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Note: Text has been edited for clarity.

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The Annual Report to OLAW

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Moderators:

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Slide 1 (The Annual Report to OLAW)

>> *George Babcock:* Susan Silk, OLAW's Director of the Division of Policy and Education will also be assisting with the live question portion of the webinar.

Our speakers today are Ms. Eileen Morgan and Dr. Patricia Brown. Eileen Morgan currently serves as the Director, Division of Assurances, in the Office of Laboratory Animal Welfare at the National Institutes of Health. Ms. Morgan previously served as a Senior Assurance Officer in the Division of Assurances within OLAW. Eileen holds a B.S. in Technology Management from the University of Maryland with an associate degree in Animal Health Technology. She is also a licensed veterinary technician. She has over 30 years of experience in animal models-based biomedical research. Her experience includes service as the Chief of the Facility Management Branch in the Division of Veterinary Resources, NIH Intramural Program. She has also held positions at the Johns Hopkins University School of Medicine, the American Red Cross Holland Laboratory, Affinity Biotech, and the Cleveland Research Institute.

Dr. Brown is the Director of OLAW. She received her Bachelor of Science degree in Animal Science from Penn State University and her veterinary degree from the University of Pennsylvania. She joined NIH in 1986 and held positions in the Veterinary Resources Program, the National Cancer Institute, and the Office of Animal Care and Use before joining OLAW in 2006 as the director. Dr. Brown.

>> *Patricia Brown*: Good Afternoon. We'd like to talk with you today about the OLAW annual report and the current requirements for reporting. As you may recall last year's report included some special reporting concerning implementation of the 2011 *Guide for the Care and Use of Laboratory Animals* ([Guide](#)). For the 2013 report and for future years, OLAW is returning to the traditional reporting elements. We will highlight these elements and how they are to be included in the annual report. We will also talk about the process of submitting your annual report to OLAW and we will share the results from our analysis of how Assured institutions reported their implementation of the *Guide* last year [2012].

Slide 2 (PHS Policy Reporting Requirements)

To start, I will discuss the basic requirement for reporting. PHS Assured institutions are required to provide a report to OLAW once every 12 months. The report is filed by the IACUC through the Institutional Official, also known as the IO. This requirement is described in the PHS Policy, [Part IV.F.](#)

Slide 3 (Reporting Periods)

OLAW now requires calendar year reporting with a January 1st to December 31st reporting period to ensure effective compliance with the reporting requirement of PHS Policy, [Part IV.F.](#) Of the approximate 1,000 Assured institutions, 985 are on calendar year reporting. The remainder of the Assured institutions will be transitioned to calendar year reporting during the next renewal of their Assurances. Non-calendar year reports are due to OLAW 30 days past the end of the 12 month reporting period. For calendar year reporting, the annual report is due to OLAW by January 31st of the following year. For example the report for calendar year 2013 is due January 31, 2014.

Slide 4 (PHS Policy Reporting Requirements)

This slide shows the formal language of the PHS Policy. It says that at least once every 12 months, the institution will provide OLAW with a written report of any program or facility change which would place the institution in a different Category than specified in its Animal Welfare Assurance. This is basically referring to the institution's animal care and use program and whether it is accredited by AAALAC, the Association for the Assessment and Accreditation of Laboratory Animal Care, International. And, any change in the animal care and use program as described in the institution's Animal Welfare Assurance.

Slide 5 (PHS Policy Reporting Requirements, continued)

>> *Eileen Morgan*: Information to be reported also includes any change in the IACUC membership. And the dates that the institution performed the semiannual program review and the dates of the semiannual facility inspections. If there are more than two dates or if the program reviews or facility inspections are conducted on a rolling schedule, then the dates, or the range of the dates the inspections were conducted should be provided as an attachment. For example, January 7-12, February 13-17, and March 10-15.

Slide 6 (PHS Policy Reporting Requirements, continued)

If there are no changes to the institution's animal care and use program, the institution is required to report to OLAW, in writing, that there were no changes and provide the dates that the semiannual program review and facility inspection evaluations were conducted.

Slide 7 (The Sample Annual Report)

I would encourage that each institution use the [Sample Annual Report](#) format provided on the OLAW website. OLAW requires the annual report be signed and dated by the Institutional Official and the IACUC Chair.

Slide 8 (Completing the Annual Report)

To complete the annual report using the sample, first download the [Sample Annual Report](#) form, save it as a Word document, then complete the report. Print the completed document and obtain the signatures. Once the annual report has been signed and converted to a PDF, it should be e-mailed to OLAW at olawarp@mail.nih.gov. This e-mail address is used exclusively for annual report submissions.

Slide 9 (The Annual Report)

I will now go through the pages of the sample and highlight the elements of the annual report. At the top of the first page, the name of the Institution, the Assurance number and the reporting period should be provided, for example January 1 to December 31, 2013.

Slide 10 (Annual Report Part 1.)

Part 1. On the first page is the section labeled Roman Numeral I. Program Changes. This section is unchanged from previous versions of the sample annual report. I will briefly review how to complete this section. If there have been no changes to the institution's program of animal care and use as described in the Assurance, check box "A." and skip the remainder of the section. If there have been any

changes in the animal care and use program, as identified in the items listed under part B., check box "B." and also all the applicable items.

The first item on the list of changes has to do with AAALAC accreditation. If an institution is listed as Category 1, which is AAALAC accredited, and they had a covered component added to their Assurance, which is not AAALAC accredited, this would result in the institution changing its status to Category 2, until such time that the new covered component achieves AAALAC accreditation. By a covered component, we mean an organization that has existing facilities and ongoing operations with PHS funding for which the institution chooses to take responsibility under their Animal Welfare Assurance.

The reverse also occurs. If a Category 2 institution achieves AAALAC accreditation during the reporting period, then the annual report would include that information and the institution's status would change to Category 1.

