

Biohazardous/Medical Waste Management and Sharps Procedures

Contents

Introduction	3
Definitions	3
Responsibilities	6
Waste Management	6
Category 1 Waste.....	6
Category 2 Waste.....	6
Category 3 Waste.....	7
Waste Treatment.....	7
Liquid Waste.....	8
Solid Waste	9
Carcass Waste	9
Sharps.....	9
Safe Sharps Handling	10
Category 1 Sharps (Regulated Biohazardous/Medical)	11
Category 2 Sharps (Non-Biohazardous, Uncontaminated).....	12
Category 3 Sharps (Non-Biohazardous, Contaminated).....	13
Glass and Broken Glass	13
Autoclave Management	14
Cycle Selection.....	15
Operation	15
Validation and Indicators	16
Training	17
Safety	17
Proper Segregation	18
Resources.....	18
Acknowledgements and sources:	18
Appendix A	20

Introduction

This procedure defines the requirements for all Kansas State University (KSU) entities that generate and manage medical, biohazardous, infectious or potentially infectious waste and those generating sharps or broken glass waste in academic and research labs, veterinary health clinics, and shops.

This document does not address solid waste generated as a result of recycling efforts on campus. It does not address special handling requirements for Biosafety Level 3 or 4 facilities. Please seek additional guidance from the Institutional Biosafety Committee (IBC) or Department of Environmental Health and Safety (EHS) on additional procedural requirements at KSU BSL 3 laboratories.

Definitions

The definitions provided are solely for the purpose of this document.

- **Bloodborne Pathogens (BBP)** - pathogenic microorganisms that may be present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).
- **Regulated Waste**
 - **Medical Waste** – Waste materials generated during diagnosis, treatment, or immunization of human beings or animals are regulated as “medical waste”. This includes sharps used in these settings that are potentially contaminated with human bodily fluids or other potentially pathogenic agents as a result of these medical and testing activities or as a result of research activities. “Regulated medical waste” **does not** include waste generated in residences or households and regular campus bathrooms. For the purposes of this document, medical waste will include waste generated in research settings if such activities include the handling of human bodily fluids/products or animals and products/waste from animals potentially exposed to infectious agents. See Examples of Category I Wastes in [Appendix A](#). “Regulated medical waste” is typically waste that contains human bloodborne pathogens, but it can include other forms of waste with the potential to cause deleterious effects on humans, animals and the environment if improperly managed or disposed.
 - **Bloodborne pathogen waste** OSHA defines “regulated waste” as any liquid or semi-liquid blood or other potentially infectious material (OPIM); contaminated items that would release blood or OIPM in liquid or semi-liquid state if compressed; items that are caked with dried blood or OPIM and are capable of releasing these materials during handling. Waste generated in clinical settings that does not meet the criteria listed here, will not be considered regulated

medical waste requiring special disposal or treatment unless it is considered a biohazard by other criteria.

- **Decontamination** - the use of physical or chemical means to remove, inactivate, or destroy bloodborne or other pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.
- **Sterilization** – A sterilization procedure is one that kills all microorganisms.
- **Disinfection** – A disinfection procedure is less lethal than sterilization. Disinfection eliminates nearly all recognized pathogenic microorganisms, but not necessarily all microbial forms.
- **Autoclave** – equipment or apparatus in which special conditions such as high or low pressure or temperature are generated to treat waste or sterilize instruments or materials.
- **Tissue Digestion** - alkaline hydrolysis (high temperature and pressure assisted process) of carcass or animal parts for the purpose of disposal.
- **Sharps** - Items capable of puncturing, piercing, cutting, or abrading the skin, including but not limited to glass or plastic pipettes, test tubes, broken capillary tubes, exposed ends of dental wires, culture slides, scalpels, razor blades, lancets, suture needles, needles, and syringes with needles. This includes laboratory slides and cover slips, petri/culture dishes, and broken ridged plastic when potentially contaminated with infectious agents (otherwise handle as laboratory broken glass).
- **Glass/Broken Glass Waste** – Glassware or glass containers in a shop, clinic or laboratory setting that are broken or may become broken during disposal. For the purposes of this procedures document, broken glass excludes intact glass containers intended for reuse; glass pipettes (which are managed as sharps); glass light bulbs (managed under separate requirements); and broken glass generated in residences.
- **Needles** – hollow needles used to inject drugs (medication) under the skin
- **Syringes** – devices used to inject medication into or withdraw fluid from the body
- **Lancets**, also called “fingerstick” devices – instruments with a short, two-edged blade used to get drops of blood for testing. Lancets are commonly used in the treatment of diabetes.
- **Auto Injectors**, including epinephrine and insulin pens – syringes pre-filled with fluid medication designed to be self-injected into the body
- **Infusion sets** – tubing systems with a needle used to deliver drugs to the body.
- **Connection needles/sets** – needles that connect to a tube used to transfer fluids in and out of the body. This is generally used for patients on home hemodialysis.
- **Biohazardous materials** – biological substances that pose a threat to the health of living organisms, primarily that of humans. Biohazardous materials are of biological origin and have the capacity to produce deleterious effects on humans or animals. This can include medical waste or samples of a microorganism, virus or toxin (from a biological source) that can affect human health and include biohazardous agents. This includes recombinant DNA introduced into humans or animals (transgenic animals)
- **Biohazardous agent** – any agent classified as Risk Group (RG) 2 through 4 (no RG 4 agents are authorized for work on KSU grounds).

