REGULATED MEDICAL WASTE MANAGEMENT PLAN

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

Contents

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. This document is also written to comply with the City University of New York (CUNY) Environmental Health and Safety Policy Manual, specifically the Regulated Medical Waste Management Policy and Procedures.

As of December 2003, York College does not generate or treat wastes that meet the regulatory definition of regulated medical wastes. However, it is the policy of York College to manage sharps (*e.g.*, gas chromatograph syringes and similar wastes) generated in chemistry laboratories as regulated medical waste. Refer to Section III. for information on the management of these wastes. Should at some point in the future, regulated medical wastes be generated and, perhaps treated, the following management practices must be considered for applicability and possible implementation.

II Responsibilities

York College administrators, faculty, staff, students, contractors and other parties on campus who may handle or generate regulated medical wastes will be 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 will be responsible for following the policies and procedures set forth in this Regulated Medical Waste Management Plan. The York College Environmental Health & Safety Officer

(EHSO) and campus administration will be responsible for ensuring that all appropriate parties on campus comply with these requirements. It is the responsibility of all to see that regulated medical wastes will be managed in a safe 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 York College generators of regulated medical wastes may be academic facilities such as laboratories as well as various facility health care operations. While York College will be responsible for maintaining compliance, a student, faculty member, staff person, supervisor, or department head could also have individual liability in the event of a violation of regulatory requirements. Federal or state environmental and health care personnel have the authority to inspect laboratories, health care areas, and other related locations for compliance with applicable regulatory requirements at any time.

Within the CUNY/York College system the following general responsibilities are identified.

York College's ***President*** will be responsible for:

- Implementation of the CUNY Regulated Medical Waste Management Policy and Procedures.
- Communicating the importance of the CUNY Regulated Medical Waste Management Policy and Procedures.

York College's ***Vice President for Finance and Administration*** will be responsible for:

- Providing adequate resources to ensure compliance with regulated medical waste regulations and the CUNY Regulated Medical Waste Management Policy and Procedures.
- Tracking and reviewing regulated medical waste compliance performance.

York College's ***EHSO*** will be responsible for:

- Reading and understand federal, state, and city laws, rules, and regulations relating to regulated medical waste and staying current with changes in the laws, rules, and regulations.
- Implementing York College's Regulated Medical Waste Management Plan which achieves the goals of the CUNY Regulated Medical Waste Management Policy and Procedures and which addresses the particular needs of York College with respect to the management of regulated medical wastes.
- Maintaining required documents and the records of regulated medical waste training, generation, shipment, and disposal.
- Training faculty, staff, students and contractors at York College for the performance of their tasks relating to regulated medical wastes in an efficient and competent fashion and providing instruction regarding the potential impact that incorrectly performed activities may have on the environment.
- Regularly inspecting areas where regulated medical wastes will be stored to ensure that regulated medical wastes will be properly identified, labeled, segregated, and stored for collection and disposal.
- Awareness of the current legal requirements concerning regulated medical waste disposal and contacting the CUNY Office of General Counsel when questions arise.
- Arranging regulated medical waste pickups and ensuring safe and complete disposal.

Regulated Medical Material Users/Regulated Medical Waste Generators

York College personnel who use or generate regulated medical materials or wastes will be required to:

- Read and understand, to the extent appropriate to their work, CUNY's Regulated Medical Waste Management Policy and Procedures, York College's Regulated Medical Waste Management Plan and associated Resource Conservation & Recovery Act (RCRA) documentation.
- Be familiar with the properties, health risks, and precautions associated with handling regulated medical material/waste from their respective work areas.
- Select and use appropriate personal protective equipment (*e.g.*, gloves, goggles, labcoat, or other measures as may be applicable) required to safely work with regulated medical material/waste.
- Contact the EHSO with questions including training, waste identification, regulations, reference materials, or other aspect of regulated medical waste management.

DASNY (Dormitory Authority of the State of New York)

DASNY also has responsibility for regulated medical waste that it and its contractors may encounter, or have the potential to encounter. For activities DASNY performs on campus, DASNY will be required to:

- Coordinate with the EHSO to evaluate environmental implications of activity and to establish specific environmental regulatory responsibilities with respect to a given project.
- Plan for removal of biological/ regulated medical waste in accordance with CUNY's Regulated Medical Waste Management Policy and Procedures and York College's Regulated Medical Waste Management Plan. If appropriate, written protocol to address regulated medical waste to be prepared, subject to the direction of the EHSO.
- Documentation of management of the biological/ regulated medical waste to be presented to the EHSO.

