



Inspection Report

BIORELIANCE CORPORATION

Customer ID: **33766**

Certificate:

Site: 001

BIORELIANCE CORPORATION

14920 BROSCHART ROAD

Type: PRELICENSE INSPECTION #1

Date: Dec-11-2009

ROCKVILLE, MD 20850

NO NON-COMPLIANT ITEMS IDENTIFIED THIS INSPECTION.

This applicant meets all requirements to be licensed as B Dealer. The license fee will be mailed to the Eastern Regional office by the applicant in the amount of \$60.00.

The following requirements were explained to the applicant:

- *License renewal requirements and procedure
- *Record-keeping requirements
- *Space Requirements
- *The Program of Veterinary Care (PVC)

NO REGULATED ACTIVITIES MAY BE CONDUCTED UNTIL THE USDA LICENSE IS ISSUED.

Prepared By:

GLORIA S MCFADDEN, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Dec-11-2009

Received By:

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

Date:

Title:

Dec-11-2009



Inspection Report

BIORELIANCE CORPORATION

Customer ID: **33766**

14920 BROSCHART ROAD

Certificate: **51-R-0082**

Site: 001

BIORELIANCE INVITROGEN

ROCKVILLE, MD 20850

Type: ROUTINE INSPECTION

Date: Apr-15-2009

NO NON-COMPLIANT ITEMS IDENTIFIED THIS INSPECTION.

Prepared By:

GLORIA S MCFADDEN, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Apr-15-2009

Received By:

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

Date:

Title:

Apr-15-2009



Inspection Report

BIORELIANCE CORPORATION

Customer ID: **33766**

14920 BROSCHART ROAD

Certificate: **51-B-0033**

Site: 001

BLDG 5

Type: ROUTINE INSPECTION

ROCKVILLE, MD 20850

Date: Feb-27-2009

NO NON-COMPLIANT ITEMS IDENTIFIED THIS INSPECTION.

Prepared By:

GLORIA S MCFADDEN, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Mar-25-2009

Received By:

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

Date:

Title:

Mar-25-2009



Inspection Report

BIORELIANCE CORPORATION

Customer ID: **33766**

14920 BROSCHART ROAD

Certificate: **51-B-0033**

Site: 001

BLDG 5

ROCKVILLE, MD 20850

Type: ROUTINE INSPECTION

Date: Feb-27-2009

NO NON-COMPLIANT ITEMS IDENTIFIED THIS INSPECTION.

Prepared By:

GLORIA S MCFADDEN, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Feb-27-2009

Received By:

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

Date:

Title:

Feb-27-2009



Inspection Report

BIORELIANCE CORPORATION

Customer ID: **33766**

14920 BROSCHART ROAD

Certificate: **51-R-0082**

Site: 001

BIORELIANCE INVITROGEN

ROCKVILLE, MD 20850

Type: ROUTINE INSPECTION

Date: Oct-07-2008

NO NON-COMPLIANT ITEMS IDENTIFIED THIS INSPECTION.

This inspection included an evaluation of the effectiveness of policy changes regarding previous NCIs.

Prepared By:

GLORIA S MCFADDEN, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Mar-25-2009

Received By:

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

Date:

Title:

Mar-25-2009



Inspection Report

BIORELIANCE CORPORATION

Customer ID: **33766**

14920 BROSCHART ROAD

Certificate: **51-R-0082**

Site: 001

BIORELIANCE INVITROGEN

ROCKVILLE, MD 20850

Type: ROUTINE INSPECTION

Date: Oct-07-2008

NO NON-COMPLIANT ITEMS IDENTIFIED THIS INSPECTION.

This inspection included an evaluation of the effectiveness of policy changes regarding previous NCIs.

Prepared By:

GLORIA S MCFADDEN, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Oct-07-2008

Received By:

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

Date:

Title:

Oct-07-2008



Inspection Report

BIORELIANCE CORPORATION

Customer ID: 33766

Certificate: 51-R-0082

Site: 001

BIORELIANCE INVITROGEN BIOSERVICES

14920 BROSCHART ROAD

Type: ROUTINE INSPECTION

ROCKVILLE, MD 20850

Date: Aug-22-2008

2.32

REPEAT

PERSONNEL QUALIFICATIONS.

