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only pathological waste, low-level radioactive waste and/or chemotherapy waste is burned.

(c) Any co-fired combustor (defined in §60.51c) is not subject to this subpart if the owner or operator of the co-fired combustor:

(1) Notifies the Administrator of an exemption claim;

(2) Provides an estimate of the relative amounts of hospital waste, medical/infectious waste, and other fuels and wastes to be combusted; and

(3) Keeps records on a calendar quarter basis of the weight of hospital waste and medical/infectious waste combusted, and the weight of all other fuels and wastes combusted at the co-fired combustor.

(d) Any combustor required to have a permit under section 3005 of the Solid Waste Disposal Act is not subject to this subpart.

(e) Any combustor which meets the applicability requirements under subpart Cb, Ea, or Eb of this part (standards or guidelines for certain municipal waste combustors) is not subject to this subpart.

(f) Any pyrolysis unit (defined in §60.51c) is not subject to this subpart.

(g) Cement kilns firing hospital waste and/or medical/infectious waste are not subject to this subpart.

(h) Physical or operational changes made to an existing HMIWI solely for the purpose of complying with emission guidelines under subpart Ce are not considered a modification and do not result in an existing HMIWI becoming subject to this subpart.

(i) In delegating implementation and enforcement authority to a State under section 111(c) of the Clean Air Act, the following authorities shall be retained by the Administrator and not transferred to a State:

(1) The requirements of §60.56c(i) establishing operating parameters when using controls other than those listed in §60.56c(d).

(2) Alternative methods of demonstrating compliance under §60.8.

(j) Affected facilities subject to this subpart are not subject to the requirements of 40 CFR part 64.

(k) The requirements of this subpart shall become effective March 16, 1998

(1) Beginning September 15, 2000, or on the effective date of an EPA-approved operating permit program under Clean Air Act title V and the implementing regulations under 40 CFR part 70 in the State in which the unit is located, whichever date is later, affected facilities subject to this subpart shall operate pursuant to a permit issued under the EPA approved State operating permit program.

§60.51c Definitions.

Batch HMIWI means an HMIWI that is designed such that neither waste charging nor ash removal can occur during combustion.

Biologicals means preparations made from living organisms and their products, including vaccines, cultures, etc., intended for use in diagnosing, immunizing, or treating humans or animals or in research pertaining thereto.

Blood products means any product derived from human blood, including but not limited to blood plasma, platelets, red or white blood corpuscles, and other derived licensed products, such as interferon, etc.

Body fluids means liquid emanating or derived from humans and limited to blood; dialysate; amniotic, cerebrospinal, synovial, pleural, peritoneal and pericardial fluids; and semen and vaginal secretions.

Bypass stack means a device used for discharging combustion gases to avoid severe damage to the air pollution control device or other equipment.

Chemotherapeutic waste means waste material resulting from the production or use of antineoplastic agents used for the purpose of stopping or reversing the growth of malignant cells.

Co-fired combustor means a unit combusting hospital waste and/or medical/infectious waste with other fuels or wastes (e.g., coal, municipal solid waste) and subject to an enforceable requirement limiting the unit to combusting a fuel feed stream, 10 percent or less of the weight of which is comprised, in aggregate, of hospital waste and medical/infectious waste as measured on a calendar quarter basis. For purposes of this definition, pathological waste, chemotherapy waste, and low-level radioactive waste are

considered “other” wastes when calculating the percentage of hospital waste and medical/infectious waste combusted.

Continuous emission monitoring system or *CEMS* means a monitoring system for continuously measuring and recording the emissions of a pollutant from an affected facility.

Continuous HMIWI means an HMIWI that is designed to allow waste charging and ash removal during combustion.

Dioxins/furans means the combined emissions of tetra-through octa-chlorinated dibenzo-para-dioxins and dibenzofurans, as measured by EPA Reference Method 23.

Dry scrubber means an add-on air pollution control system that injects dry alkaline sorbent (dry injection) or sprays an alkaline sorbent (spray dryer) to react with and neutralize acid gases in the HMIWI exhaust stream forming a dry powder material.

Fabric filter or *baghouse* means an add-on air pollution control system that removes particulate matter (PM) and nonvaporous metals emissions by passing flue gas through filter bags.

Facilities manager means the individual in charge of purchasing, maintaining, and operating the HMIWI or the owner's or operator's representative responsible for the management of the HMIWI. Alternative titles may include director of facilities or vice president of support services.

High-air phase means the stage of the batch operating cycle when the primary chamber reaches and maintains maximum operating temperatures.

Hospital means any facility which has an organized medical staff, maintains at least six inpatient beds, and where the primary function of the institution is to provide diagnostic and therapeutic patient services and continuous nursing care primarily to human inpatients who are not related and who stay on average in excess of 24 hours per admission. This definition does not include facilities maintained for the sole purpose of providing nursing or convalescent care to human patients who generally are not acutely ill but who require continuing medical supervision.

Hospital/medical/infectious waste incinerator or *HMIWI* or *HMIWI unit* means any device that combusts any amount of hospital waste and/or medical/infectious waste.

