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Note: Text has been edited for clarity.

What Every IACUC Should Know About AAALAC International

Speakers:

- Jane Na, DVM, NIH Office of Laboratory Animal Welfare, Director of Assurances
- Helen Diggs, DVM, AAALAC International, Senior Director

Broadcast Date: September 9, 2021

View Recording: https://youtu.be/-GvqP_uMesQ

Slide 1: What Every IACUC Should Know About AAALAC International

>> *Dr. Nicolette Petervary:* Hello, today is Thursday, September 9th, 2021. I am Nicolette Petervary, part of the Division of Policy and Education at OLAW, and today it is my pleasure to welcome our speakers, Dr. Jane Na and Dr. Helen Diggs, to the OLAW online seminars to present, "What every Institutional Animal Care and Use Committee (IACUC) should know about AAALAC International."

Dr. Jane Na is the Director of the Division of Assurances in the National Institutes of Health (NIH), Office of Laboratory Animal Welfare (OLAW). She completed her laboratory animal medicine residency as well as her Bachelor of Science in biopsychology and cognitive science at the University of Michigan and obtained her Doctor of Veterinary Medicine degree from Michigan State University. Prior to joining OLAW in 2017, Dr. Na was the lead analyst at the University of California, San Francisco, in the Institutional Animal Care and Use Program office.

Dr. Helen E. Diggs is the Senior Director for AAALAC International. She was previously the Attending Veterinarian, Director of Laboratory Animal Resources Center, and a Professor at the Carson College of Veterinary Medicine at Oregon State University. Prior to that she was Attending Veterinarian and Director of the Office of Laboratory Animal Care at the University of California-Berkeley. Dr. Diggs earned her Veterinary degrees from Oregon State University and Washington State University and received an Honorary Doctorate of Science from Oregon State University. She served on the Board of Directors for the Oregon Veterinary Medical Association, is a past-president of the American College of Laboratory Animal Medicine (ACLAM), served as an AAALAC International ad hoc beginning in 1994, and on AAALAC Council from 2007-2018.

It is my pleasure to welcome you to the OLAW online seminar and now to hand the microphone over to Dr. Na.

Slide 2: Learning Objectives

>> *Dr. Jane Na:* Thank you. Greetings. I'm happy to be here with you and Dr. Diggs for this OLAW webinar. The learning objectives for today's first portion of the webinar are:

- To understand the relationship between OLAW and AAALAC International
- To review important concepts related to AAALAC International and OLAW, and

- To describe the Guide Notice [\[NOT-OD-21-130\]](#) encouraging use of the AAALAC Program Description sections to complete the OLAW Domestic Assurance.

Slide 3-9: OLAW and AAALAC International Comparison Chart

-Note that the slide # changes as a new section in the chart is highlighted-

Slide 3: First, we will compare and contrast some characteristics about both. From the excerpts of the missions from OLAW and AAALAC International, we see that the goals are very similar. Both missions emphasize the humane animal care and use for quality research, testing and education

Slide 4: But OLAW is an entity of the Federal government. It's an office within the National Institutes of Health, which is one of several components of the Public Health Service, the PHS, in the Department of Health and Human Services. While AAALAC International is a private non-profit organization that Dr. Diggs will talk more about in the second portion of this webinar.

Slide 5: The Health Research Extension Act provides the legislative mandate for the PHS Policy on Humane Care and Use of Laboratory Animals ([PHS Policy](#)), which requires the use of the *Guide for the Care and Use of Laboratory Animals* ([Guide](#)) as the basis for your animal care and use program, as well as the American Veterinary Medical Association (AVMA) [Guidelines for the Euthanasia of Animals](#).

Slide 6: Since AAALAC International is a private organization, there are no corresponding laws although, like [OLAW], the *Guide* and AVMA Guidelines for Euthanasia are important documents. The *Guide* is one of AAALAC's three primary standards, which Dr. Diggs will discuss later.

Slide 7: One big difference between OLAW and AAALAC International is that oversight by OLAW is required for institutions receiving funding by any of the Public Health Service entities such as NIH, Food and Drug Administration (FDA), Centers for Disease Control (CDC), Biomedical Advanced Research and Development Authority (BARDA), or for the National Science Foundation (NSF), and National Aeronautics and Space Administration (NASA), which are based on the OLAW memoranda of understanding (MOUs) with those agencies. In contrast, AAALAC International accreditation is completely voluntary, and an institution does not need to be AAALAC accredited to obtain an Assurance and vice versa--an institution does not need to be an Assured organization to obtain AAALAC accreditation.

Slide 8: An important document that is used in OLAW's oversight is the Animal Welfare Assurance, which is essentially a description of an institutional animal care and use program. And it's somewhat similar to the AAALAC document called the Program Description.

