

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE



**OFFICIAL WARNING
NOTICE OF ALLEGED VIOLATION**

CASE NUMBER:
WA170033

VIOLATOR:
Jubilant Hollister-Stier (JHS)

Customer# 1021
Registrant# 91-R-0011
ADDRESS (City, State):
Spokane, WA

The Animal and Plant Health Inspection Service (APHIS) has evidence that on or about August 8, 2017 and April 11, 2017, you failed to comply with the regulations issued under the Animal Welfare Act (7 U.S.C. § 2131 *et seq.*) (AWA), as documented in the attached inspection report(s).

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 animals and the public interest, APHIS is providing you with this Official Warning. This Official Warning is not to be construed as a final agency action or an adjudicated finding of a violation. If APHIS obtains evidence of any violation of these Federal regulations in the future, APHIS may pursue civil penalties and other sanctions for these alleged violations and for any future violations. If you have any questions concerning this Official Warning, please contact the APHIS office telephone number listed in this notice.

APHIS OFFICIAL (Name):
Gerald Rushin

OFFICE ADDRESS:
4700 River Road
Riverdale, MD 30737

APHIS OFFICIAL (TITLE):
Assistant Deputy Administrator
Animal Care

DATE ISSUED: September 7, 2017	TELEPHONE NO: (970) 494-7478
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CERTIFIED MAIL RECEIPT NO:
7017 0530 0000 3207 5330



Inspection Report

Jubilant Hollister-Stier (J H S)
N. 3525 Regal Street
Spokane, WA 99207

Customer ID: **1021**

Certificate: **91-R-0011**

Site: 001

JUBILANT HOLLISTER-STIER (J H S)

Type: **FOCUSED INSPECTION**

Date: **08-AUG-2017**

2.31(d)(1)(xi) CRITICAL REPEAT

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

This inspection was a focused inspection to verify correction of items previously documented as non-compliant during the previous USDA inspection on April 11 2017. The facility has not yet corrected deficiencies previously cited under 2.31 (d)(1)(xi) for euthanasia of guinea pigs with carbon dioxide gas. This is a repeat critical non-compliance.

The method of euthanasia for guinea pigs in the facility utilizes tanked carbon dioxide gas delivered to a euthanasia chamber. The chamber is a galvanized tub covered with a clear acrylic plastic lid. A pressure reducing regulator is connected to the gas tank and is used to control gas pressure from the tank to the gas supply line going to the tub enclosure. No flow meter or other monitoring device is present in the system to monitor gas flow rates into the chamber. A facility manager stated the outflow pressure of gas from the tank is set at 30 psi at the regulator. The facility written euthanasia procedure states "turn on the CO2 at 20 to 50 pounds PSI until no further animal movement is observed."

The described facility procedure for euthanasia of guinea pigs with carbon dioxide gas does not meet current standards set forth in the AVMA Guidelines for the Euthanasia of Animals: 2013 Edition. The procedure in use by the facility lacks a flow meter to accurately maintain and monitor consistent gas flow rates to the chamber during the euthanasia process. The use of a tank regulator pre-set at a specific psi is not sufficient of itself to ensure that an accurate flow rate of carbon dioxide gas is being consistently delivered to the euthanasia chamber and recommended gas displacement rates are being achieved. Without an appropriate sized flow meter in place, chamber gas displacement rates may be too high or too low. This may then lead to significant pain and distress to guinea pigs during the euthanasia process.

Obtained by R

AVMA guidelines for carbon dioxide gas usage recommend a chamber displacement rate of 10-30% of chamber volume/minute. This displacement rate has been found to produce less pain and distress during the onset of unconsciousness than other rates.

Prepared By:

SECOR THOMAS, V M O USDA, APHIS, Animal Care

11-AUG-2017

Title: VETERINARY MEDICAL OFFICER 6108

Received By:

(b) (6), (b) (7)(C)

Title: SENT E-MAIL/ CERTIFIED MAIL #70132630000234151914
18-00296_001098

Date:
11-AUG-2017



Inspection Report

Overall, methods of euthanasia used must be in accordance with AVMA species guidelines and in accordance with 9 CFR part 1, unless a deviation has been previously justified in writing and approved by the IACUC.

