

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, 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 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

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

■ 2. Section 866.3373 is added to subpart D to read as follows:

§ 866.3373 Nucleic acid-based in vitro diagnostic devices for the detection of *Mycobacterium tuberculosis* complex (MTB-complex) and the genetic mutations associated with MTB-complex antibiotic resistance in respiratory specimens.

(a) *Identification.* Nucleic acid-based in vitro diagnostic devices for the detection of *Mycobacterium tuberculosis* complex (MTB-complex) and the genetic mutations associated with MTB-complex antibiotic resistance in respiratory specimens are qualitative nucleic acid-based devices that detect the presence of MTB-complex-associated nucleic acid sequences in respiratory samples. These devices are intended to aid in the diagnosis of pulmonary tuberculosis and the selection of an initial treatment regimen when used in conjunction with clinical findings and other laboratory results. These devices do not provide confirmation of antibiotic susceptibility since other mechanisms of resistance may exist that may be associated with a lack of clinical response to treatment other than those detected by the device.

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

(1) The FDA document entitled “Class II Special Controls Guideline: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of *Mycobacterium tuberculosis* Complex and Genetic Mutations Associated with Antibiotic Resistance in Respiratory Specimens,” which addresses the mitigation of risks specific to the detection of MTB-complex. For availability of the document, see § 866.1(e).

(2) The following items, which address the mitigation of risks specific to the detection of the genetic mutations associated with antibiotic resistance of MTB-complex:

(i) The device must include an external positive assay control as appropriate. Acceptable positive assay

controls include MTB-complex isolates containing one or more antibiotic-resistance associated target sequences detected by the device.

(ii) The device must include internal controls as appropriate. An acceptable internal control may include human nucleic acid co-extracted with MTB-complex containing nucleic acid sequences associated with antibiotic resistance and primers amplifying human housekeeping genes (e.g., RNaseP, β -actin).

(iii) The device’s intended use must include a description of the scope of antibiotic resistance targeted by the assay, i.e., the specific drugs and/or drug classes.

(iv) The specific performance characteristics section of the device’s labeling must include information regarding the specificity of the assay oligonucleotides for detecting mutations associated with antibiotic resistance of MTB-complex, and any information indicating the potential for non-specific binding (e.g., BLAST search).

(v) In demonstrating device performance you must perform:

(A) Pre-analytical studies that evaluate:

(1) *Frozen samples.* If there is use of any frozen samples in the device performance studies, or if there is a device claim for the use of frozen samples for testing, the effect of freezing samples prior to testing and the effect of multiple freeze/thaw cycles on both antibiotic susceptible and antibiotic resistant strains of MTB-complex.

(2) *Nucleic acid extraction methods.* Extraction methods must parallel those used in devices for the detection of MTB-complex nucleic acid and confirm that the detection of the genetic mutations associated with antibiotic resistance is not affected.

(B) Analytical studies that analyze:

(1) *Limit of Detection.* Limit of Detection must be determined in the most challenging matrix (e.g., sputum) claimed for use with the device. The Limit of Detection must be determined using both antibiotic susceptible and antibiotic resistant strains of MTB-complex. The antibiotic resistant strains must be those with well characterized genetic mutations associated with antibiotic resistance.

(2) *Analytical Reactivity (Inclusivity).* Testing must be conducted to evaluate the ability of the device to detect genetic mutations associated with antibiotic resistance in a diversity of MTB-complex strains. Isolates used in testing must be well characterized. Isolate strain characterization must be determined using standardized reference methods recognized by a

reputable scientific body and appropriate to the strain lineage.

(3) *Within-Laboratory (Repeatability) Precision Testing.* Within-laboratory precision studies, if appropriate, must include at least one antibiotic resistant and one antibiotic susceptible strain of MTB-complex.

(4) *Between Laboratory Reproducibility Testing.* The protocol for the reproducibility study may vary slightly depending on the assay format; however, the panel must include at least one antibiotic resistant and one antibiotic susceptible strain of MTB-complex.

(C) *Clinical Studies.* Clinical performance of the device must be established by conducting prospective clinical studies that include subjects with culture confirmed active tuberculosis. Studies must attempt to enroll subjects at risk for antibiotic-resistant MTB-complex; however, it may be necessary to include supplemental antibiotic resistant retrospective and contrived samples. Clinical studies must compare device results to both phenotypic drug susceptibility testing and genotypic reference methods. The genotypic reference method must be a polymerase chain reaction based method that uses primers different from those in the experimental device and confirmed by bidirectional sequencing.

Dated: October 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF COMMERCE**United States Patent and Trademark Office****37 CFR Parts 1, 2, 7, 11, 41, and 42**

[Docket No.: PTO–P–2014–0045]

RIN 0651–AC98

Renaming of Express Mail® to Priority Mail Express®

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The United States Patent and Trademark (Office) is revising the rules of practice to change the phrase Express Mail or EXPRESS MAIL® to Priority Mail Express® due to the United States Postal Service (USPS) renaming Express Mail® to Priority Mail Express® on July 28, 2013, and to make other changes to conform the nomenclature used in the

rules of practice to the current nomenclature used by the USPS.

DATES: *Effective Date:* The changes in this final rule are effective on October 22, 2014.

FOR FURTHER INFORMATION CONTACT:

Eugenia A. Jones, Senior Legal Advisor, at (571) 272-7727, or Erin M. Harriman, Legal Advisor, at (571) 272-7747; or by mail addressed to: United States Patent and Trademark Office, Mail Stop Comments-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, marked to the attention of Eugenia A. Jones.

SUPPLEMENTARY INFORMATION:

Executive Summary: Purpose: Effective July 28, 2013, the USPS changed the name of Express Mail® to Priority Mail Express®. Accordingly, the Office is revising the rules of practice to conform the nomenclature used in the rules of practice to the current nomenclature used by the USPS.

