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Association for Assessment and Accreditation of Laboratory Animal Care International

Protocol review ... How is your IACUC doing?

Protocol review is a critical responsibility of the IACUC (Institutional Animal Care and Use Committee). But according to AAALAC International evaluators, it's an area where deficiencies continue to be found.

From insufficient written protocols to confusing review processes, deficiencies in protocols and protocol review continue to be cited during AAALAC evaluations. This article will examine some recurring protocol problems, and offer some opinions on ways to address them.*

The written protocol

Good protocol review relies on thorough, well-written documents. The *Guide for the Care and Use of Laboratory Animals* (*Guide*, NRC 1996) includes a list of items to consider in preparing protocols. *(See page 10 of the Guide.)* The list includes a rationale for using animals, justification of animal numbers, experience of personnel, appropriate sedation, analgesia, and anesthesia and the safety of the working environment.

But AAALAC Council members and other laboratory animal professionals note that sometimes, the basic information isn't there, or there isn't sufficient detail presented to allow for a thorough review of the protocol.

Forms that function

In some cases, a poorly designed protocol form could be the reason why information is vague or missing. Good forms ask all the right questions and probe for specific details.

"A protocol needs to address the three Rs—reduction, replacement and refinement. If the protocol doesn't ask these questions, it's missed the boat," says Jerald Silverman, D.V.M., assistant vice president for laboratory animal resources at MCP Hahnemann University in Philadelphia, Pa. Silverman is also the column coordinator for *Lab Animal's* "Protocol Review" column, and co-editor of *The IACUC Handbook* (CRC Press 2000).

For example, rather than simply asking if anesthesia will be used, the form should ask for details such as what agent will be used, the dose, and how it will be administered.

"Protocols should be complete documents in themselves," adds Marilyn J. Brown, D.V.M., M.S., director of the animal care and use program at

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** Please note that the opinions and suggestions expressed in this article are not official AAALAC International positions. Our aim is to present a variety of views on this issue and help readers reconsider and evaluate their own protocol review processes.*

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Dartmouth Medical College and former member of AAALAC's Council on Accreditation.

Brown believes that with the aid of computers, it's not unreasonable to ask investigators to include a lot of information in their protocols, and that the questions on the forms should help prompt detailed answers.

Molly Greene, the IACUC coordinator at the University of Texas Health Science Center at San Antonio, concurs. "Instead of asking the principal investigator to 'describe the post-op procedures,' ask for specifics, such as 'How will post-op pain and distress be monitored?' 'How will such pain and distress be alleviated?' 'What pharmacologic and non-pharmacologic agents will be used?' 'Who will provide the post-op care?' 'How long will the patient be monitored?' and 'What arrangements have been made for after hours care and monitoring?" Greene says.

Greene notes that some investigators also have trouble writing a nontechnical summary of their research. IACUCs should encourage investigators to use common language and define all abbreviations—so that anyone reading the protocol can get a basic understanding of the proposed research.

Detail on experience and training

The *Guide* states that protocol review should consider the "adequacy of training and experience of personnel in the procedures used." It's not enough for an investigator to simply say they have experience.

"The IACUC should require adequate records on the experience and training investigators have in the procedures," says Silverman.

This includes everyone involved in the research—not just the principal investigator.

"You need to know *everyone* who is involved and their role. Without this information, it's difficult for the IACUC to assess their training and qualifications. It's also hard to do a risk assessment for occupational health and safety if you don't know who's involved or what they are doing," Brown says.

> "The IACUC should require adequate records on the experience and training investigators have in the procedures."

At Dartmouth College, Brown and her team ask that a "personnel appendix" for each person involved in a project be attached to the protocol. The appendix details each person's background and specific qualifications to perform their role.

At the University of California, Berkeley, IACUC chair Richard C. Van Sluyters, O.D., Ph.D., a professor in the School of Optometry, Faculty Assistant to the Vice Chancellor for Research, and an AAALAC Council member, reports that the Berkeley IACUC uses a table to display the names and qualifications of everyone involved in a protocol.

"It's no good for someone to simply say, 'I'm going to do this, I've done it lots of times and I'm good at it,'" Van Sluyters says.

The use of a table or some other type of chart is a quick way to communicate qualifications to the IACUC. The one used at Berkeley asks each person to list every procedure they will be performing and on which species each will be performed. They must indicate how they were trained to perform the procedure (hands-on assistance, direct supervision, coursework), who trained them (veterinarian, faculty supervisor, laboratory technician, postdoctoral fellow, graduate student), and how much experience they have had performing it (for example, three years, 50 animals).

Justification of animal numbers

Animal welfare regulations require that investigators justify the number of animals to be used. But AAALAC Council members say that they see protocols that don't provide adequate rationale for the numbers proposed.

"Some people base their numbers on pure arithmetic," Silverman says. "But you've got to explain where you got the numbers in the first place, perhaps looking closely at related published literature."

Reports by AAALAC International evaluators also show this as a common deficiency. According to Van Sluyters, it's even more problematic for people using transgenic animals.

"It's tougher to justify animal numbers when you're working with transgenics because there are a lot more unknowns. People tend to boost their numbers to cover all contingencies," Van Sluyters says. He adds that with a bit of effort, experienced professionals can usually provide a realistic estimate of the maximum number of animals required to establish and/or maintain a typical transgenic line in their colony. From this, they should be able to project a number not to be exceeded for their entire project.

"If they err and additional animals are required, it should be possible for the IACUC to grant the increase expeditiously, if the Chair is unable

to do so administratively," Van Sluyters says.

The justification for animal numbers should be thoroughly supported by current resources. Information collected during conferences, from journal articles, and through database searches can help provide statistical justifications and sound rationale for the number of animals used.

Detail on what's happening to the animals

Another area that can lack sufficient information is the explanation of what will happen to the animals during the course of the research. Brown notes that this detail can be the key to ensuring animal well-being and evaluating the qualifications of people involved in the protocol.

"For example, if we see a protocol that says the investigator is going to use an 18 gauge needle to inject a mouse, you know this person has never worked with mice before," Brown says. In this case, the details point toward the need for additional training prior to the procedure.

The protocol should clearly communicate what will happen to the animals during *and after* procedures. This includes an adequate description of post-procedural care and monitoring (including the use of analgesics if necessary), any unusual husbandry and housing requirements, and methods of euthanasia (if applicable).

Covering all animals

All animals should be covered by a protocol or Standard Operating Procedure (SOP).

"This includes animals that are being used for teaching and/or training purposes," adds Van Sluyters. "It also includes sentinel animals being used by the veterinarian to monitor diseases, or animals being used by the central animal care unit to make antibodies for investigators."

> The protocol should clearly communicate what will happen to the animals during and after procedures.

Van Sluyters notes that occasionally, veterinarians will forget that their own animals have to be on protocols too.

