Modified on 8/4/2024 by Jasmine Yu

KGI BIOHAZARDOUS WASTE MANAGEMENT PLAN

I. Facility Information

a. **Contact Person**: Jasmine Yu, Laboratory Safety Manager, Office Phone 909- 607-8698

Facility: Keck Graduate Institute of Applied Life Sciences

535 Watson Drive, Claremont Ca, 91711

Phone: (909) 607-0144

b. **Type of Facility**: Academic Institution (Classrooms and Laboratories)

c. **Types of biohazardous waste and monthly average generated:** Bacterial samples, Biological Safety level 1 and level 2 waste, and average waste monthly ≤ 200 lbs. There is no medical waste generated at this site, only biological waste.

d. **On site Biological Waste treatment**: KGI has Large Quantity Medical Waste Generator Permit from State of California, Department of Public Heath (CDPH), Medical Waste Management Program. Registration No. 146 and treatment NO. P-146. The permit is renewed annually. KGI has two autoclave steam sterilization units (Steris Amsco model 3023, SN: R831911001 in Building 517 and Steris AMSCO 250LS, SN: 030122328 in Building 535) to treat biohazardous waste on site.

e. No waste hauler used

f. **No offsite treatment used**.

g. **Emergency Action Plan**: KGI has two autoclaves one will provide backup service to the other.

If material needs to be transported between the two autoclaves it will be secured by using 18-20gal storage container with lid and latched lock during transport. If either one of the autoclave is down for more than 24 hours, CDPH will be notified when the machine goes down and come back to work. If both autoclaves go down for more than 7 days, a certified Biological Waste Management company will be used to dispose of waste.

h. **In the case of a natural disaster** such as, an earthquake that can potentially cause equipment failure the unit(s) would be shut down/out of service until a professional service provider can inspect the unit(s) and perform the recommended service (i.e. re-calibration, parts, leakage test, etc.) before the unit(s) can be re-started for use again.

i. **The above information is complete and correct to the best of my knowledge**:

1. Jasmine Yu on behalf of KGI

j. **No medical waste, biological samples only**.

k. **No medical waste will be produced consisting of human anatomical remains, radiological materials, or chemotherapeutic**.

l. **Pharmaceutical waste is generated by pharmaceutical compounding lab once a year**. There are three weeks of Pharmaceutical compounding lab each year. Students learn to make tablets, capsules, ointment, cream, and other drug formula. All compounding products and left over materials are collected in special pharmaceutical waste containers and picked up by North

State Environmental once a year.

II. Containment and Storage Information.

a. Infectious, Potentially Infectious, or RNA/DNA BiologicalWaste

1. any material containing or contaminated with **human pathogens**
2. any material containing or contaminated with **animal pathogens**
3. any material containing or contaminated with **recombinant DNA or recombinant organisms**
4. laboratory and clinical wastes containing **human blood products, tissue**, **cell cultures**, and other potentially infectious material (**OPIM**)
5. Used, absorbent materials contaminated with blood products, or OPIM
6. Non-absorbent, disposable devices that have been contaminated with blood, body fluids or OPIM

b. Biohazard Liners

1. **Red** biohazard liners are to be tied to prevent leakage or expulsion of contents during all future storage, handling, and transport. The biohazard bag that is used to collect biological waste within a facility shall by manufacturer certified to meet the ASTM D1709 dart drop test, provided that when the bag is prepared for transport offsite, it is placed into a USDOT-approved container lined with a biohazard bag that is ASTM D1709 and ASTM D1922 certified.
2. Red biohazard bags are to be placed for storage, handling, and transport in **rigid containers** with tight-fitting lids labeled with the words “Biohazardous Waste”, or the word “Biohazard” and the international biohazard symbol on the lids and sides so as to be visible from any lateral direction.
3. Rigid containers that hold waste shall be decontaminated by 10% bleach or by Cavicide disinfecting wipes at least once every 7 days.
4. **Medical Related Spills**: See appropriate lab protocols for proper procedure(s) on cleaning.

c. **Laboratory waste containing infectious, potentially infectious, or rDNA must be inactivated prior to washing down the sink or leaving the facility.**

1. Liquid biological waste shall be inactivated with household bleach before being poured down the drain, under running water. As a general rule, add household bleach to a finial concentration of 10%, wait 10 minutes or until dry, then rinse down the sink with copious amounts of water.
2. Alternatively, a disinfectant that is known to be effective againstthe

organism may be added to liquid biological waste to an appropriate concentration, Per the manufacturers recommendations, the wait kill time will be determined, then rinse down the sink with copious amounts of water.

