



Inspection Report

COCALICO BIOLOGICALS INC

Customer ID: 360

Certificate: 23-R-0089

Site: 001

449 STEVENS ROAD P O BOX 265

COCALICO BIOLOGICALS INC

Type: ROUTINE INSPECTION

Date: Jan-29-2010

REAMSTOWN, PA 17567

2.31 (c) (2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(c) IACUC Functions. (2) Inspect, at least once every six months, all of the research facility's animal facilities, including animal study areas, using title 9, chapter I, subchapter A-Animal Welfare, as a basis for evaluation.

1. Review of the Institutional Animal Care and Use Committee meeting minutes and the Institutional Animal Care and Use Committee semiannual report dated October 1, 2009: The Committee records indicated the PR Farm animal facility was not inspected at least once every six months.

In accordance with Animal Welfare Regulations, the Institutional Animal Care and Use Committee (IACUC) is required to inspect all of the research facility's animal facilities at least once every six months; and to submit a report of its evaluations to the Institutional Official at least once every six months to ensure the humane care and use of the animals.

Correct by: Future semiannual inspections.

2.31 (e) (4)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following: (4) A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research.

1. Review of Proposal for Use of Laboratory Animals 2009-1090 that described the use of rabbits for antisera production: The proposal failed to describe procedures for monitoring the depth of anesthesia to ensure an adequate plane of anesthesia prior to blood collection procedures.

The Institutional Animal Care and Use Committee (IACUC) should ensure that a proposal to conduct an animal

Prepared By:

JOEL RUBIN, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1059

Jan-29-2010

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Feb-01-2010



Inspection Report

activity includes a complete description of procedures intended to avoid or minimize discomfort, pain and/or distress to the animals.

Correct by: February 12, 2010.

2.33 (b) (5)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Section 2.33(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:
(5) Adequate pre-procedural and post-procedural care in accordance with established veterinary medical and nursing procedures.

1. WR Farm animal facility, Building 1: Rabbit #097790 was involved in a blood collection procedure on the same day of this inspection. The rabbit was either returned to the animal enclosure before bleeding from its right ear blood vessel was controlled or not adequately monitored for possible hemorrhage during the day, resulting in postprocedural bleeding prior to inspection as indicated by moderate amounts of blood on the rabbit's right ear, right thorax, and beneath the rabbit's enclosure.

Blood collection procedures should be followed by control of bleeding to prevent postprocedural hemorrhage and ensure the health and wellbeing of the animal.

2. WR Farm animal facility, Building 11: Rabbit #0910441 was observed nibbling on a gauze sponge that was not removed from the animal enclosure following a blood collection procedure. Ingestion of the sponge material could cause gastrointestinal disease/foreign body with associated discomfort, pain and/or distress to the animal.

An animal enclosure should not contain materials which may be harmful or cause injury to the animals.

Correct by: 1. Future blood collection procedures. 2. Gauze sponge removed at time of inspection.

Note: This inspection report amends the report dated January 26, 2010.

Prepared By:

JOEL RUBIN, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1059

Jan-29-2010

Received By:

(b)(6), (b)(7)(c)

Date:

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Feb-01-2010



Inspection Report

COCALICO BIOLOGICALS INC

Customer ID: 360

Certificate: 23-B-0028

Site: 001

449 STEVENS ROAD P O BOX 265

COCALICO BIOLOGICALS INC

Type: ROUTINE INSPECTION

Date: Jan-29-2010

REAMSTOWN, PA 17567

2.40 (b) (5)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE (DEALERS AND EXHIBITORS).

Section 2.40(b) Each dealer or exhibitor shall establish and maintain programs of adequate veterinary care that include: (5) Adequate pre-procedural and post-procedural care in accordance with established veterinary medical and nursing procedures.

1. WR Farm animal facility, Building 1: Rabbit #097790 was involved in a blood collection procedure on the same day of this inspection. The rabbit was either returned to the animal enclosure before bleeding from its right ear blood vessel was controlled or not adequately monitored for possible hemorrhage during the day, resulting in postprocedural bleeding prior to inspection as indicated by moderate amounts of blood on the rabbit's right ear, right thorax, and beneath the rabbit's enclosure.

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Correct by: 1. Future blood collection procedures. 2. Gauze sponge removed at time of inspection.

Note: This inspection report amends the report dated January 26, 2010.

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JOEL RUBIN, V M D USDA, APHIS, Animal Care

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Inspection Report

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Customer ID: 360

Certificate: 23-B-0028

Site: 001

449 STEVENS ROAD P O BOX 265

COCALICO BIOLOGICALS INC

Type: ROUTINE INSPECTION

Date: Jan-26-2010

REAMSTOWN, PA 17567

2.40 (b) (5)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE (DEALERS AND EXHIBITORS).

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An animal enclosure should not contain materials which may be harmful or cause injury to the animals.

Correct by: Future blood collection procedures.

Note: This inspection was conducted on January 26-January 28, 2010.

