

Where science and responsible animal care connect. Fall/Winter 2008

Pacific  
Rim  
Issue!

## Why is global accreditation for animal research important?

Perhaps more than any other segment of society, the scientific community is truly a global one. Every day, thousands of researchers collaborate with colleagues in other countries, and disseminate their findings worldwide.

For scientists all over the world who are engaged in biomedical research, the use of animals continues to play a critical role in their important work. In the last decade, researchers and their organizations have been paying even greater attention to the need for high international standards for animal research. Their desire to find some mechanism for "harmonizing" animal care and research standards from country to country has become a subject of considerable discussion.

AAALAC International continues to gain recognition as a credible means of providing this international standard. AAALAC International accreditation is a performance-based, peer-review program that encourages consistent, high-quality animal care and use in the context of the country's own laws and regulations. Many research programs are discovering that maintaining this highly respected international standard has multiple benefits.

"Since we received AAALAC accreditation we started having many prominent U.S. scientists coming to work in our facility, rather than simply visiting and observing as in the past," said Alex Zhang, President of Wincon TheraCells Biotechnologies Co., Ltd., in China. "We also started to receive direct overseas inquiries about CRO projects. On one occasion, a major pharmaceutical company even signed a service contract with us without visiting the facility—the accreditation in itself was convincing enough. Thirdly, we won a large grant from the Ministry of Science and Technology in China to develop nonhuman primate disease models, partially because we were the first nonhuman primate facility in the country to receive AAALAC accreditation. Overall, I would say that AAALAC accreditation has lent great prestige to our young program and we are grateful."

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aaalac update

AAALAC International is the only international program for animal research that is awarding accreditation based on a **global** standard. For this reason, there are now more than 760 research institutions in 29 countries that have earned AAALAC International accreditation. Many of these institutions note that the international nature of the AAALAC accreditation credential is a tremendous asset, especially when collaborating with institutions in other countries.

"Because science has no borders, AAALAC International accreditation makes tremendous sense, especially for research institutions hoping to partner with scientists in other countries," says Kathryn A. Bayne, M.S., Ph.D., D.V.M., DACLAM, Global Director and Director of Pacific Rim Activities. "Earning AAALAC accreditation provides an assurance that certain quality standards are being met from institution to institution, and from country to country."

*More information on applying for AAALAC International accreditation can be found online at [www.aalac.org](http://www.aalac.org).*

## Accreditation information now online in Chinese, Korean and Japanese languages

AAALAC International's web site, [www.aalac.org](http://www.aalac.org), features information on accreditation in seven languages including Chinese, Korean and Japanese.

Each language includes information on AAALAC International, how to apply for accreditation, the benefits of earning accreditation, and information on AAALAC's Program Status Evaluation service (which is often used as a precursor to applying for AAALAC accreditation).

Visit **[www.aalac.org](http://www.aalac.org)** and click on the language links at the top of the page...

ENGLISH CHINESE FRENCH GERMAN JAPANESE KOREAN SPANISH

**aaalac** INTERNATIONAL Association for Assessment and Accreditation of Laboratory Animal Care International

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**accreditation**  
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# AAALAC International to open Pacific Rim Regional Offices and appoint Regional Directors

In 2007, more than 30 percent of all new applicants for AAALAC International accreditation came from organizations located in the Pacific Rim region. And interest in AAALAC accreditation among Asian research programs continues to rise.

To meet this demand, AAALAC International is restructuring its operations in the Pacific Rim region and planning to establish Regional Directors who will hold direct responsibility for different areas in the Pacific Rim. Initially, AAALAC intends to establish a Regional Director for Southeast Asia and a Regional Director for Korea and Japan. The Regional Directors will represent AAALAC International at a variety of Asian meetings and conferences. The Regional Directors will also play a key role in facilitating and coordinating the planned Pacific Rim Section of AAALAC's Council on Accreditation. In addition, a Japanese Advisory Group has been formed to assist AAALAC in its activities in that country. A similar arrangement is being considered for Korea.

"We are very pleased with the high level of interest in AAALAC accreditation among Asian institutions," says Kathryn A. Bayne, M.S., Ph.D., D.V.M., DACLAM, who currently serves dual roles for AAALAC as Global Director and Director of Pacific

Rim Activities. "I have been honored to work with these institutions over the past several years in my capacity as part-time Director of Pacific Rim Activities. But the current demand from Asia warrants additional personnel to provide the appropriate level of support, and I am very glad that AAALAC will be able to offer expanded services to the Pacific Rim region."

