



## *What Every IACUC Should Know About AAALAC International*

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OLAW On-Line Seminar, June 11, 2009

aaalacinternational<sup>1</sup>  
Where science and responsible animal care connect. • [accredit@aaalac.org](mailto:accredit@aaalac.org) • [www.aaalac.org](http://www.aaalac.org)



## AAALAC Mission

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

*Revised 1996*

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## ILAR Newsletter – October 1965

*The AAALAC has been organized “to promote a program for the accreditation of laboratory animal care facilities which will encourage, promote and facilitate scientific research which includes the use of experimental animals.”*



# Oversight Organization Comparison

	<b>Animal Welfare Act</b>	<b>Public Health Service Policy</b>	<b>AAALAC International</b>
<b>Responsible Agency</b>	<b>USDA/APHIS</b>	<b>NIH/OLAW</b>	<b>Private Corporation</b>
<b>Applicability</b>	<b>Required of all Users</b>	<b>Required of PHS Awardees</b>	<b>Voluntary</b>
<b>Species Covered</b>	<b>Warm-blooded</b>	<b>Vertebrates</b>	<b>All</b>
<b>Standards</b>	<b>Regulations</b>	<b>PHS Policy &amp; <i>Guide</i></b>	<b><i>Guide</i> &amp; Reference Resources</b>
<b>Enforcement</b>	<b>Unannounced Inspections</b>	<b>Written “Assurance”</b>	<b>Confidential Peer Reviews</b>
<b>Sanctions</b>	<b>Legal/Fines</b>	<b>Withdrawal of Assurance Approval</b>	<b>Revocation of Accreditation</b>
<b>Link to Funding</b>	<b>None</b>	<b>Direct</b>	<b>Nearly None</b>





# AAALAC Accreditation Process

- Organization prepares Program Description
- AAALAC conducts on-site assessment
- Council on Accreditation considers findings
- Organization notified of accreditation status
- Appeal process for revocation or withhold



# Accreditation Standards

- National requirements as baseline
  - Animal Welfare Act
  - Health Research Extension Act of 1985
- *Guide* is principal standard
- AAALAC Reference Resources as applicable
- AAALAC Policy Statements



**G**uía para  
el Cuidado  
y Uso de los  
Animales de  
Laboratorio

**G**uide for  
the Care  
and Use of  
Laboratory  
Animals  
Institute of Laboratory Animal Resources  
제7판  
실험동물의 관리와  
사용에 관한 지침  
감수: 한성길, KAP J. LEE  
역자: 김길수, 양승환, 이민재, 한진수

**Р**УКОВОДСТВО  
ПО СОДЕРЖАНИЮ  
И  
ИСПОЛЬЗОВАНИЮ  
ЛАБОРАТОРНЫХ  
ЖИВОТНЫХ  
NATIONAL RESEARCH COUNCIL

**G**uide for  
the Care  
and Use of  
Laboratory  
Animals  
NATIONAL RESEARCH COUNCIL

**G**uide pour  
les Soins  
et l'Utilisation  
des Animaux  
de Laboratoire  
NATIONAL RESEARCH COUNCIL





# The “AAALAC Standard”

- Not a single document
- Encompasses the entire animal program
- Based on internationally recognized standards
  - Most are science-based
- Collective professional judgment of experts
  - Science-driven
- Applied through in-depth peer review process
  - Science-based





CONTACT | SEARCH:  GO

QUICK LINKS: ACCREDITED ORGANIZATIONS MEMBERS ONLY REFERENCE RESOURCES PROGRAM DESCRIPTION GLOBAL GATEWAY

- ABOUT AAALAC
- ACCREDITATION
- PROGRAM STATUS EVALUATION
- EDUCATION & OUTREACH
- RESOURCES
- NEWS
- PUBLICATIONS
- HOME

## Accreditation

print version email a friend

### AAALAC's Reference Resources

AAALAC International relies on the *Guide for the Care and Use of Laboratory Animals*, NRC 1996, as its primary standard for evaluating laboratory animal care and use programs. AAALAC International also refers 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. Reference Resources, first established by AAALAC in 1975, are intended to serve as references and guidelines for laboratory animal care and use programs. Reference Resources are formally reviewed and adopted by the Council and assist site visitors as they evaluate animal programs. Below is a list of the reference resources utilized by Council and information on where to obtain them.

- General**
- Biosafety**
- Education**
- Euthanasia**
- Health Monitoring**
- Occupational Health and Safety**

#### Research Related

- Administration of Substances and Removal of Blood
- Animal Surgery
- DNA Research
- Humane Endpoints
- Neoplasia



# Peer Review Process

- Program Description (PD) = organization's experts
- PD Review = AAALAC staff experts
- Site Visit = Council and organization's experts
- Council on Accreditation
  - Multiple member review of site visit report
  - Full Council review at triannual meetings
  - Committees on Consistency and Continuing Education



