

Program Review and Facility Inspection – AAALAC International Perspective

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Topics Covered

- AAALAC expectations
- Global IACUC function deficiencies
- Define the “Program Review”
- Define the “Facility Inspection”
- Follow up actions, documentation and reports
- Conclusion

AAALAC Expectations

It is common that IACUC identifies problems at any institution.

- There are mechanisms that allow the IACUC to effectively detect and correct problems.
- The IACUC has the authority and the resources to address the issues and correct them in a way that improves the welfare of the animals.



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Global IACUC Function Deficiencies (~700 site visit reports, Fall 2011 to Dec 2013)

- Protocol review: considerations- 35%
- Policies – 24%
- Protocol review: process – 12%
- **Program review / facility inspection – 12%** ←
- Oversight of activities – 9.5%
- Committee composition/participation – 7%



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What?

Facility Inspection and Program Review

A comprehensive internal review to evaluate :

- Facilities
- Program



Why?

To ensure compliance with the Guidelines and Institutional Policies (+AAALAC references)

To provide opportunity for

- education for IACUC and personnel
- constructive interaction among IACUC , animal care personnel and researchers
- evaluation and modification of the Program
- collecting evidence of good performance



When?

The Guide for the Care and Use of Laboratory Animals

“...should occur at least annually or more often as required. After review and inspection, a written report (including any minority views) should be provided to the IO about the status of the Program ”

MUSC CAF : April and October



Where?

All Animal Care and Use Facilities

- All animal facilities
- All animal study /activity areas
- Satellite areas



Study/Activity Areas

- Any building , room , area outside the core facility , in which animals are housed for less than 12 hours

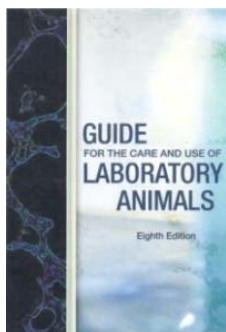


Who?

- IACUC (all or some)
- Appointed subcommittees (2?)
- sub committee + consultant (s)?
- May also assign some IACUC to review program while others inspect the Facility



Full Program Review Components! What is the Animal Care and Use “Program”?



1. Key Concepts
2. Animal Care and Use Program
3. Environment, Housing and Management
4. Veterinary Care
5. Physical Plant

Follow the *Guide*, the Institutional Policies, and the relevant AAALAC references as outlines for conducting your program review.

Also, consider if “ANY exception” to the Guide? ←



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Review of all Program Components



- **Chapter 2 - Program**
 - Regulations, policies..
 - IACUC compositions, functions and procedures
 - Personnel training
 - Occupational health and safety program
 - Disaster/emergency plan...

- **Chapter 3 - Environment, Housing and Management**
 - Animal housing, environment
 - Social management
 - Husbandry, sanitation
 - Pest control...

- **Chapter 4 - Veterinary Care**
 - Animal procurement, health and well being maintenance
 - Animal Health monitoring, treatment..
 - Emergency care
 - Surgery program
 - Anesthesia, analgesia and euthanasia...



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(April 2018)

PROGRAM REVIEW			
Issues	Finding	Suggestion and comments	Date to complete (Person in charge)
Institutional Policies	No deficiencies	-	-
Annual Review	- IACUC chair signature missing in some reviews	- Admin recheck	10/4/18
	- reviews not in order of protocol number	- Admin recheck	20/4/18
	- No list of active/ongoing protocols	- Admin prepares list for present protocols	20/4/18
Training Record	- Records not in chronological order	- Admin recheck	20/4/18
	- Attendee signature list missing for some record	- Admin makes sure list is complete and is filed on the same day.	Next training
	- Every page of attendee signature should have title, date etc. of training.	- Prepare attendee signature forms in advance.	Next training
Environment & Sanitation Record	Record not filled on daily basis	Re-train animal care takers on complete recording, CV for monitoring	18/4/18
Animal Protocols	- Researcher entered	- Review protocols for	20/4/18



Program Review Checklist Example – OLAW, U.S.A.



<http://grants.nih.gov/grants/olaw/sampledoc/checlist.pdf>

Adapt the list as applicable.

Program Items	A, M, S, C, NA*
Institutional Policies and Responsibilities	
.....	
Veterinary Medical Care	
.....	
Animal Housing and Support Areas	
.....	
Cagewash and Special Facilities	
.....	

*A = acceptable, M = minor deficiency, S = significant deficiency (is or may be a threat to animal health or safety), C = change in program, NA = not applicable



Useful Tools for Program Review Procedures

1. Review documents

- Institutional Policies and guidelines
- Relevant Standard Operating Procedures (SOPs)
- Protocol Records
- IACUC meeting minutes and other documents
- **AAALAC International Program Description (PD)**
- Other records

2. Visit the areas and meeting key personnel





- Presentations by key personnel
- Open discussions
- Combination of above

3. Use Checklists and Forms

4. Combination of above



Defining a Facility Inspection

- Animal holding facilities and 
- Functional areas for animal housing, receipt, quarantine and separation; animal support areas (i.e. feed, bedding storage, cage sanitation, etc.) 
- All animal activity areas 
- Animal transport procedures and vehicles 



Tips for Facility Inspection – Animal Rooms

Use your ears, eyes, noses and knowledge
Take a good note and always verify the deficiencies

What is the animal room function and type of study?
How is the room environment (temperature and humidity ranges)?
Observe all animals. Any housing compliance issue?
How is the animal welfare and behavior?
Look for signs of illness, pain and distress



Review relevant document if any question?
Cage cards, animal records..., any protocol drift?



If meet responsible personnel, ask questions
(watch out for consistency)

Is the facility well-maintained? Any OHS or safety issues? PPE?



