**OFFICE OF RESEARCH AND DEVELOPMENT**

**VETERANS HEALTH ADMINISTRATION**

**USDA Definition of Category E**

(Summary and Clarification by the Office of the CVMO)

Date: October 11, 2019 Guidance Document: AR2019-001

1. **Summary**

In a webinar “Q&A with the USDA – Seventh Edition” sponsored by NABR and presented by Dr. Betty Goldentyer (Associate Deputy Administrator for USDA, APHIS, AC) and Dr. Cody Yager (Supervisory Animal Care Specialist) on July 10, 2019, it was emphasized that USDA intends Category E to include specifically only animals for which appropriate anesthetics, analgesics, or sedatives are withheld because these pain-relieving drugs would have adversely affected the procedures, results, or interpretation. This is a narrower definition than many IACUCs have been applying, so this guidance is being provided to allow the field to report according to USDA’s criteria. A recording of the webinar has been posted by NABR for all members of subscribing institutions, including VA. This guidance has been reviewed by Dr. Goldentyer and Dr. Yager for consistency with USDA’s intent.

1. **Background**

The Animal Welfare Regulations (§2.36(b)(7)) require reporting of “animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery or tests”, and the USDA Annual Report form uses this exact language in the definition for column E.

Over the years, institutions have interpreted this variously, which has resulted in some animals being reported in Category E because of the potential that they might experience pain or distress, even though they are carefully monitored and receive anesthetics, analgesics, and/or sedatives. Category E was subsequently misrepresented by some as indicating the experience of “maximum pain”, rather than being related to the status of measures provided to alleviate pain.

It was emphasized in the webinar that USDA intends for institutions to adhere closely to this specific language.

1. **Clarification provided by USDA**

In the webinar, USDA made it clear that Category E is defined much more narrowly than many stations have been doing. Specifically, USDA defines Category E according to the intent of the decision to administer or withhold appropriate anesthetics, analgesics, or sedatives. Category E is for animals from which appropriate administration of these agents to relieve pain is withheld, because these agents would adversely affect the procedures, results, or interpretation. If the intent is to alleviate pain or distress by administering appropriate anesthetics, analgesics, or sedatives, Category E does not apply. The following are examples that, according to USDA, do NOT require assignment to Category E:

* animals that experience breakthrough pain in spite of receiving anesthetics and analgesics that are appropriately expected to alleviate the pain
* rare individuals that experience pain from procedures for which no anesthesia or analgesics are provided because the procedures are not generally considered to be painful
* animals for which comfort measures are provided that are appropriate and effective to relieve pain and distress (such as ice packs, heat, soft bedding, etc.), so that there is no need to administer anesthetics, analgesics, or sedatives.
* unexpected deaths
* pain or distress experienced before the need for anesthetics or analgesics can be detected and addressed, as long as the animals are appropriately monitored and the intent is to alleviate the pain and distress as needed
* food or water restrictions under appropriately controlled and monitored conditions to maintain health and to avoid pain or distress

USDA also made it clear that the assignment to Categories B-E is to be based only on procedures performed for research purposes. Any procedures performed for clinical veterinary or colony management purposes, for the benefit of the health of the individual animal or the colony, should not be considered, even if they involve potential pain (e.g., surgical delivery of puppies, treatment of wounds acquired in fights with other animals).

Taking this same approach to Category D, USDA advised that there is no requirement to assign animals to Category D simply because they are anesthetized or sedated for restraint during procedures that do not intrinsically involve more than slight or momentary pain. Thus, for example, animals that are anesthetized or sedated for collection of blood samples, imaging procedures, or irradiation, may be assigned to Category C if no other procedures requiring assignment to Category D or E are involved.

Finally, USDA clarified that client-owned pet animals participating as subjects in clinical trials are not to be reported to USDA at all, regardless of the procedures involved or the agents administered for relief of pain or distress.

1. **Your action needed**

Please re-evaluate the category assignments accordingly, and re-assign animals as necessary, in all protocols for which your IACUC has approved use of Category D or E procedures.

1. **Additional questions**

For questions on this guidance, please contact the CVMO’s Office (Alice.Huang@va.gov or Michael.Fallon@va.gov). Questions about the USDA AWAR should be referred to the APHIS Animal Care Office.