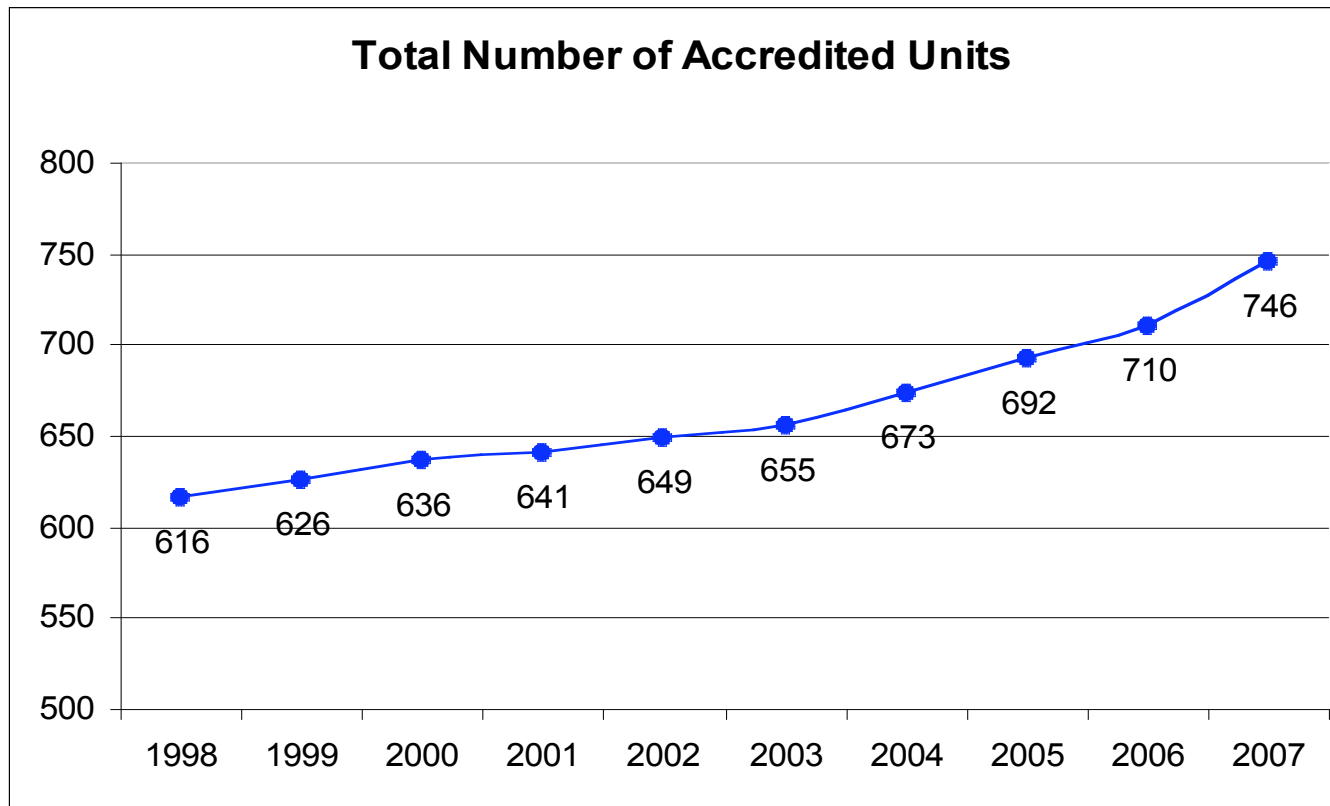
## Who is Accredited?

- Over 770 programs in 31 countries
- Top 100 NIH awardees
- All major pharmaceutical companies
- All commercial laboratory animal producers
- Government laboratories (NIH, DoD, VA, et al.)
- Large biotechnology companies
- Large contract research organizations





# Growth in Accredited Programs



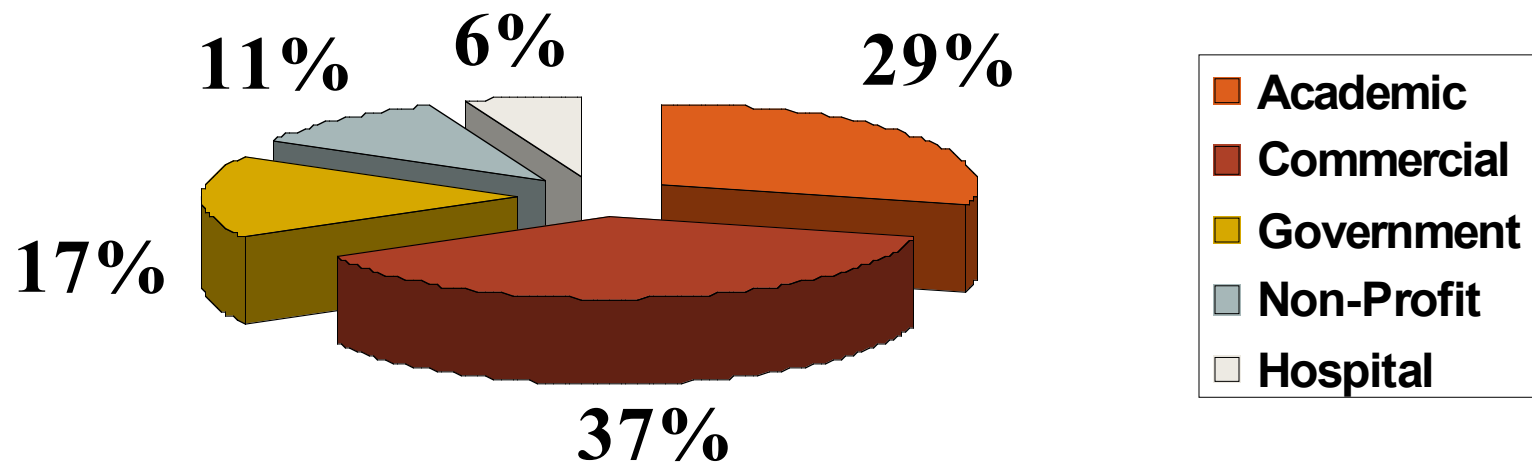


# Countries With Accredited Programs

- Austria
- Belgium
- Canada
- China/Hong Kong
- Denmark
- Egypt
- France
- Germany
- Hungary
- India
- Indonesia
- Israel
- Italy
- Japan
- Korea
- Mauritius
- Netherlands
- Norway
- Peru
- Philippines
- Russia
- Singapore
- South Africa
- Spain
- Switzerland
- Taiwan
- Thailand
- United Kingdom
  - England
  - Scotland
- USA



## Proportion of Accredited Units by Industry Sector







## What People Value Most About Accreditation ...

*From a 1998  
survey of  
accredited  
programs*

- “It assures the credibility of our program among funding sources”
- “It provides the public with a positive image”
- “It helps convince management of the need to commit resources to maintain a high-quality program”



## What People Value Most About Accreditation ...

*From a 1998  
survey of  
accredited  
programs*

- “Application of AAALAC standards ensures high-quality research and animal care, resulting in better science”
- “It conveys a high level of professionalism to the scientific community”



# Accreditation Outcomes

- Provisional Status
- Full Accreditation
- Deferred Accreditation
- Probation
- Withhold/Revoke Accreditation





## 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

The "AAALAC International i-brief" (short for "Issue Brief"), is designed to help clarify specific elements of the accreditation process, and is published as a service to accredited institutions. Feel free to distribute this i-brief to others at your organization.

## Suggestions for Improvement (SFIs)

Their purpose, what they mean, and how to respond.

### What is an SFI?

SFIs, or "Suggestions for Improvement," are items that may be included in the official report you receive from AAALAC International after an accreditation site visit. They are called SFIs because that's exactly what they are—suggestions that, in the opinion of the Council on Accreditation, will enhance your program. An SFI is an element of the peer review process that's designed to assist accredited programs by sharing the cumulative knowledge and experience of the Council.

Your institution is *not* required to respond to SFIs presented during the exit briefing, although you are free to do so (and also to disagree) through a Post Site Visit Communication (PSVC), which is a written response from your organization back to the Council on Accreditation.

