

SWELCH **2016090000796847** Insp. id

Inspection Report

UNIVERSITY OF WISCONSIN MADISON

DIRECTOR RESEARCH ANIMAL RESOURCES CENTER

1710 UNIVERSITY AVENUE 396 ENZYME INST

MADISON, WI 53726

Customer ID: 616

Certificate: 35-R-0001

Site: 001

ALL CAMPUS SITES

Type: ROUTINE INSPECTION

Date: 05-APR-2022

2.38(f)(1) Repeat

Miscellaneous.

There have been four incidents of medication dosing errors involving non-human primates (NHPs) and one incident of the incorrect divider placement for NHPs that were reported to the ACUC and OLAW since the last inspection in August 2021.

These incidents could have been prevented if the personnel followed established procedures:

-July 2021: the incorrect divider with mesh was put in place allowing two non-human primates (NHPs) to contact each other through the divider and one lost the tip of its tongue. (Affected animal was appropriately treated and recovered).

-Sept 2021: an overdose of midazolam was given to a NHP because the concentration available was different than what the infusion machine was set for.

-August 19-27, 2021: A NHP was given an overdose of a diabetes medication because the newly acquired medication was 200mg/ml and what was used prior was 50mg/ml.

-October 07, 2021: Antibiotics were at times given to the incorrect animal because the orders were written under the ID of its social partner, however some technicians knew which was the correct animal while others didn't and followed the written orders.

-January 6, 2022: one NHP had missed its daily treatments of a glucoregulatory medication and liver function support medication and a different NHP received it because the last 2 digits of the ID were verified but not the complete

Prepared By: SCOTT WELCH Date:

Title: VETERINARY MEDICAL

OFFICER

Received by Title: Attending Veterinarian Date:

05-JUL-2022

05-JUL-2022

USDA, APHIS, Animal Care

USDA

United States Department of Agriculture Animal and Plant Health Inspection Service SWELCH **2016090000796847** Insp. id

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identification number.

Handling of research animals must be done as carefully as possible.

3.75(c)(1) Critical

Housing facilities, general.

In August 2021 a NHP was found to have its hand stuck between the perch and the wall. Staff removed it and it was treated by staff veterinarians which included amputation of two digits. Records indicate it was appropriately treated and monitored for recovery. Staff also report the perch involved and all perch fixtures of this design were evaluated and reinforced as necessary to prevent further recurrence. This incident was reported to OLAW and the ACUC.

In December 2021 an enrichment device had been modified from its original design for use in a non-human primate enclosure. The enrichment device originally had a sheath with a bungie to attach to the enclosure, however the sheath became detached and when repaired it was modified to be held up with the two chains. The two chains used to suspend it within the enclosure had enough space that a macaque was able to get its head between the chains and then couldn't get back out. The facility found it caught and immediate CPR attempts were noted to be unsuccessful.

Note: The facility reports all enrichment devices of this design were removed to prevent further occurrence and noted retraining of staff on appropriate enrichment device usage and device repair procedure/reporting would be put in place. This incident was also reported by the facility to the USDA veterinary medical officers by the attending veterinarian in December 2021 and also was reported to OLAW and the ACUC.

These two incidents involving furniture-type fixtures had a serious adverse effect on the involved animals and did not provide for the safe activity for the NHPs that use them. Ensure that all furniture-type fixtures or objects remain sturdily constructed and strong enough to provide for the safe activity and welfare of nonhuman primates that use them.

Prepared By: SCOTT WELCH Date:

USDA, APHIS, Animal Care 05-JUL-2022

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Maintain correct from th	nis day forward.		
This inspection of the n	on-human primates under LVSC w	vas conducted with facility representative	es from 4/5-4/7/2022
Additional Inspectors:			
DAWN BARKSDALE, V	/ETERINARY MEDICAL OFFICER	₹.	
GWENDALYN MAGINN	NIS, Nonhuman Primate Species S	Specialist	
Prepared By:	SCOTT WELCH	HODA ADUIG Astro-LO-	Date:
	VETERINARY MEDICAL OFFICER	USDA, APHIS, Animal Care	05-JUL-2022

Date:

05-JUL-2022

Received by Title: Attending Veterinarian



Customer: 616

Inspection Date: 05-Apr-2022

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
616	35-R-0001	001	ALL CAMPUS SITES	05-APR-2022

Count	Scientific Name	Common Name
000197	Macaca fascicularis	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
001485	Macaca mulatta	RHESUS MACAQUE
000312	Callithrix jacchus	COMMON MARMOSET
001994	Total	

United States Department of Agriculture

Animal and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737 June 6, 2022

University of Wisconsin Madison 1710 University Avenue 396 Enzyme Inst Madison, WI 53726 License No. : 35-R-0001 Customer No. : 335723



Your May 10, 2022, appeal of a citation on the USDA inspection report dated April 5, 2022 was thoroughly reviewed by an Animal Care appeal panel consisting of two Supervisory Animal Care Specialists, an Assistant Director, and me. The appeal is addressed below.

The citation for Section 2.32(b) will be changed to 2.38(f)(1) and wording will be amended to reflect this section of the AWAR.

- Thank you for providing information about your training program and incident management process.
- In consideration of those processes, we will amend the wording currently on the report; "The research facility must review and ensure that all personnel involved with animals are trained adequately and qualified in a manner to prevent animal management errors and medication errors.", with "Handling of all animals shall be done as carefully as possible in a manner that does not cause trauma, physical harm, or unnecessary discomfort."

All decisions made by the appeal panel are final and represent Animal Care's final determination for this appeal.

Sincerely,

Robert Gibbens, DVM

Director, Animal Welfare Operations

USDA, APHIS, Animal Care

Roberthebilden

USDA Animal Care. Ensuring humane treatment for animals covered by the Animal Welfare Act.

May 10, 2022

Robert M. Gibbens, DVM Director, Animal Welfare Operations USDA, APHIS, Animal Care 2150 Centre Avenue, Bldg. B Ft. Collins, CO 80526

Dear Dr. Gibbens:

UW-Madison hereby appeals a citation (under **Animal Welfare Regulations 2.32 (b) Personnel qualifications**) issued after a routine inspection of the Wisconsin National Primate Research Center's (WNPRC) animal facilities on April 5-April 7, 2022. During the inspection, the USDA Veterinary Medical Officers (VMOs) reviewed minutes from each College of Letters and Sciences and Vice Chancellor for Research and Graduate Education Centers IACUC meeting that had been held since their last visit in 2021. As a result of the inspection, the VMOs issued citations under Animal Welfare Regulations 9 CFR § **2.32 (b) Personnel qualifications** and § **3.75(c)(1) Housing facilities, general**. We are not appealing the second citation.

As detailed on pages 1-2 of the inspection report (attached as Appendix I), four medication dosing errors were enumerated under the "personnel qualifications" citation. We request that the USDA remove the description of the four medication dosing errors from the inspection report as there is no evidence to suggest that they reflect non-compliance with 9 CFR § 2.32(b).

9 CFR § 2.32(a) requires research facilities to ensure that all personnel involved in animal care, treatment, and use are qualified to perform their duties. 9 CFR § 2.32(b) requires that research facilities make available training and instruction, and review qualifications of personnel, with sufficient frequency to fulfill the research facility's responsibilities to ensure that personnel are qualified and provide the requisite training. UW-Madison contends that these requirements are met at the WNRPC through its thorough training and error mitigation programs. While the incidents cited were regrettable and are taken seriously by the WNPRC and UW-Madison, the mere fact that they occurred does not support a finding of non-compliance with 9 CFR § 2.32(b). In fact, the WNRPC's low error rates for drug concentration and administration errors demonstrates the effectiveness of the WNRPC's training and error mitigation programs. Proficient, qualified professionals in every profession can make mistakes, and no training program can prevent every possible error. The WNRPC strives to minimize and prevent errors to the maximum extent possible through its thorough training and error mitigation programs, and its error mitigation program model has been adopted by other National Primate Research Centers as well other institutions with large laboratory animal use programs.

Below please find a description of WNPRC's training and error mitigation programs, as well as detailed information about the incidents cited. These details demonstrate that the incidents resulted from unfortunate human error rather than inadequate qualifications or training. Please also note that the nonhuman primates who were the subjects of the dosing errors experienced no discernible adverse clinical effects due to the errors.

