

AAALAC International: Perspectives on Regulatory Burden

Chris Newcomer, VMD, DACLAM
Executive Director
cnewcomer@aaalac.org



Fostering animal welfare and
scientific discovery since 1965

Agenda

- A brief introduction to AAALAC International
- A brief review of AAALAC's findings bearing on regulatory burden
- Q&A



Animal Care Panel 1964 Report

- *“As part of the scientific community, the Animal Care Panel has been working to define the conditions of animal care which promote sound and proper animal experimentation....
The Animal Care Panel cannot and will not proceed with this program [accreditation] without the consent and support of the scientific community.”*



AAALAC: Founded in Science, Guided by Science

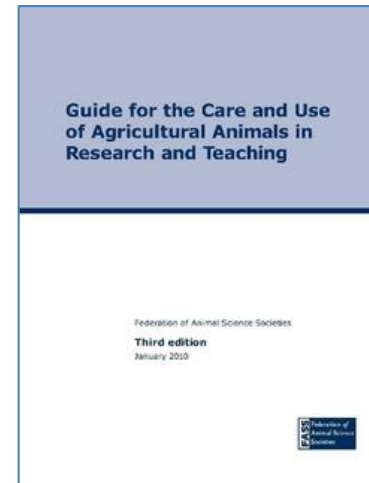
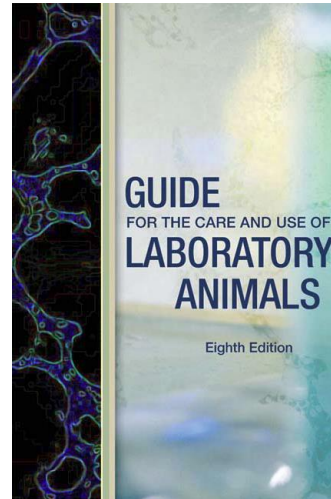
- Board of Trustees Member Organizations
 - More than half represent scientific organizations
 - Experimental biology, toxicology, agriculture, neuroscience, transgenic technology, etc.
 - Others represent veterinary medical, patient advocacy, science advocacy, and industry/academic interest groups
- Approximately one-third of the Council on Accreditation hold a Ph.D.



Core Values



Standards of Accreditation



The Council's Mission Statement

The AAALAC International Council on Accreditation promotes quality and continuing improvement of the well-being of animals used in research, testing, and teaching, the health and safety of personnel, and the animal-based research itself. These are accomplished through the conduct of peer reviews of animal care and use programs, conferring an accreditation status, educational efforts, and on-going communications with stakeholders. The Council's activities are principled in the application of performance-based standards and professional judgment within the framework of Three Primary Standards, the *Guide for the Care and Use of Laboratory Animals* (NRC 2011), the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (FASS 2010), and the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes (ETS 123), as well as applicable reference resources, and relevant governmental regulations.