All SFIs follow a common format. First they state the problem. Then they state why it's a problem and what should be done to correct it. Here's an example of an SFI as it would appear in a site visit report:



First published May 2007.

*"The doors to several animal rooms in Building 1 had missing door sweeps. [The problem.] There was a visible gap beneath the doors that could allow easy entry of vermin. [Why it's a problem.] Doors should be constructed and maintained to prevent the entry of vermin. Council encourages*

*that all animal room doors be re-evaluated and repaired, as necessary." [What should be done to correct it.]*

And another example:

*"Cleaning utensils such as brooms and mops were stored on the floor. Many were dirty and worn. [The problem.] These practices can decrease the effectiveness of room sanitation procedures. [Why it's a problem.] Cleaning utensils should be cleaned regularly and worn items should be replaced. Utensils should be stored in a neat, organized fashion that facilitates drying and minimizes contamination." [What should be done to correct it.]*

### How do SFIs differ from "mandatory items for correction?"

The report you receive from AAALAC International may include two categories of actionable items. The first are the SFIs, and the second are "mandatory items for correction." Mandatory items are considered serious problems that don't conform with national requirements, the *Guide for the Care and Use of Laboratory Animals* (the *Guide*, NRC 1996), or some other AAALAC International Reference Resource (see [www.aaalac.org/accreditation/resources.cfm](http://www.aaalac.org/accreditation/resources.cfm)), or problems that have the potential to harm people or animals. Unlike SFIs, mandatory

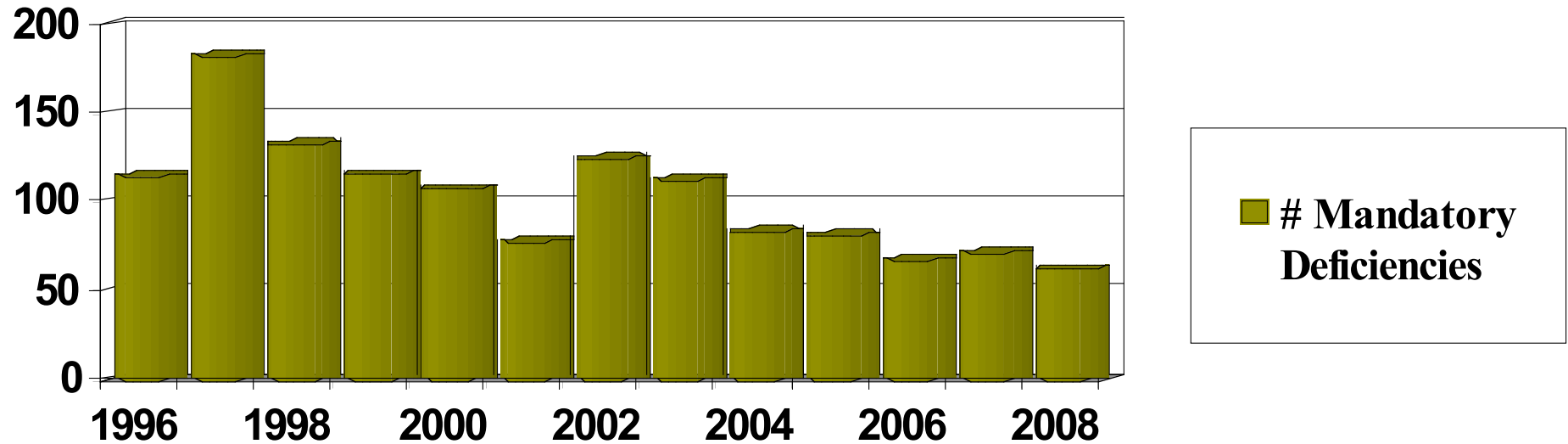
# The Animal Care and Use Program



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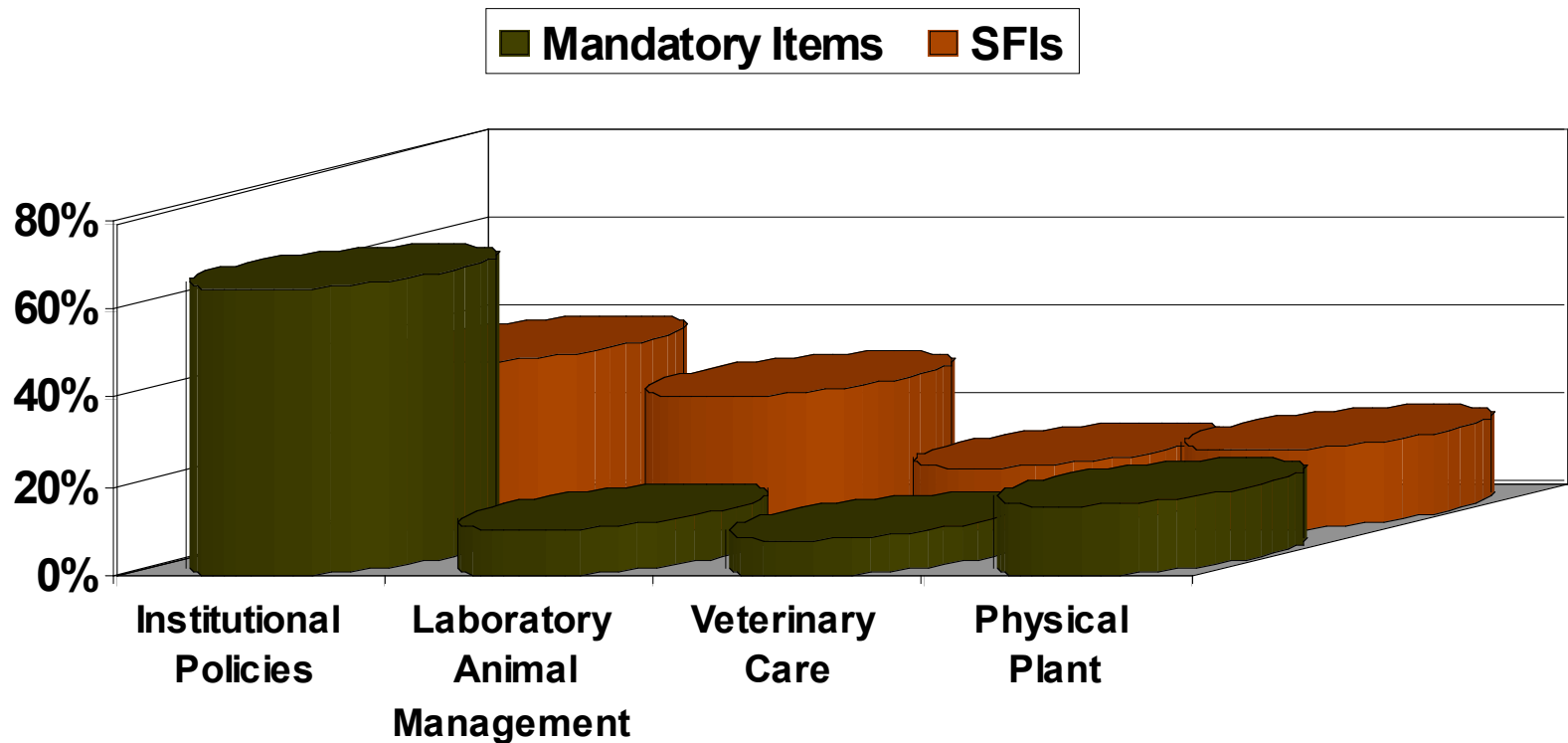
# Total Number of Mandatory Deficiencies Per Year





