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Facility Inspections

Speakers: Dawn O'Connor, University of Michigan, CPIA, and Bill Greer, University of Michigan, CPIA.

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View Recording: <https://youtu.be/y2JOR0VF4KY> (YouTube)

Slide 1 (Facility Inspections)

>> *Susan:* Hello. Today is Thursday June 28, 2018. I'm Susan Silk, the Director of the Division of Policy and Education at OLAW, and today it is my pleasure to welcome our speakers, Dawn O'Connor and Bill Greer, to the OLAW Online Seminars to present **Facility Inspections**.

Slide 2 (Animal Care and Use Program Facility Inspections)

Dawn serves as the Assistant Director for the Animal Care and Use Office [ACUO] at the University of Michigan. She began her career in 1988 at the University of Michigan. She has 20 years of regulatory experience with a Certification as a Professional IACUC Administrator (CPIA) and 10 years of experience as a veterinary technician working with multiple species. She also has served for 7 years as an AAALAC ad-hoc specialist. Dawn has extensive expertise in regulatory compliance with an emphasis on interpretation and implementation of the policies, procedures, and standards at the University of Michigan. She provides leadership and management to a compliance staff and oversees IACUC functions.

Our other speaker, Bill Greer, serves as assistant vice president for research compliance oversight at University of Michigan where he provides leadership to and oversees the University's Animal Care and Use, Institutional Biosafety, Controlled Substance, Laboratory Safety, and Autonomous Systems Compliance programs.

In partnership with the attending veterinarian and the IACUC, Bill leads the Animal Care and Use Office in fostering an environment of engagement, support, and service to the research community. Bill works with the animal care and use committee to ensure all animal research is reviewed, approved, and conducted in accordance with all appropriate

international, federal and state regulations and guidelines, as well as with specific guidelines from funding agencies, institutional policies, and appropriate accreditation standards. Bill joined the University of Michigan in May of 2016 after serving for 15 years as associate director in the Office of Research Protection at Pennsylvania State University. He also serves as the executive director and president of the IACUC Administrators Association (IAA) and is the co-director of the IAA Best Practice Meetings.

It's my pleasure to welcome you both to the OLAW Online Seminar and now to hand the microphone over to Dawn.

Slide 3 (Where to Start? What Should We Follow?)

>>*Dawn*: Thank you, Susan. Hello. When you are starting inspections, some of the questions you might ask yourself are: Where do I start? What do I follow? This slide represents a collection of guidance documents and, depending on the species and or funding you receive, will determine which guidance documents you will follow.

Slide 4 (Throughout the Webinar)

>>*Bill*: Thank you very much, Susan. Throughout the webinar, Dawn and I will be discussing inspections and how they are conducted. Dawn will look at inspections at the University of Michigan and my goal is to briefly review the regulatory requirements and discuss some alternative methods that may have been used by other institutions to conduct inspections.

We have color coded the slides. Dawn's will have a white background and they'll be reflecting the practices at the University of Michigan. And my slides have a gray background and summarize the regulatory requirements and offer other ideas for conducting inspections.

Slide 5 (Important Note)

Before we begin, it's very important to point out the [footnote on page 12](#) of the PHS Policy. It gives the IACUC the discretion to determine the best means of conducting an evaluation of the institution's program and facilities. This particular footnote is important and we'll be focusing on it throughout the webinar. What it does is allow us to think about different methods and processes to conduct facility inspections in ways that best fit the needs of our own specific institutions and the research portfolios that we support.

Slide 6 (U-M Large Biomedical Program)

>>*Dawn*: The University of Michigan's animal program is a large predominantly biomedical research program. We designed our inspection process to accommodate a large biomedical research facility with multiple locations in multiple buildings with various research needs. We are primarily a biomedical research facility with some wildlife studies. With 600 PIs and approximately 975 animal use protocols approved, we have 406,000 square feet of approved animal spaces.

Slide 7 (Areas Inspected at U-M)

The University of Michigan spans over 3 campuses with 2 biological stations. Biological stations only being visited during the summer months when active. We include all animal housing facilities and the support areas within the vivarium. We visit all 3 where live animal procedures are conducted. This includes many laboratories, procedural areas that are shared, and all dedicated rooms used for USDA covered species. Committee members review the practices within the cage wash areas, making sure to include any safety concerns with staff and or equipment.

A review of where animals are received and how the U of M transports animals within the campus requires inspections of trucks to ensure heating and air conditioning is working properly.

There are other areas not used for housing that support the research that also must be inspected. For example, this could be a necropsy room, areas where radiological procedures are conducted, as well as the storage of all drugs and supplies.

Slide 8 (What Does the IACUC Need to Inspect?)

>>*Bill*: In general, let's talk about what the IACUC needs to inspect. We've got 3 standards that identify the primary regulatory requirements for most animal care and use programs. They include the [PHS Policy](#), the [Guide](#), and the [Animal Welfare Act and Regulations](#). Those institutions that have [agricultural] facilities, may also use the [Ag Guide](#).

It is important for us to look at the definitions that these standards provide. As you can see each guidance document uses the term "facilities". [Facilities are defined in the PHS Policy](#) as any and all buildings, rooms, areas, enclosures, or vehicles, including satellites that are used for animal confinement. In addition, any areas used for animal breeding or experimental activities are also considered facilities. Experimental activities include, for example, surgical manipulation, euthanasia, and behavior studies.

When we look at the Animal Welfare Act, it defines the animal study area, but for practical purposes it is covered when applying the PHS definition of a facility. A key point under the Animal Welfare Act Regulation is that the standards included within the definition are applicable only for animals that are maintained for periods greater than 12 hours.

It is important to recognize that the IACUC is looking at areas where animals are housed or procedures are conducted and even though there is a slight difference between the PHS Policy and the Animal Welfare Act definition, we have to recognize that both requirements are focusing on animal confinement and their use.

Slide 9 (What is a Satellite Facility? A Study Area?)

Let us further talk about satellite areas and compare them to study areas. As mentioned, we have 2 primary references. In the [PHS Policy](#), any containment area outside of a core

or centrally managed facility is typically defined as a satellite. The PHS Policy also gives us additional guidance here by stating "areas in which animals are housed for more than **24** hours." The Animal Welfare Act has an almost identical definition, again, except it requires an IACUC inspection only when animals are housed or used in that location for periods exceeding **12** hours. Therefore, examples of satellite areas maybe include remote areas such as laboratories, branch campuses, or other housing locations that are located outside of the central campus.

So, locations, we also want to consider are areas where an institution subcontracts animal activities as part of a memorandum of understanding or some other management document. For example, covered components, i.e., locations, may include facilities that have been leased by the institution, and/or facilities that are providing services such as the production of custom antibodies.

Slide 10 (What Facilities Must IACUC Oversee and Inspect?)

So, what facilities must IACUCs oversee and inspect? We've mentioned the obvious which are the animal housing facilities. This would include any area where vertebrate animals, including all aquatic species, are housed. In addition to that, the IACUC must also inspect areas that support the animal care and use program. And examples would include areas such as central pharmacies, food preparation and storage areas, maybe diagnostic laboratories, and receiving docks where animals may be shipped in or shipped out of the institution.

We should also consider transport vehicles since animals could be in the vehicles going between buildings. The IACUC should also consider during the inspection, the cage wash area, and looking at both the dirty and clean side.

Institutions, through the IACUC, must oversee the surgery suite including the animal prep and recovery areas. It is also important for the committee to regularly look at imaging, X-ray areas, hazard containment facilities, areas where radiation is used in conjunction with animals and maybe behavioral testing areas.

Please note the reference at the bottom of the slide which identifies the [OLAW checklist](#) that many institutions use and additional information can be gathered using this reference.