The next item on the list asks if the program of animal care and use has changed and references the PHS Policy section IV.A.1.a through i. If so, then check the box for "Program Changes" on the annual report, and on a separate page, provide a summary of the changes. I will present a list of the types of program changes to be reported later in this presentation.

The third item on the list asks if the Institutional Official has changed. If so, check the box and provide the contact information for the new IO in Item V.

Lastly, if the membership of the IACUC has changed, check the box in "Program Changes" and provide the current membership roster in Item VI.

Slide 11 (What to Report)

What to Report: Changes in the Animal Care and Use Program. Here is the list of the types of animal care and use program changes that should be reported. It includes changes in the lines of authority or administrative reporting channels, modifications to IACUC procedures as described in Part III.D.1. through 10. of your Assurance, or modifications to the occupational health and safety program or training program.

As mentioned earlier, if the program has changed, check the box for "Program Changes" on the form, Roman Numeral I., and attach a separate piece of paper summarizing the changes. There is no need to submit a revised Assurance document for every program change, but rather submit a summary of the changes in the annual report. We will retain your changes with the annual report. OLAW will determine if a revised Assurance document needs to be submitted based on the

changes to your animal program, as described in your annual report updates. This review by OLAW, as to whether or not you need to submit a revised Assurance document, is done on a case-by-case basis.

Slide 12 (What to Report)

Here is the continued list of types of program and facility changes that should be included in the annual report:

- Change in the veterinarian, to include their qualifications, authority and percent of time contributed to the program as requested in Part III.B. of the Assurance;
- Change in the veterinarian's authority or responsibility; and
- Changes in buildings, species, or approximate number of animals housed.

Slide 13 (Annual Report Part II.)

Roman Numeral II. Part A., Program Evaluations, asks for the dates that the two required program evaluations were conducted during the reporting period. If the IACUC conducted the program evaluations on a rolling schedule over a six-month period, then attach a list of the dates when the evaluations were conducted.

Slide 14 (Annual Report Part II. continued)

Roman Numeral II. Part B., Facility Inspections asks for the dates that the two required semiannual facility inspections were conducted. If the IACUC conducted more than two inspections of each site during the reporting period, then attach a list of the dates when the inspections were conducted.

Slide 15 (Annual Report Part III.)

Roman Numeral Part III. Minority Views. If no minority views were submitted by IACUC members during this reporting cycle, then you should check Box "A." If any minority views were submitted by members of the IACUC regarding the reports listed in Part IV.F. of the PHS Policy and filed during the reporting period, then you should check box "B." and attach the minority views to the annual report. The minority views that must be attached to the annual report are those found in semiannual IACUC reports, as well as any minority view included in recommendations to the IO regarding any aspect of the institution's animal program, facilities, or personnel training. Minority views involving noncompliance reports should also be included.

Minority views do not include a "no" vote by a member during a protocol approval unless that member chooses to write a minority view regarding their vote and submit it to the IACUC. In this case the "no" vote becomes a minority view.

Slide 16 (Annual Report Part IV.)

Roman Numeral Part IV. Signatures, is the section that includes the names and signatures of the IO and Chair, and the date the annual report was signed by each.

Slide 17 (Annual Report Part V.)

Roman Numeral Part V. is the section of the report to provide information about a change in the Institutional Official.

Slide 18 (What to Report)

For changes to the Institutional Official, please provide the contact information for the IO including name, title, degree or credentials, mailing address, telephone number, fax number, and e-mail address. E-mail and phone are the primary methods OLAW uses to communicate with the institution.

Slide 19 (Annual Report Part VI.)

In the first section of Part VI, provide the name of the institution as it appears in the current Assurance, and then list the contact information for the IACUC office.

Slide 20 (What to Report)

For the IACUC office contact, provide the mailing address and e-mail address for the IACUC office along with the phone number and fax number. OLAW no longer collects contact information for the IACUC Chair in the annual report to protect the Chair's contact information from release under the Freedom of Information Act.

Slide 21 (Annual Report Part VI. continued)

If there has been a change in the Chairperson, please provide the IACUC Chairperson's name, title, and degree and credentials.

Slide 22 (Annual Report Part VI. continued)

If there have been any changes in the membership, complete the IACUC roster or you may attach an IACUC roster. The items on the IACUC membership roster that most often require revisions are the position title column, that's the third column. Please list the individual's title at the institution. Only in the case of the nonaffiliated member, should it provide a general description such as lawyer, ethicist, clergy, or retired police officer. PHS Policy membership requirements are identified in the fourth column. This column identifies the position that each individual fulfills on the committee, such as veterinarian, scientist, nonaffiliated member, or nonscientist. If a member is not one of the required four designations, then the term "member" may be used.

For alternate members, the entry should indicate the position for which they are an alternate, such as alternate scientist or alternate nonaffiliated. If the committee has

nonvoting members, they should be identified as nonvoting in the fourth column or not be listed at all on the roster. OLAW does not recognize nonvoting members as members of the committee nor do they contribute to a quorum.

Slide 23 (Annual Report Part VI. continued)

Occasionally institutions provide information about members that is not required on the roster, such as complete names, addresses, and home or office telephone numbers for members. The PHS Policy allows institutions to represent the names of the members, other than the Chair and the veterinarian, by a number or symbol in the annual report.

Slide 24 (Annual Report Part VI. continued)

For the position title, provide a general description for the nonaffiliated member, such as lawyer, ethicist, clergy, or retired police officer rather than describing them as a "community member" or "retired".

Slide 25 (Annual Report Part VI. continued)

This section of the report provides an expanded explanation of the IACUC roster membership requirements including the definitions for the required members.

Slide 26 (Submitting the Annual Report)

Once the annual report has been signed and converted to a PDF, it should be e-mailed to OLAW at olawarp@mail.nih.gov. This e-mail address is used exclusively for annual report submissions. Plans are in development for an online submission process for future years, but that is not currently available.