More specifically, the Office is changing the phrase Express Mail or EXPRESS MAIL® to Priority Mail Express® in 37 CFR 1.5, 1.6, 1.10, 2.119, 2.195, 2.198, 7.4, 11.35, 11.41, 11.42, 11.51, 41.106, 42.6, 42.105, 42.205, and 42.406. In addition, the USPS has updated the Priority Mail Express® mailing label. The mailing label now has a “date accepted” field rather than a “date-in” field, which was previously used on the Express Mail® mailing label. The Office is revising 37 CFR 1.10, 2.198, and 41.106 accordingly.

All characteristics of the Priority Mail Express® service are the same as those of the former Express Mail® service, although the mailing labels differ. The modifications to the rules are purely changes in terminology resulting from the renaming implemented by the USPS on July 28, 2013. There is no substantive change in practice before the Office as a result of these rule changes. Thus, parties still cannot use a foreign or international mail service (such as the newly renamed Priority Mail Express International®) or other forms of U.S. mail, such as certified mail, to obtain the benefit under 37 CFR 1.10 and 2.198. The procedure in 37 CFR 1.10 and 2.198 is limited to correspondence deposited in Priority Mail Express® Post Office to Addressee service of the USPS.

The changes in this final rule are effective on the date of publication in the **Federal Register**. Papers submitted prior to the effective date containing language pertaining to Express Mail® and the mailing label “date-in” field will be accepted by the Office. Papers submitted after the effective date containing language pertaining to Express Mail® and the mailing label

“date-in” field will be accepted by the Office. Although the new terminology should be used, papers submitted using the former language of Express Mail® and “date-in” will be presumed by the Office to mean Priority Mail Express® and “date accepted” after the effective date. The Office is in the process of updating its patent application transmittal forms (e.g., PTO/AIA/15, PTO/AIA/18, PTO/AIA/19, PTO/AIA/50, PTO/SB/16, PTO/SB/29) to change the reference Express Mail® Label No. to Priority Mail Express® Label No.

Costs and Benefits: This rulemaking is not economically significant under Executive Order 12866 (Sept. 30, 1993).

Background: Effective July 28, 2013, the USPS changed the name of Express Mail® to Priority Mail Express®. This final rule revises the rules of practice to change the phrase Express Mail to Priority Mail Express® and to make other changes to conform the nomenclature used in the rules of practice to the current nomenclature used by the USPS.

Discussion of Specific Rules

The following is a discussion of amendments to Title 37 of the Code of Federal Regulations, Parts 1, 2, 7, 11, 41, and 42.

37 CFR Part 1

Section 1.5: Section 1.5(a) is amended to change “Express Mail procedure” to “Priority Mail Express® procedure.”

Section 1.6: Section 1.6(a) is amended to change “Express Mail date of deposit” to “Priority Mail Express® date of deposit.” Section 1.6(a)(2) is amended to change “Express Mail” to “Priority Mail Express®.”

Section 1.10: Section 1.10 is amended to change “Express Mail” to “Priority Mail Express®” and to change “date-in” or “date in” to “date accepted.” In particular, 37 CFR 1.10(a)(1), (c), (d), (d)(3), (e), (e)(3), (g), and (h) are amended to change “Express Mail Post Office to Addressee” to “Priority Mail Express® Post Office to Addressee” and 37 CFR 1.10(a)(2), (b), (c), (c)(2), (c)(3), (d), (d)(2), (e)(2)–(4), (f), (g), (g)(2)–(4), (h), (h)(2)–(4), (i), (i)(1), and (i)(3) are amended to change “Express Mail” to “Priority Mail Express®.” In addition, 37 CFR 1.10(a)(2), (b), (c), (c)(3), (d), (e)(3), and (g)(3) are amended to change “date-in” or “date in” to “date accepted.”

37 CFR Part 2

Section 2.119: Section 2.119(b)(4) is amended to change “Express Mail Post Office to Addressee” to “Priority Mail Express® Post Office to Addressee” and 37 CFR 2.119(c) is amended to change

“Express Mail” to “Priority Mail Express®.”

Section 2.195: Sections 2.195(a), (a)(4), (e)(2)(iii), and (e)(3) are amended to change “Express Mail” to “Priority Mail Express®,” and 37 CFR 2.195(e)(1) is amended to change “Express Mail Post Office to Addressee” to “Priority Mail Express® Post Office to Addressee.”

Section 2.198: Section 2.198 is amended to change “Express Mail” to “Priority Mail Express®” and to change “date in” or “date-in” to “date accepted.” In particular, 37 CFR 2.198(a)(1), (c), (d), (d)(3), (e), and (e)(3) are amended to change “Express Mail Post Office to Addressee” to “Priority Mail Express® Post Office to Addressee” and 37 CFR 2.198(a)(1), (a)(2), (b), (c), (c)(2), (c)(3), (d), (d)(2), (e)(2)–(4), and (f) are amended to change “Express Mail” to “Priority Mail Express®.” In addition, 37 CFR 2.198(a)(2), (b), (c), (c)(3), (d), and (e)(3) are amended to change “date in” or “date-in” to “date accepted.”

37 CFR Part 7

Section 7.4: Section 7.4(b)(1) is amended to change “Express Mail” to “Priority Mail Express®.”

37 CFR Part 11

Section 11.35: Section 11.35(a)(2) is amended to change “Express Mail” to “Priority Mail Express®.”

Section 11.41: Section 11.41(b) is amended to change “Express Mail” to “Priority Mail Express®.”

Section 11.42: Sections 11.42(a)(2), (b)(2), (c)(2), and (e) are amended to change “Express Mail” to “Priority Mail Express®.”

Section 11.51: Section 11.51(a) is amended to change “Express Mail” to “Priority Mail Express®.”

