



# The AAALAC Program Description Template as a Self Evaluation Tool

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# Agenda

- The concept of a Program
- The AAALAC Program Description (PD) Template
- Engineering and Performance Standards
- Using the PD for self evaluation
- Conclusions/Recommendations



# AAALAC International

**Private, nonprofit** organization that promotes the humane treatment of animals in science through a **voluntary accreditation** program

2022: over 1050 accredited  
**institutional animal care and use programs**  
in 50 countries

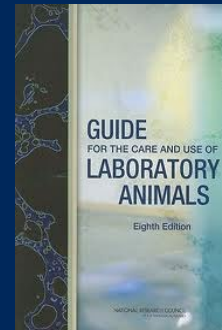




# Concept of Animal Care and Use Program

AAALAC accredits laboratory animal care and use programs

“...means the policies, procedures, standards, organizational structure, staffing, facilities, and practices put into place by an institution to achieve the humane care and use of animals in the laboratory and throughout the institution.”







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## Step 1 - Download Instructions

REGION (Language)	2016 Version <i>(updated July 2020)</i>
Instructions <b>Standard</b> (English)	<a href="#">PDF file</a>
Instructions for <b>European</b> Applicants (English)	<a href="#">PDF file</a>
Instructions for <b>Thai</b> Applicants (Thai)	<a href="#">PDF file</a>

## Step 2 - Download the Program Description

The Program Description (PD) must be submitted in English with the exception of some appendices (see the **Instructions for Completing and Submitting the Program Description** under Step 1 above, then refer to "Section III. Appendices").

REGION (Language)	2016 Version <i>(updated July 2020)</i>
PD <b>Standard</b> (English)	<a href="#">Word file</a>
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# Engineering Standards

- Fixed, objective, measurable
- Often included in legislation as requirements
- Examples: minimum cage dimensions, environmental ranges, composition committees, etc



# Performance Standards

- Outcome oriented, focused on expected results rather than the process used to achieve the results
- Allow flexibility to fit different situations
- Outcome to be defined in detail and criteria for assessing the outcome
- Requires professional judgment/input



# Example Cage Washing

?



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# Cage Washing

Whether the sanitation process is automated or manual, regular evaluation of sanitation effectiveness is recommended. This can be performed by evaluating processed materials by microbiologic culture or the use of organic material detection systems (e.g., adenosine triphosphate [ATP] bioluminescence) and/or by confirming the removal of artificial soil applied to equipment surfaces before washing. *Guide p. 73*

## Question in AAALAC Programme Description

Describe how the effectiveness of sanitisation procedures is monitored (e.g., water temperature monitoring, microbiological monitoring, visual inspections, etc.).





## Developing a Performance Standard for Adequate Sanitization of Wire-Bar Lids

Linnéa E Särén, Louise K Hammarberg, Robin J Kastenmayer, and Liselotte C Hallengren\*

The wire-bar lids on rodent cages are an integral part of the microenvironment and as such can impact rodent health and wellbeing. The *Guide for the Care and Use of Laboratory Animals* recommends changing wire-bar lids every other week but does not include a predetermined performance standard. To develop a sanitization performance standard, we evaluated the bacterial and other cellular burden of wire-bar lids over 4 wk. The results show no significant difference in ATP or bacterial burden over 3 wk of continuous use in conventional cages with standard rodent pelleted or high-fat diet or in IVC with an irradiated diet.

**Abbreviations:** RLU, relative light unit; WBL, wire-bar lid

Both the 7th and 8th editions of the *Guide for the Care and Use of Laboratory Animals* state that “In general, enclosures and accessories, such as tops, should be sanitized at least once every two weeks,” with an acknowledgment that different cage types or housing conditions may alter the frequency of cleaning.<sup>3,4</sup> However, neither edition describes a performance standard nor are

specified area. Organic debris such as food residue, urine, and feces may contain small amounts of ATP.<sup>13</sup> The amount of ATP in a sample can be determined by using a luminometer to measure the emission of light from the reaction of ATP with the luciferase enzyme and expressed as relative light units (RLU). Bacteria and other microbial contamination on surfaces can





# Sterility and Stability of Diluted Meloxicam in Compounded Multi-dose Vial after 365 Days

Hironori K Kawano,<sup>1,\*</sup> Gregory D Simonek,<sup>2</sup> Andrea D Moffitt,<sup>1</sup> John M Tahara,<sup>3</sup> and Laurie L Brignolo<sup>2</sup>

