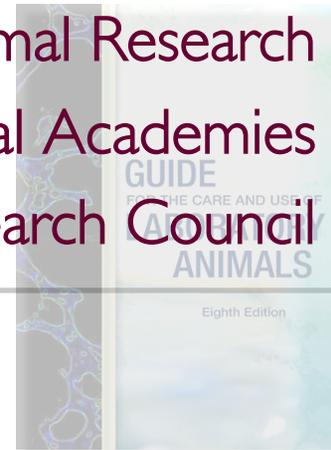
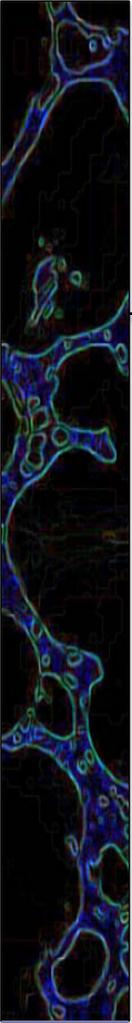


The Guide for the Care and Use of Laboratory Animals Eighth Edition

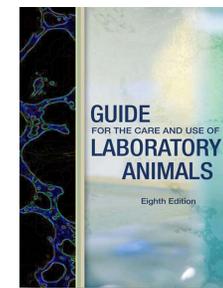
Janet Garber, Committee Chair
Lida Anestidou, Study Director
Institute for Laboratory Animal Research
The National Academies
National Research Council

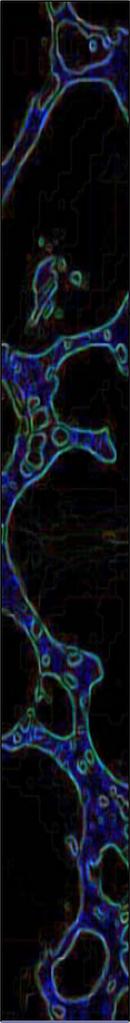




The National Academies

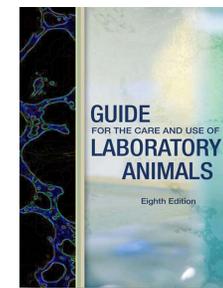
- Chartered by Congress in 1863 at the request of President Lincoln to advise the nation
- 3 Honorary Societies
 - National Academy of Sciences - 1863
 - National Academy of Engineering - 1964
 - Institute of Medicine - 1970
- And an operating arm
 - National Research Council - 1916



