AAALAC INTERNATIONAL
Connection

Spring 2003

A newsletter for people working with animals in science.

Association for Assessment and Accreditation of Laboratory Animal Care International

Overcoming the challenges of
Animal transportation

Transporting animals has always been a complex task. But in recent months, several factors have made it even more difficult. The dwindling number of commercial airlines willing to carry animals, changing regulations, and different import and quarantine laws for each individual country make transporting animals a time consuming—and expensive—aspect of biomedical research. This article will discuss some of the current issues and concerns surrounding animal transportation, and offer some suggestions for facilitating effective operations and assuring good animal care.

Welfare, reluctance, and regulations

There are several major issues surrounding animal transportation. Of overarching concern is the welfare of the animals during transport. Once animals are turned over to an airline or ground carrier, control is relinquished to the carrier and the shipper must rely on a third party to make sure the animals receive proper care.

Though it's not done intentionally, there are many examples of animals being poorly treated while under the control of carriers. Instances of animals sitting for hours on runways in airplane cargo holds; animals being lost or misrouted; animals exposed to temperature extremes; or careless, unnecessary accidents, still occur.

The second issue is the growing reluctance among airlines to transport animals.

"A year ago, 40 to 50 percent of our shipments were by air. Now it's down to 7 to 9 percent," says Laura Matthews, Transportation Manager for The Jackson Laboratory. She notes that a large part of the drop is due to the reduced number of airlines willing to carry animals on a consistent basis. "Providing consistent service to the customer and optimum conditions for the animals is a necessity that we found better met through the establishment of a dedicated ground delivery system," Matthews adds.

Nonhuman primates pose additional challenges. "Of the few commercial airlines that will still carry nonhuman primates, most will take only two to four animals at a time," says Christian R. Abee, D.V.M., M.S., Professor and Chair of the Department of Comparative Medicine at the University of South Alabama's College of Medicine, and member of AAALAC's Council on Accreditation. "So if we have a lot of animals, we may need to schedule four or five separate flights, or we wind up hiring a charter jet to get them into the country, which is very expensive."

The third, and perhaps most challenging, issue is the fact that every country has its own set of regulations regarding the import and export of live animals. Not only do these regulations change, but there is no central information

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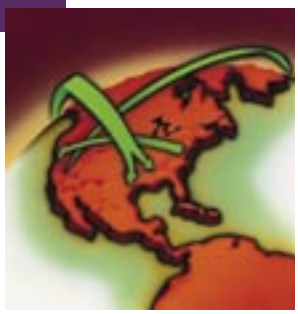

resource—no one authority—that can provide current, live animal shipping requirements for every country and every regulating organization.

Combined, these issues make transporting animals an extremely difficult process to navigate. But despite these challenges, it *is* possible to facilitate smooth animal shipments by paying attention to a few key areas …

Understand the regulations and provide proper documentation

When you ship animals to another institution, particularly if the institution is located outside the United States, you may need to comply with regulations and guidelines from a half dozen different organizations.

"There is not a single reference point to go to in order to find out what you need to do to ship your animals nationally or internationally," says Hilton J. Klein, M.S., V.M.D., Senior Director of Comparative Medicine for Merck Research Laboratories, and former president of AAALAC's Council on Accreditation.

This makes it critical for someone on staff to become familiar with the regulatory and oversight organizations, and to know where to turn for information about the latest requirements.

Key organizations include:

- **USDA, Animal and Plant Health Inspection Service, Animal Care**. This component of USDA enforces the Animal Welfare Regulations which include many requirements for transporting animals. (www.aphis.usda.gov/ac/)

- **USDA, Veterinary Services**. This division works to prevent the introduction of dangerous and costly pests and disease. They provide information on importing and exporting animals. (www.aphis.usda.gov/vs/ncie/)

- **Centers for Disease Control and Prevention** (CDC). Their Division of Global Migration and Quarantine includes information on the importation of animals into the United States. (www.cdc.gov/ncidod/dq/animal.htm)

- **U.S. Fish and Wildlife Service** (FWS). The FWS oversees regulations and permits regarding the import and export of native endangered and threatened species. (www.fws.gov)

- **Convention on International Trade in Endangered Species of Wild Fauna and Flora** (CITES). CITES is an international agreement between governments to ensure that international trade in wild animals and plants does not threaten their survival. In the U.S., the Fish and Wildlife Services is the CITES management authority. (www.cites.org)

- **U.S. Customs**. Visit www.customs.gov for U.S. import and export information.

- **Customs laws** of the receiving country. Check the trade laws for each individual country for details.

- **International Air Transport Association** (IATA). The "IATA Live Animals Regulations" set the standard for transporting live animals by commercial airlines. The publication is considered by many to be an essential reference for professionals in the business of shipping live animals. (www.iata.org)

- **Animal Transportation Association** (AATA). Publishes the "2nd Manual for the Transport of Live Animals." (www.aata-animaltransport.org)

- **Office International des Epizooties** (World Organization for Animal Health). Works to guarantee the transparency of animal disease status worldwide and the sanitary safety of world trade by developing sanitary rules for international trade in animals and animal products. OIE standards are recognized by the World Trade Organization. (www.oie.int)

Be sure to know the applicable rules regarding quarantine for your shipment, particularly for nonhuman primates. The CDC and APHIS can provide specific information on this.

Designate a point person

Designating a person to be in charge of remaining current on transportation regulations will help ensure compliance.

"International regulations are shaped by the country you are shipping to, and the regulations are frequently in a state of flux," says Klein. "In order to be effective in transporting animals, we make sure we have someone who knows the rules, regulations, and the key people at those organizations. It's not enough to learn this information one time—because the next time you ship, lots of things may have changed."

Once you understand the regulations and requirements, make sure that all necessary forms and related documentation are properly completed.

Tom Schooler, President of Animal Port Houston (a live animal freight forwarding company) and board member of the Animal Transportation Association (AATA), offers several paperwork tips ...

"First, make sure that all original documents accompany

the animals. Hand sign all documents—not doing so can hold up your shipment. Remember that the health certificate is an official international document, and the original should accompany the animals," Schooler says.

Use quality shipping containers

Schooler notes that a great deal of care should be taken to obtain proper shipping containers.

