

1                                   **DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

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3                                   **Solid and Hazardous Waste Commission**

4                                   **Hazardous Materials and Waste Management Division**

5                                   **6 CCR 1007-2**

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8                                   **Statement of Basis and Purpose**  
9                                   **and Specific Statutory Authority for**

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

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17 I.       **Statutory Authority**

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19                   These modification are made pursuant to the authority granted to the Solid and  
20 Hazardous Waste Commission in Sections 25-15-302(4.5) and 30-20-109, C.R.S.  
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22 II.       **Purpose of modification of the Section 13 regulations:**

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27 existing regulations have become outdated.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

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32 I.       **Certificate of Designation Required (Section 13.3)**

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34                   Paragraph 13.3.1(B) of this section is being modified to require that medical waste  
35 generators that self-treat their waste on-site must notify the Department about their self-  
36 treatment activities. This new requirement is a one-time notification requirement that  
37 must be provided prior to initiating medical waste treatment operations. Those facilities  
38 that already treat their own medical waste will be required to notify the Department within  
39 90 days of the effective date of the new rules.  
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41                   Paragraph 13.3.2 of this section is being modified to remove the Certificate of  
42 Designation requirement for facilities that consolidate and temporarily store medical  
43 waste prior to hauling to a treatment or disposal facility.  
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45 II. Standards for Commercial Medical Waste Storage Facilities (Section 13.5)  
46  
47 This section is being modified to remove the Certificate of Designation requirement for  
48 Commercial Medical Waste Storage Facilities.  
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50 III. Engineering Design and Operation Plan Requirements for Commercial Storage and  
51 Treatment Facilities (Section 13.7)  
52  
53 Paragraph 13.7.2(C)(4) of this section is being modified to add the requirement for  
54 Commercial Treatment Facilities to conduct radioactive material scanning of incoming  
55 waste.  
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57 IV. General Provisions – Incorporation by Reference (Section 13.2.5)  
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59 The incorporation by reference provisions of Section 13.2.5 are being modified, including  
60 updating the existing reference to 2011 editions of incorporated by reference materials in  
61 the Section 13 regulations to the latest versions in effect at the time of the November 16,  
62 2021 rulemaking hearing.  
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64 V. Standards for Medical Waste Disposal (Section 13.9)  
65  
66 Paragraphs 13.9.3(D) and 13.9.3(E) of this section are being revised to update the  
67 reference to the US Drug Enforcement Administration (DEA) regulations. The  
68 requirements previously located at 21 CFR 1307.21 were removed pursuant to a final  
69 rule published in the Federal Register on September 9, 2014 {79 FR 53520-53570}, and  
70 replaced with new regulations at 21 CFR Part 1317 for the disposal of controlled  
71 substances.  
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74 **Issues Encountered During Stakeholder Process:**  
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76 No issues were encountered during the stakeholder process.  
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79 **Regulatory Alternatives**  
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81 No other regulatory alternatives were evaluated.  
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83 **Cost/Benefit Analysis**  
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85 A cost benefit analysis will be performed if requested by the Colorado Department of Regulatory  
86 Agencies.