- **Hazardous Waste** – The term hazardous waste is reserved for chemical waste that is regulated under the Resource Conservation and Recovery Act (RCRA).
- **Radioactive Waste** – Materials that are either radioactive, have become radioactive through exposure to neutron radiation, or are contaminated with radioisotopes. Radioisotopes are any material that emits radiation spontaneously unless otherwise specified by the KSU Radiation Safety Officer (RSO).
- **Category 1 Waste** - Waste known, assumed, or suspected of being infectious to humans, plants, or animals and could cause harm if released to the environment. Infectious waste includes contaminated materials and/or sharps that are potentially contaminated with bloodborne pathogens, human fluids, human cell lines, or with biohazardous organisms (e.g. petri dishes, surgical wraps, culture tubes, syringes, blood vials). These materials are referred to as biomedical, medical, or biohazardous waste. See Examples of Category I Wastes in [Appendix A](#). These materials do not include
- **Category 2 Waste** – Waste with the appearance of medical waste that is not biohazardous and is not regulated medical waste. This would be materials that are not considered infectious, medical, or biohazardous waste. These “look-alike” waste materials may include:
 - Non-medical sharps – sharps generated in labs that **do not** handle any form of infectious, potentially infectious, medical waste, human blood or bodily fluids, or biohazardous materials.
 - Syringes and needles generated in labs that **do not** handle any form of infectious, potentially infectious, medical waste, human blood or bodily fluids, or biohazardous materials.
 - Blades, scalpels and other sharp instruments generated in labs that **do not** handle any form of infectious, potentially infectious, medical waste, human blood or bodily fluids, or biohazardous materials.
 - Broken glass slides, pipettes, and other sharp laboratory waste generated in labs that **do not** handle any form of infectious, potentially infectious, medical waste, human blood or bodily fluids, or biohazardous materials.

These materials have no contact or possible contact with or contamination by potentially infectious human or animal materials or rDNA. If sharps waste is generated in a laboratory that handles potentially infectious material/medical waste, then sharps, regardless of whether they are contaminated, will be managed as Category 1.

- **Category 3 Waste** – These wastes are contaminated with hazardous chemical or radioactive materials.
- **Medical Waste Generator** – A person whose act, process or research efforts produces medical waste. It does not include those that handle this waste for transport/disposal.

Responsibilities

Every employee of KSU that generates or handles waste identified by this document is responsible for understanding these procedures and related safety precautions and following the practices indicated. Employees are responsible for promptly reporting any hazardous or unsafe condition or activity.

Every department/college is responsible for ensuring that these requirements are followed by department/college personnel and that required training is received. Department/college specific procedures may be indicated based on activities and equipment used. These procedures should be communicated to affected employees in writing and also communicated verbally and/or in hands-on related training. Departments are responsible for providing safety engineering controls and personal protective equipment (PPE) at no cost to the employee. Employees exposed to biological hazards that pose a potential for infection or illness may need medical surveillance, vaccinations, and/or serum titers, all of which must be provided by the department. Employees must be provided with information/training on occupational injury/illness reporting. Departments/colleges are responsible for the operation, testing and maintenance of programmatic equipment (e.g., autoclaves) as applicable to these procedures.

KSU EHS is responsible for the pickup and transport of regulated or potentially regulated waste at the Manhattan campus. Other campus locations must make alternative arrangements or contact EHS for assistance with coordination of waste disposal.

