Self-Assessment Manual for Proper Management of Medical Waste

Prepared by

The Self-Assessment Project Partnership
between the
California Department of Health Services
and the
California Healthcare Association

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(Revised)

Acknowledgements

This manual was developed through a partnership agreement
Between the Environmental Management Branch
Of the California Department of Health Services
And the California Healthcare Association

State of California, Department of Health Services
Jack McGurk, Chief
Environmental Management Branch
Glenn Takeoka, Chief
Medical Waste Management Program

California Healthcare Association
Roger Richter
Senior Vice President, Professional Services

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If you have any questions regarding
medical waste management
please call:

Department of Health Services
Medical Waste Management Program
(916) 327-6904 (Northern California)
(213) 897-7570 (Southern California)

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INTRODUCTION

This manual was developed through a partnership between the Environmental Management Branch (EMB) of the California Department of Health Services (DHS) and the California Healthcare Association (CHA). Partnering is recognized as a process where organizations with a shared vision, or common interest, work together to achieve a desired outcome. Staff from EMB's Medical Waste Management Program and five member health care organizations within CHA recognized that they had a shared vision of properly handling medical waste. Through adoption of the paradigm of collaboration, they decided to jointly develop a self-assessment inspection program for properly handling the medical waste stream. The synergy created through the self-assessment project has allowed the participants to develop strategies to more efficiently manage medical waste than if these parties worked on this issue separately.

The self-assessment project developed a refreshing new way for governmental regulation of medical waste management practices at health care facilities. The April 23, 1992 findings of the bipartisan Council on California Competitiveness indicated that there was widespread lack of faith in public institutions and a strong conviction that government was no longer working. The Council found "... a picture of a government frozen, without the vision or will to formulate policies or carry out long-range plans for the benefit of all people."[1] The Council recommended several changes in the way government operates in California. They found a need for partnership, customer service training, quality management processes, and global thinking to produce a sound economy. Additionally, they recommended a new design for the governance of California, a customer-service attitude in every government employee, and a Total Quality Management program in every state and local agency to constantly improve efficiency.[2]

The Self-Assessment Project

The DHS/CHA partnership for developing this self-assessment medical waste management project was an attempt to successfully implement the recommendations and desires of the Council for a new strategy for governance by an environmental health regulatory program. It is based on the realization that government agencies no longer need to operate in a strict "command and control" strategy. Regulatory agencies do not need to be totally responsible for the entire process that is required to achieve proper handling of medical waste; but can rely on the regulated community as a partner in these efforts. This project was based on the philosophy that partnering between regulatory agencies and the regulated community holds promise for improving compliance while reducing fees and reliance on the traditional regulatory control process.

[1] Council on California Competitiveness, *California's Jobs and Future*, April 23, 1992, page 3.
[2] Ibid., pp. 6-7.

The following Mission Statement was developed by the project participants at their first meeting:

Project Mission Statement

"To develop and implement a self-auditing partnership for effective management of medical waste between the California Department of Health Services and large quantity generators operating under hospital licensing. Effective management is the proper legal, public and environmental protection, and cost control."[3]

The term "self-audit" was later changed to "self-assessment," and although the project was designed for large quantity generators operating under hospital licensing, the findings and many applications from this manual will work in all facilities generating medical waste. At the heart of the project was the desire to develop a standard self-assessment tool that would allow medical waste generators to internally assess the handling of the medical waste stream. This required that the self-assessment tool be designed to evaluate the critical factors in the waste management system. The self-assessment process was based on the premise that assessment results would be open to review by the regulatory agency. Further, if significant or major violations were discovered through the self-assessments; the generator would have a "safe harbor" for reporting them to the regulatory agency. The "safe harbor" concept allows the health care facility to report violation conditions found through the self-assessment process without being recorded and/or prosecuted as violations by the regulatory agency. Through consultation and collaboration between the regulatory agency and the generator the best means for quickly solving the problem would be jointly developed. This approach moves the regulatory agency away from a strict enforcement program and into one of education and consultation to achieve compliance with the medical waste management laws. In its January 26, 1996 edition, the *Los Angeles Daily Journal* described this self-assessment project as the "Most Promising New Program for 1996."[4] To be successful, the project participants realized that there must be a strong training component to guide implementation of the self-assessment program.

Medical Waste

The Medical Waste Management Act provides the legislative definition of medical waste (California Health and Safety Code, Section 117690). In lay terms, waste must satisfy three critical criteria in order to be classified as medical waste. These three criteria are:

1. The material must actually be a waste product. This precludes materials that have intrinsic value (such as outdated pharmaceuticals that are returned for credit) from being classified as a medical waste. On the other hand, outdated pharmaceuticals sent for treatment, as waste would be classified as medical waste.

2. The waste must be either biohazardous or sharps waste. Various forms of waste are defined as biohazardous because of the actual or presumed presence of pathogenic microorganisms. Such wastes as laboratory waste and fluid blood fall into this category and are therefore

[3] Taken from the notes of the January 8, 1996 meeting of the M*edical Waste Self-Assessment Project.*
[4] Hsaio, Peter, "Prize Policies—Evaluating Environmental Amnesty Programs," *Los Angeles Daily Journal,* January 26, 1996.

biohazardous waste. It should be noted that in the interest of more convenient regulation, some chemically hazardous wastes produced in healthcare have been removed from the jurisdiction of the hazardous waste laws in favor of being treated as biohazardous waste. Trace amounts of chemotherapeutic agents, outdated pharmaceutical wastes and tissues with trace amounts of fixatives fall into this category of biohazardous waste classification. Objects which have been used in invasive procedures such as hypodermic needles and broken glass items contaminated with blood or other biohazardous waste are considered to be sharps waste.

3. The waste must be produced as a result of a specified action in the delivery of health care. The Medical Waste Management Act (section 117690) defines this as the "...diagnosis, treatment, or immunization of human beings or animals...". Some actions such as medical research, production or testing of biologicals, accumulation of home-generated sharps waste and the removal of trauma scene waste are specifically included in the definition of medical waste.

Scope and Purpose of this Manual

The primary purpose of this manual is to assist health care facilities in complying with requirements of the Medical Waste Management Act by providing instruction in the use of a self-assessment tool to help ensure that medical wastes are properly handled, safely stored and adequately treated on-site or sent for off-site treatment at an approved facility. Although the scope of the manual addresses this purpose, it also goes further by providing information about waste minimization, sound waste handling practices and continuous quality improvement (CQI). It is hoped that this manual will provide the cornerstone for the training that will be needed by staff at facilities implementing the self-assessment program. It was intended that the manual would also serve to create uniformity of interpretation within the regulatory community of acceptable practices necessary to fulfill requirements of the Medical Waste Management Act. The manual can also serve as a reference document to assist facilities in complying with the Act.

An additional objective of this manual is to assist CQI projects within the health care community. This manual can be used as a reference document for CQI teams working on medical and solid waste source reduction, needle-stick injury prevention, medical waste management plan updating, infection control, and other improvement projects.

A Systems Approach for Managing Medical Waste

A systems approach, as emphasized throughout this manual, will result in cost-effective medical waste management. Operations within organizations are composed of systems and subsystems working to produce outcomes that fulfill the aim of each system. To achieve desired outcomes the systems must be working together and not against each other. Although this sounds very straight forward, it is surprising how many systems are not aligned and actually are competing with each other within the organization. The late quality guru, W. Edwards Deming, indicated that we must optimize the operations of the interdependent components within an organization to accomplish the aim of the system.[5] To ensure that medical waste is handled, containerized, and stored properly, the environmental services staff within a health care facility must work with the doctors, nurses, laboratory staff, and others that generate medical waste in their provision of services to patients. They must also work with purchasing staff to ensure that

[5] Deming, Edward, *The New Economics for Industry, Government, & Education*, Massachusetts Institute of Technology, 1993, page 98.

adequate red bags, storage containers, and treatment equipment are purchased in a timely manner. Input must also be provided to those that negotiate contracts for the facility to obtain services to haul away untreated medical waste for off-site treatment. Although this is not an exhaustive list of all that is involved with medical waste, it does indicate that the medical waste handling system interfaces and interacts with a number of systems within the facility.

All of these systems must work together for the good of the organization, which in this case, is the proper handling, storage, transportation, and treatment of medical waste. When this is accomplished, it will not only ensure compliance with the laws governing medical waste; but will also lead to community and worker protection. When these systems all pull together, proper medical waste handling should result. This will assist the health care facility in meeting its vision. All systems must contribute to the achievement of the vision of the organization. Those that do not contribute to accomplishing the organization's vision, should become candidates for elimination, as they are not in alignment with where the organization is headed.

Medical Waste Self-Assessment for Quality Improvement

Participation in the medical waste self-assessment program can serve as a positive step towards active review of the medical waste handling system. Once the medical waste system is understood and its operation is predictable, strategies for improvement can be initiated. Studies will be necessary to fully understand the medical waste management system. It is often helpful to determine the monthly volume of medical waste being generated. The processes and steps that the medical waste goes through from the point of generation will need to be flow-charted to understand how and where the waste is handled and stored. An assessment should be completed of reported injuries that have occurred along the path the medical waste has traveled from its point of generation. The amount of labor that goes into handling the medical waste stream should be calculated at the various points where the waste is stored, transported, and treated. Incidents of medical waste being erroneously placed in the solid waste stream should be tabulated by location where the violation occurred. An analysis of the cost of treating medical waste on-site versus having it hauled away for treatment should be undertaken.

The information from these studies can be used to determine areas where process improvement projects should be initiated. Management should strive to have CQI projects working continuously to improve the medical waste handling system in order to achieve cost efficiencies, worker safety, use, and lastly, public and environmental health protection.

Making it Easy to Comply with Medical Waste Requirements

Compliance with the Medical Waste Management Act is the responsibility of the generator of such waste. This manual is not the Act or a replacement for it. Compliance with the Medical Waste Management Act will result from proper decisions and practices being implemented on a daily basis by staff within the health care facility. Routine use of the self-assessment tool provides the health care facility with an evaluation of how their medical waste operations are functioning and allows for self-discovery and correction of violations before they are found through a routine medical waste inspection by the local enforcement agency. If this manual is to become a value-added resource, the health care facility must provide staff training in its use and make the self-assessment tool a regularly used instrument. Success will also depend on staff retention of the basic information provided by the manual, so periodic refresher training may be required as necessary.

This manual presents comprehensive coverage of the Medical Waste Management Act and common acceptable practices to meet its requirements. The self-assessment tool allows for an evaluation of the medical waste handling and treatment systems throughout the entire facility. A strategy and step-by-step process for developing a medical waste management plan are discussed in the manual. How to avoid bloodborne pathogen problems is also covered in the manual. Waste prevention and minimization techniques are reviewed in an effort to improve medical waste handling systems within health care facilities. All of this information should make it easier for generators of medical waste to comply in a cost-effective manner with the Medical Waste Management Act.

This manual was designed for use by many different classifications of workers within health care facilities who are involved with generating, handling, storing, or treating medical wastes as well as managers and staff that provide oversight or support to these operations. The major target audience for the manual are individuals responsible for oversight of the medical waste stream. This responsibility may reside with engineering staff, housekeeping, or the environmental safely and health unit. Whatever group is in charge of medical waste management should be the first to become familiar with this manual so that they can oversee implementation of the self-assessment tool throughout the health care facility. In some cases, they may become the trainers in how to use the self-assessment tool and the information provided in this manual. Use of the manual should not be limited to the front line staff. It can also serve as a reference manual or resource to management, infection control staff and CQI teams working on waste management projects.

CHAPTER 1

Developing a Workable Medical Waste Management Plan

A comprehensive medical waste management plan is the key ingredient to successfully guide the proper handling of medical waste within a health care facility. However, a plan that is not understood or followed is of little value to the institution. Training of staff to ensure that they are familiar with and understand the plan is critical to ensure successful implementation of the plan and effective handling of medical waste. This chapter will assist the reader in developing a workable medical waste management plan.

Step One: Understanding the Medical Waste Management Act

An effective medical waste management plan must have as its first priority compliance with the laws governing medical waste. An understanding of the Medical Waste Management Act is an essential first step for those tasked with drafting the medical waste management plan. The California Medical Waste Management Act is conveniently divided into the following chapters for ease of use:

Chapter 1. General Provisions
Chapter 2. Definitions
Chapter 3. Powers and Duties
Chapter 4. Small Quantity Generator Requirements
Chapter 5. Large Quantity Generator Requirements
Chapter 6. Medical Waste Haulers
Chapter 7. Medical Waste Treatment Facility Permits
Chapter 8. Treatment
Chapter 9. Containment and Storage
Chapter 10. Enforcement
Chapter 11. Suspension or Revocation

Frequent referral to the Medical Waste Management Act may be necessary by those writing the plan to ensure that what the plan calls for is consistent with the Act. Particular attention will need to be paid to Chapters 2, 5, and 9 for health care facilities that have their waste hauled to an off-site treatment facility. Those facilities that treat medical waste on-site will also need to have knowledge of the requirements of Chapter 8.

Although Chapter 6 focuses on requirements for commercial medical waste haulers, those facilities that have Limited Quantity Hauling Exemptions for hauling medical waste should read the pertinent sections of this chapter dealing with such exemptions. Several health care facilities have found it beneficial to become licensed hazardous waste haulers so that they can haul their medical waste from their clinics that are operated off-site from their main facility.

Step Two: Understanding the Current Waste Handling System at the Facility

Prior to writing or revising the medical waste management plan, the medical waste system must be thoroughly understood. The following critical factors must be known:

- where the waste is generated;
- what types of medical waste are generated;
- how it is containerized; where it is stored on an interim basis;
- how it is transported through the facility;
- where it is stored prior to transport for off-site treatment or stored prior to on-site treatment; and
- if applicable, how it is treated on-site.

Flow charting the waste stream through the facility or walking the path of the waste stream can be beneficial in understanding the various points of generation and storage that take place for the different components of the medical waste stream. This will help ensure that the medical waste management plan adequately describes all of the variables involved for the particular wastes being generated within the facility.

Once the flow of medical waste through the facility is understood, handling practices for the waste stream should be evaluated against the requirements of the Medical Waste Management Act. This review will help to ensure that compliance with the legal requirements of the Act is met for the various components of the medical waste stream including the points of generation, storage, handling, transportation, and treatment. An evaluation of the current record-keeping process should also be undertaken to ensure that adequate documentation, as required by the Medical Waste Management Act, is in compliance.

A final evaluation of the current waste handling system should be conducted from the perspective of meeting or complying with the needs of the organization, including corporate mandates for how medical waste shall be handled and treated. The following are subjects that should be considered for evaluation:

- the cost effectiveness of the current handling practices;
- whether the system is meeting the corporate image regarding environmental issues such as waste reduction, recycling, and final disposition of the treated wastes; and whether the waste handling system complies with corporate mandates for treatment modalities and finished composition of the waste regarding such solid waste concerns as moisture content and whether the treated product is still recognizable.

