

*F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

This action does not have tribal implications, as specified in Executive Order 13175. This regulatory action corrects the calculation of annual mean PM<sub>2.5</sub> concentrations and imposes no requirements on tribal governments. Thus, Executive Order 13175 does not apply to this action.

*G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks*

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

*H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

*I. National Technology Transfer and Advancement Act*

This rulemaking does not involve technical standards.

*J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This regulatory action is a technical correction to a previously promulgated regulatory action and does not have any impact on human health or the environment.

*K. Congressional Review Act*

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 50**

Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

Dated: March 14, 2017.

**E. Scott Pruitt,**  
Administrator.

For the reasons stated in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

**PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS**

■ 1. The authority citation for part 50 continues to read as follows:

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

■ 2. In appendix N to part 50, in section 4.4, paragraph (b), Equation 2 is revised to read as follows:

**Appendix N to Part 50—Interpretation of the National Ambient Air Quality Standards for PM<sub>2.5</sub>**

\* \* \* \* \*

4.4 Equations for the Annual PM<sub>2.5</sub> NAAQS

\* \* \* \* \*

(b) \* \* \*

Equation 2

$$\bar{X}_y = \frac{1}{n_{Q,y}} \sum_{q=1}^{n_{Q,y}} \bar{X}_{q,y}$$

Where:

$\bar{X}_y$  = the annual mean concentration for year  $y$  ( $y = 1, 2, \text{ or } 3$ );

$n_{Q,y}$  = the number of quarters  $Q$  in year  $y$  with at least one daily value; and

$\bar{X}_{q,y}$  = the mean for quarter  $q$  of year  $y$  (result of equation 1).

\* \* \* \* \*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 271**

**[EPA–R04–RCRA–2016–0497; FRL–9959–14–Region 4]**

**Alabama: Final Authorization of State Hazardous Waste Management Program Revisions**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** Alabama has applied to the United States Environmental Protection Agency (EPA) for final authorization of changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA has

determined that these changes satisfy all requirements needed to qualify for final authorization, and is authorizing the State’s changes through this direct final rule. In the “Proposed Rules” section of today’s **Federal Register**, EPA is also publishing a separate document that serves as the proposal to authorize these changes. EPA believes this action is not controversial and does not expect comments that oppose it. Unless EPA receives written comments that oppose this authorization during the comment period, the decision to authorize Alabama’s changes to its hazardous waste program will take effect. If EPA receives comments that oppose this action, EPA will publish a document in the **Federal Register** withdrawing today’s direct final rule before it takes effect, and the separate document published in today’s “Proposed Rules” section of this **Federal Register** will serve as the proposal to authorize the changes.

**DATES:** This final authorization will become effective on May 19, 2017 unless EPA receives adverse written comment by April 19, 2017. If EPA receives such comment, EPA will publish a timely withdrawal of this direct final rule in the **Federal Register** and inform the public that this authorization will not take effect.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–R04–RCRA–2016–0497, by one of the following methods:

- **Federal eRulemaking Portal:** [www.regulations.gov](http://www.regulations.gov). Follow the on-line instructions for submitting comments.

- **Email:** [baker.audrey@epa.gov](mailto:baker.audrey@epa.gov).

- **Fax:** (404) 562–9964 (prior to faxing, please notify the EPA contact listed below).

- **Mail:** Send written comments to Audrey Baker, RCRA Programs and Materials Management Section, Materials and Waste Management Branch, Resource Conservation and Restoration Division, U.S. Environmental Protection Agency, Atlanta Federal Center, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960.

- **Hand Delivery or Courier:** Deliver your comments to Audrey Baker, RCRA Programs and Materials Management Section, Materials and Waste Management Branch, Resource Conservation and Restoration Division, U.S. Environmental Protection Agency, Atlanta Federal Center, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office’s normal hours of operation, and special

arrangements should be made for deliveries of boxed information.

**Instructions:** EPA must receive your comments by April 19, 2017. Direct your comments to Docket ID No. EPA–R04–RCRA–2016–0497. EPA’s policy is that all comments received will be included in the public docket without change and may be made available online at [www.regulations.gov](http://www.regulations.gov), including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [www.regulations.gov](http://www.regulations.gov) or email. The [www.regulations.gov](http://www.regulations.gov) Web site is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through [www.regulations.gov](http://www.regulations.gov), your email address will be automatically captured and included as part of the comment that is placed in the public docket and made publicly available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. (For additional information about EPA’s public docket, visit the EPA Docket Center homepage at [www.epa.gov/epahome/dockets.htm](http://www.epa.gov/epahome/dockets.htm)).