37 CFR Part 41

Section 41.106: Section 41.106(d)(1) is amended to change each occurrence of “EXPRESS MAIL®” to “Priority Mail Express®” and to change “date-in” to “date accepted.”

37 CFR Part 42

Section 42.6: Section 42.6(e)(1) is amended to change each occurrence of “EXPRESS MAIL®” to “Priority Mail Express®.”

Section 42.105: Section 42.105(b) is amended to change each occurrence of “EXPRESS MAIL®” to “Priority Mail Express®.”

Section 42.205: Section 42.205(b) is amended to change each occurrence of “EXPRESS MAIL®” to “Priority Mail Express®.”

Section 42.406: Section 42.406(b) is amended to change each occurrence of

“EXPRESS MAIL®” to “Priority Mail Express®.”

Rulemaking Considerations

A. Administrative Procedure Act: This rulemaking revises the rules of practice to change the phrase Express Mail or EXPRESS MAIL® to Priority Mail Express® due to the United States Postal Service (USPS) renaming Express Mail® to Priority Mail Express® on July 28, 2013, and to make other changes to conform the nomenclature used in the rules of practice to the current nomenclature used by the USPS. Therefore, the changes in this rulemaking involve rules of agency practice and procedure and/or interpretive rules. See *Bachow Commc'ns Inc. v. F.C.C.*, 237 F.3d 683, 690 (D.C. Cir. 2001) (stating that rules governing an application process are procedural under the Administrative Procedure Act); *Inova Alexandria Hosp. v. Shalala*, 244 F.3d 342, 350 (4th Cir. 2001) (holding that rules for handling appeals were procedural where they did not change the substantive standard for reviewing claims).

Accordingly, prior notice and opportunity for public comment were not required pursuant to 5 U.S.C. 553(b) or (c) (or any other law). See *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336–37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), does not require notice and comment rulemaking for “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice” (quoting 5 U.S.C. 553(b)(3)(A))).

B. Regulatory Flexibility Act: As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 or any other law, neither a regulatory flexibility analysis nor a certification under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) is required. See 5 U.S.C. 603. Further, this rulemaking only revises nomenclature to be consistent with the current nomenclature used by the USPS, and therefore the changes in this rulemaking will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 12866 (Regulatory Planning and Review): This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The Office has complied with Executive Order 13563 (Jan. 18, 2011). Specifically, the Office has, to the extent feasible and applicable: (1) Made a reasoned determination that the benefits

justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided on-line access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 13132 (Federalism): This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

F. Executive Order 13175 (Tribal Consultation): This rulemaking will not: (1) Have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

G. Executive Order 13211 (Energy Effects): This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

H. Executive Order 12988 (Civil Justice Reform): This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

I. Executive Order 13045 (Protection of Children): This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

J. Executive Order 12630 (Taking of Private Property): This rulemaking will not affect a taking of private property or otherwise have taking implications

under Executive Order 12630 (Mar. 15, 1988).

K. Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), prior to issuing any final rule, the United States Patent and Trademark Office will submit a report containing the final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this document are not expected to result in an annual effect on the economy of 100 million dollars or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this document is not expected to result in a “major rule” as defined in 5 U.S.C. 804(2).

L. Unfunded Mandates Reform Act of 1995: The changes set forth in this document do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of 100 million dollars (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of 100 million dollars (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. See 2 U.S.C. 1501 *et seq.*

M. National Environmental Policy Act: This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. See 42 U.S.C. 4321 *et seq.*

N. National Technology Transfer and Advancement Act: The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions which involve the use of technical standards.

O. Paperwork Reduction Act: This rulemaking does not contain any information collection requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a

collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects

37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

37 CFR Part 2

Administrative practice and procedure, Courts, Lawyers, Trademarks.

37 CFR Part 7

Administrative practice and procedure, Trademarks.

37 CFR Part 11

Administrative practice and procedure, Inventions and patents, Lawyers, Reporting and recordkeeping requirements.

37 CFR Part 41

Administrative practice and procedure, Inventions and patents, Lawyers.

37 CFR Part 42

Administrative practice and procedure, Inventions and patents, Lawyers.

For the reasons set forth in the preamble, 37 CFR parts 1, 2, 7, 11, 41, and 42 are amended as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

■ 1. The authority citation for 37 CFR Part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), unless otherwise noted.

■ 2. Section 1.5 is amended by revising paragraph (a) to read as follows:

§ 1.5 Identification of patent, patent application, or patent-related proceeding.

(a) No correspondence relating to an application should be filed prior to receipt of the application number from the Patent and Trademark Office. When a letter directed to the Patent and Trademark Office concerns a previously filed application for a patent, it must identify on the top page in a conspicuous location, the application number (consisting of the series code and the serial number; e.g., 07/123,456), or the serial number and filing date assigned to that application by the Patent and Trademark Office, or the international application number of the

international application. Any correspondence not containing such identification will be returned to the sender where a return address is available. The returned correspondence will be accompanied with a cover letter which will indicate to the sender that if the returned correspondence is resubmitted to the Patent and Trademark Office within two weeks of the mail date on the cover letter, the original date of receipt of the correspondence will be considered by the Patent and Trademark Office as the date of receipt of the correspondence. Applicants may use either the Certificate of Mailing or Transmission procedure under § 1.8 or the Priority Mail Express® procedure under § 1.10 for resubmissions of returned correspondence if they desire to have the benefit of the date of deposit in the United States Postal Service. If the returned correspondence is not resubmitted within the two-week period, the date of receipt of the resubmission will be considered to be the date of receipt of the correspondence. The two-week period to resubmit the returned correspondence will not be extended. In addition to the application number, all letters directed to the Patent and Trademark Office concerning applications for patent should also state the name of the first listed inventor, the title of the invention, the date of filing the same, and, if known, the group art unit or other unit within the Patent and Trademark Office responsible for considering the letter and the name of the examiner or other person to which it has been assigned.

