Preparing for an AAALAC International Site Visit
Topics Covered

- AAALAC International site visits: Myth vs. Fact
- AAALAC speak
- Purpose of a site visit
- What to expect during a site visit
- Tips on preparing for a site visit
Accreditation = Partnership

For accreditation to work there must be a totally open and honest relationship between the accredited site and the Council on Accreditation. It is a partnership, with both sides working to provide the best animal care and use program possible. Want to know what AAALAC thinks about an issue? Give us a call!
Myth vs. Fact

- Myth: AAALAC International is a regulatory agency.

- Fact: AAALAC International is a private, nonprofit organization.
Myth vs. Fact

- Myth: AAALAC International conducts *inspections* of laboratory animal care and use programs.

- Fact: AAALAC International evaluates laboratory animal care and use programs through a voluntary, peer-review process.
Myth vs. Fact

- Myth: AAALAC International establishes policies and regulations.

- Fact: AAALAC International evaluates animal care and use programs based on recommendations in the *Guide for the Care and Use of Laboratory Animals (Guide)*, NRC 1996 and other widely accepted guidelines.
What Else Might Apply to Us?

- PHS Policy?
- PHS Assurance?
- PHS Funding?
- Animal Welfare Regulations?
- USDA species?
- Agriculture Guide?
Want a Heads Up on Other References that Site Visitors Use?

Go to: www.aaalac.org

AAALAC's Reference Resources

AAALAC International relies on the *Guide for the Care and Use of Laboratory Animals*, NRC 1996, as its primary standard for evaluating laboratory animal care and use programs. AAALAC International also refers to other specialty publications for supplemental information about procedures or techniques related to the care and use of laboratory animals. Below are select references and information on where to obtain them.

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**United States**


2. AAALAC International *Position Statements*.

Myth vs. Fact

- Myth: AAALAC International uses the same standards to evaluate animal programs outside the U.S.

- Fact: Because each country has its own set of laws and regulations, AAALAC International site visitors use a customized approach for evaluating the programs.
Myth vs. Fact

- **Myth:** AAALAC International evaluates animal care and use programs that only use animals regulated under the Animal Welfare Act.

- **Fact:** AAALAC International accreditation covers all vertebrate animals. Many programs using non-regulated species, such as rats and mice, participate in the accreditation program.
Myth vs. Fact

- Myth: An institution’s evaluation and report is available to the general public.

- Fact: AAALAC International’s accreditation process is confidential. The evaluation and its results are known solely by the institution and AAALAC International, even if deficiencies are found.
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>PD</td>
<td>Program Description</td>
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<tr>
<td>PE</td>
<td>Program Evaluation</td>
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<tr>
<td>PSVC</td>
<td>Post Site Visit Communication</td>
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<tr>
<td>CoA</td>
<td>Council on Accreditation</td>
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<tr>
<td>SV</td>
<td>Site Visit</td>
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<tr>
<td>Must</td>
<td>Really Means Must</td>
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<td>Should</td>
<td>Good Idea</td>
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Purpose of the Site Visit

- Gain thorough understanding of your program of animal care and use
- Collect evidence of good performance!
- Serve as Council’s eyes and ears
- Gather sufficient quantities of information to serve as advocate before Council
Before the Site Visit

- The Council member is assigned
- Setting the date with the institution
- The Co-Visitors are selected
  - Shared information is confidential
  - Same team never returns to same site
What do ‘They’ Know?

- Have read the current PD
- Have reviewed history of the institution
- Have previous evaluations
Site Visit Coordination

- Make hotel reservations
- Assure they know how to get where
- Local transportation to institution may be needed
- Introductory meeting at the institution commonly at 8:00 a.m. (arrival usually 7:30-7:45 am)
- Be on time!!!!
- Gracious collegial support is always the right thing to do
Entrance Briefing

- Meet with institutional leaders (looking for evidence of institutional support)
- Introduce AAALAC International
- Explanation of the accreditation process
- Explanation of the proposed daily activities
- Explanation of possible final outcomes of SV
- Offer an Exit briefing at conclusion of the SV
Program Review

- Review/clarification of aspects of program
- Clarification of Program Description
- Site visitors may request additional supporting information to gain additional information about the program
- Site Visitors may ask for protocols and other documents for later review during the SV
Program Review

- Pre-Review:
  - Questions (and responses) before hand
  - Supplemental documentation before hand

- On Site Review:
  - Page by page clarification
  - (Abbreviated versus Long)
Meeting with the IACUC

- Set aside some time to meet with IACUC
- Luncheon works well
- Describe accreditation process
- Discuss issues and talk with lay representatives
- Problem cases … IACUC solutions
- VERY important for site visitors to “get a feel” if IACUC is engaged
Meeting the Husbandry Staff

- Can set aside a prescribed time …
- Can have hallway meetings …
- Staff should be ‘familiar’ with the accreditation process
- Discuss their areas of activity
- Don’t let Site Visitors do dumb things …
- Do be around and working
Meeting the Research Staff

- Facility walk-through evaluations
- Health of animals
- Condition of facilities (Sanitation)
- Emergency Contacts and after hours vet support
- Contract and satellite facilities
- PI laboratory visits
Review of Documentation