Slide 9: One important difference in working with OLAW compared to AAALAC International is that since OLAW is an entity of the Federal Government, documents submitted to OLAW are subject to FOIA, the Federal Freedom of Information Act, while AAALAC International's accreditation process is confidential.

Slide 10: AAALAC in the PHS Policy

So, we will talk now about where AAALAC International appears and intersects with OLAW in the PHS Policy. There are several spots within PHS Policy that mention accreditation. First, each institution must assure that its program and facilities are in one of the categories: Category 1, accredited by AAALAC International or Category 2, non-accredited. All of the institution's programs and facilities [covered by their Assurance] have to be accredited in order to qualify for Category 1. And if any portion of that program is not accredited, that institution becomes Category 2 in the Assurance. Category 2, non-

accredited institutions, are required to submit a semiannual report to OLAW for review with the Assurance document that is submitted to OLAW.

AAALAC is also mentioned regarding record-keeping because an institution must keep records of any accrediting body documents. And the Annual Report to OLAW includes AAALAC International because in the Annual Report the institution submits through the Institutional Official (IO) to OLAW, any change in the institution's program or facilities that would place the institution in a different category than specified in its Assurance [is to be included].

In the 2015 revision of the PHS Policy, it specifically is noted that the only accrediting body recognized by the PHS is AAALAC International. So, they play a big role in the PHS Policy because they appear so many times.

Slide 11-16: Action/Which Document/Category 1 Accredited/Category 2 Non-accredited

Slide 11: Let's go back to comparing and contrasting, but this time let's compare and contrast Category 1, accredited institutions, with Category 2, non-accredited institutions.

As we indicated, both of those categories would indicate the accreditation status within the Assurance document, so it's the same process for both.

Slide 12: And accredited facilities have to be identified in the semiannual report to the IO. Both categories would indicate whether or not they have accredited facilities.

Slide 13: And the spot where they differ is that Category 1 (accredited institutions) do not submit their semiannual report to the IO with their Assurance, while Category 2, (non-accredited) institutions must submit that document for review by OLAW. One thing to note is that for Category 2 institutions (non-accredited), when submitting their semiannual report to the IO, they should submit only the semiannual report and not their checklist. Although the checklist may be used in the semiannual evaluations, this is not something that is required by OLAW. So again, Category 2, (non-accredited) institutions should submit the semiannual report to the [IO to] OLAW, not the checklist, with the Assurance.

Slide 14: Moving on, both Category 1 as well as Category 2 institutions maintain accrediting body determinations and documents within the institution's records.

Slide 15: And both Category 1 and Category 2 report changes in accreditation status in their annual report to OLAW.

Slide 16: So as was emphasized, the difference between Category 1 (accredited) institutions, and Category 2 (non-accredited) institutions, relates to submission of the semiannual report to the IO with the Assurance.

Slide 17: Category 1-Accredited Institution

Category 1 (accredited) institutions are only required to submit their semiannual reports to OLAW just upon request.

Slide 18: Non-Accredited Institution

This is contrasted with Category 2 (non-accredited) institutions that are required to submit the semiannual report to the [IO to] OLAW upon Assurance review, whether it's a new or renewal Assurance. And they are also required to submit the semiannual report upon request.

Slide 19: AAALAC Program Description

Moving on, I'm going to talk about the Guide Notice [NOT-OD-21-164] that was recently released as an initiative of the 21st Century Cures Act. This notice was released in order to provide flexibility to institutions to potentially use portions of the AAALAC International Program Description sections within the Domestic Animal Welfare Assurance to OLAW. The Guide Notice itself is linked, which will be in the slides. Now we'll go on to talk about the sections that can be used.

Slide 20: Post-Approval Monitoring

Regarding Post Approval Monitoring, this is section III.D.9 in the Domestic Assurance and then the corresponding sections that you can use, if you'd like, are the AAALAC Program Description section[s] 2.1. B.2., Part a and Part e.

Please note that any information that is requested within the PHS Assurance for OLAW is still required to be present and it is recommended that information from the Program Description that is not asked for in the Assurance is not provided.

Slide 21 Post-Approval Monitoring

In this case for the Domestic Assurance, these are the prompts or instructions in the Post Approval Monitoring section, and they are pretty much overlapping the portions included in the Program Description. So, this covers the majority requested, and most of the portions in the Program Description can be cut and pasted into the Domestic Assurance.

Slide 22: Occupational Health

The next section, which is actually the largest section with many components that could be used, is the occupational health and safety program, which is the Domestic Assurance Part III.E. The corresponding sections that can be used from the AAALAC Program Description are the sections on the screen.

Essentially [these include:] planning, oversight, and operation of the occupational health and safety program, as well as describing personal medical evaluation as a component of the individual risk assessment, safety considerations, general features of the medical evaluation and preventive medicine programs, and education such as training to inform personnel about allergies, zoonoses, personal hygiene, physical injuries, or special factors considering the species used such as nonhuman primates. Additionally, information about PPE and protective work clothing could be included, personal hygiene practices, and eating, drinking, and smoking policies related to appropriate hygiene.