Members of the Pacific Rim Section of the Council on Accreditation will also be named shortly after the new Regional Directors are in place. The Pacific Rim Section of the Council will lead all site visits held throughout Asia, and determine which organizations earn AAALAC accreditation.

"The Pacific Rim Section of the Council will offer outstanding expertise. This group will not only understand the AAALAC accreditation process and the standards necessary to earn accreditation, they will also have a thorough understanding of the research community in Asia and the local and national regulations specific to the countries in this region," says Dr. Bayne.

*Questions and comments can be sent to [kbayne@aaalac.org](mailto:kbayne@aaalac.org)*

## What your colleagues are saying about accreditation...

AAALAC accreditation ensures consistently high levels of health maintenance programs for our animals and animal researchers. **Chugai Research Institute** has a mission to be compassionate to the laboratory animals that are collaborative partners in our research. AAALAC accreditation confirms our respect toward laboratory animals, not merely as research subjects but as living animals that partner with us to provide better medicines. The satisfaction and pride of knowing our care and use of laboratory animals is excellent on a global level will lead us to valuable new drug discoveries. Furthermore, as one of the few pharmaceutical companies in Japan to be accredited, Chugai is a role model for the scientific and humane care and use of lab animals nationwide."

—Masao Koto, D.V.M.  
Executive Director, Chugai Pharmaceutical Co., Ltd.,  
Gotemba, Japan

The **School of Veterinary Medicine, Hokkaido University**, was awarded Full Accreditation from AAALAC International on Oct. 26, 2007. All of our faculty members and students celebrated the accreditation. We are proud of our accreditation and believe it helps citizens understand the ethics of laboratory animal use in our school. We are further convinced that accreditation will help us recruit excellent students who are interested in laboratory animal welfare."

—Takashi Agui, D.V.M., Ph.D., DJCLAM  
Professor, Laboratory Animal Science and  
Medicine, Department of Disease Control  
Graduate School of Veterinary Medicine  
Hokkaido University, Japan



## What is the “AAALAC Standard,” and how is it applied around the world?

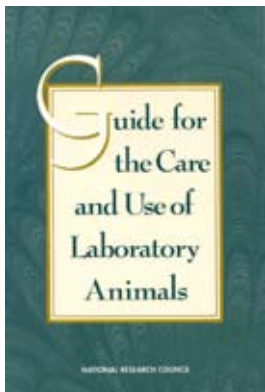
by Kathryn Bayne, M.S., Ph.D., D.V.M.

Global Director and Director of Pacific Rim Activities for AAALAC International

Sometimes people mistakenly believe that AAALAC International creates its own set of standards for evaluating animal care and use programs. Instead, AAALAC applies a combination of existing, science-based standards with a peer-review process to create the “AAALAC standard.” This is the standard that programs around the world must meet in order to earn AAALAC International accreditation.

### Guidelines used

The *Guide for the Care and Use of Laboratory Animals (Guide)*, NRC 1996, is the standard



most widely recognized throughout the global laboratory animal science community, and the *Guide* is the principal standard used by AAALAC International to evaluate animal care and use programs. The *Guide* has benefited greatly from the input of scientists, with its guidance based

on “published data, scientific principles, expert opinion and experience with methods and practices that have proved to be consistent with high-quality, humane animal care and use.”

This scientific support for the *Guide’s* recommendations—from peer-reviewed data to experiential evidence—has undoubtedly contributed to its widespread acceptance by the laboratory animal community. Its usefulness as an international standard is demonstrated by the fact that the *Guide* has been translated into a dozen different languages.

While the *Guide* is AAALAC’s principal resource used to evaluate animal care and use programs all over the world, AAALAC fully recognizes each country’s own laws and regulations and, in its reviews of animal care and use programs, combines the overarching principles of the *Guide* with the country’s legal standards.

While the *Guide* is AAALAC’s principal standard and its provisions and principles are applied world-wide, AAALAC has also developed a list of publications and other documents called “Reference Resources.” These resources are more specific than the *Guide* in a wide variety of areas, and in many cases provide examples of appropriate outcomes. The full list is available at [www.aaalac.org/accreditation/resources.cfm](http://www.aaalac.org/accreditation/resources.cfm).

### The important role of performance standards

Of significant importance is the *Guide’s* reliance on “performance standards.” The *Guide* states that, “Performance standards define an outcome in detail and provide criteria for assessing that outcome, but do not limit the methods by which to achieve that outcome. This performance approach requires professional input and judgment to achieve outcome goals.”