Overview of WNPRC Training Program

The WNPRC maintains a thorough and rigorous training program for all personnel working with live nonhuman primates (NHP) and/or NHP tissue. Individuals requesting access to WNPRC facilities are referred to the Center's Compliance, Records, Safety and Training (CRST) Unit to initiate the facility access and training process. An email is sent to requestors that outlines all requirements and provides links and a checklist for all online training modules. Individuals who will be working with NHP [e.g., Animal Care Technicians (ACTs), veterinary staff, animal research support staff, investigators and their postdoctoral, graduate, and undergraduate trainees and technical staff, and collaborators] must complete online animal safety training offered and monitored by the UW-Madison Environment, Health and Safety (EHS) Department and the Research Animal Resources and Compliance (RARC) Department. Additionally, individuals must complete the online training module and quiz for Advanced Macaque Safety Training and read all relevant standard operating procedures (SOPs) in a commercial data management system used by the WNPRC. Everyone working with NHP at UW-Madison must also complete two required primate-specific training modules: Primate Training-Online Module and the Primate Training-Hands-On Module, which the WNPRC Training Specialist teaches. The modules provide information regarding NHP behavior and psychological well-being, Herpes B information, post-exposure procedures, personal protective equipment donning and doffing procedures, appropriate techniques for approaching an NHP enclosure, restraint and transport techniques, guidance on performing health and behavior observations, an overview of various types of NHP enclosures, viral status/room entry order procedures, and safety information. Following this orientation, staff working directly with NHP must participate in a two-day basic NHP training program. The program includes a basic husbandry overview and demonstrations, an overview of the WNPRC electronic health records system (EHR), and injection training. The program also includes training sessions with Behavioral Services and Colony Services staff. Following the two-day initial training program, based on job tasks, personnel may receive at least two sessions of macaque transport training.

Following this initial training, personnel hired by Colony Services as Animal Care Technicians (ACTs) undergo at least four weeks of hands-on training, which starts with new staff shadowing experienced staff for several days. Animal Care Managers and Lead ACTs provide most of the daily job specific hands-on training for ACTs. Trainers document trainees' performance as training progresses. The trainers use comprehensive Training Guides to ensure all aspects of each task are explained, reviewed, and practiced. At the end of initial training, the trainee completes a Training Exit Quiz, which reveals areas of training that may need revisiting. Additionally, after new ACTs have completed approximately six weeks of training, the Training Specialist performs proficiency assessments to ensure that the trainees are prepared to work independently and can perform more advanced tasks. Newly hired personnel in the other units of the WNPRC Animal Services Division (e.g., Veterinary Services, Pathology Services, and Scientific Protocol Implementation) and research laboratories are trained by members of their respective units, with assistance from the Training Team, as needed. Their training is also documented as it progresses. To improve the training process, the Training Specialist has been working with all units to develop comprehensive training plans for all staff working with animals to ensure compliance, consistency, and clear expectations for trainers and trainees alike.

Annual refresher courses, proficiency assessments, re-training, and new instruction are provided to personnel throughout an individual's tenure at the WNPRC. Additional attention is paid to personnel who have erred while performing their duties or are not progressing as quickly as expected, with this additional training focused on ensuring they can successfully perform their assigned responsibilities. In addition, all staff must re-read all SOPs assigned to them at least once every two years, as well as when they are modified.

Overview of the WNPRC Error Mitigation Program

The WNPRC has a well-established, formal incident reporting procedure. The procedure ensures consistent reporting and follow-up on all errors and incidents involving NHP. The reporting system ensures each incident is thoroughly evaluated to determine its cause, preventive action is initiated, retraining is scheduled and documented, and any necessary follow-up is scheduled and executed. Following an incident, the individual(s) involved must undergo retraining, including SOP re-review. If the incident involves an animal exiting its enclosure, the individual must undergo hands-on retraining which involves repeatedly demonstrating they are proficient at the task they were doing at the time of the incident.

In February of 2013, the WNPRC Attending Veterinarian (AV), in collaboration with the Center's Compliance Manager, established the Center's Incident Prevention Working Group to study the causes of recurring incidents and to identify strategies that could reduce the recurrence of these issues. In addition to the AV and Compliance Manager, the committee is composed of the Compliance Specialist, Training Specialist, Colony Manager, Head of our Scientific Implementation Unit, a clinical veterinarian, and a staff member from a WNPRC scientist's laboratory. The Incident Prevention Working Group meets monthly to discuss incidents that occurred during the previous month, recommendations for preventing similar errors, and progress on instituting recommended changes. The Working Group also evaluates annual statistics and trends to determine if additional corrective and preventive measures are warranted.

In March of 2021, the WNPRC implemented a Root Cause Analysis and Action (RCA2) program to further augment our already rigorous Incident Response program. The primary objective of the WNPRC RCA2 program is to use a wide range of approaches, tools, and techniques to discover and then eliminate underlying causes of incidents involving our NHP to prevent incidents from recurring. The RCA2 follows up on incidents that are reportable to the IACUC, incidents that occur frequently, and near misses that had the potential to cause harm.

The RCA2 process consists of an interview with one or two members of the Compliance Team who use triggering questions focused on people and communication, policies and procedures, and the environment and equipment, which helps evaluate all aspects of an incident. Following Root Cause Interviews, the Team sums up all action ideas raised, discusses them at the next Incident Prevention Work Group meeting to decide on final action plans, and tracks the implementation of the action plans.

All individuals involved in the cited incidents had undergone the training process described above. Furthermore, the training process paired with the error mitigation process have resulted in a very low incident rate at the WNPRC.

Description of Medication Dosing Error #1 with WNPRC Response

- Text of inspection report citation: "Sept 2021: an overdose of midazolam was given to a NHP because the concentration available was different than what the infusion machine was set for."
- Synopsis of incident: On September 16, 2021, a 13-day old infant rhesus macaque (r21069) assigned to an IACUC approved protocol received an overdose of intravenous midazolam during a procedure studying the neurotoxicity of sedatives used to stop seizures and/or status epilepticus in human infants and children. Per protocol, the animal was scheduled to receive a constant rate infusion of midazolam with boluses of phenobarbital over a 24-hour period, followed by reversal with flumazenil, and necropsy approximately 12 hours after the termination of sedation. Prior to this event, WNPRC personnel had performed this exact procedure on 22 rhesus infants without incident. The most difficult component of providing clinical support to rhesus infants undergoing the extended sedation period was maintaining their hydration and electrolyte status while avoiding overhydration since the animals generally weighed no more than 500 grams. All infants assigned to the study simultaneously received a constant rate infusion of midazolam and rehydration fluid and had their electrolyte, blood gas, and blood glucose levels checked routinely throughout the procedure. When clinicians were worried about overhydrating the infants, they would generally increase the concentration of the midazolam being administered to reduce the amount of volume of fluid received. During the early AM hours of September 16, 2021, a WNPRC clinician assigned to monitor the sedated infant in question had to replace the midazolam syringe being used to administer the constant rate infusion as it was almost empty. The clinician utilized the premade syringe of midazolam (which was clearly labeled as a 5 mg/ml concentration) that had been prepared by veterinary personnel from the previous shift, but mistakenly assumed that the syringe held midazolam at a concentration of 1 mg/ml because that was what was denoted on the experimental timeline that was posted on the wall of the procedure room. Subsequently, the infusion pump was programmed with the incorrect concentration (1 mg/ml) and the infant received 3.2 ml of 5 mg/ml midazolam over a 2.5hour period (3:00-5:30 AM). When the error was discovered, the infusion was stopped immediately, and the animal remained stable and sedate until the time it received the benzodiazepine antagonist flumazenil as planned at the end of the sedation procedure. As noted on the WNPRC Anesthesia Monitoring Records (attached as Appendix II), the infant's heart rate, oxygen saturation, respiratory rate, and systolic, mean, and diastolic blood pressure remained stable throughout the post-overdose period (See 02:00 - 20:51 values for September 16, 2021, in Appendix II). The animal required an overall intravenous dose of 0.18 mg of flumazenil to reverse the midazolam overdose, but the animal recovered without issue and was euthanized as scheduled at 20:51 on September 16, 2021.
- UW-Madison (WNPRC) Response: An extensive root cause analysis procedure performed after this incident revealed the following points:
 - Varying midazolam concentrations were written on procedure paperwork that may have added to confusion about what concentration should be used.
 - The veterinary timeline could have been placed in a more visible location.
 - All staff present at the procedure were well-qualified to execute the proposed experiment and had assisted with the procedure multiple times in the past.