Slide 11 (IACUC Facility Inspections (U-M))

>>*Dawn*: Due the size of our institution, coordination of many staff members, and for our committee to be engaged with the research community, we announce our inspections. We highly encourage that laboratory staff be available for the laboratory areas in order to make a meaningful visit for all that are involved. During a 5-week period, we schedule 2 inspections groups to inspect daily in order to complete 1400 locations in 30 buildings each semiannual period.

Slide 12 (Timing of Facility Inspections)

>>*Bill*: So, Dawn mentioned about whether or not the inspection should be announced or not. I will tell you through interactions with many institutions during [[IACUC Administrators Association](#)] [Best Practice Meetings](#) that it is a common practice to announce the inspections. Most institutions find it beneficial since they are able to ensure that someone is actually there and available to help coordinate and walk through the inspection.

Moving on, one of the things to consider when planning the inspections is what timing works best for your institution. There are 2 common practices used by the [IACUC] administrative community. Facilities with smaller programs may choose to dedicate a specific time every 6 months to conduct all of its inspections. For example, the inspections may be conducted over a 2-week period.

For those institutions with larger programs, a rolling inspection process may be used. Those conducting the rolling inspections may assign, for example, a specific group of facilities to be inspected every 6 months. To elaborate, an institution may have, for example, 30 facilities that need to be inspected over a 6-month period, so they break the facilities into groups of 5 and they inspect one group during each month, with the subsequent inspection being rolled or occurring again in the following 6 months. This process will allow and enable us to ensure, as a community and as an institution, that the inspections are occurring on a regular 6-month basis.

Slide 13 (Who is on the Inspection Team U-M?)

>>*Dawn*: Who is on the inspection team? We always schedule 2 committee members as we could have USDA covered species and rodents within the same building, with 2 members – one experienced and one new member. This is an opportunity for mentoring. A staff member from our Animal Care and Use Office is present to take notes, provide guidance, and collate all the notes at the end of the inspection. For all housing and support locations in our vivarium, our laboratory animal medicine animal care supervisors are required to be present. For each of the laboratory areas, PIs and staff are highly encouraged to have representatives that are knowledgeable about the laboratory procedures and the research conducted. This will help avoid any confusions, engage the committee with the researcher, and tie back the protocol reviews to the actual science.

Slide 14 (Strategies to Facilitate Inspections at U-M)

Some of the strategies to facilitate inspections. Some of the strategies we have found to help facilitate the inspections is to provide expertise, continuity, and support by including various members of the Animal Care and Use Office, Environmental Health and Safety, and our veterinary staff.

The compliance and quality assurance staff within the Animal Care and Use Office staff provide support during and after the inspection. Once the inspection is completed these staff members will collate all the findings from not only the members of the committee,

but the EHS [environmental health and safety] group, and include them in an Excel file that is then submitted to an administrator for uploading into our electronic system that generates the reports that will be sent out to the responsible parties.

Faculty veterinarians are assigned specific buildings of clinical responsibility on our campus, each being present for those areas on inspection is also very helpful from the standpoint of the animal wellbeing, as well as their knowledge of the research projects.

Included in the committee documents, when they begin an inspection, is the location of all the rooms in which they will inspect for that inspection day. We have found it to be very helpful to provide our members with copies of the previous inspection deficiencies to ensure that they are not recurring. Additional relevant federal standard documents are also provided.

Slide 15 (Who is on the Inspection Team?)

>>*Bill*: Who is on the inspection team? Dawn has talked a lot about the University of Michigan. Now let's consider requirements and who truly must be part of the IACUC inspection team. Again, please note that I reference the footnote on page 12 of the PHS Policy. But I will make a comment that there is little to no flexibility offered under the USDA requirements. The Animal Welfare Act specifically states that at least 2 IACUC members must inspect areas that involve the use of covered species. However, we would like to focus a little bit on the PHS Policy and the flexibility that's provided through the footnote. With that let's talk about some preferences and different ways some institutions develop their inspection teams.

Although not required, remember that idea of flexibility – many, if not all institutions, do have at least one IACUC member on the team. Some institutions do find it helpful to have a member of the – for example – environmental health and safety office on the team. This allows institutions as part of their inspection to help ensure that the animal care and use program occupational health and safety program is also strong and maintaining compliance with the [Occupational Health and Safety in the Care and Use of Laboratory Animals](#) regulation book, affectionately known to us as the ILAR Blue Book. The ILAR Blue Book is the primary guidance document used to establish animal care and use programs occupational health and safety programs. It is important to note that those requirements outlined in the Blue Book are only PHS expectations and are not required under the Animal Welfare Act Regulations. The occupational health and safety representative may look at, for example, eyewash stations, hazard containment, and various things that are directly related to safety.

Some institutions may choose to include, as part of its inspection team, a representative from the physical plant. Those that have talked about this in the past have mentioned the flexibility it gives them and also the edge when corrections are needed or issues are associated with the physical plant. Typically, someone from the plant may walk through the facility and have a camera or a phone available, and when facility issues are identified,

take a snapshot so that they know the exact location and the type of concern that needs attention. At the same time, the individual may make a phone call back to plant management to schedule repairs related to physical plant maintenance. Examples may include chipping paint, dripping faucets, and rust on metal surfaces.

Some institutions also choose to have post approval monitors conduct inspections of some areas. Here is another example of flexibility – as long as your IACUC is onboard – and we'll talk more about that in a future slide. Your post approval monitor may be the one that inspects certain facilities and, with reports of findings being sent back to the IACUC, the connection has been established.

Frequently institutions choose to have a compliance staff professional as part of the team. Usually this individual is responsible for accurately documenting the findings and also getting correspondence out to PIs or other responsible parties to make sure identified concerns are corrected.

There is also some value, many institutions find, in including a veterinarian, simply because throughout the facility inspection, animals may be identified that appear to have welfare concerns that require veterinary assessment and attention. At that time, having a veterinarian on hand to do the assessment and the follow-up is very beneficial, not only to the program, but also helps to ensure our main goal of ensuring good animal welfare.

Slide 16 (What You Need to Know Prior to the Inspection)

>>*Dawn*: What do you need to know prior to your inspection? When you visit a room, start with the animals in mind and work your way outward with the microenvironment then to the macroenvironment and looking at documentation as well.

Slide 17 (What Do U-M Inspection Teams Assess?)

What do U of M inspection teams look for? Using the model previously stated with the animals and working your way outward, first priority should always be the wellbeing of the animals. How are they housed, are they getting enrichment, is it appropriate enrichment, their surroundings in and outside of the caging?

Physical Plant – from HVAC to the lighting and any building concerns. Is the facility in line with the proper housekeeping, disinfection and sanitation practices set forth in the *Guide* as well as institutional guidelines?

Food, water and bedding – does it meet the needs of each species and is [it] changed at the appropriate frequency? Is the storage of drugs and supplies in-date, locked up if controlled and recorded if necessary? A review of euthanasia procedures when visiting laboratories – does carcass storage and disposal meet the guidelines? Labeling and signage covers a lot of territory, from door signage, labeling drugs and supplies, etc.

Checking room maintenance logs for appropriate health check and the care of the animals and room parameters have proper documentation, as well as surgical records which we require at our institution to be in the animal room during the post-operative period until sutures are removed, so that inspectors can actually view those records of animals that have actually undergone procedures.

While in animal facilities and/or laboratory areas, that is always a perfect time to talk about the training the staff has received as well as to discuss any issues of compliance and safety issues that have been identified during the inspection.

Slide 18 (What Should be Assessed by the Inspection Team?)

>>*Bill*: From a general standpoint let's take a look at what should be assessed during the facility inspection. Again, I am going to reference the OLAW checklist since many of us are familiar with it, and since it is a common tool that is often used.

I really want to make sure that we all recognize and continue to keep in mind is that the priority is **always** animal health and wellbeing. The first thing during the inspection process that the inspection team should do is look at the animals. When you walk in the room, what are the conditions of the animals' environment? For example, is the room temperature appropriate for the species? Is there an excessive ammonia smell, and does the room humidity feel appropriate? Are the facilities clean? Do the animals look healthy? Rather than walking in the room and starting by looking at the ceiling for paint chips or rusty doors, the point is we really need to place our focus on the animals, make sure things look well there.

