



Early Stakeholder Outreach Infectious Waste Program Rules

Rules 3745-27-01, 3745-27-30, 3745-27-32, 3745-27-33, 3745-27-35, 3745-27-36, 3745-27-37, 3745-27-38, 3745-27-39, and Chapter 3745-28

Ohio EPA prepares early stakeholder outreach fact sheets to ensure stakeholders are brought into the review process as early as possible and to obtain additional input and discussion before development of interested party draft rules.

What do OAC Rules 3745-27-01, 3745-27-30 through 3745-27-39, and Chapter 3745-28 cover?

Ohio Administrative Code (OAC) rules 3745-27-01, 3745-27-30 through 3745-27-39, and Chapter 3745-28 provide the definitions and requirements for infectious waste generators and treatment facilities in the state of Ohio.

Why are these rules being sent out for Early Stakeholder Outreach?

Ohio EPA Division of Materials and Waste Management (DMWM) is seeking early stakeholder input on revisions to the infectious waste rules to gain feedback on opportunities to improve these rules. As part of the rule-making process, Ohio EPA is required by Section 121.39 of the Ohio Revised Code to consult with organizations that represent political subdivisions, environmental interests, business interests, and others affected by the rules. The Ohio EPA is offering your organization the opportunity to comment on these rules before the division formally proposes them.

The first step in the rule-making process is for Ohio EPA to identify that a rule needs to be amended, rescinded, or created. In response to EO 2011-01K, Ohio EPA has added an additional step to ensure stakeholders are brought into the rule process as early as possible. This additional interested party notification and request for information will allow for early feedback before the rule language has been developed by the Agency.

What changes are being considered?

- Reorganizing the infectious waste rules into their own program chapter, Ohio Administrative Code 3745-570 would allow the infectious waste rules to be more easily found in their own rule chapter instead of crammed into the existing solid waste chapter OAC 3745-27. Reorganization will reduce unnecessary duplication within the regulations and provide an easier to read and more user friendly rule set. An example of one approach to this reorganization is included with this document.
- Off-site infectious waste storage conditions and timeframes from infectious waste generators to treatment facilities would be reestablished to prevent instances of aged untreated infectious waste and illegal disposal of large accumulations of infectious waste.
- Expand infectious waste generators use of bleach as a chemical treatment method to treat additional types of infectious wastes that are not pathological, beyond the current limit of infectious stocks and cultures.
- To include alkaline hydrolysis as a treatment method approved by rule.

How can I provide input?

The Agency is seeking stakeholder input on the OAC rules 3745-27-01, 3745-27-30 through 3745-27-39, and 3745-28. When preparing your comments, be sure to:

- explain your views as clearly as possible;
- describe any assumptions used;
- provide any technical information and/or data used to support your views;
- explain how you arrived at your estimate for potential burdens, benefits or costs;
- provide specific examples to illustrate your views; and
- offer alternatives.

Written comments will be accepted through close of business Friday, April 21, 2017. Please submit input to:

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Columbus, OH 43216-1049
michelle.mountjoy@epa.ohio.gov

What if I have questions?

Please contact Alison Shockley at (614) 728-5335 or email alison.shockley@epa.ohio.gov.

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Learn more at an Ohio EPA hosted webinar.

You are invited to join an Ohio EPA hosted webinar from 10:30 a.m. to 11:30 a.m. on Tuesday, April 4, 2017, to answer questions regarding this Early Stakeholder Outreach on these rules, the general rule-making process, the opportunities for stakeholder involvement, and to listen to stakeholder suggestions. For information on how to participate in the webinar contact Michelle Mountjoy at: michelle.mountjoy@epa.ohio.gov.

Who will be regulated by these rules?

The infectious waste rules only apply to generators of infectious waste and infectious waste treatment facilities.

What input is the Agency seeking?

The following questions may help guide you as you develop your comments.