It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel. Training and instruction of personnel must include guidance in humane methods of animal maintenance and experimentation.

***On August 11, 2008, a laboratory assistant reported a hamster that was seen running loose inside the walk-in refrigerator. A live hamster was also found in a euthanasia bag inside the walk-in freezer. An internal facility investigation indicated that an experienced lab assistant failed to follow established standard operating procedures for euthanizing hamsters. Failure to follow established euthanasia procedures caused undue pain and distress for 2 hamsters and possibly 18 other hamsters. Standard operating procedures should include a mechanism of checks and balances that ensure no animal is harmed during routine euthanasia procedures. Standard operating procedures for the euthanasia of hamsters must be revised to include a mechanism of checks and balances. Additionally, the revised standard operating procedures for the euthanasia of hamsters must be implemented and maintained through routine training of all pertinent personnel to ensure animals are not subjected to unnecessary pain and distress. Correct by September 1, 2008.

2.33

(b) (4)

DIRECT NCI

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Each research facility shall establish and maintain programs of adequate veterinary care that include guidance to principal investigators and other personnel involved in the care and use of animals regarding handling and euthanasia.

***On August 11, 2008, a laboratory assistant reported a hamster that was seen running loose inside the walk-in refrigerator. A live hamster was also found in a euthanasia bag inside the walk-in freezer. An internal facility investigation indicated that an experienced lab assistant failed to follow established standard operating procedures for euthanizing hamsters. Failure to follow established euthanasia procedures caused undue pain and distress for 2

Prepared By:

GLORIA S MCFADDEN, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Aug-25-2008

Received By:

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

Date:

Title:

Aug-25-2008



Inspection Report

hamsters and possibly 18 other hamsters. An adequate program of veterinary care includes veterinary guidance to personnel regarding the euthanasia of animals. The attending veterinarian must be consulted regarding standard procedures for the euthanasia of hamsters and guidance or methods to prevent undue pain and distress associated with euthanasia. Correct by September 1, 2008.

2.131

REPEAT DIRECT NCI

HANDLING OF ANIMALS.

Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, physical harm, or unnecessary discomfort.

***On August 11, 2008, a laboratory assistant reported a hamster that was seen running loose inside the walk-in refrigerator. A live hamster was also found in a euthanasia bag inside the walk-in freezer. An internal facility investigation indicated that an experienced lab assistant failed to follow established standard operating procedures for euthanizing hamsters. Failure to follow established euthanasia procedures caused undue pain and distress for 2 hamsters and possibly 18 other hamsters. Animals should be handled in a manner that does not result in trauma or physical harm. The facility must establish a mechanism of checks and balances that ensure animals are not harmed as normal husbandry and euthanasia procedures are performed. Correct by September 1, 2008.

NOTE: The IACUC has initiated an investigation and identified areas where there was a break in procedure. Some measures to prevent such an incident in the future have been implemented and others to be explored.

This is a focused inspection to evaluate a self-reported incident. Non-compliant items from a previous inspection were also evaluated for resolution.

Prepared By:

GLORIA S MCFADDEN, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Aug-25-2008

Received By:

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

Date:

Title:

Aug-25-2008



Inspection Report

BIORELIANCE CORPORATION

Customer ID: 33766

Certificate: 51-R-0082

Site: 001

BIORELIANCE INVITROGEN BIOSERVICES

14920 BROSCART ROAD

Type: ROUTINE INSPECTION

ROCKVILLE, MD 20850

Date: Jul-15-2008

2.32

PERSONNEL QUALIFICATIONS.

It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel. Training and instruction of personnel must include guidance in humane methods of animal maintenance and experimentation, including the proper handling and care for the various species of animals used by the facility.

