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Note: Text has been edited for clarity.

What Every IACUC Should Know About AAALAC International

Speaker: Christian Newcomer, V.M.D., Executive Director, AAALAC International

Moderators: Jerry Collins, Ph.D., Division of Policy and Education, OLAW and Susan Silk, M.S., Director, Division of Policy and Education, OLAW

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Slide 1 (Title slide)

Good morning or afternoon depending on your local time zone and welcome to the next in our series of OLAW Online Seminars for IACUC Staff. My name is Jerry Collins and I will serve, along with Susan Silk, the Director of the Division of Policy and Education here at OLAW, as a moderator of today's session.

We encourage you to submit questions, online, during the presentation by today's speaker. Please direct your attention to the top left corner of your monitor. If you would like to submit a question, please type it in the text field at the bottom of the submit a question "Q & A box" in that top left corner and press the arrow to "submit." Once submitted,

your questions will appear in the upper portion of the chat box on your screen but will only be seen by you and the staff here in the office. This session will be recorded and the recording will be available to all interested parties. If you would like to access the archived version of this or previous sessions, you may do so by clicking on the heading titled [OLAW Online Seminars for IACUC Staff](#). That heading can be found under the Education section on the [OLAW website](#).

Susan, would you please introduce today's speaker? It is a pleasure to welcome Dr. Christian Newcomer to our OLAW Online Seminar Series. Dr. Newcomer is the Executive Director of the [Association for the Assessment and Accreditation of Laboratory Animal Care International](#), usually referred to as AAALAC. He has participated in AAALAC's review activities for the past 25 years.

Dr. Newcomer is a graduate of the School of Veterinary Medicine at the University of Pennsylvania. Following a year in a large animal internship at Pennsylvania State University, he entered post-doctoral training in laboratory animal medicine at the University of Michigan and was board certified by the American College of Laboratory Animal Medicine in 1982.

Prior to his appointment at AAALAC International, he held academic and leadership positions in laboratory animal medicine at the Massachusetts Institute of Technology, Tufts New England Medical Center, the University of North Carolina, at Chapel Hill, the Veterinary Resources Program here at the National Institutes of Health, and the Johns Hopkins University. Dr. Newcomer is a past president of the American College of Laboratory Animal Medicine and the American

Association for Laboratory Animal Science. Chris, I am eager to learn "What Every IACUC Should Know About AAALAC."

Greetings to all of you and I am very pleased to be part of OLAW's webinar series. I'll be talking to you today about AAALAC and what our findings are as they relate to a recent Quality Conference that we conducted in San Diego, California and to sort of give you an overview about AAALAC.

Slide 2 (AAALAC Mission)

AAALAC's mission statement revised in 1996 reads AAALAC International is a voluntary accrediting organization that enhances the quality of research, teaching, and testing by promoting humane, responsible animal care and use. It provides advice and independent assessments to participating institutions and accredits those that meet or exceed applicable standards.

Slide 3 (ILAR Newsletter - October 1965)

This is very true to the original mission statement adopted by the organization nearly 45 years ago - now - excerpt to hear from the ILAR news letter which indicated that AAALAC has been organized, quote, to promote a program for the accreditation of laboratory animal care facilities which will encourage promote and facilitate scientific research which includes the use of experimental animals.

Slide 4 (Oversight Organization Comparison)

AAALAC relishes the opportunity - often - to serve in various forums with the USDA and members of OLAW in programs which talk about the oversight of animal use in biomedical research. But, unlike those

two organizations, AAALAC is not a regulatory organization. It is, in fact, a private corporation, a not for profit corporation. It is an organization which asks you to participate voluntarily. You're not required to participate. It covers all animal species, however - in most cases - and at the discretion of the institution being visited - they typically limit the accreditation to vertebrate animal species. And it does apply universally accepted standards, the [Guide for the Care and Use of Laboratory Animals](#) being the primary standard and various other reference resources serving as ancillary standards in the process. The enforcement of the review process is limited to the revocation of accreditation. It is a confidential, peer review process. All the information is held in confidence and in the best of conditions - of course - you're fully accredited. If you fail to meet those conditions, there is the possibility of the revocation of accreditation. It is not directly linked to funding. However, there are some organizations which stress, in their literature, the encouragement for you to participate in AAALAC accreditation. And it would be conceivable that two equally rated scientific protocols - perhaps the tiebreaker might be whether or not you are participating in this independent program of oversight.

