Completing the AAALAC International Program

Description: Guidelines, Pitfalls, Advice

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Agenda

- Introduction
- Review recent changes
- Highlight challenging areas (avoiding pitfalls)
- Q & A - Discussion
Accreditation Process

- Three Phases:
  1) Pre site visit activities
  2) The site visit
  3) Post site visit activities
The Program Description (PD)

- A very detailed document which describes your program of animal care and use
- Requires intensive self-evaluation
- Provides an excellent source of information for key personnel in your program
  - Institutional training
  - Semiannual evaluations
- Provides the basis for AAALAC assessments
The Program Description Template Was Revised

Why?

- To coincide with the format of the 2011 Guide
- To better reflect global accreditation
- To encompass a greater number of species
- To minimize redundancy/duplication
- Provide embedded links to Position Statements as aids
- To prompt for information that site visitors always ask for
- To streamline the site visit process
New Feature

Embedded links to Frequently Asked Questions, Rules of Accreditation, Instructions for Completing the Program Description, etc.

Program Description

G. Note the source(s) of research funding (grants, contracts, etc.) involving the use of animals.

H. List other units (divisions, institutes, areas, departments, colleges, etc.) of your organization that house and use animals that are not included in this Description. If any of these are contiguous, physically or operationally (e.g., same IACUC/OB, same animal care staff), with the applicant unit, describe the association. Explain why such units are not part of this program application.

Contract Facilities: If the institution contracts for animal care facilities or services for animals owned by the institution, the contractor and its AAALAC International accreditation status must be identified. If a contractor's animal care and use program is not accredited by AAALAC International, a brief description, following this Program Description outline, of the relevant contractor's programs and facilities must be provided. In addition, the species and approximate average number of animals housed in the contract facilities and the approximate distance between the institution's animal facility and the contract facility must be noted. Incorporation of the contractor program into the site visit schedule will be discussed with institutional representatives. If the institution does not contract for animal care facilities or services, so note.

II. Introduction/Description (Exceptions, Contract Facilities, Animal Use Areas)

A. Please note that any IACUC/OB-approved program-wide exception(s) to the Guide and/or other applicable guidelines or regulations must be described in detail. In each appropriate section of the Program Description (e.g., sanitation, animal housing density), state the approved program-wide exception. In addition:

1. Provide the rationale for why the program-wide exception to the Guide and/or applicable regulations is necessary.

2. Provide a summary of the basis for IACUC/OB approval of the program-wide exception, including references, data and other relevant considerations. Please note that it is not necessary to supply detailed data with the Program Description; however, the site visitors may wish to see evidence at the time of the site visit.

3. Summarize the procedural details of the ongoing IACUC/OB monitoring of all approved program-wide exceptions.

B. Contract Facilities. According to the AAALAC International Rules of Accreditation, if the care of animals owned by an AAALAC International accredited institution or an institution applying for accreditation is contracted for, then AAALAC International considers the contractor's animal care programs and facilities to be an integral part of the institution's animal care and use program. Examples may include contracted research laboratories, breeding services, diagnostic/imaging facilities, quarantine facilities, etc.

If the contract facility is not separately accredited, the animal care and use program and facilities of the contractor that relate to the animals owned by the institution seeking accreditation must be included and identified as contractor-provided in the Program Description. All elements of the contract facility’s animal care and use program (personnel training, IACUC/OB review of protocols, programs and facilities, occupational health and safety program, etc.)
Helpful Hints

- Do not alter the Program Description by deleting questions that are not applicable.
- Do not reference appendices in lieu of providing a brief description directly in the Program Description.
- Do not embed attachments as links within the main document.
Helpful Hints

- Review instructions for placing text in the text boxes within the Program Description
- To insert a table into a text box, convert the table to a JPG image and insert or delete text box and insert table
Helpful Hints

- Square footage should match in the Annual Report (AR) and Program Descriptions — use the latest AR as the starting point to evaluate the square footage.
- Ensure each sub-part is answered within the main question.
- Include descriptions of all satellite facilities
- Verify the accuracy of all information
Helpful Hints

- Submit one hard copy of completed materials, unless it can be provided electronically with no more than four attachments.
- Do not submit Program Description with the tracked changes on.
- Do not bind Program Descriptions; should just use a rubber band or clip.
Completing your Program Description
COA Survey

- During early September, the COA was surveyed to inquire which sections of the PD tended to be most problematic during site visits since the new PD was implemented.