Do not fax the report and do not send a hard copy by mail or express delivery. We have found these methods require the most processing. We only accept e-mailed PDF annual reports.

Upon receipt, the annual reports are logged into our database as received and then the document is reviewed by Division of Assurances personnel. If there are program changes, these are reviewed by an Assurance Officer for compliance with the PHS Policy and the *Guide*. If OLAW has questions, we will contact the IACUC for clarification or updates. Once the report is reviewed and accepted, the IO and the IACUC will receive a letter of acceptance. A copy of the report is maintained in the Assurance file.

Slide 27 (2012 Implementation of the *Guide*)

>> *Patricia Brown*: Now we are going to switch to a new topic and discuss the outcome of your responses provided in the 2012 annual report concerning your institution's implementation of the 8th Edition of the *Guide*.

You may recall that OLAW required Assured institutions to complete at least one semiannual program review and facility inspection using the 8th Edition of the *Guide* in calendar year 2012 and to develop a reasonable plan and schedule to implement the *Guide* in their animal program. Verification of the implementation was then required to be provided in the 2012 annual report. The sample form included a series of added statements and “Yes” or “No” check boxes to allow easy verification of an institution's status.

Slide 28 (Analysis of *Guide* Implementation)

During their review of the annual reports submitted for the 2012 reporting period, OLAW Division of Assurances staff collected and compiled the responses from the various statements and “Yes” or “No” answers for over 1000 annual reports. They found that over 98% of the responses were complete in all sections of the report. This shows the attention to detail that was given by those at Assured institutions responsible for completing the 2012 report. We commend you for your efforts.

Slide 29 (Implementation of the *Guide*)

In our analysis of the responses, we found that 70% of Assured institutions reported that their programs had fully implemented the 8th Edition at the time of the report.

Slide 30 (Not Implemented, Plans in Place)

Of the 30% of institutions who had not fully implemented the *Guide* at the time of the report, 90% of them had plans and schedules in place to implement the *Guide*. Only 3% had not yet put a plan in place at the time of the report. Again, the effort on behalf of 97% of Assured institutions demonstrates your commitment to the highest standards of animal care and use.

Slide 31 (First Program Evaluation)

Also of interest was the transition that occurred from the first program evaluation that institutions conducted in calendar year 2012 to the second program evaluation. As this slide depicts, slightly more than half of institutions were using the 8th Edition of the *Guide* as part of their first program evaluation in 2012.

Slide 32 (Second Program Evaluation)

As would be expected by the second program evaluation, 95% of institutions had transitioned to the 8th Edition.

Slide 33 (Methods Used for Evaluations)

Another item of interest we thought worth sharing from the analysis of the reports is the methods institutions reported using to conduct program evaluations. This

chart shows that 61% of institutions use the [OLAW Checklist](#) exclusively for their semiannual program evaluations.

6% use the *Guide* chapter headings and 13% use some other materials to review their animal program. 10% use the OLAW Checklist and the *Guide* headings, and smaller numbers use either the OLAW Checklist with other materials, the *Guide* headings with other materials, or all three. Overall 79% use the OLAW Checklist in some combination to conduct program evaluations.

Examples of what institutions listed as other material that they use include facility standard operating procedures, institutional policies, and their AAALAC program description.

Slide 34 (Methods Used for Inspections)

The methods used for semiannual facility inspections reported follow a similar pattern to the program evaluations with 73% of institutions using the OLAW Checklist either by itself or in combination with other materials.

Slide 35 (Please Send Your Questions)

>> *George Babcock*: Thank you, Pat. Dr. Brown and Ms. Morgan will now answer your questions. We will begin with questions received prior to this seminar, but please continue to submit your questions during the live broadcast even as earlier ones are answered. If we are unable to get to all of your questions, we will append them, along with answers, to the transcript that will be posted online. As a reminder this seminar is being recorded and that recording, along with a transcript of the seminar, will be made available at the OLAW website under the general heading "Education." [[Education Resources](#)]

Slide 36 (Question 1)

>> *George Babcock*: First question. **Who must file the annual report? Does it have to be the IACUC Chair or the IO?**

>> *Eileen Morgan*: The annual report must be signed by the IACUC Chair and the IO, but any member of the institution who is authorized may submit it on behalf of the institution.

Slide 37 (Question 2)

>> *George Babcock*: Our next question. **Does the institution have to submit an annual report if they have recently renewed their Animal Welfare Assurance?**

>> *Eileen Morgan*: Yes, an annual report is required to be submitted to OLAW at least once every 12 months, regardless of when the Animal Welfare Assurance was last approved. The Assurance renewal has no bearing on the annual report.

The annual report and the Assurance document are separate requirements to OLAW. The annual report is the only document that collects the dates of the semiannual program evaluations.

Slide 38 (Question 3)

>> *George Babcock*: **If there are programmatic changes after the annual report has been submitted to OLAW, how should the institution report these?**

>> *Eileen Morgan*: Well, if the program changes occur in the new calendar year and they are not a change in the IO or a change in the IACUC contact information, they can be submitted to OLAW in the following year with the annual report. If the change is to the IO or the contact information for the IACUC, we would request that this information be provided to OLAW when the change occurs – including the mailing address, the telephone number, the fax number, and the e-mail address and – I repeat – we need the e-mail address for the IO and the IACUC office (not the IACUC Chair) – as much of our communication with institutions is electronic.

Slide 39 (Question 4)

>> *George Babcock*: **For the semiannual program review and facilities inspection, does the institution have to list all of the facilities and the dates they were inspected?**

>> *Eileen Morgan*: If the semiannual inspection of the various facilities is performed throughout the six-month period, the institution should provide us with a list of the dates or a range of the dates as the example provided in an earlier slide, of the reviews and the inspections. They should keep in mind, however, that the same areas should be inspected and reviewed on a six-month schedule so the program oversight is consistent.

