

Name: iuvo BioScience [A047]

FOR OFFICE USE ONLY

Recd  
Code A047

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
<b>Laboratory/Institution Name:</b> iuvo BioScience	
<b>Address 1:</b> 7500 W. Henrietta Road	
<b>Address 2:</b>	
<b>City, State, Zipcode:</b> Rush, NY 14543	
<b>County:</b> Monroe	
<b>Telephone Number:</b> 585-533-1672	
<b>Fax Number:</b> 585-533-1796	
<b>E-mail Address:</b> donnalee.ventura@iuvobioscience.com	

## SECTION I - GENERAL LABORATORY/INSTITUTION INFORMATION

### Ownership:

- ☒ Corporation    ☐ Government    ☐ Individual    ☐ Not For Profit    ☐ Partnership  
☐ Other: \_\_\_\_\_

### Facility Type:

- |  |  |  |
|--|--|--|
| <input type="checkbox"/> 2 Year College    | <input type="checkbox"/> 4 Year College                        | <input type="checkbox"/> Clinical or Environmental Lab |
| <input type="checkbox"/> Hospital          | <input type="checkbox"/> Medical School                        | <input type="checkbox"/> Product Testing Lab           |
| <input type="checkbox"/> Public Health Lab | <input checked="" type="checkbox"/> Research & Development Lab | <input type="checkbox"/> Veterinary School             |
| <input type="checkbox"/> Other: _____      |  |  |

## SECTION II - PROGRAM INFORMATION

### Animals (Check all that apply):

- |   |   |   |                                      |
|---|---|---|--------------------------------------|
| <input checked="" type="checkbox"/> Mice (genus mus)    | <input checked="" type="checkbox"/> Hamsters    | <input type="checkbox"/> Fish               | <input type="checkbox"/> Sheep/Goats |
| <input type="checkbox"/> Mice (wild or other)           | <input checked="" type="checkbox"/> Guinea Pigs | <input type="checkbox"/> Cats               | <input type="checkbox"/> Cattle      |
| <input checked="" type="checkbox"/> Rats (genus rattus) | <input checked="" type="checkbox"/> Rabbits     | <input type="checkbox"/> Dogs               | <input type="checkbox"/> Swine       |
| <input type="checkbox"/> Rats (wild or other)           | <input type="checkbox"/> Small Birds            | <input type="checkbox"/> Non-Human Primates | <input type="checkbox"/> Poultry     |
| <input type="checkbox"/> Other: _____                   |   |   |                                      |

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):

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Diagnostic Procedures | <input type="checkbox"/> Education/Teaching Demonstrations  |
| <input checked="" type="checkbox"/> Experimentation       | <input type="checkbox"/> Farm Production                    |
| <input type="checkbox"/> Public Display                   | <input type="checkbox"/> Public Health/Disease Surveillance |
| <input type="checkbox"/> Other: _____                     |   |

Are animals used in studies with human infectious agents? ☒ Yes ☒ No *emr 11/14/18*  
(If Yes, attach a copy of your procedures for processing medical waste generated by the animals)

### Registration/Accreditation Type:

- |  |   |                               |
|--|---|-------------------------------|
| <input checked="" type="checkbox"/> AAALAC Accredited  | <input checked="" type="checkbox"/> USDA Registered | <input type="checkbox"/> None |
| <input checked="" type="checkbox"/> Other: <u>ISO 17025 Accreditation, ISO 13485 Certification</u> |   |                               |

### SECTION III - PERSONNEL INFORMATION

CURRENT DATA				INDICATE CHANGES HERE			
<b>Laboratory/Institution Person In Charge (Name):</b> Burton, Benjamin							
<b>Title:</b> CEO							
<b>Telephone Number:</b> 585-533-1672							
iuvo Bioscience 7500 West Henrietta Rd. Rush, NY 14543							
<b>Work Hours:</b>  MON: 8:30 am to 5:00 pm TUE: 8:30 am to 5:00 pm WED: 8:30 am to 5:00 pm THU: 8:30 am to 5:00 pm FRI: 8:30 am to 5:00 pm to to				<b>Work Hours:</b>  Mon: to Tue: to Wed: to Thu: to Fri: to Sat: to Sun: to			