 Veterinary and research support staff should pre-review experimental timelines prior to the procedure to ensure all paperwork is congruent.

WNPRC staff administered over 122,000 IM, IV, or PO clinical or experimental treatments in 2021. The WNPRC's error rate with respect to drug concentration errors is .003%, which demonstrates that its personnel are trained and qualified to perform their duties. This incident does not reflect a lack of training or insufficient review of qualifications; it resulted from a mistaken assumption that could have been resolved with a phone call to the veterinarian assigned to the previous shift. A phone call was not made because it was 3:00 AM and the veterinarian responsible for the incident assumed that they knew the concentration of midazolam in the syringe.

Description of Medication Dosing Error #2 with WNPRC Response

- Text of inspection report citation: August 19-27, 2021: A NHP was given an overdose
 of a diabetes medication because the newly acquired medication was 200mg/ml and
 what was used prior was 50mg/ml.
- Synopsis of incident: From August 19-27, 2021, an obese, 7-year-old cynomolgus macaque (cy1056) diagnosed with Type II diabetes received four times more metformin (an oral hypoglycemic agent commonly used for diabetic human and nonhuman primates) than prescribed due to several errors committed by WNPRC Veterinary and Colony Services staff. During the period that the higher than prescribed dose was administered, the animal was not reported for any abnormal clinical signs. A stat chemistry panel performed on 8/27/2021 (See Table 1 below) revealed nothing more than an elevated glucose level (139 mg/dl) which was consistent with the animal's glucoregulatory abnormalities.

Table 1. Serum Chemistry Panel Values for Macaque cy1056

			GLUC	BUN	CREAT	CPK	CHOL	TRIG	SGOT	LDH	TB	GGT	SGPT	TP	ALB	ALKP	CA	PHOS	FE	NA	K	CL
id 😊	Date -	13	0	(2)	- 0	0	- 10	.0	0	0	0	0	0	0	.0	10	O	0	27	.0	C	0
cy1056	2022-01-06 09	:36	55.00	19.00	1.08	2799.00	104.00	97.00	47,00	542.00	0.40	35.00	35.00	7.60	3.60	165.00	9.40	4.70	127.00	146,80	3,87	103,60
cy1056	2021-09-01 13	11	147.00	15.00	0.99	996.00	74.00	146.00	36.00	637.00	0.30	33.00	30.00	7.80	3.60	110.00	9.80	4.00	79.00	147.10	3.94	106.90
cy1056	2021-08-27 12	28	139.00	19.00																151.00	3.50	101.00
cy1056	2021-07-08 09	:00	184,00	18.00	1.32	665.00	113.00	397.00	36.00	467.00	0.30	39,00	50.00	7,40	3.80	133.00	9,40	2,80	157,00	149,10	3,45	107.80
cy1056	2021-01-05 12	:00	71.00	18.00	1.15	2173.00	76,00	77.00	44.00	834.00	0.30	36.00	31.00	7.60	3.90	122.00	9.00	4.40	64.00	151.50	3.19	107.70
cy1056	2020-07-08 10	:00	51.00	18.00	88,0	303,00	85.00	111,00	42.00	559.00	0,40	34.00	40.00	7.60	3.80	137.00	9.00	3.90	124.00	149.40	3,23	109.00
cy1056	2019-12-10 11	00	209.00	18.00	1.14	884.00	79.00	271.00	36.00	441.00	0.40	42.00	35.00	7.60	3.90	207.00	9.70	4.90	72.00	148.20	3,61	107.10
cy1056	2019-12-05 10	:00	265.00	18.00	1.00	1106.00	78.00	251.00	36.00	613.00	0.30	37.00	33.00	7.40	3.90	204.00	10.10	4.00	132.00	146.20	3.93	107.90
cy1056	2019-08-30 12	:00	51.00	14.00	1.15	729.00	88.00	86.00	46,00	509.00	0.20	42.00	53.00	7.50	3.80	310.00	9.40	5.70	78.00	149.70	3.17	107.50

- UW-Madison (WNPRC) Response: An extensive root cause analysis procedure performed after this incident revealed the following points:
 - The veterinary staff had historically utilized metformin at a concentration of 50 mg/ml to control the blood glucose level of the animal in question, but the veterinarian in charge of the case had recently ordered a more concentrated formulation of metformin (200 mg/ml) to reduce the volume of injections of the agent because they had to be administered twice per day.

- The veterinarian who ordered the higher concentration of metformin failed to inform the veterinary technician assigned to the area that they were changing to a higher concentration of the agent.
- The veterinarian was not notified when the higher concentration metformin was delivered, thus they never changed the volume of agent to be delivered in the electronic health records system.
- The veterinary technician and ACTs who administered the agent during the period in question failed to note that a higher concentration of the agent was being utilized.
- The WNPRC already has an SOP in place that mandates that special stickers must be placed on bottles when concentration differences are made, but this SOP was not followed due to a lack of communication about the arrival of the higher concentration metformin.
- As a result of this incident, WNPRC programmers reconfigured our electronic health records system so that all drug concentrations can easily be seen on all handheld devices (e.g., iPads, laptop computers, smart phones) utilized by Center staff while administering treatments.

WNPRC staff administered over 122,000 IM, IV, or PO clinical or experimental treatments in 2021. The WNPRC's error rate with respect to drug concentration errors is .003%, which demonstrates that its personnel are trained and qualified to perform their duties. This medication dosing error was the result of a lack of communication between individuals and the failure of several individuals to verify the concentration of the agent they were administering. As demonstrated by the low overall error rate, it is not representative of inadequate qualifications or a lack of training.

Description of Medication Dosing Error #3 with WNPRC Response

- Text of inspection report citation: October 07, 2021: Antibiotics were at times given to
 the incorrect animal because the orders were written under the ID of its social partner.
 Some technicians knew which was the correct animal while others didn't and followed
 the written orders.
- Synopsis of incident: On October 6, 2021, a WNPRC veterinary technician accidentally scheduled an antibiotic treatment (cephalexin) for 4.5-year-old rhesus macaque rh3051 for five days. Per veterinary orders, the technician was supposed to schedule the antibiotic for 4.5-year-old rhesus macaque rh3050 who had sustained a tail wound and was co-housed with animal rh3051. The technician knew rh3050 had sustained a tail wound, but inadvertently prescribed the treatment in our electronic records system for rh3051. Over the next three days, the veterinary technician who entered the antibiotic treatment into the system and another animal care technician who was aware of the tail wound, administered the antibiotic to the correct animal while the animal care technicians who administered the remaining two days of treatments, provided the treatments to animal rh3051 as was indicated in the health records system. Despite missing the last two days of the prescribed antibiotic treatment, rh3050's tail wound healed without further need of veterinary intervention (see attached clinical records for rh3050 in Appendix III).
- UW-Madison (WNPRC) Response:

- The veterinary technician who inadvertently scheduled the treatment for rh3051 but administered the treatment to the correct animal (rh3050), left their position at the WNPRC soon after the incident, thus no retraining was performed for this individual.
- The ACT who administered the treatment to the correct animal (because they knew which animal had the tail wound), despite the fact the treatment was scheduled for the wrong animal, was counseled about the importance of changing incorrect treatments in the electronic health records system because other ACTs might not know which animal was injured.

As noted above in the synopses for Medication Dosing Errors #1 and #2, WNPRC staff administered over 122,000 IM, IV, or PO clinical or experimental treatments in 2021. The rate of erroneous administration of drugs to the wrong animal is very low at .01%. Furthermore, the veterinary technician who scheduled the treatment for the wrong animal had administered 1,061 treatments during their tenure at the WNPRC with just this one error and the ACT has delivered 5,149 treatments with just this one error. This demonstrates that both individuals had excellent attention to detail, sufficient training, and were well-qualified to perform their duties. The similarity of the identification numbers of the two animals played a role in the event. Rhesus monkeys acquired by the WNPRC from an outside source are assigned a six-character alphanumeric identification number upon arrival at the Center. The first two characters are a species indicator (i.e., "rh" = rhesus). The next four numbers assigned to a rhesus acquired from an outside source are a sequential four-digit numeric code that represents the order in which the animal was acquired by the WNPRC (i.e., rhesus r3050 was the 3,050th rhesus acquired by the WNPRC from an outside source). The identification number is tattooed on the rhesus monkey's chest and left inner thigh soon after arrival and any other tattoos the animal has previously received are covered with one continuous horizontal tattoo line to decrease confusion regarding the animal's WNPRC ID. It is not uncommon for animals with sequential ID numbers to be housed together, as animals from the same source or animals born just a few days apart are often compatible with one another, however, the incident most probably would not have occurred if the animals had ID numbers that were less similar since the animals' body weights were almost identical.

