

What Every IACUC Should Know About AAALAC International



OLAW Webinar
September 9, 2021

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Learning Objectives

1. Understand the relationship between OLAW and AAALAC International
2. Review important concepts related to AAALAC International and OLAW
3. Describe the Guide Notice Encouraging Use of AAALAC Program Description Sections to Complete the OLAW Domestic Assurance



OLAW	AAALAC International
Ensures the humane care and use of animals in PHS-supported research, testing, and training, thereby contributing to the quality of PHS-supported activities	Enhances the quality of research, testing and education by promoting humane and responsible research animal care and use

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Federal government	Private, nonprofit organization

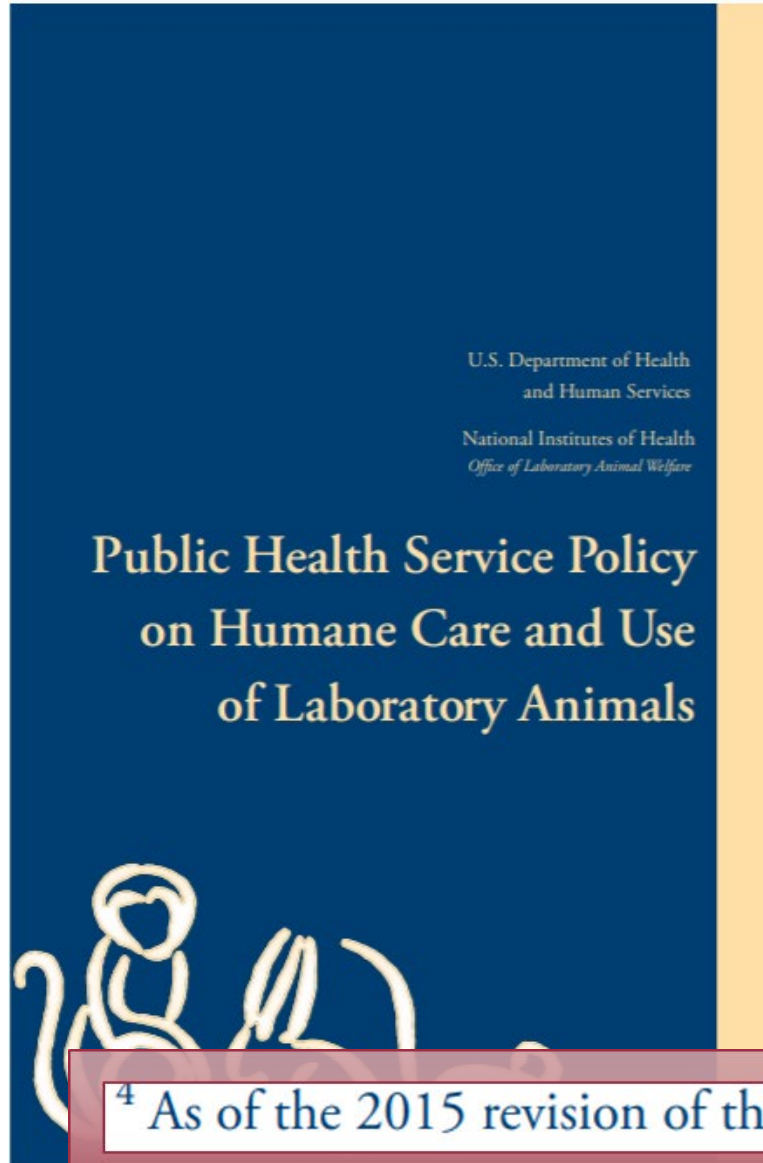
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Animal Welfare Assurance document	Program Description
Documents are subject to FOIA	Accreditation process is confidential



AAALAC in the PHS Policy

Institutional Accreditation Status in Assurance

- Category 1 – Accredited
- Category 2 – Non-accredited

Semiannual Report to the IO

Recordkeeping

Annual Report to OLAW

⁴ As of the 2015 revision of this Policy, the only accrediting body recognized by the PHS is AAALAC.

Action	Which Document(s)	Category 1 Accredited	Category 2 Non-Accredited
Include accreditation status	Assurance document	Yes	Yes

Action	Which Document(s)	Category 1 Accredited	Category 2 Non-Accredited
Include accreditation status	Assurance document	Yes	Yes
Identify accredited facilities	Semiannual Report to the IO	Yes	Yes

Action	Which Document(s)	Category 1 Accredited	Category 2 Non-Accredited
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Identify accredited facilities	Semiannual Report to the IO	Yes	Yes
Submit to OLAW with the Assurance	Semiannual Report to the IO	No	Yes

Memorandum to: [insert name and title of Institutional Official]

From: Institutional Animal Care and Use Committee

Subject: Semiannual Report of the Program Review and Facility Inspection

Date: [insert date]

This report summarizes the IACUC's results of its most recent program review and facility inspection, as required by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), Section IV.B.1.-3., the Guide for the Care and Use of Laboratory Animals (Guide), and the Animal Welfare Act (AWA) regulations, as applicable. Submission of semiannual reports to the Institutional Official is a condition of this institution's Animal Welfare Assurance with the NIH Office of Laboratory Animal Welfare (OLAW).

Since the last review, the following changes have occurred in the institution's program for animal care and use (PHS Policy IV.A.1.a.-i.): []

I. Description of the Nature and Extent of the Institution's Adherence to the PHS Policy, the Guide, and the AWA

Departures from the PHS Policy, the Guide, and the AWA.

