

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on 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. 3501–3521). 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 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; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; 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 878

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 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

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

■ 2. Add § 878.4550 to subpart E to read as follows:

§ 878.4550 Autofluorescence detection device for general surgery and dermatological use.

(a) *Identification.* An autofluorescence detection device for general surgery and dermatological use is an adjunct tool

that uses autofluorescence to detect tissues or structures. This device is not intended to provide a diagnosis.

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

(1) In vivo testing under anticipated conditions of use must characterize the ability of the device to detect autofluorescent signals from tissues or structures consistent with the indications for use.

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

(3) Performance testing must demonstrate the electromagnetic compatibility and electrical, mechanical, and thermal safety of the device.

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

(5) Performance testing must demonstrate the sterility of patient-contacting components of the device.

(6) Performance testing must support the shelf life of device components provided sterile by demonstrating continued sterility and package integrity over the labeled shelf life.

(7) Performance testing must demonstrate laser and light safety for eye, tissue, and skin.

(8) Labeling must include the following:

(i) Instructions for use;

(ii) The detection performance characteristics of the device when used as intended; and

(iii) A shelf life for any sterile components.

Dated: April 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08731 Filed 4–22–22; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2021–0775; FRL–9330–02–R8]

Approval and Promulgation of Implementation Plans; Utah; Emissions Statement Rule and Nonattainment New Source Review Requirements for the 2015 8-Hour Ozone National Ambient Air Quality Standard for the Uinta Basin, Northern Wasatch Front and Southern Wasatch Front Nonattainment Areas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving state implementation plan (SIP) revisions submitted by the State of Utah. The revisions fulfill the emissions statement rule and nonattainment new source review (NNSR) requirements for the 2015 8-hour ozone national ambient air quality standard (NAAQS) for the Uinta Basin, Northern Wasatch Front, and Southern Wasatch Front Marginal nonattainment areas. Utah submitted an emissions statement rule revision and a separate NNSR certification to meet, in part, the nonattainment requirements for Marginal ozone nonattainment areas under the 2015 8-hour ozone NAAQS. The State’s submission of the emissions statement rule revision also included revisions to emissions reporting requirements for stationary sources, which are being approved in this final rule as well. The EPA is taking this action pursuant to sections 110, 172, and 182 of the Clean Air Act (CAA).

DATES: This rule is effective on May 25, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2021–0775. All documents in the docket are listed on the <http://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., 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 <http://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Matthew Lang, Air and Radiation Division, EPA, Region 8, Mailcode 8ARD–IO, 1595 Wynkoop Street, Denver, Colorado, 80202–1129, telephone number: (303) 312–6709, email address: lang.matthew@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document “we”, “us”, and “our” means the EPA.

I. Background

The background for this action is discussed in detail in our February 1, 2022 proposal.¹ In that document we

¹ Approval and Promulgation of Implementation Plans; Utah; Emissions Statement Rule and Nonattainment New Source Review Requirements for the 2015 8-Hour Ozone National Ambient Air Quality Standards for the Uinta Basin, Northern Wasatch Front and Southern Wasatch Front

proposed to approve the SIP revision submitted by Utah which included changes to Rule R307–150 concerning the level of detail of inventory data reported by certain sources as well as implementation of an annual ozone emissions statement rule for stationary sources in ozone nonattainment areas. Additionally, we proposed to approve the SIP revision submitted by Utah certifying that the state’s previously approved NNSR permit program meets the requirement stemming from the Marginal ozone nonattainment designations of the Uinta Basin, Northern Wasatch Front, and Southern Wasatch Front areas. We proposed to approve the revisions because they were prepared in accordance with the requirements in sections 182(a)(3)(B), 172(c)(5) and 172(b) of the CAA.

EPA held a 30-day comment period on the proposed rulemaking beginning on February 1, 2022 and closing on March 3, 2022. We did not receive any comments on the proposed rulemaking during the comment period.

II. Final Action

The EPA is finalizing approval of revisions to Rule R307–150 submitted by the State of Utah on November 3, 2020, including a revision to implement an emissions statement rule which was prepared in accordance with section 182(a)(3)(B) of the CAA. The EPA is also finalizing approval of the NNSR permit program certification submitted by the State of Utah on August 2, 2021, because the certified NNSR Permit Program was prepared in accordance with requirements of sections 172(c)(5) and 173 of the CAA and fulfills the specific minimum SIP requirements of 40 CFR 51.165.

III. Incorporation by Reference

In this document, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of Rule R307–150 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 www.regulations.gov and at the EPA Region 8 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 State Implementation Plan, 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.²

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the 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 CAA. 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);
- 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, 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 CAA; and
- Does not provide 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).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where 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 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. 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 June 24, 2022. 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 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, Greenhouse gases, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: April 11, 2022.

K.C. Becker,

Regional Administrator, Region 8.

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:

Nonattainment Areas, 87 FR 5435 (February 1, 2022).

² 62 FR 27968 (May 22, 1997).

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

Subpart TT—Utah

- 2. Amend § 52.2320 by:
 - a. In the table in paragraph (c):
 - i. Revising the entries “R307–150–01”, “R307–150–02”, “R307–150–03”, “R307–150–04”, “R307–150–05”,

- “R307–150–06”, and “R307–150–07” under the heading entitled “R307–150. Emission Inventories”.
 - ii. Adding the entry “R307–150–09”.
 - b. In the table in paragraph (e), adding the entry “Ozone (8-hour, 2015) NNSR Certification” under the heading entitled “Summary of Criteria Pollutant

Attainment Plans” at the end of the table.
 The revisions and additions read as follows:

§ 52.2320 Identification of plan.
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 (c) * * *

Rule No.	Rule title	State effective date	Final rule citation, date	Comments
*	*	*	*	*
R307–150. Emission Inventories				
R307–150–01	Purpose and General Requirements	9/3/2020	[insert Federal Register citation], 4/25/2022.	
R307–150–02	Definitions	9/3/2020	[insert Federal Register citation], 4/25/2022.	
R307–150–03	Applicability	9/3/2020	[insert Federal Register citation], 4/25/2022.	
R307–150–04	Sulfur Dioxide Milestone Inventory Requirements.	9/3/2020	[insert Federal Register citation], 4/25/2022.	
R307–150–05	Sources Identified in R307–150–3(2), Large Major Source Inventory Requirements.	9/3/2020	[insert Federal Register citation], 4/25/2022.	
R307–150–06	Sources Identified in R307–150–3(3)	9/3/2020	[insert Federal Register citation], 4/25/2022.	
R307–150–07	Exempted Hazardous Air Pollutants	9/3/2020	[insert Federal Register citation], 4/25/2022.	
*	*	*	*	*
R307–150–09	Annual Ozone Emission Statement	9/3/2020	[insert Federal Register citation], 4/25/2022.	
*	*	*	*	*

* * * * * (e) * * *

Rule title	State effective date	Final rule citation, date	Comments
*	*	*	*
Summary of Criteria Pollutant Attainment Plans			
*	*	*	*
Ozone (8-hour, 2015) NNSR Certification	7/29/2021	[insert Federal Register citation], 4/25/2022.	