

**Exhibit 22**

**9/2/15 PPI response to OLAW**



**Primate Products, Inc.**

02 September 2015

Dr. Axel Wolff  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
Rockledge One, Suite 360  
6705 Rockledge Drive MSC 7982  
Bethesda, MD 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 18 August 2015. Please note concerning information previously provided by Primate Products Inc. as it relates to OLAW's understanding (1 through 5):

5) The October 2, 2014 facility inspection report and the April 21, 2015 program review were provided.

OLAW Comment: Both reports are noncompliant with the PHS Policy and OLAW guidance. There is no cover letter to the Institutional Official, no plans and schedules for correction, no responsible party listed to ensure correction, no interim status of the correction, and no completion date. Please review the enclosed sample documents and ensure that the next semi-annual report is compliant with all of these requirements. Also, refer to OLAW guidance on our website to ensure that your overall program is compliant.

*Please find attached documentation of deficiencies with schedule of correction from October 2014 and April 2015 facility inspection. Also find attached letter to the IO from the Committee dated 7 January 2015. The reports were not included in the previous response because they were not requested.*

**Provide the October 2, 2014 program review and the April 21, 2015 facility inspection reports.**

*The facility inspections and program reviews at Primate Products, Inc. are not scheduled in tandem however they do occur during the same cycle. Each function has a separate IACUC Committee meeting scheduled. The second semi-annual program review for 2014 was completed in December 8, 2014 (previously provided to OLAW) and the first semi-annual facility inspection for 2015 was performed April 14, 2015.*

Regarding new information requested:

1) Regarding prompt reporting to OLAW under PHS Policy IV.F.3:

A) Prompt reporting is applicable to all PHS-supported animal activities as well as all programmatic issues (whether PHS-supported or not). The intrusion of the bear constitutes a programmatic issue that should have been promptly reported.

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Corporate Office and Panther Tracks Learning Center

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**Primate Products, Inc.**

*Initially there was an active decision not report the incident with the bear consistent with PPI's SOP because no animal deaths or injuries occurred involving PHS supported animals. In retrospect we acknowledge OLAW's statement that the bear is considered a programmatic issue because it entered into a space where PHS supported animals are held and could possibly have resulted in a serious injury or death. Further potential incidents where programmatic issues may be involved will be discussed verbally with OLAW to determine if or not reporting should occur.*

*In regards to this specific incident PPI erected an electric fence and have not experienced a return of the animal since that period.*

- B) SOP-112 3.4.13 describes euthanasia via CO2. This is clearly not applicable to the nonhuman primates. Please correct to reflect actual practices.

*Revised SOP 112 reflecting removal of CO2 as an example of euthanasia is attached.*

- 2) Provide a copy of finalized and IACUC approved SOP addressing animal capture.

*SOP 254 Non-Quarantine Capture and Restraint of NHPs has been finalized and approved by the IACUC is attached. Training on SOP held for all necessary employees on 3 September 2015.*

- 3) Provide the corrective plans developed in response to the findings of the August 11-13, 2015 USDA site visit.

*Response with timeline, Enrichment Device Replacement Schedule, revised SOP 404 attached.*

- 4) Provide OLAW Division of Assurance an update on:
- The training program including examples of topics, frequency, and which staff members attend. Also discuss other non-institutional training opportunities for staff and training for the IACUC members.
  - The change in veterinarian with program authority. Indicate that this has been changed from Dr. Rowell to [REDACTED] and provide her qualifications. Also, provide information on the backup veterinarian.

*Requested revisions to Animal Assurance were provided to Dr. Brent Morse with the Division of Assurance on 20 August 2015, also attached.*

- 5) Confirm that when the heat lamps are in use, animals will be able to move freely in and out of the chutes to prevent possible overheating and confirm that all of these lamps will be powered by GFI outlets and that these outlets are available.

*SOP 221 Hot and Cold Weather procedures states that GFI outlets are used. There are only GFI outlets available. The chute doors are to remain open when the heat lamps are in use and SOP 221 has been revised to reflect this (see attached).*

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**Primate Products, Inc.**

- 6) Provide an organizational chart showing all PPI staff ranging from Institutional Official to the animal care and administrative staff. Show supervisory and reporting chains.

*Requested organizational chart attached.*

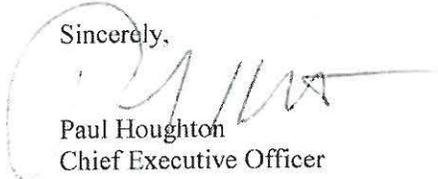
- 7) During the visit additional changes to the animal care and use program were discussed and recommendations were made by the site visitors. Please provide an update on any of these as well any other changes made to the animal and use program.

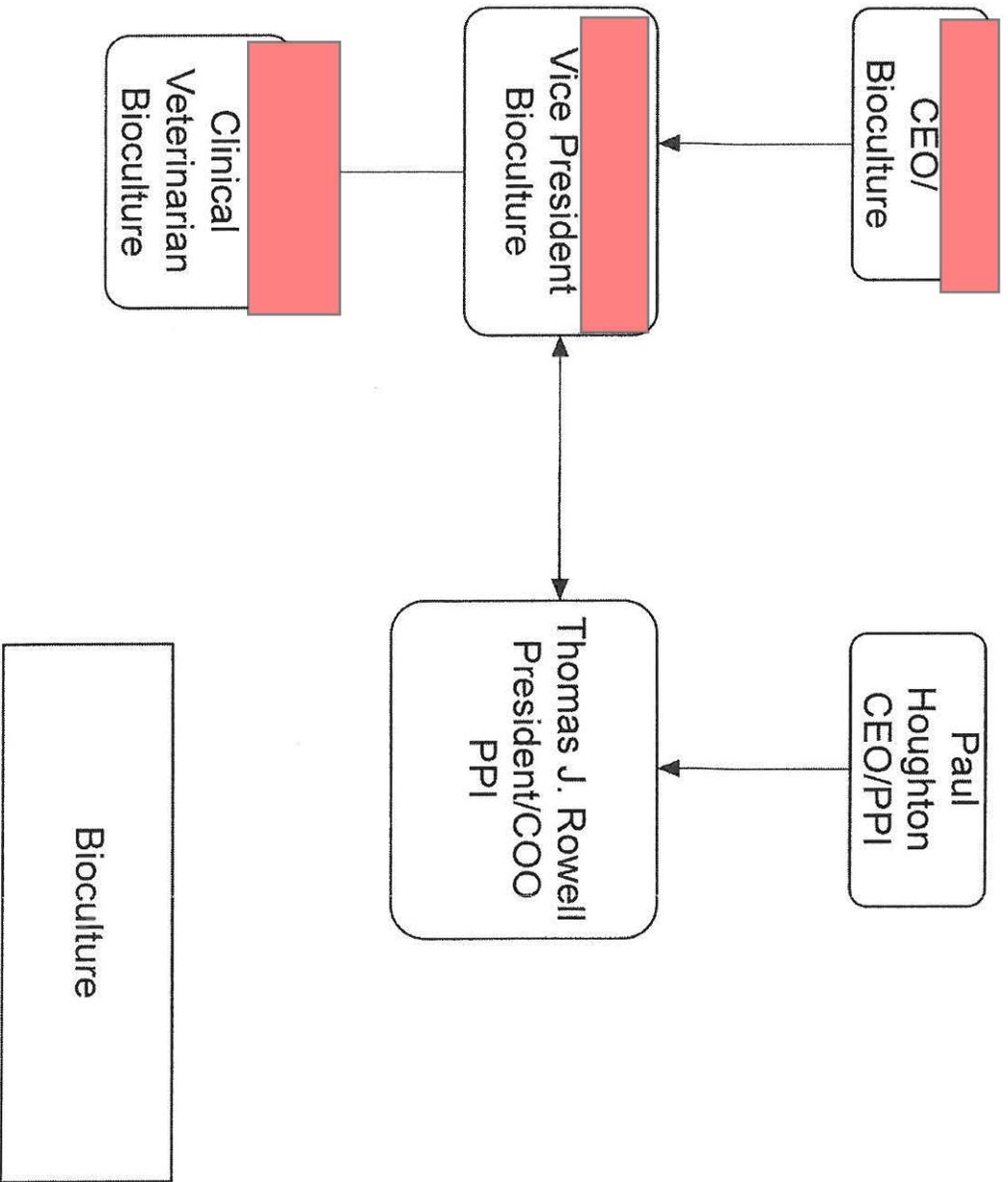
*The Institutional Official initiated the following actions regarding discussions during site visit:*

- *Replaced the non-scientific member of the ACUC to include an individual who was not directly involved with the animal welfare program.*
- *Recruited an ad hoc non-voting member to serve on the ACUC during the semiannual inspections.*
- *Assigned new Chair to the ACUC.*

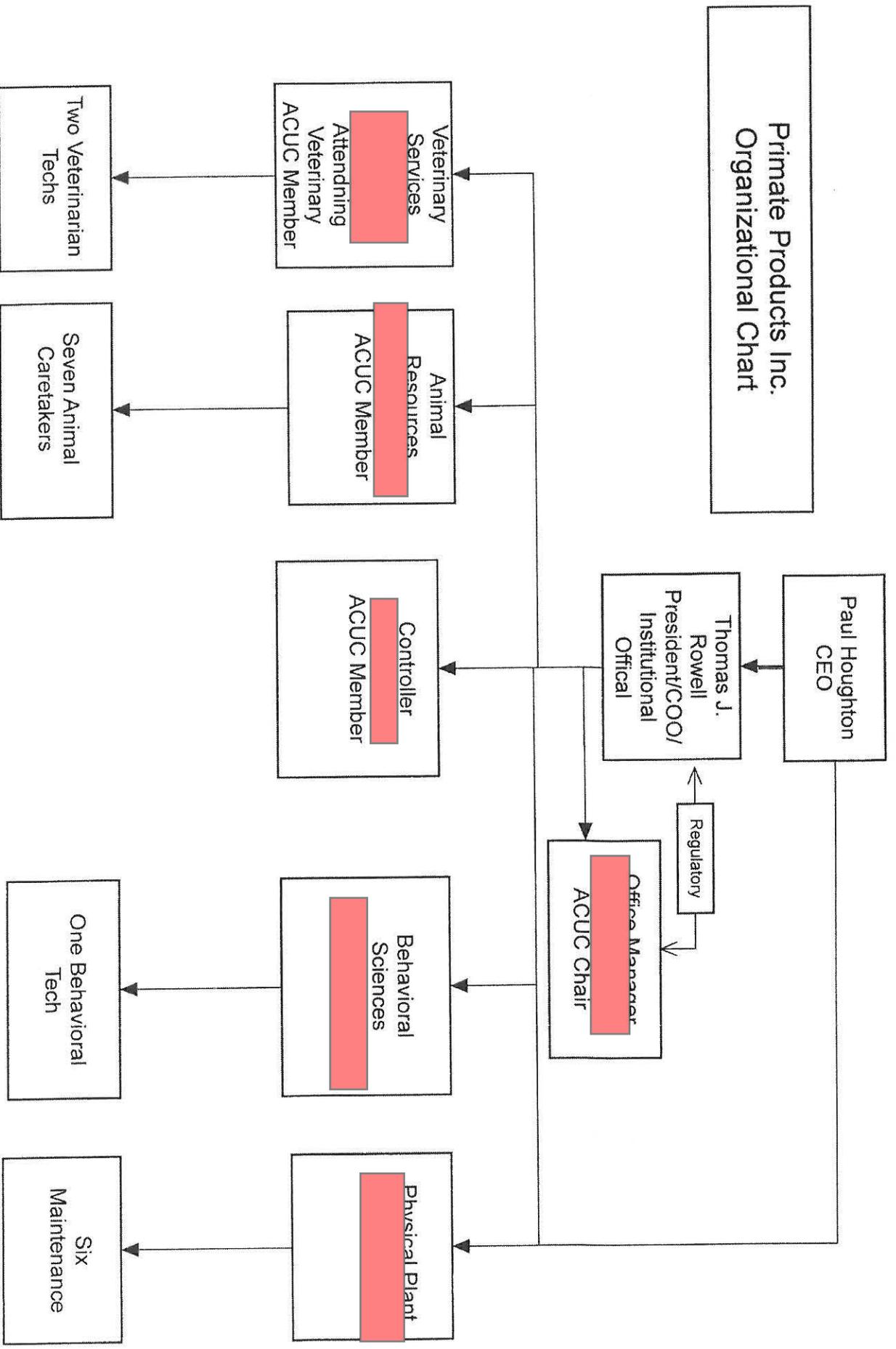
*Additional changes to the program which were made as a result of discussions with the site visitors included having the clinical veterinarian obtain her own DEA license.*

