Frequently Asked Questions

(updated September 2015)

Please note that this newly restructured FAQ page includes new and revised questions related to the 8th edition of the *Guide for the Care and Use of Laboratory Animals* (NRC 2011). If you have a question not addressed in our FAQs, please email accredit@aaalac.org. For further guidance, please refer to AAALAC International's Position Statements.

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A. AAALAC INTERNATIONAL'S ASSESSMENT PROCESS

1. AAALAC International's Three Primary Standards

I just read in an AAALAC announcement that accreditation assessments will be based on three primary standards, the 8th Edition of the *Guide for the Care and Use of Laboratory Animals* (*Guide*), NRC 2011; the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (*Ag Guide*), FASS 2010; and the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe (ETS 123). Our animal care and use program is located in the United States. Does this mean that we now have to follow ETS 123 for our program to be accredited?

The Council on Accreditation has used all three documents for several years and their adoption by AAALAC International's Board of Trustees as primary standards signifies the importance of these performance-based guidelines in the accreditation process. AAALAC's Rules of Accreditation state "The accreditable unit shall observe any and all statutes and governmental regulations which bear upon animal care and use including, but not limited to, the prevailing standards of sanitation, health, labor and safety of the jurisdiction(s) in which it is located." The scope of applicability of ETS 123 is limited to the member countries of the Council of Europe that have voluntarily ratified the

Convention, and thus it is not a prevailing standard in the United States.

There may be value, however, in reviewing AAALAC's collation of performance standards pertaining to cage/pen space excerpted from the *Guide*, *Ag Guide* and Appendix A of ETS 123 as each guidance document provides sound recommendations regarding housing environments for a variety of species. For example, while the *Guide* is silent on appropriate housing for ferrets, ETS 123 provides excellent guidance which would be useful for institutions around the globe. ETS 123 may also be used for assessments of programs located outside of Europe that have established an institutional policy to follow this standard in addition to local regulations and guidelines. AAALAC encourages institutions to make animal care and use determinations based on regulatory and funding requirements, overlaid with a performance approach that enhances animal welfare and quality science.

2. AAALAC International's Application of Performance Standards

I know that AAALAC says that it uses a performance based approach in its accreditation assessments, but what does that really mean when you come to visit my institution?

The use of performance criteria as a method to design and manage an animal care and use program was first described in the 7th edition of the *Guide for the Care and Use of Laboratory Animals* (NRC 1996), but was expanded on in the 8th edition of the *Guide* (NRC 2011). Even earlier editions of the *Guide* (NRC 1985) state that "professional judgment is essential in the application of these guidelines." As AAALAC International uses the *Guide* as a standard for its assessments, the accreditation program benchmarks whether institutions are achieving specified program outcomes (e.g., adequate sanitation), without being prescriptive regarding the exact manner in which to achieve the outcome or goal. While engineering standards specify in detail a method or technique for achieving a desired outcome, they do not provide for interpretation or modification of the technique should an alternative be equally acceptable. Alternatively, performance standards define the outcome in detail and provide measurable criteria for assessing whether the outcome is achieved. As noted in the 2011 *Guide*, the performance approach

"requires professional input, sound judgment, and a team approach to achieve specific goals." Research in laboratory animal management and science provides new information which should be used to update the performance standards used at an institution.

AAALAC International recognizes that engineering standards can serve as a useful baseline for some program elements, but considers the application of sound professional judgment to be critical to a successful and contemporary animal care and use program. For example, the 2011 *Guide* states that the recommended minimum cage height for rabbits is 16" (40.5 cm), while the U.S. Department of Agriculture's Animal Welfare Regulations require a minimum of 14" (35.6 cm). AAALAC recognizes that the acceptability of a cage height of 14" (35.6 cm) versus 16" (40.5 cm) is better judged based on a performance approach. Using the performance language in the *Guide* that animals "must have enough space to express their natural postures and postural adjustments without touching enclosure walls or ceiling," AAALAC would observe whether the rabbits' ears could be held in an upright position (if this was natural for the breed) and were not folded over by contact with the cage ceiling. AAALAC site visitors would give more consideration to the health, welfare and species-typical behavior of the animal than small differences in cage height or size. In this manner, the performance approach fosters animal welfare and quality science.

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B. ANIMALS INCLUDED IN THE AAALAC INTERNATIONAL ACCREDITED "UNIT"

1. Animal ownership

If animals owned by our institution are housed at another institution for production of antibodies, breeding transgenic colonies or quarantine, are these activities considered part of our AAALAC accredited program? Will the activities, facilities and program at the contract site be evaluated during our site visit?

AAALAC follows animal ownership in terms of defining who

is responsible for animals at an offsite program. In the examples described, your institution has confirmed ownership of the animals; therefore, if the contractor's program is not AAALAC accredited, a description of the animal care and use activities and facilities provided by the contract facility must be included in your AAALAC Program Description. The contract facility would also be visited during your triennial site visit and contractual agreements must provide for the review of the contracted facility by AAALAC site visitors. Specifically, you would need to include a detailed description of the relevant portions of the contractor's program (e.g., facilities, husbandry, veterinary care, IACUC or comparable oversight body review, etc.) for those elements of their program that pertain to or impact the care and use of your animals. The site visit team would also evaluate the portions of the contractor's facility(ies) that are relevant to your animals. If the contract facility is a significant distance from your main facility, this may have bearing on the site visit logistics, and you should contact the AAALAC International office to discuss the situation. During the scheduling of the dates of your site visit, the Council member leading the visit must be made aware that contract services are provided off-site by a non-accredited program. If you initiate a contract with a program that is not accredited between accreditation site visits, this change should be reflected in your Annual Report to AAALAC.

If the contractor's program is separately accredited by AAALAC, it will not be necessary to visit that facility during the site visit to your institution. Also, if your institution does not own the animals, but just owns the data (or intellectual property) that result from studies or procedures conducted using those animals, AAALAC will not visit the non-accredited site. The Spring 2003 issue of the Connection Newsletter contains an in-depth article on this particular subject (page 6) and is available for downloading from the AAALAC International Web site (http://www.aaalac.org/publications/newsletter.cfm). As the scope of animal ownership and responsibility may vary depending on a country's regulations, policy and/or agency guidance, AAALAC International strongly encourages institutions be familiar with local prevailing standards as well as AAALAC's approach.

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2. Invertebrate animals

We use a variety of invertebrates in our research program and I heard somewhere

that they have to be included as part of our accredited program. Can you clarify this for me?

The following statement is from the Rules of Accreditation as found on the AAALAC website:

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

Of particular concern to Council, vis-a-vis invertebrate colonies, is the inclusion of their review when such inclusion would benefit the program as a whole, or their exclusion would potentially jeopardize the overall program mission. Also, Council acknowledges the need to evaluate management of invertebrate colonies when those colonies are within a core animal facility and therefore subject to creating, or being subject to, potential adverse influences from activities in adjacent spaces. Possible areas of evaluation could include:

1. Training of personnel caring for and handling the animals.
2. Husbandry practices, including sanitation, diet, and adequate space (especially if contiguous with vertebrate holding areas).
3. Health monitoring and record keeping.
4. Species interactions for those held in the same room or area.
5. Physical plant provisions (e.g. , emergency power availability for species whose environment would be negatively impacted by a power outage).
6. Occupational health and safety risks (e.g. , GFI circuitry, zoonotic diseases, containment of mosquitoes used in malaria research, etc.).

While AAALAC does require that invertebrates used as a part of the research mission of the institution be included as part of the animal care and use program, there are many ways in which that can be accomplished. Many institutions do not have a formal protocol for invertebrate work, but notify the Institutional Animal Care and Use or Ethics Committee or comparable oversight body

(IACUC/OB) via letter about the work they will be doing with these species. Or the oversight may be a Standard Operating Procedure (SOP), policy statement, guideline, etc. , that is reviewed by the IACUC/OB and delineates the committee's responsibility over the use of invertebrates and provides guidance to investigators using invertebrates. Some of the issues the document may want to include are listed above. The intensity of oversight by the IACUC/OB may depend on such things as the species of invertebrate being used and the type of procedures being performed. Site visit teams will generally not review research activities involving lower level invertebrates such as zooplankton, sea slugs, nematodes, or mosquitoes, but will most likely review research with higher level invertebrates such as lobsters, squid or octopi. For example, if invasive procedures are being conducted on a higher level invertebrate, an IACUC/OB approved protocol may be an appropriate requirement. The guidance from AAALAC is, of necessity, flexible because it is likely that a site visit team would be very interested in the IACUC/OB oversight of invasive octopus research, as compared to oversight of work with zooplankton or nematodes.

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C. INSTITUTIONAL RESPONSIBILITIES

1. Allergy prevention

The occupational health and safety department at our institution has recently required the use of additional equipment in the animal facility to minimize exposure of personnel to animal allergens (biosafety cabinets, cage changing stations and bedding dump stations). They cite language in the 2011 *Guide* that prioritizes engineering controls for allergy prevention over personal protective equipment (PPE). What is the AAALAC position regarding engineering controls for allergy prevention?

The *Guide for the Care and Use of Laboratory Animals* (NRC 2011) does emphasize the use of "engineering or process controls" for allergy prevention. It also states that "PPE should be used to supplement, not replace, engineering or

process controls...." This guidance is made in the context of allergy prevention and early identification of personnel with emerging allergic symptoms. The *Guide* also cites the extensive literature indicating that laboratory animal allergy has become a significant issue for those in contact with laboratory animals. AAALAC International considers allergy prevention to be an important topic and a key component of the occupational health and safety program. The use of engineering controls to prevent exposure to allergens is preferred as the primary means to minimize personnel exposure. PPE should be used as an adjunct to engineering controls, rather than the foremost means of protection. Keeping in mind that the activities most associated with allergen exposure are handling animals and cages with bedding, cage changing and dumping soiled bedding in the cage wash area, appropriate engineering controls may include: proper animal facility design and function with separation of functional spaces; a well designed and functional HVAC system with appropriate airflow patterns; consideration of newer cage designs which minimize personnel exposure; and the use of containment equipment such as biosafety cabinets, cage changing stations and bedding dump stations. AAALAC International site visitors will continue to evaluate occupational health and safety programs and the methods used to prevent laboratory animal allergy through evaluation of personnel training, risk assessment by qualified occupational health and safety personnel, preventive medicine, periodic health evaluations, engineering controls, and the appropriate use of PPE.