Slide 5 (AAALAC Accreditation Process)

The AAALAC accreditation process - in summary - entails the development of a [program description](#) by the organization which is a detailed analysis of the policies, procedures, and practices that are used in support of the care and use of the laboratory animals in the program. AAALAC then uses this to conduct an on-site visit led by a member of its [Council on Accreditation](#) buttressed by other experts, who are either also Council members or members of the ad hoc

consultants to the organization. Those individuals review the program on site and develop a report which is taken back to the Council on Accreditation to consider the findings and to deliberate the status of the organization. Once that has been determined by the Council, the organization is then notified of its [accreditation status](#). And as I mentioned in the most advantageous circumstances - of course - there is a continuation or award of full accreditation. In cases where that is not the case and the organization is either revoked or withheld from its accreditation - there is an appeal process that can be used.

Slide 6 (Accreditation Standards)

Slide 7 (*Guides*)

As I mentioned - the *Guide for the Care and Use of Laboratory Animals* (*Guide*) is a primary standard in our evaluation. And the *Guide* as shown here has importance as a standard worldwide. Because many countries around the globe do not have well-developed regulatory standards for laboratory animals and hence we'll use the *Guide* as shown here in various translations.

Slide 8 (The "AAALAC Standard")

The AAALAC standard, as I mentioned, it is not a single document. It's a number of documents. It encompasses the entire animal care and use program and it is based on scientific principles. So the standards which are used are internationally recognized standards based on science. The judgment of the individuals who participate in the program are driven by science and the review process that occurs in the Council is also a science-based review process. So science is key to accreditation.

Slide 9 (Webpage screen shot)

Now I mentioned the other documents, which are used as part of the review process. These are referred to in AAALAC parlance as the [AAALAC Reference Resources](#). This is a page captured from the AAALAC webpage showing where those are located. The documents are organized according to the category they address. Those being - general documents, biosafety documents, educational documents, euthanasia, etc. These documents can be very helpful to you in addressing concerns or suggestions that are raised by the Council.

Slide 10 (Peer Review Process)

The peer review process begins, as I mentioned, with the institution's development of a program description by the organization's experts. That document then when it is submitted to the AAALAC office, undergoes review by some of our staff analysts who review it for adequacy of the content and pertinency of the content. And if additional information is needed, then we reach out back to the institution to make sure that that document is complete before it is moved into the hands of the Council members who will then use that document as the basis for the evaluation of your program. During the site visit, the site visitors interact with your organizational experts as part of the review. They do this both by reviewing the program description in some detail, by interviewing people in all phases of the program, and of course by making observations within the facilities and within the laboratories while they're onsite doing the review. And as a result of that review, the report, which goes back - then - to the Council of Accreditation - is then minimally reviewed in detail by four

other members of the Council on Accreditation who will either endorse the report or criticize parts of the report and question why a decision and conclusion have taken one direction versus another. And the result of that intensive review process by a portion of the Council is then visited by the full Council during one of its triannual meetings. And then ultimately as a result of that broader consideration, the Council will decide either to award full accreditation or some lesser status. Council takes this review process very seriously and it's certainly integral to the viability of the AAALAC review process. And they have consistently for many years been very concerned about making sure that the decisions conveyed from the Council are consistent over time. And so they have established working committees on the topic of consistency and its exercises and another committee on continuing education. Where the continuing education that is focused on is frequently on the topics that generate a lot of discussion in the Council to make sure that those topics receive an equal consideration - regardless of which section of Council they may appear in.

Slide 11 (Who is Accredited?)

AAALAC now has over [770 programs that are accredited in 31 countries](#). This includes all top 100 of the NIH awardees and about 90% of the next 100 NIH awardees. It includes all major U.S. pharmaceutical companies and the commercial laboratories which produce laboratory animals. It includes the various government laboratories, and both large and small biotechnology companies and contract research organizations.

Slide 12 (Growth in Accredited Programs)

The growth in accreditation has been quite substantial. Over 150 organizations have joined the accreditation process since 1998. And that was the point in time at which AAALAC became AAALAC International and broadened its scope of evaluation. So it's a growing - a very growing - group of organizations that are participating. About 50% of the increase since that time has been in the global, non-U.S. community and surprisingly, about 50% of that group has come from the Pacific Rim.

Slide 13 (Countries With Accredited Programs)

China being a very prominent member - here recently - especially. But this is a slide showing the countries which currently have institutions that are participating in the accreditation process.

Slide 14 (Proportion of Accredited Units by Industry Sector)

Looking at the accreditation participants by their industry sector - the breakup - as - the breakdown of this has traditionally been about 1/3, 1/3, and 1/3. Those being the academic sector, the commercial sector, and then the government, nonprofit, and hospital sector clustered together. And as I mentioned - recently because of the global developments in animal-based biomedical research, the commercial sector has been growing - particularly in non-U.S. audiences. That accounts for the fact that there is a larger piece allocated to that - the 37%.

Slide 15 (What People Value Most About Accreditation...)

