

1. United States Department of Agriculture. *Animal Welfare Act and Animal Welfare Regulations* (2013).

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RESPONSE

VMO has flexibility, but citation is justified

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The USDA Veterinary Medical Officer (VMO) was justified in issuing a noncompliant item (NCI) citation because Amici’s research technician failed to document that the analgesic was administered as outlined in the approved animal use protocol; therefore, protocol noncompliance has occurred. USDA Animal Care Policy #3 states, “Appropriate post-operative records should be maintained in accordance with professionally accepted veterinary procedures,”¹ which in general means all medications administered and treatments performed should be documented in a written form. Amici’s controlled substances log book documenting that buprenorphine had been withdrawn on a daily basis and the absence of clinical signs of pain and distress in the dogs during veterinary rounds are not a substitute for appropriate documentation in the dogs’ medical records of when the buprenorphine was administered and by whom it was administered.

Amici has a good track record with the IACUC and appears to be a conscientious investigator, which may account for why the Attending Veterinarian came to his defense. However, a lack of documentation has put Amici and the Attending Veterinarian in a weak position to sway the VMO from issuing an NCI. The VMO does have some discretion about when to cite a NCI. The USDA Animal Care Inspection guide states the following:

“For NCIs corrected prior to the inspection: The inspector may decide, using his/her own discretion, whether or not to cite the NCI. If cited, add ‘Ensure corrective actions are properly followed’, and do not give a correction date.”²

In light of the above, Amici and the Attending Veterinarian could have made a stronger case for not citing the NCI, if the following had happened prior to the VMO’s visit: (1) Amici had informed the IACUC of his research technician’s failure to document the administration of buprenorphine in the dogs’ medical records, (2) Amici had provided documentation to the IACUC that the buprenorphine doses were withdrawn and recorded, (3) Amici had documented when and how he retrained his research technician, (4) and the Attending Veterinarian had provided a report to the IACUC indicating clinical signs of pain and distress in the dogs were absent during veterinary rounds.

Had these steps been taken, the IACUC could have reviewed and potentially accepted the corrective actions. Apparently, there was no previous history of noncompliance by the Amici lab and if the actions outlined above had taken place and were presented to the VMO, they may have elected to not issue the NCI.

1. United States Department of Agriculture. *Animal Care Policy Manual* (2016).
2. United States Department of Agriculture. *Animal Welfare Inspection Guide* (2013).

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RESPONSE

If it’s not recorded, it didn’t occur

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The veterinary medical officer (VMO) was correct in issuing a citation, as there was

protocol noncompliance. Recordkeeping is essential to many fields including animal research. It serves as documentation of completed tasks and assignments and that the protocols were followed, allows researchers to brainstorm research ideas, maintains current veterinary practices¹ and is a regulatory requirement²⁻⁴.

The protocol required the dogs to receive an analgesic twice daily and there was no record that each individual animal on this record actually received appropriate treatment. The species in question, dogs, are USDA-covered species and thus are required to have a medical record that includes everything from initial purchase to final disposition⁴. Routine preventive medical procedures such as vaccinations and dewormings performed on a group of animals are often documented on a ‘herd-health’ type of record. Individual animal treatments must be documented for each animal. In addition, all records regardless of format or whether they be research lab generated or animal facility generated, must be readily available for regulatory inspection. Numerous medical record formats exist but they must meet the letter of the law, be legible and provide the necessary information for all involved in an animal’s care.

While the drug log was correct, there was no individual animal treatment record maintained. Compliance without documentation is noncompliance.

1. Field, K. *et al.* Medical records for animals used in research, teaching, and testing: public statement from the American College of Laboratory Animal Medicine. *ILAR J.* **48**, 37–41 (2007).
2. United States Department of Agriculture. *Animal Care Policy Manual* (2016).
3. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).
4. United States Department of Agriculture. *Animal Welfare Act and Animal Welfare Regulations* (2013).

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