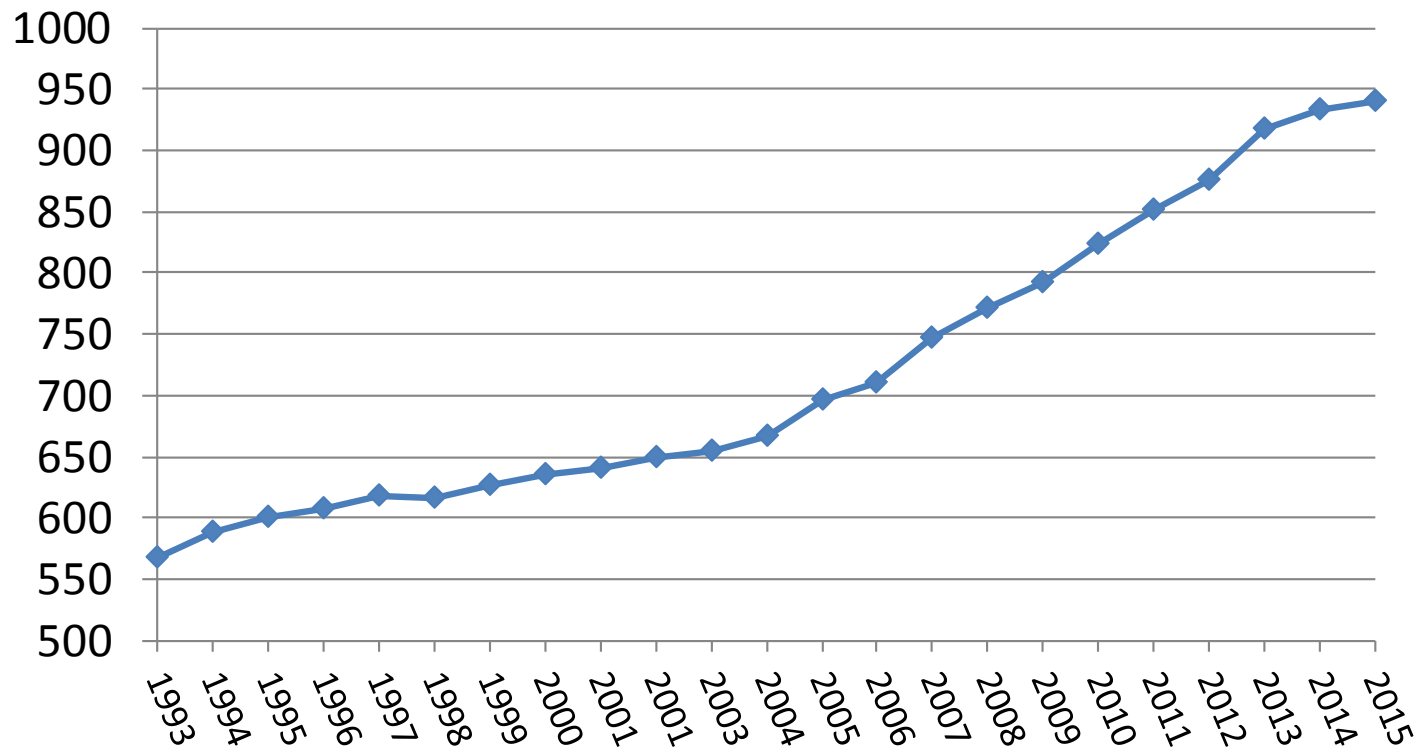


An AAALAC accredited program contributes to

- Minimizing experimental variables
- Ensuring high quality reproducible data
- Ensuring a high level of animal husbandry and care
- Ensuring a high level of humane animal use
- Ensuring a high level of occupation health and safety



Scope of AAALAC's Impact : More than 940 Accredited Units in 40 Countries



40 Countries with Accredited Units

- Australia
- Austria
- Barbados
- Belgium
- Brazil
- Cambodia
- Canada
- Chile
- P.R. China/Hong Kong
- Croatia
- Denmark
- Egypt
- Fed. of St. Kitts & Nevis
- Finland
- France
- Germany
- Hungary
- India
- Indonesia
- Israel
- Italy
- Japan
- Korea
- Malaysia
- Mauritius
- Mexico
- The Netherlands
- Norway
- Peru
- Philippines
- Russia
- Singapore
- Spain
- Sweden
- Switzerland
- Taiwan R.O.C.
- Thailand
- U.K.
- U.S.A.
- Vietnam



Trends Findings – 2011 *Guide*



- Nearly 700 institutions
- 4185 findings
- 589 Mandatory findings
- 4226 Suggestions for Improvement

Mandatory Item vs. Suggestion For Improvement

- **Mandatory Item** = a deficiency which must be corrected for Full Accreditation to be awarded or continued
- **Suggestion for Improvement (SFI)** = item which the Council feels is desirable to upgrade an already acceptable or even commendable program

Departures from the Guide/ Comparison of Reporting Requirements

In reference to a “should” statement in the Guide.