Step Three: Designing the Plan for the Needs of the Facility

The medical waste management plan must be able to meet the existing and future needs of the health care facility. Care must be taken during the design phase of the planning process to ensure that the plan is capable of handling the current waste stream as defined through steps one and two. The medical waste management system must have sufficient capacity to handle the varied components of the waste stream. If on-site treatment is provided, the plan must have backup systems or contingency plans developed in case the main treatment equipment breaks or is taken out of service for maintenance. The plan must provide direction to staff regarding handling of partially processed waste, appropriate disposal options and documentation that the issue creating the problem was responsibly resolved. The plan must also contain provisions for handling medical

waste during emergency conditions. The management plan will become the operational guidance document for the facility.

Step Four: Following the Department of Health Services' Plan Guidance

DHS' Medical Waste Management Program has developed a checklist to guide those who are writing a medical waste management plan. The checklist appears at the end of this chapter for your use and may prove helpful in the preparation of a complete medical waste management plan.

Step Five: Developing Training to Communicate the Plan

Once the medical waste management plan has been developed and adopted by the administration of the health care facility it must be communicated to the employees that are impacted by the plan. Comprehensive training must be provided that conveys to the employees how the plan will be implemented. Staff must learn their roles in successfully carrying out the plan.

The training that is developed must recognize that individuals learn in different ways and therefore multiple training strategies will be necessary. Some staff are able to read and understand the material presented to them while others must have hands on experience before they are able to adequately retain the material. Video or lecture presentations may be necessary for those that have a difficult time with reading comprehension. A comprehensive training strategy that includes all of these training techniques may be the most effective way of communicating the medical waste management plan to all staff within the health care facility.

Step Six: Evaluating the Effectiveness of the Plan

The medical waste management plan should be periodically updated to reflect improvements made in the handling of the medical waste stream within the health care facility. Staff should be encouraged and even challenged to evaluate the effectiveness of the plan. This should become a topic for periodic review by the teams working on continuous improvement within the organization.

It is recommended that the facility identify desired outcomes and develop a vision for how the medical waste system should look when it is optimally operated. This vision should also be included in the evaluation process. Progress in reducing the gap from current procedure to desired outcome should be documented as interventions are made by the facility to improve its medical waste management system.

Ideally the medical waste handing system should be analyzed to determine what critical factors contribute to its successful operation and towards fulfilling the vision of the desired outcomes. The critical factors should be measured where possible on a routine basis and placed into a database. Objectives can be developed based on these measurements utilizing the concepts of Statistical Process Control (SPC) to verify whether the system or a component of the system is in or out of control. Once the system is under control improvements can be implemented.

Managers and those involved with operating the various components of the medical waste management system should brainstorm to determine how best to measure their component of the system. They should monitor parameters of the components such as: meeting medical waste pick up times at the various interim storage areas of the health care facility; monitoring needle-stick and sharps injuries caused by improper handling and containerization; monitoring any processing

of waste done on-site to ensure adequate treatment parameters are achieved and monitoring injuries of workers involved in the generation, handling and processing of the medical waste. The data generated from these and other parameters can then be analyzed to determine where improvements can or should be instituted. Through this type of process health care facilities can evaluate and work to continuously improve their medical waste management system.

To assist health care facilities in developing their medical waste management plans a sample plan follows that covers the basic components required. Health care facilities may want to model their plans after this sample or expand upon it if they have complex issues to document. The sample demonstrates what a plan can look like and the expectations of the Department for such plans.

Medical Waste Management Plan Checklist

Date: _____

Facility Name: _____
Address: _____
City: _____
Responsible Party: _____ Phone: _____
Inspector: _____ Phone: _____

This facility has been identified as: (check one)

_____ This generator of medical waste is a new facility or did not have a medical waste management plan (MWMP) on file with the Department. Below are the items to be incorporated in the MWMP. Use this checklist with the Medical Waste Management Act (MWMA) in drafting the MWMP for this facility. If you do not have a copy of the MWMA, contact the Department and one will be provided.

_____ A review of this facility's medical waste management plan (MWMP) revealed that it did not adequately address the items checked below. The items checked below are the areas of the MWMP, which need to be revised. Use this checklist with the Medical Waste Management Act (MWMA) in revising the MWMP for this facility. If you do not have a copy of the MWMA, contact the Department and one will be provided.

The following are highly recommended or required elements of a compliant medical waste management plan.

_____ Provide the name of the contact person at the facility for matters regarding medical waste. Section 117960(a) of the MWMA.

_____ Provide the name, phone number, and address of the facility. Section 117960(b) of the MWMA.

_____ Indicate the type of facility. Section 117960 (c) of the MWMA.

_____ Indicate the types and estimated average monthly quantity, of medical waste generated. Section 117960(d) of the MWMA. See Sections 117635 and 117755 of the MWMA for types of medical waste.

_____ Indicate the on-site medical waste treatment method utilized if applicable. Section 117960(e) of the MWMA.

_____ The name and business address of the registered hazardous waste hauler utilized to have untreated medical waste removed for treatment, if applicable. Sections 117960(f)(g) of the MWMA.

_____ The name and business address of the off-site treatment facility to which the medical waste is being hauled, if applicable. Section 117960(h).

_____ Provide an emergency action plan. Indicate in the emergency action plan the actions to be taken in the event of a disruption of service as the result of a natural disaster or an equipment failure. Section 117960(i) of the MWMA.

_____ Provide a statement certifying that the information provided is complete and correct. Section 117960(j) of the MWMA.

_____ Indicate in the medical waste management plan that tracking documents and treatment records will be maintained for 3 years. Section 117975 of the MWMA.

Procedures for the processing, storage, transport, and treatment of pathology wastes (recognizable human anatomical remains), trace contaminated tissues, and chemotherapeutic containers, and mixed waste.

_____ Indicate in the medical waste management plan how recognizable human anatomical remains are to be handled or treated to ensure compliance with Section 118220 of the MWMA. Describe the procedures to be used in their handling. <u>If there are no medical wastes produced which contain or are comprised of recognizable anatomical remains, indicate this fact in the medical waste management plan, and it will not be necessary to provide procedures for the handling of these wastes.</u>

_____ Indicate in the medical waste management plan how mixed waste as specified in Section 117730 of the MWMA are to be handled. State the procedures to be used to assure proper handling. <u>If there is no mixed waste produced by this facility containing hazardous or radiological materials, indicate this fact in the medical waste management plan, and it will not be necessary to provide procedures for the handling of these wastes.</u>

_____ Indicate in the medical waste management plan how pathology and chemotherapeutic wastes are handled and treated. The medical waste management plan must contain the definition of "empty," as specified in Section 117635 of the MWMA to assure that pathology and chemotherapeutic wastes are properly handled. Describe the procedures to be employed to assure proper handling.
If these wastes are not generated or handled by this facility, indicate this fact in the medical waste management plan, and it will not be necessary to provide procedures for the handling of these wastes.

Containment and Storage

_____ Indicate in the medical waste management plan that medical waste will be contained separately from other waste at the point of generation. Section 118275(a) of the MWMA.

_____ Indicate in the medical waste management plan that the medical waste shall be placed in a red biohazard bag. Sections 118275 (b) and 117630 of the MWMA.

_____ Indicate in the medical waste management plan that sharps waste must be contained in a sharps container. Sections 118275 (c), 117750, and 117755 of the MWMA.

_____ Indicate handling procedures for pathology, trace chemotherapeutic, and mixed waste. Section 118275(d) of the MWMA.

_____ Indicate in the medical waste management plan that red biohazard bags are to be tied. Section 118280 (a) of the MWMA.

_____ Indicate in the medical waste management plan that red biohazard bags are to be placed for storage, handling, and transport in rigid containers with tight-fitting lids labeled with the words "Biohazardous Waste," or the word "Biohazard," and the international biohazard symbol on the lids and sides so as to be visible from any lateral direction. Sections 118280 (b) and 117645 of the MWMA.

_____ Indicate in the medical waste management plan that the maximum storage time of medical waste above 32 degrees Fahrenheit is seven (7) days. If stored at or below 32 degrees Fahrenheit, please state this fact in the plan and describe the storage temperature monitoring schedule (maximum storage time at or below 32° F is 90 days). Section 118280 (d) (1) 7 days and (2) 30 days (< 20 lbs./month generated) of the MWMA.

_____ Provide in the medical waste management plan the procedures to containerize sharps waste. Section 118285 (a) through (d) of the MWMA.

_____ Provide in the medical waste management plan the protocol for routine washing and decontamination of reusable rigid medical waste containers (see Section 118295 (a) (b) for approved methods, disinfectants, and use). Section 118295 of the MWMA.

_____ Provide in the medical waste management plan the techniques performed and disinfectants to be utilized in the cleanup of medical waste spills. Provide the type(s) of disinfectant, concentration and contact time used for the decontamination of spills. (See Section 118295 (b) for approved disinfectants and use.) Section 118300.

_____ Indicate in the medical waste management plan that the accumulation area used by the facility to store containers of medical waste for accumulation must be secured so as to prevent or deny access by unauthorized persons. Warning signs must be posted on or adjacent to, the exterior of the entry doors, on entry doors, gates, or lids. These warning signs must be in both English and Spanish as follows: "CAUTION—BIOHAZARDOUS WASTE STORAGE AREA—UNAUTHORIZED PERSONS KEEP OUT" and in Spanish, "CUIDADO—ZONA DE RESIDUOS — BIOLOGICOS PELIGROSO—PROHIBIDA LA ENTRADA A PERSONAS NO AUTORIZADAS," or in another language in addition to English, determined to be more appropriate. Section 118310 of the MWMA.

Limited Quantity Hauling Exemption

_____ Indicate in the medical waste management plan if off-site medical waste is transported to this facility for consolidation and/or treatment. If so, indicate the sources and the protocols in place for accepting the waste. Section 118030 of the MWMA.

Treatment

Discharge to Public Sewer System

_____ Provide in the medical waste management plan the medical waste to be treated by means of discharge to the public sewer system. Describe in detail methods to be used and the types of medical waste to be treated in this manner. Section 118215 (b) of the MWMA.

Facilities which do not treat medical waste on-site are not responsible for the information below.

Steam Sterilization

_____ Provide in the medical waste management plan standard written operating procedures for biological indicators, or for other indicators of adequate sterilization approved by the Department, for each steam sterilizer, including time, temperature, pressure, type of waste, type of container, closure on container, pattern of loading, water content, and maximum load quantity. Section 118215 (c) (1) of the MWMA.

_____ Provide in the medical waste management plan procedures established for checking recording or indicating thermometers during each complete cycle to ensure the attainment of 121 degrees Centigrade (250°. Fahrenheit) for at least one-half hour, depending on the quantity and density of the load, in order to achieve sterilization of the entire load. Sections 118165 and 118215 (c)(2) of the MWMA.

_____ Indicate in the medical waste management plan that for each treatment cycle the amount and types of medical waste treated shall be recorded and maintained as part of the treatment records. Section 118155 (f) of the MWMA.

_____ Indicate in the medical waste management plan thermometers shall be checked for calibration annually and that records of the calibration checks shall be maintained as part of the facility's files and records for a period of three years, or for the period specified in the regulations. Section 118215 (c)(3) of the MWMA.

____ Indicate in the medical waste management plan that heat-sensitive tape, or another method acceptable to the enforcement agency, shall be used on each biohazard bag or sharps container that is processed on-site to indicate attainment of adequate sterilization conditions. Section 118215 (c)(3) of the MWMA.

_____ State the course of action to be taken in the event that the heat-sensitive tape has not changed color and or the thermometer indicates that proper sterilization has not taken place. Section 118215 (c)(1) of the MWMA.

_____ Indicate in the medical waste management plan that biological indicator *Bacillus stearothermophilus*, or other indicator of adequate sterilization, as approved by the Department, shall be placed at the center of a load processed under standard operating conditions at least monthly to confirm the attainment of adequate sterilization conditions. Section 118215(c)(4) of the MWMA.

_____ State in the medical waste management plan that all records pertaining to on-site treatment shall be maintained for a period of not less than three years. Sections 117975, 118165 (b), and 118215 (c)(5) of the MWMA.

Incineration

_____ Provide a copy of the air pollution permit issued by the local enforcement agency to operate the medical waste incinerator. Section 118155 (f) of the MWMA.

_____ Indicate in the medical waste management plan the medical waste treatment standards and quality control audit procedures, such as throughput and types of waste logs, inspection checklist, maintenance records, incinerator operating procedures, and inspection of ash, and maximum amount of throughput to achieve minimum treatment standards. Sections 118155 and 118215 (a) of the MWMA.

_____ Indicate in the medical waste management plan that for each treatment cycle the amount and types of medical waste treated shall be recorded and maintained as part of the treatment records. Section 118155 (f) of the MWMA.

_____ State in the medical waste management plan that all records pertaining to on-site treatment shall be maintained for a period of not less than three years. Sections 117975 and 118165 of the MWMA.

Sample Medical Waste Management Plan

Facility: Acme Hospital
1234 Main Street
Small Town, CA 12345
(555) 123-4567

Person Responsible for Implementation of Plan: _____
Title: _____

Types of Medical Waste Generated:

BLOOD OR BODILY FLUIDS – Liquid blood elements or other regulated bodily fluids, or articles contaminated with blood or bodily fluids.

SHARPS – Syringes, needles, blades, broken glass.

ISOLATION WASTE – Waste contaminated with excretion, exudate, or secretions from humans who are isolated due to highly communicable diseases.

CHEMOTHERAPEUTIC WASTE – Trace amounts of chemotherapeutic waste.

PATHOLOGY WASTE – Recognizable human anatomical parts, human surgery specimens or tissues.

ACME HOSPITAL IS REGISTERED AS A LARGE QUANTITY GENERATOR. THE ESTIMATED MONTHLY VOLUME OF MEDICAL WASTE GENERATED IS 7000 POUNDS. ACME HOSPITAL DOES NOT TREAT ANY MEDICAL WASTE ON-SITE. ALL WASTE IS REMOVED BY A REGISTERED MEDICAL WASTE HAULER AND TREATED AT AN APPROVED OFF-SITE TREATMENT FACILITY.

