

## Common Animal Care and Use Program Issues in Pacific Rim Region



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### Flow of Presentation & Discussion

- References
  - *The Guide* (NRC 2011)
  - Reference Resources
- AAALAC Expectation, Position Statements and FAQs
- List of Common Issues
- Case Scenarios – Kahoot and discussion



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### Occupational Health and Safety Program OHSP

- Each institution **must** establish and maintain an OHSP
- The OHSP **must** be consistent with relevant regulations and should focus on maintaining a safe and healthy workplace
- The *Occupational Health and Safety in the Care and Use of Research Animals* (NRC1997)



p17-23




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### Personnel Protection

- While engineering and administrative controls are the first considerations for protection of personnel, PPE appropriate for the work environment ... should be provided.
- Personnel working in areas where they might be exposed to contaminated airborne particulate material or vapors should have suitable respiratory protection, with respirator fit testing and training in the proper use and maintenance of the respirator.


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### Recent OHSP Findings

- Lack of risk assessment
- Health professional - not involve in the medical evaluation
- Some IACUC members and/or visiting scientists - not offered participation in OHSP
- No bite/scratch exposure kits for macaques (*Macacine herpesvirus 1* or B virus)
- Inconsistent use of personal protective equipment
- Expired drugs and supplies in first aid kits
- Lack of opportunity for tetanus immunization for animal care personnel


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### Case scenario 1

OHS-Personnel Risk Assessment	Question
<ul style="list-style-type: none"> <li>▪ Although the institution had established an occupational health and safety program (OHSP), not all individuals at risk were included. Specifically, the IACUC member and the visiting scientists who perform animal work on site were excluded, such that their health and safety may be jeopardized.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>


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### Unit's Action & Council's Consideration

#### Unit's Action

- The revised occupational health and safety program management SOP was submitted which covered all employees, external research personnel, IACUC members, and visitors and specified training frequency for different levels of at-risk personnel, but failed to mention participation in the medical evaluation or the medical history questionnaire for non-employees.

#### Council's Consideration

- Fully Addressed?
- Partially addressed?
- Retain as an SFI?



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### Case scenario

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#### OHSP/Participation

- The occupational health and safety program (OHSP) covered all staff related to the animal care and use program. The animal facility inspection for hazard identification and risk assessment was regularly conducted by a qualified occupational health physician. However, the five nonaffiliated IACUC members and two contracted cleaning staff were not included. In addition, the OHSP was limited to an annual personnel health screening program, including allergy symptoms, and all animal care and use personnel received tetanus immunizations.

#### Question

- Mandatory?
- SFI?



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### Unit's Action & Council's Consideration

#### Unit's Action

- The two contracted cleaning staff and IACUC members will be included in the OHSP. However, the questionnaire and surveillance forms of those above mentioned persons have not been evaluated by the occupational health physician.

#### Council's Consideration

- Fully Addressed?
- Partially addressed?
- Retain as a mandatory item?
- Retain as an SFI?



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**Case scenario** 3

<p><b>OHS-Workplace Risk/Safety Assessment</b></p> <ul style="list-style-type: none"> <li>▪ IVIS and PET/CT imaging areas were located in the same Room 8A. Additionally, mice and rats underwent IVIS or PET/CT scan shared the same holding room. Most personnel working with IVIS were not approved to work with radiation.</li> <li>▪ At the time of site visit, there was a cage of mice was marked as "hot", after the animal underwent PET/CT imaging.</li> <li>▪ While IVIS is not involving radiation, the same location of housing and imaging of IVIS and PET/CT potentially exposing personnel who is only approved to work with IVIS with radioactive material when they enter housing or imaging area after radioactive material is used, or "hot" animal was present.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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**Unit's Action & Council's Consideration**

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ All researchers including using only IVIS and staff entering the area were trained in radiation safety training for radiation workers according to the Nuclear Safety Act.</li> <li>▪ In the case of imaging room, IVIS and PET/CT cannot be used at the same time and according to the law, lead-shielded partition is located between IVIS and PET/CT in animal imaging room.</li> <li>▪ Since animal housing room is not equipped protection method for the animal which is used for IVIS, the unit made a lead-shielded cart that could cover the exposed animal of radiation isotopes to protect for IVIS user and animal.</li> </ul>	<p><b>Council's Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as an SFI?</li> </ul>
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**Case scenario** 4

<p><b>OHS – Bite and Scratch Kit</b></p> <ul style="list-style-type: none"> <li>▪ Personnel who work in the nonhuman primate area had no access to bite and scratch emergency care kits.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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## Case scenario – Why?

### Why?

- The *Guide* states that “Because of the potential for exposure to *Macacine herpesvirus 1*, personnel who work with or handle biologic samples (blood and tissues) from macaques should have access to be instructed in the use of bite and scratch emergency care stations.”
- Personnel should have access to bite and scratch emergency care kits to ensure appropriate post-exposure treatment and follow-up. *Guide* (pp. 22-23, Medical Evaluation and Preventive Medicine for Personnel)

### What?

- The bite and scratch emergency care kits should be available to personnel working with NHP and their biologic samples. All personnel should be appropriately trained.



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## Unit’s Action & Council’s Consideration

### Unit’s Action

- Scratch kit was purchased and training was provided to personnel.

### Council’s Consideration

- Fully Addressed?
- Partially addressed?
- Retain as an SFI?



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### Facilities, Equipment and Monitoring

- The design of facilities should preferentially **use engineering controls and equipment** to minimize exposures to anticipated hazards.
- Safety equipment should be **properly maintained** and its function periodically **validated**....
- Appropriate facilities, equipment, and procedures should be used for bedding disposal.

When biological agents are used, the BMBL should be referred to.



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### Recent Safety-related Issues

- Staff not following SOPs on safety
- Chemical fume hood was not certified or properly maintained
- Biological safety cabinet was not certified regularly
- Incomplete biohazard signage
- Safety eyewash not regularly maintained
- Active gas anesthetic scavenging system was not certified or properly maintained



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### Recent Safety-related Issues

- Unsecured pressurized gas containers
- Florescent light tubes without protective covers
- Many power outlets near water were not water proof, covered or have ground fault circuit interrupter (GFCI)
- No ergonomic training



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**Case scenario** 5

<p><b>OHS - Waste Anesthetic Gases</b></p> <ul style="list-style-type: none"> <li>▪ The institute used isoflurane anesthesia for rodents without any anesthetic gas scavenging mechanism in place.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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**Case scenario – Why?**

<p><b>Why?</b></p> <ul style="list-style-type: none"> <li>▪ Hazardous agents should be contained in the study environment, for example through the use of airflow control during the handling and administering of hazardous agents.</li> </ul>	<p><b>What?</b></p> <ul style="list-style-type: none"> <li>▪ Waste anesthetic gases should be scavenged to limit exposure to personnel.</li> </ul>
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**Unit's Action & Council's Consideration**

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ An active scavenging system was installed and a photo was provided.</li> </ul>	<p><b>Council's Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as an SFI?</li> </ul>
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**Case scenario** 6

<p><b>Isoflurane Vaporizer</b></p> <ul style="list-style-type: none"> <li>▪ There were two isoflurane gas anesthesia equipment being used for rodent surgeries. There was no plan to regularly service and calibrate the isoflurane anesthesia equipment. Anesthesia SOP also did not describe any service/maintenance expectations for the equipment.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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**Unit's Action & Council's Consideration**

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ The gas anesthesia vaporizers will be sent to vendor for calibration soon, but no timeline had been provided. Future calibration schedule will be done annually, and this information was added into the SOP.</li> </ul>	<p><b>Council's Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as an SFI?</li> </ul>
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**Case scenario** 7

<p><b>OHS - Waste Anesthetic Gases</b></p> <ul style="list-style-type: none"> <li>▪ Isoflurane vaporizers in room No. 2203, 2206, and room 3107 were not calibrated at all after the purchase.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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### Case scenario – Why?

**Why?**

- The Guide states that anesthesia is one of required important components for successful surgical output, and that precision vaporizers increase the safety for anesthesia delivery.

**What?**

- The institution should periodically calibrate isoflurane vaporizers to conduct safe anesthesia.



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### Unit's Action & Council's Consideration

**Unit's Action**

- The institution conducted calibration of isoflurane vaporizers by the manufacturer.

**Council's Consideration**

- Fully Addressed?
- Partially addressed?
- Retain as an SFI?



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### Case scenario

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**Uncovered fluorescent light fixtures**

- Uncovered fluorescent light fixtures were present in both of NHP necropsy and surgical rooms.

**Question**

- Mandatory?
- SFI?



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### Case scenario – Why?

**Why?**

- Uncovered light fixtures, if wet or broken, are a potential personnel safety hazard (*Guide* Page 141, power and lighting).

**What?**

- Appropriate covers or new fixtures should be installed.



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### Unit's Action & Council's Consideration

**Unit's Action**

- Those fluorescent lighting fixtures have been covered.

**Council's Consideration**

- Fully Addressed?
- Partially addressed?
- Retain as an SFI?



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### Case scenario

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**Safety Equipment**

- A periodical inspection of biological safety cabinets in room No.101 and 214 was not conducted since October 29, 2013.

**Question**

- Mandatory?
- SFI?



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**Case scenario** 10

<p><b>OHS – Safety Procedures</b></p> <ul style="list-style-type: none"> <li>▪ Oxygen cylinders were free standing in Procedure room, Surgery room and Surgery preparation room.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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**Allergy Prevention**

[http://www.aaalac.org/accreditation/faq\\_landing.cfm](http://www.aaalac.org/accreditation/faq_landing.cfm)

<p>The <i>Guide</i> emphasizes the use of <b>“engineering or process controls”</b> for allergy prevention. It also states that <b>“PPE should be used to supplement, not replace, engineering or process controls....”</b></p> 	<p>AAALAC International considers allergy prevention to be an important topic and a key component of the occupational health and safety program.</p> <ul style="list-style-type: none"> <li>▪ The use of <b>engineering controls to prevent exposure to allergens is preferred</b> as the primary means to minimize personnel exposure.</li> <li>▪ <b>PPE should be used as an adjunct</b> to engineering controls, rather than the foremost means of protection.</li> </ul>
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### Allergy Prevention

Engineering Control Methods	AAALAC International
<ul style="list-style-type: none"> <li>▪ proper animal facility design and function with separation of functional spaces</li> <li>▪ a well designed and functional HVAC system with appropriate airflow patterns</li> <li>▪ consideration of newer cage designs which minimize personnel exposure</li> <li>▪ the use of containment equipment such as biosafety cabinets, cage changing stations and bedding dump stations.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Site visitors will evaluate occupational health and safety programs and the methods used to prevent laboratory animal allergy through evaluation of               <ul style="list-style-type: none"> <li>▪ personnel training</li> <li>▪ risk assessment by qualified occupational health and safety personnel</li> <li>▪ preventive medicine</li> <li>▪ periodic health evaluations</li> <li>▪ engineering controls, and</li> <li>▪ appropriate use of PPE</li> </ul> </li> </ul>


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### Recent Findings

- Lack of allergy questions in the personnel health questionnaire or medical evaluation form
- Lack of, or consideration of, engineering control for dirty rodent bedding disposal
- Lack of training on laboratory animal allergy


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## Case scenario

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OHS – Risk Assessment - Allergy	Question
<ul style="list-style-type: none"> <li>▪ The Medical Evaluation form used for new employees joining the unit's animal care and use program <b>did not include any assessment of preexisting allergies</b>. Site visitors were informed that after commencing employment, whenever employees sensed that they may have developed allergy symptoms, they could seek medical assessment at that time.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>


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**Unit's Action & Council's Consideration**

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ Medical evaluation for allergies was carried out by a medical doctor and preventive training was conducted</li> </ul>	<p><b>Council's Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as an SFI?</li> </ul>
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**Case scenario** 12

<p><b>OHS - Allergy</b></p> <ul style="list-style-type: none"> <li>▪ While most aspects of the occupational health and safety program (OHSP) were satisfactory, there was one concern. In Appendix 6 Personal Medical Evaluation of the Program Description, did not include the individual risk assessment and/or health history evaluation for "allergy evaluation". The site visitors asked for the record or document of allergy evaluation for personnel who worked with animals; however, the institution did not have the record or document to describe screening for laboratory animal allergies.</li> <li>▪ Personnel exposed to laboratory animals were not screened to detect those who were developing allergic symptoms (e.g., sneezing, nasal congestion, itchy eyes, cough, wheezing, shortness of breath, or hives) so that appropriate intervention measures could be taken.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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**Unit's Action & Council's Consideration**

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ The Institutions will revise SOP "safety management of the facility and laboratory" within this year.</li> <li>▪ IO decided to perform allergy test for all LAC workers within this year. It will be implemented as soon as the budget is available.</li> <li>▪ The relevant medical report form is updated to "Appendix 6: Personnel Medical Evaluation Form". However the program has not been implemented.</li> </ul>	<p><b>Council's Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as an SFI?</li> </ul>
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### Respirator Use

[https://www.aalac.org/accreditation/faq\\_landing.cfm#Respirator](https://www.aalac.org/accreditation/faq_landing.cfm#Respirator)

**If respirators are required to protect any individuals from contaminant exposure, a written institutional program (Respiratory Protection Program or Personal Protective Equipment Program) is needed.**

The program ... guidance for

- respirator selection
- medical evaluation ... of the suitability of the individual to wear the respirator
- qualitative and/or quantitative fit testing
- respirator use training to include inspection, maintenance and care, quality, quantity and flow of breathing air, and routine and emergency use procedures