Although [there are] a lot of different concepts that are included with the Program Description, there are a lot of concepts that are additional that OLAW does not request. It is recommended that you only copy and paste the portions as included in the Guide Notice and on our website so, you do not have additional information that is not necessary, because as you recall, documents submitted to OLAW can be subject to Federal FOIA, the Freedom of Information Act.

Slide 23: Occupational Health, Domestic Assurance Instructions

These are the prompts in the Domestic Assurance, [of] which some do overlap what is included in the Program Description, but there are additional caveats [or details required].

Slide 24: Training

Next is the section on training. That is the Domestic Assurance Part III.G. The relevant Program Description sections are on the screen and they include veterinary care staff training and continuing education, the animal care training and continuing education, as well as the research team required training, continuing education, and the IACUC member orientation training and continuing education.

Slide 25: Training, Domestic Assurance Instructions

The corresponding requested sections in the Domestic Assurance are as follows, which overlap with what has been requested and included in the Program Description. Although describing how the IACUC evaluates the effectiveness of the training program is something that is not necessarily included [in the Program Description]. Again, institutions must ensure that information requested and required in the Domestic Assurance is provided.

Slide 26: All the Details are Online

I know that was a lot of information and all the details can be found online.

In order to find this, from the OLAW homepage, you can click on the turquoise banner for the [21st Century Cures Act](#).

Slide 27: All the Details are Online

And from there, then you would click on the cute rat on [the AAALAC Program Description icon](#) for the sections to use in the Domestic Assurance document.

Slide 28: Contact OLAW

Or, definitely don't be shy. Please reach out to the [Division of Assurances](#) if you need any assistance. From our homepage, in the upper right, there's a search bar and you can click on Contact Us to call or contact or email a specific individual, and we would be happy to assist you with any questions, concerns or hypothetical situations. We are also available by email.

Slide 29: Learning Objectives

Today we learned the relationship between OLAW and AAALAC International, as well as important concepts related to AAALAC International and OLAW in the PHS Policy, and I described the Guide Notice for encouraging use of the AAALAC Program Description sections to complete portions of the OLAW Domestic Assurance.

And now we will proceed to our next speaker, and I will be changing over to Dr. Diggs.

>> *Dr. Helen Diggs*: Thank you, Dr. Na.

>> *Dr. Jane Na*: You're welcome. You have the reins, Helen.

{Slide numbering restarts}

Slide 2: What Every IACUC Should Know About AAALAC International

>> *Dr. Helen Diggs*: Welcome again to What Every IACUC Should Know About AAALAC International.

Slide 3: Today

Today I am going to review with you AAALAC International: general information, accreditation program and the process; Primary Standards and Reference Resources; trends in site visit findings; myths and facts; and the value of accreditation. Let's start with our mission statement.

Slide 4: AAALAC International Mission Statement

AAALAC International is a voluntary accrediting organization that ensures the quality of research, testing, and education by promoting humane and responsible research animal care and use through provision of advice and independent assessments to participating institutions and accreditation of those that meet or exceed applicable standards.

Slide 5: AAALAC International

AAALAC International was chartered in 1965. It is a non-governmental (not a regulatory agency), and it is a non-profit organization.

Slide 6: Accredits animal care and use programs

AAALAC International accredits active animal care and use programs. An animal care and use program includes animals, facilities, equipment, professional, technical, and administrative support, and policies and programs for institutional responsibilities, animal husbandry, and veterinary medical care.

Slide 7: > 1,041 Accredited Programs in 50 Countries/Regions

Since we were chartered, we have enjoyed continued steady growth over the years. Currently, we have more than 100 accredited programs in Europe and Latin America, more than 200 accredited programs in the Pacific Rim and Southeast Asia, and over 700 accredited programs in North America.

Slide 8: Accredited Programs

Accredited programs include Commercial at 46%, Universities at 27%, Government at 13%, Nonprofit at 10%, and 4% Hospitals.

Slide 9: Oversight Organization Comparison

For comparison, as Dr. Na provided for you, I am going to speak only to AAALAC International, but you can read across.

- Responsible Agency: You can see we have the USDA included here now as well.
- Private, non-profit, that's AAALAC.
- Applicability: voluntary.
- Species covered: warm blooded [for the USDA], live vertebrates [for the PHS], and most [for AAALAC International]. Most [species] for AAALAC because [only some invertebrates] are fully covered and other [invertebrates] are considered only from an Occupational Health and Safety Perspective.
- Standards: The *Guides* and ETS 123 which we call our Primary Standards. I will speak to these later in this program.
- Enforcement: Confidential Peer Reviews.
- Sanctions: Revocation of Accreditation.
- And the Link to Funding: Indirect.

