Preparing Your Laboratory For The AAALAC International Site Visit
Topics Covered in this Presentation

- 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
Let’s Start with a Small Bit of Psychoanalysis

Which of the following pictures best represents your impression of an AAALAC International site visit?
Accreditation = Partnership

‘B’ is the correct response. For accreditation to work there must be an open and honest relationship between the Duke and the AAALAC Council on Accreditation, which results in a partnership.

Accreditation is a partnership, with both sides working to provide the best animal care and use program possible.
Myth vs. Fact

- **Myth**: AAALAC International is a regulatory agency.

- **Fact**: AAALAC International is a private, non-profit, non-government organization that provides independent assessment of animal care programs.
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.
- PHS Policy
- Animal Welfare Regulations
- The ‘Guide’
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.
AAALAC Speak

- PD: Program Description
- PE: Program Evaluation
- PSVC: Post Site Visit Communication
- CoA: Council on Accreditation
- AAALAC: Association for the Assessment and Accreditation of Laboratory Animal Care, International

- Must: Really Means Must (Mandatory)
- Should: Suggestion For Improvement
AAALAC Speak

- MANDATORY (must):
  - Affect animal welfare and well-being
  - Serious human safety concern
  - Serious deviation from federal regulations
  - Serious deviation from PHS policy

- SUGGESTIONS FOR IMPROVEMENT (SFI):
  - ‘Best practices’ at other institutions
  - New ideas that might enhance the program
  - ‘Less than serious’ of all of the above mandatory items
Purpose of the Site Visit

- Gain thorough understanding of our program of animal care and use (confirm our PD accuracy).

- Collect evidence of good performance!

- Serve as Council’s eyes and ears.

- NOTE: Our SV will be our advocate before the Council of Accreditation!
What Will Not Happen

- Our information is confidential – it will not be shared.

- Our information is not FOI-able – it will not be released.

- We will not see the same site visit team again.

- AAALAC will not tell us how to fix things.
What do ‘THEY’ know?’

- They have read our current PD
- They have our previous evaluations
- They have our annual reports
- They have reviewed our institutional history
Site Visit Process

Step 1: Site Visit Coordination
Step 2: Entrance Briefing
Step 3: Program Description (PD)
Step 4: Meet with IACUC
Step 5: Meet with care staff
Step 6: Meet with research staff
Step 7: Facility Reviews
Step 8: Document Review
Step 9: Executive Session
Step 10: Exit Briefing (EB)

Then …. Post-Site Visit Communication (PSVC)
Step 1: Site Visit Coordination

- We will make hotel reservations
- We will assure the SV members get where they need to be (RDU to hotel; hotel to meals; etc.)
- We will provide local transportation
- We will be on time
- We will be gracious & collegial (right thing to do)
Step 2: Entrance Briefing

- **Purpose:** Meet with institutional leaders. The Site Team will be looking for evidence of institutional support.

- **Required Attendees:**
  - CEO/IO (Senior Administration) and …
  - Animal Program Leadership
  - University Media / Safety / Employee Health
Step 2: Entrance Briefing

- The Site Team will:
  - Introduce AAALAC & themselves
  - Explain the accreditation process
  - Explain the planned site visit daily activities
  - Explain the possible outcomes of SV
  - Offer an ‘Exit Briefing’ at conclusion of the SV
  - Field questions
Step 3: Program Desc. Review

- Review Program Description in detail …
- Clarify mysteries or mis-speak
- Required Attendees: Animal Program Leaders
  - IACUC Chairman
  - DLAR Director
  - OAWA Director
- Others as needed (IO / OESO / EH / Facilities)
Step 4: Meet with the IACUC

- Will ask for IACUC discussion:
  - About the review process
  - Semi-Annual Program Review
  - Facilities Review
  - Non-compliance Review
  - Animal use allegations
  - Problem cases … IACUC solutions
Step 4: Meet with the IACUC

- Will focus questions to:
  - Non-affiliated member
  - Scientist members

- IT IS VERY IMPORTANT FOR AAALAC SITE VISITORS TO ‘GET A FEEL’ OF THE IACUC PROCESS.
- CENTRAL ISSUE: IS THE IACUC ENGAGED?
Step 5: Meet with the Care Staff

- Usually a ‘hallway’ meeting
- Staff **MUST** be ‘familiar’ with:
  - Animal Welfare reporting process
  - Veterinary care reporting process
  - Their area of activity
- Staff **MUST NOT** let Site Visitors do ‘dumb’ things (e.g. direct path, prevent contamination)
- Staff should be around and be working
Step 6: Meet with the Res. Staff

- SV team will be looking for awareness of:
  - Normal animal behavior / discomfort / distress
  - Current health status of their animals
  - Condition of facility sanitation process
  - Veterinary emergency contacts
  - The ‘whistleblower policy’
  - How to contact the IACUC
  - Controlled drug management
  - Does the R.S. know what the protocol says?
Step 7: Facility Reviews

