

the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 872 is amended as follows:

PART 872—DENTAL DEVICES

■ 1. The authority citation for part 872 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 872.5571 to subpart F to read as follows:

§ 872.5571 Auto titration device for oral appliances.

(a) *Identification.* An auto-titration device for oral appliances is a prescription home use device that determines a target position to be used for a final oral appliance for the reduction of snoring and mild to moderate obstructive sleep apnea.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must evaluate the following:

(i) Performance characteristics of the algorithm; and

(ii) All adverse events.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions for use, including the following:

(i) Validation of the closed loop algorithm;

(ii) Mechanical integrity over the expected use life;

(iii) Characterization of maximum force, distance, and speed of device movement; and

(iv) Movement accuracy of intraoral components.

(3) Performance testing must demonstrate the wireless compatibility, electrical safety, and electromagnetic compatibility of the device in its intended use environment.

(4) Software verification, validation, and hazard analysis must be performed.

(5) The patient-contacting components of the device must be demonstrated to be biocompatible.

(6) Performance data must validate the reprocessing instructions for any reusable components.

(7) Patient labeling must include:

(i) Information on device use,

including placement of sensors and mouthpieces;

(ii) A description of all alarms; and

(iii) Instructions for reprocessing any reusable components.

(8) A human factors assessment must evaluate simulated use of the device in a home use setting.

Dated: February 14, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–02824 Filed 2–19–19; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2018–0596; FRL–9989–56–Region 10]

Air Plan Approval; OR: Lane County Outdoor Burning and Enforcement Procedure Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving and incorporating by reference into the Oregon State Implementation Plan (SIP)

the Lane Regional Air Protection Agency’s (LRAPA) revised outdoor burning rule submitted by the Oregon Department of Environmental Quality (ODEQ) on July 19, 2018. The revised rule, as it applies in Lane County, Oregon, clarifies terminology and provides additional controls of outdoor burning activities, reducing particulate emissions and strengthening the Oregon SIP. In addition, the EPA is approving but not incorporating by reference the enforcement procedures and civil penalties rule for LRAPA submitted by the ODEQ on September 25, 2018. The revised rule brings the enforcement procedures and civil penalties rule, as it applies in Lane County, into alignment with recent changes in Oregon State regulations.

DATES: This final rule is effective March 22, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R10–OAR–2018–0596. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, *e.g.*, Confidential Business Information or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at <https://www.regulations.gov>, or please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Christi Duboiski at (360) 753–9081, or duboiski.christi@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document, wherever “we,” “us,” or “our” is used, it is intended to refer to the EPA.

Table of Contents

- I. Background
- II. Response to Comment
- III. Final Action
- IV. Incorporation by Reference
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- VI. Statutory and Executive Order Reviews

I. Background

On July 19, 2018 and September 25, 2018, the ODEQ and LRAPA submitted revisions to the Oregon SIP as they apply in Lane County. On November 18, 2018, the EPA proposed to approve the LRAPA Title 47 outdoor burning rule which provided clarification and additional controls of outdoor burning activities in Lane County (83 FR 60836).

We also proposed to approve the Title 15 enforcement procedure and civil penalties rule, bringing LRAPA's rule into alignment with recently approved State rules. The public comment period for our proposed action ended on December 26, 2018. We received no adverse comments.

II. Response to Comment

We received one comment in support of the proposed approval of the LRAPA Title 47 outdoor burning rule and the Title 15 enforcement procedure and civil penalties rule. A full copy of the comment received is available in the docket for this final action.

III. Final Action

We are approving, and incorporating by reference into the Oregon SIP, the submitted revisions to the LRAPA Title 47 outdoor burning rule, Sections 001, 005, 010 (except the definition of "nuisance"), 015 (except (1)(d) and (1)(h)), and 020 (except (3), (9)(i), and (10)). The revisions to Title 47 became State effective July 13, 2018 and were submitted to the EPA by the ODEQ and LRAPA on July 19, 2018. The submitted changes clarify terminology and provide additional controls of outdoor burning activities in Lane County, Oregon.