Prepared By:

JOEL RUBIN, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1059

Jan-28-2010

Received By:

(b)(6), (b)(7)(c)

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Jan-28-2010



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2.31 (c) (2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(c) IACUC Functions. (2) Inspect, at least once every six months, all of the research facility's animal facilities, including animal study areas, using title 9, chapter I, subchapter A-Animal Welfare, as a basis for evaluation.

1. Review of the Institutional Animal Care and Use Committee meeting minutes and the Institutional Animal Care and Use Committee semiannual report dated October 1, 2009: The Committee records indicated the PR Farm animal facility was not inspected at least once every six months.

In accordance with Animal Welfare Regulations, the Institutional Animal Care and Use Committee (IACUC) is required to inspect all of the research facility's animal facilities at least once every six months; and to submit a report of its evaluations to the Institutional Official at least once every six months to ensure the humane care and use of the animals.

Correct by: Future semiannual inspections.

2.31 (e) (4)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following: (4) A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research.

1. Review of Proposal for Use of Laboratory Animals 2009-1090 that described the use of rabbits for antisera production: The proposal failed to describe procedures for monitoring the depth of anesthesia to ensure an adequate plane of anesthesia prior to blood collection procedures.

The Institutional Animal Care and Use Committee (IACUC) should ensure that a proposal to conduct an animal

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JOEL RUBIN, V M D USDA, APHIS, Animal Care

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Jan-28-2010

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Title:

Jan-28-2010



Inspection Report

activity includes a complete description of procedures intended to avoid or minimize discomfort, pain and/or distress to the animals.

Correct by: February 12, 2010.

2.33 (b) (5)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Section 2.33(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:
(5) Adequate pre-procedural and post-procedural care in accordance with established veterinary medical and nursing procedures.

1. WR Farm animal facility, Building 1: Rabbit #097790 was involved in a blood collection procedure on the same day of this inspection. The rabbit was either returned to the animal enclosure before bleeding from its right ear blood vessel was controlled or not adequately monitored for possible hemorrhage during the day, resulting in postprocedural bleeding prior to inspection as indicated by moderate amounts of blood on the rabbit's right ear, right thorax, and beneath the rabbit's enclosure.

Blood collection procedures should be followed by control of bleeding to prevent postprocedural hemorrhage and ensure the health and wellbeing of the animal.

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An animal enclosure should not contain materials which may be harmful or cause injury to the animals.

Correct by: Future blood collection procedures.

Note: This inspection was conducted on January 26-January 28, 2010.

Prepared By:

JOEL RUBIN, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1059

Jan-28-2010

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Jan-28-2010



Inspection Report

COCALICO BIOLOGICALS INC

Customer ID: **360**

449 STEVENS ROAD P O BOX 265

Certificate: **23-R-0089**

Site: 001

COCALICO BIOLOGICALS INC

REAMSTOWN, PA 17567

Type: ROUTINE INSPECTION

Date: Feb-02-2009

2.33 (b) (3)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Section 2.33(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:
(3) Daily observation of all animals to assess their health and well-being. . . That daily observation of animals may be accomplished by someone other than the attending veterinarian, and that a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian.

1. Whitesell Radcliffe Farm, Building 2, small room: One guinea pig was observed to have a right submandibular mass, approximately 2 in. in diameter. Available records failed to document or provide evidence that the swelling beneath the lower jaw was reported to the facility supervisor/manager or to the attending veterinarian for examination and possible treatment.

Animals should be observed daily for signs of abnormal conditions, illness, or injury, by persons properly trained to recognize these signs. Animal illness or injury should be reported promptly to the responsible person in the animal facility and to the attending veterinarian in order to ensure adequate veterinary care.

Correct by: Animal euthanized at time site visit.

2.36 (b) (6)

ANNUAL REPORT.

Section 2.36 (b) The annual report shall: (6) State the common names and the numbers of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.

1. Review of the Annual Report dated November 25, 2008: The report underreported under Column D the number of guinea pigs (393) upon which research, experiments, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.

Prepared By:

JOEL RUBIN, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1059

Feb-04-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Feb-04-2009



Inspection Report

The research facility should submit an amended annual report for the Federal fiscal year ending on September 30, 2008, to the Animal Care Regional Director, Eastern Region.

Correct by: February 20, 2009.

3.131 (c)

SANITATION.

Section 3.131(c) Housekeeping. Premises (buildings and grounds) shall be kept clean and in good repair in order to protect the animals from injury and to facilitate the prescribed husbandry practices set forth in this subpart.

1. Pheasant Ridge Farm, barn, procedure room: Three ceiling incandescent light fixtures were not equipped with protective covers.

Protective covers should be installed to protect the animals and food supplies from the hazard of glass fragments should the light bulbs break. Maintenance/repairs should be performed on a regular basis.

The research facility should make the necessary repairs.

Correct by: March 6, 2009.

Note: This inspection was conducted on February 2-February 4, 2009.