***On June 24, 2008, a laboratory assistant reported a hamster that was found dead in cage after the cage was removed from the autoclave. It is assumed the animal was alive prior to being placed into the autoclave. Documents indicate the cage was changed and taken to the autoclave room on June 23, 2008. There is no entry in the study or husbandry records that indicates an animal was missing. Additionally, standard operating procedures for cage changes and microisolator decontamination do not specifically address animal observation as part of the process. Standard operating procedures should include a mechanism of checks and balances that ensure no animal is harmed during routine husbandry procedures. Standard operating procedures for routine husbandry procedures, that include a mechanism of checks and balances, must be established and implemented through training of all pertinent personnel to ensure animals are not subjected to unnecessary pain and distress. Correct by July 31, 2008

2.131

DIRECT NCI

HANDLING OF ANIMALS.

Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, physical harm, or unnecessary discomfort.

***On June 24, 2008, a laboratory assistant reported a hamster that was found dead in cage after the cage was removed from the autoclave. Documents indicate the cage was changed and taken to the autoclave room on June 23, 2008. It is assumed the animal was alive prior to being placed into the autoclave. There is no entry in the study or husbandry records that indicates an animal was missing. Additionally, the standard operating procedures do not specifically address animal observation as part of the cage changing and autoclaving process. Animals should be

Prepared By:

GLORIA S MCFADDEN, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Jul-15-2008

Received By:

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

Date:

Title:

Jul-15-2008



Inspection Report

handled in a manner that does not result in trauma, overheating, or physical harm. The facility must establish a mechanism of checks and balances that ensure animals are not harmed as normal husbandry procedures (i.e. cage changing and sterilization procedures) are performed. Correct by July 31, 2008.

NOTE: The IACUC has initiated an investigation and identified areas where there was a break in procedure. Steps to prevent such an incident in the future are being explored.

This is a focused inspection to evaluate a self-reported incident. Non-compliant items from a previous inspection were also reviewed and are currently in compliance with the regulations..

Prepared By:

GLORIA S MCFADDEN, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Jul-15-2008

Received By:

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

Date:

Title:

Jul-15-2008



Inspection Report

BIORELIANCE CORPORATION

Customer ID: **33766**

14920 BROSCHART ROAD

Certificate: **51-R-0082**

Site: 001

BIORELIANCE INVITROGEN

ROCKVILLE, MD 20850

Type: --RESCINDED--

Date: Feb-28-2008

2.31 (d) (1) (iv) (A)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time;

***ACUC 95: This protocol indicates that animals will be classified under pain and distress Category D. The protocol also indicates that animals may experience neurological signs as a disease state progress. No treatment will be administered to relieve the distress the animals may experience. However, endpoints to determine euthanasia have been established. Animals that will not receive treatment to relieve distress or pain should be classified under pain and distress Category E. A scientific justification for withholding treatment is included in the approved protocol. The protocol must be reviewed by the IACUC and amended to reflect the appropriate pain and distress (Category E) based upon supporting scientific justification and/or regulatory requirements. Correct by March 31, 2008.

2.31 (e) (2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain a rationale for the appropriateness of the numbers of animals to be used.

***ACUC 244: The number of animals to be used is a range from 90-300. The justification for numbers simply states "No statistical evaluation is required." The justification for numbers is insufficient to determine that the minimum number of animals necessary will be used. A justification of numbers must address reduction to ensure appropriate animal use and should reference the design of the study and/or statistical analyses. Correct by March 31, 2008.

This is an amended inspection report of the inspection report dated FEB-28-2008 (51-B-0033 / 33766 / 204837 / 44533). The inspection reports reflects the following changes:

- the certificate number was changed from 51-B-0033 to the correct certificate number of 51-R-0082.
- Under 2.31 (d) (1) (iv) (A), the word "aproved" was cahnged to "approved".

