personnel. Relocation of animals to anywhere other than regular housing, (such as cold rooms) should require notification to the vivarium manager or supervisor to ensure that the animals are taken care of properly. Notification may have made all parties aware that the relocation of the animals should be delayed until repairs to the cooling systems were completed, or accommodation could have be made by placing another table in the cooler. It is unclear who had been taking care of feeding, water needs, and cage changing, but the exposed wires should have been reported to the area supervisor for immediate attention.

1. National Institutes of Health. *Guidance on Significant Changes to Animal Activities.* Notice NOT-OD-14-126.
2. ARENA/OLAW. Institutional Animal Care and Use Committee Guidebook 2nd edn. (OLAW, Bethesda, MD, 2002).
3. U.S. Department of Health and Human Services. Public Health Service Policy on Humane Care and Use of Laboratory Animals (2015).

Division of Laboratory Animal Resources, University of Kentucky, Lexington, KY.

A Word from OLAW

In response to a number of issues posed in this scenario, the Office of Laboratory Animal Welfare (OLAW) provides the following clarifications:

First, the PHS Policy IV.B.3.d., defines a significant deficiency as one that is a threat to the health and safety of animals.[1] In the scenario, the exposed electrical wires, while a hazard to personnel, do not pose a risk to the animals and therefore are considered a minor deficiency for reporting in the semiannual report to the Institutional Official (IO). The facility management must be promptly contacted and the wiring problem corrected.

Second, as mentioned by reviewers, the change in the protocol involves the addition of a procedure, i.e. housing mice in the school's cold room. Veterinary verification and consultation (VVC) may not be used to add a new procedure that was not previously approved on the protocol.[2] Existence of an SOP approved for other protocols does not justify the addition of a new procedure. In addition, exposing the mice to an environment outside of the recommended temperature range of the *Guide*, 68-79º F, is a change that has a negative impact on animal welfare and results in greater distress to the animals.[2, 3] Such a change must be reviewed and approved by full committee review (FCR) or designated member review (DMR).[2]

Lastly, the IACUC office used VVC incorrectly. This error allowed "the conduct of animal-related activities without appropriate IACUC review and approval".[4] Prompt reporting of this noncompliance is required.[4]

1. Public Health Service. Policy on Humane Care and Use of Laboratory Animals (US Department of Health and Human Services, Washington, DC, 1986, revised 2015).
2. National Institutes of Health. Guidance on Significant Changes to Animal Activities. Notice NOT-OD-14-126 [online]. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-126.html (National Institutes of Health, Washington, DC, 26 August 2014).
3. Institute for Laboratory Animal Research. Guide for the Care and Use of Laboratory Animals 8th edn. pp. 43-44 (National Academies Press, Washington, DC, 2011).
4. National Institutes of Health. Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals. Notice NOT-OD-05-034 [online]. http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html (National Institutes of Health, Washington, DC, 24 February 2005).

Patricia Brown, VMD, MS, DACLAM
Director
OLAW, OER, OD, NIH, HHS

RESPONSE

Collaborative decision making and navigating the red tape

Austin Fritsch

The ability to collaborate and come to a collective decision is key when reviewing the results of the semi-annual facility inspection results with the IACUC. In this case, the IACUC inspector, the vivarium director, and maintenance staff worked together seamlessly in identifying the problem of the exposed wiring and resolving the issue quickly without harm coming to animals and/or research staff that utilize the room. In reviewing ref. 1, considering that no animals or staff were harmed and that the exposed wires were quickly and safely replaced, it could be recommended that the IACUC classify this as a minor deficiency. It is always important to note that classifying deficiencies is not a one person decision, it is one that involves the IACUC and the IO cooperatively.

VVC continues to be one of the hot topics that many institutions are currently discussing. Based on the assumption that Blackmore is working at an AAALAC accredited facility, has an assurance on file with OLAW, and has an IACUC approved VVC Policy, it is my opinion that the IACUC office should have sent the modification to utilize the cold room for Blackmore's mice to DMR or FCR according to PHS Policy (IV.C.2)[2]. The deciding factor surrounding this issue is that Blackmore's original IACUC approved protocol did not include the housing of mice in a cold room. It is my interpretation that the VVC process cannot be used to add new procedures to a previously approved protocol[3] (even through the IACUC has an existing IACUC approved SOP for housing mice in the cold room) and according to ref. 4, this modification would fall under 1. b. of the guidance (resulting in greater pain, distress, or degree of invasiveness) which would mandate that it be reviewed by DMR or FCR by the IACUC. Our institution utilizes cold rooms that as a stressor experiment for the animals and the IACUC classifies this housing procedure as a type of induced stress that has potential to cause greater pain or discomfort to the animal due to the altered macroenviroment which deviate from the standards set by the Guide[5]. If the IACUC decides that the VVC policy in this case was wrongly applied, then a report would need to be sent to OLAW underlining that an unapproved significant change was made and animal-related activities took place without appropriate IACUC review and approval.