

RESPONSE

Agree to disagree

Marilyn Torchia, DVM & Tony Yaksh, PhD

In medical education, the oft-quoted philosophy on learning procedures is “Watch one, Do One, Teach One”. Although said tongue-in-cheek, the reality is that all procedures performed on humans or animals are done by human beings who are in the process of perfecting their skills.

So when is a person “adequately trained” to perform a procedure? The USDA VMO cited Great Eastern on Section 2.32(a) of the AWA Regulations, stating that the technician had not been properly trained in epidural analgesia techniques. Her proof, she claimed, was in the clinical record and in the IACUC’s decision to investigate the incident. Great Eastern’s IACUC and AV disagreed strongly, noting that the technician had been trained and had performed many other epidurals successfully. What better proof of adequate training is there than demonstration of success?

The USDA VMO was incorrect in citing the IACUC’s decision to investigate as proof of inadequate training. To the contrary, this situation is a beautiful example of how an excellent animal care and use program should work. The technician had training, there were records of such training, the technician had performed several successful epidural catheter placements, the technician felt comfortable reporting a problem to both the PI and to the veterinary staff, the dog received supplemental analgesia, the IACUC promptly investigated the problem, and there was a correction of the USDA pain category to reflect the changed nature of this particular study.

Anyone would agree that it is extremely unfortunate that the dog had to experience postprocedural pain. However, no technician and no procedure is ever 100% perfect all of the time, whether in the care of humans or animals. The best you can expect is a system in which the technician feels comfortable and compelled to call for assistance when something goes awry.

The USDA VMO in this situation disagreed with the Great Eastern IACUC strongly enough to cite the University in her inspection report. She reminded the

University that a rebuttal to the citation could be filed to explain its position. By attempting to negotiate with the inspector and her supervisor, Great Eastern has obviously pursued the first two steps of the USDA dispute resolution process.

Great Eastern must submit a formal dispute resolution request to the USDA in this case. An institution may fear disputing an inspection report because (1) it could create a difficult future relationship with the USDA VMO, and (2) the disputed finding may become available to the public through the Freedom of Information Act (FOIA) and the situation could escalate well beyond the scale of the citation.

The due process necessary for resolving an inspection finding dispute with USDA Animal Care (AC) is not clear. The USDA has not outlined in any substantive manner the time frame, the steps necessary for the retraction of inaccurate information, and the redaction of confidential or proprietary information released by the USDA to the public through the FOIA. For this reason, it is imperative that Great Eastern clearly states its institutional expectations when formally disputing an inspection finding. Those expectations, at minimum, should be that USDA AC will forward the formal request

to the appropriate official to respond to the formal appeal, enter the necessary information into the appropriate tracking system, and send an acknowledgment letter to the institution. Great Eastern should state an expected time frame for a response from the USDA. The USDA AC official should then have the responsibility to review the matter and provide an official response before releasing the inspection finding to the FOIA. It is unfortunate that currently there is easy web access to USDA inspection reports but not to the rebuttal point of view.

The IACUC system is based on performance standards, designed to allow institutional flexibility while assuring animal welfare and regulatory compliance. PHS *Policy*, the *Guide*, and AWARs do not prescribe engineering standards for training (nor could they ever hope to) but instead provide guidance to institutions on how to achieve optimal outcomes. Inherent in this type of system is room for honest disagreement between equally well-intentioned colleagues. Great Eastern must agree to disagree and pursue the dispute resolution process with USDA.

Torchia is Director, Animal Welfare Program, and Yaksh is Professor of Anesthesiology and IACUC Chair University of California San Diego, La Jolla, CA.

A word from USDA

In response to the questions posed in this scenario, the United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care (USDA, APHIS, AC) offers the following clarification and guidance:

The Animal Welfare Act regulations pertaining to IACUCs contain performance-based standards, and the USDA, Animal and Plant Health Inspection Service, Animal Care recognizes that disagreements may occur in their interpretation. In October 2000, USDA formalized the process for appealing an inspector’s findings (available at <http://www.aphis.usda.gov/ac/inspectionconcerns.html>).

We encourage research facilities to discuss any areas of noncompliance with their inspector during the inspection and exit interview. If questions persist, the facility may submit a written description of the area(s) of concern and request additional clarification. There is a short time frame (approximately 2–3 weeks) during which the inspection report is administratively processed prior to its finalization in our system. After a report is finalized, it may be made available to the public through the Freedom of Information Act (FOIA) process. No inspection report is finalized until all clarification issues are resolved, and this may occur at the inspector, supervisor, regional director, or deputy administrator levels. Any remaining disputes may ultimately have to be decided within the legal system.

Chester A. Gipson, DVM, MA

Deputy Administrator, Animal Care, APHIS, USDA