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2. Frequency of program review and facility inspection

The 2011 ILAR *Guide* (page 26) states that "Program review and facilities inspections should occur at least annually or more often as required (e.g. , Animal Welfare Act and PHS Policy)." Does this mean that if our institution is not subject to the Animal Welfare Act or PHS Policy that we can automatically reduce the frequency of our IACUC program reviews and facility inspections to an annual periodicity?

AAALAC International expects program reviews and facility inspections by the IACUC (or comparable oversight body) be conducted at a frequency and intensity that ensure

prompt identification of program issues, with rapid correction of identified deficiencies. While national or regional regulations, policies and guidelines, as well as conditions of funding, may set a minimum frequency for such reviews, of greater importance to AAALAC is evidence of a highly engaged Committee that conducts thorough evaluations of the program and facilities, ensures corrective measures are taken in a timely manner, and that the program and facilities are adequately supporting the research, testing and teaching objectives of the institution. Because the conduct of timely program reviews and facilities inspections can be an effective component of overall monitoring and oversight, AAALAC International encourages Committees to carefully consider the frequency of their evaluations in order to ensure quality animal care and science. In certain programs and circumstances, self-assessments at frequencies greater than minimally required may be prudent.

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3. Harm-benefit analysis

On page 27, the *Guide for the Care and Use of Laboratory Animals* (NRC 2011) indicates that for studies that have the potential for unrelieved pain or distress, there are special considerations for IACUC review. Specifically, the *Guide* indicates that "the IACUC is obliged to weigh the objectives of the study against potential animal welfare concerns." This seems to indicate that for studies involving the potential for pain and distress, the IACUC should conduct a "harm/benefit" analysis. What does AAALAC expect with regard to Committee evaluation of these kinds of studies?

The 2011 *Guide* specifies that the Committee is obliged to weigh study objectives against animal welfare concerns in accordance with the tenets of the Three R's. This analysis is typically already performed by IACUCs in their reviews of proposed animal studies. AAALAC International expects that IACUC's (or comparable oversight body), as part of the protocol review process, will weigh the potential adverse effects of the study against the potential benefits that are likely to accrue as a result of the research. This analysis

should be performed prior to the final approval of the protocol, and should be a primary consideration in the review process. For animal use activities potentially involving pain and/or distress or other animal welfare concerns, the AAALAC International site visitors will assess how the Committee conducts this analysis.

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4. Nonaffiliated member of the IACUC

We are considering using a former employee as our nonaffiliated member. They are no longer affiliated with our program and they are familiar with the type of research we perform. Are there any concerns with this approach?

The *Guide for the Care and Use of Laboratory Animals* (*Guide*), NRC 2011, does offer some guidance on the issue of what should be some of the traits of the nonaffiliated (public) member. The *Guide* states this person should represent the general community interests in the proper care and use of animals, should not be laboratory-animal users, and not be affiliated with the institution or be members of the immediate family of a person who is affiliated with the institution. The OLAW/ARENA Institutional Animal Care and Use Committee Guidebook (which is an AAALAC International reference resource) expands on this by stating that the nonaffiliated member can bring significant value to the committee by bringing a non-institutional perspective to the research endeavor. For programs with an NIH Assurance, OLAW provides some additional guidance in their frequently asked questions section of their website (http://grants.nih.gov/grants/olaw/faqs.htm#IACUC_1) by stating that "the unaffiliated member should have no discernable ties or ongoing affiliation with the institution, and may not be a member of the immediate family of a person who is affiliated with the institution. Immediate family includes parent, spouse, child and sibling. Appointment of an individual who is unambiguously nonaffiliated is the best way to fulfill the letter and spirit of this provision." Using a former employee as the nonaffiliated member is certainly a gray area that might come into question during a site visit based on the above guidance, especially in context of the comments about the value of that member bringing a non-institutional perspective to the research endeavor and not having any

discernable ties or ongoing affiliation with the institution. While not specifically prohibited, the Institutional Official should give special consideration to the use of a former employee as a nonaffiliated member to ensure that both the intent and the spirit of the *Guide* are being met.

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5. Post-approval monitoring

We are an accredited institution located outside the United States. The *Guide for the Care and Use of Laboratory Animals* (NRC 2011) states that "continuing IACUC oversight of animal activities is required by federal laws, regulations and policies." We don't have any specific laws or regulations requiring an IACUC, though we have other equally effective methods of program oversight (e.g. , government inspections, animal welfare officer, etc.). Will AAALAC require us to hire compliance staff to perform post-approval monitoring to maintain our accreditation?

The 2011 *Guide* notes the value of having a mechanism in place to help ensure that animal study procedures are conducted in accordance with the approved protocol. Post-approval monitoring (PAM) programs vary from reliance on existing activities performed by the IACUC (or comparable oversight body) to very extensive supplemental audits of protocols and the entire program conducted by compliance staff. Although AAALAC agrees that ensuring compliance with approved protocols is critical, AAALAC International interprets the *Guide* recommendation for a PAM program in the broadest sense for the international community, namely that there will be a system for ensuring animal procedures conform with the approved protocol or study plan.

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6. Program-wide IACUC/OB exceptions

At some recent meetings I have heard the terms "program-wide exception" and "global exception" used when talking about an Institutional Animal Care and Use

Committee or comparable oversight body (IACUC/OB) approving exceptions to the *Guide*. Can you clarify these terms for me?

The *Guide for the Care and Use of Laboratory Animals* (*Guide*), NRC 2011 supports the use of performance standards in the event that acceptable alternative methods to engineering standards are available or unusual circumstances arise. With the advent of new scientific information and new technology, there are situations where new methods or procedures not described in the *Guide* may be available and result in equal or greater welfare for the animals involved. In most cases, these exceptions involve a specific project or are limited in scope within an animal care and use program. Occasionally, exceptions are wider in scope and may involve the entire animal care and use program or even apply globally in the case of organizations with facilities in multiple countries; these are often referred to as program wide and global exceptions, respectively. In all cases where practices deviate from *Guide* standards, AAALAC expects each IACUC/OB to establish an ongoing, documentable, site specific, data driven approach that allows for approval and monitoring of exceptions to the *Guide*. These criteria are essential to ensure that performance standards are properly developed and implemented in accordance with the intent of the *Guide*.

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7. Reporting animal welfare concerns

My institution is located outside the United States and there is no government requirement for our institution to develop a mechanism for reporting animal welfare concerns, though we have good lines of communication within our institution so that we are certain that any concerns would be discussed with management. The *Guide for the Care and Use of Laboratory Animals* (NRC 2011) describes a number of specific elements of a reporting system. Are all of these required?

AAALAC International recognizes that the regulatory requirement for a defined method for reporting animal

welfare concerns is primarily limited to the United States. However, as noted in the *Guide*, it is the responsibility of everyone associated with the animal care and use program to ensure animal welfare. In some instances, this may involve having to make a formal report regarding a welfare concern. Providing a method by which such reports can be made anonymously and without fear of reprisal, and enhancing staff awareness of the importance and means of reporting animal welfare concerns through training, the posting of signage, and other communication modalities are critical elements of the reporting program. It is AAALAC's expectation that such reports will be investigated by the appropriate oversight body (e.g. , the IACUC or comparable oversight body) and that any necessary corrective actions will be taken. In addition, AAALAC International should be informed of the results of the investigation and any subsequent corrective measures.

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8. Surgery in investigator laboratories

An investigator at my institution regularly performs survival surgical procedures on rodents in her laboratory. Our IACUC has reviewed and approved these activities. The recently updated *Guide* states that the laboratory should be dedicated only to surgical activities during the time that surgery is performed. Does this mean that all other activities in the laboratory must stop while surgery is being performed? What is AAALAC's opinion?

The *Guide for the Care and Use of Laboratory Animals* (NRC 2011) states, "For most survival surgery performed on rodents and other small species such as aquatics and birds, an animal procedure laboratory, dedicated to surgery and related activities when used for this purpose and managed to minimize contamination from other activities conducted within the room at other times, is recommended." AAALAC International acknowledges that limiting nonsurgical activities in the laboratory may help to minimize contamination of the surgical area. However, AAALAC recognizes that minimizing contamination during surgery may be achieved by considering several factors. The specific location of the surgical area within the laboratory should promote the proper conduct of sterile technique, and

to the extent possible, it should be isolated from other activities in the laboratory. The surgical area should be dedicated for that purpose while surgery is performed. Other factors that may impact the risk of contamination include the invasiveness and complexity of the surgical procedure, duration of surgery, and the nature of other non-surgical activities conducted in the laboratory (i.e. their likelihood of increasing the risks of surgical contamination). For complex or long procedures, or if the layout of the laboratory does not permit a suitable dedicated surgical space, it may be advisable to temporarily stop other laboratory activities, thereby dedicating the laboratory to surgery in order to maximize the potential for a good surgical outcome. For minor surgeries of short duration, conducted in a suitable area within the laboratory, it may be acceptable to allow other laboratory activities to continue if they do not jeopardize aseptic technique. The investigator, IACUC (or comparable oversight body) and veterinarian should evaluate surgical areas to ensure they are appropriate.

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9. Non-Pharmaceutical-Grade Compounds

Our IACUC receives protocols that require use of drugs or other chemicals not formulated for clinical use, which we understand to be characterized as non-pharmaceutical-grade compounds. We would appreciate AAALAC's guidance on the distinction between pharmaceutical- and non-pharmaceutical- grade compounds and how to evaluate this aspect of these protocols.

A pharmaceutical-grade compound is defined as any active or inactive drug, biologic or reagent, for which a chemical purity standard has been established by a recognized national or regional pharmacopeia (e.g., the U.S. Pharmacopeia (USP), British Pharmacopeia (BP), National Formulary (NF), European Pharmacopoeia (EP), Japanese Pharmacopeia (JP), etc.). These standards are used by manufacturers to help ensure the products are of the appropriate chemical purity and quality, in the appropriate solution or compound, to ensure stability, safety, and efficacy.

AAALAC International acknowledges that in an animal care and use program non-pharmaceutical-grade compounds often are necessary for scientific research. Where the use of non-pharmaceutical-grade substances may be essential for the conduct of science, the goal of the IACUC (or comparable oversight body) should be to consider the health and well-being of the animals while aiding the researcher in minimizing potentially confounding experimental variables and maximizing reproducibility of the research. The Council on Accreditation will apply a performance approach to its assessment of the use of non-pharmaceutical-grade compounds, and will expect that the IACUC (or comparable oversight body) has established acceptable criteria for use of such compounds within the institution and for review and approval of their use.

AAALAC distinguishes between two scenarios when considering the use of non-pharmaceutical-grade compounds:

Clinical Use - compounds used for the clinical treatment of animals and to prevent or reduce/eliminate animal pain or distress. Whenever possible, pharmaceutical-grade compounds must be used.