Description of Medication Dosing Error #4 with WNPRC Response

- Text of inspection report citation: January 6, 2022: one NHP had missed its daily treatments of a glucoregulatory medication and liver function support medication and a different NHP received it because the last 2 digits of the ID were verified but not the complete identification number.
- Synopsis of incident: From December 31, 2021 January 5, 2022, 23-year-old, male rhesus macaque r980<u>56</u>, a pre-diabetic animal with a history of high normal liver values, did not receive its prescribed oral doses of pioglitazone (a drug which reduces insulin resistance) and denmarin (a nutritional supplement containing the antioxidant Silybin used to improve liver function). An ACT inadvertently administered the doses of pioglitazone and denmarin to 4.5-year-old, male rhesus r170<u>56</u> because the animal had the same last two numbers in its ID and lived two enclosures away from r98056. Despite missing 6 days of therapy, a serum chemistry panel run for r98056 on January 5, 2022, revealed no abnormal glucose or liver function values (See Table 2 below). Furthermore, animal r17056 revealed no discernible adverse clinical outcomes after receiving the agents prescribed for r98056.

Table 2. Serum Chemistry Panel Values for Macaque r98056

		GLUC	BUN	CREAT	CPK	CHOL	TRIG	SGOT	LDH	TB	GGT	SGPT	TP	ALB	ALKP	CA	PHOS	FE	NA	K	CL
ld 🌣	Date + ©	0	.0	0	- 0	0	- 0	0	0	0	0	0	0	0	0	0	-0	0	0	.0	O
r98056	2022-01-05 08:30	69.00	13.00	0.67	130.00	146.00	311.00	29,00	255.00	0.40	36.00	84.00	7.10	4.10	234.00	9.90	2.50	59.00	150.10	3.51	112.80
198056	2021-07-29 09:00	49.00	12.00	0.71	276.00	154.00	424.00	34.00	442.00	0.30	43.00	85.00	6.80	3.90	149.00	9.80	3.00	82.00	148.30	3.12	109.90
198056	2021-05-18 11:45	92.00	14.00	0.75	151.00	146.00	299.00	36.00	241.00	0.40	41.00	73.00	7.40	4.30	173.00	10.50	4.10	65.00	147.50	4.06	109.40
198056	2021-03-02 13:10	113.00	14,00	0.55	972.00	190.00	1315.00	43 00	489.00	0.20	33.00	96.00	7.10	3.90	245.00	10.20	3.40	64.00	144.00	4.00	105.00
198056	2021-02-10 12:00	65.00	14.00	0.59	711.00	196.00	615.00	41.00	448.00	0.30	43.00	109.00	7.10	3.90	204.00	9.80	4.20	80.00	151.00	3.29	109.30
r98056	2020-07-27 12:00	59.00	13.00	0.56	716.00	194.00	566.00	46.00	395.00	0.40	43.00	130.00	7,00	4.20	237.00	10.00	3.90	87.00	151.00	3.54	112.70
198056	2020-01-27 12:00	60.00	14.00	0.60	196.00	211.00	277,00	35.00	203.00	0.20	55.00	131.00	7.20	4,30	207.00	9.90	4.90	87.00	152.70	3,58	112.60
r98056	2019-08-13 11:43	42.00	12.00	0.60	571.00	166.00	312.00	45.00	470.00	0.30	46.00	72,00	7.20	4.10	226.00	10,20	4.40	115.00	148,80	3.40	111.70

- UW-Madison (WNPRC) Response: An extensive root cause analysis procedure performed after this incident revealed the following points:
 - The ACT felt that they were at the correct enclosure on each day they administered the medication and only confirmed the last two digits of the animal's ID. The mobile enclosures in the animal room do not have cage tags on them to confirm the enclosure number because they are changed out every two weeks during cage sanitization.
 - The ACT incorrectly believed that they were following WNPRC SOPs when they
 identified the last two numbers of the animal's ID.
 - The incident could have been avoided if the ACT had written the animal's entire ID on the souffle cup they were using to carry each day's dose of the medication to the animal room and verified the entire six-digit alphanumeric code.

The pivotal contributing factor in this incident is that two rhesus monkeys with identical ending numbers in their identification tattoos were housed only two enclosures apart in the same housing room.

Rhesus monkeys born at the WNPRC are given a six-character alphanumeric identification number at birth. The first character is a species indicator (i.e., "r" = rhesus). The first two numbers of a rhesus ID are the last two numbers of the year in which the animal was born (i.e., rhesus r98056 was born in 1998 and r17056 was born in 2017). The last three numbers of a rhesus ID indicate its birth order in the year it was born (i.e., r98056 was the 56th animal born at the WNPRC in 1998, r17056 was the 56th animal born in 2017). This ID is tattooed on an animal's chest and the inside of their left thigh as soon as they are large enough for the procedure to be performed safely (approximately 8-12 months of age).

Having two rhesus monkeys with the same last two ID numbers housed in close proximity is a relatively uncommon event at the WNPRC, since there is only one rhesus monkey from each birth year with the same two ending ID numbers. While the ACT should have verified the animal's entire ID number before administering the treatment, the individual has already administered 1,236 clinical/experimental treatments during their tenure at the WNPRC without any other errors, a track record that demonstrates the effectiveness of their training and their qualifications. The low rate of error associated with administration of drugs to the wrong animal is further evidence of the robust training and qualification of individuals at the WNPRC.

Conclusion

The WNRPC regrets all incidents involving NHP that occur at the Center whether an animal experiences adverse consequences or not, is fastidious about identifying errors, thoroughly evaluates the root cause of incidents, and is committed to implementing procedures that reduce the likelihood of error recurrence. Our annual incident rates, especially those resulting in animal injury, are consistently under 0.01%. Therefore, based on the evidence provided above, we request that the USDA remove the four medication dosing errors from the Inspection Report dated April 07, 2022, as there is no evidence that they resulted from inadequate qualifications or training or are indicative of noncompliance with 9 CFR § 2.32(b). Rather, the error rate data demonstrates that the WNPRC are well-trained and perform at a consistently exemplary level, and the WNPRC's commitment to maintaining an excellent program is reflected in its implementation of thorough training and error mitigation programs.

We would be happy to discuss these issues at greater length if the appeal committee requires further information. Thank you for granting us additional time to submit this appeal.

Sincerely,

Appendix I



United States Department of Agriculture Animal and Plant Health Inspection Service

SWELCH 2016090000780817 Insp id

Inspection Report

UNIVERSITY OF WISCONSIN MADISON

DIRECTOR RESEARCH ANIMAL RESOURCES CENTER 1710 UNIVERSITY AVENUE 396 ENZYME INST MADISON, WI 53726

Customer ID: 616

Certificate: 35-R-0001

Site: 001

ALL CAMPUS SITES

Type: ROUTINE INSPECTION

Date: 05-APR-2022

2.32(b)

Personnel qualifications.

There have been four incidents of medication dosing errors involving non-human primates (NHPs) and one incident of the incorrect divider placement for NHPs that were reported to the ACUC and OLAW since the last inspection in August 2021. These incidents could have been prevented if the personnel followed established procedures:

-July 2021: the incorrect divider with mesh was put in place allowing two non-human primates (NHPs) to contact each other through the divider and one lost the tip of its tongue. (affected animal was appropriately treated and recovered).

-Sept 2021: an overdose of midazolam was given to a NHP because the concentration available was different than what the infusion machine was set for.

-August 19-27, 2021: A NHP was given an overdose of a diabetes medication because the newly acquired medication was 200mg/ml and what was used prior was 50mg/ml.

-October 07, 2021: Antibiotics were at times given to the incorrect animal because the orders were written under the ID of its social partner, however some technicians knew which was the correct animal while others didn't and followed the written orders.

-January 6, 2022: one NHP had missed its daily treatments of a glucoregulatory medication and liver function support medication and a different NHP received it because the last 2 digits of the ID were verified but not the complete

Prepared By: SCOTT WELCH

USDA, APHIS, Animal Care

Date: 07-APR-2022

Title: VETERINARY MEDICAL

OFFICER

Received by Title: Attending Veterinarian

Date:

07-APR-2022



SWELCH 2016090000780817 Insp id

Inspection Report

identification number.

