



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

August 7, 2018

Re: Animal Welfare Assurance
#A3244-01 (OLAW Case K)

Dr. Jane Schuh
Vice President for Research and
Creative Activity
North Dakota State University
1735 NDSU Research Park Drive
Fargo, ND 58105

Dear Dr. Schuh,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated August 1, 2018, reporting noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at North Dakota State University. According to the information provided, OLAW understands that your institution's IACUC identified a programmatic deviation from the provision of the *Guide for the Care and Use of Laboratory Animals* requiring "direct and frequent communication... to the responsible veterinarian about issues associated with animal health, behavior, and well-being." The three incidents that were documented by the USDA on a June 20, 2017 inspection report and a May 23, 2018 report demonstrated a lack of understanding on the part of animal users regarding the requirement to promptly notify the veterinarian concerning unexpected animal death(s) and the need to submit such animals for necropsy and other testing. It is understood that none of the individual incidents involved animals supported with PHS funds.

Corrective measures put in place included counseling of involved individuals by the Attending Veterinarian and the IACUC Administrator. In addition, applicable SOPs and other documentation were developed. Appropriate training and documentation of training were also implemented. It is further understood that your new Attending Veterinarian has implemented several proactive measures to increase communication with animal users at your institution.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken by North Dakota State University to provide corrective measures and prevent recurrence of this noncompliance. Although these activities were not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate your cooperation in this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

August 7, 2018

Dr. Alka Chandna
Vice President, Laboratory Investigations Cases
Laboratory Investigations Department
People for the Ethical Treatment of Animals
1536 16th Street, NW
Washington, DC 20036

Dear Dr. Chandna:

The Office of Laboratory Animal Welfare (OLAW) has completed its investigation regarding allegations by People for the Ethical Treatment of Animals (PETA) concerning North Dakota State University as contained in your July 17, 2018 email to our Office with attached USDA Inspection Reports. Background information was reviewed, and interviews conducted. OLAW has determined that, although these activities were not PHS-supported, they represented a programmatic deviation from the provision of the *Guide for the Care and Use of Laboratory Animals* requiring "direct and frequent communication... to the responsible veterinarian about issues associated with animal health, behavior, and well-being." In response to these incidents, the University had already implemented several corrective and preventive measures including new SOPs, animal health and facility maintenance observation documentation, and staff training. The new Attending Veterinarian has also implemented several proactive measures to enhance communication with animal users. As a result, OLAW expects that future incidents of unexpected animal deaths will be promptly and accurately reported to the veterinary staff. OLAW shares your concern for the welfare of laboratory animals. We find no cause for further action by this office at this time.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

NDSU NORTH DAKOTA STATE UNIVERSITY

August 1, 2018

Dr. Brent Morse
Director-Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

Re: Serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* – Veterinary Care (D16-00156)-AMENDED

Dear Dr. Morse:

The *Guide* requires that a mechanism for direct and frequent communication should be established to ensure that timely and accurate information is conveyed to the responsible veterinarian about issues associated with animal health, behavior, and well-being. The purpose of this letter is to report a programmatic deviation from the provisions of the *Guide*.

North Dakota State University was cited under Section 2.33 (b) Attending Veterinarian and Adequate Veterinary Care, by the United States Department of Agriculture (USDA) on June 20, 2017 (critical) and May 23, 2018 (repeat).

- June 20, 2017 Inspection report-"A review of the institutional records showed that between 09 January 2017 and 10 May 2017, a captive colony of 22 wild-caught bats, under active IACUC approved protocol (#A16069) and housed in an institutional facility, experienced a 100% mortality loss. Losses on multiple dates were indicated on PI records but no records were available to verify that the attending veterinarian had been contacted and appropriate timely diagnostic tests conducted to determine the cause or causes of the ongoing colony mortality."
- May 23, 2018 Inspection report-"Eleven Romanov lambs died during weaning and processing in the ANPC building on March 23, 2018. At the time of the event, the lambs were under IACUC approved protocol A16045. The current NDSU IACUC Adverse Event and Protocol Deviation Reporting document requires that the PI and/or animal care staff must report an unanticipated adverse event or protocol deviation within 72 hours to the IACUC Office. The IACUC office in turn notifies the attending veterinarian. The document also stipulates that animals that die unexpectedly, or are euthanized unexpectedly in a research study, must be submitted to a veterinary diagnostic laboratory for necropsy. The institutional attending veterinarian was not informed about the lamb deaths until May 4, 2018. This was approximately 6 weeks after the adverse event occurred. Additionally, none of the eleven lambs that died were presented for necropsy to a veterinary diagnostic laboratory."