Once that's occurred, in general, we want to make sure that the facilities do meet the regulatory requirements since those requirements are established and in effect to help us and also ensure the health and wellbeing of the animals. Physical plant is a key thing and one of the main points of concern in the plant is the HVAC system and the illumination. We need to make sure that the lighting is correct for the species. For example, if albino mice or rats are housed too close to the lighting source, the level of light intensity may result in animal blindness. We need to make sure that the environmental controls are set to temperatures that are best suited for the species being housed. The enclosures should be clean, water and food should always be available, and the animals should have some sort of enrichment. For example, devices such as nestlets are often used for mice.

The committee should take a look at the surgical suites – is the area adequately supported? Are the needed resources available? We should keep in mind that the USDA surgery suites should be dedicated and aseptically maintained. Conversely, surgery locations for non-covered species need only be dedicated areas when surgical procedures are being conducted. It may behoove the IACUC to do these inspections whenever they are set up for surgery to ensure the surgery can be conducted aseptically. Rather than having a PI say during the inspection – here is where we do the surgeries and we set up only when they're needed.

Keep in mind that procedure areas are not just areas where we do animal procedures but also support animal care and use program activities. This could be a drug storage area, X-ray rooms or MRI suites. The idea is to make sure the areas are clean, they are well organized and maintained. If drugs are stored and they are not out-of-date, they are to be secured, especially if they are controlled substances. Other areas that are reviewed as part of the facility inspection process include food and water, preparation areas and bedding storage areas. Is the bedding storage area in accordance with the *Guide*? In other words, is the temperature correct? Is the food stored off the floor? Is food and water being provided to the animals ad lib? And if not, is there an SOP available to be sure that water deprivation is part of protocol or part of veterinary SOP? You can always check back later when you go back to the IACUC administrative office to verify such issues you would identify during the facility walk-through.

Appropriate sanitation practices should be in place to minimize the risk of disease. In addition, formal records are maintained to document, for example, that the environmental parameters are consistent and that they do promote good animal welfare. Formal records are also used to ensure, for example, that sanitation practices are consistent and surgically manipulated animals are receiving appropriate post-operative treatments. And these records should be reviewed during facility inspections to ensure practices are in place to ensure animal welfare is ongoing.

Slide 19 (How Does U-M Classify Inspection Findings?)

>>*Dawn*: Let's talk about how UM classifies inspection findings. How does the classification of findings occur at U of M? IACUC members are provided a checklist of areas to be inspected and what to look for in those specific locations. No findings – no documentation. However, deficiencies are documented when there are conditions that are not in line with the *Guide* or the Animal Welfare Act. If animal welfare concerns arise during an inspection, the inspectors will refer to the veterinary staff on the inspection. However, in the event there is not a veterinarian on that inspection, then they would be contacted on the spot during the inspection.

Slide 20 (How Does U-M Classify Inspection Findings?)

Classifying inspection findings. We also make the distinction that we have areas that could use enhancements to improve the program and we list those as suggestions for improvement.

Notes are not shared with the research community, they are used for internal office purposes. Notes are used for reasons that we would think that the next group would need to use for the following inspection like if there's a lighting change that they can't get in the room at a specific time, then we alter the schedule for inspecting that particular area. That's what the office uses notes for.

Slide 21 (Classification of Findings)

>>*Bill*: Let's briefly discuss the regulatory definitions for deficiencies. Typically, [deficiencies] are either classified as being significant or minor. A significant deficiency would be any finding that could pose a threat to the health, wellbeing, and/or safety of human or animals. For example, if cages of animals are found without food and/or water, such conditions could result in the dehydration of animals leading to deaths. In this particular example, the lack of water would warrant a significant deficiency and appropriate follow-up. In addition, if sick or injured animals are discovered, it may be a deficiency or may, at least, warrant a veterinary review and/or a discussion by the IACUC. Keep in mind, we're considering animal wellbeing and ensuring conditions that could result in injury and we want to make sure those conditions aren't present. If these, or any of these, types of issues are identified, they may be significant deficiencies or at a minimum just require immediate intervention in consultation with a veterinarian.

Non-functional life sustaining equipment such as an HVAC system or a watering system may result in a significant deficiency. If either one of these systems fail, in a very short time there may be a significant impact on animal health and wellbeing. During inspections, team members may find research staff conducting activities that the IACUC hasn't approved. PIs get excited about their research and sometimes start experiments before IACUC approval is granted. This is a noncompliance that must be reported to OLAW and is a significant deficiency.

Simply stated, minor deficiencies are the opposite and they are those things or those issues that do not require immediate intervention since there is no immediate threat or harm to animal wellbeing.

Slide 22 (Inspecting Satellites vs. Vivaria)

>>*Dawn*: Let's talk about inspecting satellites versus the vivaria. Again, our goal for satellite facilities and vivaria is to always have 2 to 3-person teams inspecting, the exception with a satellite is that we can and have used live video feed back to committee members for viewing. For larger vivaria facilities, we have split up members in the same facility and then consult after the inspection to go over findings. Our EHS group prefers to conduct their visit along with the IACUC inspection as this will reduce the burden for the PIs who may receive multiple inspections as well as multiple reports from various groups on campus.

Slide 23 (Conducting the Inspections)

>>*Bill*: To wrap things up and before we take questions, I want to include this slide on conducting the inspections. Again, I'm focusing on the flexibility given to institutions through the footnote on page 12 of the PHS Policy. You've heard me reference it many times, so I strongly encourage you, as an institution and as a committee, to take a look at the footnote and have discussions at your IACUC meeting and identify some flexibilities that may work for you at your institution.

Although the Animal Welfare Act Regulations includes 2 IACUC members and it indicates that both must be present during the inspection of covered species, for the non-covered species the IACUC may decide to conduct facility inspections using other available staff.

Some institutions may choose to use post approval monitors, IACUC administrators, veterinary technicians, quality assurance specialists – you can help me help build the list and you can build the list at your own institution. Particular individuals on those lists may do, for example, an inspection of a euthanasia area – in other words, the only thing that is done in this area is euthanasia. Other institutions may choose to have someone like a post approval monitor do the inspections of tissue collection areas. The important thing is to make sure there is a connection to the IACUC and developing an effective process for reporting the findings to the committee through appropriate measures. The connection to the IACUC could involve, for example, preparing and providing a report of findings to the IACUC Chair or to the committee during a full committee discussion. It's up to the institution's IACUC to decide the method of facility inspection that best suits the organization's needs.

If you have covered species, then this may not be appropriate from an AWAR perspective, however you may want to have a conversation with your USDA VMO or other representative to see where you have flexibility and what flexibility they have to offer.

Satellites can be problematic for all of us and it depends on the location of the facility. One of the methods that has been used quite successfully is video streaming or some other type of technology that allows the IACUC to be involved. The best alternative would be to use a live feed during an IACUC meeting. This process allows a committee member to assess in real time on-going activities in a specific area. Committee members can direct the videographer to stream, for example, a specific record, an animal housing facility, or a specific cage.

We have had conversations regarding the use of video technology with the USDA at IACUC Administrators Best Practices Meetings, and in all cases USDA representatives have agreed that the use of this technology is acceptable, however they strongly prefer that it be a live feed rather than photographs or still shots.

Finally, other ways that can be used are through MOUs [memorandum of understanding] and subcontracts. In this particular case, as an institution, may find it practical to have the facility overseen by the collaborating institution. In this case the MOU typically designates IACUC responsibility or oversight of an activity to the institution that can and does oversee that specific area or procedure.

I've offered 5 ideas or different ways institutions can come up with flexible methods for conducting the facility inspection. With this, we'll open it up for questions and any thoughts that you may recommend.

