MANAGEMENT AND DISPOSAL OF INFECTIOUS WASTE
RFP No. EO1873-13

ATTACHMENT N

DEPARTMENT OF HEALTH

Repeal of Chapter 11-104, "Management and Disposal of Infectious Waste"
and the
Adoption of Chapter 11-104.1, "Management and Disposal of Infectious Waste",
Hawaii Administrative Rules

Summary

1. Chapter 11-104, Hawaii Administrative Rules, entitled "Management and Disposal of Infectious Waste", is repealed.

2. Chapter 11-104.1, Hawaii Administrative Rules, entitled "Management and Disposal of Infectious Waste", is adopted.

7 JUL -9 A8:58

DEPT OF HEALTH

TITLE 11

DEPARTMENT OF HEALTH

CHAPTER 104

MANAGEMENT AND DISPOSAL OF INFECTIOUS WASTE

Repealed

§§11-104.1 to 11-104.12 Repealed. [JUL 12 2007]

HAWAII ADMINISTRATIVE RULES

TITLE 11

DEPARTMENT OF HEALTH

CHAPTER 104.1

MANAGEMENT AND DISPOSAL OF INFECTIOUS WASTE

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SUBCHAPTER 1

GENERAL PROVISIONS

§11-104.1-1 Purpose. The purposes of these rules, which shall be known as the Hawaii Rules for Management and Disposal of Infectious Waste, are to:

(1) Implement section 321-21, Hawaii Revised Statutes ("HRS"); and

(2) Establish minimum requirements for the management, treatment, transport, storage and disposal of infectious waste and treated infectious waste in order to ensure practices that will protect the health and safety of persons living in Hawaii. These rules are not intended and shall not be construed to lower the standards and requirements found in ordinances, codes, or rules established by the department or other government agencies. In all instances, the

more stringent rules shall apply.
[Eff JUL 12 2007] (Auth: HRS §§321-11, 321-20, 321-21) (Imp: HRS §§321-11, 321-21, 321-20)

§11-104.1-2 Definitions. As used in this chapter:

"Animal waste" means materials including carcasses, body parts, body fluids, blood, or bedding originating from:

(1) Animals known to be contaminated with infectious zoonotic organisms; or

(2) Animals inoculated during research.

"Authorized disposal site" means the location, other than the site of generation, where final treatment, processing, or the deposit of solid waste occurs as permitted in accordance with chapter 11-58.1 Solid Waste Management Control regulations.

"Autoclaving" means rendering sterile by exposing to steam at prescribed temperatures under prescribed pressure for appropriate time periods using Bacillus spp. spore kill time as a guide in accordance with current Clinical Laboratory Standards Institute waste management guidelines.

"Blood, blood products, and other body fluids" means all waste blood and blood products such as serum, plasma, and other blood components, and all body fluids. It includes items saturated or dripping with blood or with body fluids and those caked with dried blood or with dried body fluids.

"Body fluids" means semen, vaginal secretions, cerebrospinal, synovial, pleural, peritoneal, and amniotic fluid. It does not mean nasal secretions, sputum, tears, urine, and vomitus unless they contain visible blood.

"CDC" means Centers for Disease Control and Prevention, United States Department of Health and Human Services.

"CLSI" means Clinical Laboratory Standards Institute.

"Community" means a group of people living in the same locality under the same government.

"Contaminated sharps" means all sharp items, including but not limited to hypodermic needles, syringes, Pasteur pipettes, scalpel blades, lancets, capillary tubes, slides, and broken glass which have been used in the diagnosis, treatment or immunization of human beings or animals in research pertaining thereto, or in the production, use or testing of biologicals.

"Cultures and stocks of infectious agents" includes cultures and stocks of infectious agents from medical, clinical, and pathological laboratories, research and industrial laboratories, as well as wastes from the production of biologicals, discarded live and attenuated vaccines, culture dishes and devices used to transfer, inoculate, or mix cultures, and glassware which has contained infectious agents.

"Department" means the department of health, State of Hawaii.

"Disinfect" means to render inactive virtually all recognizable pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial endospores).

"Embalm" means to inject arterially or into a cavity a fluid or other agent of sufficient strength and quantity to accomplish a thorough disinfection and preservation of a dead human body.

"EPA" means the United States Environmental Protection Agency.

"Facility" means a building within which infectious waste is generated.

"Foreign bodies" means objects or articles introduced into the human body that require removal in a health care setting (i.e., toys, coins, metal, plastic, etc.).

