UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 4
ATLANTA FEDERAL CENTER
61 FORSYTH STREET
ATLANTA, GEORGIA 30303-8960

July 14, 2022

Ms. Kathryn Mihalek
Environmental Consultant
Safe Dispose, LLC.
1100 N 50th Street, Unit J
Tampa, Florida 33619

Dear Ms. Mihalek:

This is in response to your letter dated June 10, 2022, to the U.S. Environmental Protection Agency requesting an applicability determination (AD) for Title 40, Code of Federal Regulation (CFR), Part 60, Subpart Ec — Standards of Performance for New Stationary Sources: Hospital/Medical/Infectious Waste Incinerators, as it may apply to Safe Dispose's SD-2 Medical Waste Treatment System (SD-2 MWTS) located at Safe Dispose, LLC, in Tampa, Florida. Based on the information provided by you and research conducted by EPA Region 4, Subpart Ec does not apply to the SD-2 MWTS. The details of our AD are explained in the remainder of this letter.

Summarized Description of the SD-2 Medical Waste Treatment System

The SD-2 MWTS pyrolyzes pre-determined batched amounts [approximately 2.5 gallons volumetric capacity, which is equivalent to approximately 1.5 lbs/hr of waste (e.g., 12 lbs of waste in a 8 hour batch cycle)] of hospital waste and/or medical/infectious waste (HWMI waste) under a vacuum (absence of air/oxygen effected by a pressure altering pump) into the non-liquid products of ash, charcoal, and synthesis gas (syn gas) (primarily of hydrogen, carbon monoxide, and carbon dioxide) by an internal crucible (formed of 304 stainless steel) heated by an external electromagnetic induction coil which is in thermodynamic communication with, and disposed around, the outside surface of a crucible body. The SD-2 MWTS is equipped with a waste disposal chamber which includes a disposal body, a removable lid, and a structure that couples the lid to the disposal body, sealing the waste disposal chamber and the crucible within. The induction coil uses electromagnetic induction heat energy to rapidly pyrolyze the HWMI waste at an operating temperature of between 950 degrees Fahrenheit (°F) and 1400 °F that results in pyrolysis of the HWMI waste disposed within the crucible.

A duct, equipped with an airtight-seal thru-hole, allows syngas to flow from the waste disposal/crucible chamber to a catalytic converter. The catalytic converter (honeycomb structure with palladium, rhodium, and platinum, and may include copper, nickel, cerium, iron, manganese, or other metals) (approximately 93 mm in diameter and 50 mm in height) converts carbon monoxide and unburned hydrocarbons into carbon dioxide and water vapor. A second duct, coupling the catalytic converter and plasma chamber, allows the catalytic converter's gas to flow, by vacuum, into the thermal plasma chamber, which subjects the converter's waste gas to an accelerated jet of hot plasma, therefore incinerating the waste

gas. The discharge duct of the plasma chamber includes a heat exchanger which rapidly cools the waste gas before atmospheric venting.

The SD-2 MWTS is equipped with a control panel that comprises a user interface device, programmable logic controller, and microprocessor which receives user input and operates the microprocessor to send an electrical signal to the temperature, humidity, carbon dioxide, and oxygen sensors. The SD-2 MWTS includes a carbon dioxide sensor that detects the level of carbon dioxide within the pyrolysis chamber and if the carbon dioxide levels exceed a safe operating level, the programmable logic controller will shut the unit down. The SD-2 MWTS crucible chamber includes humidity and temperature sensors which are used to automatically adjust pyrolysis parameters according to the programmed code. The crucible chamber also includes oxygen and combustible-gas sensors which shut the unit down should a sufficient level of oxygen or combustible gas be detected within the crucible chamber. The SD-2 MTWS is equipped with an indicator light displaying the operating status of the waste destruction device.

Additional information related to the description and operation of the SD-2 MWTS may be obtained at https://patentsgazette.uspto.gov/week08/OG/classification/cpcClassGroup_B09.html.