**Docket:** All documents in the docket are listed in the [www.regulations.gov](http://www.regulations.gov) index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at [www.regulations.gov](http://www.regulations.gov), or in hard copy.

You may view and copy Alabama’s applications and associated publicly available materials from 8:00 a.m. to 4:00 p.m. at the following locations: EPA Region 4, Resource Conservation and Restoration Division, Atlanta Federal Center, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960; telephone number: (404) 562–8483; and the Alabama Department of Environmental

Management, 1400 Coliseum Boulevard, Montgomery, Alabama 36110–2059; telephone number: (334) 271–7700. Interested persons wanting to examine these documents should make an appointment with the office at least a week in advance.

**FOR FURTHER INFORMATION CONTACT:** Audrey Baker, RCRA Programs and Materials Management Section, Materials and Waste Management Branch, Resource Conservation and Restoration Division, U.S. Environmental Protection Agency, Atlanta Federal Center, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960; telephone number: (404) 562–8483; fax number: (404) 562–9964; email address: [baker.audrey@epa.gov](mailto:baker.audrey@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**A. Why are revisions to state programs necessary?**

States which have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal program. As the Federal program changes, States must change their programs and ask EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to EPA’s regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 268, 270, 273, and 279.

New Federal requirements and prohibitions imposed by Federal regulations that EPA promulgates pursuant to the Hazardous and Solid Waste Amendments of 1984 (HSWA) take effect in authorized States at the same time that they take effect in unauthorized States. Thus, EPA will implement those requirements and prohibitions in Alabama, including the issuance of new permits implementing those requirements, until the State is granted authorization to do so.

**B. What decisions has EPA made in this rule?**

On July 20, 2015 and August 15, 2016, Alabama submitted final complete program revision applications seeking authorization of changes to its hazardous waste program that correspond to certain Federal rules promulgated between July 1, 2006 through June 30, 2008, and July 1, 2011 through June 30, 2014 (also known as RCRA Clusters XVII through XVIII, and XXII through XXIII). EPA concludes that

Alabama’s applications to revise its authorized program meet all of the statutory and regulatory requirements established by RCRA, as set forth in RCRA section 3006(b), 42 U.S.C. 6926(b), and 40 CFR part 271. Therefore, EPA grants Alabama final authorization to operate its hazardous waste program with the changes described in the authorization applications, and as outlined below in Section G of this document.

Alabama has responsibility for permitting treatment, storage, and disposal facilities within its borders (except in Indian Country) and for carrying out the aspects of the RCRA program described in its revised program applications, subject to the limitations of HSWA, as discussed above.

**C. What is the effect of this authorization decision?**

The effect of this decision is that the changes described in Alabama’s authorization applications will become part of the authorized State hazardous waste program, and will therefore be federally enforceable. Alabama will continue to have primary enforcement authority and responsibility for its State hazardous waste program. EPA retains its authorities under RCRA sections 3007, 3008, 3013, and 7003, including its authority to:

- Conduct inspections, and require monitoring, tests, analyses, or reports;
- Enforce RCRA requirements, including authorized State program requirements, and suspend or revoke permits; and
- Take enforcement actions regardless of whether the State has taken its own actions.

This action does not impose additional requirements on the regulated community because the regulations for which Alabama is being authorized by today’s action are already effective and enforceable requirements under State law, and are not changed by today’s action.

**D. Why wasn’t there a proposed rule before today’s rule?**

Along with this direct final rule, EPA is publishing a separate document in the “Proposed Rules” section of today’s **Federal Register** that serves as the proposal to authorize these State program changes. EPA did not publish a proposed rule before today because EPA views this as a routine program change and does not expect comments that oppose this approval. EPA is providing an opportunity for public comment now, as described in Section E of this document.

**E. What happens if EPA receives comments that oppose this action?**

If EPA receives comments that oppose this authorization, EPA will withdraw today's direct final rule by publishing a document in the **Federal Register** before the rule becomes effective. EPA will base any further decision on the authorization of the State program changes on the proposed rule mentioned in the previous section, after considering all comments received during the comment period, and will address all such comments in a later final rule. You may not have another opportunity to comment on these State program changes. If you want to comment on this authorization, you must do so at this time.

