



United States Department of Agriculture
Animal and Plant Health Inspection Service

MWILLIAMS
INS-0000874439

Inspection Report

UNIV OF TENNESSEE KNOXVILLE OFF LAB AN CARE

2415 Fletcher Luck Lane
Third Creek Building
KNOXVILLE, TN 37996

Customer ID: 843

Certificate: 63-R-0105

Site: 001

UNIV OF TENNESSEE
KNOXVILLE OFF LAB AN CARE

Type: ROUTINE INSPECTION

Date: 15-JUN-2023

2.32(a) Critical

Personnel qualifications.

The items below indicate a lapse in training of employees, daily observations and general oversight.

***Twelve hamsters on a study protocol received high doses of a study agent. Four of the hamsters died after administration of the agent. An investigation was conducted by the IACUC who determined that while the procedure had been conducted in the past the PI had failed to refamiliarize herself with the approved procedures in the protocol. It is the responsibility of the research facility to ensure that all personnel involved in the care and treatment of animals are qualified to fulfill their responsibility and it is the responsibility of all personnel involved in the protocol to be familiar with the procedures in the approved protocol. The facility identified the cause of the incident and followed up appropriately with refresher training for all personnel involved in the care and treatment of the hamsters on study as well as provided additional monitoring and oversight of the lab.

***A young goat was found dead in its enclosure. Records indicated the goat was observed on 7/22/2022 but later found dead in its enclosure on 7/25/2022. The investigation showed the daily observation records were incomplete and could not verify that the daily observations were conducted over the weekend. A second goat from the same herd being transported for observation was found dead in the trailer at time of transport. The review for both incidents at necropsy indicate both goats were heavily parasitized but there was no documentation in the animal records indicating a decline in the goats health status or body condition.

***A pregnant mare used for a Therio lab was moved from her enclosure and relocated to another pasture to allow additional grazing. The facility routinely uses a whiteboard to track the horses. When the mare was relocated her ID was removed from the whiteboard and after the move there was a failure to continue to document her reproductive status in her individual record resulting in the PI and VREC staff losing track of her reproductive status. The lack of tracking led to a failure to terminate the pregnancy as required in the protocol. When the continued pregnancy was discovered the mare was returned to the large animal clinic where she delivered a healthy foal.

All of the incidents documented above were investigated and appropriate corrective measures put in place including increased oversight and further training in proper documentation of daily observations and completion of medical records. Corrected.

Prepared By: MICHELLE WILLIAMS

USDA, APHIS, Animal Care

Date:

22-JUN-2023

Title: VETERINARY MEDICAL
OFFICER

Received by Title: IACUC Representative

Date:

22-JUN-2023



United States Department of Agriculture
Animal and Plant Health Inspection Service

MWILLIAMS
INS-0000874439

Inspection Report

This inspection and exit interview were conducted with the Director/IACUC Chair, Attending Veterinarian, IACUC Coordinator and other Facility Representatives.

Prepared By: MICHELLE WILLIAMS
USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL
OFFICER

Date:
22-JUN-2023

Received by Title: IACUC Representative

Date:
22-JUN-2023



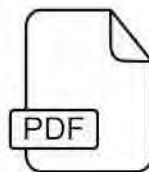
United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 843
Inspection Date: 15-Jun-2023

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
843	63-R-0105	001	UNIV OF TENNESSEE KNOXVILLE OFF LAB AN CARE	15-JUN-2023

Count	Scientific Name	Common Name
000020	<i>Equus caballus</i>	DOMESTIC HORSE
000016	<i>Capra hircus</i>	DOMESTIC GOAT
000020	<i>Canis familiaris</i>	DOG ADULT
000001	<i>Ovis aries aries</i>	SHEEP INCLUDING ALL DOMESTIC BREEDS
000083	<i>Mesocricetus auratus</i>	SYRIAN / GOLDEN HAMSTER
000008	<i>Bos taurus</i>	CATTLE / COW / OX / WATUSI
000008	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
000002	<i>Lama pacos</i>	ALPACA
000158	Total	



CFR:2.32(a)