CURRENT DATA				INDICATE CHANGES HERE			
<b>Veterinarian in Charge (Name):</b> Moorman-White, Diane							
<b>Title:</b> Attending Veterinarian							
<b>Telephone Number:</b> 585-275-2653							
<b>Work Name/Address (if different from laboratory/institution):</b> (DLAM) University of Rochester 601 Elmwood Rochester, NY 14642							
<b>Work Hours:</b>  MON: 9:00 am to 4:00 pm TUE: 9:00 am to 4:00 pm WED: 9:00 am to 4:00 pm THU: 9:00 am to 4:00 pm FRI: 9:00 am to 4:00 pm to to				<b>Work Hours:</b>  Mon: to Tue: to Wed: to Thu: to Fri: to Sat: to Sun: to			

### SECTION III - PERSONNEL INFORMATION

CURRENT DATA	INDICATE CHANGES HERE
<b>Contact Person (Name):</b> Ventura, Donna	
<b>Title:</b> Site Manager	
<b>Telephone Number:</b> 585-533-1672	
<b>Work Hours:</b>  MON: 8:30 am to 5:00 pm TUE: 8:30 am to 5:00 pm WED: 8:30 am to 5:00 pm THU: 8:30 am to 5:00 pm FRI: 8:30 am to 5:00 pm to to	<b>Work Hours:</b>  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).

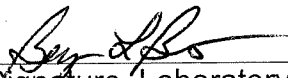
☐ No additional staff.

### 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.

  
\_\_\_\_\_  
Signature, Laboratory/Institutional Officer

CEO

\_\_\_\_\_  
Title

30-Nov-18  
\_\_\_\_\_  
Date

Institutional Animal care and Use Committee Roster  
2019 Renewal

Name	Title
Suzanne Stevens, PhD	Chair
Diane Moorman-White DVM	Attending Veterinarian
Mary Richardson, PhD, DBAT	Executive Vice President
Jane Grant MS	Community Affiliate
Thomas Bittner	Vivarium Supervisor
Donna Ventura BS	Site Manager
Brett Schneider BS	Scientist
Tammy Boudreau	Office Coordinator

Animal Care Personnel  
2019 Renewal

Name	Title	Education	Employment Status
Diane Moorman-White DVM	Attending Veterinarian	DVM	Consultant
Thomas Bittner, LAT	Manager	HS	Full Time
Scott Clark, LAT	Animal Care Associate	AAS	Full Time
Tom Davenport, ALAT	Animal Care Associate	HS	Full Time
Matthew Borragato, BS	Technician	BS	Full Time

2019 NYSDOH Renewal Application for Approval for Use of Living Animals  
luvo Bioscience A047  
November 19, 2018

- 1) luvo has enhanced the sentinel program for the animal facility. The following changes have been made:
  - a. The sentinel procedure Qualio VAP-15 defines sentinel mouse replacement as every 6 months. Due to the immunocompetency of older animals, the timeframe was shortened from 12 months to 6 months as recommended during the 2018 AAALAC site visit..
  - b. Fecal floatation and fur plucking were added to the assessment of sentinels as recommended during the 2018 AAALAC site visit..
- 2) luvo has implemented an electronic document control and training system which manages training for the vivarium staff, IACUC members and all users who handle animals.

Revision #: R-10  
 Effective Date: 8-12-2011

Attachments: 0

Written By: [Signature] Date: 7/21/11 Copies Distributed: QA, Chem, Micro  
 Safety Team Member: [Signature] Date: 7/20/11 Tox, Validations, Maint, Vivarium  
 Quality Assurance: [Signature] Date: 7-29-2011

## 1 Purpose

- 1.1 To define the requirements for disposal and tracking of Regulated Medical Waste at the Rush site.

