



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: 03-NOV-2014

2.31(c)(7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The ongoing protocol 14-004 and its 5/5/14 amendment describe surgeries and justifications for 4 treatment groups. Surgery records for 11 sheep were reviewed during this inspection and 6 of the sheep had a different surgery performed than any of the 4 treatment groups. The principal investigator failed to submit an amendment or proposed modification to the approved protocol that described what was done to the six sheep. As a result, these significant changes to surgical procedures were not reviewed by the IACUC. The facility IACUC must review and approve all proposed protocols and amendments to ensure that animal pain and distress is minimized and that proposed activities comply with the Animal Welfare regulations. Ensure that all future activities are done in accordance with the IACUC protocol and ensure that all significant changes to the ongoing use of animals are reviewed by the IACUC
Correct from this day forward.

2.31(d)(1)(4)(1) DIRECT

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The ongoing protocol 14-004 was reviewed during this inspection including the surgery records for 11 sheep. The surgery description includes the use of a paralytic to relax the intercostal musculature during the thoracotomy. Standard procedure for the facility is to monitor heart rate and blood pressure for depth of anesthesia when paralytics are in use since both parameters are known to increase if the animal is experiencing pain. The protocol calls for a cardiac bypass as part of the surgical procedure. The paralytic was shown in the records to be administered several times until the end of the cardiac bypass. Animals placed on cardiac bypass can not be adequately monitored using heart rate and/or blood pressure since the bypass machine 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 to ensure the sheep are maintained under sufficient levels of the anesthesia and analgesia while under the effects of the paralytic. See section 2.33(b)(4) below for specific examples. Adjunctive methods for assessing pain and anesthetic depth such as a peripheral nerve stimulator should be considered when paralytic agents are being used (especially when heart rate and blood pressure are unable to be monitored due to concurrent use of cardiac bypass machines or administration of cardio-active drugs). Surgery must be performed with appropriate analgesics / anesthetics and monitoring to assure that the animal is not

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experiencing pain during the procedure with the use of paralytics. Correct from this day forward.

2.33(b)(2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Protocol 13-028, which is now closed (completed), and all associated records for the 30 study animals were reviewed at this inspection. The protocol states that "Rabbits will be weighed weekly..." and weighing is widely considered a good method of monitoring health in rabbits including pain/distress.

Rabbit 10 weighed 8.6# on arrival and 8.4# at surgery 7/16/13. The rabbit was not weighed at the next group weighing 7/19/13 and was found dead 7/25/13. At that time it weighed 6# according to the records. If the rabbit had been weighed with the group 7/19 or a week after the last weight 7/23 it might have been identified for treatment in time for a positive outcome.

Rabbit 15 weighed 7.6# on arrival 7/15/13 and had surgery 7/18/13. By 8/2/13 the rabbit weighed 5.4# but no treatment was noted in the records for this rabbit. By 8/9/13 the rabbit weighed 4.8# and had suffered injuries from the other rabbits. Euthanasia was performed 8/14/13 and the necessity might have been avoided with earlier intervention.

Rabbit 25 weighed 8# on arrival 7/2/13 and had surgery 7/15/13. It was identified as having a luxating patella 7/19/13 and received two days of pain treatment. By 7/26/13 the rabbit weighed 6.6# and maintained this weight until 8/16/13. No further treatment or special consideration was noted in the records. Although it was weighed weekly there was no additional diagnostic testing or treatments provided (such as continued analgesics, individual housing, the addition of soft bedding, nutritional support, additional monitoring etc.) despite weight loss. The rabbit weighed 5.8# Friday 8/23/13 and there was no record of veterinary examination for this weight loss. The rabbit was kept through the weekend and until the study ended for that group Tuesday 8/27/13. This animal may have experienced pain or distress during the period it was maintained without treatment as indicated by 12% weight loss between weighing 8/16/13 and 8/23/13.

