Preface – Prior to distributing these comments to the membership, NABR submitted a detailed review to the USDA Animal Care management team for their consideration. In a follow up discussion with members of the management team, NABR was told that Animal Care had carefully considered the comments and will incorporate the suggestions where appropriate. During that discussion the items addressed in the detailed review were classified as either editorial in nature or policy related. Items that involved issues of policy were referred to the internal USDA staff responsible for policy issues. It should be pointed out that any changes to the Inspection Guide will take time regardless of the nature of the changes. It should also be pointed out the any changes that are made to the Animal Care Policy Manual as result of the OMB requirements mentioned below will need to be incorporated into the Inspection Guide, which will probably require additional time.

Background - The following comments where developed as part of NABR’s review of the USDA’s Research Facility Inspection Guide which can be found at http://www.aphis.usda.gov/animal_welfare/downloads/manuals/rig/complete/rig_complete.pdf. From a user’s standpoint, the utility of the electronic document could be improved if it was formatted the same way the regulations and standards are. As currently formatted online, the Inspection Guide is difficult to download, and extracting sections for the purpose of developing institutional documents is virtually impossible.

This version of the Research Facility Inspection Guide review has been revised to reflect the comments received from the USDA, which identified suggestions/comments contained in the initial review that required forwarding to the Animal Care Management team or an AC HQ Staff Officer for review and resolution. The original language in those sections so identified has been changed to read, “Comments involve policy issues.” Other sections not specifically identified by the USDA also contained comments that either referred directly to the sections that were forwarded for review and resolution or contained comments pertinent to the language in those sections. The original language in those sections has been replaced by the following language, “Comments withheld pending resolution of the policy issues.”

The comments that follow consist of a general introduction and an assessment of the individual sections that make up the manual. The comments included in this review cover
sections that could be incorporated into an institution’s documentation for its animal care and use program or ones that raise issues that need to be addressed and clarified.

**General Introduction** – On May 21, 2001, then APHIS Administrator, Ron DeHaven sent a memo to all Animal Care Inspectors along with the Research Facility Inspection Guide. In that memo, he indicated that it was the goal of the Guide to increase the quality and uniformity of reports, inspections and enforcement of the Animal Care Program. In March 2006, Update # 2 was distributed to the inspectors and the changes made from previous versions are detailed in the Introduction section of the current Guide. On March 23, 2007, Chester Gipson issued an APHIS Animal Care Stakeholder Update: “Inspection Guides Now Available,” in which he announced the availability of the Guide on-line and highlighted items of note in the new version: Protocol Review, Annual Report, Personnel Qualifications and Electronic Communications.

**Introduction** – On page 1.3.1 General Information it is stated that the Guide is an “adjunct to - not a replacement for – the 9 CFR.” It goes on to state, “that all inspection decisions must be justified by applicable sections of the regulations and standards.” The remainder of the Introduction concentrates on the formatting of the Guide and what that format is intended to convey in terms of the inspection process. On page 1.3.3 the words Must, Should and May are defined as follows:

- **Must** is used when the referenced actions are **required** by the 9 CFR regulations or standards or Animal Care Policies

- **Should** is used when the reference actions are:
  - strongly recommended but not specifically required by 9 CFR regulations/ standards or Animal Care Policies, and/or
  - directed by Animal Care Management

- **May** is used when referenced actions are optional

The use of the word or would imply that the ACP’s can be used as the basis for a citation, which is specifically prohibited in other sections of the manual.

There is a unnumbered page that highlights key changes to this version of the Guide. Of particular note on this page is the change to 7.2 involving the Inspection Report Narrative, which indicates that Animal Care Polices cannot be referenced in the Inspection Report.

**2.0 Glossary**

**2.1 Definitions** – included in this section are words from 9 CFR or the AC Policies, which appear in bold type; as well as words taken from other sources, which appear in italics.

Since only language in the CFR can be used for a NCI, the definitions from the Policy Manual should also be differentiated from those that appear in the CFR.
2.1.3 **Biomedical Research** – Comments involve policy issues.

2.1.3 **Brachiating Species** as defined appears to not include adult great apes because it is defined based on the method of locomotion and not in terms of the functional morphology. The great apes only ambulate by brachiation when very young.

2.1.6 **Covered Animal** – The definition does not take into account the amendment to the AWA dealing with rats, mice and birds bred for research.

2.1.6 **Deficiency** - This definition would appear to preclude citations for language in the ACP, “an item not in compliance with the Animal Welfare Act, or its regulations and standards. Also called a “noncompliance item,” or “noncompliant item” or NCI.”

2.1.7 **Deviation** - Comments involve policy issues.

2.1.7 **Exemption** - Comments involve policy issues.

2.1.9 **Genetically-engineered animal** - Comments involve policy issues.

