

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 52**

[EPA-R07-OAR-2017-0477; FRL-9976-09—Region 7]

**Approval of Nebraska Air Quality Implementation Plans; Infrastructure SIP Requirements for the 2010 Nitrogen Dioxide and Sulfur Dioxide and the 2012 Fine Particulate Matter National Ambient Air Quality Standards****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is taking final action to approve certain elements of State Implementation Plan (SIP) submissions from the State of Nebraska for the 2010 Nitrogen Dioxide (NO<sub>2</sub>) and Sulfur Dioxide (SO<sub>2</sub>) National Ambient Air Quality Standards (NAAQS) and the 2012 Fine Particulate Matter (PM<sub>2.5</sub>) NAAQS. States are required to have a SIP that provides for the implementation, maintenance, and enforcement of the NAAQS. Whenever EPA promulgates a new or revised NAAQS, states are required to make a SIP submission to establish that they have, or to add, the provisions necessary to address various requirements to address the new or revised NAAQS. These SIPs are commonly referred to as “infrastructure” SIPs. The infrastructure requirements are designed to ensure that the structural components of each state’s air quality management program are adequate to meet the state’s responsibilities under the Clean Air Act (CAA).

**DATES:** This final rule is effective on May 3, 2018.

**ADDRESSES:** EPA has established a docket for this action under Docket ID No. EPA-R07-OAR-2017-0477. 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, *i.e.*, 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 information.

**FOR FURTHER INFORMATION CONTACT:** Mr. Gregory Crable, EnvironmentalProtection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at (913) 551-7391, or by email at [Crable.Gregory@epa.gov](mailto:Crable.Gregory@epa.gov).**SUPPLEMENTARY INFORMATION:**

Throughout this document “we,” “us,” and “our” refer to EPA. This section provides additional information by addressing the following:

- I. Background
- II. What is being addressed in this document?
- III. Have the requirements for approval of a SIP revision been met?
- IV. EPA’s Response to Comments
- V. What action is EPA taking?
- VI. Statutory and Executive Order Reviews

**I. Background**

EPA received Nebraska’s infrastructure SIP submissions addressing the 2010 NO<sub>2</sub> NAAQS, the 2010 SO<sub>2</sub> NAAQS, and the 2012 PM<sub>2.5</sub> NAAQS.<sup>1</sup> On September 20, 2017, EPA proposed to approve certain elements of these infrastructure SIP submissions from the State of Nebraska. *See* 82 FR 43926. In conjunction with the September 20, 2017, notice of proposed rulemaking (NPR), EPA issued a direct final rule (DFR) approving the same elements of the 2010 NO<sub>2</sub>, 2010 SO<sub>2</sub>, and 2012 PM<sub>2.5</sub> NAAQS infrastructure SIP submissions. *See* 82 FR 43848. However, in the DFR, EPA stated that if EPA received adverse comments by October 20, 2017, the action would be withdrawn and not take effect. EPA received one set of adverse comments prior to the close of the comment period. EPA withdrew the DFR on November 17, 2017. *See* 82 FR 54299. This action is a final rule based on the NPR. A detailed discussion of Nebraska’s SIP submissions and EPA’s rationale for approving the SIP submissions were provided in the DFR and the associated Technical Support Document (TSD) in the docket for this rulemaking and will not be restated here, except to the extent relevant to our response to the adverse public comment we received.

**II. What is being addressed in this document?**

EPA is taking final action to approve the infrastructure submissions as meeting the applicable submission requirements section 110(a)(1). EPA is approving certain elements of the 2010 NO<sub>2</sub> and SO<sub>2</sub> infrastructure SIP submissions from the State of Nebraska

<sup>1</sup> The EPA received the 2010 NO<sub>2</sub> infrastructure submission on February 7, 2013, the 2010 SO<sub>2</sub> infrastructure submission on August 22, 2013, and the 2012 PM<sub>2.5</sub> infrastructure submission on February 22, 2016.

received on February 7, 2013, and August 22, 2013, respectively. EPA is also taking action to approve certain elements of the 2012 PM<sub>2.5</sub> infrastructure submission received on February 22, 2016. Specifically, in regard to the 2010 NO<sub>2</sub> NAAQS, EPA is approving, the following SIP submission elements related to CAA section 110(a)(2): (A) through (C), (D)(i)(I)—Prongs 1 and 2, (D)(i)(II)—prong 3, (D)(ii), (E) through (H), and (J) through (M).

