Ultimately, the site visitors did not overstep their authority by recommending a mandatory item for correction despite

A WORD FROM OLAW AND APHIS

In response to the issues posed in this scenario, the US Department of Agriculture-Animal and Plant Health Inspection Service (USDA-APHIS) and the National Institutes of Health-Office of Laboratory Animal Welfare (NIH-OLAW) provide the following clarifications:

In this scenario, a llama producing antibodies for federally funded research to study reproductive efficiency in dairy cows is found in need of veterinary care by AAALAC site visitors. In addition to a lack of veterinary care, the site visitors raise serious concerns about the lack of IACUC review of the research and the intensity of animal monitoring.

NIH-OLAW response

As noted by other reviewers, it is an institutional responsibility to provide care for all animals, not just those housed in areas listed on the Animal Welfare Assurance or supported by the Public Health Service (PHS) or National Science Foundation¹. The institution must also ensure that any standards that might not be consistent with PHS Policy do not affect or pose risks to PHS-supported activities². As the scenario fails to identify the source of the federal funds, the specific requirements of the granting agency for the conduct of research with animals are undetermined. However, the US Government Principles mandate that all federal agencies conducting or supporting research with animals ensure that veterinary care is provided³.

USDA-APHIS response

The Animal Welfare Act's (AWA) definition of "animal" excludes farm animals used

the IACUC claim that it did not have jurisdiction over the study. The *Guide*, *Ag Guide*⁴, and ACLAM⁵ all state that a

or intended for use as food or fiber, or intended for use for improving animal nutrition, breeding, management, or production efficiency⁴. The AWA regulations define "farm animals" to include llamas. Here, the institution is using the llamas to support research in dairy cows for the purposes of improving production efficiency. The use of the llamas for this purpose excludes them from the definition of "animal" and AWA regulatory requirements. Although there are no applicable AWA regulatory requirements, USDA supports the position that institutions using animals for research purposes should provide such animals with adequate veterinary care. □

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facility shall provide adequate veterinary care, which includes timely and accurate methods for communication of any abnormalities or concerns about animal health to the attending veterinarian. Finally, AAALAC has had a long standing policy of following animal ownership as a mechanism for determining inclusion in the accredited animal care and use program. Since it is assumed that Dr. Zymansky's llamas are institutionally owned animals, according to AAALAC they would be included in the accredited animal care and use program. In addition, though the College of Agriculture may not be part of the currently "accredited unit", the llamas are housed within the accredited program and may impact the health and welfare of the institutionally owned animals and may be reviewed during the site visit⁶. □

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Oversight should be uniform and consistent

In its 'Rules of Accreditation,' AAALAC discusses the topic of 'contiguous facilities'¹. To paraphrase: when programs being evaluated by AAALAC have contiguous animal care and use facilities (e.g., same floor or building) which are assigned to other units not being evaluated, "(t)he extent to which contiguous facilities are evaluated is at AAALAC International's

discretion and depends mainly on whether facilities and practices within the contiguous facilities have an effect on the facilities and programs under primary AAALAC review." Thus, it appears that the site visitors encountered conditions within the 'llama barn' they felt could have an effect on the program being evaluated, and were within their authority to recommend a mandatory

item for correction based upon the organization's stated rules that are on record.

PHS Policy mandates a similar policy in that U.S. institutions conducting PHS-supported activities "...must ensure that any standards that might not be consistent with PHS Policy do not affect or pose risks to PHS supported activities"². Thus, even though AAALAC uses the *Guide*³ as a