Name: SUNY - Downstate Medical Center [A137]

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Recd	
Code	A137

NEW YORK STATE DEPARTMENT OF HEALTH
WADSWORTH CENTER
LABORATORY ANIMAL WELFARE PROGRAM
EMPIRE STATE PLAZA, P.O. BOX 509
ALBANY, NEW YORK 12201-0509

2019 RENEWAL APPLICATION FOR APPROVAL FOR USE OF LIVING ANIMALS

SECTION I - GENERAL LABORATORY/INSTITUTION INFORMATION

CURRENT DATA	INDICATE CHANGES HERE
Laboratory/Institution Name: SUNY - Downstate Medical Center	
Address 1: 450 Clarkson Avenue	450 Clarkson Avenue, Box 47
Address 2:	
City, State, Zipcode: Brooklyn, NY 11203	
County: Kings	
Telephone Number: 718-270-1194	
Fax Number: 718-270-4095	
E-mail Address: carol.novotney@downstate.edu	josepha.scott@downstate.edu

RECEIVED
NOV 28 2018
FACILITIES MANAGEMENT

FSB 11-29-18

AW-APP01(10/2007)

SECTION I - GENERAL LABORATORY/INSTITUTION INFORMATION

Ownership:

☐ Corporation ☑ Government ☐ Individual ☐ Not For Profit ☐ Partnership
☐ Other: _____

Facility Type:

☐ 2 Year College ☐ 4 Year College ☐ Clinical or Environmental Lab
☑ Hospital ☑ Medical School ☐ Product Testing Lab
☐ Public Health Lab ☐ Research & Development Lab ☐ Veterinary School
☐ Other: _____

SECTION II - PROGRAM INFORMATION

Animals (Check all that apply):

- ☑ Mice (genus mus)
- ☐ Mice (wild or other)
- ☑ Rats (genus rattus)
- ☐ Rats (wild or other)
- ☑ Other: fruit bat, frog
- ☐ Hamsters
- ☐ Guinea Pigs
- ☑ Rabbits
- ☐ Small Birds
- ☑ Fish
- ☐ Cats
- ☐ Dogs
- ☑ Non-Human Primates
- ☑ Sheep/Goats
- ☐ Cattle
- ☑ Swine
- ☐ Poultry

Are you currently housing live animals at your institution? ☑ Yes ☐ No

If you are not currently housing live animals, do you anticipate having live animals in your facility during the next 12 months?* ☐ Yes ☐ No

*LAWP permits are issued to those institutions that maintain living animals for teaching and/or research and have the appropriate programs and facilities to properly and humanely care for those animals.

Does your laboratory/institution have an Animal Care Committee? ☑ Yes ☐ No
(If Yes, attach a copy of the Committee members)

Since your last application, have there been any changes in your animal care and use procedures (i.e. feeding programs, disease control, environmental management, humane care, euthanasia)? ☑ Yes ☐ No
(If Yes, please explain)

Note: Any procedures that require the withholding of feed and water or exposing the animals to adverse or unusual conditions should be documented in your animal use protocols and approved by your IACUC.

Living animals are used for (Check all that apply):

- ☐ Diagnostic Procedures
- ☑ Experimentation
- ☐ Public Display
- ☐ Other:
- ☑ Education/Teaching Demonstrations
- ☐ Farm Production
- ☐ Public Health/Disease Surveillience

Are animals used in studies with human infectious agents? ☑ Yes ☐ No
(If Yes, attach a copy of your procedures for processing medical waste generated by the animals)

Registration/Accreditation Type:

- ☑ AAALAC Accredited
- ☑ USDA Registered
- ☐ None
- ☐ Other: PHS Assurance

SECTION III - PERSONNEL INFORMATION

CURRENT DATA	INDICATE CHANGES HERE
Laboratory/Institution Person In Charge (Name): Novotney, Carol	Heidi J. Aronin
Title: Director	Institutional Official
Telephone Number: 718-270-1194	718-270-1025
Work Hours: MON: **8:00 am** to **5:00 pm** TUE: **8:00 am** to **5:00 pm** WED: **8:00 am** to **5:00 pm** THU: **8:00 am** to **5:00 pm** FRI: **8:00 am** to **5:00 pm** to to	**Work Hours:** Mon: to Tue: to Wed: to Thu: to Fri: to Sat: to Sun: to

CURRENT DATA	INDICATE CHANGES HERE
Veterinarian in Charge (Name): Novotney, Carol	Joseph A. Scott
Title: Director	Attending Veterinarian
Telephone Number: 718-270-1194	
Work Name/Address (if different from laboratory/institution):	
Work Hours: MON: **8:00 am** to **5:00 pm** TUE: **8:00 am** to **5:00 pm** WED: **8:00 am** to **5:00 pm** THU: **8:00 am** to **5:00 pm** FRI: **8:00 am** to **5:00 pm** to to	**Work Hours:** Mon: 8:00am to 5pm Tue: n/a to n/a Wed: 8:00am to 5pm Thu: n/a to n/a Fri: 8:00am to 5pm Sat: to Sun: to

SECTION III - PERSONNEL INFORMATION

CURRENT DATA	INDICATE CHANGES HERE
Contact Person (Name): Alvarez, Jaqueline	
Title: Administrator	
Telephone Number: 718-270-1194	
Work Hours: MON: **9:00 am** to **5:00 pm** TUE: **9:00 am** to **5:00 pm** WED: **9:00 am** to **5:00 pm** THU: **9:00 am** to **5:00 pm** FRI: **9:00 am** to **5:00 pm** to to	**Work Hours:** Mon: to Tue: to Wed: to Thu: to Fri: to Sat: to Sun: to

☐ Attach a list of all full-time and part-time animal care staff which includes the following information: Name, Full-Time or Part-Time, Title and Education Level (Highest).

☑ No additional staff.

SECTION IV - ATTESTATION

I have read the Administrative Rules and Regulations concerning the use of living animals and understand that I am fully responsible for all work involving the use of living animals. I understand that the Certificate of Approval is not transferable and the New York State Department of Health (the Department) shall be advised promptly if the individual, in whose name approval has been granted, ceases to be in charge. The facility(ies) will be operated according to all applicable laws, rules and regulations.

I understand that by signing this application form I agree to cooperate with any investigations conducted by the Department to verify or confirm information given or any other investigation conducted in connection with animal welfare in any facility identified in this application. If additional information is requested, I will provide it.

In signing this application, I hereby certify that the information I have given the Department as a basis for obtaining or retaining a certificate of approval is true and correct. As information changes, I will promptly notify the Department. Further, I understand that filing a false instrument constitutes a crime under the Penal Law of the State of New York.

Heidi J. Klein — Signature, Laboratory/Institutional Officer

Senior Vice Pres./Chief Admin. Officer — Title

11/27/18 — Date

AW-APP01(10/2007)

SECTION V - ADDITIONAL SITES WHERE LIVING ANIMALS ARE LOCATED

FIELDS	NEW SITE DATA
Site Name:	
Address 1:	
Address 2:	
City, State, Zipcode:	
Site Telephone Number:	
Site Fax Number:	
Site E-mail Address:	
Contact Person (Name):	

FIELDS	NEW SITE DATA
Site Name:	
Address 1:	
Address 2:	
City, State, Zipcode:	
Site Telephone Number:	
Site Fax Number:	
Site E-mail Address:	
Contact Person (Name):	

FIELDS	NEW SITE DATA
Site Name:	
Address 1:	
Address 2:	
City, State, Zipcode:	
Site Telephone Number:	
Site Fax Number:	
Site E-mail Address:	
Contact Person (Name):	

FIELDS	NEW SITE DATA
Site Name:	
Address 1:	
Address 2:	
City, State, Zipcode:	
Site Telephone Number:	
Site Fax Number:	
Site E-mail Address:	
Contact Person (Name):	

Appendix 7: IACUC/OB Membership Roster

Please provide a Committee roster, indicating names, degrees, membership role, and affiliation (e.g., Department/Division).

Name	Degrees/Credentials	Membership Role	Affiliation
Joseph Scott	VMD, DACLAM	Attending Veterinarian	Interim Director, DCM
Cora Kaiser	BA, RLATG	Scientist	Facility Manager, DCM
Chongmin Huan	PhD	Scientist	Associate Professor Surgery, Director Surgery Research
Dina Wilcox	BA, JD	Nonaffiliated	Family lawyer, writer, educator
Doug Ling	PhD	Chair - scientist	Associate Professor Physiology/Pharmacology
Gavin Morrow	PhD	Scientist	Associate Director, Vector Immunobiology at IAVI BioBAT
Haseeb Siddiqi	PhD	Ad-hoc, non-voting	Associate Professor Cell Biology; IBC Chair
Ivan Hernandez	PhD	Scientist	Associate Professor Pathology
Janice Brissette	PhD	Scientist	Associate Professor Cell Biology; IBC Member
Jason Dictenberg	PhD	Scientist	CEO Primary Bio, LLC Downstate Biotechnology Incubator
Julie Sharp	DVM, CPIA, DACLAM	Scientist	Director, Office of Animal Welfare
Nicholas Penington	PhD	Scientist	Associate Professor Physiology/Pharmacology
Sharon Levine-Sealy	CRA eligible, College education focus on business and finance	Nonscientist	Director of Pre-award Research Administration
Steven Young	PhD	Scientist	Research Instructor Physiology/Pharmacology

SECTION III – ANIMAL CARE STAFF
January 2018 - December 2018

ANIMAL CARE STAFF (CODED)	FULL/PART-TIME	TITLE	EDUCATION
1	FULL	VETERINARY TECHNICIAN	HIGH SCHOOL, AALAS ALAT + COLLEGE COURSES
2	FULL	LAB ANIMAL CARETAKER	HIGH SCHOOL
3	FULL	LAB ANIMAL CARETAKER	HIGH SCHOOL
4	FULL	INSTRUCTIONAL SUPPORT ASSISTANT	HIGH SCHOOL
5	FULL	SR. LAB ANIMAL CARETAKER	HIGH SCHOOL
6	FULL	SR. LAB ANIMAL CARETAKER	ASSOCIATES DEGREE
7	FULL	SR. LAB ANIMAL CARETAKER	HIGH SCHOOL
8	FULL	LAB ANIMAL CARETAKER	HIGH SCHOOL
9	FULL	OPERATIONS MANAGER	BA/AAS/RLATG
10	FULL	SR. LAB ANIMAL CARETAKER	UNIVERSITY
11	FULL	HUSBANDRY SUPERVISOR	HIGH SCHOOL
12	FULL	VETERINARY TECHNICIAN	ASSOCIATES DEGREE; AALAS-LATG; NYS VET TECH
13	FULL	LAB ANIMAL CARETAKER	HIGH SCHOOL
14	FULL	LAB ANIMAL CARETAKER	HIGH SCHOOL
15	FULL	LAB ANIMAL CARETAKER	HIGH SCHOOL CERT/ELECTRIC
16	FULL	LAB ANIMAL CARETAKER	HIGH SCHOOL
17	FULL	VET. TECH MANAGER	ASSOCIATES DEGREE
18	FULL	LAB ANIMAL CARETAKER	HIGH SCHOOL
19	FULL	SR. LAB ANIMAL CARETAKER	UNIVERSITY
20	FULL	VETERINARY TECHNICIAN	ASSOCIATES DEGREE
21	FULL	LAB ANIMAL CARETAKER	HIGH SCHOOL

DIVISION OF COMPARATIVE MEDICINE

STANDARD OPERATING PROCEDURE

Written By: C. Novotney, D.V.M	Page: 1 of 5	SOP #: 3C-5
Approved By: C. Novotney, D.V.M	**SUBJECT: Biosafety guideline for work with USDA restricted pathogens (RP): viral agents Newcastle Disease Virus (NDV), a paramyxovirus and vesicular Stomatitis (VSV), an arbovirus**	
Supersedes: All prior SOPs	Revised: 03/24/2015	

SOP 3C7 Biosafety guidelines for work with USDA restricted pathogens (RP): viral agents Newcastle Disease Virus (NDV), a paramyxovirus and vesicular Stomatitis (VSV), an arbovirus.