It's often - people often ask, "Why do people value accreditation?" And this is a question that has been asked periodically by AAALAC when it does surveys of the organizations that participate, the most recent of

which is from 1998. And I think some of these responses reflect why people are inclined to participate. There is a strong feeling that it aids the credibility and the public perception of the organization conducting animal research. And there's also quite a sense as evident in the third bullet - that once an organization commits to AAALAC accreditation - it serves as a very useful tool to keep management apprised of changes in the industry and translating those changes in the industry to changes within their program so that the institution's program will stay abreast of what's necessary for productive scientific inquiry using laboratory animals.

Slide 16 (What People Value Most About Accreditation...)

Accreditation also has been used really as a tool to attract and assure scientists as they move from organization to organization. As evident in these statements: "The application of AALAC standards assures high-quality research and animal care resulting in better science" and "It conveys a high level of professionalism to the scientific community." I think as people are in increasingly sophisticated programs of animal care and use and they choose to move to another organization, they're somewhat loath to move into an animal care and use program that has an undefined - or perhaps - a lesser standard of care for their very valuable research animals.

Slide 17 (Accreditation Outcomes)

There are various outcomes that can occur as a result of an AAALAC site visit. In a new application, it may be awarded full accreditation or may be given provisional status. And provisional status refers to the instance where the organization has some item that's mandated that must be corrected in order for the organization to be awarded full

accreditation. In existing programs, you can either have a continued full accreditation or one of two categories where your - where you have mandated corrections that you have to complete in order to be fully accredited. In the case of the deferred accreditation, this refers to items which typically are limited in scope; they do not take a huge amount of financial resources or massive reorganization of human resources or the development of complicated policies and procedures. So they're a fairly circumscribed issue which must be corrected but it seems to be a time-limited thing, which the organization should be able to do with existing resources - just with reorganization and some additional thought given to the matter. Probation - on the other hand - are items which have considerably more complexity. They're expected to take more protracted endeavor. Maybe expected - in some cases - to require the outlay of significant financial resources or the recruitment of new personnel or development of new expertise - which is going to take some time. And then finally, and rarely - but typically one or two times a year - there will either be a decision made by the Council - in the case of a new organization - to new applicant to withhold accreditation or in the case of an organization which is - has - is participating in accreditation - to revoke their accreditation. And - you know - that usually signals radical changes that have occurred that are detrimental to the program and to the animal - the use of animals in those programs.

Slide 18 (Mandatory Item vs. Suggestion for Improvement)

So I want to now have a little bit of recap some of the salient findings from the [Quality Conference](#) that AAALAC sponsored in conjunction with the PRIM&R Meeting in San Diego in March of 2009. This data - in full - is available on AAALAC's home page and entails more than 300

slides - packed full of data on different issues that talk about the trends that AAALAC has seen over the last five years in its accreditation site visits. So it covers the years from 2003 to 2008. Some of you may find this to be very useful data - if you haven't already seen it through participation in that Conference. In order to understand the data you need to know one critical distinction and that is the distinction of a mandatory item versus a suggestion for improvement. A "mandatory item" is a deficiency that must be corrected for full accreditation to be awarded or continued. And a "suggestion for improvement" is an item that the Council feels is desirable to upgrade an already acceptable - or perhaps even a commendable - animal care and use program.

Slide 19 (AAALAC i-brief)

There is another document which maybe of interest to you regarding suggestions for improvement. Because the question often comes up - well - if they're just suggestions - and we needn't do them- why should we? We have written an [i-brief](#) on this which is available again through the AAALAC home page that provides quite a bit of discussion on the value of suggestions of improvement and why the Council bothers to offer these to programs which otherwise would be accredited anyway.

Slide 20 (The Animal Care and Use Program)

The animal care and use program - you know - from the *Guide* - has four critical components: institutional policies, veterinary care, the consideration of factors in the laboratory animal environment, and animal management, and then lastly, physical plant.

Slide 21 (Total Number of Mandatory Deficiencies Per Year)

Our findings have shown that over time, the number of mandatory deficiencies that are seen in animal care and use programs participating has declined fairly substantially. So at this point in time, I can tell you that 97% of those organizations which are participating in accreditation are fully accredited. And also, at this point in time, the trend is that approximately 80% of the reviews, which come into the Council will move through the Council meeting and be continued full accreditation. This is about a 20-point improvement over 20 years ago, approximately 62% of the reviews, which came through Council would continue in full accreditation and 38% of them would have been held up by one or more mandatory items. So the biomedical community is making very good progress in the oversight and the development of their animal care and use programs.