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New “MUST”’s Animal Well-being – Aquatic Animals

- Chlorine and chloramines ...**must** be removed or neutralized prior to use in aquatic systems.
- The biofilter **must** be of sufficient size ...to be capable of processing the bioload ..entering the system.
- When utilized to disinfect an entire system ...extreme care **must** be taken to ensure that residual chlorine, chemical, and reactive byproducts are removed.

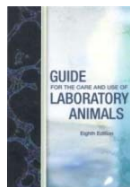


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Tips for Facility Inspection – Other Rooms

Use your ears, eyes, noses and knowledge
Take a good note and always verify the deficiencies



**What is the room function?
How is the room environment?
Is the facility well-maintained?**

Review room records if any

**Any occupational health and safety issues,
engineering control/safety equipment and PPE?**

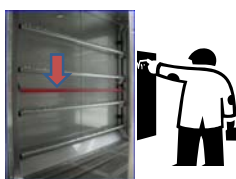


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Safety Requirements for Walk-In Cage/Rack Washers and Bulk Sterilizers*

- Cage/rack washers and bulk sterilizers, which personnel enter, are equipped with functioning safety devices that prevent staff from becoming trapped inside



Personnel are trained!

See Position Statement

<http://www.aaalac.org/accreditation/positionstatements.cfm>



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Proper Chemical Storage?



Proper Storage

- Corrosive
- Flammable
- Oxidizer?
- Reactive ?



Proper Controlled Substances Storage?



Controlled Substance Disposition Record

Item No.	Quantity	Received	Used	Inventory	Disposition	By	Date
1	100 mg	10/1/18	10/1/18	0 mg	Used for research	J. Smith	10/1/18
2	50 mg	10/1/18	10/1/18	0 mg	Used for research	J. Smith	10/1/18
3	25 mg	10/1/18	10/1/18	0 mg	Used for research	J. Smith	10/1/18
4	10 mg	10/1/18	10/1/18	0 mg	Used for research	J. Smith	10/1/18
5	5 mg	10/1/18	10/1/18	0 mg	Used for research	J. Smith	10/1/18

- License or Registration
- Controlled access
- Rigid Disposition Record



Any Surgery in Investigator Laboratories?

http://www.aaalac.org/accreditation/faq_landing.cfm



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- “Most survival surgery performed on rodents..., the space should be dedicated to surgery and related activities ... and managed to minimize contamination from other activities conducted within the room at other times.”

AAALAC's expectation

- The surgical area **should be dedicated** for that purpose while surgery is performed.
- 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.

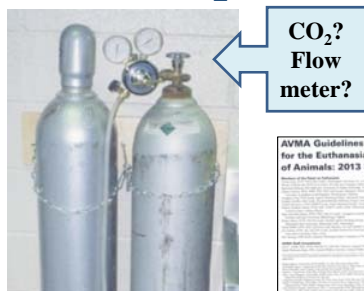
The investigator, IACUC (or comparable oversight body) and veterinarian **should evaluate** surgical areas to ensure they are appropriate.



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Compressed Gas Safety Issues?



CO₂?
Flow
meter?



Annual certifications



- Vaporizer
- Scavenging system




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Electrical Hazards

Water resistant






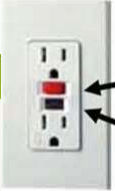


ONE OUTLET

USE THE
CORRECT
"GROUNDED"
PLUG




ONE PLUG




RESET

TEST




Tag out – Lock out




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BSL-2 Laboratory Signage



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-  Symbol
- Biosafety level 2 (BSL-2)
- Supervisor's name (or responsible person)
-  number
- Required procedures for entering and exiting
- Agent information (institutional policy)



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ABSL-2 Facility Signage

-  Symbol
- Animal Biosafety level 2 (ABSL-2)
- Supervisor's name (or responsible persons)
-  number
- General occupational health requirements
- PPE requirements
- Required procedures for entering & exiting
- Security-sensitive agent information (in accordance with the institutional policy)

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Proper Chemical Labels?



- What it is
- Expiry date



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Proper Handling of Waste?



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Example – A Summary Report of Deficiencies

Date:Members in Attendance:

Room No.	Deficiency Category	Deficiency	Plan for correction	Responsible Person	Correction Schedule and Interim Status	Date Complete

Adapt the form as applicable.
<http://grants.nih.gov/grants/olaw/sampledoc/checklist.pdf>


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AAALAC Expectation – Report to IO

- **Describing the procedures** used, locations visited, **and results** of the program review and facility inspection
- **A summary of minor and major deficiencies with a plan and timetable for correction** of each deficiency. Also need a **follow-up until completion.**
- Information regarding minority opinions
- **Report signed** by a majority of IACUC members
- **Timely completion and delivery of report** to IO



Program Review and Facility Inspection What are the common deficiencies at SVs?

- Only the facility inspection was conducted but IACUC did not review the animal care and use program
- Failure to inspect all facilities including central, satellite and off-site facilities
- Absence of a timetable to correct identified deficiencies
- Failure to ensure that corrections are made
- No indication of significant vs. minor deficiencies
- No documentation that the review was provided to the IO
- None or few deficiencies documented in the program review and facility inspection reports, but **many issues** identified by site visitors.



Examples

- Room of Inadequate Housing
- Overcrowding (rodents)
- Lighting too intense (albino rats)
- Expired feed , improper storage of feed
- Inadequate pest control program
- Lack of documentation for daily activities



Examples of Inadequate Veterinary Care

- Lack of veterinary involvement
- Veterinarian had limited experience
- Lack of drugs for relieving pain / distress
- Poor or no disease prevention program
- Relying on investigator and not vet for animal care advice and guidance
- Aseptic technique not being used
- Incomplete record of medical treatment and follow-up



Thank You!

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