Waste Management

Category 1 Waste

KSU EHS provides medical waste (Category 1) disposal services to the Manhattan campus. Most Category 1 waste may be disposed through EHS with or without prior treatment. Waste picked up by EHS is sent for commercial autoclaving. If waste generated requires incineration, contact EHS to make alternative arrangements.

Special waste treatment procedures are in place for BSL 3 facilities on campus. Refer to the facility-specific protocol or contact the [University Research Compliance Office](#) (URCO) for guidance prior to requesting EHS pick up of untreated wastes generated in BSL 3 labs.

Category 1 waste may be autoclaved onsite by KSU departments. Review the autoclave procedures in this document for requirements and guidance for autoclaving biohazardous waste on-site. Review [treatment](#) options and ensure that chemical disinfection meets CDC's Biosafety in Microbiological and Biomedical Laboratories (BMBL) requirements and/or EPA standards for disinfectants.

Category 2 Waste

Category 2 waste are not regulated materials. EHS does not pick up Category 2 waste. Regulation does not require disinfection by thermal or chemical process for this waste type.

Procedures are provided below for select Category 2 waste to ensure the safety of personnel generating, handling and managing this waste type. Refer to the [Category 2 Sharps](#) and [Glass and Broken Glass](#) sections that follow.

Sterilization or decontamination may be indicated as a standard of care for waste generated through research, which does not meet the definition of Category 1. Such treatment is at the discretion of the researcher. Guidance is available through EHS and IBC as applicable.

Category 3 Waste

Hazardous chemical and radioactive wastes are managed through EHS. In some cases, waste may contain both biological and hazardous chemical or radioactive wastes. These wastes must be managed by KSU EHS.

Category 3 waste should be managed as follows:

- Biological + Radiation = Radiation Waste
- Biological + Hazardous Chemical = Chemical Waste

Some category 3 materials may be chemically disinfected prior to EHS pick up. Ensure that disinfection solutions are compatible with the waste. The process requires prior review and approval by EHS. Whenever possible, review protocols with EHS prior to generating Category 3 wastes.

Take the appropriate [training](#) for the handling and management of regulated hazardous chemical or radioactive waste *prior* to generating these waste types.

You must obtain approval and take radiation safety training prior to obtaining or handling any radioactive materials. If you will generate radioactive mixed waste (biohazardous and radioactive) contact the institutional [Radiation Safety Officer](#) in the KSU EHS Department for instructions.

Waste Treatment

Category 1 waste may be managed through KSU EHS or treated on-site using an approved thermal (e.g., autoclave) or chemical disinfection process with demonstrable efficacy and documented validation procedures.

Chemical disinfection is dependent on the nature of the chemical disinfectant and concentration used, the pathogen present, and the contact time. For additional information refer to the [Resources](#) section below.

Thermal disinfection may be achieved through several methods, including incineration or autoclaving. Autoclave standard operating procedures (SOP) must be developed for autoclave units used at KSU for the treatment of infectious materials regardless of whether the agents are

human, plant, or animal pathogens. Operators should be trained in the proper operation of the autoclave, proper autoclave loading and appropriate waste preparation and packaging. See [Autoclave Management](#) below for additional information.

Do not provide prion contaminated materials for standard chemical or heat treatment. Contact the IBC for additional information and procedures for wastes containing, or suspected of containing prions.

Liquid Waste

Liquid biological waste should be collected in containers for autoclaving or chemical disinfection. Following autoclaving or chemical disinfection, category 1 liquid wastes may be disposed via sanitary sewer (e.g., laboratory sink). Category 3, regulated hazardous chemical or radioactive waste, may not be disposed of in a sink. Do not pour melted agarose down the drain. Allow it to cool and solidify, then dispose of it as solid waste in biohazard waste bags.

Do not autoclave hazardous chemicals, including flammable, reactive, corrosive, or toxic chemicals unless there is an EHS-approved procedure for this practice.

Vacuum flasks or traps and pour-off containers should be filled with fresh disinfectant prior to use. Collection containers should be labeled with the biohazard symbol. Glass flasks/containers should be stored in a secondary container sufficient to capture spills (if not in a BSC). House vacuum lines **must** be protected with a two trap system and HEPA filter during aspiration of infectious/biohazardous fluids. Similar protection should be provided for lab pumps.

