

**DEPARTMENT OF HEALTH & HUMAN SERVICES****PUBLIC HEALTH SERVICE****NATIONAL INSTITUTES OF HEALTH  
NATIONAL CANCER INSTITUTE**

Redacted by  
agreement.  
Frederick, Maryland 21702-1201  
National Cancer Institute at Frederick

June 20, 2019

**TO:**

Redacted by agreement.  
Redacted by agreement. National Cancer Institute at Frederick

**FROM:**

Melinda G. Hollingshead, D.V.M., Ph.D.  
Chair, NCI at Frederick Animal Care and Use Committee

**SUBJECT:**

2019 Report of the Semiannual Facility Inspections [*Inspections took place between April 15 and May 10*]

As part of the Office of Laboratory Animal Welfare animal assurance requirements, the NCI at Frederick Animal Care and Use Committee [ACUC] conducted one of the semiannual evaluations of its animal care and use program on June 20, 2019 and inspected the animal facilities between April 15 and May 10. The Environment, Health, and Safety [EHS] program conducted inspections [in conjunction with ACUC members and/or as a separate inspection]. This is the complete and final inspection report. No ACUC minority opinions were filed during this reporting period.

Redacted by agreement.

**Inspectors:**

Redacted by agreement.

**Date of Inspection:** May 7, 2019**Date of Correction:** May 14, 2019**ACUC Comments:**

The facility was organized. There were no major deficiencies noted.

Room	Deficiencies Noted	Facility Response
	Automatic watering was checked on the room logs. It is suggested to retrain care staff to document best applicable entries on the animal room husbandry log (ex. Automatic watering vs. water check).	Caretakers currently record automatic watering as a check, since this means they are actually checking water bags, the same as if they were checking water bottles.
Redacted by agreement.	Unlabeled euthanized neonates were found in a refrigerator.	Animal care staff and technical staff have been reminded to label all bags.
	Repeat: observed personnel improperly working in change stations with the sashes up. The fans were on but per the manufacturer, this practice does not optimize air circulation	Caretakers have been instructed to keep sashes down.
	Door with a blacked-out window that appeared to be blocked. If this door is unused, a sign labeled "No Exit" or "Notice-Door Blocked" needs to be affixed to the door and the doorknob removed.	This door is closed because it leads into the Hydropak Room. A sign has been attached. The window is blackened as to not allow light to enter the animal room side during the night time hours.

Room	Deficiencies Noted	Facility Response
Redacted by agreement	A dry ice container was found with the lid ajar and without labeling	Labels will be made.

Redacted by agreement

#### Small Animal Imaging Facility

Inspectors:

Redacted by agreement

Date of Inspection: April 30, 2019

Date of Correction: May 17, 2019

#### ACUC Comments:

Overall, facilities were extremely well kept, staff were knowledgeable about animal studies and equipment safety. Only minor deficiencies were found.

Room	Deficiencies Noted	Facility Response
PET	Euthanasia Guidelines missing from CO <sub>2</sub> chamber area. Recommendation: Replace missing guidelines.	Missing guidelines were replaced.
Receiving/Storage area	The mini-refrigerator used to store wet feed is not monitored for temperature. Recommendation: either place refrigerator on alarm/monitoring or keep a daily log of refrigerator temperature.	A temperature gauge has been purchased. Daily monitoring and logging temperature will be performed.

Redacted by agreement

Inspectors:

Redacted by agreement

Date of Inspection: May 7, 2019

Date of Correction: May 14, 2019

#### ACUC Comments:

Overall, the inspection team found the facility to be well organized. No major deficiencies were noted.

Room	Deficiencies Noted	Facility Response
	The investigator name was not recorded on sentinel cage cards/cage card lacking. The identification on cage was only the vendor shipment label.	This is due to recent changes in the R&Q processes we are working on determining the best practices for this facility.
	All R&Q ASPs should be listed in paper form in the office so they are accessible.	R&Q is in transition and the new PI & ASP are being determined.
	Personnel should keep a current recording of water pH dispensed by the machine /Clean side cagewash; the acidified water bottle dispenser pH level hasn't been documented as monitored since 2018.	The new caretaker will be instructed and trained on how to record this information.

Room	Deficiencies Noted	Facility Response
Cryo lab	Insufficient storage and manpower; dirty cages were observed being stored bagged on the floor in rooms.	A full-time person has recently been hired to replace deployed personnel. Additionally, due to the various health status in the different rooms have to be autoclaved individually from other rooms. Cages are autoclaved as load cycles are available due to clean/dirty traffic flow.
Cryo lab	Expired media was found in the refrigerator. The freezer also has excess ice, which inhibits closing the door. Additionally, there were stains on the counter, a jar with no label but white dried substance inside, a CO <sub>2</sub> hose on ground, and bedding & green liquid on ground.	These items will be discussed with Cryo staff.
Cryo lab	Long pipettes were sticking out of the Sharps container.	These items will be discussed with Cryo staff.
Redacted by agreement.	Clidox-S was stored on the same tray as Cidox-Activator. These should be placed on separate spill trays to avoid inadvertent mixing of incompatibles.	More containers will be purchased to keep separated.
Hallway	The fire extinguisher appeared to be last checked on 12/8/18, as indicated on the tag.	The new caretaker will be instructed and trained on how to record this information.
Redacted by agreement.	Sprayer had no label and contained unknown liquid.	Sprayer has been removed.
	The feed bin was labeled with expired dates.	The feed bin has been removed.
	Mice were observed with surgical staples from April & March. Per SOP 5.031F Embryo Transfer, staples are to be removed within 7-10 days unless exemption by ACUC.	This will be discussed with the Cryo staff.
	Mouse with treatment card to check both eyes - Treatment started on 4/8/19 and no other treatments were documented on the cage card or treatment care. The animal's left eye was resorbed/lost.	This will be discussed with Cryo staff.

Redacted by agreement.

### LASP VANS

Inspectors:

Redacted by agreement.

Date of Inspection: May 3, 2019

Date of Correction: May 20, 2019

### ACUC Comments:

Overall the building was very clean, and mice appeared very well cared for. No major deficiencies were noted.

Room	Deficiencies Noted	Facility Response
Cagewash	Suggest placement of a safety decal for the tunnel washer emergency stop.	Decal provided by EHS has been placed.
	Staff requested a separate dilution book for controlled substances.	A separate dilution book was acquired from EHS and is now in use.
Chem/car lab	Expired formalin was found, though date of expiry was recent (4/27/2019).	Expired formal has been discarded.

Room	Deficiencies Noted	Facility Response
Redacted by agreement.	Hoods were stored in large cardboard boxes in a holding room with animals. According to management this is a temporary arrangement but is not ideal.	Alternative storage space has been arranged. Work order #632133 has been placed for a request of labor crew. The stored hoods were removed on 5/24/19.
Redacted by agreement. Van	Redacted by agreement. Very clean	N/A
Redacted by agreement. Van	Redacted by agreement. Cargo Van Needs cleaning/sanitizing. Documentation appeared incomplete for the previous week.	Drivers have been reminded to please post all documentation including the sanitizing documentation. Sanitizing task in general has been reviewed and these procedures would also apply to all vans that are used for transporting animals.
Redacted by agreement. Van	Redacted by agreement. Very clean	N/A
Redacted by agreement. Van	Redacted by agreement. Needs cleaning/sanitizing	The van has been cleaned and sanitized and documented in the logbook.
Redacted by agreement. Van	Redacted by agreement. Cargo Van Very clean. Battery needs to be changed in the temperature sensor.	The battery has been replaced.

Redacted by agreement.

Inspectors:

Redacted by agreement.

Date of Inspection: April 17, 2019

Date of Correction: May 3, 2019

#### ACUC Comments:

The facility was very clean, well-organized and well run. No major deficiencies were noted.

