

February 15, 2019

Director of Animal Medicine
and Associate Professor of Pathology
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655

Dear Dr.

Your accredited animal care and use program is scheduled to be site revisited by AAALAC International during our Fall Trimester (September through November) 2019. **It is imperative that the majority of this timeframe be available for the scheduling of the site visit.** To facilitate the Council on Accreditation in assessing your institution, animals must be present during the site visit and you will need to provide AAALAC International with information regarding your program and facilities by submitting a completed Program Description¹ (2016 version) available for download from the AAALAC International web site at <http://www.aaalac.org/programdesc/index.cfm>.

In addition, please provide the following information:

- A cover letter to accompany the Program Description addressing specific requests pertinent to the site visit (e.g., specific dates that would be inconvenient, entry requirements, site visitor expertise, etc.). Some items to consider for inclusion in the cover letter or with the Program Description submission:
 - Any documents requiring signature by either the members of the site visit team or any other AAALAC representative prior to the conduct of the site visit (include a copy of the documents along with the Program Description).
 - If the facility review will entail a significant number of changes of personal protective equipment, or showering in/out of multiple areas, please so advise.
 - A telephone number and e-mail address of the personnel coordinating the site visit arrangements and the **six digit AAALAC International file number** (see the bottom of the enclosed cover letter) which has been assigned to your organization are indicated in the letter. Details regarding format, typing, and assembly are included in the Instructions to the Program Description.

¹Please note that the Council on Accreditation has completed an in-depth review of the Program Description template that has been in use since the publication of the 8th edition of the *Guide for the Care and Use of Laboratory Animals*. Based on feedback from institutional representatives preparing the Program Description, input from individual Council Members using the Program Description and the AAALAC International Executive Office staff, the Council updated the template to enhance the clarity of the intention of several questions, eliminate perceived areas of redundancy by regrouping questions, and improve the format of the document to help ensure all points in a question are addressed.

M.S., D.V.M.

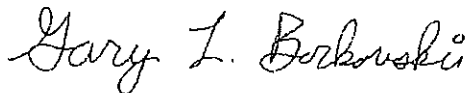
February 15, 2019

Page 2

- Submit the Program Description electronically with no more than four attachments. **Include your Unit file number in the e-mail subject line.**
 - If this is not possible, please submit one hard copy of completed materials. We request that the hard copy be **two-sided**. Do **not** staple, bind, or otherwise assemble your materials.
 - Whatever method you choose, your materials should reach us **by the deadline noted below**. We ask that you advise the AAALAC International office (programdescription@aaalac.org) if you are unable to download the Program Description template from our web site so that the document may be sent to you by an alternate method.
- Other useful information:
 - Site visits are conducted using three primary standards: the *Guide for the Care and Use of Laboratory Animals (Guide)*, NRC 2011; the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (FASS 2010); and the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe (ETS 123) as applicable.
 - AAALAC International strongly recommends that you review Council's findings and your responses from recent site visits as you prepare your Program Description. It is essential for the Attending Veterinarian and Chair of the Institutional Animal Care and Use Committee (IACUC) or comparable oversight body to be present during the site visit. Accredited programs are realizing the value of coordinating the scheduling of the site visit with management, occupational health and safety personnel, as well as physical plant staff.
 - The site visit team will wish to meet with the entire IACUC; frequently this is done during an informal lunch for the Committee members and AAALAC representatives. Thus, including representatives in the actual site visit and exit briefing would be advantageous.

The submission of the completed Program Description should reach us **by August 1, 2019**. If you have questions or need clarification of any points, please do not hesitate to contact me.

Sincerely,



Gary L. Borkowski, D.V.M., M.S., DACLAM
Global Director

GLB:sld
000343

Subject: FW: AAALAC International: Site Visit Notification Letter - #000343
Attachments: 343.PDF

From: AAALAC International <accredit@AAALAC.org>
Sent: Friday, February 15, 2019 1:21 PM
To: Subject: AAALAC International: Site Visit Notification Letter - #000343

Attached, please find a pdf version of AAALAC International correspondence regarding your next site visit. Please let us know if you have any questions.

Regards,

| Senior Program Assistant
.....

