

Special feature

The AAALAC International Accreditation Program in India



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Abstract

Science is a global enterprise, as illustrated by the number and scope of international research collaborations and scientific meetings, as well as the number of journals publishing articles from the international scientific community. As institutions seek to compete on the global market it is critical to ensure an internationally accepted level of animal care and welfare is maintained by institutions using animals for research, testing and education. AAALAC International's accreditation program utilizes the flexibility of performance standards; is sensitive to differing legal and cultural issues; promotes the "cross fertilization" of information among institutions through the site visit process; highlights best practices; and serves as a benchmark of quality. Through this process, uniform, high standards of animal care and use may be achieved under a broad range of varying national requirements because of the overarching quality assurance derived from AAALAC International's accreditation program. Accreditation of animal care and use programs in India is a fairly new proposition, but is rapidly gaining attraction. As the biomedical research enterprise in India continues to gain momentum, so too have the merits of an international quality assurance validation system become increasingly recognized. To that end, the AAALAC International accreditation program is herewith described, including observations of findings identified during on-site assessments.

Key words: accreditation, India, AAALAC

Introduction

The globalization of the biomedical research enterprise is occurring at an accelerating pace (Bayne and Miller, 2000). Increasingly, scientific collaborations and contracts cross national borders. The need for assurance that the caliber of animal research and animal welfare are consistent and that

such animal use is done in a humane and conscientious manner is of concern to the scientific community, the general public, and other stakeholders. Bridging these international interactions is a clear scientific imperative for reproducibility of results and statistical validity of data (Bayne, 2008). One way to mitigate the potential confounding effects the quality of the animals may have on the research data is to harmonize animal care practices and procedures, thereby ensuring a similar level

of animal health and welfare, and thus making the data more reproducible. By putting into place standards that promote harmonization, some assurance of quality animal care and use is achieved.

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) has been accrediting institutions in countries outside the United States since 1981. Today, more than 860 animal care and use programs in 34 countries have achieved AAALAC International accreditation. AAALAC is in a unique position to harmonize animal care and use programs as, collectively, the expert teams that conduct the on-site evaluations have visited an average of 212 institutions each year for the last six years. Thus, the AAALAC site visitors have a profound depth of experience in reviewing a wide range of animal care and use programs. The first institution in India to become accredited by AAALAC occurred in 2001. That institution, then known as the Rallis Research Center, today is Advinus Therapeutics. Eight years passed before other Indian institutions applied for and achieved AAALAC International accreditation. At the time of this writing, six institutions in India, all in the private or not-for-profit sectors have achieved accreditation, and an additional four more institutions have recently hosted their initial on-site assessment in the process towards accreditation.

The AAALAC International is a non-governmental, not-for-profit organization that has been accrediting laboratory animal care and use programs since 1965. It was the first organization in the world to provide this service and is the only organization today that provides a global accreditation service for animal research, testing and teaching programs. AAALAC is a voluntary accrediting organization that enhances the quality of research, teaching and testing by promoting humane, responsible animal care and use. It provides advice and independent assessments to participating institutions and accredits those that meet or exceed applicable standards. The AAALAC International accreditation program is science-based and sensitive to cultural and legal differences, and thus it is a logical approach for the international scientific community to adopt to facilitate the harmonization of animal care and use standards (Bayne and Miller, 2000).

The AAALAC has global regional offices to better serve the institutions currently participating in the accreditation program or desirous of becoming accredited. The headquarters office is located in Maryland, United States; a European office is located in Pamplona, Spain; and a Southeast Asia office is located just outside of Bangkok, Thailand. As a not-for-profit organization, AAALAC is guided by a Board of Trustees. This Board is comprised of scientific organizations, veterinary medical organizations, and research advocacy groups. It currently has 67 member organizations, Approximately 37 organizations represent research disciplines, 18 represent veterinary medicine or animal sciences specialty groups, and the balance represent patient or science advocacy groups and industry/academic interest groups. Of these, several are international associations, including the Asian Federation of Laboratory Animal Science, and which provide guidance to AAALAC in its global mission.

