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Note: Text has been edited for clarity.

Physical Plant Issues

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[It takes several minutes for the recording to load]

Slide 1 (Title slide)
Hello everyone and welcome to the March 2010 OLAW Online IACUC Staff Seminar entitled "Physical Plant Issues". My name is Jerry Collins and, along with Susan Silk, the Director of the Division of Policy and Education in the Office of Laboratory Animal Welfare, I will be moderating today's seminar. In addition to this seminar for IACUC Staff, OLAW also offers a seminar for Institutional Officials. We encourage you to invite your Institutional Official to join us for that seminar series. Registration information is available on the OLAW webpage at OLAW.nih.gov.

Our audience has grown considerably since the first of these seminars was presented in June of 2008. More than 400 institutions have registered to participate in today's seminars. We are encouraged by the feedback that we have received from you and encourage you – and continue to encourage you – the participants to tell your colleagues about this opportunity to enhance their understanding of the challenges associated with maintaining a well-functioning animal program. We record the IACUC Staff Seminars and make the recording available to everyone on the OLAW website in the education

section. If you have to miss a seminar, or if another time is more convenient for you, you can listen to the recorded version. We will post today's recording as soon as we are able. We will also post a transcript of the seminar and a PDF version of the slides. You'll have to wait several weeks for that, though, since it takes some time for us to prepare the transcript. When we upload the recorded seminar, the slides and the transcript, we also provide a place for you to submit questions. That way if you are listening to it at another time, or if you think of questions after listening to the live broadcast, you may still submit those questions. For today's topic, the website will collect questions until June 7, of 2010. OLAW staff will then work with Dr. Banks to answer those additional questions. And an edited document containing both questions and answers will be uploaded to the OLAW website. So even if you watch the recorded version of the seminar, there will be a way for you to ask questions about the topic. Your active participation really enhances this seminar and we appreciate your questions. Throughout the seminar, if you have a question for the speaker, we encourage you to type the question into the 'submit a question' box in the upper left corner of the screen. Only OLAW staff will see what you have written. We will address as many questions as we are able in the time available.

Today's speaker is Dr. Ron Banks. When we asked Dr. Banks for a brief bio, he suggested we simply introduce him as "Bubba." Although that was tempting, we thought it might be interesting for you to – at least – have some information about his many accomplishments. Dr. Banks serves as Director of the Office of Animal Welfare Assurance at Duke University, Durham, North Carolina. He is board certified with the American College of Veterinary Preventive Medicine and the American College of Laboratory Animal Medicine. He has served as a member of the Council on Accreditation of the Association for the Assessment and Accreditation of Laboratory Animal Care, International, AAALAC, for the last ten years. And has presented on the topic of facility design and management at several architect and engineering conferences. Dr. Banks has over 25 years of experience in federal, state and

private academic and pharmaceutical applications of animal care and use. In today's webinar, he will focus on the animal care facility and how it serves as the foundation for quality research outcomes. He will also outline the importance of a strong institutional inspection and correction process. This presentation will include many of his personal experiences as well as institutional challenges with building a foundation for experimental success using a biologic system.

We're using some new technology today in an effort to improve the sound quality. Ron will be participating from his office at Duke, while Susan and I broadcast from the OLAW offices here in Bethesda. Ron, would you please regale us with information about **Physical Plant Issues**.

Thank you Jerry, and welcome to all who are attending the webinar today. Indeed, it's exciting to be part of this new technology. Who ever would have thought? But, it is our privilege today, and mine indeed, to present on this particular topic, the most basic of all research support issues, that being the provision of appropriate and necessary husbandry and care parameters. During our discussion today, we will be referencing AAALAC International. AAALAC is the Association for the Assessment and Accreditation of Laboratory Animal Care, International. AAALAC is a not-for-profit, non-governmental independent body of assessors who validate, based on a minimum set of standards. PHS Policy does not mandate AAALAC accreditation, but PHS does recognize the value of accreditation to its Assured institutions. That bit of accreditation advertisement being said, my purpose for referencing AAALAC today is because we'll be using some of AAALAC's robust data set on institutional review outcomes as a means to define some of the more common problems in physical plant assessment. We should recognize, however, that AAALAC's data is reflective only of those roughly 750 accredited institutions which are either seeking or maintaining accreditation rather than the several thousand of institutions which use animals in research, testing and teaching. In other words, the data set I'll be

referencing is biased toward institutions who are seeking accreditation and not to the global animal care community.

Slide 2 (Topics To Be Covered)
In our discussion today, we're going to be looking at requirements versus guidelines. Requirements being regulations and policy and guidelines being best practices or good ideas. My comments are based upon an assumption that our outcome expectations are for strong and reliable research data gathered from animals which are managed in a humane and progressive environment and which do not experience unnecessary pain or distress. These caveats, though, are not simply the basis for my discussion, but are also the expectations of our host this day, OLAW, for all federally funded research [Although OLAW would prefer that all animals used in federally funded research are managed in a humane and progressive environment free from unnecessary pain and distress, OLAW's oversight authority extends only to live vertebrate animals used in PHS-funded activities].

A second target point will be to look at the goals of a desirable physical plant, in other words, what sort of vivarium infrastructure provides the most reliable research data outcomes? And as IACUC members and IACUC organizations, how can we identify where we may be falling short and improve our assessment and management of our programmatic issues. Thirdly, we'll consider the AAALAC site visit data from 2003 to 2008 and review Councils Mandatory Citations and Suggestions For Improvement (SFI) in the area of physical plant. Using the AAALAC data set, we'll focus on three of the issues and try to provide a bit more discussion on how we can best meet the needs and the requirements of these specific kinds of things. While, I will not spend any appreciable time on the resource list, it is included at the end of this presentation, which as Jerry noted, you'll be able to download from the OLAW website sometime after today's presentation. Let me note that the resources are not intended to be all-inclusive, indeed there are many others in addition to those that we'll provide with this presentation. Nor

should the resources be considered an endorsement either of [by] AAALAC or OLAW. But they can provide a starting point for the discussion of physical plant issues – what is important and how can we address them in our institution.

Slide 3 (Requirements vs. Guidelines)
Physical plant discussion is really no different than any other aspect of life. There are requirements and there are also guidelines. A requirement is a rule, a regulation or law. As an example, if we were to travel down a local highway, and the requirement was that we not exceed a limit of 45 miles per hour on a particular section of road, we should follow that requirement. Failure to do so may result in serious vehicle damage or personal injury, or a fine, or a citation, all of which may also be associated with corrective measures from the local constabulary. A guideline, on the other hand, is a roadmap toward a successful outcome which you are not required to perform in a specified manner. But it would be wise to take heed and consider the counsel of those who have gone before and have found solutions to what are, generally, common problems. For example, on that same road during wintery weather, the caution sign may encourage we drive more slowly due to the potential of freezing precipitation on the highway. The requirement is restrictive, but this guideline is really just a good thing to do. It will require us to use interpretation and also some degree of individual decision-making as we travel along this journey. And hopefully we will have safe passage.