Photographer: Michelle B.
Williams

Certificate: 63-R-0105

Date and Time: 7/13/2023 11:09
AM

Legal Name: UNIV OF TENNESSEE KNOXVILLE OFF LAB AN
CARE

Inspection No:
2016090000874440

Facility Name: UNIV OF TENNESSEE KNOXVILLE OFF LAB AN
CARE

Description: Redacted documents provided by University



United States Department of Agriculture
Animal and Plant Health Inspection Service

MWILLIAMS
INS-0000896230

Inspection Report

UNIV OF TENNESSEE KNOXVILLE OFF LAB AN CARE

2415 Fletcher Luck Lane
Third Creek Building
KNOXVILLE, TN 37996

Customer ID: **843**

Certificate: **63-R-0105**

Site: 001

UNIV OF TENNESSEE
KNOXVILLE OFF LAB AN CARE

Type: FOCUSED INSPECTION

Date: 21-SEP-2023

No non-compliant items identified during this inspection.

This inspection and exit interview were conducted with the Director/IACUC Chair.

Prepared By: MICHELLE WILLIAMS

USDA, APHIS, Animal Care

Date:

26-SEP-2023

Title: VETERINARY MEDICAL
OFFICER

Received by Title: IACUC Representative

Date:

26-SEP-2023



United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 843
Inspection Date: 21-Sep-2023

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
843	63-R-0105	001	UNIV OF TENNESSEE KNOXVILLE OFF LAB AN CARE	21-SEP-2023

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	



USDA-APHIS-Animal Care

24-00261-F-000038



ANIMAL WELFARE COMPLAINT		
Complaint No. AC23-0494	Date Entered: April 21, 2023	Processed By: Amy Benson
Referred To: Jeffrey Shepherd		Reply Due: June 19, 2023
Facility or Person Complaint Filed Against		
Name: UNIV OF TENNESSEE KNOXVILLE OFF LAB AN CARE	Customer No.: 843	License No.:
Address: 2415 Fletcher Luck Lane Third Creek Building		Email Address:
City: Knoxville	State: TN	Phone No.: (865) 974-5634
Complainant Information		
Name: [REDACTED]	Organization: SAEN	
Address:		Email Address: saen@cinci.rr.com
City:	State:	Phone No.:
How was the Complaint received? Email		
Details of Complaint: See attached.		
Results: The animal incident addressed in the complaint concerning the death of 4 of the 12 hamsters on a protocol has been verified during an inspection conducted June 15, 2023. The incident was thoroughly investigated by the Institutional Care and Use Committee at the time of the occurrence. Corrective measures were immediately put in place to provide additional training and oversight. Corrective measures taken are considered appropriate. USDA will continue to monitor the facility through regular unannounced inspections to ensure the animals are cared for as required under the Animal Welfare Act and the Animal Welfare Regulations.		
Application Kit Provided: Yes: No:		
Inspector: MICHELLE WILLIAMS		Date: June 21, 2023
Reviewed By: Jeffrey Shepherd		Date: June 23, 2023



United States Department of Agriculture

Animal and Plant
Health Inspection
Service

Animal Care

Fort Collins Office
2150 Centre Avenue
Building B, 3W11
Fort Collins, CO 80526
Phone: 970-494-7478

April 21, 2023

SAEN

saen@cinci.rr.com

Dear Complainant,

Thank you for your correspondence that we received April 18, 2023. We are reviewing your concerns and assigned tracking number AC23-0494. Please allow us enough time (30 to 60 days) to thoroughly look into your concerns. You may submit a request to the Animal and Plant Health Inspection Service (APHIS) Freedom of Information Act (FOIA) office to obtain any publicly available information regarding our review.

FOIA Requests can be submitted three ways:

1. Web Request Form: <https://efoia-pal.usda.gov/App/Home.aspx>
2. Fax: 301-734-5941
3. US Mail:
USDA- APHIS- FOIA
4700 River Road, Unit 50
Riverdale, MD 20737

Should you have any questions regarding the APHIS FOIA process or need assistance using the Web Request Form **please contact the APHIS FOIA office at 301-851-4102.**

Animal Care is a program within the U.S. Department of Agriculture (USDA) that directs activities to ensure compliance with and enforcement of the Animal Welfare Act and the Horse Protection Act. Animal Care establishes standards of humane treatment for regulated animals and monitors and achieves compliance through inspections, enforcement, education, and cooperative efforts under the Acts.

Please be assured that we will look into your concern(s) and take appropriate action(s).

Thank you for your interest into the humane treatment of these animals.

