Copies of this plan will be made available to all members of the campus community with potential to generate regulated medical waste.

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I. Purpose

The purpose of this document is to present procedures to be followed in complying with federal and New York State regulations as they apply to Regulated Medical Wastes. This document compiles in one location many of the items necessary to document compliance with NYS DEC Chapter IV, Subpart 360.10.
II Responsibilities

College of Staten Island administrators, faculty, staff, students, contractors and other parties on campus who handle or generate Regulated Medical Wastes are required to properly handle, store and label Regulated Medical Wastes and to comply with applicable federal and state regulations. All who use or handle Regulated Medical Wastes are responsible to follow the policies and procedures set forth in this Regulated Medical Waste Management Plan. The EHSO and campus administration are responsible to ensure that all appropriate parties on campus comply with these requirements. It is the responsibility of all to see that Regulated Medical Wastes are managed in a safe, healthy, and environmentally sound manner.

Under federal and state regulations, generators of Regulated Medical Waste are accountable for the management of these wastes. Civil and criminal penalties may result from failure to comply with these requirements. At College of Staten Island generators of Regulated Medical Wastes may be academic facilities such as laboratories as well as various facility health care operations. While College of Staten Island is responsible for maintaining compliance, a student, faculty member, staff person, supervisor, or department head could have individual liability in the event of a violation of regulatory requirements. Federal or state environmental and health care personnel have the authority for the inspection of laboratories, health care areas, and other related locations for compliance with applicable regulatory requirements at anytime.

Within the CUNY/College of Staten Island system the following general responsibilities are identified.

College of Staten Island President is responsible for:

- Implementation of these Regulated Medical Waste Management Policy and Procedures at the College of Staten Island.
- Communicating the importance of these Regulated Medical Waste Management Policy and Procedures throughout the organization.

College of Staten Island’s Vice President for Finance and Administration is responsible for:

- Providing adequate resources to help assure compliance with Regulated Medical waste regulations and these Regulated Medical Waste Management Policy and Procedures.
- Tracking and reviewing Regulated Medical waste compliance performance.

College of Staten Island’s EHSO Director is responsible for:

- Reading and understand federal, state, and city laws, rules, and regulations relating to Regulated Medical waste and stay current with changes in the laws, rules, and regulations.
- Developing the College of Staten Island’s Regulated Medical Waste Management Plan which achieves the goals of this Regulated Medical Waste Management Policy and
Procedures and which addresses the particular needs of College of Staten Island with respect to the management of Regulated Medical wastes.

- Implementing the College of Staten Island’s Regulated Medical Waste Management Plan.
- Maintaining required documents and records of Regulated Medical waste training, generation, shipment, and disposal.
- Training faculty, staff, students and contractors at College of Staten Island for the performance of their tasks as they may relate to Regulated Medical wastes in an efficient and competent fashion and the provision of instruction regarding the impact that their activities can have on the environment if performed incorrectly.
- Regular inspection of areas where Regulated Medical wastes are stored to ensure that Regulated Medical wastes have been properly identified, labeled, segregated, and stored for collection and disposal.
- Awareness of the current legal requirements concerning Regulated Medical waste disposal and to contact the CUNY Office of General Counsel when questions arise.
- Arrangement of Regulated Medical waste pickups and to ensure that disposal is safely and completely performed.

Regulated Medical Material Users/Regulated Medical Waste Generators

College of Staten Island personnel who use or generate Regulated Medical materials or wastes are responsible to:

- Read and understand to the extent appropriate to their work, CUNY’s Regulated Medical Waste Management Policy and Procedures, College of Staten Island’s Regulated Medical Waste Management Plan and associated Resource Conservation and Recovery Act (RCRA) documentation.
- Be familiar with the properties, health risks, and precautions required for handling their respective regulated medical material/waste.
- Become familiar with available data concerning chemicals used and wastes generated; use reference books, articles, and the College of Staten Island’s Chemical Hygiene Plan (CHP) and Standard Operating Procedures (SOPs).
- Select and use appropriate personal protective equipment (e.g., gloves, goggles, lab coat, or other measures as may be applicable) required to safely work with Regulated Medical materials.
- Contact the EHSO with any questions regarding chemical or waste management, including training, waste identification, regulations, reference materials or any aspect of regulated medical waste management.