- The goal was to obtain information to provide continuing education efforts regarding the AAALAC program description (PD) and how institutions might better complete the form.
Council Survey
(53 Council members responded)

Is information in the Program Description Adequate?

- 45% information is adequate
- 34% information is usually inadequate
- 21% information is sometimes inadequate
Council Survey

When considering all sections of the PD - which are problematic? (can choose more than one)

- Introduction: 49%
- Animal care and use program: 53%
- Program oversight: 34%
- Animal housing environment & management: 26%
- Veterinary care: 17%
- Physical plant: 17%
- Appendices: 15%
Council Survey

What are the typical deficiencies?

- Too little information is provided: 60%
- Information does not pertain to the question: 28%
- Information is too detailed (burdensome): 26%
- Information is inaccurate (compared to site visit findings): 13%
- Some questions are not answered at all: 57%
Instructions

- “Program-wide” Exceptions
  - Rationale
  - Basis of IACUC / OB Approval
  - Summary of ongoing monitoring

- Confidential/ Sensitive Information
  - FOIA?
  - Alternative's to divulging sensitive information
  - Please contact the AAALAC International office for additional guidance
Part I – Introduction

Which sections of the Introduction are most problematic?

- Organizational charts: 41%
- Other animal units: 35%
Section 1 - Introduction

- I-c – Three Primary Standards
- Choose which best fits your program

“Describe which of the three primary standards and other regulations and guidelines are used as standards for the institutional animal care and use program and how they are applied.”
Animal Care & Use Program

Which sections are most problematic?

- Collaboration: 59%
- OHS - hazard ID: 45%
- OHS - training: 28%
- OHS - experimental hazards: 41%
- OHS - personnel protection: 45%
- OHS - medical evaluations: 45%
- OHS - preventive medicine: 38%

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Section 2 – Program Management

Collaborations [Guide, p. 15]

Describe processes for assigning animal care and use responsibility, animal ownership and IACUC/OB oversight responsibilities at off-site locations (i.e., collaborations).
Training

Questions about personnel training occur throughout

1.A.2. - Personnel Management

a. Training and Education

Describe how the IACUC/OB provides oversight and evaluates the effectiveness of training programs. Describe how training is documented.

i. Veterinary and Other Professional Staff [Guide, pp. 15-16]

Provide name and credentials of veterinary and other professional staff, including the veterinary personnel listed above, and describe their qualifications, training, and continuing education.

Please do not provide curriculum vitae of personnel.
Training

Animal Care Personnel [Guide, p. 16]

- Indicate the number of animal care personnel.
- Summarize their training, certification level and type, experience, and continuing education opportunities provided.

The Research Team [Guide, pp. 16-17; 115-116; 122; 124]

1) Describe the general mechanisms, by which the institution or IACUC/OB ensures that research personnel have the necessary knowledge and expertise in the animal procedures proposed and the species used.
   a) Briefly describe the content of any required training.
   b) Describe the timing of training requirements relative to the commencement of work.
   c) Describe continuing education opportunities offered.
Occupational Health

1.A.2.b.i.1-

“Describe the process used to identify, evaluate and control experimental and other potential hazards (such as ionizing and non-ionizing radiation, chemical cleaning agents, animal bites, allergens, zoonoses, and venomous species) inherent or intrinsic to the use of animals by the institution. Describe how risks of these hazards are assessed and how procedures are developed to manage the risks.”
Occupational Health

1.A.2.b.ii.4 –

“Describe any facilities that may also be used for human-based research or patient areas, including the policies and procedures for human patient protection, facility decontamination, animal transport through common corridors or elevators, and other personnel protection procedures.”
Occupational Health

1.A.2.b.ii.5 –

“Describe any other circumstances in which animals or caging equipment are transported in common use corridors or elevators (e.g., have the potential to come in contact with individuals not associated with the animal care and use program), and measures taken to mitigate risks associated with such use.”
Occupational Health

- 1.A.2.b.ii.6 –

“If motorized vehicles are used for animal transport, describe how the driver is protected from exposure to hazards such as allergens or zoonoses.”
Hazards