- Is the general regulatory framework proposed the most appropriate? Should the Agency consider any alternative framework?
- What options are available for improving an identified concept?
- Are there considerations the Agency should take into account when developing a specific concept?
- Is there any information or data the Agency should be aware of when developing program concepts or rule language?

Ohio EPA would especially like to hear information regarding the following from stakeholders who may be impacted by the new program.

- Would this regulatory program have a positive impact on your business? Please explain how.
- If you feel that this rule has an adverse impact to business, as defined in section 107.52 of the Ohio Revised Code, please provide a summary of the estimated cost of compliance with the rules. Specifically, please identify the scope of the impacted business community; identify the nature of the adverse impact (for example, license fees, fines, employer time for compliance); and quantify, to the best of your ability, the expected adverse impact from the regulation. The adverse impact can be quantified in terms of dollars, hours to comply, or other factors.

What is the rulemaking schedule?

After the Friday, April 21, 2017, comment deadline and consideration of stakeholder input, Ohio EPA will prepare changes to OAC rules 3745-27-01, 3745-27-30 through 3745-27-39, and 3745-28. The Agency's next step is then to release a draft version of chapter 3745-750 of the OAC for interested party review and comment.

A complete summary of [Ohio EPA's rule-making process](#) is available at <http://epa.ohio.gov/Rules.aspx>. Future steps will also include formally filing to amend OAC rules 3745-27-01, 3745-27-30 through 3745-27-39, and 3745-28 with the Joint Committee on Agency Rule Review (JCARR). At that time, JCARR will include the proposed rule on their meeting agenda and take public testimony. Visit JCARR's website for meeting dates and agenda items at <https://www.jcarr.state.oh.us/>.

How can I track the program and rule-development progress?

Stakeholders are encouraged to sign up for the Agency's electronic mailing list which provides automatic updates about various topics. Registered users will receive progress updates and be notified when new information is posted on the program website (epa.ohio.gov/dmwm/dmwmnonhazrules.aspx). To sign up, go to ohioepa.custhelp.com/ci/documents/detail/2/subscriptionpage.

Contact

For more information, contact Michelle Mountjoy at michelle.mountjoy@epa.ohio.gov or (614) 728-5372.

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Possible Structure of Infectious Waste Program Chapter

A dedicated infectious waste program Chapter 3745-570 would be where the infectious waste regulations would be re-located. Chapter 3745-570 may contain references to other rule chapters for more general areas common to multiple programs such as basic definitions, administration processes, and licensing. The following structure and rule numbering is intended as an illustration of one possible structure.

- **Rule 3745-570-01 Applicability.**
- **Rule 3745-570-02 Infectious Waste Definitions.**
- **Rule 3745-570-100-199 will be reserved for Infectious Waste Generators of less than fifty pounds of infectious waste in any one month (small generator).**
 - Rule 3745-570-100 Small Infectious Waste Generators.
 - Rule 3745-570-110 Operational Requirements
 - Rule 3745-570-115 Record Keeping
 - Rule 3745-570-120 Storage and Management
 - Rule 3745-570-130 Disposal
 - Rule 3745-570-140 Treatment
- **Rule 3745-570-200 through 249 will be reserved for Infectious Waste Generators of fifty or more pounds of infectious waste in any one month (large generator).**
 - Rule 3745-570-200 Large Infectious Waste Generators.
 - Rule 3745-570-205 Registration.
 - Rule 3745-570-210 Operational Requirements
 - Rule 3745-570-215 Record Keeping
 - Rule 3745-570-220 Storage and Management
 - Rule 3745-570-230 Disposal
 - Rule 3745-570-240 Treatment
- **Rule 3745-570-250 through 299 will be reserved for Infectious Waste Generators that treat on-site.**
 - Rule 3745-570-250 Infectious Waste Generators that treat on-site.
 - Rule 3745-570-255 Registration.
 - Rule 3745-570-260 Operational Requirements
 - Rule 3745-570-265 Record Keeping
 - Rule 3745-570-270 Storage and Management
 - Rule 3745-570-280 Disposal
 - Rule 3745-570-290 Treatment
 - Rule 3745-570-290 Final Closure of Infectious Waste Treatment facilities.
- **Rule 3745-570-300 through 349 will be reserved for Infectious Waste Treatment Facilities Requiring A Permit-To-Install.**
 - Rule 3745-570-300 Requirement of a Permit-To-Install for Infectious Waste Treatment Facilities
 - Rule 3745-570-310 Permit-To-Install Application
 - Rule 3745-570-320 Additional Criteria for Approval of Infectious Waste Treatment Facility Permit-To-Install
- **Rule 3745-570-350 through 399 will be reserved for Infectious Waste Treatment Facilities Requiring Annual License.**
 - Rule 3745-570-350 Requirement of an Annual License for Infectious Waste Treatment Facilities
 - Rule 3745-570-360 Annual License Application
 - Rule 3745-570-370 Additional Criteria for Approval of Infectious Waste Treatment Facility Annual License
- **Rule 3745-570-400 through 499 Infectious Waste Treatment Methods**
 - 3745-570-400 Approved Infectious Waste Treatment Methods
 - 3745-570-405 Incineration
 - 3745-570-406 Incineration Methodology
 - 3745-570-407 Incineration Specific Operational Criteria
 - 3745-570-408 Incineration Quality Assurance
 - 3745-570-410 Autoclaving