AAALAC International
5205 Chairman's Court, Suite 300
Frederick, MD 21703-2879
Tel: 301.696.9626
Fax: 301.696.9627
www.aaalac.org

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September 5, 2019

Director of Animal Medicine
and Associate Professor of Pathology
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655

Dear Dr.

As an important measure of ensuring that high quality animal care and use programs are maintained at units accredited by AAALAC International, formal site visits to accredited organizations are conducted at three year intervals. Information obtained from these site visits, together with annual reports and direct correspondence, constitute the basis for ongoing evaluation and assessment by the Council on Accreditation.

In accordance with this practice, AAALAC International has scheduled a revisit of your animal care and use program for October 8-10, 2019. The site visitors selected to review your program are Drs _____ Council Member; and _____, ad hoc Specialists; and _____ ad hoc Consultant. Brief biographical sketches of the site visitors are included in this letter. Because of your familiarity with local lodging, the site visitors would appreciate your securing conveniently located, moderately priced individual hotel reservations (payable by the AAALAC International site visitors) for the evenings of October 7-9, 2019. Please have confirmation of the reservations sent directly to the site visitors. It would be most helpful if you could arrange to pick them up at the hotel at 7:30 a.m. on the mornings of October 8-10, 2019. Thank you.

The requested description of your animal care and use program has been received and is acknowledged with thanks. This information will greatly assist the visitors in providing a complete, well-documented report of your animal care and use program to the Council on Accreditation. Please note that the site visitors will be conducting a paperless review of your program and will not have a printed copy of the Program Description on site. In the event their electronic version is not accessible to them (i.e., internet service interruptions or computer failure); please ensure a printed version of the Program Description is available for their reference during the site visit. In addition, if there are any documents requiring signature by members of the site visit team or any other AAALAC International representative prior to the site visit, please provide a copy of the document(s) to the AAALAC International office as soon as possible after initial contact with the Council Member. Your cooperation in this regard is appreciated.

The site visit and resultant report provide the Council on Accreditation with factual information and serve as a basis for subsequent Council action. To enhance this objective, it is essential that the Attending Veterinarian and Chair of the Institutional Animal Care and Use Committee (IACUC) or comparable oversight body make arrangements to be present during the site visit. In order to conduct a thorough and complete site visit, it is required that animals be present during the site visit. Itineraries provided by the institution will be considered; however, the site visitors may exercise some discretion in planning the actual visit. Ensuring the availability of internet access for the site visitors is important. Please note that the site visit team will wish to meet with the entire IACUC; frequently this is done during an informal lunch for the Committee members and AAALAC representatives. The site visitors have been instructed by AAALAC International that their principal responsibility is to gather information for peer review by the Council on Accreditation. The Council on Accreditation is the body that will determine your institution's accreditation status.

It would be most helpful if you would have available for their review your Public Health Service Animal Welfare Assurance Statement (if applicable); recent responses to U.S. Department of Agriculture citations; any additional Institutional Animal Care and Use Committee semiannual evaluation reports and meeting minutes prepared subsequent to the submission of your Program Description; and institutional policies and procedures relevant to the animal care and use program, such as the disaster plan, the environmental enrichment plans, exercise plan for dogs, and forms used to administer the occupational health and safety program for personnel involved in the animal care and use program.

tel: 301.696.9626
fax: 301.696.9627

accredi@aaalac.org
www.aaalac.org

M.S., D.V.M.

September 5, 2019

Page 2

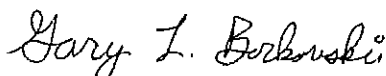
To enhance the time available for conducting the visit, the site visitors may request that you forward some or all of these documents to them in advance of the site visit as part of the Program Description review. In addition, to assist with assessment planning purposes, if the facility review will entail a significant number of changes of personal protective equipment, or showering in/out of multiple areas, please advise the site visitors.

At the conclusion of the site visit, the site visit team will conduct an Exit Briefing with personnel from the institution. The purpose of this briefing is to provide the institution with a preliminary evaluation based on findings and impressions of the site visitors. Comments and views expressed by site visitors should be construed to be independent, preliminary opinions and may not necessarily reflect the final peer reviewed judgment of the AAALAC International Council. Accredited programs are realizing the value of coordination with management and public relations. Thus, including representatives of each in the actual site visit and exit briefing appears advantageous.