Slide 24 (Questions)

>>*Susan*: Well, thank you, Bill and Dawn. That was terrific. And I'm sure the listeners do have questions. Listeners, please type your questions about facility inspection practices into the chat box on your webinar screen. OLAW may edit the questions for clarity, duplications, and fidelity to today's topic. If we cannot answer all of your questions in the time allotted, we will amend them to a transcript of this webinar which will be posted to the OLAW website. We will start with a few questions that we received before the webinar.

Slide 25 (Question 1)

Question 1. To my knowledge there is no mandate as to the frequency of calibration of isoflurane vaporizers, only recommendations based on manufacturer's specs and best practices? During facilities inspections, we find vaporizers with no calibration stickers or other signs that they have been recently, or ever, checked. What incentive is there for the PIs to send their units out for calibration when it is not required in the *Guide*? Any advice on getting PIs to follow manufacturer's specs and best practices?

>>*Dawn*: Yes, Susan, I can answer this for you. We had an issue here at our institution regarding vaporizers where we found exactly what they were talking about in this question. What we came up with is – we instituted a policy and within that policy through the IACUC, we came up with just 3 basic things that we would require a machine to have when we would do our inspections. And that would be that the machine had to be identified with a tag that we could track back to our office to know when it's been certified. We also required that the sticker must indicate when it was serviced and when its next service date would be due, and what we then did is we took it a step further and worked in conjunction with our lab animal medicine group to establish a service that the lab animal medicine group would offer every quarter to the institution. An email would go out to all the isoflurane users that would say your machine is due for service, please bring it to this specific area and we will hire a service to come in and they will service the machine and then they will do a recharge back to the investigator. Investigators have responded really well to this because we offered the service and now we don't really see a whole lot of issues or problems with machines being out of date. When they're not in use we do ask them to label them – not in use – so there is no question during an IACUC inspection.

>>*Bill*: I think, Susan, this also is an opportunity for us to discuss the fact that many times our regulatory requirements don't have specific expectations. They have some gray areas so that it allows us as institutions to identify the flexibility we need to employ at our institution. What this means is IACUCs may have to come up with some policies or may have to take a stance on specific issues, in this case through, you know, discussions with environmental health and safety and others. It may be decided that the vaporizers and other appropriate equipment needs to be looked at on a defined basis. In other words, what does the institution believe that is required in order to ensure a safe and healthy working environment for those that are using the equipment? So again, many times an

institution may find itself in a situation where it just has to take a stance and formalize it through some kind of process or practice using an IACUC policy or record.

>>*Susan*: Right, Dawn and Bill. I really like the University of Michigan's policy. I think this was – your policy uses the carrot and not the stick. You made it easy for your investigators to have those inspections, and I want to stress that the IACUC does have the authority to set up a policy like that and to enforce it. And I think you have – the IACUC has – the responsibility to do that to protect the health and safety of the animals and the people that are using those instruments.

Slide 26 (Question 2, Part 1)

Question 2 Part 1. The next question: How much flexibility does OLAW allow in the conduct of semiannual inspections? If my institution inspects Building A on January 15th, when does OLAW expect the next semiannual inspection of Building A to occur?

I'm going to answer this one, and I put the answer on the screen so that you could see it. Approximately every 6 months later [after the previous inspection] and no later than 30 days after July 15th.

[Provided by Animal Care from *USDA Inspection Guide: 7.1.2 Program of Humane Care and Use Review*. The USDA is in agreement with OLAW that the timing of the Facility Inspection can include flexibility of within 30 days of the 6 month interval from the last Review, as long as there is not forward drift of the date from year to year. To avoid forward drift, the IACUC should consider scheduling Program Reviews during the same calendar month from year to year.]

Slide 27 (Question 2, Part 2)

Question 2 Part 2. How much flexibility does OLAW allow in the conduct of semiannual inspections using a rolling inspection process?

The answer: The second inspection for each site must be approximately 6 months after the first inspection and no later than 6 months and 30 days after the first inspection. You can see a little table here where we've developed an example for you. I'll give you a minute to read that.

Slide 28 (Question 3)

Question 3. There are many other locations not used for housing or animal work in our facility, such as laundry rooms, offices for the animal care staff, showers, and staff break rooms. These spaces are contiguous to the facility. Should they be included in the inspection? What is considered a functional area? Should they be inspected? And if so, how and to what level?

>>*Dawn*: Susan, I'd like to answer this question. We struggled with this many years ago and we had actually, in any of these locations that are listed here in this question that

were inside our vivarium space, we felt were fair game in order to be inspected and to be looked at, but then the question was what are we looking at and what are we holding them to what standard? When we looked at these spaces and we didn't really see that there were any other issues, we thought we could be better addressing these issues if – or issues during the inspection we could directly relate [delegate] them to those who are supervising in that area and just ask for those areas to be, you know, cleaner, or ask to make sure that they were making sure that they were checking them on a daily basis and they were tidy and so forth. Then we decided at that point we weren't going to include spaces such as showers and staff break rooms because it didn't add value to the inspection process. But we could also make sure we looked in on them as we sort of walked by them and then gave feedback at that time.

>>*Bill*: I'll add just very quickly, Susan, I'll add that everything under the animal care and use program is overseen by the IACUC. And I, too, am going to continue to talk about the footnote on page 12 [of the PHS Policy] because the flexibility for looking at these areas is at the discretion of the IACUC. And in our particular case just a simple walk by and popping our head in the door is something that was discussed with the IACUC and they found it appropriate. And there is minimal oversight from an IACUC's perspective, but least there's some. So, it allows us to figure out where we really need to focus our efforts and spend most time when doing inspections.

>>*Susan*: And OLAW supports that idea too. The IACUC has the flexibility to determine where to focus their attention and they are overseeing the whole program.

Slide 29 (Question 4)

Question 4. A PI needs to transport rodents to a nearby institution for specialized MRI procedures. Unfortunately, the transports must occur outside the university's animal transport service hours. Is the IACUC required to conduct semiannual inspection of the personal vehicles used for transporting these animals?

>>*Dawn*: Susan, I can address this question. We struggled with this – with transporting of animals in personal vehicles. What we came up with is – we came up with a policy or guideline that indicates if you're going to transport animals in your personal vehicle there were certain things [parameters] that you needed to follow. You needed to make sure that the animals were contained in a secondary container and making sure that things were sanitized when you were done. And we also would speak with the people or talk with them about making sure they were addressing allergens if other people were riding in their car and so forth. And making sure that the air conditioning and the heating units were working appropriately. And we did that through a guideline and we highly discourage the use of personal vehicles, but there are instances where it just can't happen for certain procedures that have to be done after hours where the staff cannot accommodate the transportation at that point in time.

So, we just put parameters in place at the institutional level so that PIs who can and do use their transport [personal] vehicle would have to address that through the protocol review process and how they would handle that going forward. But we do not inspect every single vehicle where the person in a protocol says – we're going to use our certain [personal] vehicle. We used that from the institutional level and the response we get back from the protocol review.

Slide 30 (Question 5)

>>*Susan*: Seems like a reasonable solution. **Question 5**. A PI is conducting a study that involves client-owned animals that are housed in the owners' homes. Is the IACUC required to inspect the owners' homes to ensure that the IACUC-approved protocol is being followed?

>>*Dawn*: Susan, I think at an institutional level, we all look at the spaces where animals are housed. Yes, the animals are housed at the clients' homes, but there wouldn't be a requirement for you to go to the owners' home to inspect. You're looking at the protocol and you're conversing with the PI at the level of the PI to making sure things are ensured to be properly followed, but we would not inspect a client's home to see if – to make sure that procedures are being done correctly. We would just have to rely on the PI and the trust with the PI that things are happening the way they have described in their protocol.