In animal care activities, we have certain documents which are requirements that, in other words, do not transgress and other documents which are guidelines or preferred approaches or may be wise counsel to building successful physical plants. PHS Policy, the 9CFR, also known as the USDA Regulations, maybe the BMBL are examples of very definitive instructional – ah – information in these kinds of areas. Let me note that while PHS Policy is instructive, it also provides a significant degree of latitude for institutions needing to accomplish specific tasks. We often speak of the ASHRAE

standards as being requirements for ventilation within animal care and use facilities. The ASHRAE standards were designed to meet requirements of OSHA and they have been generally accepted within the animal community. We refer to 10 to 15 air changes as being the basis for ventilation in animal care areas but sometimes the standard might be counterproductive and even injurious to progressive or humane animal care and use activities. The Animal Care and Use Committee needs to be addressing these standards, apply them where applicable and, where not appropriate, provide exemptions to those standards in the best interest of the animals and also in the positive outcomes of the research. The focus needs to always be at the nose of the animal, that is the microenvironment and not what some book says we ought to do placed on some sensor in a duct in another part of the facility. The *Guide*, the document on the upper left – the green – that we're quite familiar with this, is a core expectation of PHS Policy, of AAALAC International and of many other funding agencies. The *Guide* on the screen is the *Guide for the Care and Use of Laboratory Animals*, but there are other guides which might also be employed at specific times and for specific purposes. For example, the guide for agricultural animals in agricultural research, or the guidelines for amphibians and reptiles, or maybe the guidelines for fish in research.

Slide 4 (Goals of the Physical Plant)

Features of an effective physical plant are those that are listed on the screen – seven highlights, if you will. Let's briefly run through these and look at each momentarily. A successful and effective physical plant is one that is environmentally stable. We recognize that animals are biologic systems and they can be affected by changes in their environment. Maintaining air temperature, acceptable humidity, low ammonia levels – if we're talking mammals – or a stable water condition if we're talking aquatics – are critical to the survival of the [facility] animals and important to the positive outcome of the research data. Variation in environmental stability will affect physiology. It can affect [agent] metabolism. It most assuredly will affect [heating rates], response times and, without a doubt, animal well being.

Flexibility is another component that is commonly seen in successful facilities. It is the ability for the facility to serve whatever species comes across its doorstep. Were we able to prognosticate what our researchers would be doing in six months, maybe none of us would be doing animal care activities. We'd be making lots more money doing other things. But we can't, and so then we respond to the needs of the researcher. Sometimes those needs are mice, other times those needs are – other species – rabbits, or avian, or aquatics and each have different specific needs. Which leads us, then, into accommodation. The selection of research species is often based trying to define and answer a specific model. The preferred physical plant will accommodate the needs of mice where the lights should be dim and the sounds should be soft and pheromones should be present. So we're really talking lower ventilation rates for rodents. When compared to other species like swine, where we want brighter lighting, we need plenty of enrichment devices, generally cooler temperatures for the larger animals, sound insulation because they make noise and higher ventilation rates to eliminate some of the waste products in the area.

An additional component of a successful facility is one that is research supportive. Our researchers continue to use larger and more significant-sized specialized procedures and equipment. And transporting those animals from the vivaria across campus through the weather, whether it is warm or cold, can – indeed – impart transport stress, which is a documented phenomenon and can affect research outcomes. The preferred physical plant will provide research space integral to the vivarium envelope and eliminate as much transport as possible to extra vivarium locations. The animal facility should also be ergonomically sound. It isn't news to anyone on this webinar that staff who work in the vivaria are highly skilled individuals in whom we've invested many years and several thousands of dollars. We need to keep these folks working well. It needs to be occupationally safe, which means it needs to prevent injuries to the extent possible within our staff. The best approach toward an occupationally safe facility is to build it and operate it in

a manner in which we engage ergonomic devices and we employ people-protective practices. And lastly, it needs to be disaster preventative. It is not a matter of IF we will have a disaster, it is a matter of WHEN that disaster occurs, how will we best correct the situation and return our institution to a stance where it is once again stable and functional. In some cases the answer may be frozen embryos offsite. In other cases it might be back-up energy sources, or even sister institutions where alternate housing could occur. And let's not forget that not all disasters are natural in form, they may also be personal – when staff become ill or cannot work. Recent discussions of swine flu [H1N1 influenza] have initiated several reviews at many institutions where we have broadened our horizons and looked not just at animal care but also at IACUC performance. Has our committed considered how we will function in an environment when members of the committee cannot come to the institution or may not be able to do the oversight responsibilities?

Slide 5 (AAALAC Mandatories (2003-2008): Actual Numbers)
Let's look for a moment at some of the data I spoke of earlier. The first chart shows us the years 2003 to 2008. These are actual numbers of citations or deficiencies noted by AAALAC site team visitors. These are citations or deficiencies that upon Council's review were determined to be mandatory in nature. Mandatory, in AAALAC-speak, is a concern which has the very real potential of affecting welfare, well being and safety of either humans or animals. So, the chart tells us – the news is good. From 2003 to 2008, we've had less of these sorts of insults, and therefore, things must be getting better.

Slide 6 (AAALAC Mandatories (2003-2008): Relative %)
But let's look at the relative consistency of each of the particular findings. And what we see is during this same period of time, the instances and seriousness of deficiencies associated with HVAC have actually increased. We have more concern with HVAC than we did in years past.

Slide 7 (AAALAC Suggestions (2003-2008): Actual Numbers)
We have a similar sort of presentation when we look at suggestions. Now in AAALAC-speak, a suggestion is something that is not presently affecting the welfare, well being or safety of animals or humans, but it has the potential to do so and other facilities have found ways to solve this particular issue.

Slide 8 (AAALAC Suggestions (2003-2008): Relative %)
Once again from 2003 to 2008, actual numbers have decreased. However, the relative percentages of concern have focused, once again, on the HVAC, the heating, ventilating and air conditioning. So much so that in the last year on this chart, 2008, three quarters of all observations involving physical plant related to HVAC issues.

Slide 9 (AAALAC Conclusions (Physical Plant))
Considering what those specific issues – excuse me – before we get to that point – from that chart we have – then – this list, the order of most common facility deficiencies were HVAC followed by construction guidelines, and then also functional areas.

Slide 10 (HVAC (Heating, Ventilation & Air Conditioning))
Now, considering what the order of specific issues were within the HVAC concern, we have the list on the screen. The first of which being the HVAC was incapable of maintaining temperature ranges according to *Guide* recommendations. We are all quite familiar with the chart on page 32 of the *Guide* and I'm sure you've got yours very handy, and probably open at this moment. And you will recall it reports the charted ranges for recommendations for specific and common research species. Previously specified temperature and humidity ranges can be modified to meet special animal needs and circumstances in which all or most of the facility might be designed exclusively for acclimated species having similar requirements. We do recognize that brief and infrequent moderate fluctuations in temperature

or humidity outside of those suggested ranges may be well tolerated by most species which are commonly used in research. But when extremes in external ambient conditions – some of which we've had these last few months of winter, or may have during the coming summer – when those extremes extend our designed specifications – we've got to have provisions in place which minimize the magnitude and duration of the fluctuation of temperature and humidity outside of the recommended ranges in the animal facility. These are discussions and situations in which the animal care committee plays an important and integral role. What are the ranges that are acceptable and what kind of alternative or supportive mechanisms can we provide to assure our animals stay healthy and our research stay secure?

A second major area of concern is with relative pressure differentials. That is to say air flow due to higher pressure and lower pressure areas. While not the sole solution for prevention of contamination or disease transmission, the use of direct air pressures in the vivarium serves a critical role in assuring appropriate environment and being the foundation for positive research outcomes. For example, for animals in quarantine or animals exposed to hazardous materials or non-human primates – these species and conditions should be generally kept under negative pressure. Whereas, surgery or clean equipment storage or maybe housing for pathogen-free animals should be kept under relative positive pressure with somewhat more clean air. I noted previously, and I comment again, we should not totally rely upon maintaining air pressure differentials as the only method to prevent cross contamination. But without it, we have little hope. A third important AAALAC observation during this period were institutions that had no clue of HVAC performance. In other words, performance data was not provided or was not complete. This is exceedingly troubling. Many journals, these days, are asking for conditions of animal care or use. The institution, indeed the IACUC, should be confident that any time during any day or hour of the year the animals in the institution are being held within a set confine of rigor for HVAC performance.