Medical Waste Segregation, Containment, Labeling, and Collection Procedures:

Medical waste is contained separately from other wastes at the point of generation. In non-patient care areas, solid waste is not to be disposed of in medical waste containment devices. When cleaning patient care areas, Environmental Services will place all medical wastes into RED biohazard bags labeled with the words, “Biohazard Waste.” These bags are to be impervious to moisture and have a strength sufficient to preclude ripping, tearing, or bursting under normal use and handling. The biohazard bag used must be constructed of material that will pass the 165 gram dropped dart impact resistance test as required by Standard D 170985 of the A.S.T.M. Documentation from the manufacturer of compliance with these minimum construction standards will be kept on file in the **Assistant Administrators Office.** All waste placed in a red bag is considered to be medical waste. The bags will be tied to prevent spillage in the event the bag is dumped upside down. All sharps will be placed in a sharps container labeled with the words “SHARPS WASTE” or with the international biohazard symbol and the word “Biohazard.” Sharps containers will be rigid puncture proof containers that when sealed are leak resistant and not able to be reopened without great difficulty. Sharps containers shall be considered “full” when

they reach 2/3 capacity or the manufacturer's full line. Lids on filled sharps containers must be snapped closed, taped, or otherwise sealed to prevent loss of contents prior to disposal. Medical waste will be stored and transported in rigid containers to the Biohazardous Waste Storage Area located next to the Laundry Room at the back of the building. The containers will be labeled with the words "Biohazardous Waste," or the word "Biohazard," and the international biohazard symbol. This storage area will be locked at all times. Access will be limited to Environmental Services (ES) and Engineering Department personnel and the key will be available only from the ES office. Waste consisting of medical and nonmedical waste will be handled as medical waste except as follows:

1. Medical waste mixed with hazardous waste will be treated as hazardous waste.
2. Medical waste mixed with radioactive waste will be treated as radioactive waste.
3. Medical waste mixed with hazardous and radioactive waste will be treated as radioactive waste.

CHEMOTHERAPEUTIC WASTE:

All trace contaminated (e.g., empty vials, ampoules, IV bottles/bags, tubings and sharps) will be deposited in specially marked, yellow collection container labeled with the words "Chemotherapy Waste" or "Chemo." When the container is full, without compacting, the locking lid is to be secured to prevent loss of contents prior to disposal. Gowns, gloves, and other trace contaminated non-sharps objects may also be deposited in the container. These containers are picked up by Brand X medical waste hauler for transport to an approved incineration facility when routine medical waste is hauled away for treatment.

PATHOLOGY WASTE:

All Pathology Waste will be separated from other medical waste and hazardous wastes (such as fixatives). Waste will be placed in a red bag and deposited into a specially marked secondary container labeled with the words "Pathology Waste" or "PATH." The container will be stored in the morgue refrigerator until pick-up by Brand X medical waste hauler for transport to an approved incineration facility. Once specimens or tissues are deemed waste, they shall not be stored for more than seven (7) days at a temperature above 32 degrees Fahrenheit. Placentas from obstetrics are stored in the chest freezer in the soiled utility room. This waste can be stored frozen (at or below 32 degrees Fahrenheit) for not more than 90 days. At this hospital, Environmental Services staff will pick up placenta waste and deposit it into a clean pathology container for removal by Brand X at least every two weeks.

ACME HOSPITAL accepts no medical waste from any other facility.

Medical Waste Storage Methods

All medical waste will be collected and stored in the Biohazardous Waste Storage Area until transported by the medical waste hauler. All biohazardous waste shall be stored, handled or transported in containers that are leak resistant, have tight fitting covers and are kept clean and in good repair. This area shall be marked with warning signs saying in English "CAUTION – BIOHAZARDOUS WASTE STORAGE AREA – UNAUTHORIZED PERSONS KEEP OUT," and in Spanish, "CUIDADO – ZONA DE RESIDUOS BIOLOGICOS – PELIGROSOS – PROHIBIDA LA ENTRADA A PERSONAS NO AUTORIZADAS." Biohazard bags and filled sharps containers shall not be stored for more than seven (7) days at a temperature above 32

degrees Fahrenheit. This seven (7) day period begins when any waste has been placed in the bag or container. See 118280 (B) for 30-day allowance.

All reusable rigid containers that are used for accumulation, transportation and storage of Medical Waste shall be washed and decontaminated after a maximum of seven (7) days, or more if visibly soiled. The approved method for decontamination at this hospital is the use of a bleach solution diluted 1:10. The solution should be allowed contact with the surface for a minimum of 3 minutes. The amount of solution mixed will be no more than can be used at any one time.

Medical Waste Treatment and Disposal Method

All Medical Waste will be picked up three times weekly by Brand X Hauler and transported to the off-site treatment facility identified below. Records of Medical Waste transported to Brand X will be kept in the Staff Development Office and retained for a minimum of three (3) years.

Emergency Action Plan

While it is highly unlikely that the company would experience a shutdown of operations, contingencies include use of an alternate hauler or retention of the medical waste for not more than seven (7) days from the point of generation above 0 degrees Centigrade (32 degrees Fahrenheit). Another contingency for less well-defined emergency situations would be to contact the Local Enforcement Agency (Department of Health Services, Medical Waste Program) for guidance at (916) 327-6904.

Spills are cleaned up utilizing a solution of 1/2-ounce Concept 256 germicidal in one (1) gallon of water with a contact time of three (3) minutes. The amount of solution mixed will not exceed the amount to be used at any one time.

Waste Hauler:

Brand X Medical Waste Hauler
7777 Broadway
Large Town, CA 95555
(213) 123-1234

Waste Treatment Facility:

Same... (or specify name, address, phone number, etc.)

I declare under penalty of law that to the best of my knowledge and belief the statements made herein are correct and true.

Signature/Title: _____ **Date:** _____

Witness: _____ **Date:** _____

CHAPTER 2

Medical Waste Minimization

While the major focus of this chapter is on the minimization of medical waste, additional concepts for reduction of wastes within the organization will also be covered. Most of the principles of medical waste minimization can be applied to other systems within the health care facility resulting in more cost-efficient operations and an improved bottom line on the balance sheet.

Medical waste minimization is centered on the elimination or reduction of the medical waste stream. There are several measures that can be instituted to achieve medical waste minimization including the following:

- Waste prevention – the elimination of the generation of medical waste
- Source reduction – the reduction in the amounts of medical waste generated
- Re-use – finding another use for a component so it does not become part of the medical waste stream
- Recycling – handling or treatment of the material so it can be used in another process

Understanding the Waste Systems Within the Facility

To successfully minimize wastes one must first have an understanding of why the wastes are created, where they arise, their special handling processes for worker and public safety, regulatory compliance governing the handling of the waste stream, and the varying costs of treating and disposing of these wastes. The following are the six major waste streams that can be generated in health care facilities:

1) liquid wastes,
2) solid wastes,
3) hazardous wastes
4) radioactive wastes
5) air emissions
6) medical wastes

Each of these streams is governed by a specialized set of laws and regulations to ensure worker and public safety, as well as environmental protection. Some of these wastes may be found in different physical forms such as the liquid and solid states of medical wastes.

Wastes are unwanted items that are created by the various systems and processes operating within the health care facility. The treating and disposal costs vary from one waste stream to another making it fiscally prudent to handle a waste in the cheapest waste category. Improperly categorizing as medical waste items that can legally be handled in the solid waste stream is a costly process that can easily be avoided. Preventing solid waste from being placed into the medical waste stream minimizes the amount of medical waste being generated. This saves the health care facility money by not having to handle, contain, or treat the solid wastes in the more expensive medical waste stream.

Recognizing the Need to Reduce Wastes

The handling, storage, treatment and/or disposal of wastes constitute a cost of doing business within health care facilities. Improper management of the various regulated waste streams can result in additional expenditures for failing to comply with the laws and regulations governing these waste streams. Segregation of the wastes requires employees to identify hazards. If they can't recognize the various waste streams they not only increase the cost of disposal but also increase the potential for personal or public injury. Added to this is the unknown cost created by bad publicity for failing to handle the wastes in a proper manner. A hierarchy exists for handling mixed waste streams that raises the mixed waste stream to the highest classification of the wastes comprising the waste stream. Under this classification process, solid waste mixed with medical waste takes on the classification of medical waste and the entire mixed waste stream must be handled as a medical waste. This increases the cost of handing the solid waste portion by a factor of at least 20 times over what it would have cost had the waste streams not been commingled. This same scenario can take place for other categories of wastes. The result is that a more costly waste stream is created when wastes are mixed or mishandled in an inappropriate waste category.

Essential activities in implementing a medical waste minimization program are to recognize the various waste streams, to initiate strategies to ensure that staff are aggressively trained to minimize the generation of wastes in a higher waste stream, and to ensure that the wastes do not become unnecessarily combined. These tasks will require leadership by management in the development of policies and training of staff to: 1) recognize the different waste streams, 2) utilize proper waste segregation practices, and 3) ensure that excessive wastes are not being created. For example, diapers from a nursery can be handled as solid waste; but when medical waste hampers are placed in the nursery, staff often utilize them for disposal of the diapers. This practice will unnecessarily increase the cost for disposing of the diapers because these items must now be handled as medical waste. Action must be taken by management to minimize the medical waste stream by implementing a strategy to prevent the diapers from being handled as medical waste. Staff must be provided with policy directives that baby diapers are to be disposed as solid waste and this action should be reinforced through a training program on waste handling and waste stream monitoring.

Developing Strategies to Minimize Medical Wastes

To be successful, waste minimization efforts must begin with formulation of implementation strategies. Strategies consist of plans that describe how an organizational goal will be achieved. Formal strategies contain the following three elements:

1. Goals to be achieved,
2. policies that guide or limit action, and
3. action sequences, or programs, that accomplish the goals.[6]

Management and staff must be committed to medical waste minimization to make it a successful program within the health care facility. Management must communicate the need for medical waste minimization in a manner that inspires staff to implement positive actions in this

[6] Dean, James W., Jr. and Evans, James R., *Total Quality Management, Organization and Strategy,* West Publishing Company, 1994, page 260.

direction. This can be done by publishing a “medical waste minimization strategy” to guide the waste minimization efforts within the facility. The strategy should state the goal of the medical waste minimization program and identity new policies for handling and discarding medial waste and the non-medical wastes generated in the same setting. Other actions that should be considered for inclusion in the medical waste minimization strategy include:

- plans for staff training and follow-up monitoring
- establishing a monthly tracking mechanism for waste minimization
- incentives for submitting waste minimization ideas
- percent of savings placed back into the areas of the facility where generated for capital improvements, staff training, or employee gain-sharing
- recognition or awards for achieving milestones in implementing the strategy
- formation of a team or council to oversee and coordinate the medical waste minimization strategy
- providing tangible reports, graphs and feedback to show results

If medical waste minimization is to be undertaken by the health care facility it is important to develop good baseline data of the amounts of waste generated prior to implementation of the waste minimization program. Medical waste generation data from the various units within the health care facility should be recorded on a Pareto Chart with the amounts of waste displayed in descending order from the left side of the chart. Pareto analyses can easily be used to determine the highest medical waste generating areas in which the minimization strategies should be initiated. Displaying the medical waste being generated by the various units in the facility can assist in developing “buy-in” for implementing waste minimization strategies. This information should be displayed and communicated throughout the facility.

Waste Minimization Planning

The medical waste minimization strategy should be formally approved by top management within the health care facility as a demonstration of their commitment to the program. The next step in the planning phase for medical waste minimization is to assign responsibility for the program. This responsibility can reside with an individual, a department head, team, or council. The assignment of responsibility should be done by top management. The individual or team that is assigned the responsibility for implementing and coordinating the medical waste minimization program should be empowered by management to work across organizational boundaries in carrying out the program. When management announces the waste minimization strategy and assignment of responsibility they should include an expectation of cooperation from every operational unit and individual throughout the organization.

Waste Minimization Assessment

Data regarding the current waste streams generated within the health care facility need to be gathered during the assessment phase of the program. These data should include the amounts of waste generated for the various waste streams and the cost of disposal or treatment. An assessment of the amounts of medical waste generated in the various areas of the facility should also be collected, or if this data is unknown, measurements should be made. An analysis should be completed for the medical waste generated per patient population in the facility or served by the facility for future comparisons of the effectiveness of the waste minimization program.

The assessment should provide useful information to assist in determining where to initiate the waste minimization program in order to obtain maximum waste reduction and cost efficiency. The use of Pareto Charts as mentioned in the section entitled: Developing Strategies to Minimize Medical Waste should be considered as a means of displaying this data. Plotting the amounts of wastes generated by the different parts of the health care system also gives staff from each of these areas knowledge as to the potential gains that can be recognized for waste minimization in their areas of the facility. The use of bar coding systems can assist in the waste minimization efforts by measuring and recording the medical wastes being generated in the various units of the facility on an on-going basis.

Storing the assessment data in a computer for retrospective analysis can be used to show progress as the medical waste minimization efforts are implemented. The ability to document success stories at a later date is contingent on having accurate initial assessment data.

Medical Waste Minimization Implementation

Following completion of the medical waste minimization assessment the facility should be ready to implement the medical waste minimization program. Using the data gathered during the assessment stage, decisions as to where to initiate the program should be made. The major medical waste generating areas of the facility should be targeted, as that is where the potential for the greatest accomplishments can be expected. There may be resistance to the waste minimization program because it is something new. Staff may build barriers to the successful performance of the waste minimization program because they may perceive it will create more work for them and they are already very busy. To overcome these barriers will require excellent communications about the waste minimization program and strategies must be communicated to everyone involved. Staff from the Environmental Management Branch have found in surveys of hospitals where aggressive medical waste minimization programs have been implemented that reductions of 30 to 40 percent of the medical waste stream are not uncommon. This amount of reduction in the medical waste stream results in significant cost savings.

To document impressive successes in reducing the medical waste stream, it is necessary to institute a tracking program that documents and measures the waste being generated in the various parts of the facility. As waste minimization strategies are initiated, their effectiveness can be measured by the tracking system. Impressive results may be achieved early in the program as easy to implement actions can yield big reductions. As the medical waste minimization program in the health care facility goes along it may become harder to meet percent reduction goals because the easiest reductions have already been achieved. This is another reason to institute a comprehensive program to track and document the accomplishments. Reductions achieved over the life of the program should always be shown in order to give an indication of the overall accomplishments of the program since its inception.

When a strategy for medical waste minimization is initiated and the results are less than what was expected, a thorough analysis should be made of the procedure that was implemented. This learning from failures is important so that the same strategy will not be repeated. The ability to modify the strategy and test it again for effectiveness should be an integral part of any minimization program. Learning from failures is an important step in the process of continuous improvement. Strategies that work well should likewise be studied for lessons that can be applied in other areas of the health care facility, shared through technical publications, or over the

INTERNET with other facilities. The workable medical waste minimization practices should be incorporated into the on-going operations of the health care facility through policy directives to staff. In summary, the implementation phase should consist of the following:

- applying medical waste minimization strategies to specific areas of the facility
- tracking the waste minimization efforts and comparing the results with the waste data gathered during the assessment phase of the program
- documenting results and studying the system for continuous improvement
- evaluating the waste minimization process to document success, determine training efficiency and needs
- instituting policy directives incorporating improved medical waste minimization processes
- planning new medical waste minimization pilot projects for further waste reduction

The status and results achieved should be communicated to all staff throughout the medical waste minimization process and should be incorporated into new employee orientation. Charts showing achievements should be prominently displayed to encourage further actions in waste minimization be undertaken. Storyboards depicting the actions taken and results achieved within the various units of the facility should be developed. Success stories should be communicated to the neighboring community to demonstrate that the health care facility is a good environmental steward.