Slide 31 (Question 6)

>>*Susan*: **Question 6**. Since an area used only for euthanasia doesn't necessarily fall under the PHS definition of facilities. Do euthanasia areas need to be inspected semiannually or can the IACUC establish other means for inspecting/overseeing these areas?

>>*Bill*: Again, I think that I'm going to keep pointing out [PHS Policy] page 12, page 12, page 12, the footnote. Each institution needs to determine the level of oversight they want to have for each facility. In this case, the inspection of a euthanasia area may simply be walking into the room, ensuring that the euthanasia chamber is clean, ensuring that it is properly equipped, that flow meter, pressure regulator are present. That there may be some kind of signage and documentation that provides specific instructions on the process to be followed during euthanasia. And I think if an institution is comfortable with a post approval monitor or maybe an IACUC administrator or someone else ensuring those things are in place, then I wouldn't see any problem with them being looked at on whatever basis or whatever schedule the post approval monitoring visits are occurring. For example, if somebody visited with a PI who has a euthanasia area once a year, as long as the IACUC is on board, then that inspection of that area may occur during the PAM visit and the report would come back to the IACUC if there were deficiencies or issues.

Slide 32 (Question 7)

>>*Susan*: **Question 7**. Could the IACUC authorize a compliance office staff member, for example, a PAM person or an IACUC administrator, to conduct facility inspections and only

require that staff member to report back to the IACUC when identified deficiencies aren't resolved?

>>*Bill*: This kind of is an extension of question [slide] 31 [Question 6] in that again we need to make sure that we involve the IACUC. If the committee is comfortable with a compliance staff or a PAM person doing the inspection, then absolutely. And I think depending on the discussions and the agreement between the IACUC and those that are doing the inspections, it could be appropriate for whoever is doing the inspection, i.e., the PAM person or the IACUC administrator, to only report back to the IACUC when there are deficiencies, to let them know what the deficiencies are and let them know the actions that were taking to resolve those issues. Obviously if there are issues that need IACUC oversight as far as correcting the deficiency, then it may be something that needs to be further discussed during a committee meeting.

>>*Susan*: Let me be clear about that. If there are significant deficiencies that PAM person or IACUC administrator **would** take that information back to the IACUC?

>>*Bill*: Absolutely. Depending on the level of inspections they're allowed to conduct – if there are significant deficiencies, then obviously there are expectations for the IACUC to put in place resolution plans and things like that, and obviously if there are animals involved my hopes [expectation] would be that that PAM person or that IACUC administrator has the veterinarians on speed dial to make the call when necessary.

Slide 33 (Question 8)

>>*Susan*: **Question 8**. If the IACUC is going to authorize non-committee members to do inspections, how should this authorization be documented?

>>*Bill*: This is good. I think question [slide] 31 [question 6], [slide] 32 [question 7], and [slide] 33 [question 8] allows us to talk through the whole process and ideas for flexibility. In particular, [slide] 33 [question 8], the whole idea of documenting – so it's up to the institution or the committee. An institution may choose to do the documentation in some sort of formal policy and that may include the privileges that have been given to whomever, a vet tech or a post approval monitor, may talk about the practices that need to be followed when findings are identified, et cetera.

Another institution with a smaller program may choose to document the privileges through meeting minutes based on a conversation that occurred with the IACUC. Again, it's up to the institution, but I think at the end of the day, it is important to be able to produce a document or some sort of reference that talked about the IACUC's consideration of allowing others to do inspections and the circumstances that are related.

>>*Susan*: Well, we have questions just flying in like crazy. We have about 7 minutes left. We will do as many of these as we can. Bill and Dawn, if you're available, we can run a few minutes after the hour, but we will amend any of your questions that we don't get to

to the end of the transcript and we'll consult with Bill and Dawn and we'll amend the answers on there too. So here we go. **Question A.** How does your institution compel the participation of committee members in the inspection process?

>>*Bill:* I'll chime in here first. One of the things that we do before we even appoint somebody to the IACUC is to provide details as to the expectations. We really want them to understand the time commitments that are needed. And we've made some assessments through the years and we've come up with some timelines that are related to our own specific institution. In other words, how many protocols would you have to review and things like that. But also, we ask people based on the amount of facilities that we have to inspect to make sure that they have the time to dedicate hours every 6 months to participate. Other things that we do that gives us some strength and some muscle in this is, we do offer our IACUCs a small amount of compensation to offset the time that they're away from their labs, in other words, spending on IACUC activities. So, we do have at our fingertips the ability to say, you know, we're compensating you for some of this, we have some minimum expectations that you agreed to before taking on the appointment. I understand that not all institutions have this available in their budget, so I go back to my first statement and say it's very important to make sure that IACUC or potential IACUC members understand what goes along with the appointment and the time commitment required.

>>*Susan:* **Question B.** Can a veterinarian, a voting member of the IACUC, serve as one of the two committee members needed when looking at USDA animal space or is this a conflict of interest?

>>*Bill:* It's not defined in the Animal Welfare Act Regulations nor the *Guide* or anything like that. It doesn't really talk about whether or not a veterinarian participating in an inspection of their own facility or a facility they oversee is a conflict. I think it's a valuable conversation to have at an institution level. I mean, if you think about it, just stand back and look, if the veterinarian is responsible for the vivarium and all of the things related, then it may behoove the institution, and also be for the benefit of the veterinarian, to have two separate eyes take a look at those areas that they're directly responsible for. I think it's very valuable and almost critical to have the veterinarian involved because they're the ones that can answer questions. Each institution needs to take a look at this and decide whether or not they believe there is the perception of conflict of interest of interest if a veterinarian is the official – the official member that is doing an inspection of, for example, a USDA surgery suite or USDA containment area.

>>*Susan:* **Question C.** Dawn, what would you look for when inspecting – whether indoor primary housing, that would be either cages or racks, are disinfected every 14 days or less? And what about outdoor enclosures?

>>*Dawn:* What we would look for is all of the animal housing rooms that we actually inspect – they have an animal housing room log and the requirements are on the animal

housing room log – that a husbandry person would come in on a daily basis and all of those parameters would be checked off and signed off that they were checked. You know, the humidity, the temperature, positive or negative pressure, when cages were changed and when they were cleaned and so forth and when they were sanitized. So that would all be in one documentation and then we require them to keep the current and the back and the month behind in order for us to get an idea of how things are going on in that room since the inspections only occur every 6 months.

>>*Susan*: We're one minute away from 1:00. Bill and Dawn, would you like to go on and answer some more questions or shall we close the webinar?

>>*Bill*: That's fine. I'm happy to answer as many questions as we can.

>>*Dawn*: Yes, that's good.

>>*Susan*: You listeners are lucky. We still get some more time of theirs. This is for Dawn. **Question D.** You mentioned providing a checklist to members before inspections. Is this the OLAW checklist? If not, how is it different?

>>*Dawn*: It is slightly different. It is different than the OLAW checklist. We've actually come up with different things over the years that we have felt was very important for our committee members to look at and with the addition of the aquatic species in the *Guide*, we just kind of keep adding to that list of the different parameters and the things that we would like them to look at during an inspection. It's just a quick reference checklist for them that gives them an idea of – when I walk into a room, what am I looking for? When would look unusual for me? What would look unusual for me and so forth? It's not really the OLAW checklist at all, it's our own internal list that we have come up with from past experiences of doing inspections.

>>*Susan*: And that's perfectly fine with us [OLAW]. We consider the OLAW checklist an optional document and we give it to you in Microsoft Word so that it's a live, open document so that you can change and modify it if you want to.

Question E. Let's see. Inspection of satellite facilities, via video feed, how do you address questions wanting to be asked by those viewing the video? And this is a two part one. Do you find any faults when reviewing a video feed as compared to a physical inspection?

