DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Solid and Hazardous Waste Commission/Hazardous Materials and Waste Management Division

6 CCR 1007-2

PART 1 - REGULATIONS PERTAINING TO SOLID WASTE SITES AND FACILITIES

Amendment of Section 13 Medical Waste Regulations

1) Section 13.2.5 is amended to read as follows:

13.2 GENERAL PROVISIONS

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13.2.5 Incorporation by Reference.

(A) References to material incorporated by reference in this Section 13 refer ~~to 2011 editions unless otherwise expressly noted~~ to those versions in effect on November 16, 2021, and do not include any later amendments or editions.

(B) Information concerning all materials or regulations incorporated by reference may be obtained by contacting:

Regulatory and Program Authorization Coordinator
Colorado Department of Public Health and Environment
Hazardous Materials and Waste Management Division
4300 Cherry Creek Drive South
Denver, CO 80246-1530

(C) The specific materials or regulations incorporated by reference in these regulations ~~are listed in the Statement of Basis and Purpose for this rulemaking, and~~ are available for public examination during normal business hours ~~on the Internet and~~ at the Department. All federal agency regulations incorporated by reference herein are available, at no cost, in the online edition of the Code of Federal Regulations (CFR) hosted by the United States Government Printing Office, online at www.govinfo.gov.

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2) Section 13.3 is amended by revising paragraphs 13.3.1(B) – (B)(2), and revising paragraph 13.3.2 to read as follows:

13.3 CERTIFICATE OF DESIGNATION REQUIRED

13.3.1 Exemptions - the following sites and facilities shall be approved sites and facilities for which it shall not be necessary to obtain a Certificate of Designation unless the Department determines that the site or facility may adversely affect human health and the environment:

(A) *******

(B) Medical waste generators that operate equipment for treatment of medical wastes generated onsite or that is generated through the normal operation of their business at other locations operated by the same business and self-transported by private motor carrier from their other locations for consolidation and/or treatment that ~~are in compliance with~~:

(1) ~~Section 13.3.1(A).~~are in compliance with

(i) Section 13.3.1(A).

(~~2~~ii) Section 13.6 Standards for Medical Waste Treatment~~.~~: and

(2) Notify the Department that they perform onsite treatment of medical waste. Onsite treatment notification is a one-time notification that must be sent to the Department prior to initiating treatment operations, or for facilities that are currently treating medical waste, within 90 days of the effective date of this regulation.

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13.3.2 No person, unless exempted under Section 13.3.1, shall operate a medical waste ~~consolidation, storage,~~ treatment, processing or disposal facility without having received a Certificate of Designation in accordance with Section 1.6 of these regulations.

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3) Section 13.5 is amended by deleting and reserving paragraph 13.5.2(C) to read as follows:

13.5 STANDARDS FOR COMMERCIAL MEDICAL WASTE STORAGE FACILITIES

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13.5.2 Commercial medical waste storage facilities must comply with:

(A) Section 13.1 Applicability.

(B) Section 13.2 General Provisions.

(C) Reserved ~~Section 13.3 Certificate of Designation.~~

(D) Section 13.7 Engineering Design and Operations Plan Requirements.

(E) Section 13.8 Operating Requirements.

(F) Section 13.10 Transportation Requirements.

4) Section 13.7 is amended by revising paragraph 13.7.2(C)(4) to read as follows:

13.7 ENGINEERING DESIGN AND OPERATION PLAN REQUIREMENTS FOR COMMERCIAL STORAGE AND TREATMENT FACILITIES

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(C) The Engineering Design and Operations Plan shall contain the following operational information.

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(4) A waste characterization and acceptance plan, including waste screening methods to be used, radioactive material scanning, waste exclusion procedures and rejection of prohibited wastes, handling methods for wastes that require special or non-standard handling, and a contingency plan for handling prohibited wastes.

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5) Section 13.9.3 is amended by revising paragraphs 13.9.3(D) and 13.9.3(E) to read as follows:

13.9 STANDARDS FOR MEDICAL WASTE DISPOSAL

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13.9.3 Trace chemotherapy waste and waste pharmaceuticals.

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(D) Waste pharmaceuticals that contain controlled substances must be managed in accordance with the US DEA requirements in 21 CFR 1307.11 or 21 CFR 1317~~1307.21~~.

(E) Waste pharmaceuticals that are both hazardous waste and contain controlled substances must be managed in accordance with the Colorado Hazardous Waste Act (Title 25 Article 15 Parts 1, 2, 3, and 5 CRS, as amended) and implementing regulations (6 CCR 1007-3) and the US DEA requirements in 21 CFR 1307.11 or 21 CFR 1317~~1307.21~~.

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6 CCR 1007-2

Statement of Basis and Purpose and Specific Statutory Authority for

Modification to Regulations Pertaining to Solid Waste Sites and Facilities (6 CCR 1007-2, Part 1) – Modification of Section 13, Medical Waste

Basis and Purpose

I. Statutory Authority

These modification are made pursuant to the authority granted to the Solid and Hazardous Waste Commission in Sections 25-15-302(4.5) and 30-20-109, C.R.S.

II. Purpose of modification of the Section 13 regulations:

The purpose of these amendments to the Section 13 regulations is to update the regulations applicable to medical waste treatment and temporary storage facilities. Section 13 has not been modified since 2011 and since that time, some aspects of the existing regulations have become outdated.

Discussion of Regulatory Proposal

I. Certificate of Designation Required (Section 13.3)

Paragraph 13.3.1(B) of this section is being modified to require that medical waste generators that self-treat their waste on-site must notify the Department about their self-treatment activities. This new requirement is a one-time notification requirement that must be provided prior to initiating medical waste treatment operations. Those facilities that already treat their own medical waste will be required to notify the Department within 90 days of the effective date of the new rules.

Paragraph 13.3.2 of this section is being modified to remove the Certificate of Designation requirement for facilities that consolidate and temporarily store medical waste prior to hauling to a treatment or disposal facility.

II. Standards for Commercial Medical Waste Storage Facilities (Section 13.5)

This section is being modified to remove the Certificate of Designation requirement for Commercial Medical Waste Storage Facilities.

III. Engineering Design and Operation Plan Requirements for Commercial Storage and Treatment Facilities (Section 13.7)

Paragraph 13.7.2(C)(4) of this section is being modified to add the requirement for Commercial Treatment Facilities to conduct radioactive material scanning of incoming waste.

IV. General Provisions – Incorporation by Reference (Section 13.2.5)

The incorporation by reference provisions of Section 13.2.5 are being modified, including updating the existing reference to 2011 editions of incorporated by reference materials in the Section 13 regulations to the latest versions in effect at the time of the November 16, 2021 rulemaking hearing.

V. Standards for Medical Waste Disposal (Section 13.9)

Paragraphs 13.9.3(D) and 13.9.3(E) of this section are being revised to update the reference to the US Drug Enforcement Administration (DEA) regulations. The requirements previously located at 21 CFR 1307.21 were removed pursuant to a final rule published in the Federal Register on September 9, 2014 {79 FR 53520-53570}, and replaced with new regulations at 21 CFR Part 1317 for the disposal of controlled substances.

Issues Encountered During Stakeholder Process:

No issues were encountered during the stakeholder process.

Regulatory Alternatives

No other regulatory alternatives were evaluated.

Cost/Benefit Analysis

A cost benefit analysis will be performed if requested by the Colorado Department of Regulatory Agencies.