EPA's Review of Subpart Ec

Under § 60.50c, except as provided in § 60.50c (b-h), the affected facilities to which this subpart applies is each individual hospital/medical/infectious waste incinerator (HMIWI). Under § 60.50c(f), any pyrolysis unit defined in § 60.51c is not subject to this subpart.

Under § 60.51c:

Pyrolysis means "… the endothermic gasification of hospital waste and/or medical/infectious waste using external energy." " Batch HMIWI means an HMIWI that is designed such that neither waste charging nor ash removal can occur during combustion." Primary chamber "… means the chamber in an HMIWI that receives waste material, in which the waste is ignited, and from which ash is removed." Secondary chamber "… means a component of the HMIWI that receives combustion gases from the primary chamber and in which the combustion process is completed." Small HMIWI "… means a batch HMIWI whose maximum charge rate is more than 1,600 pounds per day."

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."

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 are:

(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
(4) 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 included in this category. 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."

The definition of medical/infectious waste does not include hazardous waste listed in 40 CFR Part 261, household waste defined in 40 CFR § 261.4(b)(1), post medical/infectious waste incineration process ash, human corpses, remains, and anatomical parts that are intended for interment or cremation, and domestic sewage materials identified in 40 CFR § 261.4(a)(1).

The EPA's Applicability Determination

Based on the supporting information, as detailed above, the EPA has concluded that the SD-2 MWTS located at Safe Dispose's Tampa, Florida, facility is not an affected facility under Subpart Ec.

The basis of EPA's determination is as follows:

i.) For the purposes of this determination, the SD-2 MWTS is limited to processing "hospital waste and/or medical/infectious waste", as defined in § 60.50c.
ii.) Pyrolysis of hospital waste and/or medical/infectious waste, as defined in § 60.50c, within the SD-2 MWTS crucible chamber is achieved by an external heat energy source, the electromagnetic heat induction coil. The pyrolysis process in the crucible chamber is endothermic and operates in non-reliance on the production of exothermic heat which would be produced by the presence of combustion or incineration operations.
iii.) Gasification of the waste is achieved under a vacuum, in the absence of air and oxygen. No combustion or incineration air are provided to the crucible chamber during the pyrolysis gasification of the waste. A vacuum pump extracts pyrolysis gas from the crucible chamber, but air is not introduced into the chamber to support combustion or incineration within the crucible chamber.

iv.) Waste is not ignited within the crucible chamber
v.) No combustion or incineration flames are present inside the crucible chamber.
vi.) The operating temperature range of the SD-2 MWTS is 950F - 1400F, which is characteristic of pyrolysis.

Nothing in this AD excludes the EPA from expanding the source category in the future to include this technology in rule proposal/promulgation acts to establish standards for this technology. This determination is site-specific to the SD-2 MWTS at Safe Dispose's Tampa, Florida, facility and does not apply at other sites which may use the SD-2 MTWS. Consumers which may purchase, or lease, the SD-2 MWTS are responsible for obtaining an applicability determination from the EPA specific to their site operations. Additionally, the EPA recommends Safe Dispose review other EPA rules for applicability to the SD-2 MWTS (*e.g.*, Title 40 C.F.R. Part 60, Subpart EEEE - Standards of Performance for Other Solid Waste Incineration Units for Which Construction is Commenced After December 9, 2004, or for Which Modification or Reconstruction is Commenced on or After June 16, 2006"). Should Safe Dispose change the operation of the SD-2 MWTS beyond what is described in this determination, the EPA recommends Safe Dispose submit an applicability determination request to confirm that the changes do not trigger applicability of Subpart Ec.

This AD was coordinated with the EPA's Office of Enforcement and Compliance Assurance and Office of Air Quality Planning and Standards. If you have any questions about this AD, please contact Tracy Watson at (404) 562-8998 or by email at watson.marion@epa.gov.

Sincerely,

CAROLINE FREEMAN

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Caroline Y. Freeman
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