Research Use - compounds used to accomplish the scientific aims of the study. If available, and suitable, pharmaceutical-grade compounds are preferred; but when non-pharmaceutical-grade preparations are used, AAALAC International will expect investigators and the IACUC (or comparable oversight body) to consider the following factors:

- Use must be compliant with applicable national or regional regulatory guidelines and requirements and the requirements of relevant funding agencies;

- A scientific justification is provided;

- The pharmaceutical-grade compound is not available in the appropriate concentration or formulation or the appropriate vehicle control is unavailable

- The compound is required to generate data that are part of an ongoing study or that are comparable to previous work;

- The chemical properties of the compound are appropriate for the study and the route of administration (e.g., the purity, grade, stability in and out of solution, solution

vehicle properties, pH, osmolality, and compatibility of the solvent and other components of final preparation). In some cases the reagent-grade of the compound may be as or more pure than the pharmaceutical-grade; and

- The method of preparation, labeling (i.e., preparation and use-by dates), administration and storage of formulations should be appropriately considered with the aim of maintaining their stability and quality (i.e., to prevent inadvertent co-administration of infectious agents or contaminants).

10. Client-owned animals in veterinary colleges

Our AAALAC accredited Veterinary College is struggling over whether or not there is a requirement for client-owned animals to be covered under a protocol since they are used for teaching purposes for veterinary students during their clinical rotations, or when they become part of a research study.

AAALAC International has had a long standing policy of following animal ownership as a mechanism for determining inclusion in the accredited animal care and use program. This was highlighted in the Spring 2003 Connection Newsletter that described the AAALAC International Rules of Accreditation regarding contract facilities and how ownership determines responsibility. The concept of ownership also applies to Colleges of Veterinary Medicine where client-owned animals are brought in for care. Even though there are some teaching and research activities involved with this scenario, the animals are not owned by the institution and so therefore AAALAC does not consider them as part of the accredited program. For animals that are owned by the College of Veterinary Medicine being used for research, teaching or other purposes (e.g., blood donors), we would expect the Institutional Animal Care and Use Committee (IACUC or comparable oversight body) to provide oversight and for the animals to be covered by a standard operating procedure or protocol that is reviewed and approved by the IACUC/OB. There is nothing that prevents an institution from establishing some sort of IACUC/OB oversight mechanism for client-owned animals; on the contrary, it would reflect a high level of institutional commitment, but AAALAC does not require it. For institutions that also hold a U.S. Public Health Service

Assurance, see additional information regarding this topic at http://grants.nih.gov/grants/olaw/faqs.htm#App_8.

11.Transportation of animals used in research NEW

Recognizing the critical impact the transportation of research animals has on the quality of research and that the welfare of the animals being transported is governed by a number of regulatory agencies, what are AAALAC International's expectations to ensure humane transport of research animals?

AAALAC recognizes that the continuation of humane transportation of animals is vital to the research enterprise. However, this can be a stressful experience for the animals. The total experience of the animal during transport is influenced by many factors. It is expected that the parties involved are aware of and comply with all applicable regulatory requirements for the transportation of animals and the critical importance of ensuring that the animals are treated humanely at all times during the journey. Please refer to AAALAC International's Reference Resources (http://www.aaalac.org/accreditation/resources.cfm) for additional guidance.

The following points should be considered:

***Security*:** The consignor of the transportation containers and arrangements should ensure that the possibility of damage, misdirection and breach of biosecurity is reduced to a minimum by the use of suitably recognized reputable transport operators and sub-operators. Procedures should be in place to prevent theft or adulteration of transportation containers.

***Species specific transportation*:** Containers and transport vehicles should provide appropriate environmental conditions for the species being transported and personnel should have appropriate knowledge relative to animal biosecurity to maintain the animals' health status.

***Transportation Logistics*:** Special attention should be given to the mode of transport and the journey times should be minimized as much as possible. Journey plans should be in place with alternate plans available in case of

disruption of the original plan. The receiving institution should be informed about the itinerary and any changes in the timetable or any deviations from the plan which occur during transport. The receiving institution should have arrangements in place to receive the animals and trained personnel are available at the receiving institution to ensure the animals are removed from the shipping containers and inspected in a timely manner.

***Commercial carriers*:** When commercial carriers are used, they should be appropriately licensed, and they should use well-designed animal transport vehicles which are capable of maintaining appropriate environmental conditions for the species being transported, which are documented through appropriate record keeping. The drivers must be trained in the transport of animals and the regulations thereof. When non-commercial carriers are used they and their vehicles should be approved by the IACUC /OB.

***Planning for unexpected events*:** In case of an unexpected event, everyone in the transport chain should have a common understanding of contingency plans and knowledge of emergency contact persons who are available to respond during each segment of the journey. A clear emergency plan should be available and all the relevant information about contact persons, containment of the animals, and other relevant information should follow the animals on the crate or containers.

***Intra-institutional transport*:** When animals are being transported within an institution, the IACUC/OB should approve the vehicle(s) and the personnel who perform this function, taking into account the relevant points described in this FAQ. Responsibility of the IACUC/OB: The IACUC/OB (or comparable oversight body) and veterinarian should evaluate transportation of animals to ensure compliance with regulatory expectations as well as attention to the animals' well-being.

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D. ANIMAL ENVIRONMENT, HOUSING AND MANAGEMENT

1. Trio Breeding

The most common breeding scheme for mice at our AAALAC accredited institution is trio-breeding. While we have successfully managed many mouse colonies over the years using this system, we are uncertain that the cage space guidelines described in the 8th edition of the *Guide* allows trio-breeding schemes in standard cages. The *Guide* now states that 51 in^2 (330 cm^2) are recommended for a dam with a litter, but does not specifically mention the common practice of trio-breeding schemes in which there are two dams in a breeding cage. Will AAALAC continue to allow trio-breeding schemes in standard cage sizes?

The hallmark of the AAALAC International accreditation program is the application of performance based standards of animal care and use. Previous editions of the *Guide* have not included recommended cage space guidelines for mouse breeding, so the evaluation of cage densities for breeding mice has typically been based on performance criteria such as growth rate, pre- and post-weaning mortality, etc. Many institutions have developed IACUC (or comparable oversight body) approved breeding schemes, such as trio breeding, and have based their policies on performance indices that demonstrate successful outcomes and support animal well-being. In accordance with AAALAC International's Position Statement regarding Cage and Pen Space, performance based criteria for establishing and evaluating cage densities will continue to be considered paramount to determinations of appropriate cage size.

While the 2011 *Guide* has many performance-based guidelines regarding cage size, much of that language focuses on cages that allow animals to make normal postural adjustments and rest away from soiled areas, provide free access to food and water, and provide sufficient space for mothers with litters to allow the pups to develop to weaning without detrimental effects to the mother or the litter. With regard to trio-breeding schemes, ETS

123 also states that 51 in^2 (330 cm^2) is acceptable for a monogamous pair (outbred/inbred) or a trio (inbred).

In the United States, commonly used mouse cages measure between 75-82 in^2 (484-529 cm^2). This cage size could be appropriate for trio breeding, with the caveat that there are several factors that need to be considered when assessing the adequacy of cage space, such as average litter size of the strain(s) of mice, whether multiple litters are present in the cage and the difference in the age of the pups of different litters, growth rate, need for cross-fostering, cage dimensions, overall management and husbandry practices such as cage sanitation, etc. Cages that might be acceptable when litters are born may have insufficient space as pups grow, again depending on other factors. When considering cage space/animal density policies, the IACUC (or comparable oversight body) should consider many factors, including national or regional regulations, policies and guidelines, as well as conditions of funding, and critically evaluate objective measures of outcome-based performance standards.

2. Cage sanitation frequency

We just purchased some new ventilated isolator caging systems for our mice and rats which utilize solid bottom cages. Can we decrease our cage changing frequency below the *Guide* recommended minimum frequency of once per week?

While the *Guide for the Care and Use of Laboratory Animals* (*Guide*), NRC 2011 recommends solid bottom cages be sanitized at least once a week, it goes on to say that some types of cages might require less-frequent sanitation, which include individually ventilated cage (IVC) units.
The *Guide* stresses the use of performance standards when making these determinations. As an example, scientific studies have looked at environmental conditions (1) and cage changing frequency (2) for IVC systems and determined that under normal circumstances, changing cages in

these types of units once every two weeks provided for an acceptable environment for the mice. However, there are other factors to take into consideration. While this frequency of cage changing may be acceptable for many mice, it may not be acceptable for others (e.g., diabetic mice that exhibit increased urine output). The Institutional Animal Care and Use Committee or comparable oversight body (IACUC/OB) should review current cage changing practices for IVC units based on current literature and other factors (phenotype of the mice, type of bedding, housing density, etc.). For an IVC cage change interval longer than 2 weeks, verification of microenvironmental conditions may include measurement of pollutants such as ammonia and CO2, microbiologic load, observation of the animals' behavior and appearance, and the condition of bedding and cage surfaces. Also, as with any performance standard, there should be a system in place to monitor the outcome and report back to the IACUC/OB.

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3. Chick and piglet environmental temperature

I work at an institution that uses agricultural animals in research. Our IACUC has encountered a dilemma in determining the appropriate temperature to house some of our younger agricultural animals, specifically chicks and piglets. The ILAR *Guide* (NRC 2011) recommends that farm animals and poultry be housed at a temperature range of 16-27ºC (61-81ºF), but our researchers say that this range is too low for their young animals. How should our Committee handle this?