Room	Deficiencies Noted	Facility Response
Redacted by agreement.	It is suggested to add a Support Area Log per SOP 3.01F to document sanitation. This was noted during the last semiannual inspection as well.	A support area log will be added.
Redacted by agreement.	Instances of irregular temperature and humidity were noted.	This had been called into FME; however, they did not have access to the trend reports at the time. They have since been attached to the room logs, and facility staff has notified the manager of these irregular temps and humidity's.
Dirty side, cagewash	Corrosive acid carboy (acid powder) should be placed in a solid secondary container.	Secondary containment has been ordered.



Redacted by agreement.

Inspectors:

Redacted by agreement.

Date of Inspection: April 17, 2019

Date of Correction: May 3, 2019

**ACUC Comments:**

The facility was very clean, well-organized and well run. No major deficiencies were noted.

Room	Deficiencies Noted	Facility Response
Facility entrance	Recommend updating the old LASP phone listing.	Updated.
Corridor	Recommend updating the animal welfare reporting posting.	The updated sheet is on the office door.
Redacted by agreement.	EHS ABSL2 door sign posting is lacking.	EHS door sign is on the room door and might have been behind one of the papers. Redacted by agreement is ABSL2 at all times so personnel should always have secondary PPE when they enter that room by default. Cage cards are labeled with viral injection and date, and CAPR has the study set-up sheets. The virus and what was injected is stated on the door. Currently an old employee is listed on the sheet and that will be changed this week.
Procedure room	The room doesn't appear to have been documented as sanitized since January on the Support Area Log.	CAPR staff will address.
Procedure room	Suggest updating the front of the controlled substance log book to accurately list current accessible users.	CAPR staff is working on this with EHS.
Procedure room	Weekly eyewash checks appear incomplete for April.	This has been updated.
Procedure room	Several expired items have been found in the fridge.	This was a reagent not used for injection in mice. A label has been added to indicate that it should not be used for in vivo purposes.

Redacted by agreement.

Inspectors:

Redacted by agreement.

Redacted by agreement.

Date of Inspection: April 30, 2019

Date of Correction: N/A

**ACUC Comments:**

Overall the facility was very well kept and animals were well cared for.

No deficiencies were observed; however, it was noted by all persons on the inspection team that it would be helpful to have signs indicating required PPE and entry procedures for each animal room posted on the door of the room.

Room	Deficiencies Noted	Facility Response
	No findings	N/A

Redacted by agreement

Inspectors: Jatinder Gulani (ACUC/Veterinary Staff),  
 Date of Inspection: May 1, 2019  
 Date of Correction: May 23, 2019

Redacted by agreement

Room	Deficiencies Noted	Facility Response
Redacted by agreement	No findings	N/A
	No findings	N/A
	No findings	N/A
	<p>Xenopus laevis SOP in the protocol book is not consistent with the current husbandry practice. It is recommended to keep an updated SOP that matches with the current husbandry practices.</p> <ul style="list-style-type: none"> <li>Recorded conductivity and pH readings were out of range per the SOP present in the room; however, the readings were still within the recommended range for X. laevis.</li> <li>The SOP did not include the housing density information for 40 liter tanks. It does include housing density for the 16L tanks. Recommend to add housing density for the 40L tanks to the SOP.</li> </ul>	<p>-The "Xenbase" formatted SOP found in the Redacted by agreement binder is being replaced with a 560/22-69-specific SOP using SOP 3.016F (571) as the template.</p> <p>-This SOP will reflect the water quality parameters specific to the Pentair apparatus (XR3 and -4) as established by the manufacturer/installer.</p> <p>-Housing density information is contained in Redacted by agreement and will explicitly be listed in 560/22-69-specific SOP as shown below:</p> <p style="text-align: center;">"Housing Densities:          40 L tanks (XR4 rack): 15 adult frogs          16 L tanks (XR3 rack): 5 adult frogs"</p>
	Recommend to use a more elaborate room log, which was in the folder and was in use until 2017. This log had information like feeding schedule, health checks, room and tank cleaning schedule. The current log lacks this information.	<p>The 2017 log format will now be used with the headers shown below:</p> <ul style="list-style-type: none"> <li>Year, month, date, water temp, water conductivity, water pH, feeding, tank sanitization, room sanitization, health checks, checked by</li> </ul>
	Recommend scrubbing the tanks regularly to prevent the algae build up. Algae is not considered harmful to the frogs; however, it could potentially cause issue with the water filtration system.	Algae will be regularly removed from the front and side panes of the tanks to allow better visual inspection of animals.

Room	Deficiencies Noted	Facility Response
Redacted by agreement.	If it is helpful, the LASP Xenopus husbandry SOP 3016F could be used as a template to create one specifically for the satellite facility.	A modified version (water chemistry parameters, feeding, housing densities) of SOP 3.016F will be included in the binder for reference as mentioned above.
	Noted the use of pharmacy grade MS222. Recommend discarding the non-pharmaceutical grade MS222 from the laboratory so that someone does not use it inadvertently	The non-pharmaceutical grade MS222 has been discarded.
	No findings	N/A
	CO <sub>2</sub> does not have a lockbox in install Redacted by This will need to be	FME will be contacted to put a lockbox on the CO <sub>2</sub> regulator.
	No findings	N/A
	No findings	N/A
	No findings	N/A
	No findings	N/A
	No findings	N/A

Redacted by agreement.

Inspectors:

Redacted by agreement.

Date of Inspection: April 23, 2019

Date of Correction: May 10, 2019

#### ACUC Comments:

Overall we found the animal facility to be in excellent condition with no major deficiencies. We found no issues with the mouse in the facility. However, there are several safety issues that require resolution and/or clarification of the applicable policies.

Room	Deficiencies Noted	Facility Response
	Electrical panel EP1 does not have an arc flash assessment. This issue was reported last year and the deficiency closed but the panel is still not labelled.	EHS will resolve this.
	Drums of corrosive cage wash fluids are not placed on spill pallets or other containment devices, but the requirement for these is not clear. This was cited as a deficiency last year and closed, and the year before that and closed.	The facility is looking into the possibility of covering the floor drain in the area when it is not needed so an accidental spill would be prevented from entering the drain system.
	The airflow in multiple A2 BSCs is obstructed by rat cages of materials. This has been discussed with the Biosafety Officer and it is in fact a deficiency as it could lead to exposure to hazards in the future.	Staff has been reminded and retrained. Supervisors will monitor work stations and help employees better organize their supplies so air flow in the hoods is not impeded.

Room	Deficiencies Noted	Facility Response
	Dosimetry has not been performed in the cage dumping area since the new disposal system was installed.	EHS will schedule dosimetry readings.
Redacted by agreement.	The BSC that was turned off does not need to be running continuously. Non-exhausted cabinets are not required to run continuously. It was at one time a best practice, but now that energy conservation is more popular it is not required.	No action needed.

Redacted by agreement.

Inspectors:

Redacted by agreement.

Date of Inspection: April 16, 2019

Date of Correction: May 8, 2019

**ACUC Comments:**

The facility was very well kept and organized. No major deficiencies were noted.