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■ 3. Section 1.6 is amended by revising the introductory text of paragraph (a) and revising paragraph (a)(2) to read as follows:

§ 1.6 Receipt of correspondence.

(a) *Date of receipt and Priority Mail Express® date of deposit.*

Correspondence received in the Patent and Trademark Office is stamped with the date of receipt except as follows:

* * * * *

(2) Correspondence filed in accordance with § 1.10 will be stamped with the date of deposit as Priority Mail Express® with the United States Postal Service.

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■ 4. Section 1.10 is revised to read as follows:

§ 1.10 Filing of correspondence by Priority Mail Express®.

(a)(1) Any correspondence received by the U.S. Patent and Trademark Office (USPTO) that was delivered by the Priority Mail Express® Post Office to Addressee service of the United States Postal Service (USPS) will be considered filed with the USPTO on the date of deposit with the USPS.

(2) The date of deposit with USPS is shown by the “date accepted” on the Priority Mail Express® label or other official USPS notation. If the USPS deposit date cannot be determined, the correspondence will be accorded the USPTO receipt date as the filing date. See § 1.6(a).

(b) Correspondence should be deposited directly with an employee of the USPS to ensure that the person depositing the correspondence receives a legible copy of the Priority Mail Express® mailing label with the “date accepted” clearly marked. Persons dealing indirectly with the employees of the USPS (such as by deposit in a Priority Mail Express® drop box) do so at the risk of not receiving a copy of the Priority Mail Express® mailing label with the desired “date accepted” clearly marked. The paper(s) or fee(s) that constitute the correspondence should also include the Priority Mail Express® mailing label number thereon. See paragraphs (c), (d) and (e) of this section.

(c) Any person filing correspondence under this section that was received by the Office and delivered by the Priority Mail Express® Post Office to Addressee service of the USPS, who can show that there is a discrepancy between the filing date accorded by the Office to the correspondence and the date of deposit as shown by the “date accepted” on the Priority Mail Express® mailing label or other official USPS notation, may petition the Director to accord the correspondence a filing date as of the “date accepted” on the Priority Mail Express® mailing label or other official USPS notation, provided that:

(1) The petition is filed promptly after the person becomes aware that the Office has accorded, or will accord, a filing date other than the USPS deposit date;

(2) The number of the Priority Mail Express® mailing label was placed on the paper(s) or fee(s) that constitute the correspondence prior to the original mailing by Priority Mail Express®; and

(3) The petition includes a true copy of the Priority Mail Express® mailing label showing the “date accepted,” and of any other official notation by the USPS relied upon to show the date of deposit.

(d) Any person filing correspondence under this section that was received by the Office and delivered by the Priority Mail Express® Post Office to Addressee service of the USPS, who can show that the “date accepted” on the Priority Mail Express® mailing label or other official notation entered by the USPS was incorrectly entered or omitted by the USPS, may petition the Director to accord the correspondence a filing date as of the date the correspondence is shown to have been deposited with the USPS, provided that:

(1) The petition is filed promptly after the person becomes aware that the Office has accorded, or will accord, a filing date based upon an incorrect entry by the USPS;

(2) The number of the Priority Mail Express® mailing label was placed on the paper(s) or fee(s) that constitute the correspondence prior to the original mailing by Priority Mail Express®; and

(3) The petition includes a showing which establishes, to the satisfaction of the Director, that the requested filing date was the date the correspondence was deposited in the Priority Mail Express® Post Office to Addressee service prior to the last scheduled pickup for that day. Any showing pursuant to this paragraph must be corroborated by evidence from the USPS or that came into being after deposit and within one business day of the deposit of the correspondence in the Priority Mail Express® Post Office to Addressee service of the USPS.

(e) Any person mailing correspondence addressed as set out in § 1.1(a) to the Office with sufficient postage utilizing the Priority Mail Express® Post Office to Addressee service of the USPS but not received by the Office, may petition the Director to consider such correspondence filed in the Office on the USPS deposit date, provided that:

(1) The petition is filed promptly after the person becomes aware that the Office has no evidence of receipt of the correspondence;

(2) The number of the Priority Mail Express® mailing label was placed on the paper(s) or fee(s) that constitute the correspondence prior to the original mailing by Priority Mail Express®;

(3) The petition includes a copy of the originally deposited paper(s) or fee(s) that constitute the correspondence showing the number of the Priority Mail Express® mailing label thereon, a copy of any returned postcard receipt, a copy of the Priority Mail Express® mailing label showing the “date accepted,” a copy of any other official notation by the USPS relied upon to show the date of deposit, and, if the requested filing

date is a date other than the “date accepted” on the Priority Mail Express® mailing label or other official notation entered by the USPS, a showing pursuant to paragraph (d)(3) of this section that the requested filing date was the date the correspondence was deposited in the Priority Mail Express® Post Office to Addressee service prior to the last scheduled pickup for that day; and

(4) The petition includes a statement which establishes, to the satisfaction of the Director, the original deposit of the correspondence and that the copies of the correspondence, the copy of the Priority Mail Express® mailing label, the copy of any returned postcard receipt, and any official notation entered by the USPS are true copies of the originally mailed correspondence, original Priority Mail Express® mailing label, returned postcard receipt, and official notation entered by the USPS.

(f) The Office may require additional evidence to determine if the correspondence was deposited as Priority Mail Express® with the USPS on the date in question.