A flow meter and appropriate methodology shall be employed to ensure that accurate carbon dioxide gas flow rates and chamber displacement rates are consistently maintained and monitored by facility personnel during the euthanasia process. In conjunction, animals need to be visually monitored by personnel throughout the euthanasia process and SOPs updated with required flow meter settings. Retraining of all employees who perform euthanasia shall also be done and documented.

Regarding deficiencies previously cited on last inspection under 2.33 (b)(2), the facility has corrected the deficiencies, Contact information for the attending veterinarian and provision of emergency, weekend and holiday veterinary care have also been posted within the animal facility.

This inspection and exit interview were conducted with the Manager of Regulatory Affairs, Director of Regulatory Affairs, QC- Microbiology Supervisor and the QC - Microbiology Manager.

Obtained by R

Prepared By:

SECOR THOMAS, V M O USDA, APHIS, Animal Care

11-AUG-2017

Title: VETERINARY MEDICAL OFFICER 6108

Received By:

(b) (6), (b) (7)(C)

Title: SENT E-MAIL/ CERTIFIED MAIL #70132630000234151914
18-00296_001099

Date:
11-AUG-2017



Cust No	Cert No	Site	Site Name	Inspection
1021	91-R-0011	001	JUBILANT HOLLISTER-STIER (J H S)	08-AUG-17

Count	Species
000020	DOMESTIC GUINEA PIG
000020	Total

Obtained by R



Inspection Report

Jubilant Hollister-Stier (J H S)
N. 3525 Regal Street
Spokane, WA 99207

Customer ID: **1021**

Certificate: **91-R-0011**

Site: 001

JUBILANT HOLLISTER-STIER (J H S)

Type: --RESCINDED--

Date: 08-AUG-2017

2.31(d)(1)(xi) CRITICAL REPEAT

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (d) (1) (xi)

This inspection was a focused inspection to verify correction of items previously documented as non-compliant during the previous USDA inspection on April 11 2017. The facility has not yet corrected deficiencies previously cited under 2.31 (d)(1)(xi) for euthanasia of guinea pigs with CO2. This is a repeat critical non-compliance.

Facility procedure for euthanasia of guinea pigs with carbon dioxide does not adhere to standards listed in the current AVMA Guidelines for the Euthanasia of Animals: 2013 Edition. The guidelines allow for carbon dioxide euthanasia of laboratory rodents (which include guinea pigs) when the flow of carbon dioxide provides a displacement rate of 10-30% of chamber volume/min. This is best achieved by the use of flow meter to ensure an accurate flow rate of carbon dioxide gas is being delivered to the chamber at the recommended displacement rate (10-30% chamber volume/min).

The method currently employed by the facility lacks a flow meter and method for accurately determining the chamber displacement rate. The output dial in current use by the facility utilizes regulator pressure readings (psi) which do not provide accurate flow rates for carbon dioxide into the chamber.

Carbon dioxide exposure using a gradual fill method with chamber displacement rates from 10-30% is less likely to produce pain and distress prior to onset of unconsciousness than higher or lower rates. Methods of euthanasia used must be in accordance with AVMA species guidelines and in accordance with 9 CFR part 1, unless a deviation has been previously justified in writing and approved by the IACUC.

Obtained by R

A flow meter must be installed, SOPs updated with required flow meter settings, and retraining of employees who perform euthanasia shall be documented.

Prepared By:

SECOR THOMAS, V M O USDA, APHIS, Animal Care

08-AUG-2017

Title: VETERINARY MEDICAL OFFICER 6108

Received By:

(b) (6), (b) (7)(C)

Title:
18-00296_001026

Date:
08-AUG-2017



Inspection Report

Regarding deficiencies previously cited on last inspection under 2.33 (b)(2), the facility has corrected the deficiencies, Contact information for the attending veterinarian and provision of emergency, weekend and holiday veterinary care have also been posted within the animal facility.

This inspection and exit interview were conducted with the Manager of Regulatory Affairs, Director of Regulatory Affairs, QC- Microbiology Supervisor and the QC - Microbiology Manager.