Hospital/medical/infectious waste incinerator operator or *HMIWI operator* means any person who operates, controls or supervises the day-to-day operation of an HMIWI.

Hospital waste means discards generated at a hospital, except unused items returned to the manufacturer. The definition of hospital waste does not include human corpses, remains, and anatomical parts that are intended for interment or cremation.

Infectious agent means any organism (such as a virus or bacteria) that is capable of being communicated by invasion and multiplication in body tissues and capable of causing disease or adverse health impacts in humans.

Intermittent HMIWI means an HMIWI that is designed to allow waste charging, but not ash removal, during combustion.

Large HMIWI means:

(1) Except as provided in (2);

(i) An HMIWI whose maximum design waste burning capacity is more than 500 pounds per hour; or

(ii) A continuous or intermittent HMIWI whose maximum charge rate is more than 500 pounds per hour; or

(iii) A batch HMIWI whose maximum charge rate is more than 4,000 pounds per day.

(2) The following are not large HMIWI:

(i) A continuous or intermittent HMIWI whose maximum charge rate is less than or equal to 500 pounds per hour; or

(ii) A batch HMIWI whose maximum charge rate is less than or equal to 4,000 pounds per day.

Low-level radioactive waste means waste material which contains radioactive nuclides emitting primarily beta or gamma radiation, or both, in concentrations or quantities that exceed applicable federal or State standards for unrestricted release. Low-level radioactive waste is not high-level radioactive waste, spent nuclear fuel, or by-product material as defined by the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)(2)).

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Malfunction means any sudden, infrequent, and not reasonably preventable failure of air pollution control equipment, process equipment, or a process to operate in a normal or usual manner. Failures that are caused, in part, by poor maintenance or careless operation are not malfunctions. During periods of malfunction the operator shall operate within established parameters as much as possible, and monitoring of all applicable operating parameters shall continue until all waste has been combusted or until the malfunction ceases, whichever comes first.

Maximum charge rate means:

(1) For continuous and intermittent HMIWI, 110 percent of the lowest 3-hour average charge rate measured during the most recent performance test demonstrating compliance with all applicable emission limits.

(2) For batch HMIWI, 110 percent of the lowest daily charge rate measured during the most recent performance test demonstrating compliance with all applicable emission limits.

Maximum design waste burning capacity means:

(1) For intermittent and continuous HMIWI,

$$C = P_v \times 15,000 / 8,500$$

Where:

C=HMIWI capacity, lb/hr

P_v=primary chamber volume, ft³

15,000=primary chamber heat release rate factor, Btu/ft³/hr

8,500=standard waste heating value, Btu/lb;

(2) For batch HMIWI,

$$C = P_v \times 4.5 / 8$$

Where:

C=HMIWI capacity, lb/hr

P_v=primary chamber volume, ft³

164.5=waste density, lb/ft³

8=typical hours of operation of a batch HMIWI, hours.

Maximum fabric filter inlet temperature means 110 percent of the lowest 3-hour average temperature at the inlet to the fabric filter (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with the dioxin/furan emission limit.

Maximum flue gas temperature means 110 percent of the lowest 3-hour average temperature at the outlet from the

wet scrubber (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with the mercury (Hg) emission limit.

Medical/infectious waste means any waste generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals that is listed in paragraphs (1) through (7) of this definition. The definition of medical/infectious waste does not include hazardous waste identified or listed under the regulations in part 261 of this chapter; household waste, as defined in §261.4(b)(1) of this chapter; ash from incineration of medical/infectious waste, once the incineration process has been completed; human corpses, remains, and anatomical parts that are intended for interment; and domestic sewage materials identified in §261.4(a)(1) of this chapter.

(1) Cultures and stocks of infectious agents and associated biologicals, including: cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures.

(2) Human pathological waste, including tissues, organs, and body parts and body fluids that are removed during surgery or autopsy, or other medical procedures, and specimens of body fluids and their containers.

(3) Human blood and blood products including:

(i) Liquid waste human blood;

(ii) Products of blood;

(iii) Items saturated and/or dripping with human blood; or

(iv) Items that were saturated and/or dripping with human blood that are now caked with dried human blood; including serum, plasma, and other blood components, and their containers, which were used or intended for use in either patient care, testing and laboratory analysis or the development of pharmaceuticals. Intravenous bags are also include in this category.

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(4) Sharps that have been used in animal or human patient care or treatment or in medical, research, or industrial laboratories, including hypodermic needles, syringes (with or without the attached needle), pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.

(5) Animal waste including contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals or testing of pharmaceuticals.

(6) Isolation wastes including biological waste and discarded materials contaminated with blood, excretions, exudates, or secretions from humans who are isolated to protect others from certain highly communicable diseases, or isolated animals known to be infected with highly communicable diseases.

(7) Unused sharps including the following unused, discarded sharps: hypodermic needles, suture needles, syringes, and scalpel blades.

