

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Environmental Protection Agency (Ohio EPA)

Regulation/Package Title: Infectious Waste/Incinerator Rules

Rule Number(s): 3745-27-37, 3745-27-38, 3745-27-39, 3745-27-50, 3745-27-51,
3745-27-52, 3745-27-53

Date: June 5, 2014

Rule Type:

- | | |
|----------------------------------|---|
| <input type="checkbox"/> New | <input checked="" type="checkbox"/> 5-Year Review |
| <input type="checkbox"/> Amended | <input type="checkbox"/> Rescinded |

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language.
Please include the key provisions of the regulation as well as any proposed amendments.

These existing infectious waste regulations establish requirements for treatment, alternative treatment, and final closure of infectious waste facilities. The remainder of the infectious waste rules in OAC Chapter 3745-27 (3745-27-30, 3745-27-32, 3745-27-33, 3745-27-35, and 3745-27-36) are up to date with their five year review as a result of the Senate Bill 294 effort that took place in 2013.

The existing solid waste incinerator rules in this package address the permitting, criteria for approval, operation and final closure of solid waste incinerators and energy recovery facilities.

Pursuant to ORC 119.032, Ohio EPA has determined that these rules do not need to be amended or rescinded. A determination that these infectious waste and incinerator rules are to be retained without change is to be filed with the Joint Agency on Rule Review (JCARR).

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

Ohio Revised Code 3734.02, 3734.021, 3734.73.

3. Does the regulation implement a federal requirement? No. Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

If yes, please briefly explain the source and substance of the federal requirement.

Not Applicable.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

Not applicable. There are no federal requirements for states to adopt or to enforce infectious waste and solid waste incinerator rules under subtitle D of Resource Conservation and Recovery Act (RCRA).

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

The purpose of these infectious waste regulations is to limit the public's exposure to infectious agents. The infectious waste rules in this package establish criteria for infectious waste treatment and the permitting and closure of infectious waste treatment facilities.

The purpose of the rules regarding the permitting, operation, and closure of solid waste incinerator and energy recovery facilities is to ensure public health through the proper management and burning of solid waste.

6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

Continued minimal complaints regarding infectious treatment facility and solid waste incinerator operation, continued minimal violations of environmental laws, and the absence of environmental and health impacts are the Agency's measures of success of these regulations.

Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

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If applicable, please include the date and medium by which the stakeholders were initially contacted.

Prior to making the determination to retain the infectious waste rules without change, the Agency contacted the Ohio Hospital Association representing a significant number of infectious waste generators and the one company operating permitted infectious waste treatment facilities in Ohio (Stericycle) notifying them of the 5-year rule review process. This infectious waste treatment facility is also the only solid waste incinerator in Ohio authorized to treat infectious waste. Ohio EPA outlined the review timeframe, answered any questions they may have about the review process, and sought input on the preliminary determination to retain these rules without change. These entities did not express any objection with the Agency proceeding with the JCARR filing of a determination to retain the infectious waste rules without change.

It should again be noted that in March 2013, several of the infectious waste rules were amended to reflect statutory changes and incorporated stakeholder input and suggestions.

Ohio EPA's determination to retain the infectious waste rules without change also considered stakeholder comments received from June 11, 2013 early stakeholder outreach seeking all infectious waste stakeholders input on an Agency suggestion to re-organize the infectious waste rules including moving the rules into a separate rule chapter. This effort also sought stakeholder suggestions on improving the rules. As part of the ORC 119.032 5-year review process, the Agency reviewed these stakeholder suggestions in making the determination to retain the infectious waste rules without change. Separate of the 5-year review, Ohio EPA does intend to pursue future rule amendments to propose re-organization of the infectious waste rules as outlined in the June 11, 2014 early stakeholder outreach effort.

There currently is only one solid waste incinerator licensed in Ohio. This Stericycle solid waste incinerator is licensed to treat infectious waste in accordance with ORC 3734.05(B) and must comply with the infectious waste rules regarding treatment, management, and closure. There are no other solid waste incinerators or energy recovery facilities in Ohio subject to OAC rules 3745-27-50 through 3745-27-53. The Agency is filing a determination to retain these rules after discussion with Stericycle and to maintain the regulatory opportunity for the permitting and operation of future solid waste incinerators or energy recovery facilities.