Deviation from <i>Guide</i> should statement without IACUC approval.	Post-approval monitoring determines that cage sanitation was not performed in accordance with the <i>Guide</i> . [C.3.]	Noncompliance	Promptly	Promptly	Policy IV.F.3. NOT-OD-05-034
--	---	---------------	----------	----------	------------------------------

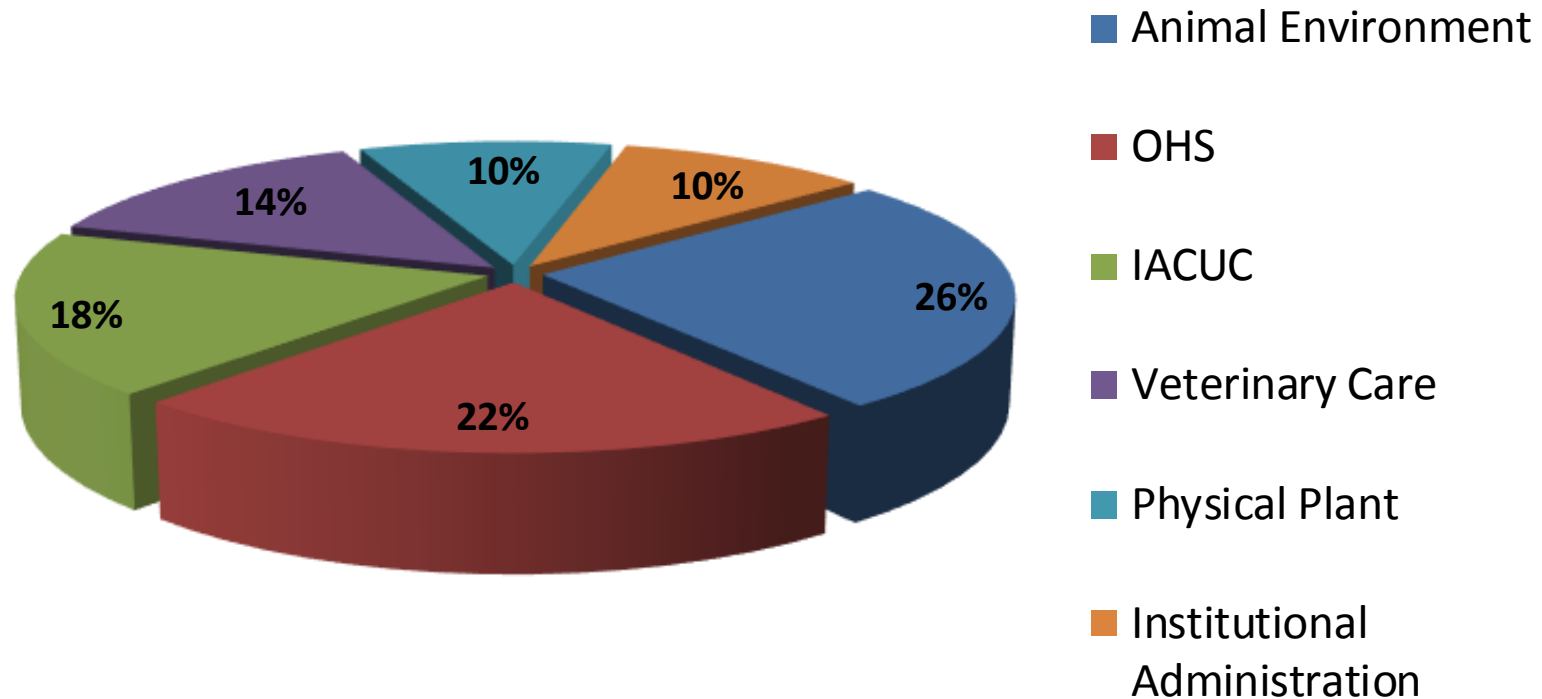
Background

PHS Policy, IV.F.3, requires that:

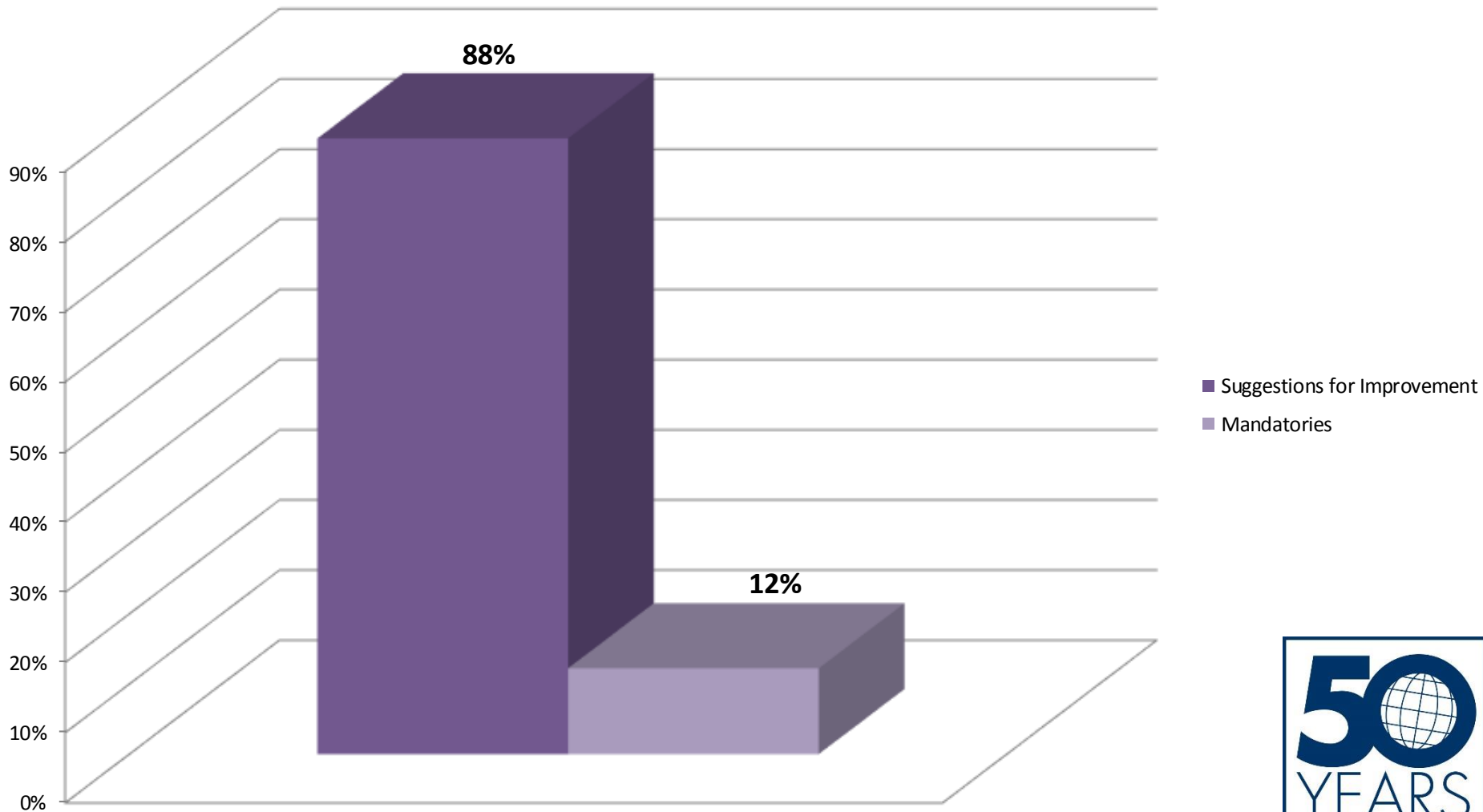
"The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

- a) any serious or continuing noncompliance with this Policy;
- b) any serious deviation from the provisions of the *Guide*; or
- c) any suspension of an activity by the IACUC."

