



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

June 10, 2022

Re: Animal Welfare Assurance
A3195-01 [OLAW Case 5E]

Dr. Mary Klotman
Dean, School of Medicine and
Vice Chancellor for Health Affairs
Duke University Medical Center
Duke South Clinic – 200 Trent Drive
(b) (4) Davidson Building
Durham, NC 27710

Dear Dr. Klotman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 25, 2022 letter reporting a noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals that occurred at Duke University. Your letter supplements the information provided in the prompt, preliminary telephone report on May 5, 2022. According to the information provided, OLAW understands that there was a manufacturer mechanical failure of an animal irradiator. An internal filter had fallen out of place resulting in a higher irradiation dose rate than expected. This resulted in unanticipated morbidity of some of the 82 mice irradiated during the period of February and March 2022. These mice received appropriate care. PHS-funded research was involved.

Corrective and preventive actions: Immediately upon identification, the use of the irradiator was halted and all investigators that used the equipment during the period of failure were notified. The investigators were instructed not to use the data collected on the mice irradiated during this period and charges were not applied during this period. In addition, the manufacturer repaired the equipment, technical personnel were retrained, and equipment quality control and monitoring procedures were refined to help prevent reoccurrence.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident, correct the noncompliance, and prevent recurrence. OLAW concurs that the incident warranted reporting. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.

Morse -S

Date: 2022.06.10 17:05:25 -04'00'

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact
Director OAWA



Duke University
Durham, North Carolina 27705

A3195-5E

Office of Animal Welfare Assurance
Campus Mail: Hock Plaza Box 2724
US Mail: 2424 Erwin Road; Suite 606; Durham, NC 27705

Voice: 919.668.6720
Fax: 919.668.6725
<https://myresearchpath.duke.edu/topics/conduct-research-animals>

May 25, 2022

Duke University; Animal Welfare Assurance # D16-00123 (A3195-01)

Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

Duke University, in accordance with PHS Policy IV.F.3., provides this report of an incident, which involved an animal activity conducted or supported with PHS-funds or other funds with OLAW oversight. This incident was reviewed and determined to be reportable by the Duke Institutional Animal Care & Use Committee (IACUC).

Reportable requirement: Conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals.

Preliminary report: A preliminary, verbal report was provided to Dr. Brent Morse on May 5th, 2022 by Dr. Anna Hampton (Duke University Office of Animal Welfare Assurance Director and IACUC Chair).

Number of animals affected: 82 mice

Date: Approximately 1 month between February and March, 2022

Description, outcome, and actions taken: There was a manufacture, mechanical failure of a share use animal irradiator. An internal filter had fallen out of place resulting in the higher irradiation dose rate than expected. This resulted in unanticipated morbidity of some mice irradiated during the period of malfunction. These mice received appropriate care.

Immediately upon identification the use of the irradiator was halted and all investigators that used the equipment during the period of failure were notified. The investigators were instructed not to use the data collected on the mice irradiated during this period and charges were not applied during this period.

In addition, the manufacture repaired the equipment, technical personnel were retrained, and equipment quality control and monitoring procedures were refined to help prevent reoccurrence.

Conclusion: The Duke IACUC completed its investigation and performed final review of the issue at the April 28, 2022 IACUC meeting. The Duke IACUC determined that the incident was reportable to regulatory, granting, and oversight bodies, where applicable. In addition, the IACUC determined that the corrective actions were appropriate and no further actions were necessary. The Duke IACUC considers this incident closed.

The Duke University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Anna Hampton, DVM, IACUC Chair at Anna.Hampton@Duke.edu or (b) (6)

Sincerely,

(b) (6)

Dr. Mary E. Klotman
Duke University
Dean, School of Medicine
Vice Chancellor for Health Affairs
Institutional Official

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, June 6, 2022 10:42 AM
To: Anna Hampton
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Duke OLAW Report (Assurance # A3195-01)

Thank you for this report, Dr. Hampton. We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Anna Hampton <anna.hampton@duke.edu>
Sent: Monday, June 6, 2022 10:35 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] Duke OLAW Report (Assurance # A3195-01)

Dear OLAW,

Please see the attached final report for Duke University (Assurance # A3195-01 / D16-00123).

Please do not hesitate to contact me if you have any questions or need additional information.

Anna

Anna Hampton, DVM, DACLAM, DACAW, CPIA
Director, Office of Animal Welfare Assurance
Chair, Institutional Animal Care and Use Committee
Duke University
2424 Erwin Road, (b) (4)
Durham, NC 27705

(b) (6)

[Duke Animal Program Website](#)

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A3195-5E

Initial Report of Noncompliance

By: BCM

Date: 5/5/2022

Time: 11:17

Person Reporting: Anna Hampton, DVM

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Duke Univ.

Assurance number: A3195

Did incident involve PHS funded activity? probably

Funding component:

Was funding component contacted (if necessary):

What happened: Inner shield was dislodged in new irradiator. Approx. 68-100 mice experienced radiation toxicity.

Species involved: Mus musculus

Personnel involved: ??

Dates and times: period of early February 2022 through March 2022

Animal deaths:

Projected plan and schedule for correction/prevention (if known):

Repair of irradiator and retraining of staff.

Projected submission to OLAW of final report from Institutional Official:

< 60 days

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Case #