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

The identified entities contacted regarding this determination to retain the infectious waste treatment and solid waste incinerator rules without change did not express any objection. Stakeholder comments provided as part of a recent June 11, 2013 stakeholder outreach effort did not indicate any ORC 119.032 criteria based need to amend the existing rules.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

Since the Agency is proposing to retain these rules without change, the use of new scientific data was not used in this rulemaking effort. However, the infectious waste treatment facility rules and solid waste incinerator rules use a scientific basis consistent with industry standards and statutory requirements of ORC 3734.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

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Ohio EPA's determination to retain the infectious waste rules without change is based upon the five-year rule review criteria in ORC 119.032. The review included consideration of stakeholder comments received from June 11, 2013 early stakeholder outreach seeking all infectious waste stakeholders input on an Agency suggestion to re-organize the infectious waste rules including moving the rules into a separate rule chapter. This effort also sought stakeholder suggestions on improving the rules. No suggestions regarding the need for alternative regulations were received. The Agency discussed the solid waste incinerator rules with the operator of the only regulated solid waste incinerator. No suggestions regarding alternative regulations were expressed.

11. Did the Agency specifically consider a performance-based regulation? Please explain.

Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

Ohio EPA's determination to retain the infectious waste rules without change included consideration of stakeholder comments and input. No suggestions to make the rule more performance-based were received.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

Ohio EPA reviewed our own regulations and performed a search of regulations from other agencies to determine if duplication was being made. To our knowledge, Ohio EPA is not duplicating another existing Ohio regulation.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

Because these rules are already effective and Ohio EPA is to file a determination to retain these rules without change, the Agency plans to continue the current efforts to ensure consistent and predictable rule implementation.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

The impacted business community includes infectious waste generators, transporters, owners or operators of infectious waste treatment facilities, and owners or operators of solid waste incinerators or energy recovery facilities.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

The nature of the adverse impact includes permit application and license fees, costs for preparing applications, disclosure statements, letters of intent, engineering plan sheets and certification reports, associated costs of maintaining compliance with the rules, performing final closure and establishing financial assurance. There are also voluntary costs of compliance for owners and operators of infectious waste treatment facilities who choose to

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seek authorization of an alternative infectious waste treatment method under OAC rule 3745-27-38.

c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.

An Ohio industry choosing to establish and operate an infectious waste treatment facility, solid waste incinerator, or solid waste energy recovery facility can anticipate an initial cost associated with the rules. Although a cost of compliance exists with these rules, it is difficult to determine a specific cost in terms of dollars because any estimate must account for a range of significant variables. The cost will naturally vary depending on the facility size, design and location. Data on the cost of permitting, operating, and closing an infectious waste treatment facility or a solid waste incinerator or energy recovery facility is limited. The Ohio regulations for these facilities are very similar to requirements of a solid waste transfer facility. An enclosed structure designed with a floor to contain and capture any spillage. U.S. EPA utilized a general assumption that the cost to build, own, and operate a transfer facility is \$10 per ton of solid waste received in the document “*Waste Transfer Stations: A Manual for Decision-making*”.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The Agency determined that the regulatory intent justifies the adverse impact to the regulated business community because regulations for the safe treatment and disposal of infectious waste and solid waste by means of incineration are mandated by sections 3734.02 and 3734.021 of the Ohio Revised Code.

The purpose of these infectious waste regulations is to limit the public’s exposure to infectious agents. The infectious waste rules in this package establish criteria for infectious waste treatment and the permitting and closure of infectious waste treatment facilities.

The purpose of the rules regarding the permitting, operation, and closure of solid waste incinerator and energy recovery facilities is to ensure public health through the proper management and burning of solid waste.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

An owner or operator of an infectious waste, solid waste incinerator, or solid waste energy recovery facility are also subject to the director’s exemption authority established under 3734.02(G) of the Ohio Revised Code and variance authority under sections 3734.02 and 3734.021(F) of the Revised Code. These sections pertain to exemptions and variations that allow for alternative means of compliance. Also, OAC Rule 3745-27-38 allows for approval of alternative methods of treatment.

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17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The director or the approved health department will evaluate the applicability of ORC section 119.14 to solid waste facilities or infectious waste treatment facilities regulated under OAC Chapter 3745-27 when assessing fines and penalties for paperwork violations and first-time offenders.

18. What resources are available to assist small businesses with compliance of the regulation?

Ohio EPA's Division of Materials and Waste Management (DMWM) and approved local health departments offer general infectious waste and solid waste management regulatory assistance. DMWM staff offer technical assistance to permit applicants and facility operators. DMWM maintains numerous documents and resources through an extensive DMWM website.

In addition, Ohio EPA's Office of Compliance Assistance and Pollution Prevention (OCAPP) is a non-regulatory program that provides information and resources to help small businesses comply with environmental regulations. OCAPP also helps customers identify and implement pollution prevention measures that can save money, increase business performance and benefit the environment. Services of the office include a toll-free hotline, on-site compliance and pollution prevention assessments, workshops/training, plain-English publications library and assistance in completing permit application forms. Additional information is available at: <http://epa.ohio.gov>.