We are also approving, but not incorporating by reference, the submitted revisions to the LRAPA Title 15 enforcement procedures and civil penalty rule, Sections 001, 005, 015, 018, 020, 025, 030, 035, 040, 045, 055, 057, 060, and 065. The revisions to Title 15 became State effective on September 14, 2018 and were submitted by the ODEQ and LRAPA on September 25, 2018. The submitted changes align LRAPA's Title 15 rule with the ODEQ's Division 12 and provide LRAPA with authority needed for SIP approval.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, we are finalizing the incorporation by reference as described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these materials generally available through <https://www.regulations.gov> and at the EPA Region 10 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by the EPA for inclusion in the SIP, have been incorporated by reference by the EPA into that plan, are fully Federally-enforceable under

sections 110 and 113 of the CAA as of the effective date of the final rulemaking of the EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.¹

V. Oregon Notice Provision

Oregon Revised Statute 468.126, prohibits ODEQ from imposing a penalty for violation of an air, water or solid waste permit unless the source has been provided five days' advanced written notice of the violation and has not come into compliance or submitted a compliance schedule within that five-day period. By its terms, the statute does not apply to Oregon's title V program or to any program if application of the notice provision would disqualify the program from federal delegation. Oregon has previously confirmed that, because application of the notice provision would preclude EPA approval of the Oregon SIP, no advance notice is required for violation of SIP requirements.

VI. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Clean Air Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described

in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);

- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and it will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 22, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a

¹ 62 FR 27968 (May 22, 1997).

petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: February 4, 2019.
Chris Hladick,
Regional Administrator, Region 10.

For the reasons stated in the preamble, 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart MM—Oregon

■ 2. In § 52.1970:

■ a. In paragraph (c), table 4 is amended by revising the table heading, the

heading for “Title 47” and the entries “47–001”, “47–005”, “47–010”, “47–015”, and “47–020” and adding a footnote number 1 to the end of the table.

■ b. In paragraph (e), remove the table “Lane County Regional Air Pollution Authority Regulations, Approved But Not Incorporated by Reference” and add in its place the table “Lane Regional Air Protection Agency (LRAPA) Rules, Approved But Not Incorporated by Reference”.

The revisions and additions read as follows:

§ 52.1970 Identification of plan.

* * * * *
 (c) * * *

TABLE 4—EPA-APPROVED LANE REGIONAL AIR PROTECTION AGENCY (LRAPA) RULES FOR OREGON¹

LRAPA citation	Title/subject	State effective date	EPA approval date	Explanations
*	*	*	*	*
Title 47—Rules for Outdoor Burning				
47–001	General Policy	7/13/2018	2/20/2019, [insert Federal Register citation].	
47–005	Exemptions from these Rules	7/13/2018	2/20/2019, [insert Federal Register citation].	
47–010	Definitions	7/13/2018	2/20/2019, [insert Federal Register citation].	Except the definition of “nuisance”.
47–015	Outdoor Burning Requirements	7/13/2018	2/20/2019, [insert Federal Register citation].	Except (1)(d) and (1)(h).
47–020	Letter Permits	7/13/2018	2/20/2019, [insert Federal Register citation].	Except (3), (9)(i), and (10).
*	*	*	*	*

¹ EPA’s approval is limited to the extent the provisions relate to section 110 of the Clean Air Act and determining compliance with and for purposes of implementation of SIP-approved requirements.

* * * * *
 (e) * * *
 * * * * *

LANE REGIONAL AIR PROTECTION AGENCY (LRAPA) RULES, APPROVED BUT NOT INCORPORATED BY REFERENCE

LRAPA citation	Title/subject	State effective date	EPA approval date	Explanation
Title 13—General Duties and Powers of Board and Director				
13–005	Authority of the Agency	3/31/2014	10/5/2018, 83 FR 50274	
13–010	Duties and Powers of the Board of Directors.	3/31/2014	10/5/2018, 83 FR 50274	
13–020	Duties and Function of the Director	3/31/2014	10/5/2018, 83 FR 50274	
13–025	Conflict of Interest	3/31/2014	10/5/2018, 83 FR 50274	
13–030	Advisory Committee	3/31/2014	10/5/2018, 83 FR 50274	
13–035	Public Records and Confidential Information.	3/31/2014	10/5/2018, 83 FR 50274	
Title 14—Rules of Practice and Procedure				
14–110	Definitions	3/23/2018	10/5/2018, 83 FR 50274	

