

How should the IACUC handle a questionable VVC change to a protocol?

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Dr. Lisa Blackmore's original IACUC protocol approval did not include the use of the school's cold room to house some of her mice, but during the course of experimentation it became necessary to use the room and Blackmore submitted a protocol amendment to the IACUC office for a change in the housing site. Because there was an existing IACUC-approved Standard Operating Procedure for housing mice in the cold room, the IACUC office forwarded the requested change to the attending veterinarian and using the veterinary verification and consultation (VVC) process¹, the veterinarian concurred with the change.

Soon afterwards, during the semi-annual inspection of animal housing areas, an IACUC inspector walked into the cold room that housed Blackmore's cages along with many cages from other mouse studies. All the animals were fine and the studies were being conducted as per the approved

protocols, but the inspector noticed exposed electrical wires that could easily be contacted by anybody working in that part of the room. The wires were above the cages housing Blackmore's mice and due to the other ongoing studies there was no place to relocate the cages. The inspector notified Blackmore and the vivarium of the problem and the vivarium director said that she would call the facilities maintenance department to have the problem remedied. The inspector advised the IACUC office and vivarium that the problem should be considered a significant deficiency because, in the inspector's opinion, it threatened the safety of personnel working in the area.

The exposed wires were quickly put into a proper conduit by the maintenance department which explained that a repair to the cooling unit had not been completed when the inspection occurred. Nevertheless, the IACUC was not entirely sure about how to

handle the inspection finding. There was no question about the safety issue for personnel but the static mouse cages were on a table that was well below the wires. The committee was not sure if a danger to personnel but not to animals constituted a significant deficiency. A second problem was that the Blackmore protocol change was implemented by VVC and NIH guidance on VVC states that changes impacting personnel safety must be approved by either full committee or designated member review¹. The committee was unsure if the inspection finding was a reportable incident to OLAW or if it was just a wake-up call for the veterinarian to be more thorough before approving a change by VVC.

How do you think the IACUC should proceed?

1. National Institutes of Health. *Guidance on Significant Changes to Animal Activities*. Notice NOT-OD-14-126.

RESPONSE

Not so simple a scenario

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At first blush, this scenario appears straightforward, however, several issues come to mind right away. The approval by VVC seemed appropriate according to NOT-OD-14-126 Guidance on significant changes to animal activities¹. The IACUC already had an SOP in place, and Blackmore's change in location had been submitted for approval. But, Blackmore's mice had not been in the cold room prior to the amendment, and in my opinion, despite the existing standard operating procedure, the veterinarian should have made a cursory inspection of the new housing area.

If exposed wires were observed, inquiries could have been made to the vivarium manager to see if there was repairs scheduled that may cause an issue involved with housing the mice in that area.

When the inspection occurred it was obvious that there was a potential danger to people working with the mice and, as stated, in the ARENA² Guidebook the PHS Policy³ places responsibility to ensure a safe working environment with the institution and the "natural point of convergence...at many institutions is the IACUC". In this instance, it was a definite safety issue for the personnel. The IACUC took the proper steps and notified the vivarium manager who promptly called facilities maintenance and the situation was quickly remedied. Was it a significant deficiency? Yes, to a point due to danger to personnel. However,

the definition of significant is unresolved or repeated deficiencies except this situation was attended to immediately by both the vivarium manager and facilities maintenance. In this case, the IACUC need not report it to OLAW since no animals were harmed. The incident will be in the minutes and in the annual report, but it was quickly resolved, and the animals were well out of danger on a table and the potential danger to personnel eliminated.

This should, however, be a wake-up call for not only the veterinarian but also the IACUC. Careful consideration of each protocol or amendment should always be the rule regardless of standard operating procedures. Changes in housing, in circumstances such as this where environmental changes are required should be inspected for safe working conditions for both animals and