"Generator" means any person who, or entity that, produces, or causes to be produced, infectious waste including, but not limited to, hospitals, clinics, laboratories, health care facilities, physicians, dentists, veterinarians, and podiatrists.

"HRS" means Hawaii Revised Statutes.

"Human pathological waste" means all tissue, organs (including placenta, tonsils, and gall bladder), and body parts, including fetal remains, appendages, and amputated limbs (other than teeth and the contiguous structures of bone and gums, and body fluids), that are removed during surgery, autopsy, or other medical procedure, or specimens of body fluids and their containers, and discarded material saturated with body fluids other than urine. This waste shall not include urine or fecal materials submitted for other than diagnosis of infectious disease. All human pathological waste, except corpses or dead human bodies, shall be considered infectious waste and shall be subject to this chapter.

"Incineration" means a process by which waste undergoes complete combustion and becomes carbonized or mineralized sterile ash under a permit issued pursuant to chapters 11-60.1, Air Pollution Control, and 11-58.1 Solid Waste Management Control.

"Infectious isolation waste" means biological waste and discarded material contaminated with blood, body fluids, excretions, exudates, or secretions from a patient or patients with diseases considered communicable and requiring isolation as defined by the current CDC's guidelines for environmental infection control in health care facilities, Morbidity and Morality Weekly Report at www.cdc.gov/.

"Infectious waste" means any waste which may contain pathogens capable of causing an infectious disease and shall include, but not be limited to, waste categorized in section 11-104.1-4.

"OSHA" means Occupational Safety and Health Administration, United States Department of Labor.

"Point of generation" means the location at which infectious waste is produced.

"Sterilization" means the use of physical or chemical procedures, including but not limited to autoclave, microwave, vitrification, and pyrolysis, to destroy all microbial life including highly resistant bacterial endospores.

"Storage" means the holding of infectious or treated infectious waste which is awaiting treatment, transport, or disposal, in such a manner as not to

constitute disposal of the waste as required under section 11-104.1-32.

"Transport" means to move infectious waste and treated infectious waste from the point of generation to any intermediate point inside or outside the facility and finally to the point of disposal.

"Transporter" means any person who, or entity that, transports infectious waste or treated infectious waste.

"Treated" or "fixed" means to be exposed to any method, technique, or process which changes the character of the waste so as to render such waste noninfectious.

"Treated infectious waste" means infectious waste which has been incinerated, sterilized, or chemically disinfected by methods delineated in section 11-104.1-21.

"Treatment byproduct" means the substance or remains of infectious waste that has been incinerated, sterilized, or chemically disinfected by methods delineated in section 11-104.1-21.

"Waste" means any material which is discarded, or is meant to be discarded. [Eff JUL 12 2007] (Auth: HRS §§321-11, 321-20, 321-21) (Imp: HRS §§321-11, 321-21)

§11-104.1-3 Prohibited acts. No person shall handle, treat, dispose of, transport, or store infectious waste or treated infectious waste except in accordance with these rules. Any infraction of this section shall be subject to administrative penalties or fines as set forth in section 11-104.1-42. [Eff JUL 12 2007] (Auth: HRS §§321-20, 321-21) (Imp: HRS §321-21)

§11-104.1-4 Categories of infectious waste.

(a) Categories of infectious waste are as follows:

(1) Infectious isolation waste;

(2) Cultures and stocks of infectious agents;

(3) Blood, blood products, and other body fluids;
(4) Human pathological waste;
(5) Contaminated sharps; and
(6) Animal waste.

(b) The following shall be exempt from the requirements of this chapter:
(1) Foreign bodies;
(2) Gall stones, kidney stones, or other calcifications; and
(3) Other tissues that are not considered human pathological waste. [Eff JUL 12 2007]
(Auth: HRS §321-21) (Imp: HRS §321-21)

§§11-104.1-5 to 11-104.1-10 (Reserved)

SUBCHAPTER 2

UNTREATED INFECTIOUS WASTE IN A GENERATING FACILITY

§11-104.1-11 Handling of untreated infectious waste within a generating facility. (a) Infectious waste shall be segregated from all other waste at the point of generation.

(b) The types of untreated infectious waste described in section 11-104.1-4 shall be managed as follows:
(1) Infectious isolation waste, cultures and stocks of infectious agents, blood, blood products, and other body fluids considered infectious, and human pathological waste shall be deposited at the point of generation into containers lined with nonsoluble plastic bags which are clearly marked with the Universal Biological Hazard symbol, or into red plastic bags.
(A) All plastic bags shall be sufficient in number and thickness to securely contain the waste completely; and

(B) All bags shall be tightly closed before being transported so as to contain the waste completely.