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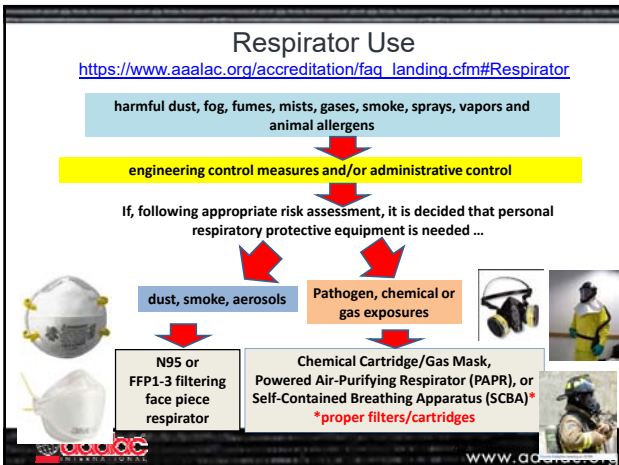
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## Unit's Action & Council's Consideration

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ Personnel required to use respirators had been medically evaluated and fit tested, and the IACUC had approved the SOP revision.</li> </ul>	<p><b>Council's Consideration?</b></p> <ul style="list-style-type: none"> <li>▪ Fully addressed?</li> <li>▪ Partially addressed?</li> </ul>
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## Case scenario

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<p><b>Respirator Use</b></p> <ul style="list-style-type: none"> <li>▪ Use of respirators (M20 tight fitting respirator with expiration valve) was required by staff for the dirty cage wash area.</li> <li>▪ Although each staff member had received medical evaluation, fit testing and training was <u>not</u> required or documented prior to use of this device.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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## Case scenario – Why?

<p><b>Why?</b></p> <ul style="list-style-type: none"> <li>▪ The RP program is a cohesive collection of written worksite-specific procedures and policies that, taken together, address all relevant respiratory protection elements, including guidance for respirator selection (including appropriate protection factors); medical evaluation by an occupational health professional of the suitability of the individual to be medically able to wear the respirator and health hazards associated with the use of respiratory protection devices; qualitative and/or quantitative fit testing, and respirator use training to include inspection, maintenance and care, quality, quantity and flow of breathing air, and routine and emergency use procedures.</li> </ul>	<p><b>What?</b></p> <ul style="list-style-type: none"> <li>▪ A Respiratory Protection Program must be established by the institution and personnel that are required to wear the indicated respiratory protection must be fit tested and trained as recommended in the Occupational Health and Safety in Research Animals (NRC, 1997), p63. Guide (pp. 21-22, Personal Protection) Occupational Health and Safety in Research Animals, (NRC, 1997), p114, paragraph 4, P63 Personal Protective Equipment (related to allergies).</li> </ul>
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### Unit's Action & Council's Consideration

#### Unit's Action

- The OHSP manager re-evaluated the working environment and recommended that respirator use was not needed and the unit confirmed discontinued use immediately. As no respirators are required, a respirator protection program is no longer required.

#### Council's Consideration

- Fully Addressed?
- Partially addressed?
- Retain as an SFI?



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### Case scenario

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#### OHS-Personnel Protection - PPE

- The PD (p.19) described respiratory protective equipment requirements for personnel exposed to hazardous chemicals or dust in the air (e.g., soiled bedding disposal, sanitation), which required employees to wear either N95 masks or chemical face masks when working with soiled bedding or chemical disinfectants respectively.
- Although there was a written policy for fit testing and medical clearance, not all of the personnel who were required to wear respiratory protection had completed fit testing, and the medical clearance component was not performed.

#### Question

- Mandatory?
- SFI?



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### Unit's Action & Council's Consideration

#### Unit's Action

- Unit provided approved SOP on selection of PPE and RPE and fit testing, and indicated that all animal users will complete fit testing within the next 6 months.

#### Council's Consideration

- Fully Addressed?
- Partially addressed?
- Retain as a mandatory?
- Retain as an SFI?



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**Case scenario** 16

<p><b>OHS-Personnel Protection -PPE</b></p> <ul style="list-style-type: none"> <li>▪ Use of respirators (N-95 or 3M 6005) was required for personnel working in the cage wash and necropsy areas (formalin preparation or exposure); however, fit testing, respiratory health evaluation and training was not required prior to use of these devices.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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**Unit's Action & Council's Consideration**

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ The unit will finish the fit testing next month. Training has not been conducted. Written respiratory protection program has not been finished.</li> </ul>	<p><b>Council's Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as a mandatory issue?</li> <li>▪ Retain as an SFI?</li> </ul>
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### Safety Requirements for Walk-In Cage/Rack Washers and Bulk Sterilizers

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

#### Safety Plan

- The safety **must** be addressed by the institution
- 3 safety plan key factors
  - 1) ease of egress
  - 2) a de-energizing\* mechanism
  - 3) personnel training

flow **stoppage of water** into the interior of the **cage washer**, along with **termination of the wash cycle** such that restart requires deliberate reactivation

**immediate termination of the sterilization cycle**, allowing **immediate opening of the door/hatch and release of the person trapped** therein



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

- The possibility of **entrapment must be eliminated**, and in the case of cage/rack washers, ideally **an emergency shut-off mechanism** that is easily accessible from anywhere inside the machine ....
- Proper instructional **signage** must be posted and equipment operators must receive appropriate **training** ...

- Following risk assessment, **other mechanisms and/or procedures**, individually or in combination, might be determined ... such as:
  1. **buddy system**, in which at least two individuals are present ...
  2. **explosion relief door latches** which open easily from the inside of the washer
  3. **lock-out system**, whereby the emergency stop mechanism, once activated, must be actively disengaged before the machine can be restarted.



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

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

#### AAALAC's Expectation

- The institution **must** provide the Council on Accreditation with sufficient evidence to demonstrate that issues regarding cage/rack washer safety have been **addressed and will be periodically reviewed**.

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### Recent Issues

- Lack of safety training for personnel operating rack washers or bulk sterilizers
- No safety signage for the use of the rack washer



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### Case scenario 17

<p><b>OHS- Rack washer safety signage</b></p> <ul style="list-style-type: none"> <li>▪ While the institute had a very good occupational health and safety program, all employees operating the walk-in rack washers received training on safety features of the equipment, and there were appropriate safety signs inside the rack washers, however, there was no instructional safety signage posted in the area.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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### Unit's Action & Council's Consideration

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ The unit placed additional safety signage and instruction outside the walk-in rack washers</li> </ul>	<p><b>Council's Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as an SFI?</li> </ul>
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**AV's Responsibilities**

- AV is responsible for the health and well-being of **all** laboratory animals used at the institutions
- AV has sufficient **authority: access** to all animals and resources to manage the veterinary care program
- AV should oversee other aspects of animal care and use (husbandry, housing) to ensure compliance with the *Guide*

Chapter 2, p14, Chapters 3 and 4




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**The AV and Veterinary Care**

- The AV is responsible for the well-being and clinical care of animals used in research, testing, teaching, and production.
- The veterinarian **must have sufficient authority**, as provided by the institution, to treat an animal and institute appropriate measures to relieve severe pain or distress, including euthanasia.