(g) Any person who mails correspondence addressed as set out in § 1.1(a) to the Office with sufficient postage utilizing the Priority Mail Express® Post Office to Addressee service of the USPS, but has the correspondence returned by the USPS due to an interruption or emergency in Priority Mail Express® service, may petition the Director to consider such correspondence as filed on a particular date in the Office, provided that:

(1) The petition is filed promptly after the person becomes aware of the return of the correspondence;

(2) The number of the Priority Mail Express® mailing label was placed on the paper(s) or fee(s) that constitute the correspondence prior to the original mailing by Priority Mail Express®;

(3) The petition includes the original correspondence or a copy of the original correspondence showing the number of the Priority Mail Express® mailing label thereon and a copy of the Priority Mail Express® mailing label showing the “date accepted”; and

(4) The petition includes a statement which establishes, to the satisfaction of the Director, the original deposit of the correspondence and that the correspondence or copy of the correspondence is the original correspondence or a true copy of the correspondence originally deposited with the USPS on the requested filing date. The Office may require additional evidence to determine if the correspondence was returned by the USPS due to an interruption or

emergency in Priority Mail Express® service.

(h) Any person who attempts to mail correspondence addressed as set out in § 1.1(a) to the Office with sufficient postage utilizing the Priority Mail Express® Post Office to Addressee service of the USPS, but has the correspondence refused by an employee of the USPS due to an interruption or emergency in Priority Mail Express® service, may petition the Director to consider such correspondence as filed on a particular date in the Office, provided that:

(1) The petition is filed promptly after the person becomes aware of the refusal of the correspondence;

(2) The number of the Priority Mail Express® mailing label was placed on the paper(s) or fee(s) that constitute the correspondence prior to the attempted mailing by Priority Mail Express®;

(3) The petition includes the original correspondence or a copy of the original correspondence showing the number of the Priority Mail Express® mailing label thereon; and

(4) The petition includes a statement by the person who originally attempted to deposit the correspondence with the USPS which establishes, to the satisfaction of the Director, the original attempt to deposit the correspondence and that the correspondence or copy of the correspondence is the original correspondence or a true copy of the correspondence originally attempted to be deposited with the USPS on the requested filing date. The Office may require additional evidence to determine if the correspondence was refused by an employee of the USPS due to an interruption or emergency in Priority Mail Express® service.

(i) Any person attempting to file correspondence under this section that was unable to be deposited with the USPS due to an interruption or emergency in Priority Mail Express® service which has been so designated by the Director, may petition the Director to consider such correspondence as filed on a particular date in the Office, provided that:

(1) The petition is filed in a manner designated by the Director promptly after the person becomes aware of the designated interruption or emergency in Priority Mail Express® service;

(2) The petition includes the original correspondence or a copy of the original correspondence; and

(3) The petition includes a statement which establishes, to the satisfaction of the Director, that the correspondence would have been deposited with the USPS but for the designated interruption or emergency in Priority

Mail Express® service, and that the correspondence or copy of the correspondence is the original correspondence or a true copy of the correspondence originally attempted to be deposited with the USPS on the requested filing date.

PART 2—RULES OF PRACTICE IN TRADEMARK CASES

■ 5. The authority citation for 37 CFR part 2 continues to read as follows:

Authority: 15 U.S.C. 1123; 35 U.S.C. 2, unless otherwise noted.

■ 6. Section 2.119 is amended by revising paragraphs (b)(4) and (c) to read as follows:

§ 2.119 Service and signing of papers.

* * * * *

(b) * * *

(4) Transmission by the Priority Mail Express® Post Office to Addressee service of the United States Postal Service or by first-class mail, which may also be certified or registered;

* * * * *

(c) When service is made by first-class mail, Priority Mail Express®, or overnight courier, the date of mailing or of delivery to the overnight courier will be considered the date of service. Whenever a party is required to take some action within a prescribed period after the service of a paper upon the party by another party and the paper is served by first-class mail, Priority Mail Express®, or overnight courier, 5 days shall be added to the prescribed period.

* * * * *

■ 7. Section 2.195 is revised to read as follows:

§ 2.195 Receipt of trademark correspondence.

(a) *Date of receipt and Priority Mail Express® date of deposit.* Trademark correspondence received in the Office is given a filing date as of the date of receipt except as follows:

(1) The Office is not open for the filing of correspondence on any day that is a Saturday, Sunday, or Federal holiday within the District of Columbia. Except for correspondence transmitted electronically under paragraph (a)(2) of this section or transmitted by facsimile under paragraph (a)(3) of this section, no correspondence is received in the Office on Saturdays, Sundays, or Federal holidays within the District of Columbia.

(2) Trademark-related correspondence transmitted electronically will be given a filing date as of the date on which the Office receives the transmission.

(3) Correspondence transmitted by facsimile will be given a filing date as

of the date on which the complete transmission is received in the Office unless that date is a Saturday, Sunday, or Federal holiday within the District of Columbia, in which case the filing date will be the next succeeding day that is not a Saturday, Sunday, or Federal holiday within the District of Columbia.

(4) Correspondence filed in accordance with § 2.198 will be given a filing date as of the date of deposit as Priority Mail Express® with the United States Postal Service.

(b) *Correspondence delivered by hand.* Correspondence may be delivered by hand during hours the Office is open to receive correspondence.

(c) *Facsimile transmission.* Except in the cases enumerated in paragraph (d) of this section, correspondence, including authorizations to charge a deposit account, may be transmitted by facsimile. The receipt date accorded to the correspondence will be the date on which the complete transmission is received in the Office, unless that date is a Saturday, Sunday, or Federal holiday within the District of Columbia. See § 2.196. To facilitate proper processing, each transmission session should be limited to correspondence to be filed in a single application, registration or proceeding before the Office. The application serial number, registration number, or proceeding number should be entered as a part of the sender's identification on a facsimile cover sheet.