"One way to address this is to create a generic protocol that covers all the animals the veterinary care unit needs," Van Sluyters says. "This isn't to suggest that you need a protocol to provide routine clinical care. But every animal used for breeding, surveillance or in any type of research, training or teaching should be on an IACUC-approved protocol or SOP."

Precautions for people

The *Guide* says that protocols and reviews should also address the safety of the working environment. The written protocol should prompt investigators to explain potential occupational health and safety issues, including the use of any hazardous agents and how they will be handled. *(For more information on occupational health and safety issues, please refer to the Spring 1998 issue of Connection for an article, "Assessing the health of your occupational health and safety program.")*

Addressing the search for alternatives

The U.S. Department of Agriculture's (USDA) "Policy 12" asks investigators using covered species to provide assurance that steps will be taken to minimize pain and distress. Like the Animal Welfare Regulations, the policy states that proposed animal activities must include: a rationale for using animals, the appropriateness of the species, and the number of animals to be used; a description of procedures to assure that discomfort or pain will be limited and a description of drugs to be used to

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minimize pain; a written narrative description of the methods or sources used to consider alternatives; and the written assurance that the activities do not unnecessarily duplicate previous experiments.

In April 2000, the USDA released a survey of its 40 animal care inspectors and nine field officers on the effectiveness of IACUC regulations. *(The complete survey can be found online at www.aphis.usda.gov/ac/iacucaugust.pdf.)* Respondents ranked "search for alternatives" as one of the biggest problems facing the facilities they inspect. The survey estimates that 600 to 800 facilities were reported to have trouble with this issue at some point.

This difficulty may stem from the requirement for a "consideration of alternatives," which continues to be misunderstood by some investigators and IACUCs, notes Dr. Nelson L. Garnett, director of the Office of Laboratory Animal Welfare at the National Institutes of Health (NIH).

"Although most protocol review forms address the question, some answers still reflect the belief that the term 'alternative' only refers to non-animal systems," Garnett says. In fact, Garnett adds, all measures taken to "limit pain and distress to that which is unavoidable" should be included in the alternative category.

"I believe that investigators and IACUCs should recognize and take credit for the 'refinement' alternatives that they routinely apply in the course of good study design and program oversight," Garnett says.

Another part of the policy that has posed challenges is the requirement to include a written narrative which describes the methods or sources used to consider alternatives.

"People continue to struggle with Policy 12's search for alternatives," says Van Sluyters. His IACUC at U.C. Berkeley now applies Policy 12 to all animals, including rats, mice and birds in anticipation that they may become covered under the Animal Welfare Act.

"We have some issues about just doing a computer search," Van Sluyters says. "Realistically, by the time new information makes it into a database, it's already old news. I think attending conferences, journal reading, serving on grant panels, reviewing manuscripts and interacting with colleagues are the ways many active researchers actually stay current."

This approach to addressing the search for alternatives is acceptable according to the revised version of Policy 12 (published June 21, 2000) which includes ways to gather information beyond a literature search. The policy states that the USDA believes a database search is the most effective and efficient way to demonstrate compliance with the requirement. However, the revised policy acknowledges that "in some circumstances (as in highly specialized fields of study), conferences, colloquia, subject expert consultants, or other sources may provide relevant and up-to-date information regarding alternatives, in lieu of, or in addition to, a database search."

The key is for investigators to address how they will reduce or refine their use of animals. They must also show that there are no applicable non-animal alternatives, and that they are not unnecessarily duplicating previous experiments. It's up to the investigator to determine the best way to justify these things—whether it's through a literature search or other means—and it's up to the IACUC to see that adequate information is provided on the protocol form so that the committee can determine whether Policy 12 has been satisfactorily addressed.

Effective review systems

Developing well-written and thorough protocols is the first step in an appropriate animal use program. The second is to create an effective process for *reviewing* those protocols.

"The language in the PHS Policy and USDA regulations is relatively specific and inflexible with regard to the review and approval process," Garnett says. "It's important to interpret that language rather literally as it relates to procedure and sequence."

The Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (PHS Policy, Reprinted October 2000), states that prior to review, each member of the IACUC must be given a list of proposed research projects to be considered. Any member of the IACUC can call for a full committee review of any of these projects.

The Policy then says that, "If full committee review is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, shall review those research projects and have the authority to approve, require modifications in (to secure approval) or request full committee review of those research projects. If full committee review is requested, approval of those research projects may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present."

Garnett feels that the smart strategy is to keep the review system as simple and consistent as possible, and to put an emphasis on pre-review screening to help the investigator produce an approvable proposal.

"Pre-review" and multilevel systems

As Garnett notes, one way to ensure a thorough review process it to use a pre-review or multilevel system that allows for questions and changes to be made to the protocol *before* its final review.

Van Sluyters agrees. "To be most effective, I feel you need a multi-tiered system. This lets you have the appropriate talent and expertise at each level to make sure the final product is good."

U.C. Berkeley employs a three-tiered approach to protocol review. The first level is an administrative review performed independently by the IACUC staff and a veterinarian or animal technician. Answers to any questions raised here are obtained before the second level of review, which is by a member of the IACUC who is also a faculty scientist. This person serves as the "primary reviewer," and looks at procedures and animal numbers, and checks to see that the protocol makes sense from both a scientific and an animal welfare perspective.

"If done correctly, a number of questions should be generated and answered between each level of review," Van Sluyters says.

The final level is an interactive, oral presentation of the protocol in front of the U.C. Berkeley IACUC committee. At this point, the protocol is usually approvable.

"When animal rights activists were giving Berkeley a lot of trouble, they said the IACUC must not be doing its job because it approved almost every protocol," Van Sluyters notes. But the number of protocols approved at Berkeley IACUC meetings is a result of the effectiveness of their pre-review system.

"I think it's a failure of our IACUC if we *fail* to approve a protocol—because protocols that aren't approvable with only minor modifications should never make it to the full meeting," Van Sluyters adds.

> … one way to ensure a thorough review process it to use a pre-review or multilevel system that allows for questions and changes to be made to the protocol before its final review.

Allowing enough time for review

By simply building ample review time into the process, IACUCs can greatly improve the quality of their review system. While unexpected grant deadlines and other emergencies will periodically require an expedited review, the regular review system should strive to include enough time to accommodate busy schedules.

On the flip side of this issue, Molly Greene warns that some IACUCs expend *too much* time and energy on protocol review at the expense of other responsibilities.

"An IACUC must consider more than 20 items when reviewing protocols, from the qualifications of the research personnel to the final disposition of the animal," Greene says. "While many of these items can be considered in a pre-review before the IACUC meeting, some IACUCs conduct the *complete* review when the full committee meets, making for fairly long meetings. This is further complicated for institutions that perform a full committee review of *all* protocols. Meetings can be so long that members leave before all the business has been concluded. Or, by the time protocol review is finished, the members are so anxious to get out that they rush through other topics or postpone them until the

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A special thanks to those who contributed to this article:

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Jerald Silverman, D.V.M., assistant vice president for laboratory animal resources at MCP Hahnemann University, column coordinator for *Lab Animal* magazine's "Protocol Review" column, and coeditor of *The IACUC Handbook* (CRC Press 2000).