Thermoregulatory mechanisms are typically not fully developed in young animals, so often higher environmental temperatures are required during the early developmental stage. Although the ILAR *Guide* does recommend that temperature range, it also states that those ranges reflect

tolerable limits for adult animals and that the selection of macro- and micro-environmental conditions depend on several factors, including the age of the animal. The *Guide* states that "young birds of some species generally require a thermal gradient in their primary enclosure to meet basic physiological processes" and "Animals should be provided with adequate resources for thermoregulation (nesting material, shelter) to avoid cold stress." Your IACUC (or comparable oversight body) may wish to refer to the *Guide for the Care and Use of Agricultural Animals in research and Teaching* (*Ag Guide*), FASS 2010 for further direction. The *Ag Guide* recommends "for chicks, a 32 to 35°C ambient temperature (90 to 95°F) initially, decreasing by 2.5°C (4.5°F) weekly to 20°C (68°F); however, for some well-feathered strains, supplemental heat may be discontinued at 3 weeks if room temperature is 22 to 24°C (72 to 75°F)." For a lactating sow and her litter, the *Ag Guide* states that the preferred thermal range for the piglets is 32°C (90°F), with a lower extreme of 25°C (77°F) and no practical upper extreme. For prenursery piglets, 3 to 15 kg (7-33 lbs), the *Ag Guide* states that the preferred range is 26-32°C (79-90°F), with a lower extreme of 15°C (59°F) and an upper extreme of 35°C (95°F). The *Ag Guide* underscores the importance of facilitating and monitoring behavioral mechanisms of thermoregulation, noting that "Within limits, birds can maintain appropriate body temperatures by moving away from or toward sources of heat when that is possible and by seeking or avoiding contact with other individuals" and that "Pig behavioral thermoregulatory behaviors are better indicators of the appropriate air temperature than a thermometer." Similar performance-based language is also offered in ETS 123 Appendix A (2006). In farm settings, animals may experience air temperatures below or above preferred air temperatures. Consideration of supplemental heat or cooling should be given when temperatures are cool or warm. The amount of heating or cooling provided should be based on animal thermoregulatory behavior and physiology. Therefore, in keeping with both the ILAR *Guide* and the *Ag Guide*, a performance approach that ensures optimal welfare of the animals should be applied.

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4. Environmental enrichment

In looking at the 8th edition of the *Guide*, there is a significant amount of new information regarding the enrichment program. It appears that the enrichment program at our institution now needs to be in writing and should be reviewed by the IACUC, researchers and veterinarian on a regular basis. In addition, the *Guide* recommends that personnel responsible for animal care and husbandry should receive training in the behavioral biology of the species under their care. Will AAALAC require all these different parties to participate in this review and should we implement a training program for staff regarding laboratory animal behavior? Environmental enrichment is an important method of improving the well-being of many laboratory animal species and may be accomplished by the provision of stimuli, structures and resources that facilitate the expression of species-appropriate behaviors. Environmental enrichment, as one component of an IACUC (or comparable oversight body)-approved behavioral management program, should be provided in a consistent manner across the animal program, with due attention to personnel and animal safety. Personnel should be made aware of the enrichment program as one aspect of the overall training program; if it appears that the enrichment program has not been implemented properly, this may indicate inadequate training. Similar to their role in providing front-line observation for clinical illnesses, personnel responsible for daily care should be adequately familiar with normal animal behavior such that abnormal behavior may be recognized and reported. Implementation of environmental enrichment should also take into account the scientific goals of the study for which the animals are used; enrichment should be considered an independent variable and, thus, suitably controlled. While the *Guide* implies that a written environmental enrichment program should be in place, AAALAC site

visitors will focus their attention on the IACUC's review of the enrichment program, documentation of the review, and implementation of the program. AAALAC expects that the enrichment program will be reviewed regularly by the IACUC, and that the IACUC adequately represents the research community and veterinarian(s) at the institution in the review of enrichment program.

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5. Multiple animal species in a housing room

Can we house mice and rats in the same room in our animal facility? They are both from approved vendors and have a similar pathogen status. We also use strict barrier techniques and equipment (e.g. , HEPA filtered ventilated racks and cage changing stations) when housing animals and performing husbandry or experimental procedures. The *Guide for the Care and Use of Laboratory Animals* (*Guide*), NRC 2011 does recommend physical separation of animals by species to prevent interspecies disease transmission and anxiety due to interspecies conflict, which is usually done by housing in separate rooms, but the *Guide a*lso states that the use of specialized equipment (ventilated caging systems, etc.) to accomplish this may also be a suitable alternative. It is important to remember that the *Guide* addresses the fact that some of the concerns that may impact this decision are whether or not the animals are from multiple sites or sources, either commercial or institutional, and their pathogen status. The *Guide* states that if two species have a similar pathogen status and are behaviorally compatible, housing them in the same room may be acceptable.

Although the housing methods and husbandry practices you described would probably be very effective in preventing disease transmission between groups of animals with a similar pathogen status, they may not necessarily prevent interspecies conflict unless the ventilated rack system was connected to the room exhaust and not exhausted

back into the room. Since rats are a natural predator of mice, there would be a concern of inducing stress/anxiety in mice housed in the same room if the mice could detect the presence of rats. We would expect the Institutional Animal Care and Use Committee or comparable oversight body (IACUC/OB) to review and either approve or withhold approval, based on data they have reviewed for this particular circumstance. For example, a few considerations of the IACUC/OB may include the ability of the mice to detect the presence of the rats through either the visual or olfactory senses, the type of research being performed and any potential effects resulting from the housing arrangement. Some references below discuss the rat/mouse predator relationship and the resulting effects on mice, which include not just anxiety and fear, but also immunological and behavioral consequences as well. Helpful references may include:

6. Calvo-Torrent A, Brain PF, Martinez M. 1999. Effect of predatory stress on sucrose intake and behavior on the plus-maze in male mice. Physiol Behav. Aug;67(2):189-96. PMID: 10477049 [PubMed - indexed for MEDLINE]

7. Apfelbach R, Blanchard CD, Blanchard RJ, Hayes RA, McGregor IS. 2005. The effects of predator odors in mammalian prey species: a review of field and laboratory studies. Neurosci Biobehav Rev. 29(8):1123-44. Epub 2005 Aug 8. PMID: 16085312 [PubMed - indexed for MEDLINE]

8. Merali Z, Levac C, Anisman H. 2003. Validation of a simple, ethologically relevant paradigm for assessing anxiety in mice. Biol Psychiatry. Sep 1;54(5):552-65. PMID: 12946884 [PubMed - indexed for MEDLINE]

9. Hebb AL, Zacharko RM, Dominguez H, Laforest S, Gauthier M, Levac C, Drolet G. 2003.

   Changes in brain cholecystokinin and anxiety-like behavior following exposure of mice to predator odor. Neuroscience.

;116(2):539-51. PMID: 12559109 [PubMed - indexed for MEDLINE]

10. Lu ZW, Song C, Ravindran AV, Merali Z, Anisman H. 1998 Influence of a psychogenic and a neurogenic stressor on several indices of immune functioning in different strains of mice. Brain Behav Immun. 12(1):7-22. PMID: 9570858 [PubMed - indexed for MEDLINE]

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6. Use of wood pallets for feed/bedding storage

We use wood pallets to store animal feed and bedding off the floor of the storage room. Is this acceptable?

Means of feed and bedding storage should protect these supplies from spoilage, contamination, deterioration and vermin infestation. To achieve these goals, it is advisable to store feed and bedding on pallets, carts or racks. This storage method also facilitates adequate cleaning of the area. In general, pallets made of non-porous material, such as plastic, are preferred because they can be sanitized and tend to have a longer use. However, wood pallets may be acceptable. When wood pallets are used, it should be assured that they are not an immediate or continuing source of contamination or vermin into the facility. Also, the presence of wood on the floor should not impede room sanitation methods. Regardless of the pallet material used, the structural integrity of the pallets should be ensured to promote a safe work environment for personnel and to protect the supplies.

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7. Social Housing and Social Experience

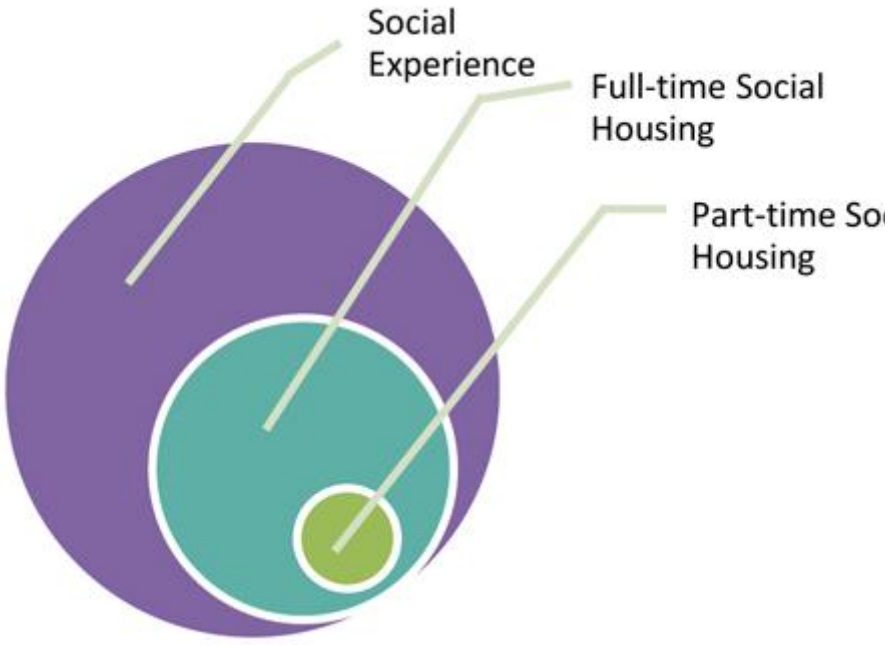
The 2011 *Guide for the Care and Use of Laboratory Animals* states that "Single housing of social species should be the exception...." We house our animals in a variety of configurations and would like further

explanation as to AAALAC's perspective and expectations regarding social housing.

The *Guide* states that "Social animals should be housed in stable pairs or groups of compatible individuals unless they must be housed alone for experimental reasons or because of social incompatibility." It is understood that research objectives, the health condition of the individual animal, and/or the challenges associated with the social behavior of some species, strains and/or sex of the animals may preclude social housing. In general, however, pair or group housing is recommended for social species (see AAALAC International's Position Statement on Social Housing, http://www.aaalac.org/accreditation/positionstatements.cfm#social).

AAALAC recognizes that there is a spectrum of social experience that can be made available to an animal based on the species, health, and use of the animal. These experiences are important because, when properly managed, they can significantly enhance the welfare of the animal. Full time social housing is the optimum manner to provide social experience. However, when full time housing with conspecifics is not possible, whether due to social incompatibility, veterinary concerns or scientific necessity, other social experiences should be considered such as part time access (e.g., overnight, when the animals are between studies, defined periods of time during the day, etc.) to full contact with conspecifics or protected contact that allows interaction through a mesh panel, grooming bars or other type of perforated barrier on either a part or full time basis. In this manner, the social experience of the animal occurs as a normal aspect of the animal's housing environment or as a separate activity that occurs outside of the primary enclosure, such as in a play yard, exercise cage, animal holding room aisle or facility corridor, etc. The staff responsible for the day-to-day management and oversight of the social experience of the research animals should be well versed in recognizing aggressive and affiliative behaviors of the various species in their care to provide for rapid identification and any necessary intervention.