Slide 10: Myth vs. Fact

Myth versus Fact. Myth: AAALAC International is part of the IACUC.

Fact: The acronyms associated with animal research can be confusing, but it is important to know that AAALAC is not linked to the IACUC, (the Institutional Animal Care and Use Committee). The IACUC is charged with local oversight of the institution's animal care and use program. As part of the site visit, AAALAC evaluates the performance of the IACUC to ensure that it is functioning well. AAALAC accreditation serves as an external third-party review.

Slide 11: Program Status Evaluation (PSE)

AAALAC has a [Program Status Evaluation](#) or better called Pre-Accreditation Evaluation. You can find this link on our website at www.aaalac.org.

The PSE or Pre-Accreditation Evaluation, is a completely confidential peer review that helps assess the quality of all aspects of your animal program, including animal husbandry, veterinary medical care, institutional policies, and the facilities where animals are housed and used. The objective of the PSE service is two-fold. First, it is meant to assist institutions in determining if their animal care and use program meets AAALAC standards by identifying weaknesses and suggesting ways to improve or correct them. Second, it familiarizes institutions with the AAALAC accreditation process and encourages them to participate. The complete details and how to apply for the program are found under the “Pre-Accreditation Evaluations,” menu on our website.

Slide 12: Myth vs. Fact

Myth versus Fact. Myth: In the United States, AAALAC International evaluates animal care and use programs that only use animals regulated under the Animal Welfare Act.

Fact: AAALAC International accreditation covers all animals used or to be used in research, teaching, or testing at accredited programs. In our Rules of Accreditation, the definition for animals is: This includes traditional laboratory animals, farm animals, wildlife, and aquatic animals. Non-traditional animals, inclusive of invertebrate species, are included where they are relevant to the program's mission.

Slide 13: Accreditation Program

The accreditation program is completely confidential, performance based, and a peer-review process.

Slide 14: The Process

So, the Process: First go to our AAALAC website and go to [Apply for Accreditation](#). This is where you will complete the Application Packet. Then you will be directed to complete a Program Description. The details of this are also on the website under Program Description. The Program Description is a detailed self-evaluation of your program. Then you will prepare for an Evaluation. The Evaluation, or Site Visit, is typically completely performed on-site, but with COVID we have been doing what we call hybrid visits. Certain review components, such as document review and IACUC meetings, are done using secured document platforms and video conferencing. The facility review, however, must be done on-site. Most site visits during the pandemic have been in the hybrid format. See the red banner on our website homepage for hybrid site visit details. After the site visit, the Council on Accreditation reviews findings and determines site visit outcomes. Institutions are then notified of their accreditation status.

Slide 15: Three Primary Standards

AAALAC relies on principles in Three Primary Standards for evaluating laboratory animal care and use programs. The *Guide for the Care and Use of Laboratory Animals*, the *Guide for the Care and Use of Agricultural Animals in Research and Teaching [Ag Guide]*, and the European Convention, ETS 123. An AAALAC Council committee is currently reviewing the new fourth edition of the Ag Guide for its use as a Primary Standard.

Slide 16: Myth vs. Fact

Myth versus Fact. Myth: AAALAC International establishes policies and regulations.

Fact: AAALAC International evaluates animal care and use programs based on recommendations in the Three Primary Standards, applicable legislation, and other references.

Slide 17: Reference Resources

AAALAC also uses other specialty publications for supplemental information about procedures or techniques related to the care and use of animals. These specialty publications are designated as "Reference Resources" and they can be found on our website, again at www.aaalac.org. The references included on this list have been formally reviewed and adopted by AAALAC International's Council on Accreditation as guidance for accredited programs and site visit teams. Although some are federal regulations, others are from the peer reviewed scientific literature. As such, the research community helps establish the standards. The standards are science-based, science-driven, and the collective professional judgment of experts.

Slide 18: Resources

In summary, resources include: AAALAC's Reference Resources, the FAQs and Position Statements I add in here, because they are also part of the Reference Resource list and found on our website. [These are] all found on our website. And your institution's Program Description, which is your own self-assessment. And these are in addition to our Three Primary Standards as stated before.

Slide 19: Myth vs. Fact

Myth versus Fact. Myth: AAALAC International uses the same standards to evaluate animal programs outside the United States.

Fact: Because each country has its own set of laws and regulations, AAALAC International site visitors use a customized approach to evaluating programs. Site visitors must be aware of applicable and pertinent local regulations when they are doing site visits.

Slide 20: Peer Review Process

A bit about the Peer Review Process. First is the Program Description. This document is used by the site visitors when they are reviewing your program and your facilities. And it is the institution's own detailed self-assessment. It follows the template that is available to accredited programs on our website.

The site visit includes Council members and the site visit team and the organization's own experts. The Council on Accreditation: multiple Council members view site visit reports. The full Council reviews reports at triannual meetings.