Regarding the 2010 SO<sub>2</sub> and 2012 PM<sub>2.5</sub> NAAQS, EPA is approving the State’s SIP submission addressing the following infrastructure elements of section 110(a)(2): (A) through (C), (D) (i) (II)—Prong 3, (D) (ii), (E) through (H), and (J) through (M). As discussed in the TSD, EPA is not acting, at this time, on section 110(a)(2)(D)(i)(I)—prongs 1 and 2, as it relates to the 2010 SO<sub>2</sub> NAAQS as those elements were not part of the state SIP submission. Section 110(a)(2)(D)(i)(I)—prongs 1 and 2, as it relates to the 2012 PM<sub>2.5</sub> NAAQS, were included in the state SIP submission. The EPA intends to act on section 110(a)(2)(D)(i)(I)—prongs 1 and 2, as it relates to the 2012 PM<sub>2.5</sub> NAAQS in a subsequent rulemaking action.

Regarding the 2010 NO<sub>2</sub> and SO<sub>2</sub> and the 2012 PM<sub>2.5</sub> infrastructure submissions and as explained in the TSD, EPA is not acting, at this time, on section 110(a)(2)(D)(i)(II)—prong 4.

As noted, a TSD is included as part of the docket to discuss the details of this action.

**III. Have the requirements for approval of a SIP revision been met?**

The state has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. A public comment period was held for the NO<sub>2</sub> infrastructure SIP from December 27, 2012, to January 28, 2013. The only comments were from the EPA, and the infrastructure SIP submission was revised to address the comments. A public hearing was held on January 28, 2013.

The state held a public comment period for the SO<sub>2</sub> infrastructure SIP from April 25, 2013, to May 28, 2013. NDEQ received comments from the Sierra Club on May 28, 2013. The state addressed the Sierra Club’s comments with no revisions to its proposed SIP. A public hearing was held on May 27, 2013.

A public comment period was held for the PM<sub>2.5</sub> infrastructure SIP from

November 23, 2015, to December 29, 2015. A public hearing was held on December 29, 2015. No comments were received.

All three submissions satisfied the completeness criteria of 40 CFR part 51, appendix V. As explained in more detail in the TSD, which is part of this docket, the revisions meet the substantive SIP requirements of the CAA, including section 110 and implementing regulations.

#### IV. EPA's Response to Comments

The public comment period on EPA's proposed rule opened September 20, 2017 the date of its publication in the **Federal Register** and closed on October 20, 2017. During this period, EPA received one comment letter. No changes were made to the proposals in this final action after consideration of the adverse comments received.

*Comment 1:* The commenter stated that with regard to 2010 NO<sub>2</sub> NAAQS, EPA has not shown that Nebraska is not significantly contributing to downwind problems due to interstate transport of NO<sub>x</sub>. The commenter specifically asserted that EPA should have addressed NO<sub>x</sub> emissions in Nebraska rather than only evaluated national level data, and that the lack of a requirement for near road monitors for phase 3 is not adequate to show no downwind issues. The commenter further contended that EPA must analyze all source categories including point sources and conduct modeling to show large point sources are not causing downwind contribution.

*Response 1:* The EPA disagrees with the commenter's assertions. As an initial matter, the question of whether emissions from Nebraska significantly contribute to nonattainment or interfere with maintenance of the NAAQS in violation of section 110(a)(2)(D)(i)(I) depends on whether there are areas in downwind states having or expected to have trouble attaining or maintaining the NAAQS. In the EPA's TSD, the EPA analyzed a variety of data and determined that there were no downwind areas in other states with air quality concerns with respect to the 2010 NO<sub>2</sub> NAAQS. EPA cited several pieces of data to support this conclusion. EPA first explained that at the time of designations for NO<sub>2</sub> in January of 2012, no areas of the country were violating the 2010 NO<sub>2</sub> NAAQS. EPA further reviewed monitoring and emissions trends since the designations and identified no areas that are having problems attaining or maintaining the NAAQS. In fact, the highest NO<sub>2</sub> near-road monitoring design value recorded in Colorado based on the most current available information at the time of

publication of the proposed rule (e.g. 2013 to 2015 data) is 72 parts per billion (ppb). Based on the most current available, certified and quality assured information (e.g. 2014 to 2016 data), the highest NO<sub>2</sub> near-road monitoring design value recorded in Colorado is 74 ppb. Both of these design values are well below the 2010 NO<sub>2</sub> NAAQS of 100 ppb. Thus, in the absence of any downwind air quality concerns, Nebraska cannot be found to contribute, let alone significantly contribute to downwind nonattainment or interfere with maintenance of the NAAQS. The commenter does not identify any flaws with EPA's assessment of the data.