>>*Bill*: We've talked about the use of video feed during many, many [IACUC Administrators Association] Best Practice Meetings, and many of our colleagues have offered some benefits and some downsides of using video technology for inspection. I think that's where it always led us to following the USDA recommendation to do it live. Obviously, the live video allows the IACUC, or whoever's viewing it, it may the attending vet and the IACUC Chair viewing the video live, but it gives you the opportunity to ask questions and to have some discussion. You can say, "show me the animal in that cage

right there because it looks like its hiding back there in the corner. Let's talk about it." You know if you don't have that opportunity, then certainly you're going to have to have additional correspondence, you may view a video, you may have notes, or questions and you're going to have to go back and forth via email or a phone call, if they have questions about this because they didn't have an opportunity to work with the videographer.

The second part of the question, obviously the best case scenario is to be able to do it live. It's not always feasible. I've seen and been part of institutions that would have housing occur miles and miles away. Maybe, in association with Michigan, it could be something up in Alaska or Puerto Rico, or somewhere else. Maybe Africa. We really do need to find some means that the committee feels is acceptable, to at least have a good idea of the type of housing, or any other thing that's applicable, that's being used. Sometimes it ends up being just a photography still shot, with some type of summary or discussion through a paragraph or some other additional information that comes in from the PI. I think it's important to recognize flexibility, again here, and it just gives us a chance to find ways to engage and oversee locations that are miles and miles away from a centrally managed area.

>>*Susan*: **Question F.** Dawn, what electronically managed system do you use to generate inspection reports? And we, as the government, can't endorse commercial products on our webinars, but could you mention some aspects of your system without naming it?

>>*Dawn*: So, the aspects of our system is, the individual who puts the information into the system can actually generate the report. It sends the actual information to the PI, it tracks when it comes back in the system in order to be reviewed, and it sends – what it does is – it sends an action item out to the individual who is responsible. They have an action item, they click on it, they write in their response, and then they just send it back to the office. We also use that same system to schedule all of our inspections, as well, and send them out to the whole research community that's involved in the inspections – so they know, one, when we're coming, what day we're coming and so forth. And so, it does track and we can actually run a report who has responded at the appropriate time and who has still not responded. And it will also send reminders that your inspection response is due in 2 days, or whatever.

>>*Susan*: OK, and this is the kind of thing that you can discuss at [IACUC Administrators Association] Best Practice Meetings; and if you want to know more about the system they use at Michigan, you can send off an email [acuoffice@umich.edu] to Dawn or Bill and get some more information.

Question G. How do you track and compare inspection trends?

>>*Dawn*: Again, when we are – we'll be pulling reports every 6 months and then we create graphs to see where we have the most amount of issues or problems or concerns.

And that's how we address any of our problems in our facilities going forward for the next time. But we also look at – seeing if most of our trends are in one specific area that we need to focus in that specific area and give more details to the committee members on how to do these inspections and how to look at the different areas. We are pulling reports and we give that to the committee during the semiannual programmatic review and give them an idea of where we have most of the programmatic issues to get feedback from the committee members to tell us how we can do a better job with our program.

>>*Susan*: **Question H.** Well this next question puzzles me a little bit. It says, “What type of records must be kept while covered species are fostered by students over school vacations and breaks?” You wouldn't necessarily see research animals going home with students over breaks – so I don't know – is it clear to you what that means, Bill or Dawn?

>>*Bill*: It's not clear to me unless it's a client-owned dog scenario. Or maybe it's a smaller institution that has some USDA covered species, i.e., cats or dogs involved in some [minimally invasive] studies and they may be housed on campus during regular business hours, but then maybe they go home with students and the care is provided there. I don't know, if those animals are still research animals during the time period they're at home, it may behoove the committee – and I don't know what the USDA would say about it – to make sure the individual that's taking the animal home is qualified to do it. It's obvious they would be – and I'm making a lot of assumptions here – but it certainly would help to have some sort of documentation here that says, “these animals are research animals, certain periods of time they are being cared for by students or researcher or laboratory technicians and, under those circumstances, the IACUC has authorized X Y Z, here are the conditions, these individuals have been qualified by the institution and the committee to care for these animals. Again, I think the importance here is to make sure the IACUC had a discussion about it so that if anyone ever asks, USDA VMO [veterinary medical officer], maybe during an AAALAC visit, something like that, if you were asked about that unique situation it wasn't just that we woke up one morning and said, “Yeah, take it home,” but had given it considerable thought.

>>*Susan*: This is where the IACUC would need more information. **Question I.** For USDA covered species, do you need 2 full IACUC members, or could an alternate member serve?

>>*Bill*: The alternate member can serve. That's the whole idea of alternate members, so it can be a full IACUC member, but the alternate member can serve. Now, the caveat is – whoever that individual is an alternate for, is working in capacity as an IACUC member for, for example, during inspections the same day, then that alternate is not qualified to be serving in an official capacity. Further explanation, if there is only one veterinarian on your committee, and you have an alternate veterinarian, and your official IACUC member that is a veterinarian is inspecting building A, then your alternate veterinarian cannot be inspecting building B at the same time. Because your alternate is actually serving in capacity as a full member only when the voting member is not available and can't function. Does that make sense, Susan?

>>*Susan*: It does, it does make sense. But, I've heard a legitimate work-around that I've heard people use for PHS species. And this [question] was [about] an alternate for USDA, so yes. In the case of the PHS Policy, we allow the IACUC to have a consultant, especially if they need the expertise of that consultant. Sometimes the alternate member can be asked by the IACUC to consult for the purpose of an inspection, but I agree with you that wouldn't work for a USDA covered species.

>>*Bill*: Yeah, again PHS Policy has flexibility. Page 12. If you're going to try something like that for USDA covered species, the interpretation that we just gave is a very strict interpretation. You may want to just talk to your VMO [veterinary medical officer] or someone else in USDA. My understanding is exactly that, the alternate can't be serving in the official capacity as long as the regular member is already functioning.

>>*Susan*: Now here's a good one. **Question J**. If the institution does not own the animals at a satellite facility, is it the institution's responsibility to perform the inspection?

>>*Bill*: It depends on how the animals are being used. If you're doing research at the site and they're being held there specifically for your research, then the IACUC has some – there is some expectation for IACUC oversight. This is one of those examples where the IACUC has to have a discussion and there needs to be some of the details brought out. For example, if somebody's doing research on zoo animals and they're going to a zoo on a regular basis and observing [nonhuman] primate function and primate activities, then obviously the IACUC doesn't have a responsibility to inspect those facilities because they're under the jurisdiction of the zoo. The same thing could be applied to an aquarium or some other facility. But the flip side, if you're holding animals at a place that you leased, and you don't own those animals, and that facility isn't under the jurisdiction of a committee or some sort of ethics board, then as an institution, we have some responsibility to make sure the animals are being housed and cared for in accordance with the *Guide* or other standards. I hope the 2 examples answered the question for whoever's asking it. In most cases, I think the example would be that going to the site where the animals are part of the zoo or an aquarium, and in that case, it's just observing animals in their facility. Hopefully, that hits it. Is that how you interpreted the question, Susan?

>>*Susan*: Yes, it is. And I'm sure if the question wasn't clear, the person will write to us. **Question K**. You said that PAM [post approval monitor] or other staff may inspect euthanasia and tissue collection areas. What about other procedure areas such as rodent imaging and rodent surgery?

>>*Bill*: Again, page 12, page 12, page 12. Sit down with your IACUC and have the discussion. If your committee believes that your PAM person is qualified or can be trained to do that inspection **and** you make a very strong connection between the committee and the individual doing the inspection and you get the reports back to the committee so that there can be discussion and understanding about the findings, then the IACUC certainly

can authorize any individual that they deem qualified to do the inspection, the authority to do the inspection on the IACUC's behalf. Again, I can't stress strongly enough that you have to make certain that your IACUC is engaged and involved. You don't want to get into a scenario where your IACUC is complacent and you're placing all these duties and responsibilities on other folks without having that connection and your IACUC's input.