The Council on Accreditation will thoroughly review the site visit report at its next regular meeting and subsequently apprise you of its collective actions and recommendations. The Council may elect to add to or delete findings presented at the Exit Briefing from the letter sent to your institution advising of your accreditation status. It is AAALAC International's intent that this peer review process results in Council recommendations that will assist you in maintaining a high quality animal care and use program.

Please feel free to contact the Council member or me regarding the AAALAC International accreditation program or any matter related to the accreditation process. Your interest and participation in this program is valued and appreciated.

Sincerely,



Gary L. Borkowski, D.V.M., M.S.
Global Director

GLB:cjp
000343

Site Visitor Information

D.V.M. is a Private Consultant. Previously, he was Head, Animal Resources, Alcon Research, Ltd.-Fort Worth, Fort Worth, Texas. Dr. [redacted] received his veterinary degree from Oklahoma State University and holds a certificate in Regulatory Affairs Compliance from Hood College. Dr. [redacted] completed a laboratory animal residency at the U.S. Army Medical Research Institute of Infectious Diseases with an emphasis on small and large animal models of infectious diseases and bio-threat agents. Dr. [redacted] is a board certified laboratory animal medicine veterinarian with more than 21 years of experience in biomedical research and development in the government, academia, and industry. Dr. [redacted] currently serves as a Council Member for AAALAC International.

V.M.D., M.S. is a Consultant, Animal Care Solutions, LLC. Previously, she was the Senior Staff Veterinarian, Laboratory Animal Health Services, The Jackson Laboratory, Bar Harbor, Maine. Dr. [redacted] received her veterinary degree from The University of Pennsylvania and masters in laboratory animal medicine from Pennsylvania State University. Dr. [redacted] is board certified in laboratory animal medicine and currently serves as an ad hoc Specialist for AAALAC International.

Ph.D., M.B.A., Principal Advisor, Science, MRIGlobal, Gaithersburg, Maryland. Dr. [redacted] earned his doctorate degree in microbiology and immunology with an emphasis in virology from Rush University, Chicago, Illinois and did his postdoctorate fellowship in virology from the National Research Council USAMRIID, Frederick, Maryland. He has expertise in BSL 1-4 biocontainment laboratories. Dr. [redacted] currently serves as an ad hoc Specialist for AAALAC International.

B.V.Sc., M.Sc., Ph.D. is Director, Center for Comparative Medicine, University of Connecticut Health Center, Farmington, Connecticut. Dr. [redacted] received his veterinary medical degree from Madras Veterinary College, India; his master's degree in health management from Atlantic Veterinary College, University of Prince Edward Island; and his doctorate degree in veterinary biomedical sciences from Louisiana State University. He completed his residency in laboratory animal medicine at SUNY Buffalo, New York. Dr. [redacted] has a wide variety of experience, including non-traditional species such as cave fish, salamanders, and bats. He is board certified in laboratory animal medicine and currently serves as an ad hoc Consultant for AAALAC International.

1. September is not looking good. Many of the key individuals including the IACUC chair will have limited availability in Sept.
2. Sometime in the first two weeks of Oct. would be an optimum time (Sept. 30-Oct 4 or Oct 7-11).
3. I figured the week of AAALAS would not be a good time for any of us (Oct. 14-18)
4. The last two weeks of Oct. and the first two weeks of Nov. are good
5. The last two weeks of Nov. would not be a good time.

Regards,

Director of Animal Medicine
Associate Professor of Pathology
UMass Medical School
Department of Animal Medicine
55 Lake Ave North
Worcester, MA 01655

From: @AAALAC.org>

Sent: Wednesday, May 30, 2018 11:52 AM

To: >

Subject: Site Visit Scheduling

Hi

It is a bit too early to try to set the exact dates of the site visit as the site visit team won't be selected for several months. We can at this time look at postponing your next site visit, which is currently scheduled for the Summer 2019 Trimester, to the Fall 2019 Trimester. AAALAC prefers to maintain a regular 3-year cycle for site visits, but also understands that there are many circumstances that may impact changing the schedule if in the best interest of the accredited program and AAALAC. If you could provide me with a very short justification, or reason, for postponing the site visit until the Fall 2019 Trimester, I'm sure we can make that happen.

