

Taking a closer look at the USDA inspection process in FY 2018

Noncompliance items are down in a number of research-related areas

B. Taylor Bennett and Matthew R. Bailey

The National Association for Biomedical Research (NABR) has monitored the USDA inspection process and reported on our findings in webinars for the past nine years. In a July 2017 Lab Animal commentary,¹ we reviewed the data for FY 2006 and FY 2016, documenting how the research community had reduced the number of citations received for items of noncompliance (NCIs) unique to research facilities. In our review of the FY 2018 inspection data, we noted there has been a further reduction in the number of citations.

In late February, the Washington Post reported there were 60% fewer citations on inspection reports in FY 2018 than in FY 2017,² suggesting that there was a change in the inspection process. The article included graphics on inspection data for the past three fiscal years for licensed and registered facilities; these graphics depicted a 'significant' drop in citations for FY 2018, but provided little context for the change. In this article, we will provide that missing context for the inspection data for research facilities.

While there was a small percentage decrease in the number of inspections (Table 1), this can be explained by the fewer number of research facilities in the USDA's list of regulated businesses³. The number of facilities with NCIs, inspection reports with NCIs, and total NCIs all declined by

Table 1 | USDA inspection results for research facilities for FY 2017 and FY 2018

	2017	2018	% Change
Inspections	1288	1257	-2
Facilities with NCIs	226	95	-58
Inspection reports with NCIs	242	107	-56
Total NCIs	380	149	-61
% of inspections with no NCIs	82%	91%	+9

more 50%, resulting in a 9% increase in the number of inspections with no citations. Prior to FY 2017, when it increased by 3% to 82%, the percentage of inspections with full compliance varied little and was in the upper 70%.

Table 2 depicts the number of NCIs for each section of the regulations governing research facilities for the FY 2017 & FY 2018. Looking at the actual sections of the regulations cited demonstrates those involving IACUCs (§ 2.31), Veterinary Care (§ 2.33) and the Standards (Part 3) accounted for 90% of the total decrease NCIs.

Some notable drops

Considering IACUC citations in more detail, the biggest decrease from FY 17 to FY 18 involved sections involving the semi-annual program reviews, inspections and reports to the Institutional Official, for which there were 38 fewer citations. The section requiring a complete description of the proposed activities had 16 fewer citations; that for methods and sources used to determine that alternatives were not available had 12 fewer. The section requiring a rationale for involving animals had 9 fewer citations, while the requirement for a review of proposed activities received no citations in FY 2018.

Regarding veterinary care issues, the use of appropriate methods for providing care saw the biggest decrease, with 10 fewer citations. This may be due in a large part to how the USDA now cites a facility for outdated drugs. This was followed by guidance to investigators with 6 fewer citations, and both daily observation and pre- and post-procedural care with 5 fewer citations.

When it comes to the Standards, the sections involving the care of nonhuman primates had 22 fewer citations; other warm blooded animals had 15 fewer citations; and rabbits, 6 fewer.

While the drop in citations issued to research facilities mirrored the overall

Table 2 | NCIs for research-specific sections of the regulations for FY 2017 and FY 2018

	2017	2018	% Change
\$2.30 Registration	6	2	-66
\$2.31 IACUC	156	32	-79
\$2.32 Personnel Qualifications	11	3	-73
\$2.33 AVAVC	62	25	-60
\$2.35 Recordkeeping Req.	5	6	+20
\$2.36 Annual Reports	7	2	-71
\$2.38 Miscellaneous -	41	37	-10
Part 3 - Standards	90	41	-54

drop to all registered and licensed facilities, the majority of the drop was the result of fewer citations for administrative activities associated with the IACUC. We also find it interesting to note that 135 of the inspections that resulted in citations in FY 2017 only had one NCI; that number fell to 62 in FY 2018. It is entirely possible that the apparent change in the inspection process is the result of the continued effort of the regulated community working with the USDA to improve the overall compliance of research facilities. □

B. Taylor Bennett* and Matthew R. Bailey

National Association for Biomedical Research, Washington, DC, USA.

*e-mail: btbdvm@yahoo.com

Published online: 24 June 2019

<https://doi.org/10.1038/s41684-019-0348-0>

References

- Bennett, B. T. & Bailey, M. R. *Lab Anim (NY)* **46**, 283–284 (2017).
- Brulliard, K. *The Washington Post*. February 26, 2019. <https://www.washingtonpost.com/science/2019/02/26/usda-is-issuing-far-fewer-citations-zoos-labs-breeders-animal-welfare-violations>
- United States Department of Agriculture Animal and Plant Health Inspection Service. https://www.aphis.usda.gov/animal_welfare/downloads/List-of-Active-Licenses-and-Registrants.pdf