>>*Susan*: They're not really running the program if they outsource everything, are they?

>>*Bill*: That's right. Page 12.

>>*Susan*: So, page 12, that's your favorite page in the Policy, isn't it?

>>*Bill*: Yep, that's my favorite page! You're right. [laughter]

>>*Susan*: I like that one, too. We still have 224 institutions on the line. That indicates a significant interest in this so, I think we'll keep going – if you're game?

>>*Bill*: Let's shoot for 2:30, I have another meeting. So, let's take 15 more minutes. Does that work?

>>*Susan*: Okay! That's what we'll do. **Question L**. You mentioned inspection of diagnostic areas as an animal support/use location. If live animals are not brought to the diagnostic location, does that location require a semiannual inspection from the IACUC?

>>*Dawn*: We focus on procedure and use locations with the respect that where live animals are being taken to and have procedures performed but we don't focus on if there's no live animal work that is happening in that area.

>>*Bill*: And I'll add – remember it's the IACUC's responsibility to oversee the animal care and use program and the diagnostic lab is part of the program. So, what I'll say, and this is kind of the theme, to consider flexibility. We talked about looking at areas that are contiguous and Dawn mentioned how we just kind of pop our head into husbandry staff locker facilities and things like that. So, you may choose just to make sure the committee knows what's going on in there. That it's clean. You know, it's up to the institution to decide how detailed an inspection of that area needs to be, so if we take the word "inspection" off the table and just say "oversight" or oversee the diagnostic area – as an institution you can figure out how you want to oversee it. You may want to do that not through a formal inspection. Maybe it's through another process. But at least you should come up with some way to ensure the IACUC knows what's going on in there and how it's being used and how it supports the animal care and use program.

>>*Susan*: **Question M**. What is considered a facility? If a location has multiple buildings, is each building a facility? Or is the entire location considered the facility?

>>*Dawn*: We have just exactly that with one of our facilities. It is multiple facilities located in one large complex. So, we call it a facility and then each building is identified by its number. But the whole entire building – multiple buildings within a building – are considered one facility.

>>*Bill*: Yes, and take a look at the definition, too. Facility is specifically defined in the document [PHS Policy III Definitions] – apply it appropriately for your institution. If you want to call an entire building a facility, that may include classrooms and offices so obviously that's not the case. So, really look at the definition and note where it says, "the confinement of animals." That is the primary point – confinement. Where are animals held or procedures conducted, things like that.

>>*Susan*: **Question N**. For animal procedures, catching fish in the wild, would you have to inspect the boat as a satellite facility?

>>*Bill*: If I were asked that by my own folks, I would say no. Because, the boat is not a place where animals are being confined. If you want an EHS component, you may choose as part of your occupational health and safety program to have an assessment of the boat and the electrofishing. And again, I'm just giving you some examples. Some institutions may say yes, this should be looked at in some way, shape, or form. It's part of the animal care program, so institutions have the flexibility to decide. If you're in a metal boat and you're doing electrofishing, you may have some concerns. [laughter]

>>*Susan*: **Question O**. Similar to Question 1, would it be standard best practice to see scales used to determine animal weights should be certified on a routine basis?

>>*Bill*: You know, one of the things that we've talked about at [IACUC Administrators Association] Best Practice Meetings – this is a funny little analogy – that as a community, we've picked all the low hanging fruit and we're starting to knock the apples off the top of the tree. So, I think when we get into things like this, we're really getting into some details where as an institution, you make the decision. If you believe that the scale may deviate over time and give you some weights that are not accurate or you're not getting data you need or information that you need to provide appropriate care to the animals or determine when one should be removed from a study, then it may behoove you as an institution from a comfort standpoint to have your scale evaluated and measurements done. I think that's very, very different than having like a biological safety cabinet certified on a regular basis. I think as an institution, you need to think, or we all need to think, as institutions – what works best and whether or not we should do things like that.

>>*Susan*: Yes, flexibility. **Question P**. What guidance is there to the inspection of laboratories which do not bring animals back to the lab for any procedures? That's another case of the apples at the top of the tree. That doesn't seem to be – that's not part of the IACUC's authority or responsibility.

>>*Bill*: I agree. Yes, I think these would be scenarios that would fall outside of the committee or maybe something that as an institution you decide should be in collaboration. To me, it's more lab safety, EHS, so it's tied to that occupational health and safety component of your program. And if you believe that your program needs to extend a little bit beyond where your animals are used simply because you're an animal user and you want some EHS involvement in the laboratories, then it would be up to you as an institution.

>>*Susan*: **Question Q.** What is your insight on unannounced visits? Do you think this would be better to identify real-time deficiencies?

>>*Dawn*: I think that can be a way to identify real-time deficiencies if you did unannounced. The issue, I believe, with unannounced is that in order to make it a valuable inspection, you really want somebody there that is knowledgeable about what is going on in their laboratory, knowledgeable about their research, and so that you can have a one-on-one discussion. Yes, you could find deficiencies that you may not find because you announced that you are coming. However, I think it makes it more valuable and it really creates a good relationship that you can build between your IACUC and your research community as you have these discussions when you do show up for an [announced] inspection.

>>*Bill*: Yes, and I'll add to that. We have these discussions all the time at [IACUC Administrators Association Best Practice] Meetings and it's not our goal to find problems, it's our goal to find good things. Truly, you want to make sure there are no deficiencies and I understand that goal. If we want to make sure there are none, how do we do that? That's where I think if you have an opportunity for post approval monitors or even your IACUC administrators to get out in the field, use that opportunity to help to find and locate potential areas of deficiencies and then you help people understand and help them get to a state where they feel comfortable that their compliance is where it needs to be. I really think if you want your semiannual inspections to be efficient, that you need to have some timing and some planning and some appointments made. Otherwise you're going to have 12 inspections scheduled for a given day and you're going to go out and you're going to get 2 of them done because the laboratory doors are locked when you get there and there's no one to talk to. That's been our experience, that's been my experience, not only here, but at other institutions that I've worked with.

>>*Susan*: **Question R.** How do you suggest visualizing mice in IVC [individually ventilated cages] isolators loaded with environmental enrichment devices – nestlets, cardboard tubes, igloos? A typical animal holding room could house up to 2,000 animals. Do you pull out a random sample of cages?

>>*Dawn*: I think that's a fair assessment – to pull out a random source of caging. Another way that you might be able to do it is if you could shine a flashlight into those cages to see if you see that animals are moving around. What we have found is that the

animals will stay closely in the nestlets and they are actually pretty healthy and pretty active at that point in time. If you suspect a problem, and any husbandry personnel or staff person, that's been well trained, really knows what they're looking for in the caging for the IVC units and so forth. But we, actually they, will sort of pull out each cage in each unit to look at the animals. But I think it's a fair assessment to pull out a certain amount of racks and a certain number of caging.

>>*Susan*: **Question S**. Here's somebody that asks about – for suggestions on how to make inspections non-policing. Or less a policing experience? Do you have any quick thoughts on that?

>>*Dawn*: I think when you go to do an inspection, and you're there to sort of collaborate, like Bill had mentioned, you're there to be there to help. You're there to give them guidance, you're there to say, "I'm here to help. I'm not here to just find everything that you're doing wrong. We want to understand what it is that you are doing. And if there are improvements, that we can help you with those improvements." So that you are not looked at and viewed like the police. I think if you go in, and it takes a special approach, to talk to people when you walk into an animal room, or when you walk into a laboratory. And knowing that you're coming, I think it makes it a little bit easier, and it makes it a little bit more collegial than just showing up unannounced. Because then they think you're actually trying to find something wrong when you show up unannounced.