Slide 22 (Percent Mandatory Items & SFIs for the Period 2003-2008)

This slide shows the relative percentage of the items that are found as suggestions for improvements and mandated items during AAALAC site visits during the last five years. And you can see that chief among them is the area of institutional policies which comprise more than 60% of the items which are cited as mandatory items in our review process. Of course much smaller numbers for the physical plant, laboratory animal management, and veterinary care segments.

Slide 23 (Percent Mandatory Deficiencies by Category (1999-2008))

If you look at this using the bar graph method - again - this reiterates that 60 to 70% of those items which are seen - they fall in the realm of institutional policies. About 20% consistently over time with some improvement lately have been related to physical plant and then in the

range of 5 to 10% for veterinary care and for issues related to laboratory animal management.

Slide 24 (Top Three Mandatory Deficiencies Identified During Site Visits)

The top three mandatory deficiencies that AAALAC has seen during this last five year period have been occupational health and safety issues, Institutional Animal Care and Use Committee issues, and heating, ventilation, and air conditioning system problems.

Slide 25 (Occupational Health & Safety)

Regarding occupational health and safety - you can see again that over the last decade - both the number of suggestions for improvement in the top line and the mandatory items in the line - the green line - have declined over time. But they continue to hover around 20% - 25% mark in the mandated items. I'm sorry - 27 items cited during 2008 that were mandatory in the area of occupational health and safety.

Slide 26 (OHSP of Total Mandatory Items & SFIs-Percent and Rank Order)

If you look at the mandatory items - this is showing the percentage they are – of the total number of mandated items that were cited by the Council over that five year interval, you can see about 27% of the items that Council deems required fell under the category of occupational health and safety. On the right side of the screen, I've listed in their rank order, how these items have been identified in the site visit report. Beginning with program administration as the most common finding, a lack of an appropriate hazard identification risk

assessment process in the second position. And then going down the list, ending with the personnel training measures as they relate to the occupational health and safety program.

Slide 27 (IACUC (or Comparable Review Function))

The Institutional Animal Care and Use Committee (IACUC) has also been an area that has received a lot of attention - both as mandated items and as suggestions for improvements by our site visitors. You can see - though - that over this 15 year period - approximately - there has been a terrific improvement in what our institutions have done to improve their IACUC processes - falling from approximately 40% back in the early 90's to less than - I'm sorry 40 items back in the early 90's, less than 20 citations in our reports during the 2008 interval. And similarly the suggestions for improvement have also fallen off fairly appreciably.

Slide 28 (IACUC (or Comparable Review Function))

In the areas that are cited for the IACUC, protocol review ranks as the number one issue which is encountered as a problem in the review of IACUC function. Again then, following down the list from that in the rank order is the IACUC review and incorporation of policies and following pertinent policies. The composition and participation of the members of the IACUC. The timeliness, the accuracy, and breadth of the semiannual evaluations and documentation and training are filling out the bottom of the list. These are clearly key items that you as IACUC members should keep your eye on.

Slide 29 (Percent Physical Plant Findings (2003-2008))

Now, moving on to areas where there is - again - occupies much lower percentage of the mandated items, and total items is the area of the physical plant findings. But you will notice on the bar graph, those which consistently stand out both as mandatory items and as suggestions for improvements - that being the issue of the heating ventilation and air conditioning systems. And other items are - appear much less frequently but they do occasionally come up as mandatory items in the AAALAC reviews.

Slide 30 (Percent Heating, Ventilation, & Air Conditioning (HVAC) of Total Physical Plant Deficiencies)

If you look at the suggestions versus the mandatory items over this last five year period - excuse me - you can see that there have been years - as in 2007 - where virtually all of the times that were mandated in this category - physical plant - were related to suggest the heating, ventilation, and air conditioning piece of it. And similarly, in 2008, the majority of those which were cited as mandatory items relate to heating, ventilation, and air conditioning. So the other areas of physical plant are apparently fairly well attended to in most programs.

Slide 31 (Percent Animal Environment, Housing and Management Mandatory Findings (2003-2008))

The laboratory animal management piece and veterinary care are a much lower percentage - in general - of the number of mandatory items and we needn't dwell on them. But do note - of the items which do stand out as mandatorics in the management area - the key issues are the adequacy of the housing of the animals, issues related to the

husbandry of the animals, and issues related to the sanitation and maintenance of the animal facility and animal caging.

Slide 32 (Percent Program of Adequate Veterinary Care Findings)

And in veterinary care, there has been a fairly consistently low level of criticism. In 2008, laudably - a very low percentage of items which were mandatory items. But you can see there - in earlier years - you know - getting close on some occasions to 10% of the total mandatory items cited were relevant to improper, inadequate programs of veterinary care.