Without doing those assessments, how does one know whether you are living within that predetermined set?

Slide 11 (HVAC (Heating, Ventilation & Air Conditioning))
The goal of the HVAC in the physical plant is really very simple – to provide a consistent environment. And the assessment, as I just noted, is a critical component of assuring you can provide the consistent environment. The extent of environmental control we based on many requirements most of which should be related to the animals, either provision of oxygen or evacuation of heat or elimination of waste products which are produced by the animals. If we plan facilities for the needs of the beast and include a capacity for these extreme days that I spoke of earlier, then, indeed, we can assure consistent and stable environment for research animals.

A secondary goal of HVAC is to control odors, allergens, particulates and metabolically generated gasses. Of these agents, allergens are probably the most problematic for people. As reports have as high as 40% of individuals working with specific common species for periods of ten years or longer developing allergies – medically significant allergies – to those species. This is most concerning when we're interested in career investment of our staff and we spend significant amounts of time and money in their education to allow them to become injured by allergens in the air, which could be controlled with effective ventilation and HVAC. For effective and reliable research outcomes, controlling metabolic generated gases, whether we're talking ammonia for mammal species, or nitrates in the aquatic species, should also be of critical concern to the IACUC. It is well recognized that higher levels of metabolic gases produce a variety of biologic functions, such as immune depression, depressed reproductive performance, base physiology changes. And that's not even to mention the humane issues or welfare issues that can come with living in a stressed environment as that.

Slide 12 (HVAC (Heating, Ventilation & Air Conditioning))

According to the *Guide*, a system should be capable of adjusting dry bulb temperatures within a one degree centigrade or two degree Fahrenheit range. This can be significantly challenging for many facilities. And some of the reasons are of our own doing. Many of our facilities have used a zonal control pattern of measuring and adjusting multiple rooms with a single master control either in an animal room or in an exhaust duct coming from that room or a supply duct going to it. In theory as long as all rooms are being managed within that same context, it tends to work fairly well. But when we change densities and put large numbers of racks in one space and not quite so many in the other, or additional equipment in one space and not quite so much in the other, it becomes much more difficult to maintain the types of tolerances that are necessary for quality animal care. Remember, committee members, just because you can stick ten more racks in the room, it doesn't mean it's the right thing to do. Without effective HVAC, you may be damaging the research outcomes of your scientists. The use of species having special needs must also be considered when we talk about temperature requirements. Hairless animals require temperatures slightly warmer than do those who are haired. And neonates require temperatures slightly warmer than the adults. Rabbits and chickens, on the other hand, tend to perform better at slightly cooler temperatures. Certain aquatics in nature are tropical and others prefer the cool waters as would be found in deep flowing streams or rivers.

Slide 13 (HVAC (Heating, Ventilation & Air Conditioning))

There are also considerations to make when reviewing resource needs at the institution. Rodents housed in static or closed caging systems will require general room temperatures that are slightly cooler than rodents which are housed in individually ventilated racking systems where the air may be changed as much as 60 times an hour. Static rodent cages can increase their internal heat load several degrees over the room temperature, so taking a room temperature measurement may indeed not tell you the conditions at the microenvironment – at the nose of the animal – where our principle

concerns should be. We must recall that these little mice in the nice little cages are very exciting little thermonuclear fusion devices creating a large amount of heat for the small volume that they're living within. Therefore large numbers of rodent cages in any room like this can shift an otherwise nominal energy requirement in a given room to something overwhelming for the HVAC. I'm being repetitive, I know, but you just can't pack rodents in the rooms just because you have space in the room where cages can fit. Indeed, animal census must match the rooms HVAC capacity.

Cage change frequency is another important consideration that needs to be reviewed when the committee makes its visits to the facility. More frequent changes are generally required in warmer rooms due to such things as urine production or aerosolization of ammonia. Bedding type also plays into this discussion of frequency of cage changing and HVAC control. Hardwood bedding, the most common bedding in most areas of the country, is less absorbent than corncob bedding or some of the paper products. But if presented to ventilated air, hardwood bedding will tend to dry out more rapidly than those other products and will tend to support less mold or less bacterial formation. The choice of bedding in the facility but be considered when defining the HVAC requirements or looking at potential room capacities.

Slide 14 (HVAC (Heating, Ventilation & Air Conditioning))
The *Guide* recommends 30 to 70 percent humidity in animal rooms and many have often asked the question "Why worry about humidity?" Well, as the chart on the screen shows – in fact we'd even zeroed this in to the 40 to 60 percent range – if we can keep the humidity somewhere near the center of the spectrum, we have less risk of developing disease, either from bacteria, viruses, fungi, mites or etc., along the way. In some parts of the country, that may mean dehumidification as is the case in North Carolina. In other parts of the country, it may mean humidification, as might be the case in the Midwest or a higher plains area. And in many parts, it may mean both dehumidification and humidification during any 24-hour period. And,

therefore, managing the facility becomes exceedingly expensive.

Slide 15 (HVAC (Heating, Ventilation & Air Conditioning))
Ventilation is another important component to talk about, indeed is the V in HVAC. According to the *Guide*, the purposes of ventilation are to supply oxygen, remove thermal loads caused by animal respiration, lights and equipment, dilute gaseous and particulate contaminants and adjust the moisture content in room air and, when appropriate, create static pressure differentials between adjoining rooms. However, establishing a room ventilation rate does not ensure the adequacy of ventilation at the animal's primary enclosure. It does not guarantee the quality of the microenvironment. This may be a new term for some in our webinar today, so let me briefly define. Microenvironment means in the simplest of terms "the nose of the animal." Our concern should not so much be what's going on in the room but what's going on in front of the animal. Is it the kind of environment necessary to maintain it, to keep it in a proper environment, growing and producing as it should? Static microisolator cages tend to have higher levels of metabolic gasses and humidity than observed in the room level. So committee, when you're walking through the room and looking, the room itself may look fine, but we need to also observe the cage and the condition of the cage and, indeed, lift the lid of the cage to consider how humid the cage may be or what level of ammonia may be occurring in that location. You can often see animals that start to sleep more frequently and more extendedly when, or if, ammonia levels get high in those cages.

Slide 16 (HVAC)
I included this chart for our discussion today to show a comparison, if you will, between the human environment and what we have in the animal facility. Let's begin with the chart on the left, typical air changes per hour in office areas. Most business offices it has recorded six to eight as being air changes per hour. I don't know if I've ever worked in an office with six air changes but that's just where I've worked. The important thing on this chart

though might be to look down at such things as a smoking area, a computer room, maybe even a copy room. In these environments, the copy room airborne particulates and chemicals need to be removed from the human space, the computer room due to the large quantities of heat buildup and the smoking area due to particulate matter in the air. While our animals don't copy papers and they don't use computers and very few of them smoke. It is still the same kinds of contexts that we want to remove from the animal spaces and therefore why 10 to 15 was originally chosen. The chart on the left shows us how effective we can be at that process. A hundred particles per cubic foot is what we're going to start with. With one air change per hour, we can eliminate those from the space in a little over four hours – with two air changes, somewhere around two hours. Whereas with four air changes, around one – eight air changes in 30 minutes and 10 to 15 can be eliminated from the room in just about that many minutes.