>>*Bill*: Yes, and I would add that the tone of your conversation has a lot to do with it. If I find something when I'm doing a facility inspection or anything else, I'll talk to them about what it is. I'll ask them if they think that's okay. And maybe after a conversation – we'll talk about why we need a record or maybe it'll be a conversation about why we need a process for ensuring that when animals are on water deprivation, that the PI is actually providing the water when they need to. But, I kind of try and kick it back to them – so it is a collaborative discussion. And they realize why we need it to be so. Or why the regulation reflects the requirement. So, it's more of how you present yourself and how facilitate the activity and the discussion as to whether it's perceived as policing or not.

>>*Susan*: Okay, we've got 2 more questions and so we're going to try to get those in in the last 3 minutes. **Question T**. What are your thoughts on using an AAALAC site visit for your semiannual facility inspections?

>>*Bill*: I wouldn't do it.

>>*Dawn*: I wouldn't do it either.

>>*Bill*: And it's for no other reason than you want to give AAALAC the opportunity to do the site visit and go through the facility as they need to. In the same breath, as an institution, you need to make sure that you're doing a thorough review of all the areas. I myself have been in situations where we had an AAALAC site visit, our last one was in

July, and our semiannual inspection was due in August. So, we actually had our site visit in July and then in August went out and did our semiannual facility inspection. Again, as an institution, you need to decide if you can actually do a thorough facility inspection while you are attending to the needs of your AAALAC team and while you're working with them and you're looking at the things they're specifically looking at and you're providing input. You certainly don't want to say to an AAALAC site team that we need to spend an extra hour in this facility because we haven't been able to look at everything. And AAALAC, they look at as much as they possibly can, sometimes random sampling throughout facilities. It depends on the team, the size of the facility, the amount of time. But I think that a semiannual inspection gets into a lot of detail that's not always the same detail that AAALAC gets into. That's just my opinion and I'm sure many others have their own opinion.

>>*Susan*: **Question U.** And the last question. If an institution is the parent organization of an NIH award which has a subcontracted institution where all of the animal work is being conducted, but no MOU exists, does the fact that the subcontracted institution has an IACUC and is PHS Assured eliminate the need for an MOU or an actual inspection from the primary awardee?

Of course, I'll answer this one. NIH Grants Policy requires a written agreement or MOU with all subawardees. In addition, the *Guide*, on page 15, requires a formal written agreement that addresses who is responsible for offsite animal care and use, who has animal ownership, and which IACUC will provide review and oversight. [The IACUC that provides oversight would be the one that is responsible for semiannual facility inspection.]

And there are more questions that we can't get to, but we will add them to the transcript. So, I would now like to thank you, Bill and Dawn. You have been so incredibly generous with your time. I'd like to thank the University of Michigan for loaning you to us. It was a great talk and the fact that we still have 170 institutions on the line [a half hour after the intended ending time of the webinar] indicates, I think, thanks and gratitude from the listeners. I also want to thank all of you listeners for participating in our webinar and special thanks to those who sent in questions.

Slide 34 (OLAW Online Seminars)

The next OLAW Online Seminar will be on September 20th, when Debra Hickman from Indiana University School of Medicine will talk to us about "Monitoring for Humane Endpoints: Developing an Appropriate Strategy". I wish everyone a good summer and look forward to having all of you join us for our next webinar in the fall. Good bye.

Additional Submitted Questions Not Addressed During the Webinar

The following questions were submitted in response to the Facility Inspection Webinar on June 28, 2018. Although we did not have time to address these questions during the webinar, OLAW and the speakers have prepared the following answers. Some questions have been condensed, compiled and otherwise edited from the original.

Question V: During IACUC inspection of labs, does the IACUC have the authority to address messy labs?

Dawn: While inspecting areas that have animal procedures, including laboratories, we should feel obligated to discuss dis-organization.

Bill: Yes, laboratories that are “messy” promote unsafe working conditions and impede the PI’s ability to perform animal use procedures in a clean and sanitary environment.

Question W: Are deficiencies or suggestions for improvement ever assigned to a party other than the PI or director of a facility? For example, if there is a facility issue, would this be assigned to the person in charge of an institute's facilities management department?

Dawn: We assigned SFI [suggestions for improvement] or deficiencies to an entire department and or groups that do vet care and husbandry.

Question X: Any input on inspection of laboratory/support areas even when the PI states that he or she has not brought animals to this location in the past 6 months? Would this also be the case for inspection of USDA covered species?

Dawn: The location remains listed as a use location on the IACUC approved protocol. We would inspect each 6 months as it is listed as an approved location which means it is available for use.

Bill: For the area to remain commissioned by the IACUC as an animal use area, the IACUC should visit the facility at least every 6 months. During the visit, the IACUC may asked what types of activities could potentially be performed in the area, and how these procedures would be conducted. Alternatively, the IACUC may inform the PI – since the area is inactive, it will be decommissioned. If this process is followed, the IACUC would need to conduct an inspection of the area before it is recommissioned.

Question Y: I am confused. I thought AWA required IACUC members to inspect the facilities not non-IACUC members.

Susan: Yes, the AWA requires two IACUC members to conduct facility inspections that house regulated species. The PHS Policy allows flexibility in the inspectors. Many

institutions always include two IACUC members on their inspection teams to be compliant with AWA regulations, whether they are inspecting facilities housing regulated species or not. These institutions find it simpler to adhere to the more stringent standard in all situations. See discussions on Slide 13 page 5, Slide 15 page 6, and Slide 23 page 10 of this document.

Question Z: Could you utilize alternate committee members in the inspection process?

Susan: See Question I. page 20 of this document.

Question AA: Do you have any stats on how many institutions offer compensation to IACUC members? (i.e., Association for the Accreditation of Human Research Protection Programs (AAHRPP) provides a survey to show compensation for IRB members. I'm looking for a similar support for other committees).

Bill: Not at this time.

Question BB: If an investigator is a co-PI for funded research in which the PI's institution is the one being the primary recipient of the funding, how would the inspection work if the housing is in a foreign country?

Eileen Morgan (Director of Division of Assurances, OLAW): There is no expectation that the domestic institution conduct an onsite semiannual inspection of the animal activity at the foreign site. OLAW requires the foreign organization to follow the [International Guiding Principles for Biomedical Research Involving Animals](#) as well as the laws, regulations, and policies governing the care and use of laboratory animals in their country of origin. Those laws may or may not require a semiannual facility inspection. There are several situations which would require the foreign organization to conduct a semiannual program evaluation, including:

- If they choose to follow the PHS Policy;
- If the foreign laws, regulations, and policies in their country include a semiannual program evaluation; or
- If the PI's written agreement between the organizations in the partnership with the primary recipient's institution included conducting a semiannual evaluation.

OLAW guidance recommends that when institutions collaborate they should define their respective responsibilities, including a formal written understanding that addresses responsibilities for animal care and use, ownership, and IACUC review and oversight (*Guide* page 15). An IACUC should notify the other IACUC of significant questions or issues raised during a semiannual program inspection of a facility housing a research activity for which that IACUC bears some oversight responsibility. See [OLAW FAQ D8](#).

Question CC: My question is related to PHS funded, non-USDA regulated activities, where the animals are outside of the centralized animal facility for less than 24 hours. Are IACUC's required to semiannually inspect PI locations, outside of the centralized animal

facility, where non-surgical procedures such as imaging, irradiation, behavioral testing, dosing, etc. are performed? What about PI locations where surgery is performed? I've recently seen several references to performing inspections only once per year for these types of locations and wondered if we were interpreting the "animal facility" definition incorrectly in the PHS Policy.

Bill: Refer back to Page 12 of the PHS Policy in footnote 8 – whatever works for your IACUC and at your institution.

Question DD: Does USDA concur with OLAW about the timing of facilities inspections?

From USDA Animal Care: 7.1.2 Program of Humane Care and Use Review. The USDA is in agreement with OLAW that the timing of the Facility Inspection can include flexibility of within 30 days of the six month interval from the last Review, as long as there is not forward drift of the date from year to year. To avoid forward drift, the IACUC should consider scheduling Program Reviews during the same calendar month from year to year.

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