Sincerely,

  
Paul Houghton  
Chief Executive Officer



Primate Products Inc.  
Organizational Chart





**Primate Products, Inc.**

**MEMORANDUM**

To: USDA File

From: Thomas J. Rowell

Date: 20 August 2015

Re: Response USDA Inspection Report 11 August 2015

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3.75 (C) (2) HOUSING FACILITIES, GENERAL.

- 1) Enrichment items in enclosures [redacted] and [redacted] were replaced 13 August 2015.
- 2) See attached plan detailing corrective actions for surface repairs/replacements.
- 3) SOP 404 revised to address periodic replacement of swings, shelves barrels etc. within animal holding pens.

3.84 (d) CLEANING, SANITIZATION, HOUSKEEPING AND PEST CONTROL.

Initiated additional measures to supplement current pest control program starting the week of 17 August 2015. These include the following:

- 1) Increased the number of rodenticide boxes throughout the animal area.
- 2) Incorporated flavor enhanced rodenticides.
- 3) Utilizing kill traps in addition to the rodenticides.
- 4) Instituted grass cutting every other week.
- 5) Eliminated the nesting space within the walls by 8 September 2015
- 6) Increase monitoring.

Pen	Remove Floor Barrels	Replace Floor Barrels	Remove/Replace Primahedron/Other Hanging Item	Remove/Replace Outside Feeders	Remove/Replace PVC Feeders with Outside Feeders	Remove/Replace Hanging Barrels	Add PVC Caps to Swings	Remove/Replace Visual Barriers	Remove/Replace small perches with big perches
	8/28/2015	9/18/2015	N/A	N/A	N/A	12/1/2015	N/A	12/1/2015	N/A
	N/A	N/A	10/1/2015	N/A	N/A	4/1/2016	6/1/2016	12/1/2015	N/A
	N/A	N/A	10/1/2015	N/A	N/A	4/1/2016	6/1/2016	12/1/2015	N/A
	N/A	N/A	10/1/2015	N/A	N/A	12/1/2015	6/1/2016	12/1/2015	N/A
	N/A	N/A	N/A	12/1/2015	N/A	12/1/2015	6/1/2016	12/1/2015	N/A
	N/A	N/A	10/1/2015	N/A	N/A	12/1/2015	N/A	12/1/2015	N/A
	N/A	N/A	N/A	N/A	N/A	4/1/2016	6/1/2016	12/1/2015	N/A
	8/28/2015	9/18/2015	N/A	12/1/2015	N/A	12/1/2015	6/1/2016	12/1/2015	N/A
	N/A	N/A	N/A	12/1/2015	6/1/2016	12/1/2015	6/1/2016	12/1/2015	2/1/2016
	N/A	N/A	N/A	12/1/2015	6/1/2016	12/1/2015	6/1/2016	12/1/2015	2/1/2016
	N/A	N/A	N/A	12/1/2015	6/1/2016	12/1/2015	N/A	12/1/2015	2/1/2016
	N/A	N/A	N/A	12/1/2015	6/1/2016	12/1/2015	6/1/2016	12/1/2015	2/1/2016
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	N/A	N/A	10/1/2015	N/A	6/1/2016	12/1/2015	6/1/2016	12/1/2015	2/1/2016
	N/A	N/A	N/A	N/A	6/1/2016	12/1/2015	N/A	12/1/2015	2/1/2016
	N/A	N/A	N/A	N/A	6/1/2016	4/1/2016	6/1/2016	2/1/2016	2/1/2016
	N/A	N/A	10/1/2015	12/1/2015	6/1/2016	12/1/2015	6/1/2016	2/1/2016	2/1/2016
	N/A	N/A	10/1/2015	12/1/2015	6/1/2016	12/1/2015	6/1/2016	2/1/2016	2/1/2016
	N/A	N/A	10/1/2015	12/1/2015	6/1/2016	12/1/2015	6/1/2016	2/1/2016	2/1/2016
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	N/A	N/A	10/1/2015	12/1/2015	6/1/2016	4/1/2016	6/1/2016	2/1/2016	2/1/2016
	N/A	N/A	10/1/2015	12/1/2015	6/1/2016	2/1/2016	6/1/2016	2/1/2016	2/1/2016
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	N/A	N/A	N/A	N/A	6/1/2016	2/1/2016	N/A	2/1/2016	2/1/2016
	N/A	N/A	N/A	N/A	6/1/2016	2/1/2016	6/1/2016	2/1/2016	2/1/2016
	N/A	N/A	N/A	12/1/2015	6/1/2016	2/1/2016	6/1/2016	2/1/2016	2/1/2016
	N/A	N/A	N/A	12/1/2015	6/1/2016	4/1/2016	N/A	2/1/2016	2/1/2016
	N/A	N/A	10/1/2015	12/1/2015	N/A	2/1/2016	6/1/2016	4/1/2016	N/A
	N/A	N/A	10/1/2015	12/1/2015	N/A	2/1/2016	6/1/2016	4/1/2016	N/A
	N/A	N/A	10/1/2015	12/1/2015	N/A	2/1/2016	6/1/2016	4/1/2016	N/A

NOTE: If a pen is empty (i.e. no animals), once an item is removed it will not be replaced until animals are scheduled to be housed in that pen.



Pen	Remove Floor Barrels	Replace Floor Barrels	Remove/Replace Primahedron/Other Hanging Item	Remove/Replace Outside Feeders	Remove/Replace PVC Feeders with Outside Feeders	Remove/Replace Hanging Barrels	Add PVC Caps to Swings	Remove/Replace Visual Barriers	Remove/Replace small perches with big perches
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	N/A	N/A	N/A	12/1/2015	N/A	4/1/2016	6/1/2016	4/1/2016	N/A
	N/A	N/A	N/A	N/A	N/A	12/1/2015	6/1/2016	12/1/2015	N/A
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	N/A	N/A	N/A	N/A	N/A	12/1/2015	6/1/2016	12/1/2015	N/A
	N/A	N/A	N/A	N/A	N/A	12/1/2015	N/A	12/1/2015	2/1/2016
	N/A	N/A	10/1/2015	N/A	N/A	12/1/2015	6/1/2016	12/1/2015	N/A
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	N/A	N/A	N/A	12/1/2015	N/A	12/1/2015	6/1/2016	12/1/2015	N/A
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	N/A	N/A	N/A	12/1/2015	N/A	12/1/2015	6/1/2016	12/1/2015	N/A
	N/A	N/A	N/A	12/1/2015	N/A	12/1/2015	6/1/2016	12/1/2015	N/A
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	N/A	N/A	10/1/2015	12/1/2015	N/A	4/1/2016	6/1/2016	12/1/2015	N/A
	N/A	N/A	10/1/2015	12/1/2015	N/A	4/1/2016	6/1/2016	12/1/2015	N/A
	N/A	N/A	10/1/2015	12/1/2015	N/A	4/1/2016	6/1/2016	12/1/2015	N/A
	N/A	N/A	10/1/2015	12/1/2015	N/A	4/1/2016	6/1/2016	12/1/2015	N/A
	8/28/2015	9/18/2015	N/A	12/1/2015	N/A	2/1/2016	6/1/2016	2/1/2016	N/A

NOTE: If a pen is empty (i.e. no animals), once an item is removed it will not be replaced until animals are scheduled to be housed in that pen.

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	N/A	N/A	10/1/2015	12/1/2015	N/A	4/1/2016	6/1/2016	2/1/2016	N/A
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	N/A	N/A	10/1/2015	12/1/2015	N/A	2/1/2016	6/1/2016	2/1/2016	N/A
	N/A	N/A	N/A	N/A	N/A	2/1/2016	6/1/2016	2/1/2016	N/A
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	8/28/2015	9/18/2015	10/1/2015	N/A	N/A	2/1/2016	6/1/2016	2/1/2016	N/A
	N/A	N/A	10/1/2015	N/A	N/A	2/1/2016	6/1/2016	2/1/2016	N/A

NOTE: If a pen is empty (i.e. no animals), once an item is removed it will not be replaced until animals are scheduled to be housed in that pen.

## Animal Welfare Assurance #A4102-01 (Amended)

- A. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

Name: [REDACTED]

Qualifications:

- Ross University School of Veterinary Medicine (2014)
- University of Wisconsin, Oshkosh BS Criminal Justice
- Worked with nonhuman primates at local zoo and in Belize prior to becoming a Veterinarian.
- Worked as a Research Veterinarian with African Green Vervets in St. Kitts.
- Authority [REDACTED] has direct program authority and responsibility for the Institution's animal care and use program including access to all animals.

Time Contributed to Program: Full time employee, 100% of time contributed to the animal care and use program

Name: Dr. Thomas J. Rowell

Qualifications

- Degrees: Bachelor of Science, Doctor of Veterinary Medicine (LSU 86)
- Training or experience in laboratory animal medicine or in the use of the species at the institution:
- USDA accreditation, licensed in Florida and Louisiana, 30 years of experience working in laboratory animal medicine and management

Time contributed to program: Full time employee, 10% of time contributed to the animal care and use program

- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

Zoonosis and Blood Borne Pathogens- all employees regardless of title or position will attend training on a yearly basis. The Attending Veterinarian or designated member of Vet Staff will conduct this training session.