Slide 17 (HVAC (Heating, Ventilation & Air Conditioning))
So – our desires to develop a stable HVAC, we recognize as depend upon several factors. What are these factors and how can we as committee members review them as we wander through? Well one of the factors is room dimension. Smaller rooms will tend to feel breezier than large rooms, and if the animals are in shoebox cages, that may not be a problem – probably is not – but if the animals are open and exposed to the room, then indeed it might have a comfort index that needs to be considered. What are the room requirements? Surgery should be positive, quarantine ought to be negative. Rodents might be positive or negative, depending upon the animal's personal health status or its relationship to other locations within the facility. Heat loads. How many animals do we have within the space? What species are there? Are there other equipment in the space, which also creates heat that needs to be changed?

Slide 18 (HVAC (Heating, Ventilation & Air Conditioning))

Bedding type? Hardwood bedding dries faster that paper or corncob products. Do we need to have changes in airflow or ventilation to accommodate either one of these bedding options? Cage change frequency. Many institutions are going to extended cycles, trying to save on labor costs, and indeed, we can do that by changing cages four or five days less frequently than we used to. But there may be increases in the humidity and ammonia levels that might be important to the well being of the animal and to the stability of the research outcome. Efficiency of air distribution. The IVCs – the individually vented cages – get air to the microenvironment, that's their principle design feature and they do it quite effectively. But is that what we're trying to do or is it too effective? In other words, do we have nude animals or neonatal animals where provision of air directly to them might actually be counterproductive or counter intuitive. Air filtration requirements. Do you want clean air in the surgery or are you trying to keep dirty air in a containment location? And monitoring frequency. At what frequency should we require that the facility be assessed? Is just before AAALAC comes sufficient? Ron's opinion: "No, it isn't." Is annually required? "I don't know. It might be a good choice for you." Do you have problematic spaces which are responsive to ambient air changes? If so, maybe every six months, or even more frequently, might be the better choice. The important issue here is that HVAC is a performance standard. I cannot tell you during our discussion today what the correct HVAC for your facility might be. Such a decision requires consideration of various factors including input from various experts, not the least of which are the animals themselves, to determine what is best for their environment and also to support positive outcomes of the research and the research operations.

Slide 19 (AAALAC Conclusions (Physical Plant))
Let's now go to the second item on the list of three we promised to talk about, and that is construction guidelines.

Slide 20 (Construction Guidelines)

We'll begin construction guidelines by also considering the frequency order of specific issues based upon that AAALAC data from 2003 to 2008. Of those items observed by the site team, floors, walls and ceilings being in disrepair or not sanitizable were most common. Second on the list was the failure to use moisture-proof electrical outlets or ground fault interrupters – the GFCI outlets – in an area where there was high water use. Inappropriate storage of cages or equipment outside or on the floor or in corridors or in animal rooms was the third most frequent thing observed by the site teams.

Slide 21 (Construction Guidelines)

Let's begin first with floors. Floor finishes must – not necessarily must – but will vary due to the intended use of the area for areas with high cleaning requirements and high traffic from rolling carts or racks. A more durable finish such as epoxy resin or methylmethacrylate, more commonly known as MMA, might be indicated. In areas where less stringent cleaning and softer equipment might be present, the use of a seamless sheet product, such as a vinyl, could be appropriate. Like in all issues there are advantages and disadvantages of each product and unfortunately our discussion today doesn't give us the opportunity to discuss these. From the committee's prospective, as you look at the environment and these spaces, you might consider long-term projections. And make recommendation to the Institutional Official that over some period of time, these floors are going to fail because of the way in which it's being used. And the institution should, therefore, consider programming the replacement of these floors at some IACUC-defined point. Floors should also be moisture-resistant and relatively smooth. In high moisture areas, floors should have adequate texture to prevent slipping. In all areas where water may be present, floors should slope to the drain. It may seem exceedingly silly, but the single most important labor saving thing any new construction or innovation project can do is to assure that the floors slope to the drain. How many places have we all seen where staff spend half a day chasing water into a drain that's at a higher level than the rest of the floor? Obviously that's not a good

environment to try to maintain. Floors must also be monolithic, in other words have one surface. If they do have joints, they should be minimal. And if they do have joints, they should be effectively sealed. And where possible, place those joints parallel to the flow of the water so that we're not chasing water across the joints, but it's flowing down in the same direction in the joint to the drain. Floors should be nonabsorbent. That's obvious. We don't want contamination that falls on the floor to stay there forever. Floors should be impact-resistant. Heavy items falling on the floor and chipping the surface will interfere with continued effective sanitization of that surface. And it will increase the chance that the floor will also delaminate and fail within the near future. As committees make visits to animal areas, when you find floors that are damaged, the strong encouragement would be to make that floor contiguous as quickly as you can. That does not mean pulling up and replacing the entire floor, but it means using a product that would seal that area. Some institutions use heavy-duty garage paint to cover the damaged area so that water will flow contiguously across the surface and will not migrate underneath at the damaged location. Floors must also be service resistant, that is to say when they are wet, they can't be slippery. They should resist cleaning agents and also biologic agents.

Slide 22 (Construction Guidelines)

We should also look at walls and wall surfaces. Wall finishes also vary due to the intended use of the area. For areas where high cleaning requirements and high traffic from rolling carts are present, a more durable finish on the walls would be indicated. Things such as an epoxy resin or methylmethacrylate, the MMA-type procedures. Consider, as well, wall guards or wall protection systems. While there may be an initial cost to the institution, they certainly protect the wall surfaces and will extend the serviceability of wall surfaces much farther than when they are not there. In areas where less stringent cleaning is appropriate a seamless sheet vinyl product or maybe FRP – fiberglass reinforced plastic – might be a good choice. Like all the other options, there are advantages and disadvantages

and our time today doesn't allow that discussion. But whatever option is chosen, the walls must be moisture-resistant and should be relatively smooth. They, once again, should be monolithic and when joints are necessary, should be minimal and effectively sealed using acrylic caulking as much as is necessary to assure that they are contiguous from space to space. Walls should be nonabsorbent and also service resistant. And when floor materials and wall materials meet, we would like to have floor materials cover the bottom of wall materials so that we have a seamless junction and liquid on the wall can flow very seamlessly onto the floor.

Slide 23 (Construction Guidelines)

Let's turn our attention for just a moment onto ceilings. Ceilings also may vary due to intended use of the area. For areas where there are high cleaning requirements more durable finishes and a solid ceiling might be the preferred choice, as an epoxy resin. In areas where there are less stringent cleaning, a suspended ceiling using plastic or some sort of vinyl ceiling panel might indeed be appropriate. If a suspended ceiling is in place, it needs to be a sanitizable, washable surface. And if the ceiling has fiberboard, these need to be programmed for replacement over some period of time, since fiberboard is not sanitizable and indeed is quite absorbent and will hold on to contamination for long periods of time, putting the research and the researchers at risk. I'll tell you, while not the best option, many older facilities may have open ceilings consisting of exposed ductwork and also conduits across the open space. The arrangement might not be the best choice but it can serve very effectively, particularly if there is a regular cleaning rotation that has been established. I don't know what that rotation might be; it's going to depend upon the facility, the amount of ductwork and what's going on in the space. But there is a trade-off. If a hard ceiling can be put in place, or a suspended ceiling to separate the ductwork from the space below, then you've eliminated a significant cost in labor. If not, then you won't be able to save those moneys and you will indeed need to improve the maintenance of the facility.

Slide 24 (Construction Guidelines)
Other issues include the electrical system and storage. The electrical system we've mentioned briefly before. I won't spend a lot of time today at this point, but indeed, if we have electrical conduits, they need to be moisture resistant and ground fault interrupters where noise is present. There should be adequate storage for equipment, supplies, food and waste. And that waste needs to be in a cooled area separate from other kinds of storage applications.