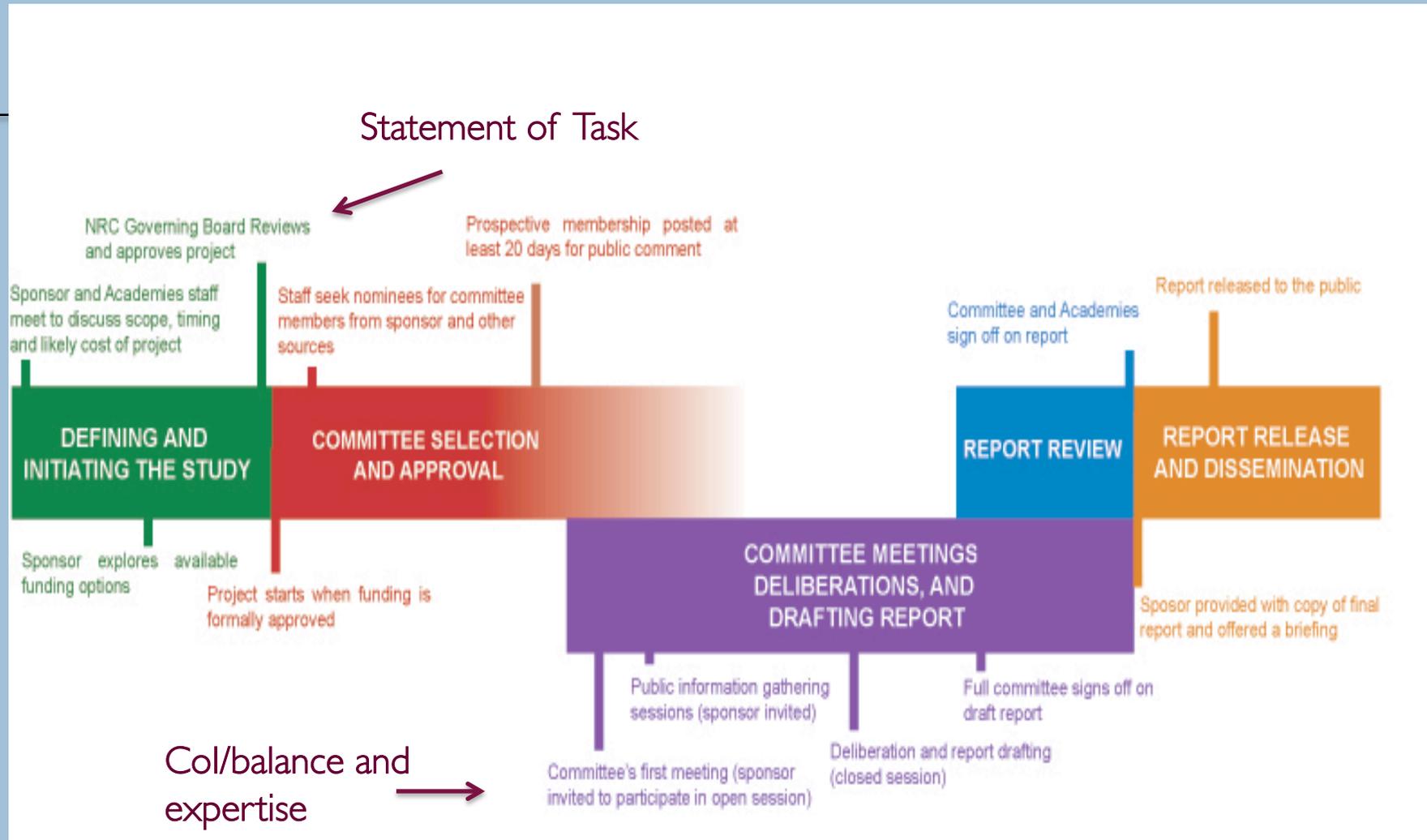


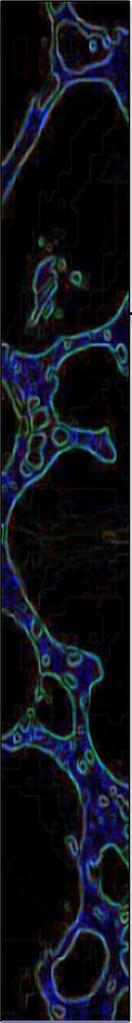
The National Academies are

- Independent and objective
- Non-profit (no compensation beyond actual expenses; also have endowment funds)
- Able to draw on leading experts from scientific and technical disciplines
 - 55% academia
 - 24% industry
 - 12% government
 - 9% non-profit



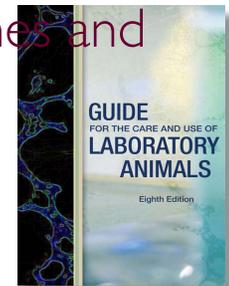
Study process (FACA section 15)

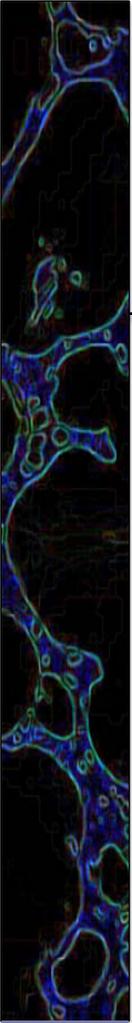




Statement of Task

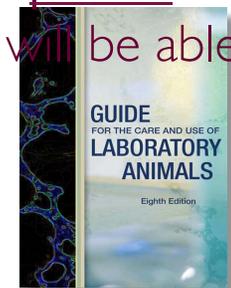
- A committee will update the 1996 version of the Guide for the Care and Use of Laboratory Animals (the Guide) to reflect new scientific information related to the issues already covered in the Guide, and to add discussion and guidance on new topics of laboratory animal care and use related to contemporary animal research programs.
- The committee will review the scientific literature published since the release of the 1996 Guide and determine whether the information in the Guide concurs with current scientific evidence. The committee will also review the literature on new technologies related to laboratory animal care and use and determine where new guidance is necessary to ensure the best scientific outcomes and optimal animal welfare.

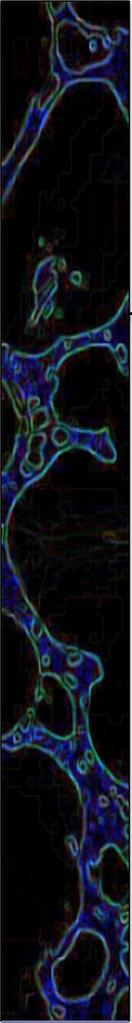




Statement of Task (cont.)

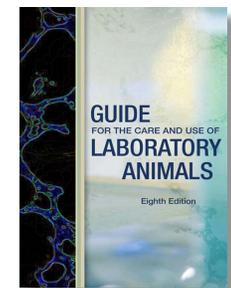
- The committee will also take into consideration all materials and discussions provided to it, including those submitted to NIH in response to the Request for Information NOT -OD-O6-011 that requested information related to the need to update the Guide. Where scientifically warranted, the guidance and recommendations of the 1996 Guide will be changed to reflect new scientific evidence, while maintaining the performance standards of the 1996 Guide. The committee will ensure that any recommendations in the Guide will be consistent with current Public Health Service Policy, the Animal Welfare Regulations, and the most recent Report of the American Veterinary Medical Association Panel on Euthanasia.
- In addition to the published report, the updated Guide will be posted on the Internet in a pdf or equivalent format such that users will be able to search the entire document at one time.