Matthews suggests starting with a good, hard, rigid shipping container. "Something that won't get damaged or become soggy if it gets wet."

After you find good containers, mark the outside clearly. There are accounts of containers being shrink-wrapped on airport cargo docks because they were not marked "Live Animals." Make sure there can be no doubt about the contents of the containers.

If you don't own good containers, there are a number of companies that build custom transport crates. These containers are made to your specifications and also meet USDA, IATA and AATA standards and requirements. Recommendations by colleagues, the AALAS list of vendors (visit www.aalas.org and click on "vendors"), and the USDA's list of registered handlers (see "Resources" on page 4) are good places to begin searching for companies. An internet search on "custom built animal transport crates" will also produce a list of possible vendors.

Monitor enclosures and ambient conditions

Using high-quality shipping containers will go a long way in making sure the animals' primary enclosure environment is comfortable. Adequate food and hydration sources must be provided—enough to account for the trip plus any possible delays. "It also helps to provide a good, absorbent bedding for the animals," Matthews says.

Be mindful of food products that could pose a customs problem. For example, some fruits or vegetables might not be permitted into some countries. The same holds true for other materials that might be found in or on animal crates, such as pieces of bark.

Just as important are the ambient conditions at the time of shipping. Excessive heat and cold are the biggest threats to animal health.

"Pay attention to the weather," says Abee. "If it's summer, you want to ship during the coolest part of the day, or perhaps at night."

"Summer and winter are the most challenging times to ship," says Matthews. "In the summer, between the body heat generated by the animals and the outside temperature, the animals can be greatly affected if their microenvironment isn't properly controlled. The fewer legs you have on the trip, the better."

"You need to be aware of each stop along the way and the conditions the animals could encounter," adds Betty Goldentyer, D.V.M., USDA's Eastern Regional Director. "Sometimes people simply don't think through the transportation process."

Communicate clearly and often

Goldentyer reports that one of the biggest problems seen by APHIS is the misrouting of animals. When this happens, the animals are sometimes stranded and may not get fed. Staying in contact with all parties involved along the way can help avoid these situations, and help ensure a smoother trip for the animals.

"It seems like a lot of problems occur between the time the animals reach the destination airport and when they are delivered to the facility," Matthews notes. To prevent these problems, representatives at the receiving airport need to be given clear instructions on handling the animals. "Some of our customers choose to be at the airport and pick up the animals themselves—they feel more comfortable doing this," Matthews says.

Abee reports that sometimes shippers will inadvertently expose the animals to contaminants by putting them in a room with other species or by getting the filter paper on the containers wet. Good communication and a bit of education can help prevent shipping company personnel from endangering the animals or compromising their health.

Decide how you will manage the process

When you're getting ready to transport animals, there are three basic ways to manage the process …

Do it yourself

As noted earlier, handling the transportation in-house is best accomplished by designating one person who will be responsible for understanding and remaining current on the regulations and guidelines. The next step is to find reliable and knowledgeable outside partners.

"You need to create a network of reputable people you can trust, and designate one person to oversee the process," Klein says.

Abee adds, "We've developed really good relationships with our local shipping people and we work closely with them in a good spirit of cooperation."

Also recognize that when so many partners and variables are involved, even the best laid plans can go awry. The key is to be prepared for emergency situations. "It's imperative to have an emergency plan in place before the animals are shipped," Klein says. "The last thing you

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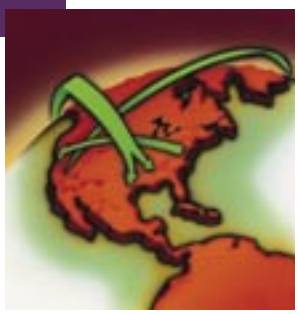


want is for animals to be held up in customs and no one available who knows what to do."

Work with an outside specialist

The second way to manage the process is to get assistance from an outside company. For a fee, intermediate handlers, like Schooler's company, can coordinate your shipments.

"Most of our time is spent collecting information for our customers—the documentation they need for a particular country, specifics on shipping containers and markings, and proper notifications and permits," Schooler says.

Abee notes that his organization uses this type of broker, particularly on the other end of international shipments. "That way, they can help us make sure we're meeting that country's regulations," Abee adds.

Talking to colleagues is the best way to find a reliable broker. A list of intermediate handlers who are registered with the USDA is also available at www.aphis.usda.gov/ac/lists/listh.pdf.

Use the other party's shipping services

If available, this is often the easiest and most reliable choice since these companies are set up to handle and track all of the details. Most large animal breeding companies such as Charles River Laboratories, Inc., Harlan, Taconic and the Jackson Laboratory operate their own climate-controlled fleet of trucks and will handle the shipping for you.

What the future holds ...

Ground transportation (when possible) is likely to become the most popular option, not only because it's more accessible than air travel, but also because it tends to allow a greater level of control. As noted above, many of the large breeding companies have purchased their own fleet of dedicated trucks for this reason—to control the transport of their animals to customers. There are also a number of private companies, such as Animal Port Houston, Frames Animal Transportation Service, O'Brien Animal Transportation and Services, and TransporTech, that have climate controlled trucks specifically for domestic transport.

The complexity and fluidity of the regulations is likely to prompt increased use of third-party brokers, or intermediate handlers, to help manage the process. But exactly how the regulations will change in the months and years ahead is unknown.

"I can't predict the future, but I'm sure transporting animals is not going to get any easier," Abee says. "If it becomes any more difficult, I'm afraid it's really going to hurt biomedical research. I would hope countries would get together to give careful, thoughtful consideration before implementing more regulations."

The new Homeland Security Act may also impact the transport of animals. Schooler notes that in light of the new department, "We need to be ready for the rules to change all the time."