Meloxicam is a common analgesic for rodents. Because meloxicam is only formulated commercially for companion animals, it requires dilution to achieve doses appropriate for small, laboratory species. Compounded multidose vial (cMDV) are often created to dilute and store a diluted drug. However, chronic cMDV use runs the risk of contamination and becoming a potential source of nosocomial infection. In this study, we created 15 cMDV by diluting meloxicam with sterile water (dilution, 1:10). cMDV were punctured once daily for 30 d. To determine the sterility of the diluted meloxicam, we assessed 8 cMDV for bacterial growth on days 0, 10, 20, 30, and 365 and tested them for endotoxin on days 0, 30, and 365. In addition, the stability of the remaining 7 cMDV was assessed on days 0, 10, 20, 30, and 365, by using liquid chromatography–diode assays. No bacterial growth or endotoxin was detected at any time point, and the drug concentrations remained stable over 365 d. Given the results this study, we believe that cMDV of diluted meloxicam can remain sterile and stable for 365 d.

**Abbreviations:** cMDV, compounded multidose vial; COX, cyclooxygenase

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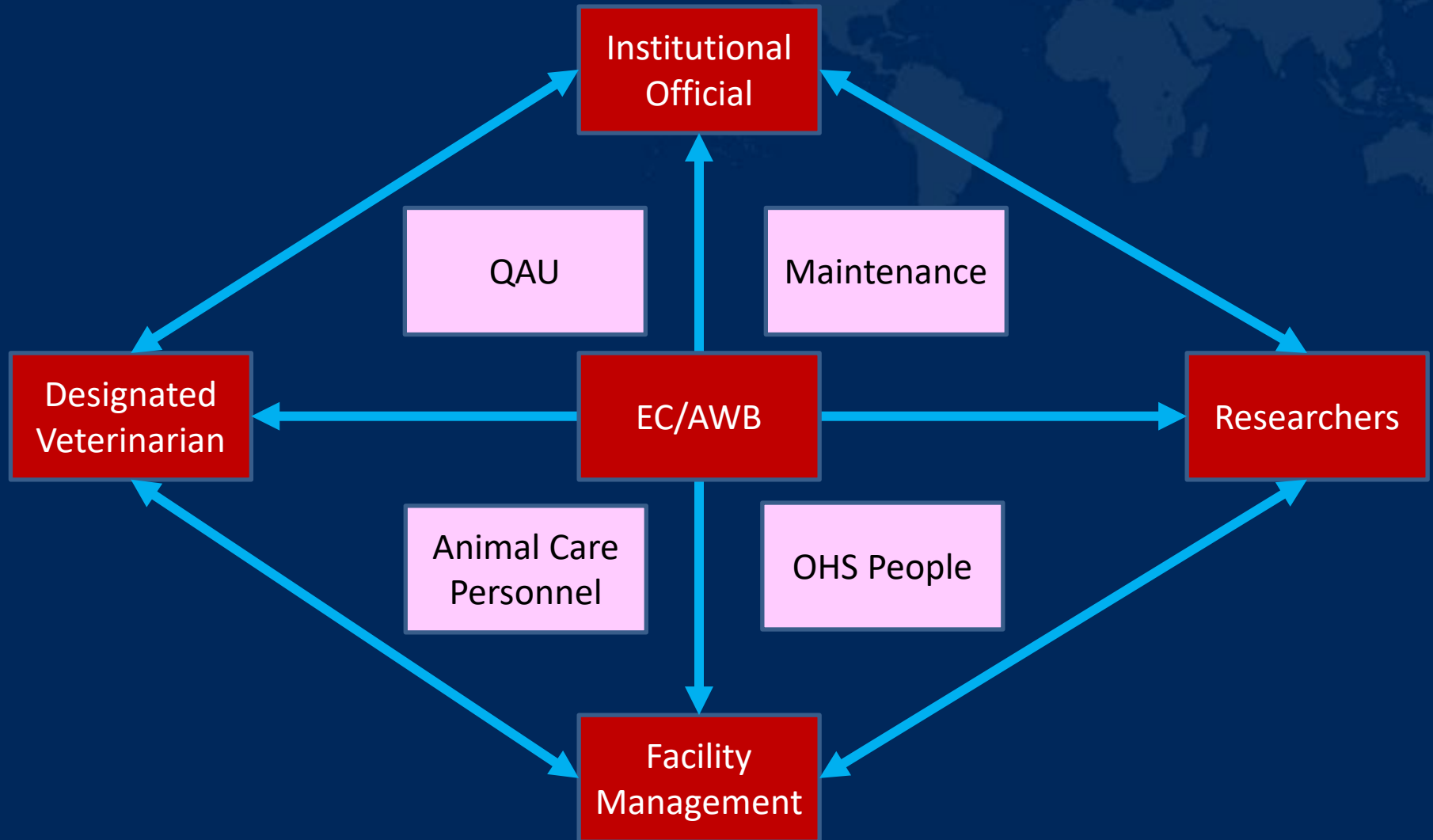
# Using the AAALAC PD...

