



Inspection Report

VIRION SYSTEMS INC

Customer ID: **80**

Certificate: **51-R-0004**

Site: 001

VIRION SYSTEMS INC

9610 MEDICAL CENTER DRIVE

Type: ROUTINE INSPECTION

ROCKVILLE, MD 20850

Date: Apr-08-2010

NO NO-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-08-2010

Received By:

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

Date:

Title:

Apr-08-2010



Inspection Report

VIRION SYSTEMS INC

Customer ID: **80**

Certificate: **51-R-0004**

Site: 001

9610 MEDICAL CENTER DRIVE
SUITE 100

VIRION SYSTEMS INC

Type: ATTEMPTED INSPECTION

Date: Mar-30-2010

ROCKVILLE, MD 20850

2.126

ACCESS AND INSPECTION OF RECORDS AND PROPERTY.

Each exhibitor shall, during business hours, allow APHIS officials to inspect and photograph the facilities, property and animals, as the APHIS officials consider necessary to enforce the provisions of the Act, the regulations and the standards. A responsible adult shall be made available to accompany APHIS officials during the inspection process.

***On March 30, 2010 at 10:30AM, the licensee failed to have a responsible person available to conduct an animal welfare inspection. The exhibitor's facility could not be inspected for compliance with the Animal Welfare Act, regulations and standards to ensure the health and well-being of the animals. This is the FIRST ATTEMPTED INSPECTION. A responsible person must be available to accompany the inspector on an animal welfare inspection. Correct immediately.

NOTE: If your hours of availability have changed, please contact me at 240-461-9169 and leave a message.

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Mar-30-2010

Received By:

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

Date:

Title:

Mar-30-2010



Inspection Report

VIRION SYSTEMS INC

Customer ID: **80**

Certificate: **51-R-0004**

Site: 001

VIRION SYSTEMS INC

9610 MEDICAL CENTER DRIVE

Type: ATTEMPTED INSPECTION

ROCKVILLE, MD 20850

Date: Mar-30-2010

2.38 (b)

MISCELLANEOUS.

ACCESS AND INSPECTION OF RECORDS AND PROPERTY.

Each research facility shall, during business hours, allow APHIS officials to inspect and photograph the facilities, property and animals, as the APHIS officials consider necessary to enforce the provisions of the Act, the regulations and the standards. A responsible adult shall be made available to accompany APHIS officials during the inspection process.

***On March 30, 2010 at 10:30am, the registrant failed to have a responsible person available to conduct an animal welfare inspection. The research facility could not be inspected for compliance with the Animal Welfare Act, regulations and standards to ensure the health and well-being of the animals. This is the FIRST ATTEMPTED INSPECTION. A responsible person must be available to accompany the inspector on an animal welfare inspection. Correct immediately.

NOTE: If your hours of availability have changed, please contact me at 240-461-9169 and leave a message.

This is an amended inspection report to correct the inspection report dated March 30, 2010. This inspection report changes 2.126 to 2.38(b). This inspection report also changes the word "licensee" to the word "registrant" and the word "exhibitor's" to "research facility".

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1048

May-10-2010

Received By:

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

Date:

Title:

May-10-2010



Inspection Report

VIRION SYSTEMS INC

Customer ID: **80**

Certificate: **51-A-0007**

Site: 001

9610 MEDICAL CENTER DRIVE

VIRION SYSTEMS INC

SUITE 100

Type: ROUTINE INSPECTION

ROCKVILLE, MD 20850

Date: Feb-24-2010

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-24-2010

Received By:

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

Date:

Title:

Feb-24-2010



Inspection Report

VIRION SYSTEMS INC

Customer ID: **80**

Certificate: **51-A-0007**

Site: 001

VIRION SYSTEMS INC

9610 MEDICAL CENTER DRIVE
SUITE 100

Type: ROUTINE INSPECTION

Date: May-05-2009

ROCKVILLE, MD 20850

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

May-05-2009

Received By:

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

Date:

Title:

May-05-2009



Inspection Report

VIRION SYSTEMS INC

Customer ID: **80**

9610 MEDICAL CENTER DRIVE
SUITE 100

Certificate: **51-R-0004**

Site: 001

VIRION SYSTEMS INC

ROCKVILLE, MD 20850

Type: ROUTINE INSPECTION

Date: Jan-13-2009

NO NON-COMPLIANT ITEMS IDENTIFIED THIS INSPECTION.
This inspection focused on IACUC records and functionality.

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

VIRION SYSTEMS INC

Customer ID: **80**

Certificate: **51-A-0007**

Site: 001

VIRION SYSTEMS INC

9610 MEDICAL CENTER DRIVE

Type: ROUTINE INSPECTION

ROCKVILLE, MD 20850

Date: Jun-24-2008

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

Jun-24-2008

Received By:

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

Date:

Title:

Jun-24-2008



Inspection Report

VIRION SYSTEMS INC

Customer ID: **80**

Certificate: **51-R-0004**

Site: 001

VIRION SYSTEMS INC

9610 MEDICAL CENTER DRIVE

Type: --RESCINDED--

ROCKVILLE, MD 20850

Date: Nov-07-2007

2.1 (d) (1) (ix)

REQUIREMENTS AND APPLICATION.

All survival surgery will be performed using aseptic procedures, including surgical gloves, masks, sterile instruments, and aseptic techniques. Major operative procedures on non-rodents will be conducted only in facilities intended for that purpose which shall be operated and maintained under aseptic conditions. Non-major operative procedures and all surgery on rodents do not require a dedicated facility, but must be performed using aseptic procedures.

***Under ASP 65, embryo transfer procedures on recipient rodents are performed using microsurgical instruments "sterilized" in 70% ethanol for 24 to 72 hours. By definition, the instruments are not considered sterile, as ethanol does not kill spores. The current sterilization method has been shown to be clinically effective, as evident by no post-operative infections. However, a qualitative method to determine the efficacy of the sterility method should be established to ensure aseptic technique is used when performing the embryo transfers. Or, another method of sterilization must be used to ensure the embryo transfers are performed aseptically. Correct by November 30, 2007.

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Nov-07-2007

Received By:

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

Date:

Title:

Nov-07-2007



Inspection Report

VIRION SYSTEMS INC

Customer ID: **80**

Certificate: **51-A-0007**

Site: 001

VIRION SYSTEMS INC

9610 MEDICAL CENTER DRIVE

Type: ROUTINE INSPECTION

ROCKVILLE, MD 20850

Date: Nov-07-2007

2.31 (d) (1) (ix)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

All survival surgery will be performed using aseptic procedures, including surgical gloves, masks, sterile instruments, and aseptic techniques. Major operative procedures on non-rodents will be conducted only in facilities intended for that purpose which shall be operated and maintained under aseptic conditions. Non-major operative procedures and all surgery on rodents do not require a dedicated facility, but must be performed using aseptic procedures.

***Under ASP 65, embryo transfer procedures on recipient rodents are performed using microsurgical instruments "sterilized" in 70% ethanol for 24 to 72 hours. By definition, the instruments are not considered sterile, as ethanol does not kill spores. The current sterilization method has been shown to be clinically effective, as evident by no post-operative infections. However, a qualitative method to determine the efficacy of the sterility method should be established to ensure aseptic technique is used when performing the embryo transfers. Or, another method of sterilization must be used to ensure the embryo transfers are performed aseptically. Correct by November 30, 2007.

NOTE: This inspection report amends the inspection report dated NOV-07-2007. This report changes the citation 2.1(d)(1)(ix) to the correct citation number of 2.31(d)(1)(ix).

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Jan-01-2008

Received By:

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

Date:

Title:

Jan-01-2008