CHAPTER 3

Bloodborne Pathogen Rule[7]

Introduction

In California, the Medical Waste Management Act (MWMA) and the Bloodborne Pathogen Standard govern two similar but uniquely distinguished cross-sections of the health-care facility waste stream. This is for two reasons. One is that the regulated wastes themselves are defined differently; the other is that the rules protect different groups of individuals.

Healthcare and solid waste workers are the chief beneficiaries of the Medical Waste Management Act but, hospital patients or members of the general public are included as well. Assuring the health and safety of all segments of the population is intended by the Act.

The Bloodborne Pathogen Standard, in contrast, is meant to protect persons who may reasonably expect exposure to the Bloodborne Pathogen during the course and scope of their employment; the responsibility for their protection is that of their employer. While Medical Waste Management Act waste must be produced as the result of an action related to the delivery of health care (or associated actions listed in the statute) Bloodborne Pathogen regulated waste is simply defined as blood, or other potential infectious materials or contaminated items as defined in the standard, regardless of how it is produced. As a result, the application of the Bloodborne Pathogen Standard extends well beyond the healthcare environment.

Definitions Pertinent to Waste Management

Under the bloodborne pathogen rule, regulated waste means "...liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological waste containing blood or other potentially infectious materials. Regulated [w]aste includes 'medical waste'..."[8]

"'Contaminated' means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on the surface or in or on an item."[9]

Summary of Key Features of the Bloodborne Pathogen Rule

Since the purpose of this document is to prepare staff to perform self-assessment inspections for compliance with the MWMA, this portion will summarize only those key features relating to waste management. It is recommended that you obtain and review the *Bloodborne Pathogens Resource Package* (1993) published by the Cal/OSHA Consultation Service.

Scope and Application

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[7] *Bloodborne Pathogens Guide to Compliance*, Cal/OSHA Consultation Services, 1993.
[8] *California Code of Regulations*, Title 8, Section 5193(b).
[9] Ibid.

The employer has the responsibility to determine which employees are at risk of potential occupational exposure. This is done during the development of the exposure control plan. (An employee is a person who is directed or controlled by the employer.) Volunteers, professional students (medical, nursing, physical, occupational or respiratory therapy students) are not covered by the standard. "Incorporated" physicians are considered employed by their corporation. However, the hospital where the physician practices may also be held responsible for creating or controlling a hazard. A hospital may also be cited for violations involving independent contractors. However, a contract agency—such as a temporary agency—would share employer responsibility with the hospital.

Certain job descriptions will determine whether an employee is covered by the standard. For example, employees who administer first aid are covered by all requirements of the regulation, including hepatitis B inoculations; while in the case of those for whom first aid duty would be only collateral to their work assignment inoculations need not be offered. And emergency response teams for whom first aid is not either a routine or collateral duty (e.g. security or spill control) are not covered by the regulation.

Definitions

The term *"reasonably anticipated"* is not defined in the regulation. The guidelines suggest that one single exposure during a working lifetime is sufficient to capture that risk under the standard. The rationale is that even one exposure could result in the employee contracting a life-threatening illness.

The guidelines distinguish *contaminated* from *regulated* waste, and advise that the former **not** be red bagged so as to not confuse this non-regulated waste stream with medical waste. However, language remains in the document suggesting that the fixed container must still be labeled as a biohazard. This inconsistency has been resolved verbally with Cal/OSHA—the biohazard symbol need not be placed on the fixed container.

Exposure Control

The exposure control plan outlines what protective measures the employer will take to minimize or eliminate employee exposure to blood or OPIM. It must be consistent with the Injury and Illness Prevention Program (IIPP)[10] because the latter must include procedures for evaluating workplace hazards. **It may be written in English only, but training of employees regarding the plan must be in the language of and at an educational and literacy level accessible to the employees. At a minimum, it must contain:**

- the exposure determination which identifies job classifications (in some cases, tasks and procedures) which could result in occupational exposure to blood and OPIM;
- a schedule of how and when other provisions of the standard will be implemented (methods of compliance), hepatitis B vaccination and post-exposure follow-up, communication of hazards to employees, and record keeping;
- the procedures for evaluating the circumstances surrounding an exposure incident.

Procedures for evaluating an exposure incident must include:

[10] *California Code of Regulations*, Title 8, Section 3203.

- the engineering controls and work practices in place;
- the protective equipment or clothing used at the time of the exposure incident;
- an evaluation of the policies and "failures to control" at the time of the exposure incident.

A copy of the exposure control plan must be given to the employee within 15 working days of his/her request, and it is recommended that it be presented as part of new employee orientation. It must be reviewed annually, and must be thoroughly updated to reflect changes in tasks, procedures and employee positions. The plan must be available to all employees, and to Cal/OSHA and NIOSH representatives.

Methods of Control

Principles of Universal Precautions or Body Substance Isolation must be applied wherever there is potential for exposure. The employer is also required to implement engineering and work practice controls to eliminate or minimize employee exposure. This may involve the evaluation of available engineering controls to determine the feasibility of instituting more advanced measures.

Appropriate Personal Protective Equipment (PPE) must be provided by the employer to protect the employee from risk of exposure. The PPE must be removed prior to the employee's leaving the work area. Gloves must be worn any time a vascular access procedure is performed. Disposable gloves must be replaced as soon as practical after they are contaminated, or as soon as feasible after a functioning barrier has been breached.

In California, disposal of all regulated waste must be in accordance with the California Medical Waste Management Act.

Containers must be:

- equipped with tightly-fitting covers;
- constructed to contain all contents and prevent leakage of fluids;
- labeled as required by the MWMA, and
- closed prior to removal to prevent spillage or protrusion of contents.

If the container becomes contaminated on the outside it must be secondarily contained and meet the same standards described above.

Sharps containers must be labeled with the biohazard symbol and the word "biohazard." Sharps containers must be kept upright, replaced routinely as described in the exposure control plan, and not be allowed to overfill.

The containers must be:

- closed immediately prior to removal or replacement;
- placed in a secondary container if leakage is possible.

The secondary container must be:

- equipped with a tightly fitting cover,
- constructed to contain all contents and prevent leakage of fluids;
- labeled as required by the MWMA.

Hepatitis B Vaccination and Post-Exposure Follow-up Procedures

The hepatitis B vaccination series must be offered to any employee who has experienced occupational exposure, except employees who have previously received the series, or who show immunity, or who are prohibited for medical reasons from receiving the vaccine. This, and post-exposure evaluation and follow-up must be made available at no cost to employees. The hepatitis B series must also be made available to new employees within 10 working days of initial assignment, after appropriate training. (An exception to this requirement is made for employees for whom first aid duty is collateral to their principal assignment.)

If an employee declines the hepatitis B vaccination, the employer must have the employee sign a declination form which contains the exact wording: " I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that be declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination at no charge to me." (Section 142.3, Labor Code.) A photocopy of the form may be used. Employees have the right to refuse the vaccine and any post-exposure evaluation and follow-up. The employee retains the right to vaccination at a later date.

In the event of exposure, the employer must identify and document the source individual, if known, unless the employer can establish that identification is not feasible, or is prohibited by law. The source individual's blood must be tested as soon as feasible, after obtaining consent, to determine HIV and HBV infectivity. If consent is unavailable and is required by law, the employer must document that consent cannot be obtained; when consent is not required by law, the source individual's blood must be tested and results documented.

Information on the potential for infection exposure must be provided to the evaluating health care professional, along with the following:

- a copy of the standard;
- a description of the employee's duties as they relate to the exposure incident;
- documentation of the route(s) and circumstance(s) of the exposure;
- the results of the source individual's blood testing, if available; and
- all medical records relevant to the appropriate treatment of the employee.

The exposed employee must be provided the results of the testing, and be informed of the laws governing disclosure of the identity and if available the results from blood testing of the source individual.

The employer is also required to provide post-exposure counseling, provided by a trained counselor. Counseling should include United States Public Health Service recommendations for prevention and transmission of HIV infection. These include refraining from blood, semen, or organ donation, abstinence from sex or using measures to prevent transmission of HIV, and refraining from breast feeding infants. This counseling must be made available regardless of the employee's decision to accept serologic testing.

Communication of Hazard to Employees

Under the bloodborne pathogen rule labels are required on red bags containing regulated waste and sharps containers. They may be either separate labels (note that the color is not red, but rather fluorescent orange or orange-red, with contrasting lettering and symbols). Red bags and sharps containers need not be separately labeled.

A trained individual must be available during the training session. Physicians who are independent agents or partners are not required to comply with the standard, and therefore need not be trained, although they may not endanger others. All other employees must receive initial and annual training. This includes employees such as collateral duty first aid personnel who have job duties which have the potential for occupational exposure. Part-time and temporary employees also must be trained on company time.

The person conducting the training is required to be knowledgeable in the subject matter covered by the elements contained in the training program in the context of the applicable workplace. Brochures, fact sheets, model plans, videotapes and a list of resources available to assist in implementation of the Bloodborne Pathogens Standard are available from the Cal/OSHA Consultation Service at 455 Golden Gate Ave. San Francisco, CA 94102, or by calling (415)703-4050

CHAPTER 4

Use of the Self Assessment Tool For Medical Waste Management

A copy of the Self-Assessment Tool appears at the end of this chapter.

Part I: Waste Management Summary

Objective: To determine the types of medical wastes generated at the facility, and that written medical waste management procedures and records are maintained. References noted below are from the California Health and Safety Code, Part 14, Medical Waste Management Act, Section 117600 *et seq.*

A. Does the facility handle the following:

1. Does your facility generate biohazardous wastes?

   Guide: See the glossary for the definition of "biohazardous wastes." Answer **yes,** if biohazardous wastes are generated on-site, or **no**, if they are not.

   (a) Are biohazardous wastes treated on-site?

   Guide: Answer **yes** or **no**. Answer **N/A** if biohazardous wastes are not generated on-site.

   (b) If **yes**, state type of treatment.

   Guide: State the type of on-site treatment used (autoclave, incinerator, etc.) in the comments section.

2. Does your facility generate liquid wastes?

   Guide: See the glossary for the definitions of liquid/semi-liquid wastes. Answer **yes,** if liquid wastes are generated on-site; or **no**, if they are not.

   (a) Are liquid wastes treated before disposal?

   Guide: Answer **yes** or **no**. Answer **N/A** if liquid wastes are not generated on-site.

   (b) If **yes**, state type of treatment:

Guide: State the type of treatment used in the comments section.

3. Does your facility generate pathology wastes?

Guide: See the glossary for the definition of pathology waste. Answer **yes** if pathology wastes are generated on-site; or **no**, if they are not.

(a) If **yes**, is the excess fixative decanted?

Guide: See the glossary for the definition of decanted. Answer **yes**, if the liquid is poured/separated from the tissue solids; or **no**, if they are not. If the answer is **no**, indicating that the fixative is not being decanted state the mechanism used to separate or treatment of the waste streams. Steps must be initiated to either decant the liquid fixative and handle it as a hazardous waste or have the waste streams separated by an outside contractor. Please indicate in the comments section how these wastes are being handled. Contact your local enforcement agency for assistance.

(b) Are pathology wastes treated on-site?

Guide: Section 118222 requires that pathology wastes be incinerated. Answer **yes,** if pathology wastes are treated on-site by incineration; or **no**, if they are not. If the answer is **no**, indicate what company picks them up and where they go for treatment in the comments section. Answer **N/A** if pathology wastes are not generated on-site.

(c) If (b) is yes, is an approved permitted incinerator used to destroy pathology wastes on-site?

Guide: Section 118222 requires that all pathology wastes be incinerated. Answer **yes**, if an incinerator is used on-site and indicate the incinerator permit number issued by the local air pollution control agency in the comments section. Answer **N/A** if pathology wastes are not generated. If the answer is **no**, contact your local enforcement agency for assistance.

4. Does your facility generate trace chemotherapeutic wastes?

Guide: See glossary for the definition of trace chemotherapeutic wastes. Answer **yes**, if trace chemotherapeutic wastes are generated on-site; or **no**, if they are not.

(a) Are trace chemotherapeutic wastes treated on-site?

Guide: Answer **yes** or **no** if trace chemotherapeutic wastes are treated on-site. Answer **N/A** if **no** chemotherapeutic wastes are generated on-site.

(b) If **yes**, is an approved incinerator used?

Guide: Section 118222 requires that all trace chemotherapeutic wastes must be incinerated. If answer is **yes**, give the incinerator permit number in the comments section. Answer **N/A** if chemotherapeutic wastes are not generated. If the answer is **no**, contact your local enforcement agency for assistance.

5. Does your facility produce outdated pharmaceutical wastes?

Guide: See glossary for the definition of pharmaceutical waste. Answer **yes** if pharmaceutical wastes are generated on-site; or **no**, if they are not.

(a) If **yes**, are outdated pharmaceuticals treated on-site?

Guide: Answer **yes** if pharmaceutical wastes are treated on-site; or **no**, if they are not. Answer **N/A** if no pharmaceutical wastes are generated on-site.

(i) If (a) **yes**, are they treated in an approved incinerator?

Guide: Answer **yes** if outdated pharmaceuticals are treated on-site in an approved incinerator and state incinerator permit number issued by the local air pollution control agency in comments section; or **no** if they are not. Answer **N/A** if waste pharmaceuticals are not generated on-site. If answer is **no**, contact your local enforcement agency for advice on obtaining a permit from the regional air quality management district.

(ii) If (a) **yes**, are they treated by an approved alternative treatment method?

Guide: Answer yes if outdated pharmaceuticals are treated on-site by an approved alternative treatment technology; or **no**, if they are not. If **yes**, state approved alternate technology in the comments section. Answer **N/A** if no pharmaceutical wastes are produced.

If the answer to both (a*i*) and (a*ii*) are **no**, pharmaceutical waste must be removed by a registered waste hauler for off-site treatment. Contact your local enforcement agency if you have any questions.

6. Does the total amount of medical wastes produced above equal or exceed 200 pounds per month (lbs./mo.)?

   Guide: See the glossary for the definitions of "large quantity generator" and "small quantity generator". Answer **yes** if 200 lbs./mo. or more of medical wastes are generated. Answer **no** if less than 200 lbs./mo. of total medical wastes are generated.

   (a) If 6 is **yes**, give the facility's large quantity generator registration number.

   (b) If 6 is **no**, give the facility's small quantity generator registration number.

   Guide: Give the appropriate generator registration number in the comments section.

B. Does the facility have a current written Medical Waste Management Plan?

Guide: See glossary for definition of "Medical Waste Management Plan" ("MWMP"). All registered or large quantity generator facilities generating medical wastes must have a written MWMP. Answer **yes** if there is a written MWMP; or no if there is none. If the answer is **no**, and the answer to Part I, A.6 is "yes," a MWMP must be written. Reference Chapter 2 of this manual for an outline of the contents of a MWMP.

1. When was the Medical Waste Management Plan was last reviewed? You should note the date.

   Guide: The MWMP is to be reviewed and amended at least annually or whenever a significant change in medical waste management practices occurs at the facility. Write in the comments section the date of the last time the MWMP was reviewed and updated.

