



Inspection Report

Pacific Biolabs
551 Linus Pauling Drive
Hercules, CA 94547

Customer ID: 1143
Certificate: 93-R-0189
Site: 002
PACIFIC BIOLABS

Type: ROUTINE INSPECTION
Date: 19-AUG-2014

2.31(e)(2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Two protocols did not contain an adequate rationale for the number of animals to be used.

ACUP 17A-08 calls for 350 rabbits to be used. The explanation for the number of animals states: "Two rabbits per material are required for a valid USP test. Three rabbits are used in the ISO method. Other implantation studies of longer duration may use up to six rabbits."

There is no explanation of how, given these numbers, a total of 350 rabbits should be approved by the IACUC for use under this study.

ACUP 17A-47, under rationale for number of animals, displays a table listing eleven procedures which require two animals each, and four additional animals as replacements. It also specifies that each rabbit will serve as its own control.

There is no explanation as to why two animals are needed per procedure, nor how the number four was derived to serve as replacements.

The IACUC should carefully review animal use proposals, and assure that the protocol proposal contains an adequate rationale for the number of animals requested for use. Failure to do so could result in unnecessary animal acquisition and use

To be corrected in these two protocols by 11/1/14, and all active protocols at the time of review.

2.38(f)(1)

MISCELLANEOUS.

A review of internal records revealed that a live rabbit was found in the carcass freezer due to a failure of staff members to verify death following a euthanasia procedure. The incident was reported to OLAW, and appropriate corrective actions had been taken by management at the time of this inspection.

Prepared By: PAMELA SMITH, D V M USDA, APHIS, Animal Care

Date:
22-AUG-2014

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Handling of all animals, including euthanasia, should be done as expeditiously and carefully as possible in a manner that does not cause behavioral stress, physical harm, unnecessary discomfort, or excessive cooling. The facility should continue to monitor the euthanasia procedures to ensure that SOPs are up to date and being followed, and that retraining has been successful.

An exit interview was conducted with facility representatives.

Additional Inspectors

Mcintosh Ashley, Veterinary Medical Officer

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1143	93-R-0189	002	PACIFIC BIOLABS	19-AUG-14

Count	Scientific Name	Common Name
000003	<i>Canis lupus familiaris</i>	DOG ADULT
000398	<i>Cavia porcellus</i>	DOMESTIC GUINEA PIG
000110	<i>Oryctolagus cuniculus</i>	EUROPEAN RABBIT
000511	Total	