The Committee for Consistency, which is our own internal Quality Assurance, reviews items that may be inconsistent with AAALAC guidance or standards. And we have a robust Continuing Education program for all Council and site visit team members.

Slide 21: ILAR Guide's Key Terms

The *Guide* uses two key terms, "must" and "should." "Must" indicates actions that are imperative for humane animal care and use. "Should" indicates a strong recommendation. Failure to comply with a "must" statement is reviewed by the site visit team as a Mandatory finding. Mandatory findings are deficiencies that must be corrected for full accreditation to be awarded or continued. Failure to comply with a "should" statement is reviewed by the site team as an SFI [Suggestion for Improvement]. SFIs are considered as an upgrade or enhancement to an acceptable or even commendable program.

Slide 22: Periodic Findings Review

Site visit reports typically result in a list of findings, either Mandatory findings or SFIs. This graph represents the most recent five-year analysis of findings, all under the 2011 *Guide*, and they are grouped together in seven component areas. Animal Environment; Occupational Health and Safety;

Oversight Body or IACUC; Veterinary Medical Care; Administrative Components which includes things like the Annual Report, Disaster Plan, and Program Description as well as others; HVAC and Physical Plant, (HVAC being heating, ventilation, and air conditioning); and the Institutional Administration, which includes such things as authority, responsibility, commitment, and organizational structure. As you see here, the two greatest challenge areas for programs are, and continue to be throughout the years, Animal Environment and Occupational Health and Safety.

Slide 23: Program Elements with the Most Suggestions for Improvement (SFI)

Program elements with the most Suggestions for Improvement or SFIs are: Workplace Safety/ Risk Assessment, Husbandry and Sanitation, Behavioral/Social Management, and Protocol Review Considerations. I'm going to give you some examples of each of these [four categories].

Workplace Safety/Risk Assessment would be: Failure to provide protective clothing and equipment to personnel working in the animal facility or an animal area. That can be found in the *Guide* pages 20 to 21. For Husbandry/Sanitation: Lack of a method for assessing and monitoring the effectiveness of primary animal enclosure sanitation. That can be found in the *Guide* page 73. Behavioral/Social Management: Inconsistent use of Environmental Enrichment. This is in our AAALAC FAQ "Environmental Enrichment," also in the *Guide* pages 52-54 and AAALAC's Position Statement on Social Housing and also in the *Guide* pages 82-83. And lastly, Protocol Review Considerations: Failure to justify animal numbers on animal use protocols. That is in the *Guide* page 25.

Slide 24: Program Elements with the Most Mandatory Findings

Program elements with the most Mandatory findings are Workplace Safety/Risk Assessment, Behavioral/Social Management, HVAC, and Euthanasia. Examples for these are Workplace Safety/Risk Assessment: Lack of a written respiratory protection program for personnel required to wear respirators. This [reference] is AAALAC's FAQ "Respirator Use." Behavioral/Social Management: The default animal housing method for the program was single housing for social species instead of social housing for social species. Note this is not a *must* in the *Guide*, but it is a Mandatory per AAALAC standards and the reference is AAALAC's FAQ "Social Housing and Social Experience" and AAALAC's Position Statement on Social Housing. For HVAC: Failure to submit an updated and/or accurate Appendix 11 HVAC system performance summary with the Program Description. And under Euthanasia: Failure to comply with the AVMA Guidelines for the Euthanasia of Animals, 2020 edition, regarding the use carbon dioxide for euthanasia of rodents.

Slide 25: Myth vs. Fact

Myth versus Fact. Myth: AAALAC imposes biomedical standards on our agricultural animal research programs. Fact: AAALAC does not hold agricultural facilities to the same criteria used to evaluate biomedical research facilities and laboratories. AAALAC expects that agricultural animal research programs meet the standards for housing and care that prevail on a high quality, well-managed farm. One of AAALAC's Primary Standards, remember, is the Ag Guide.

Slide 26: Perceptions vs. Reality

Perceptions versus reality.

Perceptions

- AAALAC *over-interprets* standards.
- AAALAC *imposes new standards*.
- Suggestions for Improvement must be followed.

Reality: AAALAC looks to science, published data, scientific principles, expert opinions, experience with proven methods and practices. State-of-the-art practices evolve, constantly evolve. Mandatory items are

based on existing standards. Suggestions for improvement are just that. And, perceived inconsistencies are continuously reviewed by AAALAC Council.

Slide 27: The Importance of Periodic Assessment

The importance of periodic assessment. After the site visit, there is a Post-Site Visit Communication between the Council member and the program contact. As a result of this correspondence, 86% of findings are resolved. After Council deliberations, the final letter, which we call the C&R letter for commendations and recommendations, goes back to the program.