III. Regulated Medical Waste management

Handling regulated medical materials and wastes requires the use of proper laboratory safety procedures. Information regarding proper management procedures will be available from the EHSO, Ext. 2662. Questions or uncertainties regarding medical waste are to be directed to the EHSO**.**

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. Responsibility begins with the accurate characterization of waste materials. Following characterization, regulated medical wastes must be properly packaged, labeled, and stored. Labels identify the material, and include the building name, floor number, room number, name of the responsible individual, and the date. If in doubt about an aspect of the waste identification, call the EHSO, Ext. 2662 for guidance. Every individual who handles or generates regulated medical waste must receive training in the safety procedures for storage and waste management outlined in Section VIII of this Plan.

WASTE IDENTIFICATION

At York College, regulated medical wastes may be 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, 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 facilities. 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 a 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 the Occupational Safety & Health Administration (OSHA) bloodborne pathogen standard, which defines saturated as referring to material that when squeezed produce free flowing fluid. The NYSDOH discourages individuals from squeezing items to determine if they are saturated. Rather, health care professionals are expected to use their experience 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, except for blocks of tissue in paraffin or similar embedding materials, discarded with these chemicals must be processed as hazardous waste,. Paraffin and similar embedding materials 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 example of sharps, other items used in the

health care or research which come in contact with infectious agents, (*e.g.*, glass or rigid plastic culture tubes, flasks, beakers, etc.), can give rise to puncture or laceration wounds and must be considered as sharps and be disposed of accordingly.

No attempt should be taken to remove the needle from the barrel of the syringe. To do so would only increase the opportunity for a 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 used**,** 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 managed as regulated medical waste 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 often 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 not meeting the definition of regulated medical waste 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."*

The 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 the New York State Department of Environmental Conservation (NYSDEC) regulations, 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.

A. 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 separated 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.

Packaging and labeling requirements - Generators must package regulated medical wastes according to the following requirements before transporting or offering for transport.

- Regulated medical waste, except for 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.
- Discarded sharps must be contained for disposal in leakproof, 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 universal biohazard symbol or the word “biohazard.”
- If outside contamination of the regulated waste container occurs, it must be placed in a second container.

Marking (identification) requirements. Generators must mark each package of regulated medical waste according to the following requirements before the waste is transported or offered for transport:

- The outermost surface of the container must be marked with a water-resistant identification tag containing the following information:
  - generator's name;
  - generator'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 as the regulated medical waste (*e.g.*, sharps, pathological 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 name; and
  - generator's address.

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

- All nonrigid 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; and
- 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 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 accumulation 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; and
- Temporary storage in an accumulation area must not exceed 72 hours.

D. Regulated Medical Waste pickup procedures

Before requesting a regulated medical waste pickup, make sure you have followed the procedures described above 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 EHSO, Ext. 2662 with your pickup request. Provide 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; and
- physical state of the material.

E. Regulated Medical Waste storage areas

A regulated medical waste storage area, should regulated medical waste be generated in the future, will need to be established. An inventory of the wastes collected will be continuously maintained by the EHSO. Proper labeling and segregation techniques will also need to be implemented. Proper identification of the regulated medical waste storage area, ensuring limited to the area, and having “No Smoking” signs posted are among items that will be necessary as noted below.

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.

A. Regulated Medical Waste disposal procedures

Before regulated medical waste is transported from York College, it 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 leakproof, have tight-fitting covers, and be kept clean and in good repair. The containers must be conspicuously labeled with the word "infectious" or the words "Regulated Medical Waste."

Regulated medical waste transporters must have permits issued by the NYSDEC.

Use of the tracking form.

A generator who transports or offers regulated medical waste for transport for off-site treatment or disposal, must complete a medical waste tracking form. Generators must obtain the tracking form from the following sources:

- for generators who transport or offer for transport 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 (See: NYSDEC Guidance for Regulated Medical Waste Treatment, Storage, Containment, Transport and Disposal or 6 NYCRR Part 364.9 Standards for the tracking and management of medical waste).

Generators 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. A generator, 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 York College before an authorization is awarded. The EHSO is the only entity on campus that can engage a regulated medical waste disposal firm. The EHSO will follow York College purchasing procedures in selecting the disposal firms.

