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*Note: Text has been edited for clarity.*

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## **Emerging Issues, USDA Perspective**

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*Moderator: Susan Silk, M.S., Director, Division of Policy and Education, OLAW*

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*<https://webmeeting.nih.gov/p62491457>*

[It takes several minutes for the recording to load]

Slide 1 (Title slide)

Hello everyone and welcome to the OLAW online IACUC staff seminar. Today is Thursday September 17<sup>th</sup>, 2009 and our seminar "**Emerging Issues: USDA Perspective**" will be presented by our guest speaker, Dr. Betty Goldentyer. I am Susan Silk, the director of the Division of Policy and Education, in the [Office of Laboratory Animal Welfare](#), and will be the moderator for today's seminar. Jerry Collins is not able to be with us in Bethesda today but he'll be back for our next seminar on December 10<sup>th</sup>, when our topic will be "**The OLAW Annual Report: What You Need to Know**". This morning I'd like to say – or for some of you, afternoon, I'd like to say a special hello to our colleagues in Alaska. They recently registered to participate in our seminars; this brings our total to 373 participating institutions from 48 of the 50 US states, one possession, and four countries. I'd like to thank Lori Hampton for registering every one of these participant groups, answering questions, retrieving lost passwords, and dozens of other tasks that a program of this magnitude demands.

Throughout the seminar, if you have a question for our speaker you may type the question into the 'submit a question' box in the upper left corner of your screen. Only OLAW staff will see what you have written. We will address as many questions as we are able in the allotted time. I especially want to thank those who sent us their questions in advance, we will be sure to address those questions.

Today's seminar will be recorded, the recorded seminar, a transcript of the text and a copy of Dr. Goldentyer's slides will be posted within a week in the Education section of the OLAW website. You can find this material at <http://olaw.nih.gov>.

And now, it is my pleasure to introduce Dr. Betty Goldentyer. Dr. Goldentyer is the Eastern Regional Director for the Animal Care program of the [United States Department of Agriculture](#) [USDA], [Animal and Plant Health Inspection Service](#) [APHIS]. Dr. Goldentyer has been with the Animal Care program since its organization as a stand-alone unit in 1988. She has been a field inspector for dealers, exhibitors and research facilities in Wisconsin, an Animal Care Specialist, supervising inspectors in the Southeast US and director for the Eastern region since 1997. Before joining APHIS, Dr. Goldentyer practiced in a small animal clinic and a large, regional humane society in the Chicago area. She is a graduate of the Tufts University School of [Veterinary] Medicine, and now Dr. Goldentyer will speak to us about **“Emerging Issues, the USDA Perspective”**.

#### Slide 2 (Emerging Issues)

Thank you Susan, and thanks so much to OLAW for including USDA in this great webinar series, and thank you for getting me all hooked up here for the webinar. What I’m going to do with the presentation is go through some of our new initiatives, some of our new programs and then an update on some of the programs that have been in the works for a while. And when we get to the question and answer session, we can get more into the nuts and bolts of the inspection process and the Animal Welfare Act Regulations.

#### Slide 3 (Pet Evacuation and Sheltering)

Since Hurricane Katrina, there’s been a heavy emphasis on pet evacuation and sheltering. And APHIS is the lead agency for Agriculture, for making sure that we have a plan to protect pets and pet owners in the event of some kind of emergency or disaster. We, in Animal Care, now have four full time positions dedicated to helping the states work through the pet evacuation plans. And that would be issues like making sure that there’s adequate transportation to get pets and pet owners out of harm’s way, for sheltering pets, and identifying animals. So we really are excited about this new initiative, and in fact, all our inspectors are being trained for emergency response duties. It may, there may come a time, when you notice your inspector is off for a while attending to some emergency response issues.

#### Slide 4 (Contingency Plans)

On that same issue of responding appropriately to emergencies, we have proposed a new rule, a new regulation, which would require that every facility develop, document, and follow an appropriate contingency plan for their animals in the event of an emergency or a disaster. I know that many of our research facilities are already ahead of the curve on this. You have disaster plans in place. This is a relatively new idea for some of the commercial dealers and exhibitors but we’re working through that. The proposed rule was published in October of 2008, we got lots of great comments in and those comments are under review now and then the next step will be a final rule on that. We do know that in an emergency, because of the nature of emergencies, plans aren’t exactly followed the way you expect but we are really hoping that, with this rule, we can put some forethought into assuring the safety of animals and then that will help ease the way through these kinds of situations.

#### Slide 5 (2008 Farm Bill)

A couple of issues from the 2008 Farm Bill, one of the things that happened to the [Animal Welfare Act](#), one of the amendments, was an increase in the maximum civil penalty. It went up to \$10,000 for each violation of the Animal Welfare Act. Now the way this works, it is in place, and the way it works, it that \$10,000 is the maximum civil penalty that the Department can levy for any kind of a violation. And then, we are given the responsibility to find an appropriate penalty. So we try to take a set of factors, mitigating, or possibly aggravating factors and adjust accordingly, and coming up with an appropriate penalty. For those, we're looking at the size of the business involved in the violations, the history of compliance by the facility, the gravity of the specific violations, and then, the good faith exhibited by the facility where the violations took place. So taking all those things into account and then coming down from the maximum.