Room	Deficiencies Noted	Facility Response
Redacted by agreement.	A Sharps container was overfilled with large pipettes; recommend using the large Sharps boxes.	The container was disposed of and staff was reminded to not overfill
	Controlled drugs: Recommend providing a current list of persons with access to the controlled drugs.	The book was updated, and a list sent to EHS.
	Amoxicillin in the refrigerator will soon be outdated.	The amoxicillin was discarded.
	Lab Diet in microisolator: The date opened was not present and the lid was not on securely. Additionally, part of the bag was hanging out of the microisolator and it was unsure if it was being kept at the proper temperature as the storage of natural ingredient diets is less than 70°F and the average room temperature per the log was 71-82°F	Staff was reminded to keep the diet in the container with the lid secure.
	Autoclave feed bag inside the feed bin doesn't appear to be labeled with the mill date.	The storage was labeled.
	Media in the refrigerator was expired.	Media was disposed.
	Personnel observed did not have eye protection.	This person was a post-doc, who immediately placed safety eye wear on. A reminder was sent to the lab manager, who then sent an email reminder to her lab.
	ABSL2 signs were not consistent and ASP/IBC info was not up to date.	ABSL2 was updated with ASP and IBC information through EHS.
	Safetygram in the hallway was outdated.	Safetygram was removed.
	Cage cards need to be updated to identify singly housed animals.	Staff were reminded about the singly housed animal policy and cage card was updated.
	Rack was not plugged in.	This was corrected immediately. Additionally, staff were spoken to and all staff were reminded about this at the Animal Care meeting.
	Please clarify if the racks are certified.	Racks have not been certified in since they arrived. Redacted by agreement.
	Xenopus cage cards were lacking the DOB.	Cards were updated.
	The dump station sign was faded and hard to read.	A new, readable sign has been made.

Room	Deficiencies Noted	Facility Response
Cagewash, clean side	Suggest labeling the emergency stop button on the tunnel washer with Safety Decal.	Machine has been labeled with a new sticker.

Redacted by agreement.

Inspectors:

Redacted by agreement.

Date of Inspection: May 10, 2019

Date of Correction: May 31, 2019

**ACUC Comments:**

The facilities were clean and well maintained. There were no major deficiencies.

Bldg.	Deficiencies Noted	Facility Response
Redacted by agreement.	Recommend moving the CO <sub>2</sub> /euthanasia station to the lab instead of on the freezer in the outer room.	It is not possible to move the euthanasia station in the laboratory area since microinjection, surgery, and other sensitive work is being performed in this room, therefore, traffic to this area should be limited to laboratory staff. Masks and other PPE are now placed in the changing room and will be put on prior to walking into the outer room.
Redacted by agreement.	ABSL1 signs need to be replaced on the laboratory doors.	Signs have been replaced.

Redacted by agreement.

Inspectors:

Redacted by agreement.

Date of Inspection: April 22, 2019

Date of Correction: N/A

**ACUC Comments:**

Overall, the facilities were found to be well organized. Staff are to be commended for maintaining clean and orderly facilities. No major or minor deficiencies were noted.

Room	Deficiencies Noted	Facility Response
	No findings	N/A

Redacted by agreement.

Inspectors:

Jatinder Gulani (ACUC/Veterinary Staff).

Redacted by agreement.

Redacted by agreement.

Date of Inspection: April 15, 2019

Date of Correction: April 24, 2019

**ACUC Comments:**

Overall, the facilities were found to be well organized. No major deficiencies were noted.



Bldg./Room	Deficiencies Noted	Facility Response
Redacted by agreement.	Expired vial of bupivacaine was present in the controlled substance drawer. As per the staff, it was not in use. The staff was asked to write "expired" with a marker on the vial so that no one uses it by mistake. It was also recommended that staff arrange the proper disposal of the expired agent.	Proper disposal was arranged and the staff was asked to write "expired" on the vial.
	There were two conductivity standard bottles with expired dates.	EHS picked up the bottles.
	Three bagged carcasses did not appear to be labeled in the dead animal fridge.	Staff was reminded to label bagged carcasses.
	Can it be clarified how often the water filter log needs to be completed? It appears to be last documented on 10/14/18.	The water filter log was for the ice machine. FME now changes the machine filter. Redacted by Edstrom changes those filters.
	There was an open autoclaved feed bag on top of a rack of cages.	The feed had just been autoclaved in. The feed does better when autoclaved in at a higher elevation. The bag split during autoclaving, which normally doesn't happen, but the staff was waiting for feed to cool before transferring to a feed container.
	There was a diluted vial of Buprenorphine HCl with an expiration date of 9/2020. Typically, the recommendation is that the diluted buprenorphine is only good for a month.	A technician will check with the PI.
	It is recommended to add tint to the window shared between the animal holding room and autoclave room to prevent effects of light exposure on the colony.	A work order (#630000) has been submitted.
	There were a few vials of Matrigel in the procedure room freezer. Some have dates on the them and some did not. The significance of the date was not clear.	The dates on the Matrigel were received dates.

Redacted by agreement.

Inspectors:

Redacted by agreement.

(Facility)

Date of Inspection: April 29, 2019

Date of Correction: May 8, 2019

### ACUC Comments:

Overall, facilities were nicely kept, staff were well aware of their responsibilities and cared for animals on their studies. Only minor deficiencies were found.

Additionally, within the lab area of building Redacted by agreement yellow tape is being used to seal an exterior door, that is currently labeled as an emergency exit. Upon discussion with the investigator responsible for the animals in the facility, the door was installed for moving equipment into the facility and should not be labeled as an emergency exit. Furthermore, the tape was installed as a temporary measure, in place a better seal, to prevent air and dust from entering the facility.

Bldg.	Deficiencies Noted	Facility Response
Redacted by agreement.	Mice within the isolator were lacking protocol number, PI, and ASP expiration date. Recommendation: add information to card on or in the isolator, or if all animal within the facility are on the same protocol, put card/sign on door indicating protocol information.	The information is posted on each isolator.
	Used tips and tubes were found in emptied distilled water bottles, without indication of contents. Recommendation: cross out distilled water and indicate these are being used as containers for non-hazardous solid waste.	"Distilled water" was crossed out and "waste" was written on the label.
	Used serological pipettes were being placed in biomedical waste bags directly. Recommendation: after bagging the used pipettes within the BSC, place bagged pipettes in a cardboard box to prevent them from piercing the bag.	The used pipettes were bagged and placed in a 5G Sharps container.
	Mini-fridge used for dead animal waste was placed directly on floor. Recommendation: raise off floor to allow for proper sanitization of floor and prevent objects from becoming trapped under equipment.	A shelf or cart will be located or purchased to hold the mini-fridge.
	"Leftover Drugs" in refrigerator without date. Recommendation: label vials with date of use and expiration date; if no longer in use dispose of drugs.	Technicians have been reminded to please date all drugs when put into use and ensure the expiration date is on the vial as well.
	For the month of April, multiple autoclave test strips were found to have failed however the log indicated autoclave strips as "pass." Recommendation: Retrain responsible personnel for reading test strips and service autoclave to ensure proper sterilization.	There was an open work order on the autoclave (#627389). This autoclave has also been monitored with spore strips, which have come back negative. Staff was reminded to rerun if the integrators do not pass.
	Racks against wall were not a regular schedule of turning to provide light to animals facing wall. Recommendation: Rotate racks daily.	The staff had signed off on the racks being rotated M-F and were not rotating the racks on the weekend. They have been reminded to rotate on the weekend as well.
	A container of Nutra-gel was found opened without the "opened" date. Recommendation: Remind staff to label containers when open	Staff has been reminded to relabel once opened.
	"Leftover Drugs" in refrigerator without date. Recommendation: label vials with date of use and expiration date; if no longer in use dispose of drugs.	Technicians have been reminded to date drugs and use expiration dates.
	Clean Cages were stored next to dirty cages without coverage. Recommendation: This was likely temporary due to cage changes being performed at the time of inspection, but if dirty and clean cages are to remain in the same space for an extended amount of time, it is recommended to cover the clean cages.	Staff has been reminded to cover the clean cages when they are in the same space as the dirty cages. They have also been asked to label both clean and dirty.
	Animal with ulcerated tumor found. Recommendation: The technician responsible for the animal was notified and they agreed that the tumor was beginning to ulcerate and that the animal would be watched and dealt with accordingly.	The technician has addressed the tumor.