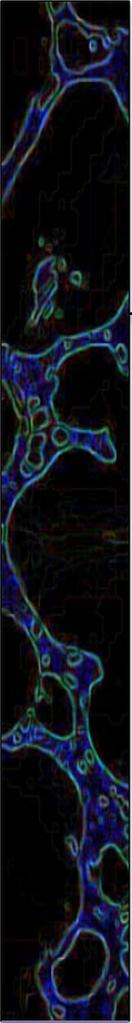




Preface

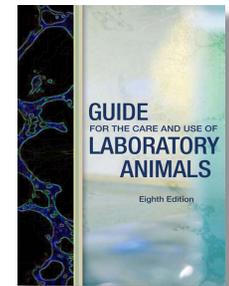
- Formal process to regularly revisit the scientific information & practice standards is needed
- Areas with insufficient data and assessment - further study is needed
 - Space and housing needs
 - Enrichment, exercise and human contact

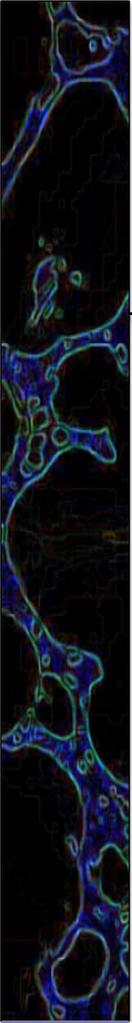




Overview

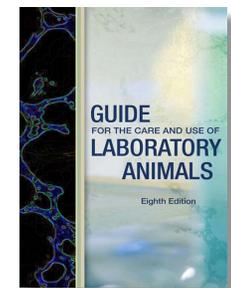
- The Committee explains the reasons for (not) updating /expanding certain sections of the *Guide*
 - Commitment to the Three Rs
 - Animal Care and Use Program
 - Aquatic species
 - Recommended minimum space and space recommendations
 - Social housing for nonhuman primates
 - Rodent female + litter category

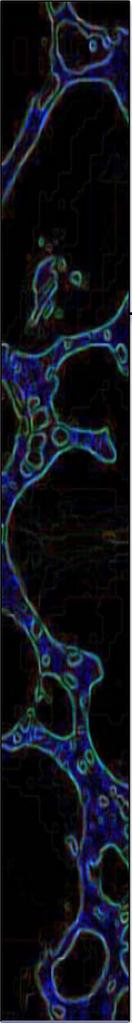




In the 8th edition of the *Guide*

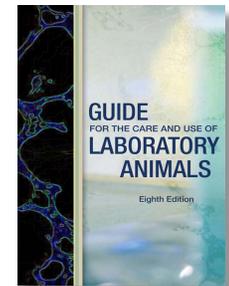
- What has changed?
- What hasn't changed?

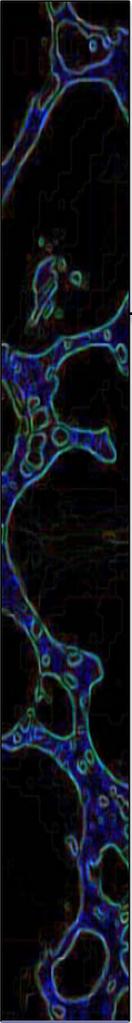




Performance Standards

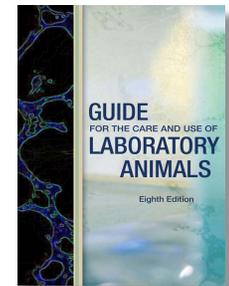
- Remains a key concept in application of the *Guide*
- Overwhelming support for this approach
- Better definition of desired outcomes
- More guidance on how to achieve the outcomes

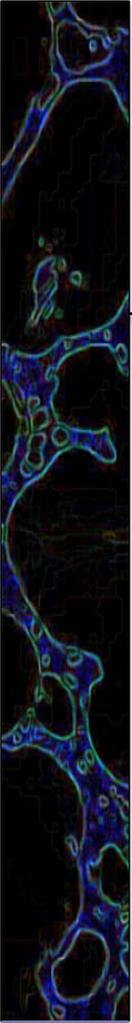




Animal Care and Use Program

- '96 *Guide* lacked clarity regarding this important concept.
- Those activities conducted by and at an institution which have a direct impact on the well-being of animals including policies and procedures, the provision of animal and veterinary care, personnel and program management and oversight, occupational health and safety, IACUC functions, and animal facility design and management.