Prepared By:

GLORIA S MCFADDEN, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Apr-25-2008

Received By:

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

Date:

Title:

Apr-25-2008



Inspection Report

Prepared By:

GLORIA S MCFADDEN, D V M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Date:

Apr-25-2008

Received By:

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

Date:

Apr-25-2008

Title:



Inspection Report

BIORELIANCE CORPORATION

Customer ID: **33766**

14920 BROSCHART ROAD

Certificate: **51-B-0033**

Site: 001

BLDG 5

Type: --RESCINDED--

ROCKVILLE, MD 20850

Date: Feb-26-2008

2.31 (d) (1) (iv) (A)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time;

***ACUC 95: This protocol indicates that animals will be classified under pain and distress Category D. The protocol also indicates that animals may experience neurological signs as a disease state progress. No treatment will be administered to relieve the distress the animals may experience. However, endpoints to determine euthanasia have been established. Animals that will not receive treatment to relieve distress or pain should be classified under pain and distress Category E. A scientific justification for withholding treatment is included in the approved protocol. The protocol must be reviewed by the IACUC and amended to reflect the appropriate pain and distress (Category E) based upon supporting scientific justification and/or regulatory requirements. Correct by March 31, 2008.

2.31 (e) (2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain a rationale for the appropriateness of the numbers of animals to be used.

***ACUC 244: The number of animals to be used is a range from 90-300. The justification for numbers simply states "No statistical evaluation is required." The justification for numbers is insufficient to determine that the minimum number of animals necessary will be used. A justification of numbers must address reduction to ensure appropriate animal use and should reference the design of the study and/or statistical analyses. Correct by March 31, 2008.

Prepared By:

GLORIA S MCFADDEN, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Feb-26-2008

Received By:

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

Date:

Title:

Feb-28-2008



Inspection Report

BIORELIANCE CORPORATION

Customer ID: **33766**

14920 BROSCHART ROAD

Certificate: **51-R-0082**

Site: 001

BIORELIANCE INVITROGEN

Type: ROUTINE INSPECTION

ROCKVILLE, MD 20850

Date: Feb-26-2008

2.31 (d) (1) (iv) (A)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time;

***ACUC 95: This protocol indicates that animals will be classified under pain and distress Category D. The protocol also indicates that animals may experience neurological signs as a disease state progress. No treatment will be administered to relieve the distress the animals may experience. However, endpoints to determine euthanasia have been established. Animals that will not receive treatment to relieve distress or pain should be classified under pain and distress Category E. A scientific justification for withholding treatment is included in the approved protocol. The protocol must be reviewed by the IACUC and amended to reflect the appropriate pain and distress (Category E) based upon supporting scientific justification and/or regulatory requirements. Correct by March 31, 2008.

2.31 (e) (2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain a rationale for the appropriateness of the numbers of animals to be used.

***ACUC 244: The number of animals to be used is a range from 90-300. The justification for numbers simply states "No statistical evaluation is required." The justification for numbers is insufficient to determine that the minimum number of animals necessary will be used. A justification of numbers must address reduction to ensure appropriate animal use and should reference the design of the study and/or statistical analyses. Correct by March 31, 2008.

This is an amended inspection report of the inspection report dated FEB-26-2008 (51-B-0033 / 33766 / 204837 / 44533). The inspection report reflects the following changes:

- the certificate number was changed from 51-B-0033 to the correct certificate number of 51-R-0082.
- Under 2.31 (d) (1) (iv) (A), the word "approved" was changed to "approved".

Prepared By:

GLORIA S MCFADDEN, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Apr-30-2008

Received By:

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

Date:

Title:

Apr-30-2008



Inspection Report

This is an amended inspection report of the inspection report dated FEB-28-2008 (51-B-0033 / 33766 / 204866 / 38763. This inspection report reflects the correct inspection date of FEB-26-2008. In addition, the following changes were made in the amended statement of the previous inspection report:

- the inspection date was changed from FEB-28-2008 to FEB-26-2008.
- the word "reports" was changed to "report".
- the spelling of the word "cahnged" was corrected to "changed".

Prepared By:

GLORIA S MCFADDEN, D V M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Date:

Apr-30-2008

Received By:

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

Date:

Apr-30-2008

Title: