

Exhibit 17

8/12/15 PPI response to OLAW



Primate Products, Inc.

12 August 2015

Dr. Axel Wolff
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive MSC 7982
Bethesda, MA 20892-7982

Reference: Animal Welfare Assurance #A4102-01 (OLAW Case F)

Dear Dr. Wolff:

Included you will find additional information requested in your letter dated 28 July 2015. Please note concerning information previously provided by Primate Product's Animal Care and Use Committee as it relates to OLAW's understanding (1 through 5):

3e) Procedures will now be performed in the surgical suite or holding building, as stated in response dated 1 July 2015.

3g) Psychological distress was not noted in any of the three primates (A3E053, A2E023, 111618); two of the three received behavioral treatments for abnormal behavior, as stated in response dated 1 July 2015. Additionally, primate A2E023 was provided behavioral treatment for picking at tail wound not animal A3E053.

4h) The IACUC confirmed that there was an isolated incident of highly concentrated bleach solution being used to clean cages. A complaint was filed with the IACUC and a review took place. Husbandry staff were retrained and procedures for acquiring bleach for cleaning was modified.

Regarding new information requested:

- 1) Institutional and IACUC oversight of the program and self-regulation is accomplished by:
 - a. Semi-annual Inspections consisting of a Program Checklist (grants.nih.gov/grants/olaw/sampledoc/checklist.htm) and a Physical Facility Walk-Through and Review.
 - b. Standard Operating Procedures (SOPs) are reviewed annually as well as before any new SOP effective.
 - c. The Environmental Enhancement Program to Promote the Psychological Well-Being of Nonhuman Primates is reviewed and/or revised annually and at any time deemed necessary by the IACUC.
 - d. Protocols are reviewed upon submission and annually.

Corporate Office and Panther Tracks Learning Center

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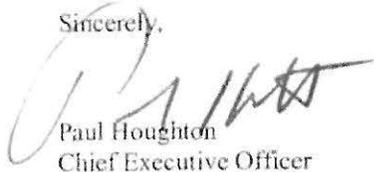


Primate Products, Inc.

- e. In addition PPI has multiple locked boxes available onsite for any staff to anonymously submit animal welfare concerns.
 - f. Lastly the company has in place a policy described in SOP 106 which is titled Stop Work Order. Any employee at any moment has the authority to order work to cease if they feel SOPs are not being applied appropriately or that a situation is occurring in which human or animal health may be compromised.
- 2) PPI adherer's to prompt reporting of programmatic items of non-compliance with all animals assigned to or supported by NIH funds consistent with Standard Operating Procedure 112 (see attached).
 - 3) Job categories of individuals designated to conduct dental procedures and reduce rectal prolapse include clinical veterinarians, veterinary technicians and assistant technicians.
 - 4) The percentage of animals chute trained are as follows: prior to the arrival of the newest group of animals on 7-29-15, 98% of the animals in group housing onsite were chute trained. As of 8-6-15, 75% of the animals in group housing onsite are chute trained (which includes the new arrivals that are in the process of being trained).
 - 5) Attached you will find the two most recent semiannual program reviews and facility inspection reports.
 - 6) Attached as requested during the most recent site visit are the two SOP's revised as a direct result of the USDA inspection; 250- Cleaning and disinfection of Outdoor Holding Areas during Quarantine and Non-Quarantine and 221- Hot and Cold Weather Procedures. Also attached the interim catch method document which we are in progress of formulating into a new SOP.

Please contact me if additional information is required.

Sincerely,



Paul Houghton
Chief Executive Officer

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SEMIANNUAL FACILITY INSPECTION REPORT PTLC

Date: 10/2/14

1. Personnel Support Areas:

LOCATION	*A	M	S	NOTES
Administrative Support Areas (Building D)				N/A
Laundry Room (Building C)		M M M M		1) 1 partial bottle expired chlorhexidine 2) 1 bottle Paramount Power open without expiration date and/or "opened on" date with initials 3) 1 bottle ice machine sanitizer cleaner open without expiration date and/or "opened on" date with initials 4) Dirty floors especially against walls and corners

2. Veterinary Procedure Areas, Laboratories, Animal Housing:

<p>General concerns:</p> <ul style="list-style-type: none"> - drug storage, control, and expiration dates - sharps disposal - anesthetic monitoring - gas cylinders immobilized - scavenging of anesthetic gases - warning signs - carcass disposal <p>Additional concerns for survival surgery:</p> <ul style="list-style-type: none"> - aseptic procedures - autoclave monitoring procedures - storage of autoclaved materials - cold sterilization procedures are appropriate

LOCATION	*A	M	S	NOTES
Exam Room (A [redacted])		X		Bugs on window
Laboratory ([redacted])	X			Hood due on 8/31/15
Necropsy Room ([redacted])	X			
Storage closet ([redacted])				
Surgery Preparation Room ([redacted])				
Biohazardous Waste Disposal & Storage ([redacted])	X			
Storage Room (A108)	X			
ICU A ([redacted])		X		Bugs in light fixture; window behind caging needs cleaned

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ICU B [REDACTED]		X	Window needs cleaned within the room
Anesthesia and necropsy certification	X		Due 2/15

3. Animal Support Areas:

Location:	Animal areas separate from personnel areas, separation of species, separation by disease status
Construction:	Corridors, doors, windows floors, drainage, walls, ceilings, HVAC, power & lighting, noise
Room/cage:	Temperature, humidity, ventilation, illumination, noise control
Pen/cage:	Sanitation, cleaning tools, food/water access, security, safety, allows undisturbed observation, size, rationale for USDA/Guide exceptions, meets physiologic, behavioral, social needs
Outdoor housing: Centiquad	Weather protection, ventilation & sanitation of shelters (no waste/moisture buildup), animal acclimation, social compatibility, roundup/restraint procedures, security
Behavioral management:	Environmental enrichment, social groups, animal activity
Food:	Feeding schedule & procedures, contamination, vendor quality control
Water:	Ad libitum unless justified, quality control procedures
Bedding:	Species appropriate, quality control procedures
Sanitation:	Cleaning & disinfection, monitoring
Waste management:	Procedures for collection, storage & disposal of waste, hazardous waste, animal carcasses
Pest control:	Regularly scheduled, documented program including control of rodent pests & insecticide use
Animal identification & records:	Centiquad/pen/cage contain required information, clinical records, accessible & appropriate
Storage:	Food & bedding, supplies, drugs & biologics, waste material, hazardous material, carcasses, animal shipping crates
Specialized space:	Receiving, quarantine, isolation, necropsy, radiography, diet preparation

LOCATION	*A	M	S	NOTES
Animal Feed Preparation Area		M		1) Food on floor
		M		2) Food in sink
		M		3) Dirty food containers and knives in sink and on countertop
		M		4) Fridge temp reading 60F
		M		5) Sticky contents on front of cabinets
		M		6) Peanut shells and rodent feces on floor in corners of room
		M		7) Trash bin full without a trash bag
		M		8) 2 forage mix storage containers that weren't labelled with date and initials
		M		9) 2.5 large pieces of rotting sugar cane in room
		M		10) Bucket labelled "Maria Enrichment Nutritional" containing roach bait, rodent control etc.
		M		11) Expired box of powdered mashed potatoes. Disposed of

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		M	immediately.
		M	12) Shelves in cupboard containing food items have dead ants on them.
			13) EE Log not filled out consistently (last entry 9-18-14).
Husbandry Storage Container			Good
PPE Room in Modular		M	1) Rodent feces on shelves
		M	2) Trash bin full without a trash bag
		M	3) Dirty under shelves
		M	4) General untidy and disorganized
Back 2 Storage/Prep Rooms in Modular		M	1) Expired 2 boxes K2 EDTA tubes. Disposed of immediately.
		M	2) Expired 1 box of alcohol prep pads. Disposed of immediately.
		M	3) Expired 2 IV sets. Disposed of immediately.
		M	4) Expired 2 Unversets. Disposed of immediately.
		M	5) Expired 1 partial bottle of sodium chloride.
		M	6) Expired 2 partial bottles of 10% neutral buffered formalin.
		M	7) Quat TB spray bottle without date/initials
		M	8) A lot of expired tubes below centrifuge.
		M	9) Expired many 5ml syringes. Disposed of immediately.
		M	10) General clutter and disorganization.
Back Porch of Modular		M	1) Dirty produce remnants in buckets and bins.
		M	2) Dirty bin of sugarcane parts and dark water.
		M	3) Large bin with wheels full of enrichment mixed with junk and trash.
		M	4) Moldy raincoat on rail.
		M	5) Junk under porch.
		M	6) Wooden pallet, loose window screen, and rusty fridge shelves sitting on porch.
		M	7) General untidiness, black parts on wood on porch etc.
Chemical Storage			Good
Bedding Storage		X	Open bedding
Feed containers			Good
New Crate Storage		X	Needs general house keeping
Animal Shipping Crate Storage			OK
Vet Storage closet		X	Expired items- disposed of immediately
Compost area			OK
Animal transportation			Good

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4. Animal Housing:

Location:	Animal areas separate from personnel areas, separation of species, separation by disease status
Construction:	Corridors, doors, windows floors, drainage, walls, ceilings, HVAC, power & lighting, noise
Room/cage:	Temperature, humidity, ventilation, illumination, noise control
Pen/cage:	Sanitation, cleaning tools, food/water access, security, safety, allows undisturbed observation, size, rationale for USDA/Guide exceptions, meets physiologic, behavioral, social needs
Outdoor housing: Centiquad	Weather protection, ventilation & sanitation of shelters (no waste/moisture buildup), animal acclimation, social compatibility, roundup/restraint procedures, security
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Pest control:	Regularly scheduled, documented program including control of rodent pests & insecticide use
Animal identification & records:	Centiquad/pen/cage contain required information, clinical records, accessible & appropriate
Transportation	
Trailer for trans	

Outdoor Animal Housing:

LOCATION	*A	M	S	NOTES
Centiquad			X	Dirt on chain link; pressure washing needs done
Centiquad			X	Loose perches
Centiquad			X	Loose perches
Centiquad				OK
Centiquad				OK
Centiquad				OK
Centiquad				Box for feed bag disposal being used for PPE disposal. PPE needs disposed of properly.
Centiquad				OK

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Centiquad				OK
Centiquad		M		1) Measuring cup hanging on fence with water and green algae inside it
		M		2) Some rusty lock parts and locks
		M		3) Some of the chutes are missing locks
		M		4) Cracks and aggregate in trough drains
		M		5) Browse and monkey waste covering drain covers
		M		6) Sharp metal pieces found in empty pens and outside of quad
		M		7) Loose PPE/trash found around outside of quad
Centiquad				Empty, maintenance was working on this quad, and it was "under construction" during inspection
Centiquad		M		1) 1/2 of a mat for processing animals dirty and lying on top of a chute
		M		2) Most chutes are missing locks
		M		3) Sharp metal ties on some of the feeders
		M		4) Rust on pipes and chain link
		M		5) Monkey waste covering drain covers
		M		6) Cracks and holes in drain troughs
		M		7) Broken plastic parts and trash around outside of quad
Centiquad		M		1) Pen A missing 1 lock
		M		2) Cracks and aggregate in drain troughs
		M		3) Standing water in chutes of Pen B
		M		4) Some rust on pipes and chain link
		M		5) Partially filled chlorine sprayer lying in the road outside of the quad
		M		6) Hose lying on ground outside of quad
		M		7) Sharp metal parts of chain link sticking out at top on outside of quad Pen D
Centiquad		M		1) Some rust on pipes and chain link
		M		2) Standing water in chutes of Pen A
		M		3) Standing water in pen and chutes of Pen B
		M		4) Standing water in Pen D
		M		5) Cracks, holes, and aggregate in drain troughs
		M		6) Broken feeder lying outside of entrance door to quad
Centiquad		M		1) Loose plastic parts and trash around outside of quad
		M		2) Both feed bin lids partially open
		M		3) Sharp metal ties on feeders
		M		4) Some chutes missing locks
		M		5) Some rust on pipes and chain link
		M		6) Too few kongs in all pens
Centiquad		M		1) Sharp metal pieces on chain link by entrance to quad
		M		2) Most locks are rusted and falling apart
		M		3) Sharp metal ties on feeders
		M		4) Rust on pipes and chain link
		M		5) Cracks, holes, and aggregate in drain troughs
		M		6) Standing water in Pen A

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Holding Building 1 (Rm [redacted])	M	1) Trash/junk covering drain trap
	M	2) Staining on floors against walls
	M	3) Monkey in cage 18 without ID on cage
	M	4) Monkey in cage 18 no kong. Fixed immediately.
	M	5) Moldy food in 2 cages' feeders without monkeys in the cages
	M	6) Standing water on left side of room by entrance
	M	7) Dirty vent
	M	8) Plastic on cages cracked
	M	9) Missing paint on walls
Centiquad [redacted]	M	1) Sharp metal pieces on chain link by entrance to quad
	M	2) Sharp metal ties on feeders
	M	3) All pens except D are lacking visual barriers
	M	4) Rust on pipes and chain link
	M	5) Aggregate in drain troughs
	M	6) All pens except C have aggregate spots on floors
	M	7) 1 of the feed storage bins has a cracked lid
	M	8) Lock parts are outside of quad on ground
Centiquad [redacted]	M	1) 1 of locks at entrance is broken/rusted
	M	2) Rusted/broken locks on most of the chutes
	M	3) Sharp metal ties on feeders
	M	4) Aggregate spots on floors of all pens
	M	5) Some rust on pipes and chain link
	M	6) Cracks in drain troughs
Centiquad [redacted]	M	1) Measuring cup hanging from fence has water and green algae in it
	M	2) Rusty locks on entrance door
	M	3) Sharp metal ties on feeders
	M	4) Metal pieces in drain troughs
	M	5) Pile of rodent traps in between [redacted] and [redacted]

Additional Comments:

- 1) General untidiness, clutter, and disorganization throughout.
- 2) Single/pair cages didn't appear to have date and initial of last sanitization.
- 3) Sharp objects and rust throughout animal areas is prevalent
- 4) Pest Control Program appears to have some problems

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IACUC Member Signatures:

Name of Member*	Degree/Cr edentials	Position Title	PHS Policy Membership Requirements **	Signatures
IACUC member		Physical Plant	Chairman/ Non-scientist	IACUC member
		Institutional Veterinarian	Scientist	
		Business Manager	Non-scientist	
		Operations Manager- PTLC	Scientist	
		Head of Behavioral Sciences	Scientist	

I. Semiannual Program Review Checklist ⁱ

Institutional Policies and Responsibilities

Date: April 21, 2015

1. Animal Care and Use Program

	A*	M	S	C	NA
• Responsibility for animal well-being is assumed by all members of the program (<i>Guide, p 1</i>) [must]	x				
• IO has authority to allocate needed resources (<i>Guide, p 13</i>)	x				
• Resources necessary to manage program of veterinary care are provided (<i>Guide, p 14</i>) [must]	x				
• Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the <i>Guide</i> (<i>Guide, pp 11, 15</i>)	x				
• Program needs are regularly communicated to IO by AV and/or IACUC (<i>Guide, p 13</i>)	x				
• Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site (<i>Guide, p 14</i>) [must]	x				
• Inter-institutional collaborations are described in formal written agreements (<i>Guide, p 15</i>)		x			
• Written agreements address responsibilities, animal ownership, and IACUC oversight (<i>Guide, p 15</i>)		x			

2. Disaster Planning and Emergency Preparedness

	A*	M	S	C	NA
• Disaster plans for each facility to include satellite locations are in place (<i>Guide, p 35, p 75</i>) [must]	x				
• Plans include provisions for euthanasia (<i>Guide, p 35</i>) [must]	x				
• Plans include triage plans to meet institutional and investigators' needs (<i>Guide, p 35</i>)	x				
• Plans define actions to prevent animal injury or death due to HVAC or other failures (<i>Guide, p 35</i>)	x				
• Plans describe preservation of critical or irreplaceable animals (<i>Guide, p 35</i>)	x				
• Plans include essential personnel and their training (<i>Guide, p 35</i>)	x				
• Animal facility plans are approved by the institution and incorporated into overall response plan (<i>Guide, p 35</i>)	x				
• Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (<i>Guide, p 35</i>)	x				

3. IACUC

	A*	M	S	C	NA
• Meets as necessary to fulfill responsibilities (<i>Guide, p 25</i>) [must]	x				
• IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (<i>Guide, p 26</i>) [must]	x				
• Continuing IACUC oversight after initial protocol approval is in place (<i>Guide, p 33</i>)	x				
• IACUC evaluates the effectiveness of training programs (<i>Guide, p 15</i>)	x				

4. IACUC Protocol Review - Special Considerations

	A*	M	S	C	NA
• Humane endpoints are established for studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock (<i>Guide, p 27</i>)					x
• For pilot studies, a system to communicate with the IACUC is in place (<i>Guide, p 28</i>)					x
• For genetically modified animals, enhanced monitoring and reporting is in place (<i>Guide, p 28</i>)					x
• Restraint devices are justified in the animal use protocols (<i>Guide, p 29</i>) [must]	x				
• Alternatives to physical restraint are considered (<i>Guide, p 29</i>)	x				
• Period of restraint is the minimum to meet scientific objectives (<i>Guide, p 29</i>)	x				
• Training of animals to adapt to restraint is provided (<i>Guide, p 29</i>)	x				

• Animals that fail to adapt are removed from study (<i>Guide, p 29</i>)	x					
• Appropriate observation intervals of restrained animals are provided (<i>Guide, p 29</i>)	x					
• Veterinary care is provided if lesions or illness result from restraint (<i>Guide, p 30</i>) [must]	x					
• Explanations of purpose and duration of restraint are provided to study personnel (<i>Guide, p 30</i>)	x					
• Multiple surgical procedures on a single animal are justified and outcomes evaluated (<i>Guide, p 30</i>)						x
• Major versus minor surgical procedures are evaluated on a case-by-case basis (<i>Guide, p 30</i>)	x					
• Multiple survival procedure justifications in non-regulated species conform to regulated species standards (<i>Guide, p 30</i>)						x
• Animals on food/fluid restriction are monitored to ensure nutritional needs are met (<i>Guide, p 31</i>)						x
• Body weights for food/fluid restricted animals are recorded at least weekly (<i>Guide, p 31</i>)						x
• Daily written records are maintained for food/fluid restricted animals (<i>Guide, p 31</i>)						x
• Pharmaceutical grade chemicals are used, when available, for animal-related procedures (<i>Guide, p 31</i>)						x
• Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC (<i>Guide, p 31</i>)						x
• Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area (<i>Guide, p 32</i>)						x
• Disposition plans are considered for species removed from the wild (<i>Guide, p 32</i>)						x
• Toe-clipping only used when no alternative, performed aseptically and with pain relief (<i>Guide, p 75</i>)						x

5. IACUC Membership and Functions

	A*	M	S	C	NA
• IACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, <i>IV.A.3.</i>)	x				
• Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user (<i>Guide, p 24</i>) ⁱⁱ	x				
• IACUC authority and resources for oversight and evaluation of institution's program are provided (<i>Guide, p 14</i>)	x				
• IACUC conducts semiannual evaluations of institutional animal care and use program (PHS Policy, <i>IV.B.</i>)	x				
• Conducts semiannual inspections of institutional animal facilities (PHS Policy, <i>IV.B.</i>)	x				
• IACUC organizationally reports to the Institutional Official (PHS Policy, <i>IV.A.1.b.</i>)	x				
• Methods for reporting and investigating animal welfare concerns are in place (<i>Guide, p 23</i>) [must]	x				
• Reviews and investigates concerns about animal care and use at institution ⁱⁱⁱ (PHS Policy, <i>IV.B.</i>)	x				
• Procedures are in place for review, approval, and suspension of animal activities ^{iv} (PHS Policy, <i>IV.B.</i>)	x				
• Procedures are in place for review and approval of significant changes to approved activities (PHS Policy, <i>IV.B.</i>)	x				
• Policies are in place for special procedures (e.g., genetically modified animals, restraint, multiple survival surgery, food and fluid regulation, field investigations, agricultural animals) (<i>Guide, p 27-32</i>)	x				
• Requests for exemptions from major survival surgical procedure restrictions are made to USDA/APHIS ^v (<i>Guide, p 30</i>) [must]					x

6. IACUC Training

	A*	M	S	C	NA
• All IACUC members should receive:					
○ Formal orientation to institution's program (<i>Guide, p 17</i>)	x				
○ Training on legislation, regulations, guidelines, and policies (<i>Guide, p 17</i>)	x				

o Training on how to inspect facilities and labs where animal use or housing occurs (<i>Guide, p 17</i>)	x					
o Training on how to review protocols as well as evaluate the program (<i>Guide, p 17</i>)	x					
o Ongoing training/education (<i>Guide, p 17</i>)	x					

7. IACUC Records and Reporting Requirements^{vi}

A* M S C NA

• Semiannual report to the IO (PHS Policy, <i>IV.B.</i>)						
o Submitted to IO every 6 months	x					
o Compiles program review and facility inspection(s) results (includes all program and facility deficiencies)	x					
o Includes minority IACUC views	x					
o Describes IACUC-approved departures from the <i>Guide</i> or PHS Policy and the reasons for each departure ^{vii}	x					
o Distinguishes significant from minor deficiencies	x					
o Includes a plan and schedule for correction for each deficiency identified ^{viii}	x					
• Reports to OLAW (PHS Policy, <i>IV.F.</i>)						
o Annual report to OLAW documents program changes, dates of the semiannual program reviews and facility inspections and includes any minority views	x					
o Promptly advises OLAW of serious/ongoing <i>Guide</i> deviations or PHS Policy noncompliance (NOT-OD-05-034)	x					
o Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC (NOT-OD-05-034)	x					
• Reports to U.S. Department of Agriculture (USDA) or Federal funding agency ^{ix}						
o Annual report to USDA contains required information including all exceptions/exemptions	x					
o Reporting mechanism to USDA is in place for IACUC-approved exceptions to the regulations and standards	x					
o Reports are filed within 15 days for failures to adhere to timetable for correction of significant deficiencies	x					
o Promptly reports suspensions of activities by the IACUC to USDA and any Federal funding agency	x					
• Records (PHS Policy, <i>IV.E.</i>)						
o IACUC meeting minutes and semiannual reports to the IO are maintained for 3 years	x					
o Records of IACUC reviews of animal activities include all required information ^x	x					
o Records of IACUC reviews are maintained for 3 years after the completion of the study	x					

8. Veterinary Care (See also next section - Veterinary Care)

A* M S C NA

• An arrangement for veterinarian(s) with training or experience in lab animal medicine is in place including backup veterinary care ^{xi}	x					
• Veterinary access to all animals is provided (<i>Guide, p 14</i>) [must]	x					
• Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use (<i>Guide, p 14</i>) [must]	x					
• Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol (<i>Guide, p 5</i>) [must]	x					
• Veterinarian provides consultation when interventional control is not possible (<i>Guide, p 5</i>) [must]	x					
• If part time /consulting veterinarian, visits meet programmatic needs (<i>Guide, p 14</i>)	x					
• Regular communication occurs between veterinarian and IACUC (<i>Guide, p 14</i>)	x					
• Veterinarian(s) have experience and training in species used (<i>Guide, p 15</i>) [must]	x					
• Veterinarian(s) have experience in facility administration/management (<i>Guide, p 15</i>)	x					

9. Personnel Qualifications and Training

A* M S C NA

• All personnel are adequately educated, trained, and/or qualified in basic principles of						
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laboratory animal science. Personnel included: [must]					
o Veterinary/other professional staff (<i>Guide, p 15-16</i>)	x				
o IACUC members (<i>Guide, p 17</i>)	x				
o Animal care personnel (<i>Guide, p 16</i>)	x				
o Research investigators, instructors, technicians, trainees, and students (<i>Guide, pp 16-17</i>)	x				
• Continuing education for program and research staff provided to ensure high quality care and reinforce training (<i>Guide, pp 16-17</i>)	x				
• Training is available prior to starting animal activity (<i>Guide, p 17</i>)	x				
• Training is documented (<i>Guide, p 15</i>)	x				
• Training program content includes: (<i>Guide, p 17</i>)					
o Methods for reporting concerns (<i>Guide, p 17</i>)	x				
o Humane practices of animal care (e.g., housing, husbandry, handling) ^{xii}	x				
o Humane practices of animal use (e.g., research procedures, use of anesthesia, pre- and post-operative care, aseptic surgical techniques and euthanasia (<i>Guide, p 17</i>)) ^{xiii}	x				
o Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, IV.A.1.g.)					x
o Research/testing methods that minimize animal pain or distress (PHS Policy, IV.A.1.g.)	x				
o Use of hazardous agents, including access to OSHA chemical hazard notices where applicable (<i>Guide, p 20</i>)	x				
o Animal care and use legislation (<i>Guide, p 17</i>)	x				
o IACUC function (<i>Guide, p 17</i>)	x				
o Ethics of animal use and Three R's (<i>Guide, p 17</i>)		x			

10. Occupational Health and Safety of Personnel

A* M S C NA

• Program is in place and is consistent with federal, state, and local regulations (<i>Guide, p 17</i>) [must]	x				
• Program covers <i>all</i> personnel who work in laboratory animal facilities (<i>Guide, p 18</i>)	x				
• Changing, washing, and showering facilities are available as appropriate (<i>Guide, p 19</i>)	x				
• Hazardous facilities are separated from other areas and identified as limited access (<i>Guide, p 19</i>)					x
• Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies) (<i>Guide, p 20</i>)	x				
• Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking policies) (<i>Guide, p 20</i>)	x				
• Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place (<i>Guide, p 21</i>)	x				
• Personal Protective Equipment for the work area is appropriate and available (<i>Guide, p 21</i>)	x				
• Program for medical evaluation and preventive medicine for personnel includes:					
o Pre-employment evaluation including health history (<i>Guide, p 22</i>)	x				
o Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate (<i>Guide, p 22</i>)	x				
o Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague) (<i>Guide, p 23</i>)	x				
o Procedures for reporting and treating injuries, including accidents, bites, allergies, etc. (<i>Guide, p 23</i>)	x				
o Promotes early diagnosis of allergies including preexisting conditions (<i>Guide, p 22</i>)	x				
o Considers confidentiality and other legal factors as required by federal, state and local regulations (<i>Guide, p 22</i>) [must]	x				
o If serum samples are collected, the purpose is consistent with federal and state laws (<i>Guide, p 22</i>) [must]	x				

• Waste anesthetic gases are scavenged (<i>Guide, p 21</i>)	x					
• Hearing protection is provided in high noise areas (<i>Guide, p 22</i>)	x					
• Respiratory protection is available when performing airborne particulate work (<i>Guide, p 22</i>)	x					
• Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include:						
o Tuberculosis screening provided for all exposed personnel (<i>Guide, p 23</i>)	x					
o Training and implementation of procedures for bites, scratches, or injuries associated with macaques (<i>Guide, p 23</i>)	x					
o PPE is provided including gloves, arm protection, face masks, face shields, or goggles (<i>Guide, p 21</i>)	x					
o Injuries associated with macaques are carefully evaluated and treatment implemented (<i>Guide, p 23</i>)	x					
• Occupational safety and health of field studies is reviewed by OSH committee or office (<i>Guide, p 32</i>)						x

11. Personnel Security

A* M S C NA

• Preventive measures in place include pre-employment screening, and physical and IT security (<i>Guide, p 23</i>)		x				
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12. Investigating & Reporting Animal Welfare Concerns

A* M S C NA

• Methods for investigating and reporting animal welfare concerns are established (<i>Guide, p 23</i>) [must]	x					
• Reported concerns and corrective actions are documented (<i>Guide, p 24</i>)	x					
• Mechanisms for reporting concerns are posted in facility and at applicable website with instructions (<i>Guide, p 24</i>)	x					
o Includes multiple contacts (<i>Guide, p 24</i>)	x					
o Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection (<i>Guide, p 24</i>)	x					

- * **A** = acceptable
M = minor deficiency
S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)
NA = not applicable

NOTES:

1. Animal Care and Use Program (#1) - two minor deficiencies noted. Was decided during the meeting that the Committee would be provided quarantine plans and memorandums of understanding for client animals held at PPI so the Committee could have full knowledge of animal well-being directives.
2. Personnel Qualifications and Training (#9) – one minor deficiency noted for Ethics and 3 R’s. Was decided by the Committee that the IACUC function as scheduled yearly per SOP 109 “Education and Training” be expanded to educate employees and the Committee on the ethics and importance of the three R’s in research.
3. Personnel Security (#11) – the Coordinator will query the COO on the measures taken for IT security at a personnel level at facility.