Slide 25 (AAALAC Conclusions (Physical Plant))
We'll turn our attention now to the last item, that being the functional areas – facilities for aseptic surgery – we'll look at three particular components, these being: non-rodent mammalian, rodent and lastly aquatic.

Slide 26 (Functional Areas (Aseptic Surgery))
For most surgical programs, functional components of aseptic surgery include the five things that are listed here and described within the *Guide*. Surgical support areas should be designed for washing and sterilizing of instruments and for proper storage of instruments. There should also be animal preparation space which is separate from surgeon preparation space, both of which connect into the operatory room which, again, is highly sanitizable, and in an area of low traffic and low traffic use. Postoperative area or a support area will be necessary for preparation of the patient post procedure and for recovery from the surgical application. I'm sorry folks, I'm one slide off. I should have gone here.

Slide 27 (Functional Areas (Aseptic Surgery))

Slide 28 (Functional Areas (Aseptic Surgery))
Let me go on then to the next one on the list – a dedicated facility for this particular species arrangement is indeed appropriate. We need to have

spaces that minimize contamination through minimal traffic, in the cleanest part of the facility, and to the extent possible utilizing positive pressure air. Monolithic surfaces are very important in this space. And the application of gas use for anesthesia purposes requires some scavenging of things in these locations.

Slide 29 (Functional Areas (Aseptic Surgery))
Rodent survival surgery does not require a dedicated space. It only requires a space where the area is clean. Indeed sterile would be preferred, but that's just not possible in all cases within a research infrastructure. Positive relative pressure is a desirable so we can be providing clean air across the space where surgery is being performed and sanitizable surfaces are indeed important. Gas scavenging will be necessary if gas anesthesia is being used and serial procedures are possible through the use of autoclaved instruments initially and gas bead sterilizer use for subsequent procedures.

Slide 30 (Functional Areas (Aseptic Surgery))
The last of the three functional areas is that of aquatic survival surgery. Dedicated space, just like rodents, is not required. Although the area should be clean and surfaces should be sanitizable. A difference from the aquatic species compared to the mammalian species is that we generally do not disinfect the skin surface of aquatics due to the antiseptic nature of the slime associated with most aquatic species. Water support though for the patient is quite critical as opposed to air support for the mammalian components. GFCI circuits are important because we're using water in part to support the patient, maintain its oxygen delivery and also to keep it moist during the procedure period. Indeed, serial procedures may be possible through autoclaving instruments initially and using some sort of sterilization process such as glass bead sterilizers for subsequent procedures.

Slide 31 (Guide to Animal Facility Inspections)

A component that may the IACUC might consider as a very exciting tool for preparing itself for facility inspections is this one listed on the screen. It is housed at the Office of Research Integrity and it is a walk through of a research facility. You can see many buttons on this screen where we can click on one of those buttons; we're actually going to click on number eight which happens to not be on that screen.

Slide 32 (Guide to Animal Facility Inspections)
We then get a second page and it describes for us various kinds of things that are important during an IACUC inspection of those facility areas. IACUCs might consider either this tool or others to refresh themselves because members very frequently do not spend their time inspecting facilities and might indeed not be up to date on the kinds of things to look at when visiting the next facility when an inspection is necessary.

Slide 33-40 (Resources & References)
We've included a number of reference resources, I'm not going to take time to go through these, they will be in the presentation in which you can download and indeed, none are specifically endorsed but they are provided to give you a sense that there are resources available whether we're talking about facility design or even facility operation on any of the items that were mentioned in today's discussion.

Slide 41 (End Slide)
Let me conclude by noting that the value of the physical plant is found not in the paneled atrium but rather in the painted animal rooms. It is the infrastructure from which successful research begins. Even more critical, the physical plant is the basis for humane and species specific care without which the ethical basis of animal care and use certainly must be questioned. No other single aspect of the animal enterprise has the ability to foster success or precipitate failure and reflect upon the good name of the institution than the physical plant. What is both insidious and also discouraging is that poor

physical plants may impact sub acute variability to research data outcome and in doing so waste time and resources and delay discovery of important human and animal healthcare issues. The importance of the physical plant does not face the street colleagues but rather the noses of the animals that are used in research and testing and also teaching. Jerry let me turn this back over to you, sir.

Why thank you, Ron, thank you for you sharing of an awful lot of wisdom in a short period of time with us. We do have some questions, both those that came in earlier and a few that are coming in now. Let me start with one that fairly long: **The Guide (page 74) states "Floors should be moisture-resistant, nonabsorbent, impact-resistant, and relatively smooth without becoming gouged, cracked or pitted." Obviously a floor surface that has deteriorated to the texture of an English muffin is not acceptable, but by the same token, it is very difficult to have or maintain tens or hundreds of thousands of square feet of flawless floor surface in animal research facilities. Some persons also might argue that pits and gouges, providing that they are grime-free, might be more sanitary than the flat floor surface given the longer contact time of disinfectant pooled in the defects. Does OLAW/NIH expect Assured institutions to fill every pit and gouge or resurface defective floors? If not, what is the threshold of pits and gouges, by size and frequency (e.g., per square foot), that once exceeded would require a floor to be refinished? If engineering standards are insufficient for addressing this question, what performance standards must be met?** A lot of questions there, Ron, I think, perhaps you will be able to consolidate that into some general concepts that will be helpful for listeners.

Yeah, I think so and where we're talking in the early 1990's, a discussion of engineering standards might, indeed, be foremost in our review. But this is not then, its now, and our attention and focus should be towards the performance criteria. In a performance context, if there is a dimple or dent in

the floor or even a fairly decent hole in the floor as long as it is sanitisable, there really is not a significant issue for our concern. Now let me go on, first to say that I'm not a member of OLAW and cannot speak on their behalf but I do believe that OLAW's focus would be the same as the AAALAC's focus – which would be the same as your IACUC's focus – and that if the floor is sanitizable, in other words, if we can wash and remove from it organic debris then whether it's perfectly smooth, whether it's brand new, or whether it's 40 years old with the wear that comes on a 40 year old floor, it really is inconsequential. The point is, keep the floors where they can – where people can work on them safely – keep them where they are sanitizable, keep them where they're contiguous and to the extent possible monolithic and you'll do just fine.

Ron, OLAW agrees with you.
That's always good to know, thank you.
[smile] That's not a blanket statement, that's just for this one.

We have another question here: **We're having a problem with water temperature. Which, according to the mechanical sensor, says 180 degrees, but the temperature tapes never seems to record 180 degrees. What are we doing wrong?** Probably not doing anything wrong, what we need to realize is that mechanical sensor recording devices are generally kept in the sump tank or the storage tank for the water in the cage washing unit. So, very well, we may have 180 degree water in that bulk storage unit so now we're going to take that water and drive it through a series of pumps, through a series of pipes, through a series of spray heads and put it on to animal equipment that has been room temperature, 70 something degrees, when it was placed inside of the rack washer. Obviously, the water temperature is going to cool down a little bit in that context. The temperature tapes, and the other kinds of systems that we use to monitor temperature, monitor the temperature of the piece of equipment that is being washed and does not monitor the temperature in the sump tank where

the mechanical sensor is occurring. What can we do to make this problem go away? Well, first of all, if it's a rack system, a washing system that uses a belt, slow down the belt speed. We allow the equipment to stay in the presence of the hot water for longer periods of time. Clearly, that's going to have a through put question that must also be addressed. But it will allow the temperature to come up to the required 180 degrees. Something else we might consider doing if it's a cabinet based washer is to extend the wash cycle. Remember also that the 180 degree temperature indication is what we need at one point during the entire sanitation cycle. It is not required on every aspect, in other words not washing and rinsing. What most institutions will do is try to achieve 180 degrees during the rinse cycle and do that once, and then everything else is just fine and works quite well.