The AAALAC International Accreditation Program-

Standards of Accreditation

Harmonizing an animal care and use program to an international level requires applying the provisions and principles of the *Guide for the Care and Use of Laboratory Animals (Guide)* (NRC, 1996 *et seq.*) and several other standards. Specifically, the country-specific legal and regulatory requirements applicable to the institution being assessed by AAALAC constitute the baseline for accreditation. No program can become AAALAC accredited if it is in violation of local legal and regulatory requirements. Once AAALAC is satisfied that these local baseline requirements are met, the *Guide* recommendations are overlayed on the local requirements to meet the AAALAC International standard. It is important to note that when local requirements are more stringent than *Guide* recommendations, the former must be met in order to achieve accreditation. In some instances, the *Guide* includes provisions not addressed in national or supranational animal welfare legislation or regulations, for example in the area of occupational health and safety. In the absence of national standards, the *Guide* recommendations are used as the basis for evaluating program elements in these areas. When necessary and appropriate, specific Reference Resources (e.g., the American Veterinary Medical Association's Guidelines on Euthanasia, 2007) are used to evaluate program components where the *Guide* is silent or not specific (see <http://www.aaalac.org/accreditation/resources.cfm> for a list of the Reference Resources used by AAALAC). Critically important is that all principles of the *Guide* must be met. Finally, the expert professional judgment of AAALAC's Council on Accreditation is applied through the peer review process before a final accreditation status is granted.

Various editions of the *Guide* have been the basis for the assessment process and for the application of performance standards. The *Guide* has recently been revised (NRC, 2010), and the updated version will be used by AAALAC International beginning in the Fall 2011. Recently, AAALAC's Board of Trustees approved the use of three primary standards by AAALAC's Council on Accreditation: the *Guide*, the *Guide for the Care and Use of Agricultural Animals in Research and Testing* (FASS, 2010) and European Treaty Series (ETS) 123 (1986). Application of these standards will depend on the geographic location of the institution and the type of animal use. Because of its reliance on these standards, AAALAC does not formulate animal care and use policies or regulations of its own as a separate standard to achieve accreditation. Each of the three primary standards is grounded in a performance-based approach to animal care and use, which is typically based on the scientific literature. A performance approach requires professional input, sound judgment, and a team approach to achieve specific goals; thus, there is some flexibility in how the desired outcome (e.g., sanitized cages) or goal is reached (NRC, 2010).

The Application Process

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. At the time of this writing, 83% of the institutions accredited in India are commercial organizations, either pharmaceutical companies or contract research organizations. AAALAC International's Rules of Accreditation stipulate that an active animal care and use program must be in place, specifically, that for a program to be accreditable it must have a reasonable activity level relative to the space available for animal holding and use. For new applicants, the active animal care and use program must be in place and operational prior to application for accreditation. AAALAC International will not conduct a site visit to new applicants that do not meet the criteria of an accreditable organization and that do not have an active animal care and use program. Accredited institutions must have all components of an active animal care and use program at the time of a site revisit, to include: animals; facilities; equipment; professional, technical, and administrative support; and policies and programs for institutional responsibilities, animal husbandry and veterinary care. An institution interested in applying for accreditation submits a two-page form which provides the AAALAC Executive Office with contact information of key personnel and designates the Attending Veterinarian and Institutional Official, as well as the Chair of the Institutional Animal Ethics Committee (IAEC) and what AAALAC refers to as the Unit Contact (that person identified by the institution to serve as the official liaison with AAALAC). This form is accompanied by the Program Description, which must be completed using the templates available on the AAALAC website.

The application for accreditation initially undergoes an administrative review by AAALAC Executive Office staff. The application is "accepted" if it is complete, specifically that it contains all the required appendices and the two page application form. If an application is found to be incomplete, the institution is contacted to request the missing information before the application can be accepted and processed. Once the missing information has been provided, the institution can be scheduled for its initial visit. The actual quality of the program—which may or may not be well described in the written materials submitted in the application—is reviewed before and during the on-site assessment using AAALAC's standards as the benchmark for assessment. This process has led to some confusion among Indian colleagues who misunderstood the difference between accepting the application and conferring accreditation. Acceptance of the application packet merely makes the institution eligible to proceed to the next phase, hosting the accreditation site visit. Acceptance of the application in no way implies that accreditation will be achieved.

Peer Review

The AAALAC International uses an interactive, peer review system that relies on expert professional judgment both in the application of performance standards and in assessing performance outcomes (Bayne and Martin, 1998). Specifically, the composition of the site visit team is tailored to the institution's animal-based research program, and includes team members familiar with the species used at the institution and the types

of research done there. The team members are colleagues who share similar experiences and knowledge base to the institutions they visit. For example, a site visitor who works at a diverse academic program would be well-qualified to conduct a site visit to another large, complex academic institution.

As an important measure of ensuring that high quality animal care and use programs are maintained at institutions accredited by the AAALAC International, formal site visits are conducted at three year intervals, and initially for institutions seeking to gain accreditation. Information obtained from these on-site assessments, together with Annual Reports and direct correspondence, constitute the basis for ongoing evaluation and assessment by the Council on Accreditation. The site visit and resultant report provide the Council with factual information and serve as a basis for subsequent Council action regarding the institution's accreditation status. The findings noted in the site visit report are deliberated upon by members of the Council on Accreditation, and thus the site visitors' observations undergo another level of peer review.