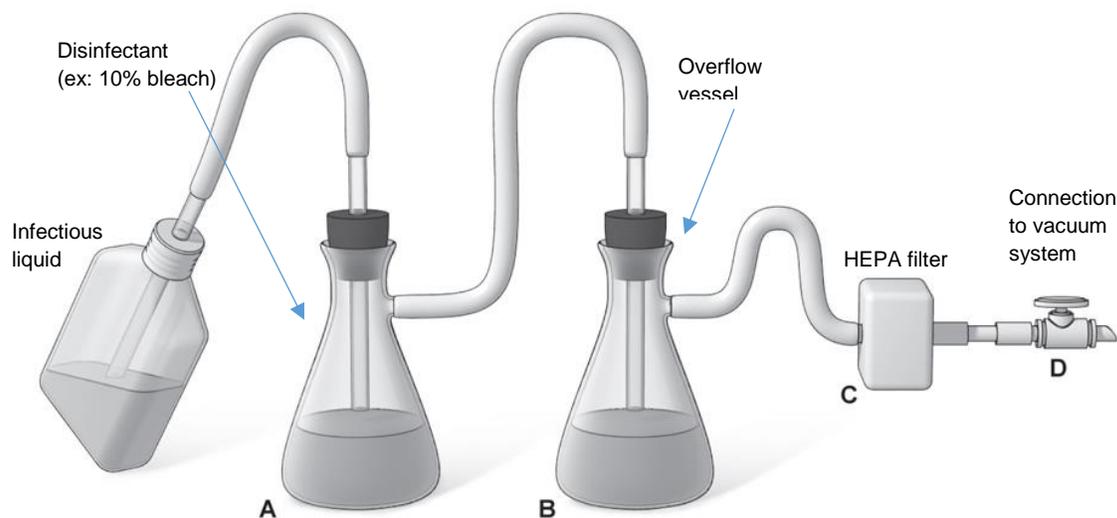


Figure 1 Vacuum System Protection (adapted from the BMBL, 5th Ed, 2009, pg322).

Solid Waste

Collect non-sharps waste in a solid walled, leak proof container lined with an autoclaveable biohazard bag. The container must be labeled with the biohazard symbol and it must have a closable lid. The label shall have the name of the generator and nature of the waste. Keep the container closed when not actively in use. Do not place non-biohazardous waste into the container. Never place glass, glass pipettes, or sharps into the container. See the [Sharps section](#) below for sharps-specific procedures. Collect pipettes separate from sharps and within pipette keeper boxes or a biohazard bag lined box to prevent bag puncture.

When $\frac{3}{4}$ or less full, securely close the bag and transfer it to a hard sided box or tote for transport. Never compress or push down on the waste container.

If transporting to on-site autoclave within the same building, bags may be transported within a wheeled wagon, tote or other deep vessel. The container side walls should exceed the height of the contents. If the waste is sent for offsite treatment and disposal, the hard sided container must be securely closed (e.g., box is taped shut) and must conform to the requirements of the medical waste disposal contractor. Contact EHS to schedule offsite disposal and for guidance on restricted materials, appropriate labeling and container selection.

Following autoclaving, the category 2 waste may be disposed in the regular trash. Once properly treated, waste containers should no longer display the biohazardous symbol. Place in plain unmarked bag/container and dispose in the trash.

Animal Waste

Animal waste (dead animals and animal parts) may be discarded through the EHS medical waste program. This waste must be kept frozen until pick-up. A department or laboratory/clinic representative must be available at the time of pick-up to ensure the correct waste is collected.

Animal waste may also be disposed onsite through tissue digestion. Please contact your department or EHS for additional information regarding waste collection for tissue digester disposal.

Animal waste infected or potentially infected with zoonotic agents must be handled as a BBP with handling procedures and personal protection equipment (PPE) appropriate to the nature of the agent and associated routes of exposure. Follow your department's infection control plan when handling infectious waste. Bagged waste must be labeled with the biohazard symbol and name of the lab PI or clinic generating the waste.

Sharps

Sharps must be disposed in an appropriate sharps container as soon as possible after use. Place waste in a rigid, puncture-resistant, leak-proof (on sides and bottom), labeled waste

container that has a secure lid with an alternate smaller opening appropriate to the type and size of waste.