1.A.2.b.v.4 –

List, according to each of the categories noted below, hazardous or potentially hazardous agents currently approved to be used in animals that are or will be maintained for more than a few hours following exposure. If the hazardous agent cannot be listed by name for security/proprietary reasons, identify it by the general category of agent and level of hazard. Note: This information may be provided as an Appendix.

a) **Biological** agents, noting hazard level (CDC Biohazard Level, Directive 93/88 EEC, CDC or USDA/DHHS Select Agent, etc.).

b) **Chemical** agents, noting general category of hazard (toxicant, toxin, irritant, carcinogen, etc.).

c) **Physical** agents (radiation, UV light, magnetic fields, lasers, noise, etc.).
Occupational Health

1.A.2.b.vii. 1-4 –

- “Identify the individual(s) and/or office responsible for developing and monitoring the medical evaluation and preventive medicine program.”

- “Describe the categories of personnel (research staff, visiting scientists, animal care staff, students, support staff, etc.) included in the program.”

- “Describe general features of the medical evaluation and preventive medicine programs, including pre-employment/pre-assignment health evaluation, periodic medical evaluations, immunization programs, and procedures for communicating health related issues.”

- “Describe special precautions or procedures for personnel exposed to potentially hazardous species (nonhuman primates, sheep, etc.) or agents (infectious agents, human origin tissues, chemicals/toxins, etc.).”
Program Oversight

Top 4 most problematic areas

- Protocol review: 29%
- Special Considerations - (protocol review): 35%
- Role of the IACUC: 18%
- PAM: 18%
1. B. 1b.i. –


A blank copy of your institution’s protocol review form should be provided as an appendix. Also include forms used for annual renewal, modifications, amendments, etc., as applicable.

Describe the process for reviewing and approving animal study protocols, including research and teaching proposals. Include a description of how animal study protocols that do not involve a formal grant proposal are reviewed and approved (i.e., pilot studies or internally funded studies). Include a description of how the IACUC/OB weighs the potential adverse effects of the study against the potential benefits that may result from the research. Describe how protocols that have the potential to cause pain or distress to animals are reviewed, alternative methodologies reviewed, veterinary input solicited, and studies controlled or overseen. Specify how animals and experimental group sizes are justified.
Protocol Review – endpoints

1.B.1c.i. –

Special Considerations for IACUC/OB Review [Guide, pp. 5; 27-33]

Experimental and Humane Endpoints [Guide, pp. 27-28]

Describe how criteria for determining alternatives to experimental (humane) endpoints are developed, approved, and applied. Include a description of monitoring systems in place for studies for which information on alternative endpoints are not available.
Protocol Review – unexpected outcomes

1.B.1c.ii. –

Special Considerations for IACUC/OB Review [Guide, pp. 5; 27-33]

Unexpected Outcomes that Affect Animal Well-being [Guide, pp. 28-29]

Describe how unexpected outcomes of experimental procedures (e.g., unanticipated phenotypes in Genetically Modified Animals) are identified, interpreted, and reported to the IACUC/OB.
Protocol Review – multiple surgeries

1.B.1.c.iv. –

Special Considerations for IACUC/OB Review [Guide, pp. 5; 27-33]

Note: One survival surgical procedure followed by a non-survival procedure is not included in this category.

1) Describe the institutional policy(ies) regarding multiple survival surgery (major or minor) on a single animal.

2) Describe the procedure for approving multiple survival surgery (major or minor) and the criteria used to determine the potential impact on the animals’ well-being.

3) Summarize the protocols currently approved that involve multiple major survival surgical procedures and the time allowed between procedures on the same animal. Describe the method of institutional monitoring.
Protocol Review – food/ fluid regulation

- 1.B.1c.v. –

**Special Considerations for IACUC/OB Review** [Guide, pp. 5; 27-33]

**Food and Fluid Regulation** [Guide, pp. 30-31]

1) Describe experimental situations that require food and/or fluid regulation. Note: This does not include pre-surgical fast. **List** title of the experiment(s), justification, species involved, and length and type of food/fluid regulation.

2) Describe animal **health monitoring procedures** and frequency (e.g., body weight, blood urea nitrogen, urine/fecal output, food/fluid consumed).