Slide 40 (Question 5)

>> *George Babcock*: **If the inspections are performed throughout the six-month period, does the report have to identify which facilities were reviewed at which times?**

>> *Eileen Morgan*: Yes, although codes may be used to designate the different facilities, the facilities and when they were visited should be listed. This allows OLAW to confirm compliance with the PHS Policy.

Slide 41 (Question 6)

>> *George Babcock*: **What happens if the semiannual dates are more than six months apart?**

>> *Eileen Morgan*: During OLAW's review of the annual report, [if] it is noted that the semiannual dates are greater than seven months apart, the institution will

receive a letter accepting the annual report but noting that the semiannual reviews were not in compliance with the PHS Policy. We will request the institution to align their next semiannual program and facility inspections to be conducted every six months. If the following year the institution again has extended intervals for program review or inspections, the annual report will be submitted to the Division of Compliance Oversight for follow up as noncompliance.

Slide 42 (Question 7)

>> *George Babcock*: And here's another question about submission. **Can we submit the annual report prior to December 31st?**

>> *Patricia Brown*: No. Prior to December 31st, the institution has not completed the full 12 months of the reporting period. Unanticipated program changes may occur in your animal care and use program in the last few months. For example, you finish your second semiannual report on October 31st and decide to submit your calendar year report to OLAW on November 1st. You are reporting for a 12-month period but you've only completed 10 months of that period, so you should wait until the end of the reporting period, December 31st, compile the annual report and submit it to OLAW prior to January 31st.

Slide 43 (Question 8)

>> *George Babcock*: **What if the annual report is submitted late?**

>> *Patricia Brown*: As I just mentioned, the annual report is due to OLAW by January 31st. On or about February 28, OLAW will determine which institutions have not complied with the PHS Policy and send reminder notices. Not submitting the report is considered noncompliance with the PHS Policy reporting requirements.

Slide 44 (Question 9)

>> *George Babcock*: **What is considered noncompliance regarding information contained in the [annual] report?**

>> *Patricia Brown*: Missing dates for the semiannual program review and facility inspection are an example, or performing the reviews in a time span that is greater than 7 months apart would also constitute noncompliance with the PHS Policy. [See also Question 6 on Slide 41.] Another example is a minority view that describes a reportable incident that was not promptly reported by the institution. Another example of noncompliance is changes that were made to the IACUC which result in a not properly constituted committee. A last example would be if the program changes that were made involving the protocol review process were not compliant with the PHS Policy for either designated member review or full committee review.

Slide 45 (Question 10)

>> *George Babcock*: **Do the minority views need to be explained in the annual report, or just the dates reported?**

>> *Patricia Brown*: The minority view, itself, needs to be provided to OLAW. If the minority view is part of the semiannual report, or is in the minutes of an IACUC meeting or in other IACUC records of recommendations to the IO, the section containing the minority view needs to be submitted with your annual report.

Slide 46 (Question 11)

>> *George Babcock*: **Is a no vote by a member when the IACUC is voting on acceptance of a protocol a minority view?**

>> *Patricia Brown*: No. Whenever an individual who feels very strongly may choose to write the reasons for his or her no vote – I'm sorry. I'm going to reread the answer to this one. **Is a no vote by a member when the IACUC is voting on acceptance of a protocol a minority view?** No, a no vote, by itself, is not a minority view. However, the individual, if they feel strongly enough, may choose to write the reasons for their no vote in the form of a minority view. If a member makes that choice, then that written objection becomes the minority view and that is what would need to be included in the annual report.

Slide 47 (Question 12)

>> *George Babcock*: **What if the IO is not available to sign the annual report?**

>> *Eileen Morgan*: The IO may assign another individual as having signature authority. That person is assigned – I'm sorry, that person is **authorized** to sign the annual report. However, OLAW must have a copy of a letter or memo on file, stating that signature authority has been assigned to another named individual and the document must be signed by the IO.

Slide 48 (Question 13)

>> *George Babcock*: And a related question. **What if the Chair is not available to sign the report?**

>> *Eileen Morgan*: A Vice Chair may sign in place of the IACUC Chair.

Slide 49 (Question 14)

>> *George Babcock*: And now some questions about adding new components. **If a new program component is added, and it's not AAALAC accredited, does that change the status of the institution from Category 1 to Category 2?**

>> *Eileen Morgan*: If **all** components of the animal program are not AAALAC-accredited, the Category would change from a 1 to a 2.

Slide 50 (Question 15)

>> *George Babcock*: And continuing on that theme. **If we open a new building that becomes part of our existing AAALAC accredited animal program, does this change the Category designation?**

>> *Eileen Morgan*: No, we would not consider your program a Category 2 because of a new building. Since all components of your current AAALAC-accredited program would be applied to the animal care and use in the new building, the addition of a new building would not change your designation. As described earlier, an example in which the Category designation would change is if your Category 1 institution were to acquire a separate component that has existing facilities and ongoing operations and is not AAALAC-accredited and has to be brought in line with your program and oversight because it needs perhaps renovations or other improvements or changes to meet AAALAC standards. During the interim period from when the component was added to your Assurance and until they attained AAALAC accreditation, your Assurance would have a Category 2 designation. If you are unsure about Category 1 or 2 designations involving covered components please contact me or an Assurance Officer to discuss.

Slide 51 (Question 16)

>> *George Babcock*: **Should changes in the Assurance be reported in the annual report or as they occur?**

>> *Eileen Morgan*: Generally changes that occur in your animal care and use program across the year should be reported to OLAW in the annual report. However, there are some exceptions that I named earlier. If the IO or the IACUC contact information changes, then you should inform OLAW as soon as the change occurs as we may need to communicate with your institution and to contact the appropriate people or office.

Slide 52 (Question 17)

>> *George Babcock*: **In preparing our OLAW annual report, we have identified some major changes that have occurred in our program including:**

- **an updated PI and IACUC member training policy;**
- **a newly developed occupational health and safety program; and**
- **new IACUC members.**

Is it correct that we include these major changes in our upcoming annual report?