We have another question about temperature: **How important is monitoring temperature inside cages on IVC racks?**
Help me with this, **are we talking while the animals are in them or are we still talking sanitation?** I think they mean while the animals are in the cages – at the nose, Ron.
Okay. In an IVC system, most of them work at either 45 or 60 air changes per hour which means you're not going to get a significant temperature deviation within that cage because of the amount of ventilation that is occurring in the cage. A good place to monitor cage temperature would either be the supply air going directly into the ventilated rack or the exhaust air coming directly from the ventilated rack. Of those two, the exhaust air would be the preferred mechanism. There are test cages that all our vendors sell which we can put on racks to evaluate conditions within that specific cage, but very honestly, with the ventilation going through IVC systems, if we have a steady temperature being provided to the rack, it's not going to be appreciably changed from the temperature that would be recorded inside the individual cage at the nose of the mouse.

Ron, on the next question, it takes us away from the nose a bit. **Is the use of min/max thermometers and the daily recording of the min and max temperatures within the last 24 hours an adequate level of monitoring?** Assuming this is the room level as opposed to the cage level. The answer here is going to be yes and no. The yes part of the answer is, if you have a history of stable temperatures and stable humidities within that space and you're using the min/max just to assure you, give you a second level of confidence that the mechanical systems are working and nothing untoward happened and, often, the reporting system is somewhere far away on campus, so it's an immediate reading of what occurred in the last 24 hours, then it's probably just fine. But if you're dealing with a facility that has a history of deviations in temperature, whether due to an aging physical plant in terms of HVAC support, whether it's due to environmental extremes, whatever the cause, that min/max thermometer is not going to tell you when things are happening and how quickly they are happening. Remember, our animals can adjust to changes in their environment but especially when those changes are fairly short in time and also limited in extent. We start getting wide swings in temperature, our animals become stressed very quickly and research will be affected even before the animals themselves start showing signs of clinical distress. So, in that case, Jerry, it's yes and no. It really depends upon the history of the facility and what's going on outside of the animal space.

Here's our next question, **I believe that you suggested an institution might consider keeping "really clean" rodents in an animal room with positive air pressure differentials. Does Council consider that an SFI?** There would be cases where that would be appropriate, if we have specific pathogen free, if we have immune-compromised animals and especially those held in the individually vented racks, those should be positive pressure. You want to protect the animals that are in that space. By the same token, if you have animals that have diseases, or are conventional or there's quarantine status, indeed those animals should be in a negative construct.

Historically, we've said that all animal housing ought to be negative; and if we look at that from a standpoint of allergen control or disease containment it does make good sense. But when we consider some of the unique transgenics, knockouts, and other really weird creatures we're working with these days and the health status of those animals being exceedingly clean, we can no longer use the provincial argument that everything must be negative. Some times we must make them positive to protect the integrity of those animal systems and those research outcomes. When we do that, there are other things that can also be considered. The ante room might be negative. The garb that are being worn in that area might be special garb, etc. But it's not fair any longer to simply say all rodent rooms must be negative.

And for the people who don't remember, let's define SFI in AAALAC-speak.

Sure, SFI in AAALAC-speak means it's a good idea, it is a suggestion, some have used the term best practice, that probably a bit of an overreach, it is something that others have found successful and Council will suggest that you also take a look at, you may find successful in your institution too. Council does not require that an institution agree to an SFI, they only require that the institution consider the SFI and make a decision whether it's good, bad or just won't work in our environment.

Ron, this next question is a bit open-ended: **If holes in the wall or floors appear, how quickly should they be repaired?** How deep is the hole and where is it located, would be the other questions I would want to know, Jerry. If the hole is minimal, say a ding from a rack rolling down a corridor, it has disrupted the paint but it has not gone through the concrete underneath, then maybe it does not need to be repaired quite as quickly as one where a piece of equipment runs into sheet rock and we now have a hole protruding into the interstitial space. If we're talking a ding in a hard surface such as concrete or maybe even a minor ding into a sheet rock surface the

application of a simple enamel paint over that area, may not be the same color, might make the facility look like circus tent but – oh well. It is contiguous, it does allow for sanitation and it does prevent contamination of that area from what might be in, or maybe what might be outside of the facility. Certainly if it goes all the way through, and a hole might go through from screws being applied to hold a device on a wall, might be a damage that occurs during a procedure, if a hole goes all the way through the indeed that should be plugged because we have no clue which vermin are hiding on the other side of that wall and which vermin may want to get into our animal spaces. Don't forget when we talk about vermin intrusion, I don't know any country, any state in this country, where we don't have wild mice and rats running nearby our animal facilities and all they need is one quarter of an inch. A mouse can slip through a hole one quarter of an inch in size. If the hole is that big, it really ought to be filled up before you go home, at least put some acrylic in it to plug it out and discourage the local residents from becoming inside inhabitants.

Ron, our next question: **When designing an OR for non-human primates, should it be under positive pressure or balanced in someway to accommodate the presence of NHPs?** Yeah that becomes a little bit more tricky, we always would prefer to have positive pressure for any animal going through survival surgery but we must also recognize non-human primates are a special case for a special condition. So in a perfect world, at least in Ron's perfect world, the operatory itself would indeed be positive to provide that sterile air over the animals working in the space and the people working in that space would be in the air flow in a manner where they would not be getting downdrafts directly off of the animal in question, considering as well that the animal is covered up with no telling how many layers of surgical draping and other kinds of material. The risk of transmitting disease or contamination from the animal to the surgeons in that area is really quite, quite slim and so our attention should be on the well being of the patient. Realizing also that non-human primates are a species that,

frankly, should be held in a negative pressure area, we would like to have overall air flow in that suite or certainly within the area where animals are being managed, say the recovery area, in a negative mode to contain any of the contamination the animal might have or give off after the surgery itself has expired. So Jerry, that's a really hard question to answer because of the conditions, a species usually held in negative pressure that for the benefit of the animal should have positive pressure during the time its abdomen or its body part is open and in the surgical environment.

We're actually going to give you a brief break here because there is a question that has come in specifically for OLAW. Dr. Brent Morse is going to be answering this particular one and the question is: **What types of physical plant issues must be immediately reported to OLAW?** That's a good question and it's not unusual for us to get asked that at conferences and consultation over the phone. OLAW expects Assured institutions to report conditions within animal facilities that either put the animals or the people working in the facility at risk or those situations where an animal facility is encountering problems and cannot meet the requirements in the *Guide for the Care and Use of Laboratory Animals.* Those types of things should be reported to OLAW, we accept preliminary reports and if the IACUC determines that at a later date that the conditions actually did not exist or that they were augmented by appropriate means then that report was only preliminary and would not be kept on record at OLAW.

Brent, I assume also that you would encourage folks to give you a call if they have some questions about that so that they can better sort it out.
That is correct. We always encourage our constituents to give us a call and consult with us over the phone here at OLAW [301-496-7163].

Thank you Dr. Morse. Ron, back to you now: **What is considered an acceptable length of time for temperature and humidity to be outside**

of *Guide* standards? Minutes? Hours? Days? I'll insert weeks, months, years.