With regard to scheduling the exact dates of the site visit, once it is decided which trimester the site visit will be scheduled for sure, you can let me know if you have limited dates for which you can accommodate the site visit. I will then make a note to make sure the assigned Council Member is chosen as early as possible and will ask them to contact you as soon as possible to make the necessary arrangements.

I hope that all makes sense, and if not, please feel free to let me know.

Kindest regards,

D.V.M., DACLAM, DACVPM
Global Director
AAALAC International
5205 Chairman's Court, Suite 300
Frederick, MD 21703
Ph: 301.696.9626 Fax: 301.696.9627

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Subject:

FW: Site Visit Scheduling

From:

Sent: Wednesday, May 22, 2019 1:25 PM

To: Subject: FW: Site Visit Scheduling

Hi – I wanted to let you know I have received your information below regarding preferences for your Fall trimester site visit, and appreciate your forward-thinking on this. Please feel free to keep my email address handy for any future correspondence.

Please plan to include this information or some version of it in your cover letter that accompanies your Aug 1 (or earlier) submission of your Program Description.

Glad our paths have finally crossed, after a bit of a gap from our days together at Pfizer!

Gary L Borkowski, DVM, MS, DACLAM

Global Director

AAALAC International

5205 Chairman's Court, Suite 300

Frederick, MD 21703-2879

Tel: 301.696.9626

Fax: 301-696-9627



Where Science and Responsible Animal Care Connect

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From: "

Date: May 16, 2019 at 11:25:25 AM MDT

To: Subject: RE: Site Visit Scheduling

Hi

We have gotten "official" confirmation that our Site visit (UMASS Medical School, unit # 000343) will be in the Fall of 2019. In working with the colleagues whom need to be available for the site visit, the following scheduling limits and opportunities have come to light:

I was wondering if its too soon to schedule our 2019 AAALAC site visit and how that can be accomplished?
We would also greatly appreciate it if site visit could occur during the Fall trimester.

Regards,

DVM, DACLAM
Director of Animal Medicine
Associate Professor of Pathology
UMass Medical School
Department of Animal Medicine
55 Lake Ave North
Worcester, MA 01655

Subject:

FW: Fall 2019 Site Visit #000343 response to PSVC

From: @aaalac.org> On Behalf Of AAALAC International
Sent: Monday, November 4, 2019 11:31 AM
To:
Cc:
Subject: RE: Fall 2019 Site Visit #000343 response to PSVC

Dear Dr.

Thank you for forwarding the PSVC to the AAALAC International office. This information will be reviewed by the Council on Accreditation.

Kindest regards,

Sr. Program Assistant, Operations
AAALAC International
5205 Chairmans Court, Suite 300
Frederick, MD 21703
tel: 301.696.9626 | fax: 301.696.9627
| www.aaalac.org

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From:
Sent: Thursday, October 31, 2019 1:31 PM
To: AAALAC International <accredit@AAALAC.org>
Cc:
Subject: Fall 2019 Site Visit #000343 response to PSVC

Dear AAALAC Colleagues:

Attached is UMASS Medical School's response to the PSCV.

Regards,

Director of Animal Medicine
Associate Professor of Pathology
UMass Medical School
Department of Animal Medicine

55 Lake Ave North
Worcester, MA 01655

From: AAALAC International
Sent: Thursday, September 5, 2019 4:08 PM
To:
Cc: "
Subject: AAALAC International – Fall 2019 Site Visit #000343

Hello Dr. DeMarco,

Attached is an AAALAC International communication from Dr. Borkowski, Global Director regarding your upcoming Site Visit.

Please contact if you have any questions.