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- 3745-570-411 Autoclaving Methodology
- 3745-570-412 Autoclaving Specific Operational Criteria
- 3745-570-413 Autoclaving Quality Assurance
- 3745-570-414 Autoclaving Validation
- 3745-570-415 Peracetic Acid and Grinding
- 3745-570-416 Peracetic Acid and Grinding Methodology
- 3745-570-417 Peracetic Acid and Grinding Specific Operational Criteria
- 3745-570-418 Peracetic Acid and Grinding Quality Assurance
- 3745-570-420 Applied Heat Encapsulation for Sharps
- 3745-570-421 Applied Heat Encapsulation for Sharps Methodology
- 3745-570-422 Applied Heat Encapsulation for Sharps Specific Operational Criteria
- 3745-570-423 Applied Heat Encapsulation for Sharps Quality Assurance
- 3745-570-424 Applied Heat Encapsulation for Sharps
- 3745-570-425 Chemical Treatment
- 3745-570-426 Chemical Treatment Methodology
- 3745-570-427 Chemical Treatment Specific Operational Criteria
- 3745-570-430 Alkaline Hydrolysis Treatment (not in rule)
- 3745-570-431 Alkaline Hydrolysis Treatment Methodology
- 3745-570-432 Alkaline Hydrolysis Treatment Specific Operational Criteria
- 3745-570-433 Alkaline Hydrolysis Treatment Quality Assurance
- 3745-570-435 PIWS 3000 Treatment (not in rule)
- 3745-570-436 PIWS 3000 Treatment Methodology
- 3745-570-437 PIWS 3000 Treatment Specific Operational Criteria
- 3745-570-438 PIWS 3000 Treatment Quality Assurance
- 3745-570-490 Alternative Treatment Technology Approval
- 3745-570-491 Request for Statewide/Site-Specific Alternative Treatment Technology Approval
- 3745-570-495 Demonstration of Treatment Standard
- 3745-570-496 Statewide/Site-Specific Alternative Treatment Technology Approval Criteria
- 3745-570-497 Director's Approval of Statewide/Site-Specific Alternative Treatment Technology
- 3745-570-498 Director modification of Statewide/Site-Specific Alternative Treatment Technology Approval
- 3745-570-499 Director Revocation of Statewide/Site-Specific Alternative Treatment Technology Approval

Chapter 3745-5b00 Administrative Chapter

Chapter 3745-501 Licensing Chapter

Chapter 3745-502 Infectious Waste Treatment Facility Host Fees