Veterinary Care

Date: April 21, 2015

1. Clinical Care and Management

	A*	M	S	C	NA
• Veterinary program offers high quality of care and ethical standards (<i>Guide, p 105</i>) [must]	x				
• Veterinarian provides guidance to all personnel to ensure appropriate husbandry, handling, treatment, anesthesia, analgesia, and euthanasia (<i>Guide, p 106</i>)	x				
• Veterinarian provides oversight to surgery and perioperative care (<i>Guide, p 106</i>)	x				
• Veterinary care program is appropriate for program requirements (<i>Guide, pp 113-114</i>)					
• Veterinarian(s) is familiar with species and use of animals and has access to medical and experimental treatment records (<i>Guide, p 114</i>)	x				
• Procedures to triage and prioritize incident reports are in place (<i>Guide, p 114</i>)	x				
• Procedures are in place to address:					
o Problems with experiments to determine course of treatment in consultation with investigator(<i>Guide, p 114</i>)					x
o Recurrent or significant health problems with the IACUC and documentation of treatments and outcomes (<i>Guide, p 114</i>)		x			
o Veterinary review and oversight of medical and animal use records (<i>Guide, p 115</i>)	x				
• Procedures established for timely reporting of animal injury, illness, or disease (<i>Guide, p 114</i>) [must]	x				
• Procedures established for veterinary assessment, treatment, or euthanasia (<i>Guide, p 114</i>) [must]	x				
• Veterinarian is authorized to treat, relieve pain, and/or euthanize (<i>Guide, p 114</i>) [must]	x				

2. Animal Procurement and Transportation/Preventive Medicine

	A*	M	S	C	NA
• Procedures for lawful animal procurement are in place (<i>Guide, p 106</i>) [must]	x				
• Sufficient facilities and expertise are confirmed prior to procurement (<i>Guide, p 106</i>)	x				
• Procurement is linked to IACUC review and approval (<i>Guide, p 106</i>)	x				
• Random source dogs and cats are inspected for identification (<i>Guide, p 106</i>)					x
• Population status of wildlife species is considered prior to procurement (<i>Guide, p 106</i>)					x
• Appropriate records are maintained on animal acquisition (<i>Guide, p 106</i>)	x				
• Animal vendors are evaluated to meet program needs and quality (<i>Guide, p 106</i>)	x				
• Breeding colonies are based on need and managed to minimize numbers (<i>Guide, p 107</i>)					x
• Procedures for compliance with animal transportation regulations, including international requirements, are in place (<i>Guide, p 107</i>) [must]	x				
• Transportation is planned to ensure safety, security and minimize risk (<i>Guide, p 107</i>)	x				
• Movement of animals is planned to minimize transit time and deliveries are planned to ensure receiving personnel are available (<i>Guide, pp 107- 108</i>)	x				
• Appropriate loading and unloading facilities are available (<i>Guide, p 109</i>)	x				
• Environment at receiving site is appropriate (<i>Guide, p 109</i>)	x				
• Policies in place on separation by species, source, and health status (<i>Guide, pp 109, 111-112</i>)	x				
• Procedures in place for quarantine to include zoonoses prevention (<i>Guide, p 110</i>)	x				
• Quarantined animals from different shipments are handled separately or physically separated (<i>Guide, p 110</i>)	x				
• Procedures in place for stabilization/acclimation (<i>Guide, pp 110-111</i>)	x				
• Policies in place for isolation of sick animals (<i>Guide, p 112</i>)	x				
• Program is in place for surveillance, diagnosis, treatment and control of disease to include daily observation (<i>Guide, p 112</i>)	x				
• Diagnostic resources are available for preventive health program (<i>Guide, p 112</i>)	x				

3. Surgery	A*	M	S	C	NA
• Surgical outcomes are assessed and corrective changes instituted (<i>Guide, p 115</i>)	x				
• Researchers have appropriate training to ensure good technique (<i>Guide, p 115</i>) [must]	x				
• Pre-surgical plans are developed and include veterinary input (e.g., location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping) (<i>Guide, p 116</i>)	x				
• Aseptic surgery is conducted in dedicated facilities or spaces, unless exception justified and IACUC approved (<i>Guide, p 116</i>)	x				
• Surgical procedures including laparoscopic procedures are categorized as major or minor (<i>Guide, pp 117-118</i>)	x				
• For nonsurvival surgery, the site is clipped, gloves are worn and instruments and area are clean (<i>Guide, p 118</i>)	x				
• Aseptic technique is followed for survival surgical procedures (<i>Guide, pp 118-119</i>)	x				
• Effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs are in place (<i>Guide, p 119</i>)	x				
• Procedures for monitoring surgical anesthesia and analgesia are in place (<i>Guide, p 119</i>)	x				
• For aquatic species, skin surfaces are kept moist during surgical procedures (<i>Guide, p 119</i>)					x
• Post-operative monitoring and care are provided by trained personnel and documented (e.g., thermoregulation, physiologic function, analgesia, infection, removal of skin closures) (<i>Guide, pp 119-120</i>)	x				
4. Pain, Distress, Anesthesia and Analgesia	A*	M	S	C	NA
• Guidelines for assessment and categorization of pain, distress and animal wellbeing are provided during training (<i>Guide, p 121</i>)	x				
• Selection of analgesics and anesthetics is based on professional veterinary judgment (<i>Guide, p 121</i>)	x				
• Painful procedures are monitored to ensure appropriate analgesic management (<i>Guide, p 122</i>)	x				
• Nonpharmacologic control of pain is considered as an element of postprocedural care (<i>Guide, p 122</i>)					x
• Procedures are in place to assure antinoception before surgery begins (<i>Guide, p 122</i>) [must]	x				
• Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated (<i>Guide, p 122</i>)	x				
• Special precautions for the use of paralytics are in place to ensure anesthesia ^{xiv} (<i>Guide, p 123</i>)	x				
5. Euthanasia	A*	M	S	C	NA
• Methods are consistent with AVMA Guidelines on Euthanasia unless approved by the IACUC (<i>Guide, p 123</i>)	x				
• Standardized methods are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species (<i>Guide, pp 123-124</i>)	x				
• Training is provided on appropriate methods for each species and considers psychological stress to personnel (<i>Guide, p 124</i>)	x				
• Procedures and training are in place to ensure death is confirmed (<i>Guide, p 124</i>) [must]	x				
6. Drug Storage and Control	A*	M	S	C	NA
• Program complies with federal regulations for human and veterinary drugs(<i>Guide, p 115</i>) [must]	x				
• Drug records and storage procedures are reviewed during facility inspections (<i>Guide, p 115</i>)	x				
• Procedures are in place to ensure analgesics and anesthetics are used within	x				

expiration date (<i>Guide</i> , p 122) [must]									
• Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely (<i>Guide</i> , p 122)									x

- * **A** = acceptable
- M** = minor deficiency
- S** = significant deficiency (is or may be a threat to animal health or safety)
- C** = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)
- NA** = not applicable

NOTES:

1. Clinical Care and Management (#1) – one minor- Committee would like the Animal Observation and Treatment form revised to include a section for the Vet Staff member completing the form to note whether the incident of treatment is due to a recurrent or significant health problem in the colony. Coordinator will modify form and circulate to necessary staff for review/approval.

ⁱ The PHS Policy requires that Assured institutions comply with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act, as applicable. The endnotes below are specific USDA regulatory requirements that differ from or are in addition to the PHS Policy. This list is not intended to be all inclusive. For additional information please refer to 9 CFR Subchapter A - Animal Welfare.

