I want to start off today’s webinar with some background information that I hope will put things in context for the examples that we will be discussing and seeking your input on.
For those of who have participated in some of our previous webinars you are probably getting a little tired of hearing me harping about the inspection process, but I don’t think this can be overemphasized. On almost a weekly and in some weeks a daily basis we at NABR see examples of institutions that are cited for alleged non-compliance for incidents that do not appear to be in accordance with the language of the regulations or standards, the guidance contained in the Consolidated Inspection Guide (CIG) or are for repeat incidences which could have been prevented.

I cannot emphasize enough the importance of having a knowledgeable team to accompany the inspector to address issues as they arise, a post inspection review process that addresses any NCI’s and establishes a plan to correct them as well as reviews possible future issues and either addresses them or prepare an explanation why you have not for the next inspection.
I also want to point out that the inspection process appears to still be evolving as we enter the second full fiscal year of the age of enforcement.

This evolutionary process can be rapid if your institution gets a new inspector or if you are subject to an inspection by a team of inspectors as part of the inspection oversight process or because of a letter to the USDA from one of the animal rights group. Michael Budke is now copying the OIG on the letters he sends to the Regional Director requesting action.

The options and processes once a stipulation agreement is received are not clearly defined as demonstrated by the fact that the updated Table of Penalty Guidelines does not appear to be a public document and NABR had to submit a FOIA request to try and get a copy of it.
Another interesting event is that the appeal process appears to have changed without stakeholder notification. A February 2012 Fact sheet describes a two step process while the link on the USDA’s Website and the Consolidated Inspection Guide contains a letter from Chester Gibson describing a three step process. This could be problematic in that with the two step process the Regional Director has the final say and it would appear, at least in some cases, the Regional Director is involved in, or is at least knowledgeable, of the initial appeal process.
Lastly it would appear that the enforcement process as described in the Inspection Requirements Handbook is proceeding to the Stipulation step without a letter of warning in some cases.

Every NCI going back three years from the start of IES involvement appears to be included in the initial stipulation agreement. Since the investigation process can take a couple of years to complete, this could result in a roll up of five or more years of NCI’s and the amount of the initial fine appear to be based on all of the NCI’s.
As we have mentioned before, the Action Plan also included publicizing enforcement actions, which Drew monitors. A recent stipulation agreement clearly emphasizes the need to manage the inspection process.

The agreement includes a fine of $8,571 for two items of noncompliance both involving veterinary care, the first item cited was for failure to notify the AV when animals with diarrhea were put on treatment. The second was for outdated drugs.

A review of the institution’s inspection reports indicated that over the past three years their inspections included 9 NCIs of which 6 were repeats and many of the repeats were for outdated drugs, and in my opinion, all of the NCI’s were preventable.
So our plan today is to take a look at some citations that have been issued and you can determine how you would have handled the situation. I have changed some of the language in the citations for the purpose of this webinar but those changes to not affect the nature of the citation.

After getting your feed back, we will discuss our take on each example.
The first example is a citation under Sec. 3.131(c) which is the Sanitation standards in Subpart F for warmblooded animals other than those specifically covered in Subparts A-D and requires that the premises be kept clean and good repair.
• Sanitation
  – At the time of the inspection there was an unsecured oxygen tank in a procedural room and rust on the floor under the tank, the wheels on the surgery cart were rusty, and the trash can was overflowing with paper towels on the floor.

The citation was for an unsecured oxygen tank in a procedural room and rust on the floor under the tank, the wheels on the surgery cart were rusty, and the trash can was overflowing with paper towels on the floor.
Does Sec. 1.131(c) give the VMO the authority to include this NCI on your inspection report?

- Yes
- No

The answer is yes, but in my mind it would be a qualified yes, Subsection (c) of this section on Sanitation includes the premises which are defined in brackets as building and grounds and would appear to include all sites on a registered research facility’s property though the language within the subsection specifically refers to protecting the animals from injury and facilitating the husbandry practices proscribed in this section. I would have questioned this citation at the time of the inspection because none of the conditions described impact either animal welfare or the proscribed husbandry practices. I would have certainly asked them to remove the reference to rust because the only place within the AWR that rust is mentioned is in 3.1 and 3.75 and that is “…excessive rust that prevents the required cleaning and sanitization, or that affects the structural strength of the surface.”
Polling Results

Does Sec. 1.131(c) give the VMO the authority to include this NCI on your inspection report?

