

**Environmental
Protection
Agency**

Hearing Summary

Rule Package: Infectious Waste Rules

Original filing date: October 17, 2024

Public comment start date: October 17, 2024

Public comment end date: November 22, 2024

Public hearing date: November 22, 2024

List of Rules: 3745-27-30, 3745-27-32, 3745-27-33, 3745-27-35, 3745-27-36, 3745-27-37, 3745-27-38, 3745-27-39, 3745-28-01, 3745-28-07, 3745-500-01, 3745-500-02, 3745-500-210, 3745-500-220, 3745-501-05, 3745-550-01, 3745-570-01, 3745-570-02, 3745-570-31, 3745-570-100, 3745-570-110, 3745-570-120, 3745-570-125, 3745-570-130, 3745-570-200, 3745-570-201, 3745-570-202, 3745-570-203, 3745-570-204, 3745-570-205, 3745-570-210, 3745-570-211, 3745-570-212, 3745-570-213, 3745-570-219, 3745-570-220, 3745-570-221, 3745-570-222

Were there any participants in this public hearing beyond Ohio EPA staff or JCARR staff?

☒ Yes

☐ No

Were there comments received during the public comment period outside of those presented at this hearing?

☒ Yes

☐ No

This hearing summary has been compiled to meet the requirements of Section 119.03 of the Revised Code. This hearing summary includes this cover sheet and the following attachments:

- 1. Attachment A - A copy of the public notice for this hearing.**
- 2. Attachment B - A copy of the sign-in sheet for this hearing.**
- 3. Attachment C - A copy of the script read into the record to begin and end the hearing.**
- 4. Attachment D - Response to comments.**

Ohio EPA's response to comments document includes the comments received, who commented, the agency response to comments, and a statement of whether or not the rule was changed due to the comments.

Ohio EPA digitally records all public hearings for rules. The digital recordings are available upon request. These recordings may be sent out for transcription if necessary.

BEFORE THE
OHIO ENVIRONMENTAL PROTECTION AGENCY

Public Notice
Proposed Rulemaking Governing
Infectious Waste Rules

Notice is hereby given that the Director of Environmental Protection, under the authority of Sections 3714.02, 3714.022, 3714.09, 3734.02, 3734.021, 3734.026, 3734.05, 3734.12, 3734.57, 3734.70, 3734.71, 3734.72, 3734.73, and 3734.74 of the Ohio Revised Code (ORC) and in accordance with ORC Chapter 119, proposes to original file the following rules of the Ohio Administrative Code:

Rule Number	Rule Title	Action
3745-27-30	Standards for generators of infectious wastes.	Rescind
3745-27-32	Standards for the operation of infectious waste treatment facilities.	Rescind
3745-27-32	Standards for the operation of infectious waste treatment facilities.	New
3745-27-33	Disposal paper system.	Rescind
3745-27-35	Standards for handling infectious wastes.	Rescind
3745-27-36	Registration requirements for generators of infectious waste.	Rescind
3745-27-37	Infectious waste treatment facility permit to install application.	Rescind
3745-27-37	Infectious waste treatment facility permit to install application.	New
3745-27-38	Alternative infectious waste treatment technology approval process.	Rescind
3745-27-39	Final closure of infectious waste treatment facilities.	Rescind
3745-28-01	Infectious waste host fee – definitions.	Amend
3745-28-07	Infectious waste host fees.	Amend
3745-500-01	General administration – applicability.	Amend
3745-500-02	General administration – definitions.	Amend
3745-500-210	Variances for solid waste facilities.	Amend
3745-500-220	Exemptions from the requirements of Chapters 3714. and 3734. of the Revised Code.	Amend
3745-501-05	Licensing requirements.	Amend
3745-550-01	Solid waste incinerator or energy recovery facility - applicability.	Amend
3745-570-01	Infectious waste – applicability.	New
3745-570-02	Definitions.	New
3745-570-31	Handling and storage of infectious waste.	New
3745-570-100	Infectious waste generators – general obligations.	New
3745-570-110	Requirements for small generators of infectious waste.	New
3745-570-120	Requirements for large generators of infectious waste.	New
3745-570-125	Registration certificate for large generators of infectious waste.	New
3745-570-130	Disposal paper.	New
3745-570-200	General requirements for infectious waste treatment facilities.	New
3745-570-201	Approved infectious waste treatment methods.	New
3745-570-202	Incineration.	New
3745-570-203	Autoclaving.	New
3745-570-204	Chemical treatment of cultures with sodium hypochlorite solution.	New
3745-570-205	Ozone exposure treatment.	New
3745-570-210	Alternative infectious waste treatment technology request.	New