Select A or B:

- ☐ A. There were no departures during this reporting period.
- ☐ B. The following departures have been reviewed and approved by the IACUC: [include reason for each departure]

II. Deficiencies in the Institution's Animal Care and Use Program

Animal Care and Use Program Review Date(s):

Select A or B:

- ☐ A. There were no deficiencies in the program during this reporting period.
- ☐ B. The following deficiencies have been identified: [describe each deficiency, identify

I. Semiannual Program Review Checklist¹

Institutional Policies and Responsibilities

Date:

1. Animal Care and Use Program ^{NEW}	A*	M	S	C	NA
<ul style="list-style-type: none">Responsibility for animal well-being is assumed by all members of the program (Guide, p 1) [must]IO has authority to allocate needed resources (Guide, p 13)Resources necessary to manage program of veterinary care are provided (Guide, p 14) [must]Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the Guide (Guide, pp 11, 15)Program needs are regularly communicated to IO by AV and/or IACUC (Guide, p 13)Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site (Guide, p 14) [must]Inter-institutional collaborations are described in formal written agreements (Guide, p 15)Written agreements address animal care, animal ownership, and IACUC oversight (Guide, p 15)					
2. Disaster Planning and Emergency Preparedness	A*	M	S	C	NA
<ul style="list-style-type: none">Disaster plans for each facility to include evacuation are in place (Guide, p 35, p 75) [must]Plans include provisions for euthanasia (Guide, p 75) [must]Plans include triage plans to meet institutional investigators' needs (Guide, p 35)Plans define actions to prevent animal deaths due to HVAC or other failures (Guide, p 35)Plans describe preservation of critical data (Guide, p 35)Plans include essential personnel training (Guide, p 35)Animal facility plans are approved by the institution and integrated into overall response plan (Guide, p 35)Law enforcement and emergency personnel are provided a copy of integration with overall plan is in place (Guide, p 35)					
3. IACUC ^{NEW}	A*	M	S	C	NA
<ul style="list-style-type: none">Meets as necessary to fulfill responsibilities (Guide, p 25) [must]IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (Guide, p 26) [must]Continuing IACUC oversight after initial protocol approval is in place (Guide, p 33)IACUC evaluates the effectiveness of training programs (Guide, p 15)					
4. IACUC Protocol Review - Special Considerations	A*	M	S	C	NA
<ul style="list-style-type: none">Humane endpoints are established for studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock (Guide, p 27)For pilot studies, a system to communicate with the IACUC is in place (Guide, p 28)For genetically modified animals, enhanced monitoring and reporting is in place (Guide, p 28)Restraint devices are justified in the animal use protocols (Guide, p 29) [must]Alternatives to physical restraint are considered (Guide, p 29)Period of restraint is the minimum to meet scientific objectives (Guide, p 29)					

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Submit to OLAW with the Assurance	Semiannual Report to the IO	No	
Maintain accrediting body determinations	Institution's records	Yes	

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Maintain accrediting body determinations	Institution's records	Yes	Yes
Report change in accreditation status	Annual Report to OLAW	Yes	Yes

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Category I - Accredited Institution



Semiannual
Report to
the IO

Upon
Request



Category 2 - Non-Accredited Institution

Semiannual
Report to
the IO

**With
Assurance
Upon
Request**





AAALAC Program Description

Optional to Use

Notice to Encourage Using
AAALAC International Program
Description Sections to
Complete Parts of the OLAW
Domestic Animal Welfare
Assurance

NOT-OD-21-130

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-130.html>

Post-Approval Monitoring

Domestic Assurance
Part III.D.9.

Program Description
Section 2.I.B.2.

a. IACUC review of ongoing
studies and protocol
reviews

e. Other monitoring
mechanisms or procedures

Post-Approval Monitoring

Domestic Assurance
Part III.D.9.

Program Description
Section 2.I.B.2.

a. IACUC review of ongoing studies and protocol reviews

e. Other monitoring mechanisms or procedures

Domestic Assurance instructions

Describe how the IACUC monitors ongoing activities (postapproval monitoring).

Describe how the IACUC conducts a complete review of previously approved protocols at least every 3 years.

Describe the annual review process for Animal Welfare Act and Regulations-covered species, if applicable.



Occupational Health

Domestic Assurance Part III.E.

Program Description Section 2.I.A.2.b.

- i.1) Planning, oversight, and operation
- ii.1)
 - a) Personal medical evaluation
 - d) Individuals with incidental exposure
 - e) Medical evaluation and preventive medicine programs
- ii.2) Educational program(s)
- ii.3)
 - a) PPE and work clothing
 - c) Personal hygiene practices
 - d) Eating, drinking, smoking policies

Occupational Health

Domestic Assurance instructions

Describe the Institution's occupational health and safety program for all personnel involved in the care and use of animals. Refer to the following relevant topics listed in the Guide:

Control and prevention strategies

Hazard identification and risk assessment and ongoing process for identification and assessment

Facilities, equipment, and monitoring

Personnel training

Personal hygiene

Animal experimentation involving hazards

Personal protection

Medical evaluation and preventive medicine for personnel (including immunizations, vaccinations, and procedures for reporting and treating bites, scratches, and injuries)

Where appropriate, describe special precautions for personnel working with nonhuman primates (e.g., tuberculosis screening, training and procedures for bites and scratches, and education regarding Macacine herpesvirus 1, formerly Cercopithecine herpesvirus 1 (Herpes B)).

Training

Domestic Assurance Part III.G.

Program Description Section 2.I.A.2.a

- i. Veterinary care staff training and continuing education (CE)
- ii. 2) Animal Care training and CE
- iii. I) a) Research Team required training
- iii. I) c) Research Team CE

Program Description Section 2.I.B.I.

- a. iii. Member orientation, training, and CE



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Program Description Section 2.I.B.I.

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Domestic Assurance instructions

Describe training or instruction provided to people caring for or using laboratory animals in the proper and humane practice of animal care and use.

Describe training or instruction in research or testing methods that minimize the number of animals required to obtain valid results and minimize animal pain and distress.

Describe training or orientation, and ongoing training opportunities provided to the IACUC members, including background materials and resources.

Describe how the IACUC evaluates the effectiveness of the training program.

Describe continuing education programs to reinforce training and provide updates to reflect changing technology.