Thus, the commenter is incorrect to state that EPA only relied on the lack of near-road monitors in Nebraska in concluding that the state is in compliance with the requirements of section 110(a)(2)(D)(i)(I). Moreover, because neither EPA nor the commenter have identified any downwind air quality problems to which Nebraska could contribute, the EPA does not agree that it was necessary to evaluate the impact of individual point sources in Nebraska, via modeling or any other analyses, on air quality in other states.

Finally, the commenter is incorrect in asserting that EPA failed to evaluate NO<sub>x</sub> emissions in Nebraska. In the TSD, EPA reviewed NO<sub>x</sub> emission trends in the state, which demonstrated that NO<sub>x</sub> emissions in Nebraska have followed a downward trend for 2011 to 2016.

EPA has demonstrated that Nebraska is not significantly contributing to downwind nonattainment or interfering with maintenance of the 2010 NO<sub>2</sub> NAAQS. Therefore, the EPA disagrees with the commenter's assertions and will approve elements of 110(a)(2)(D)(i)(I)—Prongs 1 and 2 for Nebraska's NO<sub>2</sub> infrastructure SIP submission.

*Comment 2:* The commenter stated that with respect to the PM<sub>2.5</sub> NAAQS, EPA does not have the discretion to "act at a later date." In addition, the commenter states that EPA is mandated by statute to act within 18 months of the state's submission, and that since the state's submission was received in February 2016, EPA has failed to act in a timely manner and does not have the luxury of acting at a later date. If EPA cannot approve the state's plan, the EPA must disapprove.

*Response 2:* EPA acknowledges the commenter's concern for the interstate transport of air pollutants. However, EPA disagrees with the commenter's argument that EPA cannot approve certain elements of an infrastructure SIP submission without also taking action

on the elements related to interstate transport.

EPA agrees with the commenter that it has an obligation to take action under section 110(k) on SIP submissions. However, EPA disagrees with the commenter's argument that the Agency cannot elect to act on individual parts or elements of a state's infrastructure SIP submission in separate rulemaking actions, as it deems appropriate. Section 110(k) of the CAA authorizes EPA to approve a SIP submission in full, disapprove it in full, or approve it in part and disapprove it in part, or conditionally approve it in full or in part, depending on the extent to which such plan meets the requirements of the CAA. This authority to approve state SIP submissions in separable parts was included in the 1990 Amendments to the CAA to overrule a decision in the Court of Appeals for the Ninth Circuit holding that EPA could not approve individual measures in a SIP submission without either approving or disapproving the plan as a whole. See S. Rep. No. 101-228, at 22, 1990 U.S.C.C.A.N. 3385, 3408 (discussing the express overruling of *Abramowitz v. EPA*, 832 F.2d 1071 (9th Cir. 1987)).

EPA interprets its authority under section 110(k) of the CAA as affording the Agency the discretion to approve, disapprove, or conditionally approve, individual elements of Nebraska's infrastructure SIP submission for the 2012 PM<sub>2.5</sub> NAAQS. EPA views discrete infrastructure SIP requirements, such as the requirements of section 110(a)(2)(D)(i)(I), as severable from other infrastructure SIP elements and interprets section 110(k) as allowing it to act on individual severable elements or requirements in a SIP submission. In short, EPA believes it has the discretion under section 110(k) of the CAA to act upon the various individual elements of the State's infrastructure SIP submission, separately or together, as appropriate. EPA will address the remaining elements of Nebraska's 2012 PM<sub>2.5</sub> NAAQS, infrastructure SIP submission in a separate rulemaking action or actions.

*Comment 3:* The commenter stated that with respect to the SO<sub>2</sub> NAAQS, since the state has not submitted a plan with regards to interstate transport, EPA must make a finding of failure to submit. The commenter further stated that acting is on a SIP is not discretionary and that EPA had yet to act.