3745-570-211	Approval criteria for issuance of an alternative infectious waste treatment technology approval.	New
3745-570-212	Alternative infectious waste treatment technology efficacy testing.	New
3745-570-213	Alternative infectious waste treatment technology ten year update.	New
3745-570-219	Infectious waste treatment facilities - permit and license provisions.	New
3745-570-220	Infectious waste treatment facility permit to install application.	New
3745-570-221	Permit to install issuance.	New
3745-570-222	Closure of an infectious waste treatment facility.	New

Ohio Administrative Code (OAC) Chapters 3745-27 and 3745-28 currently contain the requirements for infectious waste generators and treatment facilities. OAC Chapter 3745-500 contains multi-program administration rules, OAC Chapter 3745-501 contains solid waste, infectious waste, and construction and demolition debris licensing provisions, and OAC Chapter 3745-550 is the program chapter for solid waste incinerators.

The purpose of this rule making is to satisfy the requirements of Ohio Revised Code section 106.03. As part of this rulemaking effort, Ohio EPA re-organized the infectious waste rules into a new program chapter in OAC Chapter 3745-570 and rescinded the existing rules in OAC Chapter 3745-27. This proposed rulemaking effort aims to make the requirements clearer and easier to navigate.

The public comment period will run until November 22, 2024. A public hearing on this proposed rulemaking will be held to consider public comments in accordance with Section 119.03 of the Ohio Revised Code. Ohio EPA will be holding an in-person and virtual public hearing on the rules on November 22, 2024, at 10:30 a.m. During the hearing, the public may submit written comments on the record about the proposed rules and, if participating in person, may provide comments verbally.

The in-person hearing will be located at Ohio EPA, Suite 700, 50 W. Town Street, Columbus, Ohio 43215. Anyone wishing to participate virtually must register in advance for the meeting at: <https://attendee.gotowebinar.com/register/8610623445458662751>. Registration for the in-person hearing is not required.

Persons intending to give testimony at the hearing should notify the Ohio EPA Office of Communications and Outreach, P.O. Box 1049, Columbus, Ohio 43216-1049, (614) 644-2160 or by emailing mary.mccarron@epa.ohio.gov. Prior registration will ensure that registrants are heard ahead of those individuals who register at the hearing. Oral testimony may be limited to five minutes, depending on the number of persons testifying. All interested persons are entitled to attend or be represented and to present oral and/or written comments concerning the proposed rule-making.

Written testimony should be emailed to the attention of Michelle Mountjoy at michelle.mountjoy@epa.ohio.gov. Written comments may also be submitted to the Hearing Officer at the public hearing. Written testimony will receive the same consideration as oral testimony. All testimony received at the hearing or by close of business on November 22, 2024 will be considered by Ohio EPA prior to final action on this rulemaking proposal. Written comments submitted after this date may be considered as time and circumstances permit.

Questions regarding this rule package should be directed to Michelle Mountjoy at the Division of Materials and Waste Management at (614) 728-5372 or michelle.mountjoy@epa.ohio.gov.

To receive a copy of the proposed rules, please contact the DMWM receptionist at (614) 644-2621. In addition, full copies of all proposed rules are available for review at any Ohio EPA district office and at the Ohio EPA

central office. The proposed rules are also accessible on DMWM web page at <https://epa.ohio.gov/divisions-and-offices/materials-and-waste-management/regulations/proposed-rules>.

To request a reasonable accommodation due to a disability, visit <https://epa.ohio.gov/ada>.

Attachment B – Attendance List

Michael Goode, Ohio Department of Health

Amy Holinbaugh, Mahoning County Health Department

Lauren Stein, Lucas County Health Department

Shawn Huelsman, U.S. Department of Veterans Affairs

Kelly McQuain, Wayne County Health Department

Attachment C – Hearing Script

DMWM Infectious Waste Rules Hearing

November 22, 2024

Hello and welcome to Ohio EPA's public hearing regarding the Division of Materials and Waste Management's proposed rules. My name is Mary McCarron and I'm hosting today's public hearing. With me today from Ohio EPA are Michelle Mountjoy and Mandi Payton. In a moment, we will move to the public hearing where we will take official comments on the proposed rules.

Before we get started, I'd like to go over a few items to help our online participants navigate the GoTo platform.

On this slide you will see an example screenshot of your Attendee interface. You should see something that looks like this on your computer desktop on the right-hand side of your screen. For this public hearing, you are listening in using your computer audio. If you are having sound issues, try refreshing your browser. If that doesn't work, try logging off and logging back in.