Program Assistant
AAALAC International
5205 Chairman's Court, Suite 300
Frederick, MD 21703
Tel: 301.696.9626
www.aaalac.org

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Department of Animal Medicine
University of Massachusetts Medical School
55 Lake Ave. North
Worcester, MA 01655-00

Gary L Borkowski, DVM, MS, DACLAM
Global Director
AAALAC International
5205 Chairman's Court, Suite 300
Frederick, MD 21703-2879

MS, DVM, DACLAM
Director of Animal Medicine
Associate Professor of Pathology
UMass Medical School
Department of Animal Medicine
55 Lake Ave North
Worcester, MA 01655
31-Oct-2019

UMASS Medical School **Unit 000343** Post Site Visit Communication

Dear Gary:

We extend our thanks to our AAALAC site visitor colleagues for their careful observations and comments regarding the animal care and use program at the University of Massachusetts Medical School. The visit, on October 8-10, 2019, led by Dr. , generated seven suggestions for improvement. We appreciate the site visitors' identification of areas that we can address to improve our animal care and use program. Our response to the suggestions for improvement are as follows.

OB – Policies – Sanitation Frequency

Cage accessories, such as lids and wire bars, were washed at quarterly intervals. The IACUC had not approved the exception to the *Guide* recommended sanitation frequency. To provide satisfactory sanitation and conform with *Guide* recommendations, these cage accessories should be sanitized at least once every two weeks, unless an exception based on site specific data had been approved by the IACUC. Exceptions should be based on performance data or site-specific studies. The IACUC should re-evaluate this program wide exception using appropriate information and performance standards to ensure the health and welfare the animals are not compromised. Also, as with any performance standard, there should be a system in place to monitor the outcome and report back to the IACUC/OB.

UMASS Response: The Department of Animal will conduct a series of studies to validate our sanitation practices for cage accessories. The results will be submitted to the IACUC for approval if a departure from the "Guide" is implemented. A monitoring system and SOP will be generated, and results submitted to the IACUC at a frequency the committee deems appropriate. The following links are to publications that we will use to help design the studies.

<https://www.ncbi.nlm.nih.gov/pubmed/17089990>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5868380/>

<https://www.ncbi.nlm.nih.gov/pubmed/31064613>

OHS – Workplace Risk/Safety Assessment - Allergies

The majority of cages were changed in change hoods, however there were several areas, and , where rodent cages were changed on open carts with only dust masks for protection. This practice may expose these personnel to laboratory animal allergens and/or other hazards. According to the Guide, engineering and administrative controls are the first considerations for the protection of personnel. While PPE should be used as adjunct to engineering controls, personnel working in areas or conducting activities where they might be exposed to airborne particulate material should have suitable respiratory protection. Evaluation of the current bedding change practice should be conducted to ensure appropriate personnel protection.

UMASS Response: This issue was discussed with our Employee Health and Environmental Health and Safety Colleagues. A cage changing station will be placed in room . Due to room size constraints an engineering solution is not possible for . In this facility personnel that will be changing cages will be required to wear an N95 respirator or a PAPR if they fail to pass N95 clearance or fit testing. Cage changes will be scheduled so that investigator staff exposure to airborne particles is minimized.

OHS – Workplace risk/safety assessment – Chemical or Personnel Protection

There was the potential of ocular exposure to hazardous chemical agents for personnel working with chemicals (Quatracide and Clidox) in Rooms () without ocular protection. The lack of appropriate ocular protection may place personnel at increased risk of eye injury should ocular exposure to a hazardous agent occur. Ocular exposure to hazardous agents should be considered as part of the overall job-related risk assessment process. The risk assessment for personnel working in this area should be reviewed to ensure that appropriate protective equipment, procedures and personnel training have been implemented.

UMASS Response: This issue was discussed with Environmental Health and Safety Colleagues. Animal Medicine procedures and PPE requirements will be harmonized with EH&S policies and the following added to animal Medicine SOPs:

Clidox-S (i.e., chlorine dioxide) is irritating to the eyes, skin, and mucous membranes. It is imperative that all personnel using Clidox-S wear the appropriate personal protection equipment.

1. Protective eyewear (e.g., chemical safety goggles or face shield) must be worn when performing procedures that could result in Clidox-S coming in contact with the eyes.
2. When preparing Clidox-S solutions from concentrate, protective eyewear, Chemical resistant Lab coat (FR/CP) and impervious gloves (butyl, neoprene, nitrile rubber) are required. Wash hands after handling.
3. When using Clidox-S 1:5:1 diluted solutions, protective eyewear, and gloves are recommended. Wash hands after handling.