>> *Eileen Morgan*: Yes, the three changes that are listed need to be included in the report. For the updated PI and IACUC member training policy, a summarized description of that change should be included. For the updated occupational health and safety program, a summarized description of the change is appropriate. And of course, new IACUC members are added to an updated IACUC roster.

Slide 53 (Question 18)

>> *George Babcock*: **The following changes do not alter our animal program as much as they change the mechanism used to comply with the requirements. Do we need to include these in our upcoming annual report?**

- **first, creating a new subcommittee of the IACUC to follow up on animal use concerns;**
- **two, adding the harm/benefit analysis of animal use in research during our protocol review; and**
- **three, correcting a sentence in our Assurance concerning how we conduct designated member review.**

>> *Eileen Morgan*: Go ahead, George.

>> *George Babcock*: So those [of you] participating think of what your answers are to whether these changes need to be included in the report to OLAW. Eileen, what are they?

>> *Eileen Morgan*: As I mentioned earlier, if changes in IACUC activities as described in Part III.D. of the institution's Assurance have occurred during the reporting period, then they should be summarized in the annual report. Of the three you have described, George, a change in who follows up on an animal welfare concern is a change regarding item III.D.4. of the Assurance and should be included as a summary description in the annual report. The addition of the harm/benefit analysis would not need to be included, but the correction of your description of how the committee conducts designated member review is a change regarding item III.D.6. of the Assurance and should be included.

>> *George Babcock*: So it is important for the people that are listening to take a look at Part III.D. of their Assurance to make sure that any changes that have occurred in their program that do not match what is in their current Assurance are summarized and included in the annual report.

>> *Eileen Morgan*: Yes. A best practice for IACUCs to consider is reviewing Part III.D. 1 through 10 of their Assurance during the semiannual program review and identifying program changes that are not reflected in the Assurance and keeping a list to include these changes when the annual report is prepared to be submitted.

Slide 54 (Question 19)

>> *George Babcock*: Okay, next question. **Can you please clarify the species change notification requirement? What kind of changes are we talking about?**

>> *Patricia Brown*: If an institution formerly used only mice and rats and now they've begun research with guinea pigs, then that is an example of a program change that should be attached to the annual report.

Slide 55 (Question 20)

>> *George Babcock*: **Our IACUC just created a policy to use designated member review subsequent to full committee review in our IACUC review process. Should we report this as a program change in our annual report?**

>> *Patricia Brown*: Yes, this is the type of program change that should be included in the annual report in the attachment of program changes.

Slide 56 (Question 21)

>> *George Babcock*: **Should Interinstitutional Assurances approved by OLAW be included in the annual report?**

>> *Patricia Brown*: No. Interinstitutional Assurances are not to be included in the annual report. OLAW already has a copy of this type of Assurance because we negotiate and approve them.

Slide 57 (Question 22)

>> *George Babcock*: **If our Assurance has substantially changed, but is not due for renewal for two years, would OLAW prefer to receive the changes via the annual report or a completely new Assurance?**

>> *Eileen Morgan*: A summary of the program changes for the year in which they occurred should be attached to your annual report. You would check the box on the annual report form that says changes have occurred and then include the summary. When you submit the annual report to OLAW, it will be reviewed by our Assurance Officers who will make the determination, based on the depth of the program changes, whether or not a revised Assurance is needed. But it's not necessary to submit a revised Assurance with your annual report, unless OLAW asks you for one.

>> *Susan Silk*: We're getting lots of questions in and they're good questions, so please keep sending them. George?

Slide 58 (Question 23)

>> *George Babcock*: **If an institution has undergone an AAALAC site visit during the year would that suffice in place of the annual report?**

>> *Eileen Morgan*: No. An AAALAC site visit is not an annual report. You may be referring to the use of an AAALAC site visit to serve as one of the **semiannual facility inspections and program reviews**. That's different from the annual report. What you would submit would be the dates of your AAALAC site visit for the date of one of your two semiannual facility inspections.

Slide 59 (Question 24)

>> *George Babcock*: **If our PHS Assurance is being evaluated for renewal, would the renewal Assurance document complete the requirements of the annual report?**

>> *Eileen Morgan*: No, that's also a no. The annual report and the Assurance document are separate stand-alone documents required by the PHS Policy. Even though your Animal Welfare Assurance has recently been renewed by OLAW, you're still required to submit an annual report. The only document in which OLAW collects the dates of your semiannual program and facility inspections is the annual report.

Slide 60 (Question 25)

>> *George Babcock*: **Are the completed annual reports to OLAW posted online or available via FOIA?**

>> *Eileen Morgan*: No, although the annual reports are not posted online, they are releasable under the Freedom of Information Act if they are requested.

Slide 61 (Question 26)

>> *George Babcock*: **Can you clarify the requirements for the IACUC Chair and members' addresses, phone numbers, et cetera? Do these need to be reported if it is not the address and the phone number for the IO or the IACUC office?**

>> *Eileen Morgan*: You do not need to provide contact information for the IACUC members. We need the name of the veterinarian. We need the name of the Chair with his or her title and degree credentials. We do not need the Chair's contact information in the annual report if we have the IACUC office contact information. For the IO, we need their address, phone number, fax number, as well as their e-mail address.

Slide 62 (Question 27)

>> *George Babcock*: **This is an interesting question, what if the IACUC office does not have an e-mail address?**

>> *Eileen Morgan*: Well in that case, you may provide an alternative e-mail address used within the institution to most easily contact the IACUC.

Slide 63 (Question 28)

>> *George Babcock*: **Is e-mail submission of a PDF document the only accepted method?**

>> *Eileen Morgan*: Yes. The completed annual report sent as a PDF document in an email to olawarp@mail.nih.gov is the only method of submission for the annual report. It allows us to better track submission and send you an acknowledgement. We are also able to process the record and associate it with the electronic record of your Assurance file more efficiently than fax or hard copy reports. NIH has gone to

almost 100% electronic submission with PDF attachments for grant applications. We plan to have an online submission for the annual report in the future.