G. Regulated Medical Waste treatment

If autoclaves are operated to treat regulated medical waste as a NYSDOH-licensed facility, an approved autoclave Operating Plan must be prepared to comply with 10 NYCRR Part 70-3. If not NYSDOH-licensed, then autoclaves are subject to NYSDEC regulations (6 NYCRR Part 360-17).

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

Operating parameters for autoclaves.

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

When operating a gravity flow autoclave, regulated medical waste 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, regulated medical waste 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 regulated medical waste 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.

Regulated medical waste 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.

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. regulated medical waste 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 regulated medical waste must be autoclaved again until the proper temperature, pressure, and residence time is achieved. If any load of regulated medical waste must be autoclaved again, a report on the incident must be received within 72 hours.

Validation testing program.

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

- No regulated medical waste will be considered treated until the results of validation testing conducted on each regulated medical waste treatment unit have been reviewed and approved, in writing, by the NYDOH, in accordance with the approved validation testing program. Therefore, regulated medical waste 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 regulated medical waste treatment unit.

- Testing, and if necessary, retesting, must be conducted on each regulated medical waste treatment unit to determine the required minimum operating parameters for proper treatment of regulated medical waste. Standardized loads will be developed for the maximum design capacity of each regulated medical waste 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 regulated medical waste that is expected to be treated by the facility, including materials believed to be difficult to treat. No regulated medical waste 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 regulated medical waste must contain at least one biological indicator sample per 100 pounds of regulated medical waste 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 regulated medical waste treatment unit and the regulated medical waste treatment process, including tests of the ability of each regulated medical waste 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 regulated medical waste 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 regulated medical waste treatment unit, recording the dates and results of each challenge test and visual inspection.

- During each challenge test, each load of regulated medical waste must contain one biological indicator sample for every 200 pounds of regulated medical waste 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 regulated medical waste 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 regulated medical waste 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 regulated medical waste treatment unit. The cause of any positive biological indicator growth during challenge testing must be used to determine what adjustments are necessary to the regulated medical waste 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

- Develop Operating Plan that includes the following:
  - designation of regulated medical waste to be treated;
  - methods for segregating and handling of regulated medical waste to be treated;
  - schedule for staff training on handling and/or treatment procedures;
  - identification of treatment techniques or equipment; and
  - operating instructions/safety procedures for treatment equipment.

Procedures for validation testing:
- operating instructions/safety procedures for treatment equipment;
- procedures for monitoring treatment effectiveness/frequency of challenge;
- disposal methods for treated regulated medical waste; and
- emergency and contingency planning.

IV. Inspections

The EHSO performs inspections of the regulated medical waste storage area in compliance with NYSDOH and NYSDEC regulations.

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:

- **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 workshift 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:

- Determine if there is an immediate threat to human health. If so, evacuate the immediate area.
- Attempt to stop or contain the spill/release at the source (provided there are no health or safety hazards and the origin of the leak is known).
- 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).
- Contact the EHSO, Ext. 2662 and/or Campus Security (718) 262-2222 to provide information regarding the spill event.

The EHSO 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

Should the treatment of regulated medical waste be initiated at York College in the future, standard operating procedures will be developed.

VIII. Training

General

York College personnel who generate regulated medical waste on campus will be required to receive training appropriate to their level of responsibility. This training will be provided initially at their time of employment, and on an annual basis. Special training will also be provided by the EHSO to personnel upon request for areas with unusual regulated medical waste management requirements. Training for regulated medical waste management on campus will be updated to reflect changes to regulatory requirements. Training materials will include the following topics:

- identification of regulated medical waste;
- proper 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; and
- training required by 29 CFR 1910.1030, OSHA Bloodborne Pathogens.

Special training

Individuals with specialized duties, and anyone with oversight responsibility for packaging and transportation of regulated medical materials require additional training. Individuals who supervise or prepare regulated medical materials for transport and/or sign tracking documents must complete course work that meets United States Department of Transportation (USDOT) regulations.

IX. Recordkeeping

Recordkeeping requirements are as follows:

- York College regulated medical waste tracking documents will be signed by the EHSO. Regulated medical waste contracts will be developed and managed by the EHSO and include general regulated medical waste and spill response;
- Records of regulated medical waste tracking forms will be kept on site for a minimum of three years from the returned copy date; and
- 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.*
6 NYCRR Part 364.9 Standards for the tracking and management of medical waste
NYSDEC Guidance for Regulated Medical Waste Treatment, Storage, Containment, Transport and Disposal
For further information or answers to questions contact the York College EHSO, Ext. 2662