In the meantime, you can get your animals where they need to go, safely and comfortably, through good management, effective communication, and by developing your own network of reliable vendors who understand what it takes to ensure animal well-being during transport. §

Resources

- **AATA 2nd Manual for the Transport of Live Animals, published by the Animal Transportation Association, www.aata-animaltransport.org**
- **Animal Welfare Regulations, www.aphis.usda.gov/ac/**
- **Centers for Disease Control and Prevention (CDC), www.cdc.gov/ncidod/dq/animal.htm**
- **Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), www.cites.org**
- **International Air Transport Association, IATA Live Animal Regulations, www.iata.org**
- **Office of International des Epizooties, www.oie.int**
- **U.S. Customs, www.customs.gov**
- **USDA APHIS' list of registered animal carriers, www.aphis.usda.gov/ac/lists/listt.pdf**
- **USDA APHIS' list of registered intermediate handlers, www.aphis.usda.gov/ac/lists/listh.pdf**
- **U.S. Fish and Wildlife Service, www.fws.gov**
- **USDA Veterinary Services, www.aphis.usda.gov/vs/ncie/**

Congratulations to the institutions that earned accreditation in 2002 ...

- Ace Animals, Boyertown, Pennsylvania
- Alamogordo Primate Facility, National Institutes of Health, Holloman Air Force Base, New Mexico
- Animal Pharm Services, Inc., Healdsburg, California
- Centocor, Inc., Johnson & Johnson, Malvern, Pennsylvania
- Chiron Corporation, Emeryville, California
- College of Veterinary Medicine, The University of Georgia, Athens, Georgia
- Florida State University, Tallahassee, Florida
- Genetic Advancement Center Trans Ova Genetics, Hull, Iowa
- Lampire Biological Laboratories, Everett, Pennsylvania
- Magee-Womens Research Institute Pittsburgh, Pennsylvania
- Malcolm Randall VA Medical Center Gainesville, Florida
- New York Medical College, Valhalla, New York
- Norwegian School of Veterinary Science, Oslo, Norway
- Princeton University,* Princeton, New Jersey
- Purdue Pharma L.P. Ardsley, New York
- R.J. Reynolds Tobacco Company Winston-Salem, North Carolina
- Roswell Park Cancer Institute, Buffalo, New York
- Stowers Institute for Medical Research, Kansas City, Missouri
- Theravance, Inc., South San Francisco, California
- The University of Chicago, Chicago, Illinois

*** All eight Ivy League schools are AAALAC accredited!**

Kathryn Bayne elected vice president of ACLAM

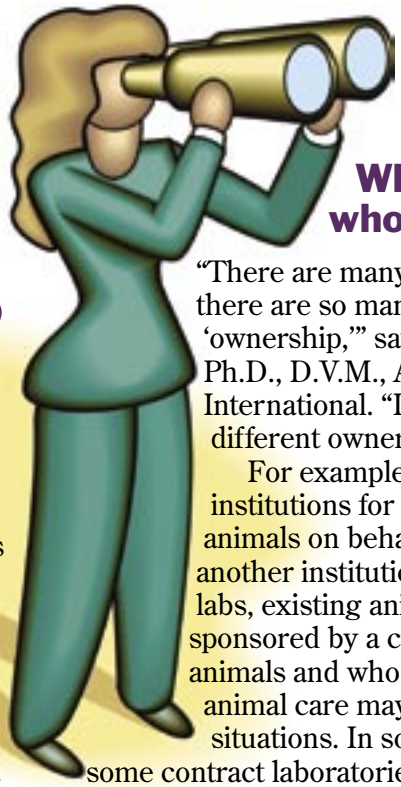
Kathryn A. Bayne, M.S., Ph.D., D.V.M., AAALAC's Associate Director, was elected vice president of the American College of Laboratory Animal Medicine (ACLAM). This position becomes president-elect then president over the next three years. ACLAM is a specialty board recognized by the American Veterinary Medical Association. Membership currently includes 663 active ACLAM Diplomates.

Dr. Bayne's experience with laboratory animal issues is extensive. Prior to her position with AAALAC, she worked at the National Institutes of Health leading a research program on nonhuman primate psychological well-being and environmental enrichment programs for primates, dogs, cats and swine. She has published over forty scientific articles and is a certified animal behaviorist.

Dr. Bayne currently serves as a member of the American Veterinary Medical Association Animal Welfare Committee. She is a reviewer for the Biobehavioral and Behavioral Processes Study Section of the National Institutes of Health Small Business Innovation Research (SBIR), and is a member of the American Association for the Advancement of Science Scientific Freedom & Responsibility Award Selection Panel. Dr. Bayne is past president of the Association of Primate Veterinarians and the DCVMA, and past Vice President of the Scientists Center for Animal Welfare's Board of Directors. She has served on the boards of the National Association for Biomedical Research, the American College of Laboratory Animal Medicine (ACLAM), ASLAP and the Lab Animal magazine editorial board. Dr. Bayne served as a member of the National Academy of Sciences (NAS) committee which developed the 7th edition of the Guide for the Care and Use of Laboratory Animals (1996), and the National Academy of Science committee that prepared the 1998 report, Psychological Well-Being of Nonhuman Primates.

During her tenure in the Public Health Service Commissioned Corps, Dr. Bayne, was the recipient of several awards. In 1993 she received the Henry and Lois Foster Award for high score on the practical portion of the ACLAM certifying examination and in 1998 she received AALAS's Joseph J. Garvey award for work related to the humane treatment of animals used in biomedical research. §

Who's responsible for Offsite Animals?



The number of institutions housing animals at places *other* than their main facility is on the rise. These "offsite" locations include contract laboratories, collaborating universities and other types of research facilities. The explosion in the use of transgenic animals with concurrent space constraints, the globalization of science (exemplified by international corporations), and the rapid pace of research, are just a few of the factors driving this trend. In the months and years ahead, it's likely that the number of institutions sharing animals or housing animals offsite will continue to escalate at an even faster rate.

In many cases, keeping animals offsite offers scientific and logistical advantages. But it has also posed some perplexing issues for institutions. Who actually *owns* these offsite animals? Who is ultimately responsible for their well-being? And if the offsite animals are housed at an institution that is *not* accredited by AAALAC International, are there implications for the accredited program?

What's at stake?

Collaboration among institutions—and sharing animals in the process—improves science. It also helps reduce the overall number of animals used. But this type of collaboration may also make oversight more difficult—especially for institutions that haven't considered their oversight role or other involvement with animals at remote locations.

"Today everybody is sharing animals," says Dennis M. Stark, D.V.M., Ph.D., Executive Director of Veterinary Sciences for Bristol-Myers Squibb and an AAALAC Council member. "This is not just an industry issue, it's an issue everywhere, including academia."