Purpose:
The goal is to ensure that said viral agents, are not spread via liquid, aerosol or contact to any other areas or animals of the Basic Science Building Animal Facility. All work with animals infected with USDA restricted pathogens is to be contained within a specifically designated room as listed on the USDA permit. All work on animals or opened used/occupied animal caging is to be conducted in a dedicated class 2 Type 2A Biosafety Cabinet (BSC) in that room.

SPECIFIC INSTRUCTIONS:
Security:

Only personnel who have gone through the Institutional procedures to obtain ID cards will be admitted to the Basic Science Building. Only personnel identified on the IACUC approved protocol will have approved room access; doors will be locked at all times. No work other than RP will be conducted in the room

1. Birds and/or swine/sheep are not to be housed in proximity or on the same floor; staff working with RP will not also work with birds/sheep/swine.
2. Only disposable caging is to be used
3. Personnel Protective Equipment (PPE) is required.
    - Disposable lab coat
    - Hair bonnet
    - Mask
    - 2 pairs of disposable gloves

- Shoe Covers

4. PPE is supplied by DLAR and will be available directly outside
5. All PPE shall be removed in the room when done, placed in bin and autoclaved by DCM personnel.
6. All personnel working in the room must be familiar with BSL2 instructions and strictly observe them.
7. Virus-containing solutions are never to be left in the hood without a scientist/research technician present.
8. Procedure for manipulation of animals
    - Don proper PPE
    - Turn on biosafety cabinet and run for at least 5 minutes before conducting any work.
    - Spray the biosafety cabinet with an appropriate disinfectant i.e. MB-10 solution (Quip laboratories) before placing the cage in the cabinet.
    - Take filter top off cage and place face down on a disinfectant pre-soaked disposable towel.
    - Gloved hands are to be frequently dipped into an appropriate disinfectant between handling of materials paying special attention not to create aerosols and splashes.
    - After manipulation of the animal, place the water bottle, food and the filter top back on the cage before removing cage from biosafety cabinet.
    - Mark cage card with the time and date of viral injection or other procedures
    - Place cage back on the shelf rack.
    - Do not open the cage in the room unless cage is brought back to a pre-sprayed biosafety cabinet that has been running for at least 5 minutes.
    - Prepare two regulated medical waste (RMW) bags (one inside the other) that will be used for the infectious waste (if you are using sharps, also prepare a separate container for sharps disposal)
    - Use the RMW bags for the trash and when full, seal and transfer to the RMW bin outside the hood.
    - Do not touch anything out of the hood with your gloves.
    - After removing gloves, wash hands with soap and water.

9. Cage changing
    - Take a clean cage set-up to include bedding, food, water bottle and top to the holding room.
    - Turn on biosafety cabinet and allow to run for at least 5 minutes.
    - Place the cage in the Biosafety cabinet which has been sprayed previously with an appropriate disinfectant.
    - Remove the cage with animal from the rack and place under changing station.
    - Transfer the animal into the clean cage ensuring that your gloved hands have been sprayed with an appropriate disinfectant.
    - Replace the wire lid with food, bottle and filter top on the clean cage.
    - Place the clean occupied cage on rack.
    - Place the filter top back on the soiled cage and follow section (11) Disposal of caging

10. Procedure for moving animals out of housing room into lab
    - Don proper PPE.
    - Turn on biosafety cabinet and allow to run at least 5 minutes before conducting any work.
    - Spray the biosafety cabinet with an appropriate disinfectant before placing cage into the cabinet.
    - Place the appropriate size cage set-up with food, wire lid and filter top into the biosafety cabinet.
    - Make sure your gloved hands are frequently dipped into an appropriate disinfectant.
    - Take off the filter top of the soiled cage and place face down on a disposable towel that has been presoaked with an appropriate disinfectant.
    - Remove the filter top of the clean cage and place face down on a disposable towel that has been presoaked with an appropriate disinfectant.
    - Transfer the animal into the clean cage ensuring that your gloved hands have been sprayed with an appropriate disinfectant.
    - Replace the wire lid with food, bottle (if needed) and filter top on the clean cage.
    - Place the cage on a cart to be transported back to the lab.
    - Place the filter top back on the soiled cage and follow section (11) Disposal of caging.
    - The dedicated animal facility elevator #18 is to be used for transport
11. Disposal of caging
    - Don proper PPE
    - Turn on biosafety cabinet and allow to run for at least 5 minutes.
    - Spray the biosafety cabinet with appropriate disinfectant before beginning any work.
    - Place an autoclavable RMW bag in the biosafety cabinet
    - Place the soiled cage with filter top on under the biosafety cabinet.
    - Spray the outside of the soiled caging with appropriate disinfectant.
    - Place the CLOSED soiled cage with bedding, food and bottle and filter top in the RMW bag
    - Do not dump the bedding into the bag. Pay particular attention not to cause aerosol by slowly placing the disposable cage into the RMW bag. Seal the bag and remove from hood.
    - Each cage set-up will be placed into one autoclavable RMW bag and sealed.
    - Place the bagged cage in secondary container for transport the autoclave location.
    - Clean the BSC and place all items into an autoclavable RMW bag.
    - Remove PPE in the room and place into an autoclavable RMW bag.
    - Close the RMW bag.
    - Seal the bag and spray the outside of bag with an appropriate disinfectant.
    - RMW from the room will be removed, placed in a secondary container which may be a standard RMW box, transported and autoclaved by DLAR on a regular basis.

- After removing gloves, wash hands with soap and water.

12. Autoclaving cages and RMW bags
    - Place each individual bagged cage in autoclave from the dirty side.
    - Each "bagged cage" will have autoclave tape placed where technician can clearly visualize that cage was autoclaved properly.
    - Place bags of RMW in autoclave at the same time
    - When cycle is done remove bagged cages and bags and prepare for disposal using RMW boxes. All items autoclaved will be removed from the dirty side of cage wash and disposed of as RMW.

13. Maintaining Daily Activity Sheet
    - A Daily Activity Sheet will be placed outside the room on the shelf containing PPE.
    - Animal care staff is responsible for checking off tasks daily (including weekends).
    - Animal care staff will check health of animal and ensure that ample amount of food and water is available to the animal.
    - Research staff is responsible for maintaining a clean work place.

14. DLAR Responsibilities
    - Sanitizing the room when empty.
    - Providing PPE, disinfectant, RMW autoclavable bags, and disposable towels.
    - Providing clean cage set-ups (cage, wire lid, food, bottle and filter top) in holding rooms as well as outside.
    - Cage changing
    - Removing RMW bag from 2-62.
    - Transporting soiled cages in a secondary container to basement for autoclaving.
    - Transporting and processing dead animals in autoclave.
    - Autoclaving bagged cages and RMW bags.
    - Monitoring room environmental conditions.

15. Disposal of carcasses
    - If rodent dies and they are housed separately, or if all animals housed in the cage die collectively, the closed cage with dead animal(s) will be placed in an autoclavable RMW bag and placed in the secondary container for transport process and autoclaving cages as stated in section (11).
    - For paired or group housed rodents, when one or more dies the cage must be taken to the biosafety cabinet which has been running for at least 5 minutes. Appropriate PPE will be donned and animal will be removed with forceps that have been soaked in appropriate disinfectant. Animal will be placed in an autoclavable RMW bag and autoclave tape will be attached to the bag. The animal will then be placed in the secondary transport container and autoclaved in the animal facility.

- The biosafety cabinet work surface or other room surfaces that may have had contact with the dead animal or cage contents will be sprayed with appropriate disinfectant.
- Once processed in the animal facility, animals will be disposed of as RMW.

16. Decontamination of room
    - Appropriate PPE and other relevant safety procedures should be in place to avoid over-exposure and contact by personnel involved with decontamination procedures.
    - Rooms requiring decontamination should be emptied of all disposable items such as paper records.
    - Gross filters should be replaced on workstations, and room air ducts.
    - All items and instruments in the room that require re-use including caging are placed in sealed containers and removed and sanitized and/or sterilized. Records required to be held, that may be contaminated and that cannot undergo verifiable decontamination, should be placed in sealed plastic and stored in the facility office.
    - Items in the room such as open racks, carts, workbenches and work stations are cleared/emptied of all movable items and left in the room.
    - Sanitation procedures are initiated by saturation spraying down of rack, cart, work surfaces all surfaces in the room with an appropriate Chlorine or quaterinary ammonia based disinfectant.
    - Wall, floor, and ceiling surfaces are sanitized by initial use of a quaterinary ammonia detergent disinfectant (do not mix or overlap use of ammonia and chlorine disinfectants due to potential release of chlorine gas) followed by adequate contact time of at least 20 minutes, followed by rinse/wet mop or sponge removal of the initial application. The room is left to dry for 24 hours.

17. HVAC - the designated room is supplied with 100% non-recirculated air exhausted to the outside without recirculation to other corridors. The BSL2 hood present in the room cannot be directly vented to the exhaust.

18. Backup Power – all housing rooms have back up power which will automatically switch over in a power failure

SECTION II – WASTE Disposal
SUNY Downstate Medical Center A137

SOP #	SOP Subject/Title	Revised Reviewed Date
S-1002	EPA Compliance policy for chemical waste disposal	11/2014
S-1003	Chemical waste management system for laboratory & industrial chemicals	12/2017
S-1101	Handling & disposal of regulated medical waste	11/2014
S-1103	Disposal of sharps	11/2014
S-1201	Animal Waste Disposal	11/2014
S-1205	Disposal of Cytotoxic Drugs	11/2014

SUNY DOWNSTATE MEDICAL CENTER
FACILITIES MANAGEMENT & DEVELOPMENT
STANDARD OPERATING PROCEDURE

SUBJECT: *EPA COMPLIANCE POLICY FOR CHEMICAL WASTE DISPOSAL*

SOP NO#: S-1002
ASSIGNED TO: All Departments

DATE PREPARED: 09/86
REVISED/REVIEWED DATE: 11/2014

PREPARED BY: BRIAN PITT

LOCATION: University Hospital, Midwood, Bedford Stuyvestant, Crown Heights, and Dialysis Center

REVIEWED BY: TIM HERZOG

INTRODUCTION:

SUNY Downstate Medical Center (DMC) is engaged in patient care, teaching, and research. The Center generates between 100 kg and 1000 kg of hazardous chemical waste per month from it's over 200 laboratories. Waste is shipped off-site in 90 days or less by an EPA licensed contractor for eventual disposal at an EPA approved facility. Waste is placed into containers of durable integrity and held for removal in the DCM Chemical Storage Room. The Chemical Storage Room meets all NFPA, NYSDEC and EPA standards (two-hour rated doors and walls, non-friction light switches and fixtures, sprinklers, and an elevator door saddle to contain spill). The entrance is located on the Loading Dock for easy access and removal.

PERSONNEL TRAINING:

The DMC has a staff of professional employees to oversee the management of hazardous waste removal. These employees have experience and training in fire and chemical safety and hazardous spill clean-up procedures.

The Center engages in a variety of training activities including the required RCRA/ DOT certification requirements.

An active, comprehensive education "Right-to-Know" program is offered by the Office of Environmental Health & Safety in chemical and fire safety for the DMC community. Clinical, laboratory, maintenance support, and professional staff receive fire safety training. Comprehensive training is being implemented for all employees who handle hazardous materials from laborers at the Loading Dock to laboratory personnel.

General spill procedures have been formulated and distributed to all affected areas and contingency plans formulated for spills occurring during non-business hours.

FIRE ALARM SYSTEM:

The DMC has an addressable audio visual interior alarm system serving all buildings. The alarm can be activated automatically by smoke detection, waterflow detection or manual pull

station within all corridors. All alarm signals are transmitted via a central Monitoring Station to the New York Fire Department.

The DMC has an active Fire and Disaster Plan whose implementation can readily be put into effect. The fire alarm system continuously monitored. Periodic testing of smoke detectors, annunicator panels, sprinkler and standpipe systems and other components of the fire alarm system are documented.

PREPAREDNESS AND PREVENTION:

The Chemical Storage Room is locked and access available only to authorized personnel. No chemicals are poured or transferred from containers. All storage containers are used only for compatible chemicals and are suitable in volume for their contents. Smoking and other ignition sources are not permitted in the Chemical Storage Room and "No Smoking" signs are affixed to the entrance.

