UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX
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OFFICE OF THE
REGIONAL ADMINISTRATOR

Landon Miller
Aemerge RedPak Services Southern California, LLC
9600 E Avenue
Hesperia, California 92345

APR 07 2017

Re: Applicability determination of 40 CFR Part 60, Subpart Ec – Standards of Performance for New Stationary Source: Hospital/Medical/Infectious Waste Incinerators to proposed project by Aemerge RedPak Services Southern California, LLC

Dear Mr. Miller,

This letter responds to your request, via email to Matt Salazar of my staff, for an applicability determination as referenced above. Aemerge is proposing construction of a system in Hesperia, CA for the destruction of hospital/medical/infectious waste (HMIW). Based on the information you provided to us, the EPA has determined that the exemption at 40 C.F.R. 60.51c in 40 CFR Part 60, Subpart Ec (HMIWI standards) for "any pyrolysis unit" would not apply to the Aemerge system. Furthermore, if constructed and operated as described, the system would be subject to the HMIWI standards.

EPA Response

In your letter, you provide the following information about the proposed project:

1. The Aemerge system consists of three components:
    a. Carbonizer
    b. Thermal Oxidizer
    c. Heat recovery steam generator
2. The first component within the system, the Aemerge carbonizer unit, is described as an inert gas "carbonization" process; i.e., the culmination of pyrolysis where carbonaceous material is converted to elemental carbon by reduction (the opposite of oxidation).
3. The Aemerge carbonizer unit is designed to process 5,800 pounds per hour of medical waste.

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4. The Aemerge carbonizer unit is endothermic.[1]
5. The waste processed in the Aemerge carbonizer unit[2] is contained in a sealed chamber (muffle) that receives indirect heat from an outer jacket that can be heated with natural gas or electric heat. The outer jacket is completely isolated from the inner muffle.
6. The Aemerge carbonizer unit uses nitrogen to blanket the waste material as it travels down the muffle by way of the drag chain. The nitrogen blanket and negative pressure in the muffle are designed to eliminate combustion and combine with high pyrolytic heat from the outer jacket to drive off volatiles from the waste in the carbonizer unit.
7. The intent of the design of the Aemerge carbonizer unit is to produce a high quality carbon with minimal ash. Example products are carbon that can be used as pigment for black coloration and char that can be charged with nutrient for landscape application.
8. The Aemerge carbonizer unit also will generate a synthetic gas (syngas), the composition of which will be largely methane.
9. The syngas then will be combusted in the second component of the Aemerge system - the thermal oxidizer.
10. The resultant heat from the thermal oxidizer is used in the third component of the system - the heat recovery steam generator (HRSG).[3]
11. Based on the construction date, if subject to the HMIWI standards, the applicable units comprising the Aemerge system would be a new source.

In accordance with §60.50c, the affected facility to which the HMIWI standards apply is each individual HMIWI constructed, in relevant part, after December 1, 2008. HMIWI is defined at §60.51c as "any device that combusts any amount of hospital waste and/or medical/infectious waste." Aemerge provides that the system as a whole will be used to destroy hospital, medical, and infectious waste, and will be constructed after December 1, 2008.

There is an exemption at §60.50c(f) for "any pyrolysis unit" where the term "pyrolysis" is defined at §60.51c as the "endothermic gasification of hospital waste and/or medical/infectious waste using external energy."[4]

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[1] You state that the Aemerge "*unit*" is endothermic. We assume you mean the carbonizer unit within the three-component system, as later in the letter you discuss the use of heat recovery after the oxidizer, the third and second components of the system, respectively (Background Item 10). Heat recovery would not be possible in an endothermic unit, as there would be no heat generated.

[2] Again, we read "unit" to mean only the carbonizer component.

[3] You state that you also intend to evaluate cleaning of the syngas and use of the syngas in internal combustion electrical generation. Pursuant to §129(g)(1) of the Clean Air Act, the term "solid waste incineration unit," in relevant part, does not include qualifying small power production facilities, as defined in section 796(17)(C) of title 16, or qualifying cogeneration facilities, as defined in section 796(18)(B) of title 16, which burn homogeneous waste (such as units which burn tires or used oil, but not including refuse-derived fuel) for the production of electric energy. Since this was not presented to the EPA as a current option, we are not evaluating that scenario.