The Institutional Animal Care and Use Committee (or comparable oversight body) and veterinarian should periodically review the strategies for providing social housing or other social experience to the animals at the institution to ensure conformance with the *Guide*.



The relative social experience of a laboratory animal.

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8. Frequency of Monitoring Rodent Traps

How often should vermin* traps (live trap or lethal) be checked by staff?

The Guide for the Care and Use of Laboratory Animals (*Guide*), NRC 2011 indicates that pest control managed by the animal care and use program personnel should be designed to prevent, control, or eliminate the presence of or infestation by pests in the animal environment. The *Guide* states (pg. 74) that "If traps are used, methods should be humane; traps that catch pests alive require frequent observation and humane euthanasia after capture" and also notes (pg. 112) that "all animals should be observed for signs of illness, injury or abnormal behavior by a person trained to recognize such signs. As a rule, such observation should occur at least daily." The *Guide* (pg. 105) further indicates that an adequate veterinary care program consists of assessment of animal well-being and effective management of pain and distress. The *Guidelines of the American Society of Mammalogists for the Use of Wild Mammals in Research*, an AAALAC International Reference Resource, indicate that lethal traps should result in a clean, effective kill and should be checked at least once a day, and in the event that an animal is still alive, it should be immediately dispatched in accordance with guidelines of the American Veterinary Medical Association.

In considering the information provided by the above references, the Council on Accreditation has determined that live mouse traps should be checked at least daily to prevent potential animal distress related to food or water deprivation. If the live trap provides food and water, then the IACUC should determine the appropriate frequency of checking traps. Alternatives to "sticky/adhesive" live board traps should be used for mice to avoid unnecessary animal distress as required by the *Guide* as part of a program of adequate veterinary care. Lethal traps (e.g., snap traps) should be checked daily so that in the event that a animal is still alive, it can be promptly euthanized. Council also considers that this guidance applies to all mice, be they laboratory or vermin mice.

*Excluding arthropods.

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E. VETERINARY MEDICAL CARE

1. Calibrating anesthetic equipment

We have a technician come to our facility to calibrate our anesthetic vaporizers on a regular basis. Does this meet AAALAC's expectations for calibration and maintenance of our anesthetic machines?There is a difference between an on-site calibration and having the vaporizer sent to the manufacturer for preventive maintenance. The services performed in each of these instances can be significantly different. During most on-site calibrations, the vaporizer is checked to ensure it is delivering the amount of anesthetic as reflected by the setting. When vaporizers are sent in for preventive maintenance, the vaporizer is broken down and a detailed maintenance is performed that includes cleaning and replacement of worn gaskets and other parts. The frequency of these types of services depends on the type of vaporizer and anesthetic being used. For example, a precision vaporizer using halothane requires more frequent calibration and maintenance due to the buildup of thymol (a preservative used in halothane) residues within the vaporizer. Other volatile anesthetics, such as isoflurane and enflurane, do not contain thymol and do not require as an intensive calibration and maintenance schedule. Note that NIOSH (Health Care Workers Guidelines/Chap5) states that all anesthetic equipment must be regularly monitored for leakage, improper design, or defects. This includes the anesthesia machine as well as the vaporizer since anesthetic machines can develop improperly functioning components such as flutter valves, gaskets, and scavenging equipment. AAALAC International expects that anesthetic machines and vaporizers are evaluated for safe and effective operation on an established schedule, consistent with the the

manufacturers recommendations. The manufacturer of your vaporizer should have recommended intervals for both on-site calibration and for maintenance that requires sending the vaporizer in to them, as well as recommended maintenance intervals for the rest of the anesthetic machine.

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2. Aseptic surgery and alcohol as a disinfectant

A researcher at our institution plans to use isopropyl alcohol to disinfect the surgical instruments she uses for a survival rodent surgical procedure. Will this be acceptable to AAALAC?

In 2001, AAALAC International published guidance on the use of alcohol as a skin disinfectant and for instrument sterilization (http://www.aaalac.org/publications/Connection/Using_Alcohol_Disinfectant.pdf). At that time, AAALAC's Council on Accreditation stated that the use of alcohol as a skin disinfectant for rodent survival surgery was acceptable, but that the blanket use of alcohol for surgical instrument preparation was not acceptable. The *Guide for the Care and Use of Laboratory Animals* (NRC 2011) upholds the position that, "Alcohol is neither a sterilant nor a high-level disinfectant." Recent evidence, however, does support that the use of alcohol may be acceptable for some procedures if prolonged contact times are used (Huerkamp 2002) or for limited numbers of serial rodent surgeries under specific conditions (Keen et al. 2010). The IACUC (or comparable oversight body) must evaluate the use of alcohol on a case-by-case basis with due consideration for animal welfare and scientific outcomes based on a review of current relevant literature, and consistent with expected surgical outcomes.

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3. Intraoperative monitoring

On page 128 of the *Guide for the Care and Use of Laboratory Animals* (NRC 2011), there is a new section which describes the importance of intraoperative monitoring during surgical procedures. The description includes evaluation of parameters such as anesthetic depth, body temperature, cardiac and respiratory rates and pattern as well as blood pressure. Will AAALAC

now require that these parameters be monitored and recorded for all surgical procedures?

Site visitors will often evaluate protocols, standard operating procedures and surgical records to assess the appropriateness of anesthesia, analgesia, intraoperative surgical monitoring, post-operative care and outcome. As stated in the 1996 *Guide* and detailed more specifically in the 2011 *Guide*, the overall goal of surgical monitoring is to "increase the likelihood of a successful surgical outcome." With that goal in mind, the Council acknowledges that the level and detail required for intraoperative monitoring can vary with the species, invasiveness and complexity of the surgical procedure, duration of surgery and other factors, such as anesthetic regimen and the use of neuromuscular blockade. In general, the greater the potential for pain or distress, procedural complexity, duration, or likelihood of an unsuccessful outcome, the greater the need for detailed, intensive intraoperative monitoring. The Council expects that the level of intraoperative monitoring and recordkeeping will be based on these factors. For example, the level of intra-operative monitoring might be minimal for short, minor procedures on rodents. In contrast, extensive intraoperative monitoring would likely be required for long, complex, major procedures regardless of the species involved. Appropriate intraoperative monitoring for non-survival surgical procedures is also expected, using the above criteria. As always, the Council will evaluate the adequacy of intraoperative monitoring using a performance based approach which assesses whether procedures meet the goals and provide a successful outcome.

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4. Rodent surgery record keeping

What level of monitoring and record-keeping are expected for rodent surgery?

There is clear general consensus in relevant resources (e.g. , the *Guide for the Care and Use of Laboratory Animals* (*Guide*), NRC 2011; *Medical Records for Animals Used in Research, Teaching, and Testing: Public Statement from the American College of Laboratory Animal Medicine*, ILAR 2007; *Rodents: Laboratory Animal Management*, NRC 1996; *Research Animal Anesthesia, Analgesia and Surgery*, SCAW 2007) that monitoring of rodents during surgery is critical so that animals are maintained under a surgical plane of anesthesia and that therapeutic intervention can be provided should unexpected physiological responses occur. Perioperative assessment of the physiological status (especially body temperature, but depending on other

factors, also respiratory rate, heart rate, blood pressure, blood gases, ECG, etc.) and anesthetic depth are valuable metrics for this purpose. Monitoring is also key to ensuring that sound research data will ultimately be collected from the animals. The level of detail contained in the records should accurately reflect the monitoring being performed.

Therefore, while AAALAC does not have a policy that stipulates the level of documentation for surgical procedures, the *Guide* does recommend that pre-surgical planning include consideration of record-keeping, and AAALAC would expect that this would occur and that the level of monitoring and record-keeping would be adjusted to the type of procedure, health of the animal, etc. Good record-keeping is also important so the Institutional Animal Care and Use or Oversight Body (IACUC/OB) can track whether or not a specific animal had undergone more than one survival surgical procedure, as multiple survival surgical procedures need to be handled in a specific manner by the IACUC/OB. To summarize, then, there is no "cookie-cutter" approach to monitoring and documentation associated with surgical procedures, but AAALAC site visitors would expect all the factors described to be evaluated by the IACUC/OB for all surgical procedures when making these determinations.

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5. Carbon dioxide (CO2) for euthanasia

The *Guide for the Care and Use of Laboratory Animals* (NRC 2011) notes the ongoing controversy regarding the use of carbon dioxide (CO2) for euthanasia due to its aversive characteristics. The *Guide* also notes that this is an area of ongoing research and that the suitability of CO2 as a euthanasia agent for small rodents should continue to be evaluated. Because of the controversy surrounding the use of CO2 in small rodent euthanasia, we are unsure of AAALAC International's expectations in this regard. Guidance on this topic would be very valuable as our institution develops a standard operating procedure on the utilization of CO2 as a euthanasia agent in small rodents.

The 2011 *Guide* states that *"Unless a deviation is justified for scientific or medical reasons, methods should be consistent with the AVMA Guidelines on Euthanasia (AVMA 2007 or later*

editions)." The 2013 AVMA Guidelines for the Euthanasia of Animals, an AAALAC International Reference Resource, categorizes CO2 euthanasia as acceptable under certain conditions and states that "Carbon dioxide exposure using a gradual fill method is less likely to cause pain due to nociceptor activation by carbonic acid prior to onset of unconsciousness; a displacement rate from 10% to 30% of the chamber volume/min is recommended.25,152,193,195" ... ... "The practice of immersion, where conscious animals are placed directly into a container prefilled with 100% CO2, is unacceptable." ... ... Carbon dioxide "must be supplied in a precisely regulated and purified form without contaminants or adulterants, typically from a commercially supplied cylinder or tank." ... ... "As gas displacement rate is critical to the humane application of CO2, an appropriate pressure-reducing regulator and flow meter or equivalent equipment with demonstrated capability for generating the recommended displacement rates for the size container being utilized is absolutely necessary."

However, as the *Guide* notes (page 13), *"The body of literature related to animal science and use of animals is constantly evolving, requiring Programs to remain current with the information and best practices."* Therefore, the appropriate displacement rate for different rodent species may change as the science regarding CO2 euthanasia develops.

Based upon these references, the Council on Accreditation developed the following expectations:

1. A 10-30% displacement rate of chamber air with CO2 gas/minute must be used when euthanizing[1] small rodents to minimize aversion, pain/distress, and escape behavior. The flow rate should be calculated to ensure the equipment meets required displacement specifications. While flow meters are the preferred method of ensuring flow rate, other methods are available.