DASNY (Dormitory Authority of the State of New York)

DASNY also has responsibility for biological/Regulated Medical Waste that it and its contractors encounter, or have the potential to encounter, for activities that DASNY performs on campus:

- Coordinate with campus EHSO to evaluate environmental implications of activity; establish specific environmental regulatory responsibilities with respect to project.
Plan for removal of biological/Regulated Medical Waste in accordance with CUNY’s Regulated Medical Waste Management Policy and Procedures and the College of Staten Island’s Regulated Medical Waste Management Plan. If appropriate, written protocol to address biological/Regulated Medical Waste to be prepared, subject to the direction of the campus EHSO.

Documentation of management of the biological/Regulated Medical Waste to be presented to EHSO.

III. Regulated Medical Waste management

Handling Regulated Medical materials and wastes requires the use of proper laboratory safety procedures. College of Staten Island’s Exposure Control Plan should be consulted for appropriate procedures, including the use of personal protective equipment. Copies of the Plan are provided throughout the campus. If a copy is not available, contact the ESHO at extension 3215. If you have any questions or uncertainties regarding medical waste contact the CHO at x-3906.

A. Regulated Medical Waste generation and identification

The success of the Regulated Medical Waste management program begins with how well individuals that generate Regulated Medical Wastes are aware of their responsibilities, beginning with the accurate characterization of waste materials. Following characterization, Regulated Medical Wastes must be properly packaged, labeled, and stored. College of Staten Island Regulated Medical Waste labels (available from CHO, see Attachment A) must be applied to waste containers located at the accumulation areas. These labels identify the material, and provide the building name, floor number and room number. If in doubt with any aspect of the waste identification, call the EHSO at extension 3213 for guidance. Every individual who will handle or generate laboratory waste must receive training in the safety procedures for chemical storage and waste management outlined in Section IX of this Plan.

WASTE IDENTIFICATION

At College of Staten Island, Regulated Medical Wastes are generated at two types of areas: academic settings (such as laboratories), and from facility operations (such as health care operations).

Chapter 180 of the Laws of 1989 broadened the New York State Regulated Medical Waste definitions to be consistent with the Federal Medical Waste Tracking Act. In doing so it increased the number of subcategories of medical waste and included many items that did not pose a risk of disease transmission but simply looked "medical." The revised definitions resulting from Chapter 438 of the Laws of 1993 reduced the number of subcategories and in
some instances, provided for further qualification of items in the subcategory. However, it is important to note that the following revised general definitions of medical waste includes wastes resulting from diagnosis and treatment of animals, as well as that produced from health care research and development. The definitions are in italics.

**Regulated Medical Waste** - means any of the following wastes which are generated in the diagnosis, treatment or immunization of human beings or animals, in research, or in production and testing of biologicals. Regulated Medical Waste does not include hazardous waste or any household waste.

**Subcategory 1: Cultures and Stocks.** "This waste shall include cultures and stocks of agents infectious to humans, and associated biologicals, cultures from medical or pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live or attenuated vaccines, or culture dishes and devices used to transfer, inoculate or mix cultures."

The key to this subcategory is understanding what is meant by agents infectious to humans. The New York State Department of Health (NYSDOH) has identified that such agents as those causing communicable diseases.

In the context of this subcategory, cultures and stocks refer to systems used to grow and maintain infectious agents *in vitro*, including, but not limited to:

- nutrient agars, gels, broths (including those utilizing human blood or blood products);
- human and primate cell lines; and
- impure animal cell lines.

The term biologicals is intended to mean preparations made from living organisms and their products which are used in diagnosing, immunizing, or treating human beings or animals, including, but not limited to:

- serums;
- vaccines;
- antigens; and
- antitoxins.