ⁱⁱ Part 2 Subpart C - Research Facilities
 - 2.31(b)(2) - “The Committee shall be composed of a Chairman and at least two additional members;... at least one shall not be affiliated in any way with the facility...such person will provide representation for general community interests in the proper care and treatment of animals.” [PHS policy requires 5 members]

ⁱⁱⁱ 2.32(c)(4) - “...No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act.” [USDA requirement additional to PHS Policy]

^{iv} 2.31(d)(5) - “...shall conduct continuing reviews of activities...not less than annually.” [PHS Policy requires a complete new review every 3 years utilizing all the criteria for initial review]

^v 2.31(d)(1)(x) - “...no animal will be used in more than one major operative procedure from which it is allowed to recover unless...(it is) justified for scientific reasons...(or is) required as routine veterinary procedure...or other special circumstances as determined by the Administrator on an individual basis.” [this last point is an additional USDA justification for multiple survival surgeries]

^{vi} 2.36 - “...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year.” [The USDA annual report has a list of requirements which differ from PHS annual report]

^{vii} 2.36(b)(3) - “...exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility’s annual report.” [Refers to USDA annual report]

viii 2.31(c)(3) - "...Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the institutional official, to APHIS and any Federal agency funding that activity." [PHS Policy requires prompt reporting to OPRR of serious or continuing noncompliance with the PHS Policy or serious deviations from the provisions of the *Guide*]

ix 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

x In addition to PHS requirements for IACUC review/application for funding, USDA regulations require:
2.31(d)(1)(ii) - "The principal investigator (PI) consider alternatives to procedures that cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources...used to determine that alternatives were not available."

2.31(d)(1)(iii) - "The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments."

2.31(d)(1)(iv) - "Procedures that may cause more than momentary or slight pain or distress to the animals will:

- involve in their planning, consultation with the attending veterinarian or his or her designee; [PHS Policy does not specify veterinary consultation]
- not include paralytics without the use of anesthesia;"

2.31(d)(1)(x) - "No animal will be used in more than one major operative procedure from which it is allowed to recover, unless justified for scientific reasons by the principal investigator, in writing..."

xi 2.33(a)(1) - "In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility." [USDA requirement additional]

xii 2.32(c) - "Humane methods of animal maintenance and experimentation, including the basic needs of each species, proper handling and care for the various species of animals used by the facility, proper pre-procedural and post-procedural care of animals, and aseptic surgical methods and procedures."

xiii 2.32(c) - additional specifications include:

- "proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility"
- "methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility..."
- "utilization of services (e.g., National Agricultural Library, National Library of Medicine) to provide information on appropriate animal care and use, alternatives to the use of live animals in research , that could prevent unintended and unnecessary duplication of research involving animals, and regarding the intent and requirements of the Act." [USDA training specifications are more detailed than PHS Policy].

xiv 2.31(d)(iv)(C) - "Procedures that may cause more than momentary or slight pain or distress to the animals will...not include the use of paralytics without anesthesia."

Interim Process for Restraint in Quads

1. Place animals in chute per Chute Training SOP 242
 - a. Once all animals are in chute, make sure that entry door is clipped closed so that animals cannot open that door.
 - b. Using extra white chute doors, begin splitting the animals into subgroups. Try to allow the animals to choose who to be split with, especially be cautious not to place a very low ranking animal with a high ranking animal as this may result in injury to one or more of the animals.
 - c. Once animals are divided into subgroups within the chute, proceed to Step F if you are using transfer boxes or Step G if you are using the chute squeeze.
 - d. If animals have not been acclimated to being divided in the chute and they appear to be stressed (e.g. vocalizing loudly, biting a cohort etc.) in the chute, especially during the division of subgroups, it may be best to release animals back to their pen and use nets for capture until they have been appropriately acclimated.
 - i. If using nets for capture, be sure to place animals in half the pen rather than the whole pen before starting to use the net.
 - ii. Place 1 NHP in the net at a time.
 - iii. Do not physically restrain animal by the tail.
 - iv. Carry the nets out of the pen do not let the NHP drag the ground.
 - e. If animals are not trained to enter the chute, or only some enter the chute (i.e. group is not completely trained), it may be necessary to only use the transfer boxes or chute squeeze for the animals that enter the chute, and then use nets for capture of the animals that do not enter the chute until the entire group is chute trained.
 - i. If using nets for capture, be sure to place animals in half the pen rather than the whole pen before starting to use the net.
 - ii. Place 1 NHP in the net at a time
 - iii. Carry the nets out of the pen do not let the NHP drag the ground
 - f. Transfer box method (this should be done with a minimum of 1 person and a maximum of 3 people)
 - i. Prior to process a one over one or 2 cages should be placed in the quad
 - ii. Place a transfer box in the first section of the chute system
 - iii. Move one NHP into the transfer box by using the white chute doors

- iv. Place the transfer box at the door of the one over one cages and open both doors so the NHP can enter the cage
 - v. Use the squeeze device in the cage to bring the NHP to the front of the cage so that the animal can be provided an IM injection for sedation.
- g. Chute squeeze method (this should be done with a minimum of 3 people and a maximum of 4).
- i. Place the squeeze device into a small section of the chute with white chute doors on each side. One person should be holding the white chute door on the side of the squeeze furthest away from the animals, the second person should be holding the squeeze, and the third person should be in charge of opening the appropriate chute doors to get the animal into the section where the squeeze.
 - ii. Once the animal is in the section where the squeeze is, the second person should move the squeeze device forward to secure the NHP, while one of the two other people provide an IM injection for sedation.
 - iii. Once the animal is sedated, the NHP can be removed from the chute.

NOTE: During the processes above, staff should be sure to be aware of how to handle themselves during the procedure. No loud, quick, rushed movements. Try to stay low, but more importantly do not directly stare at the animal's eyes. No excessive or unnecessary noises. Be patient, and work with the animals to accomplish the end goal.

 Primate Products, Inc.	Primate Products, Inc. Controlled Document	
	Title: Hot and Cold Weather Procedures	
	Document No. 221	Version: 4.0 Effective Date: 071015

Originated by:  Date 070915

Approved by  Date 07-09-15
Technical Reviewer

Approved by  Date 071015
Senior Management

 Primate Products, Inc.	Primate Products, Inc. Controlled Document	
	Title: Hot and Cold Weather Procedures	
	Document No. 221	Version: 4.0 Effective Date: 071015

1.0 Purpose:

1.0 Purpose:

1.1 To define supportive measures for non-human primates when extreme temperature conditions occur.

2.0 Persons Responsible

2.1 Monitoring: Animal Care personnel during work hours and management after hours.

2.2 Electronic monitoring systems functioning and necessary infrastructure to maintain compliance: Physical Plant

2.3 Response to increase temperatures: Animal Care personnel and Physical Plant if requested.

3.0 Materials Required

3.1 Fans

3.2 Space heaters

3.3 Indoor/ Outdoor Thermometer (w/ minimum & maximum readings)

3.4 Weather alert radio and an internet connection to the NOAA weather site for the area.

3.5 Hi-density plastic landscape pools

3.6 Canvas from the tops, tarps (5' x7'), wire hangers and plastic zip ties

3.7 Plastic barrels

3.8 Sprinklers

4.0 Frequency

4.1 Indoor facilities

4.1.1 When temperatures reach or are predicted to reach above 85.1 degrees or below 46 degrees for more than 4 consecutive hours when nonhuman primates are present.