*Response 3:* Please refer to Response 2. Additionally, in EPA's rulemaking proposing to approve Nebraska's infrastructure SIP for the 2010 1-hour SO<sub>2</sub> NAAQS, EPA stated that it was not

taking any action with respect to the good neighbor provisions in section 110(a)(2)(D)(i)(I) for this NAAQS. EPA understands the commenter's concern with respect to interstate transport. EPA will evaluate whether it is appropriate to make a finding of failure to submit in a separate action.

*Comment 4:* The commenter stated that for all three NAAQS, EPA does not have the discretion to not act on prong 4 and must act within 18 months of the state's submission. The commenter stated that EPA "does not have the luxury" of acting on a submission at a later date. If EPA cannot approve due to the state not having an approved Regional Haze SIP then EPA is required to disapprove.

*Response 4:* Please refer to Response 2. EPA is not required to act on the prong 4 elements of Nebraska's 2010 NO<sub>2</sub>, 2010 SO<sub>2</sub>, and 2012 PM<sub>2.5</sub> infrastructure SIP submissions in this particular rulemaking. Like the elements of section 110(a)(2)(D)(i)(I), prong 4 is severable from other infrastructure SIP elements and EPA interprets section 110(k) as allowing it to act on individual severable elements or requirements in a SIP submission.

With respect to the comment on prong 4, although EPA's evaluation of a state's SIP submission can be related to the status of that state's regional haze program,<sup>2</sup> Nebraska's regional haze program<sup>3</sup> is not relevant here because EPA is not taking action on that element of Nebraska's 2010 NO<sub>2</sub>, 2010 SO<sub>2</sub>, and 2012 PM<sub>2.5</sub> infrastructure SIP submissions in this rulemaking.

*Comment 5:* Initially in comments 2 through 4, the commenter indicated that this was the commenter's official notice of intent to EPA for failure to perform its nondiscretionary duty to act on the state's submission with respect to element D(i)(II)—prong 4 for the 2010 NO<sub>2</sub>, 2010 SO<sub>2</sub>, and 2012 PM<sub>2.5</sub> NAAQS, failure to perform its nondiscretionary duty to make a finding of failure to submit with respect to the interstate transport portions of SO<sub>2</sub> NAAQS, and for failing to perform its nondiscretionary duty to act on the

state's submission with regards to interstate transport of PM<sub>2.5</sub>.

*Response 5:* A public comment submitted on a proposal does not constitute notice of intent to sue the Administrator for failure to perform a nondiscretionary duty. Clean Air Act section 304(b)(2) requires a 60-day notice of a civil action against the Administrator for an alleged failure to perform a non-discretionary duty to the Administrator. EPA's regulations require that service of notice to the Administrator "shall be accomplished by certified mail addressed to the Administrator, Environmental Protection Agency, Washington, DC 20460." 40 CFR 54.2(a). The commenter's public comment submitted via *regulations.gov* does not satisfy the regulatory requirements for notices of intent to file suit against the Administrator for failure to perform a non-discretionary duty.

#### V. What action is EPA taking?

EPA is approving elements the infrastructure SIP submissions from Nebraska, which address the requirements of CAA sections 110(a)(1) and (2) as applicable to the 2010 NO<sub>2</sub> and SO<sub>2</sub> and 2012 PM<sub>2.5</sub> NAAQS. As stated in the above preamble, EPA is approving certain elements of the state's submission as meeting the submission requirements of section 110(a)(1) for all three submissions.

Regarding the 2010 NO<sub>2</sub> NAAQS, EPA is approving the following infrastructure elements of 110(a)(2): (A) through (C), (D)(i)(I)—Prongs 1 and 2, (D)(i)(II)—prong 3, (D)(ii), (E) through (H), and (J) through (M). As explained in the TSD, EPA intends to act on section 110(a)(2)(D)(i)(II)—prong 4, in a subsequent rulemaking.

EPA is approving the following infrastructure elements of 110(a)(2) as it relates to the 2010 SO<sub>2</sub> and the 2012 PM<sub>2.5</sub> NAAQS: (A) through (C), (D) (i) (II)—Prong 3, (D) (ii), (E) through (H), and (J) through (M). As discussed in the TSD, EPA intends to act on section 110(a)(2)(D)(i)(II)—prong 4, in a subsequent rulemaking and is not acting at this time on section 110(a)(2)(D)(i)(I)—prongs 1 and 2, for both the 2010 SO<sub>2</sub> and 2012 PM<sub>2.5</sub> NAAQS.