Fire Safety- all employees regardless of title or position will attend a yearly fire safety training course. This course will be given by the Director of Facilities or designee.  
Bio-hazardous Waste- all employees working hands-on with nonhuman primates (NHP), NHP bio-products, or in NHP housing areas will attend training on a yearly basis.  
Institutional Animal Care and Use Committee (IACUC)- all employees regardless of title or position shall receive annual training on the purpose and function of the IACUC. This training may be performed by any voting-member of the IACUC, the Attending Veterinarian or the Institutional Official.

Standard Operating Procedures- all employees will receive a list of SOP's to review annually and as they are revised  
Natural History and Behaviors of Macaques- all employees working directly with nonhuman primates or around nonhuman primates will

attend this training on a yearly basis. The Head of Behavioral Sciences or designee will provide this training.

All new employees working directly or indirectly with nonhuman primates will be oriented on safe procedures in the workplace which will include but not be limited to potential exposure to zoonotic diseases, nonhuman primate behaviors, all applicable Standard Operating Procedures, and proper use of personal protective equipment (PPEs). Forms will be provided to guide as to what order SOP's should be read and these forms will be completed by employee as the SOP's are read and understood. Within one month of employment, all new employees will attend an education session on the history of, need for and validity of using animals in biomedical research.

Initiation of training for Husbandry personnel will follow the Husbandry Phase Training program as attached.

Initiating in 2016, as a direct results of the April 2015 IACUC Semi-annual program review, training will be provided to all employees on the topic ethics and the Three R's in biomedical research. As PPI does not perform research or testing at this time the extent of training provided on pain and distress is limited but still provided so employees may understand the boarder scope of the field of research.

IACUC members are provided *the Guide* as a reference material and access to the AALAS learning library. Member "E" was provided "Working Safely with Nonhuman Primates" document and the IACUC SOP upon joining the Committee. [REDACTED] attended IACUC 101 and 301 in Kansas City in June 2015. [REDACTED] and [REDACTED] (and the outside member at the time) attended an IACUC Symposium in Columbus, OH in the spring of 2014.





**COPI**

 Primate Products, Inc.	Primate Products, Inc. Controlled Document	
	Title: Use of Personal Protective Equipment (PPE) by Technical Staff and Visitors	
	Document No. SOP-111	Version: 1.0 Effective Date: 02/07/14

Originated by:  Date: 02/06/14

Approved by:   
Technical Reviewer Date: 2/27/14

Approved by:   
Senior Management Date: 02/04/2014



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Appendix 2. Minimum PPE for Visitors or Maintenance Personnel

PPE	Blue Scrubs	Eye Protection	Goggles	Face Shield	Hair Cover	Dusk Mask	Filtering Face Piece Respirator NIOSH-N95	Lab Coat (Regular)	Tyvek Lab Coat	Tyvek Coveralls	Gloves - Latex or Nitrile <sup>1</sup>	Facility Shoes	Shoe Covers <sup>2</sup>	Rubber Boots w/Steel Toes	Hearing Protection
OFFICE AREA/STREET CORRIDOR															
Animal Building/Clean Corridor	X	X				X		X					X		
Outdoor Animal Holding Area	X	X				X		X							
General Entry															
Animal Holding Rooms/Pens															
CDC Quarantine - Miami <sup>1</sup>	X	X			X		X			X	X	X		X	
CDC Quarantine - PTLG <sup>3</sup>	X	X			X		X			X	X	X		X	
Non-Quarantine - Indoor	X	X				X					X	X		X	
Non-Quarantine - Outdoor	X	X				X					X	X		X	
Dosing / Bleeding Animals	X	X				X					X	X		X	
Cage Washing:															
Single Cages - Indoor															
Group Pens - Outdoor															
Inactive Rooms (clean/sanitized)	X	X						X					X		

<sup>1</sup> Hand-capturing awake primates or handling unrestrained primates, elbow length leather gloves over latex or nitrile are required  
<sup>2</sup> If facility supplied shoes are not used, then shoe covers must be used  
<sup>3</sup> Only Regulatory Agency Visitors or Maintenance responding to an emergency may be allowed to enter CDC Quarantine Rooms  
 Shaded areas indicate either option is acceptable

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 Primate Products, Inc.	<b>Primate Products, Inc. Controlled Document</b>	
	<b>Title: Use of Personal Protective Equipment (PPE) by Technical Staff and Visitors</b>	
	<b>Document No. SOP-111</b>	<b>Version: 1.0</b> <b>Effective Date: 020714</b>

**COPY**

**1.0 PURPOSE**

This SOP describes the minimum Personal Protective Equipment (PPE) requirements in the Primate Products, Inc (PPI) facilities. It applies to all staff and observers regardless of the area of the facility or their purpose for being in the facility. The PPE requirements in this SOP are intended to protect people, to support protection of animals, and to reduce the potential to spread contamination.

**2.0 REFERENCES**

N/A

**3.0 DEFINITIONS**

<u>Term</u>	<u>Meaning</u>
PPE	Personal protective equipment is any equipment or clothing required by this SOP.

**4.0 PROCEDURE**

- 4.1 All PPE required by this SOP are available in the facility or supplied by PPI. Staff is not permitted to use PPE brought in from non-approved sources.
- 4.2 The facility design allows staff to enter the facility and travel to locker rooms/change areas, supply areas, office areas, and the break area without a requirement for PPE, unless otherwise posted. Traveling to animal holding areas, PPE is required as specified in Appendices 1 and 2 of this SOP, respectively.
- 4.3 Appendices 1 and 2 list minimum protective clothing requirements. Appendix 1 is entitled "Minimum PPE for Personnel Working with Animals or Soiled Husbandry Equipment." Appendix 2 is entitled "Minimum PPE for Observers." Anyone entering the facility must meet the minimum requirements.
- 4.4 As necessary, additional PPE will be specified on a study-specific or non-routine task basis. Typical PPE, which may be specified in addition to the minimum, include gloves constructed of a specific material, eye protection, and respiratory protection.
- 4.5 Shoe covers will be donned upon entry to any room with live animals and discarded upon exit for personnel or observers not wearing facility-specific footwear.
- 4.6 Unless safety footwear is specified in the Appendices, it is expected that all PPI staff, except observers, will wear appropriate footwear in PPI facilities. Such footwear should reduce the risk of trips, falls and slips. In addition, it should provide support, stability, and provide protection from lacerations, punctures and brief chemical contact. Appropriate footwear for animal areas do not include sandals, open-toed, moccasins, flip-flops, high

 Primate Products, Inc.	<b>Primate Products, Inc. Controlled Document</b>	
	<b>Title: Use of Personal Protective Equipment (PPE) by Technical Staff and Visitors</b>	
	<b>Document No. SOP-111</b>	<b>Version: 1.0</b> <b>Effective Date: 02/07/14</b>

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heels, and those that are significantly perforated or significantly constructed of canvas, nylon, or other fabric

- 4.7 PPI employees escorting or responsible for, an observer are also responsible for ensuring the observer is wearing proper PPE.
- 4.8 Clean scrub suits:
  - Are permissible in the break room;
  - Are permissible in offices, administrative areas, and conference rooms.
- 4.9 Visibly soiled or knowingly contaminated lab coats, scrub suits, or other outer protective equipment or clothing:
  - Must be replaced with clean garments in a timely fashion;
  - Must not be worn outside of PPI;
  - Must not be worn in any food areas, break room, offices and other administrative areas.
- 4.10 Staff will not leave PPI premises with scrub suits, lab coats or facility-specific shoes.
- 4.11 The veterinary staff will ensure that the signs are posted for quarantine rooms, holding and other non-study specific rooms.

**5.0 REVISION HISTORY**

Issue #	Date	Revisions
1.0	2/6/14.	New SOP



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 Primate Products, Inc.	<b>Primate Products, Inc. Controlled Document</b> <b>Title: Use of Personal Protective Equipment (PPE) by Technical Staff and Visitors</b> <b>Document No. SOP-111</b>	<b>Version: 1.0</b> <b>Effective Date:</b>
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### Appendix I. Minimum PPE for Personnel Working with Animals or Soiled Husbandry Equipment

PPE	Blue Scrubs	Eye Protection	Goggles	Face Shield	Hair Cover	Dust Mask	Filtering Face Piece Respirator NIOSH-N95	Lab Coat (Regular)	Tyvek Lab Coat	Tyvek Coveralls	Gloves - Latex or Nitrile <sup>1</sup>	Facility Shoes	Shoe Covers <sup>2</sup>	Rubber Boots w/Steel Toes	Hearing Protection
OFFICE AREA/STREET CORRIDOR															
Animal Building/Clean Corridor	X	X				X					X	X			
Outdoor Animal Holding Area	X	X				X					X	X			
General Entry															
Animal Holding Rooms/Pens															
CDC Quarantine - Miami	X	X			X		X			X	X	X	X	X	
CDC Quarantine - PTTC	X	X			X		X			X	X	X	X	X	
Non-Quarantine - Indoor	X	X					X			X	X	X	X	X	
Non-Quarantine - Outdoor	X	X					X			X	X	X	X	X	
Dosing / Bleeding Animals	X	X					X			X	X	X	X	X	
Cage Washing:															
Single Cages - Indoor	X				X										
Group Pens - Outdoor	X				X										
Inactive Rooms (clean/sanitized)	X	X			X										

<sup>1</sup> If hand-capturing awake primates or handling unrestrained primates, elbow length leather gloves over latex or nitrile are required.  
<sup>2</sup> If facility supplied shoes are not used, then shoe covers must be used.  
 Shaded areas indicate either option is acceptable.

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	Title: Reporting to the Office of Laboratory Animal Welfare (OLAW)	
	Document No. SOP-112	Version: 2.0 Effective Date: 08/31/15



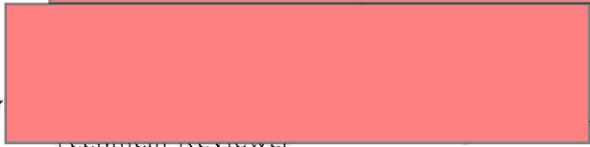
Originated by:



Date

31 Aug 15

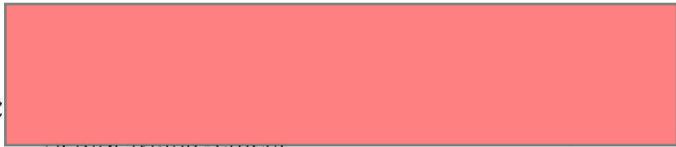
Approved by



Date

31 August 2015

Approved by:



Date

08/31/15

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	Document No. SOP-112	Version: 2.0 Effective Date: 08/21/15



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## 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 Reporting Requirements

- 3.1 At least once every 12 months, the IACUC, through the Institutional Official, shall report in writing to OLAW:
- 3.1.1 Any change in the institution's program or facilities that would place the institution in a different category that specified in its Assurance (see IV.A.2 PHS policy);
  - 3.1.2 Any change in the description of the institution's program for animal care and use as required by IV.A.1.a.-i of PHS policy;
  - 3.1.3 Any changes in the IACUC membership; and
  - 3.1.4 Notice of the dates that the IACUC conducted its semiannual evaluations of the institutions program and facilities and submitted evaluations to the Institutional Official.
- 3.2 At least once every 12 months, the IACUC, at an institution which has no changes to report as specified in IV.F.1.a.-c. Of PHS policy, shall report to OLAW in writing, through the Institutional Official, that there are no changes and shall inform OLAW of the dates of the required IACUC evaluations and submissions to the Institutional Official.
- 3.3 The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
- 3.3.1 Any serious or continuing noncompliance with OLAW Policy No. NOT-OD-05-034.
  - 3.3.2 Any serious deviation from the provisions of *the Guide for the Care and Use of Laboratory Animals*.
  - 3.3.3 Any suspension of an activity by the IACUC.