Slide 33 ("Mission Creep")

I want to close by addressing something which is frequently expressed at institutions and sometimes expressed by the scientists at institutions which is very - a very interesting to AAALAC, and which we work hard to try to address in our practices. This is the issue of "mission creep". The notion that AAALAC uses existing regulations and either fabricates new regulations or will ramp up the intensity of their criticism based on existing regulations. And the reality is that the *Guide for the Care and Use of Laboratory Animals* is now more than 12 years old. And in fact, in some areas, practices have changed radically because the technologies have evolved radically. And there is a need to - there is a need to address those changes in technology and the positive things they can bring to a program during the course of a peer review process which is intended to encourage organizations to improve their programs. So - you know - items may frequently be cited as a suggestion for improvement but they certainly would not be cited based on newly developed items during the past 12 years as the basis for creating a mandatory criticism of a program. The suggestions

for improvement are also - they're just that - and should be regarded as that. Although I already alluded to the fact that we have written a nice article trying to exhort you to take suggestions for improvement seriously and to consider adopting those - because we think in the long run - it does add value to your program. They're not mandated and you don't need to adopt suggestions for improvement. And the last point I'd make under the reality of mission creep is that not only are we acutely aware of this and have been addressing it for quite some time - nearly 20 years in my personal experience with the issue of consistency - let me assure you that AAALAC's 60 plus members of the Board of Trustees - who represent scientific organizations - are also keenly aware of the fact and continuously engaged with the Council on the topic that we should be consistent in our practices and we should not develop or exceed the existing regulatory mandates on various topics. Although there are perceptions that we sometimes over interpret standards or that we impose new standards - I think that can easily be rebutted. And certainly I am telling you here and now - as you've heard before - suggestions for improvement need not be followed although certainly would highly encourage that.

Slide 34 (Judgments Differ / No Clear Standard)

In closing I would say that - I ask you to keep in mind - and you are central - really - to the discussion of emerging standards and the quality of the programs at your institutions as members of the IACUC, that - you know - judgments do differ. In some cases, there are no clear standards. But as we see new knowledge emerging and as we see new opportunities to provide an environment which will promote our increasingly sophisticated animal-based biomedical research - you know - there is a need to look at that data which has been currently

published. Because the *Guide* - once it is published - is a static document. The findings related to the use of animals in research marches forward just as other scientific data. So it is important for you to keep your eye on the published literature related to the use of animal models and the maintenance of animal models. Just as we do - to partner with us in looking at the scientific principles based in using that data and based on that data, engage the experts at your institution just as AAALAC engages its own experts to come to sensible opinion about how new practices and best practices should be developed and incorporated into our program so we that we can stay one step ahead of the needs of science for the use of animals in biomedical research.

Slide 35 (Questions and Comments?)

And with that, I believe it is time for us to respond to any questions and comments you may have about the presentation or other aspects of AAALAC.

Thank you, Chris. We will spend the remainder of our allotted time responding to questions that we've received. Some of the questions we will begin with are ones that came in prior to the session. We would - again - remind our attendees to submit your questions to us. Since we started late, we will continue on for about 10 minutes beyond our normal expected stopping time of 3:00 Eastern Standard time. This will enable us to answer more of your questions. We hope you can stay with us - but if not - feel free to sign off. You can view the additional material in the recorded session of the seminar that will be pasted on the OLAW website within a week.

And our first question - actually the first several questions - are for OLAW. So Susan, I'm going to ask you if you could respond to them? **Does AAALAC accreditation affect an institution's status with OLAW?** Jerry, our expectation at OLAW is that all PHS Assured institutions will have high quality animal care and use programs. If the Assured institution is accredited by AAALAC, its institutional status is Category 1. Non-accredited institutions are Category 2 institutions. At all Assured institutions - both Category 1 and Category 2 - the IACUC is required - under the terms of the PHS Policy - to perform semiannual inspections and program review. The IACUC must prepare a report to the IO with the results of the semiannual inspection and program review. IOs of Category 2 institutions must submit their most recent semiannual report to OLAW as part of the Assurance review process. Category 1 institutions are also required to conduct semiannual inspections and program review and prepare reports but they are not required to submit the semiannual reports to OLAW unless requested in the Assurance Process.

Two follow-up questions. **Are there other types of accreditation that OLAW recognizes and how many PHS Assured institutions are AAALAC accredited?** Currently AAALAC is the only accrediting body that OLAW recognizes. OLAW Assures about one thousand domestic institutions. Approximately 40% of these are AAALAC accredited.