If EPA receives comments that oppose only the authorization of a particular change to the State hazardous waste program, EPA will withdraw that part of today's direct final rule, but the authorization of the program changes that the comments do not oppose will become effective on the date specified above. The **Federal Register** withdrawal

document will specify which part of the authorization will become effective, and which part is being withdrawn.

**F. What has Alabama previously been authorized for?**

Alabama initially received final authorization on December 8, 1987, effective December 22, 1987 (52 FR 46466), to implement a hazardous waste management program. EPA granted authorization for changes to Alabama's program on the following dates: November 29, 1991, effective January 28, 1992 (56 FR 60926); May 13, 1992, effective July 12, 1992 (57 FR 20422); October 21, 1992, effective December 21, 1992 (57 FR 47996); March 17, 1993, effective May 17, 1993 (58 FR 20422); September 24, 1993, effective November 23, 1993 (58 FR 49932); February 1, 1994, effective April 4, 1994 (59 FR 4594); November 14, 1994, effective January 13, 1995 (59 FR 56407); August 14, 1995, effective October 13, 1995 (60 FR 41818); February 14, 1996, effective April 15, 1996 (61 FR 5718); April 25, 1996, effective June 24, 1996 (61 FR 5718); November 21, 1997, effective

February 10, 1998 (62 FR 62262); December 20, 2000, effective February 20, 2001 (65 FR 79769); March 15, 2005, effective May 16, 2005 (70 FR 12593); June 2, 2005, effective August 1, 2005 (70 FR 32247); September 13, 2006, effective November 13, 2006 (71 FR 53989); and April 2, 2008, effective June 2, 2008 (73 FR 17924).

**G. What changes is EPA authorizing with this action?**

On July 20, 2015 and August 15, 2016, Alabama submitted final complete program revision applications seeking authorization of its changes in accordance with 40 CFR 271.21. EPA now makes an immediate final decision, subject to receipt of written comments that oppose this action, that Alabama's hazardous waste program revisions are equivalent to, consistent with, and no less stringent than the Federal program, and therefore satisfy all of the requirements necessary to qualify for final authorization. Therefore, EPA grants Alabama final authorization for the following program changes:

Description of Federal requirement	Federal Register date and page	Analogous state authority <sup>1</sup>
Checklist 214, Corrections to Errors in the Code of Federal Regulations.	71 FR 40254 7/14/06 .....	335-14-1-.02(117)(b); -02(167); -02(178); -02(180); -02(196); -02(205); -02(266); -02(273); 335-14-1-.03(2)(a)1.; -03(2)(d)1.(ii); -03(20)(a); -03(21); 335-14-2-.01(2)(c)1.(i); -01(3)(a)2.(i); -01(4)(a)20.(v); -01(4)(b)6.(i)(II); -01(4)(b)6.(ii); -01(4)(b)6.(ii)(IV)-(V); -01(4)(b)9.; -01(4)(e)2.(vi); -01(4)(e)3.(i); -01(6)(a)2.(ii)-(iv); -01(6)(c)2.; 335-14-2-.03(2)(a)3.; -03(2)(a)3.(i)-(ii); -03(2)(a)3.(ii)(I)-(IV); -03(2)(a)4.; -03(2)(a)4.(i); -03(2)(a)4.(i)(I)-(IV); -03(2)(a)4.(i)(IV) Notes 1-4; -03(5)(b); 335-14-2-.04(2)(a)/Table; -04(3)(a)/Table "K107" and "K069" entries; -04(4)(e); -04(4)(e)/Comment; -04(4)(e)/Table; -04(4)(f); -04(4)(f)/Table; 335-14-2 Appendices VII-VIII; 335-14-3-.03(5)(a)1.(iv); 335-14-3-.05(4)(b); -05(7)(b); -05(9)(a)1.; 335-14-3-.07(1); 335-14-3-.09(3)(a)1.(ii); -09(4)(b)1.(i); -09(4)(b)2.(i); -09(5)(e); -09(8)(a); -09(8)(a)5.; 335-14-5-.01(1)(g)2.; -01(4); 335-14-5-.02(4)(b)7.(iii)(II); -02(8)(b); -02(9)(b)2.(iii); 335-14-5-.06(8)(a)1.; -06(8)(a)1.(i); -06(8)(i)5.; -06(9)(a)2.; -06(9)(g)4.(i); -06(10)(h)2.; -06(12)(d); 335-14-5-.07(2)(c); -07(3)(b)8.; -07(6)-(7); -07(9)(c); -07(10)(b)1.(ii); 335-14-5-.08(1)(c); -08(3)(b)2.; -08(4)(b)7.; -08(4)(b)8.; -08(4)(e)5.; -08(6)(a)3.(i); -08(6)(d)6.; -08(6)(f)11.; -08(8)(h)1.; -08(12)(b); -08(12)(f); -08(12)(g) Letter From Chief Financial Officer; -08(12)(h)2. Guarantee For Liability Coverage; -08(12)(h)2. Recitals, Item 13(a) Certification of Valid Claim; -08(12)(h)2. Recitals, Item 14; -08(12)(i) Hazardous Waste Facility Liability Endorsement, Item 2(e); -08(12)(j) Hazardous Waste Facility Certificate of Liability Insurance, Item 2(d); -08(12)(k) Irrevocable Standby Letter of Credit; -08(12)(k) Certificate of Valid Claim; -08(12)(l); -08(12)(l) Certification of Valid Claim; -08(12)(m) Trust Agreement, Section 8(c); -08(12)(n)1. Standby Trust Agreement, Sections 3(c)(1), 3(e)(3), 12, and 16; 335-14-5-.09(6)(b)1.; 335-14-5-.10(4)(c)4. Note; -10(4)(d)4.; -10(4)(e)2.(ii)-(iii); -10(4)(e)2.(v)(I)-(II); -10(4)(e)3.(i)-(ii); -10(4)(g)1.(iii)-(iv); -10(4)(g)2.(i)(I);