That was new with the Farm Bill, as well as a prohibition on the importation of live puppies. The problem that we were facing was that puppies were coming in from other countries, most of them for the commercial pet trade. Of course, very young puppies when they're shipped – it's a stressful experience, as well as kind of an unknown disease status for those animals. So the amendment addresses that and really prohibits the importation of puppies before six months and there will be some rulemaking to put that into the Regulations. This prohibition on the import of young, live puppies does not apply to animals that are going to research, and it does not apply to private pets. It's only for animals in the commercial pet trade.

#### Slide 6 (2008 Farm Bill)

Okay, Class B Random Source dealers were addressed in the 2008 Farm Bill. And one of the requirements was that a study be conducted on the use of dogs and cats, the use of these Random Source dogs and cats in federally funded research and that was completed. In addition, Congress asked that the General Accounting Office [GAO] conduct an audit of the regulation and our enforcement efforts in the area of Class B Random Source dealers. That GAO audit is ongoing at this time and then we'll be able to look at all that information together once that is completed.

#### Slide 7 (Minimum Age Requirements for the Transport of Animals)

There are a few proposed changes in the Animal Welfare Act Regulations that are in the works. One is a requirement for a minimum age of transport for animals other than dogs and cats. The current Regulations say that dogs and cats cannot be transported, this is within the country in commercial transport, if they're under eight weeks of age. And we have found that that's very helpful to have that engineering standard of that eight week cut off. The transportation, again, is stressful and it's nice to be able to just say 'you cannot ship these animals until they're eight weeks'. But we never had that with other types of animals like exotic cats, lions and tiger cubs, primates; infant primates were being shipped in the pet trade. And so, this will help us protect those little animals going

into commercial transport. Again, this transport requirement would not apply to animals going to biomedical research. I don't know when this proposed rule will be coming out but I know that it is a priority because we had problems in this area.

#### Slide 8 (Standards for Regulation of Birds)

Okay, the definition of 'animal' as regards to rats, mice and birds changed and ever since that changed – and the corresponding change in the Regulations – we've been working on trying to develop some standards for the regulation of birds in particular. Now that change made exempted rats, mice and birds bred for research from the Animal Welfare Act Regulations and standard. What that did, by exempting them from research was kind of open up the regulation of rats, mice and birds for other purposes, not research purposes. And there are a lot birds in the commercial pet trade, a lot of birds on exhibit, as I'm sure you've seen if you go to the Zoo, aviaries, that kind of thing. So we never had any type of standards that would work for birds and we worked on proposing some standards. There was an advance notice of proposed rulemaking in 2004. And, we got some great comments. We have rewritten that, it's all in clearance and we're hoping to have some kind of standard out for that piece of the regulation of birds. Hopefully, relatively soon, but it's not imminent. Now one thing I would like to mention right here is that the way that the definition is worded 'rats, mice and birds bred for research' does leave open the question of particularly birds being used in research that were not bred for research. In other words, wild caught birds being used in research. There is a question about whether or not those animals would be regulated and how that would work if you had, say a mixed colony, or breeding of wild caught animals. We know this is an issue; can't really talk about how it is going to be addressed. But just to say that we really appreciate the comments that we got on the issue the first time around and as a proposed rule goes out for comment, we really hope, that, especially those of you with experience in that area, will comment to help us make sure that we clarify that piece and make that work for everyone.

#### Slide 9 (OIG Audits)

We've been busy with some OIG [[Office of Inspector General](#)] audits the last year or two. It is very routine in government; all the agencies regularly get audited by the Office of the Inspector General. And we've had them in the past; we know we'll have them in the future. Right now we kind of have a lot of them going on all at once. So in addition to the GAO [[Government Accountability Office](#)] audit of Random Source Class B dealers that I mentioned before, we have an audit going on in the commercial dog breeding area. We have an audit going on - on exhibitors that are oversight of exhibitors and we also have an audit going on - on horse protection. I bring this up, none of them are audits in the research area, but I do think it's good to keep an eye on these because many times the management recommendations that come out of the OIG audits are far-reaching. They go across, they delve in to our processes of inspection and enforcement that reach across the different types of industries that we regulate and might even impact the way we do business with research. Once the agency has a chance to look at the results of the audits and respond to that, all of those audits will be made public. I don't know exactly, again,

when that will be but it's just something that will be coming up, probably in the next year or so.

#### Slide 10 (Animal Care Information System)

We have a new database some of you maybe recognize the acronym LARIS - Licensing and Registration Information System – that was Animal Care's old database and it was outdated, it came to the end of its usable lifespan and so now it's been replaced as of March 1<sup>st</sup>, 2009. The new system called Animal Care Information System or ACIS. ACIS is going to help us - I mean we've already seen a lot of improvements in our ability to track facilities, to track inspections, public complaints and inventory and animals – that kind of thing. So we are appreciating that. I'm hoping that at your facilities, you will be able to see some improvement too in that this system is much more user friendly for the inspector, and we're hoping that the inspectors will be able to produce your inspection reports quicker for starters and with a lot less back and forth and correcting of things that were a problem in LARIS. So we look for that to be a benefit. As with all these databases, they kind of come on in phases and we're still in phase one. Phase two is supposed to be rolled out later this year or early 2010. One of the features of phase two that, I think, I'm looking forward to, and you know, we hope you'll take advantage of is online applications for registration and online renewals of, you know, the three year renewal of the research registration. So that could be a pretty cool application there. Our online system for the Annual Reports is not working, so we're not using that this year. But I'll get to that in a minute.