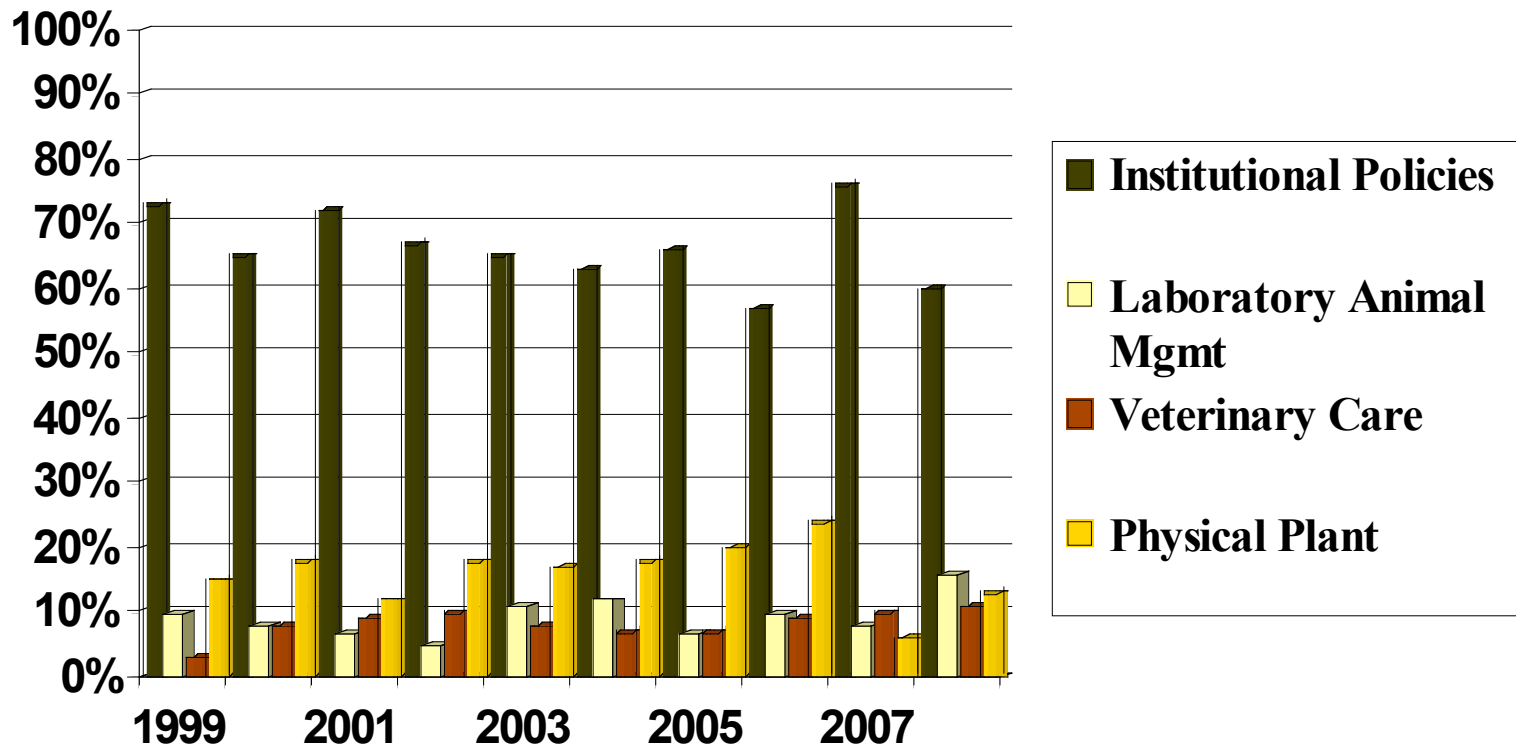


# Percent Mandatory Items & SFIs for the Period 2003-2008





# Percent Mandatory Deficiencies by Category (1999-2008)



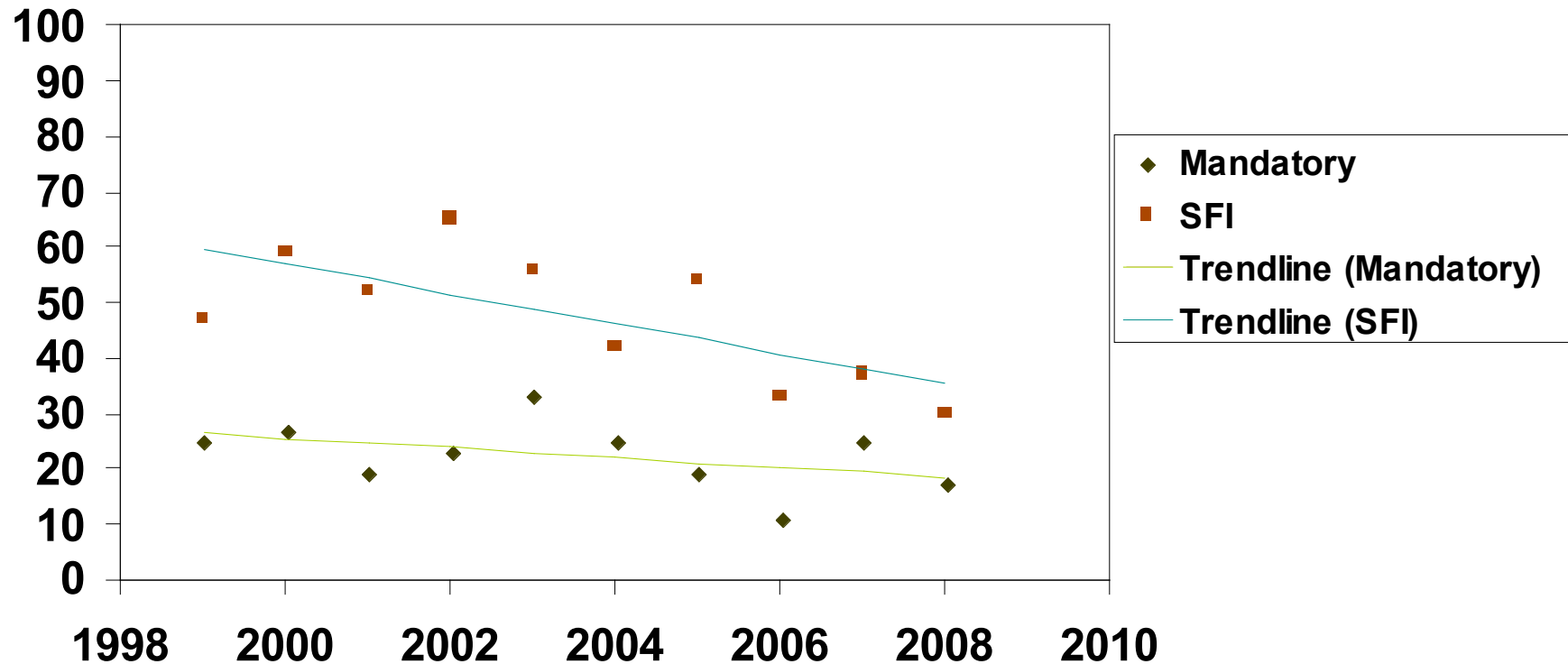


## Top Three Mandatory Deficiencies Identified During Site Visits

- Occupational Health and Safety Issues
- Institutional Animal Care and Use Committee Issues
- Heating, Ventilation and Air Conditioning System



