



## Inspection Report

Thomas D Morris Inc  
4001 Millender Mill Road  
Reisterstown, MD 21136

Customer ID: 745  
Certificate: 51-R-0046  
Site: 001  
THOMAS D. MORRIS, INC

Type: ROUTINE INSPECTION  
Date: 19-MAY-2015

### 2.31(c)(7) REPEAT

#### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Protocol 15-001 approved for 10 swine describes a non-survival surgery involving creating eight defects in the spleen. Surgery records for the six swine assigned to protocol 15-001 were reviewed during this inspection and two swine (04445, 04446) had non-survival surgery performed that involved creating ten defects in the spleen (two more than stated in the protocol). The IACUC 18 February 2015 meeting minutes document that "Some members raised the question of whether 8 spleen incisions were excessive..." when discussing a similar protocol (15-004). The facility IACUC did not approve an increase in the number of splenic defects for protocol 15-001. The facility personnel therefore, did not follow protocol 15-001 for these two swine.

Protocols 15-006 and 15-007 approved for sheep survival surgery describes post-operative pain medication with Buprenex for three days. This medication was only provided once daily for eight sheep (G4705, G4707, G4708, and G4711 on protocol 15-006; G4702, G4703, G4706, and G4713 on protocol 15-007) maintained postoperatively under these protocols. The medication chart in the protocols indicated that Buprenorphine (Buprenex) should be given every 6 or every 12 hours. See section 2.33(b)(4) below for specific ramifications. The facility IACUC did not approve the decrease in frequency in the administration of the Buprenorphine. The facility personnel therefore, did not follow protocols 15-006 and 15-007 for these eight sheep.

The facility IACUC must review and approve all proposed protocols and significant changes to ensure that the proposed activities comply with the Animal Welfare regulations. Correct by ensuring that all future activities are done in accordance with the IACUC approved protocol and all significant changes to the ongoing use of animals are reviewed and approved by the IACUC. This is a repeat non-compliant item that remains uncorrected.

### 2.31(d)(1)(4)(1) REPEAT

#### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The ongoing protocols 15-006 and 15-007 were reviewed during this inspection and include the use of a paralytic and cardiac bypass during the thoracotomy. Both protocols state that the facility "...will use invasive blood pressure

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(IBP), heart rate and rhythm to monitor the depth of anesthesia while under paralytics". Blood pressure and heart rate are known to increase if the animal is experiencing pain. The paralytic was shown in the records to be administered several times until the end of the cardiac bypass. Animals placed on cardiac bypass cannot be adequately monitored using heart rate and/or blood pressure since the cardiac bypass is controlling these functions for the heart. The sheep are under the influence of the paralytic during the cardiac bypass so an additional method of animal monitoring must be instituted and described in the protocol to ensure the sheep are maintained under sufficient levels of the anesthesia and analgesia while under the effects of the paralytic. This was previously cited for protocol 14-004 on the November 5, 2014 inspection report and no additional surgeries were conducted on this protocol.

The current protocols 15-006 and 15-007 do not specify how monitoring will occur during the period of bypass or what additional methods are in place to ensure the sheep are receiving adequate anesthesia/analgesia during cardiac bypass while under the effects of the paralytic. Surgery must be performed with appropriate analgesics/anesthetics and monitoring to assure that the animal is not experiencing pain during the procedures with the use of paralytics. Although this is a repeat non-compliant item, the registrant was verbally instructed to have the protocols address the use of paralytics with cardiac bypass before additional animal surgeries are conducted. This is a repeat non-compliant item that remains uncorrected.

### 2.33(b)(5)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

The ongoing protocols 15-006 and 15-007 both state that all animals will receive Buprenex (Buprenorphine) for three days and Ketofen for five days after surgery. Additionally, the postoperative observation sheets specify that animals with a pain score of 2 or more require pain medication.

1) Sheep G4707 (15-006) had a PM pain score of 2 on 5/15/15 (1st day after surgery) and received no additional pain medication for the score of 2 or its second dose of Buprenorphine as specified by the drug dosage chart in the protocol. The pain score for this sheep the following AM on 5/16/15 (2nd day after surgery) was still 2 indicating it had pain overnight that might have been alleviated if a second daily dose of Buprenorphine had been given the previous day. After the sheep received its daily dose of Ketofen and one dose of Buprenex in the morning, the PM pain score was 1. The sheep did not receive a second dose of Buprenorphine on 5/16/15 and the following AM pain score on 5/17/15 (3rd day after surgery) was 2. The sheep may have had a lower AM pain score if it had received its second dose of Buprenorphine the previous day.

2) Sheep G4711 (15-006) had an AM pain score of 2 on 5/17/15 (2nd day after surgery) and a PM pain score of 2 on 5/17/15. This sheep received no additional pain medication for the score of 2 or its second dose of Buprenorphine as specified by the drug chart in the protocol. The sheep may have had a lower AM pain score if it had received its second dose of Buprenorphine.

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3) Sheep G4706 (15-007) had an AM pain score of 3 on 5/16/15 (2nd day after surgery), a PM pain score of 2 on 5/16/15, an AM pain score of 2 on 5/17/15 (3rd day after surgery), and a PM pain score of 2 on 5/17/15. This sheep did not receive additional pain medication for the PM scores of 2 or its second dose of Buprenorphine as specified by the drug chart in the protocol. The sheep only received its daily dose of Ketofen and one dose of Buprenex in the morning. The persistent pain scores of 2 or more for two days for this sheep indicated it had pain that might have been alleviated if a second dose of Buprenorphine had been given in the PM.

4) Sheep G4702 (15-007) had an AM pain score of 2 on 5/16/15 (4th day after surgery). This sheep did not receive a second dose of Buprenorphine on 5/15/15 (3rd day after surgery). The sheep may have had a lower AM pain score if it had received its second dose of Buprenorphine as specified by the drug chart in the protocol.

Each research facility must establish and maintain programs of adequate veterinary care that include adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures. This assures the least pain and distress is felt by the animals. Correct by ensuring all animals receive all their post-procedural pain medications. Correct from this day forward.

This inspection was conducted on May 18, 2015 to May 20, 2015. An exit briefing was conducted with the facility Vice President; Dr. David Oelberg, VMO; and Dr. Mary Geib, VMO.

### Additional Inspectors

Geib Mary, Veterinary Medical Officer

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## Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
745	51-R-0046	001	THOMAS D. MORRIS, INC	19-MAY-15

Count	Scientific Name	Common Name
000008	<i>Ovis dalli</i>	WHITE SHEEP
<b>000008</b>	<b>Total</b>	