REQUIRED AISLE SPACE:

The Center maintains its corridors and aisles in a condition such that personnel, fire protection equipment, spill control equipment, and decontamination equipment may be transferred to other parts of the facility in an emergency situation.

ARRANGEMENTS WITH LOCAL AUTHORITIES:

Police, fire, and other emergency response personnel are both directly summoned and guided to the site of the emergency by Public Safety. Officers are trained to respond to emergency situations and direct emergency personnel to the site of the problem. In the event of a disaster (e.g. fire or explosions) emergency medical treatment can be provided at **Downstate Medical Center and/or Kings County Hospital Emergency Departments.**

RECORDKEEPING:

All manifests are completed as per Department Of Transportation guidelines. Records are permanently retained and available for inspection by the appropriate authority. The manifests include:

- An EPA identification number, name, and address of the facility
- The calendar year of the manifest
- The name and EPA identification number of the disposal contractor
- A description and the quantity of the hazardous waste the facility generates
- The method of treatment, storage, and disposal of the hazardous waste

Both quarterly and yearly tax assessments are processed and sent to the NYS Department of Taxation. An annual generator's report of hazardous waste if filed with DEC and retained for the record.

REDUCTION OF WASTE:

The institution seeks to develop a more efficient means of reducing hazardous waste. At the current time, the following procedures are practiced:

- Redistribution of chemicals occurs on both a formal and informal basis amongst member laboratories
- Recycling of recoverable waste, (e.g. silver nitrate, mercury)
- Distillation of contaminated organic solvents is performed in some laboratories. If cost effective in the future, an industrial recycler of solvents may be considered

SUNY DOWNSTATE MEDICAL CENTER
FACILITIES MANAGEMENT & DEVELOPMENT
STANDARD OPERATING PROCEDURE

SUBJECT: *CHEMICAL WASTE MANAGEMENT SYSTEM FOR LABORATORY & INDUSTRIAL CHEMICALS*

DATE PREPARED: 10/03
REVISED/REVIEWED DATE: 12/17

SOP NO#: S-1003
ASSIGNED TO: All Departments

PREPARED BY: Charmane Meghan

REVIEWED BY: Brian Pitt, Jonathan Carrelli

LOCATION: Campus-wide

INTRODUCTION:

Every person who uses chemicals is a "generator". All those who generate such waste are required to see that the waste is handled and disposed of in ways that pose minimum potential harm, both short and long term, to health and the environment.

This hazardous waste management system assures full compliance with the strict United States Environmental Protection Agency (USEPA) and the NYS Department of Environmental Conservation (NYSDEC) Laws, under the authority of the Resource Conservation and Recovery Act (RCRA), which established a "cradle to grave" system for the management of hazardous wastes.

These recommendations are based on successful application of scientific concepts that reduce or eliminate negative environmental impacts of laboratory waste. Many of these concepts have been known and utilized for years prior to the hazardous waste regulations. It is important that everyone comply with all regulations in force at any given time.

The Office of Environmental Health & Safety is responsible for performing the following:

- Identification of unknown chemicals into proper compatibility groups
- Proper packaging of chemical by compatibility groups
- Safe handling of chemicals
- Identification of hazardous waste

HAZARDOUS CHEMICAL WASTE MANAGEMENT SYSTEM:

Chemical waste generated, at the Health Science Center, are disposed of as hazardous through the Hazardous Chemical Waste Management System. It involves identification, labeling, packing, and handling.

A "hazardous waste" is a waste, or combination of wastes, which because of quantity, concentration, toxicity, corrosiveness, mutagenicity, flammability, chemical, physical, or infectious characteristics may: 1) cause, or significantly contribute to an increase in mortality or an increased in serious irreversible, or incapacitating reversible illness; or 2) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of or otherwise managed.

There are four (4) elements that are essential to any hazardous waste management system: 1) commitment of the investigation to the principles and practices of good waste management, 2) a waste management plan, 3) assigned responsibility for the waste management system, and 4) policies and practices directed to reducing the volume of waste generated in the laboratory.

1. The Hazardous Chemicals Waste Management System is Designed to Achieve Several Goals:
   A. Protection of Employee Health & Safety
      Proper evaluation, packaging, and labeling of chemicals for waste disposal protect the health and safety of employees handling hazardous chemical waste.
   B. Reduction of Hazardous Chemicals Waste throughout HSCB
      The volume of hazardous chemical waste generated at the Center can be reduced by:
      - Ordering chemicals only in quantities required for the specific use.
      - Planning every experiment so as to include consideration of the waste disposal problems:
        - Can any material be recovered for reuse?
        - Is there the possibility of replacing a hazardous reagent or solvent with one that is less hazardous:
        - Segregate any non-hazardous waste from the hazardous waste to keep the total material to a minimum.
      - Maintenance of Reagents - deterioration of labels is a common occurrence on old reagent containers. If the reagent or container has not deteriorated, the container should be relabeled. If a reagent container labels obliterated and the contents unknown, this material must be prepared for disposal.
      - Reduction of the Scale of Experiments - the use of micro-technology in the study of chemical reactions can lead to significant savings in costs of chemicals, energy, apparatus, and space. Such technology makes it possible to optimize, on a small scale, the conditions for a reaction that is to be carried out on a preparative scale so that the latter gives a high yield with minimum by-products.
      - Control of Reagents that can Deteriorate - uncontrolled accumulation of excess reagents can create storage problems and safety hazards. Chemicals that are prone to deteriorate with time can pose increasingly difficult disposal problems. Deteriorate sample of water-reactive chemicals and pyrophoric chemicals should not be allowed to remain in the laboratory. Severe hazards can be caused by peroxide-forming chemicals that have not been dated at the time limits after opening.
      - Prevention of Orphan Reaction Mixtures – Laboratory glassware containing reaction mixtures of unknown nature and sometimes of unknown origin, and pose difficult disposal problems. A laboratory chemical in a container with a missing label must be characterized as general type (e.g. aromatic hydrocarbon, chlorinated solvent, mineral acid, soluble metal salt), so that it can be disposed of safely and properly. It will generally suffice to carry out the preliminary steps of the well-known "Systematic Identification of Organic Compounds.
      - Elimination of Non-Hazardous Waste from Hazardous Waste – the following items are not considered to be hazardous. They should be collected in disposable containers or plastic bags, clearly labeled as non-hazardous waste, and put in the trash. Additional Non-Hazardous Waste determinations are provided by the Office of Environmental Health & Safety.
        - Non-Hazardous Waste

Ammonium Phosphate	Sodium Chloride
Calcium Carbonate	Sodium Citrate
Calcium Phosphate	Sodium Sulfate
Calcium Chloride	Sugar: Dextrose, Fructose
Citric Acid	Lactose, Sucrose
Chromatographic Absorbent	Pipettes and other
Lactic Acid	Glassware
Magnesium Sulfate	Potassium Carbonate
Sodium Bicarbonate	Potassium Chloride
Sodium Carbonate	Filter Paper w/o Chemical Residue

C. Compliance with Regulations – Federal, State, and Local

The chemical waste disposal policy at HSCB is in compliance with the United States Department of Transportation (DOT), the United States Environmental Protection Agency (EPA), and the New York State Department of Environmental Conservation (DEC) regulations regarding packing, labeling, and disposal of hazardous chemical wastes.

D. Exempt Waste

In addition to hazardous chemical waste, there are five (5) other types of wastes generated at HSCB. The Hazardous Chemical Waste Management System does not include any of these other types of wastes, which are:

- Non-hazardous Solid Waste – examples: garbage, rubbish, paper or cardboard refuse, non-contaminated glass
- Regulated Medical Waste – see Infection Control Manuel and separate Policies and Procedures
- Low-level Radioactive Waste – see Radiation Protection Manual
- Antineoplastics – see separate Policies and Procedures
- Asbestos Waste – see separate Policies and Procedures

E. Hazardous Chemical Waste Management Begins in the Laboratory

- Classify all liquid and residual waste into hazard and non-hazard categories
- Package all hazardous wastes according to compatibility groups
- Label all containers as prescribed
- Maintain detailed inventory records

F. Methods for Packing Wastes

- The method for disposal of laboratory wastes is the "Lab Pack"' (Packaged Lab Chemical). A 55-gallon open-top steel drum is filled with small containers or chemicals packed in and separated by an absorbing medium. All "lab packs" are in DOT specification drums (DOT 17h or 17c). All outside drums are metal, except for "F" compatibility drums, which use a 30-gallon fiber drum. The drums are of the open-head variety to allow the proper placement of the inside containers and absorbent. Inside containers are non-leaking and tightly secured sealed. Each bottle is over-packed and surrounded by a sufficient quantity of absorbent material to completely absorb liquid contents of all inside containers. In addition, the drum is full after packing with the inside containers and absorbent material to prevent breakage of inside container. The EPA prohibits the placement of incompatible wastes in the same outside container. The purpose of this restriction is to prevent any potentially dangerous reaction between the

wastes packaged in the same lab pack. The stipulation that incompatible wastes not to be packaged together is met by DOT classes and shipping requirements to designate the contents of containers i.e. one drum for flammable, one drum for corrosive.

- Non-chlorinated bulk solvents that are known to be relatively pure are packaged in 55-gallon steel bunk-type drums (DPT 17E).
- Shock-sensitive compounds and water reactive compounds receive special handling and are manifested for disposal individually.

2. Employee Health and Safety:
   A. Laboratory Personnel
      - Each laboratory shall provide suitable temporary containers for the chemical wastes (i.e. 1-gallon glass screw-cap bottles).
      - Waste solvents shall be collected separately by type. Chlorinated hydrocarbons shall be separated from non-chlorinated hydrocarbons.
      - Flammable and combustible liquid waste shall be collected in accordance with HSCB policies and procedures for the safe handling and storage of flammables.
      - Chemical waste reduction procedures should be carried under the following conditions:
        - Use safety goggles or a full face shield, aprons, gloves or a bench shield while pouring, mixing, or reacting chemicals.
        - When chemicals are being moved, they should be carried in approved secure containers to avoid accidental spillage resulting from broken containers.
        - Personnel shall be familiar with applicable emergency procedures and equipment when processing waste.
        - Any injurious substance spilled on the skin or body, or splashed in the eyes, should be washed off immediately with copious quantities of water. Any clothing that has been contaminated with an injurious substance should be removed immediately and not used again until it has been washed. After skin and/or eye have been cleansed with large quantities of water, employees are to report the incident to their supervisor and immediately go to the employee health center for treatment.
        - Appropriate personnel protective equipment, (i.e. eye protection, rubber gloves, lab coat, organic vapor respirator or a full body suit) must be worn whenever handling hazardous chemicals for disposal.
      - Direct discharge of toxic or hazardous materials (i.e. drying reagents saturated with flammable solvents) to the sewer or trash containers is prohibited.
      - Custodial employees must be considered when discarding solid wastes. These persons do not and should not expect to have hazardous chemical waste in wastebaskets.
      - All non-hazardous chemical waste, (i.e. magnesium sulfate, sodium sulfate) must be placed in disposable containers or plastic bags and clearly labeled as non-hazardous waste before it is placed in the wastebaskets.
      - Absolutely no hazardous chemical waste should be flushed down the sink drains.

   B. Maintenance Personnel

- Maintenance personnel should take proper precautions when working with solvents for painting or degreasing by wearing a vapor respirator, eye protection, and a protective apron when pouring or handling these solvents.

3. Purchasing, Use and Disposal:
   A. Safety Recommendations
      - If possible, purchase chemicals in class-size quantities only.
      - Laboratory personnel are to label all chemicals accurately with date of receipt or preparation, initialed by person responsible and pertinent precautionary information on handling.
      - Generally, bottles of chemicals should not remain unused on shelves in the lab for more than one week, in the storeroom near the lab unused for more than one month, or in the stockroom unused for more than one year.
      - Follow all directions for disposing of residues and unused portions of reagents.
      - Properly store flammable liquids in small quantities in containers with a provision for bonding to receiving vessels when the liquid is transformed.
      - Never open a reagent package until the label has been read and completely understood.
      - Have a material safety data sheet (MSDS) on hand before using a chemical.
      - Prepare a complete list of chemicals of which you wish to dispose, using the chemical waste disposal form obtainable from the Office of Environmental Health & Safety.
      - Unlabeled bottles (a special problem) must be identified to the extent that they can be classified as hazardous or non-hazardous wastes.