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#### 4.0 Reportable Incidents

##### 4.1 Examples of reportable incidents include but are not limited to the following:

- 4.1.1 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.
- 4.1.2 Conduct of animal-related activities without appropriate IACUC review and approval.
- 4.1.3 Failure to adhere to IACUC-approved protocols.
- 4.1.4 Implementation of any significant change to IACUC-approved protocols without prior IACUC approval.
- 4.1.5 Conduct of animal-related activities beyond the expiration date established by the IACUC
- 4.1.6 Conduct of official IACUC business requiring a quorum in the absence of a quorum.
- 4.1.7 Conduct of official IACUC business during a period of time that the Committee is improperly constituted.
- 4.1.8 Failure to correct deficiencies identified during the semiannual evaluation in a timely manner.
- 4.1.9 Chronic failure to provide adequate space (i.e. floor area and height) for animals in accordance with recommendations of *the Guide* unless the IACUC has approved a protocol-specific deviation from *the Guide* based on written scientific justification.
- 4.1.10 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.
- 4.1.11 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).
- 4.1.12 Failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry).
- 4.1.13 Failure to ensure death of animals after euthanasia procedures.
- 4.1.14 Failure of animal care and use personnel to carry out veterinary orders (e.g., treatments).

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4.1.15 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.

## 5.0 Reporting Information



- 5.1 Animal Welfare Assurance number.
- 5.2 Relevant grant or contract number(s) if the situation is related to an activity directly supported by PHS.
- 5.3 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).
- 5.4 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.).
- 5.5 Description of actions taken by the institution to address the situation.
- 5.6 Description of short- or long-term corrective plans and implementation schedules.

## 6.0 Reporting time frame

- 6.1 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.
- 6.2 Reports will be submitted as situations occur, and not collected and submitted in groups or with the annual report to OLAW.
- 6.3 Preliminary reports may be in the form of a fax, email, or phone call.

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Version #	Date	Revisions
1.0	July 2014	New SOP
2.0	August 2015	Removal of reference to CO2; additional information on reporting added.

 Primate Products, Inc.	<b>Primate Products, Inc. Controlled Document</b>	
	Title: Hot and Cold Weather Procedures	
	Document No. 221	Version: 5.0 Effective Date: 090115

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Originated by:  Date 090115

Approved by:  Date 1 Sept 2015  
Technical Reviewer

Approved:  Date 01 Sept 15  
Senior Management

 Primate Products, Inc.	<b>Primate Products, Inc. Controlled Document</b>	
	<b>Title: Hot and Cold Weather Procedures</b>	
	<b>Document No. 221</b>	<b>Version: 5.0</b> <b>Effective Date:</b> 09/01/15

## 1.0 Purpose:

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### 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.

2.4 The Attending Veterinarian has reviewed and provides for the following determinations:

2.4.1 That the nonhuman primates that are acclimated to the prevailing temperature and humidity at the outdoor housing facility during the time of year they are at the facility, and can tolerate the range of temperatures and climatic conditions known to occur at the facility at that time of year without stress or discomfort.

2.4.2 The shelter safely provides protection from the sun, rain, snow, wind and cold and from any weather conditions that may occur. The shelter must safely provide heat to the nonhuman primates to prevent the ambient temperature from falling below 45 °F (7.2 °C), except as directed by the attending veterinarian and in accordance with generally accepted professional and husbandry practices.

### 3.0 Materials Required

3.1 Fans

3.2 Space heaters

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	<b>Title: Hot and Cold Weather Procedures</b>	
	<b>Document No. 221</b>	<b>Version: 5.0</b> <b>Effective Date: 090115</b>

- 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 Ambient temperature in the facility must not fall below 45 degrees Fahrenheit for more than 4 consecutive hours when nonhuman primates are present, and must not rise above 85 degrees Fahrenheit for more than 4 consecutive hours when nonhuman primates are present.
      - 4.1.1.1 Audible Alarm

An audible alarm will sound when the temperature falls below 45 degrees Fahrenheit, or above 85 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 predicted to be above 85 degrees or below 45 degrees when nonhuman primates are present

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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.

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 will 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

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- [REDACTED]. In addition Centiquads [REDACTED] 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 is predicted to fall below 45 degrees Fahrenheit, 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 45 degrees Fahrenheit or predicted to fall below the same. When the heat lamps are in use the chute area will be divide in half and the front and back door will be open so animals are free to enter and leave the area. Each Centiquad is wired for 2 dual heat lamps. They must be plugged in to a Ground Fault Interrupted (G.F.I.) outlet. The animals will have someone from husbandry staff on duty making hourly rounds to ensure the safety and wellness of the animals.
- 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. 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 will be turned on daily when temperatures of 85 degrees Fahrenheit are reached. Misters must be turned off before personnel leave for the day. Pools may be used as well during hot weather.

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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
5.0	September 2015	Added wording for chute clarification; updated Outdoor temperature requirements; added section 2.4

 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: 4.0 Effective Date: 01/19/15

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Originated by:  Date: 01-19-15  
 Approved by:  Date: 01/19/15  
                   Technical Reviewer  
 Approved by:  Date: 19 Jan 15  
                   Senior Management

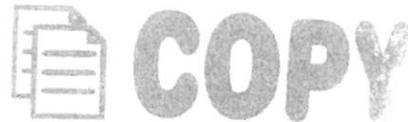
 Primate Products, Inc.	Primate Products, Inc. Controlled Document	
	Title: Cleaning and disinfection of Outdoor Animal Holding Areas during Quarantine and Non-Quarantine	
	Document No. 250	Version: 4.0 Effective Date: 01/19/15

## PURPOSE

Procedure for cleaning outdoor animal holding areas housing quarantine and non-quarantine nonhuman primates.

### 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"

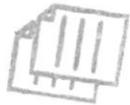
### 3.0 FREQUENCY

- 3.1 Daily

### 4.0 PROCEDURE

- 4.1 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 OAHA
- 4.2 When animals are in CDC mandated quarantine, do not begin cleaning OAHA until all animals are secured; either in the chute or divided enclosure within the OAHA.
- 4.3 Procedure for daily cleaning of OAHA:
  - 4.3.1 For OAHA in CDC Quarantine, please do the following: Starting with one pen at a time, provide forage mix in chute, open the entrance chute door and cue

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animals to enter the chute by saying "Everyone In". Allow animals to enter chute and secure chute door once all animals have entered the chute. As an alternative, especially if the animals refuse to go in the chute, the animals may be secured on one side of a divided enclosure while the other side is cleaned, and then moved and secured to the clean side so that the other side can be cleaned. Animals may also be secured in divided holding areas within the pen.

- 4.3.2 For OAHA that are Non-Quarantine, please do the following: Secure animals in chute per SOP 332 "Training- Chute Usage during Quarantine" or SOP 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 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.
- 4.3.5 Repeat steps 4.3.1 through 4.3.4 on remaining pens.
- 4.4 Weekly disinfecting of outdoor animal holding areas housing:
  - 4.4.1 Repeat step 4.3.1 or 4.3.2
  - 4.4.2 Using a sprayer, fill with water and add cleaner/disinfectant. Dilute disinfectant according to manufacturer's directions. Bleach is diluted by using 1 part bleach to 9 parts water.
  - 4.4.3 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.
  - 4.4.4 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. When animals are in CDC-mandated quarantine use low water pressure.
  - 4.4.5 Using a sprayer and cleaning solution spray perches, barrels, swings, lixits, enrichment toys, and any other hanging enrichment implements. When animals are in CDC-mandated quarantine use low water pressure.
  - 4.4.6 After all surfaces and enrichment implements are sprayed, 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. When animals are in CDC-mandated quarantine use low water pressure.
  - 4.4.7 While cleaning solution is standing repeat steps 4.4.1 through 4.4.6 on next pen

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4.4.8 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.

5.0 Documentation

5.1 Daily Quad Feeding and Cleaning Record



6.0 REVISION HISTORY

Issue #	Date	Revisions
2.1	10 15 13	[REDACTED]
3.0	April 2014	Added verbiage for quarantine outdoor housing
4.0	Jan 2014	Wording through out

 Primate Products, Inc.	<b>Primate Products, Inc. Controlled Document</b>	
	<b>Title: Enrichment Requirements, Evaluation and Maintenance for Outdoor Animal Holding Areas</b>	
	<b>Document No. 404</b>	<b>Version: 3.0</b> <b>Effective Date: 090215</b>

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Originated by:

[Redacted]

Date

090215

Approved by:

[Redacted]

Date

9-1-15

Technical Reviewer

Approved by:

[Redacted]

Date

090115

Senior Management

 Primate Products, Inc.	<b>Primate Products, Inc. Controlled Document</b>	
	<b>Title: Enrichment Requirements, Evaluation and Maintenance for Outdoor Animal Holding Areas</b>	
	<b>Document No. 404</b>	<b>Version: 3.0</b> <b>Effective Date: 09-02-15</b>

**Purpose:** To comply with the Primate Products, Inc. Environmental Enhancement Program to promote the psychological well-being of nonhuman primates.

**1.0 Persons Responsible:**

- 1.1 Husbandry Staff
- 1.2 Behavioral Staff
- 1.3 Veterinary Staff
- 1.4 Maintenance Staff



**2.0 Materials Required:**

- 2.1 Manipulanda (e.g. kongs, balls etc.)
- 2.2 Perches
- 2.3 Swings and other hanging items
- 2.4 Feeders
- 2.5 HDPE Visual Barriers
- 2.6 Barrels
- 2.7 HDPE turfboards
- 2.8 Hardware to hang items
- 2.9 Chute Doors

**3.0 Frequency:**

- 3.1 Daily
- 3.2 Whenever an outdoor animal holding area (OAHA) is being prepared to receive new animals
- 3.3 Twice a year during semi-annual behavioral observations
- 3.4 Twice a year during IACUC semi-annual inspections
- 3.5 As needed

**4.0 Procedure:**

- 4.1 Enrichment Requirements for OAHA
  - 4.1.1. All pens are required to have adequate perching available. This should include the following:
    - 4.1.1.1. PVC perches hung in corners of pens
    - 4.1.1.2. Barrels, 4 hung in middle of pen
    - 4.1.1.3. PVC swings, at least 1 hung in center of pen
    - 4.1.1.4. Other hanging items (e.g. primahedron, manzanita wood swing, PVC hanging wheel etc.), at least one hung in center of pen

 Primate Products, Inc.	<b>Primate Products, Inc. Controlled Document</b>	
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- 4.1.2. All pens are required to have a minimum of 4 feeders placed around the pen so as to provide animals with multiple feeding sites.
- 4.1.3. All pens are required to have the amount of manipulanda (e.g. kongs, balls etc.) that is appropriate for the group. Typically this will be approximately 1 manipulanda per 2 animals, but this will vary based on age/sex/species of the group.
- 4.1.4. All pens are required to have a minimum of 2 hanging visual barriers.
- 4.1.5. All pens should have a minimum of 3 HDPE turfboards attached to the outside of the pen.
- 4.1.6. All inner doors of pens must be able to be clipped open in a "Z" pattern (or securely closed).
- 4.1.7. All pens must have at least 5 chute doors per pen, 4 that are on each chute, and 1 extra hanging on the wall.
  