Well, what are the species we're talking about and how far out of *Guide* is it and has the IACUC been consulted and are there any solutions? Those would also be questions that should come into the same discussion. If we're talking a few degrees outside of the recommended standards and it's having zero impact upon the animals as measured by the veterinary staff using whichever objective criteria it uses and the IACUC has been brought into discussion, then maybe it's not an issue. If indeed we are seeing changes in the animal or if the researcher reports an impact upon research even two degrees outside of the recommended would not be appropriate or reasonable. If we're talking heavy furred species during the summer parts of the month, a few degrees warm could be very serious whereas several degrees cool would not be anywhere near as concerning. This is one of those very, very hard to answer questions but the encouragement I would give the questioner is that it should be a discussion by the animal care committee and it should be a consideration of the conditions that the animal is in and what conditions the animal might prefer not to be in, where it should not be, what we should protect it from. In other words, put some absolute, drop dead ranges we simply will not go there. We cannot go there and if we have to go there than the animals must be moved or potentially it might require euthanasia because we cannot allow the animal to be in an un-humane situation. This question also implies a little bit upon the issues of exemption to the *Guide,* if you will, exemptions to the standards or the policies. And indeed, the IACUC has the ability to provide those kinds of exemptions but those exemptions should be on a case by case basis, even at the protocol level. For specific and defined reasons, which are associated with the protocol and for which there is clear justification. The IACUC should not be exempting an entire institution just because the HVAC will not keep the temperature within the desirable ranges or within the spectrum which is most comfortable for the animals. In that context, it should be a presentation to the IO that we have an institutional problem that needs to be corrected and we would like to

work with you to resolve this, to establish a range that is most productive for the animals at our institution.

Ron, we're just about out of time. This will probably be the last question and I'm actually going to combine two of them in to one because they both relate to who is responsible for what. **The first one relates to the fact that regulations were established to protect animals, so why does the IACUC get involved with human safety and ergonomic issues, isn't that the responsibility of someone else at the institution?** And then the second question along those same lines: **Whose responsibility is it to verify that the HVAC systems are operating properly, facility mangers or physical plant personnel?** When we talk about animal care and use programs, we need to remember that the title says animal care and also animal use. Sometimes I think animal care committees will tend to focus on the animal use component and they do a grand job of overseeing experimentation and they do maybe not quite so stellar job on overseeing the aspects of animal care. So that being the overarching comment, animal care does include such things as HVAC assessments and I would not in this webinar, or in any other presentation want to prescribe how frequently or who should perform that assessment, but I would expect the animal care committee to assure that it is being done on a proper frequency and someone with a proper skills sets is assessing whether it is reasonable and/or it is appropriate. The other question, Jerry, the first one you brought into the issue of health and safety and, yes indeed, at many institutions there is a safety office who has the responsibility of overseeing the institutional safety. But it is also the animal care and use committee that oversees all programmatic issues which includes safety concerns. Those who might use a PHS checklist as part of their semiannual program review will remember that a section of that checklist includes issues associated with occupational health and with occupational safety. While, regulatory-speaking, one might argue that the IACUC's prerogative is with the safety and the use of animals that oversight of programmatic issues does extend to allowing and preparing and

working and partnering, with creating a safe working place not just for the animals but also for the people who live in those spaces.

Ron, were you going to also address the second question that Jerry combined in there? **Whose responsibility is it to verify that the HVAC systems are operating properly, facility mangers or physical plant personnel?** I sort of noted back that that would be an IACUC obligation. Now whether it is the facility manger or physical plant, the guidelines are still there and if either one of them cannot determine that the HVAC is appropriate, ventilation, etc. is appropriate then indeed the IACUC ought to enter in that discussion. What worries me sometimes is that there are institutions that will say, or people in institutions that will say it's not my responsibility – it is your responsibility. I don't think I'm going out on a limb but I will be a bit firm with my statement that – I'm sorry folks, we're in this together. This is not your responsibility, or his or mine, it is ours. The IACUC being the institution's representative and indeed the regulatory expected representative for things animal at the institution needs to assure that someone, whether it's the facility manger, the safety office, the facility office, someone has done the work and has validated that the work is indeed accurate within the guidelines that are published and in the cases of exceptions, within the exceptions that the IACUC has established.

OLAW would certainly agree with that. We have Assured institutions of all sizes and with all different focuses and so we don't have, nor do we expect, a one size fits all solution. The organization – it is incumbent upon the organization to develop the most appropriate and effective solution for them.

Ron, on behalf on the folks down here at OLAW and our colleagues throughout the country who are listening in, I really want to thank you sincerely for sharing your wealth of knowledge on this very important topic with all of us. I would remind the participants that if we haven't had the chance to answer your questions, that there will be an opportunity for

additional questions to be submitted online as I mentioned earlier in the presentation and in addition to that there will be an edited document that will provide both those questions and answers available to you.

Jerry, we have some additional questions that we can't get to because we're out of time but we have kept those questions and we will be sure to include those in the document that we put up on the Web in several weeks.

We look forward to you joining us for future sessions, we hope that you will send your comments and suggestions about this and future seminars to the OLAW email box which can be found at the bottom of the OLAW webpage. The June seminar entitled "Ethics and IACUC Responsibility" will be presented on June 10th by Dr. Ernie Prentice who is Professor and Associate Vice Chancellor for Academic Affairs at the University of Nebraska Medical Center. Thank you all for taking time to participate in this seminar and have a pleasant day.

ADDITIONAL QUESTIONS:

Has the AAALAC Council discussed recommendations on room air changes in those rooms where IVC racks are used. In that case, room air changes would be needed for macroenvironment temperature control, whereas inside the IVC cage, waste gases and heat removal is being done independent of room HVAC.
We refer to 10 to 15 air changes as being the basis for ventilation in animal care areas but sometimes the standard might be counterproductive and even injurious to progressive or humane animal care and use activities. The Animal Care and Use Committee needs to be addressing these standards, apply them where applicable and, where not appropriate, provide exemptions to those standards in the best interest of the animals and also in the positive outcomes of the research.

Were the HVAC findings associated with new / initial AAALAC program evaluations, or did they also include long term accredited facilities?
The AAALAC findings for HVAC included all facilities from the period of 2003 to 2008.

Does the Council support the validation of sanitization of cages, if cage wash cycles are not able to reach 180F or if you are unable to document that temperature being hit?
The cage wash requires validation to ensure correct performance and proper sanitization of cages. If it has been documented that the cage washer is not reaching the correct temperature for sanitization or if the temperature during cage wash cannot be documented them adequate performance of the equipment is not ensured. However, the correct sanitization of cages is not only accomplished through physical validation of the cage washer, but biological testing of the cage. Monitoring of sanitation practices should be appropriate to the process and materials being cleaned; it can include visual inspection of the materials, monitoring of water temperatures, or microbiologic monitoring.

Is a rodent surgery area that does not have positive air pressure differential considered a mandatory?
Rodent survival surgery does not require a dedicated space. It only requires a space where the area is clean. Indeed sterile would be preferred, but that's just not possible in all cases within a research infrastructure. Positive relative pressure is desirable so we can be providing clean air across the space where surgery is being performed and sanitizable surfaces are indeed important. Gas scavenging will be necessary if gas anesthesia is being used and sterile procedures are possible through the use of autoclaved instruments initially and glass bead sterilizer use for subsequent procedures.

I would like to know the contact time required for glass bead sterilizers?

Glass bead sterilization uses small glass beads and high temperature (230 ^{o}C -250^{o}C) for a recommended exposure time of 45 seconds.

Should the humidity level in a facility fall below the acceptable range (for a short time) and affect a researcher's data causing them to not be able to use this data – would this a be a reportable to OLAW?
Assured institutions are required to report conditions within animal facilities that either put the animals, or the people working in the facility at risk, or those situations where an animal facility is encountering problems and cannot meet the requirements in the *Guide for the Care and Use of Laboratory Animals*. Conditions that jeopardize the health or well-being of animals, including mechanical failures which result in actual harm or death to animals should be reported to OLAW.