   B. Substitutions
      - Reduce risks by diluting substances instead of using concentrates.
      - Use micro-semi-micro techniques instead of macro-techniques.
      - Use film, videotapes, and other methods rather than experiments involving hazardous substances.
      - Undertake all substitutions with extreme caution.

4. Identification, Classification, and Segregation of Medical Center Chemical Waste:
   Chemical wastes generated by the Medical Center laboratories, shops, and custodial services, as well as abandoned reagents, outdated medical and art supplies, solvents, thinners, oils, cleaning fluids, and their containers, shall be identified, labeled, packaged and disposed in compliance with regulations of the NYS DEC, the US EPA, and the US DOT.

   A. Collection and Segregation
      - Each laboratory or shop shall provide suitable, temporary containers for the collection of chemical wastes. Waste solvents shall be collected separately by type. Chlorinated hydrocarbons shall be separated from non-chlorinated hydrocarbons. Flammable and combustible liquid waste shall be collected in accordance with the University policies and procedures for the safe handling and storage of flammable and combustible wastes.
      - Temporary storage containers for solvent accumulation should be 1-gallon to 5-gallon safety cans outside of a hood. One-gallon glass containers can be used inside of a hood for collection of waste solvents. For lab packs, collect each

hazardous chemical waste in a separate screw-cap container. Use the smallest waste generated. The maximum acceptable container size is 1-gallon. The container the chemicals were originally shipped in is an ideal waste collection container, if it is an appropriate size. All waste containers must be tightly capped and labeled with the chemical name of the substance including the percentages of mixture. A solid waste disposal form is to be completed.

- Waste acids and alkalines shall be collected in appropriate glass containers with screw caps.
- Solid waste chemicals shall be collected in appropriate screw-cap glass bottles.

B. Identification and Labeling

Once material is declared as waste, the first responsibility for guiding its proper disposal lies with the laboratory and shop personnel. All waste chemical containers must be labeled and a waste pick-up request placed with Environmental Health & Safety when waste container is 90% full.

Waste Chemical Categories

Reactive Waste Chemical	Waste Chemical
1. Water reactive alkali metal: hydrides, peroxides, carbides – sodium/ potassium metal, sodium hydride, lithium hydride, sodium peroxide, calcium carbide	1. Inorganic acids, elements, inorganic salts: materials that do not liberate gas upon acidification
2. Organic oxidizers: benzoyl peroxide, dicumyl peroxide	2. Inorganic alkalies, non-flammable organic bases FP>130 F, includes heavy metal elements/compounds (mercury), materials that liberate gases upon acidification – sulfides, free/complex cyanide
3. Shock sensitive/explosives: diazo compounds, azides, fulminates, organic di/tri nitro compounds – diazo benzene chloride, lead, azide, mercury fulminate hydrazines, trinitro phenol (picric acid)	3. Organic solids and liquids FP>130F, includes organic acids (phenol, chloroform, acetic and formic acids) but excludes organic bases
4. Pyrophorics: elemental phosphorous, organo metallics (lithium, diethylzinc, ethyl magnesium iodine)	4. Flammable organic liquids and butyl organic bases FP>130 F (acetone, pyridine, toluene) but excludes organic acids
5. Water reactive acidic: chlorosilanes, acid halides, phosphorus halides, (methyl trichlorosilane, acetyl chloride, phosphorous trichloride)	5. Inorganic oxidizers: permangates, perchlorates, bromine, chromerge, chlorates, chlorites, nitric acids
	6. Highly toxic organic liquids/ solids: chlorophenols, carcinogens, chlorinated benzo furans, pesticides
	7. Alkaline sensitive compounds and pseudo metals: As, Se, Bi, P

All containers must be labeled describing the contents. The following information must be on each container:

- Chemical name (for mixtures, list constituents and percentages)
- Generator name or laboratory contact person
- Generator phone number
- Generator department

Identification such as "Waste Chemicals" or "Unknown" is not acceptable.

C. Removal

- Waste chemicals shall be brought by the Chemical Storage Room located at the BSB Loading Dock (basement level) by the Chemical Safety Officer. A licensed contractor picks up the waste for eventual disposal/treatment at an EPA approved toxic waste site.
- The Chemical Safety Officer will later sort all chemicals into drums and see that each drum of hazardous waste is marked and labeled in accordance with DOT regulations.
- Each drum has the following labels:
  - An US EPA – approved hazardous waste label
  - An US DOT – approved hazardous class label, when appropriate, i.e. flammable, corrosive, poison, etc.

D. Compatibility Groups

- Classification into compatibility groups provides the necessary information for disposal of waste off-site, either in Packaged Lab Chemicals (or PLs) for secure landfill disposal or as solvents for incineration.
- The EPA regulations place on the waste generator the burden of determining whether a waste is hazardous and in what hazard classification it falls. In most cases, the laboratory worker should be able to provide enough information about the waste to allow the hazard classification to be assigned.
- If the waste is not a common chemical with known characteristics, enough information about it must be supplied to satisfy the regulatory requirements and to be certain that it can be handled and disposed of safely.
- For many wastes, only the principal ingredient need be specified; however, if the waste contains a carcinogen or a heavy metal, this information should be supplied.

E. Storage

- Hazardous waste is accumulated by compatibility group in the Chemical Storage Room off the BSB Loading Dock.
- The waste is stored in durable containers for a period of 90 days or less, the area used for storage or hazardous waste is inspected quarterly for housekeeping, container integrity, and safety, and emergency equipment.

F. Uniform Hazardous Waste Manifest

- EPA Resource Conservation and Recovery Act (RCRA) regulations presently require generators who transport or offer hazardous waste for transportation for off-site treatment, storage, or disposal, to prepare a manifest, which must accompany the waste. The DOT and the EPA have designed a Uniform

Hazardous Waste Manifest form, which all States have adopted and put into effect as of 09/24/84.

- The Uniform Hazardous Waste Manifest is prepared and signed by the Office of Environmental Health & Safety for all hazardous waste shipments from the Health Science Center. (Attach a copy of Hazardous Waste Manifest form)

G. Waste Oils

- Various HSCB departments generate waste oils, which do not possess hazardous waste characteristics as defined by US CFR 40 Part 261. These oils may be disposed as a waste mineral (motor) oil.
- The following authorization procedure has been developed to eliminate confusion about whether or not a waste oil is hazardous:
    - Generators of waste oil are to call the Office of Environmental Health & Safety at x1216 or x2395, which will determine by information as to source or sampling whether or not the waste oil is in a hazardous class.

SUNY Health Science Center at Brooklyn
Office of Environmental Health & Safety
INTERNAL MANIFEST FOR HAZARDOUS WASTE DISPOSAL

Prepared By: _____

Page _____ **of** _____

Date: _____ **Department;** _____ **Building:** _____ **Room:** _____

Principal Investigator: _____ **Phone:** _____ **Initials:** _____

Container			RCRA Category			
Size	How many?	Chemical Name	Listed?	Code	CAS No.	Remarks

SUNY DOWNSTATE MEDICAL CENTER
FACILITIES MANAGEMENT & DEVELOPMENT
STANDARD OPERATING PROCEDURE

SUBJECT: *HANDLING & DISPOSAL OF REGULATED MEDICAL WASTE*

SOP NO#: S-1101
ASSIGNED TO: University Hospital & Satellite Clinics

DATE PREPARED: 09/86
REVISED/REVIEWED DATE: 11/2014

PREPARED BY: BRIAN PITT

LOCATION: University Hospital, Midwood, Bedford Stuyvestant, Crown Heights, and Dialysis Center

REVIEWED BY: TIM HERZOG

PURPOSE

To establish minimum requirements for the proper handling, disposal, and storage of regulated medical waste (RMW) including substances and materials emanating from teaching and research activities. Adherence to this policy will prevent the exposure of employees and the publics to infectious materials, in compliance with RMW regulations.

DEFINITION OF REGULATED MEDICAL WASTE

1. Materials that are discarded from treatment of patients on isolation, other than patients on reverse or protective isolation:
   - Surgical waste.
   - Obstetrical waste.
   - Biological waste, which consists of discarded excretions, exudates, secretions, suctionings, syringe and other disposable medical supplies which have come in contact with these substances and cannot be discarded directly into a sewer.
   - Any disposable item contaminated with the isolation patient's blood.
2. Pathological wastes consisting of human tissues, body fluids and their containers, and anatomical parts discarded from autopsy, surgery or other medical procedures.
3. Waste that was in contact with the blood of from patients receiving renal dialysis.
4. Discarded serums vaccines (not autoclaved).
5. Cultures and stocks of infectious agents and associated biological, including culture dishes and devices used to transfer, inoculate and mix cultures.
6. Pathogen-contaminated animal and waste materials.
7. Discarded laboratory waste, which has come in contact with pathogenic organisms.
8. Animal carcasses exposed to pathogens and their bedding and wastes.
9. Human blood and blood products.
10. Other articles being discarded that are potentially infectious and that might cause punctures or cuts including sharps such as scalpels, hypodermic needles, intravenous needles, and intravenous tubing with needles attached, that have not been autoclaved or subjected to a similar decontamination technique and crushed or otherwise rendered incapable of causing punctures or cuts.
11. Items, which are dripping with blood or are caked with dried blood.

PACKAGING OF REGULATED MEDICAL WASTE

1. Sharps - puncture resistant, spill-proof container labeled "infectious," or colored red.
2. Surgical pathology waste – fiber drums with red bagged liners labeled with the name and address of the facility and must contain 2 floatable identification tags

3. Other wastes - red bags resistant to ripping, tearing and bursting. Each bag must be imprinted with the name and address of institution.
4. In transit from generator to disposal/treatment site, wastes must be placed in cartons or drums, labeled with the legend "Infectious" or "Regulated Medical Waste" and marked with the name of the generator + transporter + shipping data.
5. All bags used for the containment and disposal of regulated medical wastes shall be red in color.

HANDLING OF REGULATED MEDICAL WASTES

1. Employees in charge of areas where infectious and other regulated medical wastes are generated shall coordinate waste pick up schedules with the Director of Environmental Services.
2. Custodial employees who handle infectious and other regulated medical wastes are required to attend in-service training conducted by the Department of Epidemiology. Such attendance will be arranged and ensured by the department head. They must also participate in the immunization program.
3. Red bags shall not be loaded to more that ¾ capacity.
4. Red bags and containers are to be transported from the source to the Basic Science Building Loading Dock in fiber drums with lids. Only freight elevators are to be used when moving infectious wastes between floors; use of passenger elevators and trash chutes is prohibited.
5. From trash carts, the red bags and containers are placed in the designated dumpster for regulated medical waste. The dumpster is removed by a licensed waste transporter and delivered to an EPA/DEC approved waste treatment site for destruction.

STORAGE:

1. Short – term storage of RMW in trash cares at source points must not exceed 24 hours on patient room floors or 72 hours in clinical laboratories.
2. All RMW collected from laboratories shall be delivered by housekeeping personnel to the Basic Science Building Loading Dock for removal. Each barrel shall be labeled "Infectious Waste" or "Regulated Medical Waste" including the name and address of the institution.
3. Infectious and other regulated medical waste shall not be stored on the premises for more than 30 days.

TREATMENT OF INFECTIOUS AND OTHER REGULATED MEDICAL WASTES

1. By incineration at an infectious waste incineration facility approved and under permit pursuant to Article 19 of the Environmental Conservation Law, which provides for complete combustion of the waste to carbonized or mineralized ash. Infectious waste so destroyed and rendered noninfectious shall be disposed of as non-hazardous waste provided it is no an otherwise hazardous waste.
2. Regulated medical waste must be treated and destroyed beyond recognition prior to handling as regular waste. The treatment process may be autoclave or another approved decontamination process.
3. By discharge to the sewage system if the waste is in liquid or semi-liquid form, unless specifically prohibited by the State Health Commissioner when such discharge may pose a threat to public health.
4. Pathological wastes consisting of recognizable human anatomical remains shall not be disposed of by burial at a landfill disposal facility, but shall be disposed of by incineration or interment unless burial at a landfill is specifically approved by the Department of Environmental Conservation.