All the Details are Online



National Institutes of Health
Office of Laboratory Animal Welfare

Office of Laboratory Animal Welfare



Policies and Law



Guidance



Education



Resources



OLAW homepage
<https://olaw.nih.gov>

21st Century Cures
Act banner
[https://olaw.nih.gov/
policies-laws/21st-
century-cures-act/](https://olaw.nih.gov/policies-laws/21st-century-cures-act/)

21st Century Cures Act – Animal Care and Use in Research

Actions to reduce administrative burden on investigators conducting animal activities while maintaining research integrity and the protection of animals.

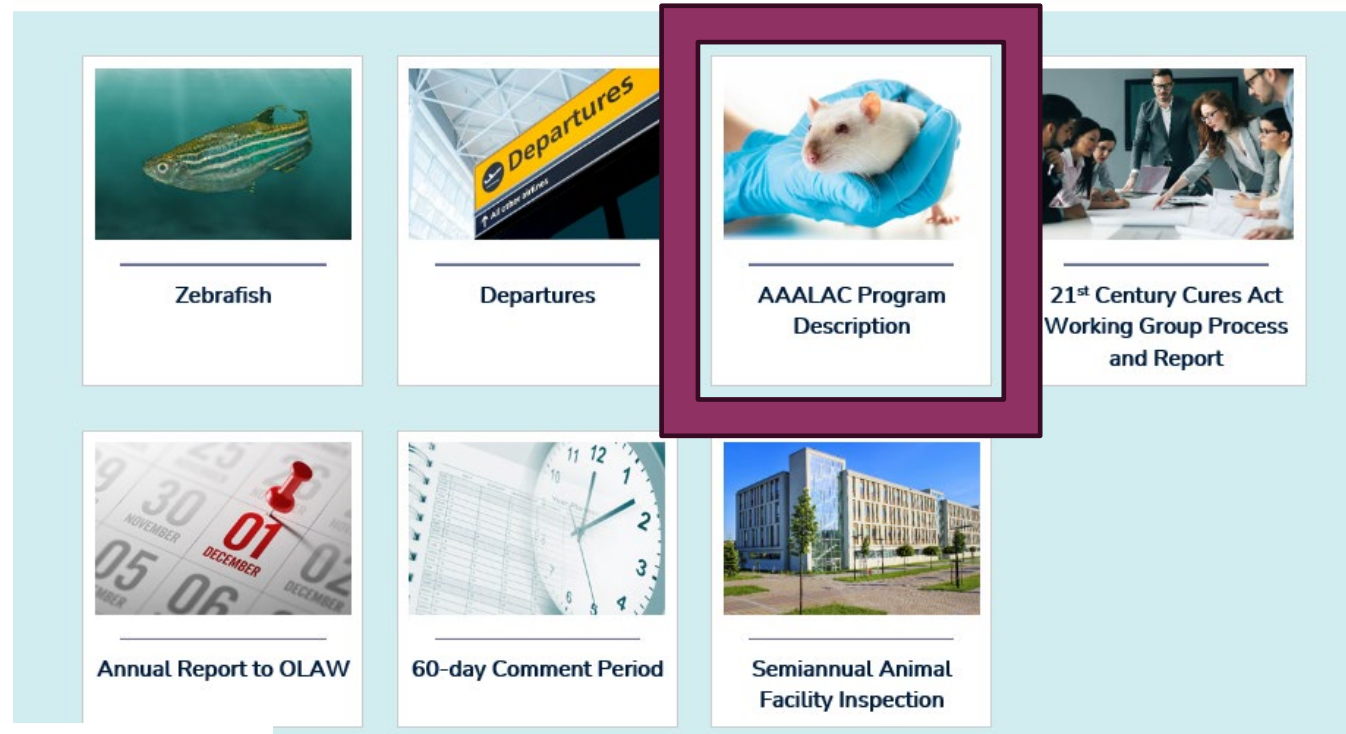


National Institutes of Health
Office of Laboratory Animal Welfare

All the Details are Online

21st Century Cures Act – Animal Care and Use in Research

The [21st Century Cures Act, Section 2034 \(d\)](#), directed the NIH, in collaboration with USDA and FDA, to conduct a review of applicable regulations and policies for the care and use of laboratory animals and to make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals.



OLAW 21st Century Cures Act Landing Page

<https://olaw.nih.gov/policies-laws/21st-century-cures-act/>

AAALAC Program Description

<https://olaw.nih.gov/policies-laws/21st-century-cures-act/AAALAC-Program-Description>

Contact OLAW



National Institutes of Health
Office of Laboratory Animal Welfare

[About OLAW](#)[Contact Us](#)

Phone

301-496-7163

Division of Assurances

olawdoa@mail.nih.gov



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Opportunities to...



Innovate.

...



Communicate.

...



Collaborate.



What Every IACUC Should Know About AAALAC International

OLAW Webinar

September 9, 2021

Helen E. Diggs, MEd, DVM, DAACLAM
Senior Director, AAALAC International

Today

- ✓ AAALAC International,
Accreditation Program and Process
- ✓ Primary Standards and
Reference Resources
- ✓ Trends in Site Visit Findings
 - ✓ Myths vs. Facts
- ✓ The Value of Accreditation



AAALAC International Mission Statement

AAALAC International is a voluntary accrediting organization that enhances the quality of research, testing and education by promoting humane and responsible research animal care and use through provision of advice and independent assessments to participating institutions and accreditation of those that meet or exceed applicable standards.