LANE REGIONAL AIR PROTECTION AGENCY (LRAPA) RULES, APPROVED BUT NOT INCORPORATED BY REFERENCE—
Continued

LRAPA citation	Title/subject	State effective date	EPA approval date	Explanation
Rulemaking				
14-115	Rulemaking Notice	3/23/2018	10/5/2018, 83 FR 50274	
14-120	Rulemaking Hearings and Process	3/23/2018	10/5/2018, 83 FR 50274	
14-125	Temporary Rules	3/23/2018	10/5/2018, 83 FR 50274	
14-130	Petition to Promulgate, Amend or Repeal Rule—Content of Petition, Filing of Petition.	3/23/2018	10/5/2018, 83 FR 50274	
14-135	Declaratory Rulings	3/23/2018	10/5/2018, 83 FR 50274	
Contested Cases				
14-140	Contested Case Proceedings Generally.	3/23/2018	10/5/2018, 83 FR 50274	
14-145	Agency Representation by Environmental Law Specialist.	3/23/2018	10/5/2018, 83 FR 50274	
14-147	Authorized Representative of Respondent other than a Natural Person in a Contested Case Hearing.	3/23/2018	10/5/2018, 83 FR 50274	
14-150	Liability for the Acts of a Person's Employees.	3/23/2018	10/5/2018, 83 FR 50274	
14-155	Consolidation or Bifurcation of Contested Case Hearings.	3/23/2018	10/5/2018, 83 FR 50274	
14-160	Final Orders	3/23/2018	10/5/2018, 83 FR 50274	
14-165	Default Orders	3/23/2018	10/5/2018, 83 FR 50274	
14-170	Appeal to the Board	3/23/2018	10/5/2018, 83 FR 50274	
14-175	Power of the Director	3/23/2018	10/5/2018, 83 FR 50274	
14-185	Request for Stay Pending Judicial Review.	3/23/2018	10/5/2018, 83 FR 50274	
14-190	Request for Stay—Motion to Intervene	3/23/2018	10/5/2018, 83 FR 50274	
14-200	Request for Stay—Agency Determination.	3/23/2018	10/5/2018, 83 FR 50274	
14-205	Request for Stay—Time Frames	3/23/2018	10/5/2018, 83 FR 50274	
Title 15—Enforcement Procedure and Civil Penalties				
15-001	Policy	9/14/2018	2/20/2019, [insert Federal Register citation]	
15-003	Scope of Applicability	6/13/1995	8/3/2001, 66 FR 40616	
15-005	Definitions	9/14/2018	2/20/2019, [insert Federal Register citation]	
15-010	Consolidation of Proceedings	6/13/1995	8/3/2001, 66 FR 40616	
15-015	Notice of Violation	9/14/2018	2/20/2019, [insert Federal Register citation]	
15-018	Notice of Permit Violations (NPV) and Exceptions.	9/14/2018	2/20/2019, [insert Federal Register citation]	
15-020	Enforcement Actions	9/14/2018	2/20/2019, [insert Federal Register citation]	
15-025	Civil Penalty Schedule Matrices	9/14/2018	2/20/2019, [insert Federal Register citation]	
15-030	Civil Penalty Determination Procedure (Mitigating and Aggravating Factors).	9/14/2018	2/20/2019, [insert Federal Register citation]	
15-035	Written Notice of Civil Penalty Assessment—When Penalty Payable.	9/14/2018	2/20/2019, [insert Federal Register citation]	
15-040	Compromise or Settlement of Civil Penalty by Director.	9/14/2018	2/20/2019, [insert Federal Register citation]	
15-045	Stipulated Penalties	9/14/2018	2/20/2019, [insert Federal Register citation]	
15-050	Additional Civil Penalties	6/13/1995	8/3/2001, 66 FR 40616	
15-055	Air Quality Classification of Violation	9/14/2018	2/20/2019, [insert Federal Register citation]	
15-057	Determination of Violation Magnitude	9/14/2018	2/20/2019, [insert Federal Register citation]	
15-060	Selected Magnitude Categories	9/14/2018	2/20/2019, [insert Federal Register citation]	
15-065	Appeals	9/14/2018	2/20/2019, [insert Federal Register citation]	

LANE REGIONAL AIR PROTECTION AGENCY (LRAPA) RULES, APPROVED BUT NOT INCORPORATED BY REFERENCE—
Continued

LRAPA citation	Title/subject	State effective date	EPA approval date	Explanation
Title 31—Public Participation				
31-0070	Hearing Procedures	3/23/2018	10/5/2018, 83 FR 50274	