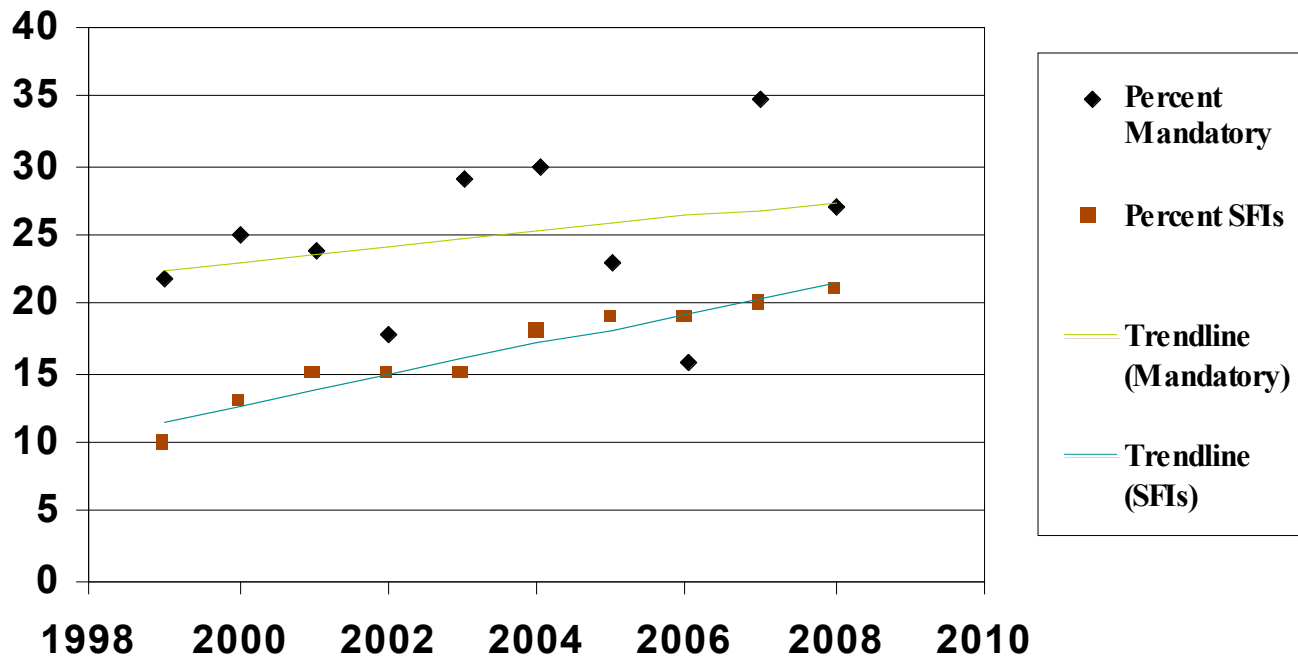
# Occupational Health & Safety







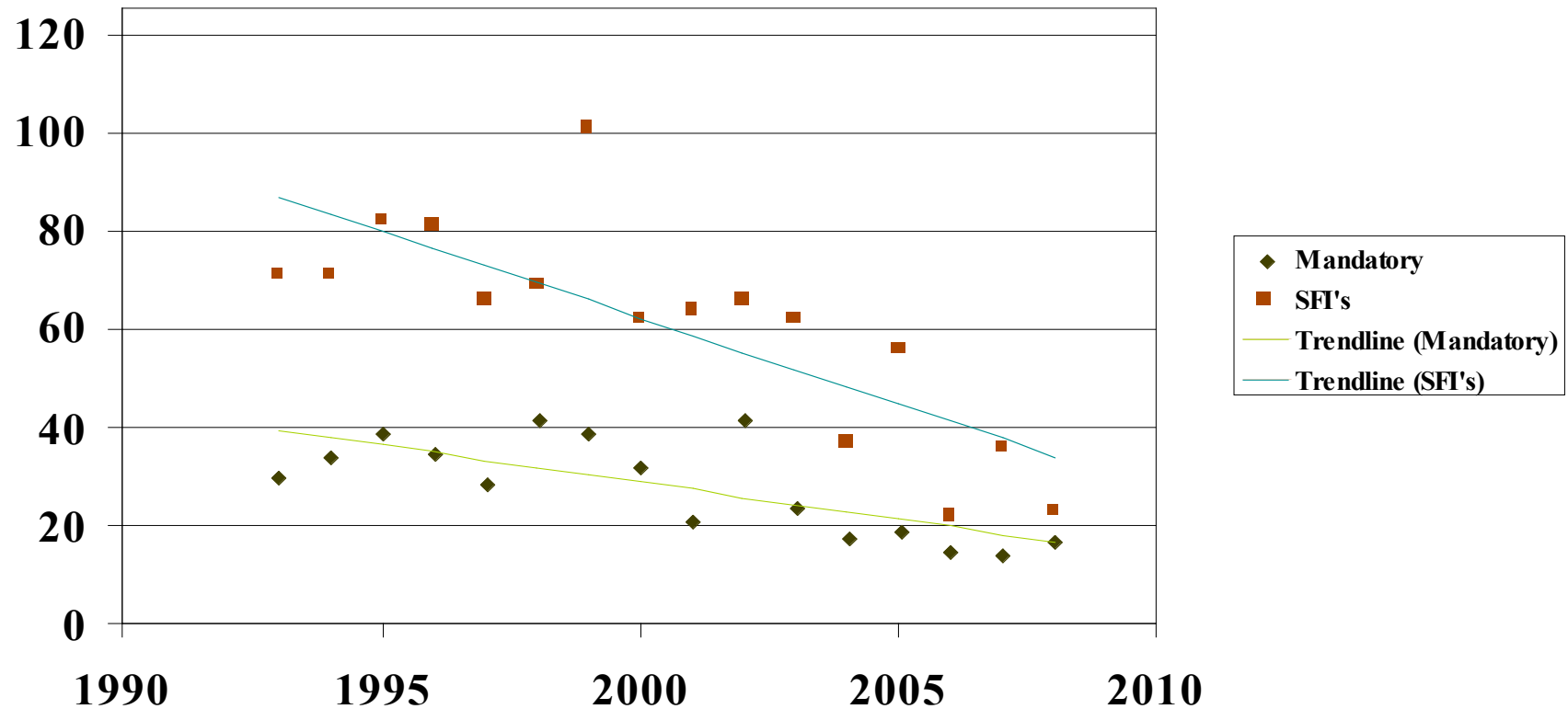
# OHSP of Total Mandatory Items & SFIs-Percent and Rank Order



- Program Administration
- Hazard Identification/Risk Assessment
- Animal Experimentation Involving Hazards
- Facilities, Procedures, Monitoring
- Medical Evaluation & Preventive Medicine for Personnel
- Personal Protection
- Personnel Training