**While the incorrect medication dosing incidents were reported not to have caused any serious adverse effects to the animals involved, these errors have a component of not carefully following proper procedures and could lead to serious harm to animals if not prevented in the future. The research facility must review and ensure that all personnel involved with animals are trained adequately and qualified in a manner to prevent animal management errors and medication errors.

Correct by 7/7/2022.

3.75(c)(1)

Critical

Housing facilities, general.

In August 2021 a NHP was found to have its hand stuck between the perch and the wall. Staff removed it and it was treated by staff veterinarians which included amputation of two digits. Records indicate it was appropriately treated and monitored for recovery. Staff also report the perch involved and all perch fixtures of this design were evaluated and reinforced as necessary to prevent further recurrence. This incident was reported to OLAW and the ACUC.

In December 2021 an enrichment device had been modified from its original design for use in a non-human primate enclosure. The enrichment device originally had a sheath with a bungle to attach to the enclosure, however the sheath became detached and when repaired it was modified to be held up with the two chains. The two chains used to suspend it within the enclosure had enough space that a macaque was able to get its head between the chains and then couldn't get back out. The facility found it caught and immediate CPR attempts were noted to be unsuccessful.

Note: The facility reports all enrichment devices of this design were removed to prevent further occurrence and noted retraining of staff on appropriate enrichment device usage and device repair procedure/reporting would be put in place.

Prepared By: SCOTT WELCH

Date:

Title: VETERINARY MEDICAL

07-APR-2022

OFFICER

Received by Title: Attending Veterinarian

Date:

07-APR-2022

USDA, APHIS, Animal Care



Customer: 616

Inspection Date: 05-Apr-2022

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
616	35-R-0001	001	ALL CAMPUS SITES	05-APR-2022

Count	Scientific Name	Common Name
000197	Macaca fascicularis	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
001485	Macaca mulatta	RHESUS MACAQUE
000312	Callithrix jacchus	COMMON MARMOSET
001994	Total	



SWELCH 2016090000780817 Insp id

Inspection Report

This incident was also reported by the facility to the USDA veterinary medical officers by the attending veterinarian in December 2021 and also was reported to OLAW and the ACUC.

These two incidents involving furniture-type fixtures had a serious adverse effect on the involved animals and did not provide for the safe activity for the NHPs that use them. Ensure that all furniture-type fixtures or objects remain sturdily constructed and strong enough to provide for the safe activity and welfare of nonhuman primates that use them.

Maintain correct from this day forward.

This inspection of the non-human primates under LVSC was conducted with facility representatives from 4/5-4/7/2022.

Additional Inspectors:

DAWN BARKSDALE, VETERINARY MEDICAL OFFICER

GWENDALYN MAGINNIS

Prepared By: SCOTT WELCH

USDA, APHIS, Animal Care

07-APR-2022

Date:

Title: VETERINARY MEDICAL

OFFICER

Received by Title: Attending Veterinarian

Date:

07-APR-2022

Appendix II

WISCONSIN NATIONAL PRIMATE RESEARCH CENTER

ANESTHESIA MONITORING RECORD

Animal ID Project # Initials √ ID (Initial) Date 20160101 Page: 7 of: 15 r21069 16 Sept 2021 Age: 13 days Investigator Anesthetist(s): Scx: Female Surgeon(s): Procedure: Extended Sedation w/Phenobarb & Midazolam: AF HT Intubation Time: Extubation Time: Procedure Start Timer Procedure End Tome: ET Tube Size (mm): See Cephalic IVC Size & Loc: Right Saphenous IVC Size & Loc Cephalic Saphenous Left Total(s) 400 Time 300 ldose or volume Fluids & CRIs midazolan nolkolin 4 Dextrose 5%+0AMA 6.5 40 4.0 3.0 3.0 20 2.0 1.5 1.5 1.0 35.5 35.3 35.1 35.3 36.7 35.0 74.9 35.8 74.L 35 Temperature (°F): (R) Symbols: 330 330 · Heart Rate 320 O Resp Rate 300 300 SpO₂ 280 x ETCO2 280 Systolic 260 Mean 240 240 Diastolic Assisted 220 220 Controlled 200 B 10 mL/kg fluid bolus 180 180 5 mL/kg fluid bolus 140 Parameters | Monitored: 130 130 ✓ Heart Rate 120 Resp Rate 110 110 ☑ SPO₂ 100 ☐ ETCO₂ 90 ✓ NIBP √ Temp ☐ ECG ☐ IBP System Used: ☐ Circle 40 ☐ NRB ☐ Ventilator ☐ Mask ☑ None Obtained by Rise for Animals. 22-04422 000063 ed to Animal Research Laboratory Overview (1840) 00010/09/2023 2 0

ANESTHESIA MONITORING RECORD WISCONSIN NATIONAL PRIMATE RESEARCH CENTER √ID (Initial) Animal ID Date Project # Initials of:18 3 Page: 8 r21069 16 Spt 2021 201 60 1 01 Midely law cas sover and -Age: 13 days Sex: Female Anesthetist(s): NA Surgeon(s): Procedure: Extended Sedation w/Phenobarb & Midazolam: NT HT Procedure Notes: Intubation Time: Estubation Time: Procedurg Start Tipue: dure End Time: ET Tube Siccing IVC Size & Loc: Lophalic Saphenous Right IVC Size & Loc: Left Cephalic Saphenous Time 500 30 45 Total(s) 30 Fluids & CRIs dose or volume Midozalum nelte/hr 4. Detunce 52 + Bazuncia za Deparase 71. + 0.9 / Naci 4.13 0.754 0.25-clh 40 40 3.0 3.0 2.0 2.0 1.5 1.0 1.0 0.5 O. (Limin) 35,4 34.9 Temperature (°F): (R) E 35.8 R4.7 34.4 24.3 35.8 34.9 34.8 34.6 Symbols: 330 330 Heart Rate 320 320 Resp Rate 300 300 SpO_2 EICO2 280 Systolic 260 260 Mean 240 240 Diastolic Assisted 220 220 Controlled 200 200 10 mL/kg fluid bolus 180 180 5 mL/kg 160 160 fluid bolus 140 140 **Parameters** Monitored: 130 130 ✓ Heart Rate 120 120 Resp Rate 110 110 SPO₂ 100 100 ☐ ETCO₂ # 41 41 41 W 4 ✓ NIBP 90 √ Temp 80 0 □ ECG 70 ☐ IBP 0 60 60 System Used: 50 50 ☐ Circle 40 40 □ NRB ☐ Ventilator 30 30 ☐ Mask ☑ None 10 10 Obtained by Rise for 000064 arch Laboratory Overview (ABle Detect 0/20/2023 eşe

ANESTHESIA MONITORING RECORD WISCONSIN NATIONAL PRIMATE RESEARCH CENTER Initials VID (Initial) Project # Animal ID Date Page: 9 of: 20160101 r21069 16 Sep.t 2021 Sex: Female Investigator: Ikonomidou Ancsthetist(s): Age: 13 days Weight (kg): 0.5 MIA Procedure: Extended Sedation w/Phenobarb & Midazolam; NT HT Surgeon(s): Procedure Notes: Hypothermia + Phenobabital/Midazolan Intubation Time: Extubation Time: Procedure Start Time O Procedure End Time: ET Tube Size (mm) Right Cephalic Saphenous IVC Size & IVC Size & Loc: Cephalic Saphenous Total(s) dose or volume Fluids & CRIs Dextrose 7% + Naci 09% 0.25ml/h 4.0 3.0 3.0 2.0 1.5 1.5 O. (L/min) 354 361 350 350 357 357 367 34.2 39.0 26.6 35.8 Temperature (°F): (R) 3410 Symbols: 330 330 Heart Rate 320 Resp Rate 300 300 SpO₂ 280 ETCO₂ 280 Systolic Mean 240 240 Diastolic Assisted 220 220 Controlled 200 B 10 mL/kg 180 fluid bolus 180 5 mL/kg 160 160 fluid bolus 140 140 **Parameters** 130 Monitored: 130 Heart Rate 120 Resp Rate 110 ✓ SPO₂ 100 ☐ ETCO₂ ✓ NIBP 90 √ Temp ☐ ECG 70 ☐ IBP 60 System Used: ☐ Circle 40 ☐ NRB 30 ☐ Ventilator 20 Mask. ✓ None 22-04422 000065 Uploaded to Animal Research Labora y Overview (John Outlow) 202923