Retained findings in the letters are only 11% of the [total] SFIs and 3% of the total Mandatory findings. Also remember that only Mandatory findings require an institutional response.

Slide 28: The Value of Accreditation

The value of accreditation:

- Improves opportunities for the inter- and intra-institutional collaborations that may result in sponsored research funding and enhanced networking.
- Leverages institutional support for facility upgrades and continuing improvements.
- *Adds credibility to the institution's program among Federal agencies such as NIH, National Science Foundation, the Department of Defense, and sponsors such as the National Institute of Food and Agriculture or Agricultural Research Services.*
- Stimulates continuous program self-assessment, benchmarking, and improvement.
- Assures the public of the institution's commitment to achieving the highest quality animal care and science.

AAALAC's periodic external assessment assures the institution, funding agencies, and the public that they are remaining diligent, staying current with regulatory requirements, ever-changing/ ever-evolving industry standards, and maintaining a high level of excellence.

Slide 29: Thank you

Thank you for participating in this webinar, and I will now turn this back to Dr. Na.

>> *Dr. Nicolette Petervary*: Thank you, everyone.

So, we thank you, Dr. Diggs, and I'd like to remind attendees that if they have questions, we will only be accepting questions through the question-and-answer feature located at the bottom middle of your screens. So please click on the question-and-answer icon located at the bottom middle of your screens to type your questions.

There's a check box in the Q&A feature that provides the option to submit questions anonymously. And now we have a few questions that we received in advance of the webinar. Let's proceed to question one.

Question 1: Does AAALAC International have any reporting requirements for accredited programs? Dr. Diggs?

>> *Dr. Helen Diggs*: Thank you, Nicolette. AAALAC's reporting expectations are on our website. Among our FAQs, near the bottom of the list, go to Maintaining Accreditation and then Reporting Requirements, and there you will find the list of adverse events to be reported promptly to AAALAC.

>> *Dr. Nicolette Petervary*: Thank you, Dr. Diggs.

Let's go on to question two.

Question 2: Aside from the hybrid site visits, has anything else at AAALAC changed as a result of the COVID-19 pandemic? Dr. Diggs?

>> *Dr. Helen Diggs*: For our accredited programs, from their viewpoint, the most notable change is the hybrid site visit model. I'd like to say though, that we are fortunate to have been able to continue performing site visits throughout the pandemic. That's thanks to an amazing office staff at AAALAC and wonderful site visitors, both Council and our ad hoc visitors. And I also want to say that our accredited institutions continue to maintain a very high quality of animal care and use programs.

>> *Dr. Nicolette Petervary*: Thank you, Dr. Diggs. We do have a few questions from listeners.

Question 3: The first one is how does the Animal Welfare and regulations, I'm assuming the Animal Welfare Act and its regulations, factor into AAALAC's resources, primary, and otherwise?

>> *Dr. Helen Diggs*: I will say that our AAALAC site visit teams are certainly very aware of the Animal Welfare Act Regulations and also OLAW requirements, as they are both Federal Agency requirements. And we do pay attention to those as we're doing our site visits, and we'll make notes to the program if there's an issue with compliance for either one of these agencies' [regulations]. If the person asking the question has a more specific question, they can contact me directly.

>> *Dr. Nicolette Petervary*: Thank you, Dr. Diggs.

Question 4: Another question, please share information regarding duties of the attending veterinarian. I'm assuming from an AAALAC perspective.

>> *Dr. Helen Diggs*: The duties of an Attending Veterinarian [and] the overall roles and responsibilities are actually posted on our website as a Position Statement. So if you go to our website, www.aaalac.org, go on to Position Statements, you will find a link to the answer to that question in greater detail than I can provide here.

>> *Dr. Nicolette Petervary*: Thank you, Dr. Diggs.

Question 5: Another question: Can AAALAC International cite a Mandatory finding if it only affects human health and not animal health?

>> *Dr. Helen Diggs*: That will depend. And it depends on where the health issue is. If it's part of the...or somehow related to the animal program, part of the animal program's facilities or program that allows such a health risk to occur, and it is an egregious risk to the health of personnel or staff or even visitors, it could possibly become a Mandatory finding. Animal health as well as human health are something that we pay attention to when we're doing our site visits.

>> *Dr. Nicolette Petervary*: Thank you, Dr. Diggs.

Question 6: Another question: Are there currently any delays in the timeline for initial accreditation posted on the website due to the pandemic? For example, the December 1st deadline for submission, and the site visits between January and March?

>> *Dr. Helen Diggs*: Not that I am aware of, but I know that postponements due to COVID are being negotiated by the Office. And so, if you go to that red banner on our homepage and click on that, there is

information in there about postponements and who to contact if you have an issue with the scheduling of your site visit.

>> *Dr. Nicolette Petervary*: Thank you, Dr. Diggs.

Question 7: Yet another question: Are AAALAC site visitors required to be vaccinated against COVID-19?

