Surviving the Age of Enforcement

B. Taylor Bennett DVM, PHD, DACLAM
Senior Scientific Advisor
National Association for Biomedical Research
It is important to understand that we are not being singled out to experience the new age of enforcement and the following quote from Dept. Secretary of Agriculture Kathleen Merrigan underscores this fact. The interview from which the quote was taken appeared in the April 6th edition of the Washington Post and the subject of the interview was the USDA’s National Organics Program - http://pqasb.pqarchiver.com/washingtonpost/offers.html?url=%2Fwashingtonpost%2Faccess%2F2002465141.html%3Ffmt%3DFT%26fmts%3DABS%26date%3DApr%26%252526%20%2B%252526%2F2010%26author%3DKimberly%2Bkindy%2Bpub%3DThe%2BWashington%2BPost%26startpage%3DA.11%26desc%3DChallenges%2Bfor%2Ba%2Borganics%2Bmarket
“I like to call this the age of enforcement. . . . There is always that period of time when people are adjusting to a new rule. What are the laws of the land? How do I comply? It is 2010. There is no longer any question about what the rules are, and there is no longer any forgiveness of any significant amount in the system for lax enforcement, for failure to comply. Among the things that the inspector general report pointed out was that we need to upgrade our enforcement mechanisms, and we are very much doing so.”
On May 20, 2010, a briefing was held to announce the changes in the inspection process. Some of you may have listened into this briefing, which was held at the USDA office in DC, but could be accessed via a 1-800 number.

On May 25, 2010, Agriculture Secretary Tom Vilsack issued a statement regarding the Office of Inspector General’s (OIG) audit of USDA’s inspection of problematic dog dealers http://www.usda.gov/oig/webdocs/33002-4-SF.pdf. In that statement (http://www.aphis.usda.gov/newsroom/content/2010/05/dog_dealers.shtml), he stated that “…USDA will reinforce its efforts under its animal welfare responsibilities, including: tougher penalties for repeat offenders and greater consistent action to strongly enforce the law.” He also stated, “APHIS has put together an action plan to address the OIG recommendations, as well as ensure the Agency enforces the Animal Welfare Act (AWA) to the fullest extent possible. We are taking immediate actions to strengthen our enforcement of the AWA, specifically in the areas of enforcement, penalties and inspector training.”
The Executive summary of the OIG Report indicated that there had been significant media coverage concerning large-scale dog dealers that failed to provide humane treatment for their animals. It also indicated that during their last audit on animals in research facilities, they found that the agency was not aggressively pursuing enforcement actions against violators of the AWA and that it assessed minimal monetary penalties against them.

The dealer audit focused on dealers with a history of violations in the past 3 years. They found that AC’s enforcement process was ineffective in achieving dealer compliance. The agency believed that compliance achieved through education and cooperation would result in long-term dealer compliance and, accordingly, it chose to take little or no enforcement action against most violators. During FYs 2006-2008, at the re-inspection of 4,250 violators, inspectors found that 2,416 repeatedly violated AWA.

AC inspectors did not cite or document violations properly to support enforcement actions. In fact, 6 of 19 inspectors did not correctly report all repeat or direct violations and some inspectors did not always adequately describe violations in their inspection reports or support violations with photos. Between 2000 and 2009, this lack of documentary evidence weakened AC’s case in 7 of the 16 administrative hearings involving dealers.

Although APHIS previously agreed to revise its penalty worksheet to produce “significantly higher” penalties for violators of the AWA, the agency continued to assess minimal penalties that did not deter violators.

In completing penalty worksheets, APHIS misused its guidelines in 32 of the 94 cases we reviewed to lower the penalties for AWA violators.
Of the 14 recommendations 11 involved the three bullets on this slide. The other three involved the internet sale of animals, security of Animal Care’s new information system and failure of IES to set up payment plans for the fines that were levied.

To ensure dealer compliance with the AWA, AC should modify its Dealer Inspection Guide (Guide) to require enforcement action for direct and serious violations. They also recommended that “no action” be deleted as an enforcement action in the Guide.

AC should provide more comprehensive training and detailed guidance to its inspectors and supervisors on direct and repeat violations, enforcement procedures, and evidentiary requirements (e.g., adequately describing violations).

AC should ensure its penalty guidelines are consistently followed and that it includes instructions to count each animal as a separate violation in cases involving animal deaths.
The action plan can be found at http://www.aphis.usda.gov/newsroom/content/2010/05/AWA_enforcement_plan.shtml. The plan indicates that the inspection and enforcement process will shift from its heretofore education focus to an enforcement focus. This shift could have a significant impact on the inspection process for research facilities. The focus has historically been on education, whereby the inspectors work with the institutions and their IACUCs to assure the welfare of the animals in each unique registered research facility. It now appears to be a more rigidly interpreted enforcement approach.