#### Slide 11 (*Electronic Freedom of Information Act*)

The electronic Freedom of Information is always a hot topic. With the eFOIA Act, all of the documents that the department considers 'frequently requested' are to be posted on the website and we are well in to that process. If you look at the website you will see that the inspection reports for commercial dealers, the Class A and the Class B dealers and the exhibitors have already been posted to the website. And the way that this has been working is that the inspector does the inspection and it goes into the database and then we have a 21 day hold, which is kind of a review period for us to be able to look through and make sure that we're comfortable with everything that's in there, for the facilities to make sure that they're comfortable, give us a call if there's an appeal intended on a particular citation. And then at the end of the 21 days, and usually about once a month, the website is refreshed; all of the inspection reports are then posted with the signatures redacted. And that includes the history, so the old inspection reports for the past three years are all posted up there. The same system will be in place for the research facility inspections. What will happen first is the stakeholder announcement will go out to all of our registered research facilities. And that will kind of start a 30 day notice that the inspection reports will be posted and then on the day when, you know, it's supposed to take effect all the inspection reports, back three years for every facility will go up on the website. I really encourage you to take a look at the way the exhibitor and dealer inspection reports are posted. It will be very similar for your inspections of your facilities.

Now the Annual Reports for the USDA are also frequently requested documents and are also posted on the website. But it's a little different process, they're going to be batched up so the 2009 reports will come in, they'll be reviewed, we'll account for everything and then they will go to the FOIA office and FOIA will read the Annual Reports and contact the facility, redact anything as necessary and then they will be posted as a whole batch. So that's a little bit different process for FOIA, but again posted on the website.

#### Slide 12 (2009 Annual Reports)

Okay, it is September and time to talk about the USDA Annual Reports. The packages were mailed to the facilities from the regional offices on Tuesday [September 15, 2009]. So you should be seeing them at your facilities next week, if you don't get it – make sure you give us a call. The reports are due back in to the regions by December 1<sup>st</sup> [2009]. Back to the FOIA issue, whatever you send in with your Annual Report, the narrative, everything, will be reviewed by FOIA prior to being posted on the website.

#### Slide 13 (2009 Annual Reports)

There, as I said, will not be an opportunity for online reporting this year. We did have that with our LARIS system, we're not really confident that we're ready to roll it out with ACIS. We're going to hold on that until 2010. So just go ahead and report hardcopy, the old-fashioned way, don't forget to include your Column E explanations and also the summary of the IACUC approved exceptions to any of the regulations or standards.

#### Slide 14 (2009 Annual Reports)

The packet's got a lot of information in it, there are tips and samples, there's a format for the Column E narrative. It's not a requirement that you use that Column E explanation sheet. It is nice because it makes sure everything is included, but if you have another format that you like that's fine too. There's also an Annual Report checklist that you might want to look at before you fire away.

#### Slide 15 (2009 Annual Reports)

When we, kind of, get into a routine of getting these Annual Reports pulled together, it can be a busy time and I know that not everyone reads the fine print all the time. But in teeny, tiny, writing above the signature of the Institutional Official are four assurance statements. By Regulation 2.36 and 2.33, the Veterinary Care Provision, the Institutional Official does assure to us each year that the institution is using professionally accepted standards, particularly in terms of pain relief. In the area of pain relief, the IO is assuring that the investigator has considered alternatives to painful procedures and the institution is adhering to all of the regulations and standards, and reporting any exceptions and that the attending veterinarian has the appropriate authority to provide adequate veterinary care. So you might just want to take a minute to read that when it's being signed off.

#### Slide 16 (Center for Animal Welfare)

Okay, we've had this initiative in the works for a while so I'll just give you a status update on our Center for Animal Welfare. The intent of the Center for Animal Welfare is to really

be a kind of a national resource, a clearing house for us to help Animal Care, deal with policy development and analysis. Our training, both internally with our own inspectors and then also to our stakeholders, and also to look at some of the animal welfare science and the new technology that we think can improve animal welfare both in terms of the Animal Welfare Act and Horse Protection Act. We're making progress. We have space in Kansas City and we also have some announcements out there to start staffing up the center. We're going to have a meeting – next week in fact [September 23, 2009] – kind of the inaugural meeting at the center which will be a conference, a workshop, dedicated to looking at the use of alternatives. That will be taking place actually in the space in Kansas City, so we are excited about that.

#### Slide 17 (Policy Manual)

We get lot of questions about where the Policy Manual is. Every time I try and say it's coming right out, it takes a little longer than we think. But prior to January of 2007, we for a long time, we've had this Policy Manual which is helping us interpret the Regulations, helping explain to the inspectors and to our stakeholders what we think the Regulations mean, what we are looking for. And in January of 2007, we were asked to look through all of our guidance documents and make sure that we've had some public comment on any significant guidance documents and it was a really good opportunity to update it as well. So the comment period on the policies closed in 2007, and we read every comment. Thank you very much for the comments. We have incorporated a lot of them into the revisions. And, Animal Care actually has finished the revisions and the document, the new Policy Manual, is in clearance in the Department. So, you know that's a good sign. Once it's up in the clearance channels, that's a good thing.

Some of the policies, as you might remember, were pretty outdated. They were irrelevant with some regulation changes or needed consolidation. It's cleaned up a lot. It's a lot smaller than it was before. I do not think you're going to notice anything really surprising or, you know, really – nothing shocking. Most of the information that was in there is just updated a little bit in a much better format. So, that is the Policy Manual.