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[FR Doc. 2019-02545 Filed 2-19-19; 8:45 am]
BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R03-OAR-2018-0508; FRL-9989-15-Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Reasonably Available Control Technology (RACT) State Implementation Plan (SIP) Under the 2008 Ozone National Ambient Air Quality Standard (NAAQS)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a revision to the State of Maryland’s state implementation plan (SIP). The State of Maryland’s SIP revision satisfies the volatile organic compound (VOC) reasonably available control technology (RACT) requirements for the 2008 8-hour ozone national ambient air quality standard (NAAQS). The State of Maryland will address RACT for oxides of nitrogen (NO_x) in another SIP submission. Maryland’s VOC RACT submittal for the 2008 ozone NAAQS includes certification that previously adopted RACT controls in Maryland’s SIP approved by EPA under the 1-hour ozone and 1997 8-hour ozone NAAQS were reviewed based on the currently available technically and economically feasible controls, and that they continue to represent RACT; a negative declaration for certain control technique guideline (CTG) categories that no facilities exist in the State for these certain categories; and adoption of new or more stringent RACT determinations where necessary. This action is being taken under the Clean Air Act (CAA).

DATES: This final rule is effective on March 22, 2019.

ADDRESSES: EPA has established a docket for this action under Docket ID

Number EPA-R03-OAR-2018-0508. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through <https://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Gregory A. Becoat, (215) 814 2036, or by email at becoat.gregory@epa.gov.

SUPPLEMENTARY INFORMATION: On August 18, 2016, the Maryland Department of the Environment (MDE) submitted a revision to its SIP that addresses the VOC requirements of RACT for the 2008 8-hour ozone NAAQS.

I. Background

A. General

Ozone is formed in the atmosphere by photochemical reactions between VOCs and NO_x in the presence of sunlight. In order to reduce ozone, the CAA requires control of VOC and NO_x emission sources to achieve emission reductions in moderate and above ozone nonattainment areas. Among effective control measures, RACT controls significantly reduce VOC and NO_x emissions from major stationary sources.

RACT is defined as the lowest emission limitation that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility.¹ Section 172(c)(1) of the CAA provides that SIPs for nonattainment areas must

¹ See December 9, 1976 memorandum from Roger Strelow, Assistant Administrator for Air and Waste Management, to Regional Administrators, “Guidance for Determining Acceptability of SIP Regulations in Non-Attainment Areas.” see also 44 FR 53761, 53762 (September 17, 1979).

include reasonably available control measures (RACT) for attainment of the NAAQS, including emissions reductions from existing sources through adoption of RACT. A major source in a nonattainment area is defined as any stationary source that emits or has the potential to emit NO_x or VOC emissions greater than a certain ton per year threshold that varies based on the ozone nonattainment classification of the area: Marginal, Moderate, Serious, or Severe. See “major stationary source” in CAA sections 182(b), 184(b) and 302. Sections 182(b)(2) and 182(f)(1) of the CAA require states with ozone nonattainment areas classified as moderate or higher to implement RACT controls on all stationary sources and source categories covered by a CTG document issued by EPA, and also on all major sources of VOC and NO_x emissions located in the area. EPA’s CTGs provide guidance for RACT control requirements for various VOC source categories. The CTGs typically identify a particular control level that EPA recommends as being RACT. In some cases, EPA has issued Alternative Control Techniques guidelines (ACTs), primarily for NO_x source categories, which in contrast to the CTGs, only present a range of possible control options but do not identify any particular option as the recommendation for what can be RACT. Section 183(c) of the CAA requires EPA to revise and update CTGs and ACTs as the Administrator determines necessary. States are required to implement RACT for the source categories covered by CTGs through the SIP.

Section 184(a) of the CAA establishes a single ozone transport region (OTR) comprising all or part of 12 eastern states and the District of Columbia,² including the entire State of Maryland. Section 184(b)(1)(B) and (2) of the CAA set forth requirements for states in the OTR. Specifically, section 184(b)(1)(B) requires the implementation of RACT in OTR states with respect to all sources of VOC covered by a CTG. Additionally,

² Only a portion of the Commonwealth of Virginia is included in the OTR.