2. When automated euthanasia systems are used displacement rates should be verified.

3. In instances where residual CO2 is expected, procedures should be in place to ensure removal of residual CO2 gas between euthanasia sessions.

4. Personnel conducting CO2 euthanasia must be competent in the procedure.

5. Confirmation of death must be assured.

6. When possible, euthanasia should be conducted in the home cage to minimize animal distress and anxiety. If home cage euthanasia cannot be practiced, the process must minimize pain and distress and the chambers should be cleaned between each use.

7. Because of their metabolic differences, great care should be taken with CO2 euthanasia of neonatal rodents, ensuring minimization of pain and distress, with due consideration of applicable laws and regulations.

8. Chambers should allow visualization of animals during CO2 euthanasia.

9. Distress vocalizations, fearful behavior, and release of certain odors or pheromones by a frightened animal may cause anxiety and apprehension in other animals. Therefore, procedures should be implemented to prevent potential distress resulting from exposure to the vocalizations and odors of frightened animals.

10. The IACUC must review and approve any deviations from the 2013 AVMA Guidelines on CO2 euthanasia using a performance based approach.

[1]This also applies to those rare cases when CO2 is used for anesthesia.

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F. PHYSICAL PLANT

1. Designing a new facility or renovation

Does AAALAC International have a checklist, or other resources, that can be used when designing a new animal facility, or conducting a major renovation, to help ensure that the facility meets accreditation standards?

AAALAC International has several resources available to assist in the design and construction of animal facilities. Animal facilities must first and foremost meet the recommendations set forth in the *Guide for the Care and Use of Laboratory Animals* (*Guide*), NRC 2011 where there is significant guidance provided on animal environment, housing, and physical plant requirements. Other resources include "The Handbook of Facilities Planning: Volume 2, Laboratory Animal Facilities" which was published in 1991, but contains detailed information which is still relevant. The order form for this book can be downloaded on the AAALAC

International website (www.aaalac.org/resources/available.cfm) and a searchable CD ROM purchased for $25.00, or a hardcopy spiral bound book for $35.00. At the same website address you can also download, for free, a copy of a PowerPoint presentation entitled "Facilities and Operations" which discusses many aspects of AAALAC International's expectations for animal facilities from a construction and operational viewpoint. A copy of a Connection Newsletter article entitled "Animal Facility Design and Renovation: Things to Consider Before Breaking Ground" can also be downloaded for free at http://www.aaalac.org/publications/Connection/Fall_1998.pdf. The American College of Laboratory Animal Medicine (ACLAM) has published a very thorough textbook entitled "Planning and Designing Research Animal Facilities" (Hessler 2009) and can be ordered from the Elsevier publishing company website (www.elsevier.com). You can also download a free copy of the National Institutes of Health (NIH) publication "NIH Design Policy and Guidelines" (2003 edition) at http://orf.od.nih.gov/PoliciesAndGuidelines/DesignPolicy/ which contains a section on animal research facilities on pages 138-213. While this document is intended to provide guidance on design and construction requirements for animal facilities built for NIH, it contains a wealth of useful information. The "Biosafety in Microbiological and Biomedical Laboratories" handbook (CDC/NIH 2009, 5th Edition) provides details on physical plant requirements for biocontainment facilities designed to house animals for research utilizing hazardous infectious agents and biological toxins. An online version of this publication is available for free on the CDC website at http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm.

While many of these resources speak to technical details of animal facility design and construction, AAALAC International uses a performance standard, or outcome, approach for evaluating animal facilities during the site visit process. The *Guide* provides a multitude of performance standards for animal facility design and construction. For example, rather than AAALAC International stating that 1/4 inch thick poured epoxy floors are required for animal facilities, AAALAC would refer to the *Guide*'s description of what is expected of an animal facility floor, such as being moisture-resistant, nonabsorbent, impact-resistant, and relatively smooth, although textured surfaces might be required in some high-moisture areas and for some species (such as farm animals). Further details are provided in the paragraph that describes additional attributes expected of an animal facility floor. The *Guide* was intentionally written using a performance standard approach since the design and size of animal facilities varies tremendously depending on the scope of institutional research activities, the species of animals to be housed, the physical relationship to the rest of the institution, and the geographic location. While performance standards allow facilities to be constructed in a variety of manners to meet the needs of each institution, the performance standard approach does not lend itself well to the development of checklists for animal facility design and construction. The best checklist would be to use the *Guide* to ensure that all applicable areas have been considered during the design and construction phases of a new animal facility or renovation of an existing facility.

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2. Emergency power supply

What are the requirements for having an emergency power supply for our animal facility?

The *Guide for the Care and Use of Laboratory Animals* (*Guide*), NRC 2011 states that: "In the event of an HVAC system or component failure, systems should at the minimum supply facility needs at a reduced level, address the adverse effects of loss of temperature control, and, where necessary, maintain critical pressurization gradients. " AAALAC does not have any independent requirements above the recommendations of the *Guide*. However, the Program Description submitted as part of your application packet, does include questions about emergency power. They are:

1. Note if emergency power is provided for the animal facility and if so, what electrical services and equipment are maintained in the event the primary power source fails.

2. Give history of power failures for the animal facility. Note frequency and duration. If emergency power was not available during a power failure, describe steps taken to ensure the comfort and well-being of the animals and the temperature extremes reached in the animal rooms during the failure.

3. Describe lighting system(s) for the animal housing facility(ies). For each species or holding room type, list light intensity, photo period (Light:Dark), construction features (e.g. , water resistance), and control (automatic versus manual). For systems automatically controlling photo period, describe override mechanisms.

4. If not previously reported, describe animal losses or health problems resulting from power, HVAC, or other life support system (e.g. , individually ventilated cages) failures, and mechanisms for reporting such incidences.

To best meet the recommendations of the *Guide* and AAALAC expectations, your Institutional Animal Care and Use or comparable oversight body (IACUC/OB), in consultation with your facilities management and scientific staff, would need to identify those components of the program that should continue to have electrical power in the event of an HVAC failure so as to prevent adverse effects to people or animals. As you might imagine, such needs will vary among institutions, depending upon the type of program (e.g. , intensive surgical load, aquatics, biocontainment), facility equipment (e.g. , rodents housed in ventilated units, freezers storing research samples), history of power failures, and facility design issues that could impact personnel safety during a power failure.

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3. Exposed pipes and ductwork in the animal facility

Can we have exposed pipes and ductwork in our animal facility?

The *Guide for the Care and Use of Laboratory Animals* (*Guide*), NRC 2011 states on page 139 that exposed plumbing, ductwork, and light fixtures are undesirable unless the surfaces can be readily cleaned. Construction materials that can not be readily cleaned, such as insulation, or materials such as exposed electrical wiring in an environment that will be constantly wet or with a high humidity level would not be acceptable. While not optimal, exposed ductwork or plumbing can be acceptable in animal rooms or support areas if they can be readily cleaned and there is a good program in place for routine sanitizing of these components. Having many horizontal surfaces in an animal facility makes sanitizing more difficult, but it can be accomplished through good practices, as long as all of the surfaces are sealed or fabricated of impervious materials that are capable of being sanitized. For animal containment facilities, the report, Biosafety in Microbiological and Biomedical Laboratories (CDC/NIH 2009), states that "Internal facility appurtenances, such as light fixtures, air ducts, and utility pipes, are arranged to minimize horizontal surface areas, to facilitate cleaning and minimize the accumulation of debris or fomites." When designing new animal facilities, you should also consider the cost of future personnel time in keeping all the ductwork and pipes clean versus the cost of placing them in the interstitial space or using a suspended ceiling. While suspended ceilings may be an alternative, they are not the most desirable type of ceiling in animal or animal support areas. But, they can be used if they are fabricated of impervious materials and free of imperfect junctions (page 138-139 of the *Guide*).

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4. Hospital stops

We are in the midst of designing a new animal facility and the architect recommended the use of "hospital stops" in the door frames because they aid in cleaning. Does AAALAC have an opinion about the use of these types of door frames?

The *Guide for the Care and Use of Laboratory Animals* (NRC 2011) states that, "Hospital or terminated stops are useful to aid in cleaning...." AAALAC international acknowledges that these types of door frames do aid cleaning and can be helpful for that reason. There may be some draw backs to these kinds of door frames in certain circumstances because there can be gaps between the door and the frame which may permit the passage of vermin or feral and escaped rodents. The *Guide* also states that, "Doors should fit tightly within their frames, and both doors and frames should be appropriately sealed to prevent

vermin entry or harborage." For areas of the animal facility in which biosecurity is paramount (barriers, holding areas for breeding genetically modified animals, etc.), careful consideration of the type of doors and frames is important to ensure proper biocontainment or bioexclusion.

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5. Humidity control

Our institution is located in a geographic area with wide seasonal swings in relative humidity. Our animal facility is able to maintain humidity in the *Guide* (NRC 2011) recommended range of 30-70%, but often does not meet the Â± 10% variation around the set point. Will this jeopardize our accreditation status?

The *Guide* does, in fact, recommend humidity be controllable within a range of 30-70% throughout the year. However, AAALAC International would assess the variation around the set point from a performance approach. Therefore, if no issues were identified by the institution or the AAALAC site visit team that would compromise the health and well-being of the animals or jeopardize the integrity of animal studies, then it is not likely that the Council on Accreditation would consider this variation a problem. If, however, animal welfare or study issues had been reported that could be linked to variation in relative humidity, then AAALAC would expect the institution to aggressively address the lack of control of humidity to ensure animal welfare and reliable data.

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6. Recycled air

The 8th edition of the *Guide for the Care and Use of Laboratory Animals* (NRC 2011) has changed the guidance offered to institutions regarding the use of recycled air to ventilate animal rooms as compared to the recommendations in the 1996 *Guide*. Can we now relax our previously rigidly held standard that no more than 50% of the air delivered to an animal room can be recycled?

AAALAC International has determined that the discussion in the 2011 *Guide* regarding recycling air should be augmented with several points noted in the 1996 *Guide*. In general, the use of non-recycled air is preferred for ventilation of most animal use and holding areas. If recycled air is used, the exhaust air should be HEPA-filtered (high efficiency particulate air-filtered) to remove airborne particles before it is recycled; the extent and efficiency of filtration should be proportional to the estimated risk. Gaseous filtration, such as with activated charcoal filters, should also be considered when recycling air. The

supply air should not exceed 50% recycled air and recycled air should be returned only to the room or area from which it was generated, except if it comes from other than animal housing areas and the source of the air poses no concerns for animal health. An exception to this recommendation would be mass air displacement clean-rooms, which generally use a minimum of 75% recirculated air due to their extremely high air exchange rates, which can be up to 700 air changes per hour for some clean-room classes. In all cases, the recycled air should be appropriately conditioned and mixed with sufficient fresh air to address air quality, thermal and humidity requirements of animals in the space. As noted in both the 1996 and 2011 editions of the *Guide*, the risk in some situations may be too great to consider recycling air.