What Looks Different?

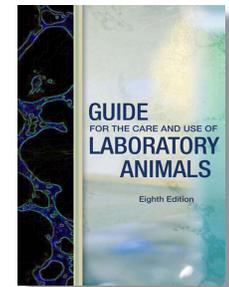
Chapters 1 & 2

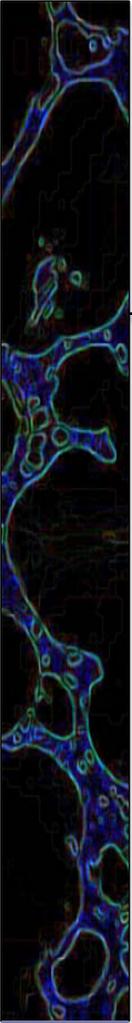
Previously:

- “Introduction”
- Chapter 1 – “Institutional Policies and Responsibilities”

Now:

- Chapter 1 – “Key Concepts”
- Chapter 2 – “Program of Animal Care and Use”





What Looks the Same?

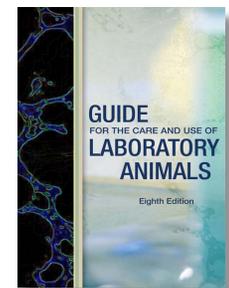
Chapters 3, 4 and 5

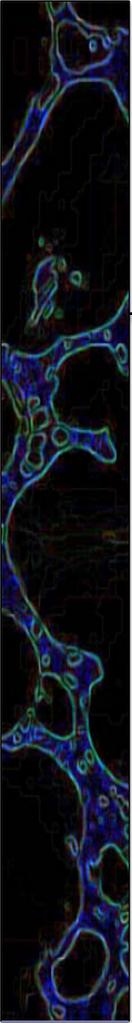
Previously:

- Chapters 2, 3 & 4

Now:

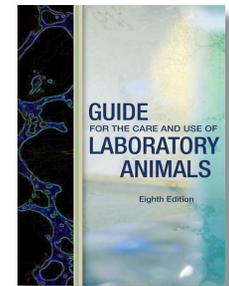
- Chapter 3 – “Animal Environment, Housing and Management”
- Chapter 4 – “Veterinary Care”
- Chapter 5 – “Physical Plant”

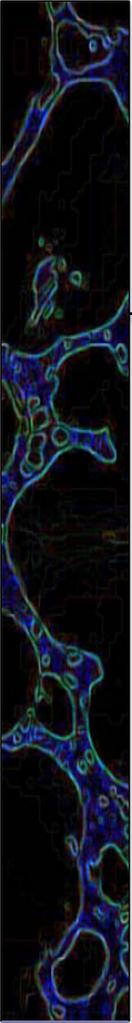




New & Expanded Topics: Chapters 1 & 2

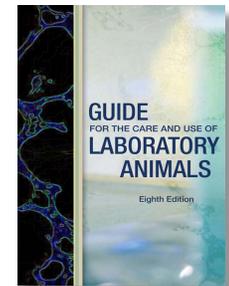
- Ethics of Animal Use & the Three R's
- Responsibilities of Key Personnel (IO, AV, IACUC)
- Institutional Collaborations
- Training and Education
- Program Oversight
 - IACUC
 - PAM
- Special Considerations for Protocol Review
- Disaster Planning and Emergency Preparedness

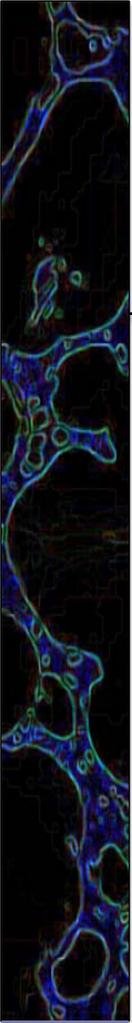




New & Expanded Topics: Chapter 3

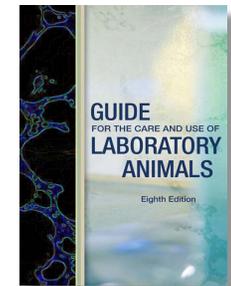
- Terrestrial & Aquatic Animals
- HVAC
- Vibration
- Environmental Enrichment
- Housing & Space Recommendations
- Procedural Habituation & Training of Animals

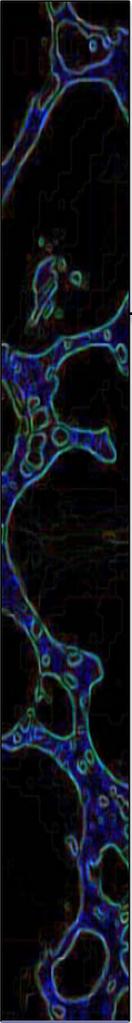




New & Expanded Topics: Chapter 4

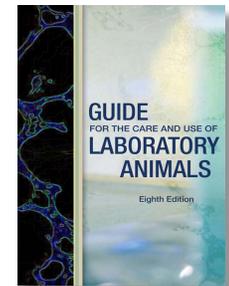
- Transportation of Animals
- Preventive Medicine – Animal Biosecurity
- Clinical Care & Management
 - Medical Management
 - Emergency Care
 - Recordkeeping
- Surgery – Intraoperative Monitoring