Last, the phrase "culture dishes and devices used to transfer, inoculate or mix cultures" refers to the use of items that have come in contact with high concentrations of infectious agents as in the recovery of such agents in culture from clinical specimens and includes:

- plastic or glass plates, flasks, vials, beakers, bottles, jars, and tubes;
- inoculation loops and wires;
- manual and mechanical stirring devices;
- rubber, plastic, and cotton stoppers and plugs;
- filtering devices made of natural and artificial substances; and
materials used to clean and disinfect items indicated above after routine use or accident.

Subcategory 2 - Human Pathological Wastes. "This waste shall include tissue, organs, and body parts (except teeth and the contiguous structures of bone and gum), body fluids that are removed during surgery, autopsy, or other medical procedures, or specimens of body fluids and their containers, and discarded material saturated with such body fluids other than urine, provided that the Commissioner, by duly promulgated regulation, may exclude such discarded material saturated with body fluids from this definitions if the Commissioner finds that it does not pose a significant risk to public health. This waste shall not include urine or fecal materials submitted for other than diagnosis of infectious diseases."

Organs, tissues and associated fluids removed as result of surgical or autopsy procedures are Regulated Medical Waste. Some confusion however could exist regarding the phrase "discarded materials saturated with such body fluids other than urine". The determining factor for these materials to be Regulated Medical Waste is if they are saturated to the point of dripping. This is consistent with OSHA’s bloodborne pathogen standard, which defines saturated as referring to material that when squeezed produce free flowing fluid. The NYSDOH does not encourage individuals to squeeze any item to determine if it is saturated. Rather, the department expects that health care professionals will use their experience and training to make this determination. Examples of body fluids include, but are not limited to blood, cerebrospinal fluid and amniotic fluid and any body fluids that are visibly contaminated with blood.

Questions have also arisen regarding the appropriate disposal of organs and tissues that have been fixed for cytological and/or histological examination. Since the fixatives are considered to be hazardous materials, organs and tissues discarded with these chemicals must be processed as hazardous waste, except for blocks of tissue in paraffin or similar embedding materials. The latter prevent the fixatives from leaching into the environment and the chemical fixatives destroy any potential pathogens in the tissue block.

Subcategory 3 - Human Blood and Blood Products. "This waste shall include: (I) discarded waste human blood, discarded blood components (e.g. serum and plasma), containers with free flowing blood or blood components or discarded saturated material containing free flowing blood or blood components; and (II) materials saturated with blood or blood products provided that the commissioner, by duly promulgated regulation, may exclude such material saturated with blood or blood products from this definitions if the commissioner finds that it does not pose a significant risk to public health."

Blood and its components, including stocks from transfusion or materials saturated with free flowing blood, are viewed as Regulated Medical Waste. Questions have been raised regarding the appropriate disposal of menses pads. OSHA has ruled that feminine hygiene products used to absorb menstrual flow are not Regulated Medical Waste. Waste containers into which these are discarded should protect individuals from physical contact with these items.

Subcategory 4 - Sharps. "This waste shall include but not be limited to discarded unused sharps and sharps used in animal or human patient care, medical research, or clinical or
pharmaceutical laboratories, hypodermic, intravenous, or other medical needles, hypodermic or intravenous syringes to which a needle or other sharp is still attached, Pasteur pipettes, scalpel blades, or blood vials. This waste shall include, but not be limited to, other types of broken or unbroken glass (including slides and cover slips) in contact with infectious agents. This waste shall not include those parts of syringes from which sharps are specifically designed to be easily removed and from which sharps have actually been removed, and which are intended for recycling or other disposal, so long as such syringes have not come in contact with infectious agents."
The single most important aspect of sharps which gives rise to fear and apprehension is their inherent ability to cause puncture wounds and/or lacerations which may create a portal of entry for infectious agents. Although syringes with attached needles are the classic examples of sharps, other items used in the delivery of health care or in research and which have come in contact with infectious agents, e.g., glass or rigid plastic culture tubes, flasks, beakers, etc., must also be considered as sharps and be disposed of accordingly. Therefore, even though many of the items identified in this subcategory do not exemplify the "classic sharp," they still can give rise to puncture or laceration wounds.