When AAALAC International assesses a program, it examines the way in which the institution uses performance standards, particularly when a protocol or practice deviates from the standards outlined in the *Guide*. The responsibility for maintaining performance standards typically resides with the institution’s animal care and use committee or ethics committee. AAALAC looks to see that the institutional oversight committee has used appropriate review criteria and has an effective review process. It’s important to note that the

same practice may be judged differently at different institutions, depending on the context it is being used within each program. The burden of proof in justifying the use of a practice lies with the institution.

## Applying the AAALAC standard internationally

AAALAC uses members of the Council on Accreditation and ad hoc Consultants/Specialists who are familiar with the local requirements to ensure that those requirements are being followed and applied. Once AAALAC is satisfied that these local baseline requirements are met, the *Guide* becomes the next standard to be applied. 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 animal welfare legislation or regulations, e.g., in the area of occupational health and safety. In such cases, two options are available. First, other local requirements may exist. In the absence of alternative local standards, the *Guide* standards are used as the basis for evaluation in these areas.

## Peer review and professional judgment

Whether or not a program is granted AAALAC International accreditation is determined by the application of expert professional judgment applied through a peer review process. To maintain consistency and uniformity of the AAALAC standard across diverse international settings, AAALAC's Council on Accreditation ensures that all principles of the *Guide* are met.

But, occasionally circumstances do arise for which there is no applicable published standard. And sometimes professional judgments may differ regarding the acceptability of practices or procedures not specifically addressed in existing standards. In these circumstances AAALAC looks to science for solutions. The Council looks for published data in the area in question. When no relevant reports are located, scientific principles and expert opinion form

the basis for resolution, with the final decision often informed by Council members' experience with proven methods or practices.

## The AAALAC International Standard—an evolving product

Thus, the AAALAC International standard is not a static document. In fact, it is not a document at all, but rather a compilation of many existing standards, guidelines and policies that encompass all aspects of an animal care and use program. The majority of these are science based—a fact that leads to the greater likelihood of acceptance and implementation by scientists around the world.

The AAALAC International standard is an evolutionary product. It continues to develop as changing international standards are interpreted through the collective professional judgment of animal care and use experts. Most importantly, the AAALAC International standard is applied through an in-depth, multi-layered, scientific peer-review process that relies heavily on performance standards. •



# Pacific Rim Council Members and Ad hoc Consultants lend their expertise to AAALAC's site visit teams

The AAALAC International accreditation process involves a comprehensive review of an animal care and use program by a team of experts. Site visits are led by members of AAALAC International's Council on Accreditation, which is comprised of some of the best animal care and use professionals and researchers from around the globe. These Council members are assisted by ad hoc Consultants who accompany Council members on site visits and make recommendations to the Council on Accreditation. These Specialists add depth to the site visit team, and understand the intricacies of balancing the research mission with animal well-being. Currently there are four Council members from Pacific Rim countries, one Council Member Emeritus and 25 ad hoc Consultants:

## COUNCIL MEMBERS:

### Montip Gettayacamin, D.V.M.

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### Y. Alex Zhang, Ph.D.

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Hokkaido University, School of Veterinary Medicine  
Sapporo, JAPAN

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### Sang-Seop Han, Ph.D.

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Samsung Biomedical Research Institute  
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**Dae Youn Hwang, Ph.D.**

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**Imelda L. Winoto, D.V.M.**

Head Department, Laboratory Animal Medicine  
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Jakarta, INDONESIA



## Ad hoc Consultants from the Pacific Rim region play a key role in the site visit process

The AAALAC International accreditation process involves a comprehensive review of an animal care and use program by a team of expert colleagues. Site visits are led by a member of AAALAC International's Council on Accreditation. These evaluators are knowledgeable in the fields of laboratory animal science and medicine, and have a deep understanding of national and local legislation.

Earning accreditation helps an institution demonstrate accountability, provide an assurance of quality, show a commitment to continued improvement, and promote animal welfare and scientific validity. Today more than 760 institutions in 29 countries (including nine Pacific Rim countries/territories) have earned AAALAC International accreditation.

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### Who are ad hoc Consultants?

AAALAC International maintains a roster of more than 200 "ad hoc Consultants and Specialists" who accompany Council members on site visits and make recommendations to the Council on Accreditation. Many of these Consultants have expertise in traditional laboratory animal medicine and science. Others have unique discipline competencies, such as applied neuroscience, behavioral science, toxicology, pharmacology or physiology. These Specialists add depth to the site visit team, and understand the intricacies of balancing the research mission with animal well-being. Serving as an ad hoc Consultant is considered one of the best continuing education and professional development opportunities available. In-person and online training are offered to all new ad hoc Consultants prior to participating in their first site visit.