Quadrifidi (i.e., quaternary ammonium compounds) can cause skin irritation and serious eye damage. It is imperative that all personnel using Quatricide wear the appropriate personal protection equipment.

1. Protective eyewear (e.g., chemical safety goggles or face shield) must be worn when performing procedures that could result in Quatricide coming in contact with the eyes.
2. When preparing Quatricide solutions from concentrate, protective eyewear, Chemical resistant Lab coat (FR/CP) and impervious gloves (butyl, neoprene, nitrile rubber) are required. Wash hands thoroughly after handling.
3. When using Quatricide diluted solutions, protective eyewear, and gloves are recommended. Wash hands thoroughly after handling.

PP – Special Facilities – Storage areas

In several areas of the animal facility () there was storage of excess clean equipment (uncovered micro-isolator and racks in cagewash and corridors). The date of sanitation was not evident, and it was unclear how long the equipment had been stored in those areas. Long term storage may create the potential for contamination of equipment. Council acknowledges that the storage of some equipment for a duration may be inevitable but recommends that it be limited, and a management plan be developed to address contamination concerns. The storage practices should be re-evaluated.

UMASS Response: Animal Medicine reviewed its storage practices. Equipment will be labeled with sanitation dates and covered after sanitation. Sanitation dates will be tracked, and equipment will be rotated to minimize storage times. Completion of the A-level cage wash project will facilitate improved storage practices. In general, our clean equipment is placed into service within a week of sanitation. Unfortunately, there is no extant definition that we could find for what constitutes “Long Term” storage of sanitized equipment. Thus, UMASS medical may conduct validation studies to evaluate sanitation of equipment if its being stored for longer than 31 days.

AE – Sanitation - Room

The facilities were generally clean and well maintained; however, the following problem area needs attention. Outside of the vivarium, the Irradiator Room () used for rodent procedures, was not being maintained in a sanitary manner. Overall the room was dusty and equipment in the room, i.e. the

fire extinguisher, was covered with dust and was not being routinely evaluated. Room sanitation and management issues should be addressed and corrected.

UMASS Response: In consultation with Radiation safety a sanitation plan for the A-level irradiator will be implemented. Since Radiation Safety is responsible for the facility, they will administer the sanitation program. Radiation Safety will implement quarterly sanitation of the A-Level irradiator room which will be documented. More frequent sanitation will be implemented if need be.

OHS – Personnel Protection - PPE

Investigative personnel in Medical School Building () ; were not wearing appropriate PPE, as defined by institutional practices for the area. Personnel were wearing reusable laboratory coats, without appropriate shoe covers. The *Guide* (Page 20) says, "Appropriate policies should be established and enforced, and the institution should supply suitable attire and PPE (e.g., gloves, masks, face shields, head covers, coats, coveralls, shoes or shoe covers) for use in the animal facility and laboratories in which animals are used. " Failure to wear appropriate protective clothing increases the likelihood of inadvertent exposure of personnel to hazards in the animal facility. Appropriate protective clothing should be provided and worn.

UMASS Response: The lab staff involved, which lead to this suggestion, were identified, and informed as to what PPE was required. Addition PPE signage will also be placed on procedure rooms within the vivarium. Appropriate PPE is provided for all UMASS animal facilities. After review with Environmental Health and Safety, Employee Health, and the IACUC, it was concluded that a PPE policy needs to be included on the IACUC web site. Although Environmental Health and Safety has a PPE policy, a document consistent with the extant policy and more specific for animal users will be generated, IACUC approved, and placed on the IACUC web site in place. Environmental Health and Safety will be responsible for compliance with the PPE policy and will conduct audits within the vivaria to help enforce compliance.

OHS Personnel Protection – Safety Procedures

Most aspects of experimentation with hazards were satisfactory. In there was a rack with several cage cards (#1128) that had handwritten notes as 'Tamoxifen'. The facility policy is to place a yellow sticker when chemical hazards are used that includes the date of injection to enable proper handling and disposal of the cage by the husbandry staff. Each type of hazard involves special considerations for its safe handling and disposal and hence proper identification is needed at the cage level. Posting and removal of hazard signs should be timely and descriptive of actual hazards to ensure that personnel are informed properly about potential hazards. The IACUC should work with Environmental Health and Safety to evaluate the use of hazard signage to ensure it is consistent with hazards actually present within the room.

