request to the USDA/APHIS and receive approval in order to allow a regulated animal to undergo multiple major survival surgical procedures in separate unrelated research protocols (USDA 1985, 1997a). |
| 2 | 35 | Facilities **must** therefore have a disaster plan. |
| 3 | 56 | At minimum, animals **must** have enough space to express their natural postures and postural adjustments without touching the 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 areas soiled by urine and feces.\* |
| 3 | 74 | Emergency veterinary care **must** be available after work hours, on weekends, and on holidays. |
| 3 | 80 | The biofilter **must** be of sufficient size (i.e., contain a sufficient quantity of bacteria) to be capable of processing the bioload (level of nitrogenous waste) entering the system. |
| 3 | 86 | Chlo­rine and most chemical disinfectants are inappropriate for aquatic systems containing animals as they are toxic at low concentrations; when used to disinfect an entire system or system components, extreme care **must** be taken to ensure that residual chlorine, chemical, and reactive byproducts are neutralized or removed. |
| 4 | 114 | Procedures **must** be in place to provide for emergency veterinary care both during and outside of regularly scheduled hours.  Such procedures **must** enable animal care and research staff to make timely reports of animal injury, illness, or death. A veterinarian or the veterinarian’s designee **must** be available to expeditiously assess the animal’s condition, treat the animal, investigate an unexpected death, or advise on euthanasia.  In the case of a pressing health problem, if the responsible person (e.g., investigator) is not available or if the investigator and veterinary staff cannot reach consensus on treatment, the veterinarian  **must** have the authority, delegated by senior administrations (see Chapter 2, Institution Official, and Attending Veterinarian) and the IACUC, to treat the animal, remove it from the experiment, institute appropriate measures to relieve severe pain or distress, or perform euthanasia if necessary. |
| 4 | 115 | All those involved in animal care and use **must** comply with federal laws and regulations regarding human and veterinary drugs and treatments.  Researchers conducting surgical procedures must have appropriate training to ensure that good surgical technique is practiced –that is, asepsis, gentle tissue handling, minimal dissection of tissue, appropriate use of instruments, effective hemostasis, and correct use of suture materials and patterns (Brown et all. 1993; Heon et al. 2006). |
| 4 | 122 | Antinociception occurs at a surgical plane of anesthesia and **must** be ascertained before surgery.  Agents that provide anesthesia and analgesia **must** be used before their expiration dates and should be acquired, stored, their use recorded, and disposed of legally and safely. |
| 4 | 124 | Death **must** be confirmed by personnel trained to recognize cessation of vital signs in the species being euthanized. |
| 5 | 134 | 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. |
| 5 | 147 | Because cryogen boil-off can lead to asphyxiation of both personnel and animals, rooms with MR scanners or in which cryogen gases are stored **must** be equipped with oxygen sensors and a method for increasing room ventilation to exhaust inert gases during cryogen filling (Klaunberg and Davis 2008). |
| 5 | 148 | Biologic agents and toxins pose a threat to animal and plant health or public health and safety, and facilities in which they are used **must** adhere to APHIS, USDA, and CDC Select Agent Regulations (CFR 2005; CDC and DHHS 1996; PL 107-188) and/or other applicable federal, state, or local regulations. |

\*Only the underlined text is a new addition.

Please be aware of OLAW Notice Number - NOT-OD-11-082, which states:

“The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([Policy](http://grants.nih.gov/grants/olaw/references/phspol.htm)) requires that Assured institutions base their programs of animal care and use on the Guide for the Care and Use of Laboratory Animals. As of June 2011, and until notified of a change through the NIH Guide for Grants and Contracts, this guidance for Assured institutions refers to the seventh edition of the Guide. OLAW recognizes that the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) will require accredited institutions (or those seeking accreditation) to evaluate their animal care and use programs according to the eighth edition of the Guide beginning in the fall of 2011. OLAW does not consider compliance with the eighth edition of the Guide to conflict with the seventh edition of the Guide.”

**Sources**:

<http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf>

<http://dels.nas.edu/resources/static-assets/ilar/miscellaneous/Guide-Presentation.pdf>

<http://www.aaalac.org/news/index.cfm>

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-082.html>