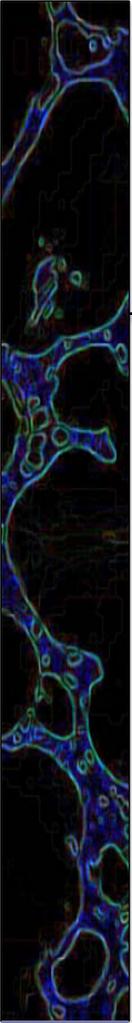




New & Expanded Topics: Chapter 5

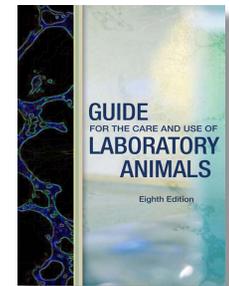
- Centralization vs. Decentralization
- HVAC
- Vibration Control
- Environmental Monitoring
- Special Facilities
- Security & Access Control

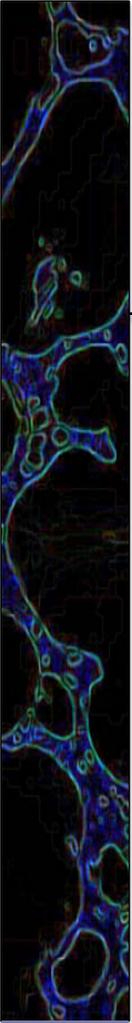




Chapter I: Key Terms used in the *Guide*

- Humane Care
- Animal Care and Use Program
- Engineering and Performance Standards
- Practice Standards
- Policies, Principles and Procedures
- Must, Should and May

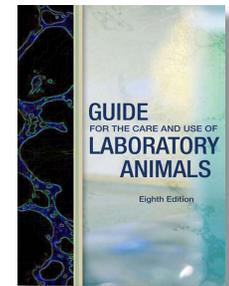


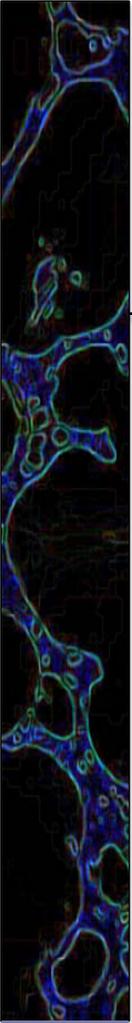


Chapter I: Practice Standards

“The application of professional judgment to a task or process over time, which has been demonstrated to benefit or enhance animal care and use.”

- Key concept expressed in comments to the Committee
- Information in peer-reviewed literature
- Time-proven experience in the field
- Modification of practices and procedures with changing conditions and new information





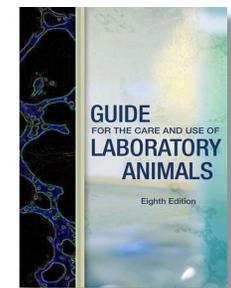
Chapter I: “Must” and “Should”

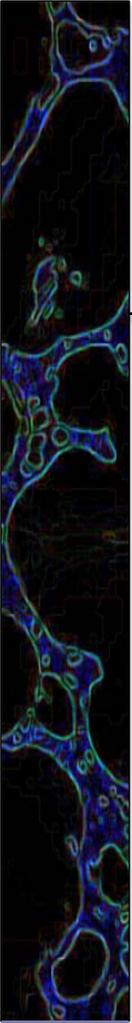
- “Must” - The verb “must” indicates actions that the Committee to Update the *Guide* consider to be imperative and are a mandatory duty or requirement.
- “Should” - The verb “should” indicates a strong recommendation for achieving a goal, however, the committee recognizes that individual circumstances might justify an alternative strategy.

Examples of “must”

Veterinary Care & Animal Well-Being

- “The institution **must** develop methods for reporting and investigating animal welfare concerns.” (Chapter 2 – New section added on reporting concerns).
- “Antinociception occurs at a surgical plane of anesthesia, and prior to surgery, adequate antinociception **must** be ascertained.” (Chapter 4 – Expansion of section on Anesthesia & Analgesia, based on NRC 2009 Pain Report).