## 2 References

- 2.1 X-012, Collection, Management, & Disposal of Hazardous Materials
- 2.2 X-028, Handling Controlled Substances
- 2.3 OSH-031, Syringe and Needle Rules and Regulations
- 2.4 VEP-006, Animal Carcass Disposal
- 2.5 6NYCRR Part 364.9, Standards for the Tracking and Management of Medical Waste
- 2.6 40 CFR Protection of Environment parts 22 and 259
- 2.7 29 CFR 1910.1030 Bloodborne Pathogens

## 3 Definitions

- 3.1 Regulated Medical Waste (RMW) - defined in 40 CFR part 22 and 259 to include the following materials which may be encountered in the Rush site's waste stream:
- 3.1.1 Cultures and stocks of infectious agents and associated biologicals
  - 3.1.2 Human blood and blood products
  - 3.1.3 All discarded sharps, whether contaminated with infectious or potentially infective agents or not. Examples are syringes, needles, surgical blades and Pasteur pipettes. Regular glass and plastic pipettes and even broken glass bottles, unless contaminated with such agents, are not considered sharps, and may be discarded with normal trash as long as protective measures are taken.
  - 3.1.4 Contaminated animal carcasses
  - 3.1.5 Discarded medical devices contaminated with such agents
- 3.2 Biohazardous - infectious to humans
  - 3.3 CFR - Code of Federal Regulations
  - 3.4 DEC - New York State Department of Environmental Conservation
  - 3.5 NYCRR - New York Code of Rules & Regulations
  - 3.6 Sharps - any contaminated object that can penetrate the skin, including but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

## 4 Responsibility

- 4.1 Department management are responsible for ensuring that only trained technicians handle regulated medical waste.
- 4.2 Technicians are responsible for reading, understanding, and following this procedure.
- 4.3 Quality assurance or designee is responsible for the storage of completed manifests.
- 4.4 Each department is responsible for packaging and transporting the RMW that it generates to the waste shed. This area was chosen so as to limit public exposure and to provide the containers with protection from the elements and from vermin.



- 4.5 The laboratory departments are responsible for maintaining the keys to the waste shed and shall ensure the waste shed is locked following use.

## 5 Materials

**NOTE:** Materials marked with an asterisk may be supplied by or purchased from the waste transporter, or may also be purchased elsewhere. An adequate supply of these materials will be maintained by the Maintenance Department.

- 5.1 Biohazard bags (orange and red)
- 5.2 Plastic bags and autoclave bags
- 5.3 \*Red sharps buckets (per 6NYCRR Part 364.9, other colors may be used as long as they are conspicuously labeled as being infectious)
- 5.4 White plastic buckets (2 gallon nominal capacity) for disposal of pipettes and broken glass that is not Regulated Medical Waste as described in section 3.1.3
- 5.5 Indelible marker and/or labels with "Biohazard" symbol
- 5.6 Packing tape
- 5.7 Cardboard cartons designated "infectious waste" or "biohazardous waste" or similar
- 5.8 Reusable Plastic Totes
- 5.9 MD-287, Bio Hazardous Waste Log

## 6 Procedure

### 6.1 Distributing Waste to the Correct Container

- 6.1.1 Waste must be placed in one of the following types of containers. Examples of materials that should be placed in each type of container are provided.

#### 6.1.1.1 Normal wastebaskets

- 6.1.1.1.1 Medical devices, either before or after being used as test articles, that are uncontaminated with biohazardous material
- 6.1.1.1.2 Rubber gloves that are uncontaminated with biohazardous material.
- 6.1.1.1.3 Unbroken glass bottles that are not contaminated with hazardous chemical or biological material
- 6.1.1.1.4 Petri dishes on which no growth of microorganisms is evident
- 6.1.1.1.5 Cell culture dishes containing non-human cells that are not infected with either pathogenic viruses or other microorganisms
- 6.1.1.1.6 Band-Aids or gauze on which small amounts of blood are absorbed.
- 6.1.1.1.7 Glass or plastic pipettes uncontaminated with hazardous chemical or biological material and uncontaminated broken glass shall be placed in the white plastic buckets supplied for this purpose
- 6.1.1.1.8 When filled, the white plastic buckets and their contents can be placed in regular wastebaskets. The purpose of the buckets is to contain the potentially dangerous broken glass, so they must be placed carefully into the regular wastebaskets so as not to spill their contents.

#### 6.1.1.2 Reusable plastic totes for most RMW (must be lined with red plastic biohazard bags)

- 6.1.1.2.1 Medical devices and rubber gloves that are contaminated with biohazardous material
- 6.1.1.2.2 Petri dishes on which microorganisms are visibly growing
- 6.1.1.2.3 Cell culture dishes containing cell lines infected with pathogenic viruses or other microorganisms
- 6.1.1.2.4 Cell culture dishes containing human cancer cells.