One point needs to be clarified. **No attempt should be taken to remove the needle from the barrel of the syringe.** To do so would only increase the opportunity for needle stick injury. The total unit should be placed in a sharps container and disposed of as Regulated Medical Waste. In those instances, however, where **only the barrel of the unit is utilized**, as found for example in infusion pump setups, then the barrel can be disposed of as solid waste provided it did not come into contact with infectious agents.

**All syringes (barrel and needle) and those other sharps which have come into contact with infectious agents** must be contained in a rigid, puncture resistant container, secured to preclude loss of contents, and either, red in color or conspicuously labeled with either the universal biohazard symbol or the word biohazard. In addition, all sharps after treatment must be destroyed to remove the risk of puncture wounds, before being disposed of as solid waste. **Glass and plastic materials (other than syringes) which have not come in contact with infectious materials need not be treated and destroyed but should be disposed of carefully as solid waste, preferably in rigid containers.** These containers are not required to be red in color or labeled with the universal biohazard symbol nor the word biohazard.

Even though they are not considered to be Regulated Medical Waste certain types of medical equipment have found their way into sharps containers. The most common type of equipment to be disposed of in this manner is endoscopes, perhaps due to the pincers found at the end of the tubing. Medical equipment should not be disposed of in this manner as it is costly and an alternative decontamination (i.e., cold sterilization) would be more appropriate.

**Subcategory 5 - Animal Waste.** "This waste shall mean discarded materials including carcasses, body parts, body fluids, blood, or bedding originating from animals known to be contaminated with infectious agents (i.e. zoonotic organisms) or from animals inoculated during research, production of biologicals, or pharmaceutical testing with infectious agents."

Again, it is important to understand that exposure to a known infectious agent is necessary before the waste should be considered as Regulated Medical Waste. In certain instances, most notably rabies, the ability to determine whether an animal has been exposed must await a specific laboratory analysis. Given the nature of the suspected infectious agent in this case, it would be prudent to manage the waste generated in handling and preparing the carcass as Regulated Medical Waste.
Preserved animals used for educational purposes are not Regulated Medical Wastes and can be disposed of as solid waste if they are not considered hazardous waste due to the fixative used to preserve the body.

**MIXTURES OF REGULATED MEDICAL WASTE AND OTHER WASTES**

- Mixtures of Regulated Medical Waste and solid waste are Regulated Medical Waste.
- Mixtures of hazardous waste and Regulated Medical Waste are Regulated Medical Waste unless subject to manifest requirements of 6 NYCRR 372, when they become hazardous wastes.

As with all classifications of waste, it is important to keep Regulated Medical Waste segregated from other types of waste to properly manage wastes and to reduce the costs of treatment and disposal.

**B. Regulated Medical Waste packaging and labeling**

**Segregation** - Generators must segregate Regulated Medical Waste intended for transport off-site to the extent practicable prior to placement in containers. Regulated Medical Waste must be into sharps, fluids (quantities greater than 20 cubic centimeters), and other Regulated Medical Waste.

**Container requirements** - Regulated waste must be placed in containers which are:

- Closable, do not overfill containers;
- Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;
- Labeled or color-coded; and
- Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.
- If outside contamination of the regulated waste container occurs, it must be placed in a second container.

**Packaging and labeling requirements** - Generators must package Regulated Medical Wastes according to the following requirements before transporting or offering for transport such waste off-site.

- Regulated Medical Waste, except for all discarded sharps, must be contained in bags that are impervious to moisture and have strength sufficient to resist ripping, tearing or bursting under normal conditions of usage and of handling. The bags must be secured so as to prevent leakage during storage, handling or transport. All bags used for containment and disposal of Regulated Medical Wastes must be red in color.
- All discarded sharps must be contained for disposal in leak proof, rigid, puncture-resistant containers that are secured to preclude loss of the contents. Such containers must be red in
color or must be conspicuously labeled with the word "infectious" or the words "Regulated Medical Waste."

**Marking (identification) requirements.** Generators must mark each package of Regulated Medical Waste according to the following marking requirements before the waste is transported or offered for transport off-site:

The outermost surface of the containment system must be marked with a water-resistant identification tag containing the following information:

- generator's or intermediate handler's name;
- generator's or intermediate handler's address;
- transporter's name;
- transporter's State permit or identification number, or if not applicable, then the transporter's address;
- date of shipment; and
- identification of contents as medical waste.

Inner containers, including red bags, sharps and fluid containers must be marked with indelible ink or imprinted with water-resistant tags. The marking must contain the following information:

- generator's or intermediate handler's name; and
- generator's or intermediate handler's address.

**Decontamination standards for reusable containers** - Generators must comply with the following requirements with respect to reusing containers:

- All no rigid packaging and inner liners must be managed as Regulated Medical Waste and must not be reused.
- Any container used for the storage and/or transport of Regulated Medical Waste and designated for reuse once emptied, must be decontaminated if the container shows signs of visible contamination.
- If any container used for the storage and/or transport of Regulated Medical Waste is for any reason not capable of being rendered free of any visible signs of contamination, the container must be managed (labeled, marked and treated and/or disposed of) as Regulated Medical Waste.

**C. Accumulation Areas**

An Accumulations Area is a temporary short-term storage area at the point of generation of the Regulated Medical Waste.

The following Accumulation Area storage requirements must be followed:

- The Regulated Medical Waste must be contained in a manner and location which affords protection from the environment and limits exposure to the public;
• The Regulated Medical Waste must be maintained in a non-putrescent state, using refrigeration when necessary;
• The Regulated Medical Waste must be stored in a manner that affords protection from animals and does not provide a breeding place or a food source for insects and rodents.
• **Temporary storage in an Accumulation Area must not exceed 72 hours.**
D. Regulated Medical Waste pickup procedures

Before requesting a chemical waste pickup, make sure you have followed the procedures previously discussed regarding container selection, labeling, handling, and storage of Regulated Medical Waste. Make sure containers are clean on the outside and have caps that are tightly closed, and are properly labeled. Call the CHO at extension 3906 with your pickup request. Be ready to give the following information:

- your name
- phone number
- department name
- building
- room number
- the type and quantity of waste to be picked up
- size of containers to be picked up
- physical state of the material

E. Regulated Medical Waste storage areas

The campus Regulated Medical Waste storage area near the loading dock in Steinman Hall is the primary storage location for Regulated Medical Wastes prior to being shipped off campus. A current inventory of the wastes collected will be continuously maintained by CHO. Proper labeling and segregation techniques will be employed. The facility will be properly identified as a Regulated Medical Waste Storage Area by the CHO and have limited access, and have “No Smoking” signs posted.

At the time the waste is generated, it must be labeled as a Regulated Medical Waste. After waste pickup and transfer to the Regulated Medical Waste Storage Area, the waste is subject to a 30-day accumulation time limitation.

The following storage requirements must be followed:

- The Regulated Medical Waste must be contained in a manner and location which affords protection from the environment and limits exposure to the public;
- The Regulated Medical Waste must be segregated from other wastes, and in a dedicated room
- The Regulated Medical Waste must be maintained in a nonputrescent state, using refrigeration when necessary;
- An outdoor storage area(s) containing Regulated Medical Waste (e.g., dumpsters, sheds, tractor trailers, or other storage areas) must be locked to prevent unauthorized access;
- Access to on-site storage areas must be limited to authorized employees; and
- The Regulated Medical Waste must be stored in a manner that affords protection from animals and does not provide a breeding place or a food source for insects and rodents.
F. Regulated Medical Waste disposal procedures

Before Regulated Medical Waste is transported from College of Staten Island, Regulated Medical Waste contained in disposable containers must be placed for storage or handling in disposable or reusable pails, cartons, drums, or portable bins. The containment system must be leak proof, have tight-fitting covers, and be kept clean and in good repair. The containers may be of any color and must be conspicuously labeled with the word "infectious" or the words "Regulated Medical Waste."

Regulated Medical Waste transporters must be permitted by the New York State Department of Environmental Conservation.

Use of the tracking form.

A generator who transports or offers for transport Regulated Medical Waste for off-site treatment or disposal, must prepare a tracking form.

- Generators must obtain the tracking form from the following sources:
  - for generators who transport or offer for transport off-site Regulated Medical Waste to an intermediate handler or a destination facility in a state which prints the tracking form and requires its use, the form from that state; and
  - for all other generators, the tracking form from New York State.
- The generator must prepare at least the number of tracking form copies that will provide the generator, each transporter(s), and each intermediate handler with one copy, and the owner or operator of the destination facility with two copies. With the exception of the generator, who when self transporting requires only two copies of the medical waste tracking form, one for himself and one for the destination facility.
- The generator must also:
  - sign the certification statement on the tracking form by hand;
  - obtain the handwritten signature of the initial transporter and date of acceptance on the tracking form; and
  - retain one copy.

The selection of a contractor for the removal, transportation, and/or disposal of regulated medical waste will be conducted in a thorough and safety conscious manner. Prospective contractors must address all safety issues raised by College of Staten Island before an authorization is awarded. EHSO is the only entity on campus that can engage a Regulated Medical Waste disposal firm. EHSO will follow College of Staten Island purchasing procedures in selecting the disposal firms.
G. Regulated Medical Waste treatment

If the autoclaves are operated by a NYSDOH-licensed facility, an approved autoclave Operating Plan, prepared to comply with 10 NYCRR Part 70-3, must be followed when using any autoclave. If College of Staten Island is not NYSDOH-licensed, then the autoclaves are subject to NYSDEC regulations.

The following is a summary of NYSDOH requirements for the Operating Plan:

Operating parameters for autoclaves.

An autoclave used to treat RMW must be operated in accordance with the following minimum requirements:

- when operating a gravity flow autoclave, RMW must be subjected to:
  - a temperature of not less than 250° F and a pressure of 15 pounds per square inch gauge (psig) for an autoclave residence time of not less than 60 minutes;
  - a temperature of not less than 275° F and a pressure of 31 psig for an autoclave residence time of not less than 45 minutes; or
  - a temperature of not less than 300° F and a pressure of 52 psig for an autoclave residence time of not less than 30 minutes;
- when operating a vacuum autoclave, RMW must be subjected to a minimum of one pre-vacuum pulse to purge the autoclave of all air, and the following:
  - a temperature of not less than 250° F and a pressure of 15 psig for an autoclave residence time of not less than 45 minutes; or
  - a temperature of not less than 275° F and a pressure of 31 psig for an autoclave residence time of not less than 30 minutes;
- the minimum operating parameters for temperature, pressure, and residence time proposed for each autoclave unit must be determined during start-up of the facility utilizing the approved validation testing program and standardized loads;
- a different combination of operating parameters for time, temperature, and pressure may be used to autoclave RMW only if such combination is first proposed by the applicant, and approved in writing by the commissioner. Biological indicators for autoclaves must be *Bacillus stearothermophilus* spores using vials or spore strips, with at least 1 x 10^4 spores per milliliter. Under no circumstances will an autoclave have minimum operating parameters less than a residence time of 30 minutes, regardless of temperature and pressure, a temperature less than 250° F, or a pressure less than 15 psig;
- RMW must be autoclaved in the container that is received at the facility, unless reusable containers are utilized. Autoclave procedures must be those described in the operation plan. Containers must be placed in the autoclave in the same manner that was used during validation testing; and
- each autoclave must have graphic or computer recording devices which will automatically and continuously monitor and record dates, time of day, load identification number, and operating parameters throughout the entire length of the autoclave cycle. Temperatures must be determined by the use of thermocouples and probes placed at approved locations within each autoclave unit. Autoclave temperature-sensing devices and time/temperature-
sensitive indicators must be placed in the specific locations of each load, as identified in the approved operation plan. Also, before autoclaving, the operator of the autoclave must affix temperature-sensitive tape to the containers, as identified in the approved operation plan. Such locations must take into consideration the coldest points in each autoclave, and those areas where steam is least likely to penetrate. These time/temperature-sensitive indicators and temperature-sensitive tape must be capable of indicating that the minimum approved temperature and residence time, or temperature, has been reached. RMW must not be considered properly treated unless all time/temperature-sensitive indicators or temperature-sensitive tapes indicate that the required time or temperature was reached during the autoclave process. If for any reason a time/temperature-sensitive indicator or a temperature-sensitive tape does not indicate that the required temperature or residence time was reached, the entire load of RMW must be autoclaved again until the proper temperature, pressure, and residence time is achieved. If any load of RMW must be autoclaved again, a report on the incident must be received within 72 hours.