- 4.2 Evaluation of Enrichment in OAHA.
  - 4.2.1. All empty pens need to be evaluated by husbandry staff before new animals are placed into the pen using the attached form (5.2).
  - 4.2.2. Evaluation should include the following:
    - 4.2.2.1. Scratch and bite marks
    - 4.2.2.2. Sharp and/or rusty edges/parts
    - 4.2.2.3. Ability to appropriately sanitize
    - 4.2.2.4. Ability for the item to continue to be utilized (e.g. if less than 50% of a kong remains, this item should be removed and replaced)
  - 4.2.3. Enrichment Evaluation in OAHA will also occur during the following times:
    - 4.2.3.1. Daily by husbandry staff on Daily Cleaning and Feeding Form (5.1)
    - 4.2.3.2. Semi-Annual Behavioral Observations by behavioral staff using the attached form (5.2)
    - 4.2.3.3. IACUC Facility Semi-Annual Inspections by IACUC members
    - 4.2.3.4. As needed by all
  
- 4.3 Maintenance of Enrichment in OAHA.
  - 4.3.1. All enrichment items must be removed/repared/replaced when they fit one or more of the below criteria:
    - 4.3.1.1. For manipulanda
      - 4.3.1.1.1. Less than 50% of item remains

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	<b>Title: Enrichment Requirements, Evaluation and Maintenance for Outdoor Animal Holding Areas</b>	
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- 4.3.1.1.2. Item can no longer be appropriately sanitized
- 4.3.1.1.3. Item is no longer safe for the animal
- 4.3.1.2. For hanging items, perches, feeders and chute doors
  - 4.3.1.2.1. Sharp and/or rusty areas on edges/parts of item
  - 4.3.1.2.2. Cracks on item
  - 4.3.1.2.3. Item can no longer be appropriately sanitized
  - 4.3.1.2.4. Item is no longer safe for the animal
  - 4.3.1.2.5. Attachment of the item is sharp, frayed, broken, unsafe etc.
- 4.3.2. All staff are responsible for removing and/or reporting items that need maintenance
- 4.3.3. Depending on the item, and the repair or replacement needed, maintenance, husbandry, or behavioral staff may be responsible.

**5.0 Documentation:**

- 5.1 Daily Cleaning and Feeding
- 5.2 Outdoor Animal Holding Area Enrichment Evaluation form

**REVISION HISTORY**

Version #	Date	Revisions
2.0	12/10/13	Reviewed <span style="background-color: red; color: red;">[REDACTED]</span>
3.0	September 2015	Entire document

# Daily Quad Feeding and Cleaning Record

**COPY**

Quad Number: \_\_\_\_\_

Function	Sunday		Monday		Tuesday		Wednesday		Thursday		Friday		Saturday	
Date:														
Head Count per Pen:	A	B	A	B	A	B	A	B	A	B	A	B	A	B
	C	D	C	D	C	D	C	D	C	D	C	D	C	D
AM Feeding														
Locks Checked														
Flush Water Lines														
Lixit Check														
**Disinfectant Used														
Cleaning Completed														
*Extra Enrichment Given (in chutes)														
PM Feeding	A	B	A	B	A	B	A	B	A	B	A	B	A	B
Obs per Pen:	C	D	C	D	C	D	C	D	C	D	C	D	C	D
Initials:														

**Notes:**

\* P = Produce, F = Forage Mix  
 \*\* B = Bleach, F = Fresh Breeze, Q = Quat  
 N = Normal, A = Abnormal

Reviewed By: \_\_\_\_\_

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### Outdoor Animal Holding Area Enrichment Evaluation Form

Owner:	Unit:	Sex:	# of Animals:	Species:	Viral:	Date:
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	Count <i>(write in)</i>	Need <i>(write in)</i>	Sharp Edges/Parts <i>(circle one)</i>	Rust on Cable <i>(circle one)</i>	Needs Replacement <i>(circle one)</i>	Comments <i>(write in)</i>
Hanging Barrels:			YES NO	YES NO	YES NO	
PVC Perches:			YES NO	YES NO	YES NO	
Visual Barriers:			YES NO	YES NO	YES NO	
PVC Swing:			YES NO	YES NO	YES NO	
Chute Doors			YES NO	YES NO	YES NO	
Other Hanging Item:			YES NO	YES NO	YES NO	

	Count <i>(write in)</i>	Need <i>(write in)</i>	Sharp Edges <i>(circle one)</i>	Needs Replacement <i>(circle one)</i>	Comments <i>(write in)</i>
Balls:			YES NO	YES NO	
Feeders:			YES NO	YES NO	
Forage Boards:			YES NO	YES NO	
Other:			YES NO	YES NO	

	# of animals in chute	Score (1,2,3 or M)	Initial/Date
Chute Check			

Checked By:	Date:	Supervisor:	Date:
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 Primate Products, Inc.	<b>Primate Products, Inc. Controlled Document</b>	
	<b>Title: Capture and Restraint of Non-Quarantine NHPs</b>	
	<b>Document No. 254</b>	<b>Version: 1.0</b> <b>Effective Date: 083115</b>

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Originated by:  Date: 8-31-15  
Approved by:  Date: 083115  
Technical Reviewer  
Approved by:  Date: 08/31/15  
Senior Management

 Primate Products, Inc.	<b>Primate Products, Inc. Controlled Document</b>	
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Purpose: To describe and implement procedures for capture and restraint of nonhuman primates (NHPs) that are not in quarantine.

1. Persons Responsible:
  - 1.1 All employees working with live NHPs that have been appropriately trained.
  
2. Materials Required:
  - 2.1. Standard non-quarantine personal protective equipment (PPE) per Standard Operating Procedure (SOP) 111
  - 2.2. Kevlar-lined leather NHP catch gloves
  - 2.3. Capture nets
  - 2.4. Prima-carriers also called transfer boxes
  - 2.5. Squeeze mechanism for chute
  - 2.6. Standard 4.3 cage with working squeeze-back
  - 2.7. Chute and extra chute doors
  - 2.8. Chemical needed for restraint/sedation
  - 2.9. Training Treats (optional)
  
3. Frequency:
  - 3.1. Whenever it is necessary to capture or restrain non-quarantine NHPs (e.g. animal movements/transfers, processing, bio-products collection, ID verification, and veterinary care etc.).
  
4. Procedure for capture and restraint of NHPs in outdoor animal holding areas (OAHA).
  - 4.1. Chute Capture and Restraint, this is the primary method and should be used in most situations.
    - 4.1.1. Place animals in chute per Chute Training SOP 242.
      - 4.1.1.1. Once all animals are in chute, make sure that entry door is clipped closed so that animals cannot open that door.
      - 4.1.1.2. Using extra white chute doors, begin splitting the animals into subgroups so that the animal or animals needed can be identified. Try to allow the animals to choose who to be split with, especially be

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- careful 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.
- 4.1.1.3. Once animals are divided into appropriate subgroups within the chute, proceed to 4.1.2. Transfer Box Method, if you are using transfer boxes or 4.1.3. Chute Squeeze Method, if you are using the chute squeeze mechanism.
- 4.1.1.4. 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.
- 4.1.1.4.1. When using nets for capture, be sure to place animals in half the pen rather than the whole pen before starting to use the net.
- 4.1.1.4.2. Place only 1 NHP in the net at a time.
- 4.1.1.4.3. Do not physically restrain animal by the tail.
- 4.1.1.4.4. Carry the nets out of the pen, do not let the NHP drag the ground.
- 4.1.1.5. 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. Refer to the aforementioned methods for net capture as well as 4.2 below.
- 4.1.2. Transfer Box Method (this should be done with a minimum of 1 person and a maximum of 3 people). NOTE: If the animal will also be chemically restrained, prior to this process at least one 4.3 standard cage should be located in the interior of the OAHA.
- 4.1.2.1. Place a transfer box in the first section of the chute system that opens (i.e. the side that is closest to the "exit" chute door).
- 4.1.2.2. Identify the NHP that is needed, and move this NHP into the transfer box by using the white chute doors.
- 4.1.2.3. Secure the doors of the transfer box, and remove the transfer box containing the NHP from the chute.

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4.1.2.4. If the animal needs to also be chemically restrained or the ID needs to be verified, place the transfer box containing the NHP at the door of the 4.3 standard cage and open both doors so the NHP can enter the cage.

4.1.2.5. Once the NHP is in the cage, use the squeeze-back in the cage to slowly bring the NHP to the front of the cage so that the animal can be identified and if needed, provided with an IM injection for chemical restraint.

4.1.2.5.1. After injection, release the squeeze-back to halfway.

4.1.2.5.2. Once sedated, the animal may be removed from the cage.

4.1.3. Chute Squeeze Method (this should be done with a minimum of 3 people and a maximum of 4). NOTE: This method should only be used for ID verification or for when chemical restraint is also necessary.

4.1.3.1. 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 is located.

4.1.3.2. 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 verify the ID. If chemical restraint is necessary, one of the two other people should provide an IM injection for chemical restraint after the ID is verified.

4.1.3.3. Once the animal is sedated, the NHP can be removed from the chute.

4.2. Net Capture and Restraint, this is the secondary method as an alternative to chute usage (this should be done with a minimum of 2 people and a maximum of 3 people). NOTE: Kevlar-lined leather catch gloves must be worn by any person that will be removing a NHP from the net.

4.2.1. Enter the OAHA, and secure one of the interior doors inside the OAHA so that only one interior door remains open.

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#### 4.2.2. Capture the NHP

4.2.2.1. Identify the NHP for capture.

4.2.2.2. It is best to capture the animal when it is moving. One catcher should be in each half of the OAHA.

4.2.2.3. The catcher on one half should encourage the animals in his/her half to move to the other half by moving towards the animals with the net. While the catcher in the other half stands by the open interior door to catch the monkeys as they move to his/her half.

4.2.2.4. The individual that is in the catching half should hold the net so that the net is pointing up and the base of the pole is pointing down. The catcher's hands should be positioned so that one hand is located near the base of the pole.