#### Slide 18 (Field Staffing / Inspections)

And last, is a little update on where we are with our field staffing and our inspection activity. We currently have 102 inspectors, that's Eastern and Western region, and our Veterinary Medical Officers as well as our Animal Care Inspectors. We have just added a Field Supervisor position so we'll now have 12 Field Supervisors and we have four Field Specialists who are also out there to help make sure that we're making good decisions and addressing the issues. We have Dr. Laurie Gage who works on exotic cats; Dr. Gary Goldberg on nonhuman primate issues. Dr. Vaughan Langman works on – he's a biophysicist, he helps us determine whether an animal is comfortable – as far as heat and cold stress. And, Dr. [Denise] Sofranko keeps busy working on elephant issues. That's everybody that we have out in the field doing inspections.

And of all – with all that in 2008, we were able to conduct 15,700 inspections of 9,600 licensed and registered facilities. Now, that total number of licensed facilities is down a little bit. We think it's probably a function of the economy; it's mostly in the commercial kennel business where the numbers have gone down a little bit. The research facility numbers, however, have stayed very stable. We always have around 1,100 research facilities. That's what we have right now. We usually conduct about 1,700 inspections and that's what we did in 2008 and I am looking for the numbers to be very similar in 2009, but we don't have them quite yet.

Slide 19 (AC Website)

There is a lot of good information on the [Animal Care](#) website. I think it is getting better and better. Particularly want to draw your attention to the eFOIA link so that there are no surprises when the research facility inspections go up. You will know exactly what it will look like.

With that, I think we can go to some questions.

Slide 20 (End slide)

Well, we have some questions that came in before the seminar, and I see that you're writing your questions in now. That's good. Keep those coming. **We are in the process of moving from an entirely paper protocol submission process to an online one. We would like the USDA perspective on a few questions.** There are several here. **[1] It is the expectation of – is it the expectation of the USDA and / or its inspectors that we would maintain a hard copy of all of our protocols for the purpose of inspections, or as part of a disaster plan? [2] If we do not need to maintain hard copies of all proposals, will we be expected to print the requested protocols at the time of our USDA inspection or would we be expected to provide the inspector with a password to log on?** Well, the inspectors need access to the protocols. It doesn't have to be hard copy, computer access is just fine. How the facility chooses to provide that computer access, whether you want to log in and let the inspector look at it or provide a password, that's kind of up to the facility. But we may, on occasion, have an inspector that asks you to print out a protocol. And that may be because there is something in particular they want to look at or, you know, it's just easier for them to deal with that particular protocol. So that may happen and hopefully, with the technology, we can work that out on an occasional basis. As far as printing the protocols out as part of a disaster plan, the contingency plan proposal is still under review. So, there aren't any specific requirements in that yet. I think some attention to access to the protocols in the event of an emergency would be appropriate, but that – how that is worked out will probably be up to the facility.

This question goes on. **[3] The new online system only provides an up to date version of the protocol without the back and forth that occurred between the IACUC and the PI. So, there really is no documentation of the review process. As long as there is no issue, is the current protocol sufficient? Should we print or**

**save each version of the protocol as it evolves, in case there is an issue?** Animal Care is not going to need the whole evolution of the protocol as it gets worked through the system. What we do need is a copy of the protocol that the IACUC is looking at and then the committee's deliberations when they look at that final protocol. There is no requirement for keeping every version of the protocol as it makes its way through the system.

The final part of this question. **[4] Are electronic signatures acceptable?** Yes. Electronic signatures are just fine. In fact, with our new Animal Care Information System, we are hoping, probably going to be in phase 3, but we're hoping to go to a digital signature ourselves so that you'll be signing off your inspection reports with a digital signature. So yes, electronic signatures are just fine.

**[If you have reported an instance of noncompliance with the] AWA Regs in your IACUC meeting minutes, and have followed up with an appropriate remediation plan, can the institution still be cited for noncompliance during their USDA inspection?** It is the institutions responsibility to stay in compliance with all the regulations and standards. So yes, there can be a citation, and we're very happy to see the IACUCs do what they're supposed to do; take on these problems, you know, do the reporting, get the corrections that are needed. So, that all goes to the functioning of a good IACUC and also to the good faith of the institution to do that. And, we really take that into consideration; you know, the good faith – you know, the well functioning IACUC. We are looking at that when we go to look for things like frequency of inspection and the type of enforcement action that might come up. So, it's a really good thing. There still can be a citation, but it's the right thing to do and really important that the IACUC recognize that.

**Has an IO ever been prosecuted for the failure of an animal program?** No. We've never had an IO personally prosecuted. The institution is the registrant, so the legally responsible party is the institution as it is registered with us. But let's say a case of noncompliance, just worse case scenario, something bad happens and it goes all the way up to a hearing in front of an administrative law judge. Well then in that case, the Institutional Official would be called as the responsible official for the registrant, which is the institution. But no, we've never had an IO personally prosecuted.

**How severe are fines for failure to meet regulatory requirements?** Well, as I mentioned, the maximum civil penalty for the violations just went up to \$10,000. That's the maximum. Then we're going to consider the mitigating factors and come up with an appropriate penalty. And, you know, good faith on the part of the institution is a really important factor. Our goal is compliance. So how do we know that a facility is going to get this taken care of and stay in compliance in the future? That's what that good faith piece is. We really take that factor into account quite a bit. Just an interesting aside on the level of civil penalties or fines that can be assessed under the Animal Welfare Act; the act gives the Secretary of Agriculture the authority to, in the person of a judge, the authority to

revoke permanently or suspend an animal welfare license for a commercial dealer or exhibiter. There is no such provision for research facilities. So often time, a commercial dealer or exhibiter that has some egregious violation – they may end up with what looks to some people like a smaller fine, but it's in conjunction with a license revocation or suspension which is very serious because they're basically out of business. So, [loss of audio]

We see that there's some problems with Betty's microphone, and we're working on that now. She's re-logging in, stay with us. Here we go. Turn that off for the echo.