"This is an issue that's going to get more challenging as more and more animals are being shuffled back and forth," says Lauretta W. Gerrity, D.V.M., Director of Animal Resources Program at the University of Alabama-Birmingham & VAMC, a former member of AAALAC's Council on Accreditation who is now an ad hoc Consultant to AAALAC. "The question is, 'who's in charge of those animals when they are at each of those places?'"

Who's the owner and who's responsible?

"There are many challenges in this area because there are so many gray areas regarding 'ownership,'" says Kathryn A. Bayne, M.S., Ph.D., D.V.M., Associate Director of AAALAC International. "I receive calls every week posing different ownership scenarios."

For example, animals may be sent to other institutions for studies. Institutions may buy animals on behalf of a study sponsored by another institution. Or in the case of contract labs, existing animals may be used for a study sponsored by a client. Who legally owns the animals and who is responsible for oversight and animal care may be different in each of these situations. In some instances, such as with some contract laboratories, the contractor requires the sponsoring institution to own the animals. In other cases, the parent institution requires the offsite organization to own the animals.

Gerrity notes that issues of ownership and responsibility may be especially challenging when dealing with primates. For example, if the original owner of a primate is conducting a long-term study and doesn't need the animal for a while, it may loan the animal to another institution to be held, or perhaps used for blood draws or other minor procedures. For a number of reasons—e.g. applying the 3 Rs and the scarcity of some nonhuman primate species—the original institution may wish to retain ownership. The responsibility for decisions regarding the health and welfare of the animal on a day-to-day basis should be determined.

Indeed, in any partnership or contract situation, the issue of who owns the animals—and who will provide oversight and care—should be clearly defined and agreed upon in advance. But there are a number of ways to do this and many variables that will affect final decisions.

Ownership and proprietary rights to the data

In addition to issues of ownership and responsibility, some institutions—pharmaceutical companies in particular—are working through possible legal issues surrounding animal ownership. Some lawyers representing these companies feel strongly that animals transferred to non-company (or "host") facilities must remain the property of the parent company. They also want the animals to be labeled with the company's name while residing at the host facility. They believe these measures will help protect future patent rights.

Stark explains that while pharmaceutical companies are eager to have research generated at collaborating institutions, legally owning the animals is risky. He says such agreements between his own institution and collaborating institutions are covered by a 'materials transfer agreement' that all parties sign. It defines who owns the animals, what standards of IACUC review are expected, what husbandry and veterinary care will be maintained, and how the animals will be identified.

"Some legal opinions note that in order to retain proprietary rights to data involving transferred animals, the source institution must retain ownership of the animals," Stark says. "But some of us in the veterinary community feel the institution sponsoring the study should be able to retain ownership of the proprietary information generated from the animals, even if the offsite facility assumes ownership of the animals. The partner facility should be willing to take on the responsibility of providing care and doing it right."

But while some legal departments are saying they want to own the offsite animals, others are saying they wouldn't own them under any circumstances.

Stark informally polled his colleagues—industry veterinarians, most of whom work for pharmaceutical companies—on the subject. Among those who responded, the majority indicated that their company would *not* own animals held at other institutions or contract research organizations. Stark notes that if he had polled the company lawyers instead of the veterinarians, he may have gotten a different response.

"The veterinary community is pushing for legal departments to *not require* that the parent company maintain ownership," Bayne observes. But she notes that many lawyers continue to feel that their patent rights may be threatened if they cede ownership to the offsite or contract facilities. "A lot of these feelings are likely due to the complexities of international intellectual property laws," Bayne adds.

For the foreseeable future, negotiations on this topic between the animal care community and legal departments are likely to continue.

Complying with rules and guidelines

Whether your institution owns the animals at the host facility or not, your institution will, in most cases, be subject to certain rules or guidelines. *Which* rules or guidelines apply depends on the organizations to which you are accountable—the USDA, AAALAC International, OLAW (the Office of Laboratory Animal Welfare), plus state and local regulations.

"A lot of times, when people get into trouble it's when the institutions don't understand the rules," says Gerrity. "It's not a case of people disregarding them."

Each of the three organizations—USDA, AAALAC International and OLAW—have slightly different views on the issue of offsite animals …

The USDA perspective: responsibility follows ownership

According to the USDA, in most cases responsibility for offsite animals is assigned to the institution that owns the animals. But if more than one facility is involved with a particular research study, USDA places responsibility for the animals being used not only with the institution that is involved in their housing and care, but also with any institution that is involved in the planning and execution of the study itself.

If an institution merely owns the animals being used in a study—but has no input or is not involved in the planning, review, approval, or conduct of the study—then USDA would not hold that institution responsible for those animals. (In fact, if that was the only involvement with animals this institution had, it would not even be required to be registered since it does not meet the regulatory definition of a research facility.) If the owning institution has any say in how those animals were to be used, however, the USDA would then hold them responsible. USDA representatives say the organization has encountered this type of situation several times in recent years, primarily with regard to transgenic animals.

"It's important to note that to the USDA, ownership encompasses more than just 'sign on the dotted line' ownership," Gerrity says. "They also want to know who is in *control* of the animals." She adds that in making this determination, USDA will look at considerations such as: Who wrote the protocol? Whose IACUC is doing the review? Who is conducting the hands-on procedures? Who houses the animals? And who provides the daily care?

Some believe that the USDA is starting to take a closer look at animals in offsite facilities.

"I think over the last three or four years we've seen more USDA inspectors paying increased attention to animals at contract facilities," notes James F. Taylor, D.V.M., M.S., Director of the Office of Animal Care and Use at the National Institutes of Health (NIH), and member of AAALAC's Council on Accreditation. This means that institutions will need to make sure that offsite facilities using regulated animals (animals other than rats, mice and birds) are registered with the USDA if they are located in the United States. And the parent institution needs to be able to clearly document ownership and who is responsible for monitoring their care.

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Ownership and AAALAC's perspective

Like USDA, AAALAC International follows ownership in terms of defining who is responsible for animals at an offsite facility. If an accredited institution does not own the animals—if they just own the data that results from the studies conducted using those animals—AAALAC does not *require* oversight by the accredited program. However, they should ensure that they are partnering with reputable organizations.