OK our next question is for our guest speaker. **Chris, what criteria does AAALAC use for farm animal barns and shelters and does it change with the funding source - for example, PHS funds?** AAALAC uses the Agricultural Guide in its general assessment (Audio

technical difficulties) *Excuse me, Chris. Try now, again. Oh!* - *we're coming through - Trying again. AAALAC uses the Agricultural Guide for the Care and Use of - yes OK.* It uses the so-called Ag Guide [the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Federation of Animal Science Societies 1999, revision pending)] for its basic criteria for the use of small domestic - *I'm sorry - I'm coming - I'm sorry folks - we're wondering whether I'm coming through or not.* - for its evaluation of animal - of the small domestic ruminants and other farm animals which are used in research animal programs. If that is appropriate for the type of research which they are being used in. If the animals are being used in research which is highly invasive and it involves sensitive procedures for which the animal requires more intensive oversight and management - then AAALAC would expect the animals to be housed in the more traditional laboratory animal setting.

Our next question - actually 2 of them - I'm going to put them together. **Do wood surfaces in barns or shelters have to be painted and what are the shelter requirements for agricultural use of food animals in pasture situations?** The Ag Guide does address and it does broach the subject of the quality of the facilities by commenting that are to be modern, well-maintained animal facilities. And subsumed under that is the idea that the facilities would be in good repair and that wood surfaces are appropriately maintained so that they could be cleaned and sanitized appropriately. The second issue or the second question relating to the maintenance of animals on pasture - animals - of course - can be kept in climatic housing conditions if they are adapted to the range of climatic conditions that they would be expected to encounter in that environment. And

typically - the shelter minimally would provide shade for the animals so the animals could control the intense heat of the summertime in a majority of the country - so they need to have shelter from inclement weather.

Next question relates to AAALAC funding. **The question is how is AAALAC funded? Is it only through institutional fees?** That is essentially how AAALAC is - is funded. The members who participate as member representatives on the Board of Trustees are asked to pay a fee to have that level of participation. And of course, there are some other ancillary activities that AAALAC conducts - training and educational outreach functions - which generate a small amount of revenue for the organization. But it's basically unit user fees.

Chris, here is an interesting question - not that others weren't - but this one sounds like it could be a bit of challenging. **How does AAALAC handle animal counts in non traditional species where hatched animals - for example, fish - may be microscopic or too small or dense numbers to accurately count?** AAALAC does not obsess over the actual animal count in this case. Thank you for that very straightforward answer.

Next question. **Are there opportunities for dialogue between the institution and AAALAC during the interval between the site visit and when Council meets to deliberate the site visit report especially if answers to questions or clarifications are desired?** This is absolutely the case. Since the late 1980s - approximately 1990 - AAALAC had instituted an exit briefing as a standard feature of the site visit. The whole purpose of the exit briefing was to foster the

atmosphere of collegiality and to allow the exchange of information between the institution and the site visitors so the site visitors would not leave the institution with misconceptions about what they observed on site or what weight should be accorded to what they observed onsite. So based (audio technical difficulty). *Excuse me for a second, Chris. I can't hear you in my earphone, all of a sudden. If we could get somebody to confirmed. OK. Ladies and gentleman, it appears as if we may have lost internet connectivity again. If someone - if you are hearing me - would you please send a short email message in the submit a question box so we can tell if we are connected or not. Thank you - so it is clear you folks are hearing me, but you're not hearing Dr. Newcomer in his microphone. We will do a quick switch and I will pass my microphone over to him. OK. Jerry you are controlling the talk? We were talking about - I forget which question we were on now.*

The exit briefing - subsequent to the exit briefing - institutions have the opportunity to reflect upon what was conveyed to them. Either act on those items and convey the information that they have successfully completed the items that were requested by the Council members in this preliminary exit briefing or to provide other updates - to provide alternate opinions, to provide considered judgments and documents to reflect why they would - you know - how they would intend to respond to those items. So the purpose is to engage the organization in an active dialogue that is timely, so that the information is completed well in advance of the Council meeting, strictly from the standpoint of our attitudes toward having a humane Council meeting where people are not asked to consider things at the last minute.

Ah - ah OK. Next question. **What are some of the most commonly seen procedures with protocol review that lead to concerns by AAALAC International?** This is an issue that I think you would really benefit from reviewing the 300 slides that are on the AAALAC DVD from the recent Quality Conference - if you would like to learn more about this in detail. Preliminarily, I would just say that there are a myriad of problems. In general, the lack of pertinent detail in protocols, the acceptance of vague generalities or assurances given by the proposer and the weak consideration of possible complications for the animal model are the antecedents to problems which most impact animal welfare negatively and for which committees are held in low regard if they are not attentive to these critical issues.