TRANSPORT AND DISPOSAL OF INFECTIOUS WASTE

1. Arrangements for transport and disposal shall be the responsibility of Environmental Services.
2. The New York State four-part manifest form shall be generated by Environmental Services when each load is removed by the transporter.
3. The manifest form procedure is:
   - 3 parts to the transporter; 1 part kept by Environmental Services
   - After the transporter delivers the load for destruction, he/she ensures that the three copies are signed by the incinerator and one is returned to the Hospital. After destruction the third copy is signed by the incinerator manager and returned to the Hospital.
     - o If the Hospital does not receive the third copy in 15 days, Environmental Services contacts the transporter.
     - o If the Hospital fails to get the final form in 30 days, Environmental Services contacts the DEC and details recovery effort.
4. Environmental Services shall maintain logs and records for 3 years.

RESPONSIBILITIES

Quality Assurance

1. Department Heads and Administrators shall be responsible for the proper disposal of infectious waste generated in their work areas by notifying the Environmental Services for clinical areas or Building Services in Non-clinical area to arrange collection and schedule (containment, quantity, frequency, precautions, mode of disposal, etc.)
2. Prescribed protective equipment (gloves, masks, etc.) shall be provided by each department and must be worn during the handling of regulated medical waste.
3. The Director of Environmental Services shall arrange an annual in-service training on handling of infectious and other regulated medical wastes through the Epidemiology Department.
4. The Directors of Environmental Services and Building Services shall review handling procedures/systems and institute improvements as necessary to ensure compliance with regulations and standard practices.

Principal investigators and laboratory supervisors are responsible to ensure compliance with the above policy and procedures. Each department is encouraged to develop its own procedure over and beyond these minimum requirements.

SUNY DOWNSTATE MEDICAL CENTER
FACILITIES MANAGEMENT & DEVELOPMENT
STANDARD OPERATING PROCEDURE

SUBJECT: *DISPOSAL OF SHARPS*

SOP NO#: S-1103
ASSIGNED TO: University Hospital & Satellite Clinics

DATE PREPARED: 09/86
REVISED/REVIEWED DATE: 11/2014

PREPARED BY: BRIAN PITT

LOCATION: University Hospital, Midwood, Bedford Stuyvestant, Crown Heights, and Dialysis Center

REVIEWED BY: TIM HERZOG

"Sharps" (any object that may cause punctures or cuts, particularly annuals or syringes with needles attached) are required to be disposed of separately from regular trash. In sealable, leak proof containers.

To achieve compliances with local laws as well as prevent infection and accidental injury to primary and support staff, clinical departments as well as research laboratories are to dispose of "Sharps" using special impervious plastic containers.

Central Sterile Service, in the basement of University Hospital (UHB Room AB-474, Ext. 4010, 2877) will coordinate the supply of containers to hospital laboratories as well as University Hospital and clinical departments.
The Office of Building Services coordinates the placement and pick-up of sharps containers in the Basic Sciences Building and Health Science and Education Building.

UNIVERSITY HOSPITAL OF BROOKLYN

A. Nursing Stations and Operating Rooms
- The Sharp Containers are periodically picked up and replaced by a licensed disposal contractor.
- Waste shall be transported in such a manner as to ensure a sanitary and hygienic environment throughout the medical center. Trash carts shall be enclosed or covered with a drop cloth and cleaners will have available a disinfectant, mop, and wipe cloths. Drippings or spillage are to be promptly cleaned up.
- Both the trash carts and the trash collection areas are to be cleaned and disinfected on a regular basis.

B. Clinical Areas and Laboratories

Procurement:
- Hospital personnel are to call Central Sterile Supply and request sharps containers placement.

Disposal:
- Containers for needles and syringes are provided by the contractor.
- Contractor picks up filled containers at least once a week and provides new containers.
- Sharps contractor takes filled containers to their facility for disinfections and treatment.
- Waste shall be transported in such a manner as to ensure a sanitary and hygienic environment throughout the medical center.

BASIC SCIENCE BUILDING & HEALTH SCIENCE EDUCATION BUILDING

1. **Procurement:**
   - It shall be the responsibility of the principle investigator to ensure adequate supply of sharps containers.
2. **Disposal**:
   - When filled, lab personnel are to check that container lids are tightly sealed and the outside of the container is free of any waste material.
   - The contractor picks up filled containers and provides new containers.
   - The contractor takes the filled containers to their facility for disinfections and treatment.
   - The drums are marked with name and address of SUNY-DMC and information about the transporter, its permit and date of shipment.
   - The transporter picks up labeled fiber drums and transports them to an approved treatment facility.
   - A waste manifest is prepared to cover shipment, and shall be countersigned by transporter and by supervisor of treatment facility. If we do not receive signed manifests from treatment facility within 45 days, we must report incident to EPA, NYS-DOH and NYS-DEC.

Surgical Experiments (non – infectious)

1. Animal Carcasses and Body Parts:
   The principle investigator place waste material in red plastic bags that bear the name and address of the SUNY DMC. The bags are sealed tightly and placed in a fiber drum lined with a red plastic bag also bearing the HSCB name and address.
2. Bedding and Waste
   - DCM personnel clean cages
     - Dogs: daily
     - Small Animals: twice a week
     - Farm Animals: three times a week
   - Bedding and waste collected by DCM employees are placed in drums lined with a thick plastic garbage bag to reduce odors and prevent insect infestation.
   - The drum is taken to the Basic Science Building loading dock on the DCM dedicated elevator.
   - Allied Sanitation picks up the waste for disposal at an approved dumpsite.
   - The Loading Dock is washed down and disinfected daily.

SUNY DOWNSTATE MEDICAL CENTER
FACILITIES MANAGEMENT & DEVELOPMENT
STANDARD OPERATING PROCEDURE

SUBJECT: *ANIMAL WASTE DISPOSAL*

SOP NO#: S-1201
ASSIGNED TO: Division of Laboratory Animal Research

DATE PREPARED: 09/86
REVISED/REVIEWED DATE: 11/2014

LOCATION: University Hospital, Midwood, Bedford Stuyvestant, Crown Heights, and Dialysis Center

PREPARED BY: BRIAN PITT

REVIEWED BY: TIM HERZOG

The Division of Comparative Medicine (DCM) is responsible for the care of all animals used in the medical center research projects. Animal care facilities are located primarily on the eighth and ninth floors of the Basic Sciences Building (BSB). A smaller number of animal rooms are located throughout BSB.

A. Radioactive Animal Waste

The DCM must be given prior notification of any project, which will involve the quartering of an animal that has been given radioactive materials. In experiments were radioisotopes have been used the Principal Investigator will:

- Collect the animal carcasses, pathological tissue, bedding, and waste. Disposable gloves are to be used and treated as radioactive waste.
- The Principal Investigator places the waste material (carcasses, pathological tissue, bedding, and waste) in plastic pails lined with a mil plastic bag. The waste is treated with lime and absorbent. The waste is then brought to a collection point designated by the Department of Radiation Physics Lab.
- A contractor that is licensed to handle and transport radioactive waste will pick up the waste and take it to an approved disposal facility.

B. Infectious Agents

- Animal carcasses, body parts, bedding, and waste are placed in autoclave bags by the Principal Investigator. Autoclaving is done as indicated.
- The tightly sealed bags are placed in fiber drums lined with red bag that bears name and address of facility. When the drums are full. They are tightly sealed with a lid. DCM custodial employees transport the drums to the BSB Loading Dock for pick up by a licensed hauler.
- The drums are marked with name and address of SUNY HSCB or UHB and information about the transporter, its permit and date of shipment.
- The transporter picks up labeled fiber drums and transports them to an approved treatment facility.
- A waste manifest is prepared to cover shipment, and shall be countersigned by transporter and by supervisor of treatment facility. If we do not receive signed manifests from treatment within 45 days, we must report incident to EPA, NYS DOH and NYS DEC.

C. Surgical Experiments (Non-Infectious)

Animal Carcasses and Body Parts:

- The Principal Investigator places waste material in red plastic bags that bear the name and address of the SUNY DMC. The bags are sealed tightly and placed in a fiber drum lined with a red plastic bag also bearing HSCB name and address.

Bedding and Waste:

- DLAR personnel clean cages
  - Dogs: daily
  - Small Animals: twice a week
  - Farm Animals: three times a week
- Bedding and waste collected by DCM employees are placed in drums lined with a thick plastic garbage bag to reduce odors and prevent insect infestation.
- The drum is taken to the BSB Loading Dock on the animal elevator.
- Allied Sanitation picks up the waste for disposal at an approved dumpsite.
- The Loading Dock is washed down and disinfected daily.

SUNY DOWNSTATE MEDICAL CENTER
FACILITIES MANAGEMENT & DEVELOPMENT
STANDARD OPERATING PROCEDURE

SUBJECT: *DISPOSAL OF CYTOTOXIC DRUGS*

SOP NO#: S-1205
ASSIGNED TO: All Departments

DATE PREPARED: 09/86
REVISED/REVIEWED DATE: 11/2014

LOCATION: University Hospital, Midwood, Bedford Stuyvestant, Crown Heights, and Dialysis Center

PREPARED BY: BRIAN PITT

REVIEWED BY: TIM HERZCG

POLICY

To safely and in conformance with federal, state, and local regulations dispose of antineoplastic drugs and drug-contaminated items.

1. Gown, gloves, mask, etc. when disposed of are to be placed in sealed chemo waste container.
   - Residual liquids, sharps, or any breakage items are to be placed in sealed chemo waste container
   - Wasted container shall not be filled to the point of over-flowing.
   - At the completion each procedure, the waste container, lid is to be securely closed.
   - The filled chemo waste container shall be labeled and placed in laboratory's hazardous chemical waste.

Expired Chemotherapy Drugs:
Antineoplastic and other toxic drugs that have reached their expired shelf-life will be returned to the Pharmacy for disposal.

- Where medication containers exceed that of a residual amount (greater then 2.54 centimeters or 3% volume) they shall be segregated by chemical category according to EPA criteria, labeled and disposed of with the laboratory's hazardous chemical waste.

Investigation Chemotherapy Drugs
Investigational drugs that have reached their expiration date or are no longer required shall be given back to the Clinical Principal Investigator who applied for a permit for their usage from the National Institute of Health (NIH). After completion of the appropriate inventory control records, the Director of Pharmacy will assist the Investigator in packaging the pharmaceuticals in accordance with the Department of Transportation (DOT) guidelines. The drugs will be returned to the NIH at the address listed below:

- Drug Repository
  Flow Laboratories, Inc.
  7655 Old Spring House Road
  McLean, VA 22101

The Pharmacy Department and the Principal Investigator will keep a permanent record of the amount of drugs returned to the Drug Repository. This record will be part of the total inventory control for investigational drugs required by the Food and Drug Administration (FDA).

SUNY DOWNSTATE Medical Center

Standard Operating Procedure
Division of Comparative Medicine

SOP Creation & Management	**SOP No.: 10-100** **Version: 1**
Implementation Date: 08/01/2018	**Page 1 of 3** **Next Review Date: 08/01/2021**
Prepared By: Keisha A. Lightbourne, Interim Administrative Director, DCM	**Approved By:**

1.0 Purpose:

To establish conventions for the creation, numbering, approval, distribution, revision, and deactivation of Standard Operating Procedures (SOPs).

2.0 Policy:

2.1. DCM shall create, implement, and manage standard operating procedures that document how they complete daily operations and how they carry out policies established by the SUNY Downstate IACUC.

3.0 Definitions:

3.1. SOP: Standard Operating Procedure
3.2. DCM: Division of Comparative Medicine
3.3. IACUC: Institutional Animal Care and Use Committee
3.4. SOP Committee: DCM Director, DCM Supervisors, and other subject matter experts as required on an ad hoc basis.
3.5. DCM Management Team: The Director of DCM and his/her supervisors.
3.6. SOP Distribution List: A list of places where SOP Binders are kept in case of an emergency where there is no power.