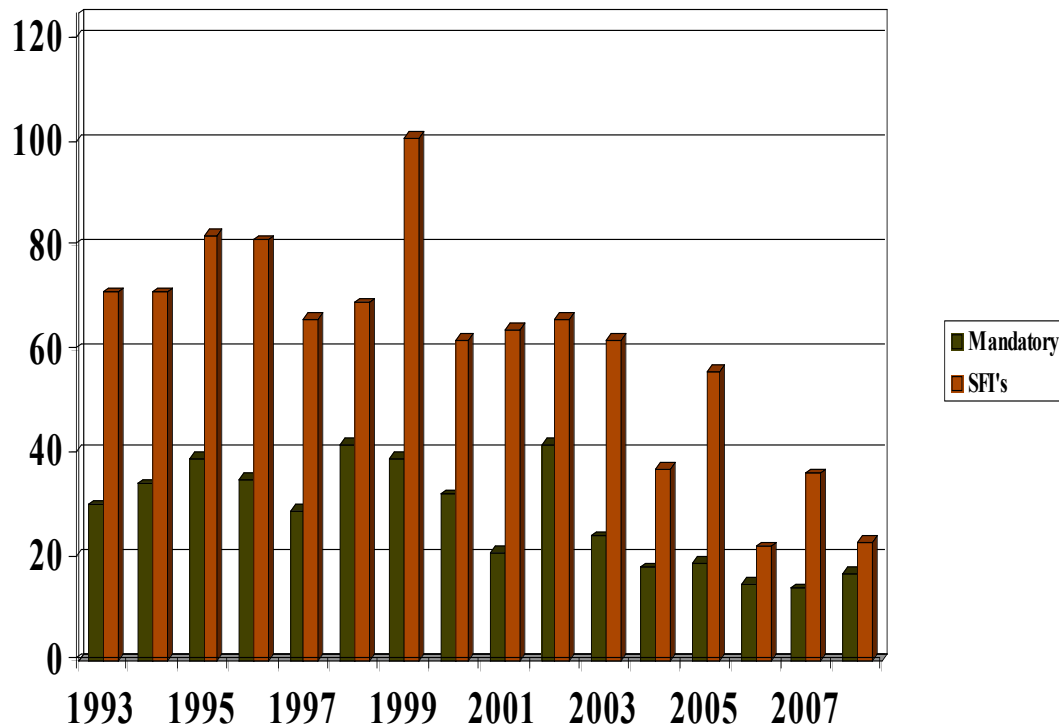


# IACUC (or Comparable Review Function)





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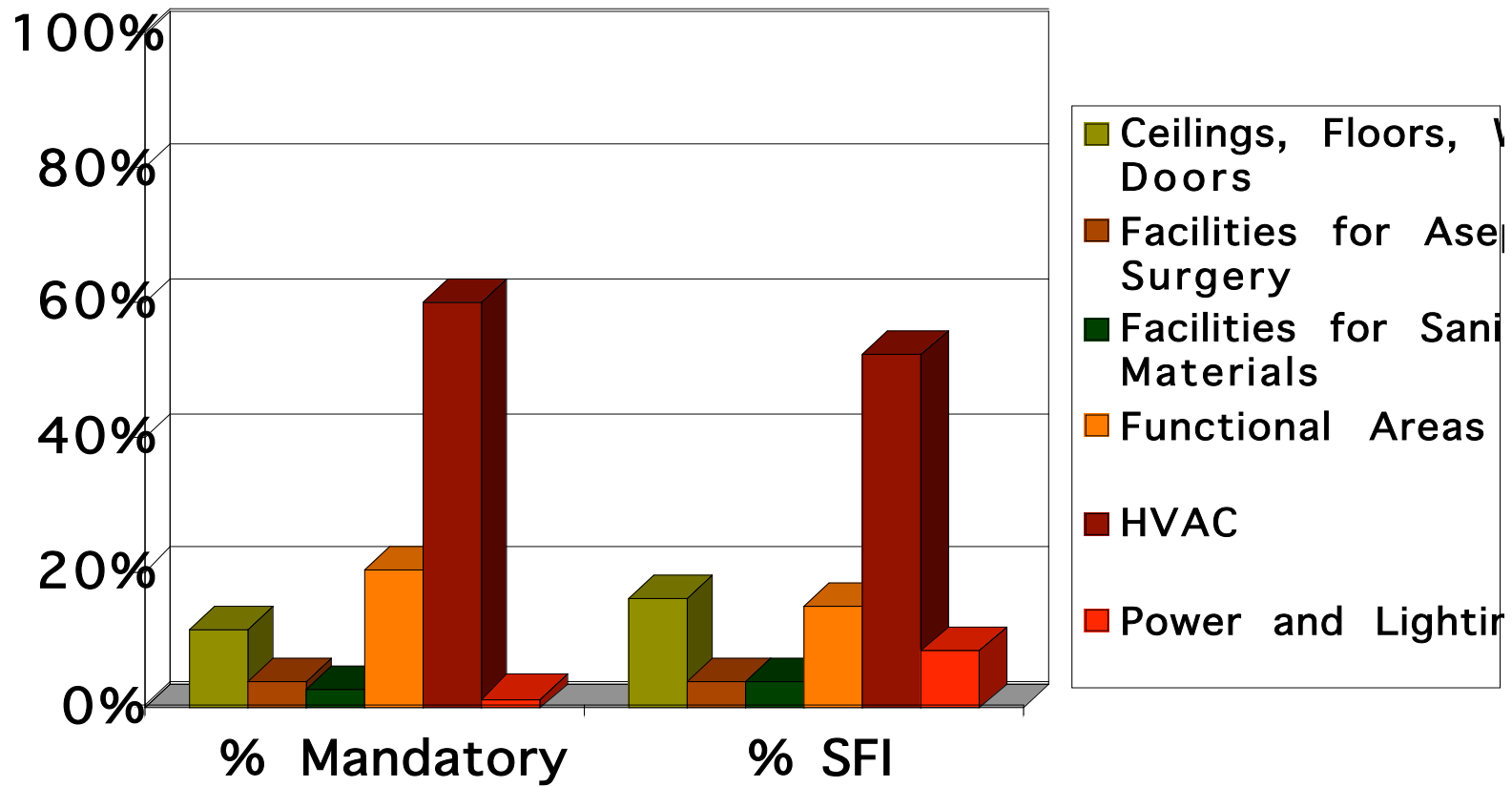


## Problem Areas

- Protocol Review