Poll Results (single answer required):

Yes: 56%
No: 34%
What if the species involved was guinea pigs?

- Yes
- No

Yes, because the same language appears in Subpart B. It should be noted though that there are some areas of the standards where the language is inconsistent from subpart to subpart so you should always double check the language before questioning a citation.
Polling Results

What if the species involved was guinea pigs?
Poll Results (single answer required):

Yes  88%
No   12%

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The second example is for a citation under Section 2.32 (a) which deals with Personnel Qualifications and describes the institution’s responsibility for providing training.
2.32 (a) - Direct

- Personnel Qualifications
  - The non-compliant item identified under Sections 2.33 (b) (3) and 3.11 (a) on the inspection report pertaining to an incident when the body of a cat was found under the resting board of an enclosure that had just completed a sanitization cycle in a mechanical cage washer has the potential to have direct and adverse effects on the health status of the animals. According to the necropsy report the cat was dead when the cage was sent through the washer.

The citation reads, “The non-compliant item identified under Sections 2.33 (b) (3) and 3.11 (a) on the inspection report pertaining to an incident when the body of a cat was found under the resting board of an enclosure that had just completed a sanitization cycle in a mechanical cage washer has the potential to have direct and adverse effects on the health status of the animals. According to the necropsy report the cat was dead when the cage was sent through the washer.”
In Accordance with the Consolidated Inspection Guide this citation could be questioned on at least two points.

- What are they?
The first and most obvious is this citation indicates that this incident represents noncompliance with three sections of the AWR and the facility was, in fact, cited for all three. In the Inspection Requirement Handbook on page 9.1.2 and in other section of the CIG, the following language appears, “If a noncompliant item falls into more than one section or subsection, cite the noncompliance only in the most applicable section or subsection for each species affected.”

The second is that by definition this cannot be a Direct NCI because the VMO indicated the animal was already dead when it went through the cage washer. A “Direct NCI” 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 the animal in the near or immediate future.”

This inspection appears to have erroneously added two citations each of which would be a direct NCI plus the Direct designation to the correct NCI to the Risk Based Inspection System, which increases the institution’s risk of further enforcement action.
The next example is of a citation under Section 2.33 (a) Attending Veterinarian and Adequate Veterinary Care.
The citation reads, “In a laboratory where anesthetized dogs were being euthanized with a solution of KCL prepared from Sigma Chemical Grade potassium chloride. Use of non-pharmaceutical drugs may not be effective and is not in accordance with currently established veterinary medical and nursing practices. Investigators are expected to use pharmaceutical grade medications whenever they are available, even in acute procedures. Non-pharmaceutical grade compounds may only be used in regulated animals under special circumstances after IACUC review and approval.”
This citation appears to be questionable for three reasons. What are they?
First, this citation appears to be based upon language in Policy 3 and not specific regulatory language and a policy cannot serve as the basis for a citation. In fact, in the Research Facility Inspection Guide on page 7.2.3, the VMOs were advised to never reference an Animal Care Policy in an inspection report. What makes this one really interesting is that Policy 3 also contains a section on Euthanasia indicating the method should be consistent with the AVMA Guidelines with the caveat that expired euthanasia drugs should not be used. Since they do not have such a caveat for non-pharmaceutical drugs, by exclusion this section of Policy 3 should not apply to drugs used for euthanasia. It should also be noted this protocol was approved and reviewed by the USDA prior to the apparent change in the Agency’s interpretation of the language in Policy 3 related to NPGC.

Second, according to the AVMA Euthanasia Guidelines the use of a supersaturated solution of potassium chloride injected intravenously or intracardially in an animal under general anesthesia is an acceptable method to produce cardiac arrest and death and is thus in accordance with currently established veterinary medical and nursing practices.