Never:

- Place sharps in regular trash bags or waste cans
- Reach into a sharps waste container (or other waste receptacles).
- Place liquids, such as full syringes, in the sharps waste container.
- Fill the container beyond the “fill” line where applicable (approved medical waste containers have a fill line). Containers **must not** be overflowing or at full capacity such that: 1) lids do not fit securely, 2) materials poke out from the opening, or 3) the capacity presents a puncture or contamination risk to individuals handling the container.
- Reuse sharps waste containers¹
- Place sharps in food containers or items resembling containers of food
- Place sharps in waste containers designed for [broken glass](#)

When ready for container disposal, transport, or treatment, ensure the lid is properly secured. Follow the procedures below for proper disposal management based on the nature of the sharps waste category. Sharps containers must be easily accessible to employees and located as close as feasible to the immediate area where sharps are used.

Safe Sharps Handling

Contaminated needles and other sharps shall not be bent, recapped or removed unless the PI/Vet/Department can demonstrate that no alternative is feasible or that such action is required by a specific medical, dental, or other procedure. Shearing or breaking of contaminated needles is prohibited.

Refer to the KSU [Workstation Precautions for BBP](#) for additional guidance in safe handling practices.

Sharps should never be placed in the regular trash. Regardless, custodial staff and all others handling waste receptacles and related bags and/or other waste transport containers must employ proper handling techniques to avoid injury. Trash receptacles/cans should have liners/bags.

- Never place hands inside of trash containers.
- If an article must be retrieved, use long-handled tongs or similar device.
- Remove bags from trash receptacles/cans by handling only portions of the liner that are on the exterior of waste receptacle/can.

¹ Programs that propose reusing containers, must obtain approval from EHS and must have an EHS Committee approved written plan in place.

- Never tamp down trash by stepping on the contents or otherwise attempting to compress the contents.
- Hold the removed liner/bag by the top of the bag and hold it away from the body.
- Transport the retrieved waste in a hard sided container.
- Place the trash liner/bag in dumpster for disposal.
- Never enter the trash dumpster to examine or retrieve materials.

Category 1 Sharps (Regulated Biohazardous/Medical)

Use only **FDA-cleared or similar** biohazardous/medical waste sharps containers appropriate for the nature of the sharps waste generated. The containers must be:

- rigid sided,
- puncture resistant,
- closable with a tight fitting lid that prevents sharps from coming out, and
- leak proof



Figure 2 - Biohazard Symbol

These are available through laboratory, medical and clinical supply vendors. These will be red or clear with the biohazard symbol affixed and the word “biohazard”. An example of the biohazard symbol is provided in Figure 2. Select a container designed so it limits the potential for contamination of container exterior/top and limits the potential for needle sticks. Container openings differ to ensure the safety of the users and containers come in various sizes with differing features such as mounting brackets. Containers not mounted should be up-right and stable during use.

Label the container with the word “Sharps” **and** the words “Biohazard” or “Medical Waste”. Sharps containers usually come with appropriate labeling, which is adequate for management during generation of waste. Additional labeling may be needed when waste container is full and ready for pickup such as PI, manager or generator name. The label must be fluorescent orange or orange-red or predominantly so, with lettering and symbol in a contrasting color. It must have the international biohazard symbol (Figure 2) and the word biohazard. A statement relating to which portion of the equipment remains contaminated (e.g., needles, blades) is also recommended.



Figure 3 - Sample Sharps Biohazardous Containers

See Figure 3 for examples of appropriate sharps containers. Never use food containers for collection or disposal of Category 1 sharps. Alternative open top containers may only be used with written EHS approval.

Place in a secondary container if leakage is possible. The secondary container must be closable, constructed to contain all contents and prevent leakage during handling and transport, and labeled as previously described. If lid does not fit securely due to damage or use of approved alternative container, tape lid securely prior to transport.

Place full sharps container in your department's designated biohazardous waste collection area. Contact the clinic or laboratory manager or department head for instruction on whether treatment (e.g., autoclaving, deactivation) prior to EHS pick up is required. [Contact EHS](#) for pick up and disposal.

Category 2 Sharps (Non-Biohazardous, Uncontaminated)

Use a container that is puncture-resistant and leak-proof. Do not use red containers. Deface any existing container markings. Clear or white regular medical sharps containers may be used as long as biohazardous markings are removed or defaced as in Figure 4. Some re-purposed plastic containers may be used to collect and store sharps that are **not contaminated** and were **not** generated in a clinic or laboratory that generates and/or handles biohazardous or other potentially infectious materials (which must be handled only as Category 1 sharps).