>> *Dr. Helen Diggs*: I don't know that I can say that there is a requirement for that. I know that many veterinarians have gotten vaccines from their states [or local regions], but I would simply say no to requirements.

>> *Dr. Nicolette Petervary*: Thank you, Dr. Diggs.

Question 8: Another question: Does a satellite facility that is not accredited make the entire institution Category 2, non-accredited?

>> *Dr. Jane Na*: Great question. Yes, if the satellite facility is part of the animal care and use program that is covered under the institution's [Animal] Welfare Assurance, if it is Category 2, that does make the entire Institution Category 2, non-accredited.

>> *Dr. Nicolette Petervary*: Dr. Diggs, do you have anything to add for that question?

>> *Dr. Helen Diggs*: I think that Dr. Na probably has the more direct answer. If there's a satellite facility and it is part of the program and there are issues in that facility when we visit it, that will be something we might have to cite or mention to the program.

>> *Dr. Nicolette Petervary*: Thank you, Dr. Diggs. We have another question about one of Dr. Diggs' slides.

Question 9: What is the time frame for the charts Dr. Diggs shared? Were the findings within a particular calendar year?

>> *Dr. Helen Diggs*: Findings are specific to the site visit, which occurs every three years.

>> *Dr. Nicolette Petervary*: Right. If the person asking this question wants to clarify, I think they mean the data that was shown on the slide.

>> *Dr. Helen Diggs*: The data was over a five-year window.

>> *Dr. Nicolette Petervary*: Thank you.

Question 10: We have another question. Could an institution that is not USDA registered still apply for AAALAC accreditation? Should USDA registration be obtained before applying for AAALAC accreditation?

>> *Dr. Helen Diggs*: There is no requirement for that [USDA registration]. And it depends really on what species of animal that institution is maintaining. If you are a small biotech and all you have is mice, you may not have a reason to be registered with the USDA [but you could be AAALAC accredited].

>> *Dr. Nicolette Petervary*: Thank you.

Question 11: We have another question. What is the expected timeline for prompt reporting of reportable incidents to AAALAC International?

>> *Dr. Helen Diggs:* Prompt depends a bit on the severity of the issue. And we would like you to make sure that you let us know if something significant is happening that we should be aware of. If you are reporting it to OLAW or the USDA, that would be significant, and we should hear about that [as well]. And there may be other situations in your facility that you think are worthy of reporting. If you have a question you can always call the Office and ask us what we think and whether it should be reported or not.

>> *Dr. Nicolette Petervary:* Thank you, Dr. Diggs.

Question 12: We have another question. How soon does AAALAC anticipate making a determination on the acceptance of the 4th edition of the Ag Guide as a primary reference? And once adopted, approximately how long might it be before those revised standards are used for evaluating programs?

>> *Dr. Helen Diggs:* I can't give you a timeline at this moment. Our Council will be meeting the third week of September and we will have an answer to that, but we have to wait until the full Council can review and answer that. Once it is approved, I think I recall that typically, for a Primary Standard, we give our programs at least a year to implement those. So I hope I'm not misstating that, but I think there will be a nice timeline, a time window, for people to review that document and incorporate whatever pieces of it they need into their programs.

>> *Dr. Nicolette Petervary:* Thank you, Dr. Diggs.

Question 13: Another question: Does AAALAC International have a place to review the roles and responsibilities of the IACUC chair? Does an accredited program have to have a chair?

>> *Dr. Helen Diggs:* So the IACUC chair should report most often directly to the IO, and oversight of the IACUC Chair's performance then would be the responsibility of the Institutional Official. And what was the second part?

>> *Dr. Nicolette Petervary:* I think that was: is an IACUC chair even required?

>> *Dr. Helen Diggs:* For the committee? I think if you read the *Guide* someone should be a designated chair [leader] for the committee. [The *Guide*, p. 13, requests "effective leadership" for the IACUC and OLAW *requires* the name of the IACUC Chair on the PHS Assurance. AAALAC requests the name of the IACUC Chair on the Annual Report.]

>> *Dr. Nicolette Petervary:* Thank you, Dr. Diggs.

Question 14: We have another question. How are field sites differentiated from satellite facilities?

>> *Dr. Jane Na:* Yes, I can start answering that for OLAW. Field sites are not part of the institution's construction, buildings, facilities, per se, and are usually meant to indicate either in the animal's natural environment or off-site and not in [an] actual specific facility or building. The oversight for field sites is still under the purview of the IACUC, and they would be required to provide oversight such as potentially getting reports back from investigators, either pictures or written summaries, because it's not required to visit or site visit the field sites although there are some locations I'm sure you would want to visit. The definition, specifically, of satellite facility does not really factor in field sites. I'm going based off it's not part of the actual facility or buildings of an animal care and use program. So hopefully that is a sufficient

answer and if not, you can certainly follow up with OLAW and/or myself if there's more to that question or if I didn't answer sufficiently. I don't know if Helen has additional information.