3) Describe **methods of ensuring adequate nutrition and hydration** during the regulated period.
Protocol Review – non-pharmaceutical grade drugs

1.B.1c.vi. –

Special Considerations for IACUC/OB Review [Guide, pp. 5; 27-33]

Use of Non-Pharmaceutical-Grade Drugs and Other Substances
[Guide, p. 31]

Describe the rationale and consideration given by the IACUC/OB for use of non-pharmaceutical grade drugs or other substances, if applicable.
Post Approval Monitoring

1.B.2. –

Post-Approval Monitoring [Guide, pp. 33-34]

a. Describe mechanisms for IACUC/OB review of ongoing studies and periodic reviews (e.g., annual review, 3-year renewals if PHS funded, etc.).

b. Describe the process and frequency with which the Committee reviews the animal care and use program and conducts facility and laboratory inspections. Detail any criteria used for exempting or varying the frequency of reviewing satellite holding facilities and animal use areas. If contract facilities or contractor-provided personnel are used, describe procedures used by the IACUC/OB to review such programs and facilities. Note: A copy of the last report of these reviews should be included as an appendix.

c. Describe institutional responses to deficiencies noted on regulatory inspection reports (e.g., government, regulatory agencies). Note: Copies of all such inspection reports for the past three years (if available) should be available for review by the site visitors.

d. Describe other monitoring mechanisms or procedures used to facilitate ongoing protocol assessment and regulatory compliance.
Environment, Housing & Management

Top 3 most problematic sections

- Review of enrichment & social housing: 62%
- Social & behavioral management: 41%
- Environmental Enrichment: 28%

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II.A.3. –

Life Support Systems for Aquatic Species [Guide, pp. 84-87]

Provide a general description of institutional requirements for enclosures using water as the primary environmental medium for a species (e.g., aquatics). Describe overall system design, housing densities, and water treatment, maintenance, and quality assurance that are used to ensure species appropriateness. Please note that facility-specific tank design and parameter monitoring frequencies should be summarized in the Aquatic Systems Summary appendix.
II.B.1 –

Primary Enclosures

Provide a description of primary enclosures used (e.g., cages (conventional, individually-ventilated cage systems (IVCS), etc.), pens, stalls, pastures, aviaries, tanks) in appendix.

a. Describe considerations, **performance criteria** and guiding documents (e.g. Guide, Ag Guide, ETS 123 and/or other applicable standards) used by the IACUC/OB to verify adequacy of space provided for all research animals, including traditional laboratory animal species, agricultural animals, aquatic species, and wildlife when reviewing biomedical, field and agricultural research studies.

b. Describe **space exceptions** to the guiding documents (Guide, Ag Guide, ETS 123, and/or applicable standards), indicating the references, considerations and performance criteria used (e.g., by the IACUC/OB) to verify adequacy of space provided for all animal species covered by the program. [Guide, pp. 55-63]
II.B.2.b –

Social Environment [Guide, p. 64]

i. Describe institutional **policy** or strategy for social housing of social species.

ii. If social animals are not socially housed, provide **justification**, as approved by the IACUC/OB.

iii. Describe steps taken with isolated or individually housed animals to **compensate** for the absence of other animals (e.g., interaction with humans, environmental enrichment, etc.).
Unexpected Outcomes

II.C.2.c –

Breeding, Genetics and Nomenclature

iii. For newly generated genotypes, describe how new phenotypes that negatively impact well-being will be monitored, managed and reported to the IACUC/OB in a manner to ensure the animals’ health and well-being.
Veterinary Care

Top 5 most problematic sections

- Biosecurity: 31%
- Surveillance, diagnosis, treatment & control of disease: 38%
- Drug storage & control: 31%
- Presurgical planning: 31%
- Anesthesia & analgesia: 44%
Physical Plant

Top 3 most problematic sections

- HVAC: 50%
- Special facilities: 22%
- Surgery: 22%
Physical Plant

- IV –


Repeat this section for each animal housing area, including agricultural settings, temporary holding areas for field studies, aquatic environments, and each IACUC/OB approved satellite housing facility. Include as an appendix the floor plans of each (if applicable) on 8.5" x 11" or A4 paper.
Physical Plant