- Policies
- Composition and Participation
- Semiannual Evaluations
- Documentation
- Training



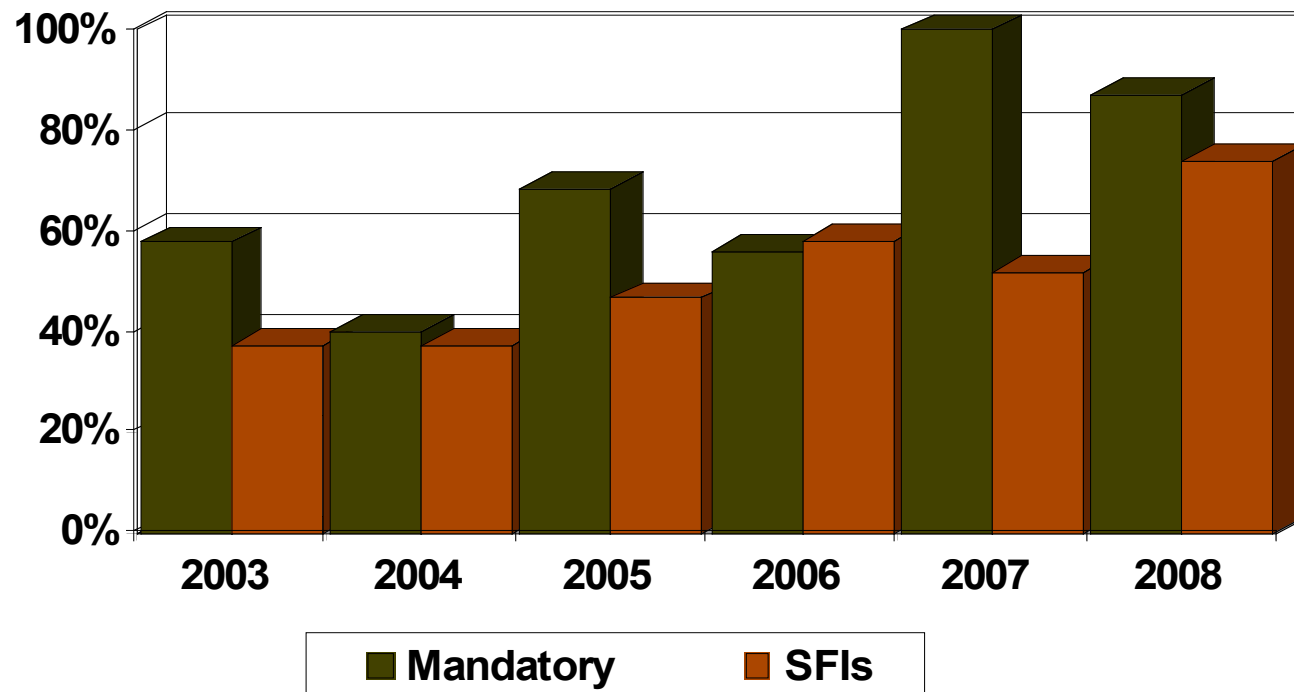
# Percent Physical Plant Findings (2003-2008)