3. Solid waste shall be inactivated by autoclave. Autoclave the waste in an autoclave bag, affix autoclave indicator tape and place in an autoclave safe tray. CDPH requires that autoclaves by monitored for effective kill. See IV. C.
4. Storage of all non-inactivated waste in this category is restricted to within the generating laboratory. Infectious or pathogenic waste must be held in a closed/covered biohazard waste container and may not be stored longer than 7 days prior to inactivation.
5. Biological waste containers and bags for material that is infectious/potentially infectious to humans must be labeled with the biohazard symbol.
6. Filled or partially filled biological waste containers and boxes should not be held for more than 7 days at temperatures above 32°F or 0°C.

III. Biological Waste Packing, Labeling, Transport & Disposal:

a. Liquid biological waste:

1. As a general rule, add household bleach to a final concentration of 10%, wait 10 minutes or until dry, then rinse down the sink with copious amounts of water.

2. Alternatively, a disinfectant that is known to be effective against the organism may be added to an appropriate concentration, Per the manufacturers recommendations, the wait kill time will be determined, then rinse down the sink with copious amounts of water.

b. Solid biological waste

1. Polypropylene biohazard bags.

i. According to the Medical Waste Management Act (MWMA) "(b) the biohazard liner that is used to collect medical waste within a facility shall be manufacturer certified to meet the ASTM D1709 dart drop test and D1922, Tear Resistance. The color of the bag shall be red. The biohazard bag shall be marked with the international biohazard symbol.
ii. Label the bag with date, PI name, room number, and telephone number before transporting to autoclave for treatment.
iii. Do not put liquid waste in the bag!

2. Bio-waste Containers

i. Sturdy, red bio-waste cans displaying the biohazard sign are used as the terminal receptacle. Line the can with approved ASTM biohazard red liner of appropriate size.
ii. Do not overfill (<2/3 full), or cause the lid of the can to stand open to waste.
iii. Do not keep bio-waste for more than 7 days.
iv. Biohazardous waste bag shall be transported outside of the lab in 18-20 gal **rigid containers** with tight-fitting lids labeled with the words "Biohazardous", or the international biohazard symbol on the lids and sides so as to be visible from any lateral direction.

3. **Sharps Containers**
    i. Before disposal, Label with date, PI name, room number, and telephone number.
    ii. Tape all seams to prevent lids from accidentally opening.
    iii. Close when ¾ full and place in waste pickup for disposal. Full sharps containers shall not be stored at room temperature for more than 30 days. They can be stored in refrigerator for longer period.
    iv. Sharps containers are picked up by North State Environmental every three months. North State Environmental company info: 1045 W Rialto Ave, Rialto, CA 92376 Phone: (909) 875-9288

IV. Steam Sterilization

a. Factors in autoclave function

1. **Steam:** The energetics of steam makes it far more efficient for sterilization and decontamination than dry heat at the same temperature. Effective steam sterilization depends on the interaction of temperature, pressure, and time, but additional conditions inside the autoclave chamber such as materials, containers, container placement, and total volume of the materials also influence sterilization success. Each of these factors must be controlled within a narrow range of values or conditions:
2. **Pressure/temperature relationship:** Pressurization to 15 psi typically "superheats" steam to about 121°C (250°F), which is adequate to kill all microorganisms and to decontaminate or sterilize in reasonable time.
3. **Time:** Other factors being equal, autoclave loads up to about 2.0 ft^3 in volume require 30- 60 minutes to sterilize at 15 psi and 121°C. Larger loads and tightly packed materials require 60 minutes.
4. **Contact:** To sterilize or decontaminate uniformly, superheated steam must contact all areas of the load. To ensure steam can reach the center of biohazard waste load, biohazard waste bags should be kept open during inactivation. If the waste is dry solid, some water may be added to the bag before autoclaving.
5. **Volume:** "Dense" materials such as media in bottles to be treated in the autoclave should occupy **no more than half** of the autoclave chamber volume, so that steam can circulate completely around and into the load. Less dense materials such as bagged waste can occupy somewhat more space but should never contact the autoclave chamber wall.
6. **Dry heat:** Some autoclaves offer dry heat cycles, which are useful for sterilizing laboratory supplies such as Kim Wipes that can withstand high temperatures but would be damaged by steam. The necessary exposure times for dry heat vary considerably depending on materials composition, packaging, load volume, and possibly other factors, and may be more than triple the time needed for steam sterilization at the same temperature. Because the required times for successful dry heat sterilization vary so much the user may need to experiment extensively with appropriate times and temperatures to develop a consistently successful dry heat sterilization protocol.