Program Components - Findings



Percent Mandatory and SFI Findings



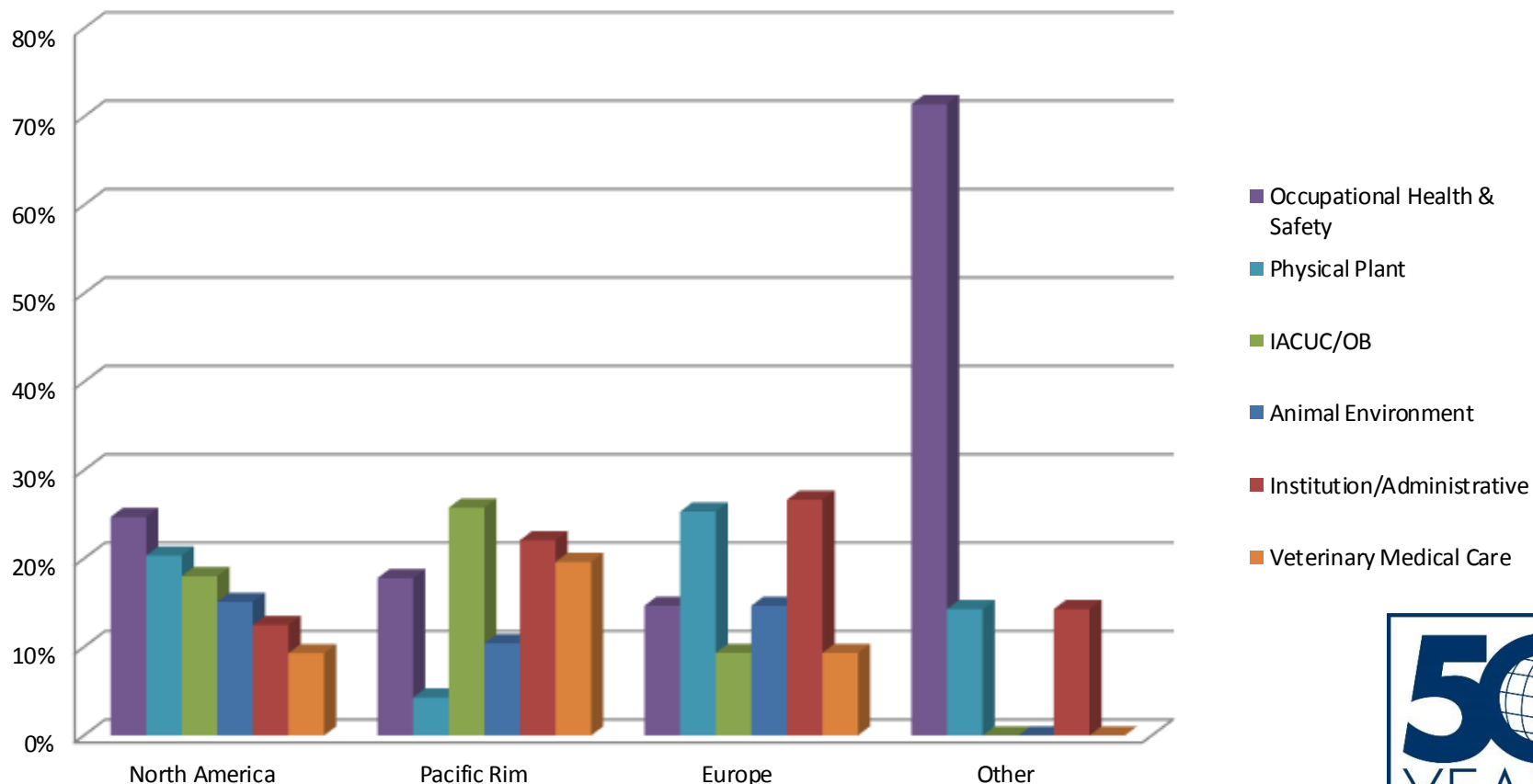
Program Components - Mandatories

- 1) Occupational Health and Safety..... 22%
- 2) IACUC/ OB..... 19%
- 3) Institutional/ Administrative..... 17%
- 4) Physical Plant..... 16%
- 5) Animal Environment..... 14%
- 6) Veterinary Care..... 12%