OFFICE OF THE VICE PRESIDENT FOR RESEARCH AND CREATIVE ACTIVITY
NDSU Dept 4000 | PO Box 6050 | Fargo ND 58108-6050 | 701.231.6542 | Fax 701.231.8098 | www.ndsu.edu/research

Shipping address: 1735 NDSU Research Park Drive | Fargo ND 58102

NDSU is an Equal Opportunity Institution

Also cited on the May inspection report was an adverse event involving pigs at the NDSU Swine Unit.

- May 23, 2018 Inspection report-"On May 9, 2018, a water line supplying drinking water to fourteen hogs located in pen 6 in the commercial room of the swine unit building, was found to be non-functional by facility personnel. The fourteen hogs were then moved to another pen with water on the same day. One of the fourteen hogs was found dead later during the day of May 09. Another hog in the group subsequently died on the morning of May 10. A third hog from the group, which had become debilitated, was euthanized on May 11. The affected hogs were under IACUC approved protocol #A17043 and were 6 months of age at the time of the event. The remaining eleven hogs from the pen survived and were reported to have no outward signs of distress nor debilitation. The facility attending veterinarian was contacted by the swine unit manager on May 10."

None of the above incidents cited by the USDA involved PHS funded animals.

The Attending Veterinarian and IACUC Administrator have met with the involved personnel for each of the events multiple times. Corrective actions were taken by both facilities, which included the following: development of standard operating procedures, implementation of daily observation logs, implementation of processes to identify broken equipment, and appropriate training and documentation of training.

On June 1, 2018, Dr. Neil Dyer accepted the full-time AV position. He had been in the interim AV-position since June 2017 after the previous AV was let go. Dr. Dyer has implemented bi-monthly meetings with small-animal and large animal facility personnel. In addition, he formed the NDSU Animal Care Advisory Committee, which has representation from each department on campus that utilizes animals. The goal of these meetings is to open communication lines across campus, to provide a venue for continuous education and improve processes and procedures.

If you have any questions regarding this incident, please contact the IACUC Office at 701-231-8114.

Sincerely,

(b) (6)

Jane Schuh, Ph.D.
Institutional Official
Vice President for Research and Creative Activity

cc: Robert Gibbens, Regional Director-USDA Animal Care-Western Division
Thomas Secor, Veterinary Medical Officer
John Wilkinson, IACUC Chair
Neil Dyer, Attending Veterinarian

(b) (6)

(b) (6)

(b) (6)

(b) (6)

(b) (6)



United States Department of Agriculture
Animal and Plant Health Inspection Service

2016082569161492 Insp_id

TSECOR

Inspection Report

North Dakota State University
1735 N D S U Research Park Drive
Research 1, P.O. Box 6050
Fargo, ND 58108

Customer ID: 1565

Certificate: 45-R-0002

Site: 001

NORTH DAKOTA STATE UNIVERSITY

Type: FOCUSED INSPECTION

Date: 23-MAY-2018

2.33(b)

REPEAT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

on Assur. Facil. Invent.
for S/A

Eleven Romanov lambs died during weaning and processing in the ANPC building on March 23, 2018. At the time of the event, the lambs were under IACUC approved protocol #A16045. The current NDSU IACUC Adverse Event and Protocol Deviation Reporting document requires that the PI and/or animal care staff must report an unanticipated adverse event or protocol deviation within 72 hours to the IACUC Office. The IACUC Office in turn notifies the attending veterinarian. The document also stipulates that animals that die unexpectedly, or are euthanized unexpectedly in a research study, must be submitted to a veterinary diagnostic laboratory for necropsy. The institutional attending veterinarian was not informed about the lamb deaths until May 04, 2018. This was approximately 6 weeks after the adverse event occurred. Additionally, none of the eleven lambs that died were presented for necropsy to a veterinary diagnostic laboratory.