4.2.2.5. When ready, the catcher should approach the NHP in a forward motion maintaining the aforementioned grip on the net. The catcher should use a scooping motion when attempting to obtain the NHP.

4.2.2.6. It may be necessary to repeat this several times before securing the primate in the net.

4.2.2.7. Once the NHP is in the net and gently lowered to the ground, twist the pole so that the net becomes closed and move the primate to a secure area.

#### 4.2.3. Removal of the NHP from the net

4.2.3.1. If the NHP is greater than 5 kg, the animal must be chemically restrained before being removed from the net.

4.2.3.2. If the NHP is 5 kg or less, the animal does not require chemical restraint before being removed from the net, but the animal may still be chemically restrained in the net if desired.

4.2.3.2.1. While wearing Kevlar-lined leather catch gloves, the catcher should grasp the NHP by the hip area from the outside of the net.

4.2.3.2.2. Once NHP's hip has been secured through the outside of the net, untwist the net, being careful not to allow the animal to escape.

4.2.3.2.3. Using the free hand, reach into the net and secure the NHP's upper arm.

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4.2.3.2.4. Once one arm has been secure, release grasp from hip area and secure the second arm behind the primate's back while applying an appropriate amount of pressure to prevent the primate from becoming loose. NOTE: arms are considered secured when animal's elbows are pointing up and catcher has both upper arms in one hand while placing his/her index finger over the NHP's elbows.

4.2.3.2.5. Once arms are secured, the catcher should use their free hand to obtain the primate's tail. When tail is obtained, the catcher should place the tail between the index finger and thumb of the hand that is already securing the arms of the NHP.

4.2.4. An alternative to removing the NHP from the net, can be to place the net against the chute entrance or the transfer box entrance, and release the animal directly from the net to the chute or the transfer box without physically handling the animal. This may be done on any size NHP.

5. Procedure for capture and restraint of NHPs in indoor animal housing areas (IAHA).

5.1. Transfer Box Capture Method of a NHP in an IAHA (this should be done with a minimum of 1 person and a maximum of 2 people)

5.1.1. Identify the animal, verifying that the identification number on the chest or inner thigh matches the number found on the cage and/or provided documentation.

5.1.2. Upon successful identification of animal, if animal is socially housed, separate from cohorts using cage dividers.

5.1.3. Place the transfer box up to the cage door, and open the door of the transfer box first, and then open the cage door.

5.1.4. If the NHP enters the transfer box, close the door of the transfer box, and if possible, reward the animal with a food treat to reinforce the likelihood that when asked to enter the transfer box again this, NHP will do so (i.e. positive reinforcement training).

5.1.5. If the NHP refuses to enter the transfer box after approximately 1 minute, unlock squeeze-back latches.

5.1.6. Using the handles located on the left and right side of the cage, slowly pull squeeze-back forward. This movement should be done in a fluid but gentle manner.

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- 5.1.7. As soon as the NHP enters the transfer box, close the door of the transfer box, and if possible, reward the animal with a food treat to reinforce the likelihood that when asked to enter the transfer box again this, NHP will do so (i.e. combination of negative and positive reinforcement training).
- 5.1.8. Be sure to return the squeeze-back to its locked normal position.
- 5.1.9. If the animal is not returning to this cage, remove the ID from the cage so as to indicate that this cage is no longer occupied.

- 5.2. Manual Capture and Restraint Method of a NHP that is 5kg or less from an IAHA (this should be done with a minimum of 1 person and a maximum of 2 people). NOTE: Manual capture and restraint may require 2 trained employees, depending on the animal's size and/or purpose of the restraint.
  - 5.2.1. Identify the animal, verifying that the identification number on the chest or inner thigh matches the number found on the cage and/or provided documentation.
  - 5.2.2. Upon successful identification of animal, if animal is socially housed, separate from cohorts using cage dividers.
  - 5.2.3. Unlock squeeze-back latches. Then, using the handles located on the left and right side of the cage, slowly pull squeeze-back forward. This movement should be done in a fluid but gentle manner.
  - 5.2.4. Once the animal is in the desired position, lock squeeze-back latches. The animal's movement should be very limited in this position.
  - 5.2.5. Prior to opening the cage door, the catcher should put on appropriate Kevlar-lined leather catch gloves. Once gloves are on, the catcher can open the cage door.
  - 5.2.6. Once the door is open, the catcher should obtain the upper arm and/or leg of the NHP.
  - 5.2.7. Once the catcher has a secure grip on the NHP's upper arm and/or leg, the catcher or second person can then unlock the squeeze-back latches, releasing the squeeze-back.
  - 5.2.8. When squeeze-back is released, the catcher should obtain a secure grip on both upper arms prior to removing the NHP from the cage.
  - 5.2.9. After animal is removed from the cage, the catcher should restrain the animal facing away from the catcher.
  - 5.2.10. NOTE: any NHP over 5kg may not be manually captured and restrained using the above method.
- 5.3. Chemical Restraint Method of a NHP in an IAHA (this should be done with a minimum of 1 person and a maximum of 2 people).

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- 5.3.1. Identify the animal, verifying that the identification number on the chest or inner thigh matches the number found on the cage and/or provided documentation.
- 5.3.2. Upon successful identification of animal, if animal is socially housed, separate from cohorts using cage dividers.
- 5.3.3. Unlock squeeze-back latches. Then, using the handles located on the left and right side of the cage, slowly pull squeeze-back forward. This movement should be done in a fluid but gentle manner.
- 5.3.4. Once the animal is in the desired position, lock squeeze-back latches. The animal's movement should be very limited in this position.
- 5.3.5. Provide the animal with an IM injection for chemical restraint.
- 5.3.6. After injection, release the squeeze-back to halfway.
- 5.3.7. Once sedated, the animal may be removed from the cage.

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6.0 Documentation:

6.1 Veterinary Activity form (VAF) and/or Animal Observation and Treatment form (AOTF)

**REVISION HISTORY**

Version #	Date	Revisions
1.0	September 2015	New Standard Operating Procedure

*① Date correction H66 083115*

Memorandum to:



From: Institutional Animal Care and Use Committee

Subject: Semiannual Review of Animal Care and Use Program and Inspection of Facilities

Date: January 7, 2015

This represents the Semiannual Report of the Institutional Animal Care and Use Committee (IACUC) to the Institutional Official, as required by the PHS Policy on Humane Care and Use of Laboratory Animals, as a condition of this institution's Animal Welfare Assurance with the Office of Laboratory Animal Welfare (OLAW), and the Animal Welfare Act and Animal Welfare Regulations, as applicable.

#### **Review of Animal Care and Use Program**

The IACUC conducted its semiannual review of the institution's animal care and use program on December 8, 2014 using the *Guide for the Care and Use of Laboratory Animals (Guide)*, and, as applicable, 9 CFR Chapter I, 2.31. The animal care and use program adheres to the PHS Policy, the *Guide*, and applicable Animal Welfare Regulations.

The following deficiencies were found in the animal care and use program:

No deficiencies were found. All aspects of the program are consistent with the PHS Policy, the *Guide*, and applicable Animal Welfare Regulations.

#### **Inspection of Animal Facilities**

The IACUC inspected the animal facilities on October 2, 2014 at PTLC, IAF and at the PPIE Doral location., using the *Guide*, and, as applicable, 9 CFR Chapter I, 2.31.

The following deficiencies were found in the animal facilities:

No significant deficiencies were found.

A list of minor deficiencies naming the person responsible and a date for correction is attached below. If the item has been corrected a completion date is added.

All facilities are consistent with the PHS Policy, the *Guide*, and applicable Animal Welfare Regulations.

### **Departures from the Guide**

The following departures from the *Guide* have been reviewed and approved by the IACUC:

Primate Products, Inc. provides appropriate social housing for new arrivals, quarantined animals, which includes pair or social housing after each animal has been screened to assure compatible viral status and thus shown to not be a health threat to other animals within the colony.

### **Minority Views**

There were no minority views expressed.

### **Protocol Review**

Since the last letter to the IO a review of active and new protocols has been conducted.

- Housing and care of Indian Origin Maccaca Mulatta was resubmitted and approved on October 14, 2014. Change of Principal Investigator.
- Temperament Appropriate Enrichment Plan Approved on September 16, 2014.
- Behavioral Training Workshop with Rhesus and Cynomolgus Macaques was submitted and approved on November 7, 2014. Change of Principal Investigator.

### **Other items**

- The annual report to OLAW is before on January 31, 2015.
- The "Letter of Assurance" renewal submission is due before January 31, 2015.
- Stefanie Nelsen was invited and has accepted your invitation to join the committee on August 4, 2014
- At large Member "B" submitted a resignation letter dated October 3, 2014.
- At large member "C" has been invited and has accepted your invitation to join the committee on November 24, 2014. Member C was formerly our "at large" member for 6 years and participated in the semi-annual review meeting on December 8, 2015.

**IACUC Members Signatures:**

Name of Member*	Degree/ Credentials	Position Title	PHS Policy Membership Requirements **	<i>Signatures</i>
IACUC member		Director of Facilities and Planning	Chairman/ Non-scientist	IACUC member
IACUC member		Institutional Veterinarian	Scientist	
		At large	Non-scientist	
		Operations Manager	Scientist	
		Enrichment/ Behaviorist	Scientist	

Date: 10-1-14

Members in attendance:	Deficiency category	Location	Deficiency and plan for correction	Responsible party	Correction schedule	Date completed
	A=Acceptable M=Minor S=Significant	PPIE				
	M	Exam	Expired K2 EDTA tubes	NA	Corrected	
	M	Lab	Water stain on 1 <sup>st</sup> ceiling light	EM	10-24	
	M		Cords and other items dusty and piled up on floor next to countertop	NA	Corrected	
	M		Rusty fly swatter hanging on wall	NA	Corrected	
	M		Cracked and dusty container of Carboline and cracked and dusty container of Activated Carbon on floor under sink	NA	Corrected	
	M		Expired tube of dexamethasone Expired bottle of honey Expired tubes Expired 2 partial bottles of chlorhexidine Expired 1 bottle phosphate buffered saline Expired 3 wing infusion sets Expired 5ml syringes Expired 3 pairs of sensistouch surgical gloves	NA	Corrected	
	M		Under sink some chemicals missing exp/in use dates	NA	Corrected	

		Temps range to 78 degrees	EM	11-14-14	
M	Feed Storage				
M	Garage	Chemical Spray bottles need re-labeled	NA	Corrected	
M	Chemical storage	chemical barrel outside was not labeled with anything	NA	Corrected	
M		Chemical barrel needs re-labeled	NA	Corrected	
M	Room	Chain hanging from the ceiling not attached to anything.	EM	No danger to animals	
M		Dark stains on floor, and pooling of water in these areas.	KM	These stains are permanent, pooling can be corrected with a squeegee	
M		Ceiling vents dirty with chipped paint.	EM	11-21-14	
M		Missing grates over floor drain.	NA	Corrected	
M		Missing paint on walls.	EM	11-21-14	
M		No mirrors on any cages.	NA	Corrected	
M	Room	Rust on frame	EM	10-24-14	
M					
M	Room	Dark stains on floor, and pooling of water in these areas.	KM	These stains are permanent, pooling can be corrected with a squeegee	
M		Ceiling vents dirty with chipped paint.	EM	11-21-14	
M		Rust on pedestal fan.	EM	10-24-14	
M		Rust on piping around walls.	EM	11-21-14	
M		Missing paint on walls.	EM	11-21-14	

