

# The top USDA citations of 2012

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Many research facilities have reported changes to the Animal Welfare Act inspection and enforcement process since the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service announced its 'age of enforcement' in 2010 (ref. 1). To determine whether there have been changes in the inspection process and to identify enforcement trends, we used information provided by the USDA on the Top Ten Deficiencies for the Fiscal Year. We then used the Animal Care Inspection Service (ACIS) database (<http://acisearch.aphis.usda.gov/LPASearch/faces/CustomerSearch.jspx>) to review citations from more than 460 individual facility inspection reports. Our analysis was at times complicated by inconsistencies in the way different inspectors cited similar events, as well as by entry errors within the ACIS database (e.g., duplicate inspection reports entered in the database). **Table 1** lists sections of the Animal Welfare Act Regulations<sup>2</sup> that were most frequently cited in USDA facility inspection reports during fiscal year (FY) 2012 and FY 2011.

## Perspectives on the citations

For FY 2012, the top deficiencies accounted for 312 of the 739 noncompliant items (NCIs) cited during 1,527 inspections of 1,081 registered facilities (**Table 1**). In both FY 2012 and FY 2011, NCIs associated with IACUCs comprised approximately 60% of the top citations. A review of the individual inspection reports revealed that many of the IACUC-related NCIs were issued to smaller institutions, which, on the basis of the citations, appeared to lack the expertise usually found in larger institutions to effectively manage animal programs.

The second most frequently cited section during FY 2012, 2.33 (b) (2), has for many years been one of the most frequently cited

**TABLE 1** | The most frequently cited items of noncompliance during FY 2012 and FY 2011

CFR section	Number of citations issued	
	FY 2012	FY 2011
1 2.31 (c) (3) IACUC – Semi-annual reports	42	61
2 2.33 (b) (2) AVAVC – Appropriate methods & availability of care	38	34
3 2.38 (b) Miscellaneous (access and inspection records)	29	30
4 2.33 (b) (3) AVAVC – Daily observation	28	28
5 2.31 (c) (1) IACUC – Programmatic review	26	21
6 2.31 (d) (1) (ii) IACUC – Alternatives	26	32
7 2.31 (e) (3) IACUC (complete descriptions)	23	34
8 2.31 IACUC functions	19	0
9 2.31 (c) (7) IACUC – Modifications	19	23
10 3.125 (a) Facilities general – Structural strength	18	0
11 2.31 (e) (2) IACUC – Species and numbers	16	27
12 2.31 (c) (2) IACUC – Inspections	14	0
13 3.131 (c) Sanitation, housekeeping	14	17

sections. Our review of the inspection reports indicated that 15 of the 38 citations received under this section in FY 2012 involved inspectors finding outdated drugs at facilities.

Another trend that became evident after reviewing inspection reports was the increasing number of citations issued on the basis of information contained in facility or animal care records. For example, almost half of the citations issued under section 2.33 (b) (3) were based on a review of facility records. In some cases, issues were self-identified by the facility, self-reported to the IACUC and properly corrected before the inspection yet still resulted in citations from the USDA. Although issuing citations on the basis of information contained in records is not new, the number of citations based exclusively on records appears to have increased in the 2.5 years since USDA announced the 'age of enforcement'.

## Suggestions

Research facilities should have a clearly defined inspection management plan in place. That plan should include having knowledgeable people involved in the process who are well versed in the regulations and are familiar with the work being conducted in all the areas subject to inspection. If issues arise and are not resolved during the inspection,

facilities should fully understand the appeals process and commit to taking the appropriate steps to address the issues, as afforded by USDA's published appeals policies<sup>3</sup>.

Because facility records often form the basis for a citation or identify an issue that an inspector may cite, each facility's records should be precise and should not contain extraneous information that is neither required by the regulations nor necessary to manage the animal care and use program. The records must completely fulfill both the regulatory requirements and the institution's internal policies and procedures. Moreover, various sets of records (protocols, medical records, research records, etc.) should be consistent with each other in terms of the procedures described and care provided.

1. United States Department of Agriculture. *APHIS' Enhanced Animal Welfare Act Enforcement Plan* (United States Department of Agriculture, Riverdale, MD, 2010). <[http://www.aphis.usda.gov/animal\\_welfare/downloads/awa/AWA\\_Enforcement.pdf](http://www.aphis.usda.gov/animal_welfare/downloads/awa/AWA_Enforcement.pdf)>
2. Animal Welfare Act Regulations. Code of Federal Regulations. Title 9, Chapter 1.
3. United States Department of Agriculture. *Animal Care Inspection Guide 5.4.1–5.4.4* (United States Department of Agriculture, Riverdale, MD, 2010). <[http://www.aphis.usda.gov/animal\\_welfare/2011\\_Inspection\\_Guide//5.4%20Inspection%20Appeals.pdf](http://www.aphis.usda.gov/animal_welfare/2011_Inspection_Guide//5.4%20Inspection%20Appeals.pdf)>