2.1.10 **IACUC Chair** is defined as, “the IACUC member who presides over the IACUC and is responsible for coordinatn all the activities of the IACUC.”

This is not how IACUCs operate at most institutions.

2.1.10 **Indoor Housing Facility** as defined includes a requirement that humidity be maintained between 30-70%, a range, which is not specifically included in the AWA Standards.

2.1.14 **Pocket Pet** is defined as “small, non-dangerous pet type animal such as flying squirrel, hedgehog, prairie dog and sugar glider.” This definition is very restrictive and not representative of what the veterinary profession considers pocket pets.

2.1.14 **Policy** is defined as “a guidance document (“interpretive rule”) which clarifies, interprets, and/or provides examples of compliance methods for existing Animal Welfare Act regulations or standards.”

This is a useful definition and is important from the standpoint that language in the policies cannot form the basis of a NCI.

2.1.15 **Quorum** is defined as a majority of the committee, which is consistent with Robert’s Rules of order but appears to be in conflict with 18.4.2 which states that a member of the IACUC with a conflict of interest cannot contribute to the quorum during the vote on an item for which the conflict exists.

2.1.17 **Significant deficiency** is defined differently than it is in 2.31 of the AWA Regulations. It is confusing to include a definition from a different source when one already exists in the regulations.

2.1.18 **Variance** – Comments withheld pending resolution of the policy issues.

### 3.0 Registration

3.1.1 **Regulated Activities** – Comments involve policy issues.

3.1.2 **Exemptions** – Comments withheld pending resolution of the policy issues.

3.5.1 **Compliance with Standards** - Comments withheld pending resolution of the policy issues.

### 4.0 Miscellaneous
4.5.1 – **Procurement of Animals** – The section on Donated Dogs & Cats is very useful information and should be incorporated into an institution’s Animal Care and Use documentation.

**5.0 Pre-Inspection Procedures**

5.3.6 **Equipment and Supplies** – This section consists of a list of standards and references that should probably be part of an institutional animal care program’s supporting documents.

**6.0 Conducting the Inspection**

6.2.7 **IACUC Review** – Comments involve policy issues.

6.3.5 **PROTOCOL REVIEW** - In the section on General Requirements, the following requirement appears, “NOTE: Routine veterinary care, housing, euthanasia, etc., may be detailed in standard operating procedures (SOPs), but the protocol must refer specifically to that SOP(s).”

This implies that a description could be a list of SOPs, which would make it difficult for the protocol to be reviewed.

6.3.6 **Specific Types of Protocols Painful/Distressful Procedures** - The following language appears, “availability of experienced personnel, especially at night and on weekends to assess and administer pain relief.”

This appears to require 24 hour staffing, which is not how most facilities currently operate.

6.3.7 **Food and/or Water Deprivation or Restriction** – This section contains the following language, “medical/research records are being maintained and contain information on the monitoring of the animals.”

With the exception of marine mammals, there is no requirement for medical records.

6.3.12 **Inspection Procedures** – Under the section on multiple major survival surgeries, it indicates that, “surgical exemption is reported on the USDA Annual Report.” This does not seem to be consistent with the language in the regulations, nor is it something that has been required in the past, even when the USDA knew that an IACUC had approved multiple surgeries.

6.5.1 **Inspection Photographs** – This section indicates that Direct NCIs should be documented with photographs and that the documentation of indirect NCIs is more discretionary.
7.0 Completion of the Inspection Report

7.2.3 Completion of the Inspection Report – Comments involve policy issues.

7.3.2 Documentation of Inspection Findings - In the section on New Non-Compliant item identified the following language appears, “Note: If an NCI is corrected during the inspection, the inspector may use his/her discretion whether or not to cite the NCI. If cited, put “Corrected during the inspection.”

This language really provides a lot of flexibility and could lead to inconsistencies in the inspection process.

7.3.2 Example 1 contains the following language, Noncompliance – Protocol #06-85 involves a surgical procedure that will cause more than momentary pain and there is no documentation in the protocol that a search was conducted. How to Comply – A search for alternatives must be conducted and reviewed and approved by the IACUC.

There is no requirement in the regulations for a literature search, thus this is not an item of noncompliance.

7.3.5 Repeat noncompliant item identified - The following language appears. “A repeat noncompliant item is: a new noncompliance of the same section and subsection cited on the previous inspection. For example, inadequate lighting cited in one building on the previous inspection has been corrected, but on the current inspection, there is inadequate lighting in another building, “a noncompliance for a different species which is the same or similar to noncompliance cited on the previous inspection.” They then use the example of an open feed container in two different species.

DO NOT list a noncompliance as corrected if you are going to be citing an NCI in the same Section and subsection or a similar NCI for a different species on the current Inspection Report.

This language would appear to put the facility in a no-win situation in that it would appear that even minor issues are never addressed.