Description of Federal requirement	Federal Register date and page	Analogous state authority <sup>1</sup>
		<p>335-14-5-.11(2)(c)1.(i)(II); -.11(2)(c)2.(ii); -.11(2)(e)1.; -.11(2)(e)2.(i)(II)-(III); -.11(4)(b)1.; -.11(7)(a)2.;</p> <p>335-14-5-.12(2)(a)2.(i)(I); -.12(3)(a)-(b); -.12(10)(b);</p> <p>335-14-5-.13(11)(c)7.; -.13(11)(d); -.13(14)(a);</p> <p>335-14-5-.14(2)(b)2.; -.14(3)(a); -.14(3)(b); -.14(5)(b)1.; -.14(15)(f)2.; -.14(18)(a);</p> <p>335-14-5-.15(5)(b);</p> <p>335-14-5-.19(3)(e)4.(iii); -.19(3)(e)4.(iv)(VI); -.19(3)(e)6.(iii)(V); -.19(4)(e); -.19(5)(a); -.19(6)(e)6.;</p> <p>335-14-5-.23(4)(a)1.; -.23(4)(a)4.(i); -.23(4)(a)5.; -.23(4)(b); -.23(4)(m)2.; -.23(4)(m)3.;</p> <p>335-14-5-.24(1); -.24(2)(a); -.24(2)(b)11.; -.24(2)(c)4.;</p> <p>335-14-5-.27(1); -.27(4)-(6);</p> <p>335-14-5-.28(1); -.28(9); -.28(15);</p> <p>335-14-5-.29(1); -.29(11);</p> <p>335-14-5-.30(2)(b)3.(iii); -.30(2)(c)3.; -.30(2)(c)3.(i); -.30(2)(d); -.30(3)(a);</p> <p>335-14-5-Appendix I/Table 1 and Table 2(d);</p> <p>335-14-6-.01(1)(c)4.; -.01(1)(c)6.;</p> <p>335-14-6-.02(3)(a)1.; -.02(5)(b)1.; -.02(7)(b); -.02(10)(c)2.;</p> <p>335-14-6-.04(7)(b);</p> <p>335-14-6-.06(1)(d);</p> <p>335-14-6-.07(1)(b)4.; -.07(2)(c); -.07(3)(b)5.; -.07(3)(d)4.(iii)-(iv); -.07(4)(b); -.07(4)(e)4.; -.07(8)(b); -.07(10)(b)1.(ii);</p> <p>335-14-6-.08(1)(b); -.08(1)(b)2.; -.08(3)(a); -.08(6)(e)11.; -.08(8)(a)1.(i); -.08(8)(b)1.(i)-(ii);</p> <p>335-14-6-.09(5);</p> <p>335-14-6-.10(4)(e)2.(v)(I)-(II); -.10(4)(i)2.; -.10(5)(b)1.; -.10(5)(b)2.;</p> <p>335-14-6-.10(8)(b); -.10(12)(c);</p> <p>335-14-6-.11(2)(d)2.(i)(I)-(II); -.11(5)(b)1.; -.11(9)(a)2.(iii)(IV); -.11(9)(b)2.; -.11(10)(b)2.; -.11(10)(b)3.;</p> <p>335-14-6-.12(6)(b); -.12(10)(b)1.;</p> <p>335-14-6-.13(11)(a)4.; -.13(12)(a)1.;</p> <p>335-14-6-.14(2)(a); -.14(2)(d); -.14(3)(b); -.14(4)(b)1.; -.14(13)(a)1.; -.14(15)(f)1.(ii); -.14(15)(g)2.; -.14(17); -.14(17)(c)-(d);</p> <p>335-14-6-.17(6)(a)1.(i);</p> <p>335-14-6-.23(2)(c); -.23(4)(a)4.(i); -.23(4)(b); -.23(6)(b);</p> <p>335-14-6-.27(4); -.27(6);</p> <p>335-14-6-.28(14);</p> <p>335-14-6-.29(1); -.29(6); -.29(8); -.29(11);</p> <p>335-14-6-.30(1)(d); -.30(2)(b)3.(i)(II); -.30(2)(b)3.(iii); -.30(2)(c)3.; -.30(2)(d);</p> <p>335-14-6-Appendix I/Tables 1 and 2;</p> <p>335-14-6-Appendix V/Table;</p> <p>335-14-6-Appendix VI;</p> <p>335-14-7-.06(1)(a);</p> <p>335-14-7-.07(1)(a)/Table;</p> <p>335-14-7-.08(1); -.08(3)-(4); -.08(7); -.08(10);</p> <p>335-14-7-.14 heading;</p> <p>335-14-7-Appendices III-VII, IX, and XIII;</p> <p>335-14-8-.01(1)(a)2.; -.01(1)(b); -.01(1)(c)1.; -.01(1)(c)3.(i);</p> <p>335-14-8-.02(1)(j)1.; -.02(2)(d)1.; -.02(2)(d)2.; -.02(4)(k)7.; -.02(5)(a); -.02(5)(b)11.(ii); -.02(5)(b)19.(iii); -.02(5)(b)21.; -.02(8)(f); -.02(9)(b); -.02(9)(g); -.02(11)(i)2.; -.02(17)(c)15.;</p> <p>335-14-8-.03(4)(b);</p> <p>335-14-8-.04(2)(c); -.04(3)(b)2.(ii)(I)-(II);</p> <p>335-14-8-.07(1)(a); -.07(3)(b)2.;</p> <p>335-14-9-.01(2); -.01(4); -.01(6)-(7);</p> <p>335-14-9-.02(5);</p> <p>335-14-9-.04(1); -.04(3); -.04(5)-(6); -.04(8)-(9);</p> <p>335-14-9-.05(1);</p> <p>335-14-9-Appendix VIII;</p> <p>335-14-11-.02(4)(b); -.02(5)(a);</p> <p>335-14-11-.03(5)(a);</p> <p>335-14-17-.02(1)(b)2.; -.02(2); -.02(2)/Table 1;</p> <p>335-14-17-.05(5)(c)3.(i); -.05(5)(c)5.; -.05(6)(a); -.05(6)(c)2.; -.05(7)(a);</p> <p>335-14-17-.06(3)(a)-(b); -.06(3)(b)1.(ii); -.06(3)(b)6.(ii)-(iii); -.06(6)(a); -.06(6)(a)2.(i)(II); -.06(7)(a)2.; -.06(8)(a)2.(iii); -.06(10);</p> <p>335-14-17-.07(4)(b)3.; -.07(5)(e); and</p> <p>335-14-17-.08(1)(b)1.</p>