AAALAC International

Established 1965

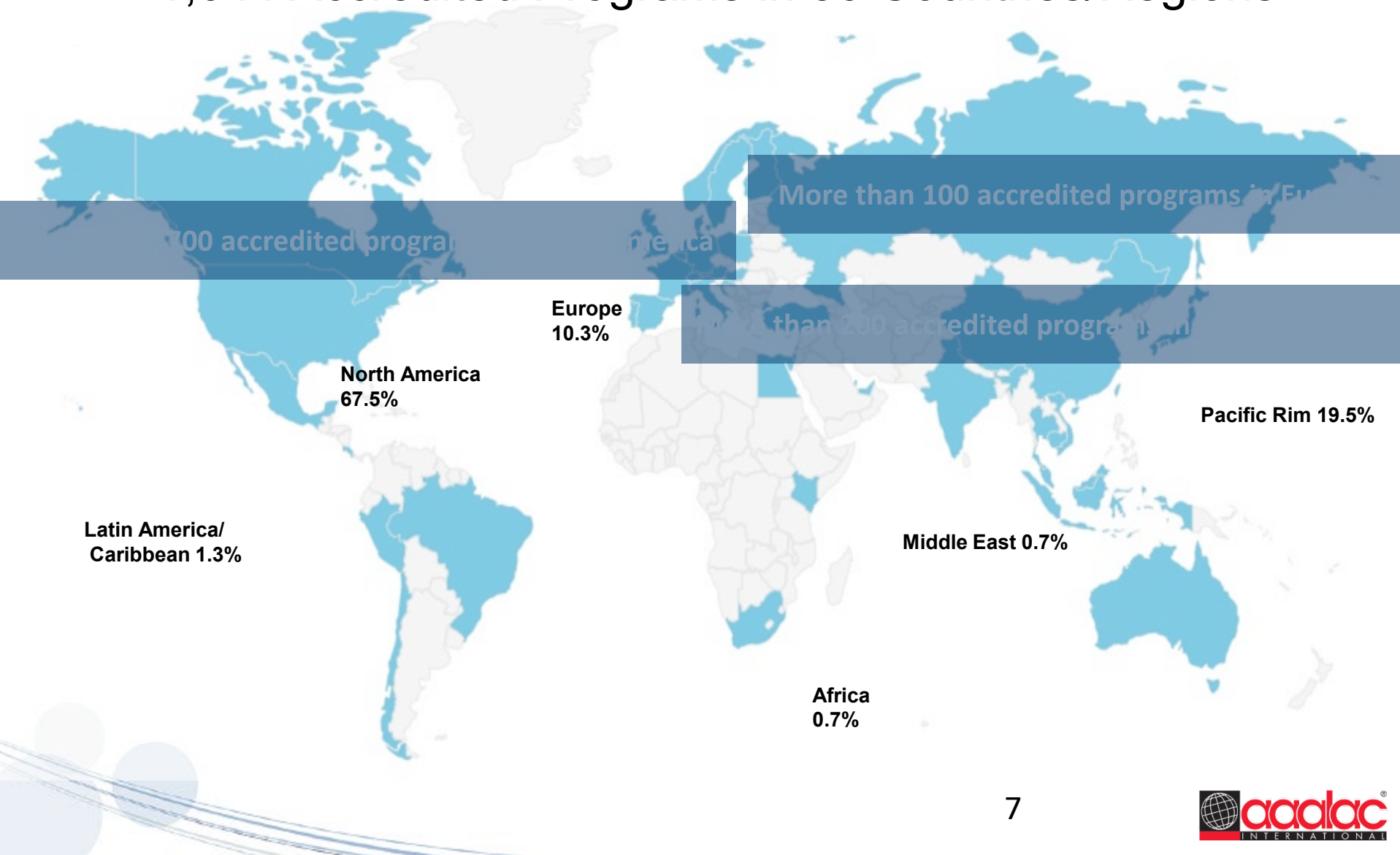
Non-governmental

Non-profit



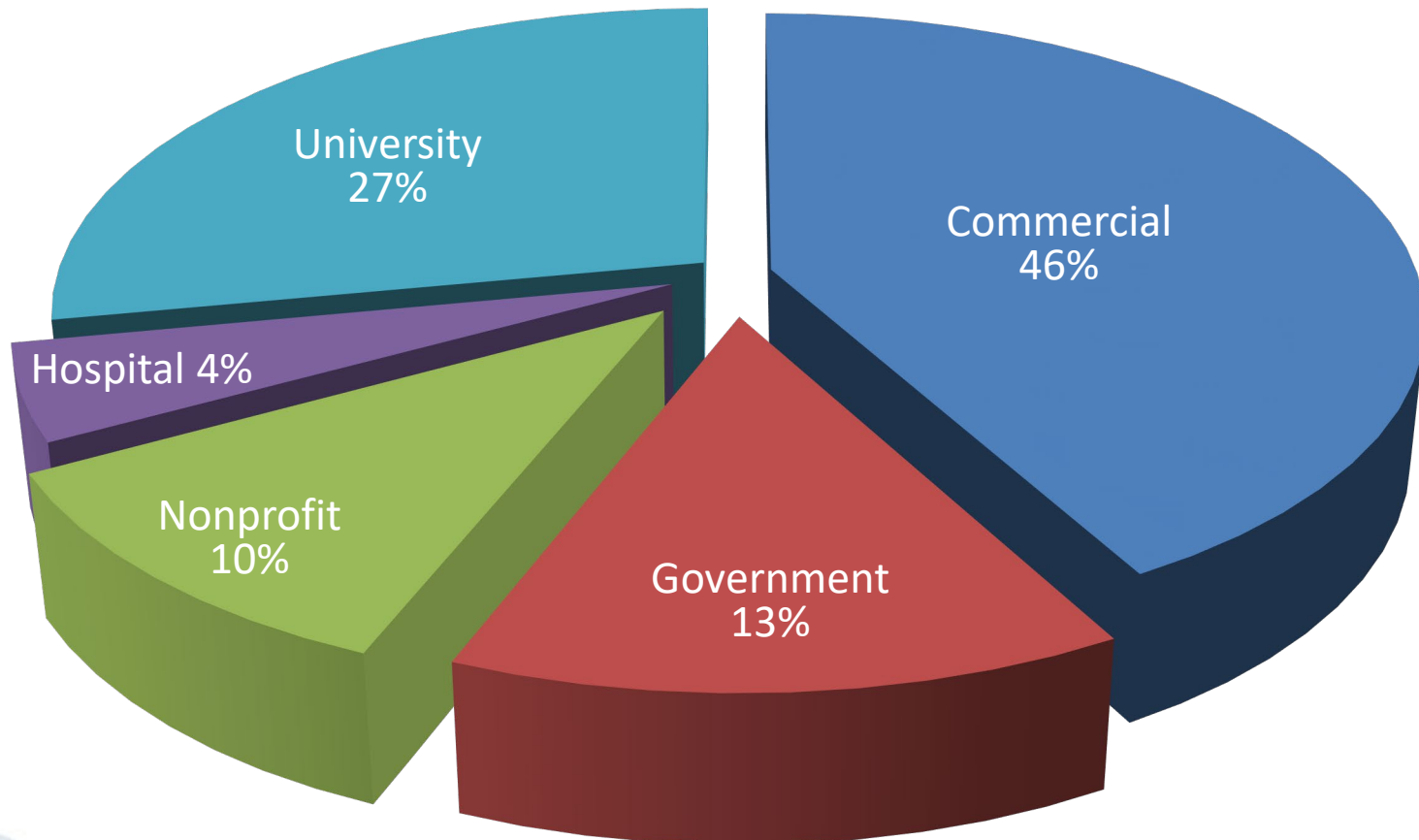
Accredits animal care and use programs.