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4.1.1.1 Audible Alarm

An audible alarm will sound when the temperature falls below 46 degrees Fahrenheit, or above 84 degrees Fahrenheit. If the alarm should go off after hours, ADT will notify the responsible authority for the building so that the proper action may be taken to provide animals with a heat source or cooling source.

4.2 Outdoors

- 4.2.1 When ambient temperatures are above or are predicted to be above 85 degrees or below 46 degrees for more than 4 consecutive hours when nonhuman primates are present

5.0 Procedure

- 5.1 Indoor Facilities when temperatures fall or are predicted to fall below the threshold;

5.1.1 Heat Source

- 5.1.1.1 The husbandry department may use heat lamps, space heaters, and other sources as determined appropriate by the Attending Veterinarian.

- 5.1.1.1.1 All sources of heat will be monitored as needed to insure proper distribution among rooms and individual cages.
- 5.1.1.1.2 Special attention must be made to the location of electrical wires. They must be fastened in a way to keep them out of reach of the animals.
- 5.1.1.1.3 They must be plugged in to a Ground Fault Interrupted (G.F.I.) outlet.

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- 5.2 Indoor facilities when temperatures rise or are predicted to rise above the threshold:
 - 5.2.1 An industrial pedestal fan will be placed in the affected animals rooms.
 - 5.2.2 Temperatures are to be recorded every hour when temperatures reach above 85.1.

- 5.3 Outdoor facilities when temperatures fall or are predicted to fall below the threshold:
 - 5.3.1 In outdoor housing wind breaks should be erected in November (earlier if deemed necessary by management) and taken down in April. The wind breaks are to be erected on the west side of the western most Centiquads, stretching across the driveways, and the northern Centiquads, continuously from the western edge of Centiquad [redacted] to the eastern edge of Centiquad [redacted]. In addition Centiquads 8 and 9 west sides and Centiquad [redacted] north side. The sheets may overlap each other. Where a wind break is not in place, i.e. a hedge or fixed tarps, and when the temperature readings fall below 46 degrees Fahrenheit for more than 4 consecutive hours, temporary tarps will be attached to the fence with plastic ties.
 - 5.3.2 Additional barrels may also be placed in the pens to provide more shelter space for larger groups of monkeys. The concrete skirts of the Centiquad pens also serve as shelter from wind elements.
 - 5.3.3 Heat lamps will be used when the temperature readings fall below 46 degrees Fahrenheit for more than 4 consecutive hours. Each Centiquad is wired for 2 dual heat lamp heaters. . They must be plugged in to a Ground Fault Interrupted (G.F.I.) outlet.
 - 5.3.4 No enclosure will be washed down while the temperature is below 50 degrees Fahrenheit. In this event the cages will be squeegeed and spot cleaned.

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Once the temperature rises above 50 degrees normal washing can begin again.

5.4 Outdoor facilities when temperatures rise or are predicted to rise above the threshold:

5.4.1 Water misters are provided on top of each pen and should be turned on daily when high temperatures are reached. Misters must be turned off before personnel leave for the day. Pools may be used during hot weather.

6.0 Documentation:

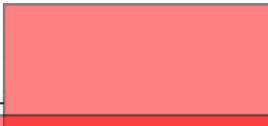
6.1 If room temperatures reach 85.1 temperatures for that room will be recorded every hour with a comparison of the room thermometer and the temperature probe reading.

REVISION HISTORY

Version #	Date	Revisions
2.0	10/16/13	New format and general info throughout [redacted] and [redacted]
3.0	Sept. 2014	Entire Document
4.0	July 2015	Removed Miami facility; updated wording throughout

COP

 Primate Products, Inc.	Primate Products, Inc. Controlled Document	
	Title: Cleaning and disinfection of Outdoor Animal Holding Areas during Quarantine and Non-Quarantine	
	Document No. 250	Version: 5.0 Effective Date: 063015

Originated by:  Date 063015

Approved by:  Date 063015
Technical Reviewer

Approved by:  Date 6-30-15
Senior Management

 Primate Products, Inc.	Primate Products, Inc. Controlled Document	
	Title: Cleaning and disinfection of Outdoor Animal Holding Areas during Quarantine and Non-Quarantine	
	Document No. 250	Version: 5.0 Effective Date: 063015

PURPOSE

Procedure for cleaning outdoor animal holding areas (OAHA) for quarantine and non-quarantine nonhuman primates. The following methods of isolating animals are used to prevent animals from getting wet and exposed to cleaning solutions, as well as to increase human safety while cleaning OAHAs.

1.0 PERSONS RESPONSIBLE

1.1 All husbandry staff

2.0 MATERIALS:

- 2.1 Water hose
- 2.2 Squeegee
- 2.3 Scrub brush
- 2.4 Pump sprayer
- 2.5 Scoop or dust pan for composting
- 2.6 Bucket or Biohazard container for composting
- 2.7 Cleaning barrel
- 2.8 Forage mix
- 2.9 Cleaner/Disinfectant
- 2.10 Personal Protective Equipment as per SOP 111 "Personal Protective Equipment"
- 2.11 Chute cover

3.0 FREQUENCY

3.1 Daily

4.0 PROCEDURE

- 4.1
- 4.2 When animals are in CDC mandated quarantine,
- 4.3 Procedure for daily cleaning of OAHA:

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- 4.3.1 For OAHA in CDC Quarantine, do not begin cleaning OAHA until all animals are secured; either in the chute or divided enclosure per SOP 332 Training – Chute Usage at Panther Tracks Learning Center.
- 4.3.2 For OAHA that are Non-Quarantine, please do the following: Secure animals in chute per SOP 332 “Training- Chute Usage at Panther Tracks Learning Center”.
- 4.3.3 After animals are secured in chute or designated area, using a squeegee or similar tool, gather all large fecal matter and old food into a pile and place into a compost bucket.
- 4.3.4 Before using the water hose to flush, unroll the chute cover over the length of the chute to prevent the animals from getting wet.
- 4.3.5 Using a hose, rinse off all fecal matter from all surfaces (i.e. perches, barrels, swings, walls, enrichment toys, etc.) being careful not to get the animals wet.
- 4.3.6 Release the NHP’s back into the pen, clean the chute cover, roll it up and move to next pen.
- 4.3.7 Repeat steps 4.3.1 through 4.3.4 on remaining pens.
- 4.3.8 After all pens are cleaned, the inside of the OAHA (ie not the pens) including the chutes and chute covers need to be cleaned and squeegeed. It is very important that these areas are not cleaned while any animals are still in the chutes as this may cause unnecessary stress to the animals.
- 4.4 Weekly disinfecting of outdoor animal holding areas housing:
 - 4.4.1 Repeat step 4.3.1 or 4.3.2Using a sprayer, fill with cleaner/disinfectant. Dilute cleaner according to manufacturer’s directions. Bleach is diluted to a 1 part bleach to 9 parts water (1% dilution of chlorine) and is stored in a 250 gallon holding tank. Using a squeegee or similar tool, gather all large fecal matter and old food into a pile and place into a compost bucket or biohazard waste container for quarantine animals.
- 4.4.2 Before using the water hose to flush, unroll the chute cover over the length of the chute to prevent the animals from getting wet.
- 4.4.3 Using a hose, rinse off all fecal matter from all surfaces (i.e. perches, barrels, swings, walls, enrichment toys, etc.) being careful not to get the animals wet and to avoid causing an aerosol of water and fecal matter.
- 4.4.4 Using the sprayer with cleaning/disinfectant solution spray perches, barrels, swings, lixits, enrichment toys, and any other hanging enrichment implements.