**Do USDA and OLAW share information about problem institutions?** Yes. Section 2145 of the Animal Welfare Act actually requires the Secretary of Agriculture to cooperate with other federal departments and agencies and any instrumentality concerned in the welfare of animals used in research. So, we are required to cooperate with OLAW and other departments and agencies on animal welfare issues. And we like to, too. Because it's really important to both of our agencies and it works very well when we work together on these issues. To that end, we do have a Memorandum of Understanding between OLAW and USDA to make sure that we're sharing information appropriately and working together when needed. So, yes.

**How does the USDA ensure consistency across VMOs [Veterinary Medical Officers] who are doing inspections?** You know, this is something that we have to work on all the time. And, probably it always will be. It's training and just the kind of guidance that we provide to the inspectors. It's reviewing the work, quality control. We want to make sure we're reviewing the inspection reports, that the supervisors are riding along with the inspectors, that the inspectors are riding along with each other so they can see how it's done. And little by little, you get closer and closer together. One of the things we really do appreciate is if a facility out there notices that something seems to be way off kilter, it's different than it seems to be at other institutions, or it's different than it was in the past. We do appreciate hearing about that. That gives us another way to look at this consistency. I know this consistency issue is a really important issue for facilities that have more than one inspector, if you have sites spread out, and you are trying to deal with two or three or four USDA inspectors; that could be a challenge. If anybody out there is in that situation and is noticing a problem, we would definitely be happy to work with you on it.

**What should an institution do if, at the time of the exit briefing, they do not agree with a citation? May they contact the VMO's supervisor before the VMO leaves the premises?** I'm going to discourage that as a way to handle it. There may be occasions when it has to be that way, but what I really would like to encourage is that each facility make every attempt to resolve this through the systems. And the reason is because it kind of puts the supervisor, the regional office, in a rough position. We do not know what's going on out there. And, it's hard to make a considered decision on the spot like that when you really don't know exactly what's going on. The better way that we have

seen, over the years, is to work through the issues as much as possible with the inspector as you're going through the facility, as you're going through the exit briefing and try to get those worked out. If that's still not a satisfactory resolution, then there is the appeal process which is spelled out on the website. And, I think those are like better ways to come up with a really good decision, if there is some kind of disagreement.

**Are photos taken by a VMO FOIAble and, if so, is there any way for an institution to redact portions of the photo?** Yes. Photos are FOIAble. In fact, pretty much anything in the possession of a [U.S.] government agency can be requested from the public, and then it's up to the FOIA Officers to determine whether it should be released to the public. But, indeed, photos are FOIAble and have been released. Now, it's not Animal Care's decision. We have a FOIA specialist who makes those kinds of decisions. But if I can guess what they might do in a situation like this, let's say proprietary business information was on the photo – or something confidential that didn't need to be released. In that case, I think the FOIA Officer's decision would be not to release the photo at all.

**How long will inspection reports remain on the website after posting? Will they be removed after three years?** I think that is the plan – to have three years of inspection reports posted on the Web at a time. So now it only gets refreshed monthly, so if something was up there three years and a month or something, it might be up there a little bit longer. But that's the plan, to have the last three years of reports up there. Now, there is one exception to that. That would be the Annual Reports and I'm sure all of you have heard about the recent HSUS [vs.] USDA lawsuit over the release of the Annual Reports. We did have some older reports that were agreed to be posted up there and so that three year timeframe is not in effect for the Annual Reports at this time.

**Is there an expectation for the emergency plans for research facilities to document the training of the plans, and is there an expectation to have a frequency of training on the emergency plan?** This – we don't have the final rule out on this yet. So, I really can't comment and don't even know exactly how the wording is going to be. But, I mean it does seem like the plan should address some kind of training. And that's about all I could say. I really have no idea if it will go into the details of the frequency of training.

**How does the new definition of exempted species effect birds being displayed in educational exhibits?** Well, Animal Care believes that the change in the definition of 'animal', which exempts birds bred for use in research, means that birds used in other types of regulated activity, like exhibition, would be regulated. So in any public exhibition of birds, would then come under the Animal Welfare Act and be regulated by Animal Care. Now, as in all of the other types of regulations that we have, once we decide that a particular activity is regulated, then we decide at what level we will be regulating that. For instance, if you sell dogs into the commercial pet trade, you need a license. But if you have only three or fewer breeding females, you don't need a license. You can sell dogs to a pet store without being covered under the Animal Welfare Act. So, I imagine that there

will be some sort of cutoff for the level of activity but we believe that this new definition will bring birds displayed on educational exhibits under the Animal Welfare Act.

**What about mice and rats bred for testing? Is this different from research in terms of the exemption?** Again, we'll have to wait for the details of the final regulations. But in general, we look at teaching, testing and experimentation as one thing. So if it's exempt for research, it would be exempt for teaching, testing and experimentation.