(2) Contaminated sharps shall be deposited at the point of generation into rigid puncture resistant and leakproof containers, red in color or clearly marked with the Universal Biological Hazard symbol.

(A) Needles shall not be recapped, purposely bent, broken by hand, or otherwise manipulated;

(B) The containers shall be located in the immediate area where sharps are used and shall not be allowed to overflow; and

(C) Prior to transport, the containers shall be closed securely to contain sharps completely and shall remain closed throughout transport, storage, and disposal. [Eff JUL 12 2007] (Auth: HRS §321-21) (Imp: HRS §321-21)

§11-104.1-12 <u>Transportation of untreated infectious waste within a generating facility.</u> (a) Untreated infectious waste shall be placed in containers sufficient to contain the waste completely. Satisfactory containers include:

(1) Nonsoluble plastic bags either red in color or clearly labeled with the Universal Biological Hazard symbol;

(2) Sharps containers as described in section 11-104.1-11(b)(2); or

(3) Sturdy leakproof containers clearly marked with the Universal Biological Hazard symbol.

(b) The number of plastic bags and the thickness of bags shall be sufficient to securely contain the waste completely from point of generation through treatment and storage.

(c) Bags used for autoclaving shall also be marked with the Universal Biological Hazard Symbol.

(d) Plastic bags and other containers of untreated infectious waste shall be tightly closed before transport. The plastic bags and other containers of waste shall be transported in leakproof rigid or semi-rigid portable containment systems or carts, clearly marked with the Universal Biological Hazard symbol.

(e) Untreated infectious waste shall be transported within a facility in a manner designed to minimize rupturing and dissemination or aerosolization.

(f) Untreated infectious waste shall not be transported with noninfectious waste unless all waste in the load is managed as infectious waste.

(g) Reusable carts, bins, and other containment systems used to transport waste must be cleaned after each use and disinfected daily when in use.

[Eff JUL 12 2007] (Auth: HRS §321-21) (Imp: HRS §321-21)

§11-104.1-13 Storage of untreated infectious waste within a generating facility. Infectious waste which is being stored while awaiting treatment, shall be stored in disposable or reusable sturdy, leakproof containers that have tight-fitting lids and the containers shall be stored in a fully enclosed, secured room. Both the leakproof containers and the secured room shall be clearly labeled with the Universal Biological Hazard symbol. These containers shall be kept in fully enclosed, secured, and well-ventilated locations which are inaccessible to animals and persons not authorized to handle the treatment, transfer, or disposal of infectious waste.

[Eff JUL 12 2007] (Auth: HRS §321-21) (Imp: HRS §321-21)

§§11-104.1-14 to 11-104.1-20 (Reserved)

SUBCHAPTER 3

TREATED INFECTIOUS WASTE

§11-104.1-21 Treatment of infectious waste within a generating facility. (a) Before disposal, infectious waste may be incinerated, sterilized, or chemically disinfected on site in accordance with the following:

(1) The current CDC recommendations on universal precautions for prevention of transmission of HIV immunodeficiency virus, hepatitis B virus and other blood borne pathogens in health care settings;

(2) The current EPA guide for infectious waste management;

(3) Part 1910, OSHA standards, of Title 29 of the Code of Federal Regulations, Subpart Z;

(4) The current CLSI waste management guidelines; and

(5) By other methods approved by the aforementioned agencies or the department.

(b) The types of infectious waste described in section 11-104.1-4 shall be treated as follows:

(1) Infectious isolation waste shall be treated by autoclaving or incineration;

(2) Cultures and stocks of infectious agents shall be sterilized or incinerated in accordance with current CLSI waste management guidelines;

(3) Blood, blood products and other body fluids, all of which are considered infectious, shall be incinerated, sterilized, or disinfected;

(4) Human pathological waste:

(A) Shall be incinerated, sterilized, or disinfected; or

(B) Alternatively, all human body parts shall be incinerated, sterilized, embalmed, and disposed of in accordance with applicable state laws governing the disposal of human remains;

(5) Contaminated sharps shall be sterilized, incinerated, or disinfected; and

(6) Animal waste shall be sterilized, incinerated or disinfected in accordance with these rules or in accordance with chapter 11-58.1, [Eff JUL 12 2007]
(Auth: HRS §321-21) (Imp: HRS §321-21)

§11-104.1-22 Storage of treated infectious waste within a generating facility. (a) Treated infectious waste that has not been incinerated shall be stored in containers that are clearly marked as treated waste which has been rendered noninfectious.

