United States Department of Agriculture Animal and Plant Health Inspection Service

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Inspection Report

W. L. Gore & Associates Inc. 1505 N. Fourth Street Flagstaff, AZ 86004

Customer ID: 1051

> Certificate: 86-R-0009

> > Site: 001

W. L. GORE & ASSOCIATES, INC.

Type: ROUTINE INSPECTION

Date: 02-JUL-2014

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INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

***The facility is performing procedures on animals that has not been reviewed and approved by the institutional animal care and use committee (IACUC).

On 4/4/14, a male canine (animal 10006), underwent an IACUC approved procedure. Before the animal was euthanized, an additional procedure (performed while the animal was anesthetized), which was not reviewed and approved by the IACUC, took place. The procedure used carotid access, to track and deploy a surgical device in a pre-measured ilio-femoral region.

On 5/28/14 animal 1576, underwent an IACUC approved procedure. Before the animal was euthanized, an additional procedure (performed while the animal was anesthetized), which was not reviewed and approved by the IACUC, took place. The procedure used carotid access to place and pass a 14 Fr long sheath into the descending aorta.

The facility stated that the additional procedures were used for practicing surgical techniques for upcoming studies. The facility requires the principle investigator or study director to fill out a form requesting the additional procedure, but the request is not reviewed and approved by the IACUC. The facility stated they are currently creating a process to include IACUC review and approval of all additional procedures.

Unapproved activities or significant changes to ongoing activities could result in unanticipated pain and distress, and put the animal's welfare at risk. Proposed activities or significant changes to ongoing activities must be reviewed and approved by the IACUC to ensure the proper care and use of animals. To be corrected by 7/18/14.

Inspection and exit briefing was conducted with a clinical veterinarian, a study director and quality assurance representatives.

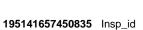
Prepared By: AARON RHYNER, D V M USDA, APHIS, Animal Care Date:

Title: ASSISTANT DIRECTOR 6077

Received by Title: QUALITY ASSURANCE Date: 15-JUL-2014

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Inspection Report

Prepared By: AARON RHYNER, D V M USDA, APHIS, Animal Care **Date:** 15-JUL-2014

Title: ASSISTANT DIRECTOR 6077

Received by Title: QUALITY ASSURANCE Date:

15-JUL-2014



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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1051	86-R-0009	001	W. L. GORE & ASSOCIATES, INC.	02-JUL-14

Count	Scientific Name	Common Name
000012	Canis lupus familiaris	DOG ADULT
000030	Ovis aries aries	SHEEP INCLUDING ALL DOMESTIC BREEDS
800000	Sus scrofa domestica	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000050	Total	