OK. The next question is. **Could you offer more examples of institutional policies problems?** So remembering Chapter 1 of the *Guide* - Institutional Policies entails a number of elements. It entails the occupational health and safety issues. It entails the IACUC, it entails the overall program of veterinary care - not the details of the program - but the overall program of having folks who are equipped to manage the difficult science of your program. And then - it also has this large, overarching component called, you know - institutional resources, institutional oversight and other big picture things which fall into the domain of the Institutional Official. And it also covers - notably - personnel training in that area. So each of those areas are sometimes cited under the institutional policies rubric during a site visit as being problematic.

Chris - the next question is. **Does AAALAC expect - does AAALAC expect the IACUC to document the review of DMR-** ah -

designated member review? AAALAC's expectation is - that you would fall under the policy that is delineated on the Frequently Asked Question page of OLAW, basically. And it is expected that there is a - that people clearly see which - what the nature of the protocol is that is being conveyed through designated member review and they do expect them - people have the right to waive the referral to designated member review and that that be documented.

The next question. **How much information does AAALAC share with USDA and OLAW?** The AAALAC program involves an independent, confidential peer review process and therefore AAALAC does not share any specific information about individual units with the USDA or OLAW.

Does AAALAC release information about an institution if requested by a group such as PETA? Absolutely not. This would be a violation of confidentiality. With the consent of the institution, AAALAC will include the organization's name in the list of programs that are posted on the AAALAC website that participate in our AAALAC accreditation program. That is the only general information that is available to the public about accredited units.

The next question. **Is there a standard or a quantity of training that AAALAC members - of IACUC members - that AAALAC looks for? So is there a standard or quantity?** AAALAC expects IACUC members to be adequately trained. And there is no minimal standard I can cite. I can certainly cite - what organizations do which is effective - and that is typically they at least have an internal process which orients new members of the committee to the relevant

regulations and guidelines - to the AVMA Panel document on euthanasia and to other relevant documents which frequently come into play in the review of protocols. AAALAC also - of course - encourages the institution to promote the development of the IACUC members by sending them to national meetings on the topics which are relevant to the function of the IACUC. But there is not a magical mandatory formula that is used as a hurdle in the evaluation of this. In essence - if a program is reviewed and there are gross deficiencies in the way the IACUC is functioning - that may be a cause for AAALAC to invoke the notion that there is inadequate training of the IACUC members.

How does AAALAC view the IACUC's role related to the requirements of occupational health and safety in a field study?

Regardless of where animals are used, there may be risks that are present either in that environment or may be intrinsic to the animal, which could pose an occupational health and safety risk to the individuals who are involved in the study. So AAALAC would expect that the IACUC would play the role of linking up the people who are involved in that program with the occupational health professionals that are responsible for overseeing the program. And then through the review of relevant data and scientific literature bearing on what the risks may be in the field study environment - it would be up to the occupational health professionals to make the judgment about what the actual requirements would be. So the IACUC's role would be limited - of course - to the role of the conductor of the orchestra, not the player of the instrument.

In a somewhat related matter - the question is - **Who should be included in the occupational health program? What if an individual does not want to participate?** All individuals with animal contact should be included in the institution's risk assessment exercise which serves as the basis for determining the distribution of medical care, preventative measures, training and other resources comprising an effective occupational health and safety program. Institutions may conceivably devise ways for some individuals to opt out of particular aspects of the occupational health and safety program. However, the basic elements consisting of the risk assessment process, the use of personal protective equipment - as appropriate, and training provisions would generally continue to be regarded and required at some level. In addition, in some areas of animal use, nonparticipation in the program would be a sufficient reason to prevent the individual from having animal contact. Medical and legal experts at your institution should be consulted if your institution intends to take this route.

Will AAALAC develop guidelines or recommendations for IACUC's responsible for handling off-site field research outside of the U.S.? It is really - AAALAC's position is this. If your institution owns an animal, which it sends to a program, which is outside of the United States for a portion of the biomedical research, AAALAC would either expect that organization to be AAALAC accredited, which would de facto be the guidelines and recommendations you're alluding to or it would want to have the option of viewing those animals as part of your - those animals and the practices that support them - as part of your accreditation. But with regard to a decision, you as an institution and as an IACUC may make, about offshore research or doing collaborative research with other organizations where you do not own

the animals - AAALAC does - it certainly does not - have any authority to comment on that and it would not generally be interested in developing guidelines and recommendations for those situations. I think it goes without saying we would minimally exhort you to ensure that the principles of the *Guide* are adhered to in those organizations. But we're not prepared to develop guidelines or recommendations specifically.

Next question. **Can the IACUC fill the scientist's role by rotating several scientists from the same department and with same credentials? Their name participation would be captured in the meeting minutes.** This would, in AAALAC's view, not be acceptable - except in the circumstance that a scientist - a scientist could be appointed as an alternate to a member sitting on the committee - and if the charter of the committee says that when the primary appointee is not there, the alternate is capable of sitting in the committee and participating as a member with the ability to vote. The notion of appointing much more than a single alternate, I think - personally - gets problematic - although I won't convey an AAALAC view on it. The basic view being you get very much a shifting landscape there, and this could lead to inconsistencies in the kinds of decisions the Committee is making over time. It is conceivable, but has to be done carefully.