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next meeting."

Greene notes that this can be prevented if the IACUC considers a meeting agenda in which all other IACUC responsibilities are discussed before protocol review, or a system that uses a designated member review for some protocols.

Setting clear criteria for the review process

IACUCs can encounter difficulties when members aren't clear about how the review process works. Writing down the criteria and the exact procedures for reviewing protocols helps eliminate confusion and makes sure everyone understands the system.

"Some institutions have unnecessary complexity in their review procedures," Garnett says. "Although usually well-intended, such procedures can result in IACUC and investigator confusion—and potential noncompliance."

Garnett adds that the use of ambiguous categories of approval, such as "provisional" or "conditional," can also lead to confusion about whether or not a project can start. Garnett also advises having a system in place for revising protocols in case of adverse events or emergencies.

Brown agrees. "It's important that the formal membership of the IACUC be aware of the criteria for reviewing and approving protocols. A clear set of guidelines should be established," Brown says. Her institution developed a written SOP that describes exactly how the IACUC will review and approve protocols.

The need for strong committee members

For the review process to work well, the IACUC needs to have members who are not afraid to be inquisitive and assertive.

"In the protocol review process, IACUC members must be willing to ask the difficult questions and not routinely defer to unsubstantiated assertions of P.I.s, or to the more outspoken individuals on the IACUC," Garnett says. "This can be especially difficult for nonaffiliated and nonscientist members who may be feeling somewhat insecure to start with."

"You want people who are willing to speak up and take a stand," Silverman adds. He also notes the critical role of the committee chair in making sure reviews are thorough. "The chair has to have the courage to *require* reviews for substantial changes in protocols."

In recruiting new members, IACUCs will be well-served by looking for candidates who will raise questions and red flags, and be diligent throughout the review process.

> "Some institutions have unnecessary complexity in their review procedures."

Using the designated reviewer system

Is it best to have the full IACUC review and approve *every* protocol? When is it acceptable to use a designated system? Is it possible to design a process that incorporates the best of both?

PHS Policy states that "if a full committee review is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, shall review those research projects and have the authority to approve, require modifications in (to secure approval) or request full committee review of those research projects."

Greene believes that many IACUCs experience trouble because they insist that *all* protocols be reviewed at a convened meeting of a quorum of the IACUC. She feels IACUCs should take full advantage of the designated member review option allowed under both PHS and USDA requirements, reserving review by the full committee for invasive studies and those protocols not subject to peer review by other scientists.

At the same time, Garnett warns that mixing elements of the 'designated reviewer' and the 'full committee review' modes can sometimes result in procedures that fail to satisfy the requirements of either.

Silverman has a personal preference for the standard system. "I think discussing protocols face to face enhances the review process," Silverman says.

Still others feel that it's fine to use a designated review, particularly for protocols that are repeated over and over, such as those used in many contract research laboratories.

Brown believes designated review is appropriate in certain circumstances, but that the IACUC needs to understand what those circumstances are.

"A clear set of guidelines has to be understood. IACUC members need

to know what kinds of protocols can be reviewed by designated reviewers," Brown says. For example, institutions may choose to categorize protocols by anticipated pain levels, automatically excluding those at a certain level of pain from the designated review system.

At Dartmouth College, they perform some designated reviews, particularly for contract laboratory work and training protocols. There can also be designated review of an investigator's response to IACUC concerns. She notes that any IACUC member can ask the chair to be appointed the designated reviewer on revisions of a particular protocol, and, because this is noted in the IACUC minutes, *all members* are aware of who has authority to approve revisions on protocols that are reviewed by designated individuals.

Van Sluyters agrees that the designated review has its place at some institutions. He adds however, that it may not work well for institutions that do a wide variety of research. He notes that they rarely use designated reviews at U.C. Berkeley. Instead, the agenda for their meetings includes a category, "Standard Review Protocols," reserved for protocols that conform completely to guidelines previously approved (and annually reviewed) by the IACUC. These involve minimal manipulation of animals (such as euthanasia for tissue and antibody production). Copies of the protocols are available to every member prior to the meeting and any member can call for one or more to be individually discussed. Otherwise, they are voted on in a block.

It's important to note that there are no regulations that say certain types of protocols shouldn't be reviewed using a designated reviewer system. The only instance in which the regulations require a full committee review is if a member has requested it. So it's up to each committee to decide what type of system will work best for their institution. And no matter what system is used, *all* members need to understand the process and be willing to speak up if they have a concern about a particular protocol.

Mechanisms for monitoring protocols

Just as important as a well-written protocol and a thorough review process is a good animal use monitoring system. Monitoring allows the IACUC to make sure the protocols are being carried out as approved.

This is another area that may often be a problem for IACUCs. In the recent USDA survey of its inspectors, respondents were asked to rank the effectiveness of IACUCs in a number of areas. The lowest ranking score (an average of 2.7 on a 1 to 5 scale) was given to "monitoring protocols."

There are, however, things that IACUCs can do to improve protocol monitoring ….

> "Talking with people in the labs also lets them communicate their concerns back to the IACUC—it creates a give and take discussion."

The semiannual review

IACUCs are required to conduct semiannual reviews of animal study and housing areas. With the right planning and attention to detail, these inspections can yield a tremendous amount of information.

Providing IACUC members with checklists, worksheets and the necessary details to take along with them on their reviews helps members do a better job comparing what is in the protocol to what is actually happening in the lab. Observing animal activity and visiting the investigators' labs also ensures a more thorough review.

"We give our IACUC members a table listing the details of every research project," Brown says. "We

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- ✔ *The IACUC Handbook*, Jerald Silverman, Mark A. Suckow, Sreekant Murthy, CRC Press, April 2000. $59.95. Visit www.crcpress.com to order.
- ✔ *The IACUC Guidebook*. Visit http://grants.nih.gov/grants/olaw/olaw.htm.
- ✔ AALAS' www.iacuc.org
- ✔ "IACUC 101" seminar periodically offered by ARENA (Applied Research Ethics National Committee). Visit www.arena.org for more information.
- ✔ *Lab Animal* magazine's "IACUC Resource Page" at www.labanimal.com/iacuc/iacuc.htm
- ✔ SCAW's "IACUC Talk" list server. Visit www.scaw.com for more information.

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also give them a worksheet with a list of questions that helps them be really thorough in their assessment."

The worksheet Brown uses at Dartmouth includes detailed questions that the reviewers pose to the people they see in the labs. Questions include, "How do you prepare the animals for surgery?" "Have you seen the protocol?" "Have you been enrolled in the occupational health and safety program?"

Answers from the people performing the day-to-day work help determine if the protocol is being followed. It also shows how well things are being communicated throughout the different levels of research staff.