Bayne says AAALAC site visitors typically see two scenarios ...

AAALAC's Rules of Accreditation regarding contract facilities

"Institutions may have contractual arrangements for certain aspects of their animal care activities with other animal care agencies/facilities. In some situations, an accreditable unit may issue a comprehensive contract whereby the contractor provides most or all specified facilities, services, personnel, animals, etc., and the animals are owned by the contractor. In this situation, AAALAC International accreditation does not extend to the contracted facilities and their associated animal care programs. However, the accredited unit may have a more limited contract in which the accredited unit owns the animals. In this latter situation, AAALAC International considers those facilities to be an integral part of the institution's animal care program. The services and facilities provided by the contractual arrangement must be included in the application and annual reports, and the facilities will be visited as a part of the institution's original and periodic site visits to determine compliance with AAALAC International standards. Contractual agreements made by AAALAC International accredited institutions or applicants must provide for the inspection of the contracted facilities by AAALAC International site visit teams. If the contract facility is separately accredited by AAALAC International and is currently fully accredited, it will not be necessary to visit that facility during the site visit."

If the offsite facility is also accredited ...

"The first scenario is that the parent institution—institution A—has arranged to have research using animals conducted at institution B, and B is also accredited by AAALAC," Bayne says. "This is an easier scenario to handle."

During the site visit of the parent institution, the AAALAC evaluators will *not* visit institution B, because B is already on its own AAALAC site visit schedule. "However, this does not mean that institution A should abdicate all responsibility for those animals," Bayne adds. "We would still expect some level of involvement by institution A's IACUC."

Although there is nothing in writing and no regulations that require it, AAALAC generally *recommends* that institution A get copies of institution B's IACUC meeting minutes and semiannual reviews *as they relate to A's animals.*

"Institution B may want to keep a lot of information private, but A certainly has a right to see information that pertains to its own animals," says Bayne.

In sum, if AAALAC is site visiting institution A, and offsite facility B is also AAALAC accredited, AAALAC will *not* visit B during A's site visit. But, AAALAC will expect A's IACUC to maintain awareness of—and appropriate involvement in—the work being done on the animals it owns.

If the offsite facility is not accredited ...

From AAALAC's perspective, the alternative scenario—when the satellite facility is not AAALAC accredited—is more difficult.

"When institution A owns the animals, and offsite facility B is *not* accredited, A must describe B's animal care and use program and facilities in its own AAALAC Program Description and annual report," Bayne says. "In this situation, institution B *will* be included in the site visit—specifically, those areas that are related to the animals owned by A. This includes all housing, support and procedure areas." Even if B is geographically far away, AAALAC will evaluate it as part of A's site-visit process.

But what level of oversight does AAALAC expect the parent institution's IACUC to have over the animals it owns at another institution?

"When the contract or offsite facility is not accredited, we suggest that the parent institution ramp up the intensity of its oversight," Bayne says. She notes that AAALAC typically recommends that this oversight include a facility inspection as part of the IACUC's semiannual review, along with other forms of long-distance monitoring.

"There's a risk in partnering with non-accredited facilities," Bayne adds. "The parent institution may be jeopardized because they are linked with that offsite facility. If something happens at the offsite facility—even if it involves animals not owned by the parent institution,

and even if the report is not factual—the negative public perception can spill over to the parent institution."

This is likely the reason why some institutions, the NIH Intramural Research Program for example, will only contract with other AAALAC-accredited institutions.

"We have many animals placed at other institutions—and the other institutions are all accredited," says Taylor. "We will only partner with accredited programs—this is one of our own ground rules."

He adds that his office *does not* expect their animal care and use committees to do site visits of those satellite facilities. "They may choose to do it, but we haven't made it a policy that they must," Taylor says. "We do say, however, that they need to have some form of oversight—whether it's handled by the veterinarian or the project officer—there needs to be someone who can verify that our expectations are being met. But we leave it to the committees to decide how they will do this."

AAALAC's own Rules of Accreditation offer some guidelines (see the sidebar on page 8 for details).

Follow the funding: OLAW's perspective

OLAW, the Office of Laboratory Animal Welfare, has oversight responsibility for all PHS-funded activities involving animals. Its jurisdiction is based on the source of support, not ownership. Dr. Nelson Garnett, Director of OLAW, emphasizes that, "It's imperative that PHS-supported institutions that subcontract, collaborate or have other such agreements with other institutions, clearly define respective responsibilities." The PHS Policy requires that all awardees and performance sites hold an approved Animal Welfare Assurance.* When an awardee institution does not have an Assurance (and cannot obtain one because it does not have an animal care and use program or an IACUC), OLAW negotiates an Interinstitutional Agreement Assurance of Compliance whereby the awardee institution will rely on the program of an Assured institution.

Assured institutions that wish to subcontract or use performance sites that are *not* Assured also have the option to amend their Assurance to cover the nonassured entity. This effectively subjugates the performance site to the Assured institution and makes the Assured institution responsible for the performance site. Garnett adds, "the Assured institution must then treat the performance site as though it were another component of the institution's program, with responsibility for occupational health, training, IACUC review, semiannual inspections, and the reporting and other requirements of the PHS Policy." (OLAW guidance on this is found in NIH Guide notice OD-01-017.)

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**Public Health Service (PHS) states that as a condition of receipt of support for research involving laboratory animals, awardee institutions must provide a written Animal Welfare Assurance of Compliance (Assurance) to OLAW describing the means they will employ to comply with the PHS Policy.*

PHS Policy on satellite facilities

PHS defines a satellite facility this way ...

"Animal Facility: Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours. "

It also says that a function of the IACUC is to inspect satellite facilities ...

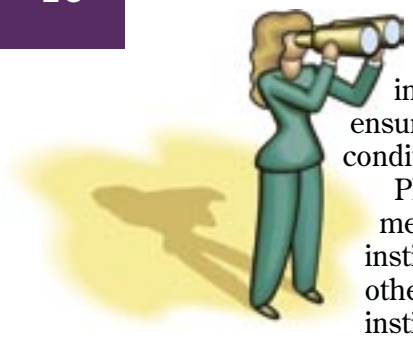
"Functions of the Institutional Animal Care and Use Committee:

As an agent of the institution, the IACUC shall with respect to PHS-conducted or supported activities:

1. review at least once every six months the institution's program for humane care and use of animals, using the *Guide* as a basis for evaluation;
2. inspect at least once every six months all of the institution's animal facilities (including satellite facilities) using the *Guide* as a basis for evaluation …"

PHS Policy is applied to satellite facilities in this way ...