Medium HMIWI means:

(1) Except as provided in paragraph (2);

(i) An HMIWI whose maximum design waste burning capacity is more than 200 pounds per hour but less than or equal to 500 pounds per hour; or

(ii) A continuous or intermittent HMIWI whose maximum charge rate is more than 200 pounds per hour but less than or equal to 500 pounds per hour; or

(iii) A batch HMIWI whose maximum charge rate is more than 1,600 pounds per day but less than or equal to 4,000 pounds per day.

(2) The following are not medium HMIWI:

(i) A continuous or intermittent HMIWI whose maximum charge rate is less than or equal to 200 pounds per hour or more than 500 pounds per hour; or

(ii) A batch HMIWI whose maximum charge rate is more than 4,000 pounds

per day or less than or equal to 1,600 pounds per day.

Minimum dioxin/furan sorbent flow rate means 90 percent of the highest 3-hour average dioxin/furan sorbent flow rate (taken, at a minimum, once every hour) measured during the most recent performance test demonstrating compliance with the dioxin/furan emission limit.

Minimum Hg sorbent flow rate means 90 percent of the highest 3-hour average Hg sorbent flow rate (taken, at a minimum, once every hour) measured during the most recent performance test demonstrating compliance with the Hg emission limit.

Minimum hydrogen chloride (HCl) sorbent flow rate means 90 percent of the highest 3-hour average HCl sorbent flow rate (taken, at a minimum, once every hour) measured during the most recent performance test demonstrating compliance with the HCl emission limit.

Minimum horsepower or amperage means 90 percent of the highest 3-hour average horsepower or amperage to the wet scrubber (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with the applicable emission limits.

Minimum pressure drop across the wet scrubber means 90 percent of the highest 3-hour average pressure drop across the wet scrubber PM control device (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with the PM emission limit.

Minimum scrubber liquor flow rate means 90 percent of the highest 3-hour average liquor flow rate at the inlet to the wet scrubber (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with all applicable emission limits.

Minimum scrubber liquor pH means 90 percent of the highest 3-hour average liquor pH at the inlet to the wet scrubber (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with the HCl emission limit.

Minimum secondary chamber temperature means 90 percent of the highest 3-hour average secondary chamber temperature (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with the PM, CO, or dioxin/furan emission limits.

Modification or *Modified HMIWI* means any change to an HMIWI unit after the effective date of these standards such that:

(1) The cumulative costs of the modifications, over the life of the unit, exceed 50 per centum of the original cost of the construction and installation of the unit (not including the cost of any land purchased in connection with such construction or installation) updated to current costs, or

(2) The change involves a physical change in or change of the method of operation of the unit which increases the amount of any air pollutant emitted by the unit for which standards have been established under section 129 or section 111.

Operating day means a 24-hour period between 12:00 midnight and the following midnight during which any amount of hospital waste or medical/infectious waste is combusted at any time in the HMIWI.

Operation means the period during which waste is combusted in the incinerator excluding periods of startup or shutdown.

Particulate matter or *PM* means the total particulate matter emitted from an HMIWI as measured by EPA Reference Method 5 or EPA Reference Method 29.

Pathological waste means waste material consisting of only human or animal remains, anatomical parts, and/or tissue, the bags/containers used to collect and transport the waste material, and animal bedding (if applicable).

Primary chamber means the chamber in an HMIWI that receives waste material, in which the waste is ignited, and from which ash is removed.

Pyrolysis means the endothermic gasification of hospital waste and/or medical/infectious waste using external energy.

Secondary chamber means a component of the HMIWI that receives combustion gases from the primary cham-

ber and in which the combustion process is completed.

Shutdown means the period of time after all waste has been combusted in the primary chamber. For continuous HMIWI, shutdown shall commence no less than 2 hours after the last charge to the incinerator. For intermittent HMIWI, shutdown shall commence no less than 4 hours after the last charge to the incinerator. For batch HMIWI, shutdown shall commence no less than 5 hours after the high-air phase of combustion has been completed.

Small HMIWI means:

(1) Except as provided in (2);

(i) An HMIWI whose maximum design waste burning capacity is less than or equal to 200 pounds per hour; or

(ii) A continuous or intermittent HMIWI whose maximum charge rate is less than or equal to 200 pounds per hour; or

(iii) A batch HMIWI whose maximum charge rate is less than or equal to 1,600 pounds per day.

(2) The following are not small HMIWI:

(i) A continuous or intermittent HMIWI whose maximum charge rate is more than 200 pounds per hour;

(ii) A batch HMIWI whose maximum charge rate is more than 1,600 pounds per day.

Standard conditions means a temperature of 20 °C and a pressure of 101.3 kilopascals.

Startup means the period of time between the activation of the system and the first charge to the unit. For batch HMIWI, startup means the period of time between activation of the system and ignition of the waste.

Wet scrubber means an add-on air pollution control device that utilizes an alkaline scrubbing liquor to collect particulate matter (including non-vaporious metals and condensed organics) and/or to absorb and neutralize acid gases.

§ 60.52c Emission limits.

(a) On and after the date on which the initial performance test is completed or is required to be completed under § 60.8, whichever date comes first, no owner or operator of an affected facility shall cause to be discharged into