"Animal Care removed ‘no action’ as an enforcement option and added a requirement that management will review enforcement actions for repeat or serious violations." This removes the VMO’s discretion to accept a facility's corrective action of an existing or previous NCI. This change would appear to increase the prescriptive nature of the inspection process and reduce the use of performance based standards.

This section also indicates that Animal Care will be updating and consolidating all Inspection Guides into one comprehensive document, which could reduce the collaborative relationship that has evolved between many facilities and the VMOs who inspect them. This new Guide is due out at the end of the month.
The action plan also contains a section on improving the supervision of inspectors. As part of this process Animal Care will identify inspectors who are not performing quality inspections using the steps below:

1) Statistical analysis of inspection data.
2) Supervisory review of inspection reports, enforcement requests and photographs.
3) Supervisory analysis during inspection.
4) Supervisory review of time and activity reports.
5) Unannounced reviews of facilities subsequent to the inspector’s activities.
The action plan also includes the development of an Inspection Requirements Handbook, which can be found at:

The attachments which accompany the Inspection Requirements Handbook can be found at:
In the Inspection Requirements Handbook there are a couple of provisions of interest. The first involves Repeat Noncompliant Items (NCI). The word ‘must’ has replaced the word ‘should’ in referring to when to designate an NCI as a repeat item. An inspector must designate an NCI as a Repeat when it involves the same section or subsection as in the previous inspection even if the citation involves different animals and/or different portions of the facility. How this impacts organizations that have one registration but different locations in different geographical areas is still unclear.

Of particular concern is the Note included, which allows an item to be considered a repeat NCI even if the previous NCI was not on the most recent inspection. In the current Research Facility Inspection Guide such a citation would be considered a recurrent or chronic NCI, which does not have the same consequences as a repeat NCI.
The second item of interest in the Handbook is the section on Inspection Photographs. It requires (the word ‘must’ is used) photographs to be taken of Direct NCIs, but also requires that photographs be taken of all other NCIs noted during the same inspection.

The same is true for a Repeat NCI. If there is a Repeat NCI, photographs of the Repeat NCI must be taken as well as photographs of all other NCIs noted during the same inspection.

Also photographs must be taken if an NCI is likely to be appealed.

Lastly, NABR has seen photographs released as a result of a FOIA request, which appeared to be based upon an inspection report that we saw online in preparing this webinar.
In the Attachments to the Handbook, the last two pages are very important. One is a flow chart on Enforcement Action Guidance and the other provides additional information on the four actions that appear at the bottom of the flow chart. These four actions are described in some detail on the second page. Which action is taken is driven by the Risk Bask Inspection System process.
This and the slides that follow are somewhat self-explanatory but the use of modifying terms does not help to clarify the whole process. I have underlined certain words and phrases to call attention to this issue.
For those you unfamiliar with some the enforcement terminology the next slide depicts the official definition of a 7060.
A 7060 is an Official Warning Letter (7060) and is a notification to an individual or company regarding an alleged violation.

This definition as well as the others that follow can be found at the website that appears on this slide.

A 7060 may be issued with or without an associated IES investigation. When a facility is still out of compliance after a 90 day re-inspection and/or when there are multiple repeat NCI’s, though how many is multiple is not clear. When there is a Direct NCI if no obvious effects on animal health or welfare, which is not consistent with the definition of a direct NCI.
Attachments to the Handbook

- Direct NCI
  - A “Direct” noncompliance is a noncompliance that is currently adversely affecting the health and well-being of the animal, or has the high potential to adversely affect the health and well-being of an animal in the near or immediate future.
Incomplete documentation of serious NCI can result in issuing a 7060, as can slow progress toward compliance. If you have had an enforcement action (except for a 90 day re-inspection) in last 3 years, you will probably move to the three star option on the menu.
The next slide contains the official definition of a stipulation.
In addition to the definition of a stipulation I have included the definition of a violation. NABR has noticed that the Agency uses this term in some of its publications when the correct term should be either non-compliant item or alleged violation.
While there must be an IES investigation prior to issuing a proposed stipulation, NABR is aware of incidences where the facility personnel were not aware that the investigation was ongoing until they received the stipulation agreement. Again the modifying terms add ambiguity to the process.
• Risk Based Inspection System
• OGC Prosecution****
  – Must have IES investigation
  – Serious NCI’s
  – Repeat direct NCIs
  – Multiple repeat direct NCIs
  – No progress toward compliance
  – Usually have previous EA(s)
  – Animal health and welfare have been impacted