>1,041 Accredited Programs in 50 Countries/Regions





Accredited Programs



Oversight Organization Comparison

Organization	Animal Welfare Act	Public Health Service Policy	AAALAC International
Responsible Agency	USDA/APHIS	NIH/OLAW	Private, nonprofit
Applicability	Required of users of Regulated Species	Required of Assured Institutions	Voluntary
Species Covered	Warm-blooded <i>(except rats, mice, birds bred for research and animals on agricultural studies)</i>	Live Vertebrates	Most
Standards	Animal Welfare Act Regulations, Part 3 Standards	PHS Policy, ILAR <i>Guide</i> , US Government Principles, AWA, AVMA Guidelines for the Euthanasia of Animals	<i>Guides</i> , ETS 123 & Reference Resources
Enforcement	Unannounced Inspections	Written "Assurance"	Confidential Peer Reviews
Sanctions	Citations, Official Warnings, Legal enforcement	Withdrawal of Assurance Approval, Revoke Funding	Revocation of Accreditation
Link to Funding	None	Direct and Indirect	Indirect

Myth vs. Fact

- Myth: AAALAC International is part of the IACUC.
- Fact: The acronyms associated with animal research can be confusing but it is important to know that **AAALAC is not linked to the IACUC** (Institutional Animal Care and Use Committee). The IACUC is charged with local oversight of the institution's animal care and use program.
- As part of the site visit, AAALAC evaluates the performance of the IACUC to ensure that it is functioning well. AAALAC accreditation serves as an external, third party review.



Program Status Evaluation (PSE)



ABOUT

ACCREDITATION PROGRAM

PRE-ACCREDITATION EVALUATIONS

EDUCATION

PAY FEES

AWARDS

RESOURCES



Confidential Peer Review

Myth vs. Fact

- Myth: In the U.S., AAALAC International evaluates animal care and use programs that only use animals regulated under the Animal Welfare Act.
- Fact: AAALAC International accreditation covers all animals* used or to be used in research, teaching or testing at accredited programs.

*Rules of Accreditation: Definition/[Animals](#) - This includes traditional laboratory animals, farm animals, wildlife, and aquatic animals. Nontraditional animals, inclusive of invertebrate species, are also included where they are relevant to the program's mission.

Accreditation Program

Completely confidential
Performance-based
Peer-review process



The Process

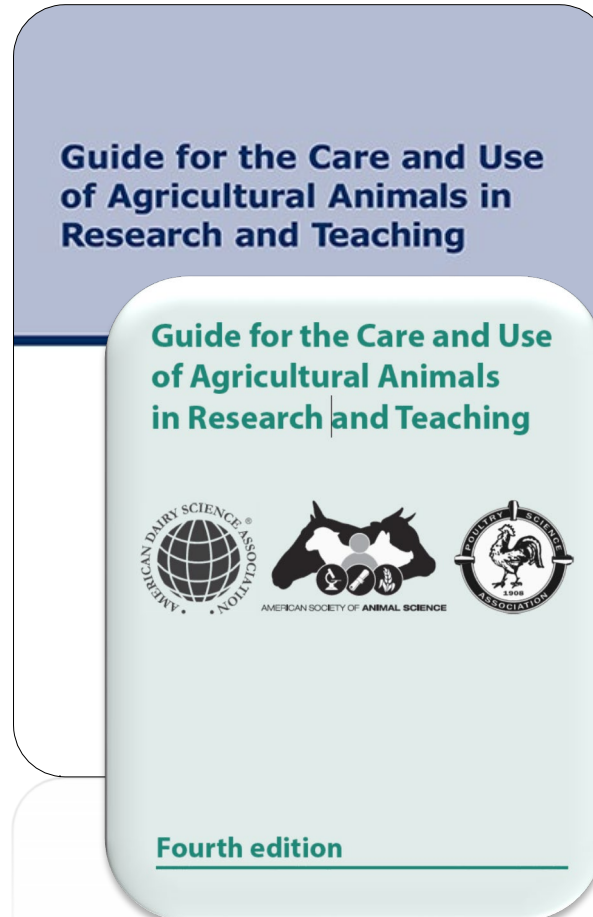
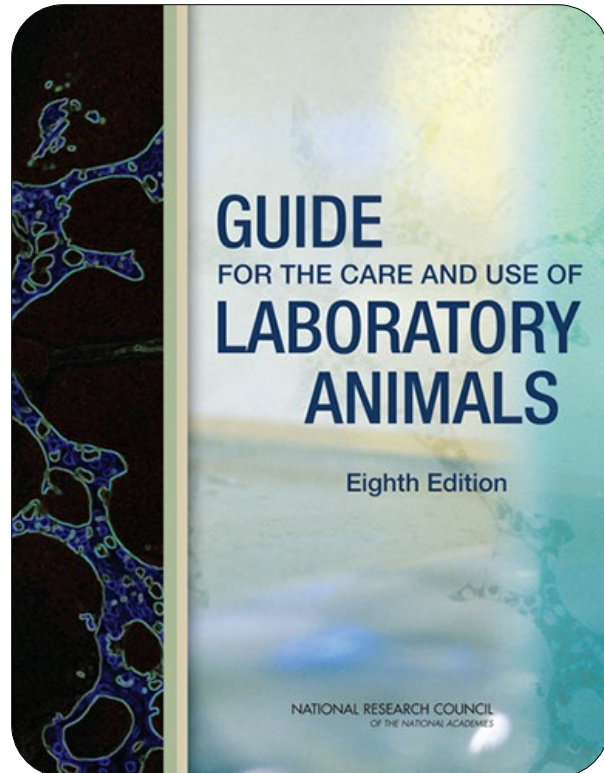
Complete the Application Packet
Develop a Program Description
Prepare for an Evaluation