Slide 64 (Question 29)

>> *George Babcock*: **Does OLAW recognize the category of nonvoting member of an IACUC and if so what responsibilities could such a member have?**

>> *Patricia Brown*: OLAW acknowledges that some institutions have persons in advisory positions who regularly attend IACUC meetings. Many of these institutions would like to identify these positions on the IACUC roster. In such cases, OLAW allows this and we will ask that the positions be labeled as "nonvoting" so that it distinguishes them from voting members of the IACUC.

Slide 65 (Question 30)

>> *George Babcock*: **Do minority views of nonvoting members of the IACUC need to be provided in the annual report to OLAW?**

>> *Patricia Brown*: Minority views for nonvoting members do not need to be provided in the annual report. However, anyone, including a nonvoting member, should have the opportunity to bring animal welfare concerns to the attention of the IACUC for consideration and investigation.

Slide 66 (Question 31)

>> *George Babcock*: **Do nonvoting IACUC members need to sign the semiannual report to the IO?** And I'm just going to point out this is the semiannual report to the IO, not the annual report to OLAW that we've been talking about a lot in this webinar.

>> *Patricia Brown*: No, only voting members of the IACUC may sign the semiannual report to the IO.

Slide 67 (Question 32)

>> *George Babcock*: **If the AAALAC site visit doesn't coincide with our semiannual inspection date, will it still be acceptable as one of our inspections?**

>> *Eileen Morgan*: To meet PHS Policy requirements, the reviews of your semiannual program and facility inspections need to be conducted within approximately 6 months of each other. If you choose to use an out of cycle AAALAC site visit for your semiannual review and facility inspection, then the next review must be 6 months from when the AAALAC site visit occurred. For example, if the reviews were on a January and July cycle, and you did a January semiannual program and facility review, but AAALAC came 3 months later in April. To use the AAALAC site visit and be in compliance with the PHS Policy, you would be changing your cycle so your second semiannual review for that reporting year was in April.

OLAW would require that you do another program review and facility inspection again in 6 months, in September. You would report all 3 inspections in the annual report. And your cycle for the following reporting year would change to April and September. Then we would hope that in 3 years when AAALAC comes again, it would be in the same time frame.

Slide 68 (Question 33)

>> *George Babcock*: **If we are not required to list IACUC member names, how does OLAW track and review the IACUC members?**

>> *Eileen Morgan*: We verify that the appropriate roles are being held by the appropriate person. If you complete columns three and four, you've given us the background and the position title of the individuals named as members and you've also given us their PHS required role, whether that is a veterinarian, scientist, nonscientist, or nonaffiliated member. However, we may ask for further information and clarification to confirm the membership reflects a properly constituted Committee.

Slide 69 (Question 34)

>> *George Babcock*: **What is the earliest date that annual reports can be submitted?**

>> *Patricia Brown*: January 1 of the year following the reporting period for calendar year reporting. For the 2013 report, the earliest date is January 1, 2014. As we stated earlier, if you submit an annual report prior to the end of the reporting period, there could be program changes that occur before the end of the reporting period and the report submitted only covers 11 months or less of that period.

Slide 70 (Question 35)

>> *George Babcock*: **What protects IACUC members from having their contact information used by animal activist organizations?**

>> *Patricia Brown*: As we noted earlier, with the exception of contact information for the IO and the IACUC office, OLAW does not keep a database of contact information for the Chair or other members of the IACUC.

Slide 71 (Question 36)

>> *George Babcock*: And now this is the last question that we received prior to this webinar. **What does OLAW do with the annual reports?**

>> *Eileen Morgan*: OLAW reviews each annual report. If there is missing information or problems with a described change in the animal care and use program or an incomplete IACUC roster is included, OLAW will ask for revisions to the report. After all items are clarified by the institution, OLAW sends an acceptance letter and the updated report is included in the Assurance file.

Slide 72 (Upcoming Webinars)

>> *Susan Silk*: And now we do have a few minutes for questions received from participants during the broadcast. You are welcome to keep sending your questions in and they will be appended, along with the answers, to the transcript. As I begin each question, you're going to hear me mention a letter. That's so Eileen and Pat know which of the questions that I'm asking and so they will have a moment or two to think about their answers.

Question A: **Would I submit a new lines of authority and responsibility for administering the Animal Care and Use Program org chart or just list any changes?**

>> *Eileen Morgan*: You can just submit a new org chart along with the annual report; that would take care of that requirement.

>> *Susan Silk*: Question B: **Can you please advise how we would need to address, in our OLAW annual report update, a program change where an external company begins to lease space in our AAALAC-accredited fully assured facility? And if that happens prior to year end 2012, how should we best address this in our program update?** And then they give us some details about their situation. **The perspective company would potentially be leasing their own animal holding space and office space, but using shared procedures space for *in vivo* work with their staff. They would order and pay for their own animals, but they would use our veterinary staff, husbandry staff, and facilities. How does this affect IACUC occupational health program, training and the other programmatic components?**

>> *Eileen Morgan*: There's lots of questions in there. I would start with saying that OLAW would see it as one animal care and use program. If there's any shared space at all, shared air handler, shared entrance ways, we would consider that one animal care and use program. So now let me address if the company, external company or lessee is PHS-funded, then all components of the Assurance would apply to the company and they would be listed as a covered component under your Assurance or have an Interinstitutional Assurance with your Assurance – with your institution. The IACUC would be responsible for the activities conducted there.

If it's not PHS-funded, the institution would not meet the criteria to be listed on your Assurance as a covered component. However, your institution should have best practices in place, institutional policies, et cetera, to ensure consistency of the program and not put the PHS-funded activities at risk.