4.0 Responsibilities:

4.1. The SOP Coordinator, as designated by the Director of DCM, is for the following:

- Coordinates the creation, review, approval, distribution, revision, and deactivation of SOPs by bringing them to the SOP Committee;
- Maintains an index of all active SOPs including maintaining unique numbers;
- Maintains a distribution list for active SOPs and ensures SOP binders and/or electronic copies are up to date;
- Ensures originals of historical SOPs and SOP revision are appropriately archived; and
- Ensures SOP sign-off documentation is maintained for each employee.

4.2. The Supervisor of each employee ensures the completion and documentation of the periodic review of and/or training on SOPs by all employees. This documentation must be submitted to the SOP Coordinator for maintenance.

4.3. The SOP Committee is responsible for the creation, review, approval, revision and deactivation of SOPs. This committee shall meet a minimum of quarterly for this purpose.

5.0 Procedures/Guidelines:

5.1. SOPs will follow the format of this document

5.2. Each SOP is assigned a unique five digit number according to the following convention.

5.2.1 The first two digits indicate the classification area of the SOP.

5.2.1.1 There are seven classification areas, as follows:

10- General Procedures
20- Personnel Procedures
30- Husbandry Procedures
40- Veterinary Care Procedures
50- Facility Sanitization and Maintenance Procedures
60- Equipment Use and Maintenance Procedures
70- Safety Procedures

5.2.2 The remaining three digits indicate the unique SOP number within each classification.

5.2.3 For Husbandry Procedures, the second digit specifies the subgroup of animals within the husbandry category.

5.2.4 The five assigned digits of the SOP number remain unchanged during review and revision cycles. If an SOP is deactivated, the SOP number will remain inactive. The SOP number will only be used again for the SOP title to which it was originally assigned for within the facility using the SOP

5.3. Any DCM staff member can request a review and revision of an SOP at any time by bringing it to the attention of the SOP Coordinator.

5.4. If creation of an SOP is required, the SOP Committee shall:

5.4.1 Assign the appropriate subject matter expert(s) for the SOP to create and submit a draft document for approval;

5.4.2 Review a draft of the SOP;

5.4.3 Approve SOPs by signing off on them and establishing an Implementation Date and/or the next review by Date as necessary; and

5.5. If the revision of an SOP is required, the SOP Committee shall:

5.5.1 Assign the appropriate subject matter expert(s) for the SOP to make any and all revisions;

5.5.2 Review a draft of the SOP. Draft SOPS with major revisions should include a corresponding change record of any changes needed and the reasons. This can be accomplished using the "Track Changes" and "Comments" features of a word

processing program. Minor revisions made to an existing SOP may be documented directly on the SOP in the revision history table found at the end of the SOP.

5.6. Upon approval of a new, revised, or deactivated SOP, the SOP Coordinator will promptly:
- 5.6.1 Revise the electronic Index of SOPs;
- 5.6.2 Upload the final version into the electronic file thereby creating a "new" version of the document (or in the case of deactivation remove it);
- 5.6.3 Incorporate into SOP binders copies of new or revised SOPs and a revised index of active SOPs, as appropriate;
- 5.6.4 Remove from the binders and destroy copies of superseded and deactivated SOPs;
- 5.6.5 Maintain an historical electronic file of original, revised or deleted SOPs, and corresponding SOP change records according to NYS record retention guidelines or three years.

5.7. The SOP Coordinator must ensure that DCM employees are aware of any new, revised, or deactivated SOPs by letting the DCM Management Team know.

5.8. When an SOP is created or revised, all affected personnel must read the SOP and sign/initial review documentation before conducting unsupervised work governed by the SOP. Obtaining this documentation and getting it to the SOP Coordinator is the responsibility of the Supervisor.

5.9. Newly hired, transferred, and temporary employees must read all SOPs that pertain to their respective assignments before conducting unsupervised work governed by SOPs. Obtaining this documentation and getting it to the SOP Coordinator is the responsibility of the Supervisor.

5.10. Periodically, Supervisors should have employees review and demonstrate competency with pertinent SOPs. Such reviews should be documented by the Supervisor and maintained by the SOP Coordinator.

6.0 Attachments:

6.1. SOP Template
6.2. SOP Index Template
6.3. SOP Distribution List

7.0 References:

Revision History:

Revision	Author	Revisions Made	Effective Date
1		•	
		•	

SUNY DOWNSTATE Medical Center

Standard Operating Procedure
Division of Comparative Medicine

Monitoring Animal Drinking Water Quality	SOP No.: 50-100 Version: 1
Implementation Date: 08/08/2018	Page 1 of 4 Next Review Date: 08/08/2020
Prepared By: Carol Novotney, DVM	Approved By: DCM SOP Committee

1.0 Purpose:

To describe the procedures for assuring the quality of potable water for research animals housed in animal facilities under the direction of the Division of Comparative Medicine (DCM).

2.0 Policy:

2.1. The New York City's Department of Environmental Protection (DEP) monitors the water in the distribution system, upstate reservoirs and feeder streams, and wells that are sources for New York City's drinking water supply in accordance with the New York State Sanitary Code and the National Primary Drinking Water Regulations. To accomplish this goal, throughout the watershed and as the water enters the distribution system, DEP continuously monitors and conducts analyses for certain water quality parameters, including microbiological, chemical, and physical measures. DEP also regularly tests water quality at nearly 1,000 water-quality sampling stations throughout New York City. The water quality report is published annually and can be viewed at http://www.nyc.gov/html/dep/html/drinking_water/wsstate.shtml.

2.2. The SUNY Downstate Basic Science Building water tank which is the local source of potable water to the DCM. It is locally monitored and maintained by Facility Maintenance & Design (FM&D) under contract with JMZ Maintenance, Inc., which provides SUNY Downstate with an annual certificate of compliance with local law 76 of the NYC Health Code after they clean, sanitize and chlorinate the water tank located on the roof. After cleaning, JMZ submits water samples for microbiological testing for coliforms and E. coli. FM&D schedules the annual testing during the summer months e.g. July or August.

2.3. DCM will twice annually conduct water quality testing midway between annual tank cleaning and/or certification.

3.0 Definitions:

3.1. EPA: Environmental Protection Agency.

4.0 Responsibilities:

4.1. The Facility Operations Manager will be responsible for ordering testing supplies, testing and documenting the results of such tests on a twice annual basis.

4.2. The Director of Environmental Health & Services will engage a vendor for additional testing if necessary.

5.0 Procedures/Guidelines:

5.1. The Facilities Operations Manager will test water quality in November and March of every year.

5.2. The testing will be completed using the WaterSafe® Test kit (well water version).

5.3. Prior to testing the Facilities Operations Manager will ensure she has enough WaterSafe® Test kits and that they are unexpired. WaterSafe® kits should be stored at room temperature and should not be opened prior to testing.

5.4. Do not use hot water or water containing bleach or detergents to test.

5.5. Do not re-use any part of a kit.

5.6. Utilizing the instructions carefully test for bacteria, lead, copper, pesticides, iron, total nitrate/nitrite, nitrite, pH, total hardness, and total chlorine.

5.7. Test four locations within the DCM Animal Facility as follows:
- 5.7.1 Clean Side of Cage Wash where water bottles are filled;
- 5.7.2 One animal housing room on the 8th floor where rodent bottles may be filled or where an automatic watering distribution system is used;
- 5.7.3 One animal housing room on the 9th floor where rodent bottles may be filled or where an automatic watering distribution system is used; and
- 5.7.4 The water reservoir tank within the 9th floor IAVI space that is used for the nonhuman primate auto-watering distribution system.

5.8. The Facility Operations Manager will vary the housing room used each time s/he tests.

5.9. The Facility Operations Manager will document test results, including any re-testing and the reports from any vendors engaged.

5.10. If water tests outside of any of the desired ranges (see Chart of Water Test Desired Values - Attachment 6.1), the Facility Operations Manager will contact the Director of Environmental Health and Services to engage a vendor for additional testing if necessary.

5.11. The Facility Operations Manager will work with Environmental Health and Services to implement any corrective actions necessary to maintain potable water.

6.0 Attachments:

6.1. Chart of Water Test Desired Values.

7.0 References:

7.1. The Guide for the Care and Use of Laboratory Animals (8th Edition)

Revision History:

Revision	Author	Revisions Made	Effective Date
1		•	
		•	

Attachment 6.1

Water Test Desired Values

EPA maximum contaminant levels or guideline standards

Bacteria	None
Lead	Below 15 ppb
Pesticides (atrazine)	Below 3 ppb
Pesticides (simazine)	Below 4 ppb
Copper	Below 1.3 ppm
Iron	Below 0.3 ppm
Total Nitrate/Nitrite	Below 10.0 ppm
Nitrite	Below 1.0 ppm
pH	6.5 to 8.5
Total Hardness	50 ppm or less
Total Chlorine	Below 4 ppm

SUNY Downstate Medical Center

Office of Animal Welfare
IACUC@Downstate.edu
office 718-270-4645

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE POLICY
Adverse & Unanticipated Outcomes Reporting
Approval Date: July 16, 2018

DEFINITIONS

Adverse/Unanticipated Outcome: An adverse and unanticipated outcome is the occurrence of an unforeseen event that negatively impacts the welfare of research animal(s), involving pain, distress, and/or death of the animal. By definition, these are not identified as potential risks or outcomes in the approved IACUC protocol (e.g., part of the risk vs. benefit analysis section of the protocol form).

REPORTING REQUIREMENTS

The IACUC is required to monitor all research activities related to animal use at SUNY Downstate Medical Center. To assist the IACUC in fulfilling this requirement, all adverse/unanticipated outcomes should be reported in a timely manner.

When to report

Examples of events that are *required* to be reported:

1) Animal mortality or morbidity as a result of experimental conditions or outcomes not described in the approved IACUC protocol.
2) Animal mortality or morbidity in excess of that described in the approved IACUC protocol.
3) Animal mortality or morbidity in excess of humane endpoints described in the approved IACUC protocol.
4) Unforeseen events that lead to the harm of the animal(s) or that cause obvious distress not justified and approved in the protocol, such as
    a) Unexpected phenotypes of genetically modified animals, or
    b) Protocol procedure complications.
5) Unforeseen events that lead to the harm of the animal(s) or that cause obvious distress not associated with the approved protocol, including events associated with
    a) Animal housing and environmental conditions (e.g., mechanical or electrical failures),
    b) Animal husbandry and veterinary care (e.g., escape from primary containment, insufficient provision of food and/or water, non-response to veterinary care),
    c) Hazardous material contamination (e.g., water or food supply contamination, spills/exposures, radiation leak), or
    d) Natural disasters.

Examples of events that are *not required* to be reported:

1) Death or morbidity of animals described as expected in the approved IACUC protocol.

2) Injury/illness unrelated to approved procedures and being treated by the clinical veterinarians.
3) Phenotypic abnormalities described in the approved protocol, common phenotypic abnormalities described in the literature (e.g., ulcerative dermatitis in specific strains), or phenotypic abnormalities that have no negative impact on animal welfare.

What to report

An optional report form to capture this information is included and on the IACUC website. Reports should include the following information:

1) PI name and Protocol number
2) Date/time of finding
3) Location of event
4) Species involved
5) Number of animals (cage card numbers if available)
6) Brief description of the event
7) Name and contact information of person reporting event (not required)

How to report

Reporting of potential adverse/unanticipated outcomes can be made in person, by phone, or by email to any of the following entities. Individuals making reports may remain anonymous and are protected from reprisals when reporting in good faith.