Validation testing program.

Each RMW treatment unit must successfully complete the approved validation testing program prior to commercial operation in accordance with the following requirements:

- no RMW will be considered treated by a RMW treatment unit until the results of validation testing conducted on each RMW treatment unit have been reviewed and approved, in writing, by the NYDOH, in accordance with the approved validation testing program. Therefore, RMW treated during validation testing must be either transported to, and treated at, an approved facility prior to disposal, or stored on-site until the results of the validation testing program have been approved, in writing, by the NYSDOH.

- validation testing and analysis procedures must be contained in the validation testing program and must be submitted to the department with the application for a permit to construct and operate. Facility start-up can not commence until the validation testing program has been approved. The results of such validation testing must be approved, in writing, by the NYSDOH before commercial operation will be permitted. Based on the results of the validation testing program, minimum operating parameters will be established for each RMW treatment unit.

- testing, and if necessary, retesting, must be conducted on each RMW treatment unit to determine the required minimum operating parameters for proper treatment of RMW. Standardized loads will be developed for the maximum design capacity of each RMW treatment unit and used in the validation testing of each unit. Standardized loads, as described in the operating plan, must simulate anticipated worst case operating conditions and make use of actual RMW that is expected to be treated by the facility, including materials believed to be difficult to treat. No RMW must be treated which has characteristics, such as a greater density or lower rate of steam penetration, different from that of the standardized load. During each validation test, each load of RMW must contain at least one biological indicator sample per 100 pounds of RMW being processed, with a minimum of five
samples per standardized load. There must be positive quality control when conducting validation testing (i.e., a biological indicator sample not exposed to treatment). Temperature probes will also be placed at locations within the standardized load in accordance with the approved validation testing program.

**Challenge testing.**

Challenge testing must include the following:

- Challenge testing must be conducted to verify the effectiveness of each RMW treatment unit and the RMW treatment process, including tests of the ability of each RMW treatment unit to completely and consistently kill the approved biological indicator. Challenge testing, using the standardized load as approved in the operation plan, must be conducted for each RMW treatment unit at least once every 40 hours of operation, and must include a detailed visual inspection as described in the maintenance and monitoring plan. A separate and detailed log must be maintained for each RMW treatment unit, recording the dates and results of each challenge test and visual inspection.

- During each challenge test, each load of RMW must contain one biological indicator sample for every 200 pounds of RMW being processed, with a minimum of five biological indicator samples for each standardized load. The operation plan must completely describe the methods of challenge testing, sampling, handling, and the biological indicator sample culturing procedures. Each biological indicator sample must be placed in the center of an approved, nonputrescible material that will simulate characteristics (i.e., type, density, composition, moisture content, and rate of steam penetration) of the RMW expected to be treated at the facility. Each biological indicator sample must be placed so it will be easily and safely removed from the load of RMW after treatment. Biological indicator sample packaging materials, methods, and the standardized load must be approved, in writing, by the NYSDOH, and contained in the operation plan. There must be positive quality control when using these biological indicator samples (i.e., biological indicator samples not exposed to treatment).

- The results of the challenge tests will be used to evaluate the working conditions of each RMW treatment unit. The cause of any positive biological indicator growth during challenge testing must be used to determine what adjustments are necessary to the RMW treatment unit, its appurtenances, and the treatment process. Upon receipt of information indicating positive biological indicator growth, immediately notify by telephone, the regional solid waste engineer in the departmental region in which the facility is located. A written incident report on the positive biological indicator growth and the actions undertaken at the facility to correct the cause of such biological indicator growth must be received within 72 hours.