**Could you please comment on whether items in the Policy Manual can be cited by the VMO on the inspection report if that item is not specifically covered in the USDA AWA Regs themselves?** The Policy Manual is designed so that what is in the Policy Manual is in the Regulations. It's our interpretation of what the Regulations say and how they are to be used by the inspector in the field. So when you look at the Policy Manual, the old one and the revision both, you will see on the very top part of each page, the top of each policy, you'll see the overarching Regulation that is being explained. So, Policy 12 is explaining what is in Section 2.31. So it – the citation – both on the policy, in the manual itself, and on the inspection reports - will be to the Regulation and not to the policy.

**Will our written responses to inspection reports be included with the online version of the inspection report?** Not at this time. The reports, if you go and look at the eFOIA website, you'll be able to see that this data is coming out of the Animal Care Information System and posted in the form of an inspection report. That's the only possible way that we could physically get all that – all those inspection reports up on the Web all the time every 21 days. So the responses that the facilities write, although they contain great information, they don't go into the database, so there is no way to automatically post them like we do the inspection reports.

**Does an Assured research institution, that means one conducting research with NIH funds, with only mice and rats for medical research, need to stay informed on the AWA and USDA Regs, even when the species used are not classified as quote animals? What is the expectation of the IACUC in this case?** This might be a good question for OLAW. From my point of view, from USDA's point of view, if there is no regulated activity, then the only reason to be knowledgeable about what USDA does regulate - would be if it came up. So let's say there – the IACUC, the Institutional Official, you know, really have no idea anything about what USDA does, and then an investigator brings in some regulated species, say a guinea pig or something. It would be important for somebody in the institution to understand that this might kick us into – if we approve this protocol – all of a sudden we're looking at that whole new bunch of stuff that we have to deal with. So I mean, I think it is important to be aware of the whole package of the Regulations, but the details I guess it would be up to the facility and how they wanted to handle that. [Susan Silk, speaking for OLAW] And I'll just chime in and say that OLAW's

expectation would be that you comply with the terms of your Assurance and with the PHS Policy, and I think all of you already know that.

The next question. **Are minutes okay as a record of deliberations of the IACUC?** Yeah, the deliberations definitely can be part of the minutes or they can be a separate document as long as it's all available and clear where everything is for the inspector.

**What is the minimum number of IACUC members needed to perform semiannual inspections in order to stay in compliance?** Two. The Regulations call for two members. We have, in some extenuating circumstances, worked around that number but generally, you want to have two of your IACUC members, two sets of eyes looking at that as you do the semiannual inspection.

**What are the future plans to include mice, rats and birds in the AWA for research and testing facilities?** Well, that would require an amendment to the Animal Welfare Act and my personal opinion is, I have plenty of work, so I have no plans for that.

You didn't bring your crystal ball today? **What level of detail does USDA want to see in IACUC meeting minutes?** This is kind of a subjective issue and I know that there is a lot of sensitivity about putting in too much detail. I mean we certainly want to see what the issues are; how they get resolved. We want to make sure that the important issues in these protocols are being raised, that everyone at the table is having the opportunity to address them. One of the things people ask is - do we need to name names. We certainly don't need that level of detail. We don't need anything verbatim, nothing like that. Just enough that someone who was not at the meeting could look at those minutes and really get the feeling for what issues were discussed and how they were resolved.

**Our institution's policy prohibits photography in the animal facility. Can we prohibit the USDA inspector from taking photos in our animal facility during their inspection?** Prohibiting the USDA inspector from taking photos is a refusal to allow inspection. That's a very serious violation of the Animal Welfare Act. So that is probably not a good thing to do. If there are other accommodations that we can work out, if you want to talk that over, some people have a - let's say a barrier facility, it's an issue of getting the camera in, or the facility is interested in taking themselves the same photographs that the inspector takes, it would be great to go through your policy with your inspector, work out those kind of issues. But no, the answer is no. You cannot prohibit the USDA inspector from taking photos.

**Regarding the Annual Report, would animals that experience unrelieved pain or distress resulting from an adverse or unanticipated event be required to be reported under Column E?** The decision point on that kind of situation is really - is this related to the research or not? Sometimes things - animals have health problems where they might have some pain or distress, develop maybe an infection, or something like that- that is completely unrelated to the research. That's a veterinary care issue. We need

documentation of it. There needs to be a record of adequate veterinary care. But, that's not the kind of incident that would be reported under Column E. There are some great examples of this type of question included in your Annual Report packet, so find that sheet that has the samples. If you still have more questions about whether or not a particular incident needs to be reported, you want to make sure you call your regional office and they will be able to talk you through that.

**Can the number of animals or number of days of violation influence the fine and raise the total above \$10k?** The \$10,000 fine maximum is per violation, so that can be calculated per animal per day. So the total fine can definitely be above 10,000 if you add in different types of violations – maybe there is more than one violation, more than one animal involved. The total could definitely be above \$10,000, but in general the \$10,000 is per violation.

**When do you anticipate the final rule on emergency plans to be effective?** You still need the crystal ball, Betty. Why didn't I bring it? You know, this is a priority. This is an important issue for all kinds of programs across government and it's not something that's going to be very difficult to bring on board. So, it's a relatively easy rule to get in place and it's a very high priority for the Department. That said, whenever I make a guess, it's usually longer than that, but hopefully within the next few months or a year.

We're now reaching the end of our time together. The last question we've had – **will these questions be posted online with the presentation?** Yes, indeed. We will post a recording of this seminar. We also will develop a transcript and that will be posted, too. You have to allow us a few days to do that. We'll get it on the Web as soon as we can and we will try to fill in any places where there have been audio difficulties.