- SV team will choose where they go. We will alert you as soon as we know. SV are looking for:
  - Working / informed / caring people;
  - Good animal care practices;
  - Good PPE / safety / OESO practices;
  - Posted veterinary care instructions;
  - Complete anesthesia / analgesia records;
  - Instructions on reporting concerns;
  - Clean, serviceable equipment;
  - Medications / fluids ‘IN-DATE’;
  - Protocols / SOPs current and available.
Step 8: Document Review

- USDA Inspection Reports
- Compliance Records
- Selected IACUC Protocols
- PHS Assurance
- IACUC meeting minutes
- Standing Operating Procedures (SOPs)
Step 9: Executive Session

- Site Visitors time to prepare for Exit Briefing
- Private room – No Duke representative
- Will discuss issues and prepare notes
- Will prepare:
  - Commendations
  - Mandatory deficiencies
  - SFI’s
  - Site Visitors initial recommendations to Council
Step 10: Exit Briefing

- Provide us with preliminary findings
- Opportunity for us to correct misinterpretations
- Verbal, not written
- Summary of program strengths and weaknesses
- Commendations of personnel when appropriate
- Discuss issues that are not clear
Step 10: Exit Briefing

IMPORTANT NOTE:

- This IS NOT the Council of Accreditation decision! This is not the end of the process!

- This IS a verbal report of what the SV team noted and where their thoughts are headed.

- This IS our best clue of what we need to enhance / resolve / clarify / modify.
Step 11: PSVC

- **Post Site Visit Communication** is our opportunity to clarify items presented at the Exit Briefing

- Provision of supplementary documents requested by the visitors
Potential Outcomes

- Continued Full Accreditation (CFA)
- CFA w/ condition
- Deferred Accreditation (DA)
- Probation
- Revoke Accreditation
Preparing for the Site Visit

- Now we know the process, but

HOW DO WE PREPARE OUR AREA FOR THE AAALAC SITE VISIT?
Preparing for the Site Visit

- **Do:**
  - Maintain program in “inspection-ready” state
  - Self-identify and resolve deficiencies
  - Keep lab involved and educated
  - Make sure practices and SOPs/protocol match
  - Everyone must be current on training
Preparing for the Site Visit

Do:

- Check drugs / fluids
- Check lab notebooks for animal care matters
- Check equipment for certification dates
- Check equipment for serviceability
- Check cleanliness of the lab and animal area
Preparing for the Site Visit

Don’t:

- Worry or panic – just be normal
- Practice “management by AAALAC”
- Stop all animal work that week
- Hide from the Site Visitors
Preparing for the Site Visit

- Don’t:
  - Mislead the Site Visitors – be accurate
  - Let the SV go where they should not go
  - Over answer the question
  - Keep silent about the good things your lab does
Preparing for the Site Visit

GENERAL ACTIONS TO CONSIDER:

- Train and educate your staff on Duke program policies
- Keep staff informed on the status of the program issues
- Be informed on national issues and debates that may be applicable to your program
- Keep tracking documents up to date
- Be aware of deficiency reporting requirements
- Talk about AAALAC in your lab meetings
- Get excited about our animal care and use program!
Preparing for the Site Visit

COMMON SAFETY ISSUES:

- Evaluate your lab spaces … ask OESO to do a lab audit?
  - Hazard Identification / Risk Assessment?
    - Job related risks
    - Personal health risks
- Waste anesthetic gas exposure
- Safe working practices in general?
Preparing for the Site Visit

COMMON SAFETY ISSUES:
- Allergy awareness and prevention
- Bite awareness and prevention
- Zoonoses awareness and prevention
- Air quality assessments performed
- Controlled drug (any drug) management
- Discard of waste materials / equipment
Preparing for the Site Visit

COMMON HUSBANDRY ISSUES:

- Clean and uncluttered lab spaces (animal)
- Follow sanitation schedules
- Checklist up to date
- Monitor effectiveness of sanitation procedures
- Have exemptions approved by IACUC
Preparing for the Site Visit

COMMON HUSBANDRY ISSUES:

- Assure cage sizes are adequate
- Caging in safe repair
- PPE being used (where appropriate)
- SOPs being followed
- Reports and follow-ups of veterinary care
Preparing for the Site Visit

COMMON VETERINARY CARE ISSUES:

- Know the method for identifying / treating sick animals
- **ALL** sick animals identified
- Documentation of Tx and resolution
- Frequency of rounds – is it sufficient for animals (?)
- Aseptic technique being used
- Anesthesia: current, documented
- Peri-operative analgesia documented
Preparing for the Site Visit

COMMON PHYSICAL PLANT ISSUES:

- Doesn’t have to be new, but …
- Good repair, clean and sanitizable
- MUST have current HVAC performance data
- Temperature and humidity monitored and appropriate (when animals are present)
- Contingency plans for likely ‘disasters’
- Managing electrical safety / lifting hazards / other laboratory hazards
Final Notes – Best Counsel

- Don’t shut down!
- Be friendly!
- SV may ask questions
- Lots of SV writing is normal
- Site visitors work in animal programs, but YOU are the experts in your area of operation!!! Show them your skills and knowledge … be proud and knowledgeable about how your care for animals, how you use animals, and how your research progresses.