UMASS Response: UMASS has well established policies and procedures for the identification and handling of chemical hazards and animals that have been treated with hazardous compounds. The lab involved with this incident was informed of the issue and immediately implemented the proper animal cage labeling. The PI was contacted, lab staff involved re-trained with respect to appropriate cage labeling, and Environmental Health and Safety will follow-up with compliance. A review of the incident with Environmental Health and Safety and the IACUC was conducted and an audit of compliance with

use of chemical hazards in animals will be conducted. The results of the audit will guide refinements to current policies and procedures for the use of chemical hazards in animals.

UMASS Medical School appreciates the thoroughness exhibited by the site visitors. We trust that our responses to the PSVC communicate the continued commitment by UMMS to maintain an exemplary program of research animal care and use and a culture of collaboration and compliance.

Sincerely,

AAALAC Correspondent

Subject: FW: Fall 2019 Site Visit #000343 response to PSVC
Attachments: Unit 000343 AAALAC 2019 PSVC-UMASS Response.pdf

From:
Sent: Thursday, October 31, 2019 1:31 PM
To: AAALAC International <accredit@AAALAC.org>
Cc:
Subject: Fall 2019 Site Visit #000343 response to PSVC

Dear AAALAC Colleagues:

Attached is UMASS Medical School's response to the PSVC.

Regards,

MS, DVM, DACLAM
Director of Animal Medicine
Associate Professor of Pathology
UMass Medical School
Department of Animal Medicine
55 Lake Ave North
Worcester, MA 01655



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Suggestions for Improvement

OB – Policies – Sanitation Frequency

Cage accessories, such as lids and wire bars, were washed at quarterly intervals. The IACUC had not approved the exception to the *Guide* recommended sanitation frequency. To provide satisfactory sanitation and conform with *Guide* recommendations, these cage accessories should be sanitized at least once every two weeks, unless an exception based on site specific data had been approved by the IACUC. Exceptions should be based on performance data or site specific studies. The IACUC should re-evaluate this program wide exception using appropriate information and performance standards to ensure the health and welfare the animals are not compromised. Also, as with any performance standard, there should be a system in place to monitor the outcome and report back to the IACUC/OB.

OHS – Workplace Risk/Safety Assessment - Allergies

The majority of cages were changed in change hoods, however there were several areas, where rodent cages were changed on open carts with only dust masks for protection. This practice may expose these personnel to laboratory animal allergens and/or other hazards. According to the Guide, engineering and administrative controls are the first considerations for the protection of personnel. While PPE should be used as adjunct to engineering controls, personnel working in areas or conducting activities where they might be exposed to airborne particulate material should have suitable respiratory protection. Evaluation of the current bedding change practice should be conducted to ensure appropriate personnel protection.

OHS – Workplace risk/safety assessment – Chemical or Personnel Protection

There was the potential of ocular exposure to hazardous chemical agents for personnel working with chemicals (Quatracide and Clidox) in Rooms () without ocular protection. The lack of appropriate ocular protection may place personnel at increased risk of eye injury should ocular exposure to a hazardous agent occur. Ocular exposure to hazardous agents should be considered as part of the overall job-related risk assessment process. The risk assessment for personnel working in this area should be reviewed to ensure that appropriate protective equipment, procedures and personnel training have been implemented.

PP – Special Facilities – Storage areas

In several areas of the animal facility () there was storage of excess clean equipment (uncovered micro-isolator and racks in cagewash and corridors). The date of sanitation was not evident and it was unclear how long the equipment had been stored in those areas. Long term storage may create the potential for contamination of equipment. Council acknowledges that the storage of some equipment for a duration may be inevitable but recommends that it be limited and a management plan be developed to address contamination concerns. The storage practices should be re-evaluated.

AE – Sanitation - Room

The facilities were generally clean and well maintained; however, the following problem area needs attention. Outside of the vivarium, the Irradiator Room () used for rodent procedures, was not being maintained in a sanitary manner. Overall the room was dusty and equipment in the room, i.e. the fire extinguisher, was covered with dust and was not being routinely evaluated. Room sanitation and management issues should be addressed and corrected.