Attachments: Attachment A - Semiannual Program Review Checklist  
Attachment B - EHS Inspection Reports

Distribution:  
ACUC Members Facility Managers

**NCI AT FREDERICK SEMI-ANNUAL PROGRAM REVIEW**  
**June 20, 2019**

**INSTITUTIONAL POLICIES AND RESPONSIBILITIES**

<b>1. Animal Care and Use Program</b>		<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
• Responsibility for animal well-being is assumed by all members of the program		X				
• IO has authority to allocate needed resources		X				
• Resources necessary to manage program of veterinary care are provided		X				
• Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the <i>Guide</i>		X				
• Program needs are regularly communicated to IO by AV and/or IACUC		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		X				
• Inter-institutional collaborations are described in formal written agreements		X				
• Written agreements address responsibilities, animal ownership, and IACUC oversight		X				
<b>2. Disaster Planning and Emergency Preparedness</b>		<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
• Disaster plans for each facility to include satellite locations are in place		X				
• Plans include provisions for euthanasia		X				
• Plans include triage plans to meet institutional and investigators' needs		X				
• Plans define actions to prevent animal injury or death due to HVAC or other failures		X				
• Plans describe preservation of critical or irreplaceable animals		X				
• Plans include essential personnel and their training		X				
• Animal facility plans are approved by the institution and incorporated into overall response plan		X				
• Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place		X				
<b>3. IACUC</b>		<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
• Meets as necessary to fulfill responsibilities		X				
• IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions		X				
• Continuing IACUC oversight after initial protocol approval is in place		X				
• IACUC evaluates the effectiveness of training programs		X				
<b>4. IACUC Protocol Review - Special Considerations</b>		<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
• 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		X				
• For pilot studies, a system to communicate with the IACUC is in place		X				
• For genetically modified animals, enhanced monitoring and reporting is in place		X				
• Restraint devices are justified in the animal use protocols		X				
• Alternatives to physical restraint are considered		X				
• Period of restraint is the minimum to meet scientific objectives		X				
• Training of animals to adapt to restraint is provided		X				
• Animals that fail to adapt are removed from study		X				
• Appropriate observation intervals of restrained animals are provided		X				
• Veterinary care is provided if lesions or illness result from restraint		X				
• Explanations of purpose and duration of restraint are provided to study personnel		X				
• Multiple surgical procedures on a single animal are justified and outcomes evaluated		X				
• Major versus minor surgical procedures are evaluated on a case-by-case basis		X				



<ul style="list-style-type: none"> <li>Multiple survival procedure justifications in non-regulated species conform to regulated species standards</li> </ul>	X				
<ul style="list-style-type: none"> <li>Animals on food/fluid restriction are monitored to ensure nutritional needs are met</li> </ul>	X				
<ul style="list-style-type: none"> <li>Body weights for food/fluid restricted animals are recorded at least weekly</li> </ul>	X				
<ul style="list-style-type: none"> <li>Daily written records are maintained for food/fluid restricted animals</li> </ul>	X				
<ul style="list-style-type: none"> <li>Pharmaceutical grade chemicals are used , when available, for animal-related procedures (<i>Guide</i>,</li> </ul>	X				
<ul style="list-style-type: none"> <li>Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC</li> </ul>	X				
<ul style="list-style-type: none"> <li>Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area</li> </ul>	X				
<b>5. IACUC Membership and Functions</b>	<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
<ul style="list-style-type: none"> <li>IACUC is comprised of at least 5 members, appointed by CEO</li> </ul>	X				
<ul style="list-style-type: none"> <li>Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user</li> </ul>	X				
<ul style="list-style-type: none"> <li>IACUC authority and resources for oversight and evaluation of institution's program are provided</li> </ul>	X				
<ul style="list-style-type: none"> <li>IACUC conducts semiannual evaluations of institutional animal care and use program</li> </ul>	X				
<ul style="list-style-type: none"> <li>Conducts semiannual inspections of institutional animal facilities</li> </ul>	X				
<ul style="list-style-type: none"> <li>IACUC organizationally reports to the Institutional Official )</li> </ul>	X				
<ul style="list-style-type: none"> <li>Methods for reporting and investigating animal welfare concerns are in place )</li> </ul>	X				
<ul style="list-style-type: none"> <li>Reviews and investigates concerns about animal care and use at institution)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Procedures are in place for review, approval, and suspension of animal activities</li> </ul>	X				
<ul style="list-style-type: none"> <li>Procedures are in place for review and approval of significant changes to approved activities</li> </ul>	X				
<ul style="list-style-type: none"> <li>Policies are in place for special procedures (e.g., genetically modified animals, restraint, multiple survival surgery, food and fluid regulation, field investigations, agricultural animals)</li> </ul>	X				
<b>6. IACUC Training</b>	<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
<ul style="list-style-type: none"> <li>All IACUC members should receive:               <ul style="list-style-type: none"> <li>Formal orientation to institution's program</li> <li>Training on legislation, regulations, guidelines, and policies</li> <li>Training on how to inspect facilities and labs where animal use or housing occurs (<i>Guide</i>,</li> <li>Training on how to review protocols as well as evaluate the program</li> <li>Ongoing training/education</li> </ul> </li> </ul>	X				
	X				
	X				
	X				
	X				
	X				
<b>7. IACUC Records and Reporting Requirements</b>	<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
<ul style="list-style-type: none"> <li>Semiannual report to the IO)               <ul style="list-style-type: none"> <li>Submitted to IO every 6 months</li> <li>Compiles program review and facility inspection(s) results (includes all program and facility deficiencies)</li> <li>Includes minority IACUC views</li> <li>Describes IACUC-approved departures from the <i>Guide</i> or PHS Policy and the reasons for each departure</li> <li>Distinguishes significant from minor deficiencies</li> <li>Includes a plan and schedule for correction for each deficiency identified</li> </ul> </li> <li>Reports to OLAW               <ul style="list-style-type: none"> <li>Annual report to OLAW documents program changes, dates of the semiannual program reviews and facility inspections and includes any minority views</li> <li>Promptly advises OLAW of serious/ongoing <i>Guide</i> deviations or PHS Policy noncompliance</li> </ul> </li> <li>Records               <ul style="list-style-type: none"> <li>IACUC meeting minutes and semiannual reports to the IO are maintained for 3 years</li> <li>Records of IACUC reviews of animal activities include all required information</li> <li>Records of IACUC reviews are maintained for 3 years after the completion of the study</li> </ul> </li> </ul>	X				
	X				
	X				
	X				
	X				
	X				
	X				
<b>8. Veterinary Care (See also next section - Veterinary Care)</b>	<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
<ul style="list-style-type: none"> <li>An arrangement for veterinarian(s) with training or experience in lab animal medicine is in place including backup veterinary care</li> </ul>	X				
<ul style="list-style-type: none"> <li>Veterinary access to all animals is provided</li> </ul>	X				

• Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use	X				
• Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol	X				
• Veterinarian provides consultation when interventional control is not possible	X				
• Regular communication occurs between veterinarian and IACUC	X				
• Veterinarian(s) have experience and training in species used	X				
• Veterinarian(s) have experience in facility administration/management	X				
<b>9. Personnel Qualifications and Training</b>	<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
• All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included:					
o Veterinary/other professional staff	X				
o IACUC members	X				
o Animal care personnel	X				
o Research investigators, instructors, technicians, trainees, and students	X				
• Continuing education for program and research staff provided to ensure high quality care and reinforce training	X				
• Training is available prior to starting animal activity	X				
• Training is documented	X				
• Training program content includes					
o Methods for reporting concerns	X				
o Humane practices of animal care (e.g., housing, husbandry, handling)	X				
o Humane practices of animal use (e.g., research procedures, use of anesthesia, pre- and post-operative care, aseptic surgical techniques and euthanasia)	X				
o Research/testing methods that minimize numbers necessary to obtain valid results	X				
o Research/testing methods that minimize animal pain or distress)	X				
o Use of hazardous agents, including access to OSHA chemical hazard notices where applicable	X				
o Animal care and use legislation	X				
o IACUC function	X				
o Ethics of animal use and Three R's	X				
<b>10. Occupational Health and Safety of Personnel</b>	<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
• Program is in place and is consistent with federal, state, and local regulations	X				
• Program covers <i>all</i> personnel who work in laboratory animal facilities	X				
• Changing, washing, and showering facilities are available as appropriate	X				
• Hazardous facilities are separated from other areas and identified as limited access	X				
• Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies)	X				
• Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking policies)	X				
• Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place	X				
• Personal Protective Equipment for the work area is appropriate and available	X				
• Program for medical evaluation and preventive medicine for personnel includes:					
o Pre-employment evaluation including health history	X				
o Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate	X				
o Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague)	X				
o Procedures for reporting and treating injuries, including accidents, bites, allergies, etc.	X				
o Promotes early diagnosis of allergies including preexisting conditions	X				
o Considers confidentiality and other legal factors as required by federal, state and local regulations	X				
o If serum samples are collected, the purpose is consistent with federal and state laws	X				
• Waste anesthetic gases are scavenged	X				
• Hearing protection is provided in high noise areas	X				
• Respiratory protection is available when performing airborne particulate work	X				
• Occupational safety and health of field studies is reviewed by OSH committee or office	X				



11. Personnel Security					
	A*	M	S	C	NA
• Preventive measures in place include pre-employment screening, and physical and IT security )	X				
12. Investigating & Reporting Animal Welfare Concerns					
	A*	M	S	C	NA
• Methods for investigating and reporting animal welfare concerns are established	X				
• Reported concerns and corrective actions are documented	X				
• Mechanisms for reporting concerns are posted in facility and at applicable website with instructions	X				
○ Includes multiple contacts	X				
○ Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection	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:

## Veterinary Care

1. Clinical Care and Management					
	A*	M	S	C	NA
• Veterinary program offers high quality of care and ethical standards	X				
• Veterinarian provides guidance to all personnel to ensure appropriate husbandry, handling, treatment, anesthesia, analgesia, and euthanasia	X				
• Veterinarian provides oversight to surgery and perioperative care	X				
• Veterinary care program is appropriate for program requirements	X				
• Veterinarian(s) is familiar with species and use of animals and has access to medical and experimental treatment records	X				
• Procedures to triage and prioritize incident reports are in place	X				
• Procedures are in place to address:					
o Problems with experiments to determine course of treatment in consultation with investigator	X				
o Recurrent or significant health problems with the IACUC and documentation of treatments and outcomes	X				
o Veterinary review and oversight of medical and animal use records	X				
• Procedures established for timely reporting of animal injury, illness, or disease	X				
• Procedures established for veterinary assessment, treatment, or euthanasia	X				
• Veterinarian is authorized to treat, relieve pain, and/or euthanize	X				
2. Animal Procurement and Transportation/Preventive Medicine					
	A*	M	S	C	NA
• Procedures for lawful animal procurement are in place	X				
• Sufficient facilities and expertise are confirmed prior to procurement	X				
• Procurement is linked to IACUC review and approval	X				
• Appropriate records are maintained on animal acquisition)	X				
• Animal vendors are evaluated to meet program needs and quality	X				
• Breeding colonies are based on need and managed to minimize numbers	X				
• Procedures for compliance with animal transportation regulations, including international requirements, are in place	X				
• Transportation is planned to ensure safety, security and minimize risk	X				
• Movement of animals is planned to minimize transit time and deliveries are planned to ensure receiving personnel are available	X				
• Appropriate loading and unloading facilities are available	X				
• Environment at receiving site is appropriate	X				
• Policies in place on separation by species, source, and health status	X				
• Procedures in place for quarantine to include zoonoses prevention	X				
• Quarantined animals from different shipments are handled separately or physically separated	X				
• Procedures in place for stabilization/acclimation	X				
• Policies in place for isolation of sick animals	X				
• Program is in place for surveillance, diagnosis, treatment and control of disease to include daily observation	X				
• Diagnostic resources are available for preventive health program	X				
3. Surgery					
	A*	M	S	C	NA
• Surgical outcomes are assessed and corrective changes instituted	X				
• Researchers have appropriate training to ensure good technique	X				
• Pre-surgical plans are developed and include veterinary input (e.g., location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping)	X				
• Aseptic surgery is conducted in dedicated facilities or spaces, unless exception justified and IACUC approved	X				
• Surgical procedures including laparoscopic procedures are categorized as major or minor	X				
• For nonsurvival surgery, the site is clipped, gloves are worn and instruments and area are clean	X				
• Aseptic technique is followed for survival surgical procedures	X				

• Effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs are in place	X				
• Procedures for monitoring surgical anesthesia and analgesia are in place	X				
• Post-operative monitoring and care are provided by trained personnel and documented (e.g., thermoregulation, physiologic function, analgesia, infection, removal of skin closures)	X				
<b>4. Pain, Distress, Anesthesia and Analgesia</b>	<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
• Guidelines for assessment and categorization of pain, distress and animal wellbeing are provided during training	X				
• Selection of analgesics and anesthetics is based on professional veterinary judgment)	X				
• Painful procedures are monitored to ensure appropriate analgesic management	X				
• Nonpharmacologic control of pain is considered as an element of postprocedural care	X				
• Procedures are in place to assure antinociception before surgery begins	X				
• Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated	X				
• Special precautions for the use of paralytics are in place to ensure anesthesia	X				
<b>5. Euthanasia</b>	<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
• Methods are consistent with AVMA Guidelines on Euthanasia unless approved by the IACUC	X				
• Standardized methods are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species	X				
• Training is provided on appropriate methods for each species and considers psychological stress to personnel	X				
• Procedures and training are in place to ensure death is confirmed	X				
<b>6. Drug Storage and Control</b>	<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
• Program complies with federal regulations for human and veterinary drugs	X				
• Drug records and storage procedures are reviewed during facility inspections	X				
• Procedures are in place to ensure analgesics and anesthetics are used within expiration date	X				
• Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely	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:

# Frederick National Laboratory

Date: 05/09/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] Lead Inspector

Subject: Location [Redacted by agreement] Animal Facility Inspections

On 05/07/2019, EHS inspected your area in [Redacted by agreement]. There were no safety or environmental deficiencies noted during the evaluation.

Your assistance during the inspection was appreciated.

If you have any questions, please contact us at [Redacted by agreement]

No Deficiencies Were Found In the Program Area.

# Frederick National Laboratory

Date: 05/03/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] Lead Inspector

Cc: [Redacted by agreement]

Subject: Location, [Redacted by agreement] Animal Facility Inspections

On 05/02/2019, [Redacted by agreement] from the Environment, Health and Safety Program, inspected [Redacted by agreement]

[Redacted by agreement] The purpose of this inspection was to evaluate your area in accordance with applicable safety and environmental requirements. To comply with NCI Contract Number HHSN261200800001E this initial inspection report is being provided to you, the Animal Facility Coordinator. Corrective action for any open deficiency is required within 30 - 45 days by the appropriate personnel. The results of future re-inspections shall be reported to the Key Person or Government authority as appropriate.

The findings identified during our inspection are noted below with the remedial action required to correct each deficiency. Your assistance during the inspection was appreciated.

If you have any questions, please contact us at [Redacted by agreement]

Following are the deficiencies we found that may need your attention.