We invite you to send us email with your suggestions for topics and ideas to make the seminars more useful to you. And, we're so glad that all of you joined us today. We look forward to having you tune in again on December the 10<sup>th</sup> [2009] when we talk about the OLAW Annual Report.

Goodbye.

### **Additional Submitted Questions Not Addressed During the Webinar**

**1. If a VMO arrives to conduct an inspection and, due to illness (pandemic has significantly reduced available staff), there is no one available to escort the VMO through the facilities. May an institution request that the inspection occur at another time?**

Explain the situation to your inspector. Depending on the facility and the circumstances, the inspector may be able to accommodate the institution by conducting a focused inspection or returning at a later date. In general, the inspector and the institution should try to complete the inspection if at all possible. There may be instances, for example a

response to an animal welfare concern or a complaint, when the inspector must conduct the inspection. If the inspector arrives at the facility and there is no one available at all, the inspector will write a citation under Section 2.126, the narrative will explain that the inspection was "attempted" and the inspector will return at a later date. If there are facility personnel available and they feel the inspection should not take place but the inspector disagrees, the inspector will write a citation under Section 2.126 and the narrative will describe a "refusal to allow inspection". Any citation on an inspection report may be appealed.

**2. While USDA states that an institution cannot be cited on Animal Care Policy (only on USDA regulations and AWA), it appears the USDA, in fact, does cite on its policies. For example, an institution is cited because a PI has not provided a search period for an animal alternatives literature search. Yet, neither the regs or the ACT specifically require a "search period" to be included when considering alternatives. Rather the regs require "a written narrative of the methods and sources used to determine....". The only place where we see the "requirement" to include a search period is in the Animal Care Policy. So, how can the USDA cite the institution in this case?**

The purpose of the Policy Manual is to clarify the regulations. The policies explain to the registrant and the inspector what constitutes compliance with the regulation. So, for this example, 2.31(d)(1)(ii) requires that the IACUC determine that the PI has provided a written narrative description of the methods and sources used to determine that alternatives were not available. If you are not sure what is meant by a "written narrative description of the methods and sources used", you can look at Policy #12 which tells you that if you use a database search to meet this requirement, the narrative should contain (among other things) the period covered by the search in order for the narrative to be considered to be in compliance with the regulation. In the absence of a reasonable explanation for not including the period covered by the search, the inspector will cite this as a noncompliance with Section 2.31(d)(1)(ii). The policies all refer to specific sections of the regulations and the AWA. The sections being clarified appear at the top of each numbered policy and will also be referenced at the beginning of any citation for a noncompliance.

**3. One of my biggest concerns is that USDA appears to be more paper focused rather than animal health and well being focused. Back in the 70s and 80s, USDA inspectors spent the majority of their time walking through animal facilities looking at animals. Today, it appears that these inspectors are spending the majority of their time looking at paper. We have seen the pendulum swing from one extreme to the other. Is there any intention by USDA to bring the pendulum into better balance?**

I agree that walking through the facilities and looking at animals is critical to assessing compliance. Inspectors will start most inspections within the facilities getting a look at the health and well being of the animals and the overall maintenance and status of the facilities. Starting with the animals and the facilities also helps the inspector decide if

there are specific protocols, medical records or other documents which will be important to review in addition to the basic IACUC review.

It is true that the 1985 amendments to the regulations, which brought in the IACUC regulations, and their implementation in 1991, changed the inspection process, and the oversight of the care and use of animals, and, I believe, changed things for the better. The contribution of the IACUC to the humane care and treatment of animals cannot be overstated. The USDA inspections, which were once a snapshot of the animals on hand at the moment, have become much more meaningful and comprehensive.

**4. Since the Helms Amendment in the 2002 Farm Bill, the definition of animal in the AWA reads: 7 U.S.C. 2132, Section 2 (g) "The term 'animal' means any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal, as the Secretary may determine is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes or as a pet; but such term excludes (1) birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research, (2) horses not used for research purposes, and (3) other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for improving animal nutrition, breeding, management or production efficiency, or for improving the quality of food or fiber. With respect to a dog the term means all dogs including those used for hunting, security, or breeding purposes." How does the new definition of exempted species affect birds being displayed in educational exhibits?**

The Helms amendment, by specifically exempting birds bred for research, lead to a change in the definition of animals which in effect brought birds used in exhibition and birds bred for the pet trade under the jurisdiction of the AWA. The agency has plans to propose regulations for the licensing and inspection of exhibitors who exhibit birds to the public, including educational exhibits. No word yet on when those proposed regulations will be published for public comment.

**5. What about mice and rats bred for testing? Is this different from research in terms of the exemption?**

Testing is considered research, as well as teaching and experimentation. It is my understanding that mice and rats bred for teaching, testing, and experimentation will be exempt.

**6. It appears that the definition of animal points to the regulation of birds that are NOT specifically bred for research or that are NOT birds (poultry) used in food/fiber/production research. Does the USDA have any intention of regulating birds that are not excluded by definition?**

Animal Care is aware that the Helms amendment raises questions about the status of birds not specifically bred for research including wild caught birds that are used in research. Although it would be premature to speculate about the exact wording of

proposed regulations on this issue, we intend to provide clear guidance. It would be very helpful if institutions with expertise in this area provide feedback and comments to the proposed regulations when they become available.

**7. Will a pre-requisite of the regulation of nonexempt birds be the promulgation of regulations that specifically address birds or the adoption of some professional organization's guidelines that specifically addresses the care and use of these species?**

Yes, there will have to be some regulatory framework prior to any regulation of birds by Animal Care.