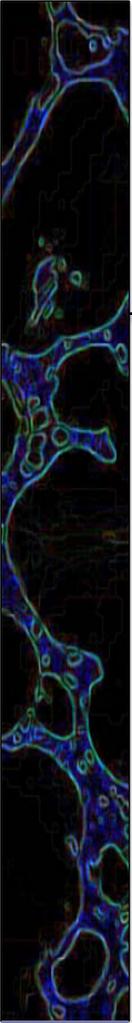




Examples of “must”

Regulatory Requirement

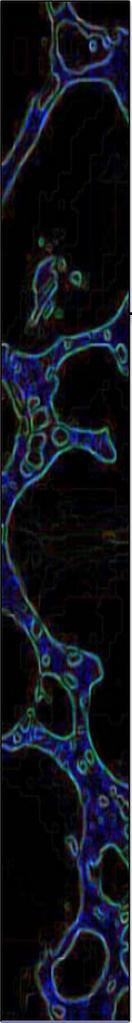
- “When applicable, request **must** be made to the USDA, APHIS by the IO to seek an exemption to limiting regulated animals from being used in only one animal use protocol with a major survival surgical procedure (CFR 1985; USDA-APHIS 1997).” (Chapter 2 – added per new USDA requirement).



Examples of “must”

Safety

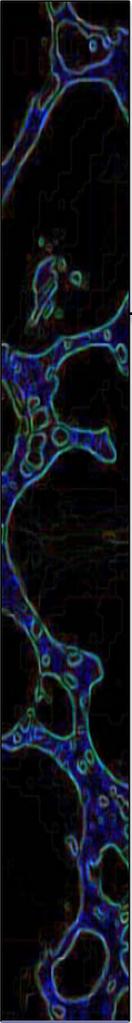
- “Rooms with MR scanners or in which cryogen is stored **must** be equipped with oxygen sensors and a method for increasing room ventilation to exhaust inert gases during cryogen filling.” (Chapter 5 – New section on imaging facilities).



Examples of “must”

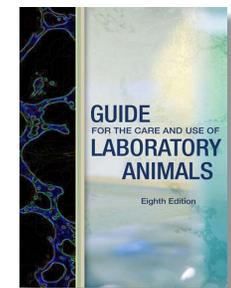
Clarification

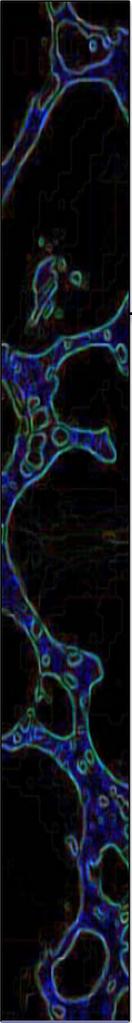
- “The *IACUC* (or institutional equivalent) is responsible for assessment and oversight of the institution’s Program components and facilities.” (Chapter 2 – clarification of responsibilities)



Chapter 2: Special Considerations for Protocol Review

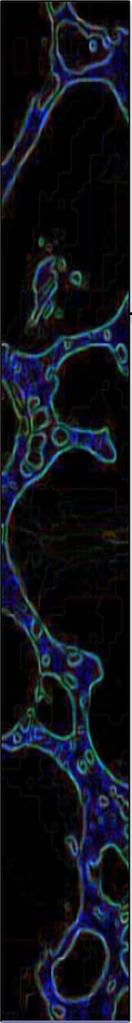
- Experimental and Humane Endpoints
- Unintended Consequences
- Physical Restraint
- Multiple Survival Surgical Procedures
- Food and Fluid Regulation
- Use of Non-Pharmaceutical Grade Chemicals and other Substances
- Field Investigations
- Agricultural Animals





Chapter 2: Post-Approval Monitoring

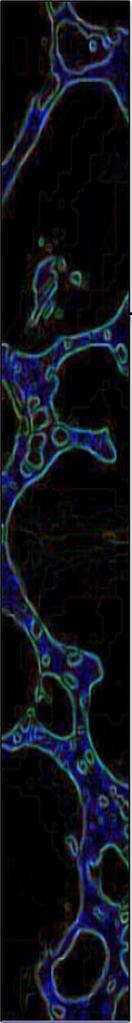
- PAM in the broadest sense:
 - All potential types of monitoring – continuing review
 - Inspections (internal and external)
 - Medical surveillance
 - Observations by animal users and care staff
- Formality and intensity depends on the size and complexity of the Program



Chapter 2: Disaster Planning & Emergency Preparedness

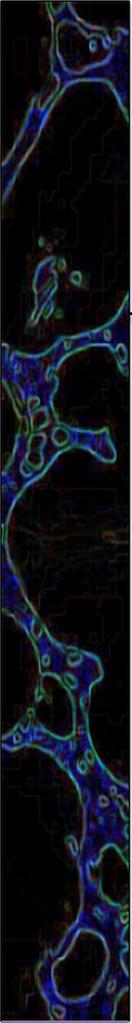
“Facilities **must** have a disaster plan.”