The following is a summary of requirements for Regulated Medical Waste facilities regulated by the NYSDEC:
1. Develop Operating Plan that includes the following:
   - Designation of RMW to be treated
   - Methods for segregating and handling of RMW to be treated
   - Schedule for staff training on handling and/or treatment procedures
   - Identification of treatment techniques or equipment
   - Procedures for validation testing
   - Operating instructions/safety procedures for treatment equipment
   - Procedures for monitoring treatment effectiveness/frequency of challenge
   - Disposal methods for treated RMW
   - Emergency and contingency planning

IV. Inspections

The EHSO performs inspections of the Regulated Medical Waste storage area in compliance with NYSDOH and NYSDEC regulations. A copy of the inspection form is included in Appendix A.

V. General procedures

Decontamination standards for reusable containers

Generators, transporters, intermediate handlers, and destination facility owners and operators must comply with the following requirements with respect to reusing containers:

- All no rigid packaging and inner liners must be managed as Regulated Medical Waste and must not be reused.
- Any container used for the storage and/or transport of Regulated Medical Waste and designated for reuse once emptied, must be decontaminated if the container shows signs of visible contamination.
- If any container used for the storage and/or transport of Regulated Medical Waste is for any reason not capable of being rendered free of any visible signs of contamination in accordance with subparagraph (ii) of this paragraph, the container must be managed (labeled, marked and treated and/or disposed of) as Regulated Medical Waste under this Part.

Universal precautions should be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids must be considered potentially infectious materials.

Contaminated work surfaces must be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly
contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

**Protective coverings**, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and environmental surfaces, must be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the work shift if they may have become contaminated during the shift.

**Broken glassware**, which may be contaminated, must not be picked up directly with the hands. Use mechanical means, such as a brush and dust pan, tongs, or forceps.

### VI. Spills

**A spill or accident that results in an exposure incident** must be immediately reported to the laboratory director or other responsible person.

If the spill is small, and there are no health or safety concerns, immediately take steps to contain, disinfect, and clean up the spilled material.

In the event of a regulated medical waste spill or leak, the person discovering the release must immediately initiate the following actions:

1. Determine if there is an immediate threat to human health, evacuate the immediate area.
2. Attempt to stop or contain the spill/release at the source (provided there are no health or safety hazards and there is a reasonable certainty of the origin of the leak).
3. Isolate all potential environmental receptors such as floor drains, catch basins, sumps, exposed soil, and runoff areas (provided there are no health or safety hazards in doing so).
4. Contact the **CHO at 3906** and/or Campus Security **718-982-2111** to provide information regarding the spill event.

The CHO or Security will direct and coordinate the spill clean-up activities and evaluate if an environmental contractor will be required to perform the clean-up activities.

### VII. Standard operating procedures

Standard operating procedures such as the **Exposure Control Plan** are found in the Appendices to this Plan, as they will likely be modified in the future.

### VIII. Training

**General**
College of Staten Island personnel who generate Regulated Medical Waste on campus are required to have training appropriate to their level of responsibility. Special training will also be provided by EHSO upon request to areas with unusual Regulated Medical Waste management requirements. Training for Regulated Medical Waste management on campus will be updated to reflect the most current regulatory requirements. Training materials will include the following topics at a minimum:

- identification of Regulated Medical Waste
- container use, marking, labeling, and on-site transportation
- Accumulation Area requirements
- storage area requirements
- tracking forms and off-site transportation
- personal health and safety, and fire safety
- training required by 29 CFR 1910.1030, OSHA Bloodborne Pathogens

X. Recordkeeping

Recordkeeping requirements are as follows:

- College of Staten Island Regulated Medical Waste tracking documents will be signed by a member of the EHSO. Regulated Medical Waste contracts are developed and managed by EHSO and include general Regulated Medical Waste and spill response.
- Records of all Regulated Medical Waste tracking forms will be kept on site for a minimum of three years from the returned copy date.
- Reports will be kept for a minimum of five years from the established submittal date.

X. Information and contacts

City University of New York; Environmental, Health, and Safety Policy Manual
OSHA, Bloodborne Pathogens; 29 CFR 1910.1030 et seq.
NYSDEC Hazardous Waste Regulations; 6 NYCRR 360 et seq.

For further information or answers to questions contact the College of Staten Island Environmental Health & Safety Office Telephone 718-982 –Extension 3215.