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## Duties of the AV - Veterinary Care

- **must** have experience, training, and expertise ...
- **must** have access to all animals
- **must** provide timely provision of veterinary medical care
- emergency veterinary care **must** be available at all times ...
- **must** have oversight of additional aspects of the veterinary care program ... such as preventative medicine ... establishment of sedation, anesthetic and analgesic guidelines, handling, and immobilization
- should have oversight of other related aspects such as housing and husbandry
- should provide guidance and oversight to surgery programs and perioperative care
- should remain knowledgeable about the latest practices and procedures ...



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## The AV's Roles on the IACUC

AV:

- should be regular, clear communication between the AV and the IACUC
- should have input in protocol review, the development of study removal criteria, and responsible conduct of research activities
- should understand the potential for adverse clinical complications that may arise from experimental procedures
- in association with IACUC, has the responsibility for determining that personnel performing surgical procedures are appropriately qualified and trained in the procedures to be performed
- in cooperation with IACUC, should be involved in classifying major versus minor surgical procedures



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

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## AV Provision

### One full-time AV

- Large programs may employ multiple veterinarians and technicians who report to the AV



### No on-site AV

- A consulting or part-time
- Visits at intervals appropriate to programmatic needs
- There must be an individual with assigned responsibility for daily care and use, and facility management.

The Guide endorses "Guidelines for Adequate Veterinary Care" (ACLAM 1996).

For an effective program, there should be a clear and regular communication between the AV and the IACUC.



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### Animal illness reporting mechanism

67

All animals should be observed for signs of illness, injury, or abnormal behavior by a person trained to recognize such signs. As a rule, this should occur daily ... more frequent might be warranted.

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The diagram illustrates the reporting mechanism. On the left, several cartoon rabbits are shown, some appearing ill. An arrow points from them to a person in a white coat, who is holding a clipboard and looking at a list of signs. From this person, an arrow points to a man in a blue suit labeled 'AV' (Attending Veterinarian). A double-headed arrow connects the AV to a woman in a pink suit labeled 'PI (Study Director)'. A red question mark is positioned above the AV and PI, indicating a point of inquiry or decision.

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### Question?

18

Our veterinarian has just graduated from a famous university. He is qualified to be an Attending Veterinarian.

YES NO

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The slide features a blue star icon with the number 18 in the top right corner. At the bottom, there are two circular buttons: a green one labeled 'YES' and a red one labeled 'NO'.

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### Question?

19

We have a large centralized facility and have 6 Attending Veterinarians. Each Attending Veterinarian looks after animals on a specific floor or area.

YES NO

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## Recent VC Issues

- Inadequate veterinary care
  - failure to recognize sick animals
  - failure to notify veterinary care team
- Inadequate animal medical records
- Lack of continuing education and training for veterinary staff
- Lack of provision of emergency veterinary care
- Expired drugs were not discarded
- Lack of controlled drugs documentation



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## Anesthesia and Analgesia Issues

- inadequate anesthesia
- inadequate pre- and post-surgical pain management
- inaccurate dosage or frequency of analgesic administration
- deviation from the approved protocol
- inadequate use and documentation of analgesics
- no preemptive analgesia for survival surgery



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## Case scenario

20

VC - Analgesia Usage	Question
<ul style="list-style-type: none"> <li>▪ Surgical and post-surgical management of pain in rodents was inadequate. The only analgesic option available was a 4% tolfedine solution, which is typically used in larger animal species such as dogs, cats, and agricultural species.</li> <li>▪ There were <u>no</u> assessment performed by the institution to confirm its effectiveness for pain management in rodent species. A review of the surgical records for Study No. 002 (myocardial infarction model) performed on several dates indicated that animals had only received one dose of the analgesic post open-chest surgery. However, in the approved IACUC protocol, at least two doses of analgesics given every 48 was described.</li> <li>▪ Similarly, a review of surgical records for bile duct occlusion to induce liver fibrosis (Record No. 79) performed two weeks ago indicated that animals had <u>only</u> received one dose of analgesic post-surgery when it was described in the IACUC approved protocol that at least three daily doses of analgesic will be administered.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SPI?</li> </ul>



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### Unit's Action & Council's Consideration

#### Unit's Action

- A copy of the training record to show meloxicam use had replaced tolfedine, and the drug dosages for mice and rats. However, there was no other supportive information provided that demonstrates successful implementation of this change, such as updating the standard operating procedure (SOP) with instruction of new drug use, clarification on whether current active animal use protocols had been amended to include meloxicam use, or mention of any post-approval monitoring to ensure dosage and frequency of analgesic use conforms with the IACUC approved animal use protocols.

#### Council's Consideration

- Fully Addressed?
- Partially addressed?
- Retain as an SFI?



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### Case scenario

21

#### Veterinary Medical Care

- A few rats in the chronic inhalation chamber in Room 2 undergoing study had porphyrin stains around their nares.
- The approved protocol described a system of scoring for clinical signs detected in these rats to help determine their humane endpoint. However, no records were available for these clinical signs observed in these rats.

#### Question

- Mandatory?
- SFI?



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### Unit's Action & Council's Consideration

#### Unit's Action

- The AV re-trained personnel on animal observation methods and record keeping for the animal observation forms.

#### Council's Consideration

- Fully Addressed?
- Partially addressed?
- Retain as an SFI?



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**22**

## Case scenario

<p><b>VC-Pain and Distress</b></p> <ul style="list-style-type: none"> <li>▪ Surgery record of a dog recently underwent major surgery to implant telemetry device in the peritoneal cavity (No. 191) showed analgesic (Ketoprofen) was provided on the day of surgery. However, <u>no</u> additional analgesic dose was provided after, or indication additional dose as needed basis based on post-surgical assessment. Additionally, study protocol (No. 218) indicated either ketoprofen or dexamethasone (as alternative) to be given on the day of surgery. So far ketoprofen had <u>not</u> been administered.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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## Unit's Action & Council's Consideration

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ Unit assigned IACUC and AV to review and approve the analgesic and dose; and dexamethasone would not be used as analgesic. Surgical record had been revised, AV to confirm the use of pre- and post-surgical medication. The protocol had been described in the protocol and reviewed by IACUC.</li> </ul>	<p><b>Council's Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as an SFI?</li> </ul>
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**23**

## Case scenario

<p><b>VC – Pain Distress</b></p> <ul style="list-style-type: none"> <li>▪ The SOP for analgesia described that both preemptive and post operation analgesia should be offered as part of the surgical plan.</li> <li>▪ In protocol No. 094 "Studies on the pathogenesis of myocardial ischemia/reperfusion injury on pig model", there was <u>no</u> preemptive analgesia described in the surgical plan. <u>No</u> preemptive analgesic was given according to the medical record, which was against unit's SOP.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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### Unit's Action & Council's Consideration

**Unit's Action**

- The AV had communicated with the researcher and revised the protocol. The preemptive analgesic with meloxicam 1 mg/kg SC was added in the follow-up experiment.