Description of Federal requirement	Federal Register date and page	Analogous state authority <sup>1</sup>
Checklist 215, Cathode Ray Tubes Rule.	71 FR 42928, 7/28/06 .....	335-14-1-.02(28)-(31); 335-14-2-.01(4)(a)22.(i)-(iv); 335-14-2-.04(9); and 335-14-2-.05(1)-(3).
Checklist 218, F019 Exemption for Wastewater Treatment Sludges from Auto Manufacturing Zinc Phosphating Processes.	73 FR 31756, 6/4/08 .....	335-14-1-.02(1)(a)(158); 335-14-2-.04(2)(b)4.; -.04(2)(b)4.(i); and -.04(2)(a)/Table.
Checklist 228, Hazardous Waste Technical Corrections and Clarifications Rule.	77 FR 22229 ..... 4/13/12 .....	335-14-2-.04(3)(a) entry for K107; and 335-14-7-.03(1)(b).
Checklist 229, Conditional Exclusions for Solvent Contaminated Wipes.	78 FR 46448 ..... 7/31/13 .....	335-14-1-.02(1)(a)177.; -.02(1)(a)248.; -.02(1)(a)312.; 335-14-2-.01(4)(a)26.; -.01(4)(a)26.(i)-(v); -.01(4)(a)26.(v)(I)-(IV); -.01(4)(a)26.(vi); -.01(4)(b)(18); -.01(4)(b)(18)(i)-(v); -.01(4)(b)(18)(v)(I)-(IV); -.01(4)(b)(18)(vi); and -.01(4)(b)(18)(vi)(I)-(II).