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7. Vibration detection and supression

We are planning the design and construction of a new animal facility and intend for the new facility to be part of our AAALAC accredited program. The 2011 *Guide* states that all vibration should be minimized with vibration suppression systems. What does this mean and how will AAALAC International address this issue once the new facility is operational?

The *Guide for the Care and Use of Laboratory Animals* (NRC 2011) mentions the issue of vibration in several sections. Page 50 states that, "Attempts should be made to minimize the generation of vibration, including from humans, and excessive vibration should be avoided. ” This statement refers to the management of laboratory animal facilities and employing practices that minimize vibration associated with animal care and research activities. On page 153 it states, "... attempts should be made to identify all vibration sources and isolate or dampen them with vibration suppression systems (ASHRAE 2007b)." This statement refers to consideration of sources of vibration that may affect the building, and especially the animal facility and animals. While it may be impractical to identify and dampen all sources of vibration that may affect the animal facility, it is recommended that major sources of vibration be considered during the planning, design and construction phases of the project. Sources such as nearby roadways, trains or even seismic activities in some geographic areas may need to be considered and, to the extent possible, dampened. Sources of vibration within the facility such as cage wash areas, elevators and heating, ventilation and air conditioning systems should also be considered so that vibration from mechanical equipment is minimized. The AAALAC International Program Description outline elicits this kind of information so that AAALAC site visitors understand the measures taken to identify and mitigate the major sources of vibration.

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8. Windows in animal rooms

Our institution is preparing to initiate the design phase of a new animal facility and we see from the new *Guide* that we should not consider including windows in our animal rooms. We had been considering putting windows in our primate rooms because our sister company in Europe does this. What is AAALAC's opinion on having windows in animal housing rooms?

The *Guide for the Care and Use of Laboratory Animals* (NRC 2011) states that "The presence of windows in an animal facility, particularly in animal rooms, creates a potential security risk and should generally be avoided." AAALAC International recognizes that the inclusion of windows in animal rooms warrants consideration of potential security issues, as well as possible variation in the circadian rhythm of animals exposed to varying periods of daylight and room temperature fluctuations. However, AAALAC also acknowledges that windows are required for certain species (e.g. , nonhuman primates, dogs, cats, pigs) in some countries and can, in fact, be beneficial for several laboratory animal species. Indeed, AAALAC currently accredits many institutions where animals are housed in rooms with windows. The institution should evaluate the use of windows in animal rooms in the context of the species housed in the room, the type of research being conducted on those animals relative to the potential impact varying light and temperature levels may have on the experimental data, and the physical security of the area when making the determination regarding the inclusion of windows. The IACUC (or comparable oversight body) and other relevant staff should be involved in this decision-making process.

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9. MR Scanners and Cryogen Gas Storage

Our animal care and use program has two MR preclinical imaging suites located in separate buildings on campus and several small areas containing liquid nitrogen storage tanks that off-gas as part of routine operations. One MR scanner is a new model (4.7 tesla) with modern safety equipment in the room including a quench pipe that vents cryogen boil off gases to the outside, standard animal room ventilation rates (18 to 20 exchanges/hour), and an oxygen sensor. The other MR scanner is an older model (4.7 tesla) without a quench pipe or oxygen sensor in the scanner room. Additionally, cryogen gases are stored in the MR space to refill the magnet. According to the 8th Edition of the *Guide*, rooms with MR scanners or in which cryogen gases are stored must be equipped with oxygen sensors and a method

for increasing room ventilation to exhaust inert gases during cryogen filling. Does this imply that we have to install oxygen sensors and ensure increased ventilation rates in all areas in which cryogen is stored or used in MR magnets?

The *Guide* states "rooms with MR scanners or in which cryogen gases are stored **must** be equipped with oxygen sensors and a method for increasing room ventilation to exhaust inert gases during cryogen filling." AAALAC International recognizes that institutions may apply a variety of alternative methods to maintain personnel safety in areas where cryogen gases are used, including the presence of quench pipes that exhaust to the outside, increased ventilation rates in rooms where gases are used or stored, separation of the operator from the MR instrument, or combinations of these measures. AAALAC International uses a performance approach to assess the adequacy of the institution's own risk assessment that involves appropriate safety personnel and takes into account these various measures to ensure personnel safety. AAALAC acknowledges that situations may exist in which the application of alternate safety measures may obviate the need for installation of oxygen sensors or specialized ventilation.

Hazard identification and risk assessment are ongoing processes and institutions should identify relevant hazards and implement commensurate safeguards for those hazards. Cryogen storage areas and MR scanner rooms have numerous hazards including oxygen depletion, metallic projectiles, and interference with pacemakers. AAALAC International expects that all institutions, through their occupational health and safety program, will conduct a critical risk assessment of hazards identified in the animal care and use program.

10. Instructional Signage for Cage/Rack Washers and Bulk Autoclaves

The AAALAC International Position Statement on safety requirements for walk-in cage/rack washers and bulk sterilizers states that proper instructional signage should be posted. Can you provide any guidance as to the use of instructional signage as referenced in the Position Statement?

For cage/rack washers and bulk autoclaves that present a risk for entrapment, it is very important that safety features be clearly identified. While the location and use of safety features such as de-energizing pull-cords/bars, explosion release door latches and emergency shut-down buttons or switches may seem obvious during training, it is easy to become confused and disoriented during an emergency situation when seconds can make a difference. All safety features should be clearly identified and be easily distinguishable or have legible instructional or identification signage. In addition, a sign should be located on the outside of the rack washer or bulk sterilizer that identifies all of the safety features of the equipment. Safety devices should be easy to see and if signs are

used to individually identify a safety device, they should be easy to read and comprehend in an emergency situation. Examples of ways to accomplish this include having brightly colored emergency pull cords/bars/buttons or having signage, examples of which include, but are not limited to, the following: signs identifying the de-energizing cables in a rack washer which read "emergency safety cable"; signs on the designated push-points on the inside of explosion release doors which read "push here"; or a sign next to the emergency stop button on a bulk autoclave which reads "emergency stop." While identification of safety features is an important consideration, personnel must be trained in safety measures to minimize their risk.

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G. ADMINISTRATION

1. What is AAALAC?

AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through a voluntary accreditation program, a Program Status Evaluation service, and educational programs. More than 950 animal care and use programs in 41 countries have earned AAALAC International accreditation, demonstrating their commitment to responsible animal care and use. These programs include academic institutions, commercial organizations, hospitals and government agencies. AAALAC has been working to promote animal well-being and enhance life sciences research and education since 1965.

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2. How is AAALAC governed?

AAALAC is governed by a Board of Trustees. The Board consists of more than 70 prestigious scientific, educational and professional organizations—they are referred to as AAALAC's "Member Organizations." Each of these Member Organizations appoints a representative to serve a three-year term on the AAALAC Board. By actively involving major organizations, AAALAC International remains responsive to the issues that members face, while making sure that members of the scientific community understand and support the AAALAC International accreditation program.

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3. What is the Council on Accreditation?

The Council on Accreditation is at the heart of AAALAC's mission and work. The Council is comprised of highly accomplished animal

care and use professionals from around the globe who conduct the program assessments that determine which institutions are awarded AAALAC accreditation. Their responsibilities include conducting site visits, reviewing site visit reports, evaluating information, reviewing yearly reports from accredited institutions, and conferring the accreditation status of institutions. The Council is divided into North American, European, and Pacific Rim Sections.

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4. How does someone become a Council member?

Council members are appointed by the Board and are typically selected from AAALAC's pool of ad hoc Consultants/Specialists (see next question). Potential new members are nominated by current Council members, Board members, or colleagues from AAALAC Member Organizations. Council members are highly qualified and knowledgeable about diverse animal program and management issues. Many are veterinarians or animal care and use professionals.

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5. What are ad hoc Consultants?

AAALAC maintains a worldwide pool of more than 300 ad hoc Consultants/Specialists who have expertise beyond the realm of traditional laboratory animal species as well as specific expertise (for example, in aquatics, or agricultural science). Many also have unique discipline competencies, such as applied neuroscience, behavioral science, toxicology, pharmacology or physiology. Ad hoc Consultants/Specialists accompany Council members on site visits and make recommendations to the Council. These specialists add depth to the site visit team. They understand the intricacies of combining research, testing and educational missions with animal well-being.

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6. How does someone become an ad hoc Consultant?

Individuals who want to become an ad hoc Consultant/Specialist submit an application to become a Consultant. Once a year, a committee of the Council reviews all applications and selects candidates based on established guidelines. Ad hoc Consultants/Specialists must have a minimum of four years training or experience in the care or use of laboratory animals. Their experience must show that they have acquired knowledge of

performance standards and regulations, and have demonstrated an interest in, and commitment to, laboratory animal science. Ad hoc Consultants/Specialists serve a three-year term.

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7. How many animal care and use programs are accredited?

Currently, more than 950 animal care and use programs in 41 countries have earned AAALAC International accreditation. These programs include academic institutions, commercial organizations, agricultural research programs, government agencies, hospitals, nonprofit organizations, and biotechnology and pharmaceutical companies.

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8. Does AAALAC make its own regulations and policies?

No, AAALAC is not a regulatory body and does not make or enforce regulations. Instead, AAALAC relies on widely accepted guidelines, such as the *Guide for the Care and Use of Laboratory Animals* (NRC 2011), and other resources. AAALAC does, however, publish "position statements" that can be used as supplemental guidelines in dealing with certain issues, such as the use of farm animals, occupational health and safety, or adequate veterinary care. AAALAC also publishes its "Rules of Accreditation," a document that lists the minimum criteria institutions must meet *before* they can apply for accreditation.

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9. How extensive is an AAALAC evaluation?

AAALAC evaluates all aspects of an animal care and use program. An animal program (as defined by AAALAC) includes an organization's procedures and overall performance in animal care and use. The basic components that are evaluated include (but are not limited to) institutional policies, animal husbandry, veterinary care and the physical plant.

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10. Are small programs eligible?

Yes. AAALAC encourages every animal program, large or small, to achieve the highest standards for responsible animal care and use. The standards used to evaluate programs are universal, and can be implemented in programs of any size. Likewise, programs using

nontraditional research animals, such as fish or birds, are also encouraged to seek accreditation.