(d) Facsimile transmissions are not permitted and if submitted, will not be accorded a date of receipt, in the following situations:

- (1) Applications for registration of marks;
- (2) Drawings submitted under § 2.51, § 2.52, § 2.72, or § 2.173;
- (3) Correspondence to be filed with the Trademark Trial and Appeal Board, except notices of ex parte appeal;
- (4) Requests for cancellation or amendment of a registration under section 7(e) of the Trademark Act; and certificates of registration surrendered for cancellation or amendment under section 7(e) of the Trademark Act; and
- (5) Madrid-related correspondence submitted under § 7.11, § 7.21, § 7.14, § 7.23, § 7.24, or § 7.31.

(e) *Interruptions in U.S. Postal Service.* (1) If the Director designates a postal service interruption or emergency within the meaning of 35 U.S.C. 21(a), any person attempting to file correspondence by Priority Mail Express® Post Office to Addressee service who was unable to deposit the correspondence with the United States Postal Service due to the interruption or emergency may petition the Director to

consider such correspondence as filed on a particular date in the Office.

(2) The petition must:

(i) Be filed promptly after the ending of the designated interruption or emergency;

(ii) Include the original correspondence or a copy of the original correspondence; and

(iii) Include a statement that the correspondence would have been deposited with the United States Postal Service on the requested filing date but for the designated interruption or emergency in Priority Mail Express® service; and that the correspondence attached to the petition is the original correspondence or a true copy of the correspondence originally attempted to be deposited as Priority Mail Express® on the requested filing date.

(3) Paragraphs (e)(1) and (e)(2) of this section do not apply to correspondence that is excluded from the Priority Mail Express® procedure pursuant to § 2.198(a)(1).

■ 8. Section 2.198 is revised to read as follows:

§ 2.198 Filing of correspondence by Priority Mail Express®.

(a)(1) Except for documents listed in paragraphs (a)(1)(i) through (vii) of this section, any correspondence received by the Office that was delivered by the Priority Mail Express® Post Office to Addressee service of the United States Postal Service (USPS) will be considered filed with the Office on the date of deposit with the USPS. The Priority Mail Express® procedure does not apply to:

- (i) Applications for registration of marks;
- (ii) Amendments to allege use under section 1(c) of the Act;
- (iii) Statements of use under section 1(d) of the Act;
- (iv) Requests for extension of time to file a statement of use under section 1(d) of the Act;
- (v) Affidavits of continued use under section 8 of the Act;
- (vi) Renewal requests under section 9 of the Act; and
- (vii) Requests to change or correct addresses.

(2) The date of deposit with USPS is shown by the “date accepted” on the Priority Mail Express® label or other official USPS notation. If the USPS deposit date cannot be determined, the correspondence will be accorded the date of receipt in the Office as the filing date.

(b) Correspondence should be deposited directly with an employee of the USPS to ensure that the person depositing the correspondence receives

a legible copy of the Priority Mail Express® mailing label with the “date accepted” clearly marked. Persons dealing indirectly with the employees of the USPS (such as by deposit in a Priority Mail Express® drop box) do so at the risk of not receiving a copy of the Priority Mail Express® mailing label with the desired “date accepted” clearly marked. The paper(s) or fee(s) that constitute the correspondence should also include the Priority Mail Express® mailing label number thereon. See paragraphs (c), (d) and (e) of this section.

(c) Any person filing correspondence under this section that was received by the Office and delivered by the Priority Mail Express® Post Office to Addressee service of the USPS, who can show that there is a discrepancy between the filing date accorded by the Office to the correspondence and the date of deposit as shown by the “date accepted” on the Priority Mail Express® mailing label or other official USPS notation, may petition the Director to accord the correspondence a filing date as of the “date accepted” on the Priority Mail Express® mailing label or other official USPS notation, provided that:

(1) The petition is filed within two months after the person becomes aware that the Office has accorded, or will accord, a filing date other than the USPS deposit date;

(2) The number of the Priority Mail Express® mailing label was placed on the paper(s) or fee(s) that constitute the correspondence prior to the original mailing; and

(3) The petition includes a true copy of the Priority Mail Express® mailing label showing the “date accepted,” and of any other official notation by the USPS relied upon to show the date of deposit.

(d) Any person filing correspondence under this section that was received by the Office and delivered by the Priority Mail Express® Post Office to Addressee service of the USPS, who can show that the “date accepted” on the Priority Mail Express® mailing label or other official notation entered by the USPS was incorrectly entered or omitted by the USPS, may petition the Director to accord the correspondence a filing date as of the date the correspondence is shown to have been deposited with the USPS, provided that:

(1) The petition is filed within two months after the person becomes aware that the Office has accorded, or will accord, a filing date based upon an incorrect entry by the USPS;

(2) The number of the Priority Mail Express® mailing label was placed on

the paper(s) or fee(s) prior to the original mailing; and

(3) The petition includes a showing that establishes, to the satisfaction of the Director, that the correspondence was deposited in the Priority Mail Express® Post Office to Addressee service prior to the last scheduled pickup on the requested filing date. Any showing pursuant to this paragraph must be corroborated by evidence from the USPS or evidence that came into being within one business day after the deposit of the correspondence in the Priority Mail Express® Post Office to Addressee service of the USPS.