>> *Susan Silk*: Question C, this is for you Eileen. **If there have been program changes which have been described in a submitted Assurance renewal, but**

the Assurance is still under review by OLAW, do we report these changes again in the annual report?

>> *Eileen Morgan*: Yes, any changes that occurred during that period of coverage that year should be included in the annual report.

>> *Susan Silk*: Eileen, here is a question D for you. **The IO will change on January 1st. Should this be on the 2013 report?**

>> *Eileen Morgan*: Since we want to know who the new IO is and that's one of the people that we communicate with, we would want the name, contact information of the new IO provided with the 2013 report.

>> *Susan Silk*: Again for you, Eileen, question E about program changes. **If an Assurance renewal was submitted mid-year, and incorporated program changes, but there have been no further program changes since then, should "A" be selected in Section I?**

>> *Eileen Morgan*: So I'm thinking that "A" is "no changes" and that would be the correct thing to do. Your current Assurance, current approved Assurance, included all of your changes that occurred earlier in the year, so it would be "no program changes" since that time.

>> *Susan Silk*: Now we'll move to question I. That one is directed for Pat. **During inspection, IACUC noticed there was no posting of a whistleblower policy. Would that be considered a minority view?**

>> *Patricia Brown*: No. That would not be considered a minority view. It would be a deficiency that the IACUC should include in its semiannual report to the Institutional Official, but it would not be considered a minority view.

>> *Susan Silk*: Question J, for Eileen. **Not sure if I understood correctly, but does the Chair's contact information no longer need to be in the annual report?**

>> *Eileen Morgan*: Yes, that's correct. We do not need the contact information for the Chair. We just need the name, title and degrees and credentials for the Chair.

>> *Susan Silk*: Here's question K, also for you, Eileen. **We have an investigator who stopped using animals in his research in 2013. Should this be noted in the annual report? And, also, is there a protocol for deactivating his animal space?**

>> *Eileen Morgan*: That does not need to be reported in the annual report. That's not something that was captured in your Animal Welfare Assurance for the institution.

>> *Susan Silk*: This other thing, Eileen, that sounds to me like an institutional decision. OLAW wouldn't really be involved in the details of animal space allotment.

>> *Eileen Morgan*: That's correct.

>> *Susan Silk*: Question M, Eileen we're not going to give you any rest. **Please talk about the time extension discussed for federal institutions as a result of the partial government shut-down.**

>> *Eileen Morgan*: So OLAW put out a Guide notice [[News Flash](#)] earlier this year on providing an extension of 30 days if you had an Assurance renewal that was due to OLAW or also if you had to complete your semiannual program and facility inspections during the time of a shutdown. [There was a partial federal government shutdown in October 2013.] So we're extending a 30-day time period for those dates [for federal animal facilities only]. So if you extended your semiannual program evaluations beyond 6 months and you are a government facility and it was because of the government shutdown, if you include a note with that, with your annual report, we would accept that as the reason for your semiannual program evaluations extending beyond the 6-month period. [Speakers overlapping]

>> *Patricia Brown*: I'm sorry I just wanted to clarify again, that only applies to federal facilities, that extension of the semiannual evaluations and program reviews, recognizing that many of those facilities were shutdown and their IACUCs were limited in their ability to conduct those inspections during the shutdown.

>> *Susan Silk*: [Question] N is for Pat. **Should the IACUC review and approve the annual report prior to the report being submitted to OLAW?**

>> *Patricia Brown*: There's no specific requirement in the PHS Policy for the IACUC to review and approve the annual report. But we would consider it a best practice that the IACUC is aware what the institution, what the Chair and the IO are signing on behalf of the institution. So as I said, it would certainly be in the best interests of the IACUC to be aware of what was in the annual report.

>> *Susan Silk*: [Question O]: **As long as the semiannual and annual are 6 months apart, does it matter when these program and facility reviews occur during the year?** Eileen?

>> *Eileen Morgan*: No, it's up to the institution to establish a consistent plan so that their program evaluations are conducted every 6 months.

>> *Susan Silk*: [Question P] Eileen, **how strict is the every 6 months requirement for the semiannual inspection reports? For example, say it's more like 6 and one-half months or 6 months and 3 weeks due to busy scientists' schedules. Is this acceptable?**

>> *Eileen Morgan*: I think that I addressed that in an earlier question or slide. But I can reiterate it here. The OLAW will give you up to 6 months and 30 days. So if you go into the 7th month, when you are conducting your reviews, then when you

submit those dates with your annual report, we will send you an acceptance letter with a note that says your program evaluations were conducted in greater than 6 months and we will ask you to arrange a schedule that's in compliance with the PHS Policy. However, if you do that again the next year, the following year, with your annual report, then we will submit your annual report to the Division of Compliance Oversight for further communication with your institution to ensure that your program evaluations are conducted every 6 months.

>> *Susan Silk*: Pat, here's a question L for you. **If noncompliance events were reported to OLAW during the reporting period, should these events also be summarized in the annual report?**

>> *Patricia Brown*: No. As noncompliance reports are submitted directly to the Division of Compliance Oversight, there is no requirement to repeat them or include them in the annual report or to summarize them in the annual report.

>> *Susan Silk*: Can – this is question R. **Can a range of dates for facility inspections without building codes be added to the report even though it wouldn't be considered a rolling inspection? Example, all inspections occurred in a 5-day period.**

>> *Eileen Morgan*: Yes, that would be acceptable for you to just give us the dates from 3/1 to 3/5 and then again 6 months later if you did it in that same schedule.

>> *Susan Silk*: We've come to the end of our time. We have lots more questions. We'll wait a week for all of you who have further questions to submit this to us by e-mail. And after that, as quickly as we're able, we'll get the transcript posted for you. I think that the recording of this webinar will go up a little bit sooner. And now, George, back to you.