- USDA Inspection Reports
- Compliance Records
- Selected IACUC Protocols
- PHS Assurance
- IACUC meeting minutes
- Standing Operating Procedures (SOPs)
Executive Session

- Site Visitors time to prepare for Exit Briefing
- Discuss issues and prepare notes
- Commendations for unit
- Mandatory deficiencies and SFI’s
- Site Visitors recommendations to Council
Exit Briefing

- Provide unit with preliminary findings and impressions
- Opportunity to correct misinterpretations or errors
- When appropriate encourage PSVC within 10 days
- Verbal, not written
Exit Briefing

- Conducted by Council member
- Summary of program strengths and weaknesses
- Commendations of personnel when appropriate
- Re-emphasize - Independent opinions of site visitors
Exit Briefing

- Discuss issues that are not clear
- Unauthorized research and procedures – Mandatory
- Significant health and safety issues for personnel and animals - Mandatory
- SFI’s - Suggestions for improvement - e.g., more intense microbiological monitoring
- May have off line comments too.
## Exit Briefing – Potential Outcomes

<table>
<thead>
<tr>
<th>If already accredited:</th>
<th>If a new application:</th>
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<tbody>
<tr>
<td>CFA</td>
<td>AFA</td>
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<tr>
<td>CFA with condition</td>
<td>Provisional</td>
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<tr>
<td>DA</td>
<td>Withhold</td>
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<tr>
<td>Probation</td>
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<tr>
<td>Revoke Accreditation</td>
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Post-Site Visit Responses

- Involve the IACUC in response to findings
- Don’t hesitate to contact Council member or AAALAC office if you have questions
- Review potential mandatory findings thoroughly
- If you have an OLAW Assurance, and findings meet their definition of a reportable event, you should report them to OLAW
Post-Site Visit Responses

- Unless you agree with findings, **DO NOT** make changes or spend money on fixes until final letter arrives.
- Final letter will include:
  - Commendations
  - Acknowledgement of any items already addressed through PSVC
  - Any mandatory items and/or suggestions for improvement
Post-Site Visit Responses

- Mandatory finding
  - a mandatory item is, in Council's judgment, a serious deviation from the recommendations of the Guide and/or other AAALAC International standards that must be corrected to achieve or continue accreditation
Post-Site Visit Responses

- Suggestion for improvement
  - An element of the peer review process designed to assist accredited programs through the sharing of knowledge and experience
  - There is absolutely no obligation for institutions to make program changes based on suggestions for improvement
Accreditation Verification Letter

- Available on request
  - Mail, phone call
  - Through the accredit mailbox (accredit@aaalac.org)
  - Can only be requested by official unit contacts

- Verifies
  - Currently accredited
  - Date of initial accreditation
Preparing for a Site Visit

**Do**
- Maintain program in “inspection-ready” state
- Self-identify and resolve deficiencies
- Keep administration involved and educated
- Make sure practices and PD match
- Ensure previous promises to AAALAC have been kept

**Don’t**
- Practice “management by AAALAC”
Preparing the IACUC

- Train and educate
- Keep informed of national issues and debates that may be applicable to your program
- Discuss and develop policies on relevant issues where clear guidance is lacking
- Document activities
- Follow deficiency reporting requirements
Preparing the OHS Program

- MUST be part of an overall animal care and use program
- Evaluate extent and level of participation
  - Risk assessment performed
    - Job related risks
    - Personal health risks
- Are all at-risk employees offered participation in an OHS program?
Preparing the OHS Program (Cont)

- Are declinations of participation documented?
- Hazard Identification performed routinely
- Waste anesthetic gas exposure
- Allergy awareness and prevention
- Zoonoses awareness and prevention
Preparing the Husbandry Program

- Keep areas clean and uncluttered
- Follow sanitation schedules
- Cage sizes adequate
- Monitor effectiveness of sanitation procedures
- Have exemptions documented and approved by IACUC
Preparing the Husbandry Program (cont)

- If SOPs in place, are they followed?
- Condition of caging
- Breeding colonies
- Checklists completed and current
- Does PPE make sense and procedures followed?
Preparing the Veterinary Care Program

- Have an effective method for identifying, treating, and following up on sick animals
  - ALL sick animals identified
  - Documentation of Tx and resolution
- Part-time veterinarian visits documented
- Frequency of rounds sufficient for facility
- Anesthesia/analgesia: current, documented
Preparing the Veterinary Care Program (cont)

- Is environmental enrichment considered for all species?
- Is aseptic technique followed for rodent survival surgeries?

OR

(Staged Event)
Preparing the Physical Plant

- Doesn’t have to be new
- Does need to be in good repair, clean and sanitizable
- MUST have HVAC performance data, current within 12 months of site visit
- Performance standards and animal room HVAC
- Temperature and humidity monitored
- Contingency plans for power loss
- Rackwash safety!!
Preparing the Staff

- Don’t shut down, we need to see daily operations
- Let PIs, technicians, caregivers know site visitors may ask questions
- Let staff know that a lot of writing is normal
Questions