Now we have moved to the four star item on the menu; prosecution by the Office of General Counsel and there is less ambiguity in the process except the third and fourth bullets seem to be somewhat redundant.
Attachments to the Handbook

- OGC Prosecution
  - An *Office of General Counsel (OGC) Complaint* gives notice to an Animal Care licensee or registrant of formal allegations regarding possible violations of the AWA or the HPA. The Complaint does not mean the respondent is guilty of these violations, but serves as a notice that they must respond and either agree to the allegations in the Complaint, or seek a hearing date before a USDA Administrative Law Judge (ALJ).
Attachments to the Handbook

- OGC Prosecution
  - A *Decision and Order* is issued by the ALJ based on the evidence presented by APHIS and the respondent. The respondent has the right to appeal this decision. A copy of a Decision and Order is available on the USDA ALJ web site.
In preparing this webinar we used the Anima Care website to review the violations which were listed in the list of most frequently cited violations supplied by the Eastern Regional Office.
Section 3.131 is for warm blooded animals other than the ones in subpart s A-E with 3.11 being dogs and cats and 3.84 being NHPs. The NCI’s here involved pest control or lack thereof, dirty supply and exhaust vents and peeling paint.

Section 2.31(c)(3) was interesting in that a number of institutions complete their reports in a timely manner but then took months to forward them to the IO. Of course, not adhering to the time lines established in the reports will be noted by the VMO.

Section 2.33(b)(1) which involved either outdated drugs or in a few cases non-pharmaceutical grade compounds. This was an area where repeats occurred that could set off the enforcement process described in previous slides.

Section 2.31(e)(3) involves the description in the protocol either lacking information or not being consistent with other sections of the proposal. Also this section is cited when research records are not consistent with the protocol.
Section 2.31(d)(1)(ii) deals with the written narrative description that alternatives were not available. I was pleasantly surprised that the NCI’s were not driven solely by the language in the policy manual.

Sections 3.1/3.74 and 3.125 which involve facilities in general were mostly the result of improperly stored feed and bedding, which in a few cases resulted in repeat citations, and interior surface issues.

The citations for Personnel Qualifications under Section 2.32 were pretty diverse, but were cited on a couple of occasions when the same incident resulted in a citation under a more appropriate section, which is not in keeping with the requirements of the inspection manual.
Section 2.33(b)(2) citations involved treatment intervals and failure to report animals that had been observed to have a clinical condition by the VMO. The treatment intervals issue involved BID or TID instructions not being 12 or 8 hours apart, respectfully. This one may be open for discussion since the terms BID and TID do not set specific time frames.

Citations for pre- and post-procedural care under Section 2.33(b)(5) were usually for failure to follow protocols, failure to document that things were done, or treatment intervals. Some of these were, in my opinion the result of overly ambitious post-op plans.
Some Observations

- Top Ten accounted for 289 of the 669 NCIs found during 1679 inspections
  - 103 were IACUC related
  - 59 were related to veterinary care – outdated drugs
  - In the majority of the cases the NCIs were preventable
- The VMO’s don’t miss much
- Focused inspections – 90 day follow up
- If a noncompliant item falls into more than one section or subsection, cite noncompliance only in the most applicable section or subsection for each species affected.

The top ten deficiencies cited in 2010 accounted for 289 of the 669 NCIs found during 1679 inspections of registered research facilities. One hundred and three were IACUC related, 59 were related to veterinary care of which the vast majority involved outdated drugs. In the majority of the cases the citations were preventable. In looking at a lot of inspection reports, I can honestly say that the VMO’s don’t miss much. In fact some of them are very, very good. The new guidelines are resulting in a lot more 90 day follow up inspection which are reported as “focused inspections”. The new inspection requirements state. “If a noncompliant item falls into more than one section or subsection, cite noncompliance only in the most applicable section or subsection for each species affected.” In spite of this NABR has seen a single incident result in multiple citations which puts the institution at greater risk for further enforcement action.
Summary

- Your AAALAC Description or Animal Welfare Assurance should describe a program that complies with the AWA
  - Just follow them
- If you put in writing you are going to do something, do it
- Be consistent within your own records
- Do whatever it takes to avoid a repeat citation
- Let the powers that be know that the regulatory environment has changed
- Don’t take it out on your VMO
The Next Webinar

- April 12, 2011
- Eighth Edition of the Guide for the Care and Use of Laboratory Animals: What’s New and What Does It Mean?
- New Inspection Guide?