### What are the responsibilities of an ad hoc Consultant?

AAALAC International ad hoc Consultants assist with conducting site visits to institutions applying for or renewing their accreditation. The site visit includes meetings with key personnel and a tour of their facilities. Site visits typically last one or two days depending on the size of the institutional program.

Ad hoc Consultants are responsible for reading background materials about the institution prior to the site visit, then participating in all facets of the site visit. Ad hoc Consultants may also be asked to assist in preparing the written report, which is submitted to the full Council on Accreditation for review. Because the accreditation process is completely confidential, all ad hoc Consultants must sign a confidentiality agreement.

### How do I apply to become an AAALAC International ad hoc Consultant?

To become an ad hoc Consultant, you must complete an application, which is available online at [www.aaalac.org](http://www.aaalac.org). New ad hoc Consultants are elected once a year, and applications should be submitted before 1 February. Completed applications should be e-mailed or faxed to Dr. Kathryn Bayne at AAALAC International, [kbayne@aaalac.org](mailto:kbayne@aaalac.org) or fax +301.696.9626. If you would like to know more about the accreditation process and the work involved, please contact Dr. Kathryn Bayne at [kbayne@aaalac.org](mailto:kbayne@aaalac.org), or visit [http://www.aaalac.org/about/adhoc\\_app.cfm](http://www.aaalac.org/about/adhoc_app.cfm). •



*Thinking about applying for accreditation?*

## AAALAC International's "Program Status Evaluation" provides pre-accreditation assessments

The AAALAC International Program Status Evaluation service is a completely confidential peer review that helps assess the quality of all aspects of your animal research, teaching or testing program, including animal husbandry, veterinary care, institutional policies, and the facilities where animals are housed and used. This review service is available to institutions prior to participating in the AAALAC International accreditation program. In recent years, research institutions throughout Asia have participated in Program Status Evaluations.

The Program Status Evaluation not only promotes the well-being of laboratory animals, it helps validate the results of research using animals. Of note, it can also serve as the first step toward achieving AAALAC International accreditation.

AAALAC International offers Program Status Evaluations to non-accredited institutions that want a "pre-accreditation" site visit. These institutions are sometimes less familiar with the accreditation process and want to find out how their programs compare to AAALAC International standards before engaging in the formal accreditation program, and the results of the Program Status Evaluation are not shared with AAALAC's Council on Accreditation. Indeed, the conduct of a Program Status Evaluation is kept completely confidential.

The Program Status Evaluation service assists institutions in determining if their animal care and use programs meet AAALAC International standards by identifying weaknesses and suggesting ways to

improve or correct them. It also helps familiarize institutions with the AAALAC International accreditation process and encourages them to participate.

AAALAC International's Program Status Evaluation service is available to companies, universities, hospitals, and other research facilities around the world who are not accredited. The Program Status Evaluation includes a comprehensive, on-site evaluation by AAALAC International professionals. A detailed written report with recommendations is provided after the on-site evaluation.

A Program Status Evaluation determines where your program stands in terms of meeting AAALAC International standards. Although a Program Status Evaluation does not guarantee accreditation following any future accreditation site visit, it will give you a sound understanding of the AAALAC International peer-review process and what an accreditation site visit team will be assessing. It will also identify areas that future site visit teams and the Council on Accreditation are likely to note as needing improvement prior to receiving accreditation and validate those aspects of the program that are functioning well.

More information is available on AAALAC International's web site, [www.aaalac.org/programstatus/index.cfm](http://www.aaalac.org/programstatus/index.cfm), or by contacting Dr. Kathryn Bayne, Global Director and Director of Pacific Rim Activities for AAALAC International, at [kbayne@aaalac.org](mailto:kbayne@aaalac.org).



## AAALAC-Accredited Organizations in the Pacific Rim:

- Advinus Therapeutics Pvt Ltd.  
India
- Astellas Pharma Inc.  
Kashima Facilities  
Japan
- BioLASCO Taiwan Co., Ltd.  
Yi-Lan Breeding Center  
Taiwan/R.O.C.
- Biototech Co. Ltd.  
Korea
- Bridge Pharmaceuticals  
Vital Bridge (China) Inc.  
P.R. China
- Chinese Academy of Medical Sciences  
& Peking Union Medical College  
Institute of Laboratory Animal Science  
P.R. China
- Chugai Pharmaceutical Co., Ltd.  
Japan
- Crown Bioscience (Beijing) Inc.  
P.R.China
- Development Center for Biotechnology  
Taiwan/R.O.C.
- Fuji Biomedix Co., Ltd.  
Kobuchisawa Research Laboratories  
Japan
- Hokkaido University  
School of Veterinary Medicine  
Japan
- HAMRI Co., Ltd.  
Testing and Research Laboratories  
Japan
- INA Research Inc.  
Testing Facility  
Japan
- INA Research Philippines  
INARP-LTI and Primate Quality Control Center  
Philippines
- Korea Food and Drug Administration  
Korea
- Korea Institute of Toxicology  
Korea
- Level Biotechnology Inc.  
Taiwan/R.O.C.
- Maccine Pte Ltd.  
Singapore
- Maccine Pte Ltd  
PT Mac Fauna  
Indonesia
- Merck & Co., Inc.  
Banyu Pharmaceutical Co., Ltd.  
Japan
- Model Animal Research Center  
of Nanjing University  
P.R. China
- National Applied Research Laboratories  
National Laboratory Animal Center  
Taiwan/R.O.C.
- National Center for Safety  
Evaluation of Drugs  
National Institute for the Control of Pharmaceutical  
and Biological Products  
P.R. China
- National Chengdu Center for  
Safety Evaluation of Drugs/  
WestChina-Frontier Pharmatech Co.  
P.R. China

- National Defense Medical Center  
NDMC-Laboratory Animal Center  
Taiwan/R.O.C.
- Naval Medical Research Center  
U.S. Naval Medical Research Unit No. 2  
(NAMRU-2)  
Indonesia
- National Shanghai Center for New Drug Safety  
Evaluation Research  
P.R. China
- Peking University, Institute of Molecular Medicine  
P.R. China
- Primate Research Center  
at Bogor Agricultural University  
Research Animal Facility  
Indonesia
- Samsung Biomedical Research Institute  
Samsung Medical Center  
Korea
- Seoul National University Hospital  
Clinical Research Institute  
Korea
- Shenyang Research Institute of Chemical Industry  
Safety Evaluation Center  
P.R. China
- SICONBREC, Inc.  
Philippines
- Singapore Health Services, Singapore General  
Hospital, Department of Experimental Surgery  
Singapore
- Sungkyunkwan University School of Medicine  
Korea
- The University of Hong Kong  
Laboratory Animal Unit  
Li Ka Shing Faculty of Medicine  
P.R. China
- Walter Reed Army Institute of Research  
U.S. Army Medical Component-Armed Forces  
Research Institute of Medical Sciences  
Thailand
- Wincon TheraCells Biotechnologies Co., Ltd.  
P.R. China
- Yonsei University, College of Medicine  
Korea



AAALAC International offers **the only international accreditation for animal research, testing and teaching programs**. When you seek AAALAC accreditation, your program receives a confidential, expert peer-review evaluation designed to help your institution promote animal welfare, ensure scientific validity, and provide quality assurance. These evaluations are led by

professionals who are based in the Pacific Rim and understand your institution's culture and mission. Join the 760+ institutions in 29 countries that have earned AAALAC International accreditation and **demonstrate your commitment to meeting high international standards** for animal care and research.

New AAALAC International Pacific Rim Regional Offices to open in 2008 / 2009. Visit [www.aaalac.org](http://www.aaalac.org) for updates.

Over the past three years, **more than 30%** of all new applications for AAALAC International accreditation have come from institutions throughout Asia.

Learn more about the benefits of earning AAALAC International accreditation at [www.aaalac.org](http://www.aaalac.org).

## ASSOCIATION FOR ASSESSMENT AND ACCREDITATION OF LABORATORY ANIMAL CARE INTERNATIONAL

Established in 1965, AAALAC International is a private, non-governmental organization that validates the quality of animal care and use programs and verifies that they meet or exceed national and international standards. AAALAC International's voluntary, confidential, peer-review accreditation process serves as a valuable adjunct to other quality initiatives and legislation, and is the only international accreditation for animal care and use programs.

Institutions seeking AAALAC International accreditation receive a comprehensive review by an international team of expert evaluators who are knowledgeable in the fields of laboratory animal science and medicine, as well as national and local legislation. Institutions that meet or exceed applicable standards are awarded accreditation—a symbol of quality assurance recognized around the world. More than 760 institutions in 29 countries, including nine Pacific Rim countries/territories, have earned AAALAC accreditation. More information is available on AAALAC International's Web site at [www.aaalac.org](http://www.aaalac.org).



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