1) Division of Comparative Medicine – DCM@Downstate.edu
2) The Office of Animal Welfare – IACUC.Welfare@Downstate.edu
3) The IACUC Chair – IACUC.Chair@Downstate.edu
4) SUNY Office of Compliance and Audit Services – 877-349-7869 or Compliance Line

SUNY DOWNSTATE Medical Center

Submit this form to one of the following:
IACUC.Welfare@Downstate.edu
IACUC.Chair@Downstate.edu
DCM@Downstate.edu
https://www.compliance-helpline.com/downstate.jsp

ADVERSE/UNANTICIPATED EVENT REPORTING FORM

For use in reporting adverse/unanticipated outcomes associated with animals used in research, testing or teaching. Refer to the IACUC Policy: *Adverse & Unanticipated Outcomes Reporting*

Principal Investigator: _____ IACUC Protocol Number: _____

Date/Time of finding: _____ Location of Event: _____

Species: _____ Number of animals: _____

Animal Cage Card #s if known_____

_____

Name/Contact Information of Person Submitting Report*:_____
(*not required; you may remain anonymous)

1. Please provide a description (include dates and details) of the adverse event/unanticipated event:

2. Please provide a description of how this event/problem was managed/resolved:

Date of Submission: _____

Outcome: ☐Treated/Recovered ☐Euthanized ☐Deceased ☐Unknown ☐Other_____

SUNY Downstate Medical Center

Office of Animal Welfare
IACUC@Downstate.edu
office 718-270-4645

INSTITUTIONAL ANIMAL CARE AND USE POLICY
Rodent Euthanasia Methods – Approval Date: October 10, 2018

Purpose
The purpose of this policy is to ensure that euthanasia procedures for rodents comply with the *American Veterinary Medical Association (AVMA) Guidelines for Euthanasia of Animals: 2013 edition*. To facilitate completion of the IACUC protocol, sample narratives for each method are provided for investigators to include in their IACUC protocols for review.

Background
Animals being euthanized should not experience pain, fear, or other significant stress prior to their death. The term euthanasia is from the greek word eu (good) and thanatos (death). Per the AVMA Guidelines, "a good death is tantamount to the humane termination of an animal's life." The Public Health Service *Policy on Humane Care and Use of Laboratory Animals* requires that euthanasia be conducted according to the *AVMA Guidelines* (OLAW). Based on the best literature and empirical evidence, these guidelines set criteria for euthanasia, specify appropriate euthanasia methods and agents, and detail conditions that must be met when using specific methods and agents. Following these guidelines assures that all animals are humanely euthanized with a minimum of pain and distress.

This policy summarizes key aspects of rodent euthanasia as set forth in the *AVMA Guidelines* and practiced at SUNY Downstate Medical Center:

- General Concepts for All Methods
- Carbon Dioxide (CO_2) Euthanasia (Above Ten Days of Age)
- Inhalant Anesthetics
- Injectable Agents
- Physical Methods without Anesthesia
- Perfusion under Anesthesia
- Euthanasia of Neonates
- Euthanasia of Fetuses
- Confirmation of Death
- Operation & Maintenance of Guillotines

For further detail, the reader is encouraged to consult the succinct, well-organized, and highly-informative *AVMA Guidelines* directly.

General Concepts for All Methods

- The method of euthanasia must be appropriate for the species and the age of the animal.
- All methods of euthanasia must be detailed on the IACUC-approved protocol to which the animal is assigned.
- All animal euthanasia must be performed by appropriately trained personnel (Guide and AVMA), listed as performing euthanasia on the IACUC-approved protocol to which the animal is assigned.
- When animals are euthanized together, they must be of the same species.
- Animals must be continually observed and never be left unattended while succumbing to any euthanasia method. Methods involving the use of chambers (e.g., inhalant carbon dioxide or

isoflurane) must use chambers constructed of a clear material and not overcrowded, providing sufficient floor space for each animal to ambulate and make normal postural adjustments.
- All methods used must result in the confirmed death of the animal; for several methods, this requires a secondary physical method of euthanasia to ensure death.
- Animal carcasses and tissues must be properly disposed of after euthanasia.

Carbon Dioxide (CO_2) Euthanasia (Above Ten Days of Age)

- Inhalation of high concentrations of CO_2 by rodents older than ten days results in a rapid decrease of intracellular pH, which in turn leads to decreased brain function and death.
- Medical grade compressed gas is the only acceptable source of CO_2 for euthanizing rodents; dry ice or other sources of CO_2 are not allowed.
- Prefilled chambers are unacceptable. Gas must be delivered in a predictable and controllable fashion, at a low flow rate of 10-30% volume displacement per minute.
    - All Division of Comparative Medicine (DCM) systems are preset to deliver a fixed flow of CO_2 within this range.
    - PIs who have received IACUC approval to use euthanasia systems in their laboratory must use either a fixed flow system similar to DCM's or a customized system utilizing both a regulator *and* a flow meter. Calculate and post the Proper steps for CO_2 euthanasia of rodents using a custom flow meter sign in the laboratory.
- CO_2 is denser than room air and will remain at the bottom of the chamber, thus the chamber will need to be emptied (e.g. placed on its side) between groups or cages.

Sample Protocol Narrative –
Animals will be placed in a clear chamber for continual observation and have CO_2 delivered at a 10-30% fill rate until breathing stops. Death will be ensured by a physical method identified in the protocol, and carcasses will be placed in DCM freezers for proper disposal. If used for subsequent animals, the chamber will be cleaned after use and placed on its side to purge the chamber of CO_2. Whenever possible, animals will be euthanized in their home cages and not comingled with animals from other cages to minimize distress.

Inhalant Anesthetics

- Agents such as isoflurane, sevoflurane, and other halogenated gases may be used as a means to euthanize rodents when delivered by either an anesthetic vaporizer or a bell jar set-up.
- If any procedure (e.g. blood collection or terminal surgery) is to be performed, a bell jar must not be used; instead, a more refined, controlled method to deliver the anesthetic must be used, i.e., a vaporizer.

Use of an Anesthetic Vaporizer with Inhalant Anesthetics

- Anesthetic vaporizers can be used to rapidly and reliably induce anesthesia followed by euthanasia in rodents when used appropriately.
- Appropriate waste gas scavenging system must be in place (e.g., properly placed and maintained charcoal canister filters).

Sample Protocol Narrative –
Animals will be placed in a clear chamber for continual observation. The oxygen flow rate will be 1.0-1.2 L/min and the vaporizer setting 3%-4%. Once the appropriate anesthetic depth is achieved, the vaporizer setting may be increased to 5% in order to induce death. Death will be ensured by a physical method identified in the protocol, the chamber cleaned, and carcasses will be placed in DCM freezers for proper disposal. When possible, animals will not be comingled with animals from other cages to minimize distress.

Use of Bell Jars with Inhalant Anesthetics

- Bell jar refers to any small, transparent, sealable container that is filled with a volatile anesthetic via a soaked absorbent material.
- The animal should only be exposed to vapors and should never come in contact with the liquid state of the anesthetic as this can be irritating. This separation should be accomplished by using a pre-fabricated container with a "shelf" or other durable screening in the container dedicated to this purpose.
- The bell jar must be used in a fume hood for proper waste anesthetic gas scavenging.

Sample Protocol Narrative –
Placement of the ***<<insert specific anesthetic agent here>>***-soaked material (e.g. cotton or gauze material) into the bell jar will occur immediately prior to placement of separator and rodents into the bell jar to prevent pre-charging of the chamber and direct contact of the animal with the anesthetic. Animals will remain in the bell jar until breathing has ceased or until anesthetic depth has been achieved, as confirmed by lack of response to stimulus such as withdrawal to toe pinch. Death will be ensured by a physical method identified in the protocol, the chamber cleaned, and the carcasses placed in DCM freezers for proper disposal. Whenever possible, animals will not be comingled with animals from other cages to minimize distress.

Injectable Agents

Barbiturates

- Intraperitoneal injection of a barbiturate, such as pentobarbital, is an acceptable method of euthanasia for rodents. Commercial barbiturate euthanasia formulations are also appropriate.
- Use of non-pharmaceutical grade pentobarbital is acceptable, as the OLAW considers Nembutal to be unavailable due to the excessive cost.
- The recommended dosage of sodium pentobarbital is 150 mg/kg for larger rodents and 250 mg/kg for mice (three times the anesthetic dose) and should be included in the drug chart of the protocol.

Sample Protocol Narrative –
Sodium pentobarbital, or a sodium pentobarbital containing agent, will be administered intraperitoneally. Animals will be monitored until breathing has ceased or until anesthetic depth has been achieved, confirmed by lack of response to stimulus such as withdrawal to toe pinch. Death will be ensured by a physical method identified in the protocol, and carcasses will be placed in DCM freezers for proper disposal.

Dissociative Agent Combinations

- Ketamine and other dissociate agents, in combination with an α-adrenergic receptor agonist (e.g., dexmedetomidine, xylazine) or a benzodiazepine (e.g., diazepam) can be administered as a means of euthanizing rodents under certain conditions.

- Doses and volumes of drugs may vary, but at least four times the anesthetic doses of ketamine combinations should be used and included in the drug chart of the protocol.

Sample Protocol Narrative –
<<Insert specific drug(s) here>> will be administered intraperitoneally. Animals will be monitored until breathing has ceased or until anesthetic depth has been achieved, as confirmed by lack of response to stimulus such as withdrawal to toe pinch. Death will be ensured by a physical method identified in the protocol, and the carcasses will be placed in DCM freezers for proper disposal.

Physical Methods without Anesthesia

- These techniques may only be used when required by the experimental design and approved by the IACUC (except for fetuses or mouse, rat, and hamster neonates ≤ ten days of age – see below).
- All personnel performing these methods are required to be trained by the Division of Comparative Medicine (DCM) and demonstrate proficiency with the technique prior to using it on experimental animals.

Cervical Dislocation without Anesthesia

- Manual cervical dislocation can be a humane technique for euthanasia of mice, and rats weighing less than 200 grams.

Sample Protocol Narrative –
The animal will be restrained in a normal standing position on a firm, flat surface and grasped by the base of the tail with one hand. A sturdy implement (e.g., metal rod) or the thumb and first finger of the other hand are placed against the back of the neck at the base of the skull. To produce the dislocation, the hand or object restraining the head is quickly pushed forward and down with while pulling with the hand holding the tail back and up at a 30 degree angle from the table. The carcasses will be placed in DCM freezers for proper disposal.

Decapitation without Anesthesia

- Specialized rodent guillotines are available and must be kept clean and in good condition with sharp blades. See "Operation & Maintenance of Guillotines" below.
- The use of a species-appropriate restrainer (e.g., DecapiCone) will reduce stress from handling, minimize the chance of injury to personnel, and improve the positioning of the animal in the guillotine.

Sample Protocol Narrative –
The animal will be restrained with a DecapiCone and its head securely placed through the guillotine opening. The guillotine level is then rapidly depressed. The carcasses will be placed in DCM freezers for proper disposal.

Perfusion under Anesthesia

- The anesthetic and perfusion agents and associated doses (the volume of perfusion agent to be administered can be listed in the dose field) must be listed in the drug table of the IACUC protocol.
- Use of agents such as formaldehyde presents a risk to the health and safety of the user. As such, their use requires review and approval of an Institutional Biosafety Committee (IBC) Application Form by the IBC.

Sample Protocol Narrative –
Animals will be under a deep surgical plane of anesthesia, confirmed by loss of reflexes (e.g., toe pinch to confirm the absence of a withdrawal reflex), before any incisions are made and until the heart stops. The thoracic cavity will be opened to expose the heart. After inserting the perfusion needle through the left ventricle into the ascending aorta and nicking the right ventricle, sufficient physiological saline to flush out all blood is perfused, followed by a similar volume of fixative. After perfusion and sample collection is complete, the carcass must be properly disposed of by placement within a plastic bag and returned to the DCM freezer designated for collection of regulated medical waste for proper disposal.

Euthanasia of Neonates

Mouse, Rat & Hamster Neonates Older than Ten Days
Follow any of the above methods.

Mouse, Rat and Hamster Neonates ≤ Ten Days Old

- Mice, rats, and hamsters of this age are developmentally resistant to hypoxia, resulting in the need for prolonged exposure (up to 50 minutes) for inhalant agents to be effective.
- Acceptable methods of euthanasia for these animals include the following which are detailed above in this document:
    - Injectable agents
        - *Sample Protocol Narrative –*
          See samples above for adult animals.
    - Cervical Dislocation without anesthesia
        - *Sample Protocol Narrative –*
          See sample above for adult animals.
    - Decapitation without anesthesia
        - See "Operation & Maintenance of Guillotines" below if using a guillotine.
        - *Sample Protocol Narrative –*
          The animal will be restrained either manually or within a DecapiCone. Decapitation will be performed with either clean sharp scissors or by rapid depression of the guillotine level once its head securely placed through the guillotine opening. The carcasses will be placed in DCM freezers for proper disposal.