ANESTHESIA MONITORING RECORD WISCONSIN NATIONAL PRIMATE RESEARCH CENTER **Initials** √ ID (Initial) Project # **Animal ID** 16 Sept 2021 20160101 Page: 0 of: VZIDLA Anesthetist(s): Weight (kg): 6,5 Investigator: Age: 13 d Surgeon(s): NA Procedure: Intubation Time: Exhibation Time: Procedure Notes: Hypothermia+ Pheno, midarola-HT Procedure Start Time: Procedure End Time: ET Tube Size (mm) IVC Size & Lot: Cephalic Saphenous IVC Size & Loc RIETE Cephalic Saphenous Total(s) 1500 30 Time dose or volume Fluids & CRIs 8.38m 7.1. Dexhore Huach long he 4.0 3.0 3.0 2.0 20 1.5 1.5 1.0 O, (L/min) 35.8 3468 36.2 35.5 25.3 36.1 34.1 15 B 25.6 Temperature (°F). R Symbols: 330 Heart Rate 320 Resp Rate 300 300 SpO₂ 280 ETCO₂ 280 Systolic 260 260 Mean 240 240 Diastolic 220 Assisted Controlled 200 200 10 mL/kg fluid bolus 5 mL/kg 160 160 fluid bolus 140 Parameters. Monitored: 130 Heart Rate 120 120 Resp Rate 110 SPO₂ 110 100 M ETCO 100 NIBP Temp 80 ☐ ECG 70 □ IBP 60 60 System Used: 50 50 O ☐ Circle ☐ NRB 30 ☐ Ventilator 30 ☐ Mask 20 20 None 2-04422 000066

WISCONSIN NATIONAL PRIMATE RESEARCH CENTER ANESTHESIA MONITORING RECORD Animal ID √ ID (Initial) Date Project # Initials r21069 16 Sept 2021 20160101 Page: of:/2 Age: 13 days Sex: Female Investigator Ancst htist(s): Procedure: Extended Sedation w/Phenobarb & Midazolam; NF HT Surgeon(s): Procedure Notes: Intubation Time: Extubation Time: Procedure Start Time? Procedure End Time: ET Tube Size (man); IVC Size & Loc. S Right / Cephalic IVC Size & Loc. light Left Cephalic Saphenous 14 00 Total(s) Time 45 **Pluids & CRIs** dose or volume 79- Dedoc 31 294 Thi/h & ulas 4.0 4.0 3.0 3.0 2.0 2.0 1.5 1.0 1.0 0.5 0.5 35.4 **ን**ፉ-ላ 35.0 35.8 35.2 35.0 35.2 35.8 35.1 35.4 34.9 34.8 O. (L/min) Temperature (°F):(R) E Symbols: 330 Heart Rate 320 320 Resp Rate 300 300 SpO_2 x ETCO2 280 280 Systolic 260 260 Mean 240 Diastolic Assisted 220 220 Controlled 200 200 B 10 mL/kg fluid bolus 180 5 mL/kg 160 160 fluid bolus 140 Parameters | Monitored: ✓ Heart Rate 120 120 Resp Rate 110 ☑ SPO₂ 0 100 ☐ ETCO₂ 100 ☑ NIBP 90 √ Temp 80 □ ECG 70 ☐ IBP System Used: 50 50 ☐ Circle 40 ☐ NRB 30 ☐ Ventilator ☐ Mask 20 ✓ None 10 000067 Uploaded to Animal Research Laboratory Overview ((ARLQ) റ്റുപ്പു) 26/2023 Œ)

√ID (Initial) Animal ID Date Project # Initials Page: 12 of: 13 r21069 16 Sept 2021 20160101 Weight (kg): 0.5 Age. 13 days Sex: Female Investigator Anesthetist(s)? Procedure Extended Sedation w/Phenobarb & Midazolam; NT HT Surgeon(s): Procedure Notes: Intubation Time: Extubation Time: Procedua Stan Ting Procedure End Time: ET Tube Since Inda IVC Size & Loc. Ocu Cephalic Saphenous IVC Size & Loc: Right Cephalic Left -Saphenous Time 1900 18 00 17 00 30 45 Total(s) Fluids & CRIs dose or volume 4.0 4.0 3.0 3.0 Isofluranc 20 2.0 1.5 1.5 1.0 0.5 0.5 O. (L/min) 35.5 35.60 35.2 Temperature (°F):(R) E 35.1 35.8 35. 35.8 35.0 35.0 35.9 35.4 Symbols: 330 330 Heart Rate 320 320 Resp Rate 0 300 300 SpO₂ ETCO₂ 280 Systolic 260 260 Mean 240 240 Diastolic Assisted 220 220 Controlled 200 200 B 10 mL/kg fluid bolus 180 180 5 mL/kg 160 160 fluid bolus 140 140 Parameters Monitored: 130 130 ✓ Heart Rate 120 120 Resp Rate 110 110 ✓ SPO₂ 00 ☐ ETCO₂ 100 ☑ NIBP 90 90 √ Temp 80 ☐ ECG 70 70 ☐ IBP 60 60 System Used: 50 50 ☐ Circle 40 40 ☐ NRB ☐ Ventilator 30 30 ☐ Mask ☑ None 10 10 Obtained by Rise for Animals. Uploaded to Animal Research Laboratory Overview (ARL®) 2006/20/20/2003

ANESTHESIA MONITORING RECORD

WISCONSIN NATIONAL PRIMATE RESEARCH CENTER

√ID (Initial) Animal ID Date Project # Initials r21069 16 SEPT 2021 20160101 of: 13 Page: 13 Age: 13 days | Sex: F Weight (kg): 0.5 Investigator. Anest heti(s): Procedure: EVTENDED SEDATION W/ ALENUBARB & MIDAZ CLUM; HT Surgeon(s): MA Procedure Notes: Intubation Time: Extubation Time: Procedure Start Tithe: Procedure End Time: 18 m IVC Size & Loc: Cephalic Saphenous Right e Och IVC Size & Loc: Cephalic Time 2000 45 2)00 30 Total(s) dose or volume Fluids & CRIs Isoflurane % 3.0 2.0 1.5 1.0 1.0 0.5 Q (L/min) Temperature (°F): Ε 35.3 34.9 35.1 35.8 Symbols: 330 Heart Rate 320 320 O Resp Rate 300 300 SpO₂ x Erco₂ 280 Systolic 260 260 Mean 240 740 Diastolic Assisted 220 Controlled 200 B 10 mL/kg fluid bolus 180 180 5 mL/kg 160 fluid bolus 140 140 Parameters. Monitored: 130 130 Heart Rate 120 120 Resp Rate 110 110 ☑ SPO₂ 100 ☐ ETCO₂ 100 ☐ NIBP 90 Temp ☐ ECG 70 ☐ IBP 60 System Used: 50 Circle 40 40 NRB ☐ Ventilator 30 30 Mask 20 √ None Obtained

ANESTHESIA MONITORING RECORD

WISCONSIN NATIONAL PRIMATE RESEARCH CENTER

WERPRE Lands V WHIPRE Lands V WINDRE Electronic Health Percord V Builds Search V Holp V

EHR DEHR

Animal Details

Assay	Assignments	Clinical	Clin Path	Colony Management	General	Husbandry	Pathology	Physical Exam	Today At Ce	enter	
4-14	Animal Porta	l Arrival	/Departure	Blood Draw History	Charges	Current Blood	Deaths	Demographics	Major Events	Notes	Snapshot

7) John Jan 1987 1887

ld	rh3050	Current Weight (kg)	8.7
Gender	female	Weight Date	2021-12-20 09:34:00.000
Avail	- b	Hold	
Room	ab110	Medical	west nile -, distemper vax
Cage	0037	Current Behavior(s)	
Condition	s	Most Recent Alopecia Score	1
#Animals In Cage	3	Most Recent BCS	3.5
Status	Alive	Source/Vendor	California National Primate Research Center
Age	4.7 years	Geographic Origin	domestic
Birth	2017-04-13 00:00:00.000	Ancestry	indian
Dam	43392	Most Recent Arrival	2020-09-23 07:00:00 000
Sire	43156	Most Recent Departure	
Most Recent TB Date	2021-07-14 00:00:00.000	Death	
Replacement Prepaid By	enpre purchase cost for end user \$8799	Pathology Notes	

Office Occion. - 6000204

More Actions ☐ Id O Date - O End Date O Category O Note O Remark O Status O Task Id O No data to show.