[4] The EPA discussed pyrolysis in the June 20, 1996, re-proposal for the HMIWI standards (see 61 FR 31736) and concurrently developed a draft regulation for pyrolysis units (see Legacy Air Docket A-91-61, Item IV-B-56). In the September 15, 1997, final rule (see 62 FR 48348) the EPA deferred on developing standards for pyrolysis units and determined that the HMIWI standards were not appropriate for pyrolysis units. Subsequently, the exemption and definition of "pyrolysis unit" were promulgated at §§60.50c(f) and 60.51c, respectively.

We do not believe that the exemption for "any pyrolysis unit" is applicable to the three-component Aemerge system. In the information you provided, the process in the carbonizer unit has been described as an endothermic "pyrolysis" process; however, the carbonizer, thermal oxidizer, and heat recovery steam generator operate as a multi-component system and therefore we must evaluate each of them as part of a system. This is because the gas stream generated in one component (the carbonizer) is immediately and continuously routed to the next component (the thermal oxidizer), and the operation of the prior carbonizer is integral to the operation of the subsequent oxidizer. Emissions are not emitted to the atmosphere until the gases have passed through all three components, including the heat recovery steam generator. Some of the units, according to your information, are endothermic (e.g., the carbonizer), while some are exothermic (e.g. the thermal oxidizer). Therefore, because the Aemerge system is not "endothermic" throughout its system, we do not believe that the Aemerge system meets the exemption for "any pyrolysis unit" as "pyrolysis" is defined in the HMIWI standards. However, this alone does not mean that the system is therefore subject to the HMIWI standards.

Section §60.51c of Subpart Ec "Definitions" states that a hospital/medical/infectious waste incinerator or HMIWI or HMIWI unit means:

> any device that combusts any amount of hospital waste[5] and/or medical/infectious waste.[6]

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[5] *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. See §60.51c.

[6] *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 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 or cremation; 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

As provided by Aemerge, the system receives HMIW. The gas produced by the destruction of the HMIW in the carbonizer unit is routed to the thermal oxidizer (the second component of the system) where the synthetic gases resulting from the gasification of HMIW are then combusted. This meets the definition of a HMIWI - a "device that combusts any amount of hospital waste and/or medical/infectious waste" - as the rule does not exclude gasified HMIW. In fact, in the February 27, 1995, proposed rule, we describe a typical HMIWI design system:

> sequential combustion operations typically are carried out in two separate chambers: primary and secondary. In the primary chamber, the waste is loaded and ignited, *the volatile organic components driven off*, and the nonvolatile materials combusted to ash. The volatile organic components released from the primary chamber are combusted in the secondary chamber. [Emphasis added]

While the muffle furnace and nitrogen blanket should not allow for ignition of the waste in the carbonizer unit of the Aemerge system, the purpose of that step is to drive the volatile organic components off to the next component, the thermal oxidizer, where those volatile organic components are then combusted. See "Background Item 6," above: "[t]he nitrogen blanket and negative pressure in the muffle are designed to eliminate combustion and combine with high pyrolytic heat from the outer jacket *to drive off volatiles*."

Therefore, as the syngas produced by the destruction of the HMIW is combusted by the thermal oxidizer within the overall Aemerge system, we conclude that the Aemerge system is combusting HMIW and is consequently subject to 40 CFR Part 60 Subpart Ec.

As a HWIMI, it does not appear from the information provided that the Aemerge system meets 40 CFR Part 241 standards for determining that a non-hazardous secondary material (NHSM) is a non-waste. To be considered a non-waste, a NHSM must be processed into a legitimate

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either patient care, testing and laboratory analysis or the development of pharmaceuticals. Intravenous bags are also included in this category.

(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. See §60.51c.

product fuel prior to introduction into the combustion unit. We are happy to speak to you further about application of the NHSM standards to your system.

In your letter, and subsequent email of February 22, 2016, you provided examples of previous determinations relating to gasification, pyrolysis, and combustion and applicability under section 129, including under section 129 rules other than the HMIWI standards. We note that each determination of applicability is made on a case "by" case basis and is specific to the source and rule in question. This determination is not based on any re-evaluation of the examples you provided, but is based on the information you provided regarding that Aemerge system in comparison with the provisions of the HMIWI standards governing the rule's applicability.

Your letter presented seven (7) statements as rationale for your position that "EPA has stated that gasification is a chemical process and is not a combustion process" and "therefore not subject to regulation under the authority of Section 129 of the CAA, which regulates solid waste combustion." We respond to those statements below:

Aemerge Statement 1:

A 1995 EPA Office of Solid Waste memorandum concludes that a unit that "operates outside of the limits of flammability" "is not an incinerator."