Please submit public comments by clicking on the question mark icon and typing them into the Questions pane on your attendee interface. All comments submitted online will be read aloud for the whole audience to hear.

You can also click the handouts button to download included documents.

For those attending in person, you may submit your testimony verbally by raising your hand and moving close to the broadcast tablet, stating your name, and proceeding with your testimony when we call on you.

PUBLIC HEARING SPEECH

Thank you for taking time to attend this hearing before Ohio EPA. The purpose of the hearing today is to obtain comments from any interested person regarding Ohio EPA's proposed rules.

Ohio EPA is proposing to original file the following amended rules in the Ohio Administrative Code Chapters.

3745-27

3745-28

3745-500

3745-501

3745-550

3745-570

Ohio Administrative Code (OAC) Chapters 3745-27 and 3745-28 currently contain the requirements for infectious waste generators and treatment facilities. OAC Chapter 3745-500 contains multi-program administration rules, OAC Chapter 3745-501 contains solid waste, infectious waste, and construction and demolition debris licensing provisions, and OAC Chapter 3745-550 is the program chapter for solid waste incinerators. The purpose of this rule making is to satisfy the requirements of Ohio Revised Code section 106.03. As part of this rulemaking effort, Ohio EPA re-organized the infectious waste rules into a new program chapter in OAC Chapter 3745-570 and rescinded the existing rules in OAC Chapter 3745-27. This proposed rulemaking effort aims to make the requirements clearer and easier to navigate.

These rules have been filed with the Joint Committee on Agency Rule Review. Copies of the rules are available for public review on our website.

All interested persons are entitled to attend or be represented, and to present written comments concerning the proposed rules. All written comments received as part of the official record will be considered by the director of Ohio EPA.

To be included in the official record, written comments must be received by Ohio EPA by the close of business, today, November 22, 2024. These comments may be typed into the GoTo platform, spoken in person today, or emailed to michelle.mountjoy@epa.ohio.gov. All emailed comments submitted for the record receive the same consideration as typed or in-person testimony given today.

Written statements submitted after today may be considered as time and circumstances permit but will not be part of the official record of the hearing.

This hearing allows citizens to provide input. Therefore, we will not be able to answer questions today.

YOU MAY NOW SUBMIT COMMENTS. I will read aloud any comments we receive in the GoTo platform. If you are attending in-person and would like to submit testimony, please raise your hand, and wait to be called on. I will keep the GoTo platform open until 11 a.m. to provide time for participants to type in comments.

CLOSING

We will close the hearing. After the hearing closes, we will accept written comments through 5:00 p.m. today. You can send those comments to the email address on the screen.

Thank you for your comments, cooperation, and participation in Ohio EPA's decision-making process. The time is now 11:00 a.m. and this hearing is concluded.



**Environmental
Protection
Agency**

**Division of Materials and Waste Management
Response to Comments**

Rules: Infectious Waste and associated multi-program rules, Ohio Administrative Code (OAC) Chapters 3745-27, 3745-28, 3745-500, 3745-501, 3745-550, and 3745-570

Agency Contact for this Package

Michelle Mountjoy, Division of Materials and Waste Management (DMWM), (614) 728-5372, michelle.mountjoy@epa.ohio.gov

Ohio EPA held a public hearing on November 22, 2024, regarding infectious waste rules. This document summarizes the comments and questions received during the associated comment period, which ended on November 22, 2024.

Ohio EPA reviewed and considered all comments received during the public comment period. By law, Ohio EPA has authority to consider specific issues related to protection of the environment and public health.

In an effort to help you review this document, the questions are grouped by topic and organized in a consistent format. The name of the commenter follows the comment in parentheses.

3745-570-31 Handling and storage of infectious waste.

Comment 1: Regarding the use of reusable sharps and RMW containers, are generators that utilize RMW companies that reside either in the State of Ohio or another state (e.g. Michigan) (required) to ensure that treatment facilities meet the standards to clean reusable containers using a Tuberculocidal disinfectant as defined by EPA regulatory standards?

Is there a Log requirement that is required that these companies will need to meet for proper disinfection?

Additionally, is there a requirement for mechanical vs. manual cleaning of these containers? (Shawn Huelsman, U.S. Department of Veterans Affairs)

Response 1: The rules in OAC Chapter 3745-570 allow the reuse of primary and secondary containers if they are constructed of non-porous material, are empty, and have been properly cleaned and disinfected. While there is no Log requirement related to the disinfection of the containers, the rule does specify the appropriate methods to be employed to properly disinfect the containers prior to reuse. Any generator seeking to reuse containers would need to ensure the appropriate standards are met prior to reuse, including the proper cleaning and disinfection of the containers. No changes are necessary in response to this comment.