- 6.1.1.3 Plastic 5-gallon buckets with lids that seal – generally used for sharps (do not line with plastic bags)

**NOTE:** Liquids shall not be emptied into buckets.

- 6.1.1.3.1 All used needles, syringes and blades, whether or not contaminated. Do not clip, disassemble or re-sheath hypodermic needles or syringes (OSH-031) prior to placing them in the container.

- 6.1.1.3.2 All used Pasteur pipettes

- 6.1.1.3.3 Regular glass and plastic pipettes contaminated with biohazardous material.

- 6.1.1.3.4 Any other glass object contaminated with biohazardous material

- 6.1.1.3.5 Biohazardous carcasses (see section 6.3.3)

- 6.1.1.4 Cardboard Cartons

- 6.1.1.4.1 Biohazardous carcasses (see section 6.3.3)

- 6.1.1.5 Chemical hazardous waste is disposed of separately as described in X-012.

## 6.2 Labeling

- 6.2.1 All containers must be labeled with the Rush site's address:

**Moog**

**STS Life Science Division**

**7500 W. Henrietta Road**

**Rush, NY 14543**

- 6.2.2 Each container must have a universal biohazard symbol affixed to it. If the container is not red, then its lid must also have such a symbol.

## 6.3 Packaging

- 6.3.1 Totes

- 6.3.1.1 Although the waste transporter disinfects these totes prior to delivery, we have no control over this process. Therefore, you must wear gloves when handling these totes.

- 6.3.1.2 Be sure the bags used to line totes don't leak; double bag if necessary. If waste is autoclaved prior to disposal, place the autoclave bags in the red biohazard bag that lines the tote or box.

- 6.3.1.3 When the tote is filled to its capacity (approximately  $\frac{3}{4}$  full) or maximum weight (see step 6.3.4), tape the bag closed and seal the tote with the lid.

- 6.3.1.4 Remove the tote to the storage area defined in section 4.4 to await disposal. Do not allow large volumes of medical waste to be stored in laboratories.

- 6.3.1.5 Complete the applicable fields on MD-287 posted in the shed.

- 6.3.2 Sharps Buckets

- 6.3.2.1 When filled to capacity (approximately  $\frac{3}{4}$  full) or maximum weight, apply the lid so that it seals. A rubber mallet may be the tool of choice for this operation.

- 6.3.2.2 Place a maximum of two sealed buckets in a tote and seal the tote with the lid.

**NOTE:** Totes are not required to be lined with red biohazard bags when used for sharps buckets.

- 6.3.2.3 Remove the tote to the storage area defined in section 4.4 to await disposal. Do not allow large volumes of medical waste to be stored in laboratories.

- 6.3.2.4 Complete the applicable fields on MD-287 posted in the shed.