**Council's Consideration**

- Fully Addressed?
- Partially addressed?
- Retain as an SFI?



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### Case scenario

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**VC - Analgesia**

- There was inadequate use and documentation of analgesics. IACUC protocols involving major and minor survival surgeries in rodents and rabbits (e.g., Protocols 002, 038, 079, 114, 187, 132, and 161) did not require pain relief intraoperatively or postoperatively.

**Question**

- Mandatory?
- SFI?



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### Unit's Action & Council's Consideration

**Unit's Action**

- Details of analgesia to be provided are now included during protocol review.
- Carprofen gel is available for veterinary prescription during urgent cases. However, no information was provided as to how analgesic use to be documented or how current surgical protocols underway could be reviewed to ensure adequate use of analgesia.

**Council's Consideration**

- Fully Addressed?
- Partially addressed?
- Retain as a mandatory issue?
- Retain as an SFI?



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**25**

## Case scenario

**Vet Care - Surgery – Post-operative care**      **Question**

- Surgical clips were used for mice after transplantation of fertilized eggs at room No. 01. However, surgical clips were not removed at all.

- Mandatory?
- SFI?

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## Unit's Action & Council's Consideration

**Unit's Action**      **Council's Consideration**

- The institution revised SOP by adding description that the surgical clips should be removed by using auto clip remover during postoperative days 5-10.

- Fully Addressed?
- Partially addressed?
- Retain as an SFI?

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**26**

## Case scenario

**Vet Med Care – Drug storage**      **Question**

- Control drugs were stored in the safety cabinets. However, many bottles of expired pethidine, ketamine and naloxone were stored with validated drugs without separation nor labelling.

- Mandatory?
- SFI?

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### Unit's Action & Council's Consideration

#### Unit's Action

- All expired drugs have been clearly labelled and separated from non-expired drugs and waiting for discarding by qualified institution.

#### Council's Consideration

- Fully Addressed?
- Partially addressed?
- Retain as an SFI?



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### Aseptic Surgery and Alcohol as a Disinfectant

[http://www.aaalac.org/accreditation/faq\\_landing.cfm](http://www.aaalac.org/accreditation/faq_landing.cfm)

- The use of alcohol as a skin disinfectant for rodent survival surgery is acceptable, **but the blanket use of alcohol for surgical instrument preparation was not acceptable.**
- The IACUC must evaluate the use of alcohol on a case-by-case basis with due consideration for animal welfare and scientific outcomes based on a review of current relevant literature, and consistent with expected surgical outcomes.

See AAALAC's guidance on the use of alcohol as a skin disinfectant and for instrument sterilization  
[http://www.aaalac.org/publications/Connection/Using\\_Alcohol\\_Disinfectant.pdf](http://www.aaalac.org/publications/Connection/Using_Alcohol_Disinfectant.pdf).



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## Recent Issues

- Alcohol was used for batch survival surgeries of rodents

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## Case scenario 27

<p><b>VC – Aseptic Technique</b></p> <ul style="list-style-type: none"> <li>▪ Instruments for survival surgery on rodents were disinfected by immersion in ethanol in some satellite laboratories.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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## Unit's Action & Council's Consideration

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ Appropriate sterilization methods were implemented to replace alcohol.</li> </ul>	<p><b>Council's Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as an SFI?</li> </ul>
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## Case scenario

<p><b>Alcohol as sterilant</b></p> <ul style="list-style-type: none"> <li>▪ The surgical instruments for mice batch operations, such as rederivation, were sterilized only by soaking into alcohol solution between each individual mice operation.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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## Unit's Action & Council's Consideration

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ The unit modified the "SOP of Biological Cleaning Laboratory Rats and Mice", in which stipulated that amount of the surgical instruments should be prepared according to the number of the animals, and a set of autoclaved surgical instrument can only be used for one animal surgery.</li> <li>▪ The staffs who perform the surgery were all re-trained.</li> </ul>	<p><b>Council's Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as an SFI?</li> </ul>
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**Preventive Medicine - Animal Biosecurity**

- All measures taken to identify, contain, prevent, and eradicate known or unknown infections that may cause clinical disease or alter physiologic and behavioral response or otherwise make animals unsuitable for research.
  - Limit exposure by physical plant
  - Separation of equipment and staff
  - Procedures and practices
  - Selecting suppliers
  - Pest control program



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**Question?** 29

We order all rodents, rabbits and dogs from reliable commercial sources.

Therefore, an animal health monitoring program is not necessary.

YES NO

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**Intra-operative Monitoring**

- AAALAC's expectation
  - [http://www.aalac.org/accreditation/faq\\_landing.cfm](http://www.aalac.org/accreditation/faq_landing.cfm)
- The level and detail required for intra-operative monitoring and recordkeeping can vary with the species, invasiveness and complexity of the surgical procedure, duration of surgery and other factors, such as anesthetic regimen and the use of neuromuscular blockade, the potential for pain or distress, procedural complexity, duration, or likelihood of an unsuccessful outcome.
- The Council will evaluate the adequacy of intra-operative monitoring using a performance based approach which assesses whether procedures meet the goals and provide a successful outcome.

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**Using CO<sub>2</sub> : Acceptable with Conditions for Small Rodents**

Conditions (p49, 100)	Notes (p49)
<ul style="list-style-type: none"> <li>▪ <b>Must</b> be supplied from a commercially supplied from a cylinder or tank.</li> <li>▪ An appropriate pressure-reducing regulator and flow meter <b>must</b> be used.</li> <li>▪ An optimal flow rate for CO<sub>2</sub> euthanasia system should displace 10-30% of the chamber volume/min.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Prefilled chambers are <u>unacceptable</u>.</li> <li>▪ Oxygen administered together with CO<sub>2</sub> is <u>not</u> recommended.</li> <li>▪ If euthanasia cannot be conducted in the home cage, chambers should be emptied and cleaned between uses.</li> </ul>

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**CO<sub>2</sub> Euthanasia for Rodents – AAALAC’s Expectation**

[http://aalac.org/accreditation/faq\\_landing.cfm#D5](http://aalac.org/accreditation/faq_landing.cfm#D5)

1. **Must** use 10-30% displacement rate of chamber air with CO<sub>2</sub> gas/minute
  - Should calculate the flow rate...
  - Flow meters are the preferred method of ensuring flow rate, other methods are available
2. When automated euthanasia systems are used, displacement rates should be verified.
3. Where residual CO<sub>2</sub> is expected, procedures should be in place to ensure removal of residual CO<sub>2</sub> gas between euthanasia sessions.
4. Personnel conducting CO<sub>2</sub> euthanasia **must** be competent
5. Confirmation of death **must** be assured.

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**CO<sub>2</sub> Euthanasia for Rodents – AAALAC’s Expectation**

6. When possible, euthanasia should be conducted in the home cage...


- If home cage cannot be practiced, the process **must** minimize pain and distress and the chambers should be cleaned between each use.