Council on Accreditation finding considerations
Institution notified of accreditation status



Three Primary Standards






Myth vs. Fact

- Myth: AAALAC International establishes policies and regulations.
- Fact: AAALAC International evaluates animal care and use programs based on recommendations in the Three Primary Standards, applicable legislation and other references.



Reference Resources



[ABOUT](#)
[ACCREDITATION PROGRAM](#)
[PROGRAM STATUS EVALUATION](#)
[EDUCATION](#)
[PAY FEES](#)
[AWARDS](#)
[RESOURCES](#)

Resources

Reference Resources

AAALAC relies on **Three Primary Standards** for evaluating laboratory animal care and use programs: the eighth edition of the *Guide for the Care and Use of Laboratory Animals* (*Guide*, NRC 2011); the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (*Ag Guide*, FASS 2010); and the *European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes*, Council of Europe, (ETS 123); along with other widely accepted guidelines. Since 1975, AAALAC International has also referred to other specialty publications for supplemental information about procedures or techniques related to the care and use of laboratory animals. These specialty publications are designated as Reference Resources. References included on this list have been formally reviewed and adopted by AAALAC International's Council on Accreditation as guidance for accredited units as well as the AAALAC International representatives during the site visit. Additionally, these references may be utilized during Council deliberations when discussing issues identified during site visits. When applicable, clarifying notes are appended to the reference, to provide additional information on any exclusions or clarification in the reference.

Click here to [view a complete list of AAALAC's Reference Resources](#).

General	—
Biosafety	—
Education	—
Euthanasia	—
Health Monitoring	—
Occupational Health and Safety	—
Research Related	—
Species Specific	—



Resources

AAALAC's
Reference Resources,
FAQs and
Position Statements

www.aaalac.org



Your
Institution's
Program
Description

Self-Assessment

Myth vs. Fact

- Myth: AAALAC International uses the same standards to evaluate animal programs outside the U.S.
- Fact: Because each country has its own set of laws and regulations, AAALAC International site visitors use a customized approach for evaluating programs.



Peer Review Process

- ✓ Program Description = Self-assessment
- ✓ Site Visit includes - Council & team and Organization's experts
- ✓ Council on Accreditation (COA)
 - Multiple Council members review site visit reports
 - Full Council reviews reports at triannual meetings
 - Committee for Consistency (Quality Assurance)
 - Continuing Education

ILAR Guide's Key Terms

Must indicates actions that are imperative for humane animal care and use.

Mandatory finding = a deficiency that ***must*** be corrected for Full Accreditation to be awarded or continued.

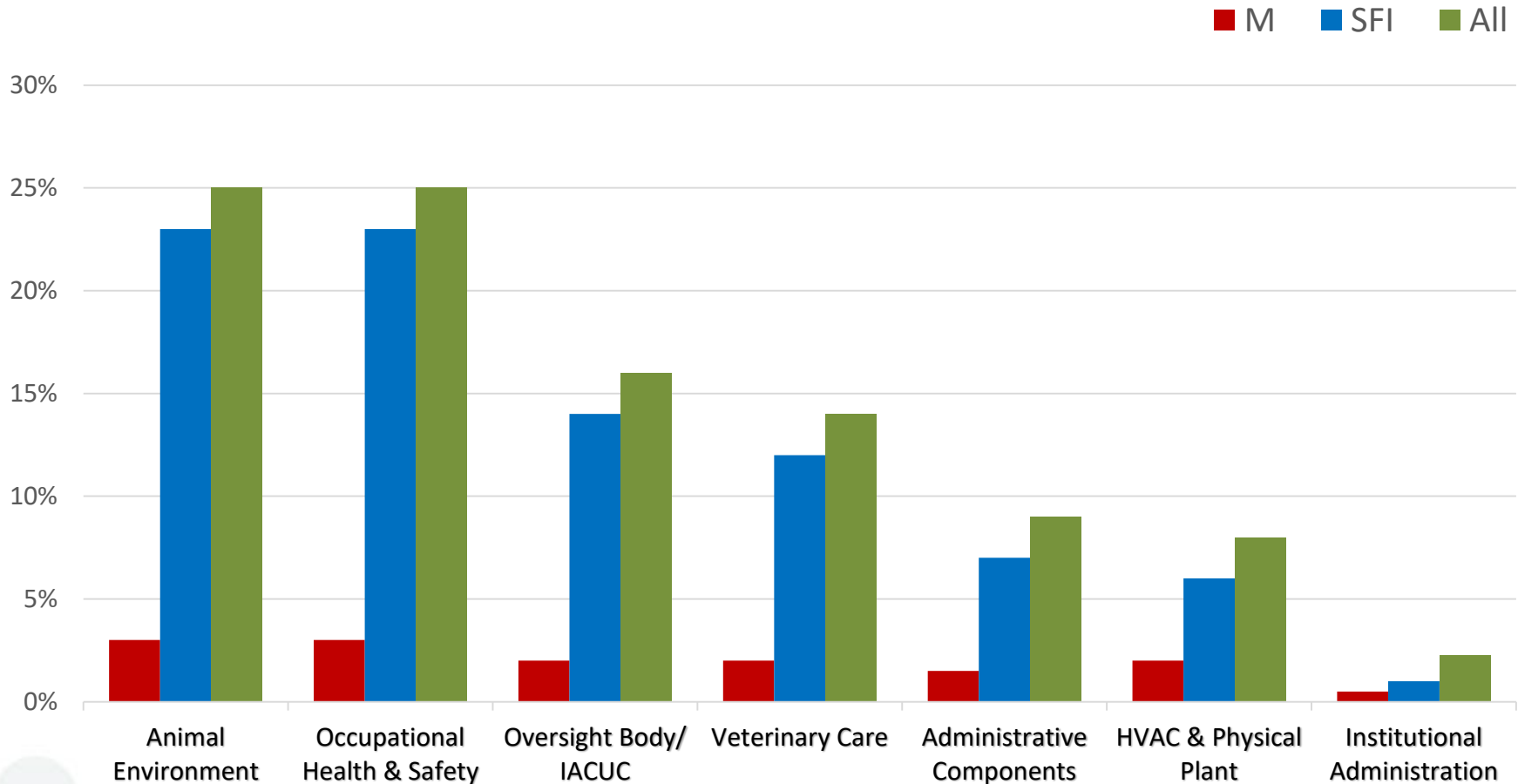
Should indicates a strong recommendation.