OHS – Personnel Protection - PPE

Investigative personnel in Medical School Building () ; were not wearing appropriate PPE, as defined by institutional practices for the area. Personnel were wearing reusable laboratory coats, without appropriate shoe covers. The *Guide* (Page 20) says, "Appropriate policies should be established and enforced, and the institution should supply suitable attire and PPE (e.g., gloves, masks, face shields, head covers, coats, coveralls, shoes or shoe covers) for use in the animal facility and laboratories in which animals are used. " Failure to wear appropriate protective clothing increases the likelihood of inadvertent exposure of personnel to hazards in the animal facility. Appropriate protective clothing should be provided and worn.

OHS Personnel Protection – Safety Procedures

Most aspects of experimentation with hazards were satisfactory. In Room there was a rack with several cage cards (#1128) that had handwritten notes as 'Tamoxifen'. The facility policy is to place a yellow sticker when chemical hazards are used that includes the date of injection to enable proper handling and disposal of the cage by the husbandry staff. Each type of hazard involves special considerations for its safe handling and disposal and hence proper identification is needed at the cage level. Posting and removal of hazard signs should be timely and descriptive of actual hazards to ensure that personnel are informed properly about potential hazards. The IACUC should work with Environmental Health and Safety to evaluate the use of hazard signage to ensure it is consistent with hazards actually present within the room.

Subject: FW: Site Visit Scheduling

From: @AAALAC.org>
Sent: Wednesday, May 30, 2018 11:52 AM
To: @umassmed.edu>
Cc:@AAALAC.org>
Subject: Site Visit Scheduling

Hi

It is a bit too early to try to set the exact dates of the site visit as the site visit team won't be selected for several months. We can at this time look at postponing your next site visit, which is currently scheduled for the Summer 2019 Trimester, to the Fall 2019 Trimester. AAALAC prefers to maintain a regular 3-year cycle for site visits, but also understands that there are many circumstances that may impact changing the schedule if in the best interest of the accredited program and AAALAC. If you could provide me with a very short justification, or reason, for postponing the site visit until the Fall 2019 Trimester, I'm sure we can make that happen.

With regard to scheduling the exact dates of the site visit, once it is decided which trimester the site visit will be scheduled for sure, you can let me know if you have limited dates for which you can accommodate the site visit. I will then make a note to make sure the assigned Council Member is chosen as early as possible and will ask them to contact you as soon as possible to make the necessary arrangements.

I hope that all makes sense, and if not, please feel free to let me know.

Kindest regards,

, D.V.M., DACLAM, DACVPM
Global Director
AAALAC International
5205 Chairman's Court, Suite 300
Frederick, MD 21703
Ph: 301.696.9626 Fax: 301.696.9627

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From:
Sent: Thursday, May 24, 2018 2:49 PM
To: >
Subject: AAALAC Site visit-Unit #000343

Hi

Subject:

FW: Unit #343 Program Description

From: AAALAC International Program Description <programdescription@AAALAC.org>

Sent: Tuesday, July 30, 2019 4:38 PM

To: @umassmed.edu>

Subject: Unit #343 Program Description



AAALAC International acknowledges receipt of your updated Program Description.

Your institution's Program Description will undergo an administrative review to ensure all requested information has been submitted. Next, a Council Member will be assigned to lead the review of your institution's animal care and use program. The lead site visitor will contact you shortly thereafter to schedule the visit.

Thank you for your submission. Please feel free to contact us should you have any questions or comments about the AAALAC International accreditation program.

Sincerely,

A handwritten signature in cursive script that reads "Gary L. Borkowski".

Gary L. Borkowski, D.V.M., M.S. DACLAM
Global Director

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From: July 30, 2019 2:58 PM

To: AAALAC International Program Description <programdescription@AAALAC.org>

Subject: UMASS Medical Program Description-000343

Dear Colleagues:

Attached is the 2019 Program Description and cover letter for UMASS Medical School. Appendices 5 and 9 are also included as attachments.

Regards,

Director of Animal Medicine
Associate Professor of Pathology