



DEPARTMENT OF HEALTH & HUMAN SERVICES

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6705 Rockledge Drive  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
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November 9, 2017

Re: Animal Welfare Assurance  
A4367-01 [OLAW Case V]

Ronald A. Otten, Ph.D.  
Acting Deputy Associate Director for Science  
Centers for Disease Control  
1600 Clifton Road NE, (b)(6)  
Atlanta, GA 30333

Dear Dr. Otten,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 6, 2017 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at the CDC National Institute for Occupational Safety and Health. According to the information provided, OLAW understands that the temperature in an inhalation chamber exceeded the established standard and also was not described in the protocol. Temperatures rose during the exposure periods and ice packs were placed in the chamber to counteract this. The rats on study experienced no morbidity or mortality due to the elevated temperature.

The immediate action taken upon discovery consisted of the Attending Veterinarian allowing the study to continue as long as the animals were not exposed to temperatures above 77 degrees F. The corrective actions consisted of modifying the room to provide improved temperature control, modifying the chamber system to maintain temperatures in a narrow range, alarming the system for elevated temperatures, amending the protocol to detail environmental conditions and posting these in the room, and having the engineering team maintain a calibration log for equipment used to monitor critical life systems which will be inspected by the Institutional Animal Care and Use Committee (IACUC).

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Contact



DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service  
Centers for Disease Control and Prevention  
National Institute for Occupational Safety and Health

## Memorandum

**Date:** November 6, 2017

**From:** Chair, CDC NIOSH (Morgantown) Institutional Animal Care and Use Committee (IACUC)

**Re:** Report of Noncompliance Incident

**To:** Ron A. Otten, Ph.D., Deputy Director, CDC/OD/OADS, and IACUC Institutional Official  
Through: Don Beezhold, Ph.D., Director, CDC/NIOSH/HELD DAB 11/6/17

Ronald Otten  
-S  
Digitally signed by Ronald Otten -S  
Date: 2017.11.06 16:43:01  
-05'00'

CDC/Morgantown Animal Care and Use Committee (IACUC), in accordance with Assurance A4367-01 and PHS Policy IV.F.3., provides this report of a protocol non-compliance. This report is divided into two sections: (1) incident investigation and findings; and (2) corrective actions.

### 1. Incident Investigation and Findings

On October 5, 2017 during the semi-annual IACUC inspection, the Attending Veterinarian (AV) noted freezer packs had been placed in a chamber holding 48 obese rats on a welding fume inhalation study. The exposure for the day had concluded and the rats were soon to be transferred to their housing cages in an adjacent animal holding room. The AV inquired of the engineer the purpose of the freezer packs and was told the chamber temperature was getting too high but the ice packs had helped. The AV asked to see the temperature readings for that day's study and noted the animals were currently at 80°F, and had started at 67°F when the exposure started 3 hours earlier. The AV notified the IACUC Chair that (a) the temperature exceeded The Guide stated normal range for rats, (b) that the temperature range over the 3 hour period was not well controlled, and (c) none of these conditions had been described in the animal use protocol. The AV also reported the rats did not appear to be distressed or anxious nor was there respiratory rate visibly increased. The rats had been undergoing daily exposures for a couple of weeks and no morbidities or deaths had occurred.

The AV, in consultation with the Principal Investigator (PI), determined the exposures could be continued with a plan that if/when the temperature in the chamber reached 77°F, the exposure would be discontinued to avoid excessive temperatures generated by the robotic welder in the same room. This plan allowed the remaining 8 experimental exposures already planned for this particular experiment to be completed.

The initial report prompted a meeting which included the PI, Developmental Engineering Research Team (DERT) engineers, facility maintenance engineers, AV, IACUC Chair and Administrator. This meeting was held to investigate the issues found during the semi-annual inspection and develop corrective actions. It was noted that there have been no reports of animal morbidity or death associated with the operation of this chamber since it was put into use for any animal species. Contributing factors to the temperature rise in this study appeared to be related to biomass in the chamber, i.e. this was the first study using obese rats and the chamber contained the upper limit of animals (48), leading to increased heat generation/ heat load which could not be dissipated as effectively. In reviewing the data from this procedure room, it was also noted that this issue was not isolated to this one study and also involved welding fume studies performed in mice where the biomass was much lower. Thus, heat



generated from the welding fume generation system was also considered to contribute to the heat load in the room.

During this meeting, it was decided that no new studies will be performed in this unit until the IACUC is assured that the chamber can maintain temperature within the range described in The Guide. Any anticipated excursions will need to be described and approved in an animal use protocol. A corrective action plan was also developed during this meeting with all critical stakeholders providing input.

## 2. Corrective Actions

The IACUC recommended the following corrective actions:

1. Facilities operations staff will make changes to the room to provide improved temperature control within the limits of the building's current system.
2. DERT engineers will add a secondary system to the inhalation exposure system that is capable of maintaining the internal chamber environment at steady state within a more narrow range and set point as stated in The Guide.
3. DERT engineers will build into the software program an alarm with an audible component to let technicians know the internal temperature is approaching temperature maximum, and if the chamber reaches the maximum, the system will be shut down.
4. The IACUC will require the PI to provide detail in their animal use protocol submissions on the environmental conditions they intend to expose animals to in the inhalation units. During experimental exposures the environmental conditions will be posted in the procedure room so all personnel involved know what parameters the IACUC has approved.
5. The DERT engineers will be required to maintain a calibration log for equipment used to monitor critical life systems based on manufacturer's recommendation and the IACUC will inspect these records during semi-annual inspections and post-approval monitoring activities.

Sincerely,

Dale W. Porter -S

Digitally signed by Dale W.  
Porter -S  
Date: 2017.11.06 12:17:07  
-05'00'

Dale W. Porter, Ph.D.  
Chair, NIOSH Morgantown IACUC

cc:

(b)(6)

## Morse, Brent (NIH/OD) [E]

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, November 07, 2017 9:40 AM  
**To:** Otten, Ronald A. (Ron) (CDC/OD/OADS); OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** CDC NIOSH HELD ACUC (CDC); Beezhold, Don (CDC/NIOSH/HELD); Porter, Dale  
(b)(6)  
(b)(6) Otten, Ronald A. (Ron) (CDC/OD/OADS)  
**Subject:** RE: CDC NIOSH (Morgantown) ACUC Report of Noncompliance Incident (Assurance: A4367-01)

Thank you for this report Dr. Otten. We will send an official response soon.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
Acting Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

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**From:** Otten, Ronald A. (Ron) (CDC/OD/OADS) (b)(6)  
**Sent:** Monday, November 06, 2017 4:46 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** CDC NIOSH HELD ACUC (CDC) (b)(6) Beezhold, Don (CDC/NIOSH/HELD) (b)(6)  
Porter, Dale (b)(6)  
(b)(6)  
(b)(6) Otten, Ronald A. (Ron) (CDC/OD/OADS) <rxo1@CDC.GOV>  
**Subject:** CDC NIOSH (Morgantown) ACUC Report of Noncompliance Incident (Assurance: A4367-01)

Dear Dr. Morse and colleagues,  
Please find the attached noncompliance report for submission to OLAW from CDC Morgantown (Assurance: A4367-01).  
Thanks,  
Ron

Ron A. Otten, Ph.D.  
Deputy Associate Director for Science  
Office of the Associate Director for Science (OADS)  
Office of the Director  
Centers for Disease Control and Prevention

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