   Note: Examples of "significant" changes include changing from one type of on-site treatment to another (i.e.; changing from steam sterilization to microwave disinfection), changing from removal of untreated medical wastes by a registered hauler to on-site treatment, change in medical waste treat-

ment facility, bringing medical waste from another facility, and/or implementing a returned needles program, etc.

2. Where is the location of the plan?

Guide: Give the physical location where the plan is filed in the comments section.

C. Does your facility have a voluntary sharps return program for its patients?

Guide: Section 118147 allows a facility to establish a voluntary sharps return program for their patients. Answer **yes** if your facility has a voluntary sharps return program for its patients; or **no,** if your facility does not have such a program.

1. If answer is **yes**, does your MWMP include the voluntary patients sharps return program?

Guide: Answer **yes** if your MWMP includes a description of the voluntary patient sharps return program including the locations in the facility that receive home-generated sharps. Answer **N/A** if you do not have a patient sharps return program. If answer is **no**, the MWMP needs to be amended to include it.

2. State the location where the sharps are returned to in the comments section.

Guide: Give the location where the sharps are received from patients in the comments section.

D. Does the facility receive home generated Biohazardous wastes/sharps from Home Healthcare providers?

Guide: Section 118030 allows home healthcare providers to transport limited quantities of medical wastes back to the facility. Answer **yes** if the facility receives sharps or other medical wastes from home healthcare providers; or **no**, if they do not.

1. If answer to D, above is **yes**, does the MWMP reflect the receipt of home-generated medical wastes?

Guide: Answer **yes** if the MWMP includes a home-generated medical waste return program. Answer **N/A** if the facility has no return program. If answer is **no**, the MWMP needs to be

revised to include the program for the return of medical wastes by home healthcare providers.

2. Where are they received?

Guide: If answer to D, is **yes**, note in the comment section the location(s) where home-generated medical waste is received at the facility.

E. Does the facility receive any medical wastes from other sources? (Discretionary Information)

Guide: Answer **yes** if any medical wastes are received from other sources, such as those noted below; or no if they are not. If the answer is **no**, go to question **F**.

1. Private physician/dentist offices, where the physician/dentist is associated with the facility or located within 400 yards of the site?

Guide: Answer **yes** if your facility has a program to receive medical waste from private physician/dentist offices, where the physician/dentist is associated with your facility/ organization; or **no,** if it does not.

2. Ambulances or air ambulances?

Guide: Answer **yes** if your facility accepts medical wastes from ambulances or air ambulances; or **no,** if it does not.

3. Other source(s)?

(I) Describe source(s).

Guide: Answer **yes** if your facility accepts medical wastes from any other sources (example: needle exchange program wastes, local law enforcement agencies, etc.); or **no** if it does not. If answer is yes, describe source(s) of medical wastes in comments section.

F. Does the facility have a source reduction plan? (Discretionary Information)

Guide: Answer **yes** if your facility has a written medical waste source reduction plan; or **no,** if it does not.

1. Are records kept on the amount of waste reduced?

Guide: Answer **yes** if records are kept; or **no**, if they are not. Answer **N/A** if there is no source reduction plan.

2. If answer to E is **yes**, where are records maintained?

Guide: Note the location of the source reduction program records in the comments section.

G. Does your facility have a medical waste recycling program? (Discretionary Information)

Guide: Note **yes** if your facility has a medical waste recycling program; or **no**, if it does not.

1. Are records kept on the amount of medical waste recycled?

Guide: Answer **yes** if recycled medical waste records are kept; or **no**, if they are not. Answer **N/A** if there is no recycling program.

2. Where is the location of the medical waste recycling program records?

Guide: Note the location of records in the comments section.

H. Does the facility track the volume or weight of waste generated? (Discretionary Information)

Guide: Answer **yes** if the volume or weight of medical waste is tracked; or **no**, if it is not.

1. If **yes**, where are records maintained?

Guide: Note the location where volume or weight records are kept in the comments section.

Part II: Consolidation and Transport

Objective: To determine the overall medical waste production of the facility and associated satellite facilities (if any); that the appropriate permits, registrations, tracking and other documents are maintained; and that medical waste storage areas meet standards.

A. Does your facility have a satellite facility(ies) generating medical wastes more than 400 yards from the main facility?

Guide: See glossary for the definition of satellite and main facilities. Medical wastes generated by any satellite facility that is greater than 400 yards from the boundary of your main

facility are considered medical wastes generated "off-site." See Sections: 117725, 117740, 117925, 117950 for reference to the 400 yard rule.
Answer **yes** if medical wastes are generated at any satellite facility; or **no**, if they are not. If there are no satellite facilities that generate medical wastes, go directly to question "B" below.

Special Note: A facility may have more than one satellite facility generating various quantities of medical wastes. The attached Form A, "Satellite Facilities Generating Medical Wastes" is used to document all the satellite facilities generating medical wastes associated with the main facility.

(a) If **yes**, and less than 200 lbs./month of medical wastes are generated by the satellite facility(ies), give the Small Quantity Generator's (SQG) registration number in the comments section.

(b) If **yes**, and 200 lbs./month or more of medical wastes are generated by the satellite facility(ies), give the Large Quantity Generator's (LQG) registration number(s) in the comments section.

(c) If the answer is **no**, go to question "B" below.

Guide: See the glossary for definitions for LQG and SQG. See Section 117680 of the code for reference to the 200 lbs./ month rule. All large quantity generators of medical wastes are required to register with the local enforcement agency.

1. Does the satellite facility(ies) located more than 400 yards away from the main facility transfer medical wastes to the main facility?

Guide: Answer **yes** if medical wastes are transferred from the satellite facility(ies) located more than 400 yards away to the main facility or **no**, if they are not.

(a) If **yes**, does the facility(ies) have a Limited Quantity Hauling Exemption (LQHE)?

Guide: See the glossary for the definition of LQHE. Answer **yes** if the satellite facility(ies) has a LQHE or **no**, if it does not.

2. Does the facility use its *own* vehicle(s) to transport medical wastes over 400 yards?

   Guide: Answer **yes** if the facility uses its *own* vehicle(s) to transport medical waste between facilities; or **no** if it does not. If **no**, give the name and number of the registered medical waste hauler used to transfer medical wastes between facilities in the comments section. If **yes**, give the facility's medical waste hauler's registration number in the comments section. Answer **N/A** if the satellite facility(ies) has a LQHE. The facility must have a medical waste hauler's registration for its own vehicle(s) if it transports medical wastes exceeding the LQHE 20 lbs./week limit.

3. Does the main facility receive medical wastes from satellite facilities greater than 400 yards away AND treats them or *any part* of them, on-site?

   Guide: Answer **yes** if the main facility receives medical wastes from other off-site facility(ies) greater than 400 yards from the main facility **AND** treats all, or *any part* of the medical wastes, on-site; or **no**, if it does not. An off-site Medical Waste Treatment Facility permit is required from the California Department of Health Services pursuant to Section 118130 whenever off-site medical wastes are brought to a facility for treatment. If the answer is **yes**, give the Off-Site Medical Waste Treatment Facility permit number in the comments section.

4. Are *any* of the medical wastes received at the main facility from the off-site facility(ies) held for transfer to another medical waste treatment center?

   Guide: Whenever any medical wastes are received at one facility and transferred in whole or part to another facility for final treatment, a Medical Waste Transfer Station permit is required from the California Department of Health Services pursuant to Section 118130. Answer **yes** if any medical wastes are transferred to another facility for final treatment; or **no**, if it is not. If the answer is **yes**, give your facility's Medical Waste Transfer Station permit number in the comments section.

B. Does your main facility treat only its *own* medical waste generated on-site or within 400 yards of its facility?

Guide: See the glossary for the definition of an On-site Medical Waste Treatment Facility. Answer **yes** or **no** if all or any part of the medical wastes generated on-site are treated on-site. If **yes**, give your facility's On-Site Medical Waste Facility permit number in the comments section. If **no,** give the name and number of the registered haulers removing medical wastes from your facility in the comments section.

1. If yes, list on-site treatment permit number and go to Part III.

2. If no, list the name and number of the hauler and go to Item C.

C. Are appropriate shipping/tracking documents issued and signed for each load removed?

Guide: Section 118040 requires completed tracking documents for each load of medical waste removed from your facility for treatment at an off-site medical waste treatment facility. The medical waste must be transported by a licensed hazardous waste hauler that is registered to haul medical waste. Answer **yes** if signed shipping/tracking documents are provided by the hauler and maintained for each shipment of medical waste from your facility; or **no**, if they are not. Answer **N/A** if no medical wastes are shipped off-site for treatment. If the answer is **no**, begin saving the tracking documents and con tact your local enforcement agency for direction. You may need to obtain copies of tracking documents from your hazardous waste hauler.

D. Are documents from Off-site Medical Waste Treatment Facilities maintained?

Guide: Documentation is required to verify receipt of medical waste by off-site treatment facilities (Section 118040). Answer **yes** if documentation is received and maintained for each load of medical waste shipped; or **no**, if it is not. If the answer is **no**, contact your hazardous wastes hauler to obtain copies of the documentation of receipt of medical waste from your facility. This information is often provided as part of the billing sent to your facility by the hauler.

E. Are all documents saved for at least 3 years?

Guide: Section 117975 requires that all documentation, including shipping/tracking and verification of destruction documents, be maintained for at least three years. Answer **yes** or **no** if required documentation is saved for at least three years. Give the location of the documentation in the comments section.

F. Are storage area(s) used for medical wastes prior to transfer off-site?

Guide: See glossary for the definition of storage area(s). The designated storage area(s) must meet several requirements noted below in 1 to 4. Answer **yes** if storage area(s) are used; or **no**, if they are not. Answer **N/A** if there is no storage area(s), as defined in the glossary, and go to "G" below.

1. Are storage area(s) secured to keep unauthorized people out?

   Guide: Outdoor storage area(s) must be secured by fencing, locks, gates, doors, etc., to assure no unauthorized person can gain entry. Depending on the location and size of the storage area(s), security measures will vary. State Department of Health Services or local inspectors will review appropriate security measures during facility inspections and may make further recommendations as needed.

2. Are storage area(s) posted with warning signs in appropriate languages?

3. Are posted signs for outdoor storage areas visible for at least 25 feet in daylight?

   Guide: Section 118310 requires that all storage area(s) have warning signs in English and other appropriate language depending on the facility's location. Warning signs must be visible from at least 25 feet in all directions during daylight. Answer **yes** for 2. if storage areas have warning signs in appropriate languages; or **no** if they do not. Answer **yes** for 3. if the signs are clearly visible for at least 25 feet in any direction in daylight; or **no**, if they are not. If the answer is **no** for either or both questions, appropriate warning signs must be posted.

3. Are outdoor storage area(s) protected from animals, the elements, and are not a breeding place or food source for insects/rodents?

   Guide: Section 118310 requires that storage area(s) for medical wastes be protected from animals, the weather, and that storage area(s) are prevented from becoming breeding places or sources of food for rodents/insects. Answer **yes** if all the requirements for protection of storage area(s) are met; and **no** if they are not. If the answer is **no**, corrective action must be instituted. Call your local enforcement agency for assistance.

G. Are emergency spill procedures and spill kits kept in the storage area and/or pick-up dock?

Guide: Emergency spill procedures and spill kits may be required for the facility as part of Section 117960(i) and 118300 of the MWMP for storage and treatment area(s) and other locations (docks, etc.) where medical wastes are picked up for shipment to treatment facilities. Answer **yes** if emergency procedures and spill kits are available as needed; or no if they are not. If the answer is **no**, corrective action must be taken to comply with the MWMP.

1. Are emergency procedures consistent with the MWMP?

Guide: The posted emergency spill procedures must be the same as the emergency procedures written in the MWMP. Answer **yes** if the posted emergency procedures are the same as the emergency procedures in the facility's MWMP; or **no**, if they are not. If the answer is **no**, corrective action must be taken to comply with the MWMP.

2. Is there a posted list of emergency numbers?

3. Is the emergency list current?

   (a) Last time updated _____.

Guide: There must be a posted list of emergency numbers that include local emergency response services (fire, police, ambulance, etc.), emergency contacts (responsible managers, supervisors, health and safety personnel, etc.), appropriate State, County, City and local agencies and other pertinent emergency numbers (CHEMTREC, Poison Control Centers, etc.). The emergency call list should be dated. To be effective the list should be updated annually or more often as needed. Answer **yes** for 2. above if there is a posted emergency list; or no if there is none. Answer **yes** for 3. above if the list is updated and has been reviewed at least annually; or **no**, if it has not. Give the date the list was last updated in the comments section. If the answer to either or both questions 2. or 3. is **no**, corrective action must be taken to post and/or review the emergency list.

Part III: Treatment/Sterilization of Medical Waste

Objective: To determine that on-site treatment is done in accordance with requirements of the Medical Waste Management Act.

A. If an autoclave is used, complete the following:

1. Are there written Standard Operating Procedures (SOPs) for unit(s)? Location of SOPs:

   Guide: Standard operating procedures (SOPs) are those protocols and procedures that are specific to the appropriate and safe operation of any autoclave used for treating medical waste. The SOPs should include the appropriate and safe handling of medical waste, wearing of appropriate personal protective equipment (PPEs) and manufacturer's recommendations for appropriate and safe use as required by section 118215 (c).

2. Are appropriate operational records kept?

   Guide: Section 118215 (c) (5) requires records be established and kept for at least three (3) years. Records to be considered: temperature/pressure and time for each sterilizer load, bio logical indicators, volume of waste treated, and maintenance records of work done on the sterilizer to keep it operational.

3. Is there a log of temperature/pressure for each sterilizer run?

   (a) Does the log show that the minimum temperature/pressure is met for each load?

   Guide: Operational records must be maintained, such as the temperature charts. Recording or indicating thermometers shall be checked during each cycle to ensure the attainment of 121 degrees Centigrade (250 degrees Fahrenheit) for at least one half-hour, depending on the quantity and density of the load to achieve sterilization of the entire load. Records to be considered should include: temperature/pressure ;of each load, the temperature chart, quantity and density of the waste, the duration of each run and any unusual condition noted during each sterilizer run.

4. Are thermometers calibrated at least once a year?

   Guide: Recording or indicating thermometers shall be checked during each cycle to ensure the attainment of 121 degrees Centigrade (250 degrees Fahrenheit). Thermometers should be calibrated on a regular basis (at least once a year). Records of

the calibration checks should be maintained as part of the facility files and records for a period of three (3) years or as specified in regulation.

5. Are biological indicators used to verify sterilizer operation at least monthly?

   Guide: Spore testing to verify the proper and effective operation of the sterilizer must be done in compliance with the on-site permit issued by the local enforcement agency. Spore testing should be conducted at least monthly unless otherwise stated in the manufacturer's recommendations or the local enforcement agency. It is recommended that all records for medical waste treatment and handling be maintained for three (3) years in one location for ease of access and review.

6. Does each red bag or sharps container have a temperature strip that clearly indicates sterilization was effective? Are temperature strips verified?