Concerns identified during the site visit are categorized as either Suggestions for Improvement or Mandatory Items for correction. Suggestions for Improvement are items which, if implemented, would enhance an already acceptable or even commendable program and they do not impact the accreditation status of an institution. Mandatory items are more serious deficiencies which must be corrected for Full Accreditation to be awarded or continued. The Council review classifies the findings observed during the on-site assessment into one of these categories. Ultimately, a formal vote is taken by the Council regarding the question of the institution's proposed accreditation status.

Initially the report of the site visit undergoes a thorough review by several other members of the Council on Accreditation before the convened meeting. Electronic discussions occur which provide the opportunity for clarifications and modifications to the site visit report before the Council convenes. The review that occurs before the convened meeting involves very senior members on the Council who serve as elected Officers of the Council. This review may then be extended into additional discussions during the convened meeting of Council. The letter that will be sent to the institution indicating the institution's accreditation status is carefully crafted, based on the review of the site visit report by the Council. The letter then also undergoes further detailed review by the Council Officers and senior staff within AAALAC International. In this way, these multiple layers of peer review help to ensure an accurate assessment of the animal care and use program and a product (i.e., the accreditation letter) that is designed to be meaningful and resourceful to the institution.

Fundamental to the accreditation process is the fact that AAALAC International evaluates the entire animal care and use program. This program is framed in the *Guide* (NRC, 1996; NRC, 2010) and each institution seeking accreditation must describe the details of the animal care and use program using a Program Description outline, provided by AAALAC, which generally follows the content of the *Guide*. Thus, the Council on Accreditation reviews the system of oversight and

monitoring of the institution's animal care and use program (e.g., by an Institutional Animal Care and Use Committee (IACUC), IAEC, or similar ethical review committee); the provision of veterinary medical care; personnel qualifications and training; the occupational health and safety program; animal housing; behavioral management; husbandry procedures and population management; animal procurement and transportation; quarantine, stabilization, and separation of species; sentinel programs; oversight of the surgery program; anesthesia and analgesia guidelines; euthanasia guidelines; structural soundness of the facility, facility maintenance, ability to prevent harborage of vermin in the facility; and proper functioning of the heating, ventilation, and air conditioning system (HVAC).

The Annual Report and Prompt Reporting

In accordance with AAALAC's Rules of Accreditation, the accredited institution must submit an Annual Report which describes elements of the animal care and use program as specified by AAALAC International. The Annual Report form is typically distributed to accredited institutions in mid-December. The report is designed to be completed and submitted in an on-line format. Questions range from updates on the contact information for key personnel, actions taken to address any Suggestions for Improvement offered by the Council on Accreditation, to declarations of issues that arose in the program during the year (such as suspended protocols). Although the Annual Report forms are distributed at the end of the calendar year, each institution may establish its own reporting period. Many Indian institutions initially chose to use the month in which they were accredited (based on the date of the letter from the Council on Accreditation), but some have moved to the calendar year for reporting. Globally, institutions also use the fiscal year, academic year or government fiscal cycle, depending on what is most convenient.

In addition, each accredited institution is expected to promptly notify AAALAC International (e.g., through written correspondence or e-mail) of adverse events relating to the animal care and use program. Examples include investigations by the government oversight bodies, as well as other serious incidents or concerns that negatively impact animal well-being. This information is included in the accredited program's file and the Council on Accreditation typically reviews this correspondence to determine how the institution addressed the problem and what systems were put in place to prevent a similar occurrence.

Accreditation Site Visit Findings

Commendations to Institutions

Although AAALAC's experience in India is limited, with accredited Indian institutions comprising less than one percent of the total number of accredited animal care and use programs, some patterns are clear in both the positive aspects of the animal research programs and in areas that have proven challenging. Across the site visits conducted to-date in India, the Council has commended the strong institutional commitment to and support for a quality

animal care and use program. In addition, the Council has consistently complimented the dedication of the staff, both professional and technical, as well as their enthusiasm, qualifications and genuine compassion and concern for the animals. Record keeping practices (e.g., standard operating procedures, training records, protocol documentation) have amply ensured thorough and detailed information. In recent years, the Council has determined that the institutions it has visited have become sufficiently familiar with AAALAC's expectations for the occupational health and safety program that it is often mentioned as a strong element of the animal care and use program.