- Pay attention to the questions and...
- Ask yourself new questions!!!



# Organization, Reporting Lines & Communication

- D. Describe the organisation and include an accurate, current, and detailed organisational chart or charts (see **Appendix 4**) detailing the lines of authority from the Institutional Official (e.g., Administrative/Compliance Responsible Person at the Institution, Certificate Holder) to the Designated Veterinarian, the Institutional Animal Care and Use Committee or equivalent Oversight Body(ies) (IACUC/OB), and the personnel providing animal care. Please include the title, name (*Note: For individuals whose information is*





# Veterinarian: Function, Authority

- b. Role of the Designated Veterinarian** [ETS 123, Article 20(c); *Guide*, p. 14; [www.aaalac.org/accreditation/positionstatements.cfm#vetcare](http://www.aaalac.org/accreditation/positionstatements.cfm#vetcare)]
- i. Describe the institutional arrangement for providing adequate veterinary care. Although individual name(s) and qualifications will be described below, identify by title the veterinarian(s) responsible for the veterinary care programme, including:
- a list of responsibilities
  - a description of the veterinarian's involvement in monitoring the care and use of laboratory animals
  - the percentage of time devoted to supporting the animal care and use programme of the institution if full-time; or the frequency and duration of visits if employed part-time or as a consultant.





# Training, Education, Competence

## 2. Personnel Management

### a. Training, Education, and Continuing Educational Opportunities

Describe *how* the IACUC/OB provides *oversight* and *evaluates the effectiveness* of training programmes and the assessment of personnel competencies. For

Animal care personnel, veterinarians, researchers...



# Interinstitutional Collaborations

## c. **Interinstitutional Collaborations** [*Guide*, p. 15]

Describe processes for assigning animal care and use responsibility, animal ownership and **IACUC/OB oversight responsibilities at off-site locations** for interinstitutional collaborations.

Do we know all institutional work performed at other institutions?



# Occupational Health and Safety

- 2) Describe methods to identify work-related hazards and the processes used to evaluate the significance of those hazards in the context of duties and tasks. Describe both common approaches and differences, if

Systematic Hazard identification and risk assessment?

Are personnel trained?



# Occupational Health and Safety

## iii. Animal Experimentation Involving Hazards [*Guide*, pp. 20-21]

- 1) List, according to each of the categories noted below, hazardous or potentially hazardous agents currently approved to be used in animals

Do we know all hazardous agents used?

Protective measures? Allergy prevention?

Medical evaluation? (pre & employment)

# AWB/EC/IACUC/OB



IACUC/OB Composition and Function

Describe Committee membership appointment procedures.

Describe frequency of Committee meetings

Describe the orientation, training, and continuing education opportunities

Describe the process for reviewing and approving animal use.

process for reviewing and approving amendments.

Describe mechanisms for IACUC/OB review of ongoing studies



# AWB/EC/IACUC/OB



Describe the process and frequency with which the IACUC/OB reviews the programme of animal care and use.

Describe the process and frequency with which the IACUC/OB conducts facility and laboratory inspections.

Describe institutional methods for reporting and investigating animal welfare concerns.

## **Disaster Planning and Emergency Preparedness** [Guide p. 35]

Briefly describe the plan for responding to a disaster potentially impacting the animal care and use programme:

**Experimental and Humane Endpoints**

**Unexpected Outcomes**

**Physical Restraint**

**Multiple Survival Surgical Procedures**

**Animal Reuse**

**Food and Fluid Regulation**



# Ethical Review

Government

- Competentes Authorities  
(National Committees)

External

- Contract Committees

Institutional

- Ethics Committees/IACUC  
Animal Welfare Bodies



# Performance Based Approach

- Is there an effective evaluation of research proposals?
- Do all animals used for research, teaching or testing belong to an approved protocol and are they provided effective oversight?
- Is animal use being conducted in accordance with the approved proposals?
- Are there appropriate institutional policies and are they followed?