Figure 4- Non-Biohazardous Sharps

To use containers other than those specifically manufactured and/or sold for sharps waste, the container must be a rigid, undamaged, and be puncture resistant. Sturdy liquid laundry detergent containers are acceptable. As a guide, containers made of polypropylene (PP) or high-density polyethylene (HDPE) displaying the recycling designations numbers of 5 or 2, respectively, are generally suitable. Look for the symbols shown in Figure 5.



Figure 5 - Plastics Packaging Resin Codes For Recycling Identification

Any original product labeling must be completely defaced or covered with proper secondary label. A sample alternate container is pictured in Figure 6. These re-purposed containers are acceptable, but not recommended due to the tendency for this to be mistaken for empty reusable/recyclable materials. If this type of

container is used, all original product marking should be removed and replaced with appropriate precautionary labeling to include:

- Sharps
- Non-Biohazardous or Non-Medical
- Do not recycle

Do not fill to capacity. Once ~3/4 full, the container must be securely closed with the original lid and taken to the dumpster. Do not leave waste in areas of public access. Custodial services is not required to take out sharps waste.

Category 3 Sharps (Non-Biohazardous, Contaminated)

Category 3 sharps waste are contaminated with regulated hazardous chemicals or radioactive materials. Confirm if your sharps waste is regulated by contacting [KSU EHS](#).

Category 3 Sharps must be stored in containers manufactured and sold for containing sharps. Do not use alternate containers such as those described in Category 2 Sharps.

If sharps are not contaminated with biohazardous/infectious materials, do not use the biohazardous symbol or red containers. Deface all markings displaying the biohazard symbol and the words biohazardous. Label the container with the appropriate hazardous waste or radiative materials label and the word “Sharps”.

If sharps are both chemical or radioactive and contaminated/potentially-contaminated with an infectious biological agent, use the type of container described for Category 1 and the biohazard symbol, in addition to the appropriate hazardous waste or radiological waste label.

Place the full sharps container in your department’s designated hazardous waste and contact [KSU EHS](#).

Glass and Broken Glass

Dispose of glassware in a box with a lid or which can be securely closed. Do not throw glassware in regular trash cans. Broken glass or glassware waste containers are available from laboratory supply vendors. Figure 5 provides examples of suitable containers. Any sturdy, undamaged corrugated box is suitable. The boxes should be lined with a 2 mil poly bag.

All containers must be clearly labeled with one of the following:

- Laboratory Glassware



Figure 4 - Alternate Sharps Container. Source: edited image from Minnesota Department of Health



Figure 5 - Sample Glassware Waste Container

- Lab Glassware Only
- Broken Glass or Glass

Keep glassware for disposal separate from all other waste in the laboratory or shop. Laboratory glassware and chemical containers cannot be recycled. Chemical and reagent containers must be empty prior to disposal. All contents must be removed by ordinary means (e.g., draining, pouring, scooping) prior to disposal.

Once the glassware waste container is three-quarters full, seal the top of the box with packaging tape and transport the closed container to the building trash dumpster. Custodial services is not required to take out laboratory or shop glassware waste.

Do not handle broken glass with your hands. Use a brush and dustpan, tongs, or forceps to pick up broken glass. Substitute plastic ware for glassware when practical in laboratories with infectious agent work.

Autoclave Management

Category 1 waste must be biologically-inactivated before it may be disposed of as regular trash. If autoclaving regulated waste for direct disposal rather than EHS and/or medical waste vendor pick up and disposal, a written waste treatment plan or protocol is required. Autoclave treatment of regulated medical waste is permitted for treatment of clinical, academic, and some research waste. Autoclaving of materials generated in BSL 3 laboratories requires procedural review by the KSU Research Compliance Office. Waste generated as part of experimentation with rDNA requires IBC review of the waste treatment protocol before it can be discarded.

At minimum, the Category 1 waste treatment plan (may be part of an infection control plan) will include:

- Units and locations (covered by plan)
- Responsible Person(s) and contact information
- Nature of waste that may be treated and restricted materials
- Departments/clinics from which waste will be received
- Unit validation and testing criteria
- Training requirements for operators
- Requirements for how generators should prepare waste
- O&M (e.g., vendor designation and frequency of service, internal processes, service vendor contact information)
- Emergency procedures and reporting
- Optional:
 - Trouble shooting techniques for unsuccessful runs
 - Template for documentation logs

The following provides information and recommended practices for autoclave management. These practices plus additional controls, documentation and employee training are required for those treating waste for direct disposal to municipal (regular) trash. Safety training is required for all employees operating autoclave units and may be provided in-house by experienced staff. Training must include review of the manufacturer's operation manual for the specific unit(s) operated.