"This Policy is applicable to all PHS-conducted or supported activities involving animals, whether the activities are performed at a PHS agency, an awardee institution, or any other institution and conducted in the United States, the Commonwealth of Puerto Rico, or any territory or possession of the United States. Institutions in foreign countries receiving PHS support for activities involving animals shall comply with this Policy, or provide evidence to the PHS that acceptable standards for the humane care and use of the animals in PHS-conducted or supported activities will be met. No PHS support for an activity involving animals will be provided to an individual unless that individual is affiliated with or sponsored by an institution which can and does assume responsibility for compliance with this Policy, unless the individual makes other arrangements with the PHS. …"



"OLAW says that the awardee institution has responsibility for ensuring that all terms and conditions of award, including the PHS animal welfare policy, are met." Gerrity says. Her institution has investigators in other countries and at other U.S. institutions performing subcontracted research on behalf of the university.

According to OLAW, Gerrity's institution maintains some responsibility for those animals because her institution is the PHS awardee institution.

What can institutions do to ensure proper oversight?

Think through the issue of responsibility

"Remember that if your institution receives PHS funding, even if you subcontract or conduct research at a performance site, you have a legal responsibility for the federal funding your institution receives," Garnett says. Part of that responsibility is met by simply ensuring that all performance sites are covered by an appropriate PHS Assurance.

"The IACUC needs to establish its realm of responsibility," Gerrity says. "IACUC members need to have it clear in their minds what they are responsible for."

Gerrity's institution has defined responsibility a bit broader than others. "But our IACUC has said, 'this is how we've defined responsibility for ourselves, based on our interpretation of AAALAC, OLAW, and USDA.'" Gerrity says. "We *voluntarily* set a higher level of oversight—this was not required, it was our choice."

At the start of any arrangement, IACUCs must answer questions about which committee will have final say in care and use issues. "Determine which committee has priority of review up front," Stark says. "Is it the person who gave the animal to you and still owns it—or the person using it?"

Develop clear criteria

Defining the boundaries of responsibility includes setting criteria for determining the IACUC's role in overseeing animals and studies at offsite facilities. "You have to develop criteria to identify those offsite studies that will require IACUC oversight," Gerrity says.

For example, some questions to help determine the institution's role in oversight might include: Will the animals be used for research, teaching and testing? Will they be cared for and used at a site registered with the USDA? Does the site have an approved PHS Animal Welfare Assurance on file with OLAW? Is the program AAALAC accredited?

Many times IACUCs will need to make judgment calls on what they will track and when. Gerrity sometimes uses what she calls an "off-the-shelf" test to determine the level of oversight needed. If her university has an investigator using antibodies produced at a contract lab, she asks if those antibodies are being produced specifically for that study. If they are, the institution will assume responsibility for overseeing the animals involved in the production of the antibodies. But if those antibodies would be produced anyway (i.e. for use at other institutions), her IACUC labels it a commercial product and leaves the oversight up to the producing site. This approach is consistent with OLAW guidance on custom antibody production contained in a March 8, 1995, OPRR Report (http://grants2.nih.gov/grants/olaw/references/dc95-3.htm).*

Gerrity also suggests that IACUCs clearly think through all issues surrounding ownership and responsibility, including questions about who will pay per diem charges and who will determine treatment for the animals.

"You also need to think about what would happen to the animals if the principal investigator leaves," Gerrity says. "Will the research continue because it's a well-developed program and there are lots of people responsible for it? Or will it stop because that one investigator is driving the research and animal use?"

Other decisions include determining which institution has the authority to euthanize the animals (should it become necessary), deciding if the offsite institution will provide their written procedures for their IACUC, veterinary care, husbandry, etc., to the source institution, and also what will happen to animals in the event of a disaster.

**OPRR Report 95-02 states "In the case that standard reagent antibodies (e.g. mouse-antihuman) are produced by a commercial supplier using their own resources and offering them for general sale, for example, through a catalogue, the institution may consider the antibodies to be 'off-the-shelf' reagents, and the supplier is not required to file an Assurance with OPRR. If, on the other hand, a supplier or contractor produces custom antibodies using antigen(s) provided by or at the request of a principal investigator, the antibodies are considered "customized" and the vendor or subcontractor must file an Assurance with OPRR."*

Create detailed agreements

As a member of AAALAC's Council on Accreditation, Stark has visited several institutions that keep animals at other facilities but have no formal agreement with them.

"While these institutions haven't faced any problems yet, it would be wise for them to outline the specifics of their arrangements—whose committee is ultimately responsible, what type of animal care and use procedures will be allowed, and so on—so that there's something in writing," Stark says. "Then if there's is a problem, it's covered. Even though the USDA doesn't require it, you really should do some formal assessment of how things will be handled."

This can be accomplished by developing a simple contract or letter of agreement that outlines these details and is signed before the animals are shipped out.

"A good contract is going to have reasonable detail on how animal husbandry, veterinary care, and so on, are going to be handled," Taylor adds.

"Put it in writing," says Garnett, "that way everyone is clear on who is responsible for what."

Ask for verification of oversight and information on their program—then follow up on a regular basis

Most institutions know to check the USDA, OLAW and AAALAC accreditation status at offsite facilities where animals will be used. But what else can be done to verify that your animals will receive proper care and use?

Along with developing clear criteria for determining responsibility and oversight, Gerrity suggests that the IACUC also decide what information it wants to request from the offsite facility.

"Ask about their USDA registration, OLAW Assurance, AAALAC accreditation and the IACUC's semiannual reviews." She notes that some institutions may be reluctant to share their internal reviews. But as Bayne noted earlier, it is reasonable (and good practice) to ask to see those internal reports that relate directly to your institution's animals.

"On one occasion, we ran into an institution that only conducted an internal review of protocols every three years," Gerrity says. "In that case we had to say, 'sorry we need you to conduct an annual review or we'll have to take our study elsewhere.'"