   Guide: Section 118215 (c) (3) requires heat sensitive tape be used on each biohazardous bag or sharps container that is processed onsite to indicate the attainment of adequate sterilization.

B. If an incinerator is used, complete the following:

1. Are there written SOPs for unit(s)? Location of SOPs:

   Guide: Standard operating procedures (SOPs) are those protocols and procedures that are specific to the appropriate and safe use of your incinerator as required in the Medical Waste Management Plan for your facility. The SOPs should include the wearing of appropriate personal protective equipment (PPEs) and manufacturer's recommendations for appropriate and safe use.

2. Are appropriate operational records kept?

   Guide: Records must be established and kept for at least three (3) years. Records to be considered: preventative maintenance of the incinerator and related equipment including calibration checks, temperature logs, operator training and ash characterization.

3. Has the ash been characterized for disposal?

Date of last ash characterization:

Guide: All ash must be characterized prior to disposal. Consult with the Department of Health Services and/or your local enforcement authority.

4. Is there a current air quality permit?

Guide: All operating incinerators must be permitted by the regional air quality management district.

C. If microwave treatment is used complete the following:

1. Are there written SOPs for the unit(s)? Location of SOPs:

Guide: Standard operating procedures (SOPs) are those protocols and procedures that are specific to the appropriate use of the ABB Sanitec microwave unit, an approved alternative treatment technology. The SOPs should include the manufacturer's recommendations for safe operation of the microwave unit including appropriate personal protective equipment (PPE) that should be used.

2. Are appropriate operational records kept?

Guide: Operational records should be maintained. It is recommended that such records be kept for three (3) years.

3. Are appropriate spore tests run? Location of spore test records:

Guide: Spore testing to verify the proper and effective operation of the microwave unit must be done in compliance with the on-site permit issued by the local enforcement agency. Spore testing should be conducted at least monthly unless otherwise stated in the manufacturer's recommendations or the local enforcement agency. It is recommended that all records for medical waste treatment and handling be maintained for three (3) years in one location for ease of access and review.

4. Have HEPA filters been tested according to manufacturer's specifications? Location of HEPA filter test records:

Guide: High efficiency particulate air (HEPA) filters are used in the ABB Sanitec approved alternative technology microwave unit. The manufacturer is responsible for establishing an effective schedule

for testing and/or replacement of HEPA filters. The on-site treatment facility is responsible for carrying out the tests and/or replacement schedule. The testing of the HEPA filter should be conducted annually. It is recommended that all records for medical waste treatment and handling be maintained for three (3) years in one location for ease of access and review.

D. Are other alternative treatment technologies being used?

Guide: If yes, enter type of technology in comment section. Section 118215 (d) requires that technologies be approved by the California Department of Health Services.

1. Are there written SOPs for the unit(s)?

   Guide: Standard Operating Procedures (SOPs) are those protocols and procedures that are specific to the appropriate and safe use of your alternative treatment technology system and/or equipment. The SOPs should include the appropriate and safe handling of medical waste, recommendations for appropriate and safe use of the approved alternative treatment equipment.

2. Are appropriate operational records kept?

   Guide: Operational records should be maintained. It is recommended that such records be kept for at least three (3) years. Records to be considered should include: temperature/pressure of loads, biological indicators, post process solution make-up if sewering, volume of waste treated, and maintenance records of preventative maintenance on equipment, including calibrations.

3. Are appropriate spore tests run?

   Guide: Spore test and/or biological indicators are required to be run at least monthly unless otherwise stated in manufacturer's recommendations and the alternative treatment technology approval from the Department of Health Services. Manufacture and/or the Department of Health Services may require every load to be tested when alternative technologies are in use. Location of spore test records? It is recommended that all records for medical waste treatment and handling be maintained in one location for ease of access and review. Records must be maintained for at least three (3) years.

4. If applicable, have HEPA filters been tested per manufacture specifications?

Guide: If HEPA filters are in use they must be tested on an established schedule to ensure that they are still effective. The manufacture is responsible for establishing an effective schedule for testing and/or replacement of HEPA filters. The on-site treatment facility is responsible for carrying out the tests and/or replacement schedule.

Location of HEPA filter test records? It is recommended that all records for medical waste treatment and handling be maintained for three (3) years in one location for ease of access and review.

E. Are logs of equipment/treatment failures kept?

Guide: All failures of equipment/processing when treating medical waste must be documented. Action taken for appropriate handling and reprocessing of the medical waste or sending it for off-site treatment shall be documented so as to ensure processing compliance.

F. Are treatment records kept for at least three(3) years?

Guide: Section 118215 (c) requires that all records related to the treatment of medical waste by steam sterilization be maintained for at least three (3) years. It is recommended that records for other treatment technologies also be maintained for three (3) years.

G. Has staff been appropriately trained for the task performed?

Guide: The Health and Safety Code, Cal-OSHA, Federal Register on "Blood-Borne Pathogens" and JCAHO all require that appropriate training be performed with any person that is involved with medical waste handling and/or treatment.

Location of training records? Records must be maintained on any person that is involved in the handling and/or treatment of medical waste.

1. Are they using appropriate Personal Protective Equipment?

Guide: When a specific medical waste treatment process is implemented, the following references shall be used as a guide and appropriate personal protective equipment (PPEs) shall be identified:

- California Health and Safety Code

- Cal-OSHA
- Federal Register on Blood-Borne Pathogens
- JCAHO

H. Are maintenance records maintained for all equipment, including ancillary equipment such as grinders and compactors?

Guide: Preventive maintenance records must be maintained on all related equipment to document and assure that the medical waste treatment process is effective and is in compliance with local, state and federal requirements. Preventive maintenance records are vital to this assurance.

Location of maintenance records: It is a common practice that preventive maintenance records are monitored and maintained in the maintenance/plant operations department of most health care facilities. This is acceptable as long as all maintenance workers know where to access these records.

Part IV: Room/Area of Waste Generation

Objective: To identify points of generation of medical waste and to document that medical waste handling practices are in place.

A. Is medical waste separated and contained at generation?

Guide: Answer **yes** if medical waste is separated and containerized at this site; or **no** if it is not. If the answer is **no**, immediate action is necessary to implement a program to properly segregate and containerize the medical waste stream. If guidance is required, contact your local enforcement agency.

B. Are approved containers used for all sharps?

Guide: Answer **yes** or **no**. Answer **N/A** if no sharps are generated at this site. If the answer is **no**, immediate action is necessary to implement a program to properly containerize sharps. If guidance is required, contact your local enforcement agency.

1. Are they appropriately labeled/identified?
2. Are they secured to prevent removal/tampering?
3. Are they changed when at the manufacturer's designated fill line; or not more than 2/3 full?

Guide: Answer **yes** or **no**. If any of the answers are **no**, immediate action is necessary to implement a program to

properly handle sharps containers. If guidance is required, contact your local enforcement agency.

4. Is supply of sharps containers adequate?

Guide: Answer **yes** or **no**. An adequate supply of sharps containers should include enough to ensure a complete change-out when all containers are 2/3 full.

C. Are approved biohazardous waste containers used?

Guide: Answer **yes** or **no** for C and C-1 through C-3. If the answer is **no**, take immediate action to bring this item into compliance.

D. Have all staff been trained in medical waste management?

Guide: Answer **yes** or **no** and document where the training records are located for the various staff classifications (i.e., nurses, physicians, dietary, maintenance, housekeeping, etc.). If the answer is **no**, immediate action should be implemented to train staff needing medical waste management training.

1. Do staff use appropriate gloves, other PPE?

Guide: See the Glossary for the definition of PPE (personal protective equipment). Answer **yes** or **no**. The PPE used may vary with the staff functions being performed. Adequacy should be determined in complying with the Medical Waste Management Plan, Bloodborne Pathogen Policy, Injury and Illness Prevention Plan, and Airborne Management Plan for the facility. If the answer is **no**, take immediate action to ensure that proper PPE is used.

E. Are medical wastes transported to a dirty utility/storage area?

Guide: Answer **yes** or **no** and go to the appropriate section after completing Part IV. If the answer is **yes**, go to part V after completing Part VI; if the answer is **no**, go to part VI after completing Part IV.

Part V: Utility Room/Intermediate Storage

Objective: To identify existing practices in relation to intermediate storage of medical waste.

A. Is the utility room/area properly secured at all times and locked if necessary?

Guide: Answer **yes** or **no**. Intermediate storage areas are not required to be locked provided they are under direct supervision/surveillance. If the answer is **no**, immediate action should be taken to bring the security of the intermediate storage area into compliance.

1. Are secondary containers in the storage area clearly labeled with appropriate symbols on the sides so as to be visible from any lateral direction?

Guide: Answer **yes** or **no**. All secondary containers are required to be labeled on all sides and the lid. If the answer is no, take immediate action to properly label the non-compliant containers. Circular containers (barrels) will be considered to be adequately labeled if they contain at least two labels approximately opposite each other on the sides and there is a label on the lid.

2. Are secondary collection containers:
   (a) Impervious and easily cleaned?
   (b) Are these containers routinely cleaned/disinfected?
   (c) Type of disinfection used?
      i. If steam heat, is proper temperature attained?
      ii. If chemical, is concentration/contact time correct?
      iii. Are staff trained in proper disinfection techniques?
   (a) Lined with appropriate red bags?
   (b) Clearly labeled and visible from all sides and top?
   (c) Kept tightly closed at all times.

Guide: Answer **yes** or **no** to each of these questions. See Section 118295. Secondary collection containers should be cleaned each time they are emptied unless the surfaces have been protected from contamination by disposable liners, bags, or other devices that are removed with the waste. **The containers must be maintained in a clean and sanitary manner.** If the surfaces are dirty or contaminated they must be cleaned and decontaminated. Following washing, the containers can be decontaminated using any of the following procedures:

- Exposure to hot water of at least 180° F for a minimum of 15 seconds.
- Exposure to chemical sanitizer by rinsing with, or immersion in, one of the following for three minutes:
- Hypochlorite solution at 500 parts per million (ppm) of available chlorine.
- Phenolic solution at 500 ppm of the active agent.
- Iodoform solution at 100 ppm of available iodine.
- Quaternary ammonium solution at 400 ppm of the active agent.

3. Are storage times for medical waste appropriate?
   (a) How long are wastes stored in this area?

   Guide: Answer **yes** or **no** and indicate the length of time the medical waste is stored in that area. Section 118280 requires that a person generating 20 or more pounds of biohazardous waste per month shall not contain or store biohazardous or sharps waste on-site for more than seven days, unless the waste is frozen or written approval has been obtained from the enforcement agency. If a person generates less than 20 pounds of biohazardous waste per month, they may store it on-site for up to 30 days. Sharps containers must be managed so that when they are full (generally accepted practice is when they reach the manufacturer's full line or 2/3 full level of the container) their lids are taped closed or they are tightly lidded to prevent loss of contents, and they are ready for disposal. Sharps containers ready for disposal may be stored for seven (7) days unless written approval has been obtained from the enforcement agency. If the answer to this question is **no**, immediate action is necessary to implement a management system for biohazardous and sharps waste storage that complies with the required storage times. If guidance is required, contact your local enforcement agency.

4. Is an approved medical waste compactor used prior to treatment?

   Guide: Answer **yes** or **no**. If the answer is **no**, go to Part VI. If the answer is **yes**, answer the following questions.

   (a) Where is the compactor located?
   (b) Is there evidence of leakage?
   (c) Is the compactor clean and well maintained?
   (d) Is it labeled with a biohazard sign?
   (e) Is the HEPA filter tested?
   - Date of last test
   - Location of records

   Guide: Section 118320 (b) (2) allows the use of medical waste compactors that have been approved for use by the California Department of Health Services. Answer the questions as indicated. Questions (b) through (e) require an answer of **yes** or **no**. If (b) is answered **yes**, or if questions (c) through (e) are answered **no**, implement action to bring the use of the compactor into compliance. If guidance is required, contact your local enforcement agency.

Part VI: Pick-Up/Transport To Loading Dock For Removal/Treatment

Objective: To identify the practices used for the handling and transporting of medical waste prior to treatment and/or removal.

A. Are the carts used to transport medical waste:

1. Impervious and easily cleaned?
2. Are transportation carts routinely cleaned/disinfected?
3. Type of disinfection used?
   (a) If stream heat, is proper temperature attained?
   (b) If chemical, is concentration/contact time correct?
4. Clearly labeled with the appropriate symbol/wording on all sides?
5. Clean and in good repair (with wheels working, etc.)

Guide: Answer **yes** or **no** to these questions. If the answer to A. is **no**, you have completed the self-assessment tool. If the answer is **yes**, please complete the questions in Part VI. **Carts used to transport medical waste must be maintained in a clean and sanitary manner.** If the cart surfaces are dirty or contaminated they must be cleaned and decontaminated using one of the following procedures:

- Exposure to hot water of at least 180° F for a minimum of 15 seconds.
- Exposure to chemical sanitizer by rinsing with, or immersion in, one of the following for three minutes:
- Hypochlorite solution at 500 parts per million (ppm) of available chlorine.
- Phenolic solution at 500 ppm of the active agent.
- Iodoform solution at 100 ppm of available iodine.
- Quaternary ammonium solution at 400 ppm of the active agent.

The carts must be clearly labeled with the biohazard symbol and the words "Biohazardous Waste" on all sides. The cart must be maintained in good working order.

If inadequate steam heat or chemical disinfection levels are not achieved in the cart disinfection process, implement steps to reach these required levels. If guidance is required, contact your local enforcement agency.

B. Are other materials on the carts (boxes, waste papers, etc.) adequately segregated from medical wastes?

Guide: Answer **yes** or **no**. When medical waste is transported within the health care facility it should be done so as not to create a hazard to the patients, general public and staff. It is recognized that a variety of transport mechanisms may be used, precautions must be taken to ensure that the medical waste is segregated

and will not pose a problem to patients, the general public and staff. Other materials(such as waste newspapers) may be transported on the carts as long as they are segregated from the medical wastes. Some health care facilities find it beneficial to use a lidded cart and pile waste newspapers or cardboard boxes on them while transporting the medial wastes to the loading dock or storage facility. Care must be taken to ensure that these waste streams are segregated, because if the paper wastes are co-mingled with the medical wastes, they must be treated as a medical waste and this adds unnecessarily to the cost of waste disposal.

C. Are the staff that load, transport and unload the carts:

1. Properly trained?
2. Using approved PPE?

Guide: Answer **yes** or **no**. See Glossary for the term PPE (personal protective equipment). The PPE used may vary with the staff functions being performed. Adequacy should be determined in complying with the Medical Waste Management Plan, Bloodborne Pathogen Policy, Injury and Illness Prevention Plan, and Airborne Management Plan for the facility. If the answer is **no**, take immediate action to ensure that proper PPE is used.