Third pharmaceutical grade saturated KCL is not available.
The next example is a citation for Section 2.31 (c)(3) Institutional Animal Care and Use Committee and refers to the semi-annual inspection process.
The report in question was approved on July 1, 2011 and sent to the Institutional Official on July 13, 2011. It listed several program and facility inspection minor deficiencies, but did not include reasonable and specific correction plans and schedules for any of the program deficiencies. In addition, the inspection reports and findings were not forwarded to the Institutional Official in a timely manner.
The question here is the regulatory requirement for submitting the annual report to the IO. Is it?
- By the next scheduled IACUC meeting
- Within fifteen days
- Prior to the next scheduled review
- None of the above

The correct answer is none of the above. The regulations are silent on the timeline for doing this. In this example the time between approval and submission to the IO was seven or eight business days depending upon what time the IACUC met and what time the report was delivered to the IO. I would have asked them to remove the reference to a timely manner.
Polling Results

QUICKPOLL

The regulations require that the semi-annual reports be sent to the IO:

Poll Results (single answer required)

- By the next scheduled IACUC meeting: 3%
- Within 30 days: 13%
- Prior to the next scheduled review: 37%
- None of the above: 79%

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The next example involves Section 2.31 (d)(1)(ii) - Institutional Animal Care and Use Committee and deals with the IACUC review of activities as it relates to avoiding or minimizing pain and distress.
The citation reads as follows, “A nonhuman primate (NHP) was kept on study despite having multiple health issues following a surgical procedure that was part of an IACUC approved protocol. The NHP was kept on study for over 23 months after developing complications to a surgical procedure. During this time repeated surgical procedures and medical treatments were performed for complications from the activity were performed. According to the staff at the facility, other animals on the same study had minimal or no complications resulting from their use in the activity.
Allowing an animal to remain on study for almost two years while undergoing repeated invasive treatments for complications of the study is not consistent with the intent of this section of the Animal Welfare Act. Keeping an animal on study under these circumstances does not avoid or minimize discomfort, distress or pain to the animal. The IACUC should determine that ongoing activities at the facility involving animals will avoid or minimize discomfort, distress or pain to the animals under their review.
Did the inspector cite the correct sections of the Animal Welfare Act?

The answer is No because the inspector is required to use the language in the regulations as a basis for the citation and not his or her perceived interpretation of the intent of Congress. I am not sure of how I would have responded to this situation but as written this citation appears to be dictating actual design and conduct of research which is prohibited by the Animal Welfare Act.
Polling Results

Did the inspector cite the correct sections of the Animal Welfare Act?

Poll Results (single answer required):

- Yes: 21%
- No: 79%
The next example involves Section 2.33 (b)(2) - Attending Veterinarian and Adequate Veterinary Care and the use of appropriated methods to prevent, control, diagnose, and treat diseases and injuries.
The citation reads, “I observed a barn cat in one of the barns. When I inquired about the preventive care provided the cat, the facility manager said there are not records available or kept on the vaccination history of the barn cats. If the cats are on the Program of Veterinary Care then records shall be maintained. If the cats are not on the Program of Veterinary Care, then they should be prevented from access or included in the Program. Because of the possibility of disease transmission to the regulated animals these cats shall be properly monitored and records maintained.”
Are the cats identified in this citation included in the definition of animal that appears in Part 1?

- Yes
- No

The answer is no, the definition of animal refers to animals that are being used or are intended for use in research, teaching, etc., etc.
Polling Results

QUICKPOLL

Are the cats identified in this citation included in the definition of animal that appears in Part 1?

Poll Results (single answer required):

Yes  15%
No   85%
That said, Does their presence in the barn constitute an item of noncompliance?

- Yes
- No

The answer is yes under Sec. 3.131 (d) – Pest Control, they should be prevented from accessing the barn.
Polling Results

Does the cat’s presence in the barn constitute an item of noncompliance?

Poll Results (single answer required):

- Yes: 70%
- No: 30%
The last example is for Sec. 2.31 (e) (3) and involves the fact that a protocol should have a complete description of the proposed use of animals.
The citation reads as follows, “Protocol XYZ –123 states that all animals were to be euthanized, but three were adopted out.”

The proper response to this NCI is?

1) Are you kidding me?
2) You can’t be serious?
3) Are you nuts?

All three have merit but I think I would find a more diplomatic way to try and get this citation excluded from the final inspection report.
Polling Results

The proper response to this NCI is:

Poll Results (single answer required):

- Are you kidding me? 90%
- You can't be serious? 40%
- Are you sure? 10%
In summary NCI’s have an additive effect, direct and repeat NCI’s accelerate the enforcement process. You should manage your program in such a way that you minimize the chances that either will occur. You should have in place a process for managing your institution’s compliance with the AWR. To do this you need to manage the inspection process to assure that accuracy during the inspections and prevent future citations.
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• Are You Sure You’re Filing Your Annual Report Properly?
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- January 8, 2013