7. Great care should be taken with CO<sub>2</sub> euthanasia of neonatal rodents...

8. Chambers should allow visualization of animals during CO<sub>2</sub> euthanasia.

9. Procedures should be implemented to prevent potential distress resulting from exposure to the vocalizations and odors of frightened animals.

10. The IACUC **must** review and approve any deviations from the 2013 AVMA Guidelines on CO<sub>2</sub> euthanasia using a performance based approach.



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**Common Euthanasia Issues**

Euthanasia methods did not follow Guide and/or AVMA Guidelines for the Euthanasia of Animal: 2013 (notably when using CO<sub>2</sub>)

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**Case scenario** 30

<p><b>VC - Euthanasia</b></p> <ul style="list-style-type: none"> <li>▪ Euthanasia SOP was in place, however the CO<sub>2</sub> euthanasia practice did <u>not</u> follow the SOP.</li> <li>▪ The flow rate stated in the SOP was not practiced and the SOP had not been updated when new euthanasia chambers were purchased.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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**Unit's Action & Council's Consideration**

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ The euthanasia SOP has been updated and training has been performed.</li> </ul>	<p><b>Council's Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as an SFI?</li> </ul>
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**Case scenario** 31

<p><b>Vet Care - Euthanasia</b></p> <ul style="list-style-type: none"> <li>▪ Although the unit has the SOP No. 202 (Euthanasia for laboratory animals) which has been revised in June 2016, however the methods of euthanasia by ether and dry ice still were included in the SOP. The AV mentioned that the unit did not practice those methods anymore.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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**Unit's Action & Council's Consideration**

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ The SOP had been revised.</li> </ul>	<p><b>Council's Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as an SFI?</li> </ul>
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## Case scenario

<p><b>Vet Care – Euthanasia Equipment</b></p> <ul style="list-style-type: none"> <li>▪ In the Room C, the CO<sub>2</sub> euthanasia equipment did <u>not</u> have a mechanism (e.g. a flow meter or equivalent equipment) to ensure correct (10-30%) displacement rate of chamber air with CO<sub>2</sub>.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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## Unit's Action & Council's Consideration

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ A CO<sub>2</sub> flowmeter had been installed and new SOP for euthanasia with CO<sub>2</sub> had been issued.</li> </ul>	<p><b>Council's Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as an SFI?</li> </ul>
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## Case scenario

<p><b>VC – Euthanasia Procedure</b></p> <ul style="list-style-type: none"> <li>▪ The Rodent Euthanasia SOP referred to the 2013 <i>American Veterinary Medical Association Guidelines for the Euthanasia of Animals</i> indicating that the CO<sub>2</sub> displacement rate of chamber volume per minute was at least 20%.</li> <li>▪ In the procedure room, the operator was not able to recall the settings for the flow rate of CO<sub>2</sub>. There were no instructions of the pressure gauge flow rates on the use of the equipment for CO<sub>2</sub> euthanasia or the gradual fill of the chamber at the rate as indicated in the SOP.</li> <li>▪ The chamber was appropriately cleaned between reuse for the next animal euthanasia procedures.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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### Unit's Action & Council's Consideration

**Unit's Action**

- The SOP was corrected and detailed instruction was posted nearby the equipment. Training record was provided.

**Council's Consideration**

- Fully Addressed?
- Partially addressed?
- Retain as an SFI?



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### Case Scenario

34

**Euthanasia Issue**

- Documentation revealed decapitation conducted for mouse or rat neonates was less than 6 days, however in Program Description and Euthanasia SOP (Euthanasia method for mouse, rat, guinea pig and rabbit), decapitation was acceptable for rodent neonates less than 10 days.

**Questions**

- Mandatory?
- SFI?



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### Case Scenario – Why?

**Why?**

- According to AVMA Guidelines for the Euthanasia of Animals: 2013, decapitation was only acceptable with condition for mouse or rat neonates less than 7 days.

**What?**

- The euthanasia method for rodent neonates should be re-evaluated



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**Unit's Action & Council's Consideration**

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ SOP was revised and training was provided to staff.</li> </ul>	<p><b>Question?</b></p> <ul style="list-style-type: none"> <li>▪ Fully addressed?</li> <li>▪ Partially addressed?</li> </ul>
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**Case scenario** 35

<p><b>VC-Euthanasia - Procedure</b></p> <ul style="list-style-type: none"> <li>▪ Cervical dislocation was performed on conscious mice without anesthesia or heavy sedation. However, personnel performing the procedure had not received appropriate training, or confirmed proficiency.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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**Unit's Action & Council's Consideration**

<p><b>Why?</b></p> <ul style="list-style-type: none"> <li>▪ <i>The AVMA Guidelines for the Euthanasia of Animals: 2013 Edition</i> states that "in lieu of demonstrated technical competency, animals must be unconscious or anesthetized prior to cervical dislocation" (p.38).</li> </ul>	<p><b>What?</b></p> <ul style="list-style-type: none"> <li>▪ Specific procedures must be instituted to ensure that personnel performing euthanasia on experimental animals are appropriately trained or qualified.</li> </ul>
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### Case scenario

<b>Unit's Action</b> <ul style="list-style-type: none"><li>▪ The institution revised the policy so that the IACUC would no longer approve cervical dislocation without anesthesia.</li></ul>	<b>Council's Consideration</b> <ul style="list-style-type: none"><li>▪ Fully Addressed?</li><li>▪ Partially addressed?</li><li>▪ Retain as an SFI?</li></ul>
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### Management & Husbandry Issues

- Inadequate monitoring of sanitation and sterilization
- Inadequate cage sanitation
- Feed storage conditions did not follow *Guide's* recommendations
- Rodent cage cards with inconsistent or insufficient information
- Insufficient vermin monitoring and control
  - Pest rodent live traps were not observed daily

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**Case scenario** 36

<p><b>Sanitation - Monitoring Effectiveness</b></p> <ul style="list-style-type: none"> <li>▪ There was no mechanism for effectiveness monitoring of sanitation for the macro and micro environment of both large and small animal facilities.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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**Case scenario – Why?**

<p><b>Why?</b></p> <ul style="list-style-type: none"> <li>▪ According to the Guide (p. 72-73), monitoring of sanitation practices should fit the process and materials being cleaned and may include the visual inspection and microbiologic and water temperature monitoring. Whether the sanitation process is automated or manual, regular evaluation of sanitation effectiveness is recommended.</li> </ul>	<p><b>What?</b></p> <ul style="list-style-type: none"> <li>▪ The unit should consider the sanitation effectiveness monitoring for animal microenvironment and macroenvironment.</li> </ul>
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**Unit's Action & Council's Consideration**

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ The new SOP of "Monitoring system for sanitation effect" has been established.</li> <li>▪ Effectiveness monitoring of sanitation was required to conduct twice per year.</li> <li>▪ The new SOP was became effective, and training was provided to relevant technical staff.</li> <li>▪ The SOP and training record was provided. The monitoring of sanitation was conducted and results were provided.</li> </ul>	<p><b>Council's Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as an SFI?</li> </ul>
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**Case scenario** 37