"Talking with people in the labs also lets them communicate their concerns back to the IACUC—it creates a give and take discussion," Brown adds. "And if they voice a concern, we make every effort possible to follow up with them."

Aside from semiannual reviews, an IACUC may choose to periodically select a few protocols at random and make unannounced visits. Greene notes that this is one monitoring method she's seen work well for IACUCs.

Record keeping and record review

Aside from laboratory visits, the records that investigators are required to keep can also reveal if protocols are being followed as approved.

"You can learn a lot about protocol compliance by reviewing the records associated with it," Van Sluyters says. He feels that the best protocol monitoring systems include a combination of laboratory visits, checking to see that records are being kept (special husbandry/diet logs, daily health checks, surgery/post-surgery, special monitoring), and reviewing those records at least semiannually.

If records are not being kept, or if they look different than what was written in the original protocol, it allows the IACUC to flag that protocol for a more thorough review. The process also gives the IACUC an opportunity to catch common warning signs, such as sudden changes in animal usage (jumps in numbers or unexpected deaths) that can signal problems.

> "It's important to develop a good relationship with animal care staff so if something looks unusual, they feel comfortable alerting the IACUC."

Comparing protocols to grant applications

Protocols that support specific PHS-funded grants must accurately reflect the research proposed in the grant application. But sometimes the two don't match.

"It's uncommon for a protocol to be reviewed and approved without change. So sometimes there's a disconnect between what is written in a grant and what is written in the final protocol that is approved by the IACUC," Van Sluyters says.

Silverman notes that his institution started comparing grant applications and protocols about seven years ago.

"When we first started, about 50 percent of the grants were different from the IACUC-approved protocols," Silverman says. Today, he says, the IACUC works with investigators to make sure there is congruency between the two. Van Sluyters notes that as part of the review process, the IACUC staff at Berkeley compare protocols to grant applications to make sure they match.

The fact is, there are no federal or other external requirements for the IACUC to review actual PHS grant proposals. It is an area, however, in which institutions may wish to evaluate their existing procedures for assuring that what a funding agency approved is actually what is taking place. This must include notification to NIH Study Sections when significant changes are made to animal protocols associated with PHS grant applications.

Encouraging feedback from animal care and use staff

One of the most effective monitoring tools an IACUC can develop is a good relationship with the animal care staff.

"It's important to develop a good relationship with animal care staff so if something looks unusual, they feel comfortable alerting the IACUC," Brown says. "This is one of the stronger arguments for having a centralized animal care program. Research staff are not unbiased, but caretakers are—their primary concern is the animals."

Animal care staff should be trained to be observant, ask questions of the research staff as necessary, and report their concerns to the appropriate people in the organization.

Monitoring animal procedures

As explained earlier, it's important for the written protocol to include adequate information on the qualifications of the people performing procedures described in the protocol. It can also be helpful to monitor the actual procedures to ensure that the researchers have sufficient expertise.

The IACUC at U.C. Berkeley has a policy of having a veterinary staff member sit in on the first animal procedure performed by every new member of the faculty and their research staff.

"No matter where new faculty members are from or their background, they must schedule their first procedures with a vet," Van Sluyters says. "It's not confrontational, we just make it a condition of approval of their first protocols. In addition to ensuring that the levels of skill and experience are adequate, it also gives the veterinarians a chance to get to know new investigators and *vice versa*. The veterinary staff member then reports back to the IACUC on the outcome of the visit and this becomes a part of the record for that investigator."

Training new members

On-the job

Protocol review training for new IACUC members ranges from formal to very informal, depending on the institution. Many learn on-the-job, sitting in on IACUC meetings and observing the review and approval process firsthand.

"But if your institution isn't discussing protocols at meetings, it's very difficult for new members to learn what to look for," Brown says. "Our new members sit in on a couple of meetings before they start reviewing protocols for the committee."

Brown adds that institutions that use primary and secondary reviewers can have new members serve as secondary reviewers until they are completely comfortable with the process.

Orientation

Some IACUCs use a formal orientation program for new members that includes a detailed discussion on protocol review. These orientations range from one-on-one meetings with a current IACUC member or the IACUC coordinator, to a series of classroom-type training sessions or meetings held by outside organizations, such as ARENA's "IACUC 101" seminar.

Others provide written IACUC manuals to new members. These materials often contain specific instructions on how the protocol review and approval process works. Copies of relevant rules, regulations, and guidelines are included as well.

Training during IACUC meetings

Along with training new members, it's also helpful to provide ongoing or refresher training for current members on protocol review and other relevant topics.

"Try to devote part of each meeting to training," suggests Van Sluyters. His IACUC uses time during each meeting to provide some type of ongoing training in areas ranging from the protocol review process, to IACUC responsibilities, to changes in rules and regulations. Members are encouraged to bring and share articles and other current resources that are likely to be of interest to committee members.

There are many ways to make sure new IACUC members are well-trained in protocol review. The key is to design some type of program—whether it's on-the-job, formal training or a combination of both—that works well for your institution.

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Not every suggestion in this article is right for every institution. And there are many additional ways to effectively address the problem areas highlighted here. The bottom line is to be aware of the common deficiencies found in protocols and protocol review systems. Then make sure your IACUC is as detailed and as diligent as necessary in creating a system that serves the unique needs of your institution, conforms with the regulations, and follows the intent of the Guide *to provide proper oversight of the care and use of laboratory animals.* ❑

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Now you can search for accredited institutions by name, type, city, state, or country. Visit the new directory page on the AAALAC Web site to perform a search or get a complete list of all AAALAC accredited organizations. Visit www.aaalac.org and click on "Accredited Organizations."

Applying AAALAC standards internationally

How does accreditation work in my country?

Is the process the same?

Yes. The steps in applying for and maintaining AAALAC accreditation are the same throughout the world.

1. First you must complete an application and an extensive "Program Description" which describes all aspects of your animal care and use program. (This is the main document AAALAC evaluators will use to review your program. It can be written in the language of your choice.)

2. Next you'll be assigned a site visit team made up of reviewers who are expert in animal care and use, as well as the specific areas of research performed at your institution, and are knowledgeable in your country's laws, regulations and policies.

3. The structure of the site visit is the same from country to country. At the beginning of the visit, the team meets with you and other institutional representatives to go over your Program Description. Next they take an extensive tour of your facility. After the tour, the team might request additional information or documentation. At the end of the visit, the team conducts an "exit briefing" where they share their initial impressions of your program.

4. Next the team prepares their final site-visit report to submit to the Council on Accreditation. In between the time when you have your site visit and AAALAC's Council on Accreditation meets to determine your accreditation status, you will have an opportunity to respond to any concerns raised during the exit briefing through "post site visit communication." The Council will consider this correspondence when it meets to review your report. A letter explaining your accreditation status will subsequently be mailed to you.