Here is another one. The next - Oh - OK. The next question. How does AAALAC view the IACUC's role related to the requirements of - no I did that occupational health and safety in a field study. I'm sorry, folks. Next question. **What happens if the professional opinion of an organization's experts is in disagreement with the opinion of**

AAALAC on a matter that is considered mandatory? Well - I would start by saying here as I have said in many other talks I've given - that - you know - professional judgment has to be based not just on the fact that the individual is a professional, it must be based on data and the recent consideration of that data and literature which rests outside of the professional. So - you know - a scientific requirement is not the requirement that any scientist may come up with. So it is important to think to reiterate, that we would expect interactions with the organization to be collegial and interactive, and of course we would be very receptive to hearing the arguments of any institution on an item which is deemed mandatory. And we would expect those items to be couched in terms of the data you collected, the relevant literature which was reviewed and the conclusions that you reached and how you reached them - and that would be entered into the Council's deliberations. The bottom line is - the Council would - of course - go through a similar process and - in the end result - if Council does not want to yield on an issue it considers to be mandatory - despite the information you've provided for its consideration - then the opinion of Council would prevail.

Next question. **How soon after a site visit must a mandatory item be corrected? What if it would require significant capital expenditures that will not be available for some time?** The amount of time allotted for the correction of mandatory items is different for new applications for accreditation and programs that are already participating in the AAALAC program. In the case of the new applicant, the maximum period of time for the correction of a mandatory deficiency is fixed at 24 months. In the case of an institution already participating in the accreditation program, the maximum period is 12

months. The Council recognizes that mandatory items vary in their dimension and complexity. This is usually the basis for the initial time allotment that is issued by the Council in the letter of recommendation sent back to the institution. The increments of subsequent time extensions allotted by the Council are typically adjusted commensurately with the institution's report of the progress it's achieved and the impediments it's encountered in the resolution of the issue.

The next question. **How do organizations gain access to AAALAC reference resources and policy statements?** The AAALAC website which is located at www.aaalac.org contains the policy statements and reference resources. In the Reference Resources Section hot links to the documents are provided, in addition to the reference citation, whenever possible.

The next question. **Does AAALAC require oversight of invertebrates?** This was alluded to in the chart I had, which compared AAALAC versus the USDA and OLAW process. AAALAC is capable of developing a team which - at the discretion of the institution - would be willing to review the invertebrate program during the overall review of the animal care and use program of the institution. In addition if - in the course of visiting the facilities that AAALAC reviews during the site visit - if there are rooms or areas of the facilities which contain both vertebrates and invertebrates - and there is some potential for the invertebrate practices and the maintenance procedures for those animals to impact the vertebrates - then AAALAC will review the invertebrate work as - may review and

comment on the invertebrate work as well - particularly if it is deemed to be detrimental - based on the vertebrate work.

Let's see. As a final question. **What kinds of records should we keep for mice and rats?** There are several types of records that are of interest to AAALAC and they fall in the realm of ensuring scientific integrity, ensuring the health and comfort of the animals and ensuring that attention to pain relief is - is appropriate for the animal. So in the case of transgenic and other very sophisticated animals - it is certainly pertinent for the scientific laboratories to maintain records so they can do adequate tracking and genotyping to ensure the animal model they're using is actually the animal model they believe they're using. In the realm of the veterinary care program, it's appropriate to keep records which sufficiently track the origins of animals, the movements of animals through facilities, and the health backgrounds on rats and mice so that if there are problems with infectious disease control or disease epidemics, those records exist for the reconstruction of the problem and dismantling and correction of the problem. And lastly, when rats and mice are used in invasive procedures, records should be maintained to ensure that the animals have been given the appropriate drugs for their anesthetic management, tranquilization, sedation, and - notably - analgesia.

Thank you Dr. Newcomer, we are most grateful to you for taking the time to participate. I also want to thank the attendees for your patience and I especially want to thank our technical staff for solving some fairly significant technical problems on the run. They've done a remarkable job of keeping us on the air this afternoon. We are finished - both with the questions and with our time. And we will remind you

that coming up on your screen momentarily will be the reminder of the upcoming talks. We hope that you will send to us your comments and suggestions - both about this seminar and about future seminars. You can send that information to the OLAW email box which can be found at the bottom of the OLAW web page. The link is OLAW help. The email address can also be found in the email you received confirming your registration. Once again, we thank you very much for your participation and hope you have a pleasant summer.