3745-570-100 Infectious waste generators – general obligations.

Comment 2: Paragraph (F). Does the (paragraph) remove the (14-day) requirement for generators? I see that the (14-day) requirement remains in effect for treatment facilities. (Shawn Huelsman, U.S. Department of Veterans Affairs)

Response 2: Through discussions with the stakeholder, Ohio EPA clarified the slight confusion between the fourteen-day timeframe in OAC Rule 3745-570-31 and the sixty-day timeframe in OAC Rule 3745-570-100. The fourteen-day timeframe in OAC Rule 3745-570-31 pertains to the duration that infectious waste can be stored by an infectious waste treatment facility before the infectious waste must be treated. The sixty-day timeframe in OAC Rule 3745-570-100 pertains to the allowable timeframe for storage by generators of infectious waste after the containers are closed and no longer in use. No changes were made in response to this comment.

3745-570-200 General requirements for infectious waste treatment facilities.

Comment 3: While reading the rules, this is unclear on what standards apply to those Generators that also treat their waste onsite vs those requirements of a true treatment facility. It also does not discuss the requirements for treating the different RMW waste streams other than for RMW contaminated with radiological substances. An example would be the current requirements for Trace Chemo and Pathological waste needing to be incinerated. Additionally, it does not mention if Generators will be allowed to treat sharps related waste with their onsite treatment methods. (Shawn Huelsman, U.S. Department of Veterans Affairs)

Response 3: OAC Rule 3745-570-200 is applicable to owners and operators of both licensed and unlicensed infectious waste treatment facilities. Chemotherapy wastes might not meet the definition of infectious waste unless the waste contains materials included under division (R) of ORC Section 3734.01. In those instances, the wastes would be addressed by the rules in the same manner as other infectious waste and chemotherapy waste is therefore not separately addressed in these rules. No changes were made in response to this comment.

3745-570-203 Autoclaving.

Comment 4: The stated appendix within the rule does not apply to all autoclaves. Typically, the autoclaves that are being utilized by generators use a Pre-vacuum vs. Gravity Displacement chamber. This changes the matrix and the requirements for holding temperature for 60 minutes. Typical Pre-Vacuum settings as set by the CDC for Human Surgical Instrumentation Sterilization is 270 Degrees F. for 3(0)-minute sterilization cycle. VA Northeast Ohio Health Care System is currently processing this at over 280 degrees F. for 35-minute sterilization cycle at a PSI of 37. This does show absolute kill of our BIs weekly but can be overkill based on current pre-vacuum technology.

It is expressed that the monitoring must be continuous. This has been expressed to us

that we need to show in 1-minute intervals, but it does not expressly state this within the regulations. With 1-minute intervals, there will be changes within the chamber due to the pulses and maintaining the chamber at such a high temperature. Sometimes these intervals are greater than + or – 2 but remains at a temperature over 280 degrees. (Shawn Huelsman, U.S. Department of Veterans Affairs)

Response 4: In response to this comment, OAC Rule 3745-570-203(C)(2)(b) will be amended to require weekly biological testing if the autoclave temperature and pressure readings are below or not within two degrees or two pounds per square inch over the corresponding reading specified in the appendix to the rule. This rule was placed in “to be refiled” status with JCARR on December 5, 2024.

Comment 5: The regulation also states to place the BI challenge pack in the center of the load. This makes sense in gravity displacement sterilizers since this is commonly where the drain is located. For Pre-Vacuum sterilizers, the best place for the challenge pack is directly over the drain which is located at the front of the unit. This is the absolute hardest place to sterilize within these chambers and where one will receive their best challenge. (Shawn Huelsman, U.S. Department of Veterans Affairs)

Response 5: In response to this comment, Ohio EPA will be amending OAC Rule 3745-570-203 to require the challenge pack to be placed in the location that poses the greatest challenge to the technology. This rule was placed in “to be refiled” status with JCARR on December 5, 2024.

Comment 6: Based on the pre-vacuum technology, the autoclave section should separate out those autoclave units that use Gravity displacement vs Pre-Vacuum since these are two different standards. Pre-Vacuum sterilizer units should look to adopt some standards stated in AAMI ST-79 since this is the common technology used in health care facilities for generator treatment (other than the locations that use ozone treatment). (Shawn Huelsman, U.S. Department of Veterans Affairs)

Response 6: The AAMI website indicates that the cited standard is applicable to medical devices, *i.e.*, devices that have been pre-cleaned and are ready to be sterilized for patient use, and does not speak to the treatment of infectious waste. No changes were made in response to this comment.

End of Response to Comments