Findings Corrected by Post Site Visit Communication

At the conclusion of each site visit, the AAALAC International representatives conduct an exit briefing for personnel from the institution. The purpose of this briefing is to provide the institution with a preliminary evaluation based on findings and impressions of the site visitors. Comments and views expressed by site visitors are independent, preliminary opinions and may not necessarily reflect the final peer reviewed judgment of the AAALAC International Council. The exit briefing offers the institution the opportunity to clarify any possible misunderstandings about the program and to provide additional information through post site visit communication (PSVC). In general, issues corrected by PSVC should not be of such significance that they entail significant expense until such time that the formal recommendations from the Council are sent by written correspondence to the institution. Rather, corrections described in the PSVC should focus on those concerns that can be corrected "with the stroke of a pen" or require immediate attention to ensure the health and safety of staff or the animals. The PSVC is considered by the Council during their review of the site visit report and determination of the institution's accreditation status.

Similar to other countries around the world, the function of the IACUC and/or IAEC, with reference to the activities stipulated by the *Guide*, were commonly identified during the exit briefing as incomplete and in need of amplification. Specifically, the conduct of semiannual program reviews and facility inspections had not been fully implemented in some cases. Less frequently, but still noted, the IACUC and/or IAEC had not reviewed and approved standard operating procedures and in a few cases had not established clear, appropriate endpoints for studies impacting animal welfare. These issues were fully addressed by PSVC. Also corrected after the site visit were items such as ensuring that animals were housed in cages in accordance with the space recommendations in the *Guide* and Committee for the Purpose of Control and Supervision on Experiments on Animals (CPCSEA) Guidelines, ensuring daily observations of all animals were performed and documented, ensuring euthanasia procedures conformed with the recommendations of the American Veterinary Medical Association (AVMA) guidelines (AVMA, 2007), and ensuring that environmental enrichment was consistently applied across the animal program. In few cases some refinements to the occupational health and safety program were recommended in the exit

briefing. For example, AAALAC site visitors occasionally noted that waste anesthetic gas was not scavenged properly, or that appropriate personal protective equipment was either not available in certain areas of the facility or not used.

Concerns Expressed to Institutions in AAALAC Correspondence

Of these numerous aspects of an animal care and use program, the three most commonly identified mandatory items requiring correction worldwide are: 1) the occupational health and safety program; 2) the function of the IACUC/IAEC; and 3) the HVAC system performance. In the Pacific Rim region the ranking is different, so that the three most commonly identified program areas requiring correction are: 1) the function of the IACUC; 2) the animal environment; and 3) the veterinary care program. In India over the last decade, issues deemed mandatory items for correction by AAALAC's Council on Accreditation were a blend of those observed globally and more specifically in the Pacific Rim. They included physical plant and equipment maintenance, cage space, sanitation practices, HVAC function, IACUC/IAEC function, daily animal observation, and a comprehensive and coordinated program of veterinary care.

AAALAC's site visit teams also offered several Suggestions for Improvement over the many years of conducting accreditation site visits in India. These included: discontinuing the use of ether as an anesthetic; ensuring fluorescent light fixtures had protective covers; discontinuing the use of picric acid to identify rodents; ensuring the provision of raised resting surfaces for dogs exposed to wet floors after cleaning procedures; ensuring the provision of enrichment to singly housed animals or correcting an inconsistent provision of enrichment to animals across the program; discontinuing inappropriate feed storage practices; implementing a health monitoring program for animals housed long-term; and ensuring a safety evaluation and categorization of test substances, as well as associated procedures for the use and disposal of these substances, to protect personnel. These suggestions typify those offered to institutions throughout the Pacific Rim region.

Conclusions

There are risks to not benchmarking the animal care and use program against those of other institutions, and thereby not working towards harmonizing animal care practices. Public relations problems, increased costs, loss of innovation, and possibly erosion of public and community trust may result when an animal care and use program becomes stagnant. In addition, potential collaborators or clients may look to place their work elsewhere if they determine that the institution does not meet an international level of quality. Thus, institutions should determine the risks of not looking outward with the value gained by learning from others. The AAALAC International accreditation program is a valuable and integral component of any quality assessment benchmarking program because it stimulates an extensive internal review and provides a comprehensive external review. Throughout the process, areas of excellence are highlighted so that these may be perpetuated and shared with others. Further, AAALAC offers for consideration by the institution a path for continuous

improvement within the animal care and use program, with the expectation that both animal welfare and science will benefit. Institutional achievement of AAALAC International accreditation denotes not only that a high standard of animal care and use has been attained and validated, but also that its program is comparable to hundreds of others around the world that have also gained accreditation. In this way, AAALAC has a key role in ensuring high standards and the global harmonization of animal care and use programs and in facilitating the international exchange of reliable research data.

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