Suggestion for Improvement (SFI) = are *considered* as an upgrade or enhancement to an already acceptable or even commendable program.



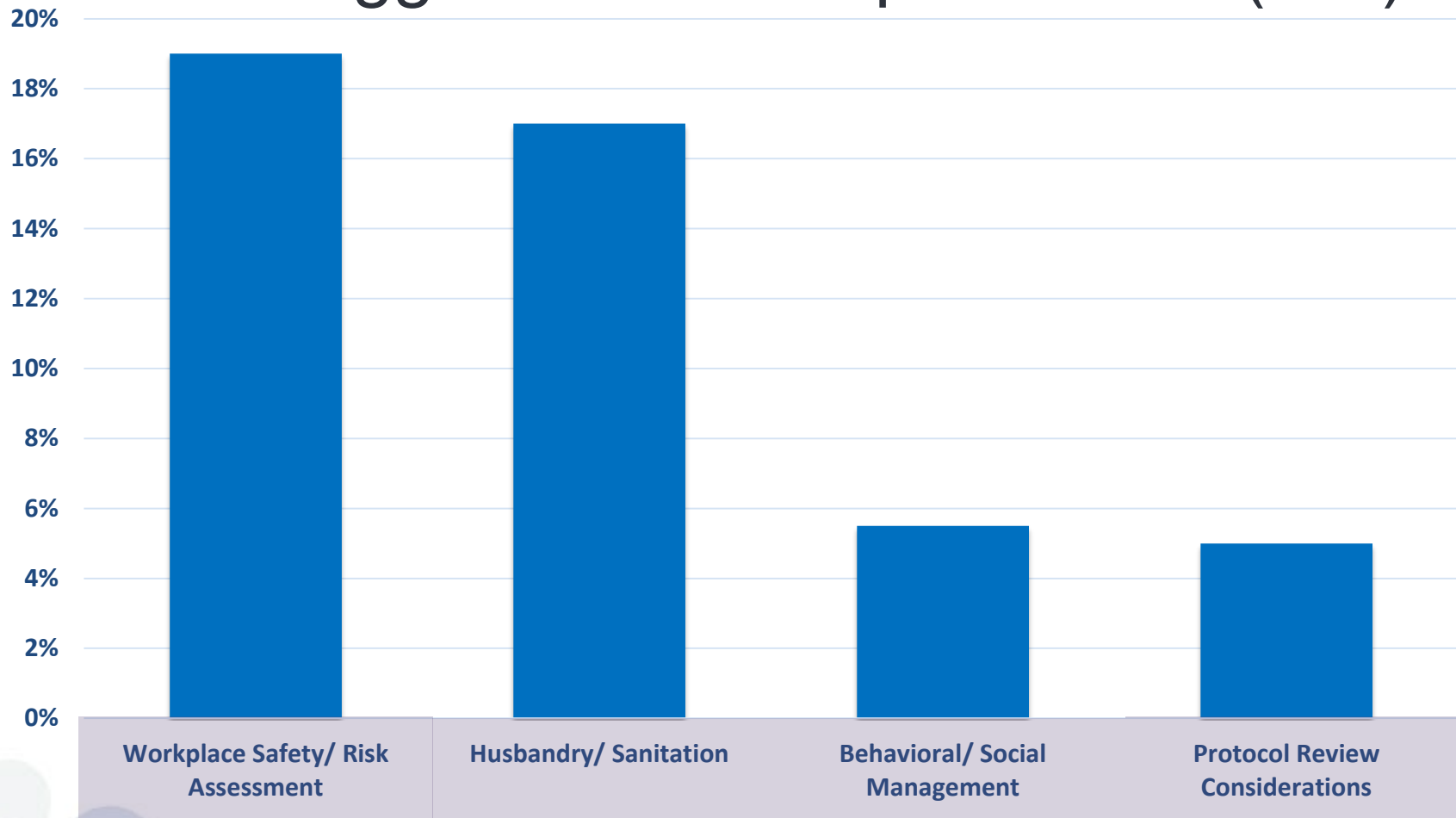
Periodic Findings Review

All SFI & Mandatory Findings

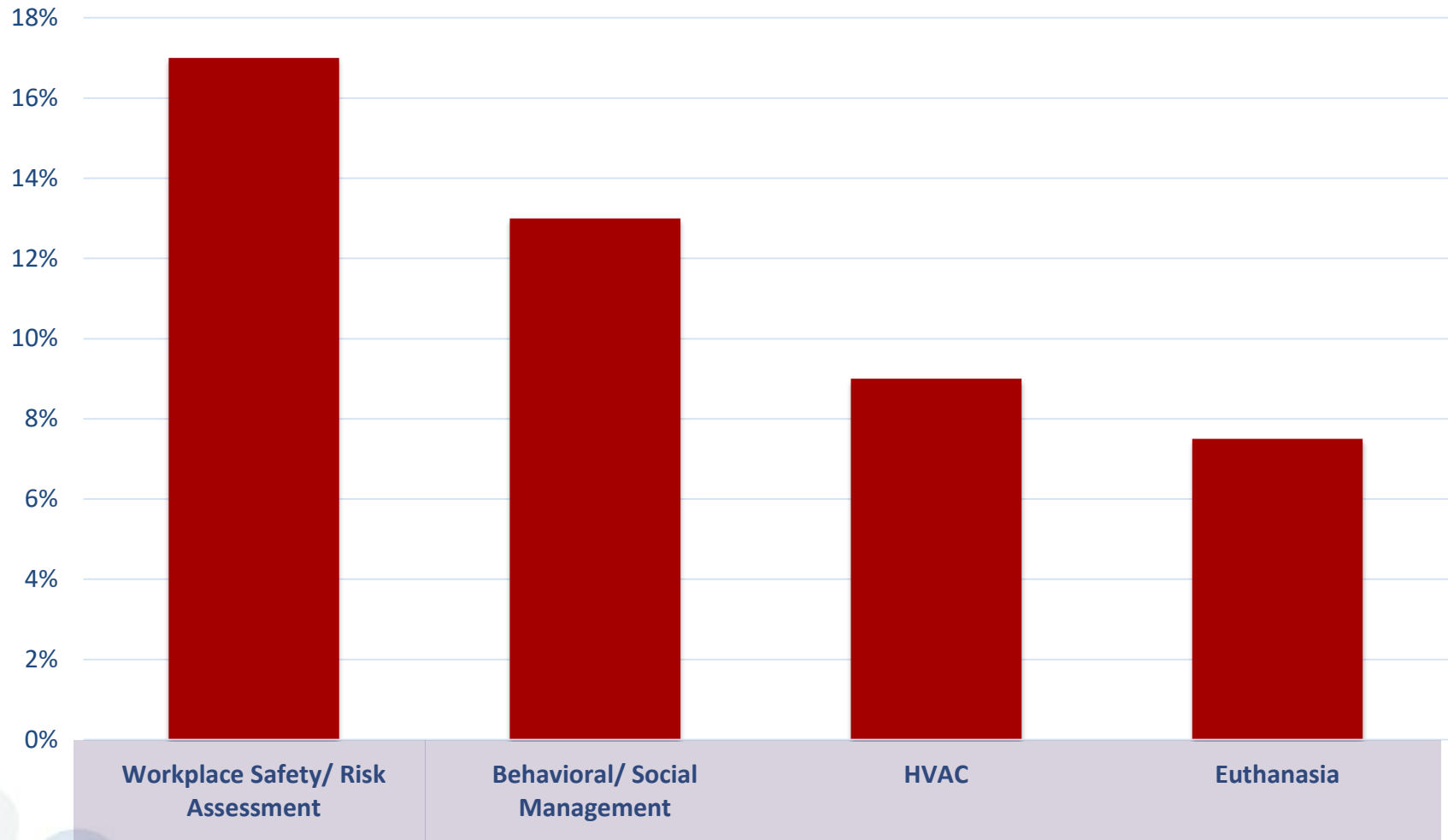




Program Elements with the Most Suggestions for Improvement (SFI)



Program Elements with the Most Mandatory Findings



Myth vs. Fact

- Myth: AAALAC imposes biomedical standards on our **agricultural animal** research programs.
- Fact: AAALAC does not hold agricultural facilities to the same criteria used to evaluate biomedical research facilities and laboratories. AAALAC expects that agricultural animal research programs meet the standards for housing and care that prevail on a **high quality, well-managed farm**. One of AAALAC's Primary Standards is the Ag Guide.

Perceptions vs. Reality

- Perceptions
 - AAALAC *over-interprets* standards
 - AAALAC imposes *new* standards
 - Suggestions for Improvement *must* be followed
- Reality
 - State-of-the-art practices evolve
 - *Mandatory* items are based on existing standards
 - *Suggestions for Improvement* are just that
 - Perceived inconsistencies are continuously reviewed by AAALAC Council

The Importance of Periodic Assessment



■ Resolved in PSVC

■ Retained in C&R as an SFI

■ Retained in C&R as a Mandatory

The Value of Accreditation

- ✓ Improves opportunities for inter- and intra-institutional **collaborations** that **may result** in sponsored **research funding** and enhanced **networking**.
- ✓ Leverages institutional support for **facility upgrades** and continuing improvements.
- ✓ Adds **credibility** to the institution's program among federal agencies, e.g., National Institutes of Health, National Science Foundation, the Department of Defense, and sponsors such as, National Institute of Food and Agriculture (NIFA) or Agricultural Research Service (ARS).
- ✓ Stimulates continuous **program self-assessment**, benchmarking, and improvement.
- ✓ **Assures the public** of the institution's commitment to achieving the highest quality animal care and science.

Thank you!

www.aalac.org



Questions?

Please click on the Question-and-Answer icon located at the bottom middle of your screens to type your questions.



Question 1

Does AAALAC International have any reporting requirements for accredited programs?





Question 2

Aside from the hybrid site visits, has anything else at AAALAC International changed as a result of the COVID-19 pandemic?





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Please click on the Question-and-Answer icon located at the bottom middle of your screens to type your questions.

Next OLAW Online Seminar: December 2021



Topic TBD