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11. Are agricultural animal programs eligible?

Yes. Programs that use agricultural animals in research or for teaching are embracing the AAALAC accreditation program. The G*uide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching* (FASS), along with the *Guide for the Care and Use of Laboratory Animals* (NRC 2011), is used to provide general parameters for the use of agricultural animals. For animals in an agricultural setting, AAALAC International takes the position that, in accredited facilities, the housing and care for farm animals should meet the standards that prevail on a high-quality, well-managed farm. For further guidance please see our Position Statement on this subject.

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12. How much does accreditation cost?

Organizations seeking and maintaining accreditation are asked to pay a one-time application fee and subsequent annual fees. Both of these fees are based on a sliding scale that generally correlates with the size of an institution's animal facility. An institution that has very few animals will pay much smaller fees than one that maintains a large vivarium and extensive support areas. The fees cover the cost of periodic site visits and administrative expenses.

AAALAC International determines the group classification during the review of the application. This classification, based primarily on the size of the facility and the time necessary to conduct a site visit, establishes a fair fee schedule. The established fee schedule may be amended as necessary to reflect the costs of operating the accreditation program. Revocation of accreditation shall be automatic if a unit is twelve (12) months in arrears for payment of fees. Please see http://www.aaalac.org/accreditation/fees.cfm for the fee schedule.

Payment may be made by check, credit card, wire transfer (contact the AAALAC International office for bank details), or purchase order.

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H. THE ACCREDITATION PROCESS

1. Program Description

What are the deadlines for submitting a Program Description to AAALAC International? When would the site visit occur?

Trimester	Program Description Due Date	Site Visit Occurs	Site Visit Report Preparation	Council Meeting
Summer	April 1	May-July	August	September
Fall	August 1	September - November	December	January
Winter	December 1	January - March	April	May

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2. Accreditation Fees

Organizations seeking accreditation are required to submit a non-refundable fee with the application materials. This fee covers the cost of the initial site visit. All applicants granted Provisional or Full Accreditation status pay an annual fee. Annual fees cover the cost of subsequent regularly scheduled triennial site revisits. The cost for interim site revisits conducted before the three-year interval, whether initiated by AAALAC International or the institution, will be borne by the institution.

AAALAC International determines the group classification during the review of the application. This classification, based primarily on the size of the facility and the time necessary to conduct a site visit, establishes a fair fee schedule. The established fee schedule may be amended as necessary to reflect the costs of operating the accreditation program. Revocation of accreditation shall be automatic if a unit is twelve (12) months in arrears for payment of fees. Please see http://www.aaalac.org/accreditation/fees.cfm for the fee schedule.

Payment may be made by check, credit card, wire transfer (contact the AAALAC International office for bank details), or purchase order.

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3. Confidentiality

How does AAALAC ensure confidentiality?

Unlike many government regulatory systems, the entire accreditation process is confidential. The accreditation evaluation and its results are kept between the organization seeking accreditation and AAALAC International—even if deficiencies

are found. AAALAC's purpose is to provide a peer-evaluation that results in valuable information organizations can use to improve their programs and achieve new levels of excellence. Board and Council members, ad hoc Consultants and AAALAC staff are all required to sign confidentiality agreements. Conflict-of-interest statements are also signed by each site visitor. AAALAC representatives agree to treat all materials as privileged, and safeguard the materials in their possession. Of course, accredited organizations are free to share their AAALAC reports if they choose to do so.

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4. Drop-In Visits

Our institution just received notice that AAALAC International will be conducting a "drop-in" visit. How does this differ from our routinely scheduled site visit and what are its implications?

Since 1989, and with endorsement of AAALAC's Board of Trustees, AAALAC has conducted drop-in visits—both "for cause" and "not-for-cause. " While very rare, drop-in visits of either type may occur between the routinely scheduled triennial visits. In both cases, relatively short notice (one day to a few days) of the pending drop-in visit is provided. The scope of the drop-in visit is typically very focused; more rarely, the entire animal care and use program may be reviewed during a drop-in visit. Costs for the drop-in visit are absorbed by AAALAC.

Occasionally, a site visit team will conduct a drop-in visit to an institution in an area where a routinely scheduled visit is occurring at another organization. These visits may be prompted by significant programmatic changes that have occurred at the institution subsequent to the routine site visit, such as critical organizational changes, an about-face in a commitment made to Council (e.g. , re-opening an animal housing area that had been closed in response to a site visit observation), etc. Such "not-for-cause" visits provide the Council on Accreditation an update as to the status/functioning of the institution.

Drop-in visits "for cause" may be conducted following a meeting of the Council on Accreditation, during which the Council has determined that an issue identified during the regularly scheduled site visit was of sufficient seriousness that immediate follow-up by the Council, in the form of an additional on-site assessment, was necessary. Occasionally, a drop-in visit "for cause" may be initiated by the Executive Office following receipt of a verifiable allegation related to the animal care and use program at an accredited institution.

Reports of observations made during either type of drop-in visit are taken to the Council on Accreditation. The observations made during a "not-for-cause" drop-in often result in no action being taken by the Council regarding the institution's accreditation status. Alternatively, the report may prompt the Council to require the institution to provide additional documentation regarding the matter, or the

Council may determine that a full site visit needs to be scheduled earlier than the typical three-year interval. The observations made during a drop-in "for cause" visit may result in no change to the accreditation status of the institution or the institution may be placed on less than Full Accreditation pending correction of the issue.

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5. "Should" vs. "Must"

The 2011 *Guide*, like its 1996 predecessor, distinguishes between and provides definitions for the terms "should" and "must" to provide the *Guide* Committee's interpretation of the relative importance of the recommendations made. It is not clear to me how these "shoulds" and "musts" translate into the mandatory items for correction and suggestions for improvement used by AAALAC International. Would you please clarify this?

The *Guide* states that, "*Must* indicates actions that the Committee for the Update of the *Guide* considers imperative and mandatory duty or requirement for providing humane animal care and use. *Should* indicates a strong recommendation for achieving a goal; however, the Committee recognizes that individual circumstances might justify an alternative strategy." Given the fundamental importance of the recommendations in the *Guide* that are prefaced with a "must," AAALAC's Council on Accreditation typically categorizes site visit findings that do not conform with a "must" statement in the *Guide* as a Mandatory item for correction. In AAALAC's nomenclature, a Mandatory item is a serious deviation from the recommendations of the *Guide*, and/or other AAALAC International standards, which has to be corrected to achieve or continue Full Accreditation. This judgment is based on the Council's assessment of the potential for the program deficiency to adversely affect the health, well-being or safety of animals or humans.

The second category of findings identified by AAALAC during the on-site assessments of animal care and use programs is comprised of Suggestions for Improvement (SFIs). These are recommendations that the Council on Accreditation feels are desirable to upgrade an already acceptable or even commendable program. SFIs are used to draw attention to recommendations that are typically denoted as "should" statements in the *Guide*. AAALAC considers the offering of SFIs to be an element of the peer review process that is designed to assist accredited programs by sharing the cumulative knowledge and experience of the Council. It should be noted that there is no obligation for institutions to make program changes based on suggestions for improvement; implementation of suggestions is, however, one means of promoting a high quality animal care and use program. Also, an SFI does not automatically become a Mandatory item for correction during the next site visit cycle if the same situation (e.g., procure, practice, etc.) is observed. However, if an issue is

identified that is a "should" statement in the *Guide*, but is one of numerous issues noted within the same program area that collectively signal a broader problem, then it may be wrapped into a Mandatory item for correction.

It is also worthwhile to note that several requirements in the *Guide* are not prefaced with the word "must." Other terminology is occasionally used to convey the same level of imperative for complying with the statement. Examples include:

- "... the IACUC **is obliged** to weigh the objectives of the study against potential animal welfare concerns."

- "Information that **is critical** to the IACUC's assessment of appropriate endpoint consideration in a protocol includes precise definition of the humane endpoint (including assessment criteria), the frequency of animal observation, training of personnel responsible for assessment and recognition of the humane endpoint, and the response required upon reaching the humane endpoint."

- "The committee **is responsible** for oversight and evaluation of the entire Program and its components...."

- "An **integral component** of veterinary medical care is prevention or alleviation of pain associated with procedural and surgical protocols." In summary, while the words "should" and "must" are generally associated with SFIs and Mandatory items for correction, respectively, the site visit finding is ultimately judged by the Council on Accreditation in the context of AAALAC's Three Primary Standards as well as the scope and impact of the issue.

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I. MAINTAINING ACCREDITATION

1. Annual Reports

Are there specific due dates for the Annual Reports?

Each year in mid-December, the AAALAC International office makes available the online Annual Report form. There are no specific due dates for submitting an Annual Report. However, AAALAC International's Rules of Accreditation require that you submit an Annual Report in order to maintain your accreditation. An institution may choose from a variety of reporting periods (e.g., University fiscal year, calendar year, federal government fiscal year, government oversight body reporting period, etc.) as the AAALAC International reporting period. Please be sure that the

period covered is continuous with previous reports (i.e., there are no gaps and all periods are covered by a report).

What type of information is provided in the Annual Report?

Annual Reports should provide notification of any:

- Protocol violations
- Animal use not approved by IACUC
- Protocol suspensions
- Changes in facility size, location, name
- Changes in IACUC composition or members
- Other changes in the animal care and use program

Can we use the same animal numbers reported to USDA for the AAALAC International Annual Report?

Yes, but remember we also need animal numbers for species not regulated by the USDA.

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2. Reporting requirements

What information should be reported to AAALAC International?

Adverse events to be reported promptly:

- Unexpected animal deaths
- Natural disasters
- Significant animal rights activities
- Inappropriate euthanasia techniques and/or failure to confirm euthanasia
- Allegations/complaints/reports regarding animal welfare concerns
- Lack of veterinary care
- OLAW/USDA investigations

Other information to be reported promptly:

- Changes in unit contact (please include degree, title, address, phone and fax numbers, and email)

- Changes in facility size, location, name if site visit is pending before Annual Report is to be submitted

Can we submit copies of incident reports sent to the Office of Laboratory Animal Welfare (OLAW or the USDA) to the AAALAC International Executive Office?

Yes, you can submit copies of correspondence addressed to OLAW or USDA regarding reportable incidences. Please note that not all issues that are reportable to OLAW or USDA require immediate reporting to AAALAC. See Question "What information should be reported to AAALAC International?"

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3. Members Only Section of the Website

I cannot access the Member's Only section. How do I get the username and password?

The username and password is provided only to the designated Unit Contact at your institution. This individual may share this information with other members of the institution.