(b) Infectious waste that has been treated and is awaiting transport for disposal shall be stored in fully enclosed, sealed containers and secured areas which are accessible only to persons authorized to handle their disposal. [Eff JUL 12 2007]
(Auth: HRS §321-21) (Imp: HRS §321-21)

§§11-104.1-23 to 11-104.1-30 (Reserved)

SUBCHAPTER 4

STANDARDS FOR INFECTIOUS WASTE GENERATORS AND TRANSPORTERS

§11-104.1-31 Transportation of infectious waste for treatment away from the generating facility. (a) Infectious waste shall be placed in containers which are sufficient to contain the waste completely. Satisfactory containers include:

(1) Nonsoluble plastic bags, red in color or clearly labeled with the Universal Biological Hazard symbol;

(2) Sharps containers as described in section 11-104.1-11(b)(2); or

(3) Sturdy leakproof containers clearly marked with the Universal Biological Hazard symbol.

(b) The number of plastic bags and thickness of plastic bags shall be sufficient to securely contain the waste completely from point of the generation through treatment.

(c) Plastic bags and other containers of infectious waste shall be tightly closed before transport. The plastic bags and other containers shall be placed in rigid or semi-rigid, tightly closed leakproof containers, which shall be clearly marked with the Universal Biological Hazard symbol prior to transport.

(d) Infectious waste in containers described in subsection (c) shall be transported away from the facility in fully enclosed, rigid, and leakproof containers or vehicle compartments, which will prevent scattering, spillage, and leakage of the waste during transport. The transport vehicle shall be labeled with a clearly visible Universal Biological Hazard Symbol.

(e) Untreated waste shall not be compacted.

(f) Containers may be disposable or reusable. Disposable containers, which have been in contact with infectious waste, shall be sterilized prior to disposal or incinerated. Reusable containers shall be cleaned after each use and disinfected daily when in use.

(g) Untreated infectious waste shall not be transported with noninfectious waste unless all waste in the load is managed as infectious waste.

[Eff JUL 12 2007] (Auth: HRS §321-21) (Imp: HRS §321-21)

§11-104.1-32 <u>Disposal of untreated infectious waste and treated infectious waste.</u> (a) All infectious waste shall be treated in accordance with these rules. Infectious waste that has not been treated at the generating facility shall be released to a medical waste treatment facility as permitted in accordance with chapter 11-58.1.

(b) Treated infectious waste that has not been incinerated shall be stored in containers that are clearly marked as treated waste which has been rendered noninfectious.

(c) All treated human body parts shall be disposed of in accordance with other applicable state laws governing the disposal of human remains.

(d) Incinerator ash, treated infectious waste, and treatment byproducts shall be disposed of only in state permitted landfills or authorized sites in accordance with chapter 11-58.1. [Eff JUL 12 2007] (Auth: HRS §321-21) (Imp: HRS §321-21)

§11-104.1-33 Infectious waste management plan. (a) Each infectious waste generator and transporter of untreated infectious waste shall have a written plan that contains policies and detailed procedures that:

(1) Outline the handling, safe and effective management, and disposal of infectious waste in accordance with these rules; and

(2) Ensure the health and safety of persons living in Hawaii and the environment in accordance with applicable federal, state, and local regulations, which include, but are not limited to, those regulations issued by the CDC, OSHA, EPA, and CLSI, as well as chapter 11-58.1, chapter 11-62, and chapter 14, Revised Ordinances of Honolulu.

(b) A copy of this plan shall be kept in the administrative offices of the generator and the transporter.

(c) The plan shall also provide for contingencies in emergency situations. At a minimum, this shall include, but not be limited to, procedures to be used in the following circumstances:

(1) Spills of liquid infectious waste. The plan shall include provisions for containment, protection of personnel, clean up procedures, disinfection and disposal of the spill residue and contaminated containers;

(2) Rupture of plastic bags or other loss of containment. The plan shall include provisions for containment, protection of personnel, clean up procedures, disinfection, and repackaging of waste; and

(3) Equipment failure. The plan shall include contingent arrangements for waste storage, transportation, and treatment.

