

Policy Watch: putting the new terms on USDA inspection reports into perspective

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A USDA Stakeholder Announcement released on September 22, 2016 (ID: USDAAPHIS/bulletins/16620a4) explained that two new terms will appear on USDA inspection reports: focused inspections and critical noncompliant items. These terms now appear on inspection reports and in the Animal Care Inspection Service (ACIS) database, allowing interested parties the ability to identify facilities that have undergone a focused inspection or been cited for a critical noncompliant item. These changes have raised some questions and concerns within the regulated community. This commentary will attempt to put those changes into perspective.

According to the announcement, “A focused inspection is an unannounced inspection that, for a variety of reasons, does not cover the entire facility.” A search of the ACIS database for “focused inspections” done in preparing this commentary found a total of 18, with the first one so designated in the database dated August 17, 2016.

Also defined in the announcement is a *direct* noncompliant item (NCI), as one that at the time of the inspection is “having a serious or severe adverse effect on the welfare of an animal or has the high potential to have that effect in the immediate future”. A *critical* noncompliant item is not defined but examples are provided. One example which should be of interest to the research community is, “all direct NCIs – as well as other NCIs that resulted in serious, adverse impacts on the welfare of an animal (including NCIs that occurred outside of the USDA inspection process).” So a critical noncompliant item is an event which occurred prior to an inspection and had an

adverse impact on animal welfare. Such an event could be one that was noted by the inspector in medical records, in IACUC minutes, or self-reported to the USDA or other federal agencies that operate under an MOU with the USDA.

The announcement also indicates that “*Direct, repeat and critical NCIs* may result in more frequent USDA inspections.” This statement is consistent with the January 31, 2011 Animal Care Enforcement Actions (EA) Guidance for Inspection Reports that appeared in previous editions of the Animal Care Inspection Guide. A search of the ACIS database for FY 2016 indicated that there were 4 direct, 44 repeat and 46 critical NCIs. A review of the actual inspection reports containing critical NCIs reveals that, with one exception, the term “Critical” only appeared on the actual reports generated after September 2016, but a review of all the reports provides examples of what types of events are being so classified. Of the critical citations on inspection reports, two could have been cited as direct noncompliant items because they were observed during the actual inspection process. The most frequently cited noncompliant item involved §2.33 Attending Veterinarian and Adequate Veterinary Care (ID: USDAAPHIS/AC/BlueBook/AWA/508comp) which was cited 16 times. Three of those citations involved lack of appropriate documentation of the program of veterinary care; four involved the use of appropriate methods for the diagnosis and treatment of medical problems and four for the observation of medical problems and communicating those problems to the attending veterinarian. There were 12 critical citations under

§2.38 Miscellaneous involving handling of animals and half of those involved nonhuman primates. There were eight critical citations involving sections within Part 3 of the regulations and four of those involved nonhuman primates, two of which involved escapes due to alleged cage design issues as opposed to improper handling. There were six critical citations for §2.31 IACUC issues with three involving IACUC functions, two reviews of proposed activities and one involving makeup of the committee. There were three citations for noncompliance with §2.32 Personnel Qualifications and all these involved adverse outcomes following experimental procedures. Data available for the past three fiscal years for research facilities at the time of this commentary was prepared includes 4,102 inspection reports of which 114 included a total of 145 critical citations, which represent approximately 10% of the total citations. During that same period, direct citations accounted for less than 2% of the total citations.

The changes that have taken place in how inspections and citations are identified on the inspection reports and entered into the ACIS database should not impact the overall enforcement process for individual facilities. The critical NCI designation has been used for years, included in the database and considered in the overall enforcement process. The fact that this information is now easily accessible in the database along with the inspections that are focused on a specific issue will make that information readily available to those interested in obtaining it, and institutions should be aware and prepared to respond when confronted with such information.

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