EPA Response:

CAA Section 129 does not define combustion nor do any of the underlying regulations promulgated pursuant to section 129. We evaluate applicability based on the specific rule's regulatory applicability provisions, as well as the technical support documents which were used to develop the standards, in comparison to the facts presented in a specific case. General statements that may have been issued for other purposes do not compel specific applicability determinations under section 129.

Aemerge Statements 2 and 3:

In response to comments on the Commercial/Industrial Solid Waste Incineration Rule (CISWI), EPA reiterated the position made in the Non-Hazardous Secondary Materials (NHSM) Rule – essentially that gas is not a solid waste, except in the rare case that it becomes containerized.

EPA Responses 2 and 3:

The characterization by Aemerge oversimplifies NHSM and "contained gas." A gas may be a solid waste subject to section 129, unless the particular rule explicitly were to exempt it from the rule's scope. Furthermore, based on the facts presented to us so far, we do not believe that "contained gas" needs to be explored for the Aemerge system, for the reasons described above; i.e., the three chambers operate as a system to combust gas produced by the destruction of the HMIW, thus meeting the definition of a HMIWI - a "device that combusts any amount of hospital waste and/or medical/infectious waste."

Aemerge Statement 4:

Section 129 of the CAA applies to solid waste incineration units where the term "solid waste incineration unit" means "a distinct operating unit of any facility which combusts any solid waste material from commercial or industrial establishments or the general public."

EPA Response 4

We agree with this general statement; however, it does not support concluding that the Aemerge system is not a HMWI, as the system both contains a component that in fact combusts waste gases and as a whole serves that purpose.

Aemerge Statement 5:

Aemerge asserts that EPA's information on the Gasification Rule[7] states EPA's position that gasification is a chemical process and is not combustion. As gasification is not combustion, gasification units cannot be combustion units regulated under Section 129 of the Clean Air Act.

EPA Response 5:

EPA notes that the Gasification Rule was vacated and subsequently re-promulgated without an exemption for gasification. See 80 FR 18777. Irrespective of that vacatur, EPA agrees that gasification alone is not combustion. However, for the reasons discussed in the body of this letter, we do not believe that the Aermerge system is comprised of gasification alone, but in fact involves a component (and therefor an overall system) that combusts HMIW.

Aemerge Statement 6:

In the December 19, 2013, letter from the EPA to MaxWest, EPA determined that neither the gasification, nor the oxidation of the syngas was regulated under the sewage sludge incinerator (SSI) standard for that facility.

EPA Response 6:

The determination of applicability of the SSI standards to MaxWest does not pre-judge the determination of applicability of the HMIWI rule to Aemerge. We note, moreover, that the applicability and definitions of the types of units in the SSI standards and the HMIWI standards are different. For example, the SSI rule limits the definition of sewage sludge to liquid, solid, or semi-solid forms of the waste, which HMIWI does not.

Aemerge Statement 7:

EPA used the overall net energy input as the criteria regarding the definition of "pyrolysis unit" in the HMIWI rule when determining the applicability of the HMIWI standards to a facility owned by Statewide Medical Services.

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[7] Aemerge refers to the 2008 Final Rule regarding the Regulation of Oil-Bearing Hazardous Secondary Materials from the Petroleum Refining Industry Processed in a Gasification System To Produce Synthesis Gas as the "Gasification Rule." See 73 FR 57.

EPA Response 7:

Although we are not revisiting previous determinations of applicability for the purposes of this response, we note that the determination you mentioned predates promulgation of the NHSM rule and the ruling in *NRDC v. EPA*, 489 F.3d 1250 (DC Cir. 2007) (''NRDC''). The court stated that section 129 unambiguously requires any unit that combusts ''any solid waste material at all'' to be regulated as a ''solid waste incineration unit.'' Id. For the reasons discussed in the body of the letter, we believe that the Aemerge system combusts HMIW and does not meet the exemption for any "pyrolysis unit."

This determination is based on the information provided by Aemerge to the EPA. Should any of the facts change, a new applicability determination may need to be made. This determination was coordinated with the Office of Air Quality Planning and Standards, the Office of Enforcement and Compliance Assurance, the Office of General Counsel and EPA Region IX.

Thank you for your request and for the information you included about your proposed project. If you have any questions about our response, please contact my staff, Roshni Brahmbhatt, at (415) 972-3995.

Sincerely yours,

for Alexis Strauss
Acting Regional Administrator