## Program is Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
[Redacted by agreement] (b) (5)				

## EHS is Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
[Redacted by agreement] (b) (5)				



### FME is Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
(b) (5)				

# Frederick National Laboratory

Date: 05/09/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] - Lead Inspector

Cc: [Redacted by agreement]

Subject: Location, [Redacted by agreement] Animal Facility Inspections

On 05/07/2019, [Redacted by agreement] from the Environment, Health and Safety Program, inspected [Redacted by agreement] AF. The purpose of this inspection was to evaluate your area in accordance with applicable safety and environmental requirements. To comply with NCI Contract Number HHSN261200800001E this initial inspection report is being provided to you, the Animal Facility Coordinator. Corrective action for any open deficiency is required within 30 - 45 days by the appropriate personnel. The results of future re-inspections shall be reported to the Key Person or Government authority as appropriate.

The findings identified during our inspection are noted below with the remedial action required to correct each deficiency. Your assistance during the inspection was appreciated.

If you have any questions, please contact us at [Redacted by agreement]

Following are the deficiencies we found that may need your attention.

## Program is Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
[Redacted by agreement] (b) (5)				
Materials used and stored in laboratory are not labeled.	[Redacted by agreement]	Clearly identify materials used and stored in the laboratory.	Unlabeled spray bottle containing an unknown liquid	Resolved

## FME is Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
[Redacted by agreement] (b) (5)				

# Frederick National Laboratory

Date: 05/02/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] Lead Inspector

Cc: [Redacted by agreement]

Subject: Location: [Redacted by agreement] Animal Facility Inspections

On 05/02/2019, [Redacted by agreement] from the Environment, Health and Safety Program, inspected [Redacted by agreement]. The purpose of this inspection was to evaluate your area in accordance with applicable safety and environmental requirements. To comply with NCI Contract Number HHSN261200800001E this initial inspection report is being provided to you, the Animal Facility Coordinator. Corrective action for any open deficiency is required within 30 - 45 days by the appropriate personnel. The results of future re-inspections shall be reported to the Key Person or Government authority as appropriate.

The findings identified during our inspection are noted below with the remedial action required to correct each deficiency. Your assistance during the inspection was appreciated.

If you have any questions, please contact us at [Redacted by agreement]

Following are the deficiencies we found that may need your attention.

## Program is Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
Acids stored with flammables.	[Redacted by agreement]	Relocate acids to segregated storage, remote from flammable liquids.	Isopropyl alcohol in corrosive cabinet with hydrochloric acid	Resolved
Incompatible materials are stored together.	[Redacted by agreement]	Move incompatible materials to separate storage locations.	Windex (ammonia) stored with bleach	Resolved

# Frederick National Laboratory

Date: 05/24/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] Lead Inspector

Cc: [Redacted by agreement]

Subject: Location, [Redacted by agreement] Issue Inspections

On 05/24/2019, [Redacted by agreement] from the Environment, Health and Safety Program, inspected [Redacted by agreement]. The purpose of this inspection was to evaluate your area in accordance with applicable safety and environmental requirements. To comply with NCI Contract Number HHSN261200800001E this initial inspection report is being provided to you, the [Redacted by agreement]. Corrective action for any open deficiency is required within 30 - 45 days by the appropriate personnel. The results of future re-inspections shall be reported to the Key Person or Government authority as appropriate.

The findings identified during our inspection are noted below with the remedial action required to correct each deficiency. Your assistance during the inspection was appreciated.

If you have any questions, please contact us at [Redacted by agreement].

Following are the deficiencies we found that may need your attention.

## Program is Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
Inhalation hazards or Particularly Hazardous Substances (PHSs) used outside of an exhausted engineering controls.	[Redacted by agreement]	Only use inhalation hazards or PHSs inside of properly exhausted engineering controls.	Isoflurane used in A2 BSC without active scavenging. No potential for exposure over 2 ppm due to room ventilation but exposure should be as low as reasonably achievable. Resolved by installation of exhausted nose cone (checked by EHS) the next day.	Resolved

# Frederick National Laboratory

Date: 05/02/2019  
To: [Redacted by agreement]  
Thru: [Redacted by agreement]  
From: [Redacted by agreement] Lead Inspector  
Cc: [Redacted by agreement]  
Subject: Location, [Redacted by agreement] Animal Facility Inspections

On 05/02/2019, [Redacted by agreement] from the Environment, Health and Safety Program, inspected [Redacted by agreement].  
[Redacted by agreement] The purpose of this inspection was to evaluate your area in accordance with applicable safety and environmental requirements. To comply with NCI Contract Number HHSN261200800001E this initial inspection report is being provided to you, the Animal Facility Coordinator. Corrective action for any open deficiency is required within 30 - 45 days by the appropriate personnel. The results of future re-inspections shall be reported to the Key Person or Government authority as appropriate.

The findings identified during our inspection are noted below with the remedial action required to correct each deficiency. Your assistance during the inspection was appreciated.

If you have any questions, please contact us at [Redacted by agreement].

Following are the deficiencies we found that may need your attention.

## Program is Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
Exits are not free of obstructions.	[Redacted by agreement]	Relocate items to appropriate storage area.	Drum in front of exit door.	Resolved

## FME is Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
Fire extinguisher tag not initialed to indicate monthly inspection.	[Redacted by agreement]	FME will ensure the monthly inspection requirement is met.	Outside [Redacted by agreement] Not checked in April 2019	Resolved



# Frederick National Laboratory

Date: 05/02/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] Lead Inspector

Cc: [Redacted by agreement]

Subject: Location, [Redacted by agreement] Animal Facility Inspections

On 05/02/2019, [Redacted by agreement] from the Environment, Health and Safety Program, inspected [Redacted by agreement]. The purpose of this inspection was to evaluate your area in accordance with applicable safety and environmental requirements. To comply with NCI Contract Number HHSN261200800001E this initial inspection report is being provided to you, the Animal Facility Coordinator. Corrective action for any open deficiency is required within 30 - 45 days by the appropriate personnel. The results of future re-inspections shall be reported to the Key Person or Government authority as appropriate.

The findings identified during our inspection are noted below with the remedial action required to correct each deficiency. Your assistance during the inspection was appreciated.

If you have any questions, please contact us at [Redacted by agreement]

Following are the deficiencies we found that may need your attention.

## Program is Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
(b) (5)				

## EHS is Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
(b) (5)				

## FME is Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
(b) (5)				

# Frederick National Laboratory

Date: 05/10/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] - Lead Inspector

Subject: Location, [Redacted by agreement] Animal Facility Inspections

On 05/03/2019, EHS inspected your area in Building [Redacted by agreement]. There were no safety or environmental deficiencies noted during the evaluation.

Your assistance during the inspection was appreciated.

If you have any questions, please contact us at [Redacted by agreement]

No Deficiencies Were Found In the Program Area.

# Frederick National Laboratory

Date: 05/13/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] Lead Inspector

Cc: [Redacted by agreement]

Subject: Location, [Redacted by agreement] Animal Facility Inspections

On 04/23/2019, [Redacted by agreement] from the Environment, Health and Safety Program, inspected [Redacted by agreement]. The purpose of this inspection was to evaluate your area in accordance with applicable safety and environmental requirements. To comply with NCI Contract Number HHSN261200800001E this initial inspection report is being provided to you, the Animal Facility Coordinator. Corrective action for any open deficiency is required within 30 - 45 days by the appropriate personnel. The results of future re-inspections shall be reported to the Key Person or Government authority as appropriate.

The findings identified during our inspection are noted below with the remedial action required to correct each deficiency. Your assistance during the inspection was appreciated.

If you have any questions, please contact us at [Redacted by agreement]

Following are the deficiencies we found that may need your attention.

## Program is Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
[Redacted by agreement] (b) (5)				

## FME is Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
[Redacted by agreement] (b) (5)				

# Frederick National Laboratory

Date: 05/20/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] Lead Inspector

Subject: Location, [Redacted by agreement] Animal Facility Inspections

On 04/16/2019, [Redacted by agreement] from the Environment, Health and Safety Program, accompanied by [Redacted by agreement] inspected [Redacted by agreement]

The findings identified during our inspection have been resolved.