Mouse, Rat and Hamster Neonates ≤ Seven Days Old

- The methods described above for these species at ≤ ten days of age are appropriate.
- Hypothermia may also be used to induce anesthesia in pups ≤ seven days of age followed by a physical method to ensure death.

Sample Protocol Narrative –
Animals ≤ seven days of age will be placed in a clear open container (to prevent escape but allow air movement) within a refrigerator or on ice to induce hypothermia. Animals will never come into direct contact with the cooling agent. Once anesthetized, a secondary physical method listed in the protocol will be performed to ensure death, and the carcasses will be placed in DCM freezers for proper disposal.

Guinea Pig Neonates

Guinea pigs have precocial pups. All guinea pigs, regardless of age must therefore be euthanized by one of the above methods.

Euthanasia of Fetuses

- Rodent fetuses are unconscious in utero and do not respond to hypoxia.
- If the dam is euthanized and the abdomen is not penetrated, the fetuses will subsequently die.
- If the dam is euthanized and the abdomen is penetrated, the fetuses must be individually euthanized based upon the following criteria:

Mouse, Rat and Hamster Fetuses at Greater than 15 Days of Gestation; Guinea Pig Fetuses at Greater than 35 Days of Gestation

Sample Protocol Narrative –

Fetuses will be anesthetized with hypothermia by submerging the fetus (with the amniotic sac intact) in cold (4-8°C/35-39°F) physiological saline until the fetus becomes completely immobile and then rapidly frozen by immersion in liquid nitrogen while anesthetized. If at any point the fetus is allowed to breathe, it must be decapitated with sharp scissors or a scalpel blade.

Mouse, Rat and Hamster Fetuses ≤15 Days of Gestation; Guinea Pig Fetuses ≤ 35 Days of Gestation

- No further method of ensuring or confirming death of such fetuses is required.

Confirmation of Death

Inadequate exposure time to CO_2 or anesthetic agents may result in animals that appear dead but wake up from the deep anesthesia later on. Confirming death by verifying the loss of vital signs (heartbeat, respiratory movements) is unreliable due to the rodents' small size. A secondary physical method of euthanasia to ensure death is therefore required for all animals after use of CO_2, inhalant anesthetics, or injectable euthanasia agents, prior to carcass disposal. The protocol should indicate which procedures will be followed to ensure death – multiple selections can be made to provide flexibility for personnel. The selections are listed below:

- Decapitation
- Cardiac perfusion
- Remove of vital organs (e.g. heart, lungs, brain)
- Opening of the chest cavity to induce bilateral pneumothorax
- Cutting the major blood vessels to induce exsanguination (e.g. aorta, vena cava)
- Cervical dislocation in adult rodents (not permitted for rats ≥ 200 g, per *AVMA Guidelines for the Euthanasia of Animals: 2013 Ed.*)

Operation & Maintenance of Guillotines

There are many factors that could impact the frequency in which a guillotine requires maintenance (including sharpening of the blade), such as blade quality, the species and size of animals being decapitated, and the volume and frequency of use. Thus, the maintenance interval may vary widely and should be based on overall performance, including ease of use, e.g., force required, smoothness of operation. For

laboratories that use the same species and size of animals, guillotine performance should be used to establish a temporal maintenance interval.

Guidelines and Procedures

- For unanesthetized rodents, the use of plastic cones (e.g. DecapiCones) or another size-appropriate holding device is required to restrain animals to reduce distress from handling, minimize the chance of injury to personnel, and improve positioning of the animal in the guillotine.
- When in use, a properly maintained guillotine of appropriate size will decapitate the animal cleanly with minimal force. Before each use of a guillotine, it should be checked for rust, lack of visible nicks or other damage to the cutting edges and cleanliness. The operator should ensure that the action is smooth with no perceptible binding or resistance. Since there are varying sizes of guillotines available, the equipment chosen should be appropriate for the size of the animal.
- The IACUC also recommends testing the guillotine for sharpness on suitable materials before its use on live animals. A sharp blade will cut the test material cleanly with minimal force without dragging it between the blades or showing signs of sticking.
- Devices should be cleaned after each use, maintained in good working order, and serviced on a regular basis. Depending on species involved and volume of use, investigators may need to have devices sharpened more frequently.
- Devices may require lubrication with silicone or silicone-teflon aerosol spray after cleaning.
- If the equipment is found to be in less than good working condition, alternative properly maintained guillotines or approved euthanasia procedures must be used.

Guillotine Maintenance Recordkeeping

A maintenance record should be kept for all guillotine(s) and include information related maintenance, inspections and sharpening for each device. The records should be in close proximity to the device and made available for review as part of the IACUC's semi-annual site visits, during post-approval monitoring, inspections performed by internal and external stakeholders and self-assessment activities.

REFERENCES

American Veterinary Medical Association Guidelines for Euthanasia of Animals: 2013Edition (AVMA)

American College of Laboratory Animal Medicine: Report of the ACLAM Task Force on Rodent Euthanasia (ACLAM)

Animal Research Advisory Committee Guidelines for the Euthanasia of Rodent Fetuses and Neonates (2016) (ARAC)

Guide for the Care and Use of Laboratory Animals, 8th Edition (Guide)

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INSTITUTIONAL ANIMAL CARE AND USE POLICY
Social Housing
Approval Date: April 2, 2018

SCOPE

This policy applies to all animals owned by SUNY Downstate Medical Center (DMC) for use in teaching, research, or exhibition on IACUC approved protocols. The purpose of this policy is to define what constitutes a social species as well as what is considered an acceptable justification for single housing of a social species at DMC. The intent of this document is to define the IACUC's policy and to provide guidance to investigators.

BACKGROUND

The *Guide for the Care and Use of Laboratory Animals* states that members of a social species should be socially housed whenever possible. The Guide indicates that, "Appropriate social interactions among members of the same species (conspecifics) are essential to normal development and well-being (Bayne et al. 1995; Hall 1998; Novak et al. 2006). When selecting a suitable social environment, attention should be given to whether the animals are naturally territorial or communal and whether they should be housed singly, in pairs, or in groups. An understanding of species-typical natural social behavior (e.g., natural social composition, population density, ability to disperse, familiarity, and social ranking) is key to successful social housing." The IACUC recognizes that there are certain scenarios that would preclude the social housing of animals. This policy details general categories of exceptions to the social housing policy and the IACUC approval requirements for each category.

This policy explains the requirements of and offers guidance for the following topics:

- Key concepts
- Standard Exceptions
- Research-related single housing
- Clinically-related single housing
- Isolation housing

KEY CONCEPTS

1. Social housing is the default housing paradigm for all social species.
2. When available, animals procured from commercial vendors should be obtained as stable pairs/groups and then maintained as pairs/groups.
3. When possible, investigators should consider social housing when designing experiments that may interrupt an animal's social housing status. For example, if two rats are pair-housed, every effort should be made (when scientifically relevant) to end the study for both animals simultaneously, rather than leave one animal singly housed for an extended period of time.
4. A USDA animal's "incompatibility" will be determined by a DCM veterinarian and documented in the animal's clinical record by the veterinary staff, unless covered by an exception within this policy.
5. Non-USDA incompatible rodents are covered by either the standard exceptions in this policy, an exemption approved by the IACUC, or DCM veterinary-approved exemption.
6. Temporary single housing (clinical or experimental reasons) should be for the minimum time necessary, and then the animal(s) returned to social housing.

7. Singly housed animals will continue to receive species-appropriate enrichment (determined by the DCM veterinary staff), unless scientifically contraindicated and approved by the IACUC. Isolated animals will received additional enrichment at the direction of DCM veterinarians and documented.
8. Singly housed animals will be housed in visual, auditory, olfactory and/or tactile range with conspecifics whenever possible.
9. Singly housed animals may need gradual introduction to conspecifics and close supervision by DCM to prevent injury or trauma.

STANDARD EXCEPTIONS

There are various scenarios in which single housing is the acceptable housing paradigm; *justified based on social incompatibility resulting from* [likely] *inappropriate behavior,* [and] *veterinary concerns regarding animal well-being* (AAALAC). There is no need for DCM veterinary approval (or documentation within the medical record) or an IACUC exemption to this policy for these scenarios. The IACUC approves these scenarios with approval of this policy.

1. Asocial animals – Not all members of a social species are necessarily socially compatible; social housing of incompatible animals can induce chronic stress, injury, and even death (Guide, p. 64). All research and teaching animals currently used are considered social animals, except: adult boars, unfamiliar adult male mice, and sexually mature male rabbits that have not been previously social housed.
2. Socially Incompatibility – Animals lacking documented socially compatibility (e.g., aggression, health status, gender) will be singly housed. Socially incompatible animals (other than mice) may have attempts at repairing under the oversight of the DCM veterinarian. Mice that have been separated due to fighting will remain in single housing (unless breeding), and every attempt will be made to remove only the mouse that seems to be the "aggressor" while leaving the remaining group intact.
3. Male Mice – In some mice, standard caging may induce overt aggression in groups of males, resulting in social stress and injury (Guide, p. 53). While groups of young male mice delivered in a group or raised together as littermates should continue to be group housed, male mice separated for experimental studies or for breeding should not be reintroduced into a group of other male mice.
4. Breeding Colony Management –
    a. Male Breeders: Intact male breeders of any species separated for breeding should not be reintroduced into a group of other intact male animals and can be singly housed between mating with females.
    b. Pregnant Females: Pregnant females may be singly housed to minimize stress prior to and during parturition.
    c. Weaning Animals and Female Breeders: Animals may be singly housed at weaning when litter makeup contains a single sex or single genotype. Female mice may be singly housed after litters are weaned while subsequent breeding schemes are being coordinated.
5. Non-breeding Animals – Intact males and females of the same species should not be group housed with members of the opposite sex unless breeding is approved by the IACUC, and then only when breeding is needed as part of the research activities.

6. Attrition – Animals may be singly housed due to attrition of cage mates (e.g., clinical or research endpoints) or uneven number of animals. Efforts should be made to introduce socially compatible cage mates as appropriate.
7. Quarantine – Animals may be singly housed during quarantine prior to entering a facility or conditioned colony when not received in established pairs or groups.
8. Procedures Requiring Anesthesia –
    a. Pre-operative animals: In cases where fasting is required prior to surgery or other procedures requiring sedation or anesthesia, animals may be singly housed for the period of time in which food is removed prior to the procedure.
    b. Post-operative animals: While whenever possible, post-surgical animal should be group housed, it is acceptable to singly house animals post-operatively up to 14 days for recovery, observation and incision healing. Post-operative single housing >14 days must be covered by either research- or clinically-related single housing described below.

RESEARCH-RELATED SINGLE HOUSING

Social animals should be housed in stable pairs or groups of compatible individuals unless they must be housed alone for experimental reasons (Guide, p. 51). These *experimental reasons* must be approved by the IACUC prior to initiating single housing for USDA species (>12 hours) and for non-USDA species (>24 hours). The justification should be defined for the shortest period of time necessary.

Single housing of social species should generally be limited to experiments and/or animal models in the following categories, although other justifications will be considered by the IACUC:

- Studying isolation stress
- Individual feed or water intake monitoring
- Activity monitoring (e.g. beam break, etc.)
- Experimental instrumentation
- Avoiding cross contamination for infectious disease models, vectors, test articles, etc.

Individual IACUC approval is not needed for scenarios described above in "Standard Exceptions".

CLINICALLY-RELATED SINGLE HOUSING

DCM veterinarian(s) may require social animals to be housed individually for veterinary medical and/or animal welfare concerns. Exemptions from single housing for veterinary care purposes are documented in the animal's health record and, for USDA regulated species, reviewed every 30 days unless the basis for the exemption is a permanent condition. IACUC approval is not required for veterinary care exemptions from social housing.

ISOLATION HOUSING

There may be research- or clinically-related reasons to house an animal within a room by itself, without visual, auditory, olfactory, or tactile access to conspecifics. The IACUC will review research-related requests for isolation housing as described above. The DCM Veterinarian will notify the IACUC Chair and Office of Animal Welfare of clinically-related isolation housing, for discussion at the next convened IACUC meeting.