- IV.B.1 –

Functional Areas and Operations

Heating, Ventilation, and Air-Conditioning (HVAC) [Guide, pp. 139-140, 143]

a. Describe the mechanical systems used to provide temperature, humidity and air pressure control. Include details such as the use of variable air volume (VAV) systems, and additional key features of HVAC systems affecting performance.

b. Describe construction features that minimize the potential for adverse consequences to animal well-being, such as re-heat coils that fail closed or that are equipped with high-temperature cut-off systems.

c. Describe how critical air pressures, ventilation, and temperature are monitored and maintained in the event of a system or component failure.

d. Describe procedures for monitoring animal facility mechanical systems and notifying appropriate personnel in the event of a significant failure that occurs outside regular work hours.
Appendices

Top 3 most problematic sections

- Organizational charts: 37%
- Animal usage form: 53%
- HVAC summary: 40%
# Appendices

## Animal Use Form - A

<table>
<thead>
<tr>
<th>TYPE OF SCIENTIFIC PROCEDURES</th>
<th># OF PROTOCOLS</th>
<th>SPECIES</th>
<th>APPROX #/YEAR</th>
<th>PRINCIPAL INVESTIGATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver macrophage-harvest euthanized</td>
<td>15</td>
<td>mice</td>
<td>1500</td>
<td>J.A. Smith</td>
</tr>
<tr>
<td>Embryo transfer</td>
<td>5</td>
<td>mice</td>
<td>2500</td>
<td></td>
</tr>
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<td>Stapling devices-survival surgery</td>
<td>1</td>
<td>dogs</td>
<td>15</td>
<td>K. C. Day</td>
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<tr>
<td>Thoracotomy/vascular implant-survival surgery</td>
<td>6</td>
<td>dogs</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Bone grafting</td>
<td>2</td>
<td>dogs</td>
<td>12</td>
<td></td>
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<tr>
<td>Teaching demonstration</td>
<td>1</td>
<td>dogs</td>
<td>02</td>
<td></td>
</tr>
<tr>
<td>Catherization (chained)</td>
<td>2</td>
<td>NH primates</td>
<td>04</td>
<td></td>
</tr>
<tr>
<td>Infectious disease</td>
<td>2</td>
<td>NH primates</td>
<td>45</td>
<td></td>
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<tr>
<td>Neurosurgery</td>
<td>4</td>
<td>grey squirrel</td>
<td>15</td>
<td></td>
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<tr>
<td>Motor nerve stimulator implantation</td>
<td>1</td>
<td>pigs</td>
<td>16</td>
<td></td>
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<td>Pyrogen testing</td>
<td>2</td>
<td>rabbits</td>
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<tr>
<td>Antibody production-Freunds Adj</td>
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<td>rabbits</td>
<td>09</td>
<td></td>
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<tr>
<td>Corneal laser surgery</td>
<td>4</td>
<td>rabbits</td>
<td>24</td>
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### Appendices

**Animal Use Form - B**

<table>
<thead>
<tr>
<th>Protocol Title</th>
<th>IACUC/OB No.</th>
<th>Principal Investigator</th>
<th>Species</th>
<th># Animals Approved</th>
<th>Pain &amp; Distress Category (1)</th>
<th>Special Considerations (use checkmark if applicable)</th>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>SS (2)</td>
<td>MSS (3)</td>
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</tbody>
</table>

(1) Please provide a description / definition of any pain/distress classification used within this Appendix.

(2) Survival Surgery (SS)

(3) Multiple Survival Surgery (MSS)

(4) Food or Fluid Regulation (FFR)

(5) Prolonged Restraint (PR)

(6) Hazardous Agent Use (HAU)

(7) Non-Centralized Housing and/or Procedural Areas (NCA), i.e., use of live animals in any facility, room, or area that is not directly maintained or managed by the animal resources program, such as investigator laboratories, department-managed areas, teaching laboratories, etc.
Appendices