Talking to others that have worked with the offsite facility is another good way to find out about their program.

Taylor adds, "My personal feeling is that I like to see institutions find some proactive way of making sure that the partner is doing things the way they should. It's like any other contractual arrangement—you should have some kind of auditing process to verify that what you're paying for is what you're getting."

Garnett suggests, "Ask for documentation. If the awardee institution is relying on the IACUC review and inspection at another institution, then it's prudent to obtain evidence that there is appropriate oversight as required by PHS Policy."

Decide how protocols will be reviewed and approved

Determining how protocols will be reviewed and approved is another decision that needs to made up front. For AAALAC-accredited institutions, this decision is likely to depend on whether or not the offsite institution is accredited, and its past performance.

If an offsite animal care and use program is *not* accredited, the parent institution can decide whether or not it will accept the protocol being used by the offsite program. In some situations, the IACUC may fully accept their protocol and find it to be in complete compliance. But Bayne notes that because of slight differences in the animal study proposal forms, some institutions choose to perform a dual review of protocols—the parent institution reviews it, then the IACUC at the offsite program also reviews it.

continued on page 13 ...

Suggested checklist for working with contract and offsite facilities ...

- Get your IACUC to establish its "realm of responsibility"—when and how it will assume oversight of offsite animals.
- Establish who owns the animals.
- Create detailed agreements (perhaps a contract or letter) when working with offsite programs. Make it clear who owns the animals, whose IACUC is responsible, and who will make the day-to-day decisions about animal care.
- Check your compliance with OLAW and USDA (as necessary), and review AAALAC's Rules of Accreditation as they relate to offsite animals.
- Ask for information that will verify the quality of the other institution's animal care and use program. Check their USDA registration, PHS Assurance, AAALAC accreditation status, and internal reviews. Talk to other institutions that have partnered with them in the past.
- Decide how protocols involving offsite animals will be reviewed and approved. A dual review is not required, but some choose to do it—it's up to the IACUC to decide.
- Consider periodic visits to the site to monitor care and quality.
- Call the AAALAC office if you have additional questions or concerns!

Web resources:

- www.aaalac.org/rules.htm
- http://grants1.nih.gov/grants/olaw/olaw.htm
- www.aphis.usda.gov

The impact of proposed changes to the Appendix of Convention ETS 123

by Dr. Egil Berge, Assistant Director for European Activities for AAALAC International

In 1986 the Council of Europe (CoE) issued Convention (ETS 123) setting out the standards on the protection of vertebrate animals used for experimental and other scientific purposes.

Every five years thereafter, the Secretary General of the CoE has to convene multilateral consultations of the parties which take part in the Convention to examine the advisability of revising the Convention. Several documents have been adopted during these multilateral consultations, such as the "Resolution on education and training of persons working with laboratory animals" in December 1993, and the "Resolution on the acquisition and transport of laboratory animals," adopted in May 1997.

In May 1993, the German Federal Ministry of Food, Agriculture and Forestry, and the German Federal Health Office, with the support of Directorate-General XI (DG XI) of the European Commission, organized the "Berlin Workshop" to critically review the recommendations given in Appendix A of the Convention, and in the virtually identical Annex II of the European Union's Directive 86/609/EEC. The Appendix deals with specific aspects of maintenance and care of laboratory animals by species.

In April 1997, another initiative of DG XI looked at the results of the Three Rs of Russell and Burch (1959) during a conference entitled, "Target 2000 – Reducing Animal Experiments by 50 Percent."

At the present time, a revision of Appendix A is progressing. Appendix A states guidelines for the accommodation and care of the animals covered by Article 5.1 of the Convention. Some final proposals for modification are ready for submission for approval at the next Multilateral Consultation of Parties. These parts are:

- The general section of Appendix A
- Species specific provisions for rodents and rabbits
- Species specific provisions for dogs
- Species specific provisions for cats

Draft provisions not yet ready for submission include:

- Species specific provisions for ferrets
- Species specific provisions for farm animals
- Species specific provisions for birds
- Species specific provisions for fishes
- Species specific provisions for amphibians and reptiles (if deemed necessary)

Perhaps the most significant proposed changes, especially given the cost implications, are those related to cage sizes and environments. In this regard, the more significant changes for rodents concern hamsters and large rats. But even more drastic changes are planned for rabbits, dogs and cats. Enrichment of their environment is another new topic designed to increase the well-being of animals.

Dr. Egil Berge

The modifications focus especially on the aspects of animal maintenance that would permit more social interaction in stable harmonious groups. Proposed increases in enclosure sizes and their enrichment are intended to allow the animals to express normal behaviors and to enable conspecifics to adequately reduce competitive situations. Along with the changes in the sizes of the cages or pens, the modifications also allow for the possibility of subdividing the area into places for particular activities.

The philosophy of the revisions is reflected in the modified titles of the chapters, for example, "housing and enrichment " instead of "caging," and "flooring, substrate, litter bedding and resting material" instead of "bedding." Some new and important chapters are added including "education and training," "enrichment," "records," and "identification." These paragraphs are also the most modified or expanded parts of the new version of Appendix A. Following are several examples of new provisions in the proposed revisions of the general section of Appendix A.

4.5.1. Introduction

All animals should be allowed adequate space to express a wide behavioral repertoire. Animals should be socially housed wherever possible and provided with an adequately complex environment within the animal enclosure to enable them to carry out a range of normal behaviors. Restricted environments can lead to behavioral and physiological abnormalities and affect the validity of scientific data. Consideration should be given to the potential impact of the type of accommodation, and of the environmental and social enrichment programs on the outcome of scientific studies to avoid the generation of invalid scientific data and consequential animal wastage. The housing and enrichment strategies used in breeding, supplying and user establishments should be designed so as to fulfill the needs of the species housed and to ensure that the animals can make the best use of the space allowed. Their design should also take into account the need to observe the animals with minimum disruption and to facilitate handling. Suggested minimum animal enclosure sizes and space allowances are included in the

subsequent individual species sections. Unless otherwise specified, additional surface areas provided by enclosure additions such as shelves should be provided in addition to the recommended minimum floor areas.