7.3.6 For a repeat NCI, an enforcement action must be recommended on an Enforcement Action sheet.

This language does not seem to provide for any use of professional judgment for the overall level of compliance or the nature of the items of noncompliance.

7.3.7 Recurring/Chronic noncompliance item - The following language appears, “A recurring or chronic noncompliant item is the same or similar noncompliance which is not found on consecutive inspections, i.e., it is cited on one inspection, then re-occurs on the 3rd and/or a subsequent inspection.”
For large facilities, this could result in the appearance of being a noncompliant program even though they are routinely in compliance.

7.4.1 Correction Date – This section contains useful information on the correction date process.

7.5.1 Extension of the Correction Date - This section contains useful information on the process for extending a correction date.

7.6.1 – Indirect & Direct Noncompliant Items – This section contains useful information on indirect and direct items of noncompliance with examples.

7.8.1 – Inspection Appeal Process - This section contains useful information on the appeals process.

8.0 Specific Types of Inspections

9.0 Post-Inspection Procedures

9.2.1 Delivery of the Inspection Report – This section indicates that having the registrant sign a hand delivered inspection report is the preferred method of delivery and that in the event that an inspection report is not completed during the inspection process that a detailed and thorough exit briefing should occur before the VMO leaves the premises.

10.0 General Facilities

10.8.1 Structure and Construction – This section contains the following language under the heading Exception – “If a research facility has developed, documented, and followed an effective and appropriate maintenance program for its animal facilities, a violation may not exist.”

This exception appears to be intended to address the language found under the Criteria section, which states “is maintained in good repair.” This would seem to imply that if a research facility had a maintenance program that identifies and schedules things for repair that an item (such as painting) waiting to be completed would not be cited during and inspection.

11.00 Primary Enclosures

11.2.4 Compatible Grouping – Comments withheld pending resolution of the policy issues.

11.3.1 Sanitation – The list of acceptable methods should include the combination products consisting of a detergent and disinfectant.
12.0 Husbandry

13.0 Transportation

13.7.2 Primary Conveyance – Comments involve policy issues.

14.0 Records

14.1.3 Annual Report, Content – contains examples of how to report unexpected pain/distress or animal incidents.

These examples are excellent and should, if utilized, prevent institutions from over reporting animals in Column E

14.1.4 Reporting Exceptions – Comments involve policy issues.

14.3.1 Health Records – The following language appears, “Health records are not specifically required by the AWA regulations, except for marine mammals. Therefore, a lack of health records or inadequacy of the health records may not be cited as a stand-alone violation, except for marine mammals.”

14.7.1 Veterinary Care Records – This includes the following required records: written program of veterinary care, acclimation statements and attending veterinarian or IACUC-approved exception/exemptions to the regulations/standards.

IACUC approved items should be part of the IACUC records.

15.0 Veterinary Care

15.3.1 Health Records – Under the section on Requirement the language cited above appears again.

“Health records are not specifically required by the AWA regulations, except for marine mammals. Therefore, a lack of health records or inadequacy of the health records may not be cited as a stand-alone violation, except for marine mammals.”

15.4.1. – Necropsy Requirement – The regulations only require necropsies on marine mammals.

15.5.2 Recommended records – In this section, the records that a research facility should maintain are listed and include: health records, surgery records, and necropsy records. The section then goes on to say, NOTE: These records are not specifically required by the AWA regulations and standards, except for marine mammals. Therefore, a lack of any of these records or inadequacy of these records may not be cited as a stand-alone violation, except for marine mammals.
16.0 Personnel

17.0 IACUC Membership

17.1.1 Appointment of IACUC – This section should include reference to the PHS Policy, which allows the CEO to delegate the responsibility for appointing members of the IACUC to the Institutional Official (IO).

17.2.1 Chairperson – The duties described for the chairperson are not realistic in most institutions and should include reference to staff and/or a designee(s) who handle the day-to-day administrative issues.

18.0 IACUC Functions

18.1.2 Criteria – Comments involve policy issues.

18.3.1 Reports to the Institutional Official – Comments involve policy issues.

18.4.2 Procedure for Biomedical Research - In the Procedure section, the following language appears, “If an IACUC member has a conflicting interest with a protocol being reviewed, e.g., is personally involved, that member may Not:
• contribute to the constitution of a quorum

Robert’s Rules of Order define a quorum as, “the number present not the number voting”. IACUC members with conflicts should either vote present or abstain from voting.

18.4.2 Changes in Protocols – This section contains excellent information on what constitutes a significant change in a protocol and describes how minor changes can be handled.

18.5.7 Exceptions/Exemptions – Comments involve policy issues.

Summary – The Research Facility Inspection Guide is an important document that should be part of the resources used to manage an animal care and use program. The current electronic version is a big improvement over the version first available, but a paper copy is easier to use and should be made available to all attending veterinarians.