Cycle Selection

Autoclaves or steam sterilizers have the ability to adjust the time, temperature and pressure by cycle. Use the appropriate cycle based on the nature of the type of waste or load and volume. Review the manufacturer recommendations and read the operation manual for the unit to help determine the proper unit type and cycles needed for the anticipated waste type.

The processing time needed for effective sterilization is dependent on load size, type of container, and moisture content.

Liquid loads may require a gravity cycle with slower exhaust rate to minimize boil-over.

Operation

Designate an individual(s) responsible for oversight of the unit to include ensuring proper operation and maintenance, validation, and testing of the unit and associated documentation (Responsible Person). Use a qualified contracted service professional to perform repairs. Do not operate autoclaves that are not in good repair. Label units that are not functioning properly. An annual inspection and service contract is recommended and is the responsibility of the department/college.

An autoclave log is required. Even if the unit is equipped with paper print outs for run data, a separate log is needed to document problems, testing, repairs, kill validations, dates/times, and related operators and/or vendors.

Develop standard operation procedures (SOP) for operators that are specific to the unit and nature of the loads. They should include logs, testing, and operational steps in accordance with the manufacturer's operation instructions/manual. Train staff on the SOP and have these readily available or posted. Treatment of Category 1 materials by autoclave require that the SOP include testing and validation steps and frequency. The SOP are a user document and are not a substitute for the written treatment plan, but may be incorporated.

Steps for Autoclave:

1. Close and lock door
2. Choose appropriate cycle (e.g., gravity, liquid, or dry) based on material.
3. Set time and temperature (if using custom cycle)
4. Start cycle

5. Fill out log
6. Leave door closed during operation
7. Abort cycle and report any problem to the responsible person or PI.
8. Do not open until the cycle is complete and temperature and pressure return to safe range.
9. Upon completion of cycle, allow load to stand for 10 minute in the chamber to allow steam to clear and trapped air to escape from hot liquids.
10. Use appropriate personal protective equipment (heat-resistant gloves and eye protection).
11. Don't agitate containers or remove caps (super-heated liquids present a hazard)
12. Move items from the autoclave and place in area designated or marked for hot materials and allow these to cool before handling without heat resistant gloves.
13. Shut autoclave door.

Place an "out of service" sign on units that are not operating properly. Document the problem in the autoclave log. Contact your service provider for repair and testing.

Validation and Indicators

Autoclave efficacy is verified by several means. Indicators check the performance of an autoclave to ensure a specific performance standard. The four basic types of indicators are:

- Visual indicators (chemical/tape) measure one or more physical conditions of the autoclave cycle. The most commonly used visual indicator is autoclave tape, which contains a heat-sensitive ink that changes color from white to a visible pattern following processing. This indicates only that a specific temperature (121°C) was achieved. However, it does not validate decontamination effectiveness. Used outside of the container, it verifies only that target temperatures were achieved in the chamber, outside of the container. It does not verify that temperature was achieved inside the load.
- Mechanical indicators are integrated into the autoclave and record the time-temperature-pressure profile attained during a cycle.
- Biological indicators are composed of a standardized population of heat-resistant bacterial spores such as *Geobacillus stearothermophilus*, most commonly in the form of spore vials. They are used to determine if the sterilization cycle parameters were sufficient to kill the test microorganisms.
- Chemical indicators or strips test the time, temperature, and quality of steam exposure and are calibrated to mimic the results obtained using the traditional *Bacillus stearothermophilus* biological indicator tests (i.e., spore tests). However, chemical integrator strips give immediate results rather than requiring the 24-48 hour post-autoclave incubation period necessary for spore germination and growth.

Various practices can affect the inactivation of autoclaved biological wastes. Follow recommended practices to avoid diminishing autoclave effectiveness.

- Open bags prior to run
- Add water to the bag (as indicated) if contents are unlikely to generate steam (dry goods)
- Do not overfill bags or the autoclave chamber
- Use the appropriate size unit for the nature and size of the anticipated loads
- Ensure sufficient run times and temps

Training

All operators and the responsible person must receive training prior to starting work with autoclaves. Training is the responsibility of the department/college. Training should be reviewed or refreshed anytime operation procedures or SOPs change and if there is concern or incident indicating that review is warranted.