<p><b>Sanitation - Monitoring Effectiveness</b></p> <ul style="list-style-type: none"> <li>▪ In the NHP and dog housing areas, cages were washed by hand. The manual sanitation methods did not appropriately consider procedures to assess the adequacy of sanitation.</li> <li>▪ Also, there was no program in place to measure the effectiveness of sanitation of secondary enclosures such as walls, floors and ceilings.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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**Case scenario – Why?**

<p><b>Why?</b></p> <ul style="list-style-type: none"> <li>▪ The Guide (p. 73) states, “Whether the sanitation process is automated or manual, regular evaluation of sanitation effectiveness is recommended.”</li> </ul>	<p><b>What?</b></p> <ul style="list-style-type: none"> <li>▪ Procedures to regularly evaluate the effectiveness of sanitation of NHP and dog cages, as well as secondary enclosures should be implemented.</li> </ul>
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**Unit’s Action & Council’s Consideration**

<p><b>Unit’s Action</b></p> <ul style="list-style-type: none"> <li>▪ The unit will implement RODAC contact plates to assess the effectiveness of sanitation of primary enclosures, but no information as to whether secondary enclosures e.g. walls and floors would be assessed.</li> </ul>	<p><b>Council’s Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as an SFI?</li> </ul>
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**Case scenario** 38

<p><b>Monitoring Effectiveness</b></p> <ul style="list-style-type: none"> <li>▪ The regular sterilization function was limited to the annual service by the vendor and daily air removal testing. There were no biological indicators or validation methods of proper sterilization process of materials.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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**Unit's Action & Council's Consideration**

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ Both autoclave tape and biological indicator will be used as monitoring process.</li> <li>▪ Staff was trained on use of biological indicator.</li> </ul>	<p><b>Council's Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as an SFI?</li> </ul>
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**Case scenario** 39

<p><b>Documentation</b></p> <ul style="list-style-type: none"> <li>▪ Animal room husbandry logs were inconsistent or incomplete. Records for entry into the animal facility showed that no staff entered the animal rooms each weekend, meaning mice and rats undergoing efficacy studies of natural products had not been observed daily. The unit confirmed that no staff observed the animals on weekends although emergency veterinary care was available</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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## Case scenario – Why?

### Why?

- All animals should be observed for signs of illness, injury, or abnormal behavior by a person trained to recognize such signs.
- As a rule, this should occur at least daily, but more frequent observations may be required, e.g. when animals are approaching a study endpoint. Professional judgment should be used to ensure that the frequency and character of observations minimize risks to individual animals and does not compromise the research for which the animals are used.

### What?

- Such records should be completed and periodically audited to ensure that appropriate procedures are followed.



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## Unit's Action & Council's Consideration

### Unit's Action

- The unit has confirmed that an SOP is in place that states that animals should be observed daily including weekends and holidays, and have provided assurances that staff would receive re-training in the issue. Details of the working schedule for weekdays and holidays was provided and updated in SOP and a record of daily animal area entry was provided as of the SV date that included weekends.

### Council's Consideration

- Fully Addressed?
- Partially addressed?
- Retain as an SFI?



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## Case scenario

40

### Vermin Control

- Glue boards were used as wild rodent traps in the feed and bedding storeroom, and in the dirty corridor.

### Question

- Mandatory?
- SFI?



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### Case scenario – Why?

**Why?**

- The Guide states (pg. 74) that "If traps are used, methods should be humane; traps that catch pests alive require frequent observation and humane euthanasia after capture".

**What?**

- Alternatives to "sticky/adhesive" board traps should be used to avoid unnecessary animal distress.



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### Unit's Action & Council's Consideration

**Unit's Action**

- The glue boards were replaced with live rodent traps and monitored daily.
- The pest control SOP was revised and relevant staff were trained.

**Council's Consideration**

- Fully Addressed?
- Partially addressed?
- Retain as an SFI?



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### Case scenario

41

**Husbandry – Food/Water**

- The PD stated that the temperature in animal food storage rooms was maintained between 26 and 28 degrees C, which exceeds the *Guide* recommended 21 degrees C or less.
- The higher temperatures were observed in the two food storage rooms (No. 2 and 3). While it was explained that the feed manufacturer verbally assured that the nutritional quality was not compromised at those higher temperatures and that feed was delivered weekly, there was no documentation that the IACUC had reviewed the justification and approved this exception to the *Guide*.

**Question**

- Mandatory?
- SFI?



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### Case scenario – Why?

**Why?**

- Storage at higher than recommended temperatures may compromise the nutritional value of diets.

**What?**

- Diets should be stored at the recommended temperatures or, if not, this deviation from the *Guide* should be evaluated by the IACUC to ensure the nutritional quality can be maintained during the storage period.



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### Unit's Action & Council's Consideration

**Unit's Action**

- The unit has adjusted the temperature control to at or below 21 °C.
- An analysis to the diet was conducted by a third party laboratory to indicate the quality of the animal feed met acceptable criteria when stored between 26 and 28 °C for 7-10 days.
- The IACUC plans to discuss whether or not to approve an exception to temperature guidelines for short term food storage.

**Council's Consideration**

- Fully Addressed?
- Partially addressed?
- Retain as an SFI?



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**Humidity control**



Page 44

Humidity should be controllable within a range of 30-70% throughout the year

**If no issues were identified by the institution nor the AAALAC site visit team that would compromise the health and well-being of the animals or jeopardize the integrity of animal studies, then it is not likely that the Council on Accreditation would consider this variation a problem.**

[http://www.aaalac.org/accreditation/faq\\_landing.cfm](http://www.aaalac.org/accreditation/faq_landing.cfm)

**AAALAC's expectation**

AAALAC International would assess the variation around the set point from a **performance approach.**

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**Recycled air** 




Page 47

AAALAC International has determined that the discussion in the 2011 *Guide* regarding recycling air should be augmented with several points noted in the 1996 *Guide*.

- The use of **non-recycled air is preferred** for ventilation of animal use and holding areas.
- If recycled air is used, the **exhaust air should be HEPA-filtered** (high efficiency particulate air-filtered) to remove airborne particles before it is recycled; the extent and efficiency of filtration should be proportional to the estimated risk.....
- The supply air **should not exceed 50% recycled air** and recycled **air should be returned only to the room or area from which it was generated**, except if it comes from other than animal housing areas and the source of the air poses no concerns for animal health.

[http://www.aaalac.org/accreditation/faq\\_landing.cfm](http://www.aaalac.org/accreditation/faq_landing.cfm)



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**Question?** 42

AAALAC International site visitors will review animal room temperature ranges, but relative humidity (RH) data are not critical for some animal species because the RH may fluctuate depending on room activities.

YES
NO

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43

### Question?

Our HVAC recycles 50% of the exhaust air directly into the same animal areas from which the air was derived to assist with cost savings.  
This is not a problem.