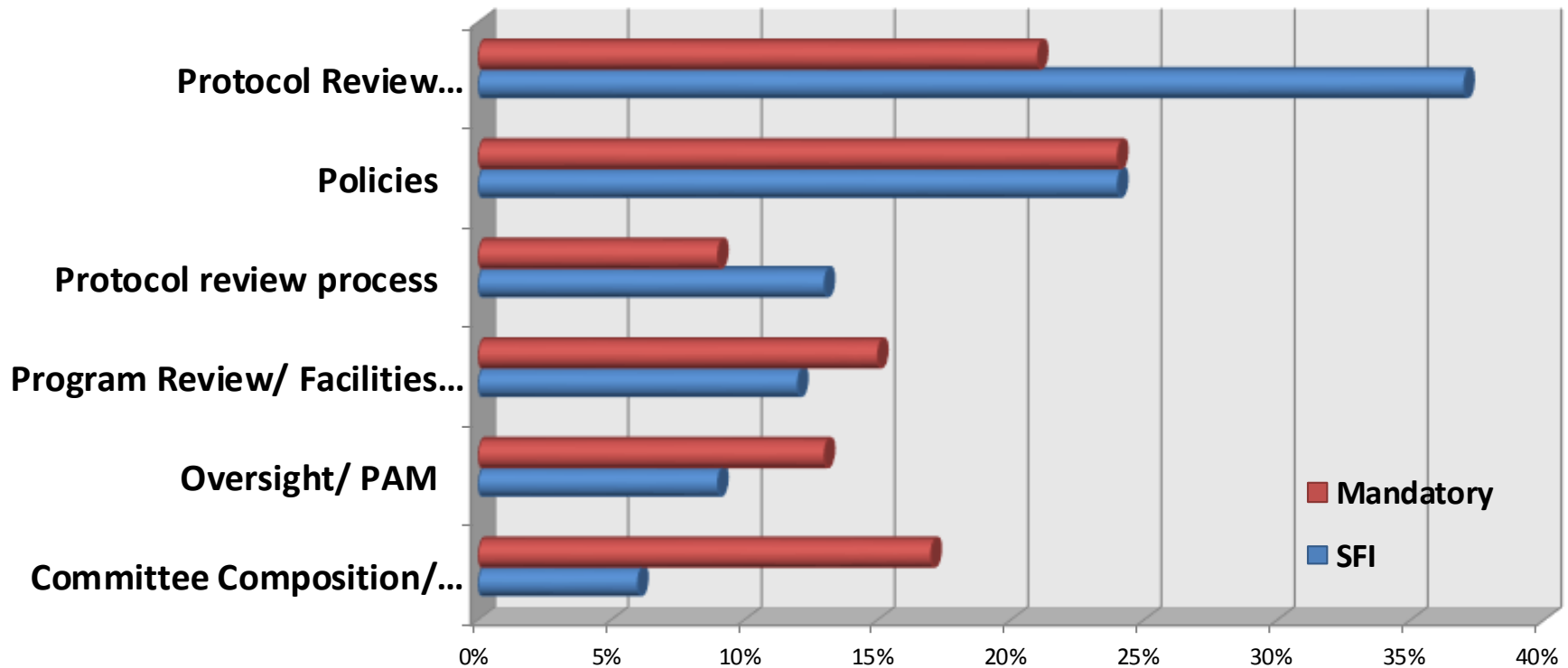


Program Components

Percent Mandatory Items by Geographical Region



IACUC-Related Findings



IACUC - Policies

- Reporting animal welfare concerns 51%
- SOP's/ Guidelines 35%
Euthanasia, tumors, sterile surgery, analgesics, social housing, environmental enrichment, etc.
- Cage density/sanitation frequency 8%
- Collaborations 7%