SELF-ASSESSMENT TOOL

INSTITUTION: _____

ADDRESS/LOCATION WHERE SELF-ASSESSMENT CONDUCTED:

_____

UNIT: _____

DATE OF ASSESSMENT: _____

ASSESSMENT _____ **of** _____ **ASSESSMENT/yr**

SIGNATURE OF ASSESSOR: _____

SIGNATURE OF ADMINISTRATOR: _____

Review Checklist	*Yes*	*No*	*N/A*	*Comments/Justification*
Part I: Waste Management Summary				
A. Does the facility handle the following:				
1. Biohazardous waste?				
(a) Are biohazardous wastes treated on-site?				
(b) If yes, state type of treatment:_____				
2. Liquid waste?				
(a) Are liquid wastes treated before disposal?				
(b) If yes, state type of treatment: _____				
3. Pathology waste?				
(a) Is the excess fixative decanted?				
(b) Treated on-site?				
(i) If yes, in an approved incinerator? Give permit #_____				
4. Trace chemotherapeutic waste?				
(a) Treated on-site?				
(i) If yes, in an approved incinerator? Give permit #_____				
(b) Sent off-site for treatment?				
5. Out-dated pharmaceutical waste?				
(a) Treated on-site by incineration?				
(i) Is an approved incinerator used? Give permit #_____				
(ii) By an approved alternative treatment? State technology used:_____				
6. Does the total amount of medical wastes produced above equal or exceed 200 pounds per month?				
(a) If yes, give large quantity generator reg. #:_____ If no, give the small quantity generator #_____				
B. Does the facility have a current Medical Waste Management Plan (Plan)?				
1. Date the Plan was last reviewed? _____				
2. Where is the Plan located? _____				
C. Does the facility have a voluntary sharps return program?				
1. If yes, does your Plan include the voluntary return program?				
2. Where are the sharps returned? State location:_____				

Review Checklist	*Yes*	*No*	*N/A*	*Comments/Justification*
D. Does the facility receive home-generated sharps waste?				
1. If yes, does the Plan reflect the receipt of home-generated sharps?				
2. Where are they received? _____				
E. Does the facility receive any medical wastes from other sources?				
1. Private physician or dentist offices more than 400 yards from facility?				
2. Ambulances or air ambulances?				
3. Other sources? Describe: _____				
F. Does the facility have a source reduction plan?				
1. If yes, are records kept on amount of waste reduced?				
2. If yes, where are records maintained? _____				
G. Does the facility have a recycling program?				
1. If yes, are records kept on amount of waste recycled?				
2. If yes, where are records maintained? _____				
H. Does the facility track the amount of waste generated?				
1. If yes, where are records maintained? _____				
Part II: Consolidation and Transport				
A. Does the facility have satellite facilities more than 400 yards away generating medical waste? *If "no," go to B. If "yes," give reg. #*_____				
1. Do these satellite facilities transfer medical waste to the main facility?				
(a) If yes, does the facility have a LQHE?				
2. Does the facility use its own vehicles to transport medical waste >400 yards from its premises?				
(a) If yes, list the hauler # _____				
3. Does the main facility receive medical waste from off-site and treat it at the facility?				
(a) If yes, go to A. 4, below.				
(b) If no, list name of company hauling waste and go to B.				
4. Does the main facility treating satellite waste have an off-site treatment permit?				
(a) If yes, give Off-site Permit # _____				
B. Does the facility treat its medical waste on-site?				
1. If yes, list on-site treatment permit # and go to Part III.				
2. If no, list name/# of hauler and go to C. _____				
C. Are appropriate shipping/tracking documents issued and signed for each load removed?				
D. Are documents from tracking/off-site treatment kept?				
E. Are they saved for at least 3 years? Location of shipping/tracking and treatment documents: _____				
F. Is the storage area for medical waste prior to transport off-site:				
1. Properly secured to keep unauthorized people out?				
2. Equipped with warning signs in appropriate languages?				

Review Checklist	*Yes*	*No*	*N/A*	*Comments/Justification*
3. Posted with signs legible during daylight from 25 ft. away?				
4. Protected from animals and elements; not a breeding place or food source for insects/rodents?				
G. Are emergency spill procedures kept/posted at the pick-up dock?				
1. Is the spill procedure consistent with the Medical Waste Management Plan?				
2. Is there a posted list of emergency numbers?				
3. Is this list current? (last updated on ___/_____/____)				
Part III: Treatment/Sterilization Of Medical Wastes				
A. If autoclave(s) are used, complete the following:				
1. Are there written Standard Operating Procedures (SOP) for the unit(s)? Location of SOPs: _____				
2. Are appropriate operational records kept?				
3. Is there log of temp/pressure for each sterilizer run?				
(a) Does the log show that minimum temp/pressure are met for each load?				
4. Are thermometers calibrated at least once a year?				
5. Are biological indicators used to verify sterilizer operation at least monthly? Name of indicator used: _____ Location of records for 1 - 5 above: _____				
6. Does each red bag or sharps container have a temperature strip that clearly indicates sterilization was effective?				
(a) Are temperature strips verified?				
B. If an incinerator is used, complete the following:				
1. Are there written SOPs for the unit(s)? Location of the SOPs:_____				
2. Are appropriate operational records kept?				
3. Has the ash been characterized for disposal? Date ash last characterized: _____				
4. Is there a current air quality permit?				
C. If microwave treatment is used complete the following:				
1. Are there written SOPs for the unit(s)? Location of the SOPs:_____				
2. Are appropriate operational records kept?				
3. Are appropriate spore tests run? Location of spore test records:_____				
4. Have HEPA filters been tested per manufacturer's specifications? Location of HEPA filter test records: _____				
D. Are other alternative treatment technologies being used?				
1. Are there written SOPs for the unit(s)? Location of the SOPs:_____				
2. Are appropriate operational records kept?				
3. Are appropriate spore tests run? Location of spore test records:_____				
4. If applicable, have HEPA filters been tested per manufacturer's specifications? Location of HEPA filter test records: _____				
E. Are logs of equipment/treatment failures kept?				

Review Checklist	*Yes*	*No*	*N/A*	*Comments/Justification*
F. Are treatment records kept for at least 3 years?				
G. Has staff been appropriately trained for the tasks performed? Location of training records: _____				
1. Are they using appropriate PPEs? (gloves, coveralls, eye protection, etc.)				
H. Are maintenance records maintained for all equipment, including ancillary equipment such as grinders and compactor? Location of maintenance records: _____				
Part IV: Room/Area Of Waste Generation				
A. Is medical waste separated and contained at generation?				
B. Are approved containers used for all sharps?				
1. Are they appropriately labeled/identified?				
2. Are they secured to prevent removal/tampering?				
3. Are they changed when not more than 2/3 full?				
4. Is supply of sharps containers adequate?				
C. Are approved biohazardous waste containers used?				
1. Are they appropriately labeled/identified?				
2. Are containers lined with appropriate red bags?				
3. Are bags properly sealed/twist-tied to prevent spills?				
D. Have all staff been trained in medical waste management? Location of records: _____				
1. Do staff use appropriate gloves, other PPE?				
E. Are medical wastes transported to a dirty utility/storage area? *If "yes," go to Part V.* *If "no," go to Part VI.*				
(b) Are these containers routinely cleaned/disinfected?				
(c) Type of disinfection used?				
i. If steam heat, is proper temperature attained?				
ii. If chemical, is concentration/contact time correct?				
iii. Are staff trained in proper disinfection techniques?				
(d) Lined with appropriate red bags?				
(e) Clearly labeled and visible from all sides and top?				
(f) Kept tightly closed at all times?				
3. Are storage times for medical waste appropriate?				
(a) How are long wastes stored in this area?				
4. Is an approved medical waste compactor used prior to treatment?				
(a) Where is the compactor located? _____				
Part V: Utility Room/Intermediate Storage				
A. Is the utility room/area properly secured at all times and locked if necessary?				

Review Checklist	*Yes*	*No*	*N/A*	*Comments/Justification*
1. Are the secondary containers in the storage area clearly labeled with appropriate symbol on all sides?				
2. Are secondary collection containers:				
(a) Impervious and easily cleaned?				
(b) Is there evidence of leakage?				
(c) Is the compactor clean and well maintained?				
(d) Is it labeled with a biohazard sign?				
(e) Is the HEPA filter tested? Date of last test: _____ Location of records: _____				
Part VI: Pick-Up/Transport To Loading Dock for Removal/Treatment				
A. Are the carts used to transport medical wastes:				
1. Impervious and easily cleaned?				
2. Are transportation carts routinely cleaned/disinfected?				
3. Type of disinfection used?				
(a) If steam heat, is proper temperature attained?				
(b) If chemical, is concentration/contact time correct?				
4. Clearly labeled with the appropriate symbol/wording on all sides?				
5. Clean and in good repair (with wheels working, etc.)?				
B. Are other materials on the carts (boxes, waste papers, etc.) adequately segregated from medical wastes?				
C. Are the staff that load, transport and unload the carts:				
1. Properly trained? Location of training records: _____				
2. Using approved Personal Protective Equipment?				

APPENDICES

Appendix A:

Preventing the Most Frequently Found Medical Waste Violations

Appendix B:

Glossary

Appendix A

Preventing the Most Frequently Found Medical Waste Violations

This chapter identifies and describes the most frequently found violations of the law by inspectors from EMB's Medical Waste Management Program and actions that can be taken to prevent these conditions, or to correct them should they occur. The violations are listed for both large and small quantity generators of medical waste. Large quantity generators are defined in the Medical Waste Management Act (϶117680)[11] as: *....a medical waste generator that generates 200 or more pounds of medical waste in any month of a 12-month period.* A small quantity generator is defined in ϶117760 as: *….a medical waste generator that generates less than 200 pounds per month of medical waste.* The most frequently found violations of the Medical waste Management Act are categorized and listed as follows:

Most Frequently Found Violations For Large Quantity Generators

1. ϶117960: Failure to file with the local enforcement agency a complete and accurate Medical Waste Management Plan.

Comments: Medical Waste Management Plans describe how the various types of medical waste that are generated within a facility are to be handled, stored, and treated. If untreated medical waste is removed from the facility for off-site treatment, the plan must include the name and address of the registered hazardous waste hauler that transports the waste off-site for treatment. The name of the off-site treatment facility where the medical waste is transported for treatment must also be provided if applicable. The information contained in the plan must be complete and accurate.

Corrective Action: It is the facility's responsibility to develop and maintain an accurate, up-to-date Medical Waste Management Plan. It is EMB's policy to work with the generator to develop or update the plan as needed. Chapter 4 of this manual contains the pertinent information necessary to develop and maintain a workable Medical Waste Management Plan.

2. ϶118280: Failure to properly containerize biohazard bags.

Comments: This violation most frequently is found in facilities that use a hamper-type support for biohazard bags, or where such bags are placed directly on the floor. Red biohazard bags are to be placed for storage, handling, or transport in rigid containers that are leak-resistant, have tight-fitting covers, and are kept clean and in good repair. Red biohazard bags used with hamper holders have been found to be effective in some surgery room settings where people are not likely to come in direct contact with the bag or its

[11] All sections (϶) cited in this document refer to the California Health and Safety Code, unless otherwise indicated.

contents. Use of biohazard bags and hampers in patient rooms has the potential to bring visitors or staff in contact with the bag or its contents and is not considered to be approved storage and containerization of the bags. Biohazard bags must be containerized for storage and not stored directly on the floor or other surface.

Corrective Action: Use biohazard bags with hampers only in surgery rooms where public and staff access is strictly controlled. Biohazard bags in all other areas should be kept in rigid containers that are leak resistant, clean, in good repair, and covered with a tight fitting lid. Biohazard bags must not be stored directly on the floor; but must be placed in rigid containers.

3. **Э117635 (f): Improper management of biohazardous waste that is comprised of human surgery specimens or tissues which have been fixed in formaldehyde or other fixatives or waste that is contaminated through contact with, or having previously contained, trace amounts of chemotherapeutic agents.**

Comments: The most common violative conditions found within this category involve the pathology and trace chemotherapeutic waste stream not being segregated from the rest of the biohazardous wastes to ensure that these wastes are incinerated. Additionally, free liquid of fixatives or chemotherapeutic agents can not be considered as a part of this waste stream.

Corrective Action: Segregate all pathology and trace chemotherapeutic wastes at the point of generation and place in secondary containers that are properly labeled so that these wastes will be sent for incineration. Biohazardous waste that is contaminated through contact with, or having previously contained chemotherapeutic agents, must be segregated for storage and placed in a secondary container that is labeled “Chemotherapy Waste,” “CHEMO,” or other labeling as approved by the Department. The labeling shall be provided on the lid and on the sides and be visible from any lateral direction. Similarly, human surgery specimens or tissues which have been fixed with formaldehyde or other fixatives, shall be segregated for storage after the free liquid fixative has been removed and, when placed in a secondary container, that container shall be labeled on the lid and sides with the words “Pathology Waste,” “Path,” or other labeling approved by the Department.

4. **Э118275 (b): Not using red biohazard bags to containerize and store medical waste.**

Comments: The most frequently found violation of this type was using orange bags instead of red bags to containerize biohazardous waste. Another violative condition is created when biohazardous waste is not handled properly at the point of generation and is mistakenly placed in the solid waste stream in solid waste containers.

Corrective Action: Biohazardous waste must be placed in red biohazard bags conspicuously labeled with the words “Biohazardous Waste” or the international biohazard symbol and the word “BIOHAZARD.” The Department has approved a special dissolvable red colored bag for use with the OREX® processor. The OREX® process treats biohazardous waste such as gowns, drapes, and sponges made of polyvinyl alcohol that dissolve when treated in the processor in a wash at 190E F.

5. **Ə118310: The enclosure for the storage of medical waste containers is not secured and does not have warning signs.**

Comments: This violation is found where the external storage areas are not adequately secured to prevent unauthorized individuals from gaining access to medical waste containers being stored prior to being processed at the facility or being hauled to an off-site treatment facility for processing. When the price of commodities increase there is generally a corresponding rise in the number of instances of people going through waste storage areas to collect recyclable materials. In the process of going through the waste, the individuals have no regard to the health impacts their actions may create to themselves and the community as a whole. Materials thrown out of a storage area may be transported to other parts of the community where they may have a negative impact by being traced back to the facility. Some individuals seek unauthorized access to the storage area in search of needles and syringes.

Corrective Action: Generators should evaluate their exterior medical waste storage areas in an effort to ensure that these areas are protected against unauthorized entry. In some cases the generator may be required to redesign the area to offer improved protection against unauthorized access including the use of locks on receptacle lids, gates, or entry doors. The enclosure must also provide that the medical waste be protected against animals and the natural elements. Additionally, the storage area must not become a breeding area or food source for insects and rodents. The storage area must have adequate warning signs posted in English, Spanish and other languages deemed to be appropriate by the infection control staff or local enforcement agency. The signs shall be readily legible during daylight hours at a distance of 25 feet.

6. **Ə118215 (c) (1-5): Steam sterilization for on-site medical waste treatment is not being conducted according to the requirements of the law.**

Comments: This violation is found where large quantity generators with on-site treatment are using autoclave technology but their process is found to be lacking standard written operating procedures, recording or indicating thermometers, use of heat sensitive tape and the keeping of required records.