Training must include:

- The specific SOPs developed for the nature of the loads and unit type,
- Restricted materials
- safety practices and PPE required,
- spill or incident response procedures,
- documentation/log requirements,
- proper loading and unloading,
- failure reporting,
- Out of service signage posting, and
- Injury reporting and response.

Safety

Autoclaves generate steam/high heat, high pressure and potentially vapors that can be hazardous to operators. Risks include burns (e.g., hot surfaces, residual steam, hot fluids scalds), hand and arm injuries (when closing doors), injuries due to explosions, and inhalation of hazardous vapors (when inappropriate materials are autoclaved). To avoid injury, personnel that operate autoclaves must be trained on the proper operation of the unit and the appropriate protective measures. Large autoclave units should have an exhaust vent above the autoclave door/opening.

Follow manufacturer's recommendations for safe and proper operation specific to the model.

Safe Practices:

- Wear Personal Protective Equipment (PPE) including a lab coat, scrubs and/or apron; heat insulating gloves that cover all hand and forearm (when handling equipment during operation); eye protection (when unloading autoclave); closed toed footwear.
- Do not seal containers.
- Never open the door to an autoclave if there is water running out of the bottom. Clogged steam lines, equipment malfunction, or plugged drains may cause a buildup of scalding water.
- Do not open the door until the pressure is zero and the temperature is at or below 121°C at the end of a cycle. Don't stand directly in front of the door when opening the chamber.
- Never superheat liquids. Superheating is a condition that occurs when liquids are at a temperature above their normal boiling point but do not appear to be boiling. Any disturbance of the liquid could cause some of it to violently flash to steam and spray. In situations where personnel are in a hurry to remove flasks or bottles from the autoclave, the superheated liquids may boil out of their containers or explode.

Proper Segregation

Reserved

Resources

- [CDC BMBL](#)
- [OSHA BBP Standard](#)
- [KSU EHS Medical Waste webpage](#) (request medical waste removal and waste containers)
- [Radioactive Waste Pickup Request](#)
- [Hazardous Waste Pickup Request \(chemical\)](#)

Acknowledgements and sources:

- [CDC BMBL](#)
- Purdue Biosafety Section
- University of Nebraska Lincoln Sharps SOP
- Arizona State University SOP Safe Autoclave Operations
- University of Illinois
- University of Connecticut Biological Waste Guide
- Brandeis University Glassware Handling and Disposal
- University of Tennessee [Biosafety Program](#)

- University of Ottawa

Appendix A

Examples of Medical Waste (Category I Waste):

- Body fluid, solid, or semi solid material that is potentially infectious
- Items that are freely dripping liquid or semi-liquid blood or "potentially infectious materials" or could readily release infectious materials if compressed
- Items containing dried blood or "potentially infectious materials" that could release flakes if compressed or otherwise handled
- Human blood and blood products, including serum, plasma, and blood components
- Hemodialysis waste of all items that were in contact with the patient's blood (tubing, filters, towels, gloves, aprons, lab coats) and any other contaminated disposable equipment)*
- Human or animal isolation wastes (blood, excretion, exudates, secretions, and items contaminated with these) from humans or animals that have been isolated to protect others from communicable diseases (unless testing confirms waste is non-infectious).
- Surgery or autopsy tissue, organs, or body parts (e.g., adenoids, appendix, tonsils, amputated digits, hands, feet, arms or legs), also known as pathological wastes
- Surgical and autopsy wastes (e.g., soiled dressings, sponges, drapes, lavage tubes, drainage sets, underpads, and surgical gloves) that were in contact with infectious agents
- Cultures or stocks of any virus, bacterium or other organism including discarded live attenuated vaccines and the items used to transfer, inoculate or mix cultures
- Tissues, organs, body parts, bedding, carcasses, and body fluids from experimental animals that were exposed to infectious agents
- Teeth (extracted in dentistry)
- Laboratory wastes that have been in contact with BBP or other potentially infectious materials, including gloves, coats and aprons (unless appropriately sterilized or testing confirms these waste are non-infectious)
- Discarded medical equipment and its components that have been in contact with BBP or other potentially infectious agents (unless appropriately decontaminated).
- Any other discarded item or waste that poses a threat to human or animal health or the environment
- Sharps waste from laboratories and clinics that generate medical waste and/or handle potentially infectious materials.