Sincerely,

Elizabeth Goldentyer, D.V.M.
Deputy Administrator
USDA, APHIS, Animal Care

MRP.APHIS.AC.Complaints

From: saen@cinci.rr.com
Sent: Tuesday, April 18, 2023 7:33 PM
To: Gibbens, Robert – MRP-APHIS; APHIS-AnimalCare
Subject: [External Email]Prosecute the University of Tennessee

[External Email]

If this message comes from an **unexpected sender** or references a **vague/unexpected topic**;
 Use caution before clicking links or opening attachments.
 Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov



Dr. Robert Gibbens
 4/18/23
 Director, Animal Welfare Operations, USDA/APHIS/AC,
 Via email: robert.m.gibbens@aphis.usda.gov ; animalcare@usda.gov

Dr. Gibbens,

I am writing to you today to file an Official Complaint against the University of Tennessee (UT), Knoxville (63-R-0105), regarding unapproved procedures performed on 12 hamsters, 4 of whom died.

I have obtained an 11/11/22 report filed by UT which admits to the violation (noncompliance). It states: *"The University of Tennessee, Knoxville, in accordance with Assurance Number D16-00392 and PHS Policy IV.F.3 provides this report of noncompliance regarding twelve Syrian hamsters used for virulence testing by a post-doctoral research associate; virulence testing was not reviewed or approved by the IACUC in the Principal investigator's (PI) animal study entitled "Leptospira Research - Experimental Inoculation in Hamsters." (Emphasis added)*

The report continues: *"The bacterial agent was injected on 9/13/22 and the three hamsters receiving the highest dose were found dead by lab animal facility staff during a routine check on 9/17/22. A fourth animal was found dead on 9/19/22."*

According to the report an earlier unapproved study of this type was also performed, but no fatalities were involved: *"An experiment has been conducted earlier this year in which doses of 10⁶, 10⁷, and 10⁸, cells were used to inoculate hamsters."*

As you know, all projects involving regulated species, such as hamsters, must be approved by the IACUC before they are performed. The report overtly states *"virulence testing was not reviewed or approved by the IACUC in the Principal investigator's (PI) animal study."* Therefore both of these unapproved studies would violate *Sec. 2.31 Institutional Animal Care and Use Committee (IACUC)*

Each hamster death may violate *Sec. 2.33 Attending veterinarian and adequate veterinary care*, and this code section may also be violated by the fact that according to this report there was: *"Failure to record required second daily health checks of the animals during the second experiment was noted."*

Since at least 4 animals died as a result of these non-compliances, it is clear that these incidents meet the requirement for issuance of the more serious CRITICAL violations, which requires that the noncompliance had *"a serious or severe adverse effect on the health and well-being of the animal,"* there is no more serious or severe an adverse effect than one which causes death.

It must also be noted that the symptoms of leptospirosis infection include fever, vomiting, abdominal pain, diarrhea, and severe muscle pain. Therefore the 2022 annual report for UT must list these hamsters in Column E and explain their use in an experiment involving unrelieved pain. Unfortunately, the 2022 annual report for UT is not available online, but it should already have been filed. If no hamsters are listed in Column E then UT has also violated the reporting requirements of *Sec. 2.36 Annual Report*.

Since University of Tennessee, Knoxville, staff negligence has unnecessarily killed at least four hamsters, in unapproved experiments (to say nothing of the symptoms experienced by the other 8 hamsters), I must insist that you take the most severe action allowable under the Animal Welfare Act and immediately launch a full investigation, and at the conclusion of the investigation issue the maximum fine allowable against the University of Tennessee, Knoxville (63-R-0105) -- \$12,722 per infraction/per animal for all twelve hamsters — a potential total of \$147,264. I look forward to hearing from you in the near future about the fate of this facility.