AAALAC Expectation:

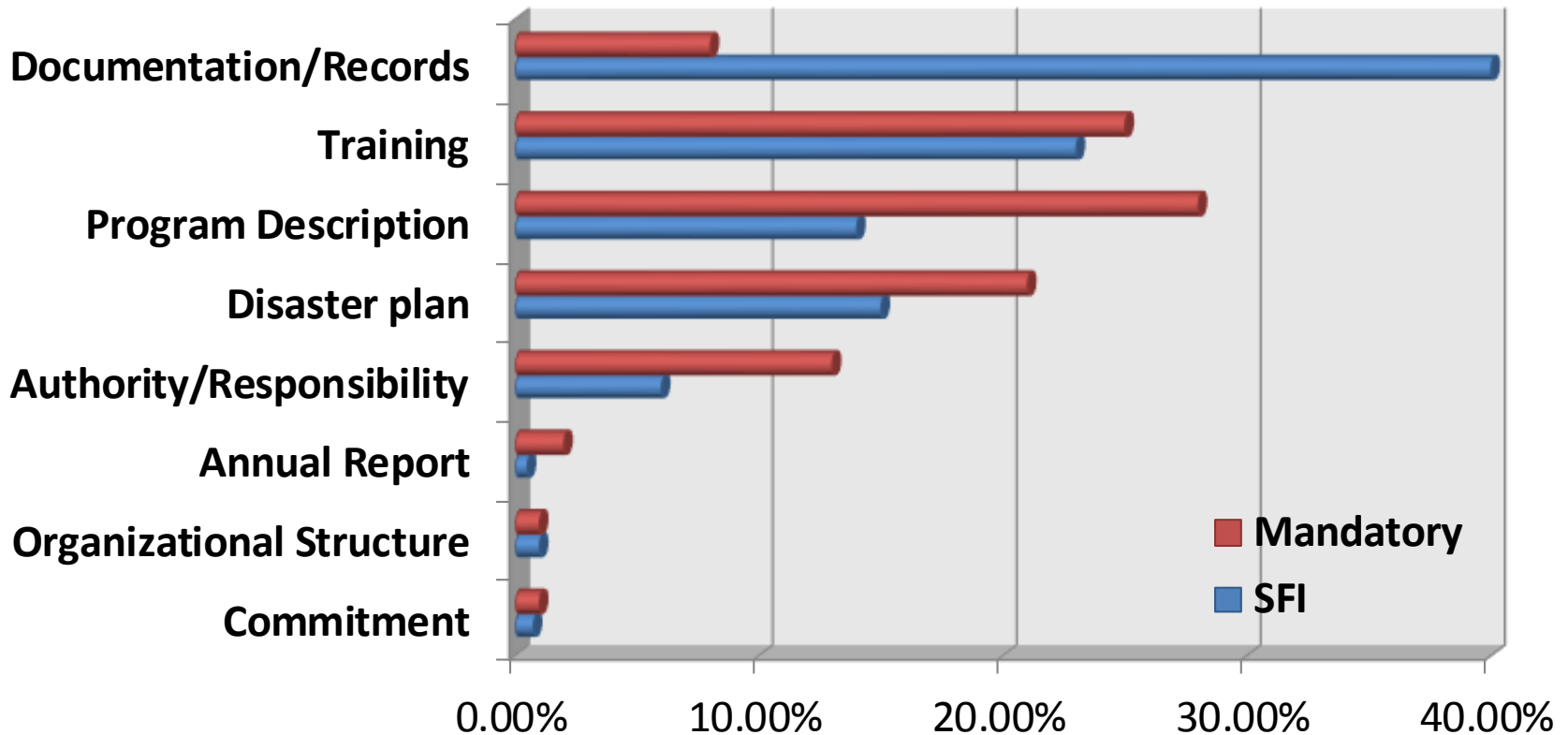
No specific list..., If you establish a policy/ guideline.....follow it.