Your assistance in resolving any deficiencies was appreciated.

If you have any questions, please contact us at [Redacted by agreement]

The following deficiencies have been resolved:

## EHS was Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
Laboratory entrance sign is missing, or contains incomplete/incorrect information.	[Redacted by agreement]	Maintain an up-to-date information sign on the entrance to the laboratory. The information should communicate hazards located within the area as well as after-hours contact information.	Need to update door sign with current ASP and IBC information	Resolved

## FME was Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
Door latch is broken and does not allow for door to open, shut and latch properly.	[Redacted by agreement]	FME will repair door latch to operate properly.	Door latch seems to be in good working order but door hits door frame not allowing for contact with strike preventing door from closing securely. This has the potential to impact airflow.	Resolved
Emergency Light is not operating properly	Corridor	FME will repair the emergency light.	[Redacted by agreement] left light bulb is out	Resolved

# Frederick National Laboratory

Date: 05/01/2019

To: [Redacted by agreement.] [Redacted by agreement.]

Thru: [Redacted by agreement.]

From: [Redacted by agreement.] Lead Inspector

Subject: Location, [Redacted by agreement.] Animal Facility Inspections

On 04/22/2019, EHS inspected your area in [Redacted by agreement.] There were no safety or environmental deficiencies noted during the evaluation.

Your assistance during the inspection was appreciated.

If you have any questions, please contact us at [Redacted by agreement.]

No Deficiencies Were Found In the Program Area.



# Frederick National Laboratory

Date: 05/28/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] Lead Inspector

Subject: Location [Redacted by agreement] Animal Facility Inspections

On 05/14/2019, [Redacted by agreement] from the Environment, Health and Safety Program, inspected [Redacted by agreement]  
[Redacted by agreement]

The findings identified during our inspection have been resolved.

Your assistance in resolving any deficiencies was appreciated.

If you have any questions, please contact us at [Redacted by agreement]

The following deficiencies have been resolved:

## EHS was Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
Laboratory entrance sign is missing, or contains incomplete/incorrect information.	[Redacted by agreement]	Maintain an up-to-date information sign on the entrance to the laboratory. The information should communicate hazards located within the area as well as after-hours contact information.	Door sign indicates ABSL-1 instead of BSL-1	Resolved

# Frederick National Laboratory

Date: 04/30/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] Lead Inspector

Subject: Location [Redacted by agreement] Animal Facility Inspections

On 04/30/2019, EHS inspected your area in [Redacted by agreement]. There were no safety or environmental deficiencies noted during the evaluation.

Your assistance during the inspection was appreciated.

If you have any questions, please contact us at [Redacted by agreement].

No Deficiencies Were Found In the Program Area.

# Frederick National Laboratory

Date: 05/20/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] Lead Inspector

Subject: Location, [Redacted by agreement] Animal Facility Inspections

On 05/20/2019, EHS inspected your area in [Redacted by agreement]. There were no safety or environmental deficiencies noted during the evaluation.

Your assistance during the inspection was appreciated.

If you have any questions, please contact us at [Redacted by agreement].

No Deficiencies Were Found In the Program Area.

# Frederick National Laboratory

Date: 05/20/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] Lead Inspector

Subject: Location, [Redacted by agreement] Animal Facility Inspections

On 05/14/2019, [Redacted by agreement] from the Environment, Health and Safety Program, inspected [Redacted by agreement]  
[Redacted by agreement]

The findings identified during our inspection have been resolved.

Your assistance in resolving any deficiencies was appreciated.

If you have any questions, please contact us at [Redacted by agreement]

The following deficiencies have been resolved:

## EHS was Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
Laboratory entrance sign is missing, or contains incomplete/incorrect information.	[Redacted by agreement]	Maintain an up-to-date information sign on the entrance to the laboratory. The information should communicate hazards located within the area as well as after-hours contact information.	Door sign indicates ABSL-1 instead of BSL-2	Resolved

# Frederick National Laboratory

Date: 05/20/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] Lead Inspector

Cc: [Redacted by agreement]

Subject: Location, [Redacted by agreement] Animal Facility Inspections

On 05/20/2019, [Redacted by agreement] from the Environment, Health and Safety Program, inspected [Redacted by agreement]

[Redacted by agreement] The purpose of this inspection was to evaluate your area in accordance with applicable safety and environmental requirements. To comply with NCI Contract Number HHSN261200800001E this initial inspection report is being provided to you, the Animal Facility Coordinator. Corrective action for any open deficiency is required within 30 - 45 days by the appropriate personnel. The results of future re-inspections shall be reported to the Key Person or Government authority as appropriate.

The findings identified during our inspection are noted below with the remedial action required to correct each deficiency. Your assistance during the inspection was appreciated.

If you have any questions, please contact us at [Redacted by agreement]

Following are the deficiencies we found that may need your attention.

## Program is Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
[Redacted by agreement] (b) (5)				

## EHS is Responsible for Correcting the Following Deficiencies



Deficiency	Space	Remedial Action	Comments	Status
(b) (5)				

# Frederick National Laboratory

Date: 05/01/2019  
To: [Redacted by agreement]  
Thru: [Redacted by agreement]  
From: [Redacted by agreement] Lead Inspector  
Cc: [Redacted by agreement]  
Subject: Location, [Redacted by agreement] Animal Facility Inspections

On 04/22/2019, [Redacted by agreement] from the Environment, Health and Safety Program, accompanied by [Redacted by agreement] inspected [Redacted by agreement]. The purpose of this inspection was to evaluate your area in accordance with applicable safety and environmental requirements. To comply with NCI Contract Number HHSN261200800001E this initial inspection report is being provided to you, the Animal Facility Coordinator. Corrective action for any open deficiency is required within 30 - 45 days by the appropriate personnel. The results of future re-inspections shall be reported to the Key Person or Government authority as appropriate.

The findings identified during our inspection are noted below with the remedial action required to correct each deficiency. Your assistance during the inspection was appreciated.

If you have any questions, please contact us at [Redacted by agreement].

Following are the deficiencies we found that may need your attention.

## Program is Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
Materials used and stored in laboratory are not labeled.	[Redacted by agreement]	Clearly identify materials used and stored in the laboratory.	Pitchers inside of isolators used for pouring water not labeled.	Resolved
Materials used and stored in laboratory are not labeled.	[Redacted by agreement]	Clearly identify materials used and stored in the laboratory.	Pitchers inside of isolators used for pouring water not labeled.	Resolved

# Frederick National Laboratory

Date: 05/28/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] Lead Inspector

Subject: Location, [Redacted by agreement] Animal Facility Inspections

On 05/14/2019 [Redacted by agreement] from the Environment, Health and Safety Program, inspected [Redacted by agreement]  
[Redacted by agreement]

The findings identified during our inspection have been resolved.

Your assistance in resolving any deficiencies was appreciated.

If you have any questions, please contact us at [Redacted by agreement]

The following deficiencies have been resolved:

## EHS was Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
Laboratory entrance sign is missing, or contains incomplete/incorrect information.	[Redacted by agreement]	Maintain an up-to-date information sign on the entrance to the laboratory. The information should communicate hazards located within the area as well as after-hours contact information.	Door sign indicates ABSL-1 instead of BSL-1	Resolved

# Frederick National Laboratory

Date: 04/30/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] Lead Inspector

Cc: [Redacted by agreement]

Subject: Location, [Redacted by agreement] Animal Facility Inspections

On 04/29/2019, [Redacted by agreement] from the Environment, Health and Safety Program, inspected [Redacted by agreement] AF. The purpose of this inspection was to evaluate your area in accordance with applicable safety and environmental requirements. To comply with NCI Contract Number HHSN261200800001E this initial inspection report is being provided to you, the Animal Facility Coordinator. Corrective action for any open deficiency is required within 30 - 45 days by the appropriate personnel. The results of future re-inspections shall be reported to the Key Person or Government authority as appropriate.