<sup>1</sup> The Alabama provisions are from the Alabama Hazardous Waste Management Rules 335-14-1, effective May 27, 2008 (Checklists 214 and 215); March 31, 2009 (Checklist 218); March 26, 2013 (Checklist 228); and March 31, 2015 (Checklist 229).

**H. Where are the revised State rules different from the Federal rules?**

We consider the following State requirements to be more stringent than the Federal requirements: Rules 335-14-2-.01(4)(a)26.(v)(IV) and 335-14-2-.01(4)(b)(18)(v)(IV) (from RCRA Cluster XXIII, Checklist 229) because, in addition to the three types of records required by the federal regulation, the State requires generators to maintain in their onsite records, documentation that verifies that “no free liquids” were present in the container prior to shipment. The Federal requirements found at 40 CFR 261.4(a)(26)(v) and 261.4(b)(18)(v) do not include this record keeping requirement. These requirements are part of Alabama’s authorized program and are federally enforceable.

EPA cannot delegate the Federal requirements at 40 CFR 261.39(a)(5), 261.40, and 261.41 contained in the Cathode Ray Tubes Rule set forth in 71 FR 42928 (July 28, 2006). Although Alabama has adopted these requirements at Rules 335-14-2-.05(1)(a)5., 335-14-2-.05(2), and 335-14-2-.05(3), EPA will continue to implement those requirements.

**I. Who handles permits after the authorization takes effect?**

Alabama will issue permits for all the provisions for which it is authorized and will administer the permits it issues. EPA will continue to administer any RCRA hazardous waste permits or portions of permits which EPA issued prior to the effective date of this authorization until they expire or are terminated. EPA will not issue any more permits or new portions of permits for the provisions listed in the Table above after the effective date of this authorization. EPA will continue to implement and issue permits for HSWA

requirements for which Alabama is not authorized.

**J. How does today’s action affect Indian Country (18 U.S.C. 1151) in Alabama?**

Alabama is not authorized to carry out its hazardous waste program in Indian Country within the State, which includes the Poarch Band of Creek Indians. EPA will continue to implement and administer the RCRA program in these lands.

**K. What is codification and is EPA codifying Alabama’s hazardous waste program as authorized in this rule?**

Codification is the process of placing the State’s statutes and regulations that comprise the State’s authorized hazardous waste program into the Code of Federal Regulations. EPA does this by referencing the authorized State rules in 40 CFR part 272. EPA is not codifying the authorization of Alabama’s changes at this time. However, EPA reserves the amendment of 40 CFR part 272, subpart B, for the authorization of Alabama’s program changes at a later date.

**L. Administrative Requirements**

The Office of Management and Budget (OMB) has exempted this action from the requirements of Executive Order 12866 (58 FR 51735, October 4, 1993), and therefore this action is not subject to review by OMB. This action authorizes State requirements for the purpose of RCRA 3006 and imposes no additional requirements beyond those imposed by State law. Accordingly, I certify that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this action authorizes pre-existing requirements under State law and does not impose any additional enforceable duty beyond

that required by State law, it 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). For the same reason, this action also does not significantly or uniquely affect the communities of Tribal governments, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely authorizes State requirements as part of the State RCRA hazardous waste program without altering the relationship or the distribution of power and responsibilities established by RCRA. This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant and it does not make decisions based on environmental health or safety risks. This rule is not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

Under RCRA section 3006(b), EPA grants a State’s application for authorization as long as the State meets the criteria required by RCRA. It would thus be inconsistent with applicable law for EPA, when it reviews a State authorization application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. Thus, the

requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the “Attorney General’s Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings” issued under the executive order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

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 document 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 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). This action will be effective May 19, 2017, unless objections to this authorization are received.