M		Missing grates over floor drain.	KM	11-21-14	
M		Several cages have jagged plastic screwed onto the sides of their cage	EM	12-31-14	
M	Room	Rust on pillar upon entering room.	EM	11-21-14	
M		Dark stains on floor, and pooling of water in these areas.	KM	These stains are permanent. pooling can be corrected with a squeegee	
M		Ceiling vents dirty with chipped paint.	EM	11-21-14	
M		A lot of rust throughout room (e.g. on cage stands, pipes etc.)	EM	11-21-14	
M		Missing paint on walls.	EM	11-21-14	
M		Missing grates over floor drain.	KM	11-21-14	
M		Rusty tool in room on cart.	NA	Corrected	
M		No mirrors on any cages.	NA	Corrected	
M	Room	Steady water leak from around the hose creating a pool of water in the front corner of the room.	KM	10-17-14	
M		Ceiling vent dirty and chipped paint.	EM	11-21-14	
		Dark stains on floor.	NA	These stains are permanent	
M		Missing grate over the floor drain.	KM	11-21-14	
M	Room	Rust on frame: floor grates missing; drain pan pulling from wall	KM/EM	12-31-14	
		<b>Non animal related</b>			
	Admin	Floors are dirty, and stained.	KM	Floors are clean but stained.	
		Ceiling light by printer is out.	NA	corrected	
		Missing paint and/or marks on most walls and doors.	EM	11-10-14	
		Dirty ceiling vents.	EM	10-17-14	
	Outside	Pile of wood and metal	EM	Gone	
		Garbage in general	KM	Picked up	

		Cigarette disposal is full of butts and water	KM	10-13-14	
	Laundry	Washer leaks; shelves need repaired	EM	11-24-14	
		1)			

Date: 10/2/14

Members in attendance:					
Deficiency category (S or M)	Location	Deficiency and plan for correction	Responsible party	Correction schedule	Date completed
M	Bldg laundry	Expired Chlorhexidine	NA	Corrected	N/A
M	Bldg laundry	General housekeeping needed	KM	10-24-14	
	Modular				
M	Modular-Food prep	General cleaning	NA	corrected	N/A
M		Miss labeled/un-labeled storage containers	NA	Corrected	N/A
M		Fridge temperature needs regulated/monitored	SN	12-1-14	
M		EE log book not up to date	NA	corrected	N/A
M	Modular-PPE Room	General cleaning	NA	Corrected	N/A

M	Modular-Prep Room	General cleaning	NA	Corrected	
M		Expired NaCl	NA	corrected	
M		Quat container with no dates/initials			
M		General cleaning	NA	corrected	
M	Bedding Storage	Open bag of bedding	NA	corrected	
M	New Crate Storage	Needs general housekeeping	NA	corrected	
M	HE	<ol style="list-style-type: none"> <li>1) Lock on main door broken-<b>CORRECTED</b></li> <li>2) Bee issue at main entrance door on inside of building-<b>CORRECTED</b></li> <li>3) Room 104 temp alarm broken- <b>10-31-14</b></li> <li>4) Standing water in corners of hallway- <b>corrected</b></li> <li>5) Half bag of monkey chow in hallway on top of biohazard container- <b>CORRECTED</b></li> <li>6) Live roaches sitting in top corners of ceiling- <b>10-17-14</b></li> <li>7) Insulation blowing out of vents into hallway and animal rooms- <b>corrected</b></li> </ol>	EM/KM		See notes under deficiency for dates.
M	HB	<ol style="list-style-type: none"> <li>1) Old broom outside of HB1- <b>corrected</b></li> <li>2) Bucket of metal feeders and kongs outside of HB1-<b>corrected</b></li> <li>3) Missing paint of walls- <b>11-14-14</b></li> <li>4) Dirty water bottles and used bite scrub brushes in sink in hallway- <b>corrected</b></li> <li>5) Clutter on carts in hallway- <b>10-24-14</b></li> </ol>	EM/KM		See notes under deficiency for dates
M	HB	Standing water in corners of room- empty room- <b>corrected</b>	NA		
M	HB	<ol style="list-style-type: none"> <li>1) Styrofoam cooler on biohazard trash can in room</li> <li>2) Tank of something sitting in water in corner of room</li> <li>3) 1 ceiling light out in room- <b>corrected</b></li> <li>4) Plastic on cages cracked- <b>12-31-14</b></li> <li>5) Missing paint on walls- <b>corrected</b></li> </ol>	KM/EM	10-17-14	See notes under deficiency for dates

M	HB		<ol style="list-style-type: none"> <li>1) Water leaking from hose for lixit attachment behind last 2 cages on the right side of the room</li> <li>2) Water leaking from hose for lixit attachment at the front on the right side of the room</li> <li>3) Standing water in the right front corner of room</li> </ol>	NA	corrected	NA
M	HE		Missing paint on walls	EM	11-14-14	
M	HE		<ol style="list-style-type: none"> <li>1) Water leaking from hoses for lixit attachments</li> <li>2) Standing water in room along walls and in corners</li> </ol>	EM/KM	corrected	
M	HE		<ol style="list-style-type: none"> <li>1) Missing paint on walls</li> <li>2) 1 ceiling light cover missing</li> <li>3) 1 ceiling light cover falling off</li> <li>4) Dirty ceiling</li> <li>5) Dirty vent</li> </ol>	NA	corrected	
M	HE		<ol style="list-style-type: none"> <li>1) Empty/unoccupied cages are dirty</li> <li>2) Ceiling has water droplets that are dripping</li> <li>3) 1 ceiling light is out in room</li> <li>4) Dirty transport box in room</li> <li>5) Standing water in corners of room</li> </ol>	NA	corrected	
M	HE		<ol style="list-style-type: none"> <li>1) Biohazard trashcan is outside of room without a bag in it- <b>corrected</b></li> <li>2) Missing paint on walls - <b>11-14-14</b></li> </ol>	KM/EM		See notes under deficiency for dates
M	HE		<ol style="list-style-type: none"> <li>1) Standing water on floors against walls- <b>corrected</b></li> <li>2) Plastic on cages cracked- <b>12-31-14</b></li> </ol>			
M	HE		<ol style="list-style-type: none"> <li>1) Biohazard trashcan is outside of room without a bag in it</li> <li>2) 2 monkeys without mirrors</li> <li>3) IDs of monkeys are on cages that those monkeys no longer occupy</li> </ol>	KM	10-13-14	
M	HE		<ol style="list-style-type: none"> <li>2) Moldy food in 2 cages' feeders without monkeys in the cages</li> <li>3) Standing water on left side of room by entrance -<b>corrected</b></li> <li>4) Plastic on cages cracked- <b>12-31-14</b></li> </ol>	KM	10-13-14	
M	HE		<ol style="list-style-type: none"> <li>1) Trash/junk covering drain trap</li> <li>2) Staining on floors against walls</li> <li>3) Monkey in cage 18 without ID on cage</li> <li>4) Dirty vent</li> <li>5) Missing paint on walls- <b>11-14-14</b></li> </ol>	KM	Removed trash 10-9-14	

S = significant deficiency. M = minor deficiency (a significant deficiency is or may be a threat to animal health or safety)




S = significant deficiency, M = minor deficiency (a significant deficiency is or may be a threat to animal health or safety)

Date: 10/2/14

Members in attendance:

CUC memb

Deficiency category (S or M)	Location	Deficiency and plan for correction	Responsible party	Correction schedule	Date completed
M	PTLC Quads	All clips need removed.	KM	12-31-14	
M		Rust on fencing and pipes (Q19, Q20, Q21, Q22, Q23, Q24 & Q25)	EM	10-31-14	
M		Chutes and or pen doors missing locks (Q17, Q19, Q20A, Q22)	KM	10-24-14	
M		Rusty locks (Q17, Q23, Q25, Q26)	KM	10-17-14	
M		Cracks in troughs/drains (Q17, Q19, Q20, Q21, Q23, Q25)- <b>Not animal related</b>	EM	12-31-14	
M		Sharp metal on feeders (Q19, Q22, Q23, Q24, Q25, Q26)	NA	corrected	
M		Standing water (Q20B, Q21A, B & D, Q23A)	NA	corrected	
M		Sharp metal on chain link (Q20D, Q23-entrance, Q24-entrance)	NA	corrected	

M		Loose trash		NA	corrected	
M		Used rodent traps/bait on ground between		NA	Corrected	N/A
M		Heavy dirt on fence		KM	10-24-14	
M		Loose perches (Q2&3)		NA	Corrected	N/A
M		No visual barriers aside from pen		SN	11-28-14	
M		Too few KONG		NA	corrected	N/A
M		Chain link on roof needs replaced		SN	11-28-14	

S = significant deficiency, M = minor deficiency (a significant deficiency is or may be a threat to animal health or safety)

Memorandum to: Thomas J. Rowell, IO

From: [REDACTED] IACUC Chairperson *HKS  
1 Sept 2015*

Subject: Semiannual Review of Animal Care and Use Program and Inspection of Facilities

Date: 1 September 2015

The discovery was made during the compilation of documents after the August 2015 OLAW and USDA joint inspection that there was no letter to the previous Institutional Official regarding the 14 April 2015 semi-annual facility inspection and 21 April 2015 semi-annual program review. As newly appointed Chair of the IACUC the following is being presented ex post facto.

This represents the Semiannual Report of the Institutional Animal Care and Use Committee (IACUC) to the Institutional Official, as required by the PHS Policy on Humane Care and Use of Laboratory Animals, as a condition of this institution's Animal Welfare Assurance with the Office of Laboratory Animal Welfare (OLAW), and the Animal Welfare Act and Animal Welfare Regulations, as applicable.

#### Review of Animal Care and Use Program

The IACUC conducted its semiannual review of the institution's animal care and use program on 21 April 2015 using the *Guide for the Care and Use of Laboratory Animals (Guide)*, and, as applicable, 9 CFR Chapter I, 2.31. The animal care and use program adheres to the PHS Policy, the *Guide*, and applicable Animal Welfare Regulations.

The following deficiencies were found in the animal care and use program:

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.
4. 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.

All items noted a minor deficiencies were addressed with the necessary members of Primate Products, Inc. staff and updated/corrected.

### **Inspection of Animal Facilities**

The IACUC inspected the animal facilities on 14 April 2015 at PTLC, using the *Guide*, and, as applicable, 9 CFR Chapter I, 2.31.

The following deficiencies were found in the animal facilities:

No significant deficiencies were found.