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Then scrub surfaces and rinse. When animals are in CDC-mandated quarantine use low water pressure.

- 4.4.5 After all surfaces and enrichment implements are sprayed with cleaning solution, scrubbed and rinsed, apply cleaning solution on walls and floors and let cleaning solution stand for at least 10 minutes on all surfaces and items. After 10 minutes, all surfaces should be rinsed thoroughly. When animals are in CDC-mandated quarantine use low water pressure.
- 4.4.6 Once step 4.4.7 is completed, return to previous pen and thoroughly rinse all surfaces and items. Repeat these steps for all remaining pens.
- 4.4.7 The screen/tarp will be disinfected after each use in quarantine. It will be raised above the ground where it can be rinsed thoroughly, saturated with a disinfectant (minimum of 10 minutes contact time) and again, rinsed thoroughly. The screen/tarp must be completely dry before it is folded for next use. The chute cover will be disinfected after each use in quarantine. It will be saturated with disinfectant (minimum of 10 minutes contact time on each side) and again rinsed thoroughly. The chute cover must be completely dry before it is folded for next use.

5.0 Documentation

- 5.1 Daily Quad Feeding and Cleaning Record.

6.0 REVISION HISTORY

Issue #	Date	Revisions
2.1	10 15 13	B [REDACTED]
3.0	April 2014	Added verbiage for quarantine outdoor housing
4.0	Dec 2014	Wording through out
5.0	June 2015	Entire document



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 Primate Products, Inc.	Primate Products, Inc. Controlled Document	
	Title: Reporting to the Office of Laboratory Animal Welfare (OLAW)	
	Document No. SOP-112	Version: 1.0 Effective Date: 7/8/14

Originated by



Date

8 July 14

Approved by:



Technical Reviewer

Date

7-8-14

Approved by:



Senior Management

Date

070814

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 Primate Products, Inc.	Primate Products, Inc. Controlled Document	
	Title: Reporting to the Office of Laboratory Animal Welfare (OLAW)	
	Document No. SOP-112	Version: 1.0 Effective Date: 7/8/14

1.0 Purpose

1.1 To describe the policy Primate Products, Inc. (PPI) will comply with for reporting to the Office of Laboratory Animal Welfare (OLAW) on incidents involving animals owned or supported by Public Health Service (PHS).

2.0 Persons Responsible:

- 2.1 The Institutional Animal Care and Use Committee (IACUC)
- 2.2 The Institutional Official (IO)
- 2.3 Attending Veterinarian (AV)

3.0 Reportable Incidents

- 3.1 Any serious or continuing noncompliance with OLAW Policy No. NOT-OD-05-034.
- 3.2 Any serious deviation from the provisions of the Guide for the Care and Use of Laboratory Animals.
- 3.3 Any suspension of an activity by the IACUC.
- 3.4 Examples of reportable incidents include but are not limited to the following:
 - 3.4.1 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.
 - 3.4.2 Conduct of animal-related activities without appropriate IACUC review and approval.
 - 3.4.3 Failure to adhere to IACUC-approved protocols.
 - 3.4.4 Implementation of any significant change to IACUC-approved protocols without prior IACUC approval.
 - 3.4.5 Conduct of animal-related activities beyond the expiration date established by the IACUC
 - 3.4.6 Conduct of official IACUC business requiring a quorum in the absence of a quorum.
 - 3.4.7 Conduct of official IACUC business during a period of time that the Committee is improperly constituted.
 - 3.4.8 Failure to correct deficiencies identified during the semiannual evaluation in a timely manner.
 - 3.4.9 Chronic failure to provide adequate space (i.e. floor area and height) for animals in accordance with recommendations of the

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Guide unless the IACUC has approved a protocol-specific deviation from the Guide based on written scientific justification.

- 3.4.10 Participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained.
 - 3.4.10.1 This does not include workshop participants where trained personnel, that are appropriately qualified and trained, are providing training opportunities to students/workshop participants.
- 3.4.11 Failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures).
- 3.4.12 Failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry).
- 3.4.13 Failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO₂).
- 3.4.14 Failure of animal care and use personnel to carry out veterinary orders (e.g., treatments).
- 3.4.15 IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the Guide, or the institution's Animal Welfare Assurance.

4.0 Reporting Information

- 4.1 Animal Welfare Assurance number.
- 4.2 Relevant grant or contract number(s) if the situation is related to an activity directly supported by PHS.
- 4.3 A full description of any potential or actual effect on PHS-supported activities if the situation is not directly supported by the PHS but is in a functional, programmatic, or physical area that could affect PHS-supported activities (e.g., inadequate program of veterinary care, training of technical/husbandry staff, or occupational health; inadequate sanitation due to malfunctioning cage washer; room temperature extremes due to HVAC failures).
- 4.4 Full explanation of the situation, including what happened, when and where, the species of animal(s) involved, and the category of individuals involved (e.g., principal or co-principal investigator, technician, animal caretaker, student, veterinarian, etc.).
- 4.5 Description of actions taken by the institution to address the situation.

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4.6 Description of short- or long-term corrective plans and implementation schedules.

5.0 Reporting time frame

- 5.1 PPI will notify OLAW of incidents promptly and without delay. Since incidents require a full explanation of circumstances and actions taken, and the time required to fully investigate and devise corrective actions may be lengthy, an authorized institutional representative (e.g. Attending Veterinarian, IACUC Chair, etc.) can provide a preliminary report to OLAW as soon as possible and follow-up with a thorough report once action has been taken.
- 5.2 Reports will be submitted as situations occur, and not collected and submitted in groups or with the annual report to OLAW.
- 5.3 Preliminary reports may be in the form of a fax, email, or phone call.

Version #	Date	Revisions
1.0	July 2014	New SOP

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Wednesday, August 12, 2015 12:05 PM
To: 'Thomas Rowell'
Subject: RE: OLAW A4102-F

Thanks Jeff. We'll review carefully and respond soon.
Axel

From: Thomas Rowell [mailto: [REDACTED]@primateproducts.com]
Sent: Wednesday, August 12, 2015 11:31 AM
To: [REDACTED] (NIH/OD) [C]
Cc: Wolff, Axel (NIH/OD) [E]; Paul Houghton
Subject: RE: OLAW A4102-F

Joan,

Attached is Mr. Houghton's response with attachments. Please distribute as needed. j

From: [REDACTED] (NIH/OD) [C] [mailto: [REDACTED]@od.nih.gov]
Sent: Tuesday, July 28, 2015 10:56 AM
To: [REDACTED]@primateproducts.com; [REDACTED]@primateproducts.com'
Cc: [REDACTED]@primateproducts.com';, John (NIH/OD) [E]; [REDACTED] (NIH/OD/ORS) [E]; [REDACTED] (NIH/NIAID) [E]
Subject: OLAW A4102-F

Good afternoon Mr. Houghton,

Attached please find Dr. Axel Wolff's response for OLAW A4102-01, Case-F.

If you have any questions, feel free to contact us by phone or by email.

Thank you,

[REDACTED]
*Project Analyst
Office of Laboratory Animal Welfare
National Institutes of Health
6705 Rockledge Drive, Suite 360
Bethesda, MD 20892
301-594-2506*