How do we know if light in an animal room is too bright and what difference does it make for the animals? What about noise?
Guide for the Care and Use of Laboratory Animals: Lighting should be diffused throughout an animal holding area and provide sufficient illumination for the well-being of the animals and to allow good housekeeping practices, adequate inspection of animals-including the bottom-most cages in racks-and safe working conditions for personnel. Light in animal holding rooms should provide for adequate vision and for neuroendocrine regulation of diurnal and circadian cycles (Brainard 1989). Noise produced by animals and animal-care activities is inherent in the operation of an animal facility (Pfaff and Stecker 1976). Therefore, noise control should be considered in facility design and operation (Pekrul 1991). Assessment of the potential effects of noise on an animal warrants consideration of the intensity, frequency, rapidity of onset, duration, and vibration potential of the sound and the hearing range, noise-exposure history, and sound-effect susceptibility of the species, stock, or strain.

Lighting and noise requirements are species specific and several reference guides are available to provide information for the correct lighting and noise level acceptable to accommodate the species housed.

Light intensity is measured in lux or foot-candles with a photometer approximately 1 meter (3 ft) above the floor in several locations within the animal room.

What is more important - a performance based standard or an absolute temperature or humidity range? Do climate factors, i.e., seasonal problems with temperature or humidity provide a justification to use performance standards rather than published ranges?

Guide for the Care and Use of Laboratory Animals – 8th Edition.
Prepublication Copy:

Engineering Standard means a standard or guideline that specifies in detail a method, technology or technique for achieving a desired outcome, and does not provide for modification in the event that acceptable alternative methods are available or unusual circumstances arise. Engineering standards are prescriptive and provide limited flexibility for implementation. However, an engineering standard can be useful to establish a baseline, and are easier to use in evaluating compliance.

Performance standard means a standard or guideline that, while describing a desired outcome, provides flexibility in achieving this outcome by granting discretion to those with responsibility for managing the animal care and use program, the researcher, and the IACUC. The performance approach requires professional input, sound judgment and a team approach to achieve specific goals. It is essential that the desired outcomes and/or goals are clearly defined, and that appropriate performance measures are regularly monitored, in order to verify success of the process. This approach can be advantageous because many variables (such as the species and previous

history of the animals, facilities, expertise of the people, and research goals) can be taken into consideration so that the implementation of the standard can be best tailored to meet the recommendations in the *Guide*.

Ideally, engineering and performance standards are balanced, setting a target for optimal practices, management and operations while encouraging flexibility and judgment, if appropriate, based on individual situations (Gonder et al. 2001).

If bedding in individually ventilated racks is dry and ammonia levels are sufficiently low, can we extend the frequency of cage changes to 3 or 4 weeks, with spot changing as needed?

Guide for the Care and Use of Laboratory Animals – 8th Edition. Prepublication Copy: The increased use of individually ventilated cages (IVCs) for rodents has led to investigations regarding the maintenance of a suitable microenvironment with extended cage sanitation intervals and/or increased housing densities (Carissimi et al. 2000; Reeb-Whitaker et al. 2001; Schondelmeyer et al. 2006). By design, ventilated caging systems provide direct continuous exchange of air,when compared to static caging systems that depend on passive ventilation from the macroenvironment. As noted above, decreased sanitation frequency may be justified if the microenvironment in the cages, under the conditions of use (e.g., cage type and manufacturer; bedding; species; strain; age; sex; density; and experimental considerations), is not compromised (Reeb-Whitaker et al. 1998). The goal of any sanitation program is to maintain adequate air quality, sufficiently clean and dry bedding, and clean cage surfaces and accessories. Verification of microenvironmental conditions may include measurement of pollutants such as ammonia and CO_2; microbiological load; observation of behavior and appearance of the animals; and condition of bedding and cage surfaces.

If all cages in a room are individually ventilated and vented to the outside, why do we have to continue to monitor room level HVAC data?

The function of the HVAC is to control the macroenvironment and while the IVC functions to control the microenvironment, the heat load and physical demands of the equipment and personnel must be accounted for by the HVAC. The macroenvironment impacts the microenvironment, especially if IVC air is supplied from the room air.

Why are we required to store food 6 inches away from the walls and where does it state that in the regulations?

Animal Welfare Regulations: Storage. Supplies of food and bedding must be stored in a manner that protects the supplies from spoilage, contamination, and vermin infestation. The supplies must be stored off the floor and away from the walls, to allow cleaning underneath and around the supplies.

Many facility standard operating procedures do state 6 inches from the wall for food storage.

In one of your slides you said that surgical instruments must be autoclaved - why can't we use cold or gas sterilization?

For clarification, the webinar slides pertaining to “Functional Areas (Aseptic Surgery)”, Slides 27-30, list “Autoclave” as a method of sterilization for surgical support, but do not state that this method must be utilized. Gas sterilization of instruments or equipment is acceptable and in some instances required due to the type of material.

Guide for the Care and Use of Laboratory Animals: Specific sterilization methods should be selected on the basis of physical characteristics of materials to be sterilized (Schofield 1994). Autoclaving and gas sterilization are common effective methods.

Algae in a fish tank is an indication of healthy water. So, do we need to clean the algae off the tank to make it proper for keeping fish? How frequently?

Guide for the Care and Use of Laboratory Animals – 8th Edition. Prepublication Copy: Algal growth is common in aquatic systems. Algal growth is increased with the presence of nitrogen and phosphorous, particularly in the presence of light. Algal species seen with re-circulating systems are generally non-toxic, though species capable of producing toxins exist. Excessive algae growth may be an indication of elevated nitrogen or phosphorous levels. Algae are typically removed using mechanical methods, i.e., scrubbing or scraping. Limiting algal growth is important to allow for visualization of animals in the enclosure. Cyanobacteria (commonly called blue-green algae) growth is also possible and may be common in freshwater aquaculture situations. The same factors that promote algae growth also promote cyanobacteria growth. As with algae, while most species are harmless, some species can produce clinically relevant toxic compounds (Smith et al. 2008). The frequency of cleaning and disinfection should be determined by water quality, which should permit adequate visualization of the animals, and animal health monitoring.

Our IACUC recently cited us for feed pellets which had dropped on the floor of the feed room. Why was this an issue?

Guide for the Care and Use of Laboratory Animals: Animal-colony managers should be judicious in purchasing, transporting, storing, and handling food to minimize the introduction of diseases, parasites, potential disease vectors (e.g., insects and other vermin.

Areas in which diets and diet ingredients are processed or stored should be kept clean and enclosed to prevent entry of pests. Food should be stored off the floor on pallets, racks, or carts. Unused, opened bags of food should be stored in vermin-proof containers to minimize contamination and to avoid potential spread of disease agents.

Do we need to maintain 10-15 air changes her hour in the cage wash area.

The goal of the HVAC in the physical plant is to provide a consistent environment. To provide a consistent environment there must be environmental control. The extent of this control is based on many requirements most of which are related to the animals, either by the provision of oxygen, evacuation of heat, or the elimination of waste products which are produced by the animals. The HVAC in the cage wash area, as part of the facility, must be controlled to provide this environmental consistency within the facility, but also needs to provide personnel with a safe working environment.

I am not clear whether animal holding rooms should be positive pressure or negative pressure.

Animals in quarantine or animals exposed to hazardous materials or non-human primates should be generally kept under negative pressure. Housing for pathogen-free animals should be kept under relative positive pressure.