>> *Dr. Helen Diggs*: I'll just say that for us it will depend a little bit on how the field site is used and are there structures there, is there a staff there during the day? Is this a field site with tents where you're out on the ground observing birds or catching wild rodents and you're only there for a day or two or a week or two and then gone. That's not a facility, per se, it's not something that we might be able to even visit. If we can visit it, we might try. We would be willing to do that. If a satellite facility, we think of more as a structured facility I think, as Dr. Na mentioned, but there's going to be a little variation there and I don't want anyone to take this to the bank and say, ah-ha, we don't count because, in the eyes of AAALAC, if you have animals there and you're using them, we're going to want to know a little bit about that [activity] if it's part of your accredited program.

>> *Dr. Nicolette Petervary*: Thank you, Dr. Diggs. I'm going to skip over to this one question because I think this is something that is very pertinent, especially now.

Question 15: Please describe the hybrid site visit. How long will this continue? Can you describe the process in a little bit more detail?

>> *Dr. Helen Diggs*: I can do that here, but I know we're running out of time. What I will do is direct you to our website and there is actually a video, it's also in PowerPoint, that walks you through the hybrid site visit and how it is conducted and performed. And I think it would be a better service for you, the questioner, to do that and actually get your answers through that video and it is on our website. It is Site Visits during COVID-19, or some name like that. And how long will hybrid site visits continue? I would love to say that they will stop as soon as this pandemic ends and I would like that to be sooner than later. However, I think there are aspects of the hybrid site visits which many of our programs are enjoying. And actually [hybrid site visits] are helping with some of the review process and the timing process and certainly the participation of people in the process because they can log on to Zoom and be part of the meeting or the overview right from their offices. So there are some aspects of the hybrid visit that I think AAALAC senior executive staff will be looking at as things that we might want to continue into the future. Even after, praise be, this pandemic has ended.

>> *Dr. Nicolette Petervary*: Thank you. Dr. Diggs, we have one more question for AAALAC International.

Question 16: Is there a minimum census a facility due for a site visit should have for the site visitors to come for the inspection? For example, will they come for the site visit if the facility is housing less than 250 rodents?

>> *Dr. Helen Diggs*: You just have to be housing one rodent, one animal, for us, but if you have no animals, we cannot do your facility visit. We cannot inspect facilities and do a site visit for you if you do not have animals on site. So remember that. I site visited a facility once and they had three pigs and so we went ahead with the visit, but we had to have the pigs there [at least one]. Hopefully that answers your question.

>> *Dr. Nicolette Petervary*: Thank you, Dr. Diggs. We are coming fairly close to the end of the webinar so if there are any other questions you may type them into the chat box now and any questions we have not gotten to during this session we will address and append to the end of the transcript. So, this is one more opportunity to get in a few quick questions because we only have a minute or two left. So please do that. And once again, to type in your questions,

please do click on the question-and-answer icon located at the bottom and middle of your screen to type your questions. And there's a check box in the Q&A feature that provides the options to submit questions anonymously.

Thank you. We've run out of time, and I would like to thank Dr. Na and Dr. Diggs for sharing this important information. This concludes the webinar. Once again, you will be able to have your questions answered in a transcript that is to follow. Please look on our website for that in the future. And this concludes the webinar.

Please join us for the next OLAW online seminar in December with a topic to be determined. Thank you again for attending and thank you to Dr. Na and Dr. Diggs for sharing their expertise. And good-bye.

Questions received in the Q&A that were NOT answered during the LIVE session, per above.

Question A: Are there instances in which adverse events are reportable to AAALAC and not OLAW (or vice versa)?

AAALAC response: Yes, there could be. Example: Human safety and/or egress issues for the institution's cage/rack washer might be an AAALAC concern and not necessarily an OLAW concern.

OLAW response: Information on what is and is not reportable to OLAW is found on the Noncompliance Reporting website at <https://olaw.nih.gov/guidance/reporting-noncompliance.htm>, and the OLAW Division of Compliance Oversight is always happy to field your questions and assist you in determining what is and is not reportable to OLAW.

Question B: Can facilities request site visitors be vaccinated against COVID-19 and get confirmation of vaccine status? Or request a negative COVID test within a specific time frame? This is required by our institution.

AAALAC response: Yes, AAALAC will comply, as possible, with an institution's access requirements.

Question C: I believe USDA requires a single USDA registration for an entity unless a portion of the entity (e.g., a facility that is clear across the country that has its own administration) is clearly a separate administrative unit. The separate administrative unit can get its own USDA registration. Does AAALAC operate similarly with respect to accreditation?

AAALAC response: Yes, separate administrative programs can be accredited separately. Contact the AAALAC Office with questions or for guidance.

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