- Heating, Ventilation and Air Conditioning (HVAC) System Summary

  Summarize the heating, ventilation and air conditioning (HVAC) information for each animal facility, including all satellite facilities, indicating: a) source(s) of air, b) air recirculation rates if other than 100% fresh air, c) air exchange rates, d) relative pressure differentials, e) humidity control, and f) date of most recent measurement/evaluation. Include all animal holding rooms, (including satellite holding rooms), surgical facilities, procedure rooms, and support spaces integral to animal facilities (e.g., cage wash, cage and feed storage areas, necropsy, treatment, etc.). Air exchange rates within animal holding rooms and cage washing facilities are required. Air exchange rates may be important to maintain air quality in other areas; however, measurements may be left at the discretion of the institution. Information may be provided in another format, providing all requested data is included. HVAC information should be provided from assessments obtained within the past 12 months.
## Appendices

### Heating, Ventilation and Air Conditioning (HVAC) System Summary

<table>
<thead>
<tr>
<th>Room No.</th>
<th>Use</th>
<th>Air Source</th>
<th>Treatment Filtered/Absorbers, etc.</th>
<th>Air Changes</th>
<th>Pressure</th>
<th>Humidity Control</th>
<th>Date Assessed</th>
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<td>10</td>
<td>Surgery</td>
<td>100% Fresh</td>
<td>HEPA</td>
<td>15</td>
<td>+</td>
<td>Y</td>
<td>8/92</td>
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<tr>
<td>125</td>
<td>Holding Room</td>
<td>100% Fresh</td>
<td>HEPA</td>
<td>12</td>
<td>-</td>
<td>Y</td>
<td>8/92</td>
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<tr>
<td>135</td>
<td>Holding Room</td>
<td>100% Fresh</td>
<td>Coarse filter/charcoal</td>
<td>10</td>
<td>-</td>
<td>Y</td>
<td>8/92</td>
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<td>150</td>
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<td>100% Fresh</td>
<td>None</td>
<td>10</td>
<td>-</td>
<td>Y</td>
<td>7/92</td>
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<td>175</td>
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<td>HEPA</td>
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<td>7/92</td>
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<td>200</td>
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<td>30% Recirculated</td>
<td>Coarse filter</td>
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<td>-</td>
<td>Y</td>
<td>7/92</td>
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<td>210</td>
<td>Feed Storage</td>
<td>50% Recirculated</td>
<td>Coarse filter</td>
<td>10</td>
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<td>Y</td>
<td>7/92</td>
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<td>215</td>
<td>Storage</td>
<td>70% Recirculated</td>
<td>Coarse filter</td>
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<td>-</td>
<td>Y</td>
<td>4/92</td>
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<td>300</td>
<td>SPF Room</td>
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<td>HEPA</td>
<td>15</td>
<td>+</td>
<td>Y</td>
<td>4/92</td>
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<td>A100</td>
<td>Swine Facility</td>
<td>100% Fresh</td>
<td>N/A</td>
<td>variable fan</td>
<td>N/A</td>
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<td>A-12</td>
<td>Pole Barn</td>
<td>100% Fresh</td>
<td>N/A</td>
<td>climate dependent</td>
<td>N/A</td>
<td>N</td>
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Appendices

- Aquatic Systems Summary* – Part I

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<thead>
<tr>
<th>Location (1)</th>
<th>Species (2)</th>
<th>Group / Individual (3)</th>
<th>Water Type (4)</th>
<th>Pre-treatment</th>
<th>Circulation (5)</th>
<th>Filtration (6)</th>
<th>Disinfection (e.g., UV, ozone)</th>
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### Appendices

- **Aquatic Systems Summary** – Part II

<table>
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<tr>
<th>Location (from Part I)</th>
<th>Temperature</th>
<th>Salinity</th>
<th>pH</th>
<th>NH₄</th>
<th>NO₂</th>
<th>NO₃</th>
<th>Dissolved O₂</th>
<th>Total Dissolved gases</th>
<th>Other. Please List (2):</th>
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Summary

- 66% of the Council members believed that submitted PD’s lacked sufficient information
  - Too little or inaccurate information
- The most problematic sections of the PD
  - OHSP
  - IACUC
  - Social Housing
  - Environmental Enrichment
  - Disease Surveillance
  - Anesthesia & Analgesia
  - HVAC
  - Appendices (org charts, animal usage, HVAC data)

- Interestingly – prior to the 2011 Guide the top 3 areas most cited findings:
  1. OHSP
  2. IACUC
  3. HVAC
Questions?
Please contact us!
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www.aaalac.org
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