These three rabbits all had weight loss that could indicate pain or distress. Monitoring methods must be conducted as outlined in the IACUC approved protocol. Additionally, animals exhibiting clinical signs of injury, illness, or pain (such as significant decreases in weight) must be referred to the attending veterinarian for appropriate diagnosis and treatment. Monitoring data must additionally be reviewed for trends that might indicate problems that would respond to treatment. Treatment must be initiated in a timely manner to assure the animals are not living with pain or distress that could be controlled. 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. Correct from this date forward.

2.33(b)(4) DIRECT

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ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Section 2.33(b)(4) Veterinary Care: The surgery records of three sheep on the ongoing protocol 14-004 documented signs of pain that were not appropriately addressed by the surgery personal of the principal investigator.

Sheep B3379 had thoracic surgery that included several administrations of a paralytic drug on 6/11/14. During the cardiac bypass there was a notation that the animal was kicking. A paralytic was administered with the analgesic and increase in the anesthetic agent. As stated in the protocol the analgesia and anesthetic should be allowed to bring the animal to plane III anesthesia before the administration or re-administration of a paralytic to ensure the animal is not experiencing pain during the surgical procedure.

Sheep B3382 had thoracic surgery that included several administrations of a paralytic drug on 6/11/14. Both the heart rate and the blood pressure increased after the cardiac bypass and remained at that level until the end of the surgery, about 45 minutes. The heart rate increased from an average of 73 to 106 and the blood pressure increased from an average of 79/50 to 102/76. During the 45 minute period with the elevated heart rate and blood pressure the gas anesthetic was decreased from 2% to 1% for the last 30 minutes. No additional analgesics were administered during this 45 minute period. An additional dose of paralytic drug had been given during the cardiac bypass so the sheep would have been under the influence of the paralytic. Pain was then not appropriately addressed in this sheep, the sheep should have received an agent for pain relief which would lead to a decrease the heart rate and blood pressure.

Sheep B3386 had thoracic surgery that included several administrations of a paralytic drug on 6/13/14. After the incision the average heart rate increased from 92 to 144 and the average blood pressure increased from 83/61 to 119/101. An analgesic was given to decrease the pain and the resulting high blood pressure. Five minutes later the heart rate was 149 and the blood pressure 112/91. Metoprolol (not an analgesic or anesthetic) was given to decrease the high heart rate and blood pressure. The use of Metoprolol was not included in the protocol. Eight minutes later the heart rate was 103 and the blood pressure was 106/79 and an additional dose of the paralytic drug was administered. The cardiac bypass was initiated four minutes later. As the protocol indicates, an increase in heart rate and blood pressure indicates perception of pain by the animal. The increase in heart rate and blood pressure were considered signs that the sheep was experiencing pain. Giving a drug that affects heart rate and blood pressure prevents these parameters from being used to monitor pain when paralytics are used. The sheep did not have its pain addressed before additional paralytic was given.

Paralytic agents prevent the animal from moving even if it experiences pain. Heart rate and blood pressure often increase when animals experience pain and are therefore used to evaluate the depth of anesthesia in lieu of muscle responses such as eye twitch. When heart rate and blood pressure rise during anesthesia, additional pain relieving (analgesic) and/or anesthetic agent are necessary to assure the animal is not experiencing pain. This is especially important in animals that are unable to respond due to a paralytic agent. Based on the examples above, the

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veterinary guidance on use of paralytics to include monitoring with appropriate response does not appear to be adequate as required by the Animal Welfare Act Regulations. Each research facility veterinarian must provide guidance on appropriate monitoring and subsequent treatment by personnel involved in handling, immobilization, anesthesia, analgesia, tranquilization and euthanasia. This assures the least pain and distress is felt by the animals. Correct for all future surgeries.

An exit briefing was conducted with the facility Vice President and facility Veterinarian.

Additional Inspectors

Miller Dana, Supervisory Animal Care Specialist

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	03-NOV-14

Count	Scientific Name	Common Name
000005	<i>Ovis dalli</i>	WHITE SHEEP
000008	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000013	Total	