**a. How will the USDA view a closed colony of wild caught owls that are bred in-house generation after generation? Are they purpose-bred and therefore exempt?**

**b. If yes, what happens when the PI introduces a newly wild caught owl into the colony every couple of years to ensure genetic diversity and vigor? Is the colony now regulated or just the newly introduced bird?**

These are good questions. Our intention is that, with feedback from our stakeholders, we can come up with a workable set of regulations that answers just this type of question.

**8. It would be much easier for us if OLAW and USDA had one set of rules, if all the rules were all the same. Can you do this for us?**

We certainly try to coordinate as much as possible and in fact Section 2145 of the AWA requires that "Secretary shall consult and cooperate with other Federal departments, agencies, or instrumentalities concerned with the welfare of animals used for research..." That said, the AWA has a specific purpose and specific requirements and in those areas where the controlling statutes do not overlap, there will be some differences.

OLAW adds: Proposed new guidance is routinely reviewed by sister agencies before the guidance is issued to the public (e.g., OLAW FAQs are reviewed by USDA AC before they are posted at <http://grants.nih.gov/grants/olaw/faqs.htm>). For many years USDA, FDA, and OLAW have had a Memorandum of Understanding (MOU). The first paragraph describes the purpose of the MOU. "The participating agencies share a common concern for the care and welfare of laboratory animals used in research and testing. Each agency, operating under its own authority, has specific responsibilities for fostering proper animal care and welfare. This agreement sets forth a framework for reciprocal cooperation which will assist each agency in meeting its responsibilities in promoting proper laboratory animal care and welfare. Implementation of this agreement is intended to maintain and enhance agency effectiveness while avoiding duplication of efforts to achieve required standards for the care and use of laboratory animals." You can read the rest of the MOU on the OLAW website at <http://grants.nih.gov/grants/olaw/references/finalmou.htm>.

**9. Could you clarify the USDA interpretation on categorizing endoscopic procedures such as laparoscopy?**

Currently, USDA considers laparoscopy to be a major operative procedure. We are aware of significant advances in this area and are reviewing this interpretation. If the IACUC feels that there are special circumstances surrounding a particular procedure, we recommend the institution discuss the specifics with their inspector.

**10. If an institution successfully appeals a citation within 21 days, will the original report, with the repealed citation, still be posted on the website?**

If an inspection report is appealed in the first 21 days, AC will hold the report off the web until the appeal is resolved. If the inspection report is amended, the original report and the amended report will both be posted to the web, unless the original report contained some information that causes a safety or security concern. If there is personal information or some security concern in the original report, that report will be reviewed by the FOIA office and only released in a redacted format.

**11. Can the number of animals or number of days of violation influence fine and raise total above 10K?**

Section 2149 of the AWA states that each violation and each day during which a violation continues shall be a separate offense. That means that civil penalties can definitely be above \$10,000 in total. That section also requires the Secretary to give due consideration to the appropriateness of the penalty with respect to the size of the business, the gravity of the violations, the person's good faith and the history of previous violations.

**12. If a PI requests animals to be sent to a satellite facility with no PHS Assurance but the satellite does have an AWA registration, if the Institution adds the offsite location to their PHS Assurance does the institution become responsible for any of the offsite location's USDA citations?**

There are many different kinds of contracts, agreements and partnerships when it comes to using satellite or offsite facilities. As far as the USDA portion of the question goes, in general, if an institution is responsible for the animals at an offsite facility (including making decisions about the research activities and decisions about veterinary care and euthanasia), then that offsite facility should be part of the institution's USDA registration, even if the institution/satellite housing the animals is also registered. If the facility is remote, it will be considered a 'site' and inspected separately from the main facility. Once any area is part of the institution's registration, that institution is responsible for compliance. That responsibility is not retroactive; however, inspection reports from prior inspections should be available and can be very helpful in assuring future compliance.

**13. Is a registered research facility required to get a dealers license if they wish to transfer animals to another registered research facility?**

A dealer's license is usually required to sell animals to another facility, licensing is not required for donations or transfers. Federal or state owned entities have different requirements and should contact their regional office if there are questions.

**14. How are wildlife rehabilitation and research animal sanctuaries regulated under USDA? Follow-up if no, any plans to regulate such establishments?**

Anyone who exhibits regulated animals to the public requires a Class C exhibitor's license and will be inspected by USDA. Some rehabilitators and sanctuaries do not do any public exhibition at all and therefore, do not come under the AWA. Some states do regulate rehabilitators and sanctuaries. I am not aware of any initiatives to change the definition of exhibitor.

**15. Please compare and contrast the new Center for Animal Welfare with the existing AWIC?**

We see the Center and AWIC as very complimentary. AWIC serves as an outstanding resource for information that can improve animal care and use in research, teaching, testing, and exhibition. The Center will coordinate and expand Animal Care's outreach efforts to improve compliance, identify and provide technical training to Animal Care inspectors, identify areas of humane care and use that are in need of research, and help assure that Animal Care makes the best, science based decisions on future regulations, and inspection and enforcement efforts.

**16. Do you think you will be increasing the number of inspectors?**

Over the years we have been slowly increasing the number of inspectors. At the same time, we've taken on increased activities in other mission areas such as pet evacuation and sheltering in emergencies and Horse Protection. With the current economic climate, most agencies are not expecting large increases in budget and staffing but with the importance of our mission we are always hoping for additional resources.