Bertou decide number and the

More Actions (Active Assignments)

Id O Gender O Project O Protocol O Title O Project Avail O Investigator O Assign Date O Release Date O Status O Task Id O rh3050 female 20150801 g005246 spf breeding colony b 2021-01-22 Completed 1299826

Problem Unt - readour

Id Current Room Current Problem Number Date Observed - Date Resolved Category O Remark Cage rh3050 ab110 0037 1 2021-10-01 2021-10-11 Surgery: Minor (Clinical) Dorsal Tail BAse- Meloxicam Malekia - Hilloso Weight Summary: Last Weight 8.7 kg 2021-12-20 09:34:00.000 (14 days ago) Date: # Weights Avg Weight Min Weight Max Weight Max Pct Change Previous 30 Days: 1 8.7 kg 8.7 kg 8.7 kg Previous 90 Days: 3 8.52 kg 8 26 kg 8.7 kg 5.3% Previous 180 Days: 4 8.04 kg 6.6 kg 8.7 kg 31.8% Graph Last Year Weight: rh3050 rh3050 Weight 8.5 Weight (kg) 2020-11-10 2021-01-07 2021-12-20 2021-03-05 2021-05-02 2021-06-29 2021-08-26 2021-10-23 Date More Actions Percent Change Id * O Date -O Weight (kg) Current Weight (kg) % Change Relative To Current Interval (Months) Remark rh3050 2021-12-20 09:34 8.7 8.7 0.0 0.0 rh3050 2021-11-01 09:08 1.0 8.6 8.7 1.2 rh3050 2021-10-0713:32 8.26 8.7 5.3 2.0 0 rh3050 2021-07-14 13:39 6.6 8.7 31.8 5.0 7 rh3050 2021-06-22 11:20 5.0 8.7 24.3 0 rh3050 2021-05-04 09:18 6.26 8.7 39.0 7.0 rh3050 2021-04-28 06:44 6.2 8.7 40.3 7.0 rh3050 2021-02-03 09:30 5.92 10.0 8.7 47.0 rh3050 2020-12-01 09:48 5.77 8.7 50.8 120 rh3050 2020-10-27 09:30 68.0 13.0 5.18 8.7

rh3050 2020-10-14 09:30

rh3050 2020-09-30 09:30

rh3050 2020-09-15 00:00

4.96

5.09

5.59

8.7

8.7

8.7

14.0

14.0

15.0

75.4

70.9

55.6

WINDSH Units > WINDSH Labs >

22-04422_000072

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EHR DEHR

Animal Details

Assay	Assignments Clinical Clin Path	Colony Manageme	nt General Husbar	ndry Pathology	Physical Exa	m Today At Center					
Abstrac		S 155		Diarrhea Calendar	Full History	*	Irregular Obs	Problem List	Procedure Codes	Surgical History T	
San F	History Plus Dos - rhal650										
	⊞ ≜ ⊖						1161				
(11)	Full History Plus Obs										
(×	t ▼ DATE(Date) <= Mon Oct 25 2021 00:00	<u> </u>									
	id O Date Y - O Project	Dataset O	Remark		0	Description		0			
0	rh3050 2021-10-06 07:37	Irregular Observations				No irregular Observations					
0	ф3050 2021-10-06 07:37	Irregular Observations	cut on the base of tail, F	side, actively bleed	ing	Trauma Location: tail					
О	rh3050 2021-10-06 09:57 300901	Clinical Remarks				S/O: Recheck of trauma: \$ amount of serosanguinou A: Sutures partially dehiso P: Begin tx as prescribed	us discharge, Anir ced, Mild non-pur	mal is BARH, too ulent discharge	k treats., present. Per DVM, st	art cephalexin tx.,	
	6 h3050 2021-10-06 14:02	Irregular Observations				No Irregular Observations	5				
D	rh3050 2021-10-07 08:04 300901	Drug Administration				Code: cephalexin (c-5313 Route: oral, Volume: 3 mL, Amount: 150 mg	30),				
0	rh3050 2021-10-07 08:19	Irregular Observations	Scabbing on base of ta	il							
()	rh3050 2021-10-07 11:30 2015080	1 Ultrasounds	Not Pregnant or too ea	rly to detect							
D	rh3050 2021-10-07 12.10	Irregular Observations				No Irregular Observations					
0	rh3050 2021-10-07 12:56 300901	Drug Administration				Code: cephalexin (c-5313 Route: cral, Volume: 3 mL, Amount: 150 mg	30),				

П	Id O Date Y - O Project	Dataset 💌 P	Remark	0	Description
	rh3050 2021-10-07 13:32	Weight			Weight: 8.26
0	rh3050 2021-10-08 07:58 300901	Drug Administration			Code: cephalexin (c-53130), Route; oral, Volume: 3 mL, Amount: 150 mg
	rh3050 2021-10-08 08:04	Irregular Observations			No Irregular Observations
О	rh3050 2021-10-08 10:51 300901	Clinical Remarks			S/O: Recheck of wound to tail base: Site is closed and dry with mild erythema and mild swelling. Suture A: Wound is healing WNL. No signs of infection or discharge., P: Monitor healing progress and for problem resolution. Comment as needed.
0	rh3050 2021-10-08 12:21 300901	Drug Administration			Code: cephalexin (c-53130), Route: oral, Volume: 3 mL, Amount: 150 mg
	rh3050 2021-10-09 07:14 300901	Drug Administration			Code: cephalexin (c-53130), Route: oral, Volume: 3 mL, Amount: 150 mg
	rh3050 2021-10-09 08:12	Irregular Observations			No Irregular Observations
0	rh3050 2021-10-09 14:02 300901	Drug Administration			Code: cephalexin (c-53130), Route: oral, Volume: 3 mL, Amount: 150 mg
	rh3050 2021-10-10 08:14	Irregular Observations			No Irregular Observations
	rh3050 2021-10-11 06:48	Irregular Observations			No Irregular Observations
О	rh3050 2021-10-11 11:00 300901	Clinical Remarks			S/O: recheck of wound on dorsal tail base, wound is open about 2 cm long by 8 mm wide on dorsal/ rig around wound., A: healing trauma, no sign of infection, expect wound will continue to heal by second intention., P: no additional treatment or monitoring necessary.
	rh3050 2021-10-12 07:42	Irregular Observations			No Irregular Observations
0	rh3050 2021-10-12 09:26 20150801	Ultrasounds	Not Pregnant or too early to detect		
0	rh3050 2021-10-12 12:12	Irregular Observations			No Irregular Observations
0	rh3050 2021-10-13 07:34	Irregular Observations			No Irregular Observations
O	rh3050 2021-10-13 14:02	Irregular Observations			No Irregular Observations
Ü	rh3050 2021-10-14 07:59	Irregular Observations			No Irregular Observations
0	rh3050 2021-10-14 13:37	trregular Observations			No Irregular Observations

,0	(•	Date 🕇 🐣	O Pro	oject	Dataset	0	Remark		0	Description	0
	rh3050	2021-10-15 07	7:22		Irregular Observations					No irregular Observations	
	rh3050	2021-10-16 06	5:46		Irregular Observations					No Irregular Observations	
	rh3050	2021-10-17 08	8:16		Irregular Observations					No Irregular Observations	
	rh3050	2021-10-18 06	6:56		irregular Observations					No Irregular Observations	
	rh3050	2021-10-18 13	3:05		trregular Observations					No Irregular Observations	
	rh3050	2021-10-19 08	8:20		Irregular Observations					No Irregular Observations	
	rh3050	2021-10-19 1	3:52		Irregular Observations					No Irregular Observations	
	rh3050	2021-10-20 0	7:52		Irregular Observations					No Irregular Observations	
	rh3050	2021-10-20 0	9:25 20	150801	Ultrasounds		Not Pregnant				
	m3050	0 2021-10-20 1	4:13		Irregular Observations					No Irregular Observations	
	m3050	0 2021-10-21 0	6:38		Irregular Observations					No Irregular Observations	
	rh305	0 2021-10-22 0	8:02		Irregular Observations					No Irregular Observations	
	rh305	0 2021-10-24 0	17:37		Irregular Observations		a .			No irregular Observations	
	rh305	0 2021-10-25 0	06:40		trregular Observations			Powered by LabKey		Menses: LM	



SWELCH **2016090000780817** Insp_id

Inspection Report

UNIVERSITY OF WISCONSIN MADISON

DIRECTOR RESEARCH ANIMAL RESOURCES CENTER 1710 UNIVERSITY AVENUE 396 ENZYME INST

MADISON, WI 53726

Customer ID: 616

Certificate: 35-R-0001

Site: 001

ALL CAMPUS SITES

Type: ROUTINE INSPECTION

Date: 05-APR-2022

2.32(b)

Personnel qualifications.