Corrective Action: The Medical Waste Management Plan for the facility should be reviewed to determine if it contains the proper procedures to follow for the autoclave process. If the Medical Waste Management Plan is found to be deficient in this area it should be amended to include the proper practices to follow throughout the autoclaving process. The plan must include proper operating procedures and a description of how the process is audited to ensure adequate treatment takes place. Operational records of the treatment process specified in the plan must be maintained at the facility for a period of three years.

7. **Ə117730: The medical waste stream contains either hazardous or radiologic waste and therefore constitutes a mixed waste that can not be handled under the provisions of the Medical Waste Management Act.**

Comments: The Medical Waste Management Act provides for the handling and treatment of medical waste. When the medical waste stream is found to contain radioactive and/or

hazardous waste in addition to medical waste, the entire waste stream is elevated to the higher waste stream category. Medical waste that contains hazardous waste must be treated as a hazardous waste. Medical waste that contains radioactive material must be treated as a radioactive waste. When medical waste additionally contains both hazardous and radioactive waste, it must be treated as a radioactive waste. The options for treating hazardous and radioactive wastes are fewer than treating the medical waste stream. There are more regulatory requirements and increased costs for handling, treating and disposing of the hazardous and radioactive wastes when compared to the medical waste stream.

All of the medical waste off-site treatment facilities are required to monitor medical wastes for radioactivity. Their radioactive detection equipment is set to alarm at three (3) times background levels for radiation. They are required to report to EMB all wastes that alarm at 1,000 micro R per hour or equivalent. The off-site treatment facilities are allowed to set aside for a 48-hour decay period all wastes that are no higher than this level. Wastes that exceed the 1,000 micro R per hour level are immediately set aside in a secured area and the radiation safety officer at the generator's facility and a health physicist from the Department of Health Services' Radiologic Health Branch are notified and draft a plan for handling the radioactive material.

Corrective Action: Care must be taken not to create a mixed waste stream. The medical waste stream must be segregated at the point of generation and red bagged so that it can be readily identified. No matter how much care is taken, some trace amounts of radioactive materials may reach the medical waste stream. This is most frequently caused by diapers being placed in the medical waste stream from incontinent individuals that have received a diagnostic procedure or treatment using a radioactive material. The residual amount of radiation that may be found in these diapers is small and decays quickly. To protect against radioactive wastes becoming a problem for the medical waste stream, it is common practice for large quantity generators to have a radiation detection screening device at their facility to ensure their loads of medical waste do not contain radioactive materials. This is a good strategy as it prevents violations of the Medical Waste Management Act and violations of the radioactive materials license issued to the facility.

8. Э118295 (a): The hot water used to sanitize reusable rigid containers for medical waste is not of sufficient temperature (180°F) to achieve disinfection.

Comments: Reusable containers used for medical waste must periodically be washed and decontaminated by a method approved by the local enforcement agency. One of the approved methods is washing the containers and decontaminating them by exposing them to hot water of at least 180 F. Frequently, the water used to disinfect the reusable containers has not been of sufficient temperature resulting in a violation of the Medical Waste Management Act.

Corrective Action: The temperature of the sanitizing water used to disinfect reusable containers must reach 180° F for a minimum of 15 seconds. The water heater or booster unit may need to be adjusted to ensure that this temperature is reached. An alternative to using a hot water sanitizing process, is to use chemical disinfection. Exposure to a chemical sanitizer rinse or immersion in one of the following chemical solutions for three minutes is allowed:

A. Hypochlorite solution of 500 parts per million (ppm) available chlorine.
B. Phenolic solution of 500 ppm active ingredient.
C. Iodoform solution of 100 ppm available iodine.
D. Quaternary ammonium solution of 400 ppm active agent.

9. Э118300: Lack of adequate decontamination procedures for any leak or spill of medical waste.

Comments: Every generator of medical waste must be prepared to handle a medical waste spill at their facility in order to protect the health of their clients, workers, and the community. Precious time can be saved and the spill minimized if a plan is in place at the facility and staff are sufficiently trained in its execution so that it can quickly be put into effect.

Corrective Action: Medical waste spill containment and decontamination procedures must be made a part of the Medical Waste Management Plan and Emergency Action Plan for the facility. Staff should be made familiar with these plans and periodic discussions and/or exercises regarding implementation serve as beneficial proactive prevention measures.

10. Э117995: The medical waste generator failed to register and pay fees.

Comments: Many large quantity generators of medical waste failed to register and pay the required fees to EMB where it serves as the local enforcement agency. This violation was more common during the first few years following passage of the Medical Waste Management Act and its new requirements for registration and fee payments. The Legislature made it clear in passing the Act that the Medical Waste Management Program would be totally fee supported and this directive has been carried out. The self-assessment project is an attempt to reduce the reliance on government to be totally responsible for bringing about correct handling of medical waste through a typical “command and control” strategy. Instead, a partnership between the regulated community and government has been developed using the self-assessment tool and this manual as the cornerstones of an educational and consultative strategy for program implementation. The self-assessment concept places responsibility for proper medical waste management with the generator where it can be most effectively implemented on a day-to-day basis. This hopefully will reduce the need for annual, or more frequent, inspections from the regulatory community and result in reduced fees to the generators.

Corrective Action: Large quantity generators of medical waste must register and pay the required fees as outlined in the Medical Waste Management Act. These generators may want to take advantage of lowered fees and improved medical waste handling practices by joining the self-assessment process once it is made available.

Most Frequently Found Violations For Small Quantity Generators

Many of the violations that were discovered at large quantity generators were also found at small quantity generators. Small quantity generators of medical waste should review the list of violations found at large quantity generators to ensure they are not making similar mistakes in their waste handling practices. Additionally, the following violative conditions were often found at small quantity generators of medical waste and particular attention should be paid to these types of conditions in order to avoid creating violations of the Medical Waste Management Act.

1. **Э118285: Sharps waste not being placed into a sharps container or being improperly containerized and/or labeled.**

   Comments: EMB has received numerous complaints from the public, city and county solid waste management departments, law enforcement officers, and other agencies regarding improper disposal of needles and syringes. Most often these complaints focus on disposal of needles and syringes into solid waste containers by medical, dental and other health practitioners. As more communities recycle their solid waste stream, in an effort to meet 50 percent reduction levels by the year 2000 for solid wastes going to landfills, more attention is being focused on disposal of sharps waste. An increasing number of communities are using materials recovery facilities (MRFs) to sort their solid waste stream and hand sorting of these wastes often leads to needle-stick injuries to the workers. Although some of these needle-stick injuries result from unregulated home-generated sharps wastes being placed into the solid waste stream, all generators of needles and syringes must use diligence in the way they handle their sharps waste.

   Corrective Action: Used needles and syringes must be placed in sharps containers that are properly labeled with the words "sharps waste" or with the international biohazard symbol and the word "BIOHAZARD." When full, sharps containers must be taped closed or tightly lidded to prevent loss of contents. Sharps containers ready for disposal can not be stored for more than seven days without permission from the enforcement agency. The storage time for full sharps containers can be controlled through proper management of the timing when sharps containers become full. Several sharps containers can be made to become full at similar times so that they can all be picked up for disposal at an off-site treatment facility at the same time. There are several other possible methods for handling sharps waste. Several sharps mail-back systems have been approved for use within California. A sharps treatment system (Isolyser® Sharps Management System) for use on-site has been approved as an alternative treatment technology that allows these special sharps containers to be disposed of in the solid waste stream once solidified.

2. **Э117945: Failure of small quantity generators, that are not required to register under the Medical Waste Management Act because they do not treat medical waste on-site, to maintain an information document and tracking documents.**

   Comments: All small quantity generators of medical waste that do not treat the waste on-site are required to have an information document at their facility that explains how they handle the medical waste they generate. Additionally, they are required to keep medical waste tracking documents for a period of two years.

Corrective Action: Small quantity generators that do not treat their medical waste on-site must develop and maintain an information document in their files that indicates how the generator contains, stores, treats, and disposes of their medical waste. Records of medical waste transported off-site for treatment must be maintained. These transportation records can be in the form of tracking documents and must show the quantity of waste transported off-site, the date transported, and the name of the registered hazardous waste hauler or individual hauling the waste under provision of a limited quantity hauling exemption. These records must be kept for two years.

Armed with information as to the most frequently found violations of the Medical Waste Management Act, health care facilities should review their Medical Waste Management Plan and current operating procedures used to handle medical waste to ensure that they do not repeat the mistakes made by others. Correction of violative conditions found through the self-assessment process could save the facility from being a candidate for formal enforcement action and public embarrassment at a later date.

APPENDIX B

Glossary

Biohazardous waste: See Section 117635 of the Medical Waste Management Act.

Biological indicators: Organisms which, by virtue of their failure to grow—or other such observable phenomenon—provide objective proof of the efficacy of a treatment system.

Bloodborne Pathogen Standard: Title 8, California Code of Regulations General Industry Safety Order 5193. Defines employer responsibilities for the assurance of the health and safety of employees in matters of potential exposure to blood and bodily fluids; presumes those fluids to contain HIV, HBV, or other infectious agents.

Body Substance Isolation (BSI): Often used synonymously with Universal Precautions (q.v.). However, whereas Universal Precautions refers to a limited set of body fluids, BSI applies to all body fluids. Thus, in managing medical wastes, this standard would result in the potential capture as medical waste of a larger segment of the total waste stream.

Containerized: Placed in a container. Containerization of medical waste, of biohazard bags, or of sharps waste, is subject to specific requirements found, respectively, in Sections 118275, 118280, and 118285 of the Medical Waste Management Act.

Decanted: (A liquid) carefully separated from any denser solids contained therein by pouring, so as to minimize the residual liquid remaining. Trace chemotherapeutic.

Exposure Control Plan: 8 CCR 5193 (c)(1) A plan set forth in the Bloodborne Pathogen Standard to eliminate or minimize the potential occupational exposure of each employee to bloodborne pathogens. It consists at a minimum of an exposure determination (by tasks and job classification), procedures for implementing required elements of the Standard, and exposure incident evaluation protocols.

HBV: Hepatitis B Virus The causative agent of type B hepatitis.

HEPA filters (high efficiency particulate air): Air filters which will capture virtually 100% of respirable particles in air (10 micrometers and less) down to roughly 10^{-2} micrometers in size. Used to maintain biological isolation of negative pressure chambers in which aerosolized biohazardous agents may be produced.

HIV: Human Immunodeficiency Virus. The causative agent of acquired immunodeficiency syndrome (AIDS).

Large quantity generator: A producer of 200 or more pounds of medical waste per month. (See Section 117680 of the Medical Waste Management Act.)

Limited Quantity Hauling Exemption: An exemption, issued to a generator of less than 20 pounds of medical waste per week (or their employer), from the general requirement that all haulers of medical waste must be registered as hazardous waste haulers with DTSC.

Liquid or semi-liquid wastes: Wastes in a liquid physical state, or containing solid matter carried in sufficient liquid to allow it to flow as a liquid.

Main facility: A healthcare organization's principal location for the administration of health care.

Medical Waste Management Plan: A plan developed by a medical waste generator communicating to the enforcement agency specific handling, storage, treatment and disposal practices which the generator will employ in compliance with the law. (See Sections 117935 and 117960 of the Medical Waste Management Act).

Medical Waste: See Section 117690 of the Medical Waste Management Act.

Off-site medical waste treatment facility: A medical waste treatment facility is not a generator of medical waste, or which accepts waste from other any other generators which are greater than 400 yards away **and** which are not physicians or surgeons on staff of the facility treating the waste.

On-site Medical Waste Treatment Facility: A facility which treats only medical waste produced at the health-care facility which houses it, or which is generated 400 yards or less away or by physicians and surgeons who are on staff of the facility and are small quantity generators. (See Sections 118140 and 118415 of the Medical Waste Management Act.)

Pathology waste: Medical wastes which are either recognizable anatomical parts, or which are human tissue specimens containing residual fixative. Pathology waste must be treated by incineration. (See Sections 118220 and 118222 of the Medical Waste Management Act.)

Personal Protective Equipment (PPE): Barrier protection such as gloves, suits, eye/face-protection. It must be sufficient to prevent blood or OPIM from reaching skin, eyes, mouth or other mucous membranes under normal conditions of use.

Pharmaceutical waste: See Section 117747 of the Medical Waste Management Act.

Satellite facility: A health care facility operating as a part of a main facility, but at a location other than the main facility. For purposes of medical waste management, a satellite facility is offsite if it is more than 400 yards from the main facility.

Sharps containers: Means a rigid puncture –resistant container that when sealed, is leak resistant and cannot be reopened without great difficulty. See Section 117750 of the Medical Waste Management Act.

Sharps: See Section 117755 of the Medical Waste Management Act.

Small quantity generator: A producer of less than 200 pounds of medical waste per month. (See Section 117760 of the Medical Waste Management Act.)

Spore test: A microbiological test whereby spores of a test organism are exposed to treatment conditions, thereafter incubated to encourage germination and growth of vegetative organisms. If there is no growth, the treatment was successful.

Standard operating procedures: Written minimum operating parameters for the operation of a steam sterilizer. Operating records confirming adherence to these and related procedures must be maintained for a minimum of three years. (See Section 118215 (c)(1) of the Medical Waste Management Act.)

Storage area: A designated accumulation area, or offsite point of consolidation, or transfer station, or other registered facility, for the holding of medical waste, in accordance with the requirements of Chapter 9. (See Section 117765 of the Medical Waste Management Act.)

Universal Precautions: The application of exposure protection to all potential exposure situations, based on the presumption that any of a specified set of human bodily fluids (blood and blood products, and body fluids listed as "Other Potential Infectious Materials" in the Bloodborne Pathogen Standard) which may be present has come from an infected individual. (First promulgated by Centers for Disease Control in August 1987 [MMWR 1987; 36 (Suppl no. 2S)] and June, 1988 [MMWR 1988; 37: 377-383].)

[1] Council on California Competitiveness, *California's Jobs and Future,* April 23, 1992, page 3.

[2] Ibid., pp. 6-7.

[3] Taken from the notes of the January 8, 1996 meeting of the *Medical Waste Self-Assessment Project,* January 23, 1996.

[4] Hsiao, Peter, "Prize Policies - Evaluating Environmental Amnesty Programs," *Los Angeles Daily Journal,* January 26, 1996.

[5] Deming, W. Edwards, *The New Economics For Industry, Government, Education,* Massachusetts Institute of Technology, 1993, page 98.

[6] Dean, James W., Jr. and James R. Evans. *Total Quality Management, Organization, and Strategy,* West Publishing Company, 1994, page 260.

[7] Sources: *Bloodborne Pathogens Guide to Compliance.* CAL/OSHA Consultation Services: 1993.

[8] Title 8, *California Code of Regulations,* Section 5193(b).

[9] ibid.

[10] Section 3203, Title 8, *California Code of Regulations.*

[11] All sections (ɜ) cited in this document reference the California Health and Safety Code unless otherwise indicated.