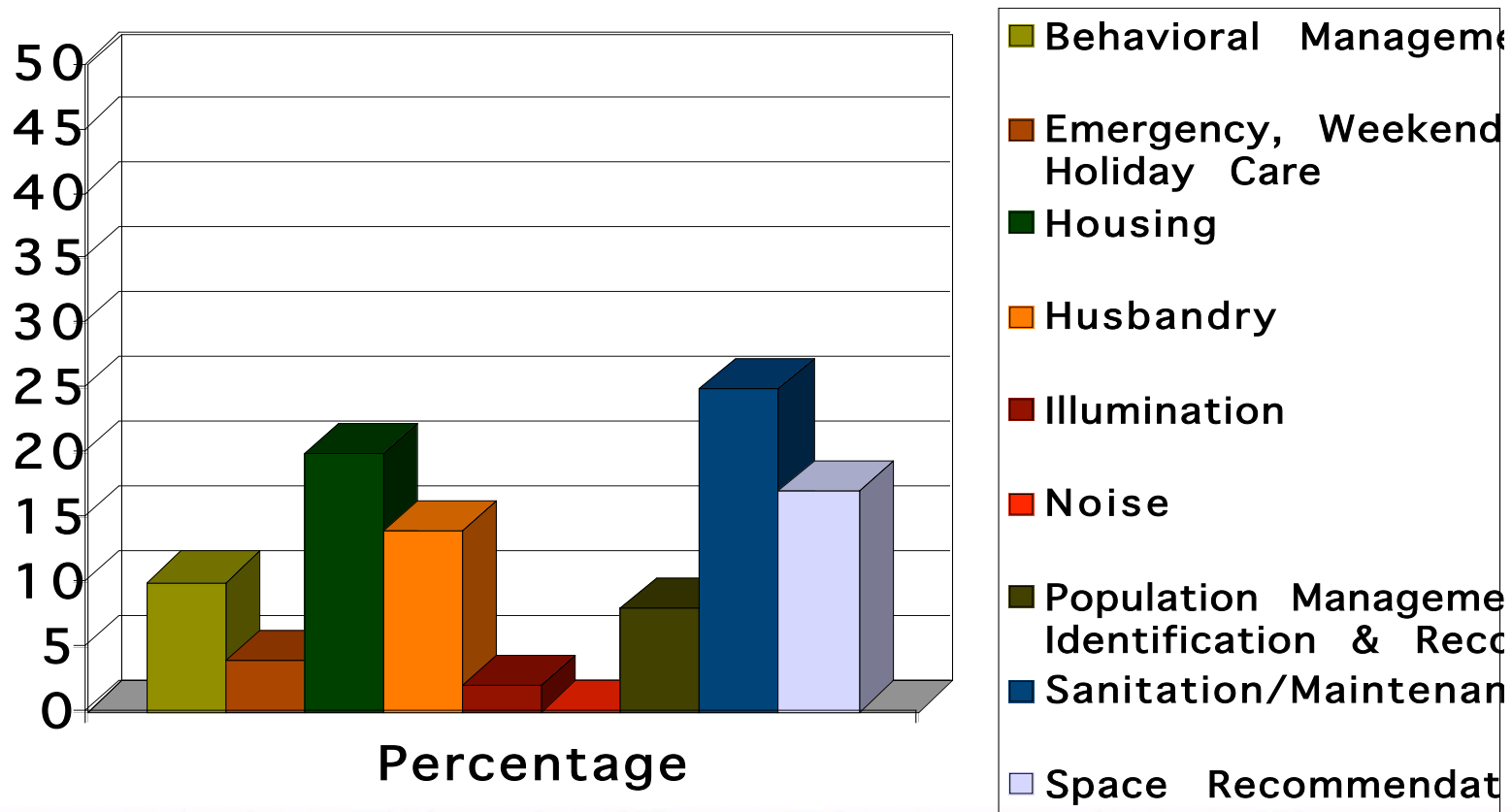




## Percent Heating, Ventilation, & Air Conditioning (HVAC) of Total Physical Plant Deficiencies

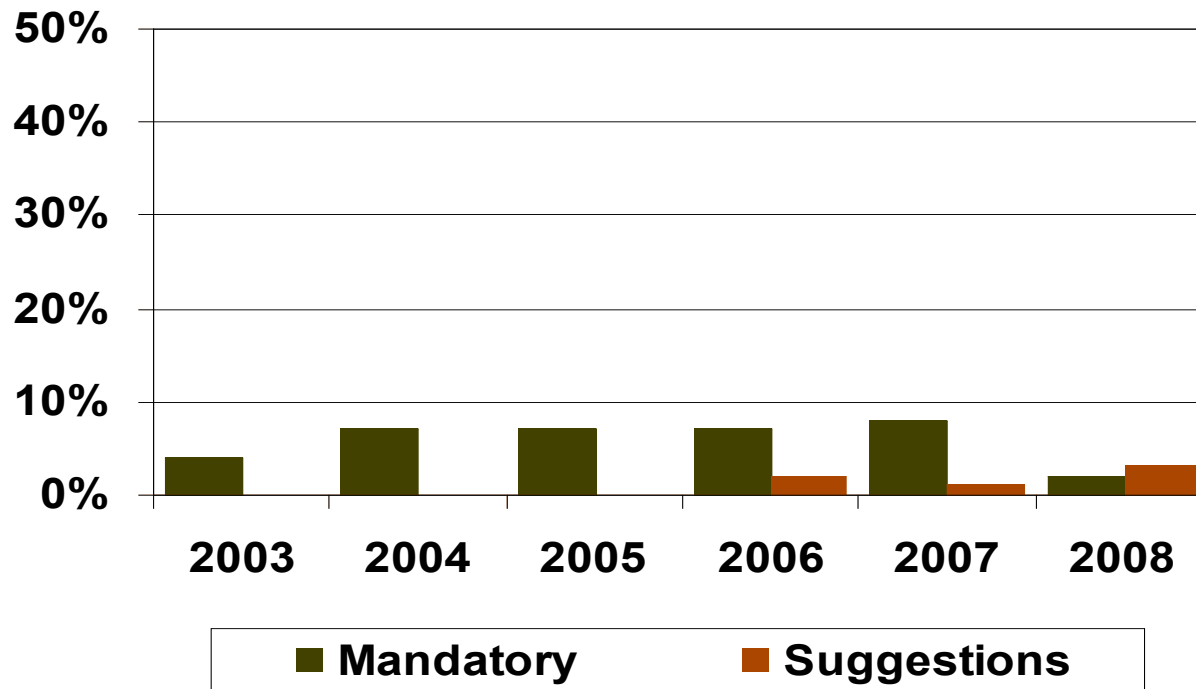


# Percent Animal Environment, Housing and Management Mandatory Findings (2003 – 2008)





# Percent Program of Adequate Veterinary Care Findings





# “Mission Creep”

- Reality
  - *Guide* is over 12 years old
  - State-of-the-art practices have evolved
  - “Mandatory” items always based on existing standards
  - “Suggestions for Improvement” are just that
  - AAALAC’s BOT representatives are continuously engaged on this topic
- Perceptions
  - AAALAC over-interprets standards
  - AAALAC imposes new standards
  - “Suggestions for Improvement” must be followed





## Judgments Differ/No Clear Standard

- AAALAC looks to science
  - Published data
  - Scientific principles
  - Expert opinion
  - Experience with proven methods/practices
- Example: alcohol as a disinfectant



# Your Questions and Comments Please

aaalacinternational

Where science and responsible animal care connect. • [accredit@aaalac.org](mailto:accredit@aaalac.org) • [www.aaalac.org](http://www.aaalac.org)