(e) If correspondence is properly addressed to the Office pursuant to § 2.190 and deposited with sufficient postage in the Priority Mail Express® Post Office to Addressee service of the USPS, but not received by the Office, the party who mailed the correspondence may petition the Director to consider such correspondence filed in the Office on the USPS deposit date, provided that:

(1) The petition is filed within two months after the person becomes aware that the Office has no evidence of receipt of the correspondence;

(2) The number of the Priority Mail Express® mailing label was placed on the paper(s) or fee(s) prior to the original mailing;

(3) The petition includes a copy of the originally deposited paper(s) or fee(s) showing the number of the Priority Mail Express® mailing label thereon, a copy of any returned postcard receipt, a copy of the Priority Mail Express® mailing label showing the “date accepted,” a copy of any other official notation by the USPS relied upon to show the date of deposit, and, if the requested filing date is a date other than the “date accepted” on the Priority Mail Express® mailing label or other official notation entered by the USPS, a showing pursuant to paragraph (d)(3) of this section that the correspondence was deposited in the Priority Mail Express® Post Office to Addressee service prior to the last scheduled pickup on the requested filing date; and

(4) The petition includes a statement that establishes, to the satisfaction of the Director, the original deposit of the correspondence and that the copies of the correspondence, the copy of the Priority Mail Express® mailing label, the copy of any returned postcard receipt, and any official notation entered by the USPS are true copies of the originally mailed correspondence, original Priority Mail Express® mailing label, returned postcard receipt, and official notation entered by the USPS.

(f) The Office may require additional evidence to determine whether the correspondence was deposited as Priority Mail Express® with the USPS on the date in question.

PART 7—RULES OF PRACTICE IN FILINGS PURSUANT TO THE PROTOCOL RELATING TO THE MADRID AGREEMENT CONCERNING THE INTERNATIONAL REGISTRATION OF MARKS

■ 9. The authority citation for 37 CFR part 7 continues to read as follows:

Authority: 15 U.S.C. 1123, 35 U.S.C. 2, unless otherwise noted.

■ 10. Section 7.4 is amended by revising paragraph (b)(1) to read as follows:

§ 7.4 Receipt of correspondence.

* * * * *

(b) * * *

(1) International applications under § 7.11, subsequent designations under § 7.21, requests to record changes in the International Register under § 7.23 and § 7.24, and petitions to the Director to review an action of the Office’s Madrid Processing Unit, when filed by mail, will be accorded the date of receipt in the Office, unless they are sent by Priority Mail Express® pursuant to § 2.198, in which case they will be accorded the date of deposit with the United States Postal Service.

* * * * *

PART 11—REPRESENTATION OF OTHERS BEFORE THE UNITED STATES PATENT AND TRADEMARK OFFICE

■ 11. The authority citation for 37 CFR part 11 continues to read as follows:

Authority: 5 U.S.C. 500, 15 U.S.C. 1123, 35 U.S.C. 2(b)(2), 32, 41.

■ 12. Section 11.35 is amended by revising the introductory text of paragraph (a)(2) to read as follows:

§ 11.35 Service of complaint.

(a) * * *

(2) By mailing a copy of the complaint by Priority Mail Express®, first-class mail, or any delivery service that provides ability to confirm delivery or attempted delivery to:

* * * * *

■ 13. Section 11.41 is amended by revising paragraph (b) to read as follows:

§ 11.41 Filing of papers.

* * * * *

(b) All papers filed after entry of an initial decision by the hearing officer shall be filed with the USPTO Director. A copy of the paper shall be served on

the OED Director. The hearing officer or the OED Director may provide for filing papers and other matters by hand, by Priority Mail Express®, or by other means.

■ 14. Section 11.42 is revised to read as follows:

§ 11.42 Service of papers.

(a) All papers other than a complaint shall be served on a respondent who is represented by an attorney by:

(1) Delivering a copy of the paper to the office of the attorney; or

(2) Mailing a copy of the paper by first-class mail, Priority Mail Express®, or other delivery service to the attorney at the address provided by the attorney under § 11.40(a)(1); or

(3) Any other method mutually agreeable to the attorney and a representative for the OED Director.

(b) All papers other than a complaint shall be served on a respondent who is not represented by an attorney by:

(1) Delivering a copy of the paper to the respondent; or

(2) Mailing a copy of the paper by first-class mail, Priority Mail Express®, or other delivery service to the respondent at the address to which a complaint may be served or such other address as may be designated in writing by the respondent; or

(3) Any other method mutually agreeable to the respondent and a representative for the OED Director.

(c) A respondent shall serve on the representative for the OED Director one copy of each paper filed with the hearing officer or the OED Director. A paper may be served on the representative for the OED Director by:

(1) Delivering a copy of the paper to the representative; or

(2) Mailing a copy of the paper by first-class mail, Priority Mail Express®, or other delivery service to an address designated in writing by the representative; or

(3) Any other method mutually agreeable to the respondent and the representative.

(d) Each paper filed in a disciplinary proceeding shall contain therein a certificate of service indicating:

(1) The date on which service was made; and

(2) The method by which service was made.

(e) The hearing officer or the USPTO Director may require that a paper be served by hand or by Priority Mail Express®.

(f) Service by mail is completed when the paper mailed in the United States is placed into the custody of the U.S. Postal Service.

■ 15. Section 11.51 is amended by revising paragraph (a) to read as follows:

§ 11.51 Depositions.

(a) Depositions for use at the hearing in lieu of personal appearance of a witness before the hearing officer may be taken by respondent or the OED Director upon a showing of good cause and with the approval of, and under such conditions as may be deemed appropriate by, the hearing officer. Depositions may be taken upon oral or written questions, upon not less than ten days' written notice to the other party, before any officer authorized to administer an oath or affirmation in the place where the deposition is to be taken. The parties may waive the requirement of ten days' notice and depositions may then be taken of a witness at a time and place mutually agreed to by the parties. When a deposition is taken upon written questions, copies of the written questions will be served upon the other party with the notice, and copies of any written cross-questions will be served by hand or Priority Mail Express® not less than five days before the date of the taking of the deposition unless the parties mutually agree otherwise. A party on whose behalf a deposition is taken shall file a copy of a transcript of the deposition signed by a court reporter with the hearing officer and shall serve one copy upon the opposing party. Expenses for a court reporter and preparing, serving, and filing depositions shall be borne by the party at whose instance the deposition is taken. Depositions may not be taken to obtain discovery, except as provided for in paragraph (b) of this section.