b. Container Selection

1. **Place biohazard liners in a rigid container during autoclaving**. Liners are available in a variety of sizes, and some are printed with an indicator that changes color when processed.

i. After autoclaving, red biohazard liners are placed in a black trash bag with a label on outside indicating (decontaminated, date, lab number) for disposal to land field trash.
ii. Polypropylene liners are impermeable to steam, and for this reason should not be twisted and taped shut, but **opened loosely at the top**. This will create an opening through which steam can penetrate.

2. **Polypropylene containers and pans.** Polypropylene is a plastic capable of withstanding autoclaving, but resistant to heat transfer. Therefore, materials contained in a polypropylene pan will take longer to autoclave than the same materials in a stainless steel pan. To decrease the time required to sterilize material in these containers,
   i. Remove the lid (if applicable).
   ii. Turn the container on its side when possible.
   iii. Select the container with the lowest sides and widest diameter possible for the autoclave.
   iv. 30-60 min is required to completely inactivate biohazard waste if using polypropylene pan.
3. **Stainless steel containers and pans.** Stainless steel is a good conductor of heat and is less likely to increase sterilizing time, though is more expensive than polypropylene. If autoclaving in stainless steel pan, shorter time may be sufficient to inactivate biohazard waste.
4. **Preparation and Loading of Materials**
   i. Fill liquid containers only half full and loosen caps or use vented closures.
   ii. Always put bags of biological waste into pans to catch spills.
   iii. Position biohazard bags on their sides, with the bag neck taped loosely.
   iv. Leave space between items to allow steam circulation.
   v. Household dishpans melt in the autoclave. Use autoclavable polypropylene or stainless steel pans.
5. **Cycle Monitoring**
   i. Both autoclaves are equipped with a chart recorder to record, temperatures, pressure and run times. Please look at each tape when run is complete to ensure that the run was successful**.**
6. **Cycle Selection**
   i. Use liquid cycle (slow exhaust) when autoclaving liquids or biohazard waste, to prevent contents from boiling over.
   ii. Select Gravity cycle (fast exhaust) for glassware and other solid stuff.
   iii. Use Gravity cycle (fast exhaust and dry cycle) for wrapped items.
7. **Time Selection**
   i. Take into account the size of the articles to be autoclaved. A 2-liter flask containing 1 liter of liquid takes longer to sterilize than four 500 mL flasks each containing 250 mL of liquid.
   ii. Material with a high insulating capacity (high sided polypropylene containers) increases the time needed for the load to reach sterilizing temperatures.
   iii. Autoclave bags containing biological waste should be autoclaved for 90 minutes in plastic pan or 60 min in stainless steel pan with the bag open to assure decontamination.
   iv. Autoclave time needed to kill all spores can also depends on efficiency of autoclave unit. 535 autoclave needs 90 minutes no matter which pan is used.
8. **Removing the Load (Approved PPE Required)**
   i. Check that the chamber pressure is zero.
   ii. Wear lab coat, eye protection, heat insulating gloves, and closed-toe shoes.

iii. Stand behind door when opening it.
iv. Slowly open door only a crack. Beware of rush of steam.
v. After the slow exhaust cycle, open autoclave door and allow liquids to cool for 10 minutes before removing.