# Performance Based Approach

- Is there a routine and effective evaluation of the animal care and use program?
- Are the key institutional representatives (e.g., the Institutional Official) informed of the outcome of the ethical review process?
- Are corrective actions taken when/if deviations are identified?
- Do all personnel involved in the process have the appropriate training and competence?



BRILL

JOURNAL OF APPLIED ANIMAL  
ETHICS RESEARCH (2020) 1–22

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# Evaluation of Ethical Review and Oversight Processes by AAALAC International

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## a. **Environmental Enrichment**

- i. Describe the structural elements of the environment of primary enclosures that may enhance the well-being of animals housed (e.g., resting boards, privacy areas, shelves/perches, swings, hammocks).

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- ii. Describe nonstructural provisions to encourage animals to exhibit species typical activity patterns (e.g., exercise, gnawing, access to pens, opportunity for exploration, control over environment, foraging, access to a den or refuge, burrowing, nesting materials, toys/manipulanda, browsing, grazing, rooting, climbing).

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## b. **Social Environment** [ETS 123, Appendix A, pp. 14-15, 18-109; *Guide*, p. 64]

- i. Describe institutional expectations or strategies for [social housing](#) of animals.

# Involvement of all parties?



## 1. Husbandry

### b. Drinking Water

#### a. Food [BT]

### c. Bedding and Nesting Materials

Source, quality control, treatment?

## Cleaning and Disinfection of the Micro- and Macro-Environments

Effectiveness?

Describe the programme for monitoring and controlling pests (insects, rodents, predators, etc.). Include a description of.

## 2. Population Management 75-77]

### a. Identification

### b. Breeding, Genetics, and Nomenclature

Coordination researchers?

# Veterinary Care



## **A. Animal Procurement and Transportation**

Quality  
evaluation?

Health monitoring program?  
Quarantine?

## **B. Preventive Medicine**

## **C. Clinical Care and Management**

Surveillance, treatment,  
records, drug control...

# Veterinary Care



## D. Surgery

Pre/Intra/Post;

Facilities/Procedures; Aseptic technique?

## E. Pain and Distress

Management: Who? How?

Agents, equipment...

## F. Anaesthesia and Analgesia

## G. Euthanasia

Methods, equipment, confirm.

# TRAINING

# Physical Plant



**Centralised (Centrally-Managed) Animal Facility(ies)**

Conventional/SPF; finishes; security...

**Satellite Animal Housing Facilities**

Conditions? OB oversight?

**Emergency Power and Life Support Systems**

Back up for what? HVAC performance?

**Other Facilities**

Imaging, behavioral, irradiation...





# Appendices examples

**Appendix 4: Organisational Chart(s)**

**Appendix 9: IACUC/OB Protocol/Project Form**

**Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary**

**Appendix 16: Lighting Summary**

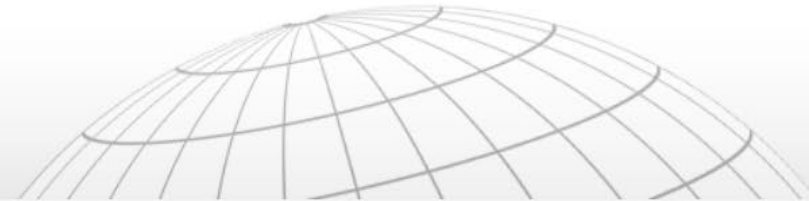


# Conclusions/Recommendations

- Consideration/Organization of all program elements
- Questions; Challenge tradition
- Coordination with other key players
- Adapt to particular environment
- Available tool: AAALAC Program Description

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### Global 3Rs Awards Program

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INTERNATIONAL CONSORTIUM *for*  
INNOVATION & QUALITY  
*in* PHARMACEUTICAL DEVELOPMENT



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**The Global 3Rs Awards program** recognizes significant innovative contributions toward the 3Rs of animal research to advance ethical science, by any researcher<sup>1,2</sup> (nominated author, principal investigator, or research team leader) in academia or industry in any area of biology (e.g., basic science, discovery, development, teaching,



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Questions?



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