Animal Care & Use Program Oversight & Monitoring – The AAALAC Perspective

Gary L. Borkowski
June 26, 2019
13th TALAS International Conference

AAALAC Accreditation

1. Voluntary (collegial, confidential, welfare)
2. Peer review
3. Scientific validity through quality animal care
4. Collaboration in a global marketplace
5. Demonstrates accountability
6. Stimulates continuous improvement
7. Advocacy for every institution

www.aaalac.org
Over 1000 Accredited Programs

Pacific Rim Growth

AAALAC International Accredited Units in Pacific Rim

Pacific Rim Section

2 Pacific Rim Sections
Who Is AAALAC International

- Member Organizations
  - ICLAS, FELASA, AFLAS, ANZCCART, JCLAM, KCLAM, European Federation of Pharmaceutical Industries and Associations
- Board of Director
- CEO, Global Director and three Senior Directors
- Volunteer international experts
  - 60+ Council on Accreditation members
  - 300+ ad hoc Specialists/Consultants

Rules of Accreditation
Updated June 2018

- Definitions
- Standards
- Fees
- Procedures
- Site Visits and site visitors
- Granting and denying accreditation
- Accreditation Status
- Hearing and appeals
- Certificates
- Confidential records
Section 1. Definitions
Animals

- All animals used or to be used in research, teaching or testing at accreditable units are to be included and evaluated in accordance with the standards set forth in Section 2 of these Rules.
- These include traditional laboratory animals, farm animals, wildlife, and aquatic animals.
- Nontraditional animals, inclusive of invertebrate species, are also included where they are relevant to the unit's mission.

Animal Ownership

Rules of Accreditation
All animal programs and facilities of the accreditable unit must be included in the application and evaluated...

Program Description (PD) and Site Visit
All animals owned by the institution:
- At all buildings
- At satellite facilities, and investigator laboratories
- At contractor's facility if the contractor's program is not AAALAC accredited
Criteria for Accreditation

- AAALAC International accredits active animal care and use programs.
- An active animal care and use program includes: animals; facilities; equipment; professional, technical, and administrative support; and policies and programs for institutional responsibilities, animal husbandry and veterinary care.
Accreditable Unit

- Any public or private institution, organization, or agency maintaining, using, importing, or producing animals for purposes of scientific research, teaching, or testing may be accredited.
- The **appropriate administrative entity** making application is the accreditable unit, and its animal care and use programs and facilities are evaluated to determine accreditation status.
  - All animal programs and facilities of the accreditable unit must be included in the application and evaluated.

Section 2. Standards

- The *Guide for the Care and Use of Laboratory Animals (Guide)*, 8th Edition (NRC 2011), 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.
- The accreditable unit shall observe any and all statutes and governmental regulations which bear upon animal care and use including, but not limited to, the prevailing standards of sanitation, health, labor and safety of the jurisdiction(s) in which it is located.
  - ...
**The Three Primary Standards**

AAALAC relies on Three Primary Standards for evaluating laboratory animal care and use programs: the eighth edition of the *Guide for the Care and Use of Laboratory Animals* (Guide, NRC 2011); the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (Ag Guide, FASS 2010); and the *European Convention* for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe; (ETS 123); along with other widely accepted guidelines. Since 1975, AAALAC International has also referred to other specialty publications for supplemental information about procedures or techniques related to the care and use of laboratory animals. These specialty publications are designated as Reference Resources. References included on this list have been formally reviewed and adopted by AAALAC International’s Council on Accreditation as guidance for accredited units as well as the AAALAC International representatives during the site visit. Additionally, these references may be utilized during Council deliberations when discussing issues identified during site visits. When applicable, clarifying notes are appended to the reference, to provide additional information on any exclusions or clarification in the reference.

**Table: Languages**

<table>
<thead>
<tr>
<th>Mandarin Chinese</th>
<th>Japanese</th>
<th>Traditional Chinese</th>
<th>Portuguese</th>
<th>Malaysian</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Mandarin Chinese" /></td>
<td><img src="image2" alt="Japanese" /></td>
<td><img src="image3" alt="Traditional Chinese" /></td>
<td><img src="image4" alt="Portuguese" /></td>
<td><img src="image5" alt="Malaysian" /></td>
</tr>
<tr>
<td>Thai</td>
<td>Spanish</td>
<td>Russian</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

www.aaalac.org
Local Requirements and The Guide

- When no animal welfare law in the country – Follow the Guide’s recommendations
- When some areas of animal welfare are not addressed in the local regulations – Follow the Guide’s recommendations
- If the local regulations and requirements are specific and more stringent than the Guide’s recommendations – Must follow the local requirements!

Engineering, Performance, and Practice Standards

(Pages 6-7)

- Performance Standards
- Engineering Standards
- Practice Standards

Practice standard means the application of professional judgment by qualified, experienced individuals to a task or process over time, which has been demonstrated to benefit or enhance animal care and use. Much of the basis for professional judgment comes from information obtained from the peer-reviewed scientific literature and textbooks.
AAALAC International’s Application of Performance Standards

- AAALAC International recognizes that engineering standards can serve as a useful baseline for some program elements, but considers the application of sound professional judgment to be critical to a successful and contemporary animal care and use program.
- Harmonizing the institutional procedures and practices using performance standards approach.
A comprehensive evaluation

Main Components of the Program

- Institutional administration/ resources
- IACUC composition/ function
- Animal environment/ management
- Occupational health and safety
- Veterinary care program
- Physical plant/ facilities
Two categories of findings

- **Mandatory** – a deficiency that must be corrected in order to maintain (or attain) full accreditation
- **Suggestion for Improvement (SFI)** – a deficiency that if corrected would improve your program, but correction is not essential to maintaining full accreditation status

---

**Site Visit ≠ Inspection (Peer Review)**

Site Visit = Understanding + Initial Evaluation

**Documentation Review**
- Program Description (PD)
- Policies and SOPs
- IACUC records, protocols,…
- OHS records
- Personnel training records
- Animals and animal room records
- Facility system records: HVAC,…

**Facility Tour**
- Suitable and safe facility
  - Animal health & welfare
  - Research quality
- Animals
- Animal care & use practices/performance
  - consistency and safety
- Meet and talk to personnel

The entire process is completely confidential.
A Typical one-day Site Visit Schedule

Entrance Briefing
- Program Description Review
- Facility Tour (meet personnel)
- Lunch with IACUC
- Document Review
- Executive Session (conclude findings)

“Exit Briefing” = Preliminary Opinion
Allow correction/clarification = PSVCs

Exit Briefing

Assessment Process

The same process applied globally
- Rely on local requirements first and address the gaps by following the Guide recommendations
Accreditation Process

Request or download application package

PD Preparation

Submit Program Description (PD)

Pay an application fee

Site Visit: 1 COA member + 1* ad hoc (peer review, on-site evaluation)

Post site visit communications
(correction mandatory deficiencies and addressing improvement issues)

Program Evaluation (PE)

Reviewed by 4 Council members

Council’s deliberation, 3 meetings/year
(January, May, and September)

A letter to the institution include:
commendation, accreditation result,
acknowledgment,
[Conditions, mandatory and SFIs]
(clarification and retraction)

Thank You!

accredit@aaalac.org
www.aaalac.org