Based upon review of the state's infrastructure SIP submissions for the 2010 NO<sub>2</sub> and SO<sub>2</sub> NAAQS as well as the 2012 PM<sub>2.5</sub> NAAQS, and relevant statutory and regulatory authorities and provisions referenced in the submissions or referenced in Nebraska's SIP, EPA believes that Nebraska has the infrastructure to address all applicable required elements of sections 110(a)(1)

and (2) (except otherwise noted) to ensure that the 2010 NO<sub>2</sub> and SO<sub>2</sub> NAAQS and the 2012 PM<sub>2.5</sub> NAAQS are implemented in the state.

#### VI. 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, 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);
- 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 (Public Law 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 EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible

<sup>2</sup> EPA's 2013 Guidance of Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2) provides that "[o]ne way in which prong 4 may be satisfied for any relevant NAAQS is through an air agency's confirmation in its infrastructure SIP submission that it has an approved regional haze SIP . . . ." 2013 Guidance at 33, [https://www3.epa.gov/airquality/urbanair/sipstatus/docs/Guidance\\_on\\_Infrastructure\\_SIP\\_Elements\\_Multipollutant\\_FINAL\\_Sept\\_2013.pdf](https://www3.epa.gov/airquality/urbanair/sipstatus/docs/Guidance_on_Infrastructure_SIP_Elements_Multipollutant_FINAL_Sept_2013.pdf).

<sup>3</sup> Federal Implementation Plan for Best Available Retrofit Technology Determination, 77 FR 40150 (July 6, 2012).

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 CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 4, 2018. 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, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate

matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: March 15, 2018.

**James B. Gulliford,**

*Regional Administrator, Region 7.*

For the reasons stated in the preamble, EPA amends 40 CFR part 52 as set forth below:

**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 CC—Nebraska**

■ 2. Amend § 52.1420(e) by adding entries “(32)”, “(33)” and “(34)” in numerical order to read as follows:

**§ 52.1420 Identification of Plan.**

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(e) \* \* \*

**EPA-APPROVED NEBRASKA NONREGULATORY PROVISIONS**

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA Approval date	Explanation
(32) Section 110(a)(2) Infrastructure Requirements for the 2010 NO <sub>2</sub> NAAQS.	Statewide .....	2/7/13	4/3/2018, [Insert <b>Federal Register</b> citation].	This action addresses the following CAA elements 110(a)(2)(A) through (C), (D)(i)(I)—Prongs 1 and 2, (D)(i)(II)—Prong 3, (D)(ii), (E) through (H), and (J) through (M). [EPA-R07-OAR-2017-0477; FRL-9976-09-Region 7].
(33) Section 110(a)(2) Infrastructure Requirements for the 2010 SO <sub>2</sub> NAAQS.	Statewide .....	8/22/13	4/3/2018, [Insert <b>Federal Register</b> citation].	This action addresses the following CAA elements 110(a)(2)(A) through (C), (D)(i)(II)—Prong 3, (D)(ii), (E) through (H), and (J) through (M). [EPA-R07-OAR-2017-0477; FRL-9976-09-Region 7].
(34) Section 110(a)(2) Infrastructure Requirements for the 2010 PM <sub>2.5</sub> NAAQS.	Statewide .....	2/22/16	4/3/2018 and [Insert <b>Federal Register</b> citation].	This action addresses the following CAA elements 110(a)(2)(A) through (C), (D)(i)(II)—Prong 3, (D)(ii), (E) through (H), and (J) through (M). [EPA-R07-OAR-2017-0477; FRL-9976-09-Region 7].

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****45 CFR Part 5b**

[Docket Number NIH-2016-0001]

RIN 0925-AA63

**Privacy Act; Implementation**

**AGENCY:** National Institutes of Health (NIH), Department of Health and Human Services (HHS).

**ACTION:** Final rule.

**SUMMARY:** The Department of Health and Human Services (HHS or Department), through the National Institutes of Health (NIH), is issuing this final rule to make effective the exemptions that HHS/NIH proposed for a subset of records covered in a new Privacy Act system of records, System No. 09-25-0225, NIH Electronic Research Administration (eRA) Records (NIH eRA Records). The new system covers records used in managing NIH research and development applications and awards throughout the award lifecycle. The listed exemptions are necessary to maintain the integrity of the NIH extramural peer review and award processes, and will enable the agency to prevent, when appropriate, individual record subjects from having access to, and other rights under the Privacy Act with respect to, confidential source-identifying material in the records.