9. **Service:** A professionally trained service provider will inspect the autoclave according to the autoclave manufacturer's recommendations for inspection intervals and service. Most such recommendations are based on cumulative hours of use rather than specific calendar intervals. Autoclave gauges will be calibrated at least annually. If an autoclave fails to function correctly or a user finds a problem between scheduled inspections, the unit must be professionally serviced. **Do not resume operation of an autoclave until** it has been inspected and repaired. Call Jasmine Yu at x78698 to report any problem.

c. Testing Autoclaves for Effectiveness

1. Autoclaves used for pathogen kill-loads or clean glassware sterilizing cycles, should be routinely tested once per month for killing effectiveness. Before placing newly calibrated autoclaves into service, killing effectiveness testing must be completed.
2. The method of testing is using commercially available biological indicators with spores (usually *Bacillus stearothermophilus or Geobacillus stearothermophilus*). We use MAGNAamp (MA/6) from Mesa Labs.
3. The spore test kits are placed in the center of a typical load and run through a sterilization liquid cycle for 60minutes.
4. The ampule is incubated with the non-autoclaved ampule as positive control at 57C for 48 hours.
5. To remove the ampule from the biohazard bag without exposure to the contents, tie a string to the neck of the ampule.
6. If growth is noted in the autoclaved ampule, repeat the test.
7. If the second test still shows positive result, contact Steris for inspection of the unit.
8. Don't resume use of the unit until spore test result is negative after autoclave.
9. Autoclaves will be tested before being placed into service, and then retested monthly for effectiveness.

d. Method of Testing

1. *A commercially available test* indicator kit that uses bacterial spores (*Bacillus stearothermophilus*) is the approved method of testing autoclave efficiency. Most spore vial test kits require 56 to 60 ° C incubation of the autoclaved test vial along with a non- autoclaved control vial for 24-48 hours. Incubation causes surviving spores to grow, which validates the test.
2. *New autoclaves* before placing an autoclave into service, a test load approximating the weight and density of the type of waste generated shall be autoclaved with test spore vials. The spore vial should be placed in the middle of the waste inside the bag. The appropriate parameters for sterilization including temperature, pressure, and treatment time shall be determined in this way.
3. *Autoclaves already in use:* **Monthly** testing will be done by placing a spore vial in the very center of a biohazard waste load and keeping the liner open prior to autoclaving.
4. *Spore Test Storage Information*: Please read the spore vial product information sheet for appropriate storage information. MAGNAamp

ampule should be stored at 4C. Each batch of vials has an expiration date. Vials should not be used after their expiration date.

e. **Recordkeeping :** The following records regarding autoclave use must be kept for a minimum **three** years before disposal:
   1. Autoclave use log: Each load of material inactivated shall be logged as follows:
      i. Date, time, and operator's name
      ii. Type of content loaded
   2. Confirmation of sterilization
      Printing record shows the temperature, pressure, and length of time the load is sterilized. Please note that temperature sensitive autoclave tape is not sufficient to indicate that the load reached sterilization conditions because the tape will change color at lower temperatures. **So save the autoclave print-out**.
   3. Maintenance record shall be in place for each autoclave unit. This shall include the following: date when the problem begins and ends, what is the problem, who comes to repair, how is the problem solved

V. Training

a. All employees who handle biological waste shall be trained regarding the proper segregation, handling, packaging, labeling, storage, transport and treatment of biological waste. Refresher training is required annually.

b. Records of the training session shall be maintained by the lab PI for each employee, along with an outline of the training program. Training records shall be retained for a period of three (3) years.

VI. Disinfecting Techniques

a. Before leaving the BSL 2 area all sample carriers will be wiped down with Cavicide and/or 8% Vesphene and will sit twenty minutes prior to transport. 10% bleach may also be used, or 70% ethanol depending on samples being used.

b. All work surfaces and any spills of the material will be decontaminated by treatment with a microbicide (e.g. 8% Vesphene, undiluted Cavicide, or similar) for 20 minutes.10% bleach may also be used, or 70% ethanol depending on samples being used. All remaining liquid will be collected by paper towels and autoclaved.

VII. Deploy Spill Cart in the need of spill contamination

VIII. Appendix A autoclave log sheets

IX. Appendix B autoclave maintenance record sheets

X. Appendix C Treated Biological Waste label

Appendix A. AUTOCLAVE USER SIGN-UP SHEET

Date	Operator (full name) /lab	Contact (email, phone)	Contents of load	Sterilizing time	Notes

Appendix B. AUTOCLAVE MAINTENANCE SHEET

Date call the service	Problem description	Technician/com-pany name	Date service provided	Is the problem solved? How?

The material contained in this bag meets the definition of “Treated Biomedical Waste”.
The material has undergone steam sterilization or chemical disinfection to render this waste harmless and biologically inert. I further certify by my signature that this container DOES NOT contain sharps, glass, or needles which might puncture this bag or container.

Sign_______________________Date_______________
Contact Number________________________________

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