4.5.2. Housing

Animals, except those which are naturally solitary, should be socially housed in stable groups of compatible individuals. Single housing should only occur if there is justification on veterinary or welfare grounds. Single housing on experimental grounds should be determined in consultation with the animal technician and with the competent person charged with advisory duties in relation to the well-being of the animals. In such circumstances, additional resources should be targeted to the welfare and care of these animals. In such cases, the duration should be limited to the minimum period necessary and, where possible, visual, auditory, olfactory and tactile contact should be maintained. The introduction or re-introduction of animals to established groups should be carefully monitored by an adequately trained staff, to avoid problems of incompatibility and disrupted social relationship. The possibility of social housing should be promoted by purchasing compatible individuals when procuring animals of gregarious species.

4.5.3. Enrichment

All animals should be allowed sufficient space of adequate complexity to express a wide range of normal behaviors. They should be provided with a degree of control and choice over their environment to reduce stress-induced behaviors. This may be achieved by using appropriate enrichment techniques, which extend the range of activities available to the animal and increase their coping activities. In addition to social activities, enrichment can be achieved by allowing and promoting physical exercise, foraging, manipulative and cognitive activities, as relevant to the species concerned. Environmental enrichment in animal enclosures should be appropriate to the species-specific and individual needs of the animals concerned. Forms of enrichment should be adaptable so that innovations based on new understanding may be incorporated. The enrichment program should be regularly reviewed and updated. Animal care staff should understand the natural behavior and biology of the species, so that they can make sensible and informed choices on enrichment. They should be aware that all enrichment initiatives are not necessarily to the advantage of the animal and therefore should monitor their effects and adjust the program as required.

If implemented, these changes could have a significant impact on institutions conducting biomedical research. To receive a complete copy of the currently available proposed modifications, send your request to accredit@aaalac.org. Dr. Berge can be reached at eberge@aaalac.org.

... Offsite animals continued from page 11

"Neither the PHS Policy nor Animal Welfare Regulations *require* a dual review of protocols, " Bayne emphasizes. "But some institutions *choose* to do it as a way to make sure they have all their bases covered—especially when they are working with a non-accredited program." Published NIH guidance, endorsed by USDA, states: "If both institutions have full PHS Assurances, they may exercise discretion in determining which IACUC reviews research protocols and under which institutional program the research will be performed. It is recommended that if an IACUC defers protocol review to another IACUC, then documentation of the review should be maintained by both committees. Similarly, an IACUC would want to know about any significant questions or issues raised during a semiannual program inspection by another IACUC of a facility housing a research activity for which that IACUC bears some responsibility or exposure." (NIH -OD-01-017, at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-01-017.html)

Consider periodic visits to the site

A final way to ensure proper oversight of offsite animals is to schedule periodic visits to the satellite facility. Again, the choice to do this depends on many factors.

"Because of the higher level of oversight we've set for ourselves, we have one partner institution that we will periodically visit," Gerrity says. "But most places we *don't* visit—we rely on their IACUCs, and keep track of what's going on through correspondence."

The IACUC may choose to send a representative (e.g. the institutional veterinarian) to observe or even videotape the animals periodically, or they may just request to see reports and documents. This is at the discretion of the institution. Decisions about site visits will vary based on the type of work being done, the species used, and the relationship between the two institutions.

• • •

There are many factors that determine what level of oversight the parent institution will have over a particular offsite facility. And there are numerous ways to implement a good oversight system. The bottom line is the institution and IACUC can't simply relinquish responsibility for animal research that is contracted out to someone else or performed at another site. A clear plan for working with these sites needs to be developed and monitored to comply with regulations and guidelines, and to ensure the well-being of offsite animals. §

AAALAC at AALAS 2002

San Antonio, Texas

1) AAALAC International Program Analyst **Darlene Brown** (r) assists visitors to the AAALAC booth.
2) AAALAC Associate Director **Kathryn A. Bayne** (r) with Dr. and Mrs. Nathan Brewer.
3) (l to r) Council members **J.R. Haywood** and **Ronald E. Banks** with AAALAC Council Coordinator **Sandy Dexter**.
4) (l to r) AAALAC Executive Director, **John G. Miller**; ICLAS's Secretary General, **Steven P. Pakes**; AALAS President, **Craig S. Frisk**; and AAALAC Board Member **Harry Rozmiarek**.
5) Council member **Ronald E. Banks** answers questions at the AAALAC workshop on the technician's role in earning accreditation.
6) AAALAC Executive Director **John G. Miller** with raffle winner, **Theresa Balch** of Texas.
7) Council President **Douglas W. Stone** (center) explains the accreditation process to workshop participants.
8) Council member **Brian L. Ermeling** (r) and University of Otago, New Zealand's **John C. Schofield** at the International Luncheon.

AAALAC receives the first Bennett J. Cohen Animal Stewardship Award

AAALAC International was awarded the first-ever Bennett J. Cohen Animal Stewardship Award. The award was presented at the 53rd AALAS (American Association for Laboratory Animal Science) National Meeting in San Antonio, Texas, in October.

The Cohen award was created to recognize those individuals or organizations that have achieved prominence in promoting and advancing the "three Rs" of replacement, reduction and refinement in the use of laboratory animals in research, teaching or testing, first described in 1959 by Russell and Burch.

"I'm very pleased to accept this award on behalf of all of the organizations and institutions that believe in—and actively participate in—the AAALAC accreditation program," said John G. Miller, D.V.M., AAALAC's executive director. "Through the day-to-day activities of members of the AAALAC community, the thoughtful words of Russell and Burch are transformed into actions that bring the intended benefits of those words to both science and the animals that serve it." §

Connection

Connection is published 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 650 institutions in 18 countries 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.

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Staff:

John G. Miller, D.V.M.
Executive Director
jmiller@aaalac.org

Kathryn A. Bayne, M.S., Ph.D., D.V.M.
Associate Director
kbayne@aaalac.org

Lori Wieder, Editor/Designer
lwieder@aaalac.org

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11300 Rockville Pike, Suite 1211
Rockville, Maryland 20852-3035
301.231.5353 phone
301.231.8282 fax

In Europe: Avenue de Tervuren 402
1150 Brussels, Belgium
+32.2.761.6678 phone
+32.2.761.6679 fax

accredit@aaalac.org

www.aaalac.org

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