**DATES:** This final rule is effective April 3, 2018.

**FOR FURTHER INFORMATION CONTACT:** Celeste Dade-Vinson, NIH Privacy Act Officer, Office of Management Assessment, National Institutes of Health, 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, Maryland 20852, telephone 301-496-4606, fax 301-402-0169, email [privacy@mail.nih.gov](mailto:privacy@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** In accordance with the Privacy Act of 1974 (Privacy Act), the exemptions were described in a Notice of Proposed Rulemaking (NPRM) published for public notice and comment on December 8, 2016 (81 FR 88637). The new system of records was described in a System of Records Notice (SORN) published for public notice and comment the same day (81 FR 88690). Only certain confidential source-identifying information was proposed to be exempted, from the accounting of disclosures, access and amendment, and notification provisions in subsections (c)(3) and (d)(1) through (4) of the Privacy Act, based on subsection (k)(5) of the Act. One comment was received

on the NPRM and no comments were received on the SORN. No changes to the proposed exemptions or to the SORN were made as a result of comment received. The NIH research and development award programs provide funds through contracts, cooperative agreements, and grants to support biomedical and behavioral research and development projects and centers, training, career development, small business, and loan repayment and other research programs. The NIH is responsible to Congress and the U.S. taxpayers for carrying out its research and development award programs in a manner that facilitates research cost-effectively and in compliance with applicable statutes, rules and regulations, including 42 U.S.C. 217a, 281, 282, 41 U.S.C. 423 and 45 CFR part 75. The NIH uses an award process that relies on checks and balances, separation of responsibilities, and a two-level peer review system to ensure that funding applications submitted to the NIH are evaluated in a manner that is fair, equitable, timely, and free of bias. The two-level peer review system is authorized by 42 U.S.C. 216, 42 U.S.C. 282(b)(6), 42 U.S.C. 284(c)(3), and 42 U.S.C. 289a and governed by regulations at 42 CFR part 52h, "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects." The two-level system separates the scientific assessment of proposed projects from policy decisions about scientific areas to be supported and the level of resources to be allocated, which permits a more objective and complete evaluation than would result from a single level of review. The two-level review system is designed to provide NIH officials with the best available advice about scientific and technical merit as well as program priorities and policy considerations. The initial or first level review involves panels of experts established according to scientific disciplines, generally referred to as Scientific Review Groups (SRGs), whose primary function is to evaluate the scientific merit of grant applications. The second level of review of grant applications is performed by National Advisory Boards or Councils composed of both scientific and lay representatives. The recommendations made by these Boards or Councils are based not only on considerations of scientific merit as judged by the SRG but also on the relevance of a proposed project to the programs and priorities of the NIH. Referees are those individuals who supply reference or other letters of recommendations for a grant or cooperative agreement applicant.

Confidential referee and peer reviewer identifying material is contained in records such as reference or recommendation letters, reviewer critiques, preliminary or final individual overall impact/priority score records, and/or assignment of peer reviewers to an application and other evaluative materials and data, which referees and peer reviewers provide to the NIH Office of Extramural Research (OER) under express promises that they will not be identified as the sources of the information, and which NIH/OER compiles solely for the purpose of determining applicants' suitability, eligibility, or qualifications for federal contracts, grants, or cooperative agreements. To the extent that records in System No. 09-25-0225 are retrieved by personal identifiers for individuals other than the referees and reviewers (for example, individual applicants), the exemptions for the new system will enable the agency to prevent, when appropriate, those individual record subjects from having access to, and other rights under the Privacy Act with respect to, confidential source-identifying material in the records.

Under the Privacy Act (5 U.S.C. 552a), individuals have a right of access to records about them in federal agency systems of records, and other rights with respect to those records (such as notification, amendment, and an accounting of disclosures), but the Act permits certain types of systems of records (identified in section 552a (j) and (k)) to be exempted from certain requirements of the Act. Subsection (k)(5) permits the head of an agency to promulgate rules to exempt from the requirements in subsections (c)(3) and (d)(1) through (4) of the Act investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal contracts, to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence.

On December 8, 2016, HHS/NIH published a System of Records Notice (SORN) describing the new system (81 FR 88690). On the same date, HHS/NIH also published a Notice of Proposed Rulemaking (NPRM) (81 FR 88637) proposing to exempt a subset of records in the system of records under subsection (k)(5) of the Privacy Act from requirements pertaining to providing an