* * * * *

PART 41—PRACTICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

■ 16. The authority citation for 37 CFR part 41 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), 3(a)(2)(A), 21, 23, 32, 41, 134, 135, and Public Law 112–29.

■ 17. Section 41.106 is amended by revising paragraphs (d)(1) and (e)(3) to read as follows:

§ 41.106 Filing and service.

* * * * *

(d) *Specific filing forms*—(1) *Filing by mail.* A paper filed using the Priority Mail Express® service of the United States Postal Service will be deemed to be filed as of “date accepted” on the Priority Mail Express® mailing label; otherwise, mail will be deemed to be filed as of the stamped date of receipt at the Board.

* * * * *

(e) * * *

(3) Service must be by Priority Mail Express® or by means at least as fast and reliable as Priority Mail Express®. Electronic service is not permitted without Board authorization.

* * * * *

PART 42—TRIAL PRACTICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

■ 18. The authority citation for 37 CFR part 42 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), 6, 21, 23, 41, 135, 311, 312, 316, 321–326 and Public Law 112–29.

■ 19. Section 42.6 is amended by revising paragraph (e)(1) to read as follows:

§ 42.6 Filing of documents, including exhibits; service.

* * * * *

(e) * * *

(1) *Electronic or other mode.* Service may be made electronically upon agreement of the parties. Otherwise, service may be by Priority Mail Express® or by means at least as fast and reliable as Priority Mail Express®.

* * * * *

■ 20. Section 42.105 is amended by revising paragraph (b) to read as follows:

§ 42.105 Service of petition.

* * * * *

(b) Upon agreement of the parties, service may be made electronically. Service may be by Priority Mail Express® or by means at least as fast and reliable as Priority Mail Express®. Personal service is not required.

■ 21. Section 42.205 is amended by revising paragraph (b) to read as follows:

§ 42.205 Service of petition.

* * * * *

(b) Upon agreement of the parties, service may be made electronically. Service may be by Priority Mail Express® or by means at least as fast and reliable as Priority Mail Express®. Personal service is not required.

■ 22. Section 42.406 is amended by revising paragraph (b) to read as follows:

§ 42.406 Service of petition.

* * * * *

(b) Upon agreement of the parties, service may be made electronically. Service may be by Priority Mail Express® or by means at least as fast and reliable as Priority Mail Express®. Personal service is not required.

Dated: October 10, 2014.

Michelle K. Lee,

Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office.

[FR Doc. 2014-24891 Filed 10-21-14; 8:45 am]

BILLING CODE 3510-16-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R07-OAR-2014-0500; FRL-9918-11-Region 7]

Approval and Promulgation of Implementation Plans; State of Kansas; Infrastructure SIP Requirements for the 2010 Nitrogen Dioxide National Ambient Air Quality Standard

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve elements of a State Implementation Plan (SIP) submission from the State of Kansas addressing the applicable requirements of Clean Air Act (CAA) section 110 for the 2010 National Ambient Air Quality Standards (NAAQS) for Nitrogen Dioxide (NO₂), which requires that each state adopt and submit a SIP to support implementation, maintenance, and enforcement of each new or revised NAAQS promulgated by EPA. 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 CAA.

DATES: This final rule is effective November 21, 2014.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-R07-OAR-2014-0500. All documents in the electronic docket are listed in the <http://www.regulations.gov> index. 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, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at <http://www.regulations.gov> or in hard copy at U.S. Environmental Protection Agency, Region 7, 11201 Renner Boulevard, Lenexa, Kansas 66219 from 8:00 a.m. to

4:30 p.m., Monday through Friday, excluding legal holidays. The interested persons wanting to examine these documents should make an appointment with the office at least 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: Ms. Lachala Kemp, Air Planning and Development Branch, U.S. Environmental Protection Agency, Region 7, 11201 Renner Boulevard, Lenexa, KS 66219; *telephone number:* (913) 551-7214; *fax number:* (913) 551-7065; *email address:* kemp.lachala@epa.gov.

SUPPLEMENTARY INFORMATION:

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

- I. Background
- II. Summary of SIP Revision
- III. Final Action
- IV. Statutory and Executive Order Review

I. Background

On August 28, 2014, (79 FR 51277), EPA published a notice of proposed rulemaking (NPR) for the State of Kansas. The NPR proposed approval of Kansas’ submission that provides the basic elements specified in section 110(a)(2) of the CAA, or portions thereof, necessary to implement, maintain, and enforce the 2010 NO₂ NAAQS.

II. Summary of SIP Revision

On March 19, 2013, and May 9, 2013, EPA received SIP submissions from the state of Kansas that address the infrastructure elements specified in section 110(a)(2) for the 2010 NO₂ NAAQS. The submissions addressed the following infrastructure elements of section 110(a)(2): (A), (B), (C), (D), (E), (F), (G), (H), (J), (K), (L), and (M). Specific requirements of section 110(a)(2) of the CAA and the rationale for EPA’s proposed action to approve the SIP submission are explained in the NPR and will not be restated here. No public comments were received on the NPR.

III. Final Action

EPA is approving Kansas’ submissions which provides the basic program elements specified in section 110(a)(2)(A), (B), (C), (D), (E), (F), (G), (H), (J), (K), (L), and (M) of the CAA, or portions thereof, necessary to implement, maintain, and enforce the 2010 NO₂ NAAQS, as a revision to the Kansas SIP. This action is being taken under section 110 of the CAA. As discussed in each applicable section of the NPR, EPA is not acting on section

110(a)(2)(I)—Nonattainment Area Plan or Plan Revisions Under Part D, and on the visibility protection portion of section 110(a)(2)(J).

IV. Statutory and Executive Order Review

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” under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Orders 12866 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, 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 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, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249,