For more details on the accreditation process, visit www.aaalac.org, or contact kbayne@aaalac.org.

What standards does AAALAC apply?

AAALAC relies on "performance standards" to evaluate animal care and use programs. Performance standards look at the outcome that's achieved (for example, the overall health and well-being of the animals). While "technical" or "engineering standards" (such as cage size) vary slightly from country to country, performance standards are remarkably similar.

In the United States, AAALAC reviewers use the *Guide for the Care and Use of Laboratory Animals* (NRC 1996) as a baseline for both technical and performance standards, along with local and national regulations for animal research. Outside the United States, AAALAC uses the *Guide* as the benchmark for evaluating performance standards—but not necessarily for technical standards.

For an institution to earn accreditation, it must meet the intent of the *Guide* for achieving

optimum performance standards for animal well-being and operate a high quality animal care and use program. It's acceptable for technical standards to differ, as long as they comply with local laws and requirements.

"When AAALAC evaluates a program outside of the United States, we're looking to see if it meets the general principles for performance that are outlined in the *Guide*," says Christine M. Parks, D.V.M., Ph.D., director, RARC, University of Wisconsin-Madison and a member of AAALAC's Council on Accreditation.

"It's really applying performance standards to the nth-degree—we're *not* trying to force people to do things the U.S. way," says Parks who has led site visits in Peru, the Philippines, France, Belgium and Switzerland.

Bradford S. Goodwin, Jr., D.V.M., executive director for the Center for Laboratory Animal Medicine and Care at the University of Texas Houston Health Science Center, concurs. "We look to see how the *Guide* applies to their program. We're not trying to impose U.S. standards," says Goodwin, a Council member who has led AAALAC site visits in Korea and Denmark.

Are there areas that commonly fall short of AAALAC standards?

Although every program is unique, there are two areas that are commonly cited as not meeting the performance standards needed for AAALAC accreditation. Institutions inside *and* outside the United States tend to experience the most trouble in these two areas.

Oversight

AAALAC reviewers look to see that there is proper oversight of the animal care and use program. In the United States, this function is performed by an IACUC (Institutional Animal Care and Use Committee). Under U.S. law, IACUCs are assigned specific responsibilities and are required to perform a very specific set of oversight activities.

In other countries it's not necessary to have the exact equivalent of an IACUC to earn accreditation. But it is necessary to make sure that effective systems for oversight are in place to monitor all aspects of the animal care and use program.

"Some countries use 'ethics committees' that perform functions similar to a U.S. IACUC," Parks says. "In other countries, there might be several different entities that are, in sum, fulfilling the role an IACUC and the intent of the *Guide*. We look at the total picture of what an institution is doing, and recognize that there are many ways to reach a good outcome."

Occupational health and safety

Many countries, including the United States, emphasize the importance of a comprehensive occupational health and safety program. In other countries, this aspect of an overall program may receive significantly less attention.

"Though AAALAC doesn't impose the U.S. standards for an occupational health and safety program on other countries, we do recognize that a prime concern of any animal program is to make sure no people are harmed," Parks says. "We look at what the institution is doing and what mechanisms for health and safety are already in place, then identify critical gaps. We don't go in and suggest that they build a U.S.-style program."

> "When AAALAC evaluates a program outside of the United States, we're looking to see if a program meets the general principals for performance that are outlined in the Guide."

Are there special considerations for non-U.S. institutions?

Choosing a Program Status Evaluation

Some institutions, particularly those outside the United States, opt to undergo a "Program Status Evaluation" (PSE), before applying for accreditation. The PSE follows the same process as the accreditation program, except the evaluation team's report is not forwarded to the Council on Accreditation for review. Instead, this comprehensive report (which includes the evaluation team's findings and recommendations) is sent directly to the institution. A PSE familiarizes institutions with the accreditation process, provides a thorough evaluation, and offers advice on how to address any deficiencies identified in the program.

Language barriers

Another consideration is potential language barriers, and subtle differences in meaning or interpretation. AAALAC tries to assign a reviewer from the institution's country to the site visit team, but this is not always possible. In these instances, it can be helpful

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How does accreditation work in my country?

for the institution to enlist the assistance of a bilingual person who is familiar with laboratory animal care and use and can act as a translator.

"During one overseas review, the institution employed a consultant who is a laboratory animal veterinarian to help translate throughout the site visit," Goodwin says. "He even translated the entire exit briefing to the staff so they could be involved in the process."

(Note: Sometimes AAALAC can be of assistance in identifying good candidates for translators, so be sure to discuss language needs with the AAALAC office prior to your site visit.)

Understanding the purpose of questions

From time to time, institutions outside of the United States become concerned about the number of questions asked by members of the AAALAC site visit team. Be aware that when AAALAC reviewers ask a lot of questions, it does *not* mean that things are wrong or that there is a problem. They are simply working to collect as much information as possible.

"We ask a lot of questions because we want to understand all aspects of the program and how things are done," Parks says. "This lets us be good advocates for the institution when the entire Council deliberates over the institution's site visit report."

For more information on applying for AAALAC accreditation and to request an application, send an e-mail to accredit@aaalac.org. ❑

International institutions share their thoughts on accreditation

Utrecht University Central Laboratory Animal Institute (CLAI)

The Netherlands

Utrecht University is one of the largest and oldest universities in The Netherlands and has an extensive biomedical research program. The Central Laboratory Animal Institute (CLAI) was established in 1989 as a new centralized unit designed to facilitate biomedical research in which laboratory animals are involved. From its inception, quality, customer service and animal welfare were key issues for the Institute.

Using ISO 9000 and AAALAC to gauge quality

CLAI was established as a non-profit organization. Initially, they chose ISO 9000 as the backbone for their quality management system. The institution has earned ISO 9002 and ISO 9001 certification, proving that their management system is customer oriented and meets the basic qualifications needed to gain customer confidence.

"But ISO 9000 does not give insight into the way laboratory animals are treated and used in the facility," says Harry van Herck, D.V.M., CLAI's adjunct director. "As far as we know, AAALAC is the only worldwide operating institution addressing accreditation of laboratory animal programs from animal welfare and personnel safety points of view." This prompted CLAI to apply for AAALAC accreditation.

Site visit points toward solutions

Dr. van Herck says his team was positively surprised by the process of the site visit. "The AAALAC site visit was performed by experts coming from the field of laboratory animal science and we felt that they did their job thoroughly," adds van Herck. "They correctly identified the problems we were wrestling with, found a positive way to communicate them, and were also able to provide clues as how to solve them."

Differences noted between AAALAC and other quality assurance programs

Dr. van Herck says that the accreditation process was clearly communicated by AAALAC in advance, so there were no surprises. But he did notice some differences

Additional reading

"AAALAC International: Using Performance Standards to Evaluate an Animal Care and Use Program," by Kathryn Bayne, M.S., Ph.D., D.V.M., and David P. Martin, V.M.D., *Lab Animal*, April 1998, Volume 27, No. 4.