- 6.3.3 Cardboard Cartons for Biohazardous Animal Carcasses

- 6.3.3.1 Place biohazardous animal carcasses in red bags, affix a universal biohazard sticker if necessary and store the bags in the chest freezer in the air systems room at the back of the vivarium.
- 6.3.3.2 Shortly prior to pickup, place the carcasses in a 5 gallon bucket and seal the lid on the bucket
- 6.3.3.3 Place the buckets in cardboard cartons imprinted with the universal biohazard sign and seal the carton with three strips of tape across the top. Also tape the bottom of the carton.
- 6.3.3.4 Affix a label to the box indicating the contents are "Pathogenic" and write on the box "Dispose by Incineration" or "Incinerate".
- 6.3.3.5 If boxed material leaks or the box appears to have water stains, you will have to repackage it.
- 6.3.3.6 Remove the carton to the storage area defined in section 4.4 to await disposal.
- 6.3.3.7 Complete the applicable fields on MD-287 posted in the shed.
- 6.3.4 The maximum weight for totes and cardboard cartons and its contents shall not exceed 45 lbs.
- 6.4 Tracking Regulated Medical Waste Disposal
  - 6.4.1 At the time of pickup, the transporter will inventory the containers to be removed, weigh them, and prepare a four-part New York State tracking form.
  - 6.4.2 The transporter will enter the weight of the material picked up, sign the tracking form. One signed copy will remain on site and is forwarded to Quality to be recorded and filed. The transporter will retain the remaining three copies.
  - 6.4.3 The Designation (final disposal) facility will accept the waste, sign the tracking form, give one copy to the transporter, and keep one copy for its own records. Manifests will be available on-line within 15 days of the delivery of waste at the disposal facility.
  - 6.4.4 Quality can access these manifests by going to [www.stericycle.com](http://www.stericycle.com), clicking on Medical Waste Services, and then clicking on Customer Manifest Archive. Hard copies can be obtained.
- 6.5 Tracking Medical Waste Receipt
  - 6.5.1 Medical Waste generated by other Moog facilities may be transported to the Rush facility in accordance with all applicable regulations as long as the facility generates less than 50 lbs/month.
  - 6.5.2 Tracking forms must be completed by the transporter and maintained by Quality.
- 6.6 Exception Reporting
  - 6.6.1 Within 35 days, Quality should verify that the tracking form bearing the signature of the destination facility's owner or operator has been completed by going on line. If verification of receipt is not confirmed, Quality must try to determine the location of the waste.
  - 6.6.2 If, after 45 days, a signed tracking form is still not received, then an Exception Report must be filed by the next day with the state and the EPA Regional Administrator (as indicated below). The Exception Report includes both a letter from Moog explaining our efforts to locate the waste and the results of such efforts, and a legible copy of the original tracking form.
    - 6.6.2.1 EPA Regional Office
      - Region II
      - Air and Waste Management Division
      - 26 Federal Plaza
      - New York, New York 10278
      - 212-264-5166
    - 6.6.2.2 (Participating State Program)
      - New York State DEC
      - 625 Broadway
      - Albany, New York 12233
      - Tracking Forms: 518-485-8394
      - Other Inquiries: 518-457-3254

6.7 Transport by other than a small quantity generator must be performed by a DEC approved transporter such as the following or equivalent:

6.7.1 Our current contractor is:

Stericycle, Inc.  
3472 Progress Drive  
Dunkirk, NY 14048  
716366 4444  
Emergency Phone:  
1-800-234-0051

## 7 Revision History

The following are approved changes incorporated into revision numbers indicated below	
Revision	Description of Change
9	<p>Section 5.4, 7.1.1.7 and 7.1.1.8: Clarify manner in which non-contaminated materials that do not qualify as 'sharps' but that still could pose a mechanical hazard are to be discarded.</p> <p>Add sections 6, 8, 9 and 10.</p> <p>Apply current documenting format rules</p> <p>Update SOP numbers, and changed "QA" to "RA" throughout.</p> <p>Deleted references to: HMT, 336 Summit Point Drive, and their loading dock site for pick up.</p> <p>7.1.4 Reference to radioactive material and RAD-002 expunged.</p> <p>7.3.1.3, 7.3.3.3, Reference to and Attachment 1 removed.</p> <p>Added sections 7.5 and 7.6 to include information on our DEC approved transporter, and the "will call" option, and that small quantity generators may transport the waste themselves.</p> <p>7.5.2.2 DEC address changed</p>
10	<p>Periodic Review (CAPA 10-044)</p> <p>Header, updated company name from STS to MMDG, Rush and updated STS/Ethox to Moog throughout – Moog acquisition/ company rebranding (Reference EPCR 11-025)</p> <p>Section 2, removed PT-005 from References, not necessary – added titles to standards and added standard 29 CFR 1910.1030</p> <p>Section 3, added definitions for sharps</p> <p>Step 4.3, changed RA to Quality</p> <p>Section 5, added MD-287 to Materials</p> <p>Deleted Sections that do not apply to this work instructions</p> <p>Step 6.1.1.5, removed reference to "normal human cells". All human cells shall be treated as RMW</p> <p>Section 6.1.1.3, added NOTE to ensure liquids are not emptied into buckets and added step 6.1.1.3.5 to include animal carcasses</p> <p>Approximated capacity, steps 6.3.1.3 and 6.3.2.1</p> <p>Section 6.3.2, added step to place buckets in totes to reflect current practice and added NOTE to include totes do not need to be lined when used for buckets</p> <p>Step 6.4.4; revised to define how completed manifests are available on line</p> <p>Added step 6.5 to include tracking waste received from other Moog facilities</p> <p>Updated current contractor, step 6.7.1</p>