There have been four incidents of medication dosing errors involving non-human primates (NHPs) and one incident of the incorrect divider placement for NHPs that were reported to the ACUC and OLAW since the last inspection in August 2021. These incidents could have been prevented if the personnel followed established procedures:

-July 2021: the incorrect divider with mesh was put in place allowing two non-human primates (NHPs) to contact each other through the divider and one lost the tip of its tongue. (affected animal was appropriately treated and recovered).

-Sept 2021: an overdose of midazolam was given to a NHP because the concentration available was different than what the infusion machine was set for.

-August 19-27, 2021: A NHP was given an overdose of a diabetes medication because the newly acquired medication was 200mg/ml and what was used prior was 50mg/ml.

-October 07, 2021: Antibiotics were at times given to the incorrect animal because the orders were written under the ID of its social partner, however some technicians knew which was the correct animal while others didn't and followed the written orders.

-January 6, 2022: one NHP had missed its daily treatments of a glucoregulatory medication and liver function support medication and a different NHP received it because the last 2 digits of the ID were verified but not the complete

Prepared By: SCOTT WELCH Date:

USDA, APHIS, Animal Care 07-APR-2022 **Title:** VETERINARY MEDICAL

OFFICER

OFFICER

Received by Title: Attending Veterinarian Date: 07-APR-2022



SWELCH **2016090000780817** Insp_id

Inspection Report

identification number.

**While the incorrect medication dosing incidents were reported not to have caused any serious adverse effects to the animals involved, these errors have a component of not carefully following proper procedures and could lead to serious harm to animals if not prevented in the future. The research facility must review and ensure that all personnel involved with animals are trained adequately and qualified in a manner to prevent animal management errors and medication errors.

Correct by 7/7/2022.

3.75(c)(1) Critical

Housing facilities, general.

In August 2021 a NHP was found to have its hand stuck between the perch and the wall. Staff removed it and it was treated by staff veterinarians which included amputation of two digits. Records indicate it was appropriately treated and monitored for recovery. Staff also report the perch involved and all perch fixtures of this design were evaluated and reinforced as necessary to prevent further recurrence. This incident was reported to OLAW and the ACUC.

In December 2021 an enrichment device had been modified from its original design for use in a non-human primate enclosure. The enrichment device originally had a sheath with a bungie to attach to the enclosure, however the sheath became detached and when repaired it was modified to be held up with the two chains. The two chains used to suspend it within the enclosure had enough space that a macaque was able to get its head between the chains and then couldn't get back out. The facility found it caught and immediate CPR attempts were noted to be unsuccessful.

Note: The facility reports all enrichment devices of this design were removed to prevent further occurrence and noted retraining of staff on appropriate enrichment device usage and device repair procedure/reporting would be put in place.

Prepared By: SCOTT WELCH Date:

Title: VETERINARY MEDICAL

OFFICER

Received by Title: Attending Veterinarian Date: 07-APR-2022

USDA, APHIS, Animal Care

07-APR-2022



SWELCH **2016090000780817** Insp_id

Inspection Report

This incident was also reported by the facility to the USDA veterinary medical officers by the attending veterinarian in December 2021 and also was reported to OLAW and the ACUC.

These two incidents involving furniture-type fixtures had a serious adverse effect on the involved animals and did not provide for the safe activity for the NHPs that use them. Ensure that all furniture-type fixtures or objects remain sturdily constructed and strong enough to provide for the safe activity and welfare of nonhuman primates that use them.

Maintain correct from this day forward.

This inspection of the non-human primates under LVSC was conducted with facility representatives from 4/5-4/7/2022.

Additional Inspectors:

DAWN BARKSDALE, VETERINARY MEDICAL OFFICER

GWENDALYN MAGINNIS

Prepared By: SCOTT WELCH Date:

USDA, APHIS, Animal Care 07-APR-2022

Title: VETERINARY MEDICAL

OFFICER

Received by Title: Attending Veterinarian Date:

07-APR-2022



Customer: 616

Inspection Date: 05-Apr-2022

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
616	35-R-0001	001	ALL CAMPUS SITES	05-APR-2022

Count	Scientific Name	Common Name	
000197	Macaca fascicularis	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY	
001485 000312	Macaca mulatta Callithrix jacchus	RHESUS MACAQUE COMMON MARMOSET	
000312	Total	COMMON MARMOSET	

From: (b) (6), (b) (7)(0

To: McHenry, Kerry A - MRP-APHIS

Subject: Re: USDA

Date: Wednesday, June 1, 2022 8:02:09 PM

Received. Thank you!



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From: McHenry, Kerry A - MRP-APHIS < kerry.mchenry@usda.gov>

Sent: Wednesday, June 1, 2022 6:54:27 PM

To:(b) (6), (b) (7)(C) covance.com>

Subject: [External] USDA

EXTERNAL: This email originated from outside of the organization. Do not click any links or open any attachments unless you trust the sender and know the content is safe.

Hi Doc,

Please find attached inspection report and animal inventory from today's visit. No need to sign the report, simply reply to this email that it has been received.

Great working with you today, thank you!

Best regards,

Kerry

Kerry McHenry DVM

Veterinary Medical Officer USDA APHIS Animal Care

2150 Centre Ave., Building B, Mailstop 3W11

Fort Collins, CO 80526-8177

Office: 970-494-7478

Office email: animalcare@usda.gov

Cell: 330-224-5970

Email: kerry.mchenry@usda.gov

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SWELCH **2016090000796847** Insp. id

Inspection Report

UNIVERSITY OF WISCONSIN MADISON

DIRECTOR RESEARCH ANIMAL RESOURCES CENTER

1710 UNIVERSITY AVENUE 396 ENZYME INST

MADISON, WI 53726

Customer ID: 616

Certificate: 35-R-0001

Site: 001

ALL CAMPUS SITES

Type: ROUTINE INSPECTION

Date: 05-APR-2022

2.38(f)(1) Repeat

Miscellaneous.

There have been four incidents of medication dosing errors involving non-human primates (NHPs) and one incident of the incorrect divider placement for NHPs that were reported to the ACUC and OLAW since the last inspection in August 2021.

These incidents could have been prevented if the personnel followed established procedures:

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Prepared By: SCOTT WELCH Date:

Title: VETERINARY MEDICAL

OFFICER

Received by Title: Attending Veterinarian Date:

05-JUL-2022

05-JUL-2022

USDA, APHIS, Animal Care

USDA

United States Department of Agriculture Animal and Plant Health Inspection Service SWELCH **2016090000796847** Insp. id

Inspection Report

identification number.

Handling of research animals must be done as carefully as possible.

3.75(c)(1) Critical

Housing facilities, general.

In August 2021 a NHP was found to have its hand stuck between the perch and the wall. Staff removed it and it was treated by staff veterinarians which included amputation of two digits. Records indicate it was appropriately treated and monitored for recovery. Staff also report the perch involved and all perch fixtures of this design were evaluated and reinforced as necessary to prevent further recurrence. This incident was reported to OLAW and the ACUC.

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Prepared By: SCOTT WELCH Date:

USDA, APHIS, Animal Care 05-JUL-2022

Title: VETERINARY MEDICAL

OFFICER

Received by Title: Attending Veterinarian Date: 05-JUL-2022



SWELCH **2016090000796847** Insp_id

Inspection Report

Maintain correct from th	nis day forward.		
This inspection of the n	on-human primates under LVSC w	vas conducted with facility representative	es from 4/5-4/7/2022
Additional Inspectors:			
DAWN BARKSDALE, V	/ETERINARY MEDICAL OFFICER	₹.	
GWENDALYN MAGINN	NIS, Nonhuman Primate Species S	Specialist	
Prepared By:	SCOTT WELCH	HODA ADUIG Astro-LO-	Date:
	VETERINARY MEDICAL OFFICER	USDA, APHIS, Animal Care	05-JUL-2022

Date:

05-JUL-2022

Received by Title: Attending Veterinarian



Customer: 616

Inspection Date: 05-Apr-2022

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
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Count	Scientific Name	Common Name
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001485	Macaca mulatta	RHESUS MACAQUE
000312	Callithrix jacchus	COMMON MARMOSET
001994	Total	