#### List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Hazardous waste transportation, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

**Authority:** This action is issued under the authority of sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6912(a), 6926, and 6974(b).

Dated: March 9, 2017.

**V. Anne Heard,**

*Acting Regional Administrator, Region 4.*

[FR Doc. 2017-05464 Filed 3-17-17; 8:45 am]

**BILLING CODE 6560-50-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Part 10

RIN 0906-AA89

### 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Interim final rule; further delay of effective date with comment.

**SUMMARY:** The Health Resources and Services Administration (HRSA) administers section 340B of the Public Health Service Act (PHSA), which is referred to as the “340B Drug Pricing Program” or the “340B Program.” The January 5, 2017 final rule sets forth the calculation of the ceiling price and application of civil monetary penalties, and applies to all drug manufacturers that are required to make their drugs available to covered entities under the 340B Program. This interim final rule delays the effective date of the final rule published in the **Federal Register** (82 FR 1210, (January 5, 2017)) to May 22, 2017. Commenters are also invited to provide their views on whether a longer delay of the effective date to October 1, 2017, would be more appropriate.

**DATES:** As of March 20, 2017, the effective date of the final rule published in the **Federal Register** (82 FR 1210, January 5, 2017) is further delayed to May 22, 2017. Comments on the delay of the effective date to May 22, 2017, as well as comments on alternatively delaying the effective date further to October 1, 2017, must be submitted on or before April 19, 2017.

**ADDRESSES:** You may submit comments, identified by the Regulatory Information Number (RIN) 0906-AA89, by any of the following methods. Please submit your comments in only one of these ways to minimize the receipt of duplicate submissions. The first is the preferred method.

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow instructions for submitting comments. This is the preferred method for the submission of comments.

- **Email:** [340BCMPNPRM@hrsa.gov](mailto:340BCMPNPRM@hrsa.gov). Include 0906-AA89 in the subject line of the message.

- **Mail:** Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857.

All submitted comments will be available to the public in their entirety.

Please do not submit confidential commercial information or personal identifying information that you do not want in the public domain.

**FOR FURTHER INFORMATION CONTACT:** CAPT Krista Pedley, Director, OPA, HSB, HRSA, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857, or by telephone at 301-594-4353.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In September 2010, HHS published an advanced notice of proposed rulemaking (ANPRM) in the **Federal Register**, “340B Drug Pricing Program Manufacturer Civil Monetary Penalties” (75 FR 57230, (September 20, 2010)). HHS subsequently published a notice of proposed rulemaking (NPRM) in June 2015 to implement civil monetary penalties (CMPs) for manufacturers who knowingly and intentionally charge a covered entity more than the ceiling price for a covered outpatient drug; to provide clarity on the requirement that manufacturers calculate the 340B ceiling price on a quarterly basis; and to establish the requirement that a manufacturer charge a \$.01 (penny pricing policy) for drugs when the calculation equals zero (80 FR 34583, (June 17, 2015)). The public comment period closed in August 2015, and HRSA received approximately 35 comments. After review of the initial comments, HHS reopened the comment period (81 FR 22960, (April 19, 2016)) to invite additional comment on specific areas of the NPRM: 340B ceiling price calculations that result in a ceiling price that equals zero (penny pricing); the methodology that manufacturers utilize when estimating the ceiling price for a new covered outpatient drug; and the definition of the “knowing and intentional” standard to be applied when assessing a CMP on manufacturers who overcharge a covered entity. The comment period closed May 19, 2016, and HHS received approximately 70 additional comments.

On January 5, 2017, HHS published a final rule in the **Federal Register** (82 FR 1210, (January 5, 2017)) and comments from both the NPRM and the reopening notice were considered in the development of the final rule. The provisions of that rule were to be effective March 6, 2017; however, HHS issued a subsequent final rule (82 FR 12508, (March 6, 2017)) delaying the effective date to March 21, 2017, in accordance with a January 20, 2017, memorandum from the Assistant to the President and Chief of Staff, entitled