Obtained by R

Prepared By:

SECOR THOMAS, V M O USDA, APHIS, Animal Care

08-AUG-2017

Title: VETERINARY MEDICAL OFFICER 6108

Received By:

(b) (6), (b) (7)(C)

Date:
08-AUG-2017

Title:
18-00296_001023



Cust No	Cert No	Site	Site Name	Inspection
1021	91-R-0011	001	JUBILANT HOLLISTER-STIER (J H S)	08-AUG-17

Count	Species
000078	DOMESTIC GUINEA PIG
000078	Total

Obtained by R



Inspection Report

Jubilant Hollister-Stier (J H S)
N. 3525 Regal Street
Spokane, WA 99207

Customer ID: 1021

Certificate: 91-R-0011

Site: 001

JUBILANT HOLLISTER-STIER (J H S)

Type: ROUTINE INSPECTION

Date: 11-APR-2017

2.31(d)(1)(xi) CRITICAL

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (d) (1) (xi)

Facility procedure for euthanasia of guinea pigs with carbon dioxide does not adhere to standards laid forth in the current AVMA Guidelines for the Euthanasia of Animals: 2013 Edition. The guidelines allow for carbon dioxide euthanasia of laboratory rodents (which include guinea pigs) when the flow of carbon dioxide provides a displacement rate of 10-30% of chamber volume/min. This is best achieved by the use of flow meter to ensure an accurate flow rate of carbon dioxide gas is being delivered to the chamber at the recommended displacement rate (10-30% chamber volume/min).

The method currently employed by the facility lacks a flow meter and method for accurately determining the chamber displacement rate. The output dial in current use by the facility utilizes regulator pressure readings (psi) which do not provide accurate flow rates for carbon dioxide into the chamber.

Carbon dioxide exposure using a gradual fill method with chamber displacement rates from 10-30% is less likely to produce pain and distress prior to onset of unconsciousness than higher or lower rates. Methods of euthanasia used must be in accordance with AVMA species guidelines and in accordance with 9 CFR part 1, unless a deviation has been previously justified in writing and approved by the IACUC.

A flow meter must be installed, SOPs updated with required flow meter settings, and retraining of employees who perform euthanasia shall be documented.

Correct by 05-15-2017

Obtained by R

Prepared By:

SECOR THOMAS, V M O USDA, APHIS, Animal Care

18-APR-2017

Title: VETERINARY MEDICAL OFFICER 6108

Received By:

(b) (6), (b) (7)(C)

Title: SENT BY E-MAIL
18-00296_001027

Date:
18-APR-2017



Inspection Report

2.33(b)(2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

The program of veterinary care lacks detail regarding facility procedures for contacting the attending veterinarian for animal related issues and for provision of emergency, weekend and holiday veterinary care.

Timely and direct communication of animal related issues by animal facility staff to the attending veterinarian is important for the well-being and health of research animals.

Each research facility shall establish and maintain programs of adequate veterinary care that include the use of appropriate methods to prevent, control, diagnose and treat diseases and injuries, and the availability of emergency, weekend and holiday care. Contact information for emergency, weekend and holiday veterinary care needs to be prominently posted in the animal facility and outlined in the written program of veterinary care.

Correct by 05-15-2017

This inspection and exit interview were conducted with the Microbiology Manager, Microbiology Supervisor, Regulatory Affairs Specialist and Director of Regulatory Affairs.

Additional Inspectors

Goplen Ann, Veterinary Medical Officer

Mckinnie Carolyn, Supervisory Animal Care Specialist

Obtained by R

Prepared By:

SECOR THOMAS, V M O USDA, APHIS, Animal Care

18-APR-2017

Title: VETERINARY MEDICAL OFFICER 6108

Received By:

(b) (6), (b) (7)(C)

Title: SENT BY E-MAIL
18-00296_001028

Date:
18-APR-2017



Cust No	Cert No	Site	Site Name	Inspection
1021	91-R-0011	001	JUBILANT HOLLISTER-STIER (J H S)	11-APR-17

Count	Species
000078	DOMESTIC GUINEA PIG
000078	Total

Obtained by R