"International Harmonization of Animal Care and Use: The Proof is in the Practice," by John G. Miller, D.V.M., *Lab Animal*, May 1998, Volume 27, No. 5.

"Assessing Animal Care and Use Programs Internationally," by Kathryn Bayne, M.S., Ph.D., D.V.M., and John G. Miller, D.V.M., *Lab Animal*, June 2000, Volume 29, No. 6.

between AAALAC and other quality assurance programs.

"Compared to GLP and ISO, the AAALAC accreditation process differs in two ways which seem to be interconnected. AAALAC starts with a rather extensive questionnaire before performing a site visit," van Herck says, referring to the preparation of the Program Description. "ISO and GLP provide only global guidelines, then identify specific issues during the site visit. The AAALAC questionnaire forces you to look at your own organization from both an animal welfare and personnel safety point of view."

Dr. van Herck adds that in the case of ISO and GLP, the decision about whether an institute will be certified or not is primarily decided by the site visitors. "In contrast, AAALAC uses a peer review system in which the answers to the questionnaire and the reports of the site visit are reviewed by members of AAALAC's Council on Accreditation."

"In my experience, the AAALAC process provided valuable information about the level of laboratory animal science at which we were operating," Herck says. "It gave us solid input for our ISO 9000 quality management system, and allowed us to implement improvements concerning laboratory animal science and personnel safety issues. I feel an integration of ISO 9000 and AAALAC is optimal to implement, maintain, and improve quality management systems in laboratory animal institutions."

RCC Ltd.

Switzerland

RCC Ltd. is an independent Swiss company with headquarters in Itingen. Today it is one of Europe's foremost contract research and consulting organizations, employing approximately 400 staff at facilities in Switzerland and Germany. The company has five operating divisions delivering services in the areas of toxicology, genetic toxicology and cell biology, environmental chemistry and pharmanalytics, registration and consulting, and biotechnology and animal breeding.

Using accreditation as an international symbol of quality

As a contract research organization operating internationally, RCC wanted to demonstrate its competence in the areas of animal welfare and animal care.

"We wished to obtain acknowledgment from an independent, internationally recognized organization. This was considered equally important in both the toxicology and animal breeding divisions," says Gunter Menne, Ph.D., head of RCC's Biotechnology and Animal Breeding Division and member of the RCC Executive Committee.

"Our aim is to use AAALAC accreditation as a way of instilling confidence in our clients regarding RCC's respect for animal welfare issues," Menne says.

RCC had to decide whether to apply for ISO 9000, EN 45001 or for AAALAC accreditation. "We chose AAALAC accreditation because animal welfare was considered more relevant to our needs than the other quality systems," Menne says.

Surprised by the thoroughness of the site visit

"We were surprised by the very intensive evaluation of all our animal rooms and the associated technical support areas. During inspections for GLP, GMP and EN 45001, the inspections are generally restricted to spot-checks in some representative rooms," Menne says. "We were also surprised about the

continued next page ...

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International institutions share thoughts on accreditation

extensive discussions on our occupational health program."

Colleagues throughout the country congratulated RCC on its achievement. "One client commented that RCC had obtained the 'Gold Standard,' and all of them were very interested in getting information on how to apply for accreditation," Menne says.

Discussions with evaluators prove valuable

Menne reports that the discussions they had with AAALAC's team of experienced site visitors was the most valuable part of the accreditation process.

Menne adds, "AAALAC accreditation provides further support to our local procedures which ensure a strict control on animal welfare and care. The necessity to document our program for AAALAC, and the open and friendly atmosphere during the site visit, promotes discussion and allows us to reevaluate existing procedures which ultimately benefits the animals."

Development Center for Biotechnology

Taiwan

The Development Center for Biotechnology (DCB) is a non-profit research and development organization designed to promote and upgrade the biotechnology industry in Taiwan. DCB's primary areas of research and development using laboratory animals include toxicology, immunology, animal vaccine testing, and monoclonal and polyclonal antibody production.

Setting new standards

"We wanted to achieve high standards for laboratory care and use programs in Taiwan," says Chou C. Hong, D.V.M., Ph.D., chief of DCB's Laboratory Animal Resource Division on why the company chose to apply for AAALAC accreditation. "We also wanted to be the leader of laboratory animal care and use programs in Taiwan and Southeast Asia, and promote good laboratory animal care and use programs throughout Asia." They felt AAALAC accreditation would help them achieve these goals.

Hong and his team were fully prepared for the accreditation process because they had already participated in a "Program Status Evaluation" (PSE) by AAALAC. (A PSE follows the same structure as the accreditation program, but the final report goes back to the institution, not to AAALAC's Council on Accreditation.)

Site visit provides insight into trends

Hong says the most valuable part of the accreditation process was learning about other experiences and trends in laboratory animal care and use from the site visit team. He cited the value of the team's insights and comments.

Hong also reports that the accreditation process helped foster strong cooperation and commitment from the company's administrators, and garner financial support for the animal care and use program.

Becoming a role model for others

"Others in our country praise our achievement of accreditation," Hong says. "Some institutions have already asked for our help and for us to share our experiences to help them improve their programs. Our animal facility and laboratory animal care and use programs have become role models for others."

Boehringer Ingelheim Pharma KG

Germany

Boehringer Ingelheim Pharma KG, a subsidiary of BI International GmbH, is an international pharmaceutical and health care company founded and based in Germany. Current research and testing at Boehringer Ingelheim concentrates on pulmonary diseases, cardiovascular diseases, metabolic

<harmonization>

What is AAALAC's role in international harmonization?

As the world becomes more global, it's imperative that international scientific partnerships and shared data be based on similar standards for performance and quality. Only then can the scientific community be assured that the data is reliable. AAALAC accreditation helps ensure that animal care and use programs are meeting a similar set of benchmarks.

"The concept of a truly international accreditation program, one that is science-based and sensitive to cultural and legal differences, is logical and consistent within the framework of the international scientific community," says John G. Miller, D.V.M., AAALAC's executive director in "International Harmonization of Animal Care and Use: The Proof is in the Practice." (*Lab Animal*, May 1998)

Today, institutions in 16 countries have earned AAALAC accreditation. They are: Belgium, Canada, Denmark, Egypt, England, France, Germany, Indonesia, Korea, Peru, Philippines, Switzerland, Taiwan, Thailand, The Netherlands and the Untied States.

diseases, central nervous system diseases and oncology.

Boehringer's division of animal resources supports all of Boehringer's research and development that uses animals in research or testing. Informal discussions at an AALAS meeting (the American Society of Laboratory Animal Science) and direct communication with an AAALAC Council member prompted Boehringer to apply for AAALAC accreditation.

Discussion and recognition is valuable

"The critical comments and discussions during the site visit with highly qualified colleagues were the most valuable parts of the accreditation process," says Dr. Klaus-Dieter Schulz, who was on staff at the time and led the initial accreditation process.