Sincerely,



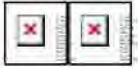
(b) (6), (b) (7)(C), (b) (7)(D)
 [redacted], SAEN

Attachment: 1 University of Tennessee, Knoxville, OLAW Report

1081-B State Route 28 #280 Milford, OH 45150

513-575-5517

www.SAENonline.org





United States Department of Agriculture

Animal and Plant Health
Inspection Service

Animal Care

Riverdale, MD Office:
4700 River Road
Unit 84
Riverdale, MD 20737
Voice 301.851.3751
Fax 301.734.4978

VIA: UPS Delivery Service

August 24, 2023

UNIV OF TENNESSEE KNOXVILLE OFF LAB AN CARE

2415 Fletcher Luck Lane
Third Creek Building
KNOXVILLE, TN 37996

OFFICIAL WARNING NOTICE OF ALLEGED VIOLATION

Re: Reference number TN230053

Dear Sir or Madam:

We believe that you failed to comply with the Animal Welfare Act (7 U.S.C. § 2131 et seq.) (AWA), and its implementing regulations, as described in the attached Official Warning. Our agency, the Animal and Plant Health Inspection Service (APHIS), is responsible for enforcing the AWA, and regulations and other agriculture laws that help prevent the spread of animal and plant pests and diseases and ensure the welfare of animals.

After providing you with an opportunity for a hearing, we may pursue civil penalties of up to \$10,000, subject to adjustments for inflation, or other sanctions, for each alleged violation described in this Official Warning. Although we have authority to pursue penalties for the type of alleged violation(s) described in this Official Warning, we have decided not to pursue penalties in this instance so long as you comply, in the future, with the AWA and regulations.

What happens if I do not comply in the future? If you fail to comply in the future, we may pursue criminal penalties, or we may pursue civil penalties for the alleged violations described in this Official Warning, in addition to any penalties we may pursue for any future violations.

What should I do if I have questions? If you have any questions concerning this Official Warning, contact Jeffrey Shepherd, Assistant Director of Field Operations, at jeffrey.shepherd@usda.gov or call our main office at (970) 494-7478, between 9:00 a.m. and 5:00 p.m. Mountain Standard Time.

I am a small business owner and have comments or concerns regarding APHIS's enforcement of animal and plant health laws. Who should I contact? If you have comments about APHIS's enforcement of animal and plant health laws, please contact Sarah Helming, the APHIS Small Business Ombudsperson, at (301) 851-2248. If you prefer to comment to someone outside APHIS, contact the Small Business Regulatory Enforcement Ombudsman at <http://sba.gov/ombudsman>, email ombudsman@sba.gov, or 1-888-REG-FAIR. The SBA Ombudsman's office receives comments and annually evaluates federal agency enforcement activities for their responsiveness to the special needs of small businesses.

Sincerely,

Dr. Roxanne Mullaney, D.V.M.
Acting Deputy Administrator
APHIS Animal Care



<p>UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE</p> <p>USDA</p> <p>OFFICIAL WARNING</p> <p>NOTICE OF ALLEGED VIOLATION</p>	<p>CASE NUMBER: TN230053</p>
	<p>ALLEGED VIOLATOR: UNIV OF TENNESSEE KNOXVILLE OFF LAB AN CARE</p>
	<p>ADDRESS (City, State, ZIP Code): KNOXVILLE, TN 37996</p>
<p>The U.S. Department of Agriculture has evidence that on or about the date(s) listed below, you or your organization committed the following alleged violation(s) of Federal laws:</p> <p>Date of Alleged Violation: June 15, 2023</p> <p>9 C.F.R. § 2.32(a) Personnel qualifications.</p> <p>It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel.</p>	

The Animal and Plant Health Inspection Service (APHIS) published federal regulations to ensure the welfare of animals and help prevent the spread of animal and plant pests and diseases. Since violations of the regulations can have serious and costly impacts that are detrimental to the public interest, APHIS is providing you with an Official Warning for the alleged violation(s) described above. This Official Warning is not to be construed as a final agency action, or as an adjudicated finding of a violation. If APHIS obtains evidence of any future violation of these federal regulations, APHIS may pursue civil penalties, criminal prosecution, or other sanctions for this alleged violation(s) and for any future violation(s). If you have any questions concerning this Official Warning or alleged violation(s), please contact the APHIS official listed in this notice.

APHIS OFFICIAL (Name): Dr. Roxanne Mullaney, D.V.M.	OFFICE ADDRESS: 4700 River Road, Unit 84 Riverdale, MD 20737	
APHIS OFFICIAL (Title): Acting Deputy Administrator, APHIS, Animal Care	DATE ISSUED: August 24, 2023	TELEPHONE NUMBER: (970) 494-7478

APHIS FORM 7060

Previous editions may be used

Rev. 4-23-21