DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
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

July 24, 2020

Re: Animal Welfare Assurance
A3143-01 [OLAW Case 1C]

Dr. Camille P. Wicher
Vice President, Corp. Ethics and
Research Subject Protection
Roswell Park Cancer Institute
Elm & Carlton Streets
Buffalo, NY 14263

Dear Dr. Wicher,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of a June 25, 2020 report, endorsed by you, regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Roswell Park Cancer Institute. According to the information provided, OLAW understands that, due to a broken spring within the door locking mechanism, 20 mice could not be removed from an irradiator for approximately 2-1/2 hours on June 15th. When instructions for how to safely open the door were received, three of the mice had expired. The remaining mice received supportive care and recovered. The irradiator was removed from service until repaired by the manufacturer. It was stated that this activity was not PHS funded.

Corrective and preventive measures included posting the instructions for releasing the lock should a malfunction of the lock mechanism ever reoccur.

OLAW appreciates the prompt consideration of this matter by the Roswell Park Cancer Institute, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. OLAW concurs that the incident warranted reporting. Although this activity was not PHS funded, the application of the expectations of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. 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: 2020.07.24 11:54:21 -04'00'

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

cc: IACUC Contact

43143 - 10

ROSWELL PARK®
COMPREHENSIVE CANCER CENTER

Michael T. Moser, Ph.D.
Chair Institutional Animal Care and Use Committee (IACUC)
A457 Carlton House
Buffalo, NY 14263
Phone: 716 845-1155
FAX: 716 845-1258
michael.moser@roswellpark.org

(b) (6)

To: **Candace Johnson, Ph.D., RPCI Institute Official, President and CEO**
From: **Michael T. Moser, Ph.D., Chair RPCI IACUC**
DATE: **June 25, 2020**
Re: **Animal Welfare Concern Resulting from Malfunction of the Irradiator Locking Mechanism**

This memo is to report an animal welfare concern that occurred on the morning of Monday June 15, 2020. Dr. Sandra Sexton, Laboratory Animal Shared Resource (LASR) Attending Veterinarian notified IACUC (e-mail 2:19 pm 06/15/2020) that due to a malfunction of the locking mechanism of LASR's Mark 1 cesium irradiator 20 mice were confined inside the irradiator for 2 ½ hours following a routine 6 minute irradiation procedure (IACUC protocol; 1413M PI: Dr. G, Funding; Private Agency). Unfortunately, 3 of the mice died while confined in the irradiator and the remaining 17 mice upon removal from the irradiator received immediate care (SQ fluids and placed in cages with water and food) and have recovered completely.

The malfunction of the release mechanism appeared to be caused by the failure in the safety interlock switch in the tower of the irradiator where the cesium source is raised and lowered, and this malfunction prevented the door switch from activating and releasing the door lock. The 2 ½ hour delay was a result of safety concerns because of the cesium source. C&C Irradiation Service the vendor for maintenance of the Mark 1 irradiator was immediately contacted however due to their California location and the time difference the call providing instructions on the procedure for releasing the door lock was not returned until ~2 hours later. LASR followed the SOP for the irradiator which included notification to Roswell's Radiation Safety Officer (RSO) for external monitoring of alarms directly to local authorities resulting from tampering with security locks. Following instructions on how to open the irradiator provided by C&C Irradiation Service Dr. Sexton and the LASR staff were able to release the lock and rescue the mice. After removal of the mice the irradiator was taken out of service and an appointment was made with C&C Irradiation Service for repair. Routine maintenance and repair of the locking mechanism on the Mark 1 irradiator were completed on Friday June 19th. A spring had broken inside the safety interlock switch within the locking mechanism and this caused the release mechanism of the lock to malfunction. According to C&C Irradiation Service, issues with the locking mechanism are very rare with the Mark 1 irradiator. LASR has posted the instructions for releasing the lock should a malfunction of the lock mechanism ever reoccur. The Mark 1 irradiator has been in LASR for over twelve years and this is the first time there has been any issue with the locking mechanism. The Mark 1 irradiator receives annual routine maintenance which was most recently performed in October 2019.

The IACUC committee at the recent meeting of the full committee (06/23/2020) discussed the animal welfare concerns resulting from the malfunction of the irradiator locking mechanism and confinement of 20 mice and the resulting death of three of those mice. The IACUC feels that LASR's immediate response was appropriate and that the death of the 3 mice was unfortunate but unavoidable given the circumstances and rarity of a locking mechanism malfunction. LASR's posting of the instructions for the procedure to release the lock on the irradiator door in the rare event of future lock malfunction is the appropriate preventative action and that no further action regarding this incident is requested. Although the confinement of 20 mice inside the irradiator and the resulting death of 3 of the mice was caused by a mechanical failure and LASR acted appropriately, given the circumstances, the IACUC believes this is an animal welfare concern and therefore may be reportable. If you have any additional questions, require clarification or further action by the IACUC please feel free to contact me.

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, July 17, 2020 7:17 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Incident report Roswell Park

Thank you for this report, (b) (6) We will send a response soon.

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

From: (b) (6)
Sent: Wednesday, July 15, 2020 12:12 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Johnson, Candace <Candace.Johnson@RoswellPark.org>
Subject: Incident report Roswell Park

OPRR Assurance #A-314301.
USDA Regis. #21-R-032

Dear Dr. Morse,

Please accept the enclosed report as required by 9 CFR 2.31 (c) (3) and (d) (7) Subchapter A of the Animal Welfare Act, as well as PHS Policy IV.F.3.

Corrective action has been instituted as per the attached document. Roswell Park Cancer Institute 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, please do not hesitate to contact me at (b) (6)

Thank you in advance for your cooperation in this matter.
Sincerely,
Candace S. Johnson, Ph.D.
President and CEO

(b) (6)