Dr. Oliver Rau, who currently heads the section for laboratory animal resources at Boehringer, says that in his view, the most valuable aspect of accreditation is "to see our house from an external, critical perspective."

"As an international pharmaceutical company, we are interested in having global acceptance and appreciation," Rau says. He adds that Boehringer continues to maintain its accreditation because the staff is proud to "achieve an acknowledged level of high quality in the laboratory animal unit."

Both Schulz and Rau were surprised by AAALAC's level of focus on documentation and details. But Schulz adds that, "Quality assurance is an absolute prerequisite today. AAALAC accreditation meets the specific demands of laboratory animal facilities better than most GLP inspections." ❑

For a complete list of accredited institutions outside of the United States, visit www.aaalac.org and click on "Accredited Organizations."

<congratulations>

Newly-accredited institutions!

Aventis Pasteur Inc., Swiftwater, Pennsylvania

Korea Food and Drug Administration, Seoul, South Korea

Nemogen, Inc., Providence, Rhode Island

TGA Sciences, Inc., Medford, Massachusetts

The Pennsylvania State University, University Park, Pennsylvania

Samsung Biomedical Research Institute, Samsung Medical Center, Seoul, South Korea

SkeleTech, Bothell, Washington

Sungkyunkwan University School of Medicine, Suwon, South Korea

Valentis, Inc., The Woodlands, Texas

Wyeth-Lederle Vaccines, Pearl River, New York

New Member Organizations, join AAALAC's Board

This fall, two new Member Organizations were elected to AAALAC's Board of Trustees: the Applied Research Ethics National Association (ARENA), and the Association of Minority Health Professions Schools (AMHPS).

By becoming a Member Organization, ARENA and AMHPS are demonstrating their support for AAALAC's mission and the accreditation program. Both will assist in governing AAALAC as members of the board. AAALAC's board currently consists of representatives from more than 50 of the most prestigious scientific, research and educational organizations in the United States and Europe.

ARENA is a national service organization for professionals interested in bioethics. Its purpose is to enhance the ethical conduct of research and medicine by promoting educational activities, networking, resolution and/or amelioration of mutual problems, and the professional advancement of its members. ARENA is a leader in educating professionals and the public about Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs). For more information on ARENA, visit www.arena.org.

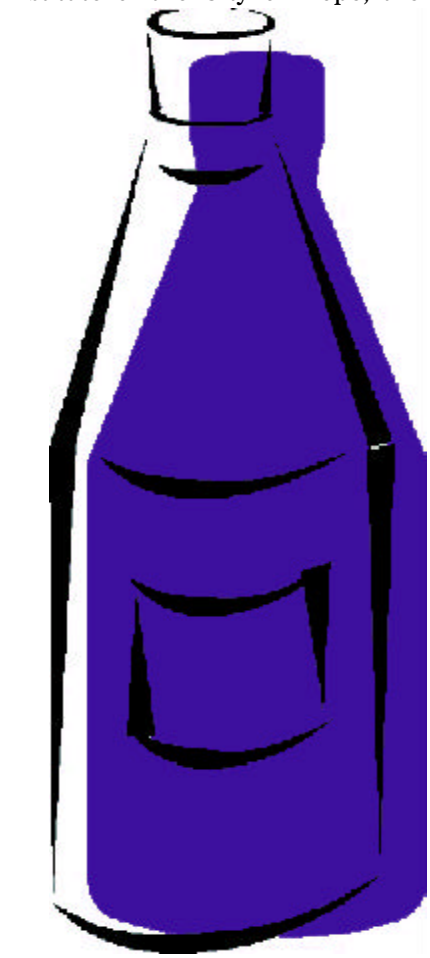
AMHPS is a national organization that works to improve the health status of African-Americans and other minorities, improve the representation of African-Americans and other minorities in the health professions, and strengthen research and education programs to improve the role of minorities in providing health care.

From AAALAC's perspective ...

Alcohol as a disinfectant

We've heard from many people who have questions about the appropriateness and effectiveness of using alcohol as a skin and sole surgical instrument disinfectant in rodent survival surgery. For some institutions, part of the confusion stems from a sentence in the *Guide for the Care and Use of Laboratory Animals* (NRC 1996, p. 62) that says, "Alcohol is neither a sterilant nor a high-level disinfectant." No further specifics are offered.

To help clarify this statement and answer questions about the use of alcohol in rodent surgery, AAALAC's Council on Accreditation formed a subcommittee to research and address this issue. Chaired by Herod L. Howard, D.V.M., M.P.V.M, director of the Animal Resources Center for the Beckman Research Institute of the City of Hope, the committee also included J.R. Haywood, Ph.D., professor of pharmacology at the University of Texas Health Science Center at San Antonio, and Kathy Laber, D.V.M., M.S., director of the Animal Resource Center of the Medical University of South Carolina. Their findings and recommendations are discussed below.



Alcohol as a skin disinfectant

The goal prior to surgery is to rapidly kill bacteria at the site of the planned incision. Alcohols are well-suited for this. After application, their antibacterial effects result in falling bacterial counts that can last up to several hours.

The committee noted several sources that support the use of alcohol as a skin disinfectant:

- ✔ Research has shown that a one-minute alcohol immersion or scrub is as effective as a four- to seven-minute scrub with Chlorhexidine or Iodophors.
- ✔ An article by Cunliffe-Beamer cited in the *Guide* supports alcohol for rodent skin disinfection prior to surgery.
- ✔ The World Health Organization has designated alcohol "the gold standard against which all other skin disinfectants should be measured."

> For these reasons, the Council accepts alcohol as a skin disinfectant for rodent survival surgery.

Instrument sterilization

Prior to surgery, instruments should be rid of all forms of microorganisms to prevent postoperative wound infections. But this is sometimes difficult due to the grooves on instruments that can trap protein-rich material.

According to APIC (Association for Professionals in Infection Control and Epidemiology), ethyl alcohol and isopropyl alcohol are not effective in sterilizing instruments because they lack sporicidal activity and can't penetrate protein-rich materials. Isopropyl alcohol also lacks the ability to kill hydrophilic viruses. For these reasons, alcohol is classified as an intermediate level disinfectant.

Most investigators have access to autoclaves, gas sterilizers, hot beads, flames, chemicals or boiling water which can be used to properly sterilize the equipment. The *Guide* sets the standard for aseptic technique which includes sterilizing instruments and appropriately trained personnel. In the Council's view, departure from *Guide* recommendations places an additional responsibility on the IACUC to provide appropriate scientific justification, performance data, and/or monitoring to support alternative practices.

> For these reasons, the Council cannot accept blanket use of alcohol for surgical instrument preparation.

The IACUC must evaluate the use of alcohol on a case-by-case basis, look at all the variables, include a review of relevant literature, and implement ongoing monitoring procedures. In sum, they must justify the use of alcohol as the sole surgical instrument disinfectant from both scientific and animal welfare perspectives. ❑

If you have questions or would like additional details on the committee's review, send an e-mail to kbayne@aaalac.org.

AAALAC at AALAS 2000

AAALAC's executive director Dr. John Miller (right), discusses the AAALAC accreditation program with Dr. Ulysses McElyea.

Sandy Dexter, AAALAC's Council coordinator, staffs the booth with Council members (from left) Dr. Ron Banks, Dr. Brad Goodwin and Dr. Dale G. Martin.

Council president Dr. Hilton Klein (right) and vice president, Dr. Doug Stone, brief new AAALAC ad hoc consultants during an orientation breakfast.

Dr. Kathryn Bayne, AAALAC's associate director, and former Council member Dr. John Harkness, provide guidance during a workshop, "The Technician's Role in the AAALAC Accreditation Process."

Edward A. Green awarded AAALAC's Deena M. New Award

Edward A. Green was presented with the Deena M. New Award, an honor recognizing outstanding performance among members of the AAALAC International staff.

Since 1996, Green has served as a program assistant for AAALAC, specializing in computer support. He is an expert in scanning technology, and has played an important role in helping AAALAC improve the quality, consistency and cost-effectiveness of its accreditation procedures and internal operations.

The Deena M. New Award is given to select AAALAC International employees in recognition of dedication and service in furthering the association's objectives. "Ed truly exemplifies this caliber of dedication, and we are pleased to present him with this award," said Kathryn Bayne, M.S., Ph.D., D.V.M., associate director for AAALAC International who nominated Green for the honor. ❑

New officers lead AAALAC's Board

AAALAC International elected six new officers to lead its Board of Trustees at its annual meeting on September 24, 2000. AAALAC's Board is made up of representatives from more than 50 of the most prestigious scientific, research and educational organizations in the United States and Europe. The officers are:

Chair
Philip B. Carter, Ph.D.
Professor of Microbiology and Immunology
College of Veterinary Medicine
North Carolina State University
Dr. Carter represents the Association for Gnotobiotics on AAALAC's Board.

Vice Chair
Maureen K. Powers, Ph.D.
Professor, Department of Molecular and Cellular Biology
University of California – Berkeley
Dr. Powers represents the Association for Research in Vision and Ophthalmology.

Secretary
Sonya K. Sobrian, Ph.D.
Associate Professor,
Department of Pharmacology
Howard University College of Medicine
Dr. Sobrian represents the Neurobehavioral Teratology Society.

Treasurer
Harry Rozmiarek, D.V.M., Ph.D.
Professor and Chief,
Laboratory Animal Medicine
University of Pennsylvania
Dr. Rozmiarek represents the American College of Laboratory Animal Medicine.

At-large member
Loren D. Koller, D.V.M., Ph.D.
Professor, Pathology/
Immunology/Oncology
College of Veterinary Medicine
Oregon State University
Dr. Koller represents the Society of Toxicology.

At-large member
Floyd J. Malveaux, M.D., Ph.D.
Vice President for Health Affairs and
Dean, College of Medicine
Howard University
Dr. Malveaux represents the Association of American Medical Colleges. ❑

<meet the staff>

Darlene Brown, LATG program analyst

As AAALAC's program analyst, Darlene helps coordinate the work of the key bodies of AAALAC—its Executive Committee, Board of Trustees and the Council on Accreditation. Darlene is also instrumental in coordinating AAALAC's outreach efforts among accredited institutions and the public.

Carmen Wallin Council secretary

Carmen provides the majority of administrative functions needed to support the work of AAALAC's Council on Accreditation. From correspondence to data entry to meeting preparation, Carmen's work ensures that the accreditation program continues to thrive.

Langston Willis program assistant/ communications

As AAALAC's primary customer service representative, Langston is responsible for making sure people get the resources and answers they need. He also plays a critical role in supporting AAALAC's public outreach and public relations efforts.

News to note ...

Darlene Brown

Carmin Wallin

Langston Willis

Accredited institutions must report adverse events

Accredited institutions that experience adverse events affecting their animal care and use program must promptly notify AAALAC International in writing. Adverse events would include things such as a USDA investigation, HVAC failure resulting in animal loss, or other serious incidents or concerns that negatively impact animal welfare. This requirement is reflected in AAALAC's Rules of Accreditation.

The requirement is designed to assist accredited institutions in times of crisis. Depending on the situation, AAALAC may be in a position to provide guidance or suggest steps to correct the problem. It is also critical for the Council on Accreditation to remain fully informed, so that when they review programs they can provide meaningful evaluations and suggestions for improvement. As with all other interactions with AAALAC, communication regarding adverse events remains completely confidential. ❑

Accreditation for satellite facilities

Accredited institutions may use facilities located away from the primary site to support animal-based research, testing or educational activities. AAALAC uses the following guidelines to determine if a satellite facility must be included in the accreditation of the primary program, or if it can be accredited as a separate unit.

- If the oversight, management and operation of the animal care and use activities in the separate (satellite) facilities are dependent upon the main animal care and use program (e.g., they share administration, mission, personnel, budget, equipment, etc.), **then they are considered part of the accreditable unit and must be site visited**.

- If the separate facilities are located some distance apart, the time required to travel between them will be considered in determining the category of the institution and the annual fee. If the oversight, management and operation of the satellite facilities are *not* dependent on the primary unit, **they may be considered separate programs, and AAALAC accreditation may be extended to each one**.

For questions, please contact Dr. Kathryn Bayne, kbayne@aaalac.org. ❑

Connection

Connection is published three times a year by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC), a private nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. More than 630 institutions around the world have earned AAALAC accreditation, demonstrating their commitment to responsible animal care and use, and good science.

Comments and submissions for Connection are welcome and should be directed to the editor.

Articles and information in Connection can be duplicated with attribution.

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Associate Director

Lori Wieder, Editor/Designer

Send in your 2000 AAALAC Annual Report

To maintain your accreditation, your institution must complete an Annual Report every year. This year there are several ways to submit your report:

1. Complete the hard copy that was sent to your institution in December and mail it to the AAALAC office: AAALAC International, 11300 Rockville Pike, Suite 1211, Rockville, MD 20852.

2. Download and print out a copy of the form from the AAALAC Web site. Complete the form and mail it to the AAALAC office. Visit www.aaalac.org/annualreport.htm to download a copy.

3. Complete and submit your annual report online by visiting the private Web address listed in the letter you received in December. If you no longer have the letter, send an e-mail to sdexter@aaalac.org for instructions.

We encourage you to submit your AAALAC annual report in conjunction with your institution's chosen reporting period (i.e. calendar year, fiscal year, or USDA reporting period). If you have any questions, please contact Sandy Dexter at 301/231-5353 or sdexter@aaalac.org. ❑

Connection
Connecting science and responsible animal care.

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