A list of minor deficiencies naming the person responsible and a date for correction is attached below. If the item has been corrected a completion date is added.

All facilities are consistent with the PHS Policy, the *Guide*, and applicable Animal Welfare Regulations.

### **Departures from the *Guide***

The following departures from the *Guide* have been reviewed and approved by the IACUC:

Primate Products, Inc. provides appropriate social housing for new arrivals, quarantined animals, which includes pair or social housing after each animal has been screened to assure compatible viral status and thus shown to not be a health threat to other animals within the colony.

### **Minority Views**

There were no minority views expressed.

### **Protocol Review**

Since the last letter to the IO a review of active and new protocols has been conducted: 2001-15 "Bio-products Tissue Collection in Animals being euthanized"- new IACUC submission form and updated protocol.

2002-15 "A Protocol for the collection of biological fluids and tissues from the Rhesus, Cynomolgus and African Green Monkey"- new IACUC submission form and updated protocol.

2001-15 Amendment I- change in Study Veterinarian

2002-15 Amendment II- change in Study Veterinarian, change in Principal Investigator, and addition of prescription of analgesics after CSF collection.

**Other items**

At large Member "D" accepted previous IO's invitation to join the Committee on 25 February 2015.

At large Member "D" submitted a resignation to the Committee 6 April 2015.

At large member "E" accepted previous IO's invitation to join the Committee on 13 April 2015. The new committee member toured the PTLC facility. The new member received and read the "Working with Nonhuman Primates" orientation.

 accepted previous IO's invitation to join the Committee on 25 April 2015.

Date: 4/14/15

Members in attendance:	Location	Deficiency and plan for correction	Responsible party	Correction schedule	Date completed
M	Bio-products/Vet Storage Container	Expired items- removed immediately	NA	NA	041415
M	[Redacted]	Pen [Redacted] - visual barriers clips need replaced 16 April 2015 Pen C - misters do not work 23 April 2015 Biohazard bag doesn't fit container properly 16 April 2015	EM/KM	01 May 2015	complete
M	[Redacted]	Pen [Redacted] - visual barrier clips need replaced 16 April 2015 Biohazard bag doesn't fit container properly 16 April 2015 Back door need 2 <sup>nd</sup> lock 23 April 2015	EM/KM	01 May 2015	complete
M	[Redacted]	Pen [Redacted] - visual barrier clips need replaced 16 April 2015 Biohazard bag doesn't fit container 16 April 2015 Back door needs 2 <sup>nd</sup> lock 23 April 2015	EM/KM	01 May 2015	complete
M	[Redacted]	Pen [Redacted] - need different hanging enrichment 5 May 2015 Pen [Redacted] - misters do not work 23 April 2015 Pens [Redacted] - need chute locks-16 April 2015	EM/KM/SN	01 May 2015	complete
M	[Redacted]	Pen [Redacted] - needs chute lock	KM	01 May	042815
M	[Redacted]	Pen [Redacted] - needs chute lock and visual barrier clips need replaced	KM/EM	01 May	042815
M	[Redacted]	Pen [Redacted] - misters do not work 23 April 2015 Floor between pens A&B is missing chunk of cement; water pooling on floor (01/June) 20 May 2015	EM	01 May/ 01 June	complete
M	[Redacted]	Pens [Redacted] - need chute locks 28 April 2015 Pen [Redacted] barrel in back needs repaired at attachment 23 April 2015	EM/KM	01 May 2015	complete

M			Pen C- Prima-hedron needs fixed and re-hung 28 April 2015 Pen D- need chute locks; misters do not work 23 April 2015	EM/KM	01 May 2015	complete
M			Zip tie on chute door Bug light unplugged	KM	01 May 2015	042115
M			Bug light unplugged 21 April 2015 PVC pipe covered in algae 16 April 2015	KM	01 May 2015	complete
M			Pen B- area of floor has peeled off	EM	Sept 2015	043015
M			Pen A- need chute locks 18 April 2015 KMM Pen B- misters do not work 23 April 2015 Pen C&D- barrel hanging cables need repaired/replaced 23 April 2015	EM/KM	01 May 2015	complete
M			Rodent droppings 16 April 2015 KMM Clips need replaced on split gate and swings 16 April 2015 KMM Peeling paint on pipes (June 2015) 20 May 2015	EM/KM	01 May 2015 01 June 2015	complete
M			Rodent droppings 16 April 2015 KMM Clips need replaced on split gate and swings 23 April 2015 Peeling paint on pipes (June 2015) 20 May 2015	EM/KM	01 May 2015 01 June 2015	complete
M			Rodent droppings 16 April 2015 Clips need replaced on split gate and swings 23 April 2015 Peeling paint on pipes (June 2015) 20 May 2015	EM/KM	01 May 2015 01 June 2015	Complete
M			Rodent droppings 16 April 2015 Clips need replaced on split gate and swings 23 April 2015 Peeling paint on pipes (June 2015) 20 May 2015	EM/KM	01 May 2015 01 June 2015	complete
M			Clips need replaced on split gate and swings 28 April 2015 Peeling paint on pipes 29 April 2015 Floors need repaired (Sept 2015) 10 June 2015	EM/KM	01 May 2015 01 June 2015 01 May 2015/ Sept 2015	complete

M		Rodent droppings	EM/KM	01 May 2015	042615
M		Clips need replaced on split gate and swings	EM/KM	01 May 2015	041615
M		Clips need replaced on split gate and swings	EM/KM	01 May 2015	complete
M	HE	Water supply gate valve covered in algae 16 April 2015 Clips need replaced on split gate and swings 23 April 2015 Acrylic shuttle doors on cages have sharp broken edges- need removed 103- 21 April 2015 106- 20 April 2015 107- 20 April 2015 104 - 28 April 2015 105- 1 May 2015	KM	01 May 2015	complete
Date: 4/14/15					
Members in attendance:					
IAF					
Deficiency category (S or M)	Location	Deficiency and plan for correction	Responsible party	Correction schedule	Date completed
M	Bldg A	Recovery stackable holding units need solid divider between top and bottom unit and bottom unit and floor "Stay Behind Line" - paint peeled; needs repainted	MB	Sept 2015	5-4-15
M	Bldg B	Rusted wire on chute; needs to be replaced	MB	Sept 2015	4-15-15
M	Bldg C	Bio-hazard trashcan needs a lid Metamucil containers need opened on date and initials Yellow forage mix storage box - rust on hinges	MB	May 1 2015	4-15-15
M	Walk-in Refrigerator Container	Peanut butter and other opened food items need opened on date and initials	MB	May 1 2015	4-15-15

M	Dry Food Container	Open feed bags not in covered barrel- taken care at time of inspection	NA	NA	041415
	GENERAL	Animal housing not equipped with feeders as per <i>the Guide</i>	MB	Sept 2015	Guide was double checked and feeders are satisfactory
		Bait Stations- no in use dates; vermin control monitored on a tablet- is in use date needed on actual bait station? Not in the SOP 502 regarding pest control	MB	May 1 2015	
		Many Bio-hazard barrels missing biohazard symbol	MB	May 1 2015	4-15-15
		Some fire extinguishers missing inspection tags 1 Tag missing replaced by ABD fire equipment	MB	May 29 2015	4-15-15
		Inspection tags are made of paper and were soggy. Should not be in the quarantine area.	MB	May 29 2015	4-15-15
		Make sure all entryways into individual animal areas are painted yellow so people don't trip.	MB	May 29 2015	4-15-15
		Not following PPI SOP's	MB	May 29 2015	

**Wolff, Axel (NIH/OD) [E]**

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**From:** Morse, Brent (NIH/OD) [E]  
**Sent:** Tuesday, August 25, 2015 8:36 AM  
**To:** [REDACTED]  
**Cc:** Wolff, Axel (NIH/OD) [E]; Paul Houghton [REDACTED] Thomas Rowell  
**Subject:** RE: Amended Animal Welfare Assurance #A4102-01

Thank you for this information [REDACTED]. Your Assurance file with OLAW will be updated to reflect the recent changes and additions.

Sincerely, Brent Morse

Brent C. Morse, DVM, DACLAM  
Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

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**From:** [REDACTED] [mailto:\[REDACTED\]@primateproducts.com](mailto:[REDACTED]@primateproducts.com)  
**Sent:** Thursday, August 20, 2015 12:43 PM  
**To:** Morse, Brent (NIH/OD) [E]  
**Cc:** Wolff, Axel (NIH/OD) [E]; Paul Houghton [REDACTED] Thomas Rowell  
**Subject:** Amended Animal Welfare Assurance #A4102-01

Dr. Morse,

Please find attached letter of explanation from Institutional Official and amendments to Primate Products, Inc. Animal Welfare Assurance #A4102-01.

Please advise as to if anything further is needed in regards to our Assurance at this time.

Thank you for your assistance during this process.

Regards,

[REDACTED]  
Primate Products, Inc.  
Ph: [REDACTED]  
Fax: [REDACTED] telephone # [REDACTED]

[REDACTED] NIH/OD) [E]

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**From:** [REDACTED] (NIH/OD) [E]  
**Sent:** Wednesday, September 02, 2015 10:44 AM  
**To:** [REDACTED]  
**Subject:** RE: OLAW response for OLAW case A4102-F

Good morning [REDACTED] and Thank you. Dr. Wolff will respond soon.

Regards,  
Joan

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**From:** [REDACTED] [mailto:[REDACTED]@primateproducts.com]  
**Sent:** Wednesday, September 02, 2015 10:32 AM  
**To:** [REDACTED] NIH/OD) [E]  
**Cc:** Thomas Rowell; Paul Houghton; Wolff, Axel (NIH/OD) [E]  
**Subject:** FW: OLAW response for OLAW case A4102-F

Good Morning [REDACTED]

Attached is Mr. Houghton's response with attachments.

Please distribute as needed.

Thank you,

**From:** "Ward, Joan (NIH/OD) [C]" <wardjoa@od.nih.gov>  
**To:** [REDACTED]@primateproduct.com"; [REDACTED]@primateproduct.com>, "Thomas Rowell"  
[REDACTED]@primateproducts.com>  
**Cc:** [REDACTED]@primateproducts.com> [REDACTED] (NIH/OD) [E]" <[REDACTED]@OD.NIH.GOV>,  
[REDACTED] NIH/OD/ORS) [E]" [REDACTED]@mail.nih.gov>, [REDACTED] NIH/NIAID) [E]" [REDACTED]@niaid.nih.gov>,  
[REDACTED] (NIH/OD/ORS) [E]" [REDACTED]@ors.od.nih.gov>, "Betty.J.Goldentyer@aphis.usda.gov"  
<Betty.J.Goldentyer@aphis.usda.gov>  
**Subject:** OLAW response for OLAW case A4102-F

Good morning Mr. Houghton,

Attached please find Dr. Axel Wolff's response and the Semiannual report of the Program Review and Facility Inspection for OLAW case A4102-F

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

Thank you,

[REDACTED]  
*Program Specialist  
Office of Laboratory Animal Welfare  
National Institutes of Health*