YES
NO

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 **Some HVAC & Facility Issues**

- HVAC issue – high NH<sub>3</sub> levels, poor ventilation
- Inadequate facility repair issues that impede sanitation:
  - Peeling paint
  - Floor and wall cracks
  - Rust
- An animal quarantine room has maintained positive air pressure differentials

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**Case scenario** 44

<p><b>HVAC - Temperature</b></p> <ul style="list-style-type: none"> <li>▪ In all animal housing rooms, daily temperature fluctuation was more than <math>\pm 1</math> °C.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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**Case scenario – Why?**

<p><b>Why?</b></p> <ul style="list-style-type: none"> <li>▪ The range of daily temperature fluctuations should be kept to a minimum to avoid repeated large demands on the animals' metabolic and behavioral processes to compensate for changes in the thermal environment (Guide p. 43-45).</li> </ul>	<p><b>What?</b></p> <ul style="list-style-type: none"> <li>▪ The heating, ventilation, and air conditioning (HVAC) system should be evaluated for its ability to maintain environmental control as the Guide recommends.</li> </ul>
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**Unit's Action & Council's Consideration**

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ The institution adjusted the air conditioning system in the animal rooms to minimize temperature fluctuations.</li> <li>▪ Temperature logs were provided.</li> </ul>	<p><b>Council's Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as an SFI?</li> </ul>
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**Case scenario** 45

<p><b>Air Pressure Differentials</b></p> <ul style="list-style-type: none"> <li>▪ According to the PD, the four quarantine rooms shared the corridors with SPF rooms and had positive pressure. These included quarantine room where rodents newly arrived from non-approved vendor were housed. In contrary, three surgery rooms had negative pressure relative to adjacent area.</li> <li>▪ There was no other indicator to check the air pressure.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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**Unit's Action & Council's Consideration**

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ Unit has changed all of the IVC blowers used in the quarantine rooms to negative pressure.</li> <li>▪ All three operating rooms had been changed and maintained at positive pressure.</li> <li>▪ The unit planned to change four quarantine rooms to negative pressure in 3 months.</li> </ul>	<p><b>Council's Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as an SFI?</li> </ul>
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**Case scenario** 46

<p><b>HVAC – Air Pressure Differentials</b></p> <ul style="list-style-type: none"> <li>▪ In the Program Description Appendix 11 (HVAC System Summary), the Necropsy Room's relative room pressure was recorded as 'N/A'.</li> <li>▪ In this room, there were 2 hoods for performing NHP necropsies with the use of formalin. Although records indicated that in-house checks on the function of the 2 hoods were performed every 3 months, when the motors were switched on, the exhaust ventilation was not adequate to remove formalin fumes and protect personnel from exposure to infectious NHP pathogens.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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## Case scenario – Why?

### Why?

- The Guide (page 139) says that 'Areas for quarantine, housing and use of animals exposed to hazardous materials, and housing of nonhuman primates should be kept under relative negative pressure...'. The Guide (page 19) also says that 'The facilities required to support the occupational health and safety program (OHSP) will vary depending on the scope and activities of the Program. Their design should preferentially use engineering controls and equipment to minimize exposure to anticipated hazards'.

### What?

- Engineering controls in the Necropsy Room (i.e. relative room pressure and exhaust hood ventilation) must be risk assessed again so that when NHP necropsies are performed, conditions which minimize the potential exposure of personnel to formalin fumes and infectious zoonotic NHP agents are adequately in place, and infectious zoonotic NHP agents are adequately in place.



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## Unit's Action & Council's Consideration

### Unit's Action

- repair works on the 2 exhaust hoods had been carried out.
- However, no evaluations had been performed on the partial room pressure of the Necropsy Room.

### Council's Consideration

- Fully Addressed?
- Partially addressed?
- Retain as an SFI?



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## Program Description (PD) Issues

- Lack of important information in PD
  - Appendix 11: HVAC system summary
  - Missing satellite animal and/or procedure rooms/labs/areas/
- Numerous errors or incorrect information
- Missing information of some species
- Several questions were not answered



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## Case scenario 47

<p><b>HVAC - Air Pressure Differentials</b></p> <ul style="list-style-type: none"> <li>▪ HVAC Room pressure control lack of information. At the time of the site visit, insufficient information was provided regarding specific room (e.g. dog quarantine, NHP quarantine and housing rooms), air pressure differentials.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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## Case scenario – Why?

<p><b>Why?</b></p> <ul style="list-style-type: none"> <li>▪ Heating, ventilation and air conditioning (HVAC) information performance data is crucial in the regular assessment of HVAC system function.</li> </ul>	<p><b>What?</b></p> <ul style="list-style-type: none"> <li>▪ Areas for quarantine and housing of NHP or animals exposed to hazardous materials should be kept under relative negative pressure and measurements made to determine that is indeed the case.</li> <li>▪ The instructions for completing the Program Description require the provision of performance data on the heating, ventilation, and air conditioning (HVAC) system(s) for all animal facility areas. Current detailed by room HVAC system performance data should be provided.</li> </ul>
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**Unit's Action & Council's Consideration**

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ The unit has updated the relative negative pressure of NHP rooms and quarantine rooms within the PD, and will implement a manual record of pressure differentials.</li> </ul>	<p><b>Council's Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as an SFI?</li> </ul>
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**Case scenario** 48

<p><b>Program Description</b></p> <ul style="list-style-type: none"> <li>▪ The program description did not capture the additional 8,500 sq. ft. of pharmacology animal rooms space on the first floor of the vivarium which had active protocols mentioned in the PD.</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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**Unit's Action & Council's Consideration**

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ The institute revised the PD and included the additional space.</li> </ul>	<p><b>Council's Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as an SFI?</li> </ul>
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**Case scenario**

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<p><b>Program Description</b></p> <ul style="list-style-type: none"> <li>▪ The cat had been used for the experiment in the program. However, no related information was noted in the PD.</li> <li>▪ ...</li> </ul>	<p><b>Question</b></p> <ul style="list-style-type: none"> <li>▪ Mandatory?</li> <li>▪ SFI?</li> </ul>
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**Case scenario – Why?**

<p><b>Why?</b></p> <ul style="list-style-type: none"> <li>▪ AAALAC International's Instructions for completing the Program Description for the Institutional Care and Use Program indicated that an accurate PD is essential to AAALAC International program review process.</li> </ul>	<p><b>What?</b></p> <ul style="list-style-type: none"> <li>▪ The unit must evaluate and revise its PD to ensure that it accurately describes current use of animals in the program.</li> </ul>
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**Unit's Action & Council's Consideration**

<p><b>Unit's Action</b></p> <ul style="list-style-type: none"> <li>▪ The revised PD was updated and all information for the use of cats in the program was provided.</li> </ul>	<p><b>Council's Consideration</b></p> <ul style="list-style-type: none"> <li>▪ Fully Addressed?</li> <li>▪ Partially addressed?</li> <li>▪ Retain as an SFI?</li> </ul>
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