Direct and timely communication with the attending veterinarian and appropriate diagnostic testing are essential to the well-being of all institutional animal herds, flocks and colonies when unexpected mortality or morbidity occurs. A mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior and well-being is communicated to the attending veterinarian.

Not PHS\$

2.131

CRITICAL

HANDLING OF ANIMALS.

On March 23, 2018, while weaning and processing Romanov lambs in the ANPC building, facility personnel found eleven Romanov lambs dead inside a temporary holding pen located along the east wall of the sheep area. The

Prepared By:

SECOR THOMAS, D.V.M

SECOR THOMAS, D.V.M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER 6108

Received By:

Title:

Date:

31-MAY-2018

Date:

31-MAY-2018



Inspection Report

sheep were under IACUC approved protocol #A16045 at the time of the event. The attending veterinarian for the institution was informed of the lamb deaths by ANPC personnel on May 04, 2018. On May 11, 2018, following an investigation of the deaths, the attending veterinarian contacted the USDA inspector (VMO) to inform the USDA of the adverse event and investigation results.

The holding pen was empty at the time of USDA inspection on 05-23-2018. Discussion with facility personnel revealed that 150 lambs and 63 ewes had been placed into the pen on 03-23-2018 for the purpose of staging the lambs for weaning, elastrator band placement and vaccinations. Approximately ninety minutes after the pen had been filled, barn personnel discovered the sheep had piled to one side of the pen and eleven lambs had died. The lambs, which were 8 to 13 weeks of age at the time, had not yet undergone any of the weaning procedures described above. Square footage of the pen was measured at the time of USDA inspection and was found to be approximately 348.5 square feet (25' 2" L (length) X 13' 2" W (width), with an additional 10' 11" L X 4" W wall cove area).

Handling of all animals shall be done as expeditiously and carefully as possible, and in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort. Failure to restrain and handle animals properly may result in increased animal distress, injury or death.

During the inspection, facility representative proffered corrective actions to help prevent future mortalities during weaning and processing of lambs. The corrective actions include: reduced ewe and lamb group sizes in holding pens when processing, additional training for students and personnel on handling, increased observation frequency during processing, and timely communication with the attending veterinarian when issues occur.

Correct this date forward.

3.130

CRITICAL

WATERING.

On May 09, 2018, a water line supplying drinking water to fourteen hogs located in pen 6 in the commercial room of the swine unit building, was found to be non-functional by facility personnel. The fourteen hogs were then moved to another pen with water on the same day. One of the fourteen hogs was found dead later during the day of May 09. Another hog in the group subsequently died on the morning of May 10. A third hog from the group, which had become debilitated, was euthanized on May 11. The affected hogs were under IACUC approved protocol #A17043 and were 6 months of age at the time of the event. The remaining eleven hogs from the pen survived and were

Prepared By:

SECOR THOMAS, D.V.M

SECOR THOMAS, D.V.M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER 6108

Received By:

Title:

Date:

31-MAY-2018

Date:

31-MAY-2018



Inspection Report

reported to have no outward signs of distress nor debilitation. The facility attending veterinarian was contacted by the swine unit manager on the morning of May 10. The facility attending veterinarian contacted the USDA inspector (VMO) on the morning of May 11 2018 to inform the USDA of the adverse event.