Prepared By:

JOEL RUBIN, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1059

Feb-04-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Feb-04-2009



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Customer ID: **360**

449 STEVENS ROAD P O BOX 265

Certificate: **23-B-0028**

Site: 001

COCALICO BIOLOGICALS INC

REAMSTOWN, PA 17567

Type: ROUTINE INSPECTION

Date: Feb-02-2009

2.40 (b) (3)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE (DEALERS AND EXHIBITORS).

Section 2.40(b) Each dealer or exhibitor shall establish and maintain programs of adequate veterinary care that include: (3) Daily observation of all animals to assess their health and well-being. . . That daily observation of animals may be accomplished by someone other than the attending veterinarian, and that a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian.

1. Whitesell Radcliffe Farm, Building 2, small room: One guinea pig was observed to have a right submandibular mass, approximately 2 in. in diameter. Available records failed to document or provide evidence that the swelling beneath the lower jaw was reported to the facility supervisor/manager or to the attending veterinarian for examination and possible treatment.

Animals should be observed daily for signs of abnormal conditions, illness, or injury, by persons properly trained to recognize these signs. Animal illness or injury should be reported promptly to the responsible person in the animal facility and to the attending veterinarian in order to ensure adequate veterinary care.

Correct by: Animal euthanized at time site visit.

3.131 (c)

SANITATION.

Section 3.131(c) Housekeeping. Premises (buildings and grounds) shall be kept clean and in good repair in order to protect the animals from injury and to facilitate the prescribed husbandry practices set forth in this subpart.

1. Pheasant Ridge Farm, barn, procedure room: Three ceiling incandescent light fixtures were not equipped with protective covers.

Protective covers should be installed to protect the animals and food supplies from the hazard of glass fragments should the light bulbs break. Maintenance/repairs should be performed on a regular basis.

Prepared By:

JOEL RUBIN, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1059

Feb-04-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Feb-04-2009



Inspection Report

The dealer should make the necessary repairs.

Correct by: March 6, 2009.

Note: This inspection was conducted on February 2-February 4, 2009.

Prepared By:

JOEL RUBIN, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1059

Feb-04-2009

Received By:

(b)(6), (b)(7)(c)

Date:

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Feb-04-2009



Inspection Report

COCALICO BIOLOGICALS INC

Customer ID: **360**

Certificate: **23-R-0089**

Site: 001

COCALICO BIOLOGICALS INC

449 STEVENS ROAD P O BOX 265

Type: ROUTINE INSPECTION

Date: Feb-26-2008

REAMSTOWN, PA 17567

2.31 (d) (1) (ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(d) IACUC review of activities involving animals. (1) In order to approve proposed activities or proposed significant changes in ongoing activities. . . .The IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: (ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e. g., the Animal Welfare Information Center, used to determine that alternatives were not available.

1. Review of Protocol 338A (Standard Operating Procedure) that described blood collection procedures involving guinea pigs: The proposed procedure described collection of blood by cardiac puncture which may cause more than momentary or slight pain and/or distress to the animals. Available records failed to contain a narrative description pertaining to the methods and sources used to consider alternatives to procedures that may cause more than momentary or slight pain and/or distress to the animals or to provide evidence to determine that a search for alternative procedures was conducted and to determine that alternatives were not available.

The Institutional Animal Care and Use Committee (IACUC) should ensure that a proposal to conduct an animal activity provides the required narrative description of the methods and sources used to consider alternatives to procedures that may cause more than momentary or slight pain and/or distress to the animals. All procedures must be reviewed and approved by the IACUC to ensure the appropriate care and use of the animals.

Correct by: March 14, 2008.

2.36 (b) (6)

ANNUAL REPORT.

Section 2.36 (b) The annual report shall: (6) State the common names and the numbers of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.

Prepared By:

JOEL RUBIN, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1059

Feb-28-2008

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Feb-28-2008



Inspection Report

1. Review of the Annual Report dated November 28, 2007: The report failed to include under Column D the number of guinea pigs (783) upon which research, experiments, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.

The research facility should submit an amended annual report for the Federal fiscal year ending on September 30, 2007, to the Animal Care Regional Director, Eastern Region.

Correct by: March 14, 2008.

Note: This inspection was conducted on February 26-February 28, 2008.

Prepared By:

JOEL RUBIN, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1059

Feb-28-2008

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Feb-28-2008



Inspection Report

COCALICO BIOLOGICALS INC

Customer ID: **360**

Certificate: **23-B-0028**

Site: 003

PHEASANT RIDGE FARM

449 STEVENS ROAD P O BOX 265

Type: ROUTINE INSPECTION

Date: Feb-26-2008

REAMSTOWN, PA 17567

No noncompliant items identified at time of site visit.

Note: This inspection was conducted on February 26-February 28, 2008.

Prepared By:

JOEL RUBIN, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1059

Feb-28-2008

Received By:

(b)(6), (b)(7)(c)

Date:

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Feb-28-2008