>> *George Babcock*: We have not selected the dates for the 2014 webinars, but they will be held, as this one was, on Thursdays, at 1:00 p.m. eastern standard time or eastern daylight savings time in March, June, September, and December. We'll let you know on the OLAW listserv and RSS Feed as soon as we select the dates and the topics. If there's a topic you'd particularly like us to discuss, send an e-mail with your suggestion to the address listed on the slide. I would like to thank Pat and Eileen for speaking today. And I would like to thank all of the participants for listening and for the great set of questions that were sent in. I would like to wish everyone good, happy holidays and look forward to our next webinar in March of 2014. Thank you.

Additional Submitted Questions Not Addressed During the Webinar

Question S: Does the AAALAC site visit count as a program review as well as a facility inspection?

Answer: Yes, the AAALAC site visit can be used as both program review and facility inspection. Please remember to adjust your review and inspection dates, if needed, to comply with the PHS Policy requirement for semiannual program review and facility inspections.

Question T: How strict is the every 6 months requirement for the semiannual inspection reports. For example, say it's more like 6 and one half months, or 6 months and 3 weeks, due to busy scientists' schedules. Is this acceptable?

Answer: During OLAW's review of the annual report, if it is noted that the semiannual dates are greater than 7 months apart, the institution will receive a letter accepting the annual report but noting that the semiannual reviews were not in compliance with the PHS Policy. We will request the institution to align their next semiannual program and facility inspections to be conducted every 6 months. If the following year the institution again has extended intervals for program review or inspections, the annual report will be submitted to the Division of Compliance Oversight for follow up as noncompliance.

Question U: Can a range of dates for facility inspections (without building codes) be added to the report even though it wouldn't be considered a "rolling inspection"? Example, all inspections occurred in a 5-day period (3/1 – 3/5).

Answer: You should list the range of dates during which the inspection was conducted. A rolling inspection is one in which some buildings are inspected each month, each quarter or other interval. Whether you are doing all the inspections in one range of dates, or are spreading out the inspections during the year, you should report to OLAW what occurred and you should make sure that both inspections of a given location occur 6 months apart.

Question V: I may have misunderstood, but it seemed two different answers were given for questions regarding facility inspection dates. If your program has multiple buildings that are reviewed on a rolling basis, does a date range (start and end date of schedule) suffice or does each building have to be listed separately? This could be tricky since we also conduct lab audits in the same buildings on a rolling schedule, but it does not match the facility inspection dates.

Answer: Provide OLAW the list of locations and the dates or range of dates that those areas were inspected on a separate attachment along with the annual report.

You may code the buildings if you'd like. The institution should ensure that both inspections of a given location occur every 6 months. Labs could be listed separately to avoid confusion.

Question W: If you are adding a private veterinary practice as a performance site for recruiting patients for a research protocol, would this make your institution a Category 2 institution because not all components are AAALAC accredited?

Answer: No, it would not affect your AAALAC Category status.

Question X: Our PHS Assurance was revised and approved by OLAW. Does this constitute a reportable program change?

Answer: No.

Question Y: We are revising our Assurance for renewal and the revised Assurance has new language that would normally be reported as a change to an existing Assurance. Should those changes be included that will not go into effect until the next reporting period in the new Assurance?

Answer: No.

Question Z: We have added written policies during the past year. These policies are not new from a procedure standpoint. We have been doing these procedures previously and only now added them in writing. Is this considered a program change?

Answer: If the new policy affects a section of your animal care and use program described in the Assurance, the veterinary medicine program, the occupational health and safety program, the training program, or the IACUC procedures, Part III.D.1 through 10, then it would be considered a program change to be included in the annual report. A specific example of a policy change to be described in the annual report would be a change in the process for protocol review, such as DMR or DMR subsequent to FCR.

Question AA: Is it a program change if you stop using a certain species or only if you add a species?

Answer: Change in species is a change in the institution's program. Please report both adding species and ceasing to use species in the annual report.

Question BB: How large a change in animal numbers held in the facility would need to be reported in the annual report?

Answer: A large change should be reported, such as adding a wing, facility or new species to the program.

Question CC: **We have a new building with a new vivarium. It will not hold animals until after Jan 1. Do we need to report the new facility in this annual report?**

Answer: A new building is a change in the institutions facilities. Please include the new building in your annual report along with a projected date when you think the building will start to house animals.

Question DD: **Can the names of IACUC members and other listed individuals on minority views be replaced with numbers or symbols?**

Answer: Yes, the names of IACUC members or individuals in minority views may be coded.

Question EE: **Minority views – do these have to relate to semiannual program review or can they occur at any time of the year during protocol review?**

Answer: Minority views can be related to any issue that the IACUC is responsible for; they are not restricted to any specific issue or time period. Please be sure to follow any procedures or policies regarding minority views that are described in your Assurance. The minority views are those found in semiannual IACUC reports, as well as any minority view included in recommendations to the IO regarding any aspect of the institution's animal program, facilities, or personnel training that were submitted at any time during the reporting year. Minority views involving noncompliance reports should also be included.

Question FF: **Our institution fully implemented the 8th Edition of the *Guide* during 2013. Do we need to address this in the annual report?**

Answer: No, if you had not implemented the *Guide* as planned, you would have to report this as a noncompliance. Implementation of the *Guide* as required does not need to be reported to OLAW.

Question GG: **When a new IACUC Chair discovers that the previous IACUC did not report failure to comply with the Institution's Assurance, should the new Chair describe when noncompliance began? (For example, our Assurance says "Personnel who work with animals are ... required to fill out a health evaluation questionnaire, which is reviewed by the College's medical staff" but this evaluation by the medical staff did not take place until the new Chair took office.)**

Answer: This is a noncompliant situation and should be reported to the Division of Compliance Oversight as required by the PHS Policy IV.F.3.a. as described on the OLAW website [Reporting Noncompliance](#). You may make an initial report by calling 301-496-7163. The most important dates for this noncompliance report are the dates that the Chair discovered and corrected the noncompliance. You are not required to report noncompliance in the annual report to OLAW. [END]