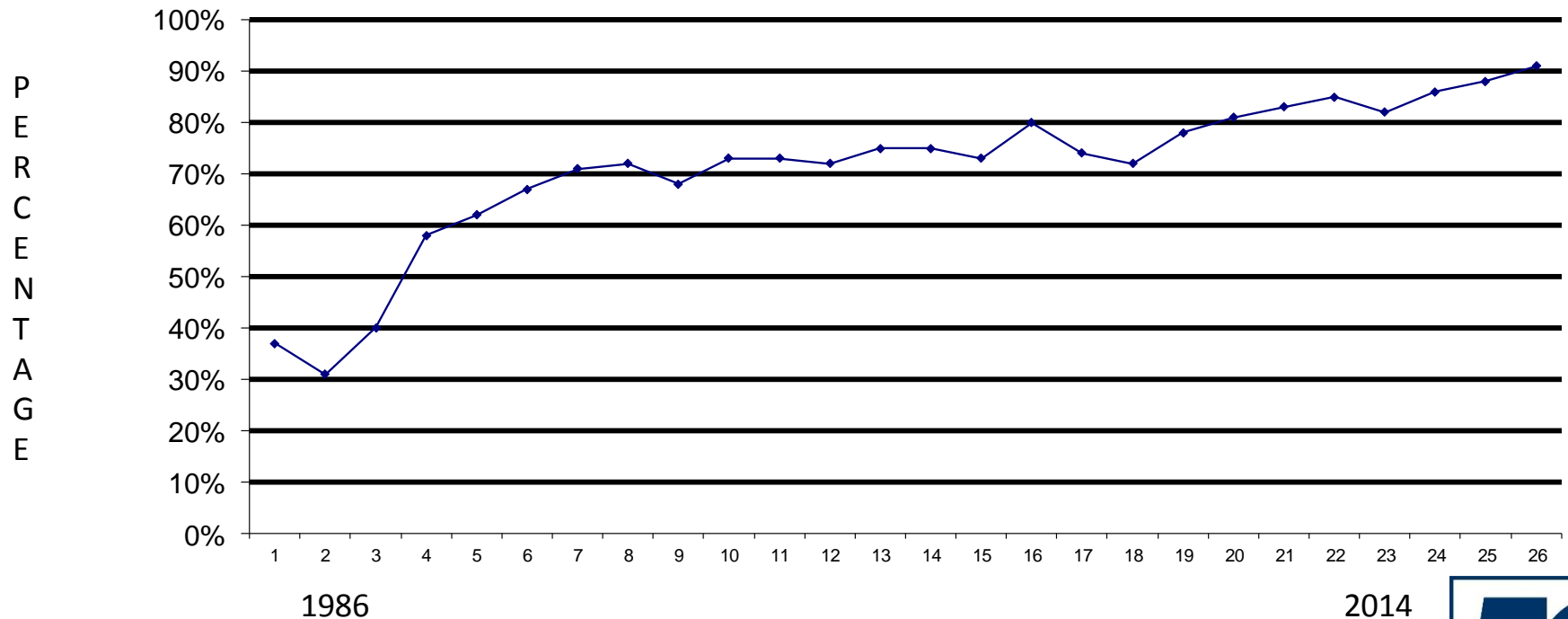
Protocol Review Considerations

Sub-Category	%
Description of Procedures	20%
Pain and Distress	18%
Non-pharmaceutical grade compounds	18%
Experimental and humane endpoints	11%
Review of guidelines/SOP's	6%

Institutional Administration - Findings



Incidence of Immediate Success in Accreditation (No Mandatory Findings)



Accreditation Success Improved Over Time (1986-2014)



Thank you!

www.aaalac.org
accredit@aaalac.org



Fostering animal welfare and
scientific discovery since 1965