- Prevent animal pain, distress and deaths
- Potential loss of ventilation, cooling, heating or water
- Triage
- Trained personnel



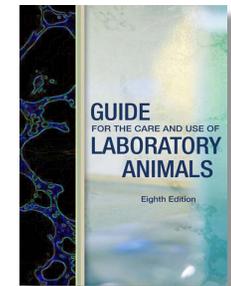
Chapter 3: Terrestrial & Aquatic Animals

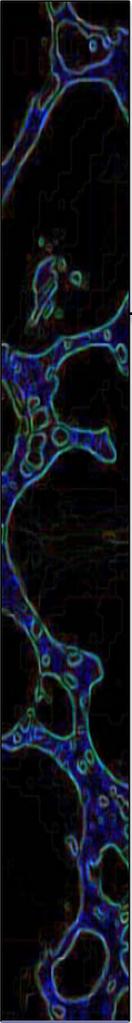
- Water Quality (composition of the water)
 - Temperature
 - pH & Alkalinity
 - Nitrogen Waste Products
 - Conductivity/salinity
 - Hardness
 - Dissolved oxygen
- Life Support System (LSS)
 - Physical structure used to contain the water and animals
 - Equipment used to move and /or treat the water



Chapter 3: Housing Environment

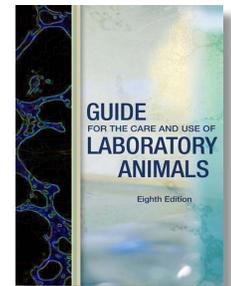
- Noise & Vibration
- Temperature & Humidity
 - Thermoneutral Zone (TNZ)
 - Lower Critical Temperature (LCT)
 - Resources for thermoregulation (e.g., nesting materials)
- Ventilation & Air Quality
 - Individually Ventilated Cage (IVC) Systems
 - Variable Air Volume (VAV) Systems

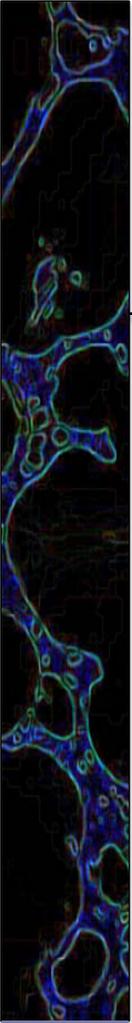




Chapter 3: Environmental Enrichment

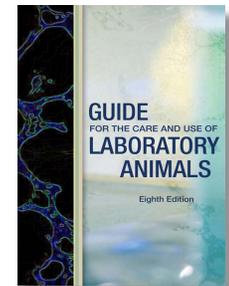
- Expanded section
- Stresses social housing for social animals
- Not all enrichment is beneficial
- Enrichment is an independent variable and should be appropriately controlled
- Nesting material is discussed as a component of bedding

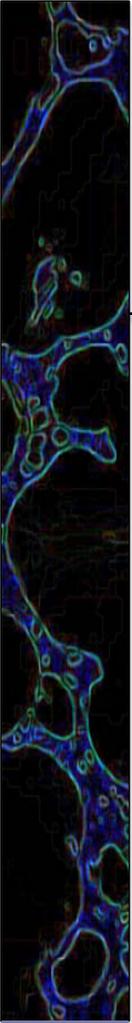




Chapter 3: Space Recommendations

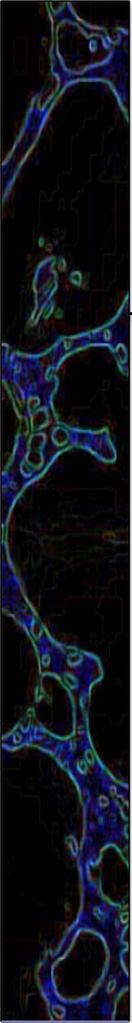
- Expanded discussion of considerations for housing
 - performance standards
- Stresses pair/group housing
- Tables include specific comments
- Few changes in the recommendations





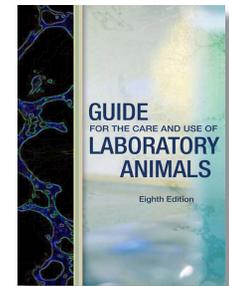
Chapter 3: Space Recommendations (cont.)