The findings identified during our inspection are noted below with the remedial action required to correct each deficiency. Your assistance during the inspection was appreciated.

If you have any questions, please contact us at [Redacted by agreement]

Following are the deficiencies we found that may need your attention.

## Program is Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
Expired drugs, chemical or supplies not disposed of.	[Redacted by agreement]	Dispose of expired drugs, chemical and supplies through Waste Management [Redacted by agreement]	Expired bleach spray	Resolved

# Frederick National Laboratory

Date: 05/24/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] Lead Inspector

Subject: Location [Redacted by agreement] Animal Facility Inspections

On 04/29/2019 [Redacted by agreement] from the Environment, Health and Safety Program, inspected [Redacted by agreement]  
[Redacted by agreement]

The findings identified during our inspection have been resolved.

Your assistance in resolving any deficiencies was appreciated.

If you have any questions, please contact us at [Redacted by agreement]

The following deficiencies have been resolved:

## Program was Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
Expired drugs, chemical or supplies not disposed of.	[Redacted by agreement]	Dispose of expired drugs, chemical and supplies through Waste Management [Redacted by agreement]	Expired hydrogen peroxide	Resolved

## FME was Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
Biological Safety Cabinet annual certification has expired.	[Redacted by agreement]	Coordinate with FME to schedule the cabinet for annual certification.	C137505- Out of Certification	Resolved
GFCI protection is not utilized for equipment/locations in wet or highly conductive locations.	[Redacted by agreement]	Utilize ground-fault circuit interrupter (GFCI) protection for equipment/locations in wet or highly conductive locations.	Outlet above sink is not GFCI	Resolved



# Frederick National Laboratory

Date: 05/01/2019

To: [Redacted by agreement]  
Thru: [Redacted by agreement]

From: [Redacted by agreement] Lead Inspector

Cc: [Redacted by agreement]

Subject: Location [Redacted by agreement] Animal Facility Inspections

On 04/22/2019 [Redacted by agreement] from the Environment, Health and Safety Program, accompanied by [Redacted by agreement] inspected [Redacted by agreement]. The purpose of this inspection was to evaluate your area in accordance with applicable safety and environmental requirements. To comply with NCI Contract Number HHSN261200800001E this initial inspection report is being provided to you, the Animal Facility Coordinator. Corrective action for any open deficiency is required within 30 - 45 days by the appropriate personnel. The results of future re-inspections shall be reported to the Key Person or Government authority as appropriate.

The findings identified during our inspection are noted below with the remedial action required to correct each deficiency. Your assistance during the inspection was appreciated.

If you have any questions, please contact us at [Redacted by agreement]

Following are the deficiencies we found that may need your attention.

## Program is Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
Materials used and stored in laboratory are not labeled.	[Redacted by agreement]	Clearly identify materials used and stored in the laboratory.	Clidox spray bottles not labeled or label had worn off so that the contents of the spray bottle was not obvious.	Resolved

# Frederick National Laboratory

Date: 04/30/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] Lead Inspector

Subject: Location, [Redacted by agreement] Animal Facility Inspections

On 04/29/2019, EHS inspected your area in [Redacted by agreement]. There were no safety or environmental deficiencies noted during the evaluation.

Your assistance during the inspection was appreciated.

If you have any questions, please contact us at [Redacted by agreement].

No Deficiencies Were Found In the Program Area.

# Frederick National Laboratory

Date: 05/28/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] Lead Inspector

Subject: Location, [Redacted by agreement] Animal Facility Inspections

On 05/14/2019 [Redacted by agreement] from the Environment, Health and Safety Program, inspected [Redacted by agreement]  
[Redacted by agreement]

The findings identified during our inspection have been resolved.

Your assistance in resolving any deficiencies was appreciated.

If you have any questions, please contact us at [Redacted by agreement]

The following deficiencies have been resolved:

## Program was Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
Heat producing or high amperage appliances (microwave, coffee pot, refrigerator, freezer, etc.) are not plugged directly into a wall outlet.	[Redacted by agreement]	Plug equipment directly into an outlet. Have additional outlets installed if necessary.	Stirring hot plate plugged into power strip	Resolved

## EHS was Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
Laboratory does not have an emergency contact sign affixed to entrance.	[Redacted by agreement]	EHS will post an emergency contact sign.	Door sign indicates ABSL-1 instead of BSL-1	Resolved

# Frederick National Laboratory

Date: 05/20/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] Lead Inspector

Cc: [Redacted by agreement]

Subject: Location [Redacted by agreement] Animal Facility Inspections

On 05/20/2019 [Redacted by agreement] from the Environment, Health and Safety Program, inspected [Redacted by agreement]. [Redacted by agreement] The purpose of this inspection was to evaluate your area in accordance with applicable safety and environmental requirements. To comply with NCI Contract Number HHSN261200800001E this initial inspection report is being provided to you, the Animal Facility Coordinator. Corrective action for any open deficiency is required within 30 - 45 days by the appropriate personnel. The results of future re-inspections shall be reported to the Key Person or Government authority as appropriate.

The findings identified during our inspection are noted below with the remedial action required to correct each deficiency. Your assistance during the inspection was appreciated.

If you have any questions, please contact us at [Redacted by agreement]

Following are the deficiencies we found that may need your attention.

## Program is Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
Flammable liquids not in use are not in a flammable storage room or flammable storage cabinet.	[Redacted by agreement]	Limit flammables outside of a storage room or cabinet to working quantities.	Jug of acetone stored on shelf. Removed to flammable storage.	Resolved
Hazardous chemicals are stored and/or dispensed above eye level.	[Redacted by agreement]	Relocate chemicals so that storage and/or dispensing is below eye level.	Jug of bleach stored on shelf above eye level. Removed.	Resolved

# Frederick National Laboratory

Date: 05/01/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] - Lead Inspector

Subject: Location [Redacted by agreement] Animal Facility Inspections

On 04/22/2019, EHS inspected your area in [Redacted by agreement]. There were no safety or environmental deficiencies noted during the evaluation.

Your assistance during the inspection was appreciated.

If you have any questions, please contact us at [Redacted by agreement]

No Deficiencies Were Found In the Program Area.



# Frederick National Laboratory

Date: 05/13/2019

To: [Redacted by agreement]

Thru: [Redacted by agreement]

From: [Redacted by agreement] Lead Inspector

Cc: [Redacted by agreement]

Subject: Location, [Redacted by agreement] Animal Facility Inspections

On 04/30/2019, [Redacted by agreement] from the Environment, Health and Safety Program, inspected [Redacted by agreement]. The purpose of this inspection was to evaluate your area in accordance with applicable safety and environmental requirements. To comply with NCI Contract Number HHSN261200800001E this initial inspection report is being provided to you, the Animal Facility Coordinator. Corrective action for any open deficiency is required within 30 - 45 days by the appropriate personnel. The results of future re-inspections shall be reported to the Key Person or Government authority as appropriate.

The findings identified during our inspection are noted below with the remedial action required to correct each deficiency. Your assistance during the inspection was appreciated.

If you have any questions, please contact us at [Redacted by agreement].

Following are the deficiencies we found that may need your attention.

## Program is Responsible for Correcting the Following Deficiencies

Deficiency	Space	Remedial Action	Comments	Status
[Redacted content]				

(b) (5)

Deficiency	Space	Remedial Action	Comments	Status
(b) (5)				
Personal Protective Equipment (PPE), such as lab coats or coveralls and closed-toe shoes, not worn.	Redacted by agreement	Wear appropriate PPE for the type(s) of work being performed.	Safety glasses not worn. Discussed with occupant.	Resolved
(b) (5)				

**FME is Responsible for Correcting the Following Deficiencies**

Deficiency	Space	Remedial Action	Comments	Status
(b) (5)				