No hogs were present in pen 6 during USDA inspection on May 23, 2018. Discussion with facility representatives revealed that ceiling work had been done in the room prior to the event and the hogs had been temporarily moved to another pen in the room. According to the corrective action report supplied by the facility, a nylon fitting on the valve of the water line supplying water to the pen had been found to be defective at the time the hogs were initially removed from pen 6. The hogs were then moved back into the pen (pen 6) on May 02. Facility personnel discovered that the water line fitting had not been repaired and the line was non-functional on May 09 2018. Subsequent necropsy of one of the hogs that died (VDL Ascension Report #18-5104) revealed findings consistent with dehydration and water deprivation.

If potable water is not accessible to the animals at all times, it must be provided as often as necessary for the health and comfort of the animal. Failure to provide potable drinking water at adequate frequency or amounts may result in undue stress, dehydration, debilitation or death.

During the inspection, facility representative proffered corrective actions to help prevent potential future mortalities. The corrective actions include: a daily observation checklist which includes all watering devices, timely reporting of animal issues to the attending veterinarian, and a reporting system to the facility manager and personnel when broken or non-functional equipment is found. Newly installed dry erase boards for reporting equipment issues were also observed to be present in the swine unit at the time of USDA inspection.

Correct this date forward.

The inspection and exit interview were conducted with the Attending Veterinarian and the IACUC Coordinator on May 23 and May 24 2018.

This amended inspection report replaces report id # 2016082569157896 previously submitted, signed and dated on 05-24-2018.

(Amended inspection report sent on 05-31-2018 by certified mail # 7013 2630 0002 3415 1518)

Prepared By:

SECOR THOMAS, D.V.M

SECOR THOMAS, D.V.M USDA, APHIS, Animal Care

Date:

31-MAY-2018

Title: VETERINARY MEDICAL OFFICER 6108

Received By:

Title:

Date:

31-MAY-2018



Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1565	45-R-0002	001	NORTH DAKOTA STATE UNIVERSITY	23-MAY-18

Count	Scientific Name	Common Name
000081	<i>Ovis aries aries</i>	SHEEP INCLUDING ALL DOMESTIC BREEDS
000009	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000090	Total	

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Wednesday, July 18, 2018 9:22 AM
To: 'Dr. Alka Chandna'
Subject: RE: Concerns re treatment of animals at North Dakota State University

Hello Dr. Chandna,

OLAW acknowledges receipt of your email below with attachment. We will evaluate the reports and investigate if appropriate and take any required actions.

Regards, Brent Morse

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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Dr. Alka Chandna [mailto:AlkaC@peta.org]
Sent: Tuesday, July 17, 2018 11:11 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: Concerns re treatment of animals at North Dakota State University

Dear Dr. Morse,

Kindly find attached a U.S. Department of Agriculture inspection report, dated May 23, 2018, documenting "critical" and "repeated" violations of Animal Welfare Regulations at North Dakota State University (NDSU; PHS Assurance # D16-00156, A3244-01). The incidents documented in the report appear to us to also violate the Public Health Service Policy on Humane Care and Use of Laboratory Animals and the provisions stipulated in the Guide for the Care and Use of Laboratory Animals. We do not know whether the incidents in the report are covered by NDSU's Assurance and would be grateful if you could investigate the matter. If any of the animal deaths documented at NDSU occurred in connection with taxpayer-supported projects, we ask that your office initiate action to ensure that those funds are promptly returned to the government.

Thank you for your time and consideration.

Sincerely,

Alka Chandna

Alka Chandna, Ph.D.
Vice President, Laboratory Investigations Cases
Laboratory Investigations Department
People for the Ethical Treatment of Animals

1536 16th Street NW, Washington, DC 20004

The more we learn of the true nature of non-human animals, especially those with complex brains and corresponding complex social behavior, the more ethical concerns are raised regarding their use in the service of man -- whether this be in entertainment, as "pets," for food, in research laboratories, or any of the other uses to which we subject them. – Dr. Jane Goodall



Division of Compliance Oversight

Record of Call for Case # A3422 -

Date & Time	Message	Initials
7/19/18 4:10	Spoke w/ [REDACTED] (b) (6) They will send report to OLAW re: Reporting to A/V. Crowding of lambs + lack of water to hogs not PHS\$ + not programmatic and not reportable to OLAW	
		zmn