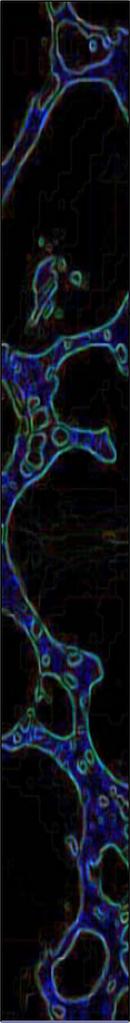
- Rats & Mice – Recommended space for female + litter
- Rabbits – cage height changed from 14” to 16”
- Nonhuman Primates
 - Expanded “Monkeys” from 7 to 8 groups
 - Separate recommendations for chimpanzees



Chapter 4: Veterinary Care

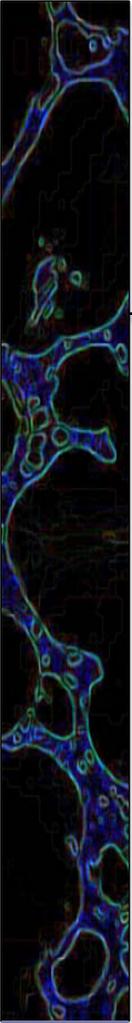
- Transportation – Expanded
 - Intra- and inter-institutional transport
 - Biosecurity during transport
- Animal Biosecurity (in Preventive Medicine)
- Clinical Care and Management
 - Medical Management
 - Emergency Care
 - Recordkeeping





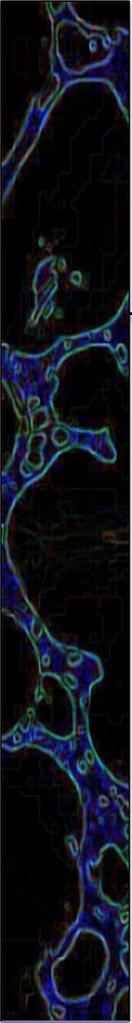
Chapter 4: Veterinary Care (cont.)

- Surgery – Expanded
 - Training
 - Surgical Procedures – Major vs. Minor
 - Intraoperative Monitoring



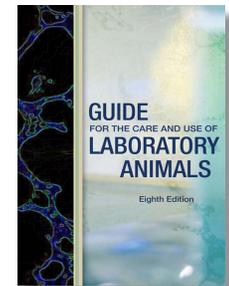
Chapter 5: Physical Plant

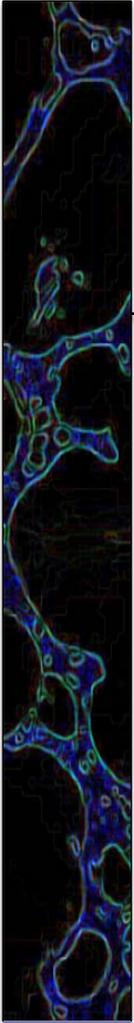
- HVAC
 - IVCs
 - VAV Systems (vs. constant volume systems)
 - Pressurization
- Vibration Control
- Environmental Monitoring
- Security and Access Control



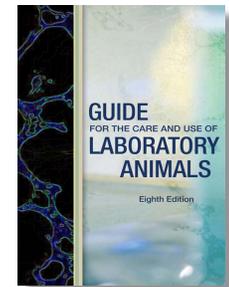
Chapter 5: Specialized Facilities

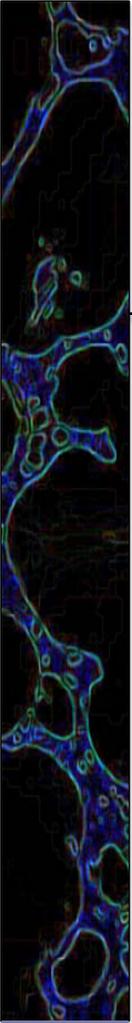
- Surgery
- Imaging
- Barrier Facilities
- Whole Body Irradiation
- Behavioral Studies
- Aquatic Species Housing





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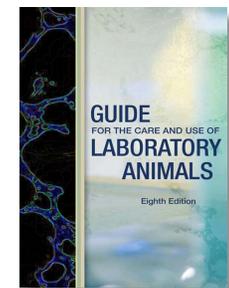


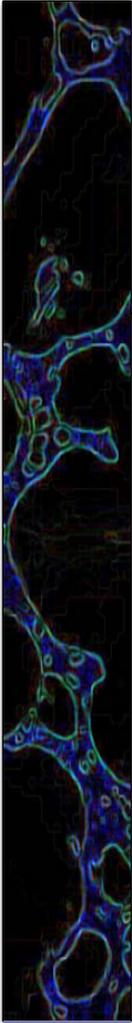


Chapter 3: Space Recommendations – Nonhuman Primates I

Monkeys:

- Group 1: Up to 1.5 kg – 2.1 sf/30" h
- Group 5: Up to 20 kg – 8 sf/36" h
- Group 6: Up to 25 kg – 10 sf/46" h
- Group 7: Up to 30 kg – 15 sf/46" h
- Group 8: > 30 kg – 25 sf/60" h





Chapter 3: Space Recommendations – Nonhuman Primates II

Chimpanzees:

- Juveniles: Up to 10 kg – 15 sf/60” h
- Adults: > 10 kg - ≥ 25 sf/84” h