[Eff JUL 12 2007] (Auth: HRS §321-21) (Imp: HRS §321-21)

§11-104.1-34 Exemption for placenta. (a) Upon negative findings of infection or hazard after appropriate testing of the mother by a health care facility or physician and confirmation of the findings on a release form established by the department, a placenta may be released by a health care facility or generator to the woman from which it originated or to the woman's designee.

(b) The health care facility or generator shall develop a procedure to ensure the safe management and transport of the placenta and may follow the requirements as set forth in this chapter or by the CDC, the EPA, the CLSI for clinical laboratory waste management or the OSHA or other similar guidelines.

(c) The procedure for the management and transport of placenta shall be set forth in writing and shall be available for the department's review.

(d) The release form must be signed by the mother, physician, and health care facility authority. One copy of the release form shall be filed in the patient chart and one copy shall be sent via facsimile transmission to the department. [Eff JUL 12 2007] (Auth: HRS §§321-21; 321-30) (Imp: HRS §§321-21; 321-30)

§§11-104.1-35 to 11-104.1-40 (Reserved)

SUBCHAPTER 5

ENFORCEMENT

§11-104.1-41 Enforcement. (a) If the department determines that any person has violated any provision of this chapter, any provision of chapter 321, HRS, or any term or condition of an exemption issued pursuant to this chapter, the department may:

(1) Issue an order assessing an administrative penalty in accordance with section 321-20, HRS, for any past or current violation; or

(2) Require compliance immediately or within a specified period of time; or

(3) Issue an order pursuant to paragraph (1) and require compliance pursuant to paragraph (2).

(b) Any order issued pursuant to this section shall state with reasonable specificity the nature of the violation, the factual bases for the finding(s) of violation, and the right to request an administrative hearing and retain legal counsel. The order shall be sent to the alleged violator by certified mail.

(c) Any order issued under this chapter shall become final, unless not later than twenty days after receipt of the notice of order by certified mail, the alleged violator serves or sends the department a written request for a hearing before the director. Any penalty imposed under this chapter shall become due and payable twenty days after receipt of the notice of order by certified mail unless the alleged violator requests in writing a hearing before the director. Whenever a hearing is requested on any penalty imposed under this chapter, the penalty shall become due and payable only upon completion of all review proceedings and the issuance of a final order confirming the penalty in whole or in part. Upon request for a hearing, the director or director's designee shall require that the alleged violator appear before the director for a hearing at a time and place specified in a notice of hearing and answer the charges complained of.

(d) Any hearing conducted under this section shall be conducted as a contested case hearing under chapter 91, HRS. If after a hearing held pursuant to this section, the director or the director's designee finds that the violation or violations have occurred, the director or the director's designee shall affirm or modify any penalties imposed or shall modify or affirm the order previously issued or issue an appropriate order or orders. If, after the hearing on an order or penalty contained in a notice, the director or the director's designee finds that no violation has occurred or is occurring, the director or the director's designee shall rescind the order or penalty or both.

(e) Nothing in this section shall be construed to limit penalties provided elsewhere. [Eff JUL 12 2007] (Auth: HRS §§321-21, 321-20) (Imp: HRS §§321-20, 321-21)

§11-104.1-42 Penalties. (a) Any person, corporation, health care facility, clinic, laboratory, or agency that violates any of the provisions of this chapter shall be subject to an administrative penalty not to exceed one thousand dollars for each separate offense. Each day that a violation exists or continues may constitute a separate offense. The violator shall also be subject to the provisions of section 321-20, HRS and shall be entitled to pursue the remedies provided therein including recourse to administrative contested case proceedings in accordance with chapter 91, HRS.

(b) Other than those situations in which a request for an exemption is granted, the following individuals and entities shall be responsible for the handling, transport, treatment, storage, or disposal of any infectious waste or treated infectious waste that is not in accordance with this chapter:

(1) The generator of the waste;

(2) Any person who, or entity that, by contract, agreement, or otherwise has arranged to treat, store, transport, or dispose of the waste; and

(3) Any person who, or entity that, accepts or accepted any treated or untreated infectious waste for treatment, storage, transport, or disposal. [Eff JUL 12 2007] (Auth: HRS §§321-20, 321-21) (Imp: HRS §§321-20, 321-21)

§11-104.1-43 Severability. If any provision of this chapter or the application thereof to any person or circumstances is held invalid, the remainder of this chapter, or the application of the provision to other persons or circumstances, shall not be affected thereby. [Eff JUL 12 2007] (Auth: HRS §321-21) (Imp: HRS §321-21)